WISER 3 DIODE LASER

L A 12D 001.X

USER MANUAL

CE 0051

INDEX

1. INTRODUCTION

Diode laser LA12D001.x (commercially identified as WISER 3) is a medical device that uses a laser source.

This user manual is issued with reference to all products listed at the following chapter which differ each other in wavelength and power emission according to the table below. If not specified otherwise, the generic code LA12D001.x refers to all devices.

DOCTORSMILE is the commercial brand related to all products manufactured by Lambda SpA.

1.1. VERSIONS LIST

L A 12D 001.1

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	16W	8W	976 nm	24,5 W Peak
Module2	8W	8W	808 nm	
Module3	500mW	500mW	635 nm	

L A 12D 001.2

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	16W	8W	915 nm	24,5 W Peak
Module2	8W	8W	808 nm	
Module3	500mW	500mW	635 nm	

L A 12D 001.3

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	16W	8W	976 nm	24,5 W Peak
Module2	8W	8W	808 nm	
Module3	500mW	500mW	450 nm	

L A 12D 001.4

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	16W	8W	976 nm	20,5 W Peak
Module2	4W	4W	450nm	
Module3	500mW	500mW	635 nm	

L A 12D 001.5

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	16W	8W	808 nm	20,5 W Peak
Module2	4W	4W	450nm	
Module3	500mW	500mW	635 nm	

L A 12D 001.6

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	16W	8W	976 nm	16,0 W Peak

L A 12D 001.7

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	16W	8W	808 nm	16,0 W Peak

L A 12D 001.8

Model	Peak Power	CW Power	Wavelength	Total peal power
Module1	4W	4W	450 nm	4,0 W Peak

1.2. INTENDED USE

This laser equipment named “DIODE LASER” is a medical device and its application fields are:

- **DENTAL SURGERY**
- **DENTISTRY**
- **DENTAL THERAPY**

1.2.1. Examples of use

Some application fields are orthodontics, endodontics, periodontology, herpes therapy, canker sores, chelitis, conservatives, whitening, care and maintenance of implants-peri-implantitis.
The use is temporary, related only to the therapeutic application.

1.2.2. Intended users and place of use

The ability and technical knowledge of dentistry and of the doctor who carries out the therapeutic application correctly guide the choice of the type of treatment
The device is designed to be only used by specialized medical personnel who have received specific training on the use of the laser device.
It must be only used within medical and/or dental studios, hospitals or other adequate sanitary structures.

1.2.3. Intended patients, clinical applications, practical suggestions and possible side effects

The medical device “DIODE LASER” is intended for patients suffering from oral problems related to the dental system, the temporomandibular system, the musculoskeletal system, therefore mainly for adult patients, but there are no contraindications to the use of the "diode laser" also on patients of other age groups.

There are no exclusions in subjects who can be treated with the device using the treatments described in the document **AMNII78 Clinical Protocols**.

The bibliography currently available, at international level, does not reveal any contraindication in the use of the diode laser in the applications field reported in the intended use.

The laser has many beneficial effects on human tissue given the correct values of power, frequency and application time. With high values of power and other inappropriate parameters it may though cause either undesired vaporization or necrosis in the radiated tissue.
Should necrosis be desired, as in cases such as photodynamic therapy or in the equivalent use of the scalpel, it will be unavoidable that along with the targeted tissue, the closest surrounding tissue might be damaged as well. The extent of such harm is essentially determined by the energy density provided to that tissue and exposure time. In many cases the harm will turn out as light and tolerable compared to the benefits.

The user should therefore very attentively check the following parameters, in order not to cause undesired effects on the patient:

- Power
- Diameter of the tip
- Distance between the end of the tip and the tissue spot
- Continuous or pulsed laser emission
- Application time

In case of whitening activity, use in the presence of infections, gingival lesions or carious diseases on the dental elements must be avoided.

	ATTENTION
	The improper use of this laser device might lead to unwanted, sometimes dangerous effects.

1.3. SYMBOLS USED

Symbol "Attention"

The text enclosed in this space and described by the "Attention" symbol indicates a dangerous situation that may result in materials damages or minor to moderate injuries.

Symbol "Danger"

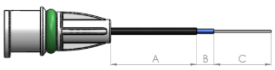
The text enclosed in this space and described by the symbol "Danger" indicates a dangerous situation that can lead to a situation directly connected to serious or fatal injuries.

Symbol "Information"

The text contained in this space and described by the "Information" symbol indicates useful information on the device for the user.

1.4. APPLIED PART

The device is provided with applied parts TYPE B:

FIBER HANDPIECE		TIP	
FLAT TOP HANDPIECE		WHITENING TOOL	
REVIVE HANDPIECE		BIOTIP (for biostimulation)	

2. SAFETY

DANGER

The device must be installed in environments with electrical systems compliant with the regulations in force in your country.

DANGER

Do not allow the use of the device to non-professional operators or who have not read the instruction manual.

Always check the device is in good condition.

ATTENTION

Do not simultaneously touch the accessible contacts of the connectors on the device (fiber connector and USB connector) and the patient

ATTENTION

Do not use the device if any part of it is defective or worn. In this case, contact authorized technicians.

ATTENTION

Replace the defective or worn parts only with original and guaranteed spare parts.

DANGER

The device is not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen or with nitrous oxide.

ATTENTION

Do not use the device in the presence of liquids on the floor.

DANGER

Do not modify the device without the manufacturer's authorization, the use of unapproved accessories and/or unauthorized modifications may cause imminent dangers, injury or damages to persons and materials.

ATTENTION

Any installation, modification and maintenance operations must be carried out with the device switched off, in the absence of the patient and exclusively by qualified personnel authorized by the manufacturer.

2.1. ESSENTIAL REQUIREMENTS

The device within its casing and in the test conditions described maintains operation and emission stability within the standard tolerance of ± 20%.

2.2. GENERAL SAFETY DISPOSITIONS

During its normal use, the laser device laser exposes the human body to laser light radiation; therefore it is important to scrupulously read and follow all the safety dispositions listed in this chapter.

- Never leave the fiber end diode opening on the laser without protection cap.
- Absolutely avoid putting fingers inside the laser aperture or looking directly inside it.
- Do not simultaneously touch the accessible contacts of the connectors on the device (fiber connector and USB connector) and the patient to avoid unexpectable high contact current can flow through the patient.

Any serious injury related to this medical device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

	ATTENTION
	The beam delivery system of the device is the optical fiber, the use of the laser beam with the patient must be done exclusively using the fiber and tip. The device cannot be used without fiber connected. Laser aperture and fiber connection are marked with specific labels

Mobile communication devices, radio frequencies (including antenna cables and external antennas) must not be used closer than 30 cm (12 inches) to any part of the device, including the cables specified by the manufacturer. Otherwise the performance of the device may be degraded.

The following device is not compatible in simultaneous operation with other high frequency surgical equipment

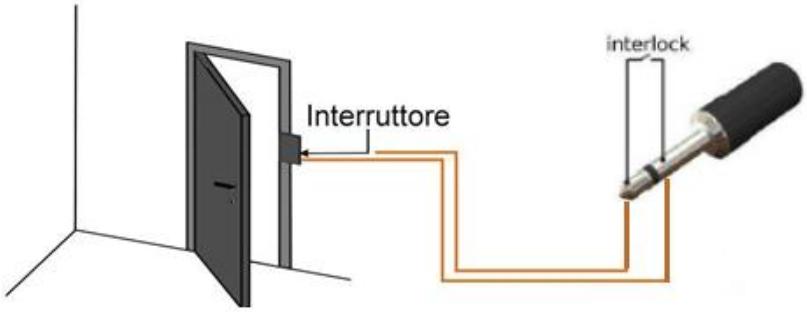
2.3. WORKING AREA

After the device has been delivered and its content checked it is necessary to prepare the place where the laser will be used. Doors must limit the working area, and each of these doors must visibly carry a safety label like the one shown in this figure.

No one other than the authorized personnel can have access to the laser system area of use.
All personnel present must scrupulously follow all the individual safety measures.

The medical laser is protected by unauthorized use through a digital key (password) and an interlock safety system, which is managed by connecting the interlock connector to the device.

It is possible to connect the interlock with a remote switch as shown in the picture below.



2.4. INDIVIDUAL SAFETY MEASURES

All the safety measures here described must be scrupulously followed in order to avoid accidental exposure to laser radiation.

- The personnel authorised to work inside the laser working area must wear protective eyewear.
- Never direct the laser beam towards the eyes.
- Never look into the fibre connector.
- The fibre connector must always be covered either by the fibre or the protection cap.
- Eliminate from the operative area all reflecting and metallic objects, including personal belongings such as watches and rings since these objects risk reflecting the laser beam.
- In case of danger immediately press the emergency button.
- Turn off the main switch when the laser is not in use.
- The intrinsic characteristics of the diode laser ray, if not correctly used, could set some non-metallic material on fire. It is therefore advisable to follow these simple rules very carefully:
- Do not point the laser ray towards any clothing.
- We recommend that only appropriate light coloured, and completely dry clothing be worn.
- Remove all potentially flammable materials such as paper, wood, or plastic.
- Never use flammable gas during laser use.
- Any solvent or inflammable solutions must be allowed to completely evaporate before using the laser.
- Avoid using any potentially inflammable anesthetic or gases such as oxygen or nitrous oxide. The high temperature produced in normal use of the laser equipment may ignite some materials such as cotton or wadding when saturated with oxygen. It is also important that all inflammable solutions normally used to disinfect should be allowed to evaporate before using the laser equipment. Attention should be drawn to the danger of ignition of dangerous gases.

2.5. OCULAR RISK

Eyes can be seriously damaged in case of unprotected exposure to laser light. For this reason it is compulsory to wear protection glasses both for the operator and for the people present in the work area.

Use only glasses with the same specifications as those supplied. In case of breakages or other necessities, it is advisable to contact the supplier to request the same or similar glasses with the same characteristics as those supplied.

According to standard EN 60825 CEI 76-2 II ed. the following values of OD optical Density and DNRO Nominal Distance of Optical Risk have been calculated.
The supplied glasses conform to the European standard EN 207 and have an Optical Density 5 or greater, at the diode emission wavelength.

Model	**LA12D001.1**			**LA12D001.2**			**LA12D001.3**		
Wavelength	976	808	635	915	808	635	976	808	450
Laser	Diode			Diode			Diode		
Emission	Continue/Pulsed			Continue/Pulsed			Continue/Pulsed		
Power	16	8	0.5	16	8	0.5	16	8	0.5
Divergence	220 mrad			220 mrad			220 mrad		
Diameter	0.2mm			0.2mm			0.2mm		
Exposure time	5 s			5 s			5 s		
Observation	Direct Light			Direct Light			Direct Light		
DO (at 0.1 m)	3.1	3.2	3.2	3.2	2.2	2.2	2.2	3.1	3.2
DNRO [m]	*2,770*			*2,806*			*2,770*		

Model	LA12D001.4			LA12D001.5		
Wavelength	976	450	635	808	450	635
Laser	Diode			Diode		
Emission	Continue/Pulsed			Continue/Pulsed		
Power	16	4	0.5	16	4	0.5
Divergence	220 mrad			220 mrad		
Diameter	0.2mm			0.2mm		
Exposure time	5 s			5 s		
Observation	Direct Light			Direct Light		
DO (at 0.1 m)	3.1	3.1	2.2	3.1	*3.4*	2.2
DNRO [m]	*2,510*			*3.,590*		

Model	LA12D001.6	LA12D001.7	LA12D001.8
Wavelength	976	808	450
Laser	Diode	Diode	Diode
Emission	Continue/Pulsed	Continue/Pulsed	Continue/Pulsed
Power	16	16	4
Divergence	220 mrad	220 mrad	220 mrad
Diameter	0.2mm	0.2mm	0.2mm
Exposure time	5 s	5 s	5 s
Observation	Direct Light	Direct Light	Direct Light
DO (at 0.1 m)	3.1	3.4	3.1
DNRO [m]	*2,440*	*3,590*	*2,510*

3. CERTIFICATIONS

3.1. CE DECLARATION OF CONFORMITY

For MEDICAL LASER device named

L A 12D 001.x S/n: ____

Manufactured by

LAMBDA SpA

Under Annex II of directive 93/42/CEE, except point 4, transposed from DL 46/97 and its integration with standard 2007/47/CE issued with Law Decree 37 of 25/01/2010 and with the application of standard 99/05/CE.

The writer LAMBDA S.p.A. company, situates in Via Dell'Impresa 1, Brendola (VI), Italy, manufacturer of the device reported, declares under sole responsibility that:

this device satisfies all the essential requirements required by Annex of Directive 93/42/CEE on Medical Devices and its integration with standard 2007/47/CE; design, construction and final checks are carried out as described by the Complete System of Quality Warranty approved

in date 20/01/2020 da IMQ S.p.A., Via Quintiliano n.43 – 20138 Milano (Italy)

under the requirements of Directive 93/42/CEE at Annex II.

The company also ensures and declares under its responsibility:

1. that the device is considered belong to Class IIb.
2. that the manufacturer agrees to maintain and make available to the competent Authority, the following technical documents, specified in Annex II, at point 6.1, of Directive 93/42/CEE for a period of ten years from the last product manufacture date:
   - *this Conformity Declaration;*
   - *the documentation of the complete system of Quality Warranty;*
   - *the communications at Notified Body relating to any adjustment of complete system of Quality Warranty;*
   - *the description of design, manufacture, sterilization and product performance;*
   - *decisions and reports of Notified Body relating to revision of complete system of Quality Warranty;*
   - *decisions and reports of Notified Body relating to product design testing*
   - *decisions and reports of Notified Body relating to any design changes*
   - *decisions and reports of Notified Body relating to periodic inspection conducted at the company;*
   - *decisions and reports of Notified Body relating to unforeseen inspection conducted at the company*

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Timbro e firma dell'amministratore delegato:

LAMBDA SpA
Via dell'Impresa - 36040 Brendola (Vi) - ITALY
Ph. +39 - 0444.349165 - Fax +39 - 0444.349954
Web www.lambdaspa.com
E-mail info@lambdaspa.com

3.2. CE CONFORMITY MARKING

CE
0051

This product is marked with the CE label according to the European standard applicable for medical devices: CEE 93/42.

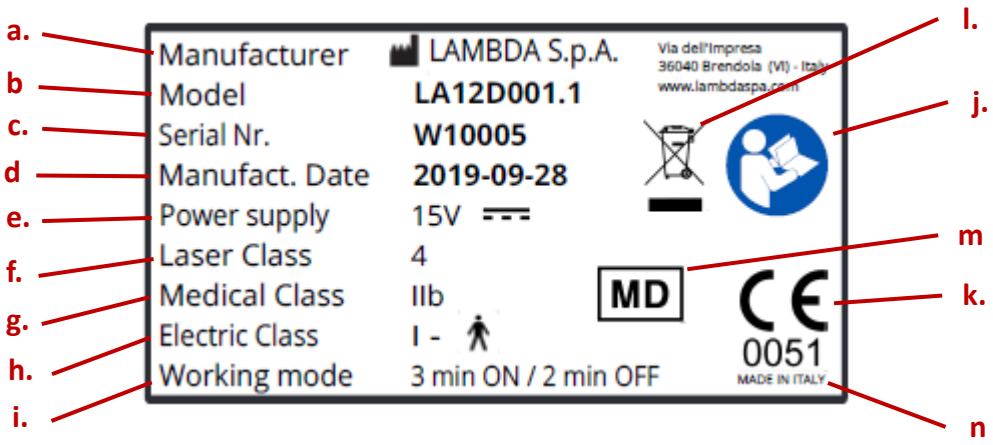
The manufacturer of this product is:

LAMBDA SpA
via dell'Impresa 1
36040 Brendola (VI)- Italy
+39 0444 349165
info@lambdaspa.com

3.3. NAMEPLATE

The nameplate label reports the following data:

a. Manufacturer (Name and address)
b. Device code (model)
c. Device Serial Nr.
d. Manufacturing Date
e. Power supply voltage
f. Laser class
g. Medical class (and applied part)
h. Insulation class
i. Discontinuous operation mode
j. Warning symbol: “Read carefully the instruction manual before using the device"
k. CE symbol
l. Disposal symbol: “the device at the end of its life must be disposed separately as a special product”
m. “Medical device”
n. “MADE IN ITALY”



3.4. WARNINGS

The device works discontinuously as per data reported in the nameplate and at the chapter “TECHNICAL SPECIFICATIONS”.

The *manufacturer* is not responsible for the direct and indirect effects due to the use of the device. These effects remain under the direct responsibility of the medical personnel performing the treatments.

The *manufacturer*, the *assembler*, the *installer* and the *importer* do not consider themselves responsible for the safety, reliability and performance of the device, unless the points mentioned above are respected.

The *manufacturer* makes the technical details of design outlines and test instructions available, prior to written request, so that the qualified personnel authorized by LAMBDA SPA will be enabled to repair or maintain those parts of the system that the manufacturer consider as possible to repair.

The device has been tested in accordance with ESD test - criterion B - and so there may be conditions of transient artifacts on the display, always momentary and due to indirect electric shock events. The transitory is temporary, the equipment is always operative and the operator does not have to implement any intervention.

3.5. ACCEPTANCE OF RESIDUAL RISK

LAMBDA SpA has implemented all the provisions required by the regulations to make the device compliant with the standards and the level of operational risk is acceptable. The user is obliged to strictly follow all the safety instructions contained in this manual. By using the device, the user accepts the residual electrical, thermal and optical risks inherent to the device.

Since the tests are mostly "LINE TEST", but some are necessarily "TYPE TEST", by using the device the user accepts the residual electrical, thermal and optical risks inherent in the device.

4. INSTALLATION

4.1. CHECK ON DELIVERY

Upon arrival of the goods and in the presence of the carrier, it is important to pay accurate attention that the shipped material is correct and intact. In particular:

- The number of parcels and corresponding codes.
- The external packaging conditions and inside for damaged parts.
- Compare the contents of the package with the attached packing list.

It is important to immediately notify the carrier of all possible non-conformities found during checking. The *manufacturer* states that in accordance with national and international laws, the customer always takes full responsibility for the shipped goods. Unless previously specified, the goods are always shipped without insurance.

4.2. ENVOIREMENT REQUIREMENTS

Keep the laser in a dry and clean ambient with the following requirement:

- TEMPERATURE: 10°C - 30°C
- HUMUDITY: 30% - 70%
- ATM. PRESSURE: 700 – 1060 hPa.

4.3. CONDITION OF USE

ATTENTION

INSTALLATION MUST BE CARRIED OUT BY AUTHORIZED PERSONNEL ONLY.
Unauthorized installation brings immediately to the warranty interruption.

In the room previously prepared for the laser use, remove all unnecessary inflammable material and verify that the electric power panel complies with the current safety norms. Check the electric power to see if it matches the laser system's electric requirements.

- Place the device in a flat stable position.
- Be sure that the device has been maintained in these environment conditions for at least 2 hours before turning the device on.
- Protect the laser from direct sun light to avoid possible system overheating.
- Do not place the laser next to walls (minimum distance of 10 cm) or other locations that could decrease air exchange. Do not cover the air vents even partially during use.
- Place the device so that it is easy to disconnect the device from the network plug
- Place the laser device at a safe distance from other machinery, to avoid possible electromagnetic interference.
- While working do not cover the machine with things or clothes.

4.4. ELECTRIC REQUIREMENTS

It is important to verify that the power cable is not damaged before using the laser system. In particular, the cable plug must be compatible with the powering network socket. Do not use adapters, extensions or multiple sockets of any type.

The power supply complies with the CEI EN 60601-1 standard and has the following features::

Model	SINPRO MPU101-106
Input Voltage:	100 ÷ 240 V ∿
Frequency:	50 ÷ 60 Hz
Output voltage:	15 V ⎓
Max absorbed current:	6.66 A

The external power supply is an integral and indissoluble part of the medical device.

ATTENTION

Do not use power supplies other than those supplied. If replacement is necessary, contact LAMBDA SpA or an authorized dealer for original spare parts.

4.5. DELIVERY AND STORAGE

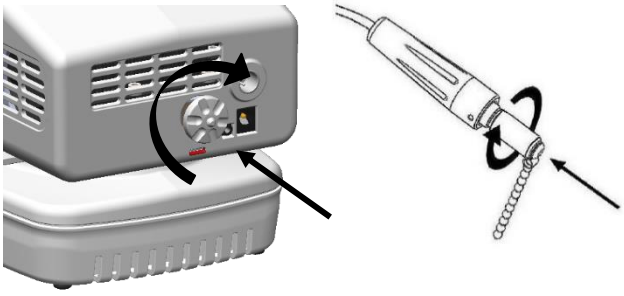
ATTENTION

LAMBDA SPA is not responsible in any case for losses and / or indirect damages of any kind that the goods may suffer due to transport that does not comply with the above specifications.

In case of the device must be moved from different rooms of the same building, disconnect the power supply and move the device (it is not necessary to disconnect the fiber). Take care not to damage the fiber.

Should you need to move or ship the laser between different buildings, follow these indications:

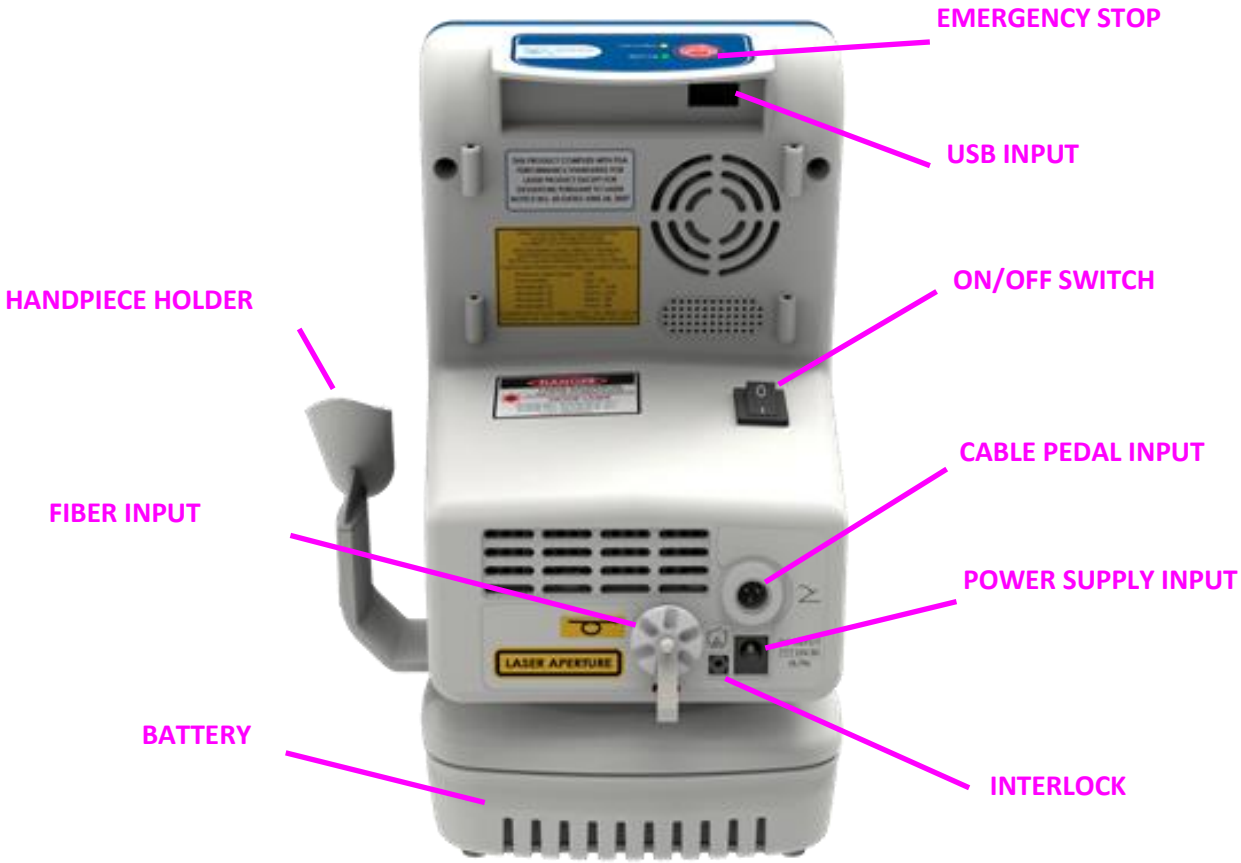
- Always contact the dealer or LAMBDA SPA before any shipping.
- Always use packaging material supplied on delivery for transport. If not available it is necessary to apply for a new packaging.
- Disconnect all cables accessories (optical fiber, power supply interlock, footswitch)
- If fiber is not connected, THE LASER APERTURE AND THE FIBER CONNECTOR MUST ALWAYS BE COVERED WITH THE PROTECTIVE CAP



During storage, follow the environmental requirements reported in the "TECHNICAL SPECIFICATIONS" chapter of the manual and reported on a specific label both on the casing and on the packaging of the device.

5. OPERATION MODE

5.1. OVERVIEW



ACCESSORIES INCLUDED

OPTICAL FIBER BOX

INCLUDES:

FIBER/HANDPIECE
INTERLOCK
SWAB

TIP

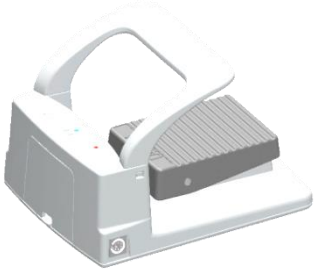
5 BOXES

01 tip ENDO (Blue - box 04)
01 tip PERIO (Yellow - box 04)
01 tip SURGERY (Green - box 04)
01 tip IMPLANT (White - box 04)
01 tip THERA (Black - box 04)

PIEGA TIP (30° - 60° - 90°)
MANIPOLO SBIANCAM.
TIP BIOSTIMOLAZIONE

ACCESSORIES BOX

POWER SUPPLY WITH CABLE



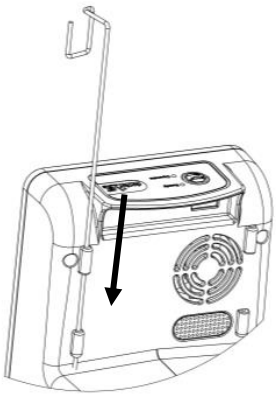
BLUETOOTH PEDAL
(WITH ADDITIONAL CABLE)

PROTECTIVE GOGGLES (N.3 PZ)

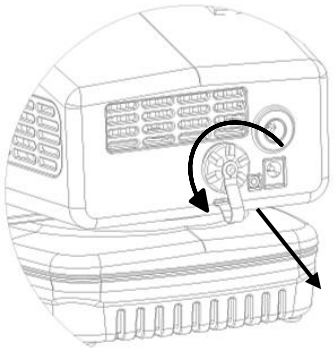
LASER RADIATION LABLELS (2 PZ)

USER MANUAL
PROTOCOLS
CE CERTIFICATE

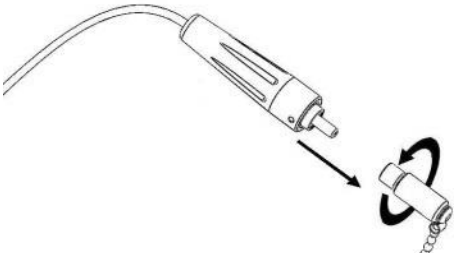
5.3. LASER DEVICE PREPARATION



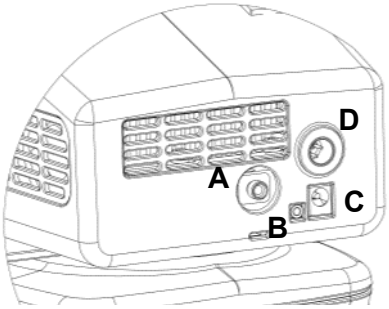
1. Insert the fiber holder (A) into the dedicated hole.



2. Remove the protective cap of the diode output.

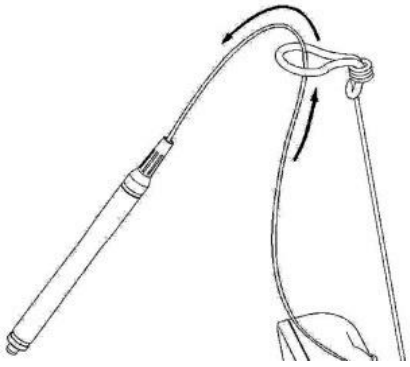


3. Remove the protective cap of the fiber

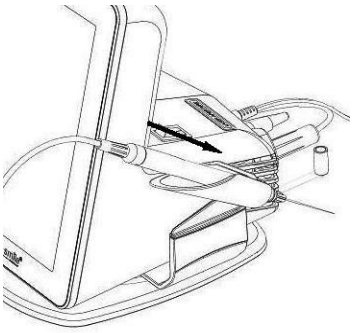


4. Insert and screw the fiber (A), connect interlock (B) and power supply (C).

D connector is for the cable of the pedal



5. Insert the optical fiber inside the ring of the fiber holder



6. Put the handpiece in the handpiece holder when not in use

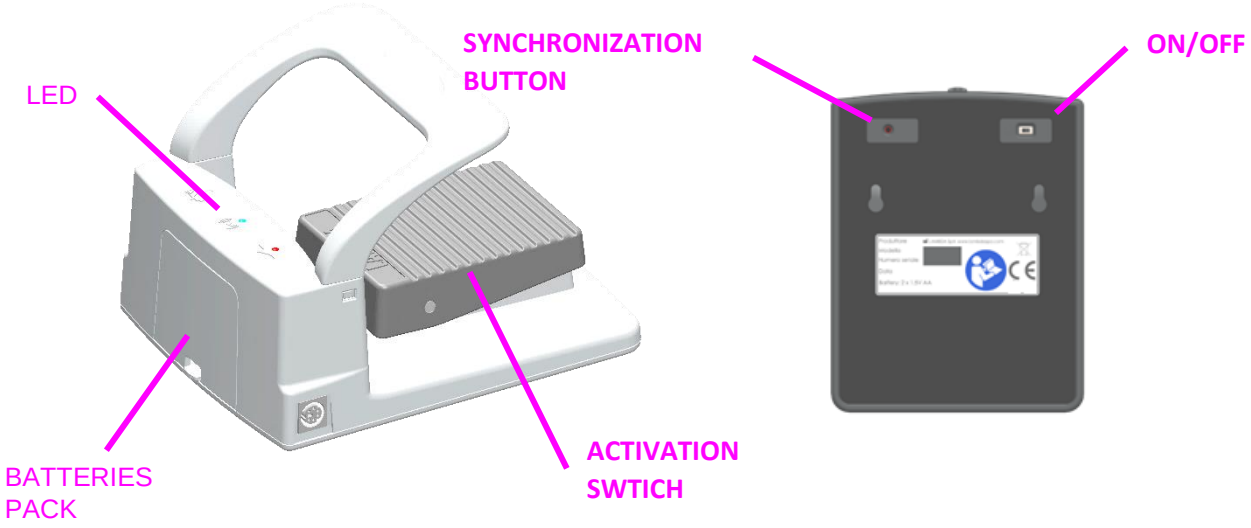
5.4. PEDAL INSTALLATION

The Bluetooth pedal is powered by N.3 non-rechargeable 1.5V AA batteries. Make sure that they are present in the battery compartment before proceeding.

Turn on the pedal using the switch on the bottom.

The flashing red LED indicates that batteries are running low. Replace the batteries.
The green LED is on when the pedal is pressed.
The blue LED indicates the process of association of the pedal to the laser.

- On fixed: active connection
- Flashing slow: not connected
- Fast flashing: in association



To associate the pedal with the laser, enter the settings menu and select Bluetooth/pedal. Press the red button on the bottom of the laser while starting the association process from the laser screen.

In case of malfunctioning or if the “LOW BATTERIES” led switches on, replace the batteries using only equivalent batteries.

Replacement of the pedal batteries can be done by the user; remove the cover placed in front of the pedal and replace batteries.

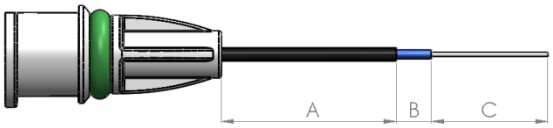
If the problem remains contact Service of Lambda Spa or your dealer.

At delivery, the pedal is provided already synchronized.
The above procedure is required in case of pedal replacement.

5.5. HANDPIECE AND TIP INSTALLATION

On delivery of the device the tips supplied in the packaging have not been sterilised

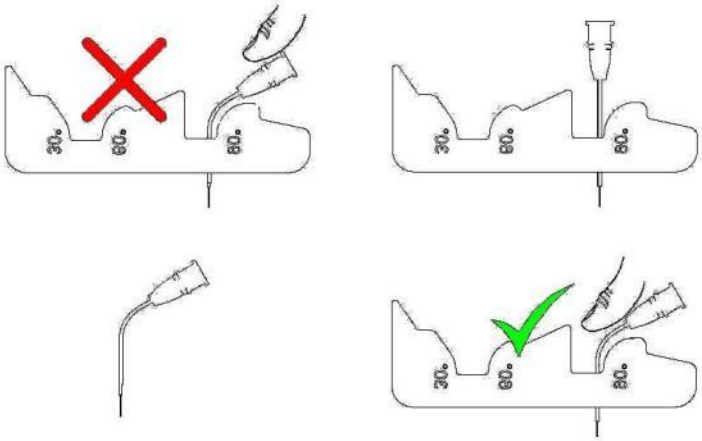
Different tip sizes are available for different applications. They are colour-coded for easy identification. The tips include a screw on ring.



APPLICATION	COLOUR CODE	Size	Ø Tip
ENDODONTICS	BLUE	A 25mm B 3mm C 15mm	200µm
PERIODONTICS	YELLOW	A 25mm B 3mm C 10mm	400µm
SURGERY	GREEN	A 25mm B 3mm C 5mm	300µm
IMPLANT	WHITE	A 25mm B 3mm C 8mm	300µm
THERAPY	BLACK	A 25mm B 3mm C 5mm	400µm
WHITENING	GREY		
BIOTIP	GREY		
FLAT TOP	GREY		
REVIVE	GREY		

TIP BENDING

Use only the accessory provided to bend the tip as required.



1. Insert the tip in the hole of the tip shaper

2. Bend the tip to obtain the desired shape by pressing the metal part.

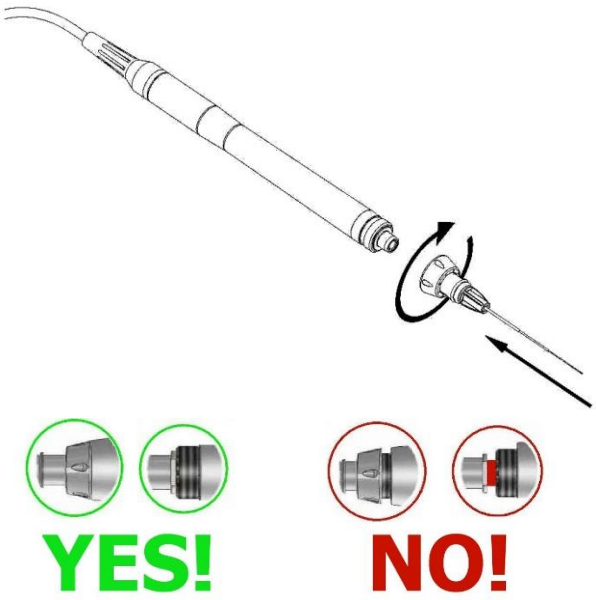
1. Insert the tip in the hole of the tip shaper
2. Bend the tip to obtain the desired shape by pressing the metal part.

ATTENTION

Do not press the plastic part of the tip when applying pressure.

Verify the correct bending and the light is transmitted correctly through the tip before the use..

TIP INSTALLATION AND REMOVAL



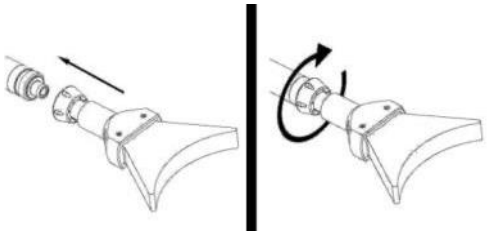
1. Remove the protection cap from the handpiece. Take the tip and the plastic ring out of the package. Insert the tip in the handpiece.
2. Once the tip is in place insert the ring through the tip.
3. Push the ring until you hear a click that confirms that the ring is correctly in place.
4. Screw the ring tightly to avoid any tip movement

To remove the tip, unscrew the ring and gently pull out the tip. Replace the protection cap or insert a different tip.

WHITENING AND STIMULATION ACCESSORIES INSTALLATION

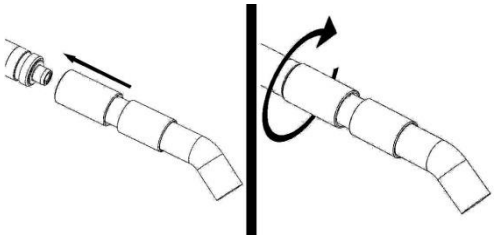
WHITENING TIP (LARGE AREA ARCH)

For whitening procedures, screw the large area whitening accessory to the handpiece, after removing the protection cap.



BIOSTIMULATION TIP

For intraoral biostimulation procedures screw the appropriate tip on the handpiece.



FLAT TOP (optional)

For extra-oral biostimulation procedures, insert the connector of the Flat Top in the Wiser handpiece tip.

REVIVE (optional)

For small skin surgery protocols

ATTENTION

Never leave the output lens unprotected.

Always install the protective cap after removing tips or other accessories.

The handpiece lenses are very delicate and may be damaged by the penetration of fluids, smoke, steam or dust.

Absolutely avoid touching and looking directly inside

6. CLEANING AND STERILIZATION

ATTENTION

Every component which can enter in contact with the patient must be sterilized. Separate all the elements and clean them carefully before sterilizing, by removing any trace of organic residual.

6.1. HANDPIECE MAINTENANCE

the handpiece is made up of two separable parts: the main laser body attached to the fibre and an autoclavable screw on cylinder.

Handpiece body
(NOT AUTOCLAVABLE)

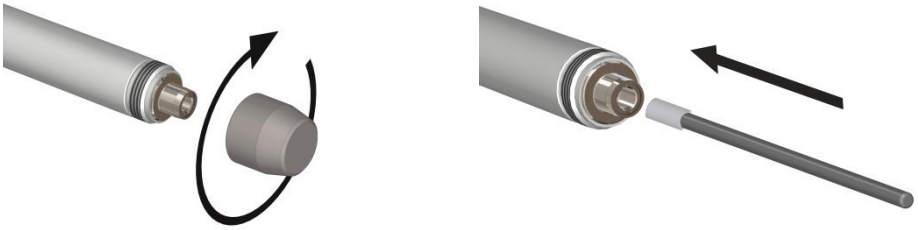
Removable cylinder
(AUTOCLAVABLE)

To remove the cylinder, unscrew the protection cap, or remove the tip.
Then unscrew it from the laser body

.

It is important to clean the output lens every week to ensure optimal power output:

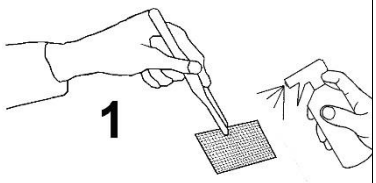
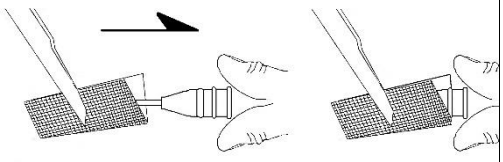
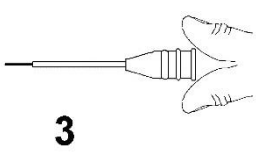
Remove the tip or the protection cap from the output lens. Insert the special cleaning swab in the opening
Rotate the swab clock wise to perfectly clean the lens.
Then reinstall the protective cap



6.2. CLEANING AND STERILIZATION

It is suggested to always clean and disinfect handpiece and tip before sterilization to remove any trace of organic residual.

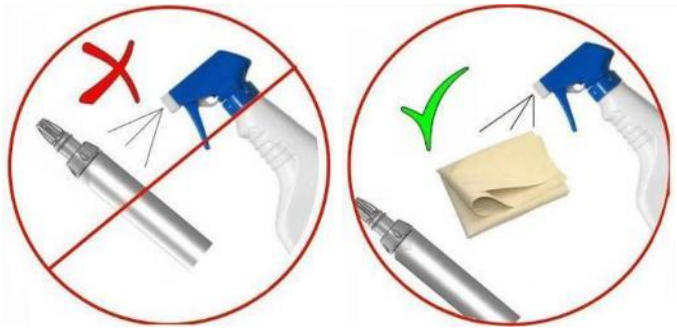
CLEANING AND DISINFECTION

		
1. Soak a piece of gauze in the sterilization liquid.	2. Wrap the tip in the gauze and let stand for 10 minutes.	3. Before use, ensure that the fibre and the metal part of the tip are completely dry.

ATTENTION

Never spray liquid directly to the handpiece.

Liquid can enter inside the handpiece and damage the optical components inside.



STEAM STERILIZATION (IN AUTOCLAVE)

Disposable tips, biostimulation tip and the external handpiece cylinder can be sterilised according to the standard method in autoclave (at 121°C for 18 min.).

ATTENTION

Optical fiber and whitening tool cannot be sterilized in autoclave.

The number of cycles of sterilisation in autoclave for the tips is limited to two
It is suggested the operator makes a careful inspection of the sterilised parts after each cycle to confirm its integrity. In particular verify that the covering does not show signs of deterioration, breakages or holes.

Do not dispose of used or damaged tips in the environment. Disposal must always conform to national and/or regional laws in place. You may take the fibres to be disposed of to your dealer who will arrange for their proper disposal as legally required.

7. SYSTEM OPERATION

	DANGER
	Before the use of laser, ensure that all safety measures described in this manual have been put into place.

	DANGER
	All users (doctors and patients) have to use protective goggles.

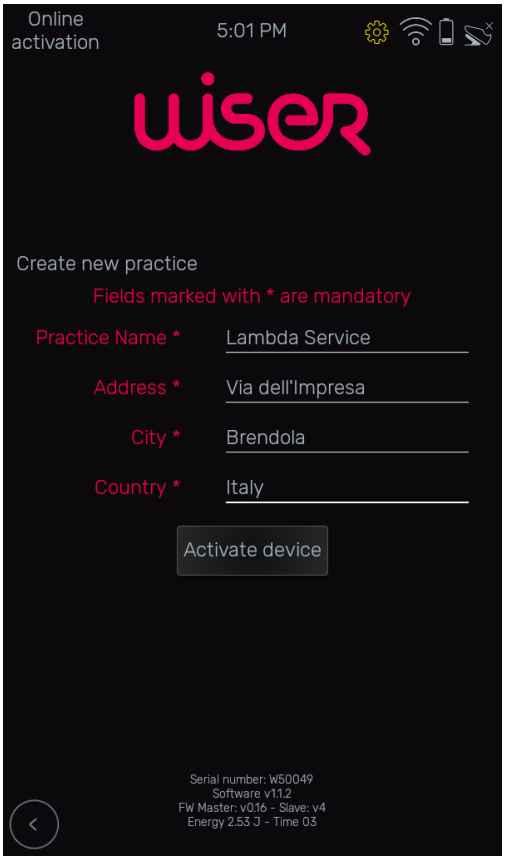
	DANGER
	Each deviation/modification from what here described can cause an exposure to dangerous levels of irradiation.

	ATTENTION
	The medical laser is protected by unauthorized use through a digital key (password) which must be digited every time the device switches on..

7.1. FIRST ACTIVATION

Turn on the laser using the main switch on the rear of the machine.

At the first start-up it is necessary to activate the device



ON-LINE ACTIVATION

	A Wi-Fi connection is required .

1. Press the button “SETUP INTERNET CONNECTION” to connect the device to Wi-Fi network.

2. Fill the fields with the medical studio data and press button “ACTIVATE DEVICE”.

3. You will receive an email with the request of registration confirmation by using a specific activation link.

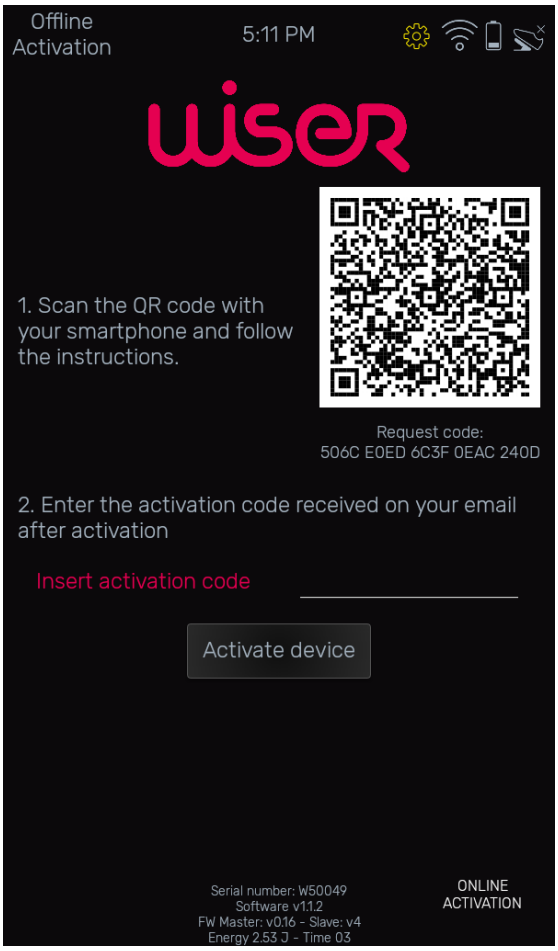
OFF-LINE ACTIVATION

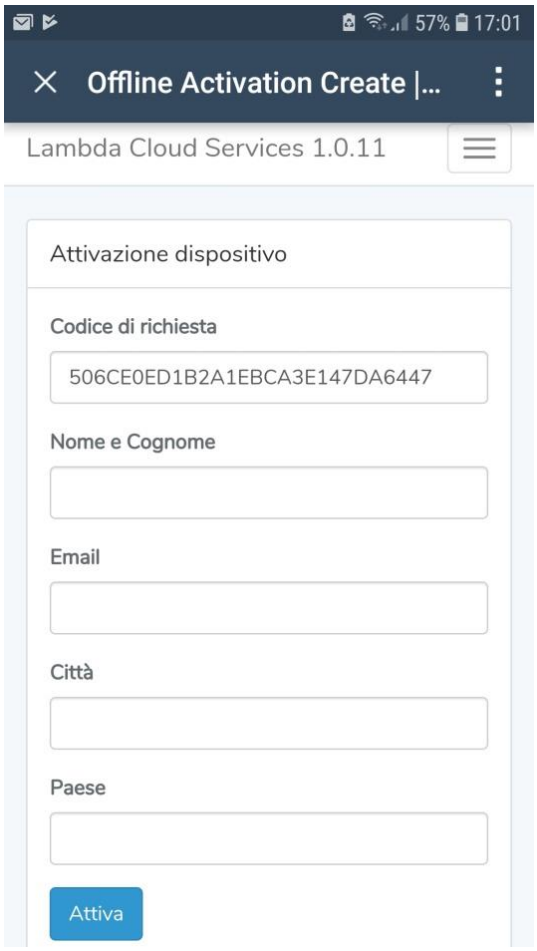
If Wi-Fi connection is not available, it is possible to follow the off-line procedure by pressing the relative button (on bottom right of the screen).

It is required a QR code scanner to proceed (the scanner can be downloaded with a free application).

After QR code scanner, a web page will be automatically loaded in the browser; fill all the medical studio data and proceed by pressing “ACTIVATE”.

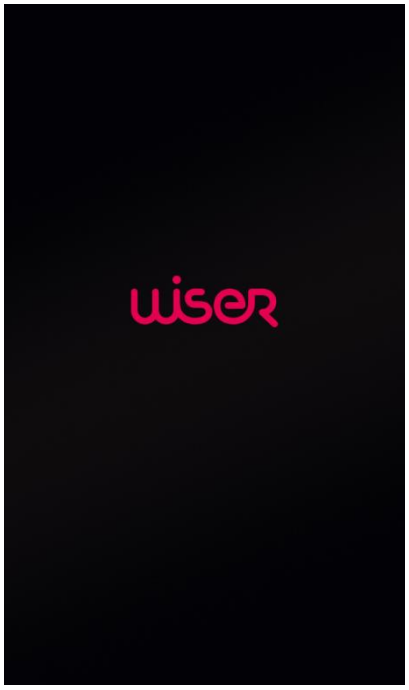
An email will be sent to the email address recorded containing the activation code which must be written in laser device screen.
Press button “ACTIVATE DEVICE” to complete the registration.





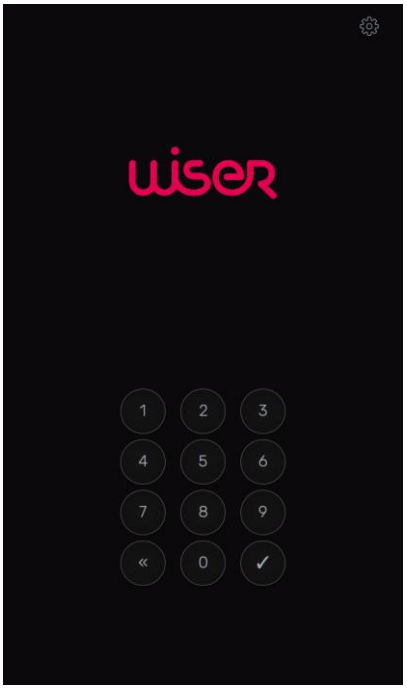
7.2. DEVICE SWITCH-ON

Turn on the laser using the main switch on the rear of the machine



Press the display to accede.to the psw screen.

***Note**: the starting message can be different from the shown one.*

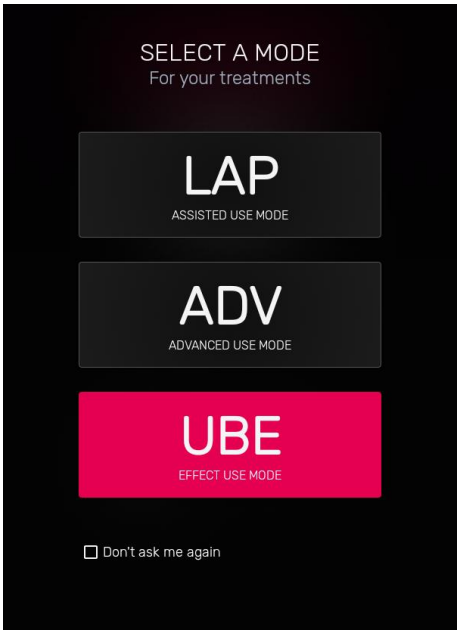


Insert the default password 1-1-1-1-1

***Note:** the password can be modified at any time from the setup menu.*

Home page: treatment list:

7.3. TREATMENT SELECTION



The Wiser laser can be used in three different modes:

- LAP MODE: assisted mode
- ADVANCE MODE
- UBE MODE: effect mode

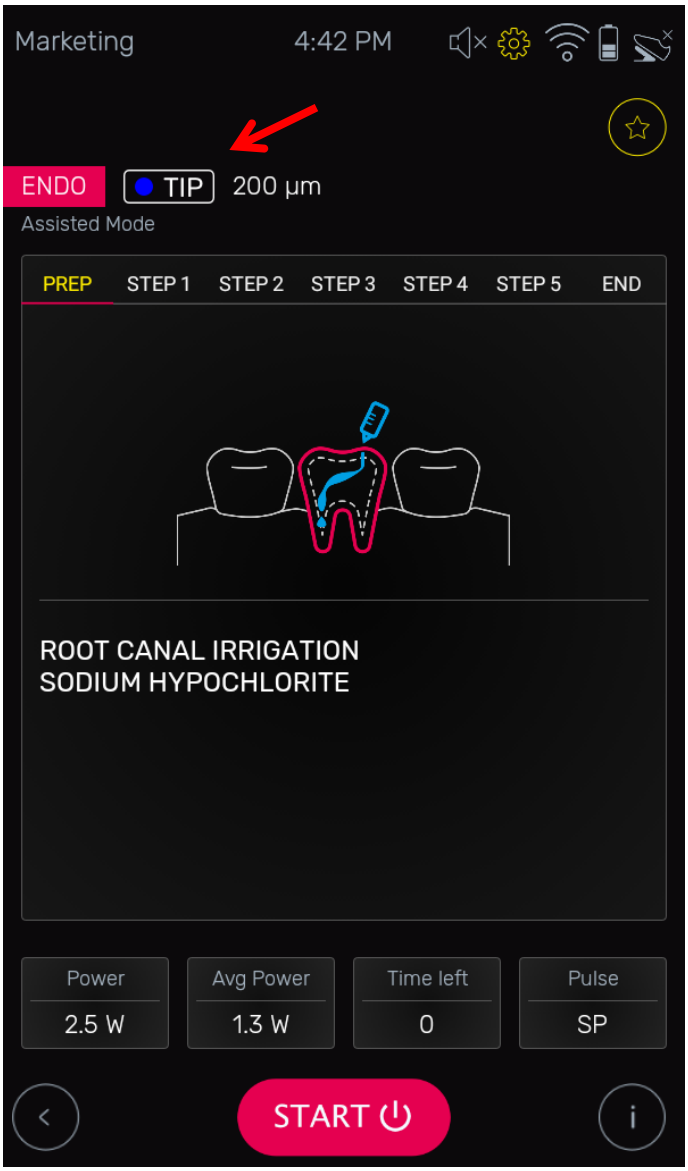
In each mode, the indication of the tip to be used is reported next to the treatment name.

ASSISTED MODE (LAP)

The laser device guides the user splitting the treatment in single phases with pre-set values of power and timer.
These values cannot be modified and each phase changes automatically.

Once the timer ends, the procedure will move automatically to the following step updating parameters and instructions.

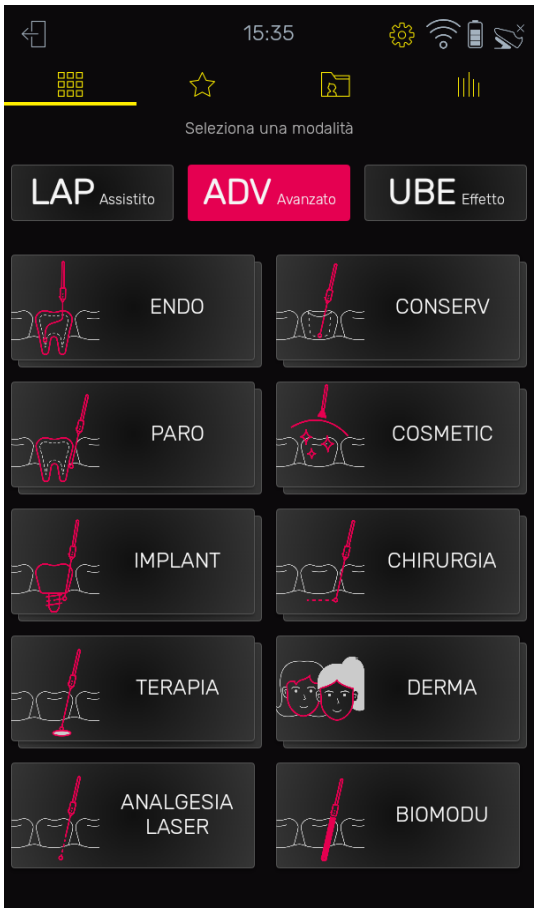
It is not possible to modify the setting.



TREATMENT LIST

- ENDODONTICS
- PERIODONTICS
- IMPLANT
- HERPES & APTHAE
- DESENSITIZATION
- WHITENING
- SURGERY
- BIOSTIMULATION

ADVANCE MODE (ADV)



TIMER

POWER 450-808

POWER 635

Each protocol is defined with pre-set parameters (power, pulse type, timer) which can be manually modified.

Power and pulse can be modified not individually for each single diode but as average value between the two channels (in a proportional way with preset ratio).

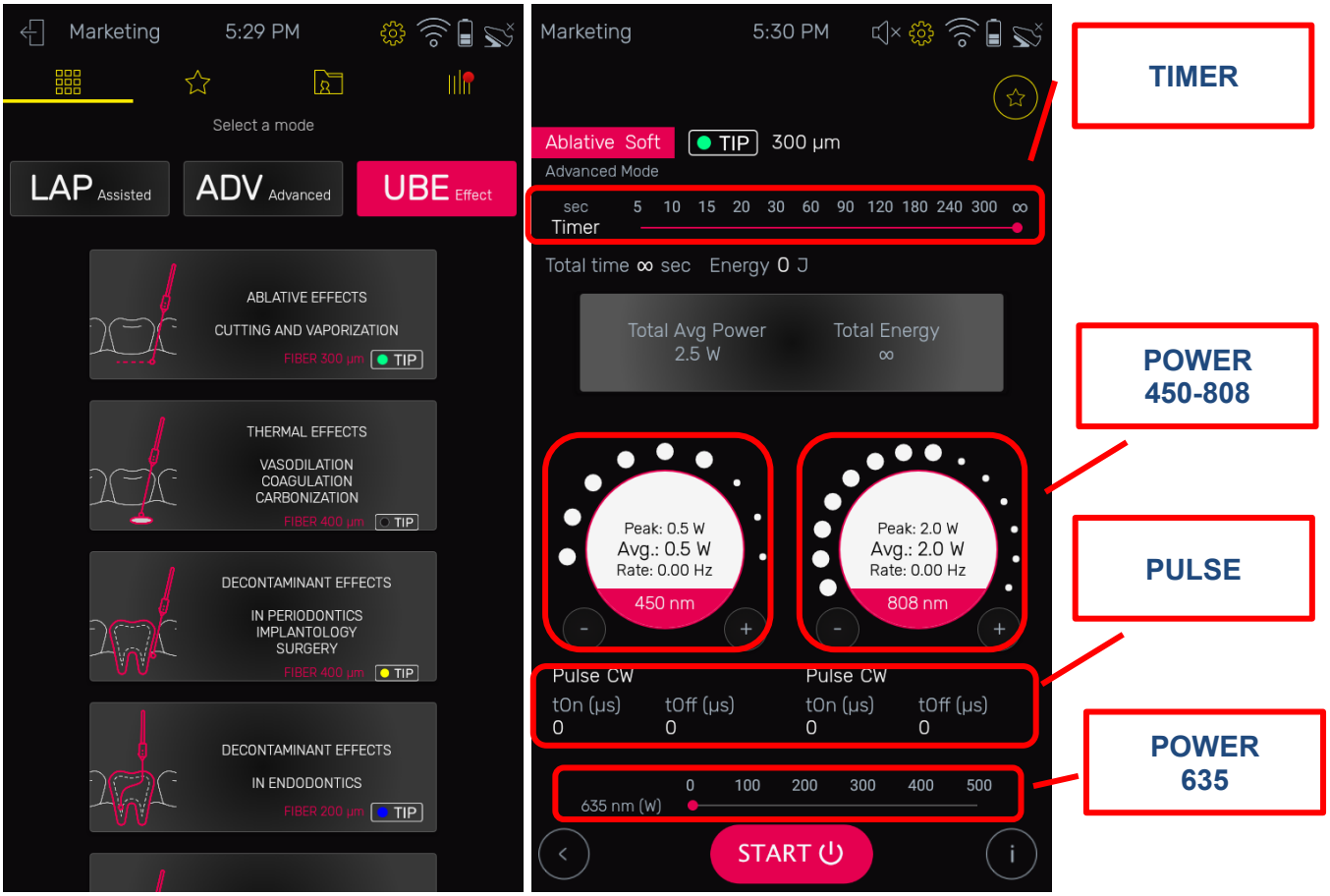
1. **ENDODONTICS**
   - root decontamination
   - pulp capping
   - Apicectomy
2. **PERIODONTICS**
   - gum analgesia
   - Pocket decontamination
   - Gum recession
3. **IMPLANT**
   - exposure
   - perimplantitis
   - alveolus decontamination
4. **THERAPY**
   - herpes simplex
   - aphthae
   - cheilitis angle
   - desensitization
   - trismus (TMJ)
   - biostimulation
   - analgesia laser
   - PDT
5. **ANALGESIA LASER**
6. **CONSERVATIVE**
   - Groove decontamination
   - Cavity decontamination
   - Glazing
7. **COSMETICS**
   - whitening single
   - whitening arch
   - Haemangioma
   - Gum smile
   - Depigmentation
   - fibroma
8. **SURGERY**
   - granulotic tissue
   - normal tissue
   - fibrotic tissue
   - boost
   - coagulation
   - sulcus preparation
   - gingivectomy
   - frenectomy
   - hyperplasia
   - abscess
   - granulomas
9. **DERMA**
   - Skin surgery in CW
   - Skin surgery in MP
   - Skin surgery in SP
   - Skin Depigmentation CW
   - Skin Depigmentation SP
   - Skin Bioregeneration
10. **BIOSTIMULATION**

EFFECTS MODE (UBE)

The effects mode has N.5 main category, with different preset treatments (effects) : soft, medium, hard, very hard, boost.

La lista dei trattamenti utilizzabili è:

- ABLATIVE
- THERMAL
- DECONTAMINANT
- BIOSTIMULATING



Each protocol is defined with pre-set parameters (power, pulse type, timer) which can be manually modified.

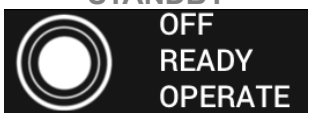
In this mode, power and pulse can be modified individually for each single diode.

ATTENTION

In presence of some treatments (for example in surgery where tissue ablation is requested) the use of a canula is required for the aspiration of fumes which may contain organic residues.

7.4. LASER ACTIVATION

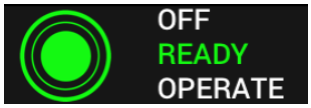
STANDBY



Press the button 

to activate mode **READY.**

READY



The device is now ready for the use.

OPERATE

Press the pedal to enable **OPERATE** mode and generate laser emission.
The yellow signs starts to blink to highlight the laser emission.
Release the footswitch or touch any point of the display to stop laser emission and return in **STANDBY** mode.

ATTENTION

The laser emission is highlighted by an acoustic and visual signal (yellow signs starts to blink).

DANGER

Before using the pedal, be sure to have worn all the individual safety devices and directed the laser beam to the correct target.

The laser device will automatically switch in STANDBY mode after an inactivity period of some minutes.

7.5. EMERGENCY STOP

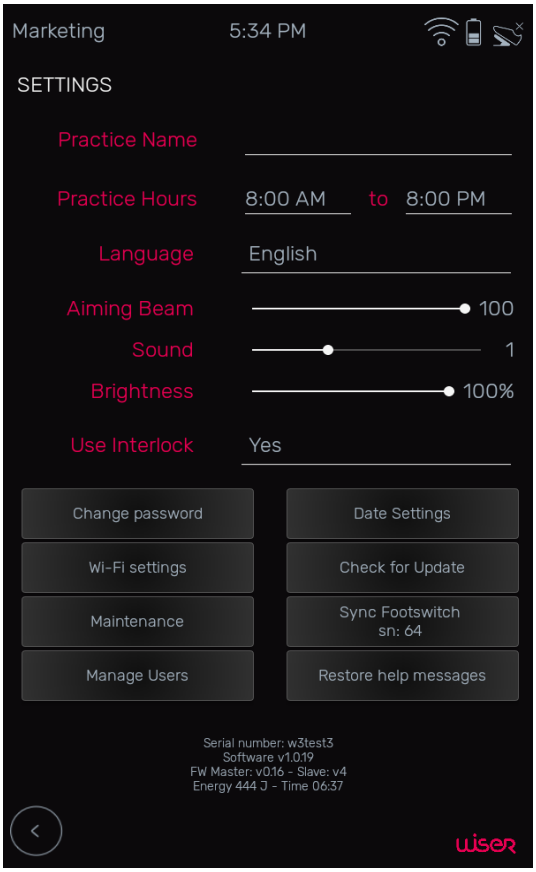
IN CASE OF EMERGENCY you can interrupt laser emission by pressing the red emergency button on top of the laser.
Any pressure to this button will immediately block the system and the emission of radiation in progress and a pop-up message “Emergency button” appears; press “OK” to reactivate the device

7.6. VISUAL SIGNALS

The device is equipped with two leds (Ready / Operate) placed above the display.

The Ready led (green) switches on in READY mode.
The Operate led (orange) switches on in OPERATE mode.

7.7. SETTING MENU



Select the Setting menu icon  to enter in the setting menu:

Practice Name / Hours:

Language

Pointer: Set the intensity of the aiming beam (%)

Sound: set the intensity of the audio (3 levels)

Brightness: Set the display contrast

Use interlock: enable/disable the external interlock system

Change password

Date: Set date and time of the device

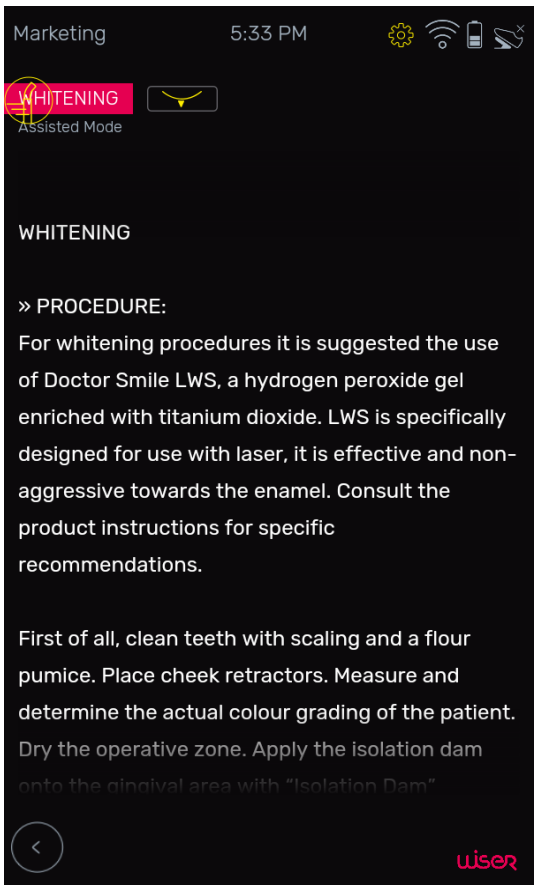
Wi-Fi: enable/disable and set the internet connection

Update check: Check if a new SW release is available (in Wi-Fi mode if enable or with a USB key if connected)

Pedal synchronization: permit to synchronize a new pedal

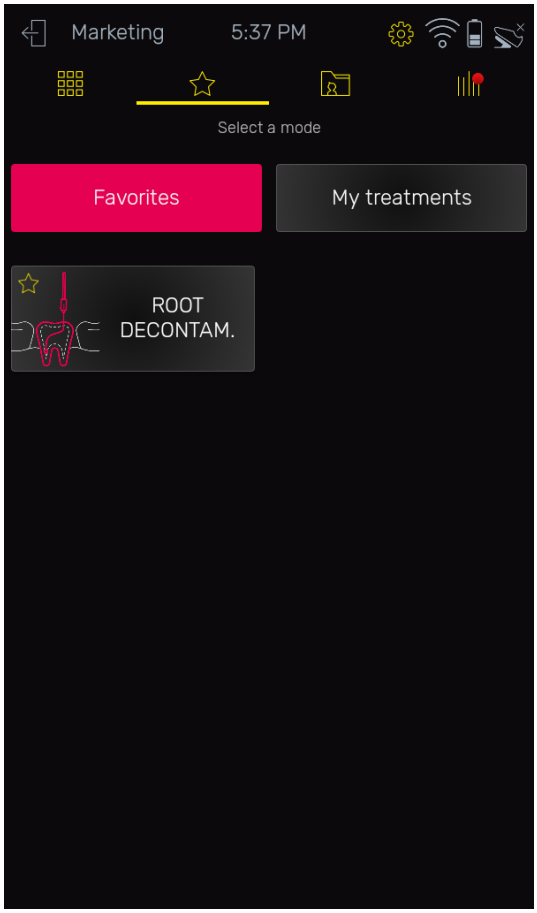
Press button  to save and exit

7.8. INFORMATIONS



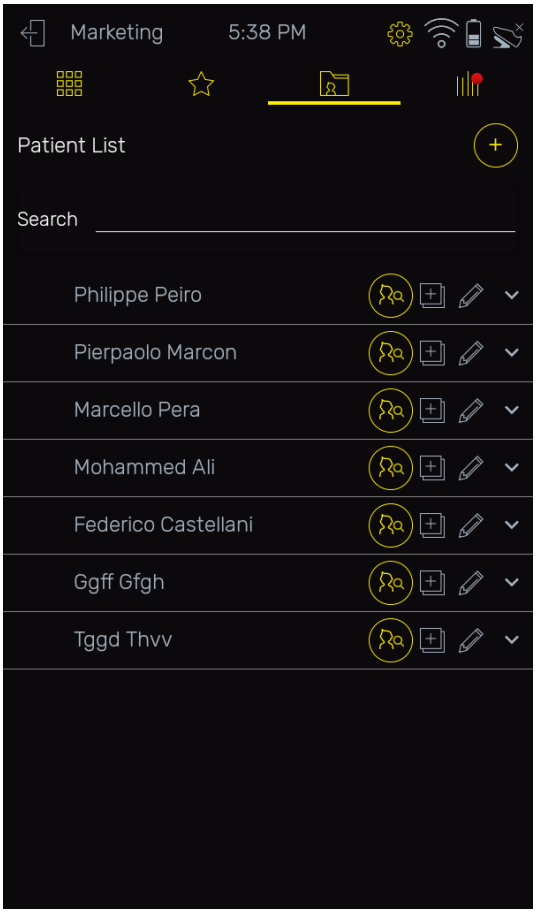
Press button “info” (available for any treatment) to read the protocol instructions 

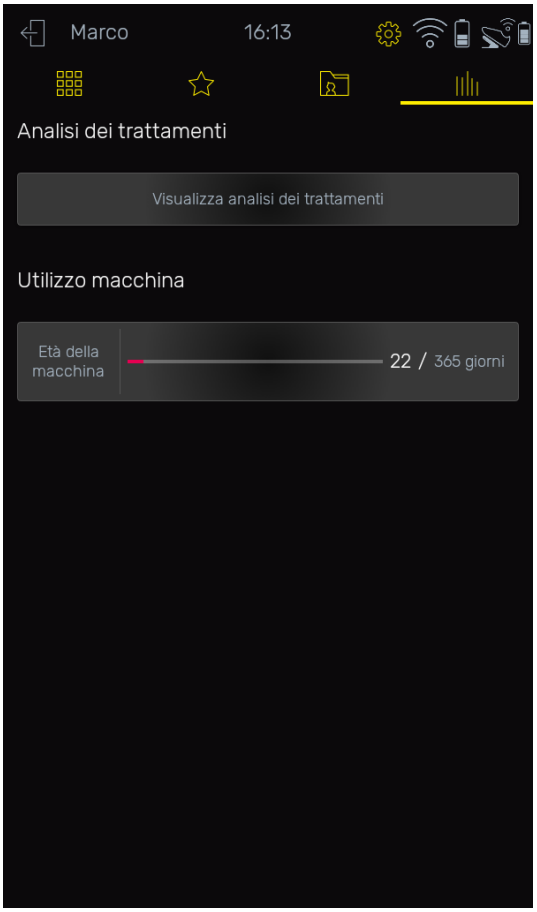
7.9. FAVOURITSE AND PATIENT LIST



From main screen it is possible to have access to the following functionalities:

- Create a list of favorite treatments
- Create a list of patients and relative agenda
- Verify the counters and the time of use of the device





7.10. SWITCHING OFF

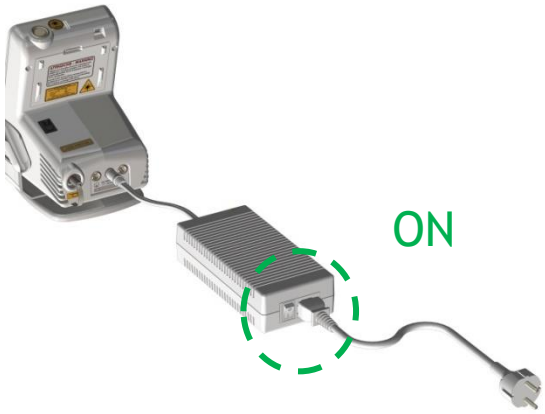
Press the main switch on the back of the laser to switch off the device.
DO NOT LEAVE THE DEVICE SWITCHED ON WHEN NOT USED

7.11. WIRELESS MODE / BATTERY RECHARGE

The device can be used without external power supply thanks to an internal power system made of a lithium battery (“INTERNALLY POWERED”).

The battery life depends on the charge level and on the laser parameters used (emission mode, power and timer).

To charge the battery connect the power supply to the device and to the network, and turn on the switch on the power supply and verify that the green led lights up.
The system will charge whether the laser is turned on or off.
The battery level is evidenced by the icon present on the top-right of the display.



CHARGING

NOT CHARGING

If the laser does not charge properly (The battery is not charged completely or their life is reduced), it may be necessary to replace the rechargeable battery located in the lower part of the device.

ATTENTION

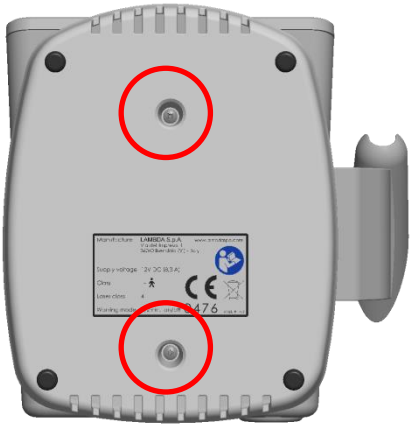
Only use official batteries provided by LAMBDA SpA or authorized reseller.

DANGER

The battery replacement must be performed only by authorized and trained personnel.
To guarantee a reserved access, it is present a safety label on the battery pack cover.

The use of different batteries or an incorrect connection may cause explosion or damage and injury to device and persons..

To remove the battery, unscrew the N.2 lower cross screws and remove the battery cover.
Unplug the battery connector.
Take the new battery and plug it (the connector is designed so that it is not possible to invert the polarity).
Place the battery inside the battery cover and fix it using the N.2 cross screws.



ATTENTION

Before fixing the screws, take attention the battery cable is placed correctly to avoid the screws can cut the cables.

DISPOSAL:
Damaged or unserviceable batteries must not be dispersed n the environment. Battery disposal but be made in accordance with national/regional legislation. LAMBDA SpA can replace the batteries and dispose of them correctly.

7.12. EXTERNAL CONNECTION

The following device is provided with an external USB Type A connector and the WI-FI connection with the only function of Debugging (test and resolution of software errors) and Technical Assistance (application and data update).

The software can be updated through the guided procedure in the settings menu; if the internet connection is enabled the device will automatically advice the presence of any new versions of the software.

The USB port cannot be used during normal operation of the device. Its use is limited to trained person who uses safety precautions against the risk of damage from electrostatic discharges (see further details in the dedicated chapter).

8. MAINTENANCE

ATTENTION

The aiming beam pass through the same delivery system (optical fiber) of the laser beam, so it is strongly suggested to verify periodically the integrity of the fiber, included handpiece and tip

If the aiming beam is not visible or its intensity is reduced, this could be a possible sign of failure (handpiece, fiber or laser source). If a relevant power decrease is detected, do not proceed to use the laser device and immediately contact the Service dept. of your DEALER.

If required, Lambda SpA declares its availability to provide technical documentation (as electric drawing, bill of materials, calibration and testing instructions, others) about laser devices only to authorized personnel.

The device cannot be maintained while it is in use.

8.1. PERIODICAL MAINTENANCE

All the maintenance operations below mentioned must be carried out by a specialised technician authorised by the manufacturer. Personnel must be adequately equipped and must apply tests and requirements according to norm CEI EN 62353

It is strongly recommended a periodical maintenance and power calibration of the device every two years to guarantee the correct operation.
The power measure must be performed with a suitable power meter and the deviation between the power set the one measured must be lower than 20% in continuous emission mode (CW).

It is also required to subject the device to a periodical electric safety check (as per standard CEI EN 62353) at least every 24 months only by authorised people.

The test report must be provided to LAMBDA SpA (technical dept.)

8.2. GENERAL CLEANING

All cleaning operations must only be conducted with the machine switched off and disconnected from power.

ATTENTIONE

If the fiber is disconnected from the device, never leave the fiber connector and the laser aperture without protective cap.

The optical parts of these components are very delicate and may be damaged by the penetration of fluids, smoke, steam or dust.

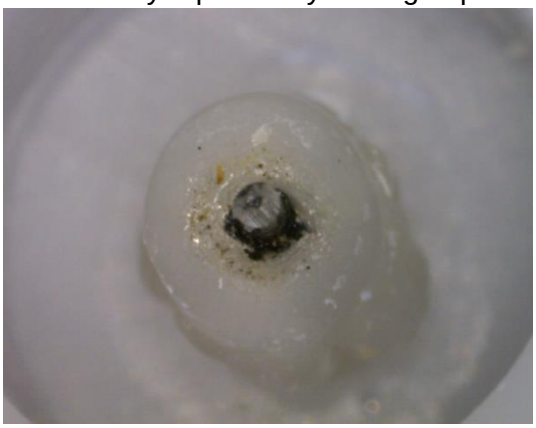
The equipment does not require particular cleaning operation but it is advisable that the following general rules be followed:

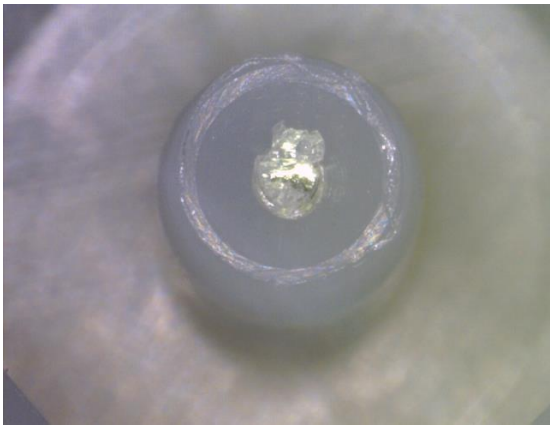
a. Keep the working area clean by using vacuum cleaners to remove dirt and dust.
b. Handpiece and tip must be cleaned as described at the related chapter.
c. Use a soft cloth to clean the metal or plastic surface of the machine.
   Take care not to damage the safety labels.
d. Do not use sharp instruments for the areas difficult to clean.
e. Do not use aggressive detergents.
f. Clean and disinfect the glasses only with soapy water. Do not use alcoholic solution to avoid any damage to the lenses. For more information refer to the leaflet inside glasses bag.
g. Do not clean and insert fingers or any other object inside the optical cavity of the diode.

8.3. CHECK AND CLEANING OF TIP AND HANDEPIECE

In general, damaged or dirty tip can due to severe failure of handpiece, optical fiber and laser source.

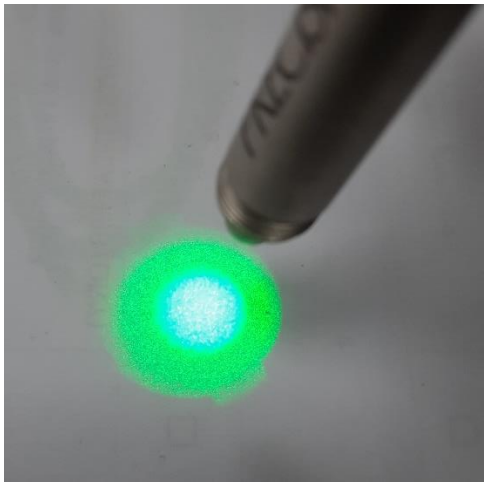
Verify the tip before each use.The pictures below show example of damaged tip (input section). Immediately replace any damaged part.





If low power is detected and tip are in good conditions, it is possible to check the handpiece lens.

- Verify the shape and intensiti of aiming beam, no black dots must be present
- Using a thermal paper, shoot laser at 1W and verify the paper is burned

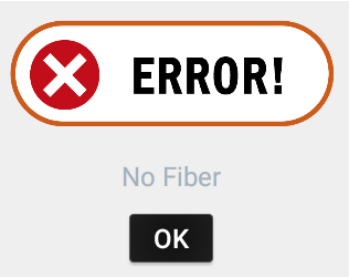


LENS WORN / DAMAGED

- Low intesity light
- Spot shape with black dots and not clean

9. SYSTEM ERRORS

A pop-up message will appear whenever a system error occurs.

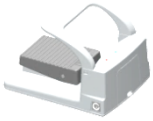


ERROR	DESCRIPTION
Interlock	If an external interlock network is not present, verify the interlock check is disabled. If an external interlock network is present verify that the event is under control (for example, the opening of a door) or check that the connections are correct
Footswitch	Verify the Bluetooth footswitch is correctly synchronized with the device. Repeat the synchronization procedure if necessary. Verify the footswitch is switched-on and the batteries are charged. Connect the cable and test the footswitch
Fiber	Verify the fiber supplied is correctly inserted in the appropriate socket.
Release footswitch	If footswitch is pressed it is not possible to enable the READY mode. Release the footswitch and try again.
Emergency button	The STOP button has been pressed; press OK to reactivate the device.
Overtemperature	The diode temperature is too high; the device stop automatically. Switch off the device and let it cool down for few minutes. Verify the device is not close to a heating source.
Communication error (CPU2)	Communication error between Android and microprocessor. Switch off and on again the device.

Contact your service assistance if the error persists

10. SPARE PARTS

Product	Code	Product	code
DOCTOR SMILE WISER 3 LASER	**LA12D001.x** 	**HANDPIECE**	**LAFIO022.2** (for LA12D001.1) **LAFIO022.3** (for LA12D001.5) 
HANDPIECE COVER	**LOMAN042.1-A/NC** 	**SAFETY GOGGLES**	**LOEYW002.0** (for LA12D001.1) **LOEYW022.0** (for LA12D001.5) 
BIOSTIMULATION TIP	**COFIL0057-L/NC** 	**LARGA AREA WHITENING TIP**	**LAACS099.3** 
HANDPIECE LENS CLEANER SWAB Box 25 pcs	**LAACS072.25** 	**BENDING TIP TOOL**	**LAACS056.2** 
FLAT TOP HANDPIECE	**LAFIO028.1** 	**REVIVE HANDPIECE**	**LAFIO030.1** 
BATTERIES FOR PEDAL WIRELESS **3 pcs**	**CEBAT0003** 	**RECHARGEABLE BATTERY**	**CEBAT0020** 
INTERLOCK	**LAACS041.1** 	**FIBER HOLDER**	**LMDGN075.1** 
EXTERNAL POWER SUPPLY	**MAALI074.0** 	**CABLE FOR POWER SUPPLY**	**CECAV0004** 

WIRELESS FOOTSWTICH Bluetooth	**LAACS001.16** 	**WIRE PEDAL**	**LAACS001.7** 
LASER DANGER LABEL	**LAACS008.1** 	**METALLIC SUITCASE**	**MMCAS069.0** 

Product	Code
TIP SURGERY Box 4 pcs - green	**LATSU302.4** 
TIP IMPLANTS Box 4 pcs -white	**LATIM302.4** 
TIP THERAPY Box 4 pcs - black	**LATHE402.4** 
TIP ENDODONTICS Box 4 pcs - blue	**LATEN202.4** 
TIP PARODONTICS Box 4 pcs - yellow	**LATPA402.4** 

Product	code
DOCTOR SMILE LWS - WHITENING KIT  - 1 syringe LWS whitening gel 5 g (35% H2O2) - 1 syringe LWS desensitizing gel - 1 syringe LWS “liquid dam” - 3 Tip for whitening - 1 Tip for desensitizing - 1 Tip for liquid dam	**LPLWS004.1**
DOCTOR SMILE LWS DESENTITIZING GEL  - 1 syringe desensitizing gel 2 ml - 2 Tip	**LPLDS001.1**

11. SPECIFICATIONS

Manufacturer	LAMBDA SpA Via dell'Impresa - 36040 Brendola (VI) - Italy
Models	LA 12D 001.1 (635-808-976 nm) LA 12D 001.2 (635-808-915 nm) LA 12D 001.3 (450-808-976 nm) LA 12D 001.4 (635-450-976 nm) LA 12D 001.5 (635-450-808 nm) LA 12D 001.6 (976 nm) LA 12D 001.7 (808 nm) LA 12D 001.8 (450 nm)
Power supply input voltage	100 ÷ 240 V ~
Power supply input frequency	50 ÷ 60 Hz
Max absorbed current	1.5 A
Power supply output	15 V ⎓ - 6.7 A max
Power supply voltage	15 V ⎓
Max output current	6.0 A
Wavelength	635-808-976 nm - LA 12D 001.1 635-808-915 nm - LA 12D 001.2 450-808-976 nm - LA 12D 001.3 635-450-976 nm - LA 12D 001.4 635-450-808 nm - LA 12D 001.5 976 nm - LA 12D 001.6 808 nm - LA 12D 001.7 450 nm - LA 12D 001.8
Max optical power output	25 W - LA 12D 001.1 25 W - LA 12D 001.2 25 W - LA 12D 001.3 21 W - LA 12D 001.4 21 W - LA 12D 001.5 16 W - LA 12D 001.6 16 W - LA 12D 001.7 4 W - LA 12D 001.8
Power sensitivity	± 20%
Aiming beam	< 2 mW @ 520 nm
Power indication	Digital 0.1 W ÷ 25.0 W
Power resolution	0.1 W
Emission mode	Continuous / pulsed
Pulse type - pre-set values -	Adjustable: pre-set values or manual
	CW: Continuous wave
	MP: T_{on}=200ms; T_{off} = 500ms
	SP: T_{on}=10ms; T_{off} = 10ms
	SNP: T_{on} = 500µs; T_{off} = 1000µs
	SSP: T_{on} = 20µs; T_{off} = 20µs ~ 25000 Hz
	PSP: T_{on} = 30µs; T_{off} = 70µs
	BOOST: T_{on} = 20µs; T_{off} = 40µs

Pulse duration sensitivity	± 5%
Pulse duration (Ton)	Adjustable 20 µs - CW
Pulse intervals (Toff)	Adjustable 20 µs - 999 ms
Emission duration	Continuous or by timer
Adjustment of duration of emission	adjustable OFF ÷ 300 sec
Timer sensitivity	variable
Footswitch	Wireless pedal standard Bluetooth @ 2,4 GHz, module type Low-Energy
External connections	Pedal + interlock
Battery	11.2 V – 7200 mAh (Lithium ions - rechargeable)
Optical fibre connector	SMA 905
Optical fibre length	2 m
Optical fibre connector	200 µm
Maximum power output	25 W
Output beam divergence (N.A.)	12,7° (0,22 rad)
Operation mode	Discontinuous operation: 3 min/ON – 2 min/OFF
Envoirenment pollution degree	2
Power supply	Double alternative supply: • Connected to network through external power supply • Internal batteries (“internally powered”)
Laser class	4
Electrical insulation class	I (only if device connected to its certificated power supply)
Applied part	Type B -
Medical class	IIb
Protection against anaesthetics	This device is not suitable for use with a mixture of inflammable anaesthetic with air, oxygen or nitrogen dioxide
Device IP level	IPX0 (no protection from liquids)
Footswitch IP level	IPX1 (only protection from vertical liquid drops)
Working conditions	TEMP.: 10 ÷ 30 °C HUMIDITY: 30 ÷ 75% ATM. PRESSURE: 700/1060 hPa
Storage conditions	TEMP.: 10 ÷ 30 °C HUMIDITY: 30 ÷ 75% ATM. PRESSURE: 700/1060 hPa
Cooling system	Air
Dimensions	230 x 155 x 160 (A x L x P) [mm]
Weight	1,87 kg ca.

12. SAFETY LABELS

On the laser there are safety labels that include danger notes for the operator and information about the laser device's characteristics.
These labels must always be kept in good conditions and should be replaced if they are damaged.
Use mild products when you clean the laser.

ET-1: Plate data and CE conformity
ET-2: Connections symbols
ET-3: Laser class and emission data
ET-4: Electrostatic discharge
ET-5: DANGER Laser radiation
ET-6: Batteries data and storage requirements
ET-7: Footswitch label
ET-8 Storage requirements


Interlock connector


Pedal connector


Read user manual before use

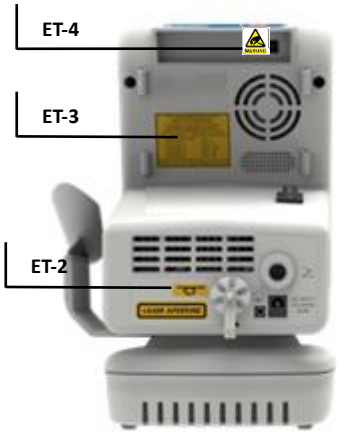

Recycling - Use separate collection

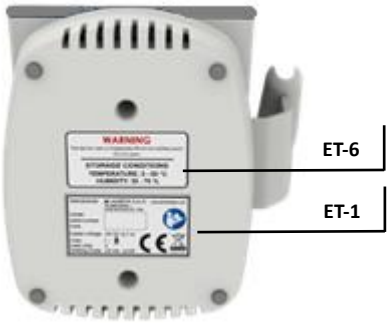

Manufacturer

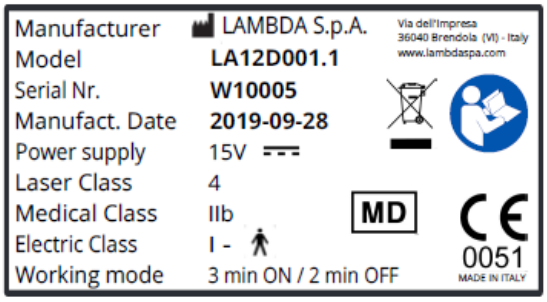

DC voltage


Applied part Type B

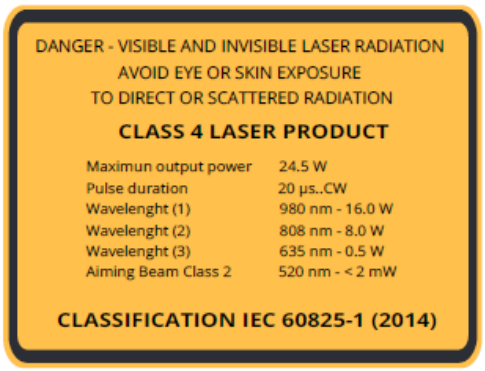
MD
Dispositivo medico



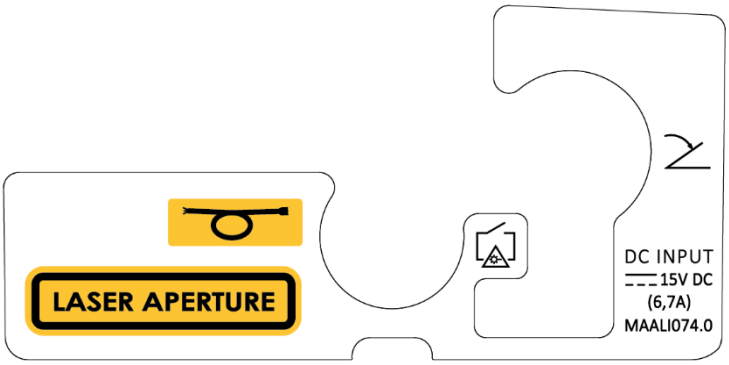




ET-1



ET-3



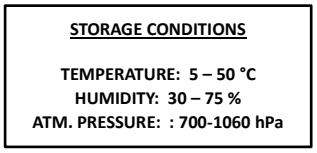
ET-2

ET-4

ET-5

ET-6

ET-7



ET-8

13. EMC REGULATIONS (ELECTROMAGNETIC COMPATIBILITY)

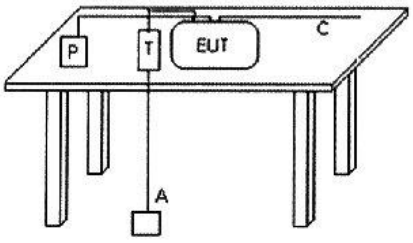
The existence of regulations for the electromagnetic compatibility is essential to ensure the safety of the appliances and systems, in that there are electromagnetic phenomena with various levels of intensity present in the area where these appliances are normally used.
This means that to ensure the electromagnetic compatibility, the device must function correctly within its foreseen working environment.
The electro-medical appliance warrants particular precautions with respect to EMC (Electromagnetic Compatibility) and must be installed and put into service in conformity with the EMC information contained in this manual.

	ATTENZIONE
	portable and mobile radio-communication appliances can affect the operation of the device.

	ATTENZIONE
	the device must not be used near or placed on or underneath other appliances.

List and set-up of linkable cables to the appliance

A - Power cable (2m);
C - Interlock cable (5m);
P - Footswitch cable (2.9m);
T - Power supply;
EUT – laser device.



	ATTENZIONE
	do not use cables or accessories different from those specified. Use only cables and accessories supplied with the equipment or otherwise sold by the manufacturer. Use of alternative cables may cause possible malfunction, an increase in emissions or a reduction in immunity of the device..

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in industrial (professionals) and hospital establishments. If used in domestic establishments this device could not guarantee an adequate protection for radiofrequency communication systems. The user could be required to use special devices against radio noise.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2,4,5,15kV in air	±8kV contact ±2,4,8,15 kV in air	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 IEC 61000-4-4	±2kV Frequency 100KHz	±2kV Frequency 100KHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 cycle at 0,45,90,135,180, 225,270,315° 0% U_T; 1 cycle 70% U_T; 25/30 cycles Single phase at 0°	0% U_T; 0,5 cycle at 0,45,90,135,180, 225,270,315° 0% U_T; 1 cycle 70% U_T; 25/30 cycles Single phase at 0°	Mains power quality should be that of a typical commercial or hospital environment.
	0% U_T; 250/30 Cycles	0% U_T; 250/30 cycles	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – recommended separation distance			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3V 150kHz to 80MHz 6V in ISM da 150kHz a 80MHz	3V 6V	Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance not lower than 30cm**
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.7GHz	3V/m Professional environment	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Notes: (1) At 80MHz and 800MHz, the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m. c The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			

Recommended separation distances between portable and mobile RF communications equipment and the laser device

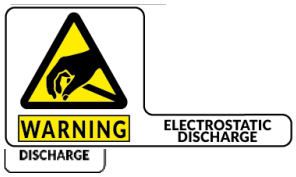
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the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

Test frequency	Band	Service	Modulation	Max power	Distance	Immunity level
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380-390	TETRA 400	Pulse modulation (b) 18 Hz	1,8	0,3	27
450	430-470	GMRS460, FRS 460	FM (C) Deviation ± 5KHz sinusoidal 1 KHz	2	0,3	28
710	704-787	LTE Banda 13, 17	Pulse modulation (b) 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Banda S	Pulse modulation (b) 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; TETRA CDMA 1900; GSM 1900; DECT; LTE Bande 1, 3, 4, 25; UMTS	Pulse modulation (b) 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450. LTE Banda 7	Pulse modulation (b) 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation (b) 217 Hz	0,2	0,3	9
5500						
5785						

(b) The main frequency must be modulated using a square wave signal with a 50% cycle

(c) As an alternative to FM modulation, a 50% pulse modulation with a frequency of 18 Hz can be used, as this does not represent the actual modulation but the worst condition.

13.1. ESD (ELECTROSTATIC DISCHARGE)



WARNING**:** pin connectors identified with the ESD warning label must not be touched or connected unless all safety indications are implemented. Only technicians authorized properly trained on ESD risks may perform operations on such places**.**

Technicians must firstly verify that the power supply is properly grounded and free from defects.

The device is provided with USB connection only for trained personnel who use safety tool against the risk of electrostatic discharge.
During use they must wear a grounding bracelet, grounded to the device ground connectors. The connection to connectors must only be done with the device turned off, but with the power connector inserted and the bracelet grounded.

To disconnect connectors proceed inversely: turn off the device, without removing power supply. Then remove grounded ESD bracelet carefully.

13.2. DEVICE DISPOSAL

European standard 2012/19/UE about Waste Electrical and Electronic Equipment (WEEE)

This symbol on the product or on its packaging indicates that this product shall not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

The recycling of materials will help to conserve natural resources. For more detailed information about recycling of this product, please contact your local city office, your household waste disposal service or the shop where you purchased the product.

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14. WARRANTY

The manufacturer guarantees its clients that the products are free of defects and are guaranteed for two years. This warranty is not valid for any defect, fault or damage caused by improper use or inadequate maintenance and care. The manufacturer is not obliged to provide assistance under warranty to repair damage caused by other personnel not authorised by the manufacturer.
In order to obtain assistance under this warranty, clients must contact the manufacturer to advise the problem.

All consumable parts such as fibres, tips and the handpiece are not covered by the warranty, included workman time required for the reparation and components replacement.

The client is responsible for transport and possible insurance expenses for the return of the products to the service provider. The manufacturer will repair the products under warranty with transport costs at customer's expense.

Lasers shipped without the original packaging will not be accepted for any reparation, even under warranty.
Damage caused in transit/transport or negligence is not covered by the warranty.

In the case of an indication of a fault, a label has to be placed on the device container with a brief description of the faults encountered.
In order to speed up the return of the device, indicate the name and telephone number (area code and telephone number, or direct number and/or department extension) of the client.

Under this warranty, the manufacturer will repair or exchange any product returned to the Client Service Department during the warranty period, once the technical service has examined the product and found it to be defective at the fault of the manufacturer.
The manufacturer is not responsible or at fault or with good reason, for any damage or unforeseen, direct, indirect, accidental or consequent delays during the period necessary for the repair of the equipment.

CUSTOMER SERVICE CONTACTS
service@lambdaspa.com
+39 0444 349165
+39 342 8672177