



Serial
number:

SAFE LASER

Medical Laser Devices OWNER'S MANUAL

☐ Safe Laser® 150



☐ Safe Laser® 500 Infra



☐ Safe Laser® 1800 Infra



“New generation of soft lasers”

Version 2.2 (2018.08.25.) © Safe Laser Trade Ltd.

www.safelaser.eu

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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, e.g. surgery (thermal effects: cutting, vaporization, coagulation)

Safe Laser® instruments belong to the group of therapeutic „soft-lasers”.

In case of soft-lasers the photochemical reaction effect of the laser light is used to initiate beneficial biological processes.

How does the soft laser therapy work?

In 1947, researchers indicated that the mitochondria in our cells are photosensitive and react differently to various wave lengths (colors). Out of the entire spectrum the red (e.g.. 660nm) and infrared (e.g. 808nm) lights have the strongest curing effect.

The photo acceptor molecules of the energy receiving cells become activated from the effect of soft laser light and are capable of activating other molecules. These chemical reactions are initiated in neighboring cells and consequently the tissue.

What are the physiological effects of the soft laser light?

The soft laser treatment has three known curing effect on the human body:

1. **Biostimulating effect – stimulates the self-healing ability of the body!**
2. **Antiphlogistic effect**
3. **Pain reducing effect**

A Safe Laser® devices can be divided into 2 main categories:

1. Red (660 nm) light emitting lasers: Safe Laser® 150
2. Infra (808 nm) light emitting laser: Safe Laser® 500 Infra, Safe Laser® 1800 Infra

Light of infra (808nm) laser is hardly visible to the naked eye, therefore it is equipped with four red LED lamps, to show that the device is powered on.

What diseases may the lasers be used for?

The red (660nm) laser effects the surface of the skin to the depth of 3cm, playing an important role in healing inflammations, reducing pain and treating other disorders **on the surface of the skin**.

The Safe Laser (880nm) Infra laser's light is absorbed by **significantly deeper layers of tissue**, allowing its biological effects to be seen at depths between 8-10cm. This excels it at the **treatment of musculoskeletal disorders**, reducing pain and inflammation while accelerating the healing of muscles, tendons and joints.

Furthermore, in greater doses it is suitable for the regeneration of the cartilage surface and the cartilage itself.

Experience from usage shows that the infrared laser is more efficient at pain relief.

Furthermore, by using appropriate accessories, the Safe Lasers are also suitable for treating diseases which can be healed by lighting into the nasal mucosa.

Introduction of Safe Laser® devices

The Safe Laser® family of **products** are medical devices belonging to risk category II.a due to decree 4/2009.(III.17.) EüM (Ministry of Healthcare).

The instruments contain a special **„safe laser” technology** based on the principle that the parallel laser beam, which is dangerous to the naked eye is modified by a specific optical system so that **it becomes harmless to the eye**. (see: www.safelaser.eu)

Thanks to this Safe Laser technology this special „soft laser” is a medical device which can be **used safely not only in hospitals and clinics, but also at home** by the patients themselves without safety goggles. — (Class 1 laser device)

Laser risk classification according to EN60825-1:2014 “Radiation safety requirements for laser products” .

SL500 Infra and SL1800 Infra — class 1 laser device

SL150 (660nm red) — class 2 laser device

The Safe Laser® family devices can be used effectively alone or complementary to other therapies. The application of the laser light treatment is painless, and with regular usage shortens the recovery time of various diseases, without any known side effects. The **Safe Laser®** devices can be combined with any other therapies.

Optional accessories (for each device):

Fiber optic, nasal funnel treating head
(rubber ring adapter is required to connect)



Problems and diseases that can be treated with Safe Laser

(Indications - Detailed treatment protocol: www.safelaser.eu)

	SL150	SL500 Infra	SL1800 Infra
Effective depth of treatment (Absolute penetration depth)	~ 3cm	~ 8cm	~ 10cm



During usage, it is imperative to consider the effective treatment depth!

Musculoskeletal disorders (supplementary therapy)

Injuries:

- Contusion (haematoma), strain (distorsion), rupture of taenia (muscle or tendon) and fracture

Injuries resulting from overstrain:

- Tendinitis, myositis, bursitis
- Inflammation of periostil at the point of adhesion and sticking of muscles (e.g. tennis players' elbow inflammation at the point of adhesion of the muscle to the lower arm as a result of overstrain)

Degenerative disease:

- Joint wear, arthrosis - (The SL150 is suitable for the treatment of small joints only!)
- Joint inflammation (arthritis)
- For disease affecting the vertebral column (e.g. lumbago), the device has pain relieving and inflammation decreasing effects
- Muscle diseases e.g. muscle pain, limited movement (contracture)
- Rheumatic pain (rheumatoid arthritis)

Musculoskeletal disorders may cause problems and pains in various areas of the body including numerous joints. This pain is often felt not at the source, but in various other locations in the form of "referred pain."

For effective pain relief and treatment, it is advisable to find not only the painful areas but also the trigger points of the referred pain.

Time of healing of traumatic injuries is shortened by laser therapy!

Apply the laser therapy post-surgery 1-2 times/day to reduce healing time.

In case of fractures/bone breakages, a small window would be cut into the plaster covering the affected limb, allowing the light from the laser to come into contact with the body directly, significantly assisting in the process of ossification.

Dermatological conditions (SL 150, 500, 1800)

- The device assists the healing of tissue in case of epidermal surface injuries, bruises/ scratches, post-operative wounds alongside bedsores and ulcers.
- Assists in the healing of herpes.
- SL150 - Assists in the healing of acne.

Dental and oral diseases

Diseases of skin surface and mucous membrane (e.g. herpes, mouth wounds, ulcers, sores) and gingivitis, periodontitis, gum bleeding can be treated more efficiently with the **optional fibre optics**.

The deeper penetration of the 808nm Safe Laser 500 and 1800 Infra make them suitable for pain relief.

With these two devices, dental problems can be effectively handled not only with the **optional fibre optics**, but also from the outside (through the cheek)

The **SL150** device must be used with the optional **fiber optics accessory** for dental and oral applications.

Safe Laser® 150, 500, 1800 devices:

- Relieves post-operative toothaches and inflammations alongside helping the recovery of soft and bone tissue.
- It assists in the healing of periodontal inflammation and periodontal atrophy.
- Assists in the healing of gum inflammation.
- Reduces the healing time of gum and oral mucosa (e.g mucositis, aphtha)

Safe Laser® 500 és 1800 Infra devices (SL150 not applicable):

- Relieves the acute pain from orthodontics, and promotes faster movement of the teeth (reduces the orthodontic process/time)

Otolaryngology complaints (SL 150, 500, 1800)

- In many cases, the device reduces or eliminates tinnitus.
- In the case of acute hearing loss, treatment with the fiber optic will result in better hearing. The main cause of the acute hearing loss is the insufficient local circulation due to bacterial or viral inflammation, and a systematic blood circulation problem. Owing to the laser's local anti-inflammatory effect, it improves the circulation in the inner ear, which can lead to improved hearing.
- It relieves the symptoms of sinusitis and respiratory inflammation.

Treatment with the Safe Laser® devices

Place the Safe Laser in contact with the sore or damaged area, enlightening it for a given time, then moving it to the next area in need of treatment. (disposable protective caps can be ordered).

Larger sore or damaged areas can be treated by moving the Safe Laser from point to point, treating each area sequentially. Generally the points sensible to pressing are to be treated.

For the effective treatment of deep tissue, it is recommended that the Safe Laser be pressed tightly to the surface of the skin, slightly depressing it.

If the laser cannot be placed in contact with the surface of the skin, due to an open wound, then it should be held at the closest possible distance to the target area (max 0.5 cm). In this case, treatment time should be prolonged by one minute at each point in order to allow for adequate energy transfer into the body for healing!

Duration of treatments (in one spot!):

Different energy quantities (Joules) are required for different treatments to achieve efficient healing.

Higher energy quantities can be delivered by prolonged irradiation of treatment area.

The SL500 Infra and SL1800 Infra devices have the same quantity of energy delivered per unit of area, therefore the treatment times are equivalent.

The treatment area of the SL1800 Infra is approximately x4 larger than that of the SL500 Infra device, which increases the efficiency and possible penetration depth of the laser light.

Dose (Joule /cm ²)	SL150	SL500 Infra	SL1800 Infra
4 -5 Joule energy per points Strains, bruises, muscle spasms, improvement of microcirculation, light musculoskeletal injuries, acute and chronic inflammations, dental and mouth disorders, dermatologic diseases.	3 minutes	1 minute	1 minute
15 Joule energy - per points Pain relieving, serious musculoskeletal disorders.	10 minutes	3 minutes	3 minutes
25 Joule energy per points Cartilage regeneration, musculoskeletal injuries in deeper layers, rupture of taenia, muscle or tendons, fractures (in the beginning even twice per day)	Not applicable	5 minutes	5 minutes
With fiber optic 4-25 Joule energy (on surface and in deep layers)	40 sec - 4 min	25 sec - 3 min	10 sec - 1 min
With radiation-absorbing head 4 Joule energy	3 min	3 min	3 min

Frequency of treatment:

Frequency of the treatment depends on the time elapsed since the problem arose.

1. Acute diseases (recently arisen) and treatment of post-surgery cases:

Treatments are to be applied **daily** during 1-2 weeks, later 3 times per week until the cessation of symptoms. **Improvements may be noticed after 1 day** of treatment, or even after the first treatment.

2. Treatment of chronic (lasting) diseases (arisen earlier than 6-8 weeks):

Prolonged diseases are to be **treated less frequently**. Use the laser instrument **3 times per week** until the cessation or significant decrease of symptoms.

In case of chronic (prolonged) diseases duration of the healing process is naturally longer (days, weeks, maybe months).

Following the first treatments mild tingle may be felt, several hours later the **pain may increase in case of several chronic diseases (treatment reaction), but this is temporary**. The intensity of the pain will decrease as the number of treatments increase, and will cease after 3-4 treatments. After this, the healing will begin. Such treatment reaction is a normal accompanying phenomenon indicating the patient's reaction to the therapy.

If we observe that **the aching joint neither improves nor deteriorates**, then it is likely that it was treated with a dosage that was too low (duration of irradiation was too short).

Individual sensitivity varies person by person. Doses of treatment keep accumulating slowly, so the treatment reaction (e.g. increase of pain) may appear sooner or later (cca. after 4-5 weeks) and only then will the subjective improvement be felt.

If by chance the **pain increases or becomes prolonged** as a result of treatments, it may mean that the **dosage of the treatment was too high**. Over-treatment does not cause lasting harm. In this case several treatments are omitted and the therapy is continued with lower doses (less sessions or shorter duration).

One of the reason of the accompanying pain is the sudden restart of microcirculation (flow of blood in the smallest veins) in the stagnant areas. Decomposition products (not carried away) accumulated in the stagnant areas suddenly enter the circulation, therefore nausea, fatigue or malaise may seldom occur (following treatment of large areas with high doses).

More frequent or prolonged treatments does not necessarily accelerate healing, because there is a biological limit beyond which cells can not be further stimulated by irradiation!

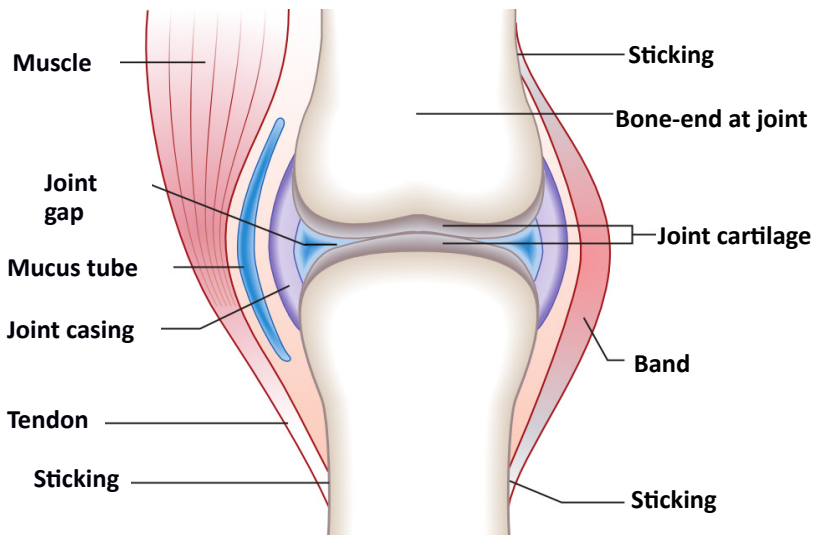
Designating places of treatment:

For muscles: Pressure sensitive areas are to be treated with the device, after they have been identified through touching of the muscles.

For joints: Treatment generally occurs in line with the joint gap.

Joints can be better reached by bending the limbs, so the inner part of the joint can be enlightened. Sensitive areas of the muscles moving the joints are treated as well.

For tendons: Treatment is applied at sticking of tendons, muscle-tendon transition and pressure-sensitive points.



Even if the treatment points aren't precisely identified, therapy can still be effective as the spread of the Safe Laser's light is large.

When to expect improvement as a result of the treatment?

In certain cases laser light provides rapid results. Improvements come into effect **within minutes/hours** in following cases: pain soothing, reduction of acute inflammations, bettering of microcirculation, muscle strain, resolution of muscle cramp.

Concerning other problems the effect may be noticed within **days/weeks**.

Contraindications:

- In case of pregnancy irradiation of abdomen is forbidden because of the potentially dangerous increase of congestion!
- Usage of the instrument is forbidden on persons suffering of serious blood coagulation problems!
- Do not enlighten: tumor areas,
thyroid (in case of super-activity) and breast area,
fungus infected skin surfaces,
implanted pacemaker!
- Direct irradiation of colored moles may be dangerous, because it qualifies as status prior to cancer.
- **Never treat yourself without precise medical diagnosis by doctor**, because the Safe Laser® 500 Infra can decrease pain, but is not always capable of eliminating the root of the problem and may obscure serious diseases temporarily!

Laser Safety Instructions

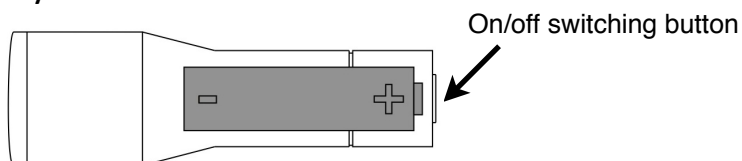


The diffused laser light of the Safe Laser® devices is less dangerous for the eye compared to other laser instruments. Nevertheless the user of the device is obliged to comply with the laser safety measures to avoid possible dangers originating from its usage!

- **"Class 1 category"** and **"Class 2 category"** laser devices according to Safety of laser products. Part 1: Equipment classification and requirements (IEC 60825-1:2007). For classification the requirements of the standard prescribed for diffused radiation were applied.
- Measurement made by: Wigner Physical Research Centre – Optics Laboratory
- Do not look directly into laser light, do not direct it into the eyes of others!
- To enlighten round the eyes is forbidden!
- **To avoid the accidental sighting of laser light the instrument is to be switched on after placing it on the skin surface. Having finished the treatment switch it off before removing from the skin surface!**
- Safe Laser® 500 Infra must be locked and stored out of sight of children!
- **Do not use damaged or malfunctioning device! To dismantle the optic or to switch on the device with damaged optic is FORBIDDEN!**

Installation and usage of the Safe Laser devices

- Before the first usage read the manual carefully!
- Observe the „Laser Safety Instructions“ (see page 8)!
- It is advisable to clean the instrument after unboxing due to hygienic reasons. According to standard ISO 10993-1:2009 the parts of the instrument touching tissues, cells and bodily fluids conform to requirements of biocompatibility.
- A disposable protective cap can be ordered, which provides adequate hygiene.
- **Insertion of battery:**



- **The instrument shall be used exclusively with the provided electronically protected battery 18650 type 3.6V DC.** Other type batteries may cause damage of the laser and results in loss of warranty.!
- Always start the treatments with a charged battery! After 500 charging cycles, or if battery life is significantly reduced, please replace the battery.
- Always lock the device away after use so that it shall not get into incompetent or children's hands!
- The laser can be used in temperatures between 10-35 °C.
- The SL1800 Infra warm up during the usage due to its high performance. This is a normal phenomenon and does not negatively affect the usage or the healing effectiveness of the device.
- In case of any malfunction or damage, do not keep using it.
In order to avoid any possible danger, it may be serviced by the manufacturer only.

Technical data

	SL150	SL500 Infra	SL1800 Infra
Max. power output	150mW	500mW	1800mW
Power density	40mW/cm2	180mW/cm2	180mW/cm2
Wave length	660nm laser	808nm laser	
Power	3.6V DC, 1 piece of type: 18650 battery		
Life expectancy	7 000 hours	10 000 hours	

Maintenance and repair

- The device does not require specific maintenance.
- Protect the optical surface from pollution, if necessary clean it avoiding scratches. (with watery, alcoholic detergent)
- Use the instrument only with the described battery type!
- Replacing and charging battery the patient can do themselves.
- The device must be protected from humidity, heat radiation and dropping!
- Do not reuse the disposable protective cap to avoid danger of infection!
- Operating temperature: +10°C, max. +35°C
- Repair of the device may be accomplished by the manufacturer only!
- The Safe Laser® devices are made in Hungary.
- AT the end of their lifecycles the devices can be returned to the manufacturer for safe disposal.

Storage

Safety rules must be kept during storage of the instrument by the user.

Storage temperature: -10 ° C, max. +45 ° C

The laser is to be stored locked away from children in safe place.

If not in use for an extended period it is reasonable to remove batteries from the device.

Warranty card

Name of distributor: Phone:

Address of distributor:

Stamp of distributor:

Date of purchase: Signature of salesperson:

Validity of warranty: Serial number: SN

Service: Safe Laser Trade Ltd. Tel.: +36 70 383 0181, info@safelaser.eu
Hungary, 1139 Budapest, Kartács street 8. 4/4.

Warranty

The Manufacturer/Distributor (Obligor) provides warranty for the instrument for a 2 years period following the purchase. Warranty does not cover damages which originate from not observing rules written in the usage instruction or caused by natural forces.

IMPORTANT TO KNOW

- 1/. The Customer can validate their warranty claim with the warranty card, so it is to be kept.
- 2/. Require the distributor to indicate exactly the day of purchase on the warranty card.
- 3/. Lost warranty card cannot be replaced.
- 4/. Warranty repairs can be carried out by indicated service centres only on the basis of valid Warranty Card.
- 5/. Any correction, deletion or transcription or entry of untrue data in the Warranty Card results in the invalidation of the Warranty Card.
- 6/. Irregular filling-in or failure of issue to the customer of the Warranty Card does not influence the validity of warranty obligation.

Rights of the customer according to the warranty:

The customer has the rights determined in the Act on Civil Code 2008. XLVII.§3., 6., 7., and Government Decree 151/2003.(IX.22.):

(1) In case of defective performance the Customer

a) first of all – optionally – may demand repair or replacement except if the fulfillment of the chosen warranty demand is impossible or if it would result in disproportionate extra cost for the Obligor compared with the other way of fulfillment, taking into account of the value of the serviced thing in flawless state, the gravity of breach of contract and the inconvenience caused to the Customer by fulfillment of the warranty right;

b) may require – optionally – adequate price discount or cancellation of contract if the customer is not entitled neither for repair nor replacement or if the Obligor has not undertaken neither repair nor replacement or he cannot meet the obligation with the conditions included in section (2).

No cancellation may take place on account of minor deficiency.

Insomuch owing to the defect of the consumer good the Customer validates his replacement demand within three working days following the purchase (installation), the Obligor may not refer to disproportionate extra costs, but he is obliged to replace the consumer's good in case if the defect prevents its normal usage.

(2) The repair or replacement – taking into account the properties and function reasonable expected by the Customer – must be accomplished within due date without significant inconveniences caused to Customer. The Obligor should make all effort to accomplish the repair or replacement within at most fifteen days. Only new equipment part may be fixed in the consumer's good in the course of repair.

(3) Insomuch the Obligor does not undertake or accomplish the repair of the instrument until due date The Customer himself may repair or make repaired by third person the defect on the Obligor's charge.

The Customer may address his demand for repair directly to the Manufacturer/Distributor or to the service indicated on the warranty card as well. The Customer shall let know the complaint to the Obligor in depending on the circumstances shortest possible time after having found the defect. A complaint let known in due time shall be regarded the complaint conveyed within two months after finding the defect. The Customer is responsible for damages due to belated information. The warranty period is prolonged with part of the repair time during which the Customer could not use the product according to its normal function.

The warranty does not cover:

- damages as consequence of unreasonable usage,
- in cases of soiling, mechanical damage, vandalism due to improper protection or if the instrument is opened and/or dismantled during the warranty period.

1. Annex

Concerning the electromagnetic compatibility (EMC) of the Safe Laser® 150, 500 Infra, 1800 Infra devices manufactured by Safe Laser Bt. the conformities presented in the following tables were established:

According to Table EN 61601-1-2:2007 5.2.2.1.1.:

Manufacturer's declaration – electromagnetic emissions		
The Safe Laser® 150, 500 Infra, 1800 Infra devices were designed for usage in electromagnetic environments specified as follows. The purchaser or user shall make certain that the instrument will be used in such environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	1. group	The Safe Laser® 150, 500 Infra, - 1800 Infra uses RF (radio-frequency) energy for its inner function only. So its RF emission is very low, it is unlikely that it causes any interference with other neighboring equipment.
RF emissions CISPR 11	B class, EMC-110119/1, Passed; 30-1000 MHz	The Safe Laser® 150, 500 Infra, - 1800 Infra instrument are suitable for usage in any place including households as well
Harmonic emission IEC 61000-3-2	B class, EMC-110119/1 Passed; 0.15 - 30 MHz	
Voltage change, flicker emission IEC 61000-3-3	Passed	

According to Table EN 61601-1-2:2007 5.2.2.1.2.:

Manufacturer's declare – electromagnetic immunity			
The Safe Laser® 150, 500 Infra, 1800 Infra devices were designed for usage in electromagnetic environments specified as follows. The purchaser or user shall make certain that the instrument will be used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Noise immunity against electrostatic discharge (ESD) disturbances IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	Passed Qualification: normal function within set limits	Floors must be made of concrete or ceramic tiles. In case of floors made of synthetic material the relative humidity shall be at least 30%.
EFT (Electrical fast transient/burst) Noise immunity to signals. IEC 61000-4-4	± 2 kV L, N, PE- between ground	Non applicable. Battery operation.	--
Noise immunity to shock waves (Surge) IEC 61000-4-5	± 1 kV between L - N ± 2 kV between L-N ground	Non 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	Non applicable. Battery operation.	--
Voltage (50/60 Hz) magnetic field	3 A/m	Passed Qualification: normal function within set limits	The magnetic field of supply voltage must have a traditional or typical hospital atmosphere location characteristics.
Note: UT supply voltage level prior to application of the test			

According to Table EN 61601-1-2:2007 5.2.2.1.4.:

Manufacturer's declare – electromagnetic immunity			
The Safe Laser® 150, 500 Infra, -1800 Infra devices were designed for usage in electromagnetic environments specified as follows. The purchaser or user shall make certain that the instrument will be used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Noise immunity to conducted RF signals on power line	3 Vrms	Passed	Portable and mobile RF communication equipment is not to be used nearer to the The Safe Laser® 150, 500 Infra, 1800 Infra instrument then the recommended separation distance, which can be calculated with the following formula. — $d=[3,5/V1] \sqrt{P}$ — $d=[3,5/E1] \sqrt{P}$
	150 KHz–80 MHz	Qualifications: normal operation within the prescribed limits [V1] V	
Noise immunity to radiated RF signals	3 V/m	Passed	80 MHz-800 MHz — $d=[7/E1] \sqrt{P}$ 800 MHz-2,5 GHz where P is the max. power of the transmission (W) according to its manual and d is the recommended separation distance (m). (E.g.: in case of a cell phone: $d=[7/2]^{1,41}= 4,935 \text{ m}$ Close to the devices interference can occur between devices with the following symbol 
	80 MHz-2,5 GHz	Qualifications: normal operation within the prescribed limits [E1] V/m	

According to Table EN 61601-1-2:2007 5.2.2.1.6:

Recommended separation distance between the Safe Laser® 150, 500 Infra, 1800 Infra devices and portable/mobile communication equipment			
The Safe Laser® 150, 500 Infra, 1800 Infra devices shall be operated in such electromagnetic environment, where radiated RF disturbances are controlled. The purchaser/user of the The Safe Laser® 150, 500 Infra, 1800 Infra can prevent electromagnetic interference by observing the minimum separation distance.			
Identified maximum power of transmission W	Separation distance according to the frequency of transmitter (m)		
	150 KHz-80 MHz	80 MHz-800 MHz	800 MHz-2,5 GHz
	— $d=[3,5/\sqrt{P}] \sqrt{P}$	— $d=[3,5/\sqrt{E1}] \sqrt{P}$	— $d=[7/\sqrt{E1}] \sqrt{P}$
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 device meets the EMC requirements for medical devices.

Explanation of the labels put on the instrument



2409 CE Conformity marking



Manufacturer's symbol



Date of production



Type B patient classification

SN

Serial number



Electronic waste! DO NOT throw away to trash!



Read the Owner's Manual

IP21 Ø 28 mm rigid external body, protected from vertical water drops



Laser usage warning sign

Manufacturer's Proof of Compliance

Company: **Safe Laser Bt.**

Address: **1139 Budapest, Kartács Street 8. 4/4.**

as manufacturer

we state and declare that our product

Name : **Therapeutic Laser Device**

Safe Laser® 150 serial number: from 0015

Safe Laser® 500 Infra serial number: from 0004

Safe Laser® 1800 Infra serial number: from 0041

is conforming to the requirements of

Classification: II.a (93/42/EEC on Medical Devices, Annex I., II., V.)

furthermore the requirements of RoHS 2 2011/65/EU Directive (2011.06.08.), as well.

Certificating organization and its identification (notified body): 2409

CE Certiso Ltd.

2040 Budaörs, Gyár u. 2.

Number of the certificate: **144783-18-09-05**

Validity of the certificate: **04. September 2023.**

Budapest, **04. 09. 2018.**


Rózsa Tamás

Managing Director

Medical certification:



144783-18-09-05

EC CERTIFICATE

Full Quality Assurance System **Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

CE Certiso Ltd. (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: **1139 Budapest, Kartács utca 8. 4. em. 4., HUNGARY**

Scope:

Therapeutic laser equipment

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
soft laser	Safe Laser 150	laser light therapy	SL150	II.a
soft laser	Safe Laser 500 Infra	laser light therapy	SL500	II.a
soft laser	Safe Laser 1800 Infra	laser light therapy	SL1800	II.a

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

ID number of the related audit report: 56-CE-180618

Issue: 1

Issued: 05 September 2018

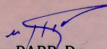
First issued: 05 September 2018

Start date of certified status: 05 September 2018

Expires:

04 September 2023




Valter PAPP, Dr.
General Manager



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NB ID number: 2409



SAFE LASER

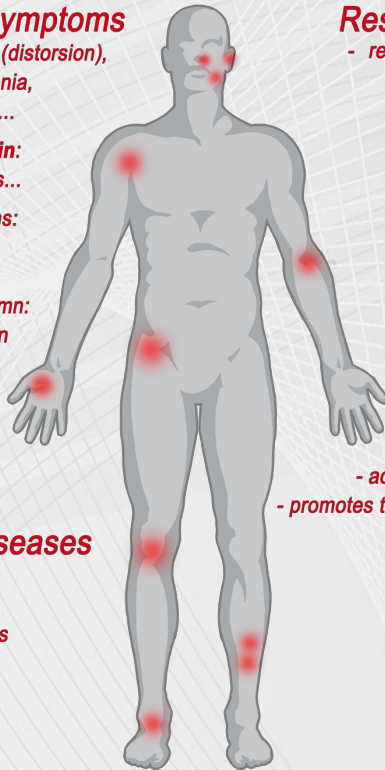
“New generation of soft lasers”

Musculoskeletal symptoms

- **Injuries:** contusion, strain (distorsion), haematoma, rupture of taenia, muscle or tendon, fracture...
- Disorders due to **overstrain:** tendinitis, myositis, bursitis...
- **Degenerative** deformations: joint wear, arthrosis, joint inflammation (arthritis), disorders of vertebral column: pain relieving, inflammation decrease (e.g. lumbago), muscle diseases: muscle pain, limited movement (contracture), rheumatic pain (rheumatoid arthritis)

Dermatological diseases

- bruises
- post-surgery wounds
- initiates of healing of ulcers
- herpes...



Respiratory inflammations

- relieves the symptoms of sinusitis and respiratory inflammation

Ear complaints

- tinnitus
- acute hearing loss

Dental diseases

- toothaches, inflammations
- gum inflammation, gingivitis
- herpes, mouth wounds
- gum and oral mucosa (mucositis, aphtha)
- acute pain in case of orthodontics
- promotes the faster movement of the teeth

Diabetes

- initiates of healing of ulcers

Cosmetics

- acne, pimple, pigment spots

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