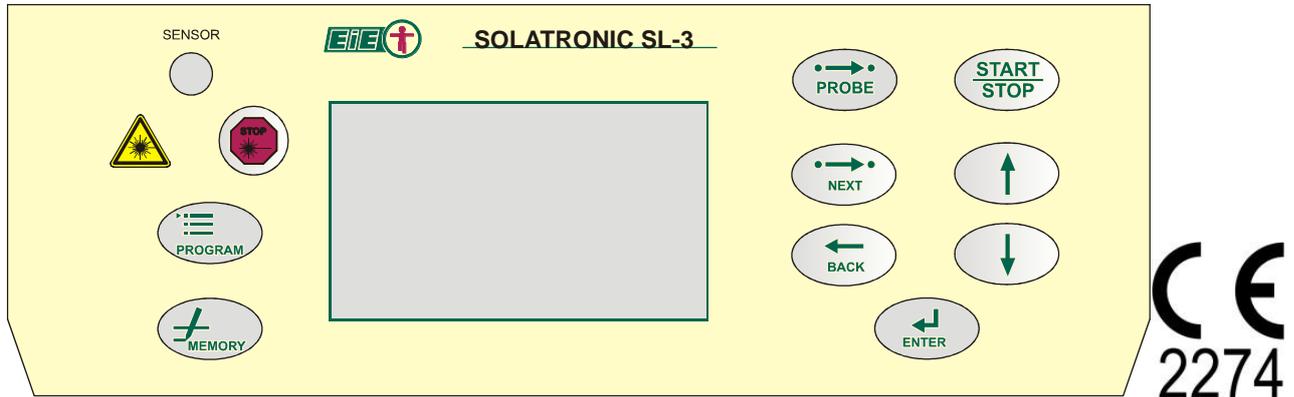


SOLATRONIC SL-3

Ultrasound and 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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Series: 2025-02/A



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WARRANTY CARD

Name and model of the product: **SOLATRONIC SL-3**

Serial number Date of production.....

Warranty period: 24 months from the date of purchase.

Conditions of warranty:

1. The selling party is obliged to deliver the fully fit equipment to the customer.
2. Warranty card is valid only with the date of sale stamped and signed by the seller.
3. Exploitation of the product must be conducted according to the instructions for use.
4. All warranty and post-warranty repairs will be done by the manufacturer or by the authorised and qualified service.

The warranty does not cover:

1. Accessories which are subject to the natural wear and tear in the route of exploitation (electrodes, cables, bands, pads, sacks, eyewear, etc.).
2. Mechanical damages which did not rise from the fault of the producer.
3. Damage to cables (cracks, breaking and the like), which can happen under the intensive exploitation.
4. Occurrence of up to 2 bad pixels on graphic display.
5. Necessary periodic technical tests.

The warranty ceases to be valid in the case of:

1. Expiry of the warranty period.
2. Lack of required periodic technical tests.
3. Repairs done by the user or an unqualified service.
4. Non-observance of correct exploitation as described in the instructions for use.

All customer complaints should be sent to the above address.

.....
Stamp and signature of the manufacturer

.....
Date of purchase

.....
Stamp and signature of the seller

Confirmations of technical service

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I. APPLICATION

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

WARNING: 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

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

SOLATRONIC SL-3 is a modern, microprocessor controlled unit for ultrasound 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, ultrasound heads of different sizes and magnetic field applicators.

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

WARNING: Any treatment with SOLATRONIC SL-3 should be performed carefully by a qualified physiotherapy technician.

WARNING: 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.

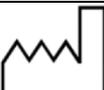
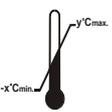
WARNING: The ultrasound heads (applicators, probes) are calibrated and dedicated to an individual device. Using the heads with other devices without the calibration can result in using wrong treatment parameters. DO NOT use the heads with another device without previous calibration by the manufacturer.

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			
	CE mark		Medical device
	Unique device identifier		Manufacturer
	Date of manufacture		Serial number
	Catalogue number		Caution
	Electrical device type BF		Fuse
	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			
	Maximum allowed temperature range		Keep dry
	The maximum allowable load on the package		This side up

II. TECHNICAL SPECIFICATION

II.1. Nominal operating conditions

• Heating time	1 min
• Time of continuous work	24 h
• Power supply (single phase)	~230 V 10%, 50 Hz, 50 VA
• Laser device class	3B
• Insulation class	I type B
• Ambient temperature	10°C ÷ 40°C
• Relative humidity	up to 85%
• Atmospheric pressure	780-1060 hPa

II.2. Additional specifications

• Internal treatment clock (ultrasound)	30 s ÷ 30 min.
• Internal treatment clock (laser)	1 s ÷ 99 min.
• 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 $\pm 10\%$.

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 μ J
• 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 ± 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 cluster probe 720 mW / R:

- total continuous power 720 mW
- number of diodes 9
- wavelength 660 nm ±10 nm
- single diode power 80 mW
- effective area of treatment 50 cm²

modulated work mode:

- range of power (adjusted) 10 ÷ 720 mW
- frequency of pulse repetition 5 ÷ 9999 Hz

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

- total continuous power 1040 mW
- number of diodes 5 (R) + 4 (IR)
- R wavelength 660 nm ±10 nm
- R single diode power 80 mW
- IR wavelength 808 nm ±10 nm
- IR single diode power 160 mW
- effective area of treatment 50 cm²

modulated work mode:

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

SP-3 cluster probe 1440 mW / IR:

- total continuous power 1440 mW
- number of diodes 9
- wavelength 808 nm ±20 nm
- single diode power 160 mW
- effective area of treatment 50 cm²

modulated work mode:

- range of power (adjusted) 10 ÷ 1440 mW
- frequency of pulse repetition 5 ÷ 9999 Hz

II.4. Technical data – ultrasound

NOTICE: The ultrasonic powers below are given with accuracy ± 20%.

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

SU-1 treatment head

- effective treatment area 1,33 cm²
- ultrasound frequency 1 MHz lub 3,3 MHz
- power density (continuous mode) 0,1 ÷ 2,5 W/cm²
- peak power density (modulated mode) 0,1 ÷ 3 W/cm²
- type of beam collimated
- ingress protection code IPX7
- BNR < 6:1

SU-5 treatment head

- effective treatment area 5 cm²
- ultrasound frequency 1 MHz lub 3,3 MHz
- power density (continuous mode) 0,1 ÷ 2,5 W/cm²
- peak power density (modulated mode) 0,1 ÷ 3 W/cm²
- type of beam collimated
- ingress protection code IPX7
- BNR < 6:1

SUP-6 treatment head

- effective treatment area 6x3 cm²
- ultrasound frequency 1 MHz lub 3,3 MHz
- power density (continuous mode) 0,1 ÷ 2,5 W/cm²
- peak power density (modulated mode) 0,1 ÷ 2,5 W/cm²
- type of beam collimated
- ingress protection code IPX7
- BNR < 6:1

Device parameters

- max. continuous power 12,5 W
- pulse frequency 10 – 150 Hz
- working modes continuous or pulsed
- duty factor 5 – 100%

NOTICE: In modulating mode of operation, the maximum continuous power density must not be exceeded.

NOTICE: If another treatment is started in addition to the ultrasound treatment, the maximum power (continuous and modulated) is limited to 1 W/cm².

II.5. 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

Subject	EMC Standard or Examination Method	Resistance test level
		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, ± 1kV, ± 2 kV
Disturbances conducted and induced from RF fields	PN-EN 61000-4-6:2014	3V (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	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
Supply breaks		
Magnetic fields of the supply mains frequency	PN-EN 61000-4-8:2010	30 A/m 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:



Emission levels for the professional medical care company and environment of the domestic medical care			
Subject	Applied Standard	Allowed levels and /frequency bands MHz	
Harmonics of current	PN-EN 61000-3-2:2014	The device meets the requirements of the Standard and due to small power does not require any testings.	
Fluctuations of voltage and light flickering	PN-EN 61000-3-3:2013	The device meets the requirements of the Standard and due to small power does not require any testings.	
Conducted RF emission	PN-EN 55011:2016 Group 1, Class B	66 dBµV (quasi-peak.) 56 dBµV (avr.)	0,15 - 0,5
		56 dBµV (quasi-peak.) 46 dBµV (avr.)	0,5 - 5
		60 dBµV (quasi-peak.) 50 dBµV (avr.)	5 - 30
Radiated RF emission	PN-EN 55011:2016 Group 1, Class B	Electrical field at 10 m distance	
		30 dBµV/m (quasi-peak.)	30-230
		37 dBµV/m (quasi-peak.)	230-1000

Cables used with the device:

- cables connecting the ultrasound head to the device up to 2 m
- cables connecting the laser probes to the device up to 2,5 m
- mains cable up to 1,8 m

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

IMPORTANT: Telecommunication equipment using radio frequencies may affect operation of this device.

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

II.6. 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
- control magnet 1 pcs
- instructions for use 1 pcs
- warning signs for use on doors 1 set
- gel for ultrasound treatments 0.5L (if an ultrasound head is ordered with a device)

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]

Basic accessories – ultrasound:

- Ultrasonic applicator (head) 1,3 cm²: **SU-1**
- Ultrasonic applicator (head) 5 cm²: **SU-5**
- Ultrasonic applicator (head) 6x3 cm²: **SUP-6**

WARNING: If a laser applicator will be used with the device, protective equipment for the patient and the operators (eyewear) is necessary.

WARNING: The manufacturer does not take any responsibility for using with SOLATRONIC SL-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.

For ultrasound treatments, at least one ultrasound applicator is needed.

The accessories connected for each therapy do not affect in any way the other therapies with the note below.

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.
2. 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.

3. 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.

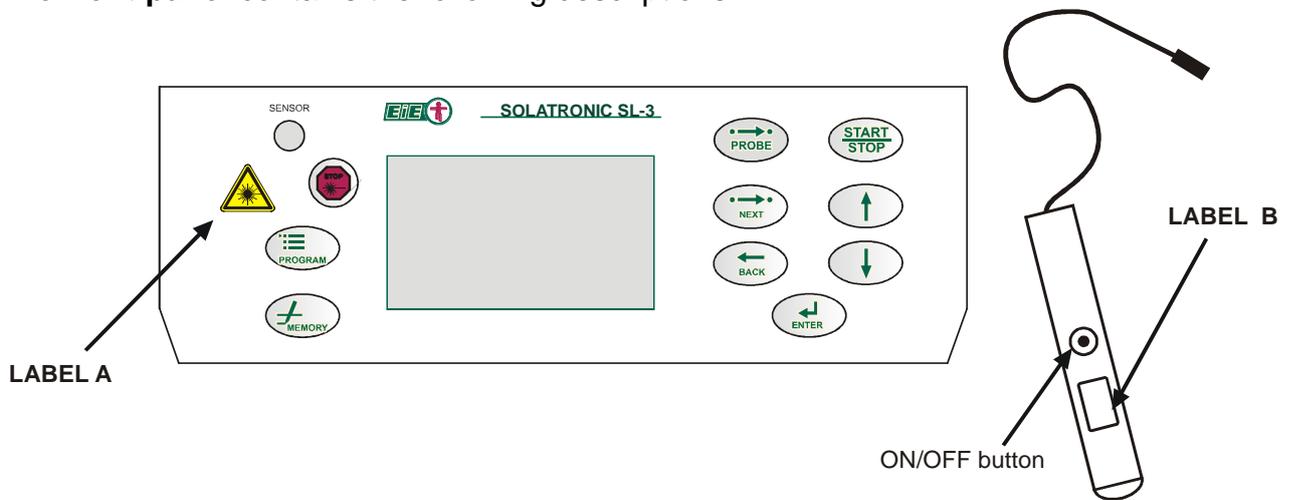
IMPORTANT: The ultrasound heads are calibrated and dedicated to an individual device. Using an non-calibrated ultrasound probe can result in using inaccurate parameters, which may lead to usage of too high power. Please contact the manufacturer for calibration of the ultrasound probe (for example coming from another device or newly bought).

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):



The front panel contains the following descriptions:



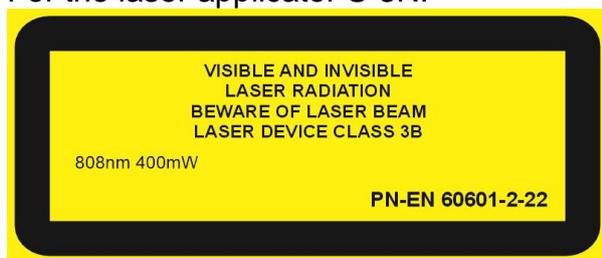
Label A – on the front panel

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



Back panel:

For the laser applicator S-3N:



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 and ultrasound 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

The cables for treatment ought to be connected to appropriate sockets:

- Yellow– Laser applicators
- Blue – Ultrasound heads

For ease of use the plugs and sockets have the same colours respectively.

IMPORTANT: Plug has an automatic lock protecting it from falling off from the socket (when connecting one should hear a “click”). The plug fits the socket only in the position with the arrow symbol up. When disconnecting, one should gently pull the plug out, but strong enough to unlock it, avoiding to turn the plug around while in the socket. When disconnecting, the plug should be held near the socket, avoid pulling the plug by the cable, otherwise the cable may be broken.

IV.4. Switching on

WARNING: Do not switch on and off the device when electrodes are put on the patient. This may cause the patient to receive unpleasant electric shock.

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

IMPORTANT: 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 “1”.

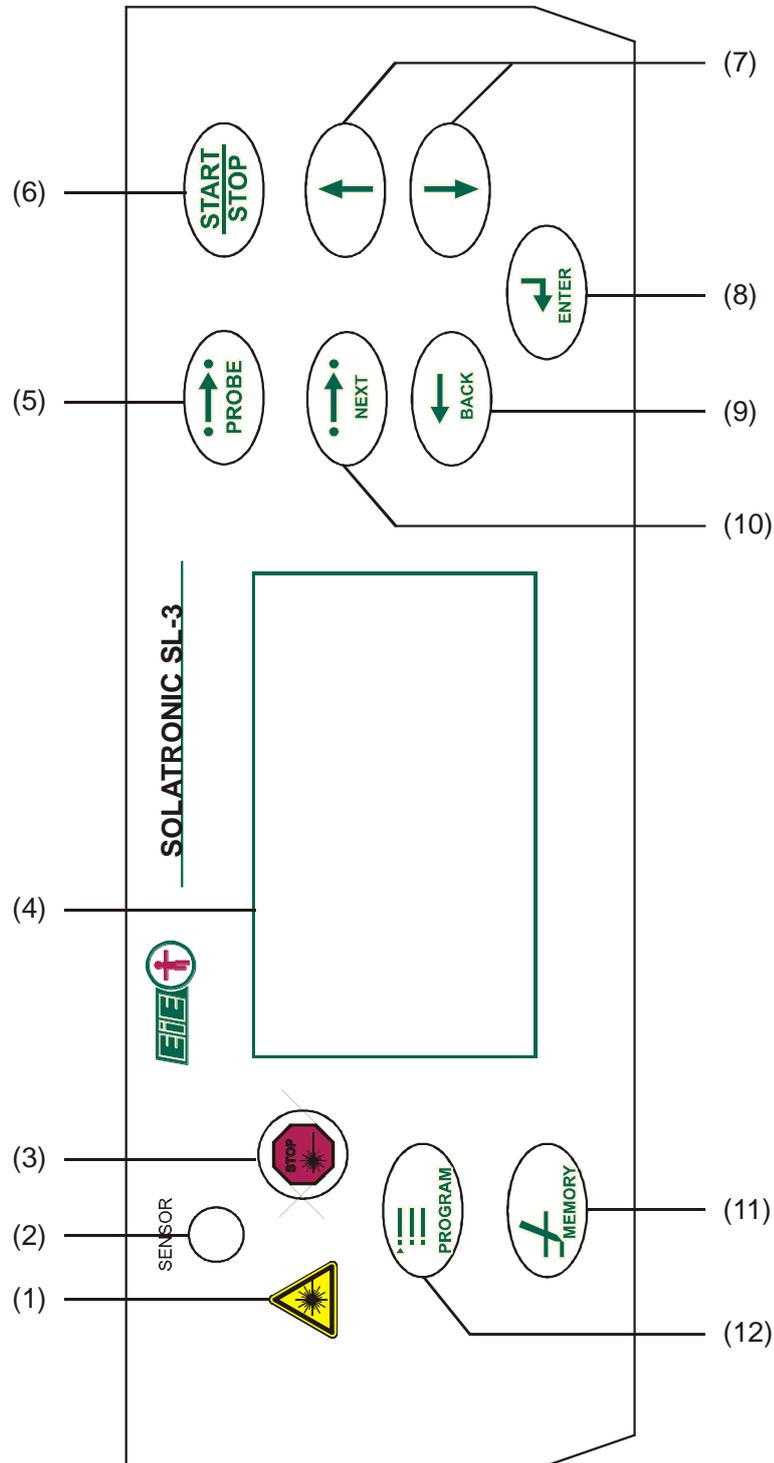
V. OPERATION AND HANDLING OF THE DEVICE

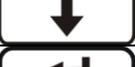
WARNING: All treatments using SOLATRONIC SL-3 should be performed carefully by a qualified physiotherapy technician. Otherwise, the therapeutic effects may be limited and the patient and staff may be exposed to health risks.

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 measurement	
3		Emergency energy turn OFF	
4		Colour LCD screen with touch panel	
5		Change of the type of therapy	
6		Turn ON / OFF the treatment	
7		Parameter value setting	Increase value of the parameter
			Decrease value of the parameter
8		Accept the choice	
9		Move to menu for additional functions or return to the previous screen	
10		Go to next item on the screen	
11		Individual sets of parameters saved by the user	
12		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

WARNING: All treatments using SOLATRONIC SL-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 the first class. 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.

Lasertherapy treatments

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

WARNING: 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 entering the protective password.

Ultrasound treatments

WARNING: The ultrasound heads are calibrated and dedicated to an individual device and should only be used with the device they were calibrated for. Do not use the heads that are not calibrated with a given device, instead send them to the manufacturer for calibration. The heads without proper calibration may not work properly or may show inaccurate parameters.

When switching on, observe the following sequence:

- connect the applicators and/or electrodes
- 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. Choice of therapy

This can be done as follows:

- either press the LCD screen with your finger in the area of desired applicator (treatment clock) – the device will show the treatment parameters for the selected channel.
- or press the button , an option selection screen will appear (respectively for the left and right channel):

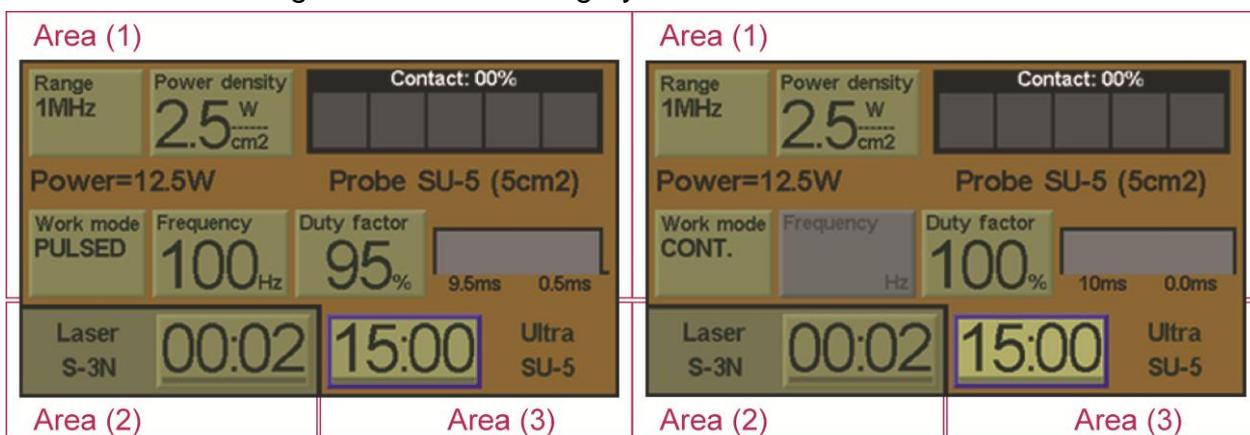
The choice is confirmed by touching the appropriate item on the screen. It is possible to withdraw pressing „Close”.

The chosen therapy is marked with a blue frame, and in the field (1) relevant parameters are displayed.

NOTICE: Switching over between applicators can take about 1 s. Wait until the device has switched over to the chosen applicator.

V.3.2. Main screen

After turning on the device the screen for editing treatment parameters shows up. Fields that cannot be changed are coloured in grey.



There are 3 main areas on the screen:

- (1) – parameters area
- (2) – applicator 1 area (here laser)
- (3) – applicator 2 area (here ultrasound)

In areas (2) and (3) the times of treatment and the type of detected applicator, or the kind of the selected current are displayed. When there is no probe in a channel, the sign „-----”

is displayed. The probe chosen for edition / current is indicated by blue frame around timer. Treatment parameters are displayed in area (1).

V.3.3. Applicator areas

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



There are the following fields in these areas:

(2a): related applicator symbol

„Laser” – laser socket

„Ultra” – ultrasound socket

(2b): type or lack of applicator / current or if the current is missing

for lasertherapy: „S-1N”, „S-2N”, „S-2B”, „S-3N”, „SP-1B”, „SP-2B”, „SP-3”, „---”

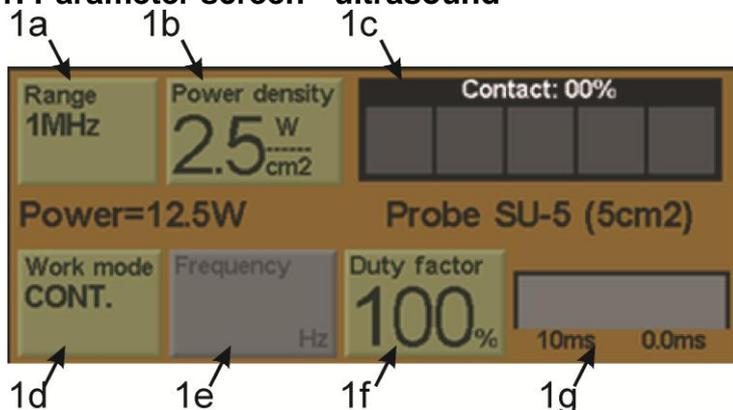
for ultrasound therapy: „SU-1”, „SU-5”, „SUP-6”, „-----”

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

V.3.4. Parameter screen

In area (1), treatment parameters for the selected applicator are displayed and edited.

V.3.4.1. Parameter screen - ultrasound



There are following fields:

(1a): parameter: ultrasound frequency [MHz]

(1b): parameter: power density [W/cm²]

- for continuous work mode it is peak value and mean value at the same time
 - for impulse work mode it is peak value
- Mean value is the product (ratio) of peak value and duty factor

(1c): graphic representation of the degree of treatment head contact with the patient's body

(1d): parameter: work mode (continuous / pulsed)

(1e): parameter: pulse frequency (for pulsed mode)

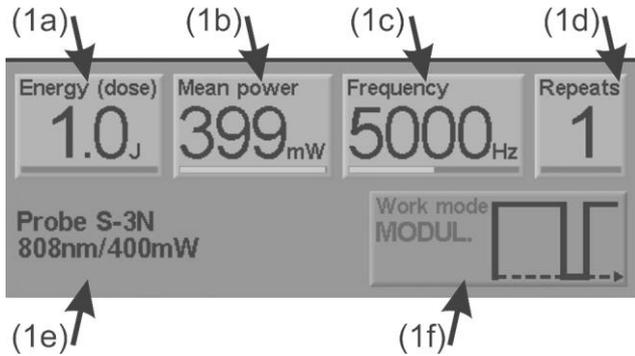
(1f): parameter: duty factor for pulsed mode [ratio: duration of pulse to the repetition period]

(1g): graphic representation of pulsed mode [first number is the pulse time, second the break time]

V.3.5.1. Parameter screen – lasertherapy

Laser point probes

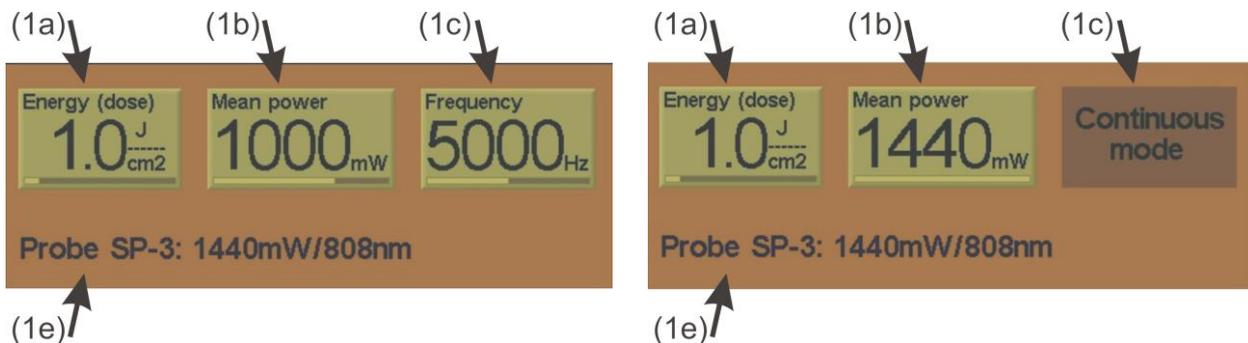
Screen of a point probe:



- (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 (SP-1B, SP-3)

Screen of laser cluster probe (one-wavelength):

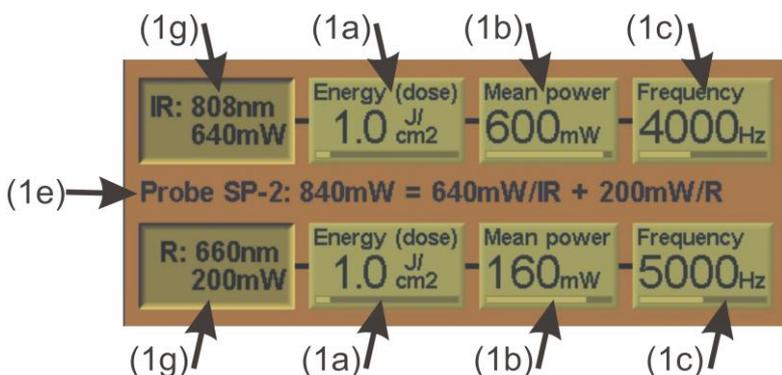


Items in area (1):

- (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 (SP-2B)

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)

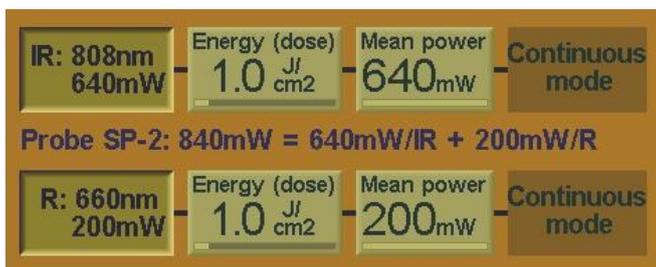
(1e): description of connected applicator

(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:



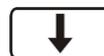
V.3.5. Selection of parameter

We can choose a parameter in one of the two ways:

- pressing with a finger on the LCD in the field of the desired parameter
- repeatedly pressing , which consecutively selects parameters.

The parameter chosen for edition is marked by pulsating brightness.

V.3.6. Changing the parameter value

Regulation (change of value) is done only with buttons  and  on the keyboard. Longer pressing of any of the two keys gives a fast change. In some parameter numeric fields there is a strap at the bottom showing the presently chosen value compared to its limits.

V.4. Performing treatments – lasertherapy

V.4.1. Ranges of parameters

- The following parameter ranges are specified in II.3 „Technical data – laser”
 - mean power
 - frequency
- For point probes it is possible to set:
 - dose 0,1 ÷ 200 J
 - time 1 s ÷ 99 min.
 - number of repetitions of dose 1 ÷ 99
- For cluster probes it is possible to set:
 - dose 0,1 ÷ 10,0 J/cm²
 - time 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.3.5. „Treatment parameters screen – lasertherapy” 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 radiates 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 radiates 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 radiates laser light in short pulses of high power with given frequency (available in applicator S-1N)

V.4.5. Starting treatment

- To switch the probe in the “ready” mode (ready for emission) press . 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.4.6 “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 remaining repetitions is shown on the screen.

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

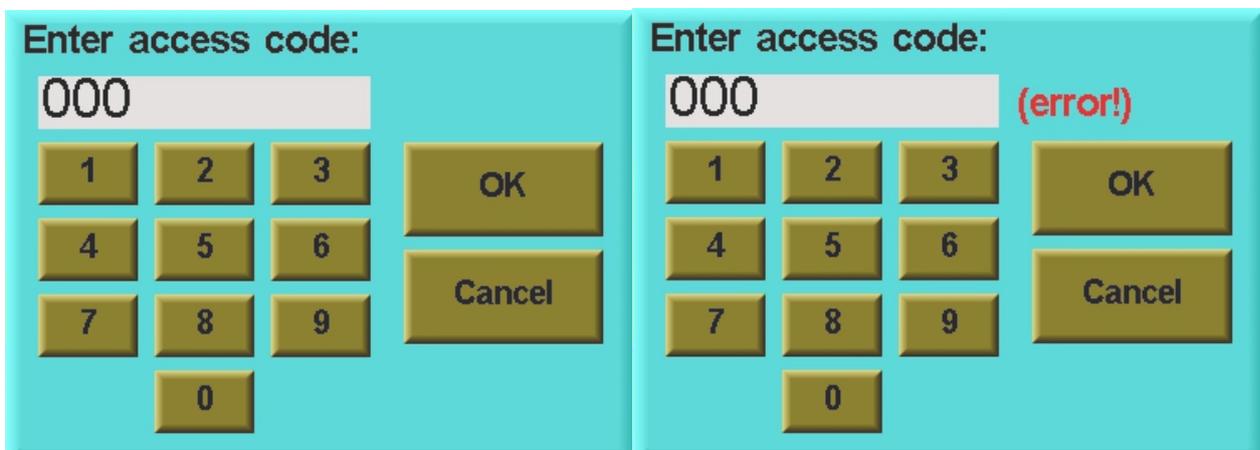
NOTICE: If the treatment is not started within one minute after starting the readiness mode, for safety reason the “ready for emission” mode is stopped. The following information appears:



V.4.6. 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 . 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.4.7. 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.9. „Information given by the unit during work”.

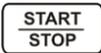
V.4.8. Termination of treatment

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.9 „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.4.9. Treatment with repetitions

In the case of laser treatments where more than one point has to be consecutively radiated, SOLATRONIC SL-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.4.10. Types of laser irradiation

V.4.10.1 Irradiation of point

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

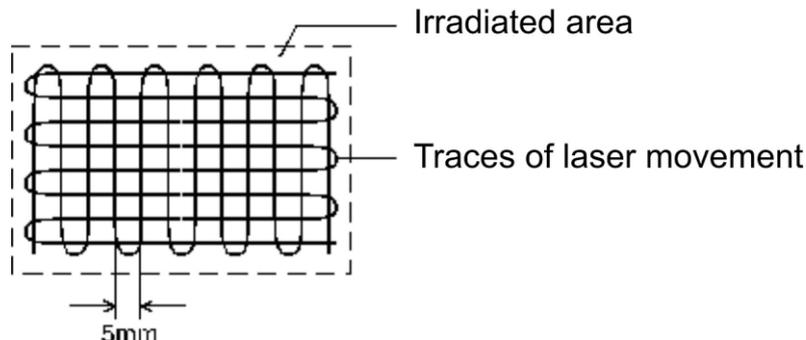
V.4.10.2 Irradiation along the line

- 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.4.10.3 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.4.11. 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

<p style="text-align: center;">Additional functions</p> <p>Version: 2024-01 LAS: N=0 (0), T=00:00 (00:00) Probe (S-3N): N=4797 (4797), T=08:02 (08:02) ULT: N=0 (0), T=00:00 (00:00)</p> <p style="text-align: center;"> Laser probe test Ultrasound test Options </p>	<p style="text-align: center;">Laser power measure</p> <p style="text-align: center;"> Probe S-3N Put the probe near sensor Press the button Wait 5s </p> <p style="text-align: center;">5s P=?</p> <p style="text-align: right;"> Close </p>
--	--



- In order to start the power measurement, first chose the proper applicator and press . 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 applicator

V.5. Performing treatments – ultrasound therapy

V.5.1. Ranges of parameters

The following parameter ranges can be set as specified in II.4 „Technical specification – ultrasound”

- acoustic frequency
- power density
- work mode (continuous /pulsed)
- pulse frequency (for pulse mode only)
- duty factor (for pulse mode only)
- treatment time 30 s ÷ 30 min.

NOTICE: The power density for the modulated mode is limited to the value of maximum continuous power density (see. II.4 „Technical specification – ultrasound”).

V.5.2. Increments of change of parameters

Power: one step is 0,1 W/cm²

Treatment time: one step is 30 s

Pulse frequency: one step is 1 Hz

Duty factor: one step is 5%.

V.5.3. Work modes (ultrasound)

Continuous mode means an uninterrupted ultrasound wave emission.

Pulsed mode means that ultrasound wave is interrupted at a given pulse frequency and duty factor. Duty factor is a ratio of the emission time to the pulse period.

V.5.4. Treatments in water

Treatment heads are suited for treatments in water.

Treatment heads may be immersed in water up to 2/3 of their length.

IMPORTANT: Do not soak applicator's cable in water.

V.5.5. Starting treatment

In order to start a treatment first set the parameters and then press . The signalling diode on the probe lights up, timer on it starts counting down and the state of connection of the applicator with the patient is shown.

WARNING: Remember to put the treatment gel on the applicator head.

V.5.6. Monitoring the contact applicator/patient

The device controls state of connection between the front of the treatment head and the patient. It is shown on the screen in percentage. This indication is approximate; it does not show the exact area of contact.

If the contact indication is equal to or higher than 50%, time of treatment is counted down.

If there is no contact (or lower than 50%), then:

- ultrasound emission is stopped (but the treatment is not terminated)
- treatment time is not counted down
- sound signal starts and light diode on the applicator starts flickering
- state of connection is still monitored
- if there is no connection for 1 minute, treatment is stopped and a relevant message shown

If the contact is restored the treatment is automatically continued.

Weak contact may result e.g. from:

- too weak tightening of the treatment head with the patient
- treatment head is touching too small area of the patient's body
- lack of or too little amount of treatment gel
- too much patient hair in the treatment area on the body

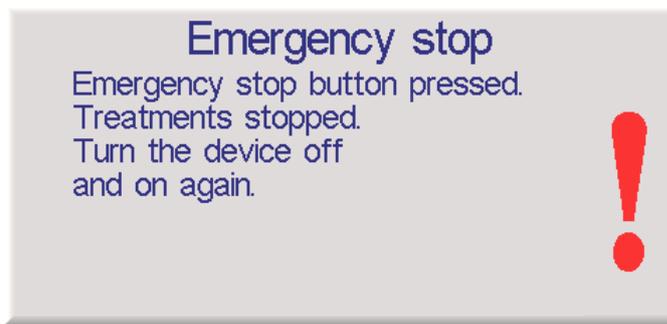
V.5.7. Termination of treatment

Treatment ends in one of the following cases:

- Time of treatment runs out.
Then the signal diode on the applicator turns off, the timer background turns green and the end of treatment sound signal starts, which may be stopped by pushing any button.
- By pressing the emergency stop . Then the emission is immediately stopped.

NOTICE: When the end of treatment results from the emergency stop, then in order to continue the treatment it is necessary to switch the device OFF and ON.

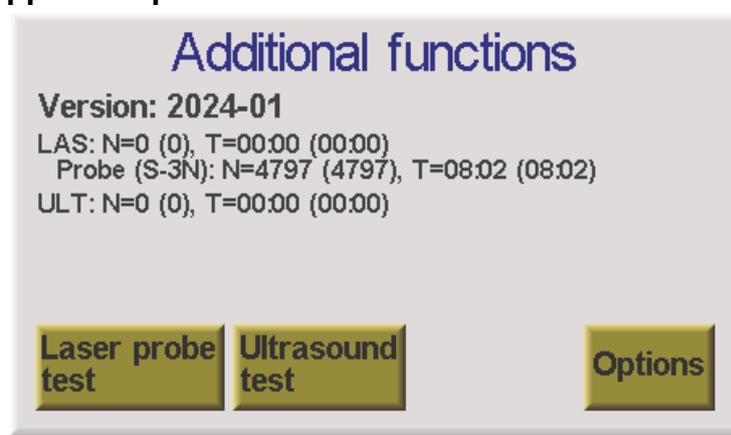
Using this button interrupts all active treatments.



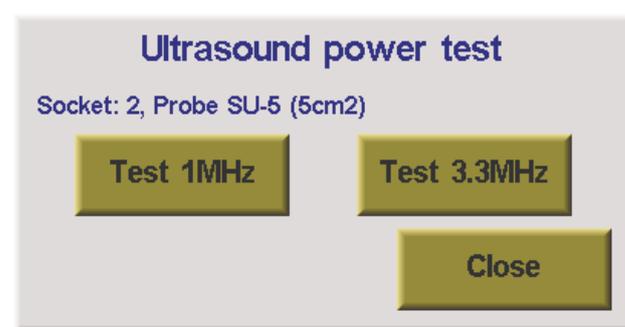
- Pressing the button 
- Longer than 1 minute break of the contact applicator/patient
- Malfunction was detected in the device or in the applicator – treatment is stopped automatically. ("Specific situations are detailed in section V.12. 'Information reported by the instrument during operation'").

When the end of treatment results from malfunction, the suitable information appears on the screen and shall stay on until OK is pressed. Necessary actions to remove malfunction should be taken, depending on the kind of malfunction. Assistance of a qualified maintenance technician may be required.

V.5.8. Ultrasonic applicator power test



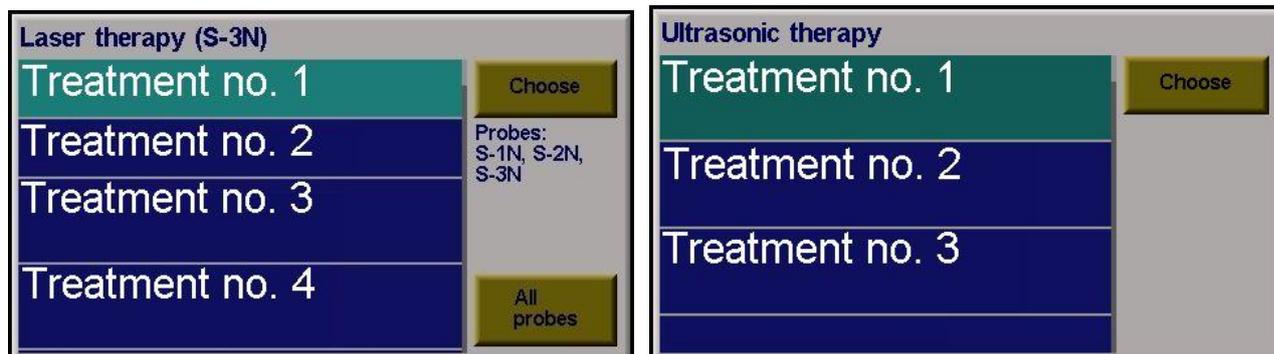
- There will be additional functions of the device. One of them is the ultrasonic test. Press the **“Ultrasound test”** button.
- To run the power test, select the ultrasonic applicator under test, position it with its forehead upward and drip water, quite a lot, but so that it does not run off the forehead.



- To run the power test, select the first frequency and observe the effect. Then add water again and select the second frequency. If the probe is working properly, most of the water should be vaporized. The effect is stronger for a frequency of 1 MHz.

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  is pressed, a list of programmed illnesses appears on the screen (arranged according to illness type):



A list of indications is displayed according to the selected treatment.

Use   buttons or touch the screen to choose the item. Alternatively you may press the screen and while pressing move your finger up or down for browsing through the list.

The selection is confirmed by pressing "Choose" on the screen or by pressing the  button.



You may discontinue using PROGRAM function by pressing  or  button at any moment.

NOTICE: If no applicator is connected or a treatment is currently active in a channel, then the buttons for program selection are not active for this channel.

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

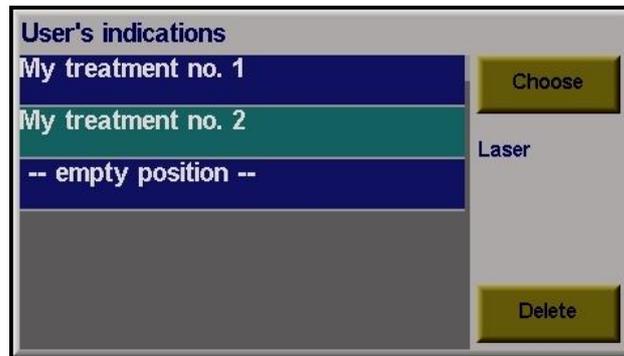
This function allows saving parameters' values which are most often used for by user. You may assign them to illnesses or patient names.

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.



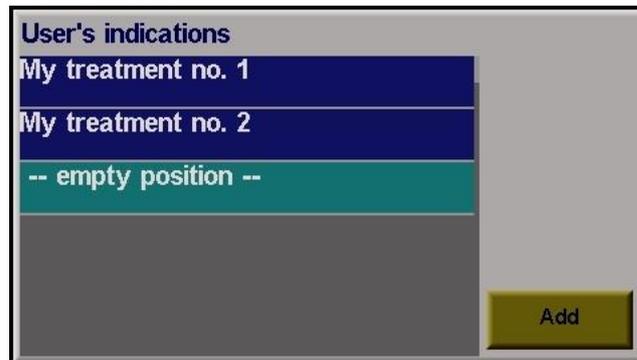
Use   buttons or touch the screen to choose the desired item. Alternatively you may press the screen and, while keeping pressed, move your finger up or down to browse through the list. Confirm your selection with the button “Choose”.

You may resign from using the MEMORY function by pressing  or  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

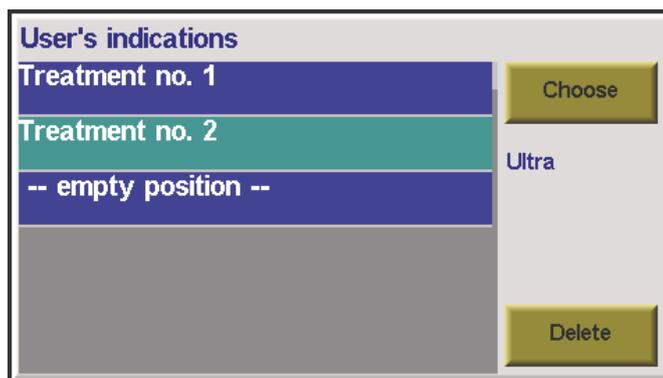
When ready, the description is confirmed by pressing .

You may discontinue using **MEMORY** function by pressing  or  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



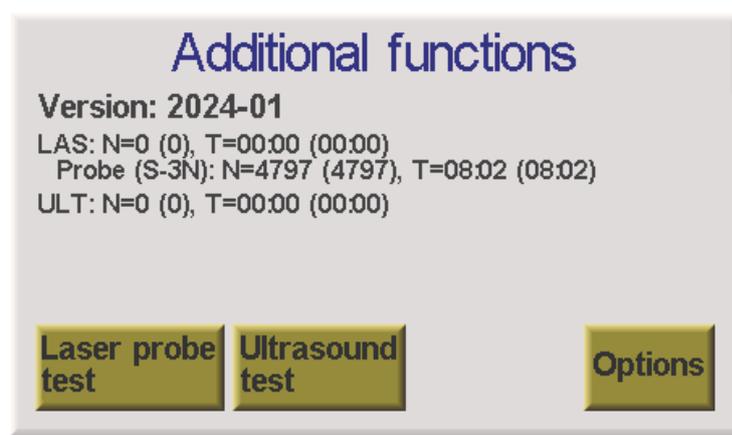
- press **DELETE** on the screen; a window will appear with a request for confirmation



- 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).

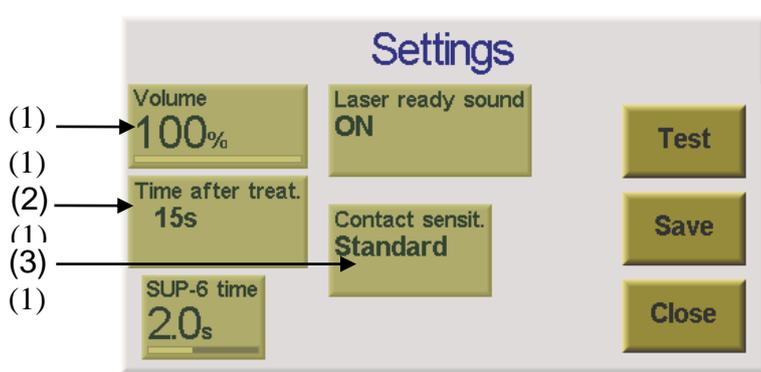


You may use them to do the following:

- check the software version
- check the number of performed treatments (does not include the ones interrupted before the set time) and their total time (all treatments and those with the laser applicators separately)
The Numbers and times after the “=” sign concern the period since the date of manufacturing, while the ones provided with parentheses are counted since the last service.
- Start the power test of laser
- Start the electrotherapy electrode test
- Set the sound signal parameters (including the end of treatment signal)
- Set the sensitivity of the ultrasound probe contact detection

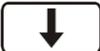
V.8.1. Setting (Options)

Pressing „Options” on the “Additional functions” screen calls up the following window:



Description of the fields:

- (1) Setting the sound volume 0 –100%.
- (2) Time of the sound signal after the end of treatment (choose from list):
15 s, 30 s, 1 min, 2 min, not terminated
- (3) Detection sensitivity of the probe/body acoustic contact during the ultrasound treatment

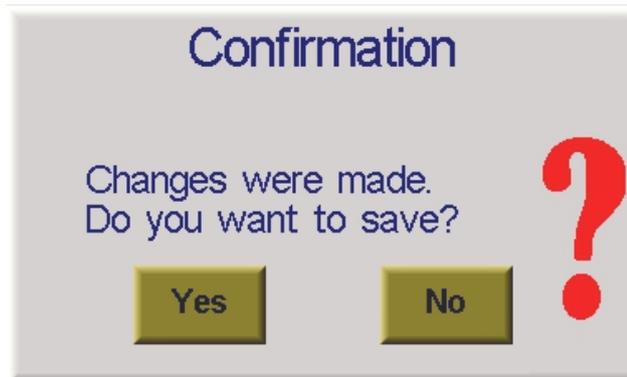
Touch the field to be changed and use the keys   to alter choice.

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

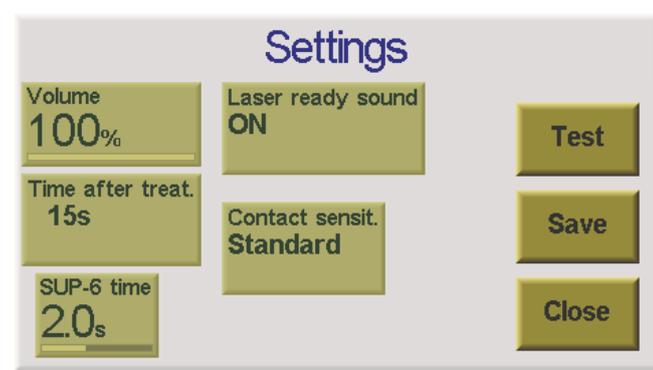
To check up the sound volume press the **Test** key.

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

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



V.8.2. Setting the sensitivity of the ultrasound applicator contact detection



The choice is by indicating the chosen field and pressing keys  .

The field can be chosen directly on the display, or by means of the key .

The “standard” setting is the most sensitive, it can be changed into less sensitive “medium” and “low” levels.



The “medium” level is half less sensitive than “standard”. The “low” level is a quarter of the “standard” level. Lowering sensitivity helps to avoid frequent pauses during treatment because of temporary loss of contact.

To exit this window and save the values do the same as in the preceding section.

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



- Laser: "Ready for emission" is OFF; No activity for over 1 min.



- The door opened (if the door switch is installed)



- Ultrasound: No contact of the ultrasound head with the patient's body



- Ultrasound: the applicator non-operational



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.

- 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.

WARNING: 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”.

WARNING: 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.

WARNING: The use of therapy for patients under the age of 8 years is possible following a positive specialist medical opinion.

IMPORTANT: 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: Operating the device in close proximity (up to a few metres) to a source of shortwave or microwave therapy may cause the output signal to become unstable and the device to malfunction.

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.

Additional for lasertherapy

WARNING: 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.

WARNING: 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.

WARNING: The laser treatments with SOLATRONIC SL-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.

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.

Additional for ultrasound

WARNING: Before starting treatment it is necessary to make sure the patient has no blood flow disturbances or metal objects in the treatment area. Otherwise internal burns may occur resulting from the tissue density change when blood flow is limited (especially periosteum burn by a “standing wave” effect).

WARNING: It is forbidden to use ECG gel as connecting agent for the treatment head.

IMPORTANT: During treatment with ultrasound head a small part of vibration may be transmitted to holding part of the applicator and to therapist’s hand. This exposure is very low and should have no significant effects. Sometimes therapists complain about ailments resulting from work with ultrasound treatment heads but it possibly results from work physiology of hand. People who work long time with ultrasound heads should avoid limb overuse and possible desecration formation. We advise working more with shoulder and systematic relieving of the tension of wrist.

VI. MAINTENANCE

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.

IMPORTANT: 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 no 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.3. „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.

VI.5. Maintenance of applicators

IMPORTANT: The device, and especially applicators, should be protected from shocks, hits and falling which may result in mechanical damage.

IMPORTANT: Periodically (for example everyday before starting treatment) check up the applicator cables for damage. The repairs of the ultrasound or laser cable should be done by an authorised service. For other damages: see p. VI.3. „Repairs”.

Ultrasound heads

After each treatment the treatment head should be cleaned of gel and dried with soft cloth. Then after drying it should be disinfected with gauze or cotton slightly moistened with 70%

solution of ethyl alcohol. Next treatment may be started after the agent/alcohol dries out. This procedure prevents the microorganism transmission between patients.

Laser probe

After each treatment the laser terminals of the probes should be cleaned and disinfected with gauze or cotton slightly moistened with 70% solution of ethyl alcohol. Next treatment may be started after the agent/alcohol dries out.

NOTICE: Protect the lens of probes from scratching.

NOTICE: Laser diodes have limited emission time (2-5 years is typical, depending on the use), therefore one should periodically check the emitted power as described above. Errors in probe work may result from cable breaks or main unit damage. In other cases the diode has to be replaced by the manufacturer.

VI.6. Disposal of the worn 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, in accordance with current legislation.

VII. MEDICAL DESCRIPTION

WARNING: 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.

WARNING: Treatments with SOLATRONIC SL-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.

WARNING: 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 SOLATRONIC SL-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
 - 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
 - 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
 - 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
 - Temporomandibular joint pain
 - Temporomandibular disorders
 - Chronic discogenic sciatica
 - Analgesic effect
 - Inflammation
 - Flexor tendon injury
 - Spinal cord injury
- Neurological conditions and neuropathies
 - Ulnar neuropathy
 - Trigeminal neuralgia

- Radiculopathy
- 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
 - 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
 - Chronic prostatitis (prostadinitis)

VII.2.2. Basic indications for ultrasound therapy

- Rheumatology and musculoskeletal disorders
 - Osteoarthritis
 - Osteoarthritis of the hip joint
 - Osteoarthritis of the knee joint
 - Ankylosing spondylitis (Bechterev's disease)
 - Fibromyalgia
 - Lower back pain
 - Sciatica
- Orthopedics and sports medicine
 - Pain syndromes such as:

- Spinal pain syndromes
- Tennis elbow
- Shoulder pain
- Myofascial pain
- Heel bone spurs
- Achilles tendonitis
- Condition after an injury to the ankle joint
- Lateral epicondylitis
- Tendonitis
- Adhesive capsulitis
- Tendinopathy
- Quervain's tendon sheath inflammation
- Carpal tunnel syndrome
- Dentistry and oral disorders
 - Temporomandibular joint pain and trismus
 - Masticatory myalgia
- Dermatology and tissue regeneration
 - Treatment of bedsores
 - Venous leg ulcers
 - Shin ulceration
- Neurological disorders
 - Treatment of nodules in multiple sclerosis

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.
- 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.3.2. Contraindications to ultrasound therapy

- Cancers and conditions after their surgical removal (consent of an oncologist required)
- Pregnancy
- Bleeding disorders
- Circulatory failure
- Heart arrhythmia
- Pacemaker
- Peripheral blood supply disorders
- Thrombophlebitis
- Acute inflammatory processes and febrile conditions
- Severe general condition and exhaustion
- Incomplete bone growth
- Conditions after X-ray therapy
- The presence in the tissues of metal foreign bodies

- Severe vegetative neurosis
- Unexplained neuralgia
- Advanced vascular calcification
- Skin changes, especially in the course of infectious diseases
- Generalized atherosclerosis and atherosclerotic conditions of the limbs
- Bronchiectasis
- Gastrointestinal bleeding

Ultrasound must not be used for safety reasons in some areas of the body: the area of the heart and cardiac segment, lungs, parenchymal organs of the abdominal cavity, brain, testicles, eyes, bones, and especially epiphyses in children and adolescents, the area of the medulla oblongata (the maximum height of sounding is the C4 segment of the cervical spine) and areas adjacent to the area where the laminectomy (excision of the vertebral arch) was performed. The clusters of lymph nodes - armpits, elbows, popliteal and groin must not be treated also.

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.

Side effects that have been reported during ultrasound therapy include burns, the appearance of blisters on the skin, rashes and swelling, tingling, pain, difficulty moving, and tinnitus. If cavitation is too intense, cell death and internal bleeding can occur.

VIII. METHODOLOGY OF TREATMENTS

WARNING: Treatments with SOLATRONIC SL-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 losses 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).

VIII.2. Methodology of ultrasound treatment

In ultrasound therapy, it is customary to use a frequency of 1 MHz for deeper tissues and 3 MHz for surface tissues, in accordance with half-depth rule. From the point of view of the methodology of performing the procedure, the appropriate selection of this parameter is crucial for its effectiveness. In practice, each ultrasound treated area must be assessed for the depth of the target tissue, the abundance of surrounding tissue, and the proximity of the bone. The values given in the table of indications are the proposed base values, but each person applying ultrasound should individually select all treatment parameters, including the carrier frequency.

IX. LITERATURE

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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.

Device's type		SL-3			Device's number				
No	Question								
1.	How do you grade therapeutic effectiveness of the device in its treatments compared with similar devices of different producers?								
Very 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 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.	Is the information provided in the instructions for use and on the device clear and does it provide the necessary information?								
Very poor		Poor		Average		Good		Very good	
6.	If the device has been serviced (repaired) please evaluate the quality of the service:								
Very 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	
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Can the content of the instructions be improved? If so, what should be changed?

Yes		No		I cannot decide	
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