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SOGA Committed to improving the treatment experience of doctors andpatients

Manufacturer information

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User Manual

Dental Diode Laser

Model: ILaser I

℞ only

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Address: D906, Yinxing Technology Building No. 1301, Sightseeing Road, Xinlan Community, Guanlan Street, Longhua District, Shenzhen, Guangdong, China.

Please read this instruction manual carefully before using the product to prevent lack of iveness and injuries caused by incorrect operation.

TABLE OF CONTENT

01.Basic information

1.1 Description

The **Dental diode laser** is designed, developed and produced by Shenzhen Soga Technology Co., Ltd.; It is intended to incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva. The product is composed of laser host (including internal power system, laser drive system, optical path system, liquid crystal operation display, emergency stop button), Handpiece part, fiber optic tip. Utilize semiconductor laser to provide stable power laser.

Classification of FDA: GEX / Class II Classification of CE: Class IIb

1.2 Intended use

Indication of use

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue; marginal and interdental gingival and epithelial lining of free gingiva; frenectomy; frenotomy; biopsy; operculectomy; Implant recovery; gingivectomy; gingivoplasty; gingival t roughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of deseased epithelial lining ; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions ; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; Fibroma removal; Gingival incision and excision; Treatment of canker sores; herpetic ulcers of the oral mucosa; Laser soft tissue curettage; Reduction of gingival hypertrophy;.

Intended user

Federal law restricts this device to sale by or on the order of a dentist or physician or licensed practitioner.

Patient Population

No restriction on the applicable population.

Contraindications

(1) Patients which sensitive to light or red light;

(2) Patients with cardiac pacemaker.

Intended use environment

- **Training environment:**

  Only licensed professionals who have reviewed and understood this User Manual should use this device. Additional training from a SOGA Authorized Representative is strongly recommended.

- **Operating environment**

  Environment temperature: 20 ℃ ~ 35 ℃

  Relative humidity: ≤80%

- **Transportation and storage environment**

  Transportation temperature: -20℃ - +55℃

  Storage temperature: -20℃ - +55℃ Relative humidity: ≤93%RH

- **Intended use period**

  Frequency: Once a day for a patient.

  Duration: Less than 2 hours

1.3 Structure

Diagram 1. Entity diagram.

No.	Name
①	Touching screen
②	Emergency stop button
③	Indication light
④	Fiber optic tip
⑤	Laser emission button
⑥	On/Off button
⑦	Unlock key
⑧	Power increase key
⑨	Power reduction key
⑩	Light path system
⑪	Laser generator
⑫	Internal power system

1.4 Shipping list

Name	Amount
Mainframe (With handpiece part)	1
Fiber optic tip	8
Charging adaptor	1
Fiber optic cleaner	1
Fiber bender	1
Laser area symbol	1
Protection glasses	2
Handpiece cover	1

There are some special tools included:

1. Fiber optic cleaner

The stain might block the laser from a long-term accumulation, resulting in an unexpected heat concentration, which affect the performance of the device. Fiber optic cleaner is used to clean dirt or stain on the ceramic joint column, so on to reduce performance attenuation and extend the serve life of dental diode laser.

Diagram of Fiber optic cleaner

2. Fiber bender

Over-bending fiber optic tip is potentially to break the optical fiber, this product is designed to assist the fiber optic tip bending. Provides a gentle angle change way.

Structure of Fiber bender

- **Usage:**

  Insert the capillary part of the fiber optic tip into the cavity of the Fiber bender, and bend it to the intended Angle slowly.

  Remind do not to bend the fiber optic less than 90°

Schematic diagram

3. Handpiece cover

The handpiece cover can be disassembled and needs to be sterilized after each use. It required to be sterilized before use. Refer section 5.3.

Fig. Structure of Handpiece cover

4. Self-configuration asseccory

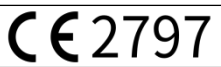
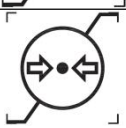
The Dental diode laser offer a port for door interlock switch. It allows the user to connect a door interlock switch to reduce the risk that unintended personnel enter the operation area.

Usage:

a) User install a door interlock switch on the Dental diode laser, the door interlock switch port specification is a YC8-5PIN port.

b) When the door interlock switch is connected, the screen will indicate “Door interlock switch is connected”.

1.5 Marking description

Marking symbol	Description
	Consult instructions for use
	Warning symbol, Need in pay attention.
	Laser hazard exists
	Laser emission output hole
	Laser radiation warning
	An Explanatory label of the laser feature.
	An detail explanatory / warning label of the laser feature.
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Manufacturer information
	EU representative information
	EU CE marking, with Supervision Notified body number.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the range of humidity to which the medical device can be safely exposed.
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date after which the medical device is not to be used.

02.Safety relevant matters

2.1 Summary

Dental diode laser (ILaser I) is a security level 4 class of laser system. The user must ensure that the equipment is working properly and under safe working conditions prior to each use.

Core objective:

- Use only normal status device.
- Protect yourself and third parties from danger.
- Avoid environmental pollution.

2.2 Notification before use

The Fiber optic tip has not processed, please notice it is important to processing according Chapter 5 prior use.

The equipment must only be operated by personnel who can use it correctly, who have been trained and have relevant knowledge and experience; The manufacturer is not liable for any loss caused by the use of this equipment by untrained persons.

The product must be cleaned and maintained according to the instructions when it is not in use for a long time.

Only the parts and accessories provided by our company are allowed to be used; The company will not be responsible for any loss or injury caused by non-use of the parts provided by the company.

Make sure there are no metallic or reflective objects such as necklaces, reflective instruments or reflective brackets etc. in the operating area.

Make sure that indoor personnel wear protective glasses before operation. Manufacturer has offer a protective glasses with specific wavelength (830-1100mm).

Close the doors and windows of the treatment room to prevent accidental leakage of the laser.

Make sure the operator knows how to turn off the laser in case of an emergency before using it.

Place a small fire extinguisher and water in the treatment room.

2.3 Proper usage

"Proper use" includes all of the following instructions and ensures that all inspection and service tasks are completed.

Harmful radiation exposure may occur if the control or adjustment device is not used as required, or if each step is performed.

Fiber optic tip are removable/consumable parts. If damaged, please contact the manufacturer for replacement or purchasing.

Do not place any liquid on the device.

If liquid seeps into the device, press the emergency stop switch button immediately and notify customer service.

All optical components, especially laser transmission system components, must be carefully handled and protected, and kept clean and dust proof; Use environment should also be kept clean.

Only direct laser light on the treatment site is allowed.

Do not direct the optical fiber aperture directly at the eyes.

Avoid accidentally firing laser. Turn off the power switch when not in use for a long time to avoid accidentally triggering the transmitter switch.

When the laser is not in use, move it away from the operator's area of activity. Avoid soft tissue adhesion to the fiber tip. This can cause local overheating and cause the tip of the fiber to singe or fall off. If this happens, wipe the fiber with a medical alcohol gauze. Continue the operation after the medical alcohol volatilizes, and re-cut the optical fiber if necessary.

Do not spray detergent directly on the body of the laser system.

It shall not be used in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide.

If the fiber optic tip requires direct contact with oral soft tissue, ensure that the fiber-optic tip has been carbonized (Initiated) before contact.

2.4 Characteristic notification

NOHD (nominal ocular hazard distance): The distance of the beam irradiance or irradiation equal to the maximum permissible exposure (MPE) of the corresponding cornea.

Indicate the laser area and do not allow unauthorized personnel to enter this area during treatment.
(NOHD is 3.03m, edge of setting laser area shall be longer than 3.03 meter.) Put up laser warning signs.

The minimum bending radius of optical fiber tip should be not less than 2.5cm in the process of use, otherwise it may cause damage to the equipment. (Manufacturer has offered a bending set for optical fiber tip).

The laser can ignite non-metallic materials. All flammable materials must be removed from the working area or kept wet during operation. A laser can ignite a solution containing alcohol and/or acetone.

Care must be taken when using oxygen, which is highly combustible.

Do not leave solution residue in the operating area. Volatile gas may be absorbed by materials such as surgical drapes and bring safety risks.

Surrounding tissue may be irradiated unintentionally during laser therapy, and over irradiation can lead to tissue damage, perforation of blood vessels, and bleeding. Doctors should set the patient as low power dose as possible.

For cutting use, please initiate the fiber optic tip first or use a pre-initiated fiber optic tip.

2.5 Environmental pollution

Disposal material including:

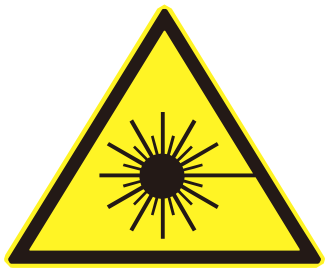
- Equipment beyond its service life
- Removable parts
- Consumable

For the sake of human safety and environmental protection, the generated waste must be recycled or disposed of in a safe manner. Comply with the appropriate national regulations, otherwise there may be a risk of environmental pollution.

2.6 Label in treatment area

The manufacturer will provide a laser warning mark for each laser system.
We suggest that signs be posted at the door of the laser treatment room to alert people entering the room.

Laser area symbol:



During operation, the maximum allowable radiation intensity in this area may be exceeded and the "laser area" must be segregated and laser warning signs posted.

There is a very large distance between the laser and the NOHD, and this whole area of laser application should be considered as the laser area.

Warning lights, triangular yellow laser warning signs and other visible signs must be set up at the entrance of the laser operating room.

03.Installation

3.1 Open package

Receiving the ILaser I dental diode laser in the presence of the shipper, the user should be check by following steps:

1. Check the completeness of packing cases. If there is any damage to the outer packing, the shipper should sign a statement of damage.
2. Check the completeness of accessories according section 1.4.
3. Check whether the device and accessories are normal.
4. If any composition is missing or damaged, please immediately communicate with the shipper and notify SOGA.

3.2 Installation

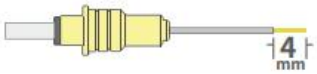
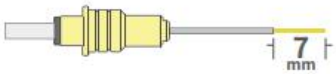
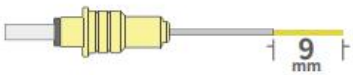
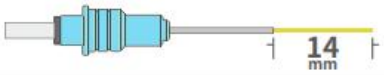
Mainframe installation

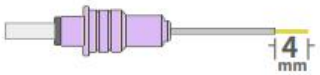
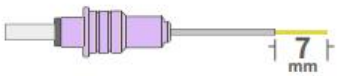
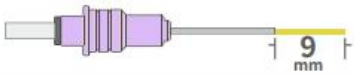
The Dental diode laser is an integrated device without installation need.

Please check completeness of device according section 1.4 which will affect the safety and intended usage.

Replacement and installation of the Fiber Optic Tip

1. Fiber optic tip models:

Non-initiated	Models	Diameter	Length	Application
	F4-4	400um	4	Surgery
	F4-7	400um	7	Periodontology
	F4-9	400um	9	Periodontology
	F2-14	200um	14	Root canal
	F2-20	200um	20	Root canal

Pre-initiated	Models	Diameter	Length	Application
	PF4-4	400um	4	Surgery
	PF4-7	400um	7	Periodontology
	PF4-9	400um	9	Periodontology

We will offer six frequently-used fiber optic tips with your first purchasing as below:

Model	Amount
F4-4	1
F4-7	1
F4-9	1
F2-14	1
F2-20	1
PF4-4	1
PF4-7	1
PF4-9	1

If you have additional need, please contact with your local dealer.

2. Cleaning in installation

Both the dustproof plug accompanies with device and the fiber optic tip have same dustproof quartz column structure.

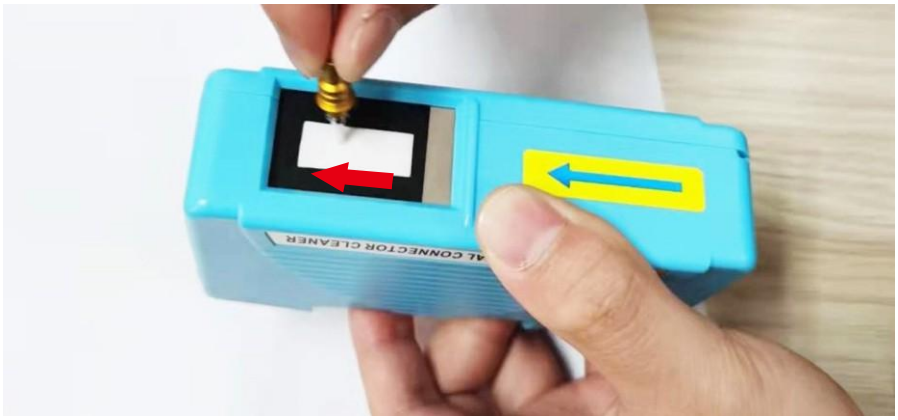
Diagram of Dustproof quartz column (Dust proof plug above, fiber optic tip below).

Before each intend to plug in the dustproof quartz column (either dustproof plug and fiber optic tip), clean the dustproof quartz column with Fiber optic cleaner as below step:

Usage:

1. Pressing the operation button, the application surface will be revealed;

2. Rub the ceramic plug perpendicular to the surface of the non-woven surface in the direction of the labeling arrow.



3.3 Attentions

Pay attention to the use environment. Please check according to Section 1.2.5 before use.

04.Operation instruction

4.1 Interactive interface description

Diagram of interactive interface

Number	Component name	Function description
①	Touching Screen	Parameter setting which including duty cycle, laser emission time, parameter recommendation selection. Change the state between ready state and standby state. Battery status.
②	Emergency stop button	In any case, the laser can be turned off with pressed this button, and the device enters the shutdown state.
③	Indication light	Indicates device state
④	Laser emission button	Laser will emission if press this button in standby state.
⑤	Power button	Device power switch
⑥	Unlock key	After the device is powered on, the blue light of this button will be on, the device is locked, and the laser cannot be emitted. Press this button. When the blue light of the button goes out, the device is unlocked. Press the laser emission button, and the laser will be emitted.
⑦	Power increase key	When the unlock key is locked, press this key to increase the laser power.

⑧	Power reduction key	When the unlock key is locked, press this key to reduce the laser power.

4.2 Treatment operation

1. Pre-use inspection

Before starting treatment, please inspect according the warning in Chapter 2.

2. Boot

Press the power switch, the device will enter the passcode interface.

3. Passcode input

When starting up, the system will require operator to input a password: Enter the password 1 2 3 4 5 6. If the code is wrong or not been input, the system will not enter the standby state.

If the code is correct, the device will enter the standby state (Standby button is activated).

4. Tip Initiating

If the fiber optic tip requires direct contact with oral soft tissue in this treatment, ensure that the fiber optic tip has been carbonized (Initiated) before contact or using the tip that was Initiated (Models start with PF).

Initiating procedure:

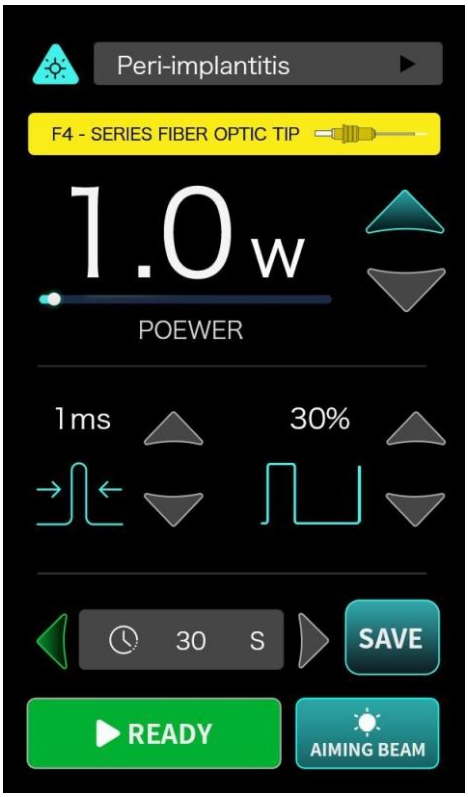
Before use, contact the articulating paper with the optical fiber in the optical fiber tip, initiated the laser (1W) for about 5S, make the optical fiber tip carbonized, clean the ashes, and then start the treatment use.

5. Indication selection

Select intended indications in below box: 

The corresponding parameter will automatically set.

It able to change duty cycle, emission period, and power according therapeutic schedule of physician.



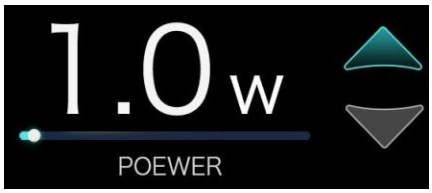
The interface will prompt to select the corresponding fiber optical tip.

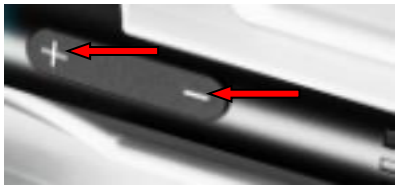
If the parameters of preset values are inappropriate, the corresponding parameters can be adjusted according to the actual situation.

6. Parameter setting

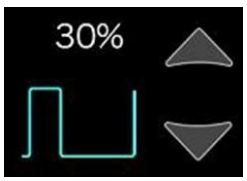
Before starting treatment, please inspect according the warning in Chapter 2.

- The buttons in the following two pictures can set the laser output power from 0.1 to 8.0 W:



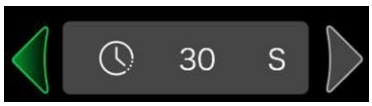


- The device able to set Duty cycle in below button from 10% to 100%:



(100% is the CW mode)

- The device able to set emission period in below button from 1 to 999 seconds:



7. Parameter saving

There is a saving button below, which can save parameter of indications:

8. Emission Ready state

Press the Standby button to inactivate the standby state.

Press the Ready button to enter ready state, The indication light will show green color and the aiming beam will emit.

You can also use the unlock key to complete the same operation.

The system switches from standby to ready with a 2-second delay, so that the operator has time to align the aiming beam to the intended location.

9. Emission

Press the Laser emission button to emit laser, the indication light will be flashing orange color with a continuous beep sound.

10. Emission pause

Press the Standby button to pause laser emission.

Under the emergency situation, you can press the Emergency stop button to stop laser emission.

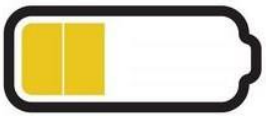
11. Turn off

After the treatment, be sure to turn off the laser immediately by press the power switch.

In case of emergency, no matter what state the device is in, press the emergency stop button, the device will immediately shut down and the laser will immediately stop emitting.

12. Charge

The screen showing battery status:



Using the adaptor and cable offer by the manufacturer.

When the charging is over, the green light on the adaptor will turns on.

4.3 Special function description

A. Mode Changing

The dental diode laser has two modes:

- CW mode (Continuous wave): Continuous energy output, mainly use in the condition that the lesion is small in size or volume or requires rapid surgery.
- CW mode (Continuous wave): Continuous energy output, mainly use in the condition that the lesion is small in size or volume or requires rapid surgery.

- DW mode (Pulse wave): The duration of laser output varies periodically, there is a parameter adjust the Duty cycle. This mode mainly uses in large size lesion or long-term treatment.

$$Dutycycle = \frac{pulse\ width}{1\ S}$$

B. Aiming beam

The device is equipped with a red aiming beam whose radius is the same as the application laser. The position of the aiming beam should be used as launching site indication during treatment.

Aiming beam is a good way to check the integrity of the transmission system. If the points of the aiming beam are not at the end of the transmission system, or their intensity is reduced, or they do not appear to converge, this indicates that the transmission system may be damaged or not working properly.

! To prevent this situation please use the device according this instruction, if above happened, please contact with local dealer or SOGA.

C. Visible and audible laser emission signals

When laser is emitting, A high-frequency buzzer sounds, and a laser emission signal appears at the screen, indicating that the laser is emitting.

D. Passcode lock

When you start up, the system will be required for a password. If not input or out it wrong, the system will not enter the working interface.

The default password is 123456.

05.Reprocessing

5.1 Body contact information

The component of the product in contact with patient body are shown in the table below:

Component	Contacting tissue	Material	Contact period	Contact time
Fiber optic tip	Soft tissue	Quartz	Each treatment	Less than 1 hour
Handpiece cover	Soft tissue	Stainless steel	Each treatment	Less than 1 hour
Handpieces	Soft tissue	Stainless steel	Each treatment	Less than 1 hour

The Fiber optic tip is a disposable component, it is advice that using a new Fiber optic tip for a single treatment or for diff erence patient.

The Handpiece cover is intended to prevent blood foam from splashing on the device enclosure and lead to cross-infection.

Spaulding Classification: Semi-Critical Devices

The parts need processing:

Component	Process
Fiber optic tip	Sterilization
Handpiece cover	Sterilization

The dentist/ clinician should wear clinical gloves and cover the device handpiece part with sterilized handpiece cover prior to use. The sterilization for the handpiece cover is in section 5.2.

To pervert cross infection, please use the handpiece cover prior to use.

5.2 Cleaning/Disinfection Procedure

The enclosure (including screen, button and handpiece part) should be cleaning disinfected before use and after the removal handpiece cover;

The cleaning/disinfection process is below:

1. Wipe the enclosure including the screen and buttons with clean cloth to clean the smudges or fluids.
2. Wipe with an 75% alcohol wet cloth. The cloth should be free of liquid leakage.
3. Then wipe with a dry clean cloth.

Do not spray detergent directly on the body of the product.

5.3 Sterilization Procedure

The Fiber optic tip and the handpiece cover need to be sterilized before use. Please sterilize the fiber optic tip and handpiece cover according below procedure:

1. Prepare and preheat the sterilizer and sterilization pouches.
2. Put the Fiber optic tip or the handpiece cover into sterilization pouches and seal up.
3. Put the sealed into sterilizer and set sterilizer parameter to:

Type of Sterilizer	Temperature	Min Time	Drying Time
Gravity Displacement	121°C(250°F)	20minutes	0minutes
	132°C(270°F)	15minutes	15-30minutes
Dynamic-Air-Removal (Pre-Vacuum)	132°C(270°F)	4minutes	20-30minutes
	134°C(EUonly)		

4. Start the sterilizer procedure.
5. After sterilization, check whether the Fiber optic tip is damaged by deformation, breakage, crack, etc.

After the checking, they can be used after cooldown for 30 min.

06.Maintenance and Troubleshooting

6.1 Maintenance

Device maintenance and maintenance period

IF the device is leave unused for more than a month, it should be processed according the procedure in section 5.2.

If the life time is expired, the device will indicate and lock down the device.

Calibration

- **Dental Diode Laser will need to calibrate every 24 months after received.**

Before the annual calibration date, please contact the local dealer or manufacturer for calibration;

In addition to the normal annual calibration, when the aiming beam is visible-reduced or not visible, please contact your local dealer or manufacturer for calibration.

Serve life information

- The dental diode laser has a mechanism that the device will indicate serve life ending information and lockdown the device when the device expired 5 years serve life.
- There is also with a mechanism for user to establish that the device is still within performance qualification:

1. Prepare a white printing paper.
2. Power on the Dental diode laser and adjust the laser power to 0.1W.
3. Press the Power button to enter the Laser launch state.
4. Aim the aiming beam to the white printing paper.
5. The dental diode laser having performance failure if the aiming beam is not visible or conspicuous.

- Please follow the instructions from Section 2.5 for appropriate disposal of devices that fail.

6.2 Troubleshooting

Dental diode laser assembly with an internal warning system, once appear the error, the device will stop workingimmediately.

- In the event of failure, please refer to the maintenance table to eliminate one by one
- If the error still cannot be removed, please contact SOGAcustomer service or the local dealer.

Troubleshooting form:

Error	Reason	Remedial measure
Screen touch failure	Calibration screen required	Quickly click on the blank space of the screen for 10 times. When you hear the "drop", the blue screen calibration mode appears. Follow the cross cursor on the screen and click... Until the calibration is completed
Fiber breakage	Incorrect use or the number of times of optical fiber use has been reached.	Replace an sterilized fiber optic tip and continue to use it
The device suddenly shuts down without an error message or the error message does not match the fault that occurred	Unknown security error	Contact with local dealer or SOGA customer service
Display function keys are not responsive or do not correspond	Internal damage ofcircuit board	Shut down the device, and contact with local dealer or SOGA customer service
Set values and output data display is abnormal, incomplete, or typographically incorrect	Unknown related security error	Shut down the device, and contact with local dealer or SOGA customer service
No aiming beam appears at the aperture	Aiming beam function failure/fiber damage/control circuit failure	Restart the device, If the device is still error, please contact with local dealer or SOGA customer service

6.3 Maintenance considerations

- In order to guarantee The Dental diode laser has been in a state of normal use and asset value, it Suggest for safety inspection service every year.
- Authorized repair and service representative of SOGA Company products
  1. Trained technicians from SOGA Company or one of its branches.
  2. Trained technicians of the local distributor assigned by SOGA Company
- The operator, the person in charge of the device and the user must use the device in accordance with local medical deviceregulations
- Do not repair the device without authorization. Significant maintenance and repair of the device will be handled only by a qualified Dental Diode Laser service technician. The device key is held by an authorized professional.
- Do not attempt to open the interlock or damage the housing, which is designed for safety protection.
- Please retain the container for possible repair or upgrade during the warranty period.

●The fiber optic tip can be stored for two years without opening the package. If you start to use it, we suggest you use it once after sterilization. In case of repeated use, please follow the sterilization requirements.

07.Performance parameter

Size	18cm x 16cm x 26cm
Weight	1.8 Kg
Laser classification	Diode laser, class IV
Wavelength	980nm±20nm
Laser power	0.5W-8W Adjusting step 0.1W
Working mode	Continuous working（CW）, Pulsing mode (DW)
Duty cycle	10%~100%
Pulse width	10ms~ 900ms
Fiber optic diameter	0.2mm±0.1mm, 0.4mm±0.1mm
Aiming beam wavelength	650nm±20nm
Aiming beam power	＜5 mW

- **Safety related parameter**

Shock proof type	Internal electric source
Shock protection classification	Type BF
The degree of protection	Ip20
Running Mode	Continuous working
Laser exposure protection level	IV classification
Power supply	Internal lithium battery DC 4.2V
Shelf life	5 years
Fiber optic tip validity	2 years

- **The dental diode laser has a mechanism that the device will indicate serve life ending information and lockdown the device when the device expired 5 years serve life.**

08.EMC information

8.1 EMC related warning

Dental diode laser (ILaser I) in conformity with the relevant requirements of the EMC IEC 60601-1-2 standard.

The user shall install and use the EMC information provided in the random file.

Portable and mobile RF communication equipment may affect Dental diode laser (ILaser I) performance, avoid strong electromagnetic interference in use, such as close to the cell phones, microwave ovens, etc.;

Dental diode laser (ILaser I) should not be close to or stacked with other equipment, if used must be close to or stacked, validation should be observed in its use of configuration can run normally.

8.2 Guidelines and Manufacturer's Statement

Electromagnetic emission		
Dental diode laser (ILaser I) is intended to use in below electromagnetic environment, the following provisions of Dental diode laser (ILaser I) of buyers or users should ensure that its use in the electromagnetic environment:		
Emission test	Conformity	Electromagnetic environment–Guidance
RF emission CISPR 11	Group 1	Dental Diode Laser (ILaser I) uses RF energy only for its internal functions. As a result, its RF emission is low and there is little chance of interference with nearby electronic devices.
RF emissions CISPR 11	Type B	The Dental Diode Laser (ILaser I) is suitable for use in all installations, including homes and residential public low- voltage power grids directly connected to home providers.
Harmonic emissions IEC 61000-3-2	Inapplicability	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Inapplicability	

Electromagnetic immunity			
Dental diode laser (ILaser I) is intended to use in below electromagnetic environment, the following provisions of Dental diode laser (ILaser I) of buyers or users should ensure that its use in the electromagnetic environment:			
Immunity test	IEC 60601 test level	Conform level	Electromagnetic environment–Guidance
ESD IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should be wood, concrete or tile, and if they are covered with synthetic materials, the relative humidity should be at least 30%
EFT IEC 61000-4-4	±2kV to the power cord ±1kV to input/output	Inapplicability	Inapplicability
Surge IEC 61000-4-5	±1 kV difference-mode voltage ±2 kV common-mode	Inapplicability	Inapplicability
Voltage dips, short interruptions and voltage changes on the power input line IEC 61000-4-11	<5 % UT, for 0.5 cycles (On UT,,>95% sags) 40 % UT, for 5 cycles (On UT,,60% sags) 70 % UT, for 25 cycles (On UT,,30% sags) <5 % UT, for 5s (On UT,>95% sags)	Inapplicability	Inapplicability
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	The power frequency magnetic field shall have the level characteristics of the power frequency magnetic field typical of the site in a typical commercial or
Note: UT refers to the AC network voltage before applying the test voltage			

<table>
<tr><th colspan="4">Electromagnetic immunity</th></tr>
<tr><td colspan="4">Dental diode laser (ILaser I) is intended to use in below electromagnetic environment, the following provisions of Dental diode laser (ILaser I) of buyers or users should ensure that its use in the electromagnetic environment:</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>IEC 60601 test level</td><td>Electromagnetic environment –Guidance</td></tr>
<tr><td>RF transmission
IEC 61000-3-4</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V/m</td><td rowspan="2">Portable and mobile RF communications devices should not be used in any part of Dental Diode Laser (ILaser I) closer than the recommended isolation distance, including cables. The distance shall be calculated by the formula corresponding to the transmitter frequency.
Recommended distance:
$d = 2.1\sqrt{P}$
$d = 2.1\sqrt{P}$ 80 MHz to 800 MHz
$d = 3.2\sqrt{P}$ 800 MHz to 2,5 GHz
P is the maximum output of the transmitter that the transmitter manufacturer provides, with a watt (w) unit, and d is the recommended distance of separation, with meters (m).
The field strength of the fixed RF transmitter is determined by surveying the electromagnetic fielda, and in each frequency range B should be lower than the coincidence level.
Interference may occur near devices marked with the following symbols.</td></tr>
<tr><td>RF radiation
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">Note 1: At 80MHz and 800MHz, the higher frequency band formula is used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection by buildings, objects and the human body.</td></tr>
<tr><td colspan="4">a The field strength of fixed t ransmitters, such as the base stations of wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radios, and television broadcasts, is not theoretically predictable. In order to evaluate the electromagnetic environment of fixed RF transmitter, the survey of electromagnetic field should be studied. If the field intensity at the location of Dental Diode Laser (ILaser I) is measured to be higher than the RF coincidence level of the above-mentioned application, then Dental Diode Laser (ILaser I) shall be observed to verify its normal operation. If abnormal performance is observed, supplementary measures, such as reorientation or positioning of Dental Diode Laser (ILaser I), may be necessary.
b he field intensity should be less than 3 V/m over the entire frequency range from 150 kHz to 80MHz.</td></tr>
</table>

The recommended isolation distance between portable and mobile RF communication devices and Dental Diode Laser (ILaser I)

Dental Diode Laser (ILaser I) is intended for use in a radiated RF harassment controlled electromagnetic environment. Depending on the maximum power output of the communication device, purchasers or users of Dental Diode Laser (ILaser I) can prevent EMI by maintaining the minimum distance between their portable and mobile RF communication devices (transmitters) and Dental Diode Laser (ILaser I) by following the recommendations below.

The rated maximum output power of the transmitter in W	Isolation distance /m for different frequencies of the transmitter		
	150 kHz ~ 80 MHz $d=1.2\sqrt{p}$	80 MHz ~ 800 MHz $d=1.2\sqrt{p}$	800MHz ~ 2.5GHz $d=2.3\sqrt{p}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the table above, it is recommended that the isolation distance D, in meters (m), be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer in watts (W).

Note 1: At 80MHz and 800MHz, the higher frequency band formula is used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection by buildings, objects and the human body.

09.Warranty period

Dental Diode Laser (ILaser I) is guaranteed warranty in the event of quality failure of the product within 12 months after delivery for non-human reasons. Within 60 days after the delivery of handle, fiber optic fiber tip and other accessories, in case of quality failure of the product itself for non-human reasons, the company promises warranty

In order to comply with the warranty, any internal adjustment or replacement of the equipment shall be performed by SOGA or its authorized agents. SOGA's warranty liability is limited to the products mailed back to the company for warranty and replacement. SOGA has the option of on-site repairs in the buyer's area.

The warranty does not cover damage to the main engine and accessories caused by:

- Improper operation and abuse;
- Accident or damage caused by customer's negligence, such
- as productdrop; Damage caused by rain, water, humidity, etc.;
- Damage caused by external heat, splashing of food or liquid, etc.
- The warranty does not cover physical damage to the surface of the product, including scratches, cracks and other damage to the shell, touch screen and exposed parts.

The company shall not assume any liability or compensation for the repair of the customer in addition to the contract.

The Company disclaims any implied warranty of merchantability or fitness for a particular purpose.

The Company shall not be liable for any accidental or inevitable damage caused in the course of delivery.