Dental laser

Operating manual

Contents

1 General Information

Dental laser is a class 2 diode laser available in version:

Max. output 4 W +/- 1.0 W; max. pulse frequency 200 Hz

Documents provided for device operator

- Operating instructions
- Inspection report
- Warranty card

Operating instructions version date

Version	Change	Date

Manufacturer's liability

Warranty and liability：

- Setup and start up of the device is carried out by company staff or persons entitled by manufacturer to do so (obligatory subsequent to course).
- Installation and safety measures comply with national standards and regulations.
- The device is operated in accordance with the operating instructions.
- No changes are made in the device or its accessories unless approved by the manufacturer.

Warranty:

A 12-month warranty is provided for the **Dental laser** system. If a deficiency is manifested within 12 months that is not the result of improper handling or operation, the right of the purchaser to subsequent repair and restitution shall be valid instead of the purchaser's right to price reduction or contract annulment

2 Labelling

The following labels are at the laser:

Danger for laser

Laser output window

External interlock connector on

3 Warnings

Here is a summary of important instructions concerning technical and operational safety:

3.1 Possible danger for patient and operator

A laxity in following or a not following of the operating instructions, prescribed procedures etc. can under circumstance cause a risk to patient and operator.

3.1.1 Protective goggles

The energy output of the laser light exceeds the tolerance range of the eye and can therefore cause irreparable eye damage. To avoid eye damage, all persons in the room must wear the prescribed protective goggles.

3.1.2 Laser area

The room in which the device is operated must be equipped in accordance with the accident prevention regulations. The electrical installations must comply with CE. The operator, or a laser safety officer designated by him, is responsible for such equipment and compliance.

3.1.3 Invisible laser radiation. Laser class 4

Avoid exposure of eyes and skin to direct or scattered radiation!

3.1.4 Accessories

Only applicators, hand pieces and protective goggles listed as LASER accessories may be used.

3.1.5 Conditions for the environment

The device must not be operated in an explosive atmosphere from any source whatever.

3.1.6 Duty of wearing protective goggles

Application staff, the patient and all other persons in the room must wear the laser protection goggles supplied as accessories by LASER during laser device operation.

3.1.7 Laser area

The operator must ensure that the treatment room is clearly labelled as such and that no persons can enter the room during use of the Dental laser without the proper protective goggles.

3.1.8 Do not look directly in the laser beam

It is not permitted to look into the laser beam, either directly or using optical devices.

3.1.9 Remove the key

When the device is not in use, the key must be removed from it.

3.1.10 Emission switch

In case of intentional or unintentional actuation of the emission switch, unshielded laser radiation is emitted at the fibre tip.

3.1.11 Toxic exhaust fumes
Caution, laser smoke may contain deadly tissue particles. Use and extraction device.

3.1.12 Danger of explosion
Do not store explosive or inflammable materials in the immediate vicinity.
Use of inflammable narcotic gases of oxidizing gases such as nitrogen or oxygen should be avoided. Some materials, e.g. cotton, which are saturated with oxygen, may burst into flame at the high temperatures occurring in proper use of the device. Solvents, for instance in glues and flammable solutions, used for cleaning or disinfection purposes, should be allowed to evaporate before the laser is started up.

Gases emitted by the body may also be inflammable!

3.1.13 Cleaning of the device
Before starting up the device for the first time, the applicators, hand pieces and tips should be cleaned using the spray and wipe disinfection method both before and after use.
To clean / disinfect the device, first pull the mains plug. Make sure no liquids enter the housing openings.

3.1.14 Service and Maintenance
Service and maintenance tasks must be carried out only by authorized and trained personnel (with the exception of replacement of fuses).

3.1.15 Incorrect Service and Maintenance
Use of control or adjustment equipment or methods other than what is specified here may result in dangerous radiation extension.

3.1.16 In case of damage of the Dental laser
If the system is damaged or there is any evidence that it is not functioning properly, operation must be ceased immediately and the manufacturer must be informed.

3.2 Possible reasons for damage of the Dental laser

A laxity in following or a not following of the operating instructions can result in damage to the device or instruments.

3.2.1 Proper Cooling
The ventilation grids of the device must not be obstructed.
During operation make sure that a minimum distance of 20 cm is maintained between the lateral ventilation slits and the walls.

3.2.2 Punctual change of the fibre heads
The applicators should no longer be used when less than 5 mm of fibre remain. Handle applicators carefully—do not press them, put heavy loads on them or hold them at a slant! Changing the applicator can be realized in any operating status. However, make sure the foot switch is not actuated.

3.2.3 Careful handling of the fibre heads

The flexibility of the fibres is limited. Pressing, bending, stretching or compressing them too strongly may break the fibres.
If this rule is not complied with, the transmission system may be damaged and/or the patient or application staff may be injured.

3.2.4 Effect of the cleaning agents

Make sure the disinfectants / cleaning agents used are bactericidal (incl. TbB), fungicidal and virucidal (incl. HBV).

3.2.5 Consider the exposure times

Comply with the exposure times set out by the manufacturer for the disinfection and cleaning solutions used.

3.2.6 Put on of the cleaning agents

Use a spray bottle or a soft clothe for surface disinfection of the device, foot switch, fibres and hand pieces. The membrane keyboard and display can be treated in the same way. Use spray disinfection on the TIPS.

3.3 Useful additional information

This calls attention to important and useful additional information. Not complying with it could result in a device disturbance or false measurements.

3.3.1 Emergency off switch

Actuating (pressing) of the EMERGENCY OFF switch separates the device from the mains completely, upon which it will not show any function at all. After the EMERGENCY OFF switch is actuated, the device can be re-activated after a few seconds—i.e. the desired mode can then be selected.

3.3.2 Inspection of the transmission system

Since the aiming beam takes the same path through the laser transmission system as the working beam, it provides for a suitable method of checking the laser transmission system for damage: Direct the aiming beam at a white surface (paper). A completely round spot of light should be seen. If the aiming beam does not appear, its intensity is reduced or it is scattered, this may indicate that the laser transmission system is damaged or not functioning properly!

3.3.4 Protection of the optic elements

The Dental laser is equipped with high-precision optics in the hand piece. Foreign objects such as dust or moisture may therefore result in reduced output. For this reason, a protective cap or fibre head must be placed on the laser emission opening while the hand piece is cleaned. We also recommend putting a protective cap or fibre head in place when the laser is not in use to prevent dust from getting inside.

4 Proper use

The **Dental laser** is a laser device in laser class 2 that was developed for dental applications and can be used in the following areas:

- Decontamination of tissue, implant and tooth surfaces
- All types of surgical incision
- Bio stimulation and laser puncture, therapy

The intended user / operator group for this laser device are dentists. They must be given instructions and training on the risks involved in use of laser radiation and in handling the laser (laser protection officer). The laser device may only be operated in a laser safety area; all persons present in this area (user, patient, assisting personnel, …) must wear laser protection goggles that meet the specifications in chapter 2!
The basic laser device is used to select the parameters and generate the laser light, which is then emitted by means of an emission switch (hand or foot switch). A glass fibre integrated in a hand piece is used to transmit the laser light. At the distal fibre end, the laser beam is emitted when the switch is actuated in accordance with the mode and parameters selected. This laser beam can be used to treat the above-named indications in the areas of incision and irradiation. For the therapeutic applications, inserted tips are used as spacer elements. These tips can only be used in the T-mode of the laser device!

5 Protective and safety measures

The device may only be started up after the operator has received the required instruction and training and only in compliance with the applicable regulations and safety specifications.

5.1 Side effects

1. Carbonisation / Necrotic zones:
At high output levels and/or remaining at one spot for a longer period, tissues may suffer irreversible damage in the above-named forms.
Remedy: Avoid high output levels, keep fibre in controlled motion!

5.1.2 Unpleasant odours:
Tissue evaporation caused by intended photothermic effect.
Remedy: Use saliva ejector!

5.1.3 Noise:
Cutting noise caused by tissue evaporation.
Remedy: None, noise unavoidable

5.1.4 Heat up of hard substance, potential destruction:
If the device is used outside the intended area, harmful side effects may occur due to heat up of hard substance (tooth, bone) at high outputs and under long exposure.
Remedy: Use device only in accordance with instructions, do not apply to hard substance!

5.2 Risk of alternating-side disturbance

There is no risk of alternating-side disturbances during treatment!

5.3 Risks / risk estimation

5.3.1 Risk from energy,
caused by electricity, heat, mechanical force, non-ionising radiation, electromagnetic fields, movable parts or acoustic pressure

- minimum risk level [1)]

5.3.2 Biological risks,
caused by bio contamination, bio incompatibility, false emission (substance, energy), toxicity, infection, pyrogenicity or degradation of active substance

- minimum risk level [1)]

5.3.3 Environmental risks,
caused by electromagnetic disturbance, insufficient energy supply (over voltage, under voltage), hindrance of cooling system function, operation under other than regulation ambient conditions, incompatibility with other devices, unintentional mechanical damage or soiling resulting from waste products

- minimum risk level [1)]

5.3.4 Risks arising from use of the device,
caused by improper labelling, insufficient operating instructions, insufficient accessory specifications, complicated operating instructions, operating instructions do not exist or are separated from device, untrained personnel, insufficient warning of side effects, false measurements and other aspects of measurement technology, incorrect diagnosis, errors in data transmission, false interpretation of events or incompatibility with consumables or other products

- minimum risk level [1)]

5.3.5 Risks resulting from malfunctions, maintenance and ageing of device,
caused by insufficient performance characterization for planned use, insufficient maintenance, unintended use, useful life of device has expired, loss of mechanical integrity, insufficient packaging (soiling, contamination) or unsuitable re-use

- low risk level [2)]

[1)] Definition key "minimum risk":
Levels of risk for determined dangers are considered "minimum" if occurrence of one or more of the designated risks would result in injuries—caused by the product both during proper use as intended or in case of an error—to the operator, the patient or other persons in the immediate vicinity that would be so minor that the above-named persons would not be expected to suffer any health and/or physical damage or hindrance in any form whatever.

[2)] Definition key "low risk":
Levels of risk for determined dangers are considered "low" if occurrence of one or more of the designated risks would result in injuries—caused by the product both during proper use as intended or in case of an error—to the operator, the patient or other persons in the immediate vicinity that would be so minor that the above-named persons would not be expected to suffer any permanent or long-term health and/or physical damage or hindrance in any form whatever.
Use of vasoconstrictors in local anaesthesia for invasive treatment is not necessary. This applies in particular to treatment of pregnant patients or patients with cardiac damage in their histories.

5.4 Residual risk

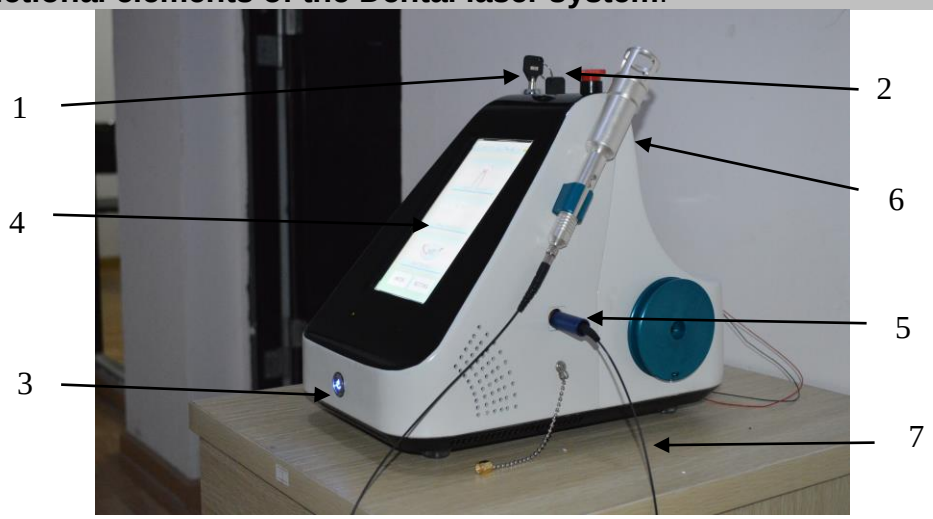
Taking into account the potential side effects, the resulting residual risks are acceptable in terms of endangerment due to the intended application and use of the laser system and accessories. Therefore, no restrictions are issued for use of the system Dental laser when used properly.
Participation in OP courses such as those offered by LASER will ensure that the operator (laser protection officer) is instructed as to the risks inherent in laser radiation and proper handling of the laser device (see also p. 9, "Proper use").
On-site functional testing of the device followed by instruction in use of the device will provide the operator with instruction in handling and operation of the laser device.

5.5 Contraindications

No contraindications are known.

6 Installation

6.1 Functional elements of the Dental laser system.



1.Key switch
2.Emergency switch
3.Laser emission indicator
4.Display / Touch panel
5.Socket for transfer fibre
6.Hand piece
7.Transfer fibre

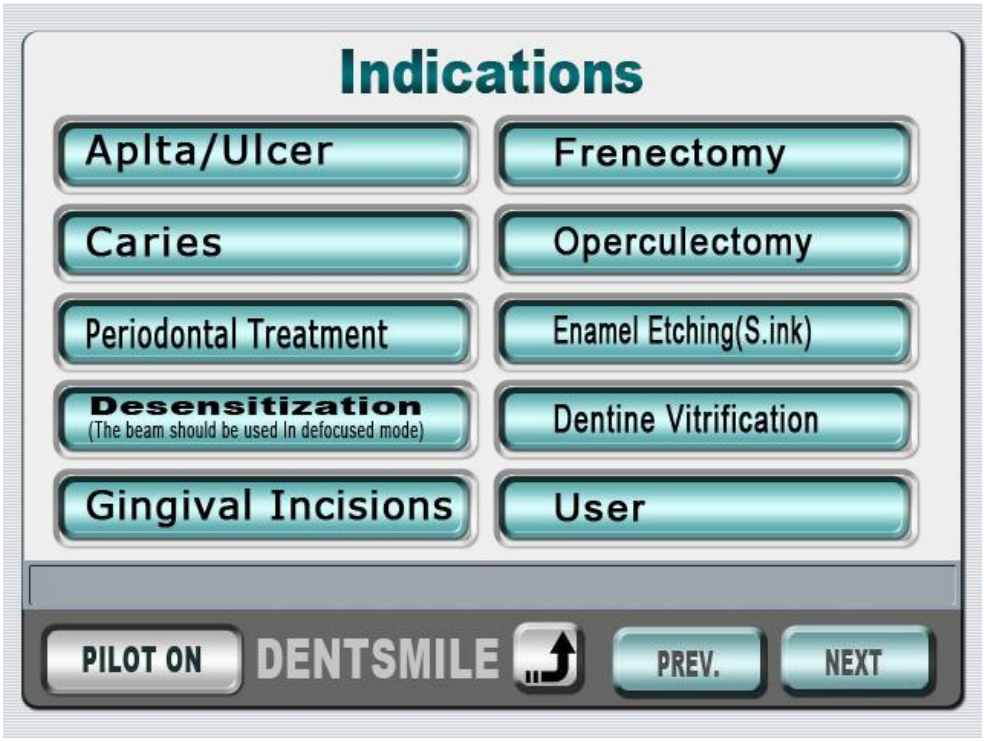
6.2 Preparation for start-up

- Before being switched on, the device should have been set up for at least one hour at room temperature.

- Insert powersupply cable into a shockproof socket
  (220 V / 50-60 Hz or 100-110V / 50-60 Hz)
- Screw fibre connection into the socket for transfer fibre
- Insert the interlock plug into the interlock socket until it clicks in
- Insert the foot switch plug into the switching socket until it clicks in
- Make sure the emergency switch is not pressed
- Insert the key

7 Start-up

- Turn the key rightward
- The control display of the **Dental laser** lights up. The following selection menu appears, display:

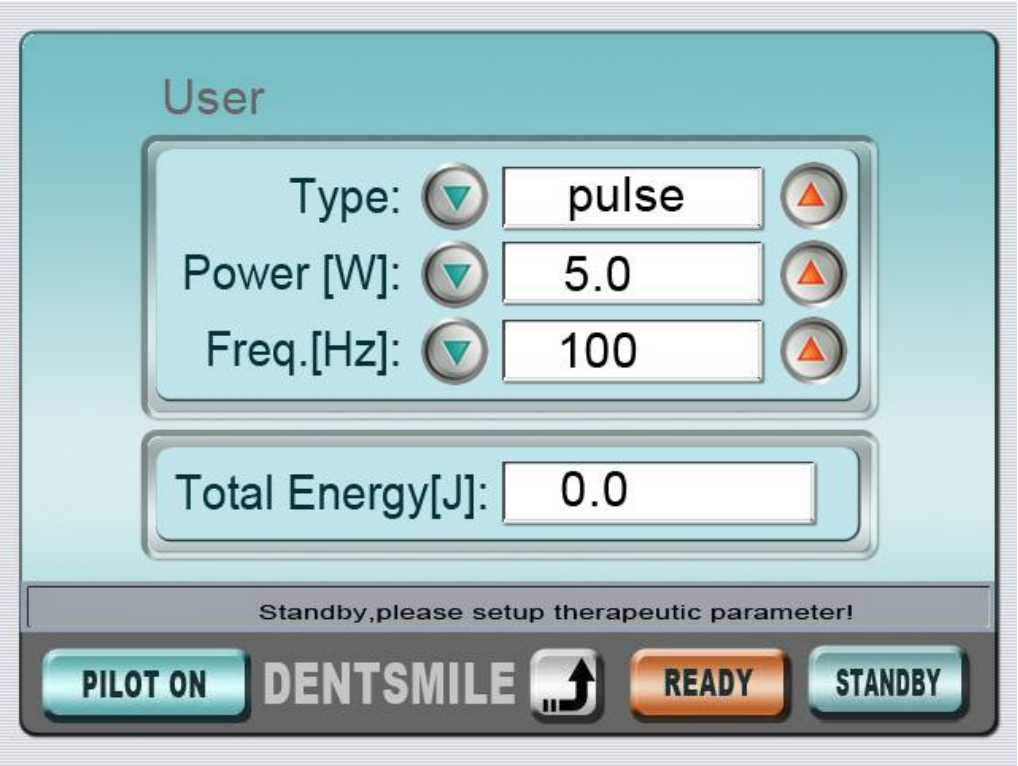


(Basis menu photo**)**

Dental laser is now ready for operation.

All laser functions are set by pressing on the display with a finger. Do not press on the display with hard or pointed objects, since this would damage the sensitive display.
There are seventeen work mode inside, Through the seventeen key you can change work mode.

8 Operation



TYPE: The laser is emitted continuously or pulse.

Power: Power field show output power of the laser
△/▽: Press to set the output power 1-5W

Freq: Show the pulse frequency
△/▽: : Press to set the pulse frequency(1-100Hz)

Total Energy: Show the total energy

Standby : To select Standby mode

Ready: To select Ready mode. Radiation is possible only in the Ready mode.

Pilot ON/OFF: To switch the Aiming light on/off. Aiming light only radiates in the Ready mode.

9 Handling the fibre heads

The fibre heads must be disinfected prior to application using the spray and wipe disinfection method (see also chapter 10. Cleaning and disinfection).
Attach fibre to the hand piece.

10 Cleaning and disinfection

The device housing and foot switch should be disinfected and cleaned once a day in accordance with the spray and wipe disinfection method.
Accessories (fibre heads, hand pieces and tips) must be disinfected and cleaned after each use in accordance with the spray and wipe disinfection method. Spray and wipe disinfection is must be done according to the information on the disinfectant used.

11 Maintenance

Once a year, the device must be subjected to a safety inspection on the basis of these operating instructions and the medical product manual. Such inspections can only be performed properly by personnel qualified on the basis of their training, knowledge and practical experience and who are not subject to supervision in their inspection activities.

1. Check radiation output in all application modes.
2. General functional check
3. General visual check
4. Protection line test
5. Contingency device current test
6. Safety concept check

If the device is not subjected to this inspection by the deadline, all warranty and liability provided by the manufacturer shall be nil and void.

12 Error messages / Elimination

Temperature high!Cooling...	The laser should be work at temperature below 35°C. If not, inform LASER Service.
Temperature low,please increase the room temperature	The laser functions should be work at temperatures above 10°C. Depending on cooling, it may take as long as 60 min. until the device reaches ambient temperature.
Interlock opened	Check safety lock
Fiber not connected	Connect fiber
Cover opened	Close the cover board

13 Accessories

The following accessories are available for the laser system:

1 Instruction Manual
1 Fibre 400 µm
1 Footswitch
1 Interlock
1 Fibre holder
1 Power cable
1 Hand piece
1 Protective goggles

14 Technical data

Laser diode: Diode

Wavelength: 810 nm +/- 10nm
Beam divergence: 25° (NA = 0,22)
Pulse mode power: 1 – 4 W, dependent on the operation mode
Continuous power: 1 – 4 W (CW)

Frequency: 0.2-200Hz
Aiming laser: Laser diode
Output performance: < 1 mW
Wave length: 635 nm

Transmitting system: HPCS glass fibre, NA = 0.37
Length: 1 .5m

Basis unit:
Voltage supply: 110 V AC, 50/60 Hz
Current consumption: 0.9 A
Protection class: 1 B, not waterproof, flammable

Laser cooling unit: TEC and air-cool

Ambient conditions:

	Operation	Storage
Temperature	20 – 35°C	0 – 50°C
Rel. atmospheric humidity	30 – 70%	30 – 70%

The Dental laser must be operated on a non-oscillating area. Strong shocks, for example to overthrow the unit lead to destruction of the device and must be prevented.

The Dental laser corresponds to the requirements of the EN 60601-1-2, “Electromagnetic compatibility”.

15 Use capability

The use capability of the device is limited by the use-dependent natural wear on the mechanical and/or electronic components with laser diodes. Operational status of the device can be extended by means of regular annual maintenance procedures (safety inspection) and attentive care. It is not possible to indicate a time period for operational life due to user-related frequency of use.

The use capability of the hand piece is at least 5 years on the basis of the material composition used.