CE 0197

Dental Diode Laser Systems
User Manual

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0. INTRODUCTION

The SOLASE Pro dental diode laser is a surgical and therapeutic device produced by LAZON Medical Laser Co., Ltd., designed for dental soft tissue indications, laser periodontal procedures as well as teeth whitening and pain relief. It cannot be used for oral hard tissue.

The laser uses a laser diode as the beam source to radiate laser light, which is delivered to the operating area by a fiber cable. Wireless technology is applied to connect the base unit with the wireless footswitch. The laser can be powered by an external mains power supply or an internal replaceable Li-ion battery.

The FastFiber tips are designed as disposable material, which helps to prevent cross infections and simplify the preparation. Three types of FastFiber tips are provided - 400μm, 300μm, and 200μm – for the use of surgery, periodontics and endodontics respectively. A tip bender is also delivered within the package to help bend the tip to any angle.

The SOLASE Pro laser is a Class 4 laser product which may cause injuries in improper handling. Therefore, it MUST be operated only by trained and qualified personnel. Users are required to read this User Manual carefully before using the device. For any question, please contact LAZON Medical Laser or our authorized service representative.

1. INDICATIONS, CONTRAINDICATIONS AND MEDICAL PRECAUTIONS

1.1. Indications

The indications for use of the subject device are given below.

1) Dental soft tissue indications

Incision, excision, vaporization, ablation, and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Operculectomy
- Pulpotomy
- Soft tissue crown lengthening
- Treatment of herpetic and aphthous ulcers of the oral mucosa

2) Laser periodontal procedures

- 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 mobility.)

3) Whitening

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleach of teeth

4) Pain Relief

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of the muscle.

CAUTION: The SOLASE Pro cannot be used for hard tissue surgery.

1.2. Contraindications

All clinical procedures performed with SOLASE Pro must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment and exercise caution for general medical conditions which might contraindicate a local procedure; such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency or any medical conditions or medications that may contraindicate use of certain

light/laser type sources associated with this device. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment. SOLASE Pro treatment may be contraindicated for patients suffering from photodermatosis, photosensitive patients, and patients who are taking photosensitive drugs. Conditions such as pregnancy or pacemakers are not known as contraindications for laser light energy.

1.3. Medical Precautions

WARNING: Never direct the laser beam toward a person's eye or thyroid gland.

WARNING: The eyes of patients, dentists and assistants must always be protected with the laser protective eyewear provided within the unit, even when only the aiming beam is activated.

2. SAFETY

2.1. Safety Classification

- Working beam (according to IEC/EN 60825-1:2014): Class 4
- Aiming beam (according to IEC/EN 60825-1:2014): Class 2
- Protection against electric shock: Class I, Type B applied part
- Laser protective eyewear conform to standard DIN EN207 Annex II of the Directive 89/686/EEC with protection level L5 for the wavelength range of 190-450nm and 800-1100nm
- Degree of protection of wireless footswitch：IPX8

2.2. Operator

The SOLASE Pro Laser MUST be operated only by trained and qualified personnel. The operators should master the laser surgery and be familiar with the manual knowing how to choose the proper operating parameters according to indications. They must know how to protect themselves and the patients against hazardous laser radiation and take proper actions in dangerous situations. We suggest all operators be trained before their operations of the SOLASE Pro laser.

CAUTION:
Operators will be required to enter a password to access the laser functions. Please keep this code and don't leak it to avoid unauthorized use.

SAFETY

CAUTION:
Federal law restricts this device to sale or on the order of a physician.

2.3. Laser Radiation Hazards

- Never direct the laser or aiming beam towards any person's eyes! All personnel presenting in the room must keep their laser protective eyewear.
- Never direct the laser to the human body except for the treatment region, the laser radiation may cause skin burns.
- Never direct the laser beam toward paper, plastics, textile or other inflammable materials. They could catch fire due to the high temperatures produced by the laser beam.

WARNING: A risk of fire and/or explosion exists when the laser output is used in the presence of Flammable materials, solutions or gases, or in an oxygen enriched environment. The high temperature produced in normal use of the laser equipment may ignite some materials, for example, cotton wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

WARNING: Laser fume and/or plume may contain viable tissue particulates.

SAFETY

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

WARNING: Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. The laser beam will be reflected to create potential hazards.

2.4. Nominal Ocular Hazard Distance (NOHD)

The Nominal Ocular Hazard Distance (NOHD) of the SOLASE Pro Laser is 4.55 meters @450nm, 1.18 meters @635nm, 5.42 meters @810nm, and 4.36 meters @980nm, calculating from the distal end of the optical fiber.

2.5. Laser Protective Eyewear

All persons present in the room (patient, dentist, and assistant) must always wear the laser protective eyewears from the SOLASE Pro package.

Before using the laser protective eyewear, please make sure that your laser protective eyewear:

- are not damaged
- conform to protection level L5 from standard EN 207
- are suitable for the working wavelength (labeled on the eyewear)

These instructions apply particularly when using eyewear supplied from outside sources that are not included in the scope of delivery of the SOLASE Pro Laser.

WARNING: Never use optical instruments such as microscopes, eye loupes or magnifiers together with the original protective eyewear. Otherwise sufficient eye protection can no longer be ensured.

2.6. Optical Fiber Cable and FastFiber Tip

- Do not sharply bend, twist or knot the fiber cable, which leads to the damage to the fiber and harm to the patient and laser operator.
- Prior to each use, please examine the optical windows of the handpiece body to make sure there are no dirt or dust contaminations which can cause overheating and damage of the connector, raising the risk of fire hazards.
- If the optical cable or the FastFiber tip is damaged during operation, the operator must immediately stop laser and get it replaced. Otherwise it can cause overheat of the connector, raising the risk of fire hazards.
- After the operation, please cover the distal end of the handpiece body with the protective cap to keep clean of the optical windows.
- The FastFiber tip is designed only for single use. It must be disposed of after each patient use.

3. INSTALLATION AND OPERATION

3.1. Packing List

The SOLASE Pro package includes the following parts:

No.	Name		Quantity
1	Base Unit		1
2	Handpiece Body (with Protective Cap)		1
3	FastFiber Tip	200μm	3
4		300μm	7
5		400μm	10
6	Handpiece Sleeve		2
7	Wireless Footswitch		1
8	Whitening Handpiece (optional)		1
9	Disposable Whitening Shield (optional)		4
10	Therapy Handpiece (optional)		1
11	Biostimulation Handpiece (optional)		1
12	Laser Protective Eyewear		2
13	Patient Goggle		1
14	DC Power Adapter with Cord		1
15	Tip Bender		1
16	User Manual		1

Table 2.1 List of standard package

WARNING: No modification of this equipment is allowed.

3.2. Structure

- Base Unit

Figure 3.1 Front view of the base unit

Figure 3.2 Back view of the base unit

- Handpiece body

Figure 3.3 Handpiece body

- Wireless Footswitch

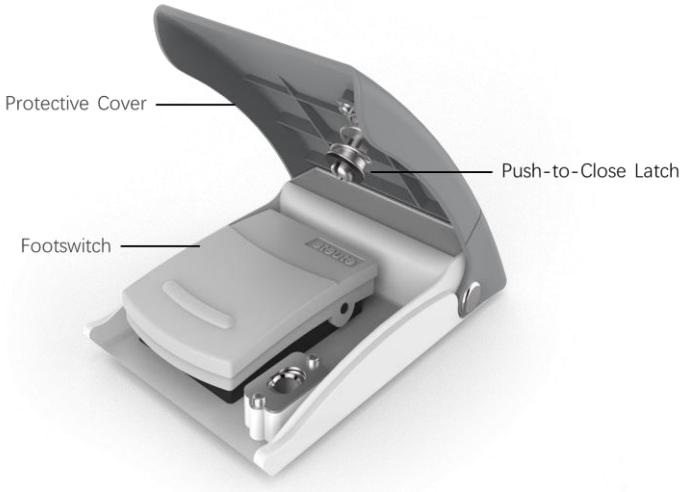


Figure 3.4 Wireless footswitch

3.3. Environment and Equipment Requirement

Electrical Supply: 100-240VAC, 50-60Hz

Working Temperature: 10-30℃

Relative Humidity: 15-70%

Atmospheric Pressure: 710-1060hPa

WARNING: To avoid the risk of electric shock, this equipment must be connected to a mains supply with protective earth.

NOTE: Place the SOLASE Pro Laser on a flat horizontal plane to avoid shake.

NOTE: Do not cover or block air vents to ensure enough cooling of the laser.

3.4. Installation and Setting Up

3.4.1. Install Power Adapter or Use Rechargeable Battery

a) Powered by Power Adapter

Connect the power adapter to a wall outlet (100-240VAC, 50-60Hz), and then insert the DC power connector into the DC IN socket at the back of the base unit with an arrow marked on the top (Figure 3.5) until it “click” into place.

To disconnect the DC power adapter from the base unit, unplug the power cord from the wall outlet and grab the connector at the part marked with an arrow and slowly pull it straight back.

CAUTION: The DC power connector has a snap-locking feature, helping to prevent accidental disconnection. To unplug from the socket, grabbing and pulling at the part marked with an arrow is necessary. Inappropriate or forced plugging may break the connector.

CAUTION: Only use the DC power adapter from package or others authorized by LAZON. Damages caused by using of unauthorized power adapter are not be covered and lead to an automatic void of LAZON warranty.

Figure 3.5 Connect DC power adapter to the base unit

b) Powered by Battery

The SOLASE Pro Laser can be powered by a chargeable battery inside the base unit when the power adapter is disconnected. To charge the battery, connect the DC power adapter to the DC IN socket after plugging into a wall outlet. When charging, the charging indicator on the front panel will light up, and will go out after fully charged. The indicator will flash when charging is abnormal. Before first use, fully charge the battery for at least 4 hours.

3.4.2. Remote Interlock

Remote interlock is used with a door switch to prevent unintentional entry. Once the door is opened, the interlock circuit triggers and the laser emission is immediately shut off. The interlock connector used by SOLASE Pro is a standard 3.5mm audio jack. To use this function, connect the remote interlock cable to the door switch and plug it into the interlock socket located at the back of the base unit. The door switch should be a normally closed switch. Therefore, the interlock circuit can be cut when the door is opened, and then the laser emission is interrupted with an error message appears on the screen. To clear this error, please close the door and press “Clear” button on the screen.

NOTE: If you don’t need this feature, don’t connect the interlock cable to the base unit.

3.4.3. Install FastFiber Tip

The SOLASE Pro Laser provides disposable FastFiber tips with three types of core diameters - 200μm, 300μm, and 400μm, in the color of pink, blue and grey respectively. Please choose proper FastFiber tip before use. ***The FastFiber tips must be cleaned and sterilized before use***. For instructions on how to sterilize the tips, refer to Section 6.4.1.

To install, insert the handpiece sleeve from the front of the handpiece body and screw it clockwise until snug, then insert the FastFiber tip to the handpiece sleeve and click into place (Figure 3.6).

Operators can use a bender to bend the tip to the angle needed for best

handling. Do not bend the tip to an angle higher than 60°, that makes it easy to break during laser emission.

Figure 3.6 Disposable FastFiber tip assembly

Pull the FastFiber tip straight back to disconnect it (Figure 3.7).

Figure 3.7 Remove the disposable FastFiber tips

The tip end may be contaminated during operation due to the accumulation of tissue debris. In this case, please stop lasing and regularly wipe off the tip with a sponge dipped with water. Do not use flammable solvents such as alcohol when cleaning a hot tip!

WARNING: The FastFiber tips are for SINGLE USE ONLY. Reuse significantly increases the chance of patient cross-infection!

CAUTION: The FastFiber tips must be disposed of in a sharps container after use.

3.4.4. Whitening Handpiece (Optional)

The whitening handpiece is used for light activation of bleaching materials in tooth whitening procedures. It should be disinfected before use. For instructions on cleaning and disinfection, refer to Section 6.4.2.

The method of installing the whitening handpiece on handpiece body is similar to that of the FastFiber tip. The disposable whitening shield should be installed on whitening handpiece to avoid water condensing which may lead to the damage to the optical system (Figure 3.8). The shields must be cleaned and sterilized before use. For instructions on how to sterilize the shields, refer to Section 6.4.1.

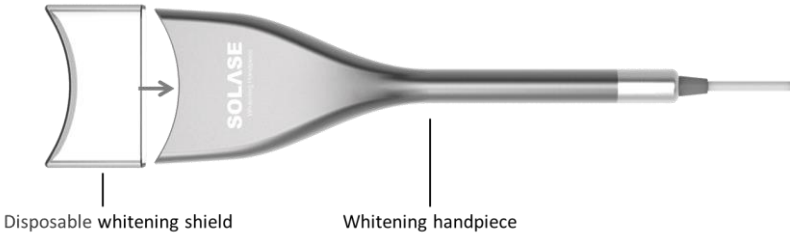


Figure 3.8 Disposable whitening shield

WARNING: The disposable whitening shields are for SINGLE USE ONLY and should never be reused!

CAUTION: The whitening handpiece cannot be sterilized in the autoclave, as it may damage the internal optics.

3.4.5. Therapy Handpiece (Optional)

The therapy handpiece can be used for pain relief. It should be disinfected

prior to use. For instructions on cleaning and disinfection, refer to Section 6.4.2. The diameter of the light spot can be changed from 10mm to 30mm by rotating the focus ring (Figure 3.9).

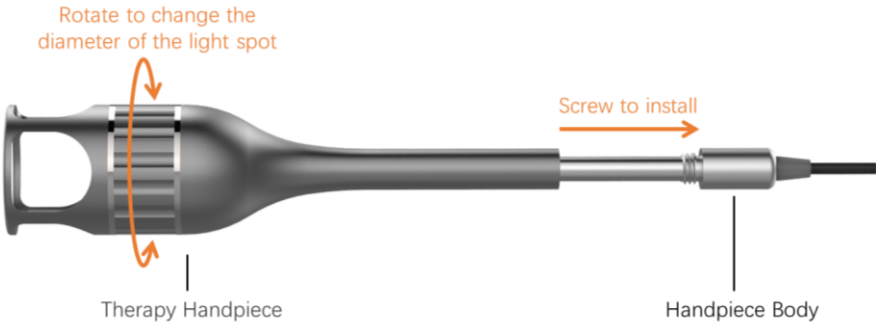


Figure 3.9 Therapy handpiece

CAUTION: The therapy handpiece cannot be sterilized in the autoclave, as it may damage the internal optics.

3.4.6. Biostimulation Handpiece (Optional)

Different from the therapy handpiece, the biostimulation handpiece is typically used for relatively small areas inside the mouth. It should be sterilized with autoclave before use. For instructions on cleaning and disinfection, refer to Section 6.4.3.

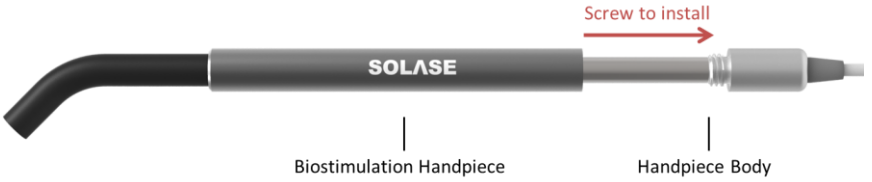


Figure 3.10 Biostimulation handpiece

3.4.7. Turn on the SOLASE Pro Laser

To access the SOLASE Pro App:

1) Turn on the power switch of the base unit and the green status indicator on the front panel will light.
2) The laser starts to self-check, which may last for more than 30 seconds. Please wait patiently. After successful self-check, the device will ask you to enter a 4-digit password. If you forget the password, please contact us or our authorized service representative to reset the password.

NOTE: The factory default password is "0000". To change your password, refer to section 4.4.4.

3.4.8. Use Aiming Beam to Check the Integrity of the Delivery System

As the aiming beam passes down the same delivery system as the working beam, it provides a good way of checking the integrity of the delivery system.

Figure 3.11 Aiming beam spot emitted from good fiber compares with that from bad fiber

Place the distal end of the laser handpiece perpendicular to a piece of white paper at distance of 5-10 mm. Turn on the aiming beam and adjust it to maximum brightness. The visible light should be transmitted from the handpiece, and a well-formed round spot should appear. If the spot is not

round in shape or its density is reduced, the beam delivery system may be defective. Replace the laser delivery system and try again. If problems still exist, please contact us or our representative for assistance.

WARNING: Never emit the laser if the aiming beam is not present or has a significantly different shape.

3.4.9. Enter READY Mode

Press “READY” button and the laser gets into the READY mode. The status indicator will show orange light. Now you can activate laser by pressing wireless footswitch.

NOTE:
STANDBY mode: The laser is not capable of emitting the working beam even if the wireless footswitch is activated.
READY mode: The READY mode keeps the laser equipment enabled so that it is capable of emitting laser when the wireless footswitch is activated.

3.4.10. Activate Laser by Pressing Wireless Footswitch

In READY mode, the laser is activated when the wireless footswitch pressed, with a beeping sound indicating that the laser energy is present, and the orange status indicator begins flashing. Release the footswitch, the laser stops and the beeping sound disappears. To re-adjust the laser parameters, please press the "STANDBY" button to back into “STANDBY” mode firstly.

3.4.11. Tip Initiation

Soft tissue has a weak absorption for wavelength of 600-1300nm. The laser energy cannot be well absorbed by the soft tissue and cannot reach the temperature required for cutting when using 810nm or 980nm laser. So, when lasers are used in contact mode to make an incision or excise soft tissue, they often need “initiation” of the laser tip end. An energy absorbing material is used to absorb the emitted laser and is rapidly heated to several hundred degrees. This “hot tip” is used to melt proteins thus separating the tissue.

The “initiation” steps are as follows: Prepare a dark paper (such as articulating paper), move the end of the fiber tip gently on the paper with the laser power set to 0.7W CW. The tip end will retain the pigment of the paper. Observe the aiming beam against a surface. If it is still clearly visible, repeat more times.

Actually, the tip initiation by articulating paper or wood is not satisfied, as the pigmentation in the tip end is quickly burned off during laser surgery, resulting in a decrease of cutting efficiency. The operators have to initiate the tip again and again to continue the operation.

LAZON has developed a new pre-initiated tip with durable, peel-resistant black coating. The specially crafted coating withstands high temperature during laser cutting of up to hundreds of degrees, ensuring a smooth and fast surgical treatment.

NOTE:
Protein has a strong absorption for 450nm laser, so there is no need to initiate the tip when using this wavelength.

3.4.12. Emergency Stop

In case of emergency, press the red Emergency Stop button to turn off the laser emission immediately. A beeping sound will appear, and the status indicator begins to flash red light with an error message “Emergency stop is triggered” appearing on the screen. To clear the error, click “Clear” button on the screen.

NOTE:

There are other ways to stop laser emission besides the Emergency Stop:

1) Turn off the power switch of the laser.
2) Release the wireless footswitch.
3) Press the “STOP” button on the screen.

3.4.13. Quit READY Mode

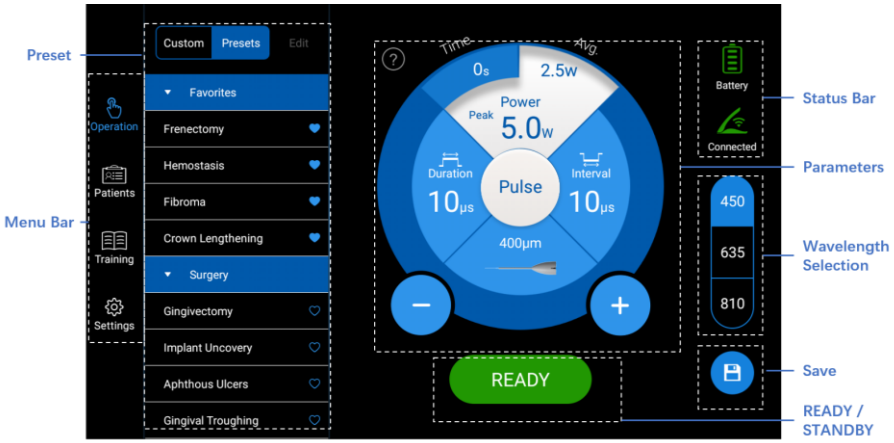
Press the “STANDBY” button to quit READY mode.

3.4.14. Power Off

After treatment, turn off the power switch and wind the fiber cable around the fiber spool to avoid damage. Place the handpiece body onto handpiece holder with protective cap to keep the optical window clean.

4. SOFTWARE OPERATION

4.1. Operation Screen



1) Status Bar: Include connection status and battery status.

- Connection status: Indicate the connection status between wireless footswitch and the base unit. When the footswitch is not triggered for a long time (5 minutes), it will be disconnected from the base unit to extend battery life, with the "Offline" icon displayed. The connection between the footswitch and the base unit is quickly established once the footswitch is activated, with the "Connected" icon displayed. Please replace the battery of the footswitch when “Low” icon appears (for details refer to section 6.1.2).

- Battery status: Indicate the power supply of the laser, which can be

powered by a battery (battery symbol) or DC power adapter (the plug symbol). If it is powered by a battery, battery level can be counted in real time by the number of the frame.

2) Parameters: The adjustable parameters include Peak Power, Pulse Duration, Pulse Interval, Handpiece Type, Emission Duration and Laser Mode.

- Peak Power: Peak power is formally defined as the maximum optical power a laser pulse will attain. In CW mode, peak power is equal to the average power.
- Average Power: The Average Power changes automatically with Peak Power, Pulse Duration and Pulse Interval.
- Pulse Duration: Range from 10μs to 0.9s. 635nm cannot be set to pulse mode.
- Pulse Interval: Range from 10μs to 0.9s. 635nm cannot be set to pulse mode.
- Handpiece Type: Six types of handpiece are available to choose, including 200μm FastFiber, 300μm FastFiber, 400μm FastFiber, Whitening Handpiece, Therapy Handpiece, and Biostimulation Handpiece.
- Emission Duration: The software records the total emission time of the laser if this parameter is set to “0 s”. If modified, such as set to "200 s", the total emission time is recorded and counts down to "0 s", ending with an automatic stop of laser emission.
- Laser Mode: Including CW mode and pulse mode. The Pulse Duration and the Pulse Interval are not adjustable under CW mode. 635nm cannot be set to pulse mode.

NOTE: Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, pulse duration and interval settings, mode of operation, as well as the accessories (e.g. tip type) and other procedural requirements. Closely observe and monitor clinical effects and use your judgment to determine the clinical parameters and approach for the treatment; make appropriate power, pulse length, and interval adjustments to compensate for varying tissue composition, density, and thickness. Always start treatment at the lowest power setting for the specific indication and increase as required. LAZON assumes no responsibility for parameters, techniques, methods, or results.

NOTE:
CW mode (Continuous Wave Mode): Imply a continuous, uninterrupted laser beam as long as the laser is activated.
Pulse mode: Laser delivers its energy in the form of a single pulse or a train of pulses.

3) READY / STANDBY Button: Users could access READY mode by pressing the “READY” button. Or press “STANDBY” button to return to STANDBY mode.
4) Menu Bar: Users can access the submenus through the Menu Bar, which includes four submenus - Operation, Patients, Training and Settings.
5) Preset: Select a protocol according to your treatment. You can:

- Select the factory-loaded presets which are recommended by the manufacturer.
- Alternatively, choose or save your own presets.

6) Wavelength selection: Users can choose the most suitable laser

wavelength according to their needs. The 450nm has strong absorption for protein and is very suitable for soft tissue cutting, coagulation and hemostasis; 635nm is normally used in laser therapy; 810nm and 980nm laser can be used for soft tissue cutting, coagulation and hemostasis, and can also be used for anti-inflammatory.

7) Save: Use this button to save patient treatment records or custom presets.

4.2. Patients

After each treatment, the patient treatment record can always be saved by press the “Save” button on the Operation screen. If the patient has not been saved before, "Save Record to New Patient" should be selected; if the patient already exists, "Save Record to Existing Patient" should be selected. For each record, the user can always fill in the remarks of the treatment. Press “Use” button and the setting of the record will be automatically set.

The available patient information includes name, gender, date of birth, email, phone number, emergency contact, insurance number, occupation, home address, drug allergy, and remarks. Name and gender are required.

4.3. Training

It contains the following parts：

1) Quick Start: Digital version of Quick Start.
2) User Manual: Digital version of the User Manual.
3) Literature: Some literatures about laser dentistry.
4) FAQ: Some frequently asked questions are listed. We recommend to read these FAQs before using the laser.

4.4. Settings

4.4.1. Volume

Drag the slider to the left to decrease the volume, or right to increase it.

4.4.2. Brightness

Aiming beam and screen brightness can be adjusted. Drag the slider to the left to decrease the brightness, or right to increase it.

4.4.3. Language

Current available languages include Simplified Chinese, English, French, German, Italian, Spanish, Polish and Portuguese.

4.4.4. Change Password

Enter your old password and your new password, confirm your password and save.

4.4.5. Multi-accounts

Users can set up multiple sub-accounts, and each sub-account can be set with independent passwords, patient records and custom presets. Note that only the administrator account has the authority to add sub-accounts and modify sub-account information.

4.4.6. Upgrade

The laser will automatically check the new version of software once connected to WiFi. When new version is available, press "Update Now" and the laser will update to the latest software. The speed of the updating depends on the network speed. If your network speed is slow, the process may last from several to ten minutes. Do not turn off the power during the updating!

4.4.7. More Settings

SOFTWARE OPERATION

1) Counter: The user can replace the Emission Duration in the Operation Screen with "Energy" or "Fluence" to count up or down. The unit of Energy is J, and the calculation formula is Energy = Time * Average Power. The unit of Fluence is J/cm^2, and the calculation formula is Energy Density=Time * Average Power / Beam Area.

NOTE: Different laser handpieces have different beam areas. For whitening handpiece, phototherapy handpiece and bio-stimulation handpiece, the beam area is defined as the cross-sectional area at the laser exit window, which are 9.1cm^2, 7.1cm^2 (when the beam diameter is 3cm) and 0.5cm^2 respectively; For fiber tips of 200μm, 300μm and 400μm, the beam area is all defined as 0.1cm^2.

2) Time Setting: The user can use the network-provided time, or customize the time. To use the network-provided time, the WiFi must be connected firstly.

3) About: some information about the manufacturer.

   In this setting, users can also restore factory settings. Pressing this button deletes all your data saved in SOLASE Pro, including custom presets and patient records. Confirm with caution!

   The user can also unpair the wireless footswitch. This operation will delete the pairing between your laser and your footswitch, so that the laser can be paired with other footswitch.

5. TECHNICAL DATA

Laser	Laser Classification	Working beam: Class 4 (according to IEC/EN 60825-1:2014)
	Wavelength	For SOLASE-976: 450±10nm, 635±10nm, 980±10nm For SOLASE-808: 450±10nm, 635±10nm, 810±10nm
	Max Power Output	For SOLASE-976: CW 3W±20%, pulse 5W±20% @450nm CW 400mW±20% @635nm CW 8W±20%, pulse 12W±20% @980nm For SOLASE-808: CW 3W±20%, pulse 5W±20% @450nm CW 400mW±20% @635nm CW 6W±20%, pulse 9W±20% @810nm
	Pulse Duration	10μs-0.9s
	Pulse Interval	10μs-0.9s
	Pulse Repetition Rate	Up to 50kHz
	Laser Mode	CW or pulse mode
	FastFiber Tip Diameter	200μm, 300μm, 400μm
	Aiming Beam	⩽5mW, 635nm
	Fiber Cable Core Diameter	200μm
	Numerical Aperture (NA) of Fiber Cable	0.22
	Fiber Cable Connector	SMA-905
	Fiber Cable Length	1.7 meters
	Nominal Ocular Hazard Distance (NOHD)	4.55 meters @450nm, 1.18 meters @635nm 5.42 meters @810nm, 4.36 meters @980nm

TECHNICAL DATA

	Surface area of whitening handpiece	9cm^2
	Surface area of therapy handpiece	0.79cm^2 - 7.1cm^2
Electrical	Protection Against Electric Shock	Class I Me Equipment Type B Applied Part
	Power Supply Input	100-240VAC, 50-60Hz
	Power Supply Output	15VDC, 6A
	Battery Pack	Lithium Ion Rechargeable, 11.1V, 5000mAh
Others	Laser Protective Eyewear	Protection level of L5 in 190-450nm and 800-1100nm
	Size	214 x 150 x 149 mm
	Weight	1.6 kg

6. MAINTENANCE AND SERVICE

6.1. Battery

6.1.1. Rechargeable Battery of the Base Unit

The SOLASE Pro Laser has a built-in lithium-ion rechargeable battery. To ensure better battery life and safety, please follow the instructions below:

1) Lithium-ion batteries are susceptible to temperature, do not use or store the battery at very high or low temperature. In particular, the use at high temperature (above 60℃) causes irreversible damage to the battery.
2) Lithium batteries have no memory effect. They can be charged at any time.
3) If the battery leaks, stop the laser and replace the battery immediately.

NOTE: To ensure the safety of the user, the SOLASE Pro automatically stops emission when the temperature of the lithium-ion battery is above 50℃.

6.1.2. The battery of Wireless Footswitch

The wireless footswitch uses two AAA battery. When the battery is low, the status icon on the Operation screen appears as “Low”. To replace the battery, follow the steps below:

1) Use a Phillips screwdriver to remove the screws and open the battery cover of the wireless footswitch.
2) Detach the battery terminal to remove the old battery.
3) Replace with new AAA batteries and attach it to the terminal. Be careful of the connection with the correct polarity!
4) Reinstall the battery cover and screw it tightly.

6.2. Power Calibration

Laser calibration is recommended to be performed every 12 months to maintain the accuracy of the laser output. If you need power calibration service, contact LAZON or your authorized service representative.

NOTE: It is recommended to use your own laser power meter to check whether the actual laser output deviates from the set value by more than ±20%. Do not use a SOLASE Pro exceeding this limit and contact LAZON or your authorized service representative immediately for power calibration.

6.3. Replacement of Fiber Cable

The optical cable is already connected to the base unit in the shipping package. We do not suggest users disconnect the cable unless it is damaged, thus avoid the reduction of the coupling performance.

To change the optical cable, please follow the steps below:

1) Use a Phillips screwdriver to remove the screws and open the battery cover of the base unit.
2) Unscrew the old fiber connector counterclockwise, pull out the silicone plug, and take out the entire fiber cable.
3) Insert the new fiber cable back into the hole, screw the fiber connector clockwise, and reinstall the silicone plug.
4) Reinstall the battery cover and screw it tightly.

NOTE: SOLASE Pro uses standard SMA-905 fiber connector.

6.4. Cleaning, Disinfection, and Sterilization

6.4.1. Cleaning and Sterilizing Instructions for the disposable tip, the handpiece sleeve, the whitening shield, and the tip bender

The FastFiber tip, the handpiece sleeve, the whitening shield, and the tip bender must be clean and steam sterilized prior to use. The parameters of autoclaving should be:

- Cycle Type: Gravity displacement;
- Temperature: 121℃ (250℉);
- Sterilization Time: 30 minutes;
- Dry Time: 30 minutes;
- Packaging Method: Pouch per AAMI recommendations

6.4.2. Cleaning and Disinfecting Instructions for Whitening Handpiece and Therapy Handpiece

In order to prevent cross-contamination, the whitening handpiece and therapy handpiece should be cleaned and disinfected prior to each use by a soft cloth dipped with disinfectant, e.g. CaviWipes™ or other similar products, to remove the dust after each use and leave it for at least 5 minutes, and then wipe it with a new dry cloth.

CAUTION: The whitening handpiece and therapy handpiece are not autoclavable, which causes damage to the optical system.

6.4.3. Cleaning, Disinfecting and Sterilizing Instructions for the Biostimulation Handpiece

The head of the biostimulation handpiece must be sterilized in the autoclave

before each use with the same parameters as FastFiber tip. The sleeve of the biostimulation handpiece is not autoclavable, which causes damage to the internal optics.

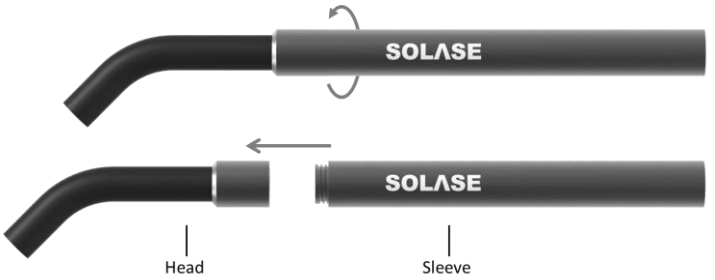


Figure 6.1 Remove the head of the biostimulation handpiece

6.4.4. Cleaning and Disinfecting Instructions for the Base Unit

The base unit should be cleaned and disinfected by the method of wipe-disinfection, which is similar to the cleaning of the therapy handpiece and whitening handpiece. Please turn off the power switch and unplug the DC power adapter from the base unit before cleaning.

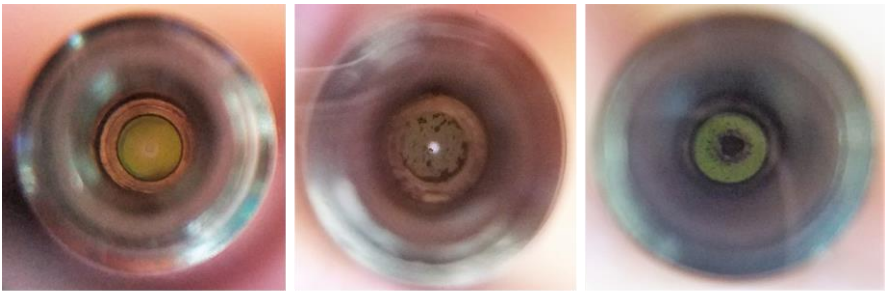
CAUTION: Wear latex gloves when cleaning.

CAUTION: Do not use corrosive disinfectants (such as bleach).

CAUTION: Never spray to disinfect the SOLASE Pro. Spray disinfection may allow liquids to penetrate into the device.

6.4.5. Cleaning Instructions for the optical window of the handpiece body

The optical window of the handpiece body is easily contaminated with dust, resulting in a drop of the laser output. We recommend checking and cleaning the optical window each time before use of the laser.



Good optical window: Clear and transparent | Contaminated with dust | Damaged

Use the following method for cleaning:

a) Use compressed air to blow off the dust from the optical window.

b) If dust remains, use Microbrush to clean the optical window.

6.5. Troubleshooting

Title	Fix
PCB too hot	Switch off the device for 5-10 minutes to cool off the PCB.
Laser module too hot	Stop laser emission for 5-10 minutes to cool off the laser module.
Laser module too cold	The SOLASE Laser cannot emit laser if the ambient temperature is too low. Place it to a warmer room and try again. If the problem persists, please contact LAZON or your authorized service representative.

Battery too hot	Switch off the device for 5-10 minutes to cool off the battery.
Emergency stop triggered	Press “Clear” on the screen.
Remote interlock triggered	Close the door which has connected to the remote interlock and press “Clear” on the screen.
The battery of the base unit is running low	Recharge the battery of the base unit.
The battery of the footswitch is running low	Replace the battery of the footswitch (see section 6.1.2).
Optical fiber not connected	Connect the optical fiber into the fiber adapter on the base unit.
PD level high	Make sure that the fiber cable is properly connected to the base unit, and that the type of handpiece displayed on the screen is the same as the one actually used. If the problem persists, please contact us for laser power calibration.
PD level low	
Fan not work	Contact LAZON or your authorized service representative.
Temperature too hot	Stop laser emission for 5-10 minutes to cool the laser
Ambient temperature is too low	If your current room temperature is below 5°C, the laser will not start because the temperature is too low. Please try to start the laser again by placing the laser above 5°C.
The temperature of optical cable connector is too high	The optical cable connector may be burnt. Contact us to check and replace the optical cable.

6.6. Transportation

The SOLASE Pro is susceptible to damage if being banged, dropped, jarred and jolted. For this reason, do not transport the laser unless it is wholly

packaged inside its original case, with the distal end of the handpiece body protected with a protective cap.

For long-distance transportation, the case should be packed appropriately, e.g., put in a box with stuffing fillers. The package should also be kept dry and water-resistant during transportation.

Transportation requirements:

- Temperature: 2-40℃
- Relative Humidity: 15% -75%
- Atmospheric pressure: 710 hPa to 1060 hPa
- A dry and clean environment without corrosive gases

6.7. Storage

When not in use, the SOLASE Pro Laser should be stored in a cool and dry place without dust and shock, as heat, moisture, dust, and shock cause severe damage to the laser. For long-term storage, please charge the lithium battery of the base unit to 40%. Remove the battery of the wireless footswitch. Store the laser in the case.

Storage requirements:

- Temperature: 2-40℃
- Relative Humidity: 15% -75%
- Atmospheric pressure: 710 hPa to 1060 hPa
- A dry and clean environment without corrosive gases

CAUTION: Make sure the distal end of the handpiece is protected from dirt with a protective cap.

APPENDIX A – SYMBOLS DESCRIPTION

General warning sign

NOTE

Batch Code

Manufacturer

Date of Manufacture

Type B applied part

Approved for sale in the European Union

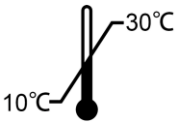
Refer to the instruction manual/ booklet

Compliant with U.S. regulations for radio transceivers

Authorized representative in the European community

Serial Number

DO NOT REUSE



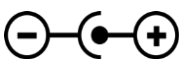
Temperature limitation

Emergency Laser Stop

Remote interlock connector

SYMBOLS DESCRIPTION

Dispose of waste consistent with regulations



Connection socket for DC power adapter

Interference is possible in the vicinity of the device

Use by

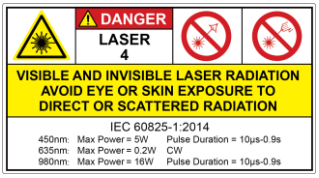
Orientation of the DC power adapter

For maintenance personnel only

Fiber protection warning

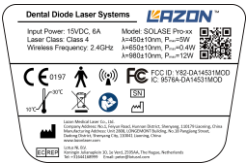
Laser Aperture at Fiber End

Non-professional do not open the cover



Warning Label: visible and invisible laser radiation

Footswitch Label



Informative Product Label

APPENDIX B - LABELS POSITION

APPENDIX C - LIMITED WARRANTY

1. The Warranty Period

The SOLASE Pro Dental Diode Laser is warranted to be free from defects in materials and workmanship for a period of one (1) year from the date of purchase when used under normal operating conditions as described in this manual. This warranty does not apply to the laser handpiece, fiber cable, protective eyewear, FastFiber tips, and the built-in battery, which shall be warranted against defective materials and workmanship for a period of 90 days from the date of purchase.

The warranty period starts from the purchase date on the customer's valid purchase voucher (tax invoice). If proof of purchase cannot be provided, the manufacture date as recorded by LAZON plus three months will be deemed to be the start of the Warranty Period (this is to make up for the time cost of transportation and storage at the distributors).

For faulty products of which the warranty has expired, the maintenance will incur a cost.

2. The Maintenance Commitment

LAZON products will be repaired by parts maintenance or parts replacement, and the parts that are replaced shall be owned by LAZON. Replacement parts does not necessarily mean new parts, but we guarantee the replacement parts are LAZON original parts, and are superior to or equal to the replaced parts in terms of performance.

Products are only eligible in their original countries / regions of purchase. A full service charge will be incurred if you carry the product from the original countries / regions to others for maintenance or other service.

LIMITED WARRANTY

The LAZON Medical Laser Co., Ltd. reserves the right to make changes in design or to modify such previously manufactured products.
This warranty does not include labor, postage or delivery charges.

3. Attention

If any of the following situations occurs, LAZON will not provide free maintenance:

1) Accidental damage occurs during transportation
2) Software upgrades due to wrong installation, or failure or damage caused by using the product in a non-work environment
3) Appearance damage (caused by burns, distortion, etc.)
4) The products have been repaired by non-LAZON repair center or unauthorized personnel
5) The warranty seal is torn or has traces of being opened.
6) Damage caused by using a power cord or power adapter that are not approved by LAZON.
7) Malfunction or damage caused by force majeure (such as earthquake, lightning strike, flood, fire, etc.)

APPENDIX D - EMC DECLARATION

The SOLASE Pro dental diode laser needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents; Portable and mobile RF communications equipment can affect the SOLASE Pro dental diode laser, even the equipment meet the requirement CISPR 11.

Guidance and manufacturer's declaration – electromagnetic emissions		
The SOLASE Pro dental diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the SOLASE Pro dental diode laser should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SOLASE Pro dental diode laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The SOLASE Pro dental diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the SOLASE Pro dental diode laser should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical

IEC 61000-4-4	± 1 kV for input/output lines	± 1 kV for input/output lines	commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the requires continued operation during power mains interruptions, it is recommended that the SOLASE Pro dental diode laser is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Not applicable Note: The SOLASE Pro dental diode laser does not contain components susceptible to magnetic fields, such as Hall elements or magnetic field sensors. Therefore, the EUT is deemed to meet the requirement without actual testing.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

EMC DECLARATION

The SOLASE Pro dental diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the SOLASE Pro dental diode laser should assure that it is used in such an electromagnetic environment.

IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the SOLASE Pro dental diode laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM, and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SOLASE Pro dental

diode laser is used exceeds the applicable RF compliance level above, the SOLASE Pro dental diode laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SOLASE Pro dental diode laser.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SOLASE Pro dental diode laser

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2,5 GHz $d = 1.17\sqrt{P}$
0.01	0.12	0.12	0.07
0.1	0.37	0.37	0.22
1	1.17	1.17	0.70
10	3.69	3.69	2.21
100	11.67	11.67	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic or decreased electromagnetic immunity of this equipment and result in improper operation. The cable of the laser has a length

of 1.7m.

WARNING：Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the (Me equipment or Me system) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING：Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

APPENDIX E - DISPOSAL

Within the European Economic Area, this laser is subject to Directive 2002/96/EC as well as the corresponding national laws. This directive requires environmentally sound recycling/disposal of the product. The product must not be disposed of as domestic refuse! Before disassembly or disposal of this laser, it must be completely prepared (disinfected, sterilized).

For the area outside of Europe, please observe the disposal regulations applicable in your country.

Contact your local government's recycling or solid waste management department to learn more about the services it provides. LAZON Medical Laser Co., Ltd. would be pleased to assist you in answering questions of proper device disposal.