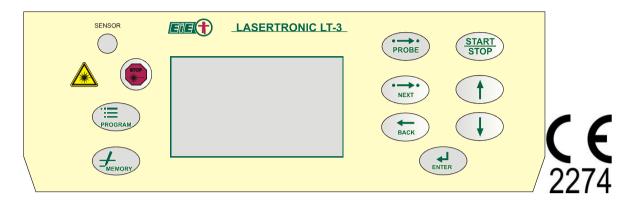
LASERTRONIC LT-3

Laser Biostimulation



INSTRUCTIONS FOR USE

NOTICE! PROTECT THE MANUAL FROM LOSS. THIS MANUAL IS PART OF THE EQUIPMENT

NUMBER:

In the case of loss, instructions are sold after this number is given.

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MANUFACTURER: Elektronika i Elektromedycyna M.Lewandowski Sp.J. 05–402 OTWOCK, ul. Zaciszna 2, tel./fax +48 22 779 42 84; tel. +48 22 710 08 39 www.eie.com.pl e-mail: office@eie.com.pl

WARRANTY CARD

Name and model of the product: LASERTR	ONIC LT-3
Serial number	Date of production
Warranty period: 24 months from the date of	f purchase.
3. Exploitation of the product must be co	the fully fit equipment to the customer. ate of sale stamped and signed by the seller. anducted according to the instructions for use. s will be done by the manufacturer or by the
exploitation (electrodes, cables, band 2. Mechanical damages which did not ris	se from the fault of the producer. I and the like), which can happen under the
The warranty ceases to be valid in the case 1. Expiry of the warranty period. 2. Lack of required periodic technical tes 3. Repairs done by the user or an unqual 4. Non-observance of correct exploitatio	sts.
All customer complaints should be sent to th	e above address.
	Stamp and signature of the manufacturer
Date of purchase	Stamp and signature of the seller

Confirmations of technical service

TABLE OF CONTENTS

I.	APPLICATION	.4
	I.1. Meaning of symbols used in this manual	4
	I.2. Intended purpose of the device	
	I.3. Other symbols used on the device	5
Ш	. TECHNICAL SPECIFICATION	
	II.1. Nominal operating conditions	
	II.2. Additional specifications	
	II.3. Technical data – laser	
	II.4. EMC requirements	
	II.5. Storage and transportation conditions	9
Ш	I. ACCESSORIES	10
	III.1. Equipment supplied with the device	10
	III.2. Basic accessories	10
	III.3. Connecting the device with accessories	10
11	/. PREPARING OF THE DEVICE FOR USE	
١١		
	IV.1. Labels' placement	10
	IV.3. Connection of cables and treatment applicators	
	IV.4. Switching on	
	-	
V	. OPERATION AND HANDLING OF THE DEVICE	14
	V.1. Front panel description	14
	V.2. Preparation for treatment	15
	V.2.1. Connection of applicators	15
	V.2.2. Switching on	
	V.3. Information presented by the device	
	V.3.1. Main screen	16
	V.3.2. Applicator areas	
	V.3.3. Parameter screen	
	Area (1) shows treatment parameters for chosen applicator	
	V.4. Performing treatments	
	V.4.1. Ranges of parameters	
	V.4.1.1 "Two colour" probe SP-2B	
	V.4.2. Mutual recalculation of lasertherapy parameters	
	V.4.3. Increments of change of parameters	
	V.4.4. Work modes	
	V.4.5. Starting treatment	
	V.4.6. Parametr selection	
	V.4.7. Changing the value of a parameter	20
	V.4.7.1 Steps for changing parameters during adjustment	
	V.4.8. Lasertherapy access code (password)	
	V.4.9. Temporary pause during laser treatment (pause)	21
	V.4.10. Termination of treatment	
	V.4.11. Treatment with repetitions	
	V.4.12. Types of laser irradiation	
	V.4.12.1 Irradiation of point	
	V.4.12.2 Irradiation along the line	
	V.4.12.3 Irradiation of surface with a point applicator	22

LASERTRONIC LT-3

V.4.13. Measurement of power of a laser probe	
V.5. Scanning applicator operation	
V.5.1. Treatment screensV.5.2. Beginning of treatment	
V.5.3. Pause	
V.5.4. End of treatment	
V.5.5. Distance measurement modes	
V.5.6. Shapes of treatment area	
V.5.6.1 Operator's own treatment area shape	
V.6. PROGRAM function (build-in treatment parameters)	
V.7. MEMORY function (user's own parameters)	
V.7.1. Favourite parameter sets	
V.7.2. Reading the previously saved settings from MEMORY	
V.7.3. Saving treatment parameters in MEMORY	
V.7.4. Deleting an item from MEMORY	
V.8. Additional functions	
V.8.1. Setting (Options)	32
V.9. Information given by the unit during work	
V.10. Helpful general informationV.11. Safety of treatments	
V.12. Abbreviated operation diagram	
VI. Maintenance	
VI.1. Checking the proper operation of the device	
VI.2. Proper working environment	
VI.3. RepairsVI.4. Maintenance and cleaning	
VI.5. Maintenance of laser applicator	
VI.6. Disposal of the warn out equipment	
VII. MEDICAL DESCRIPTION	
VII.1. Intended patient group	
VII.2. Indications	
VII.2.1. Basic indications for lasertherapy	
VII.3. Contraindications	41 11
VII.4. Side effects	
VIII. METHODOLOGY OF TREATMENTS	
VIII.1. Methodology of lasertherapy treatment	43
IX. LITERATURE	44

I. APPLICATION

I.1. Meaning of symbols used in this manual.

<u>WARNING:</u> This symbol indicates that it is absolutely necessary to acquaint with and remember the following information regarding safety of use of the device. Failure to consider such warnings may cause deterioration of health or even death.

IMPORTANT: This symbol indicates essential advice helping to prevent the damage of the device or equipment as well as the important general information.

NOTICE: This symbol indicates useful hints making the operating of the device easier.

I.2. Intended purpose of the device

LASERTRONIC LT-3 is intended for use in professional healthcare facilities by a qualified physiotherapy technician.

LASERTRONIC LT-3 is a modern, microprocessor controlled unit for double-channel electrotherapy and laser biostimulation. It has the state-of-the-art user interface (a colour graphic screen with touch panel). It can work with various types of laser probes emitting red and infrared light.

Basic application of LASERTRONIC LT-3 is in rheumatology, injuries of different aetiology, sport medicine, traumatology and pain relief. It can be also used in orthopaedics, neurology and the blood circulation treatments.

A detailed description of the therapeutic indications can be found in chapter VII. "MEDICAL DESCRIPTION".

<u>WARNING:</u> Any treatment with LASERTRONIC LT-3 should be performed carefully by a qualified physiotherapy technician.

<u>WARNING:</u> The manufacturer takes no responsibility for using this device in violation of the instructions for use recommendations, especially if the obligatory servicing is neglected or the device is used by the unqualified staff.

IMPORTANT: Device is an electrical device like a TV-set, radio or hair dryer so the operator should observe the basic safety precautions:

- do not pour water or other liquids on the device
- do not open the device's case
- do not cover the ventilation vents
- do not expose the device to shaking, moisture or dust.

NOTICE: The device has pre-programmed average treatment parameters for typical diseases (PROGRAM function) and has the option of their individual adjustment. You can also save settings of treatment parameters individually selected by the operator (MEMORY function).

I.3. Other symbols used on the device

ON THE DEVICE				
C€	CE mark	MD	Medical device	
UDI	Unique device identifier		Manufacturer	
~~	Date of manufacture	SN	Serial number	
REF	Catalogue number	Ţ	Caution	
*	Electrical device type BF		Fuse	
[ji	Consult instructions for use or consult electronic instructions for use		Door emergency switch connection	
Laser radiation symbol			Equipment should be disposed of according to the regulations for disposing of electrical devices	
ON THE PACKAGE				
-x'Cmin.	Maximum allowed temperature range	Ť	Keep dry	
x kg max.	The maximum allowable load on the package	<u></u>	This side up	

II. TECHNICAL SPECIFICATION

II.1. Nominal operating conditions

Heating timeTime of continuous work1 min24 h

Power supply (single phase) ~230 V 10%, 50 Hz, 70 VA

• Laser device class 3B

Insulation class
 Ambient temperature
 Relative humidity
 I type B
 10°C ÷ 40°C
 up to 85%

Atmospheric pressure 780-1060 hPa

II.2. Additional specifications

• Dimensions 335 x 270 x 125 mm

• Weight (without accessories) 2,5 kg

II.3. Technical data - laser

NOTICE: The powers and energies of the laser light below are given with accuracy $\pm 20\%$.

NOTICE: Times and frequencies below are given with accuracy ± 10%.

S-1N point probe (pulsed) 50 mW / IR:

•	wavelength	905 nm ± 10 nm
•	mean power (depending on frequency)	50 mW
•	pulse power	50 W
•	pulse energy	10 μJ
•	pulse width	200 ns
•	frequency of pulse repetition	5 ÷ 5000 Hz

S-2N point probe 40 mW / R:

• wavelength 660 nm ±10 nm

• continuous power 40 mW

modulated work mode:

range of power (adjusted) 1 ÷ 40 mW
 frequency of pulse repetition 5 ÷ 9999 Hz

S-2B point probe 80 mW / R:

• wavelength 660 nm ±10 nm

• continuous power 80 mW

modulated work mode:

range of power (adjusted) 1 ÷ 80 mW
 frequency of pulse repetition 5 ÷ 9999 Hz

S-3N point probe 400 mW / IR:

• wavelength 808 nm \pm 20 nm

• continuous power 400 mW

modulated work mode:

range of power (adjusted) 1 ÷ 400 mW
 frequency of pulse repetition 5 ÷ 9999 Hz

SP-1B cluste	rprobe	720	mW /	'R:
--------------	--------	-----	------	-----

total continuous powernumber of diodes720 mW

• wavelength 660 nm ±10 nm

single diode power
 effective area of treatment
 50 cm²

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 5 ÷ 9999 Hz

SP-2B cluster probe 1040 mW / R+IR:

total continuous power
 number of diodes
 R wavelength
 R single diode power
 1040 mW
 5 (R) + 4 (IR)
 660 nm ±10 nm
 80 mW

IR wavelength
 IR single diode power
 808 nm ±10 nm
 160 mW

IR single diode power
 effective area of treatment
 50 cm²

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 10 ÷ 1040 mW
 5 ÷ 9999 Hz

SP-3 cluster probe 1440 mW / IR:

• total continuous power 1440 mW

• number of diodes 9

wavelength
 single diode power
 808 nm ±20 nm
 160 mW

• effective area of treatment 50 cm²

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 5 ÷ 9999 Hz

SK-1 scanning probe, 480mW / R + IR:

total continuous power
 number of diodes
 wavelength R
 single diode power R
 wavelength IR
 80mW (+/- 20%)
 wavelength IR
 808nm ±10nm

• single diode power IR 400mW (+/- 20%)

II.4. EMC requirements

This equipment requires special attention for EMC environment conditions and must be installed according to the information given below. The user should provide such conditions for proper functioning of the equipment.

EMC emission resistance

		Resistance test level
Subject	EMC Standard or Examination Method	Professional health care facility environment and home health care environment
Port on the casing		
ESD	PN-EN 61000-4-2:2011	± 8 kV contact, ± 2; 4; 8; 15 kV by air
RF radiation	PN-EN 61000-4-3:2014	10 V/m rms before modulation) 80 MHz – 2,7 GHz , modulation: 80% AM, 1kHz
Proximity RF fields from wireless radio equipment	PN-EN 61000-4-3:2014	p. 8.10 of the Standard (Table 9)
AC. Mains Port		
Fast transients (BURST)	PN-EN 61000-4-4:2013	± 2 kV, freq. 100 kHz
SURGES	PN-EN 61000-4-5:2014	Line to line ± 0.5 kV, ± 1 kV Line to earth ± 0.5 kV, ± 1 kV, ± 2 kV
Disturbances conducted and induced from RF fields	PN-EN 61000-4-6:2014	3 V (rms before modulation) 0,15 – 80 MHz, 6 V (rms before modulation) in the ISM band and in the radiofrequency bands 0,15 and 80 MHz, modulation: 80% AM and 1 kHz
Voltage drops DIP Supply breaks	PN-EN 61000-4-11:2007	0% U _T ; 0,5 T in 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U _T ; 1 T; and 70% U _T ; 25 T; single phase 0° 0% U _T ; 250 T
Magnetic fields of the supply mains	PN-EN 61000-4-8:2010	30 A/m
frequency		50 Hz

^{*)} Radiation of stationary radio transmitters should not exceed the above declared levels.

Disturbances may be observed close to devices marked with the following label:



professional	Emission levels for the professional medical care company and environment of the domestic medical care				
Subject	Applied Standard		requency bands MHz		
Harmonics of current	PN-EN 61000-3-2:2014	The device meets the requirement small power does nod require any	ents of the Standard and due to testings.		
Fluctuations of voltage and light flickering	PN-EN 61000-3-3:2013	The device meets the requirement small power does nod require any	ents of the Standard and due to testings.		
_		66 dBµV (quasipeak.) 56 dBµV (avr.)	0,15 - 0,5		
Conducted PN-EN 55011:2016 RF emission Group 1, Class B	56 dBμV (quasipeak.) 46 dBμV (avr.)	0,5 - 5			
		60 dBμV (quasipeak.) 50 dBμV (avr.)	5 - 30		
Dadiated	DN EN 55044-2046	Elecrical field a	t 10 m distance		
Radiated RF emission	PN-EN 55011:2016 Group 1, Class B	30 dBμV/m (quasipeak.)	30-230		
Group 1, Class B		37 dBμV/m (quasipeak.)	230-1000		

Cables used with the device:

- cables connecting the laser probes to the device up to 2,5 m
- mains cable up to 2,5 m

IMPORTANT: Using cables exceeding the limits may cause increased emission or lower resistance of the device.

<u>IMPORTANT:</u> Telecommunication equipment using radio frequencies may affect operation of this device.

Working environment: Health care facilities and domestic medical care environments.

II.5. Storage and transportation conditions

The device with accessories should be stored in the original packaging observing the following conditions:

• ambient temperature 5°C ÷ 40°C

relative humidity
 up to 85% condensation-free

• atmospheric pressure 780-1060 hPa

The device with accessories should be transported in the original packaging observing the following conditions:

• ambient temperature -10°C ÷ 45°C

relative humidity
 up to 95% condensation-free

atmospheric pressure 780-1060 hPa

NOTICE: Do not expose the device or accessories to outdoor weather conditions.

III. ACCESSORIES

III.1. Equipment supplied with the device

•	mains cable	1 pcs
•	T-0,315AL, 250V fuse	2 pcs
•	warning signs for use on doors	1 set
•	instructions for use	1 pcs

III.2. Basic accessories

Basic accessories - laser:

Laser probes (applicators)

S–1N : point probe	50 mW / IR	[pulse mode]
S–2N : point probe	40 mW / R	[continuous and modulated mode, adj. power]
S-2B: point probe	80 mW / R	[continuous and modulated mode, adj. power]
S–3N : point probe	400 mW / IR	[continuous and modulated mode, adj. power]
SP–1B : cluster probe	720 mW / R	[continuous and modulated mode, adj. power]
SP–2B : cluster probe	1040 mW / R + IR	[continuous and modulated mode, adj. power]
SP-3: cluster probe	1440 mW / IR	[continuous and modulated mode, adj. power]
SK-1 : scanning probe	480mW / R + IR	[continuous and modulated power work mode]

<u>WARNING:</u> The manufacturer does not take any responsibility for using with LASERTRONIC LT-3 accessories other than those of EiE. It is acceptable to use the equipment having a certificate of compatibility with the EiE requirements.

IMPORTANT: Regular control of connecting cables is recommended.

III.3. Connecting the device with accessories

The control device allows you to perform the treatments of individual therapies with the appropriate equipment. Without accessories, the device is not applicable. At least one laser applicator is needed for laser therapy treatments.

IV. PREPARING OF THE DEVICE FOR USE

WARNING: Thoroughly read the instructions for use before using the device.

- 1. If the device was for some time in temperature below 0°C (e.g. in transport) it should be unpacked and left in room temperature for about 4-8 hours. Only then it can be plugged into mains and switched on.
- The device should be placed in such a place that connected cables (especially the mains cables) are not exposed to pulling or tearing by persons passing by. Such a situation may expose people to an electric shock and the equipment to damage or destruction.
- It is recommended to remove the protective sticker from the display. Gently lever up the sticker with your nail and remove it. Leaving the sticker on may impair the vision of the display.

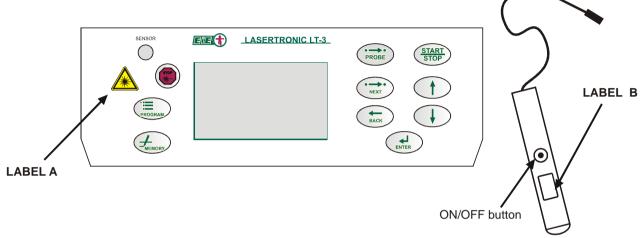
IV.1. Labels' placement

If laser treatment is performed, the door to the treatment room should be labelled as follows (signs are included as accessory):



WARNING - VISIBLE AND INVISIBLE
LASER RADIATION
PROTECT EYES
FROM DIRECT AND DISSIPATED
RADIATION

The front panel contains the following descriptions:

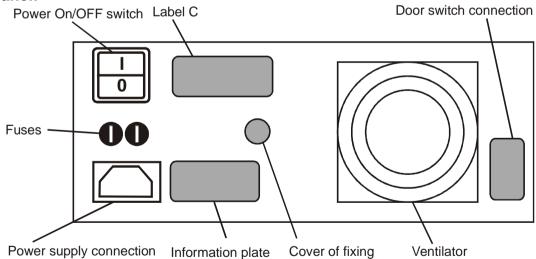


Label A – on the front panel

Label B – on the laser probe; shows output end of the probe - the one where laser beam goes out.



Back panel:



Labels C i D – on the back panel

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B

Probes which may be used with the unit:
905nm 10µJ 200ns 50mW (impulsowa) 660nm 80mW
5x660nm/40mW+4x808nm/160mW 808nm 400mW
9x808nm/160mW
9x660nm/40mW
PN-EN 60601-2-22

Information labels for laser applicators For the laser applicator S-1N:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B

905nm 10

µJ 200ns 50mW (pulsed)

PN-EN 60601-2-22

For the laser applicator S-2N:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B
660nm 40mW
PN-EN 60601-2-22

For the laser applicator S-2B:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B
660nm 80mW
PN-EN 60601-2-22

For the laser applicator S-3N:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B
808nm 400mW
PN-EN 60601-2-22

For the laser applicator SP-1B:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B

9x660nm/80mW

PN-EN 60601-2-22

For the laser applicator SP-2B:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B

5x660nm/80mW+4x808nm/160mW

PN-EN 60601-2-22

For the laser applicator SP-3:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B

9x808nm/160mW

PN-EN 60601-2-22

For the scanning probe SK-1:

VISIBLE AND INVISIBLE
LASER RADIATION
BEWARE OF LASER BEAM
LASER DEVICE CLASS 3B
660nm / 80mW + 808nm / 400mW
PN-EN 60601-2-22

IV.2. Recommended workplace organization

The control unit should be positioned firmly in the workplace before treatment: on a table, desk or trolley, near the mains socket ~230 V 10% 50 Hz. The device should be placed at a suitable height which allows easy manipulation of controls on the front panel. Sunlight, or other bright light may dim the screen and decrease LEDs visibility, so the front panel should not be lit with direct light.

It is recommended that the workplace organization allow for easy and uninterrupted access to all controls and accessories. Special care must be taken to put the mains and connecting cables aside from the area where people move as this may cause accidental stumbles or pulling of the cable. Between treatments, the cables should be put aside safely not to be pressed or broken by a drawer or cabinet doors. Laser probes should be put aside on a holder when not in use, this protects them from mechanical damage.

NOTICE: In particular, care should be taken to ensure easy access to the power switch (on the rear panel of the device).

IV.3. Connection of cables and treatment applicators

IMPORTANT: Connection and disconnection of applicators must only be done when the device is switched off.

One or two laser probes can be connected to the front sockets of the apparatus

IV.4. Switching on

IMPORTANT: Before switching on the POWER button connect treatment probes to the sockets in front of the device.

<u>IMPORTANT:</u> This device is manufactured with the insulation of the first class. Connect the device to the socket with grounding pin.

The device is turned on by the POWER button on the back panel into position "I".

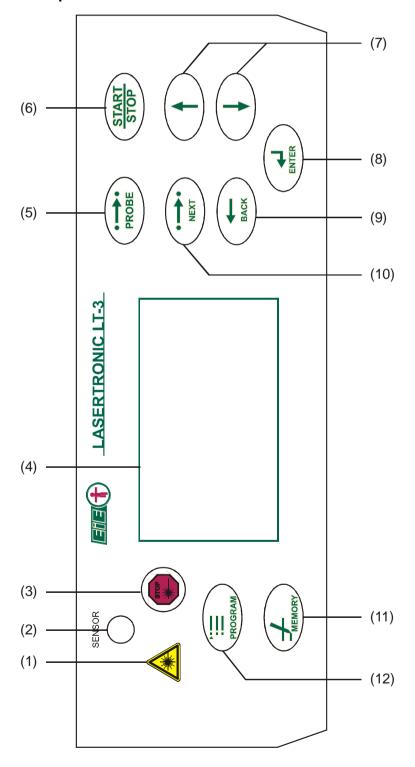
V. OPERATION AND HANDLING OF THE DEVICE

<u>WARNING:</u> All treatments using LASERTRONIC LT-3 should be performed carefully by a qualified physiotherapy technician. Otherwise, the therapeutic effects may be limited and the patient and staff may be exposed to health risks.

NOTICE: A number in parentheses, ex. (10) used in the test refers to a corresponding number on the front panel in the drawing in part V.1. "Front panel description".

NOTICE: In this chapter, if the character "+" accompanies a button icon, it means that two respective buttons should be pressed simultaneously.

V.1. Front panel description



No.	Symbol	Description			
1		Warning label			
2		Sensor for laser power measuren	nent		
3	STOP	Emergency energy turn OFF			
4		Colour LCD screen with touch pa	nel		
5	●○○ SELECT	Change of the type of therapy			
6	START STOP	Turn ON / OFF the treatment	urn ON / OFF the treatment		
7	1	Parameter value setting	Increase value of the parameter		
,	7 Parameter value setting		Decrease value of the parameter		
8	ENTER	Accept the choice	Accept the choice		
9	BACK	Move to menu for additional functions or return to the previous screen			
10	●→● NEXT	Go to next item on the screen			
11	MEMORY	Individual sets of parameters saved by the user			
12	PROGRAM	Pre-programmed parameter sets for various treatments			

V.2. Preparation for treatment

V.2.1. Connection of applicators

Before turning on the device, therapeutic probes and cables should be connected as described in IV.3. "Connection of cables and treatment applicators"

V.2.2. Switching on

<u>WARNING:</u> All treatments using LASERTRONIC LT-3 should be performed carefully by a qualified physiotherapy technician. Otherwise, the therapeutic effects may be limited and the patient and staff may be exposed to health risks.

WARNING: In the case of abnormal functioning of the device, which may result in danger to the operator or patient, stop the treatment immediately and proceed as in chapter VI. "Maintenance".

IMPORTANT: Before switching on check the condition of the cables. If they are damaged, call for a qualified maintenance technician to repair them.

IMPORTANT: This device is manufactured with the insulation of class I. Connect the mains supply cable to the socket at the back of the device, and plug the cable into the wall socket with a grounding pin.

NOTICE: Do not bend the cables at acute angles and do not wind them up tight, because they can be damaged.

<u>WARNING:</u> Before turning on the device, both the patient and the staff must put on protective eyewear. Otherwise the laser light can damage the eyes.

<u>WARNING:</u> To safeguard against turning on the laser by unauthorised persons, turn off the power if the laser is not used. Turning it back on will require gentering the protective password.

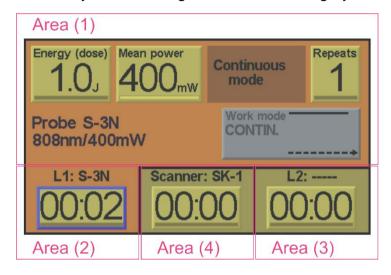
When switching on, observe the following sequence:

- connect the laser applicators
- put protective laser eyewear on if lasertherapy is to be performed (both the patient and the staff)
- connect the device to the mains power supply
- turn on the power button on back panel

V.3. Information presented by the device

V.3.1. Main screen

After turning on the device the main screen shows up. It allows edition of treatment parameters. Fields which may not be changed are coloured in grey.



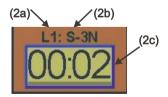
There are 3 main areas on the screen:

- (1) parameters area
- (2) applicator 1 area
- (3) applicator 2 area
- (4) laser scanner

In areas (2), (3) and (4) times of treatment for related applicators are displayed, together with its type. In case when there is no probe in a channel, the sign "----" is displayed. Probe chosen for edition is indicated by blue frame around timer. Treatment parameters are displayed in area (1).

V.3.2. Applicator areas

Areas (2), (3) and (4) are related to applicators' sockets.



There are the following fields in these areas:

(2a): Corresponding socket symbol ("L1" – socket 1., "L2" – socket 2.)

(2b): Type of probe or lack of applicator ("S-1N", "S-2N", "S-2B", "S-3N", "SP-1B", "SP-2B", "SP-3", "SK-1", "----")

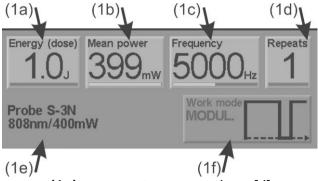
(2c): Time of treatment for a given applicator

V.3.3. Parameter screen

Area (1) shows treatment parameters for chosen applicator.

Laser point probes

Screen of a point probe:



(1a): parametr: energy dose [J]

(1b): parametr: mean power [mW]

(1c): parametr: modulation frequency (for modulation mode) or pulse frequency (for pulse mode)

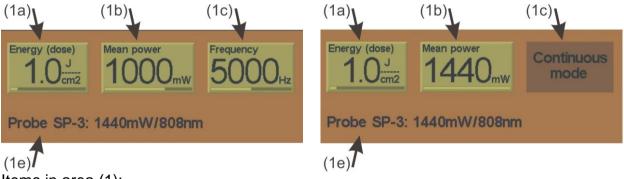
(1d): parametr: number of repetitions

(1e): description of the connected probe

(1f): probe work mode (continuous / modulated / pulse)

Laser cluster probes - one-wavelength

Screen of laser cluster probe (one-wavelength):



Items in area (1):

(1a): parametr: energy density [J/cm²]

(1b): parametr: mean power [mW]

(1c): parametr:

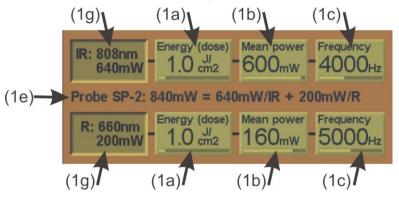
modulation frequency (for modulated mode)

• work mode type (for continuous mode)

(1e): description of the connected applicator

Laser cluster probes - double-wavelength

It operates with two wavelengths, so the SP-2B probe has a different parameter screen:



Items in area (1):

(1a): parametr: energy dose [J/cm²] (1b): parametr: mean power [mW]

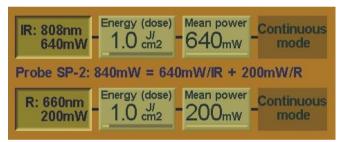
(1c): parametr:

- modulation frequency (for modulated mode)
- work mode type (for continuous mode)

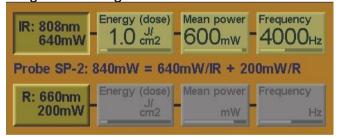
(1e): description of connected applicator

(1g): emission on / off for chosen laser wavelength in SP-2B

This same screen is for the continuous work mode (maximum power):



Single wavelength turned off:



V.4. Performing treatments

V.4.1. Ranges of parameters

- The following parameter ranges are specified in II.3 "Technical data laser"
 - mean power
 - frequency
- The point probes have the following additional settings:

dose
 time
 time
 1 s ÷ 99 min.

• number of repetitions of dose 1 ÷ 99

• The cluster probes have the following additional settings:

dose
 time
 0,1 ÷ 10,0 J/cm²
 1 s ÷ 99 min.

V.4.1.1 "Two colour" probe SP-2B

In this probe it is possible to switch ON and OFF diodes of a chosen wavelength. It can be done by touching the field (1g) (see V.3.3. "Treatment parameters screen" above) on the screen. The displays of inactive wavelength will be greyed.

V.4.2. Mutual recalculation of lasertherapy parameters

Change of one parameter results in recalculating other parameters in the following way:

- change of energy dose recalculates the time of treatment
- change of power recalculates the time of treatment (and frequency in case of S-1N applicator)
- change of number of repetitions recalculates the time of treatment
- change of frequency in case of S-1N applicator recalculates the time of treatment and power
- change of time recalculates the power (only for point probes)
- if recalculated parameter would go off its range, the change is not possible

V.4.3. Increments of change of parameters

The point probes

Mean power regulation in the whole range: increment is 1 mW.

Time regulation: increment is 1 s

Energy dose regulation: increment is 0,1 J Frequency regulation: increment is 10 Hz

Cluster probes

Mean power regulation in the whole range: increment is 10 mW.

Energy dose regulation: increment is 0,1 J/cm² Frequency regulation: increment is 10 Hz

V.4.4. Work modes

The work mode of laser applicators depend on the type of applicator and chosen power.



Modulated work mode – the applicator radiaties laser light in pulses at the set frequency and the pulse width depending on mean power (available in applicators S-2N, S-2B, S-3N, SP-1B, SP-2B, SP-3)



Continuous work mode - the applicator radiaties laser light without breaks with maximum available power (available in applicators S-2N, S-2B, S-3N, SP-1B, SP-2B, SP-3)



Pulse work mode - the applicator radiaties laser light in short pulses of high power with given frequency (available in applicator S-1N)

V.4.5. Starting treatment

Chose the applicator with SELECT or touching the field on the screen.
 NOTICE: Switching over from one applicator to another may take up to 1 second. You have to wait until the applicator is changed.

- To switch the probe in the "ready" mode (ready for emission) press START STOP. The sound signal starts (if it was activated in the menu of additional functions).
- The description of the applicator type changes colour to white. Progress bar under timer shows time left till the end of treatment. The background colour of timer is:
 - Yellow when in the ready mode or the emission mode
 - Green after end of treatment (when the whole dose has been emitted)

• Typing down password may be required as described in V.4.8 "Lasertherapy access code (password)" below.

For starting treatment point the applicator output side to the treatment area on the patient and press the button on the applicator once. Emission starts, which is signalled with a sound and by the blue light on the applicator.

During treatment the time left till the end of treatment is shown on the screen. If repetitions of dose were set, the time shown on timer is the time till the end of a single dose (one repetition) and the number of remining repetitions is shown on the screen.

NOTICE: During the lasertherapy treatment it is not possible to change parameters.

NOTICE: If the treatment is not started within one minute after starting the readiness mode, for safety reason the "ready for emission" mode is stopped. The following information appears:



V.4.6. Parametr selection

The treatment parameter can be selected:

- by pressing your finger on the LCD display in the relevant parameter field
- by pressing the NEXT, that cyclically changes the selection of the next parameter

The selected parameter (which can be changed) is indicated by flashing (cyclical change in brightness).

V.4.7. Changing the value of a parameter

The parameter value is changed using the buttons _____ i ____. By holding down one of these buttons for a longer period of time, the parameter is quickly changed automatically. On numerical parameters, there is a bar at the bottom showing the currently set value within the limits of its variation.

V.4.7.1 Steps for changing parameters during adjustment Laser point applicators

Adjustment of average power over the entire range: change in 1 mW increments.

Adjustment of time: change in 1 s steps Dose adjustment: 0.1 J increments Frequency adjustment: 5 Hz steps

Cluster laser applicators

Adjustment of average power over the whole range: change in 10 mW increments.

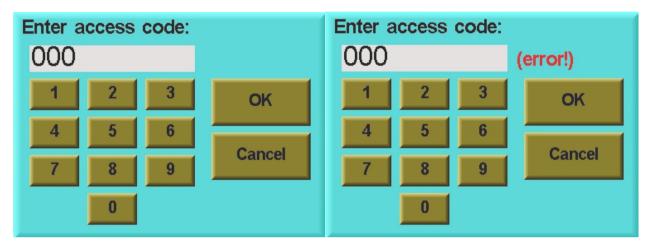
Adjustment of dose: change in increments of 0.1 J/cm2

Frequency adjustment: 10 Hz steps

V.4.8. Lasertherapy access code (password)

NOTICE: Access code protects laser from being used by unauthorised persons.

In order to start readiness mode (laser ready for emission) press stop. If this is the first laser applicator activation after turning on the device (or the laser treatment has not been performed for 60 minutes), the device asks for the access code. The access code is 3 last digits of the device serial number (**SN**) which is printed on the label on the back of the unit.



If a wrong code is typed, a message "error!" is displayed on the screen in red. You have to type the code again.

V.4.9. Temporary pause during laser treatment (pause)

During treatment you can stop emission by pushing the button on the applicator once. The next pushing of the button continues treatment.

If the treatment is stopped and not continued within one minute, the ready for emission mode is stopped and information is shown as in p. V.5.2. "Beginning of treatment".

V.4.10. Termination of treatment

Treatment ends up in one of following cases:

- The time of treatment elapses signal "ready for emission" on the probe stops, the timer background turns green; sound signal starts, which may be stopped by pushing any button.
- When the emergency stop button is pressed.
 emission is immediately stopped and ready for emission signal stops

NOTICE: When emergency stop was used, in order to continue treatments you have to turn the device off and on again. Pressing the emergency button stops all treatments.



Pressing the button

 Malfunction was detected in the device or in the applicator – treatment is stopped automatically (possible options are described in p. V.11 "Information given by the unit during work").

In the case of emergency end of treatment, the related information appears on the screen and will be displayed until OK is pressed. Necessary actions should be taken to remove the malfunction, depending on the kind of it. Assistance of a qualified maintenance technician may be required.

V.4.11. Treatment with repetitions

In the case of laser treatments where more than one point has to be consecutively radiated LASERTRONIC LT-3 has special function for setting the number of doses repeated. You can set from 1 to 99 repetitions of dose with the same parameters.

When more than 1 repetition is set, after the end of dose in a particular place, emission stops and a signal is produced. Than you have to move applicator to the next area on the patient and push the button on the applicator. The emission of the next dose starts.

NOTICE: For safety reasons the number of repetitions is reset to 1 after the full cycle has been emitted. You have to set it again in every treatment.

NOTICE: During emission the device displays the time left till the end of single energy dose repetition.

NOTICE: Setting the repetition number is possible only for the point probes.

V.4.12. Types of laser irradiation

V.4.12.1 Irradiation of point

- use a point applicator
- keep the applicator no higher than 2 cm above the irradiated area

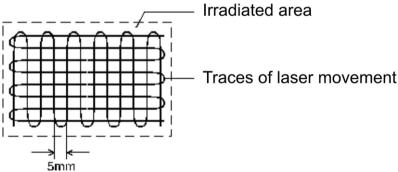
V.4.12.2 Irradiation along the line

- use a point applicator
- move the applicator evenly along the line, no higher than 2 cm above the treated area, at a speed of 2 cm per second, changing direction when end of line is reached

V.4.12.3 Irradiation of surface with a point applicator

NOTICE: For irradiation of big surfaces we advise to use the multi-diode ("cluster") probes.

During surface irradiation with a point applicator move the applicator no higher than 2 cm over the treated area, at 2 cm per second. Move along the parallel lines spaced by 5 mm, changing direction at the end of line. Then change direction perpendicularly and start moving along parallel lines. The method of movement is shown here:



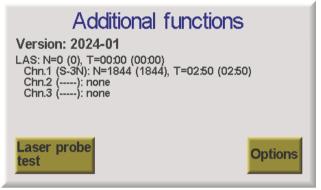
V.4.13. Measurement of power of a laser probe

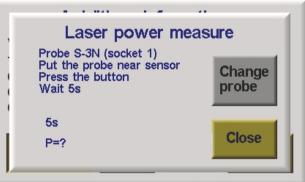
WARNING: During treatments, the operator and patient must wear eye protection. Otherwise the eye vision can be damaged.

The device has the following functions for assuring proper work of laser applicators:

- During laser emission the feedback signal from laser diode is checked. When deviation is higher than +/- 20% of the nominal, the malfunction of applicator is signalled.
- The device is equipped with a power measurement sensor on the front panel, which can be used in the way described below.

Type of measurement of power of a laser applicator







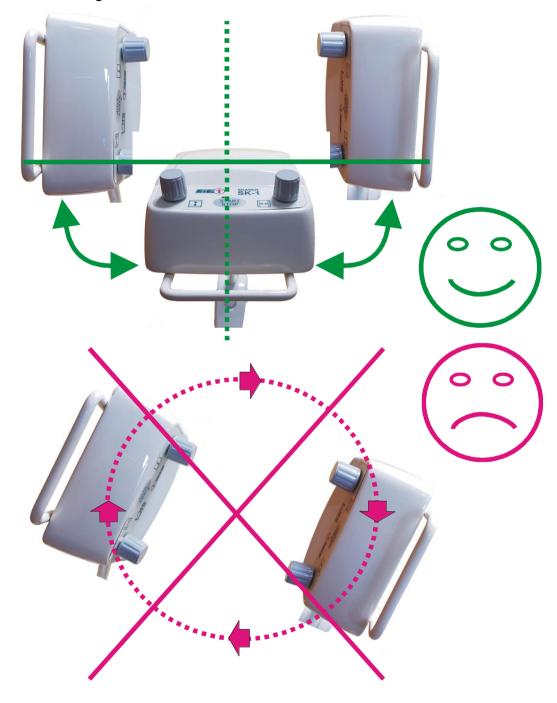


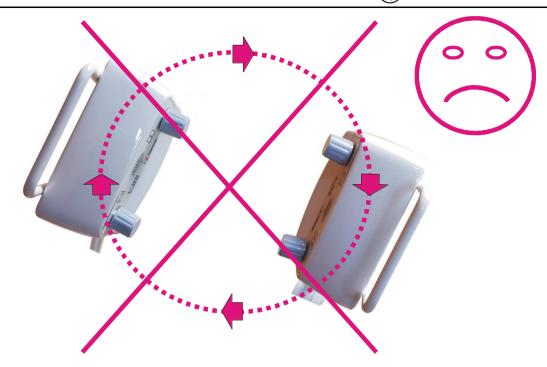
- In order to start the power measurement, first chose the proper applicator and press • In order to start the power measurement, first chose the proper applicator and press • BACK . Additional functions will appear. Chose "Laser probe test".
- The button on the applicator will light up showing ready for emission mode. Press the
 probe to the sensor (white circle in the upper left corner of the keyboard) and press the
 button on the applicator. The emission and measurement of power starts and continues
 for 5 seconds.
- During the test pay attention to hold the applicator's end tightly to the sensor. It should be positioned at (90°) to the sensor. Inaccuracy of the angle usually underrates the readout.
- When the measurement comes to an end, the value measured (in mW) is displayed on the screen. The value should not deviate more than +/-20% from the nominal value of a given applicator. In other case, the test should be repeated with careful attention to tight and proper holding of the applicator to the sensor. If several tests do not give the proper value, contact the manufacturer or authorised service.
- The value measured stays on the screen until "Close" is pressed and then the device automatically returns to the main screen.

• The **Change Probe** button on the power measurement screen is used to select a different probe for measurement if a second probe is connected.

V.5. Scanning applicator operation

IMPORTANT: During positioning of scanning applicator one must not turn it more than 100° from the horizontal level and, after each treatment, one has to turn it back to horizontal level. Failure to observe this may often result in turning the applicator around one way, which results in breaking the safety wire first and next causes mechanical damage of cables inside.





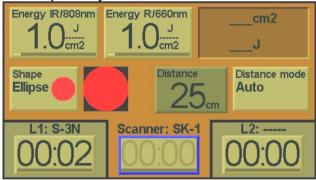
V.5.1. Treatment screens

Treatment parameters may be set in two different modes: full or simple. The method of selection the mode is described in p.V.5.6 (BACK), Options, Parameter mode).

Full mode

Parameters:

- Time adjustment: change in increments of 30 s
- Dose adjustment (total R+IR): change in increments of 0.1 J/cm2
- Time and dose are reciprocally recalculated.



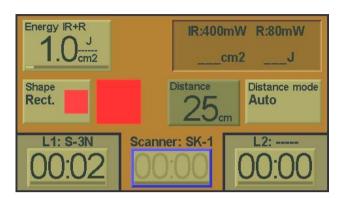
Screen of treatment parameters (full mode) includes the following:

- Dose IR/808nm allows setting of dose of infrared light emission [in J/cm²]
- Dose R/660nm allows setting of dose of red light emission [in J/cm²]
- **Shape** allows choosing the shape of irradiation
- Picture of chosen shape shows the chosen shape, in particular operator's own shape
- Distance depending on chosen mode of measurement, it shows the measured distance or allows its setting
- Measurement mode allows setting of distance measurement mode (see p.Błąd!
 Nie można odnaleźć źródła odwołania. below)
- Information area (upper right corner) shows the current treatment area and total energy dose

Simple mode

Parameters:

- Dose adjustment for wavelength R: 0.1 J/cm2 increments
- Dose adjustment for IR wavelength: 0.1 J/cm2 increments
- Time is automatically calculated with an accuracy of 1 s



In simple mode screen of treatment parameters includes in place of doses separated in full mode:

• **Dose IR+R** – allows setting of total dose of light emission [in J/cm²] for both wavelengths

Additionally in the information area there is information about power of each laser source.

V.5.2. Beginning of treatment

In order to perform treatment with laser scanner (scanning applicator/probe), after standard preparation for treatment, one should:

In the device:

- Chose the shape of treatment area
- Set irradiation parameters (dose R, dose IR)
- With button start emission ready mode
 The contour of chosen shape will be shown in emission ready mode.

Next, one should:

- Put the applicator over the area to be treated
- Set the size of treatment area with applicator knobs
- With button (on the applicator) start the treatment (emission mode)

NOTICE: The device calculates the treatment area and adjusts time of treatment according to dose of power which is set.

NOTICE: When the treatment is started no parameters can be changed.

V.5.3. Pause

When the treatment is started (emission is on) pushing the button (on applicator / probe) causes a pause — entering into ready for emission mode. Only then one can regulate settings, shape or size of treatment area. Doses cannot be regulated in pause mode. Changing the treatment area will cause the selected dose to be the maximum value that will be irradiated on the patient. In some areas, the exposure may be lower.

Pushing the button (on applicator / probe) again starts the treatment again.

V.5.4. End of treatment

The treatment is ended (stopped) when:

- Time of treatment expires
- The button stop is pushed (on the control unit)
- The button is pushed (emergency stop; restarting of the device is needed)

V.5.5. Distance measurement modes

There are following distance measurement modes (applicator output to patient distance):

Automatic

In this mode the distance measured is used for calculating the size of treatment area and time of treatment (according to dose set) and for stabilizing the size of treatment area. Stabilization means automatic adjusting the size of treatment area despite of patient being closer or farther away from the applicator (in limited range).

• Semi-automatic

In this mode the distance measured is used for calculating only the size of treatment area and time of treatment (according to dose set). There is no stabilization of size of treatment area.

Manual

In this mode the distance is set manually by the operator as a parameter on the screen. The distance set is than used for calculating the size of treatment area and time of treatment.

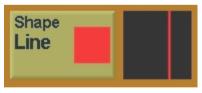
NOTICE: In automatic and semi-automatic mode special attention should be paid when measuring distance to small body parts (e.g. palm of hand, shoulder, knee etc.). In such a case the measuring sensor may receive the distance to the object behind (e.g. a floor, a wall) and calculated data will be wrong. When no good measurement can be obtained it is advised to change the mode to manual and set the distance manually.

V.5.6. Shapes of treatment area

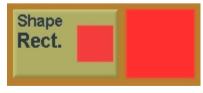
It is possible to chose the following shape of treatment area:



Treatment area is an ellipse. Irradiation is uniformeven.



Treatment area is rectangular in contourshape. Irradiation is made with moving line.



Treatment area is rectangular. Irradiation is uniformeven.



Treatment area is rectangular.

Irradiation is made with so called Lissajous figures (curves within rectangle).

It is the classic irradiation method for scanning applicator, which has a disadvantage of high non-uniformity between different points in treatment area.



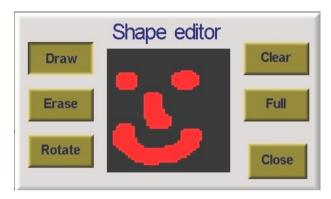
Treatment area is sketched set by the operator. Irradiation is uniformeven.

V.5.6.1 Operator's own treatment area shape

Operator's own treatment area shape allows drawing different shapes on the screen which are used as contours during irradiation. This allows for:

- Adapting to irregular shape of the area which is to be treated (e.g. wounds or scars) or
- Isolate from the irradiation places that should not be irradiated (e.g. birthmarks or moles)

In order to draw your own shape first chose "User's" shape. Than push the picture of shape. The following screen will appear:



In the middle there is drawing area. Touching with a finger extends irradiation area (when "Draw" is chosen). If "Erase" is chosen, touching the screen deletes irradiation area.

Particular functions explanation:

- **Draw** drawing mode is on
- Erase deleting mode is on
- Rotate rotates the picture, so the operator can adjust the position of picture to the
 actual position of irradiation area on the patient; each touch turns the position to the
 right by 90°)
- Clear all area is cleared
- Full all area is chosen for irradiation
- **Close** exits the edition screen (the irradiation shape is saved). The same is done by pushing the button on the keyboard next to the screen.

V.6. PROGRAM function (build-in treatment parameters)

PROGRAM is a pre-programmed collection of optimal sets of device parameters suitable for selected illnesses. When the button program is pressed, a list of programmed illnesses appears on the screen (arranged according to illness type):

Using buttons for browsing through the list or touching the screen you can choose the position needed. Alternatively you can touch the screen with the finger and pull slightly down or up for browsing.

Accept your choice of disease unit by pressing the field with type of applicator to be used – to the right of the list. If only one applicator is connected, the button may be used instead.

"List change" field may be used for selecting a list sorted for currently connected applicators or all disease units irrespectively of connected applicators.



You can stop using PROGRAM function at any moment by pressing BACK or PROGRAM

NOTICE: If no applicator is connected or a treatment is started in a given channel you cannot choose the indication for this channel.

V.7. MEMORY function (user's own parameters)

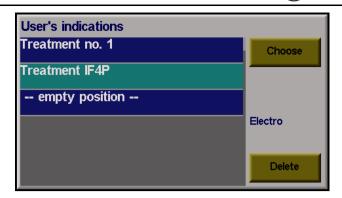
This function allows saving parameters' values which are most often used by the user. You may assign them to illnesses or patient names.

V.7.1. Favourite parameter sets

Using the MEMORY function one can create a collection of individual ("favourite") settings. It is possible to make your own settings or to copy the settings from the available programmes. To copy a ready program to MEMORY, select it as in p. V.6. "PROGRAM function" and then save it as in p. V.7.3. "Saving treatment parameters in MEMORY"

V.7.2. Reading the previously saved settings from MEMORY

You can use the treatment previously saved in MEMORY by pressing button. The list of saved items will show up on the screen.



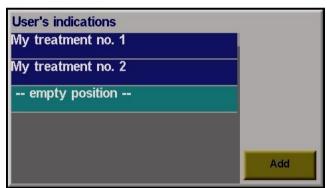
Use buttons or touch the screen to choose the desired item. Alternatively you may press the screen and, while keeping pressed, move your finger up or down to browse through the list. Confirm your selection with the button "Choose".

You may resign from using the MEMORY function by pressing BACK or MEMORY button at any moment.

V.7.3. Saving treatment parameters in MEMORY

To save treatment parameters in **MEMORY**:

- · choose treatment parameters when the device is in the edition mode
- press , the list of saved items appears on the screen
- Using buttons or touching the screen chose the item "--empty position--"



press ADD button – the window for entering the description shows up



- you may change the position of the cursor with buttons or by touching the screen
- description of the item is entered with the keyboard shown on the screen

- tabs at the lower end of the keyboard mean:
 - CAPS capital letters on/off
 - SPACE inserting space
 - BACKSPACE deleting of last symbol to the left of the cursor
 - NEWLINE adding new line after the cursor

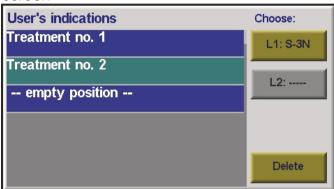
When ready, the description is confirmed by pressing

You may discontinue using **MEMORY** function by pressing button at any moment.

V.7.4. Deleting an item from MEMORY

In order to delete an item from **MEMORY** do the following:

• choose item in the list which is to be deleted - with buttons or touching the screen



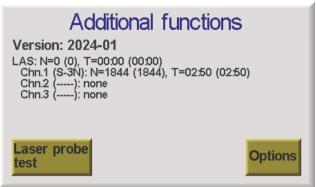
 press DELETE on the screen; a window will appear with a request for confirmation



press YES to delete item or NO to quit deleting

V.8. Additional functions

Press button to access the additional device functions (from the main parameter edition screen).

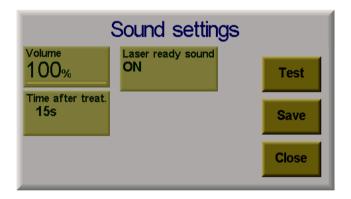


You may use them to do the following:

- check software version
- check number of performed treatments (those stopped before full emission are not counted)* and the total time of treatments (separately for the device and currently connected laser applicators)*
- begin laser power measurement (laser probe test)
- set sound parameters (including end of treatment signal)
- set laser scanner edition mode (full or simple)

V.8.1. Setting (Options)

Pressing "Options" on the "Additional functions" screen calls up the following window:



Fields on the screen have the following meaning:

- **Volume:** Setting volume in the range 0% 100%.
- **Time after treat.:** Time of signal after end of treatment, in sequence: 15s, 30s, 1min, 2min, endless
- Ready sound: Chose if the sound signal at ready for emission (readiness mode) is to be turned ON or OFF
- Parameters mode: Change laser scanner parameters edition mode (full/simple)

Touch the field to be changed and use the keys to alter choice.

The field can be chosen directly on the display, or by pressing the key

To check up the sound volume press the **Test** key.

The settings chosen should be accepted with the **Save** key.

To exit the setting window press the **Close** or BACK key. If there were any changes made that have not been saved, the request for confirmation will appear:



V.9. Information given by the unit during work

During treatment, the unit constantly monitors the parameters of the treatment. When an error is detected, all treatments are stopped and one of following messages is shown on the screen.

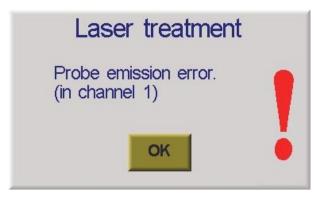
Malfunction of the fan:



Problems with the transmission of laser applicator



Error of the laser probe emission



The door opened (if the door switch is installed)



This messages can be closed by pressing **OK** and then the device automatically switches over to the parameter edition mode.

NOTICE: Most frequent cause of fault is disconnection or break in applicator's cable. When the error occurs please check the connection of all cables in the sockets on both sides and search for possible damages of the cables.

If this does not help, you have to contact an authorised service.

V.10. Helpful general information

A comment on using the touch screen:

IMPORTANT: Use the touch screen with care, because the screen is not resistant to hits or scratches. In particular, do not hit it with sharp objects (like pen or nails). The strength necessary for activating a "button" on the screen is similar to that used when pressing the external keyboard.

- The device detects the type of applicator connected.
- The device detects a break in the electrotherapy circuit and signals it with sound. The treatment is not stopped.
- If a break is detected in an ultrasound or a magnetotherapy applicator the treatment is interrupted and an appropriate message displayed.
- The device is designed for a continuous use. It is not necessary to switch it off during breaks between treatments.
- Avoid unnecessary using of the emergency stop.

V.11. Safety of treatments

WARNING: In the event of any serious incident related to the use of a device, it is essential to report this information to the manufacturer and to the relevant competent authority of the Member State dealing with the safety of medical devices. In Poland, such an authority is:

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

Al. Jerozolimskie 181C, 02-222 Warsaw

e-mail: incydenty@urpl.gov.pl

fax: +48 (22) 492 11 29

WARNING: It is necessary to interview the patient about the contraindications against the treatment, before the treatment is started.

<u>WARNING:</u> In case of untypical device behaviour, which may be dangerous to the patient or staff, stop the treatment immediately and follow the guidelines of the chapter VI. "Maintenance".

<u>WARNING:</u> To avoid the risk of electric shock, the appliance must be connected to a mains supply with a protective earthing connection.

WARNING: Do not make any modifications to the device.

<u>IMPORTANT:</u> Treatment applicators (probes and heads) should be protected from shocks and mechanical damage. Applicator damage may be not visible from outside and may result in faulty work.

IMPORTANT: Care should be taken not to transfer bacteria from one patient to another or to the staff. Pay attention to the hygiene of patients and staff. Applicators and eyewear must be properly cleaned and disinfected with proper agent (70% solution of ethyl alcohol or a suitable disinfectant is recommended).

The application of the agent should be checked up in the manufacturer's datasheet. It is also advised to put it to test on a small area of a probe and check on the possible damage after some time (e.g. after 24 hours).

NOTICE: The device must be switched off by setting the power switch in the position "O" after daily treatments.

<u>WARNING:</u> The device belongs to the laser Class 3B. Laser ray emitted is dangerous for eyes, both directly, and also if reflected from a mirror-like surface. However, this radiation is harmless for the skin.

WARNING: In case of laser treatment, when the device is switched on, the patient and staff and everybody present in the room must wear protective eyewear.

<u>WARNING:</u> It is forbidden to direct the laser probe at any direction other than the place of treatment and particularly not in the direction of eyeballs.

<u>WARNING:</u> The laser treatments with LASERTRONIC LT-3 should be performed in dedicated premises, so that the third persons would not be endangered by accidental laser emission. All reflecting surfaces (glass, glossy tiles, chromium plated objects, etc.), which could accidentally reflect the laser beam, should be excluded from this premises.

WARNING: No information was found on the use of laser therapy in people with dark skin colour, therefore laser therapy is not recommended for such people.

LASERTRONIC LT-3

WARNING: Prior to treatment, ensure that the patient has not used cosmetic or photosensitising medicines (antibiotics, sulfonamides, herbs) in the vicinity of the treatment site.

IMPORTANT: Place the supplied warning labels on the door of the laser treatment room.

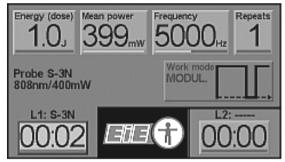
NOTICE: When using the laser scanner pay attention to move the scanning head and the mobile stand gently, in order to avoid accidental damage of the equipment from hitting objects or falling.

V.12. Abbreviated operation diagram

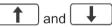
The following diagram shows most important screens of user interface and basic directions for using different functions. Notes shown below are only examples.

ATTENTION! During treatment always wear protective eyewear. Irradiation of the eveball may result in blindness!

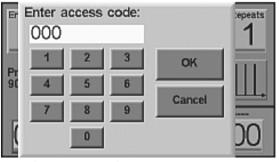
1. Main screen



- a. At the bottom there are treatment timers for left (L1) a. Enter additional functions by pressing and right (L2) socket; over timer there is type of applicator connected to related socket.
- b. At the top there are treatment parameters for chosen applicator (marked with blue frame on timer).
- c. Chose parameter for edition by touching the screen or pressing Parameter starts blinking.
- d. Change value of parameter with



2. Access code

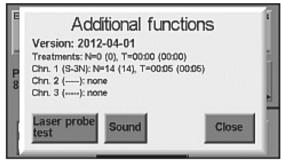


a. At first starting of emission you have to enter access code. It is the last 3 digits of serial number (SN) at back of device. You have to enter the code again if there was no operation for 60 minutes.

3. Starting treatment

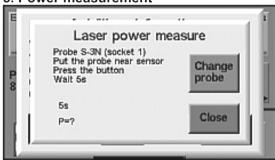
- a. Choose the applicator by touching timer or pressing Treatment will start for applicator marked with blue frame on timer.
- b. Press start for entering ready for emission mode. a. Pressing of
- c. Start emission with button on the applicator.

4. Additional functions



when in main screen. You can enter power test here.

5. Power measurement



a. Act as in information on the screen. Test result show laser power of applicator in mW and if it is positive / negative.

6. Emergency stop



stops power supply of applicators. Turn the device off and on again for further use.

VI. MAINTENANCE

NOTICE: The addresses of authorised service are available at the manufacturer's office (see: the cover of this manual).

VI.1. Checking the proper operation of the device

- The unit should be periodically checked every 12 months throughout the time of exploitation.
- Emitted power of all laser probes and the accuracy of the built-in power meter should be checked every 12 months.
- Laser power meter used should be of the class 10%.
- The checking can be done only by the manufacturer or authorised service having a manufacturer's certificate.
- The periodical technical tests should be made at the user's workplace, because the work environment of the unit has to be checked.

<u>IMPORTANT:</u> If the device fell down, before the next switching on call for the authorised service to inspect the device. There may be invisible damages that can bring about a faulty operation.

VI.2. Proper working environment

Observing the recommendations given below will help keep the device in good technical condition and will assure a long and undisturbed use.

- Power supply mains should be checked systematically, there should be no breaks, sparking or similar disturbances.
- Equipment should not work in humid environment or one with steam, salts, sulphides etc. in the air. Pay attention there are any rooms for inhalation, hydrotherapy, pools or similar if in vicinity. If you cannot avoid such situation, the room with electrotherapy equipment must be insulated from such influences.
- Work environment should not be dusted or littered, because the fan may get blocked by the accumulated dust and dirt. Break-down of the device may occur, similarly to a PC computer. This may be avoided by systematic (e.g. once a month) cleaning of the fan with a vacuum-cleaner (see VI.1. "Repairs").
- The device should not be heated by an external radiator, heater, direct sunlight etc. Overheated electric devices may break down.

VI.3. Repairs

Should any faulty operation occur, the equipment ought to be delivered to an authorised service having a manufacturer's certificate for such repairs or directly to the manufacturer for check up or repair.

If the mains switch indicating that the device is switched on is not illuminated, have the fuse, located on the rear panel of the device (a spare fuse is provided) checked and replaced if necessary by a qualified service technician.

IMPORTANT: All repairs can be performed only by the manufacturer or authorised service.

NOTICE: When sending equipment to the service or manufacturer, remember to enclose all cables and accessories used with the unit and also a detailed description of failure (conditions of work, features of error etc.), your address and contacts (phone, e-mail).

NOTICE: Check the service authorization certificate for it may not be authorized to conduct specific controls or repairs (concerns especially laser probes).

VI.4. Maintenance and cleaning

The device should be cleaned of accumulating dirt.

- At least once a month clean the fan on the back panel and ventilating holes at the bottom of the device. Turn the power off and remove dust with a vacuum-cleaner, keeping the muzzle for at least 1 min at the apertures.
- Clean the device with a soft moistened cloth or sponge, but not too wet, not to let water inside.
- Protective eyewear should be cleaned with a cloth suitable for normal corrective glasses.

NOTICE: Do not use paint or varnish solvents to clean the device.

NOTICE: The following must not be used to clean leather items: waxes, strong detergents, bleaching agents, agents containing petrol, oils and solvents, agents that scratch the surface, natural leather cleaners.

VI.5. Maintenance of laser applicator

After each treatment point probes should be cleaned and disinfected with gauze or cotton slightly moistened with ethyl alcohol (70% solution is recommended). Next treatment may be started after the alcohol dries out. Proper probe work may be checked with test function according to point V.5.13 "Power measurement".

NOTICE: Protect the lens of probes from scratching.

NOTICE: Laser diodes have limited emission time (2-5 years is typical) depending on intensity of use. Therefore you should check the emitted power dose as described with power measurement function as described in p. V.5.13. "Power measurement". Errors in correct dosage may result from cable breaks or main unit damage. In other case the diode has to be replaced by the manufacturer.

NOTICE: Scanner: There is an exit port cover on the underside of the scanning head. It should be periodically dry cleaned with eyeglass cleaning cloth or lightly dusted.

VI.6. Disposal of the warn out equipment

- Predicted exploitation time of the device is 10 years, provided that it is properly used and maintained according to user's manual and put to periodic technical service.
- After this time the device may be still used as long as it is serviced by the authorised service according to its condition. It can be further used if approved by the authorized service or by the manufacturer. Especially service intervals can be shortened in comparison to the nominal ones.
- After the exploitation time is over or end of usage, the device should be handed over for disposal to a company dealing with disposal of electronic equipment, equipment, in accordance with current legislation.

VII. MEDICAL DESCRIPTION

<u>WARNING:</u> Recommendation of this manual are of general nature. They should be adjusted individually to every patient.

WARNING: In doubts consult a doctor of appropriate speciality.

<u>WARNING:</u> Treatments with Lasertronic LT-3 must be done by a qualified physiotherapist under the supervision of a medical doctor. Otherwise the therapy effects may be limited and the patients may be exposed to the risk of health deterioration.

<u>WARNING:</u> Treatments must be conducted according to the instructions for use and all safety recommendations.

WARNING: The maximum dose of laser radiation should not exceed 2000 mJ/cm².

VII.1. Intended patient group

The Lasertronic LT-3 can be used with patients of all ages, taking into account the counterindications listed below in p. VII.3. "Contraindications".

VII.2. Indications

VII.2.1. Basic indications for lasertherapy

- Rheumatology and musculoskeletal disorders
 - Osteoarthritis
 - Pain reduction in osteoarthritis
 - Osteopenia
 - o Osteoporosis
 - Cervical spondylosis
 - Ankylosing spondylitis
 - Osteoarthritic changes of small joints
 - Inflammations of the joint capsule
 - Analgesic effects
- Orthopedics and sports medicine
 - Painful shoulder syndrome
 - Painful back syndromes
 - o Inflammation of the lateral epicondyle of the humerus / tennis elbow
 - Biceps tendonitis
 - Sheath inflammation of the de Quervain's tendon
 - Inflammation of the plantar fascia
 - Posterior tibial tendon dysfunction
 - o Ankle joint sprain
 - Fracture of the wrist bone
 - Fractures of the radius bone of the arm
 - Fractures of the wrist and hand
 - Delayed healing of bone fractures
 - o Temporomandibular joint pain
 - Temporomandibular disorders
 - Chronic discogenic sciatica
 - Analgesic effect
 - Inflammation
 - o Flexor tendon injury
 - Spinal cord injury
- Neurological conditions and neuropathies
 - Ulnar neuropathy
 - o Trigeminal neuralgia

- Radiculopathy
- o Peripheral neuropathic pain
- Neuropathic pain
- Pain associated with hemiplegia
- Carpal tunnel syndrome
- Morton's neuroma
- Dentistry and oral disorders
 - Analgesic effect after orthodontic procedures
 - Dentin pain hypersensitivity
 - Caries
 - Gingivitis
 - Periapical healing of the tooth
 - Alveolar inflammation
 - Delayed eruption of the tooth
 - Reducing inflammation of the oral mucosa caused by chemoradiotherapy
 - Traumatic ulcers associated with dentures
- Dermatology and tissue regeneration
 - Ulcers
 - Diabetic foot ulcers
 - Venous ulcers
 - Oral ulcers
 - Bedsores
 - o Burns
 - Wound healing
 - Burn wounds of the lower extremities
 - Hypertrophic scars after burns
 - Post-surgical scars
 - Stretch marks (striae)
 - Inflammatory acne
 - Horizontal wrinkles on the neck
 - Purulent skin diseases
 - Herpes
- Gynecology
 - Bartholin's gland cyst or abscess
 - Atrophy of the vulva and vagina
 - Lichen sclerosus of the vulva
- Laryngology and upper respiratory tract disorders
 - Chronic rhinosinusitis
 - Earditis / otitis media
- Urology and diseases of the male reproductive system
 - o Chronic prostatitis (prostadinitis)

VII.3. Contraindications

VII.3.1. Contraindications to lasertherapy

- Application to the eyeballs
- Pregnancy. Do not treat uterus region. Other regions may be treated, yet special attention is needed.
- Haemorrhage. Do not treat patients with haemorrhage because intensification of symptoms may occur.

LASERTRONIC LT-3

- Cancer. Do not treat undiagnosed changes. It is possible to treat patients with cancer during palliative therapy as analgesic therapy - with patient's agreement after being informed.
- Thyroid gland. Do not treat thyroid gland.
- Immunosuppressive therapy. It is not recommended to use laser biostimulation with this therapy.

VII.4. Side effects

Side effects that may rarely occur at the irradiation site during laser therapy include: a warm sensation, burning, moderate pain, rash, appearance of blisters on the skin, changes in skin pigmentation, numbness, itching. Burns can also occur if equipment is used inappropriately. There have also been isolated cases of fatigue, palpitation, hazy vision, difficulty moving, dizziness and headaches after laser therapy treatments and keratitis following exposure to the cornea.

VIII. METHODOLOGY OF TREATMENTS

<u>WARNING:</u> Treatments with Lasertronic LT-3 must be done by a qualified physiotherapist. Otherwise the therapy effects may be limited and the patients and the staff may be exposed to the risk of health damage.

NOTICE: Treatments must be conducted according to the user's manual and especially all safety recommendations described in it must be observed.

VIII.1. Methodology of lasertherapy treatment

Dose:

WARNING: The maximal dose should not exceed 2000 mJ/cm².

For acute states the energy dose range is (50 ÷500) mJ/cm².

For chronic states the energy dose range is (500 ÷ 2000) mJ/cm².

Detailed power doses adequate for various illnesses can be found in the enclosed bibliography. The time of a single treatment is up to 20 minutes – depending on the size of area treated (usually shorter). The number of treatments is 5-60, depending on type of illness.

Irradiation techniques may be divided into contact and non-contact.

These may be further divided into: point, line and area treatment.

The contact technique means direct placement of lens on the spot treated. The non-contact technique means that lens is 2 or less centimetres over the area treated, without touching the area.

Whenever possible, the contact technique should be used, because the radiation energy loses are lower.

- Surface irradiation is used when illness concerns the surface of the patient's body.
- Line irradiation is used when the ill area is shaped as a straight or a broken line.
- Point irradiation is used for a single spot or a series of small spots (including the acupuncture points).

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Please fill in the following questionnaire. Your opinions are very helpful in fulfilling your expectations concerning our equipment.

USER'S QUESTIONNAIRE

Please pick your answer and mark it with an X.

D	evice's	type			LT-3			Device's number					
No	Question												
1.		do you grade therapeutic effectiveness of the device in its treatments compared with similar devices of rent producers?											
Ve	ry low			Low		Average		Good		Very good			
2.	What is the reliability of the device during use?												
Very unreliable			Unreliable				Average		Rather reliable		Reliable		
3.	How d	How do you grade easiness of operating this device?											
Very difficult			Difficult				Average		Easy		Very easy		
4.	Does the device meet expectations?												
Very poorly				Poorly			Average		Highly		Very highly		
5.		s the information provided in the instructions for use and on the device clear and does it provide the necessary information?										е	
Very poor			Poor				Average		Good		Very good		
6. If the device has been serviced (repaired) please evaluate the quality of the service:													
Ver	y poor			Poor			Average		Good		Very good		
Has not been serviced													
Can the ease of use be improved? If so, how?													
		Yes			No			I cannot	decide				
													
	C	an the	COI	 ntent of th	e instri		ons be im	oroved? If	so. what	should be	changed?		
	Yes		No No			I cannot decide							
									···				

Please enter which conditions are most frequently treated:

DISEASE

THERAPY

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\/\hat l	vind of another	therapy would	ou like to use	in your work)					
				-						
c/										
Other	notes on the u	se of the device:								
Please name the position of the person filling in this questionnaire:										
Please name the kind of place at which the device is used::										
Hospital	Outpatients	Physiotherapy	Home visits	Sanatorium	Other					
15 - 55	clinic	practice	2 2 2 2 2 3 2 3 3 3 3 3 3 3 3 3 3 3 3 3		(please name)					
		p. 5.50.00			(15.23.23.13.11.5)					

Thank you for filling in this questionnaire.

Pease send filled questionnaire by e-mail: office@eie.com.pl
or by post: EiE, 05–402 Otwock, ul. Zaciszna 2, Poland

