TriLux Laser

Dental Diode Laser

User Manual

contents

1.Basic information

1.1 Description

The dental diode laser is designed, developed, and produced by Guilin Yikeshi Medical Instrument Co.,Ltd. It is intended for incision, excision, vaporisation, ablation, and coagulation of oral soft tissues, including marginal and interdental gingival, as well as the epithelial lining of free gingiva. The product comprises a laser host (which includes the internal power system, laser drive system, optical path system, liquid crystal operation display, and emergency stop button), a handpiece, and a fibre optic tip. It utilises a semiconductor laser to provide stable power.

FDA Classification: GEX / Class II

CE Classification: Class IIb

1.2 Intended Use

Indications for Use

- This dental laser system is designed for a wide range of intra-oral and extra-oral surgical procedures, including but not limited to:
- Soft tissue incision, excision, coagulation, and vaporization.
- Treatment of gingival tissues, including marginal and interdental areas, epithelial lining, and gingival troughing.
- Procedures such as frenectomy, frenotomy, biopsy, operculectomy, and implant recovery.
- Gingivectomy, gingivoplasty, and crown lengthening.
- Haemostasis of donor sites and removal of granulation tissue.
- Laser-assisted flap surgery and debridement of diseased epithelial lining.
- Incision and drainage of abscesses, tissue retraction for impressions, and papillectomy.
- Removal of diseased, infected, inflamed, or necrotic soft tissue within the periodontal pocket.
- Sulcular debridement to improve clinical indices, including gingival health, bleeding, probe depth, attachment loss, and tooth mobility.
- Pulpotomy, both as a standalone procedure and as an adjunct to root canal therapy.
- Treatment of oral lesions, including canker sores and herpetic ulcers.

- Reduction of gingival hypertrophy and fibroma removal.

Intended User

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

Patient Population

There are no restrictions on the applicable population.

Contraindications

- Patients sensitive to light or red light.
- Patients with cardiac pacemakers.

Intended Use Environment

Training Environment

Only licensed professionals who have reviewed and understood this User Manual should use this device. Additional training from a Xpedent authorised representative is strongly recommended.

Operating Environment

- Environmental Temperature: 20°C to 35°C
- Relative Humidity: ≤80%

Transportation and Storage Environment

- Transportation Temperature: -20°C to +55°C
- Storage Temperature: -20°C to +55°C
- Relative Humidity: ≤93% RH

Intended Use Period

- Frequency: Once a day for a patient.
- Duration: Less than 2 hours.

1.3 Structure

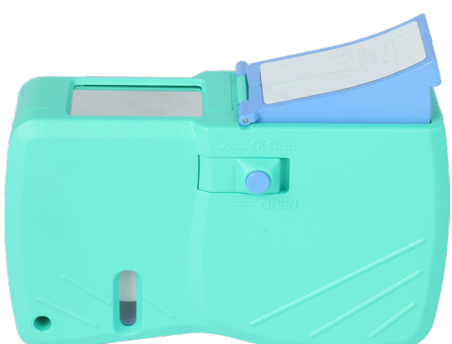
1.4 Shipping list

Name	Amount
Mainframe (With handpiece part)	1
Fiber optic tip	16
Charging adaptor	1
Fiber optic cleaner	1
Fiber bender	1
Laser area symbol	1
Protection glasses	3
Handpiece cover	1

There are some special tools included:

（1） Fiber optic cleaner

Stains may accumulate over time, potentially blocking the laser and resulting in unexpected heat concentration, which can adversely affect the performance of the device. A fibre optic cleaner is employed to remove dirt or stains from the ceramic joint column, thereby reducing performance degradation and extending the service life of the dental diode laser.



(2) Fiber bende

Over-bending of the fibre optic tip may potentially break the optical fibre. This product is designed to assist in bending the fibre optic tip, providing a gentle angle change to minimise the risk of damage.

Insert the capillary part of the fibre optic tip into the cavity of the Fibre Schematic Diagram Bender, and bend it to the intended angle slowly. Please remember not to bend the fibre optic tip to an angle of less than 90°.

(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.

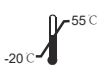
(4) Self-configuration asseccory

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.

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
	Refer to the user manual for proper usage instructions.
	Laser hazard warning—exercise caution.
	Indicates the laser emission point.
	Laser radiation present—take precautions.
	Detailed laser feature information and warnings.
	Single use or single patient per procedure.
	Manufacturer contact information.
	EU representative contact details.
	Safe temperature range for use and storage.
	Safe humidity range for use and storage.
	Safe atmospheric pressure range.
	Batch code for traceability.
	Do not use after the indicated expiry date.

2. Safety relevant matters

2.1 Summary

Dental diode laser (TriLux Laser) 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 fibre optic tip has not been processed; please note that it is essential to follow the procedures outlined in Chapter 5 prior to use.
- The equipment must only be operated by personnel who are trained and possess the relevant knowledge and experience to use it correctly.
- The manufacturer is not liable for any loss caused by the use of this equipment by untrained individuals.
- The product must be cleaned and maintained according to the provided instructions when not in use for an extended period.
- Only parts and accessories supplied by our company are permitted for use; the company will not be responsible for any loss or injury resulting from the use of parts not provided by us.
- Ensure that there are no metallic or reflective objects, such as necklaces, reflective instruments, or reflective brackets, in the operating area.
- All personnel in the treatment room must wear protective glasses before operation.
- The manufacturer provides protective glasses with a specific wavelength range of 830-1100 nm.
- Close the doors and windows of the treatment room to prevent accidental laser leakage.
- Ensure that the operator is knowledgeable about how to turn off the laser in case of an emergency before beginning the procedure. Additionally, place a small fire extinguisher and a container of 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 devices are not used as required, or if each step is not performed correctly.
- Fibre optic tips are removable and consumable parts.
- If damaged, please contact the manufacturer for replacement or purchase.
- Do not place any liquid on the device.
- If liquid seeps into the device, press the emergency stop switch immediately and notify customer service.
- All optical components, especially those in the laser transmission system, must be handled carefully, protected, and kept clean and dust-free.
- The operating environment should also be maintained in a clean condition.
- Only direct laser light onto the treatment site is permitted. Do not direct the optical fibre aperture towards the eyes, and take care to avoid accidentally firing the laser.
- Turn off the power switch when the device is not in use for an extended period to prevent unintentional activation of the transmitter switch.
- When the laser is not in use, reposition it away from the operator's area of activity.
- Avoid soft tissue adhesion to the fibre tip, as this can cause local overheating and may result in the tip of the fibre becoming singed or detaching. If this occurs, wipe the fibre with medical alcohol gauze. Continue the operation after the alcohol has evaporated, and re-cut the optical fibre if necessary.
- Do not spray detergent directly onto the body of the laser system.
- The device must not be used in the presence of flammable anaesthetic gases mixed with air or with oxygen or nitrous oxide.
- If the fibre optic tip requires direct contact with oral soft tissue,

ensure that the fibre optic tip has been carbonised (initiated) before making 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 ensure that unauthorised personnel do not enter this area during treatment.
- The Nominal Ocular Hazard Distance (NOHD) is 3.03 metres; therefore, the edge of the designated laser area must extend beyond this distance.
- Display appropriate laser warning signs.
- The minimum bending radius of the optical fibre tip should not be less than 2.5 cm during use; otherwise, it may cause damage to the equipment.
- The manufacturer provides a bending set for the optical fibre tip.
- The laser can ignite non-metallic materials; therefore, all flammable materials must be removed from the working area or kept wet during operation.
- Be cautious when using solutions that contain alcohol and/or acetone, as they can also ignite.
- Oxygen is highly combustible, so care must be taken when using it. Do not leave any solution residue in the operating area, as volatile gases may be absorbed by materials such as surgical drapes, presenting safety risks.
- Surrounding tissues may be unintentionally irradiated during laser therapy, and excessive irradiation can lead to tissue damage, perforation of blood vessels, and bleeding.
- Practitioners should set the laser to the lowest power dose possible for patient safety.
- For cutting procedures, initiate the fibre optic tip first or use a pre-initiated fibre 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 Labelling in the Treatment Area

The manufacturer will provide a laser warning label with each laser system. We recommend displaying these signs at the entrance to the laser treatment room to alert individuals entering the area.

Laser area symbol

During operation, the maximum permissible radiation intensity in this area may be exceeded. Therefore, the "laser area" must be clearly segregated, and appropriate laser warning signs must be displayed.

The distance between the laser and the Nominal Ocular Hazard Distance (NOHD) is significant. As such, the entire laser application area should be designated as a controlled laser zone.

Required Safety Measures:

- Install warning lights at the entrance to the laser operating room.
- Display triangular yellow laser warning signs and other visible indicators.

3. Installation

3.1 Unboxing and Inspection

Upon receipt of the device, follow these steps to ensure proper delivery and condition:

- Check Packaging: Inspect the outer packaging for damage. If damage is found, request a signed damage statement from the courier.
- Verify Contents: Confirm all accessories listed in Section 1.4 are included.
- Inspect Device: Ensure the device and accessories are in proper working order.
- Report Issues: If any components are missing or damaged, contact the courier immediately and notify Xpedent.

3.2 Device Setup

- Main Unit: The device is fully integrated and requires no installation. Verify all components are complete (refer to Section 1.4) to ensure safety and proper functionality.
- Fibre Optic Tip: Follow the instructions for replacement and installation as needed.(1) Fiber optic tip models:

Non-initiated	Models	Diameter	Length	Application
	E4-4	400um	4	Surgery
	E4-7	400um	7	Periodontology
	E4-9	400um	9	Periodontology
	E2-14	200um	14	Root canal
	E2-20	200um	20	Root canal

Pre-initiated	Models	Diameter	Length	Application
	IE4-4	400um	4	Surgery
	IE4-7	400um	7	Periodontology
	IE4-9	400um	9	Periodontology

With your first purchase, we will provide six commonly used fibre optic tips as follows:

Model	Amount
F4-4	2
F4-7	2
F4-9	2
F2-14	2
F2-20	2
PF4-4	2
PF4-7	2
PF4-9	2

(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 inserting the dustproof quartz column (either the dustproof plug or fibre optic tip), clean it using the fibre optic cleaner as follows:

a.Reveal the Application Surface: Press the operation button to expose the cleaning surface.

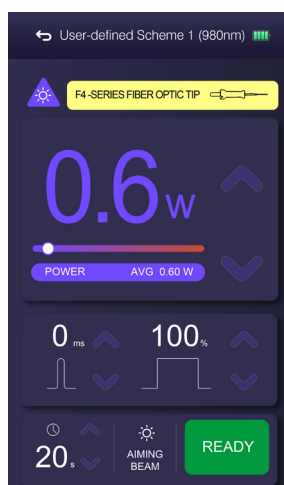
b.Clean the Quartz Column: Rub the ceramic plug perpendicular to the non-woven surface in the direction of the labelled arrow.

3.3 Important Notes

- Use Environment: Ensure the operating environment meets the requirements outlined in Section 1.2.5 before use.

4. Operation instruction

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



4.1 Interactive interface description

Component Name	Function Description
Touch Screen	Used for parameter setting, including duty cycle, laser emission time, and parameter recommendation selection. It also changes the state between ready and standby modes, and displays battery status.
Emergency Stop Button	In emergencies, pressing this button will immediately shut off the laser, ensuring safety.
Indication Light	Indicates the state of the device.
Laser Emission Button	The laser will emi t when this button is pressed in standby mode.
Power Button	Device power switch.
Unlock Key	After powering on the device, the blue light on this button will illuminate, indicating that the device is locked and the laser cannot be emitted. Pressing this button will unlock the device, turning off the blue light, allowing the laser to be emitted when the laser emission button is pressed.
Power Increase Key	When the unlock key is activated, pressing this key will increase the laser power.
Power Reduction Key	When the unlock key is activated, pressing this key will decrease the laser power.

4.2 Treatment operation

(1) Pre-Use Inspection

Before starting treatment, please conduct an inspection as per the warnings outlined in Chapter 2.

(2) Booting the Device

Press the power switch; the device will then display the passcode interface.

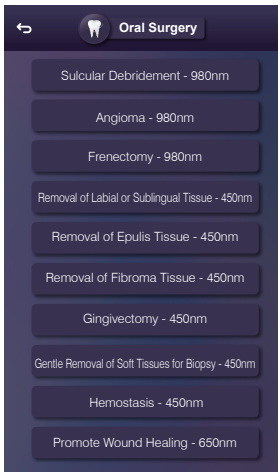
(3)Passcode Input

Upon startup, the system will require the operator to input a password: Enter the code 1 2 3 4 5 6. If the code is incorrect or not entered, the system will not proceed to standby mode. If the code is correct, the device will enter standby mode (the standby button will be activated).

(4)Tip Initiation

If the fibre optic tip requires direct contact with oral soft tissue during this treatment, ensure that the fibre optic tip has been carbonised (initiated) before making contact, or use a pre-initiated tip (models that start with PF).

Initiation Procedure:



Before use, contact the articulating paper with the optical fibre in the optical fibre tip. Initiate the laser at 1W for approximately 5 seconds to carbonise the optical fibre tip. Clean away any ashes before commencing treatment.

(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.

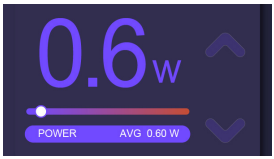
If the parameters of preset values are inappropriate, the corresponding parameters can be adjusted according to the actual situation.

(6)Parameter setting

Before starting treatment, please conduct an inspection in accordance

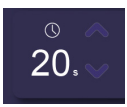
with the warnings outlined in Chapter 2

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%:

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

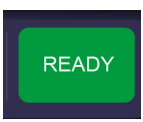


(7)Parameter saving

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 activate the laser. The indication light will flash orange, accompanied by a continuous beep sound.

(10) Emission pause

Press the Standby button to pause laser emission. In an emergency situation, you can press the Emergency Stop button to immediately halt laser emission.

(11)Turn off

After the treatment, be sure to turn off the laser immediately by pressing the power switch. In case of an emergency, regardless of the device's current state, press the Emergency Stop button. The device will shut down immediately, and the laser will stop emitting.

(12)Charge

The screen displays the battery status. Use the adaptor and cable provided by the manufacturer. When charging is complete, the green light on the adaptor will turn on.

4.3 Special function description

(1) Mode Changing

The dental diode laser has two modes:

CW Mode (Continuous Wave): This mode provides continuous energy output and is mainly used for small lesions or when rapid surgery is required.

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

DW Mode (Pulse Wave): In this mode, the duration of laser output varies periodically, with adjustable duty cycle parameters. It is primarily used for larger lesions or long-term treatments.

(2) Aiming Beam

The device is equipped with a red aiming beam that has the same radius as the application laser. The position of the aiming beam should be used as an indicator for the launching site during treatment. The aiming beam is also a reliable method for checking the integrity of the transmission system.

If the aiming beam's points are not located at the end of the transmission system, if their intensity is reduced, or if they do not appear to converge, this may indicate that the transmission system is damaged or not functioning properly.

Note: To prevent these issues, please use the device according to these instructions. If any of the above problems occur, please contact your local dealer or Xpedent.

(3) Visible and Audible Laser Emission Signals

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

(4) Passcode Lock

Upon startup, the system will require a password. If the password is not entered or is entered incorrectly, the system will not proceed to the working interface. The default password is 123456.

5. Reprocessing

5.1 Body contact information

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

Name	Contacting tissue	Material	Contact period	Contact time
Fiber optictip	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 advisable to use a new fiber optic tip for each treatment or for different patients. The handpiece cover is designed to prevent blood and foam from splashing onto the device enclosure, helping to prevent cross-contamination.

Spaulding Classification: Semi-Critical Devices.

The parts need processing:

Component	Process
Sterilization	Sterilization
Handpiece cover	Sterilization

The dentist or clinician should wear clinical gloves and cover the handpiece of the device with a sterilized handpiece cover prior to use. The sterilization procedure for the handpiece cover is outlined in section 5.2. To prevent cross-contamination, please ensure that the handpiece cover is used before each procedure.

5.2 Cleaning/Disinfection Procedure

The enclosure (including the screen, buttons, and handpiece area) should be cleaned and disinfected before use and after the handpiece cover is removed. The cleaning and disinfection process is as follows:

- Wipe the enclosure, including the screen and buttons, with a clean cloth to remove smudges and fluids.
- Wipe with a 75% alcohol wet cloth. Ensure that the cloth is free of liquid leakage.
- Finally, wipe with a dry, clean cloth. Do not spray detergent directly onto the body of the product.

5.3 Sterilization Procedure

The fiber optic tip and the handpiece cover must be sterilized before use. Please follow the procedure below to sterilize these components:

- Prepare and preheat the sterilizer along with the sterilization pouches.
- Place the fiber optic tip or handpiece cover into the sterilization pouches and seal them securely.
- Place the sealed pouches into the sterilizer and set the sterilizer parameters as follows:

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-Remova (Pre-Vacuum)	132°C(270°F)	4minutes	20-30minutes
	134°C(EUonly)		

- Start the sterilization procedure. After sterilization, check the fiber optic tip for any damage, such as b.deformation, breakage, or cracks. The fiber optic tip and handpiece cover can be used after they have cooled down for at least 30 minutes.

6. Maintenance and Troubleshooting

6.1 Maintenance

Device Maintenance and Maintenance Period

If the device has been left unused for more than a month, it should be processed according to the procedure in section 5.2.

If the device's lifespan has expired, it will indicate this and lock down the device.

Calibration

The dental diode laser needs to be calibrated every 24 months after receipt. Before the annual calibration date, please contact your local dealer or the manufacturer for calibration. In addition to the normal annual calibration, if the aiming beam is visibly reduced or not visible, please contact your local dealer or manufacturer for calibration.

Service Life Information

The dental diode laser has a mechanism that indicates when the service life is ending and will lock down the device when it reaches the end of its 5-year service life. Additionally, there is a mechanism for users to verify that the device is still within performance qualification:

- Prepare a sheet of white paper.
- Power on the dental diode laser and adjust the laser power to 0.1W.
- Press the Power button to enter the laser launch state.
- Aim the aiming beam at the white paper.
- The dental diode laser is deemed to have a performance failure if the aiming beam is not visible or conspicuous. Please follow the instructions in Section 2.5 for the appropriate disposal of devices that fail.

6.2 Troubleshooting

The dental diode laser is equipped with an internal warning system. If an error occurs, the device will stop working immediately.

In the event of a failure, please refer to the maintenance table to troubleshoot the issue step by step. If the error cannot be resolved, please contact Xpedent customer service or your local dealer for assistance.

Issue	Possible Cause	Recommended Action
Screen Touch Malfunction	Screen calibration required	Quickly tap on a blank area of the screen 10 times. The blue “drop” calibration mode will appear. Drag the pen from the top-left corner of the screen to the bottom-right corner until calibration is complete.
Fibre Breakage	Incorrect usage or the maximum number of uses of the optical fibre has been reached	Replace and sterilise the fibre optic tip before using it again.
Device Suddenly Switches Off	Unknown security error	Contact the local dealer or Xpedent customer service.
Display Function Keys Unresponsive	Internal damage to the circuit board	Switch off the device and contact the local dealer or Xpedent customer service.
Abnormal Set Values and Output Data	Unknown related security error	Switch off the device and contact the local dealer or Xpedent customer service.
No Aiming Beam Appears at the Aperture	Aiming beam function failure / fibre damage / control circuit fault	Restart the device. If the issue persists, please contact the local dealer or Xpedent customer service.

6.3 Maintenance Considerations

To ensure that the dental diode laser remains in a state of normal use and retains its asset value, it is recommended to conduct a safety inspection service annually. This service should be performed by authorized repair and service representatives of Xpedent Company products, which include:

- Trained technicians from Xpedent Company or its branches.
- Trained technicians from local distributors authorized by Xpedent Company.

Operators, device managers, and users must utilize the device in accordance with local medical device regulations.

Do not attempt to repair the device without authorization. Significant maintenance and repairs should only be conducted by qualified dental diode laser service technicians. The device key should be held by an authorized professional.

Please do not attempt to open the interlock or damage the housing, as these are designed for safety protection. Retain the container for potential repair or upgrades during the warranty period.

The fiber optic tip can be stored for two years without opening the

package. Once you start using it, we suggest using it once after sterilization. In the case of repeated use, please adhere to the sterilization requirements.

7. Performance parameter

The dental diode laser is equipped with a mechanism that indicates when the service life is ending. The device will lock down once it has reached the end of its 5-year service life.

Parameter	Details
Dimension (L x W x H)	165mm × 160mm× 275mm
Weight	2 Kg
Laser Classification	Diode laser, class IV
Wavelength	980nm±20nm
Power Output	0.5W - 8W, step 0.1W
Power Modes	Continuous working (CW), Pulsing mode (DW)
Duty cycle	10% - 100%
Pulse width	10us - 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

Parameter	Details
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

8. EMC information

8.1 EMC Related Warning

The dental diode laser (TriLux Laser) complies with the relevant requirements of the EMC IEC 60601-1-2 standard. Users must install and utilise the EMC information provided in the accompanying documentation.

Portable and mobile RF communication equipment may affect the performance of the dental diode laser (TriLux Laser). To avoid strong electromagnetic interference during use, maintain a distance from devices such as mobile phones, microwave ovens, and similar equipment.

The dental diode laser (TriLux Laser) should not be placed close to or stacked with other equipment. If it is necessary to stack or position it near other devices, validation should be performed to ensure that it operates normally in that configuration.

8.2 Guidelines and Manufacturer's Statement

Electromagnetic emission		
Dental diode laser (TriLux Laser) is intended to use in below electromagnetic environment, the following provisions of Dental diode laser (TriLux Laser) 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 (TriLux Laser) 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 (TriLux Laser) 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			
The dental diode laser (TriLux Laser) is intended for use in the following electromagnetic environment. Buyers or users should ensure that the following provisions are observed for the appropriate operation of the dental diode laser (TriLux Laser) in this environment:			
Immunity test	IEC 60601 test level	Conform level	Electromagnetic environment-Guidance
ESD IEC 61000 - 4 - 2	±6 kV Contact ±8 kV A ir discharge	±6 kV Contact ±8 kV Air discharge	Floors should be wood, concrete or synthetic materials, the relative humidity of the place 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 voltage	Inapplicability	Inapplicability
Voltage dips, short interruptions and voltage variations on the power input line IEC 61000 - 4 - 11	<5 % UT, for 0.5 cycles 40 % UT, for 5 cycles (On UT, >80 % sags) 70 % UT, for 25 cycles (On UT, >70 % sags) <45 % UT, for 5s (On UT, >65 % 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 characteristics of the power frequency magnetic field in a typical commercial or industrial place. Note: UT refers to the AC network voltage before applying the test voltage

Electromagnetic immunity			
Dental diode laser (TriLux Laser) is intended to use in below electromagnetic environment, the following provisions of Dental diode laser (TriLux Laser) of buyers or users should ensure that its use in the electromagnetic environment:			
Immunity test	IEC 60601 test level	IEC 60601 test level	Electromagnetic environment - Guidance
RF transmission IEC 61000 - 4 - 4	3 V/m 150 kHz to 80 MHz	3 V/m	Portable and mobile RF communications devices should not be used in any part of Dental Diode Laser (TriLux Laser) electromagnetic environment. Isolation distance, including cable length, shall be calculated by the following formula according to the transmitter's power: 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 is the maximum output of the transmitter, the transmitter unit is watt (W), and is the recommended distance of separation, with meters (m).
RF radiation IEC 61000 - 4 - 3	3 V/m 80 MHz to 2.5 GHz	3 V/m	The field strength of the fixed RF transmitter is determined by surveying the electromagnetic fields, and in each case, the value should be lower than the confidence level. Interference may occur near devices with the following symptoms: - Noise on audio systems - Image on video systems
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.			
[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 (TriLux Laser) is measured to be higher than the RF coincidence level of the above-mentioned application, then Dental Diode Laser (TriLux Laser) shall be observed to verify its normal operation. If abnormal performance is observed, supplementary measures, such as reorientation or positioning of Dental Diode Laser (TriLux Laser), may be necessary. [b] he field intensity should be less than 3 V/m over the entire frequency range from 150 kHz to 80MHz.			

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

Dental Diode Laser (TriLux Laser) 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 (TriLux Laser) can prevent EMI by maintaining the minimum distance between their portable and mobile RF communication devices (transmitters) and Dental Diode Laser (TriLux Laser) 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 p	80 MHz~800 MHz d=1.2 p	800MHz~2 .5GHz d=2.3 p
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For 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.

9. Warranty Period

The dental diode laser (TriLux Laser) is covered by a warranty for quality failures that occur within 12 months after delivery, provided these failures are not due to human error. For the handle, fibre optic tip, and other accessories, the warranty covers any quality failures within 60 days after delivery, again provided these are not due to human error.

To maintain the warranty, any internal adjustments or replacements of the equipment must be performed by Xpedent or its authorised agents. Xpedent's warranty liability is limited to products returned to the company for warranty and replacement. Xpedent also reserves the right to offer on-site repairs in the buyer's area.

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

- Improper operation and misuse;
- Accidents or damage resulting from the customer's negligence, such as dropping the product;
- Damage caused by rain, water, humidity, etc.;
- Damage caused by external heat, splashes 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 casing, touchscreen, and exposed parts. The company shall not assume any liability or compensation for repairs carried out by the customer beyond those stipulated in the warranty.

The company disclaims any implied warranty of merchantability or fitness for a particular purpose. Furthermore, the company shall not be liable for any incidental or consequential damage that may occur during the delivery process.

Warranty Card

Name of Customer		(I) For Distributor
Address Details		
Postal Code		
Tel		
Model		
Machine ID		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

Guilin Yikeshi Medical Instrument Co.,Ltd.
D-8,Guilin National High-tech Zone Information Industrial Park, Chaoyang Road,Qixing District,Guilin,Guangxi,541004,P.R.China
Postal Code: 541004
Tel: 0086 0773 5805522
Fax: 0086 0773 5805522
Email: sales@xpediency.cn
Website: www.xpedent-intl.com

Distributor:

Seal

Warranty Card

Name of Customer		(II) Return to Manufacturer
Address Details		
Postal Code		
Tel		
Model		
Machine ID		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

Guilin Yikeshi Medical Instrument Co.,Ltd.
D-8,Guilin National High-tech Zone Information Industrial Park, Chaoyang Road,Qixing District,Guilin,Guangxi,541004,P.R.China
Postal Code: 541004
Tel: 0086 0773 5805522
Fax: 0086 0773 5805522
Email: sales@xpediency.cn
Website: www.xpedent-intl.com

Distributor:

Seal

Cut along the dashed line

Warranty Instruction

I Period validity

Terms of service: We offer 12 months warranty repair to the equipment based on the date of sale on the warranty card, and charged maintenance for the life of the product.

II Range of warranty

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

III The following are beyond our warranty

1. The damage caused by disobeying the operation instruction or lack of the needed condition.

2. The damage caused by unsuitable operation or disassembly without authorization.

3. The damage on product that caused by users' unexpected drop or impact to product.

4. The damage caused by unadvisable transportation or preservation.

5. There isn't the seal of distributor or the warranty card isn't filled in completed.

Warranty Instruction

I Period validity

Terms of service: We offer 12 months warranty repair to the equipment based on the date of sale on the warranty card, and charged maintenance for the life of the product.

II Range of warranty

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

III The following are beyond our warranty

1. The damage caused by disobeying the operation instruction or lack of the needed condition.

2. The damage caused by unsuitable operation or disassembly without authorization.

3. The damage on product that caused by users' unexpected drop or impact to product.

4. The damage caused by unadvisable transportation or preservation.

5. There isn't the seal of distributor or the warranty card isn't filled in completed.

EC REP **Xpedent Austria GmbH**
Millennium Park 9 6890 Lustenau Austria

Guilin Yikeshi Medical Instrument Co.,Ltd.
D-8,Guilin National High-tech Zone Information Industrial Park,
Chaoyang Road,Qixing District,Guilin,Guangxi,541004,P.R.China
Postal Code: 541004 Tel/Fax: 0086 0773 5805522
Email: sales@xpediency.cn Website: www.xpedent-intl.com

TriLux Laser V1.0 28.Feb.2025