

Serial No:

OWNER'S MANUAL

Safe Laser products

“The new generation of soft-laser devices”

☐ SL30



☐ SL150



Contents

• Laser basics	2
• Description of the Safe Laser devices	3
• Soft laser effects	3
• The diseases witch can be treated with Safe Laser devices	3
• Treatment time and frequency	5
• First steps and usage	6
• Technical details	6
• Laser safety instructions	7
• Contraindications	7
• Service, repair and storage	8
• Contact Us	8
• Warranty	8
• Manufacturer's Proof of Compliance	13
• Medical Certification	14

Laser basics

In terms of biological effects lasers can be divided into two main categories:

- High power = "hard lasers" - surgical lasers
- Low power = "soft lasers" - therapeutic lasers



High power lasers (due to the very strong thermal effect) are capable of different surgical procedures, eg. surgery (thermal effects: cutting, vaporization, coagulation)

Soft lasers are using the laser light's photochemical effect to start the beneficial biological processes.

Safe Laser devices are low power (30-150mW) therapeutic "soft" lasers.

Description of the Safe Laser devices

Safe Laser devices are medical devices within a risk class II.a. based on the regulation 4/2009 of the Minister of Health. (III.17.).

The devices are made with a special "Safe Laser" technology, which means that the laser's parallel to eye hazardous beam is transformed with a special scattering surface in a way that is completely safe for the eyes. (www.safelaser.eu)



With the presenting of **Safe Laser devices a new generation of soft-lasers was created**, which can be safely used not only in hospitals, medical stations but even at home! (without the laser safety goggles)

The devices allow for multiple therapies. Suitable for direct use to the skin surface as "local" treatment or to the mouth, ear or guided into nostril to cure more diseases.

Safe Laser devices can be used effectively as a primary or as a complementary therapy. The use of laser phototherapy is painless, with regular use the healing time can be reduced and has no known adverse side effects! Can be combined with any other drug and therapy.

Soft laser biological effects

For the clinical practice there are three major fields of utilization of the soft laser effect - pain killing, antiphlogistic and biostimulating effect.

Biostimulation: promotes metabolism, assists cell processes, stimulates reproduction, helps immunization, and increases the number of collagen cells.

In summary in promotes self healing. It has no allergic reactions, neither harmful electrical or radiation load.

In a considerable part of cases the therapeutic effect and clinical improvement are simultaneously due to two or sometimes all the three factors. Thus reviewing the medical fields the following main groups should be mentioned:

- pain diseases or diseases accompanied by pain,
- inflammatory diseases or lesions associated with inflammation,
- non-epithelizing ulcers or associated diseases.

The wavelength of Safe Laser 30 and Safe Laser 150 devices is 660nm (red). This is the “therapeutical window” which has several benefits for living tissues.

The diseases (indications) witch can be treated with Safe Laser devices

Prior to and during therapy, depending on the nature and severity of the disease, it is essential to consult the competent specialist (in a polyclinic, clinic or hospital).

Skin diseases:

- chronic inflammation, herpes simplex, herpes zooster,
- ulcus cruris, non-healing ulcers, multiform exudative erythema, hypertrophic scars, alopecia areata

Oral cavity diseases:

- aphta, herpes, chronic inflammation, trigeminus neuralgia, posttraumatic pain, postoperative pain, parodontosis, parodontitis, gingivitis, temporo-mandibular joint lesions, asyalia



Oto-rhino-laryngologic diseases:

- chronic rhinitis, allergic chronic rhinitis, pharyngitis

Ophthalmology:

- ophthalmic herpes zooster

Laser acupuncture

- according to the indication circle of the profession



Vascular diseases:

- obliterative vascular diseases, postthrombotic syndrome, ulcer developed on the ground of varicosity and vasculitis, sicca pregangrenic condition, decubitus

Musculoskeletal symptoms, rheumatology, sports injuries:

- Small joint, muscle and tendon injuries, inflammation, strain, sprain, contusion, abrasion, bruise
- reumatoid arthritis, arthropathies, arthrosis, other motility organ lesions

Neurology:

- pain syndromes, degenerative spinal pain, radiculopathies, rehabilitation of those with locomotor disorders, lesions associated with hypertonicity, childhood motility disorders, contractions, Little disease, conditions following brain vascular events (paresis, motility disturbances, flexural contractions) inactivity muscular hypotrophy, atrophy, solution of forced

Ear Complaints:

- inflammation, pain, tinnitus, ear itching

Diseases can be treated with nostril light (laser beam directed to the nostrils)

- accelerates the healing: colds, flu, relieve symptoms of nasal inflammation
- relieve symptoms of allergy, asthma, hay fever
- The laser light's biostimulation effect has an additional beneficial effect on the circulatory system.



Treatment time and frequency:

Two kind of treatments are possible with the Safe Laser devices.

1. Skin surface treatment: SL30, SL150
2. Mouth, nose, ear treatment: SL30, SL150 with nasal accessory

Safe Laser 30	Safe Laser 150	Safe Laser 150 with nasal accessory
3-3 minutes on each nose and ear	3 minutes, placed on skin	3-3 minutes on each nostril

Treatment of acute illnesses (the disease has recently been generated):

- The treatment should be applied for the first 1-2 weeks every day than three times a week until resolution of symptoms.

Treatment of chronic (prolonged) illness (generated previously 6-8 weeks):

- The extended period of illness should be treated less often. The first two weeks 3-4 times a week and 2-3 times a week until significant decrease in their symptoms.
- Chronic (long-standing) diseases to cure naturally take longer (days, weeks, months). After the first treatment, the pain may increase, but this is a temporary phenomenon.
- With long-term (several months) recovery processes first apply a 10-day daily treatment later a 3-5 occasions a week.
- A longer-term treatment is not necessarily speed up the healing process, because there is a biological limit, after the cells can't be further stimulated!

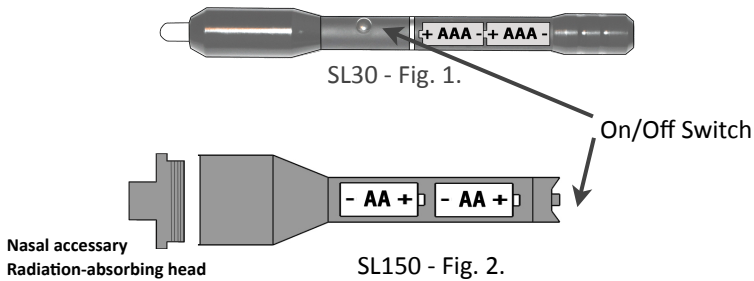


Cure with nasal laser irradiation

- It is recommended for continuous daily use separately for each nostril.

First steps and usage

- Please read the instruction manual carefully before use!
- Before first use clean parts of the laser directly in contact with skin.
- Place the batteries into the equipment. Observe the correct polarity of the batteries (+ sign forward) as indicated in Fig. 1. and Fig. 2.



- Apply the laser to the desired skin surface first, and then turn on the laser by the switch according Fig.1 and 2. This way you can avoid the accidental eye irradiation.
- After using always close the laser in a safe place to avoid incompetent usage.
- If the laser is damaged or does not work properly do not use the laser. There is no user-repairable part of the laser inside.

Technical details

	SL30	SL150
Max. power	30mW	150mW
Wavelength	660nm	660nm
Power	2 x 1,5V DC, 2x AAA batteries	2 x 1,5 V DC, 2x AA batteries
Life expectancy	10 000 hours	10 000 hours

Laser Safety instructions



The light of the Safe Laser devices is less dangerous than the beam of ordinary lasers. However the laser safety rules have to be kept by everybody, and it is the duty and the responsibility of all the users of the lasers.

- “**Class-2**” laser product according to MSZ EN60825-1 (IEC 60825- 1-4:2007). At the categorization the requirements for scattered radiation were applied.
- The measurement was made by: Wigner Research Centre for Physics, Hungarian Academy of Sciences Optical Laboratory.
- It is forbidden to stare directly into the beam!
- The radiation emitted by the laser equipment is not dangerous for the eye, because of the eye’s automatic blink reflex (for which 0,25s his reaction time) provides protection. There is not need for safety glasses.
- The laser must be closed from the reach of children!
- Do not use the laser if damaged or did not work properly!
Repairing of the laser can only be made in manufacturer's service!.

Contraindications

- Irradiating the lower abdomen or the nasal mucosa of pregnant women or the open fontanelles of babies is prohibited because of the (potentially dangerous) increase of hyperemia!
- The use of the laser device is prohibited for people suffering from severe blood clotting problem or a state of acute stroke.
- Do not beam the area of
 - Malignant tumors
 - The thyroid and breasts
 - Fungal skin surfaces
- Direct radiation of paint moles can be dangerous, since it constitutes pre-cancer-forming state.
- Do not beam deliberately into the eyes or around the eyes!
- Do not treat the area of unknown pain!
- **Ask your doctor or pharmacist about the use of Laser device!**

Service and repair

- The laser does not need service.
- Optical surfaces have to be kept clean, in case of need it can be cleaned with soft tissue and mild detergents.
- The equipment can only be serviced by the manufacturer!

Storage

During storage the safety rules also have to kept keeping in mind that children and unauthorized personnel must not have access to the laser. The laser have to be stored in a clean place and have to be protected from direct heat.

Contact Us

Dealer's name:

Dealer's address:

Dealer's phone No.:

Service phone No.:

Warranty

The manufacturer guaranties repair or replacement of of the laser against material and productions defects within 1 year form purchase. Warranty can not be applied for damages due to elementary diseases or improper usage (as described by the manual).

Day of purchase:

Last day of the warranty:

Signature/stamp

1. Annex

For the Safe Laser devices (SL30 and SL150) electromagnetic compatibility (EMC) conform to the following tables for devices electromagnetic compatibility (EMC) have been identified :


Az EN 61601-1-2:2007 5.2.2.1. 1. according to table:

Manufacturer's declaration - electromagnetic immunity		
The Safe Laser 30/150 devices intended for use in the electromagnetic environment specified below. The customer or the user must make sure to use the device in such an environment.		
Emissions Test	Compliance	Electromagnetic environment
RF emissions CISPR 11	1. class	Safe Laser 30/150 RF (radio frequency) energy is used only for internal functions. Therefore, its RF emissions are very low, it is unlikely to cause any interference in the immediate near located devices.
RF emissions CISPR 11	B class, EMC-110119/1, Passed; 30-1000 MHz	The devices Safe Laser 30/150 are suitable for use with in all establishments, including the household as well.
Harmonic emissions IEC 61000-3-2	B class, EMC-110119/1 Passed; 0.15 - 30 MHz	
Voltage change, flicker emission IEC 61000-3-3	Passed	

Az EN 61601-1-2:2007 5.2.2.1. 2. according to table:

Manufacturer's declaration - electromagnetic immunity			
The Safe Laser 30/150 devices intended for use in the electromagnetic environment specified below. The customer or the user must make sure to use the device in such an environment.			
Immunity test	IEC 60601 According test	Compliance Level	Electromagnetic environment
Noise immunity against electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	Passed Qualifications: normal operation within the prescribed limits	The floors should be wood, concrete or ceramic tile reason. In case of synthetic material floor of the relative humidity should be at least 30%.
EFT (Electrical fast transient/burst) Noise immunity to signals. IEC 61000-4-4	± 2 kV L, N, PE- ground	Not applicable. Battery operation	--
Noise immunity to shock waves (Surge) IEC 61000-4-5	± 1 kV L - N between ± 2 kV L, N – ground	Not applicable. Battery operation	--
Noise Voltage chamfers (DIP), voltage outages (Interruption) interference resistance IEC 60601-4-11	$<5\% U_T$, $>95\%$ DIP; 0,5 per. $40\% U_T$, 60% DIP; 5 per. $70\% U_T$, 30% DIP; 25 per. $<5\% U_T$, $>95\%$ DIP 5 s	Not applicable. Battery operation	--
Voltage (50/60 Hz) magnetic field	3 A/m	Passed Qualifications: normal operation within the prescribed limits	The magnetic field of supply voltage must have a traditional or typical hospital atmosphere location characteristics .
Note: U_T supply voltage level prior to application of the test			

Az EN 61601-1-2:2007 5.2.2.1. 4. according to table:

Manufacturer's declaration - electromagnetic immunity			
<p>The Safe Laser 30/150 devices intended for use in the electromagnetic environment specified below. The customer or the user must make sure to use the device in such an environment.</p>			
Immunity test	IEC 60601 According test	Compliance Level	Electromagnetic environment
Noise immunity to conducted RF signals on power line	3 Vrms 150 KHz–80 MHz	Passed Qualifications: normal operation within the prescribed limits [V1] V	<p>Portable and mobile RF communications equipment can not be used closer to the Safe Laser 30/150 devices within the recommended separation distance, which can be calculated as shown in the following formula.</p> $d = [3,5/V1] \sqrt{P}$ <p>—</p>
Noise immunity to radiated RF signals	3 V/m 80 MHz-2,5 GHz	Passed Qualifications: normal operation within the prescribed limits [E1] V/m	<p>$d = [3,5/E1] \sqrt{P}$</p> <p>80 MHz-800 MHz</p> <p>—</p> <p>$d = [7/E1] \sqrt{P}$</p> <p>800 MHz-2,5 GHz</p> <p>where P is the max. power [W] , in terms of the instructions manual and d is the recommended separation distance [m].</p> <p>(For a mobile phone:</p> <p>$d = [7/2] \sqrt{1,41} = 4,935 \text{ m}$)</p> <p>Close to the devices interference can occur between devices with the following symbol.</p> 

Az EN 61601-1-2:2007 5.2.2.1. 6. according to table:

Recommended separation distances between portable and mobile communications equipment and the Safe Laser 30/150 devices.			
The Safe Laser 30/150 devices must be operated in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Safe Laser 30/150 devices can prevent electromagnetic interference in compliance with the minimum separation distance.			
The maximum transmit power W	Separation distance according to frequency of transmitter (m)		
	150 KHz-80 MHz — $d=[3,5/\sqrt{P}] \sqrt{P}$	80 MHz-800 MHz — $d=[3,5/\sqrt{E1}] \sqrt{P}$	800 MHz-2,5 GHz — $d=[7/\sqrt{E1}] \sqrt{P}$
0,01	0,1167	0,1167	0,2333
0,1	0,3689	0,3689	0,7379
1	1,1667	1,1667	2,3333
10	3,6894	3,6894	7,3788
100	11,6667	11,6667	23,3333

Based on the above, the devices meet the EMC requirements for medical devices.

Explanation of labels affixed to the device



2409 CE Conformity marking



Symbol of Manufacturer



Date of production



Type B patient classification

SN

Serial number



Electronic waste , DO NOT throw away to trash !



Read the Owner's Manual

IP21 Protected against Ø 12,5 mm rigid bodies and vertically falling water drops



Laser warning sign

Manufacture's Proof of Compliance

We, as the manufacturer: Safe Laser Bt.

Headquarters: Hungary, 2011 Budakalasz, Fecske u. 7.

make a statement about it, that our product:

Name: Therapeutic Low-intensity Laser Devices

Safe Laser 30 and Safe Laser 150

Serial number: (from) 2013/0015

Meets the requirements of the related requirements of the directive 93/42/EEC on Medical Devices, Annex I., V.

Organization for certification and testing:

CE Certiso Ltd. (NB2409)

2040 Budaörs, Gyár u. 2.

EC Certificate number: 144446-13-08-16

First issued: 16 August 2013

Expires: 15 August 2018

Budakalasz, 02 April 2014


CEO Safe Laser



144446-13-08-16

EC CERTIFICATE
Production Quality Assurance
Directive 93/42/EEC on Medical devices, Annex V

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Safe Laser Bt.

Headquarters:

2011 Budakalász, Fecske u. 7. HUNGARY

Scope:

Therapeutic laser equipment

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class	Start date of certified status
therapeutic low-intensity laser	Safe Laser	laser light therapy	SL30	II.a	16 August 2013
soft laser	Safe Laser 150	laser light therapy	SL150	II.a	04 April 2014

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 56-CE-130704

Issue: 2

Issued: 04 April 2014

First issued: 16 August 2013

Expires:

15 August 2018**CE Certiso**

Orvos- és Kórháztechnikai
Ellátó és Tanúsító Kft.
2040 Budaörs, Gyár u. 2.
Irányítószám: 23147049-2-13

Valter PAPP
Valter PAPP, Dr.
 General Manager