K-LASER®
Blue Derma

Operating instruction
English

Title – Operating Instruction K-Laser Blue Derma (English language)
Date – 24/10/2019
Rev. ZE

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kiwa certified CERMET
Organismo accreditato da ACCREDIA
Body accredited by ACCREDIA
CERTIFIED MANAGEMENT SYSTEM
ISO 13485:2016

CE
0476

The device is manufactured in compliance with the provisions of Council Directive 93/42/EEC and 2007/47/CE concerning medical devices.

1 Warning and safety information

1.1 Highlighting of warning and safety information

To prevent personal injury and/or material damage, you must observe the warning and safety information provided in the present operating instructions.

All such information is highlighted by signal words as follows:

Notice
for additional information;

Caution
if there is any risk of damage to the device;

Warning
if there is any hazard to the life or health of persons.

➢ This symbol indicates that you have to take action.

↳ This symbol indicates that a certain result will occur.

1.2 Intended use

K-Laser Blue is developed as portable laser device in the following version
Derma: 445 nm with 8 W in CW, 10 W in pulsed mode, 970 nm with 3 W in CW,
total power 445 nm + 970 nm of 13 W and 660 nm with 100 mW.
The following table summarizes in detail the intended use based on the device model:

Surgery:	- incision and coagulation of soft tissue.
Dermatological surgery:	- benign skin disease *(nevus, keratosis, fibromas…)*;
	- pigmented and vascular lesions;
	- mild to moderate acne vulgaris.
Therapy:	- muscular & skeletal pathologies;
	- osteoarticular diseases;
	- edemas;
	- soft tissue injuries;
	- wound healing;
	- laser acupuncture.

The operator can set up the parameters manually in order to be able to use the equipment with his specific requirements.
The device can be used in medical practice, in physical therapy centers and in sport facilities. The device can be used in an ambulatory for surgical and medical practice.

Notice
The device may be operated only by medical qualified personnel. The applicable occupational safety regulations and accident prevention measures and the current operating instructions must be complied with.

Notice
Users are obliged to use only faultless materials, to ensure correct application and to protect themselves, the patient and other persons against hazards.

Warning
The device must not be used in areas where an explosion hazard exists or in the vicinity of highly flammable materials.

Warning
Public legal requirements may include special safety regulations concerning protection against laser radiation. These requirements must be fulfilled.

Warning
Failure to use the settings specified in this manual or perform the actions described here may lead to a dangerous exposure to radiation.

1.3 Instructions on use of the laser protective goggles

Before using the laser protective goggles, please read and observe the instructions for use provided by the manufacturer and attached to the goggles in the case.

Before using the laser protective goggles, please make sure:

- the laser protective goggles are not damaged;
- the laser protective goggles conform to standard EN 207 and EN 208;
- the laser protective goggles are equivalent to the technical features listed in paragraph 4.1.

These instructions apply particularly when using goggles supplied from an outside source that are not included in the scope of delivery of the device.

⚠ Warning

Check the laser protective goggles before each use. In case of damage, do not use the goggles and replace them (see chapter Spare parts and optional).

1.4 Interferences caused by mobile wireless phones

⚠ Caution

To ensure safe operation of medical electrical equipment, the use of mobile wireless phones in practice or hospital environments may be avoided.
Mobile devices, or radio frequencies (including cables for antenna and external antenna) must not be closer than 30 cm (12 inches) respect every part of the device, included the power cable provided by the manufacturer. Otherwise performance degradation of the device could happen.

⚠ Caution

Not use the laser unit with surgical high frequency devices.

1.5 Disposal of main unit and parts

ℹ Notice

TO ALL OPERATORS pursuant to the Legislative Decree of the 14th of June 2014, n. 49, actuation of directive 2012/19/EU on the waste of the electrical and electronic equipment.

The sign of the barred trash bin displayed on equipment or packaging thereof indicates that upon completion of its life cycle, it should be disposed of separately from other waste.
The separate disposal of dead equipment is the producer's responsibility. Therefore, the user must contact the producer and follow their established procedure for its disposal.

The proper disposal of this equipment will automatically provide for the recycling and proper processing and disposal of the same which helps to prevent possible negative effects on our environment and health, and encourages the recycling of its parts. The improper or illegal disposal by the user will entail the application of administrative sanctions according to the laws and regulations in force.

ℹ Notice

Contact the distributor of your Country for the correct disposal of the main unit.

ℹ Notice

Handpieces, optic fibers, tools for cutting and disposable tips may be disposed in the domestic refuse. Please disinfect or sterilize the parts prior to disposal.

1.6 Safety precautions

Each device is manufactured in compliance with the provisions of Council Directive 93/42/EEC (MDD) and 2007/47/CE concerning medical devices. Always observe the following precautions:

⚠ Warning

When disconnecting the optic fiber from the device, always cover the connector with the special protection cap. Otherwise the unit may be permanently damaged. Make sure that no dust or dirt can enter the connections of the optic system.

⚠ Caution

Any use of the controls or setting options in a manner other than the one described here may lead to a dangerous exposure to radiation. Manufacturer is not responsible for damages caused to the non-correct use of the device or to the disrespect of the instructions and caution indicated in the present manual.

⚠ Caution

Never place your finger or any other objects in the optical connectors. This could cause damage to the optical instrument.

⚠ Caution

Switch the device OFF immediately in case of an emergency. To do this, press the “LASER STOP” button below the touch screen on the front side of the control unit.

⚠ Warning

Observe all labels on the device.

⚠ Warning

Operation of this laser unit by unauthorized persons must be prohibited in order to prevent incorrect or improper use. Laser equipment not in use must be protected against unauthorized access. This can be achieved for example by switching off the laser unit after use, so that the electronic access key must be entered prior to further operation.

⚠ Warning

Never direct the laser beam toward a person’s eye or thyroid gland. All persons present in the room (patient, operator and assistant) must always wear the laser protective goggles delivered along with the device.

⚠ Warning

Never use optical instruments such as microscopes, eye loupes or magnifiers together with the original protective goggles. Otherwise sufficient eye protection can no longer be ensured.

⚠ Warning

Oxygen-saturated materials such as cotton wool can catch fire owing to the high temperature that the unit reaches during operation. Label removers and flammable solutions used for cleaning and disinfecting the device should be allowed to evaporate before using the device. Observe fire hazards caused by flammable gases.

⚠ Warning

The unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen or nitrogen monoxide.

⚠ Warning

Never direct the laser beam toward paper, plastics or objects with dark surfaces. They could catch fire due to the high temperatures produced by the laser beam.

⚠ Caution

Avoid interference between the laser emission and any optical sensors of devices operated in the vicinity of the device.

⚠ Caution

Do not place the unit near heat sources. Do not cover the convection openings for air cooling on the sides of the unit.

⚠ Caution

The device may be operated only by authorized personnel. In order to prevent false or improper use, the device must not be used by unauthorized persons. Do not write down the electronic access key somewhere else in order to reduce risk of misuse of the laser by unqualified persons. Please turn off the unit after the use.

⚠ Warning

Set up the laser unit properly and completely before putting it into operation.

⚠ Warning

Make sure that the electrical system is equipped with the required devices for protection against direct and indirect contact (thermomagnetic switches, residual current circuit breakers) and has been set up by a qualified electrician in compliance with the applicable standards. National directives regarding electrical installations must be observed.

⚠ Warning

Verify that the line voltage corresponds to the voltage indicated on the rating plate of the adapter or in the technical specifications.

⚠ Warning

Do not use the device if a visual inspection shows that it has been damaged.

⚠ Warning

If you accidentally spill any liquid on the unit, immediately stop treatment, disconnect the power cable and contact your local depot or your authorized service center for assistance.

⚠ Caution

Never under any circumstances try to disassemble the device. This is limited exclusively to trained and authorized personnel.

⚠ Caution

Switch the device OFF immediately in case of fiber breakage.

⚠ Caution

The use of this device close to or over (above or under) other devices must be forbidden because an improper functionality could happen. If needed to do this, the unit and the other ones must be maintained under control to verify the correct functionality.

⚠ Caution

The device may only be operated with the Sinpro MPU101-106 power supply and the power cable provided.

Operation with other power supplies may result in failure or destruction of the laser unit and the use of power cables not provided by Eltech K-Laser can compromise the conformity of the device regarding emissive requirement and immunity. If any power supply, power cable or accessory other than the one recommended is used, the approval of the entire unit automatically becomes void and the warranty expires.

⚠ Caution

The use of accessories, transductors or power cables not provided by the manufacturer of the device, could increase the electromagnetic emission and decrease the electromagnetic immunity of the device.

⚠ Warning

It is recommended not to use the handpiece for therapy in direct contact to skin of the patient, but to keep distance from the skin and always move it!

⚠ Warning

Before therapeutical treatment with the handpiece for therapy, please treat fix points, keeping a distance of at least two centimetres from the skin of the patient, in particular if you are using CW (continuous emissions), in order to check the sensibility of the patient and the energy density, especially if the patient's skin is particularly brown.

⚠ Warning

In case of the use of the handpiece for therapy it is recommended to verify that the part to treatment not present neo of great dimension or dark zones that could absorb excessive amounts of energy. In this case protect with dioxide of titanium or zinc the treatment part.

⚠ Caution

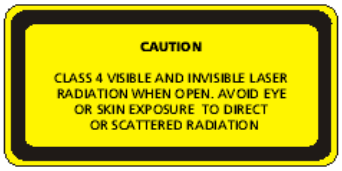
Laser fume and/or plume may contain viable tissue particulates.

ℹ Notice

For the use of handpieces, please read carefully specific instructions and warnings.

2 Symbols and abbreviations

2.1 Symbols on the device

Symbol	Description
	Type B applied part according to IEC 60601-1.
CE 0476	CE mark in accordance with Council Directive 93/42/EEC and 2007/47/CE, stating the manufacturer's Notified Body.
 20XX	Date of manufacture (year).
	Please refer to manual first.
	Do not dispose with domestic waste.
DC IN	Connection socket for DC input from the power supply.
	Connection socket for scanner handpiece (not implemented).
	Connection socket for interlock.
	Connection socket for USB.
	Laser radiation warning.
	Specification of laser output power and wavelength of IR and aiming beam (see also Chapter "Technical data"). Verifies the compliance of the device with IEC 60825-1.
	Warns of potential laser radiation hazards when opening the laser unit.
	Warns of Class 4 laser radiation hazards when using the unit.

	“LASER STOP” button: Press this button in case of an emergency.
	Operate the unit exclusively with the MPU101-106 power supply.
	Pairing button of the wireless footswitch.

2.2 Glossary

Continuous emission	Continuous laser emission;
Pulsed emission	Pulsed laser emission (Chopped Mode);
Frequency	Number of laser pulses per second;
Hertz	Unit of measure for frequency;
Interlock	Safety device that stops laser radiation when the door of the treatment room is opened;
Joule	Unit of measure for emitted energy;
Watt	Unit of measure for laser power.

2.3 Abbreviations

cm^2	Square centimeter;
Hz	Hertz;
s	Seconds;
W	Watt;
mW	Milliwatt (one thousandth of a watt);
J	Joule;
nm	Nanometer;
V	Volt;
IR	Infrared diode;
NOHD	Nominal ocular hazard distance in compliance with the Standard IEC 60825-1.

3 Technical Data

3.1 Specification

According to the applicable standards, each device is classified as follows:

- Class I, Type B according to IEC 60601-1 of electrical safety;
- Class IIb according to Council Directive 93/42/EEC;
- Class A according to IEC 60601-1-2 of the electromagnetic compatibility;
- Class IV laser product according to IEC 60825-1 of laser product;
- Degree of protection according to IEC 60601-1: medical unit IP20 (enclosure not water-proof), IPX5 for footswitch.

3.2 Device specification

Specification	Derma
Laser type	Diode GaAlAs
Laser system	Class IV (according to IEC 60825-1)
Device classification	Class IIb (according to Council Directive 93/42/EEC)
Wavelength (nm)	445 nm ± 5 nm; 660 nm ± 10 nm; 970 nm ± 15 nm
445nm+970nm total power (W) ±20%	13
445 nm CW power (W) ±20%	8
445 nm in pulsed mode (W) ±20%	10
970 nm CW power (W) ±20%	3
Max power 660 nm (mW)	100
Emission mode	CW (continuous wave), pulsed, modulated 1 Hz to 10 kHz
IP degree of protection	Laser unit: IP20; footswitch (cover not waterproof): IPX5 (according to IEC 60601-1)
Insulation class	Class I, type B (according to CEI EN 60601-1)
Aiming beam	660 nm ± 10 nm, max. 1mW
NOHD	12.46 m max
Divergence of the beam	2.3° without handpiece
Start	Wireless footswitch
Power supply	Rechargeable battery pack and external power supply Sinpro MPU101-106, 100 - 240 VAC, 47 - 63 Hz
Display	Full color, graphical LCD touchscreen
Dimensions (W x L x H)	180 x 200 x 190 mm
Weight	Approx. 1300 g (incl. handpiece and rechargeable battery pack)

3.3 Wireless footswitch specification

Model designation:	NanoLOC AVR;
Frequency:	2.4 GHz – 2.4835 GHz (ISM band);
Transmitting power:	< 2 mW (short-range device);
Modulation type:	Multi Dimensional Multi Access (MDMA).

3.4 Transport and storage

The device comes in a box that ensures proper and easy transport.
In its original transport packaging, the device can withstand the following ambient transport conditions:

- Temperatures from - 40°C to + 70°C;
- Relative humidity from 10% to 90%;
- Atmospheric pressure from 800 hPa to 1060 hPa.

⚠ Caution

Do not leave the device in a vehicle parked in the sun. The inside temperature of the car could thus heat up to a point where individual components may be damaged.

Notice

The rechargeable battery must be fully charged regularly. After six months of no charging (storage) the rechargeable battery might lose its loading capacity and might not be rechargeable anymore.

3.5 Operating conditions

The device may be operated in the following environmental conditions:

- Temperatures from + 10 °C to + 33 °C;
- Relative humidity from 10% to 95%;
- Atmospheric pressure from 800 hPa to 1060 hPa.

⚠ Caution

Following transport and storage, let the device adapt to room temperature for about one hour prior to operation to reduce the risk of malfunctions caused by condensation.

4 Installation

Any national or local regulations stipulating that the device may be installed only by trained personnel must be strictly observed.

4.1 Standard equipment

The following components are included in the package:

Quantity	Designation
1	Laser unit
1	Rechargeable battery pack inside the unit
1	No contact surgical tip
1	Skin spot tip
1	Minor telangiectasia tip
1	Leg telangiectasia tip
2	Optic fiber tip (320 µm) for contact surgery
1	Tool for optic fiber
1	Set of disposable tip and bending tool
1	Interlock connector
1	Laser protective goggles: >315-450 DIRM LB5 (OD5+); >450-460 DIRM LB3 (OD3+); 808-1070 D LB6 + I LB8 + R LB7 (OD8+); 650-680 650-680 0,01W 2x10E-6J RB1 (OD1-2)
1	Laser protective goggles (darker): >315-450 DIR LB5 (OD5+); >450-460 DIR LB3 (OD3+); 620-<650 DIR LB1 (OD1+);650-<680 DIR LB2 (OD2+); 755-1090 D LB6 + IR LB7 (OD7+); 620-635 0,01W 2x10E-6J RB1 (OD1-2); 650-665 0,1W 2x10E-5J RB2 (OD2-3)
1	Ocular protector (for patient): 315-1400 D L7+ I L9+ R L8
1	Power supply Sinpro MPU101-106
1	Power cord
1	Wireless footswitch
1	User manual
1	Set of warning labels
1	Danger sign

Quantity	Designation	Picture
1	Handpiece for therapy (MP383)	
1	Contact surgical handpiece body (MP384)	
1	Sleeve for surgical handpiece body (MP385)	
1	No contact surgical handpiece body (MP386)	
1	ENT handpiece (MP388)	

4.2 Spare parts and optional

Quantity	Designation
1	Rechargeable battery pack
1	Optic fiber with connector
1	Handpiece for therapy
1	Contact surgical handpiece body
1	Sleeve for surgical handpiece body
1	Optic fiber tip (320 µm) for contact surgery
1	Tool for optic fiber
1	Set of disposable tip and bending tool
1	No contact surgical handpiece body
1	No contact surgical tip
1	Skin spot tip
1	Minor telangiectasia tip
1	Leg telangiectasia tip
1	ENT handpiece
1	Endo handpiece
1	Optic fiber (400 µm, 3 m) for Endo handpiece
1	Optic fiber (600 µm, 3 m) for Endo handpiece
1	Interlock connector
1	Laser protective goggles: >315-450 DIRM LB5 (OD5+); >450-460 DIRM LB3 (OD3+); 808-1070 D LB6 + I LB8 + R LB7 (OD8+); 650-680 0,01W 2x10E-6J RB1 (OD1-2)
1	Laser protective goggles (darker): >315-450 DIR LB5 (OD5+); >450-460 DIR LB3 (OD3+); 620-<650 DIR LB1 (OD1+);650-<680 DIR LB2 (OD2+); 755-1090 D LB6 + IR LB7 (OD7+); 620-635 0,01W 2x10E-6J RB1 (OD1-2); 650-665 0,1W 2x10E-5J RB2 (OD2-3)
1	Ocular protector (for patient): 315-1400 D L7+ I L9+ R L8
1	Power supply Sinpro MPU101-106
1	Power cord
1	Wireless footswitch
1	User manual
1	Set of warning labels
1	Danger sign
1	Transport case
1	Trolley with support for tips

4.3 Power supply

➢ Connect the power cable to the DC IN socket at the back of the device.

⚠ Caution

The device may only be operated with the Sinpro MPU101-106 power supply. Operation with other power supplies may result in failure or destruction of the laser unit. If any power supply other than the one recommended is used, the approval of the entire unit automatically becomes void and the warranty expires.

⚠ Warning

The use of any power supplies other than the one recommended may cause overheating and failure of the laser unit or damage of batteries.

The device is supplied with a rechargeable battery and therefore can be used without connected power cable. The status of the rechargeable battery and whether the power cable is actually connected will be always displayed on the touch screen.

Notice

There will be a warning if the rechargeable battery will reach a low level of capacity.

Notice

While operating, should the charge level of the battery be below 5%, the green led will flash at 5 “ intervals to remind the user to plug in the unit.

The device is fully functional and can be run while charging the battery.

➢ Charge the battery completely.

Notice

The rechargeable battery is automatically charged, also during the device use, in the event of power supply connection.

Notice

The rechargeable battery must be fully charged regularly. After six months the rechargeable battery might lose its loading capacity and it may not be rechargeable anymore.

Notice

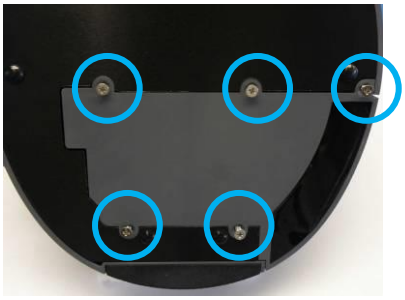
To have a precise indication of the battery charge status, please perform a periodic battery calibration process every 3 months. See chapter “Set up” for further details.

4.3.1 Replacing the rechargeable battery

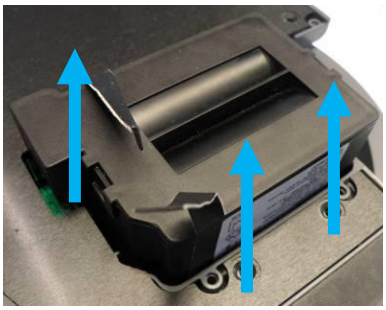
If the rechargeable battery does not charge more than 30% the battery needs to be replaced.

Removing and replacing the battery:

- ➢ Extract the handpiece and unroll completely the fiber;
- ➢ Remove the 5 cross head screws of the grey battery cover;



- ➢ Pull out the battery by the appropriate strap;



- ➢ Mount the new battery.
- ➢ Replace the battery cover taking care the fiber lock will be in the proper position and screw gently. Do not screw too firmly.
- ➢ Plug in the power supply connector and switch on the device;

- ➢ Enter in Setup menu, select battery calibration.

A message screens asks to confirm the battery calibration process.

- ➢ Press OK to confirm;
- ➢ Unplug the power supply connector and wait until the device switches off automatically;
- ➢ Then plug in the power supply connector and charge for 2 hours.

⚠ Caution

Only use the specific battery pack provided by Eltech K-Laser s.r.l. (see chapter spare parts and optional).

4.4 Optic fiber with connector

The device is supplied ready to be used. The operator is able to perform needed treatment simply plugging an handpiece to the connector.

Optic fiber with connector

Notice

The user can attach an handpiece, simply plugging it to the connector.
When attaching or detaching the parts, we recommend to slightly rotate the two parts. The rotation of the two parts makes the operation easier.

Attach

Detach

The user must hear a sound (click) locking the parts. This guarantees a correct connection.

Notice

Clean the lens of the connector with a dry, soft cloth. Please proceed carefully not to scratch and damage the components.

Caution

Always cover the connector with the special protective cap. Make also sure that no dust or dirt enter the connector. Otherwise the unit may be permanently damaged. Use a soft cloth to clean it.

Caution

Always cover the connector and the optic fiber with the special protection caps if the fiber is dismounted to make sure that no dust or dirt can enter inside. Otherwise the unit may be permanently damaged.

Caution

Always cover the connector with the special protective caps provided for this purpose after the removal of an handpiece.

Initial check

Caution

Prevent dust, dirt and foreign particles from entering the optic system.
Make sure that the optic system is always cleaned: before, during and after the use.

Warning

Do not use the device if the aiming beam is not visible. If the aiming beam projects no pattern at all, check that the eventual deactivation. Adjust the aiming beam brightness in the surgical area.

⚠ Warning

Never direct the laser beam toward a person's eye or thyroid gland. All persons present in the room (patient, operator and assistant) must always wear the laser protective goggles delivered along with the device.

⚠ Warning

Before and during the emission laser verify that the aiming beam is present and that it projects a regular shape. If it does not come projected some shape, or if it is much irregular one, the optic fiber or the device could be damaged. In this case, proceed as follows:

- Switch off the laser and check the optic fiber as well as the fiber connection for mechanical damage;
- If the optic fiber is damaged;
- If you cannot detect any damage on the optic fiber and the signal of the aiming laser is not visible, switch off the laser and contact Authorized Service Center.

4.4.1 Handpiece for therapy

This optics has a defocused handpiece of 32 mm diameter, that guarantees a spot of 40mm ± 0.1 mm at 2 cm from the surface. This handpiece has a defocused fixed spot size and the maximum available fluence cannot exceed 1.5 W/cm^2.

A) Optic fiber with connector

B) Handpiece for therapy

Initial check

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that it is always cleaned: before, during and after the use.

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

➢ The operator can attach the handpiece for therapy (B) to the connector (A). When attaching or detaching the parts, we recommend to slightly rotate the two parts. This guarantees an easier connection. The user must hear a sound (click) locking the parts. This guarantees a correct connection.

⚠ Warning

Before treatment, please treat fix points, keeping a distance of at least two centimetres from the skin of the patient, in particular if you are using CW (continuous emissions), in order to check the sensibility of the patient and the energy density, especially if the patient's skin is particularly brown.

⚠ Warning

During laser therapy use, this handpiece is not applied in a single and fixed point, but it is applied all around the part to be treated.
During treatment, always move the handpiece!

⚠ Warning

It is recommended to verify that the part to treatment not present neo of great dimension or dark zones that could absorb excessive amounts of energy. In this case protect with dioxide of titanium or zinc the treatment part.

4.4.2 Contact surgical handpiece

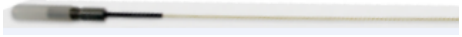
This handpiece is made of the following parts:

A) Optic fiber with connector

B) Contact surgical handpiece body

C) Sleeve for contact surgical handpiece body

D) Disposable tip



E) Optic fiber tip

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that it is always cleaned: before, during and after the use.

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

⚠ Caution

The disposable tip is supplied non-sterile. It must be sterilized before use.

Initial check

⚠ Warning

Every time before using the handpiece, make sure that the optic fiber tip, the disposable tip, the bending tool and the sleeve have been disinfected and sterilized in autoclave.

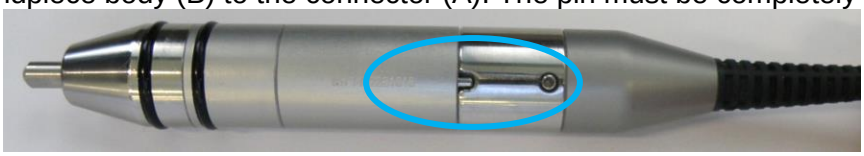
ⓘ Notice

The optic fiber tip, the disposable tip, the bending tool and the sleeve can be sterilized in an autoclave with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure without damage.

Contact surgical handpiece body assembly

➢ The operator can attach the handpiece body (B) to the connector (A). When attaching or detaching the parts, we recommend to slightly rotate the two parts. This guarantees an easier connection. The user must hear a sound (click) locking parts. This guarantees a correct connection.

➢ Attach the handpiece body (B) to the connector (A). The pin must be completely in the groove.



Disposable tip assembly

➢ Attach the disposable tip (D) firmly on the sleeve (C) prior to mounting the optic fiber tip (E).

⚠ Caution

Check whether the disposable tip is damaged before attaching it. Replace it if necessary.

⚠ Caution

Please check that the disposable tip is firmly attached prior to each use.

⚠ Warning

Always use the disposable tip with the fiber and check the correct fixation.

⚠ Warning

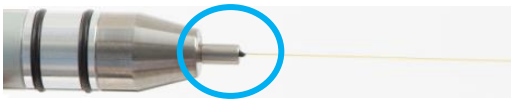
To avoid the risk of damaging optic fiber tip use only provided disposable tips.

Optic fiber tip assembly

➢ Remove the protective cap from the optic fiber tip and preserve it for the fiber sterilization.

➢ Remove the protective cap from the handpiece body and preserve it.

➢ Insert the optic fiber tip into the handpiece body and screw it firmly.



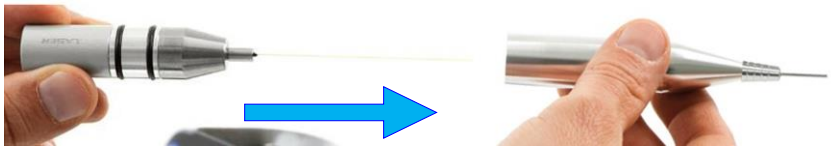
⚠ Warning

Slightly tighten the optic fiber tip so that it can be easily loosened. Make sure not to overwind!

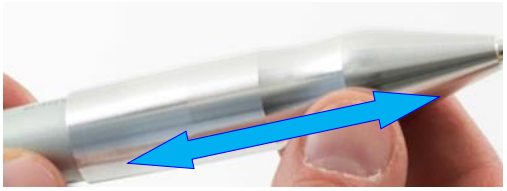
⚠ Caution

Never use the laser without fiber, check for correct fixation.

➢ Insert the handpiece body into the sleeve making sure that the optic fiber tip easily slides.



➢ Slide the sleeve to regulate the optic fiber tip. The optic fiber tip must protrude at least 1 cm out of the disposable tip.



⚠ Warning

If the optic fiber tip does not protrude at least 1 cm out of the disposable tip, there is a risk that the disposable tip will heat up.

⚠ Warning

In the event of the sleeve is left inserted for a long time, it could happen that it is "glued" to the gasket. If it happens, move the sleeve with more strength till the complete removal of the part.

Adjustment of the optic fiber tip

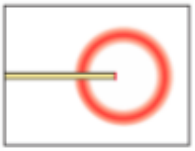
➢ Notch the optic fiber tip with the blade of the tool.

➢ Bend the optic fiber tip at the notched location. It breaks at the notched location with a smooth, perpendicular fracture surface.

Notice

Press firmly but do not squeeze the optic fiber tip. Just a little notch is needed to achieve a perfect result.

➢ Check to see if the aiming beam projects a uniform circular pattern. To do this, aim the optic fiber tip vertically at a white background located approx. 5 cm away.



➢ If the aiming beam projects no pattern at all, adjust the aiming beam brightness or only an uneven pattern, cut off another one to two millimeters.

Warning

The aiming beam must not be aimed toward a person's eye. It comprises an intensive light source even when set to a low power level. Always wear protective goggles.

➢ Now you can bend the disposable tip with the bending tool to the angle that you need for best handling.

Warning

Do not move the optic fiber tip in the disposable tip after having bent the tip, risk of fiber damage!

Caution

The optic fiber tip may be damaged if it is seriously bent or improperly inserted inside the handpiece.

After treatment

➢ Please bend back the disposable tip as straight as possible before extracting the optic fiber tip within the disposable tip.

⚠ Caution

If the optic fiber tip is slid in a bent disposable tip the optic fiber tip surface may be destroyed (danger of optic fiber tip breakage).

➢ As soon as you disassemble the optic fiber tip after treatment make sure to protect the connector of the optic fiber with the protective caps.

⚠ Caution

Cover the connectors with the special protective caps provided for this purpose each time the handpiece is disassembled.

⚠ Caution

Prevent dust, dirt and foreign particles from entering the optic fiber connections and the optic system. Make sure that the optic system is always cleaned: before, during and after the use. Otherwise the unit may be permanently damaged.

⚠ Warning

After each use, make sure to clean and disinfect the handpiece parts.
Disinfect and sterilize the optic fiber and the sleeve.

4.4.3 No contact surgical handpiece

This handpiece is made of the following parts:

A) Optic fiber with connector

B) No contact surgical handpiece body

C) Set of no contact surgical tip

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

Initial check

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that the optic system is always cleaned: before, during and after the use.
During treatment, clean the lens of the handpiece body with a dry gauze.

⚠ Warning

Every time before using the handpiece, make sure that the no contact surgical handpiece body has been disinfected and the set of no contact surgical tip has been disinfected and sterilized in autoclave.

ⓘ Notice

The set of no contact surgical tip can be sterilized in an autoclave with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure without damage.

No contact surgical handpiece body assembly

➢ The operator can attach the handpiece body (B) to the connector (A). When attaching or detaching the parts, we recommend to slightly rotate the two parts. The rotation of the two parts makes the operation easier. The user must hear a sound (click) locking the parts. This guarantees a correct connection.

No contact surgical tip assembly

Screw the no contact surgical tip on the handpiece body.

⚠ Caution

Check whether the surgical tip is damaged before attaching it. Replace it if necessary.

⚠ Caution

Please check that the surgical tip is firmly attached prior to each use.

⚠ Warning

The aiming beam must not be aimed toward a person's eye. It comprises an intensive light source even when set to a low power level. Always wear protective goggles.

Based on the selected handpiece, different spots can be obtained at 2 cm from the surface:

Grey: 2.85 mm± 0.1 mm
Green: 5 mm± 0.1 mm
Red: 5 mm± 0.1 mm
Blue: 5 mm± 0.1 mm

After treatment

⚠ Warning

After each use, make sure to clean and disinfect the handpiece parts.
Disinfect and sterilize the no contact surgical tips.

4.4.4 ENT handpiece

This handpiece is used for treating small areas, few square centimeters, and with low powers because the point of application has high power density.

A) Optic fiber with connector

B) ENT handpiece

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

Initial check

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that the optic system is always cleaned: before, during and after the use.

⚠ Warning

Every time before using the handpiece, make sure that the ENT handpiece has been disinfected and sterilized in autoclave.

ℹ Notice

The ENT handpiece can be sterilized in an autoclave with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure without damage.

➢ The operator can attach the ENT handpiece (B) to the connector (A). When attaching or detaching the parts, we recommend to slightly rotate the two parts. This guarantees an easier connection. The user must hear a sound (click) locking the parts. This guarantees a correct connection.

⚠ Caution

Check whether the ENT handpiece is damaged before attaching it. Replace it if necessary.

⚠ Caution

Please check that the ENT handpiece is firmly attached prior to each use.

⚠ Warning

The aiming beam must not be aimed toward a person's eye. It comprises an intensive light source even when set to a low power level. Always wear protective goggles.

⚠ Warning

Be careful because the point of application has high power density.
Do not absolutely exceed more than 1.0 W in the average power and treat zone at distance at least of 4 cm. During treatment, always move the handpiece!

ℹ Notice

Before starting treatment, the device will ask the operator to select optic in use.
In case of ENT handpiece selection, the power will be automatically adapted to an average power of 0.5W. Total energy to be delivered will be consequently decreased

After treatment

⚠ Warning

After each use, make sure to clean and disinfect the handpiece parts.
Disinfect and sterilize the ENT handpiece.

4.5 Care of handpiece's fiber

The handpiece mounts a flexible hose to protect the optic fiber from damage.
For proper functioning and upkeeping, it must be handled with care, especially when winding and unwinding in its proper seat about the device.

⚠ Warning

Do not unwind once the yellow sticker on the fiber appears.
Unwinding beyond the yellow sticker may damage the optic fiber irreparably!

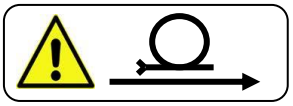
Marker of optic fiber's end.

⚠ Warning

The fiber must be wound around the device counter clockwise.
Should it be wound differently will damage the fiber irreparably!

⚠ Warning

The arrow of the label shows the correct winding of the fiber.



⚠ Warning

The optic fiber may be damaged if it is seriously bent, pitched or improperly routed.

⚠ Warning

Bear in mind the maximum bending radius of the optic fiber:

- 2 cm: Short-term (during treatment): 100 x radius of optic fiber;
- 3 cm: Long-term (during storage): 600 x radius of optic fiber.

⚠ Caution

The flexible hose that protects the fiber can be cleaned by gauze soaked with no alcohol disinfectant.

4.6 Interlock

As foreseen by the normative the device is supplied with connector interlock for the automatic interruption of the emission laser at distance.
Such connector is normally connected to a switch which interrupts the functioning of the laser in case a person enters in the room in which it is used.

Notice
The installation must be performed by a qualified electrician who is also responsible for the installation and maintenance of the electrical system to which the device is connected.

Notice
Please request the technical data sheet with wiring diagram for the installation of the interlock device.

Notice
Additional or different safety precautions required by the applicable national or local regulations for the protection of operators, assistant personnel, or patients must also be observed.

4.7 Wireless footswitch

The wireless footswitch must be assigned to the device via a registration.
To register the footswitch, proceed as follows:
- In “Set-up” select the item “Set-touch”.
- Press the key to start the procedure.
- Follow the on-screen instructions.

Caution
Touch a grounded metal part before opening the housing to prevent damage to the PC board due to electrostatic discharge.

Caution
Prior to changing the batteries, switch the device off at the main switch. This prevents accidental triggering.

Removing and replacing the batteries:
- Remove the screws from the bottom of the footswitch.
- Remove the cover and replace the battery (2 AA type cells).

Be careful to insert it with the correct polarity (minus pole facing spring).
- Place the battery holder back again in the compartment and close it with the cover.
- Screw the screws at the bottom of the footswitch.

Notice
After changing the batteries, switch the device and check the complete functionality of the footswitch. It is not necessary to register again the footswitch again at the device after changing batteries.

5 Operation

5.1 Start the device for the first time

Notice

Touchscreen functionality: When the touchscreen is touched by the finger the touch field is highlighted. As soon as the finger leaves the touchscreen the action will be activated.

Notice

Symbols/Icons on the LCD:

Name	Explanation	Symbol
Battery state	Information concerning the battery status. Press the icon to check the battery percentage.	
Connected / charging battery	Battery is connected to power supply and charging.	
Information	Press it to see device information.	
OK	Operator confirms and activates action.	
Back	Operator goes back one screen.	
Clear	Press it to delete in case of wrong typing.	
Save	Operator saves an application.	
OK (Laser)	Laser is being activated.	
Delete	An application will be deleted.	
‘Plus’ and ‘Minus’	Operator is able to count up and down numerical value.	
‘Forward’ and ‘Backward’	Operator is able to scroll forward and backward the pages of a list.	

5.2 Switch on/off power

After starting the device by switching on the on/off button on the backside of the control unit the yellow LED will be on.

Notice

Remember to switch on also the power supply.

Notice

While the device is booting, a screen will remember the user to carefully read the manual before unit use.

Notice

The device can be switched off in different ways:

- Press the battery icon and then confirm the action;
- Press the on/off button and then confirm the action;
- Keep pressed the on/off button on the backside of the unit.

In case of the device is switched off, the laser diode is permanently disconnected from power supply.

Notice

The laser main switch on/off does not disconnect the battery loading circuit, i.e. the batteries are loaded even if the laser is off.

Notice

In case of emergency press the laser stop button. Note that the laser is interrupted and restarted in a safe mode but not switched off.

Notice

The device is provided of standby mode that allows to increase the use of the device in battery. In this mode, the device switch off the screen and emits blue flashes every 2 seconds. Touch the screen to reactivate the device.
The standby is active in case of the device is not used for 5 minutes (not during emission).

5.3 Enter pin code

The device may be operated only by authorized personnel. So for security purposes the device has an electronic key. After boot, the device will ask to digit the pin code, which consists of a sequence of 4 keys.

The code is **0 0 0 0**.

Press it to delete in case of wrong typing.

Press it to confirm the pin code.

Press it to see device information.

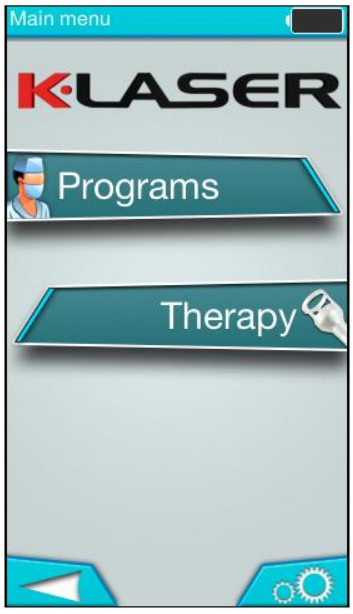
⚠ Warning

The device may be operated only by qualified personnel. Do not give the access to unauthorized third parties.

Do not write down the electronic access key somewhere else to reduce the risk of misuse of the laser by unqualified persons. Please turn off the unit after the use.

5.4 Main menu screen

After entering the pin code, the device shows the main menu.



Press it to go to Programs area.

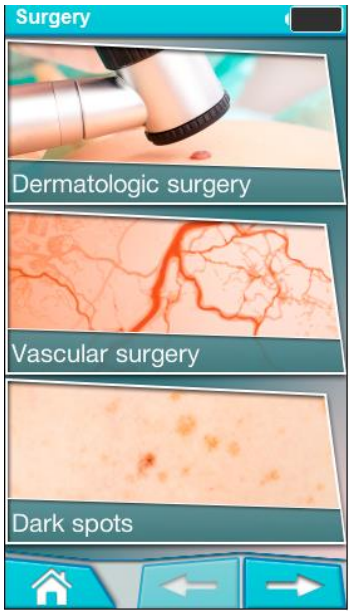
Press it to go to Therapy area.

Press it to go back one screen.

Press it to go to Setup.

5.5 Programs

After selection, you can enter in the following screen.

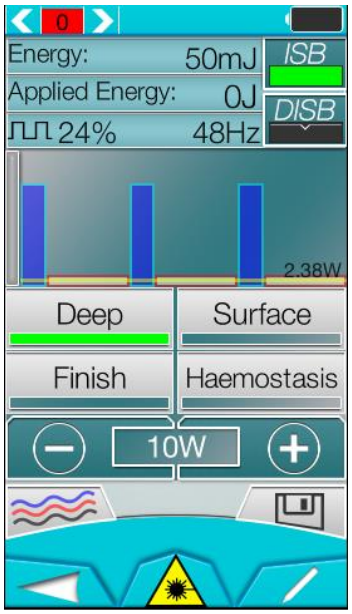


Press it to go to the selected area.

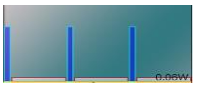
Arrows used to scroll forward and backwards, if more than one page on the list is present.

Press it to the main menu.

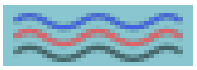
After selection of the following area **Dermatologic surgery** the following screen is displayed.



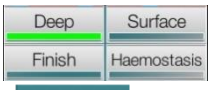
Different levels of the red aiming beam can be defined.



Graphic of the laser impulse.

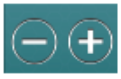


Wavelength selector. Press it to select needed wavelengths, in individual or combined way.



Treatment phases. 

if available.



Press to increase or decrease the value.

ISB modality. It is on if the green bar is present.

DISB modality. It is on if the green bar is present.

Press it to save a treatment.

Press it to go back one screen.

Press it to enter a manual screen. User confirmation is needed.

Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

The device will automatically define the following parameters:

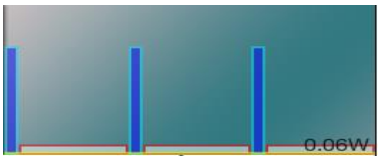
Energy — The device calculates the energy delivered according to selected power and time.

Applied energy — The device shows the energy emitted during treatment.

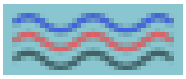
Duty Cycle (%) — The duty cycle is defined as the ratio between the pulse duration (when the laser beam is actually actuated) and the total period of time (which is the time from the beginning of a pulse to the beginning of the next pulse).

Frequency (Hz) — The device calculates the frequency of the impulse based on the Ton – Toff by the operator.

The explanation of the impulse profile on the screen is described into more details.



The impulse is displayed in light blue.Horizontal line and numerical value on the right represent the average power that the device automatically calculates.
If ISB modality is on, a bar with red profile (970nm emission) is present on the base among the impulses.
If ISB modality is off the bar doesn't appear.
If DISB modality is on, a yellow part is present over the light blue impulse. Maximum emissive power of 445 nm and 970 nm combined. If DISB modality is off, the part doesn't appear.



It allows to select wavelengths, in single or combined modality.

445nm selected: the impulse is light blue.

970nm selected: the impulse is yellow.

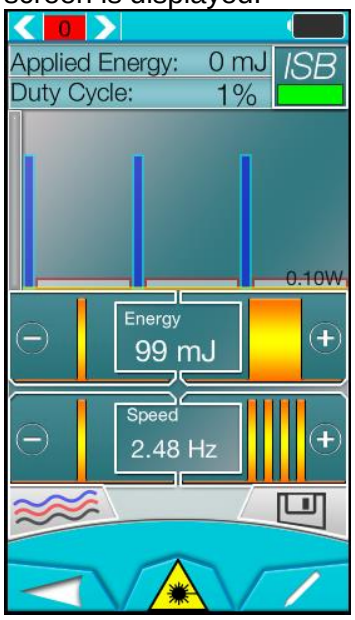
445nm + 970nm selected: the impulse is violet.

The explanation of the following icons is described into more details.

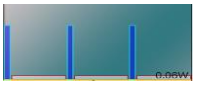
The following phases can be selected:
Deep, Surface, Finish, Haemostasis or CW.
The selected phase has a green background.

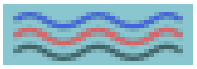
If the - / + keys are pressed, the peak power can decrease or increase, varying also the average power of the emission.

After selection of the following areas: **Vascular surgery**, **Dark spots** and **Podiatry** the following screen is displayed.



Different levels of the red aiming beam can be defined.


Graphic of the laser impulse.


Wavelength selector. Press it to select needed wavelengths, in individual or combined way.


Energy of each emitted impulse.


Speed: number of impulses emitted in a second.

ISB modality. It is on if the green bar is present.


Press it to save a treatment.


Press it to go back one screen.


Press it to enter a manual screen. User confirmation is needed.


Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

Where predicted the device allows to directly enter into a manual area.
The device will automatically define the following parameters.

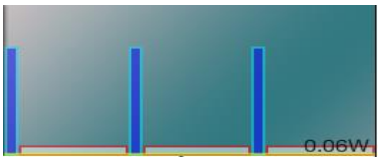
Applied energy

The device shows the energy emitted during treatment.

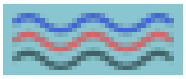
Duty Cycle (%)

The duty cycle is defined as the ratio between the pulse duration (when the laser beam is actually actuated) and the total period of time (which is the time from the beginning of a pulse to the beginning of the next pulse).

The explanation of the impulse profile on the screen is described into more details.



The impulse is displayed in light blue. Horizontal line and numerical value on the right represent the average power that the device automatically calculates.
If ISB modality is on, a bar with red profile (970nm emission) is present on the base among the impulses.
If ISB modality is off the bar doesn't appear.


It allows to select wavelengths, in single or combined modality.


445nm selected: the impulse is light blue.

970nm selected: the impulse is yellow.

445nm + 970nm selected: the impulse is violet.

The explanation of the following icons is described into more details.

Energy of each emitted impulse. The peak power is fixed and it is shown on screen. If the - / + keys are pressed, the base of the impulse is modified and this means that time and consequently energy of the impulse decreases or increases.

Speed: frequency of impulses emitted in a second.
If the - / + keys are pressed, frequency (number of impulses in a second) decreases or increases.

Warning

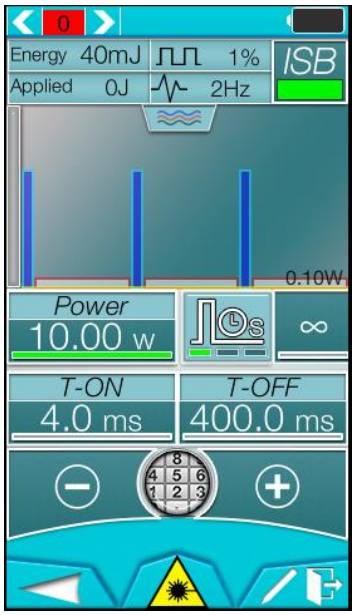
Follow carefully the indications written in the manual and in the software of the device. Do not to treat spider vein's in patient with a skin type higher than 1. You can evaluate, eventually, this treatment in patients with a skin type 2 only after having performed some tests of melanin reaction and then adapting the treatment parameters according to the single patient.

Notice

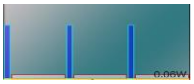
Before starting spider vein's treatment of the Vascular area, the device asks to select the patient skin type, based on the Fitzpatrick tone scale. These treatments can be applied only for light skin.

Notice

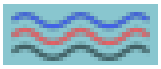
If the key  is pressed, the device warns the operator that is entering in manual area and asks confirmation before proceeding. After confirmation, you will enter in the following area. In some areas, the device will directly show this screen.



Different levels of the red aiming beam can be defined.



Graphic of the laser impulse.



Wavelength selector. Press it to select needed wavelengths, in individual or combined way.

ISB modality. It is on if the green bar is present.

DISB modality. Where predicted. It is on if the green bar is present.

Number of impulses or emissive time in seconds.

Number of the impulses or emission time.

Press to increase or decrease the numerical value.

Press it to go back one screen.

Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

Press it to save a treatment.

Where predicted. Press it to save a treatment directly from this screen.

The device will automatically define the following parameters:

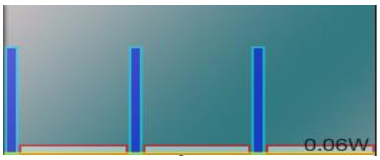
Energy — The device calculates the energy delivered according to selected power and time.

Applied — The device shows the energy emitted during treatment.

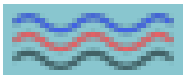
Duty Cycle (%) — The duty cycle is defined as the ratio between the pulse duration (when the laser beam is actually actuated) and the total period of time (which is the time from the beginning of a pulse to the beginning of the next pulse).

Frequency (Hz) — The device calculates the frequency of the impulse based on the Ton – Toff by the operator.

The explanation of the impulse profile on the screen is described into more details.



The impulse is displayed in light blue. Horizontal line and numerical value on the right represent the average power that the device automatically calculates.
If ISB modality is on, a bar with red profile (970nm emission) is present on the base among the impulses.
If ISB modality is off the bar doesn't appear.
If DISB modality is on, a yellow part is present over the light blue impulse. Maximum emissive power of 445 nm and 970 nm combined. If DISB modality is off, the part doesn't appear.



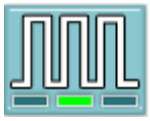
It allows to select wavelengths, in single or combined modality.

445nm selected: the impulse is light blue.

970nm selected: the impulse is yellow.

445nm + 970nm selected: the impulse is violet.

The setting of the impulse can be performed in under described modalities.



Pulse modality. Sets the number of the impulses. It can be defined by pressing numeric keyboard or by **-/+** key to increase or decrease the number of impulses.

Frequency modality. Sets the emission time expressed in seconds.
It can be defined by the user by pressing the numeric keyboard or by **-/+** key to increase or decrease the number of seconds. The 0 value on numeric keyboard corresponds to a laser emission in an infinite sequence. This is shown as ∞.

CW modality. Where predicted. Sets the emission time expressed in seconds in continuous wave (CW). In this modality Ton is automatically set in **CW** and Toff in **--**. The 0 value on the numeric keyboard corresponds to a laser emission in an infinite sequence. This is shown as ∞.

Number of the impulses to be shot or emission time.
Press the numeric keyboard or **-/+** key set the desired value.

Notice

The infinite symbol (∞) indicates that the laser is able to emit for an endless time.

A numerical value (**n**) indicates that the laser emits **n** Ton impulses in the modality, Ton impulses for a total of **n** seconds in the modality and a single impulse of **n** seconds in the modality.

Notice

The shown total energy is referred to one only Ton impulse in the modality, the number and the time of the Ton impulse in the modality and to the set seconds in the modality.

To manage the parameters select the field that will be highlighted with a green square and then press:

Minus / Plus key or

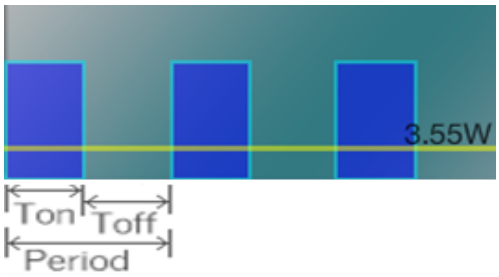
to enter in a Keyboard to implement the modification.

Power — Setting can start from a minimum of 0,1 W to the max power delivered by the device. It can be set by step of 0.01W pressing **-/+** or by numeric keyboard.

T - ON — Time (in ms) during which the laser is emitting. It is adjustable between CW, 0.1 – 999 ms.

T - OFF — Time (in ms) during which the laser is off. It is adjustable between 0.1 – 999 ms.

The following graphic helps the user to understand the shape of the impulse to be set.

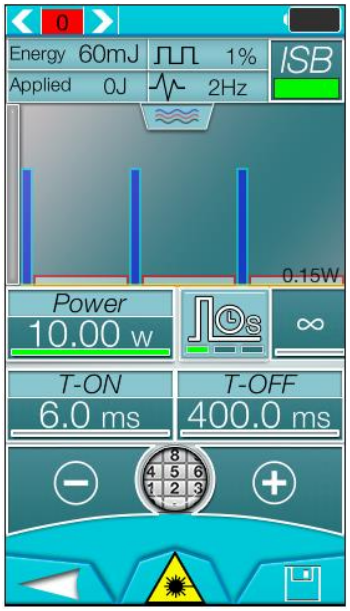


Ton is the time during which the laser is emitting.
Toff is the time of the impulse during which the laser is off.
The height of the impulse is the peak power of emission.
The yellow line and the numerical value represent the average power that the device automatically calculates on the base of Ton, Toff and power set by the operator. This line gets on and off based on the average power.

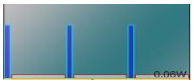
Warning

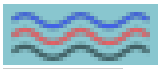
In order to increase the energy and thus the tissue cutting strength, it is recommended to decrease the **T-OFF** time, rather than to increase the **T-ON** time. In this way the energy of each impulse remains the same but the impulses' frequency increases. So the thermal damage around the treated tissue is limited.

In **Manual** area the device allows to select the optic to be used.
After selection, the device displays the following screen.



Ten different levels of the red aiming beam can be defined.


Graphic of the laser impulse.


Wavelength selector. Press it to select needed wavelengths, in individual or combined way.

ISB modality. It is on if the green bar is present.


Number of impulses or emissive time in seconds.

Number of the impulses or emission time.


Press to increase or decrease the numerical value.


Press it to go back one screen.


Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used


Press it to save a treatment.

Notice

In all the no contact tip the CW modality is not available.

The device will automatically define the following parameters:

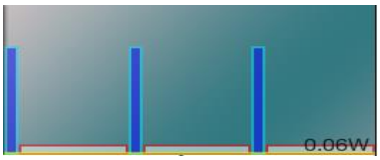
Energy — The device calculates the energy delivered according to selected power and time.

Applied — The device shows the energy emitted during treatment.

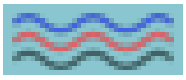
Duty Cycle (%) — The duty cycle is defined as the ratio between the pulse duration (when the laser beam is actually actuated) and the total period of time (which is the time from the beginning of a pulse to the beginning of the next pulse).

Frequency (Hz) — The device calculates the frequency of the impulse based on the Ton – Toff by the operator.

The explanation of the impulse profile on the screen is described into more details.



The impulse is displayed in light blue. Horizontal line and numerical value on the right represent the average power that the device automatically calculates.
If ISB modality is on, a bar with red profile (970nm emission) is present on the base among the impulses.
If ISB modality is off the bar doesn't appear.



It allows to select wavelengths, in single or combined modality.

445nm selected: the impulse is light blue.

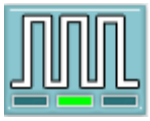
970nm selected: the impulse is yellow.

445nm + 970nm selected: the impulse is violet.

Notice

In the handpieces not in contact the CW mode is not available.

The setting of the impulse can be performed in under described modalities.



Pulse modality. Sets the number of the impulses. It can be defined by pressing numeric keyboard or by **-/+** key to increase or decrease the number of impulses.

Frequency modality. Sets the emission time expressed in seconds.
It can be defined by the user by pressing the numeric keyboard or by **-/+** key to increase or decrease the number of seconds. The 0 value on numeric keyboard corresponds to a laser emission in an infinite sequence. This is shown as ∞.

CW modality. Where predicted. Sets the emission time expressed in seconds in continuous wave (CW). In this modality Ton is automatically set in **CW** and Toff in **--**. The 0 value on the numeric keyboard corresponds to a laser emission in an infinite sequence. This is shown as ∞.

Number of the impulses to be shot or emission time.
Press the numeric keyboard or **-/+** key set the desired value.

Notice

The infinite symbol (∞) indicates that the laser is able to emit for an endless time.

A numerical value (**n**) indicates that the laser emits **n** Ton impulses in the  modality, Ton impulses for a total of **n** seconds in the  modality and a single impulse of **n** seconds in the  modality.

Notice

The shown total energy is referred to one only Ton impulse in the  modality, the number and the time of the Ton impulse in the  modality and to the set seconds in the  modality.

To manage the parameters select the field that will be highlighted with a green square and then press:

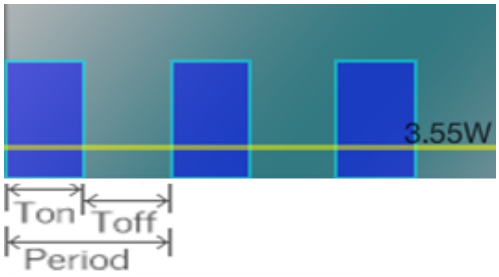
 Minus / Plus key or  to enter in a Keyboard to implement the modification.

Power Setting can start from a minimum of 0,1 W to the max power delivered by the device. It can be set by step of 0.01W pressing **-/+** or by numeric keyboard.

T - ON Time (in ms) during which the laser is emitting.
It is adjustable between CW, 0.1 – 999 ms.

T - OFF Time (in ms) during which the laser is off.
It is adjustable between 0.1 – 999 ms.

The following graphic helps the user to understand the shape of the impulse to be set.



Ton is the time during which the laser is emitting.
Toff is the time of the impulse during which the laser is off.
The height of the impulse is the peak power of emission.
The yellow line and the numerical value represent the average power that the device automatically calculates on the base of Ton, Toff and power set by the operator. This line gets on and off based on the average power.

⚠ Warning

In order to increase the energy and thus the tissue cutting strength, it is recommended to decrease the **T-OFF** time, rather than to increase the **T-ON** time. In this way the energy of each impulse remains the same but the impulses' frequency increases. So the thermal damage around the treated tissue is limited.

Notice

Press the key  to save treatment. The saved treatment is stored in the Manual area.

Notice

You can rename an already stored treatment. Press the key  .

Notice

Treatments can be removed from the list. In the Manual area press the  .

When the desired values are defined, the user can:
press the button to save treatment.

↳ Device asks to insert the name.
➢ Confirm the action.
↳ The treatment is saved into Manual area.

or

press  to start working. The laser is armed:

↳ Device warns to wear protective goggles.
➢ After confirmation the green LEDs start lighting.
↳ After a delay of 2 seconds the aiming beam is switched on.
↳ The laser is now ready for operation.

Notice

The user can disable the sound pressing the sound icon present on the laser activation screen. The sound is disabled for the current treatment.

Warning

All persons present in the room must wear the laser protective goggles as soon as it is advised during use.

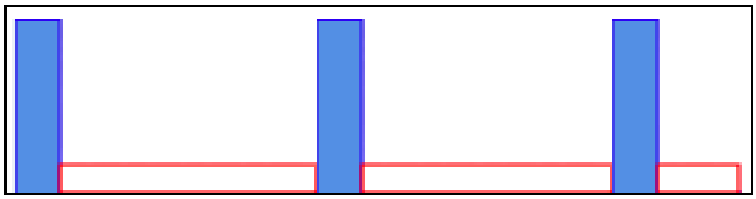
Notice

Before starting a laser treatment in battery operation please reconfirm the battery status.

When you actuate the foot switch the laser starts emitting. At the same time, two yellow LEDs at the upper right and left end of the device control unit light up as well as the laser active bar on the touch screen and the audible alarm sounds. When you release the foot switch to interrupt treatment, the laser is deactivated, but remains ready for operation.

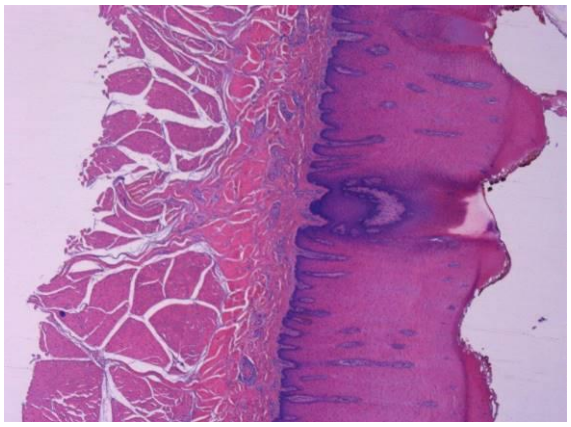
ISB and DISB
The ISB and DISB keys on the top right hand corner will provide a graphic representation of the activated wavelengths and the modality in which they can be combined for surgical applications. These modalities are K-Laser patented for quality surgical performance unique to these devices.

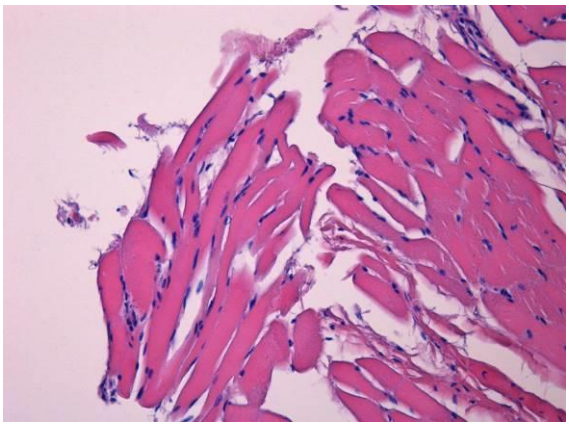
ISB – Intelligent Surgical Blue



The T-ON of the 445 nm wavelength emission for surgical applications is represented in blue. The red bar represents the IR emission during the T-OFF to perform bio-stimulation of the tissue that is being surgically treated.

The images below represent the outcome of the histological test on lingual tissue after an incision made in **ISB** modality.

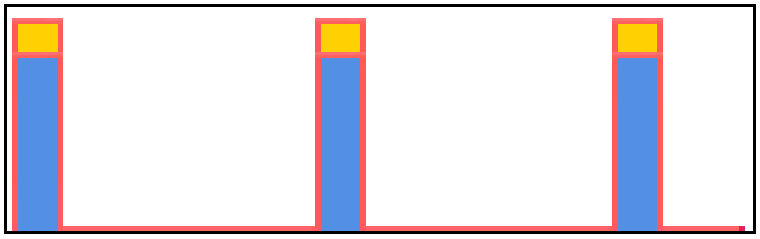




The **ISB** modality executes an incision with characteristics superior to those of an IR laser, inasmuch as, there is no presence of interstitial edema or other damage to the cells; the edges of the surgical incision are perfectly defined and the surrounding tissue remains healthy.

Furthermore, the incision made in the **ISB** modality, is superior to that of a bistoury, in as much as it hinders bleeding; in fact K-Laser Blue has a superior hemostasis during surgery.

DISB – Deep Intelligent Surgical Blue

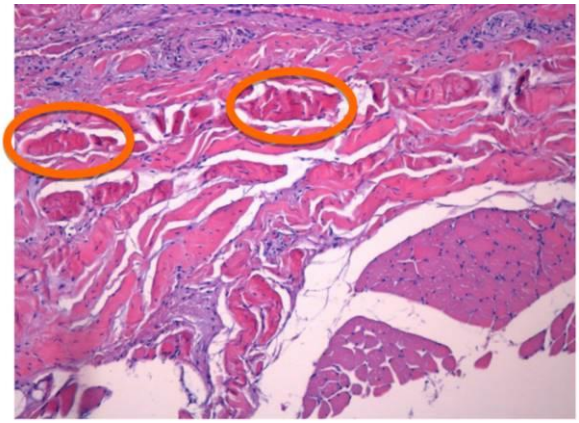


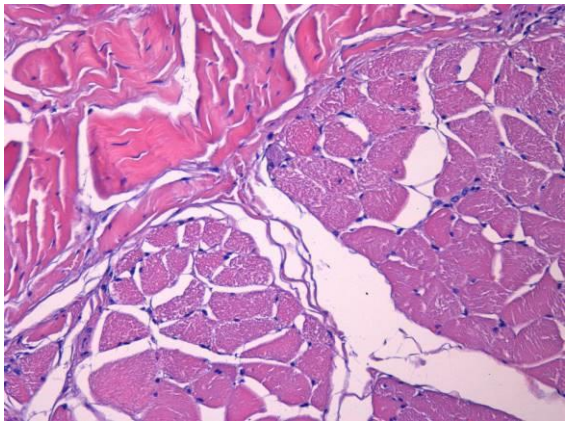
The blue bar represents the emission of the 445 nm wavelength in surgery, and the yellow bar the emission of IR wavelength that coupled with the Blue during the T-ON facilitates deeper incisions.

⚠ Warning

Activate the **DISB** modality only if the tissue to be surgically removed by evaporation protrudes at least 2 mm from the top layer of the skin. Infact **DISB** modality is able to go deeper.
Deactivate the **DISB** modality for protrusions lower than 2 mm to avoid going past below the top layer of the skin.
Regarding protrusions below 2 mm with respect to the top layer of the skin, it is recommended to use only the **ISB** modality.

The images below represent the outcome of the histological test on lingual tissue after vaporizing the tissue in **DISB** modality.

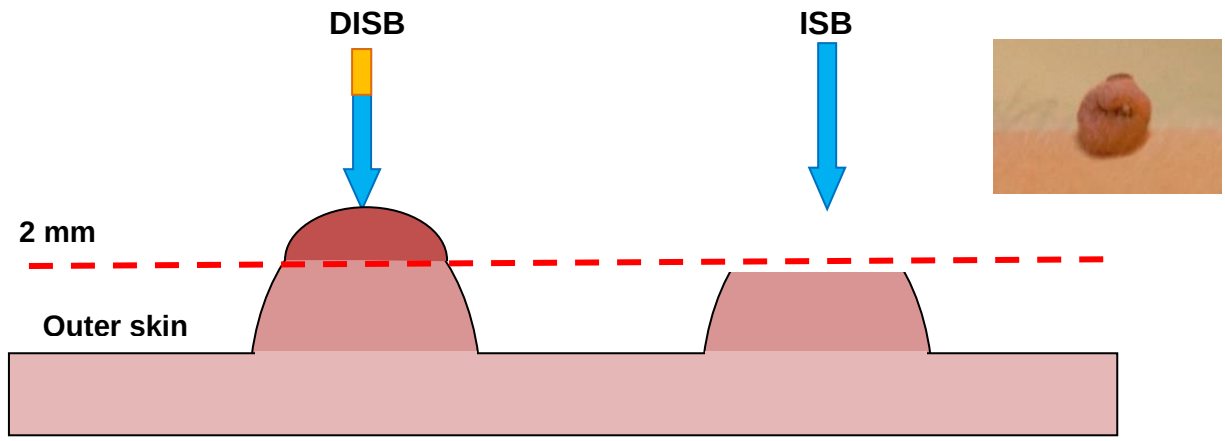




The **DISB** modality has a vaporizing property for faster removal and stripping away tissue that must be completely removed.
This modality is ideal for the removal of protruding tissue masses above 2mm from the skin's outer layer.

From images it is possible to evaluate the damage at tissue level. Note the interstitial edema, identifiable as the white areas within the red areas, small cracks and curly reddened tracks in the same areas that represent distressed tissue.

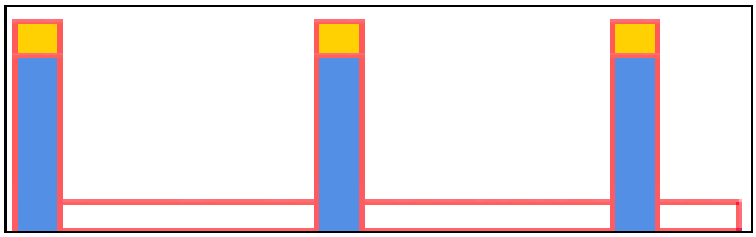
The image below is a graphic representation of the **DISB** and the **ISB** modality, i.e. for the treatment of a raised papillomatous nevus.



The **DISB** modality has a vaporizing property for faster removal and stripping away tissue that must be completely removed. This modality is ideal for the removal of protruding tissue masses above 2mm from the skin's outer layer.

The incision made in **ISB** modality is superior to that of a IR laser, with the edges of the incision perfectly defined and surrounding tissue perfectly healthy.

DISB + ISB – Deep Intelligent Surgical Blue combined with Intelligent Surgical Blue



When both these modalities are activated, deep surgery may be performed during the T-ON with the benefit of the bio stimulation with the IR during the T-OFF.

5.6 Therapy

After choosing a treatment from the list, the following screen appears:

Press it to change screen in order to modify parameters..

Press it to go back one screen.

Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

Press it to the main menu.

⚠ Warning

All persons present in the room must wear the laser protective goggles as soon as it is advised during use.

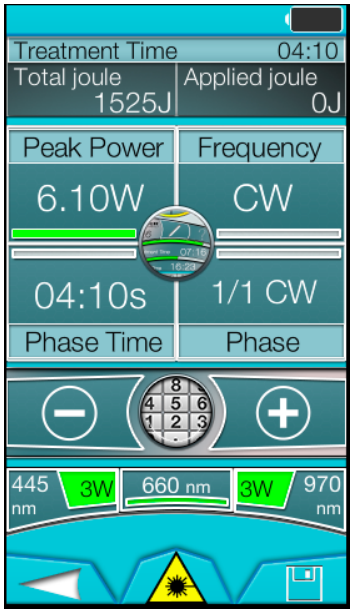
Notice

Before starting a laser treatment in battery operation please reconfirm the battery status.

Notice

From the list of the treatments press  to remove the treatment, press  to rename it.

The user can manage parameters pressing  and the following screen will appear.



Select the field to be modified and then press +/-

Green : selected field.
Grey: not selected field.

Press it to count up and down numerical value.

Press it to go back previous therapy area.

Press it to enter in the numeric keyboard.

Allow to select the wavelengths:
Green : selected field.
Grey-Green: not selected field.

Press it to go back one screen.

Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

Press it to save a treatment.

⚠ Warning

All persons present in the room must wear the laser protective goggles as soon as it is advised during use.

ℹ Notice

Before starting a laser treatment in battery operation please reconfirm the battery status.

The following fields allow the operator to manage the treatment parameters.

Peak
Frequency
Phase time

Selecting this field and pressing the numeric keyboard is possible to modify the parameters. It is also possible to set parameters by touching - /+.

Phase

Pressing this field and the numeric keyboard is possible to add a new phase (the new one is created and it is positioned after the selected one) or delete the current one. The treatment is composed up to twelve phases.

The selected wavelength is highlighted in a green field.

The not selected wavelength is highlighted in a grey-green field.

On the event the operator needs to modify and adjust the power, the selected wavelength is highlighted in a red field.

Each wavelength can be singularly selected.

For each treatment phase, the device keeps trace of the performed modifications. The followings images show the colors used for the status identification.

In this screen:

The operator is working in this phase. No modifications have been performed respect to the already present values..

The phase is present but not currently used. No modifications have been performed respect to the already present values.

The phase is present but not currently used. At least one parameter has been modified respect to the already present values.

The following steps explain the parameters management.

- Select  and select the phase to be modified.
- Select the needed parameters.

To manage the parameters select the field that will be highlighted with a green square and then press:

Minus / Plus key or 

to enter in a Keyboard to implement the modification.

The operator

can modify	cannot modify
(Peak) Power	**Average power**
Wavelength	
Frequency	
Phase time	
Phase	

The device automatically manages the following parameters:

Treatment time — Treatment total time. This value is automatically calculated by the device.

Total Joule — The device automatically calculates the energy delivered during treatment (in J) based on the power settings and the time.

Average (power) — The device automatically calculates the average power based on power and duty cycle.

Notice

Treatment time and Total Joule are automatically calculated by the device and they cannot be set by the user. The other parameters can be modified.

The operator can select the following areas to manage a treatment:

(Peak) Power — It is the peak power and it is adjustable between 0.1 W and max value of the model. In 0.01 W increments by numeric keyboard or by touching  .

Notice

For the use of optics, please read carefully specific instructions and warnings.

Average power — The device calculates the average power from the power values and duty cycle.

Frequency — Frequency can be set in an infinite modality by selecting CW or may be adjusted from 1 - 10000 Hz by numeric keyboard or touching  1 Hz at a time.

Phase time — The time of each phase is adjustable between 1 to 999 s by numeric keyboard or by touching 

Phase — The treatment is composed up to twelve phases.
Select the phase icon and touch the keyboard to add a new phase or delete the current one.

Wavelength — Wavelengths are selectable to be used one at a time or combined.

For the treatment management:

- ➢ Set the parameters for the first phase and proceed for the maximum number of 12 phases.
- ➢ To delete completely a phase, select it and then press delete phase.
- ➢ To confirm the treatment press the save button and insert the name.
- ➢ After pressing the confirmation button, the device will store the treatment.

Press  to arm the laser.

- ↳ Device warns to wear protective goggles.
- ➢ After confirmation the green LEDs start lighting.
- ↳ After a delay of 2 seconds, the aiming beam is switched on.
- ↳ The laser is now ready for operation.

Notice

Before the laser emission starts, the device will ask the operator to verify the optics in use.

When you actuate the switch the laser starts emitting. At the same time, two yellow LEDs at the upper right and left end of the device control unit light up as well as the laser active bar on the touch screen and the audible alarm sounds. When you release the switch to interrupt treatment, the laser is deactivated, but remains ready for operation.

Notice

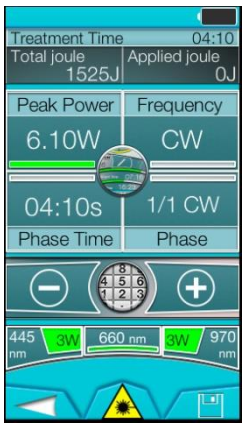
The user can disable the sound pressing the sound icon present on the laser activation screen. The sound is disabled for the current treatment.

Notice

In base of the selected frequency (CW or chopped modality), the aiming beam emits in a different way, as described:

- **CW**: the aiming beam is fixed, not flashing;
- **Modulated**: the aiming beam is slowly flashing;

The following explanation describes treatment saving options:



Before treatment, you can press the button  and enter in a menu that allows you to:

- save this treatment.

Moreover it is always possible to modify the parameters in order to customized the treatment. Press the button  to store modifications.

5.7 Set-up

The following area allows the operator to personalize the device. Select the interested area to enter in the following screen and so set the function.

Set date and time of the device.
Date format (dd/mm/yy or mm/dd/yy).
Time format (24hours notation): hh:mm.
See relative paragraph for further explanation.

Choice of different preset languages, date and number format. They will be automatically applied after confirmation.

Set level of display brightness by using the arrow. Press OK for confirmation.

Set personal pin code.
See relative paragraph for further explanation.

Select volume level of warning sound and press button sound by using the arrows. Press OK for confirmation.

Battery calibration process.
Follow the instruction displayed on screen.

Configure the switch emission modalities:

- **Single touch**: laser active if fingerswitch is kept pressed.
- **Double touch**: laser is active at the first pressure of the fingerswitch. Second pressure disables the emission.
- **RRT**: Remote Restart Control.

Software update.
Follow the instruction displayed on screen.

⚠ Caution

Use only USB (class 2.0 or above) memory devices with authorized software updates

Notice

Remember to connect the power supply before performing software update.

History. Display and download the performed treatments.

⚠ Caution

Do not leave the USB stick inserted in the device during normal use. As predicted, connect it for the software update and history file download only.

Press it to go back one screen.

5.7.1 Date&Time

The key allows the operator to set date and time.

Press it to increase and decrease day, month and year.

Press it to increase and decrease hour and minute.

Press it to go back one screen.

Press it to confirm date and time.

5.7.2 Change P.I.N.

The key allows to modify the pin code of the device.

Digit the new pin code. Confirm by pressing OK.
The numeric pad always displays the used key code.

Press it to confirm the new P.I.N.

Press it to go back one screen.

⚠ Warning

The device may be operated only by qualified personnel. Do not give the access to unauthorized third parties.

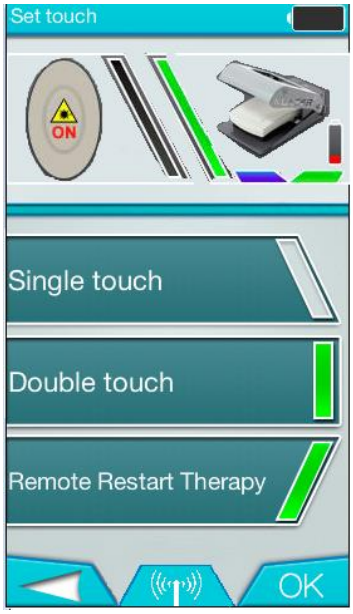
Do not write down the electronic access key somewhere else in order to minimize the risk of misuse of the laser by unqualified persons. Please turn off the unit after the use.

Notice

In case the operator forgets the pin code, digit the super pin code **2974**. It cannot be modified.

5.7.3 Set touch

This key allows the operator to set the switch modality.



Single touch	Laser active if fingerswitch is kept pressed.
Double touch	Laser is active at the first press of the fingerswitch. Second press terminates the emission.
Remote Restart Therapy	Remote Restart Control. Perform a treatment again using the button on the handpiece.
	Press it to select the finger switch (optional).
	Press it to select the wireless footswitch.
	Operator goes back one screen.
	Press it and follow the instruction on screen to set the pairing to the footswitch.
	Press it to confirm the switch modality.

Notice

The green bar shows the selected modality.

Notice

Single touch. If the switch is kept pressed, the message “LASER ON” appears and at the same time, yellow LEDs light up, audible alarm sounds and laser starts emitting. At the switch release, the laser is deactivated, but remains ready for operation.

Notice

Double touch. At the first pressure of the switch, the message “LASER ON” appears, at the same time, yellow LEDs light up, audible alarm sounds and laser starts emitting. At the switch release, the laser is still active. Press the switch a second time to deactivate the laser.

Notice

In Surgical area the device automatically disables Double touch modality.

Notice

The **RRT** (**R**emote **R**estart **T**herapy) modality allows to perform again a complete treatment without removing the hands from the handpiece. It is sufficient to press the fingerswitch one time to close the “completed therapy” window.

- In **Double touch**, the second pressure of the fingerswitch enables the termination of the laser beam.
- In **Single touch** modality excludes **RRT** and vice versa.

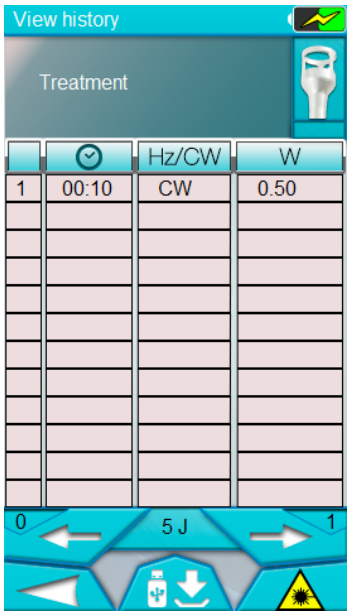
5.7.4 History

The history stores the performed treatments and allows the operator to download them onto a USB stick.

View History	View history. Press the button to check data of the performed treatments.
Export history	Save history. Press the button to download data of the performed treatments. Proceed as instructed on the screen.
	Press it to go back one screen.

Press **View history** to visualize the screen to set year and month to be consulted. Use the arrows to scroll the date.

Confirming the choice with OK, the device will show the treatment's parameters as in the following screen.



	Press it to go back one screen.
	Press it to export performed treatments into the USB stick.
	Laser armed to perform the screened treatment. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

⚠ Warning

All persons present in the room must wear the laser protective goggles during use.

At the end of each application the device stores the following parameters in the History file.

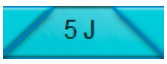
In the upper part of the screen date&time and treatment's parameters are shown.

Number of the treatment phases (in case the operator performs more than 12 phases, the device will show only the last 12).

Single phase time.

Emissive modality (modulated (1-10000 Hz) or continuous (CW)).

Average power.



Total emitted energy (even in case the operator performs more than 12 phases, the device calculates the total emitted energy).

Arrows used to scroll treatments and number of pages to be scrolled.

The device allows the user to choose the following different file formats:

TXT Format available on any text program.

CSV Format used to exchange data between spreadsheets.

Press **Export history** or  to export the treatments directly into the USB stick Class 2.0.

Notice

The file name of the complete list has ".txt", ".csv" extension.

5.8 Error messages and warnings

Laser Stop	The laser has been deactivated by pressing “Laser Stop” button.	**Interlock open**	Please wait until the interlock is closed. Check interlock plug on back of machine..
Wear protective goggles	Before proceeding it is advised to put on the laser safety goggles.	**PIN code not correct**	Wrong pin code was entered. Please try again.
Delete treatment	Delete treatment	**Insert USB device**	Plug the USB device into USB connector.
Error. Wrong USB device	The USB device was not accepted. Please plug it in again or try another USB device.	**Connect plug to the DC-IN**	Connect the DC-IN connector to the device.
Battery low. Please recharge.	The battery level is low and needs to be charged.	**Battery very low. Estimated power for 180 s.**	The battery level is very low (remaining power for 180 seconds) and needs to be charged.
Wait laser source cooling.	To avoid damage of the laser source please wait and let the device cool down..	**Fan not working. Switch off the device.**	Cooling fan is not working. To avoid damage please switch off the device and let it cool down for a while.
Name already present.	The name is already present in the list.	**Error Contact service.**	A malfunction has occurred. Please contact authorized service center.

6 Indications, contraindications and medical precautions

6.1 Indications

K-Laser Blue is developed as portable laser device in the following version
Derma: 445 nm with 8 W in CW, 10 W in pulsed mode, 970 nm with 3 W in CW,
total power 445 nm + 970 nm of 13 W and 660 nm with 100 mW.
The following table summarizes in detail the intended use based on the device model:

Surgery:	- incision and coagulation of soft tissue.
Dermatological surgery:	- benign skin disease *(nevus, keratosis, fibromas…)*; - pigmented and vascular lesions; - mild to moderate acne vulgaris.
Therapy:	- muscular & skeletal pathologies; - osteoarticular diseases; - edemas; - soft tissue injuries; - wound healing; - laser acupuncture.

6.2 Contraindications

⚠ Warning
Do not treat directly over cancer or tumor.

⚠ Warning
Do not treat on gravid uterus.

⚠ Warning
Never direct the laser beam toward a person's eye or thyroid gland. All persons present in the room (patient, operator and assistant) must always wear the laser protective goggles delivered along with the device.

6.3 Precautions

⚠ Warning
It is recommended not to use the handpiece for therapy in direct contact to skin of the patient, but to keep distance from the skin and always move it!

⚠ Warning
Before therapeutical treatment with the handpiece for therapy, please treat fix points, keeping a distance of two centimetres from the skin of the patient, in particular if you are using continuous emissions, in order to check the sensibility of the patient and the energy density, especially if the patient's skin is particularly brown.

⚠ Warning
In case of the use of the handpiece for therapy it is recommended to verify that the part to treatment not present neo of great dimension or dark zones that could absorb excessive amounts of energy. In this case protect with dioxide of titanium or zinc the treatment part.

7 Post treatment cleaning

⚠ Warning

Before cleaning, switch off the device and disconnect the power cable from the power supply.

7.1 Cleaning of the unit

Clean the device and the accessories with a dry, soft cloth to remove dust. More stubborn spots can be removed with a damp cloth.
You can disinfect them using any of the products that are commonly used to disinfect medical electrical equipment, e.g. MinutenWipes from Alpro and Caviwipes TM.
Observe the instructions provided by the manufacturers of these disinfectants.

ℹ Notice

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

ℹ Notice

Please proceed carefully not to scratch and damage the foil on the touchscreen.

ℹ Notice

The device may be disinfected only by wiping it. Do not use spray disinfectant on the device.

ℹ Notice

Optic fiber can be damaged easily if it suffers excessive flexion or is used in an incorrect way. This fact can compromise the usefulness of the treatment.

⚠ Caution

The flexible hose that protects the fiber can be cleaned by gauze soaked with no alcohol disinfectant.

⚠ Caution

Spray disinfection may allow liquids to penetrate into the device! Do not use spray disinfection for the device! Use only wet cloth.

7.2 Cleaning of the handpiece for therapy

⚠ Warning

Before cleaning, switch off the device and disconnect the power cable from the power supply.

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that the optic system is always cleaned: before, during and after the use.

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

Clean the optic with a dry, soft cloth to remove dust from the handpiece. More stubborn spots can be removed with a damp cloth.

Notice

In the event of dirty spots on the external lens use a cotton bud to clean it, taking care not to extremely press the optic part. More stubborn spots can be removed with a proper lens cleaner. Wait the complete evaporation of the detergent before using the handpiece.

You can disinfect it using any of the products that are commonly used to disinfect medical electrical equipment, e.g. MinutenWipes from Alpro and Caviwipes TM.
Observe the instructions provided by the manufacturers of these disinfectants.

Notice

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

Notice

Clean the optic with a dry, soft cloth to remove dust from the lens that preserve the optics. More stubborn spots can be removed with a damp cloth. Please proceed carefully not to scratch and damage the lens.

7.3 Cleaning of the contact surgical handpiece

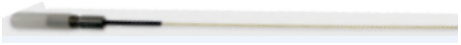
⚠ Warning

Before cleaning, switch off the device and disconnect the power cable from the power supply.

Optic fiber with connector

Contact surgical handpiece body

Sleeve for contact surgical handpiece body



Optic fiber tip

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that the optic system is always cleaned: before, during and after the use.

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

You can disinfect it using any of the products that are commonly used to disinfect medical electrical equipment, e.g. MinutenWipes from Alpro and Caviwipes TM.
Observe the instructions provided by the manufacturers of these disinfectants.

ℹ Notice

All debris must be removed from the optical fiber tip before it is detached from the handpiece.

ℹ Notice

Use only not spray disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

ℹ Notice

Do not use spray disinfectant or insert disinfectant on the handpiece optics!

ℹ Notice

Cover with the proper protective caps the connectors.

ℹ Notice

Clean the optic with a dry, soft cloth to remove dust from the optics. More stubborn spots can be removed with a damp cloth. Please proceed carefully not to scratch and damage the parts.

Cleaning and disinfection

➢ All debris must be removed from the optic fiber tip before it is detached from the handpiece.
➢ Disinfect the optic fiber tip.
➢ Please bend back the disposable tip as straight as possible before moving the fiber within the disposable tip.

⚠ Caution

If the optical fiber tip is moved in a bent disposable tip the surface of the optic fiber may be destroyed (danger of optical fiber breakage).

➢ Use the tool to notch the optic fiber approx. 4 mm from its distal.
➢ Remove the disposable tip from the handpiece and dispose it.

➢ Remove the sleeve and clean it with a suitable brush under running water.
➢ Disinfect the sleeve.

➢ Remove the optic fiber tip and insert the protective cap.
➢ Clean the optic fiber tip with a suitable cloth under running water.
➢ Disinfect the optic fiber tip.

➢ Remove the handpiece body.
➢ Insert the protective caps of the handpiece body and handpiece socket.
➢ Clean and disinfect the handpiece body.
➢ Clean and disinfect the optic fiber with connector.

➢ After use clean and disinfect the tool.

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after each removal of the handpiece.

⚠ Caution

Prevent dust, dirt and foreign particles from entering the optic fiber connections and the optic system. Make sure that the optic system is always cleaned: before, during and after the use. Otherwise the unit may be permanently damaged.

Sterilization

➢ Sterilize the optic fiber tip, the disposable tip, the bending tool and the handpiece sleeve.

ⓘ Notice

The optic fiber tip, the bending tool and the handpiece sleeve and can be sterilized in an autoclave with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure without damage.

7.4 Cleaning of no contact surgical handpiece

⚠ Warning

Before cleaning, switch off the device and disconnect the power cable from the power supply.

Optic fiber with connector

No contact surgical handpiece body

Set of no contact surgical tip

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that the optic system is always cleaned: before, during and after the use.

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

You can disinfect it using any of the products that are commonly used to disinfect medical electrical equipment, e.g. MinutenWipes from Alpro and Caviwipes TM.
Observe the instructions provided by the manufacturers of these disinfectants.

ℹ Notice

Do not use spray disinfectant on the handpiece optics!

ℹ Notice

Use a gauze soaked with no alcohol detergent to clean the handpiece optics. Clean and disinfect the no contact surgical tips.

ℹ Notice

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

ℹ Notice

Clean the optic with a dry, soft cloth to remove dust from the handpiece.
Please proceed carefully not to scratch and damage the parts.

Sterilization

➢ Sterilize the set of no contact surgical tip.

ℹ Notice

The set of no contact surgical tip can be sterilized in an autoclave with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure without damage.

7.5 Cleaning of the ENT handpiece

⚠ Warning

Before cleaning, switch off the device and disconnect the power cable from the power supply.

⚠ Caution

Prevent dust, dirt and foreign particles from entering the handpiece.
Make sure that the optic system is always cleaned: before, during and after the use.

⚠ Caution

Always cover the connectors with the special protective caps provided for this purpose after the removal of the handpiece.

You can disinfect the optic using any of the products that are commonly used to disinfect medical electrical equipment, e.g. MinutenWipes from Alpro and Caviwipes TM.
Observe the instructions provided by the manufacturers of these disinfectants.

Notice

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

Notice

Clean the optic of the handpiece with a dry, soft cloth. More stubborn spots can be removed with a damp cloth. Please proceed carefully not to scratch and damage the optic.

Sterilization

➢ Sterilize the ENT handpiece.

Notice

The ENT handpiece can be sterilized in an autoclave with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure without damage.

8 Maintenance and service

8.1 Maintenance

The device does not require special maintenance. In case of malfunctioning, see chapter Technical support, repair and testing.

However, it is recommended taking the following actions at regular intervals:

Action	**Frequency**	**Responsible**
Check of the optic fiber	Before each treatment session	Operator
Check of the battery	Every 3 months	Operator
Safety checks	Every 2 years	Authorized Service Center.

Notice

Check the optic fiber and handpieces based on the indications written in paragraphs 4.4 and following.

Notice

Concerning battery verification, check the paragraph 5.7 and follow the instruction directly on the device display.

Notice

If national or local legal regulations require additional safety checks for your laser unit, these regulations must be complied with and the corresponding checks must be performed.

The manufacturer accepts responsibility for the safety of the laser unit only if the following requirements are fulfilled:

- Modifications of the laser unit or repair work may be performed only by authorized personnel.
- The electrical installations in the rooms where the device is used must fulfill the applicable legal requirements.
- The unit must be used in compliance with the instructions provided in the present manual.

8.2 Troubleshooting of simple defects

In case of malfunctioning, proceed as follows:

First of all, be sure that operation steps have been carried out correctly.

The touchscreen of the device remains dark after switching it on.

- Check the connection of the power cable and/or check the rechargeable battery.

When using an interlock device the laser will not be stopped and blocked after interrupting the circuit.

- Check the connection of the interlock device.

There is no aiming beam or it does not project a uniform circular pattern.

- Check if the optic fiber is damaged. If the optic fiber is damaged, replace it with a new one.
- Check if the connection of the optic fiber to the handpiece is damaged.

Wireless foot control is not working.

- Check the battery of the wireless footswitch.
- Check the registration of the wireless footswitch.
- Check if the wireless footswitch is chosen in the set-up submenu.

If you cannot solve the malfunctioning, switch off the laser and contact an Authorized Service Center.

8.3 Safety check

The following safety checks must be performed every 24 months by a qualified service engineer.

- Visual inspection of the unit and its accessories for mechanical damage that might impair operation;
- General function check;
- Check of the visual and audible indicators;
- Check the electrical safety;
- Check the power emission of the laser;
- Check the cleaning of the optics.

8.4 Technical support, repair and testing

In case technical support, contact the following address:

ELTECH K-LASER s.r.l.

Via Castagnole, 20/H,

31100 Treviso, Italy

Phone +39 0422 210 430

Fax +39 0422 297 137

Email service@klaser.it

Before sending the device to the Service Center, it is required to disinfect the device and accessories as written in the present manual.
The device may be sent in for repair or for safety inspection only in its original packaging, including all accessories.

Eltech K-Laser s.r.l. is the only provider of technical service for its products, unless otherwise indicated by the company. This is to guarantee the product's safety and for the preservation of the product's characteristics.

9 Manufacturer’s declaration on electromagnetic compatibility

9.1 Definitions

Notice

The device complies with all requirements for electromagnetic compatibility according to IEC 60601-1-2.

9.1.1 Emission (electromagnetic)

When electromagnetic energy is emitted by a source.

9.1.2 Interference immunity

The ability of a device or system to work without errors even if there is electromagnetic interference.

9.1.3 Immunity level

The maximum level of a certain electromagnetic interference that affects a particular device or system, where the device or system remains operative with a certain level of performance.

ELECTROMAGNETIC EMISSION		
EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The unit uses RF energy only for its internal function. The RF emission is therefore very low and it is improbable that nearby electronic devices might be disturbed.
RF Emission CISPR 11	Class A	The unit is suitable for use in all establishments, except for those destined to domestic use and those directly connected to the public, low-voltage power supply network, that supplies establishments destined for residential use. provided the following warning is heeded: **Warning:** The equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

INTERFERNCE IMMUNITY			
The unit is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.			
Immunity test	EN 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000 - 4 - 2	+/- 8 kV contact discharge +/- 15 kV air discharge	+/- 8 kV contact discharge +/- 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst EN 61000-4-4	+/- 1 kV for input and output lines +/- 2 kV for power supply lines	+/- 1 kV for input and output lines +/- 2 kV for power supply lines	The quality of the line power supply should be that of a typical commercial or hospital environment
Surge EN 61000-4-5	+/- 2 kV differential mode	+/- 2 kV differential mode	The quality of the line power supply should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	Ut = 0%, 0.5 cycle (0, 15, 90, 135, 180, 225, 270 and 315°) Ut = 0%, 1 cycle Ut = 70%; 25/30 cycles (@ 0 degree) Ut = 0% 250/300 cycles	Ut = 0%, 0.5 cycle (0, 15, 90, 135, 180, 225, 270 and 315°) Ut = 0%, 1 cycle Ut = 70%; 25/30 cycles (@ 0 degree) Ut = 0% 250/300 cycles	The quality of the line power supply should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the unit be powered by an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

RF IMMUNITY			
The unit is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.			
Immunity test	EN 60601-1-2 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF EN 61000-4-6	3 Vrms from 150 kHz a 80 MHz	3 Vrms from 150 kHz a 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. d=1,2 . √P from 150 kHz to 80 MHz d=1,2 . √P from 80 MHz to 800 MHz d=2,3 . √P from 800 MHz to 2,5 GHz where “P” is the maximum output power rating of the transmitter manufacturer and “d” is the recommended separation distance in meters.
Radiated HF EN 61000-4-3	3 Vrms from 80 MHz to 2.7 GHz	3 Vrms from 80 MHz to 2.7 GHz	
	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:		

RECOMMENED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE UNIT

The model is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (in watts)	Separation distance according to frequency of transmitter (in meters)		
	From 150 kHz a 80 MHz D= 1,2 . √P	From 80 MHz a 800 MHz D= 1,2 . √P	From 800 MHz a 2 GHz D= 2,3 . √P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance “d” in meters can be determined using the equation applicable to the frequency of the transmitter, where “P” is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer

Notice

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

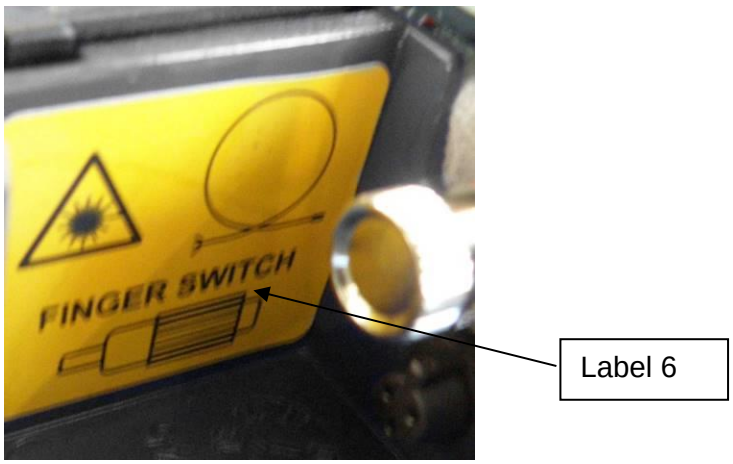
10 Appendix

10.1 Appendix A – Label positions

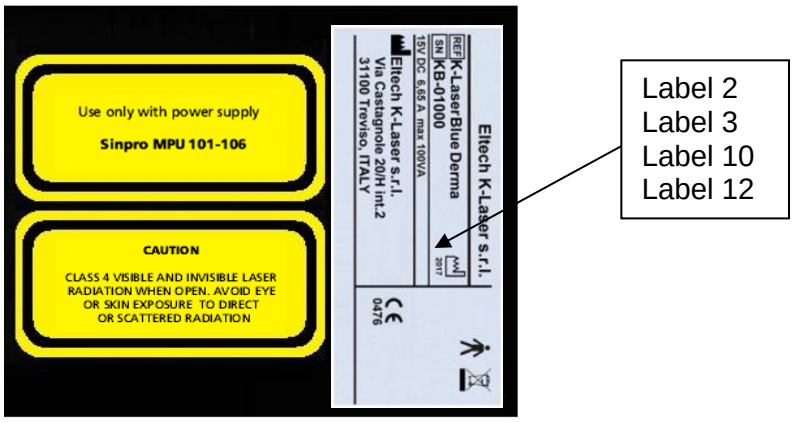
The following figures show the positions of the labels on the device.

Picture 1: front side

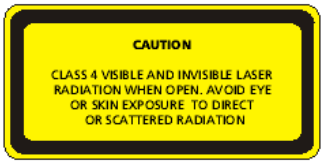
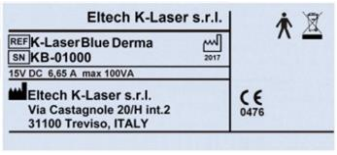
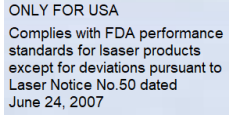
Picture 2: rear side

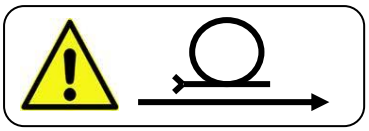


Picture 3: inner side



Picture 4: bottom

LABEL	EXPLANATION
	Label_1: Warns of exposure to class 4 laser radiation hazards when using the laser unit.
	Label_2: Warns of potential laser radiation hazards when opening the laser unit.
	Label_3: Use only with power supply Sinpro MPU 101-106.
	Label_4: Specification of laser output power and wavelength of diode and aiming beam.
	Label_5: Laser radiation warning.
	Label_6: Fiber connection.
	Label_7: DC in for power supply.
	Label_8: Socket for Interlock.
	Label_9: Socket for USB.
	Label_10: K-Laser Blue Derma. Identification serial number of the device.
	Label_11 Laser stop.
	Label_12: FDA clearance. (Only for Us market)

	Label_13: Correct fiber winding
	Label_14: On/off the device