LITE MEDICS

THE DENTAL DIODE LASER

USER MANUAL

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This user manual is issued with reference to the product LITEMEDICS diode laser.
This laser equipment is a medical device, and its application field is:

- Dentistry

The manufacturer is not responsible for the direct and indirect effects due to the use of the system. These effects remain under the direct responsibility of the medical staff carrying out the operation.
We therefore recommend the user to respect the following instructions:

- The system must be used in conformity with the instructions contained in this manual, concerning both safety measures and use of the system;
- The installation, and any alteration, recalibration and maintenance must be made solely by qualified staff authorized by the manufacturer;
- The electric system of the environment to which the laser is meant for must be in accordance both with the IEC regulations and the local prescriptions in force;

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 the manufacturer will be enabled to repair or maintain those parts of the system that the manufacturer consider as possible to repair.

Disposal of Old Electrical & Electronic Equipment (Applicable in the European Union and other European countries with separate collection system)

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.

CE conformity marking

CE 0476 This product is marked with the CE label according to the European standard applicable for medical devices: CEE 93/42.
The number 0476 reported under this label indicates the competent body that has issued this certification.

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1. INSTALLATION

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. It is important to immediately notify the carrier of all possible non-conformities found during checking. Please verify:

- the number of parcels and corresponding codes.
- the external packaging conditions and inside for damaged parts.

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.

FACILITY REQUIREMENTS / WORKING ENVIRONMENT

In the room previously prepared for the laser use, remove all unnecessary inflammable material and verify that the electric power panel is in conformity with the current safety norms. Check the electric power to see if it matches the laser system's electric requirements. The laser place of use will have to be identified with the appropriate labels supplied together with laser accessories.

- Place the laser on a steady, even surface
- Keep the laser in a dry place with a temperature from 15° to 30°C and 30% to 70% relative humidity
- Be sure that the device has been maintained in these environment conditions for at least 2 hours before turning the device on.
- It is advisable to keep the laser away from direct sun light, to avoid possible system overheating.
- Do not place the laser next to walls or other locations that could decrease air exchange.
- 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.

INSPECTION OF ELECTRIC CONNECTIONS/POWER SUPPLY

It is highly 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 or multiple sockets of any type. Moreover, the electrical network must provide an efficient grounding protection.

The power supply provided with the LITEMEDICS laser fulfils the CEI EN 60601-1 regulation. Such power supply has the following characteristics:

Input voltage: 100 – 240 AC	Output voltage: 12 V DC
Frequency rate: 47 – 63 Hz	Max output current: 5.25 A

CAUTION: never use a different power supply from the one provided. In case of malfunctioning or any other necessity address the supplier and order the same power supply or one equivalent to the one provided with the equipment.

SHIPPING AND HANDLING

Should you need to move or ship the laser, it is recommended to scrupulously follow these indications:

- Always use packaging material supplied on delivery for transport. ANY LASER SHIPPED WITHOUT THE ORIGINAL PACKAGING WILL NOT BE ACCEPTED FOR SERVICE.
- The power switch must be turned off.
- Disconnect all cables connected to the laser system main body and in particular the power cable.
- the fibre connector on the laser and on the fibre must be covered with the special cap supplied.

GENERAL SAFETY MEASURES

Failure to comply with precautions and warnings described herein may lead to exposure to dangerous optical radiation sources. Please comply with all safety instructions and warnings.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

DANGER: Do not use this unit if you suspect it of functioning improperly or other than described herein.

CAUTION: This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating of the device may help to eliminate the interference.

Follow these safety instructions before and during treatments:

All operatory entrances must be marked with an appropriate laser warning sign included .

Do not operate in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser is used. Attention should also be drawn to the danger of ignition of endogenous gases.

All persons present in the operatory must wear protective laser eyewear.

CAUTION: Periodically inspect laser eyewear for pitting and cracking. For replacement or additional protective laser eyewear, please contact your authorized dealer.

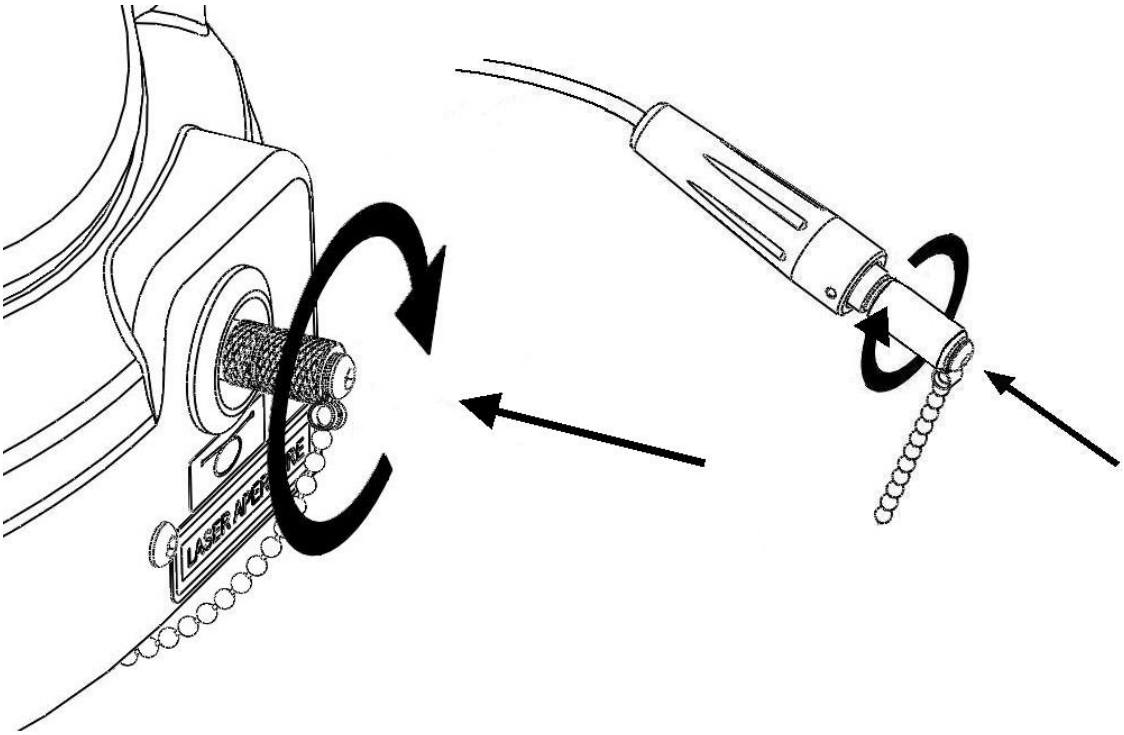
- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam at anyone's eyes.
- Press STANDBY (Standby button) on the control panel before turning off unit.
- Always press STANDBY on the control panel before exchanging handpieces or disposable tips.
- Move the toggle switch (located on rear panel) to OFF position before leaving unit unattended.

DANGER: Do not open unit housing at any time. Danger from optical radiation may exist.

WARNING: Be aware that the metal / plastic cannula on the tips may become hot during use. Avoid contact of the cannula with any tissue.

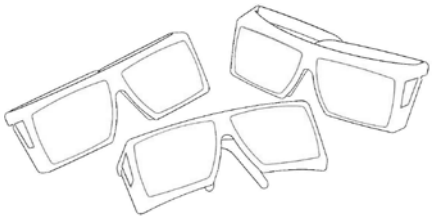
WARNING: Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces, the laser beam will reflect and create a potential hazard.

WARNING: Never leave the connector plug of the diode's optical fibre without protection. The optics placed inside this port is very delicate and subject to break easily in case of penetration of liquids, smoke, steam or things of other kind. Absolutely avoid putting fingers inside the laser aperture or looking directly inside it.



WORKING AREA

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



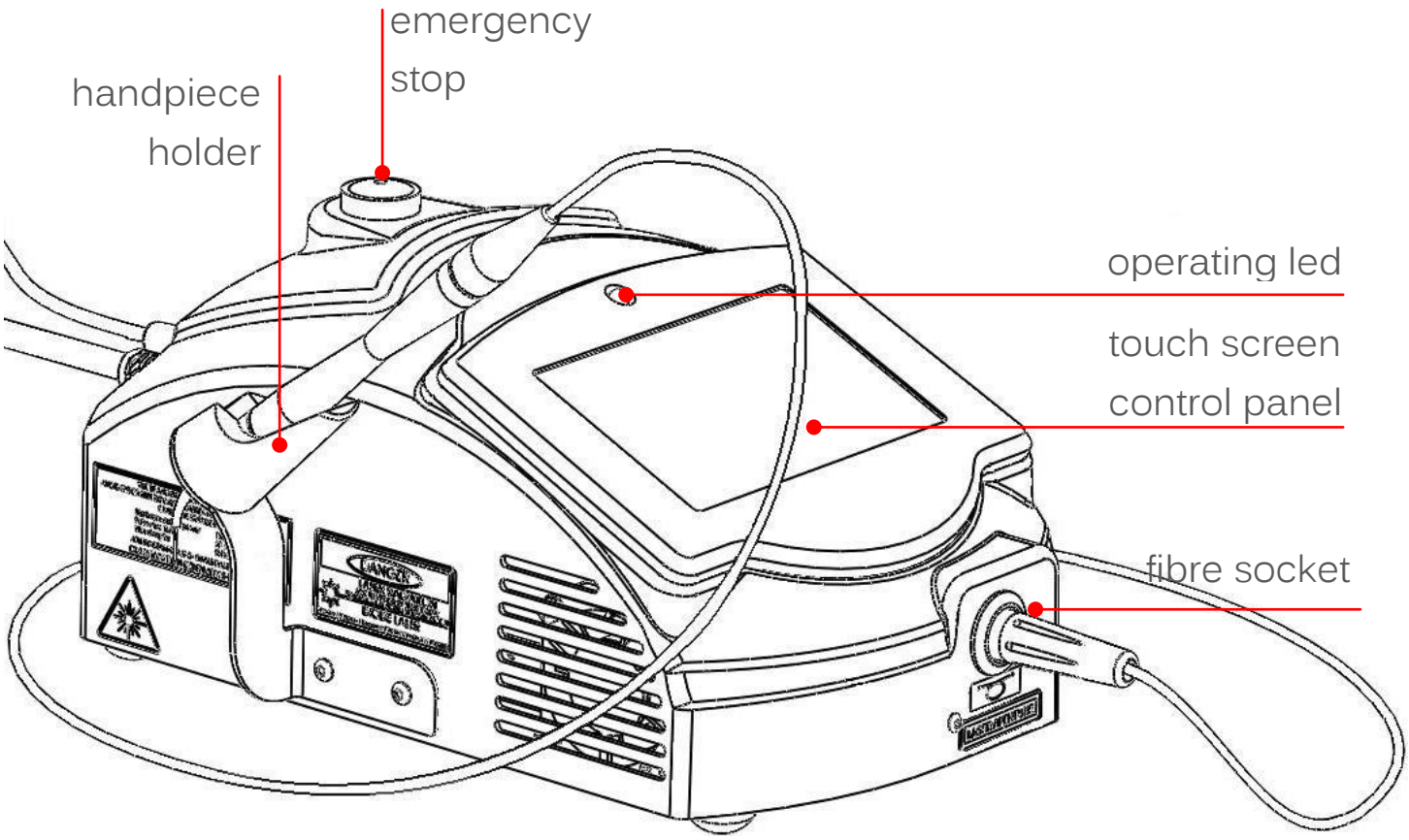
- The personnel authorised to work inside the laser working area must wear protective eyewear
- Never direct the laser beam towards the eyes.
- Never look into the fibre connector.
- The fibre connector must always be covered either by the fibre or the protection cap
- Eliminate from the operative area 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 anaesthetic or gases such as oxygen or nitrous oxide. The saturation of oxygen may ignite many types of materials such as cotton or wadding exposed to laser radiation. It is also important that all inflammable solutions normally used to disinfect be allowed to evaporate before using the laser appliance.

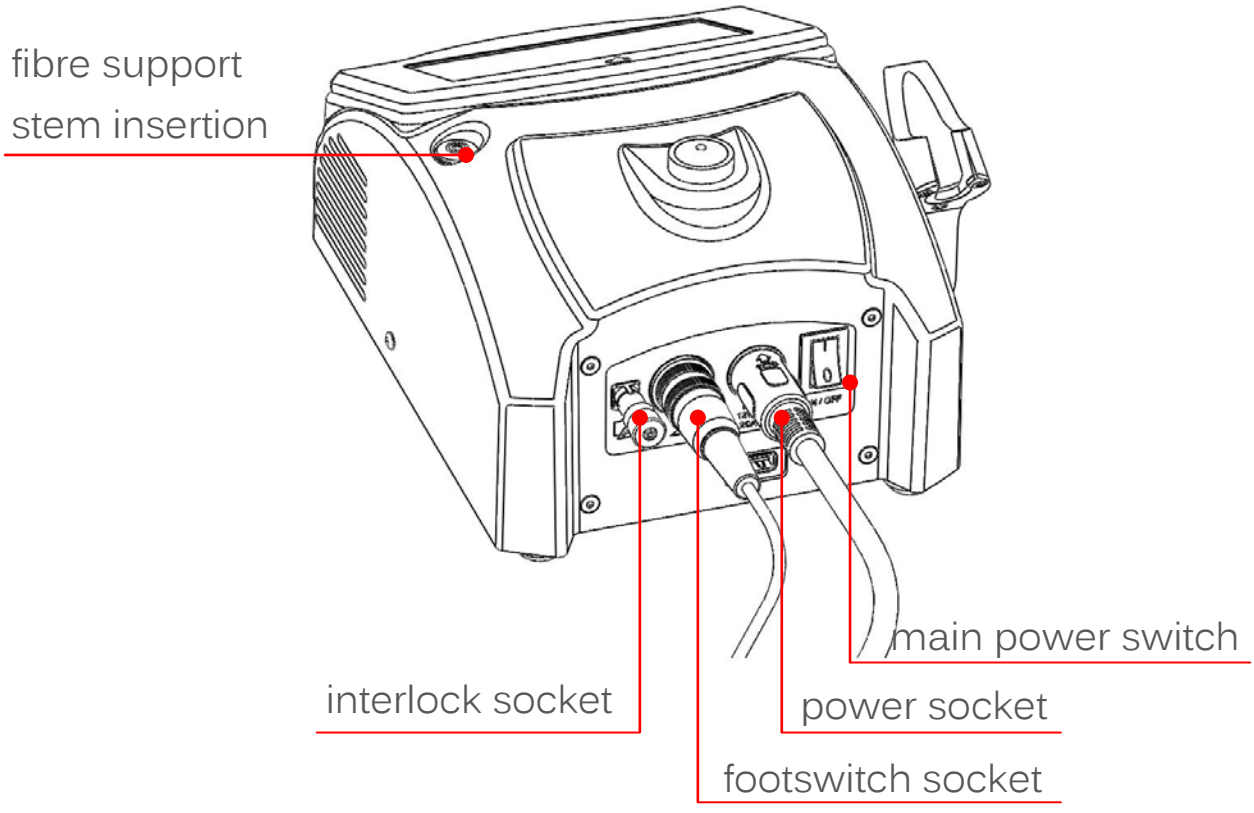
INDIVIDUAL SAFETY MEASURES - OCULAR RISK

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, patient and for the people present in the work area.
The protection glasses provided are in accordance with the European norm EN 207 and have an Optical Density 5 at the wavelength of emission from the diode.

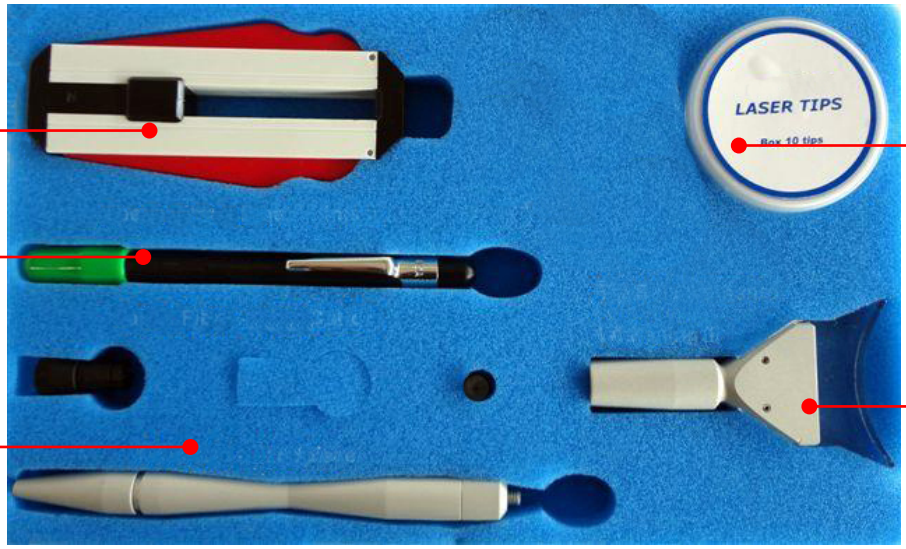
Use solely glasses with the same specifications of those provided.

OVERVIEW OF THE DEVICE





ACCESSORY KIT



STERILISATION OF PARTS IN CONTACT WITH THE PATIENT

WARNING: on delivery of the device the handpiece, the optic fibre and all the other components supplied in the packaging have not been sterilised. Before each use ensure that these parts are sterilised.

All the parts that can come into contact with organic parts of the patient can and must be sterilised. In particular the parts of the system that can be sterilised are:

- the handpiece (bottom cap, handpiece body, lock ring)
- the optic fibre

The parts that cannot be sterilised are:

lens for whitening
single use plastic tip

WARNING: All components must be separated before sterilization to remove any possible solid organic residue.

Sterilization can be carried out according to the standard method in autoclave (at 121°C for 20 min). The number of cycles of sterilisation in autoclave is limited and we suggest that the operator make a careful inspection of the sterilised parts after each cycle to verify their integrity:

- handpiece: verify if there are signs of abrasion, cracking or changes in size, structure and/or colour.
- optic fibre: verify that there are no signs of deterioration, cracking or holes.

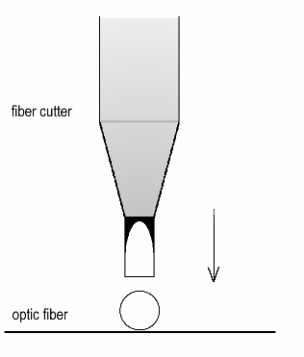
In case of deterioration or in case of doubt, replace the components.

Do not dispose of the fibres and 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.

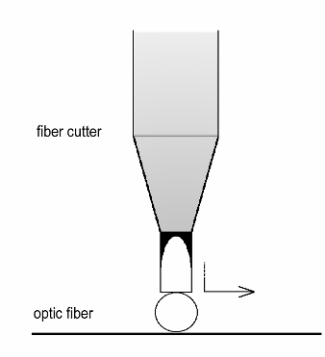
FIBRE PREPARTION

For optimal laser use the optic fibre must be cut after each use to renew the surface for perfect lasing. Remember to activate the fibre after each cut for optimal surgical performance when required by the protocol and when using special handpiece terminals.

1. **Skinning:** insert the fibre into the fibre-skinner. Hold the end of the fibre in one hand and the fibre-skinner in the other: press and gently pull the fibre-skinner. We recommend skinning the fibre for at least 3cm. Use the special ruler printed on the skinner for reference.
2. **Cutting:** lay the nude fibre on a smooth and hard surface. Place the fibre-cutter perpendicular to the nude fibre at 1 cm from the end. Apply a slight pressure and make a single cutting movement to avoid splitting. Do not use excessive pressure. If the cut is not accurate at the end of the fibre, it will cause a lack of performance of the laser and bad results in treatments.

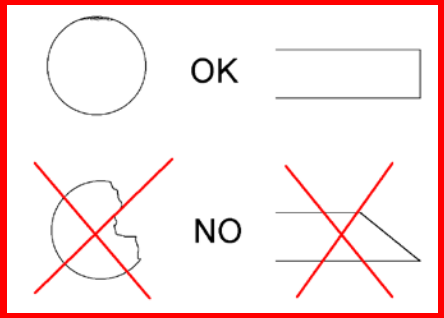


Step 1: place the cutter perpendicular to the fibre



Step 2: make a single cutting movement with a light pressure

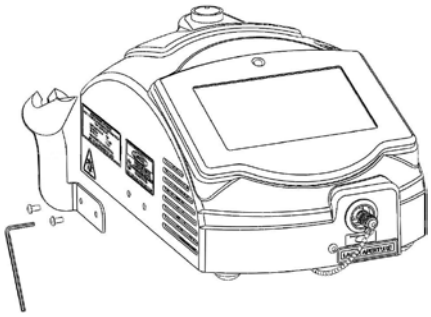
3. **Splitting**: split the fibre with both hands by bending it on the cut spot.
4. **Checking:** check the surface of the fibre with the naked eye, so as to be sure that the cut is neat and even. If the cut is proper, turn on the aiming beam and point the fibre on a white surface to check the red spot: you must see a good red circle.
5. **Activation (Initiation):** Before starting, activate the fibre by switching on the laser beam and directing it for a few of seconds against a dark coloured scrap of paper.



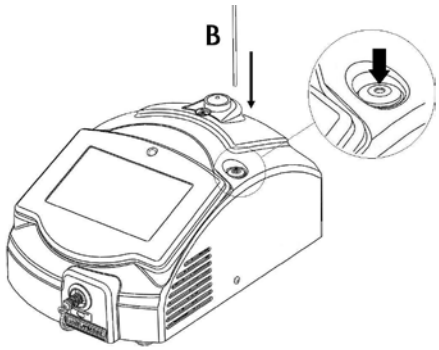
WARNING: the aiming beam is a good means of verifying the integrity of the system . If the beam spot is missing from the distal extremity of the transmission and if the intensity is reduced or seems diffused, this can indicate that the transmission system has deteriorated or is not working properly.

PRE-OPERATIVE INSTALLATION

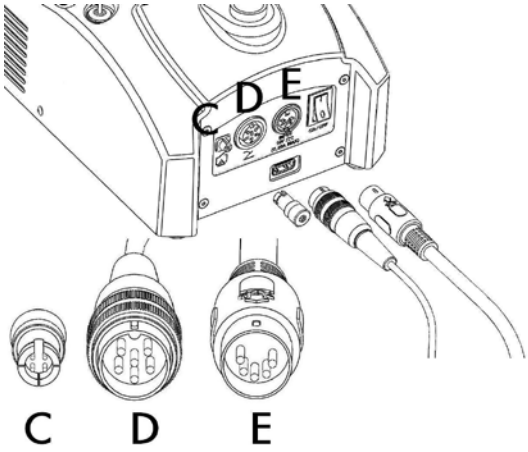
See the included quick -start guide for the step by step illustrated procedure.



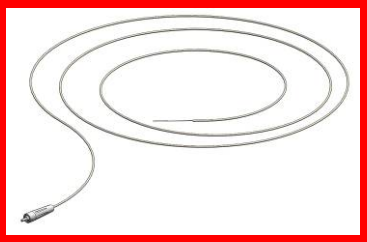
1. Place the laser body on a flat steady surface. Attach the handpiece holder to the laser body using the screws and key supplied.



2. Insert the fibre holder into the appropriate hole B on the laser body.



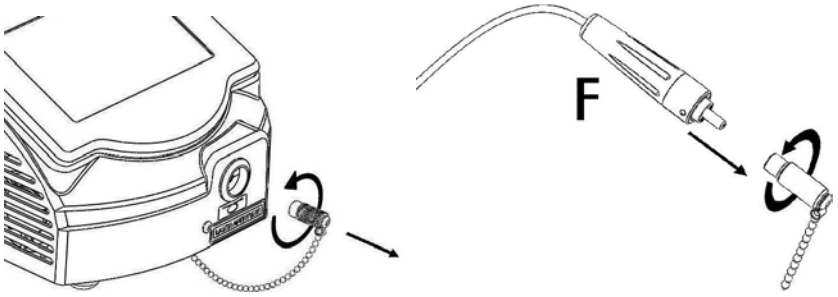
3. Insert the external interlock C, the footswitch D and the power cable E in the appropriate sockets on the back of the device. Screw the footswitch connector to the socket.

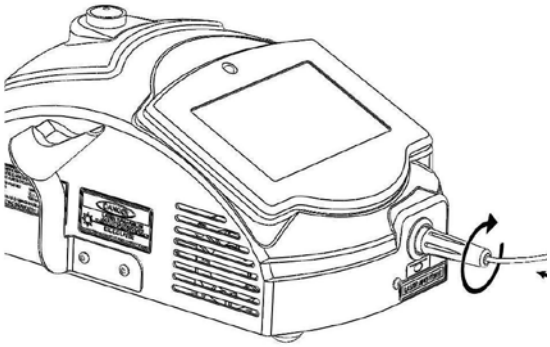


CAUTION: Potential hazards may arise when inserting, bending or improperly securing the optical fibre. If the manufacturer recommendations are not scrupulously followed it may lead to damage to the fibre, the delivery system and/or harm to the patient or user.

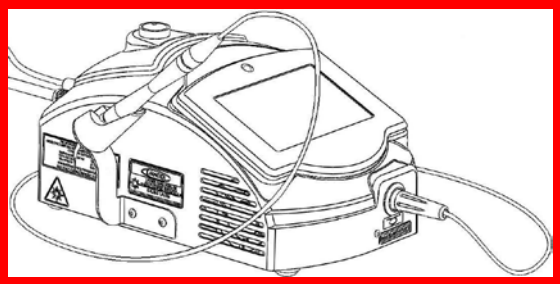
CONNECTING THE FIBRE TO THE LASER

1. Remove the protection caps on the fibre and on the laser body.





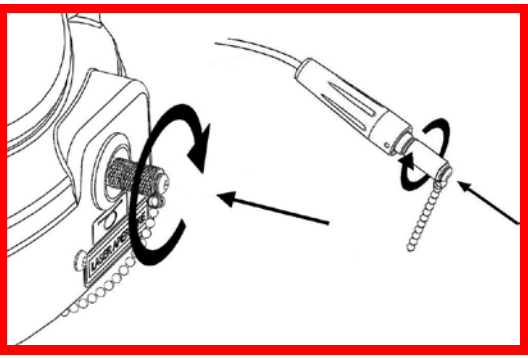
2. Plug the fibre connector into the socket on the laser body and turn the connector clockwise until it comes to a complete stop.



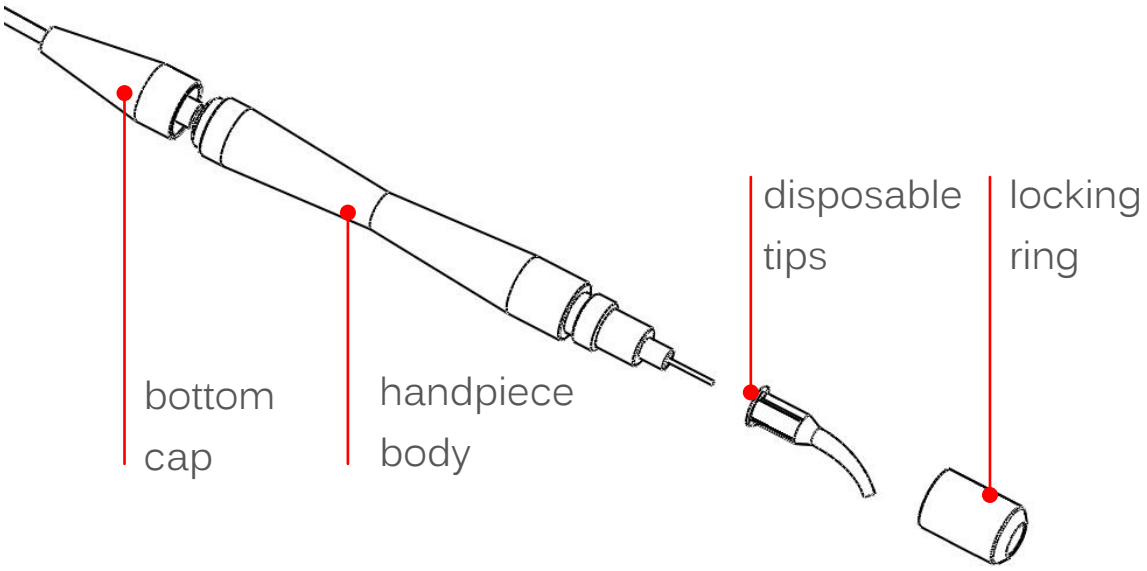
CAUTION: The optical fibre is very fragile. Avoid leaving the fibre where it might be trampled or shocked. Do not remove the fibre unless it is necessary for system transport or sterilisation.

Use the metal support included in the accessories to hold the fibre and insert the handpiece in the holder when the laser is not in use.

CAUTION: always replace the protection cap on the fibre socket of the laser body when the fibre is not inserted. Any dust or gas that enters the laser will damage the laser source.



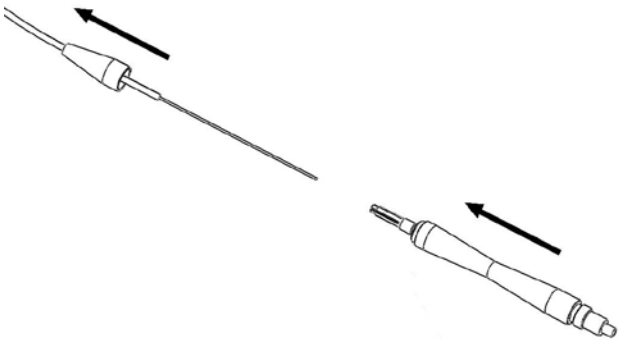
THE HANDPIECE



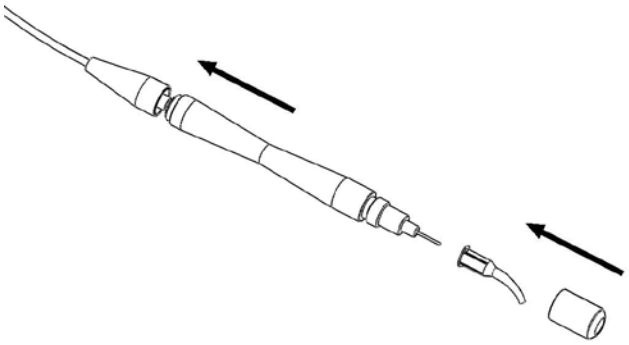
INSERTING THE FIBRE INTO THE HANDPIECE

WARNING: always CLEAN THE FIBRE with ordinary disinfectant before inserting it in the handpiece.

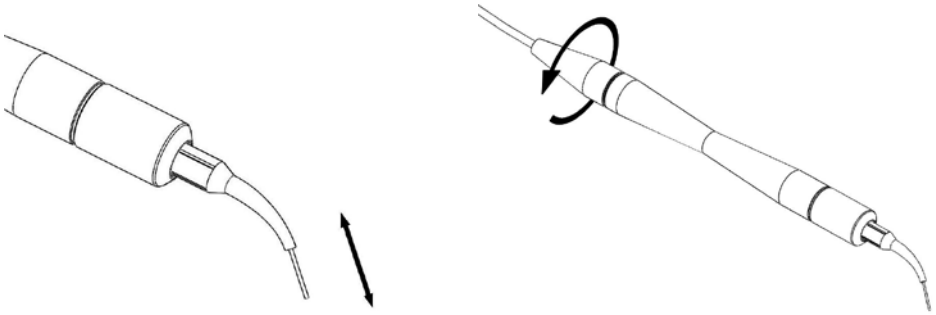
1. Hold the body of the handpiece and unscrew the bottom cap. Insert the optical fibre through the hole of the bottom cap and through the base of the handpiece until it goes out of the other end.



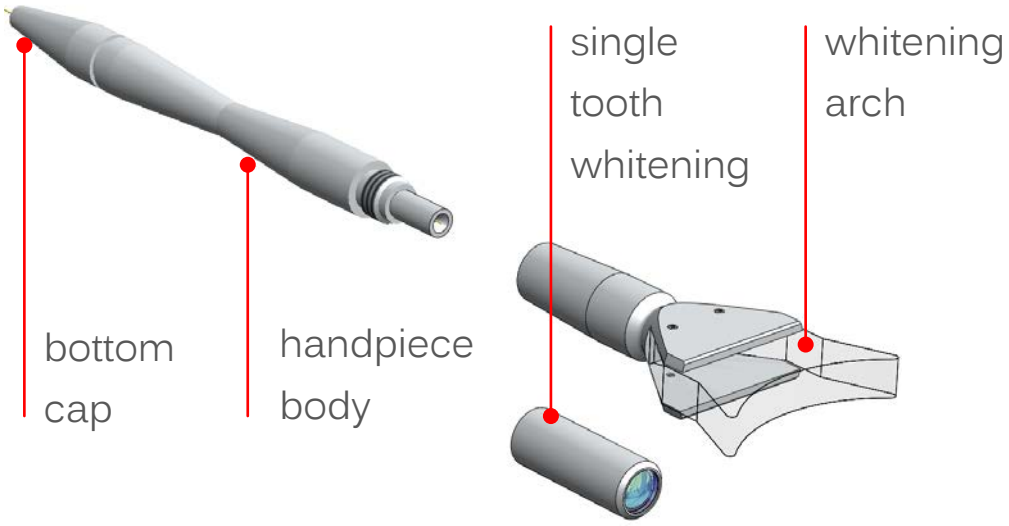
2. Adjust the fibre so that it sticks out of the handpiece to the desired length, then screw in the bottom cap slightly. Insert the fibre through the tip and then insert and screw the locking ring.



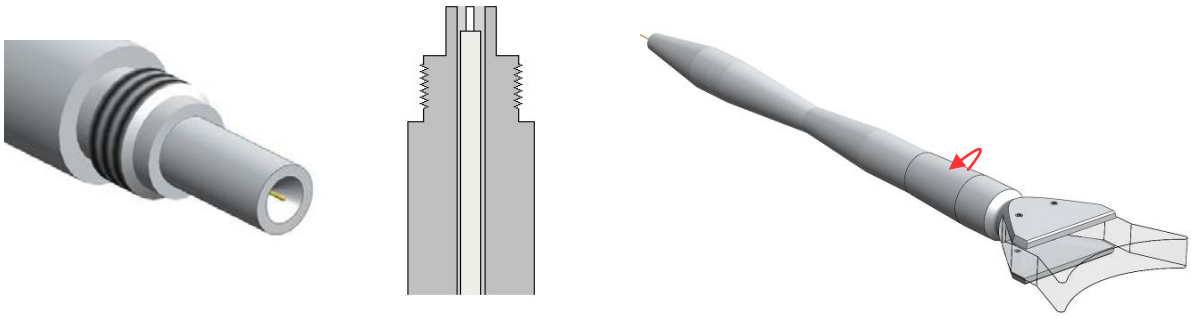
3. If necessary, adjust the output length of the fibre by unscrewing the bottom cap.



WHITENING HANDPIECE PREPARATION



Prepare the fibre with a good cut. Remove the locking ring from the handpiece.



2. Insert the fibre into the handpiece until it reaches the top. The fibre must not exit the border of the adaptor, as shown in the diagram. If necessary, adjust the output length of the fibre by unscrewing the bottom cap

3. Insert and screw the large whitening arch (or the small lens - optional -for single tooth whitening.

STARTING THE LASER

WARNING: Before following the system set up procedure ensure that all safety measures described in this manual have been put into place.

- Verify that the power cable is connected.
- Verify that the interlock is inserted.
- Insert the optical fibre
- Turn on the laser using the main switch on the rear of the machine

1. The system shows a start up screen. **Note**: the start message may be different from this one and may be modified by manufacturer without notification.

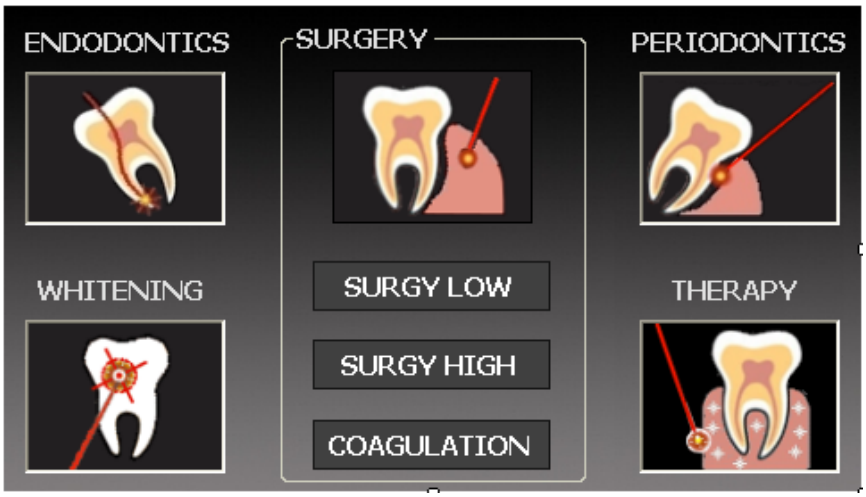
2. Insert the default password 11111

3. The system will verify that the footswitch and interlock are in place. If they are not the following error warning will appear.

4. If you wish to change the language of your laser, press the icon on the lower left hand corner of the password screen before entering the password. Select from the available languages.

THE MAIN PANEL

The main panel is a colour touch screen display that allows direct treatment selection, laser activation and protocol visualization.



WARNING: Any adjustments or procedures different from those specified herewith, can cause exposure to dangerous levels of radiation.

WARNING: Use your clinical judgement to determine all aspects of treatment including but not limited to the pre-set laser treatment. Closely observe and monitor clinical effects and use your judgement to determine the correct approach for the operation.

TREATMENT SELECTION

The LITEMEDICS laser contains the following preset treatments:
ENDODONTICS
PERIODONTICS
WHITENING
THERAPY
SURGERY (LOW, HIGH, COAGULATION)

To select the desired treatment simply press the icon or the name of the treatment.

TREATMENT CONTROL PANEL

A screen containing all the laser parameters will appear. On the upper left hand the pulse type and timer are shown; in the centre the power level and the average power level; on the lower right hand corner is the info button for protocol access; the central button for laser activation; to return to the main screen press the arrow on the bottom left hand corner.

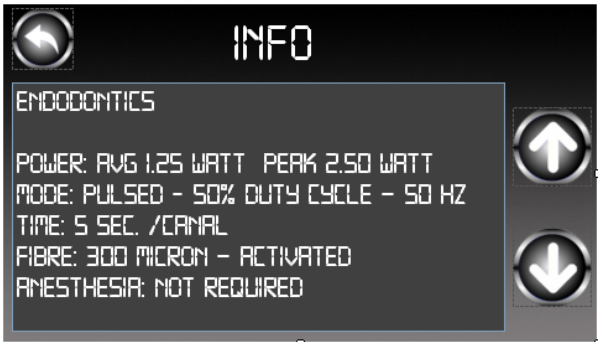
POWER SELECTION

The power dial shows the preset power and the average power emission based on the pulse type.

Use the + and – buttons to change the power settings.

TREATMENT INFO

To read more about the selected treatment directly on the screen press the information icon.



This will open a screen about the selected treatment, with a summary of laser parameters, useful clinical information and lasing tips.

With up and down arrows you can scroll the text. The left arrow takes you back to the treatment panel.

LASER ACTIVATION

CAUTION: Before beginning verify that all safety measures have been followed and the all personnel present are wearing appropriate eye wear.

Once you have selected the desired treatment, the system will be in the stand by mode (green).

- Push the *standby/ready/operate* key:

- From the s*tand by* state, the system will pass to the *ready* mode. The icon will turn yellow and the indicator lamp start blinking. The laser source is now active but operation is not possible.

- Press the s*tandby/ready/operate* key again. The icon will turn red and operation is now possible, since the footswitch is enabled.

The system will automatically deactivate the laser (will enter the STANDY BY mode) if it is not used for some minutes. Never leave the laser unattended when the laser source is activated. Turn off the laser when it is not in use. The system will go into stand by also if other keys are pressed or a different treatment is selected. Press the *standby/ready/operate* key again to restart lasing.

- Direct the handpiece to the targeted tissue;
- Press footswitch;
- The system will start to emit laser radiation and this is signalled both by sound and visible indicators (orange led). The system also shows on display a picture warning for laser emission.
- Release the footswitch to stop laser emission.

DEACTIVATING THE LASER SOURCE

Push *ready/stand by* key. The system will go into the stand by state and disable the footswitch. The system will go into stand by also if other keys are pressed or a different treatment is selected. Press the *standby/ready/operate* key again to restart lasing.

SWITCHING OFF THE SYSTEM / EMERGENCY STOP

Put the system in stand-by. Press the main switch on the back of the laser.

IN CASE OF EMERGENCY you can interrupt laser emission by pressing the red emergency button on top of the laser. Any pressure applied to this button will immediately block the system and the emission of radiation in progress. After pressing the emergency button do not forget to press the main switch.

LITEMEDICS LASER

specifications	
Input of power supply	100 – 240 VAC
Network frequency	47-63Hz
Maximum current absorbed by the network	0.5A (@230V)
Output of power supply	12VDC - 5.25A max
Supply voltage for the system	12VDC
Max absorption of the system	4.5A
Maximum power output on the work point	8W
Medical class	II B
Isolation class	I
Part applied	Type B
Protection against anaesthetics	This device is not suitable for use with a mixture of inflammable anaesthetic with air or oxygen or nitrogen dioxide.
Protection level IP	IPX0
Procedural use	Continuous with alternative load: active 5 min, pause 1 min.
Working conditions	TEMP.: 10 to 30 °C HUMIDITY: 30 to 75% ATM. PRESSURE.: 700/1060 hPa
Storage conditions	TEMP.: 5 to 50 °C HUMIDITY: 30 to 75% ATM. PRESSURE: 700/1060 hPa
External connections	Pedal; interlock
Cooling system	Air
Laser class	IV
Dimensions	150x200x120 (LxPxA) mm
Weight	1.7 kg ca

laser source	
Wavelength	980±10 nm
Maximum laser source power	8W
Wavelength of aiming beam	635±10 nm
Aiming beam power	1mW

emission	
Power indication	Digital from 0.1W to 8.0W, 0.1W step
Impulse mode	CW continuous emission MP: T_{on}=200ms; T_{off}=500ms SP: T_{on}=10ms; T_{off}=10ms SSP: T_{on}=20µs; T_{off}=20µs PSP:T_{on}=30µs; T_{off}= 70µs SNP:T_{on}=500µs; T_{off}=1ms BOOST: T_{on}=150µs; T_{off}= 350µs (optional)
Mode of emission	Continuous or by timer
Laser shutter	Foot Switch
Adjustment of duration of emission	from 1 to 99 seconds
Stability of emission power	± 20%

optical fibre	
Connector	SMA 905
Length	2 ÷ 3m
Diameter	300 µm (320 µm)
Maximum output power peak from fibre	12W
Output beam divergence (N.A.)	14° (0.22)

SAFETY LABELS

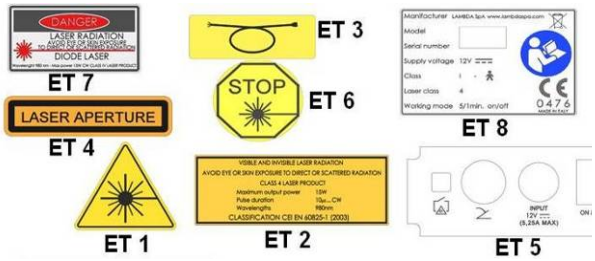
On the laser there are safety labels that include danger notes for the operator and information about the laser device's characteristics. These labels must always be kept in good conditions and should be replaced if they are damaged. Use mild products when you clean the laser.

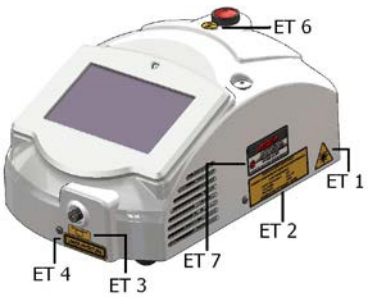
ET-1: Warning laser radiation
ET-2*: explanatory label
ET-3: laser aperture at the end of the fibre
ET-4: laser aperture
ET-5: rear label with symbol
ET-6: emergency stop
ET-7: laser radiation
ET 8: information


Caution! Consult the user manual for additional information


Interlock connector


Footswitch connector





6. MAINTENANCE

GENERAL CLEANING INSTRUCTION

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

Never leave the connector socket on the laser without protection. The diode laser inside this port is very fragile and will break easily in case of fluid penetration, smoke, steam or objects of any kind. Absolutely avoid putting fingers into this port and looking directly inside.

Do not smoke inside the environment where the laser machine has been placed. Smoke will damage the diode laser irreversibly.

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

1. Keep the working area clean, using vacuum cleaners to remove and dirt and dust.
2. Use a soft cloth to clean the metal or plastic surface of the machine. Take care not to damage the safety labels.
3. Do not use sharp instruments for the areas difficult to clean.
4. Absolutely don't try to clean the inside of the cavity that houses the tip connector: the diode there lodged is particularly delicate and easily subject to break.
5. Take particular care in cleaning the control panel, avoiding the use of aggressive detergents.
6. Take particular care in cleaning the edge of fibre connector before any usage. Use a specific fibre cleaner. This operation will avoid fibre damage and power loss.

PERIODICAL MAINTENANCE

WARNING: all the maintenance operations below mentioned must be carried out by a specialised technician authorised by the manufacturer. Contact your dealer for further information.

Recalibration

We recommend that the calibration of the system be verified every two years or when you have the impression that there is a variation in the emission values of the laser source. To verify, use a power-meter capable of measuring laser radiation wavelengths between 800 nm and 1100 nm and a maximum power of 8W. Verify that the shift between the power indicated on the display and the one measured is below 20% in continuous emission mode (CW).

ERROR MESSAGES

The system will warn the operator of any malfunction by a message on the display and a warning sound. It will then automatically enter a safety mode and the laser source will be automatically deactivated.
The system does not allow the operator to enter the ready state until the causes of all the errors signalled have been solved. Once an error is signalled it is necessary to repeat the activation procedure to make the laser operative.
Take note of the signalled errors so that they can be referred to the service department..

Interlock not connected

Verify that the interlock connector supplied is correctly inserted in the appropriate socket.
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.
Call the help desk service if the error persists.

Fibre not connected

Signal generated in the event that the system finds that the optic fibre is missing. Insert the fibre and proceed with the activation procedure.
Call the help desk service if the error persists.

Footswitch not connected

Signal generated in the event that the footswitch connector has not been inserted.
Insert the connector to the socket and proceed with the activation procedure.
Call the help desk service if the error persists.

Electric failure

Signal generated in the event that the system finds an electric problem. Turn off the device, wait for few minutes and then turn it on again. Repeat laser source activation procedure.
Call the help desk service if the error persists.

Temperature error

This type of error appears when system temperature inside the machine is out of the working range. The system independently goes into a safety mode, switching off all the power sections and going into stand-by state.
Switch the machine off and leave it switched off in a cool environment for at least two hours.
Call the help desk service if the error persists.

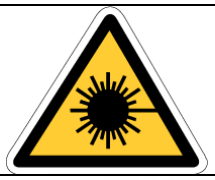
8. ACCESSORIES AND SPARE PARTS

ACCESSORIES INCLUDED

01 Foot Switch
03 Protective glasses
01 Handpiece
01 Optical fibre 300µm l= 3m
01 Metal optical fibre holder
01 Handpiece set - Whitening Large area
01 Box 20pcs handpiece curved tips
01 fibre skinner
01 fibre cutter
01 Interlock
01 Power supply + cable
02 Laser danger Sticker
01 CD (Video protocols/User Manual)

SPARE PARTS

CODE	DESCRIPTION	PHOTO
LITE-WHITE	WHITENING TIP ø 1cm For single tooth whitening	
LITE-ARCH	WHITENING ARCH 4cm SIZE For single tooth whitening	
LITE-BIOTIP	BIOSTIMULATION TIP ø 1cm Suitable for therapy biostimulation	
LITE-CASE	TRANSPORT SUITCASE Plastic case with inner foam space	
LITE-FIBER_2	OPTICAL FIBER Ø200 µm ENDO Length 3m with protective silicon	
LITE-FIBER_3	OPTICAL FIBER Ø300 µm OMNI Length 3m with protective silicon	
LITE-HANDY	STANDARD HANDPIECE Anodized aluminium handpiece	

LITE-TIPS	BOX 20PCS LASER TIPS Suitable for standard handpiece	
LITE-GOOGLES	SAFETY GOGGLES for 980nm diode laser	
LITE-CUTS	OPTICAL FIBER CUTTER Cleaver pen	
LITE-STRIP	OPTICAL FIBER STRIPPER Silicon wire stripper	
LITE-WARNING	LASER WARNING SIGN 02 triangle stickers	
LITE- BROCHURE	DISTRIBUTION LITEMEDICS CATALOGUE 150 copies	
LITE-FLYER	WAITING ROOM PATIENT FLYER 100 copies	
LITE-PROMO	POSTER 60X120 LITEMEDICS	

Photos of the accessories are only indicative and may vary without notice.

9. 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.

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 REPARTION, 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.

PRODUCT CERTIFICATION

CERMET

Conform to 93/42/CEE directive

CE Conformity statement

CODE: LA7D0100.3

According to part II of standard 93/42/CEE, except point 4, issued with Law Decree 46/97 and its integration with standard 2007/47/CE issued with Law Decree 37 of 25/01/2010. The writer **LITEMEDICS** seated in Via F. Stella 5 Milano Italy designer and distributor of the product manufactured by the industrial company LAMBDA- Italy, of the above mentioned devices, takes responsibility to state that:
such devices do fulfil all necessary qualifications required by Standard 93/42/CEE, Part I about the Medical Devices its integration with standard 2007/47/CE; their design, production and final check-up are carried out according the relevant instructions taken from Quality Guarantee System certified on 31/01/2001 by CERMET, according to the prescription from Standard 93/42/CEE, part II.

The firm also does guarantee and takes responsibility to state that:

1. The devices are to be considered as belonging to **Class II B**.

2. The manufacturer engages himself in keeping and leaving at disposal of the Qualified Authority the following technical documents, as specified in Part II, paragraph 6.1, of Standard 93/42/CEE for a period of ten years since the ultimate date of manufacture of the product:

a. The present conformity statement;
b. The documents relevant to the Complete Quality Guarantee System
c. The comments to the Notified Company relevant to possible equalizing or correction in the Complete Quality Guarantee System
d. Details relevant to the design, manufacture, sterilizing and performance of the product;
e. Decisions and reporting by the Notified Company, relevant to the revision of the Complete Quality Guarantee System;
f. Decisions and reporting by the Notified Company, relevant to the examination of the design of the product;
g. Decisions and reporting by the Notified Company, relevant to possible changes in the design
h. Decisions and reporting by the Notified Company, relevant to periodic inspections
Decisions and reporting by the Notified Company, relevant to unexpected inspections

Stamp and signature of the managing director:

LAMBDA SpA

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