



*iLase*TM

User Manual

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1 Introduction

1.1 DESCRIPTION

The iLase™ dental soft tissue laser is a surgical device designed for a wide variety of dental soft tissue procedures. The iLase uses a solid state laser diode as a source of invisible infrared radiation. The energy is delivered to the treatment site via a single-use fiber optic tip assembly. Several types of tips are available for use with the iLase to perform different procedures.

The iLase system consists of two elements:

- ▶ The iLase Handpiece contains the laser diode, the replaceable fiber optic tip, removable cover with integrated finger grip, a main body with control electronics, integrated selector-switch, organic LED (OLED) display, and rechargeable battery. The iLase Handpiece delivers laser energy, under user control, to the treatment site.



Figure 1 - 1:
iLase handpiece and fiber optic tip*

- ▶ The iLase Charging Station is used for charging and storing the iLase and replacement batteries. The iLase and discharged batteries are placed in receptacles in the charging station where they are automatically recharged. Up to four batteries with or without main bodies attached may be charged at one time.



The Charging Station contains four charging indicator lights located on the front panel of the charger. There is one indicator for each of the battery receptacles at the top of the unit. When the indicator displays an amber color, the battery is charging. A green light indicates that the Battery is fully charged. The charging station is powered by a low voltage power supply that connects at the rear of the unit.

1.2 INDICATIONS FOR USE

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:

- ▶ Excisional and incisional biopsies
- ▶ Exposure of unerupted teeth
- ▶ Fibroma removal
- ▶ Frenectomy
- ▶ Frenotomy
- ▶ Gingival troughing for crown impressions
- ▶ Gingivectomy
- ▶ Gingivoplasty
- ▶ Gingival incision and excision
- ▶ Hemostasis and coagulation
- ▶ Implant recovery
- ▶ Incision and drainage of abscess
- ▶ Leukoplakia
- ▶ Operculectomy
- ▶ Oral papillectomies
- ▶ Pulpotomy
- ▶ Pulpotomy as an adjunct to root canal therapy
- ▶ Reduction of gingival hypertrophy
- ▶ Soft tissue crown lengthening
- ▶ Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
- ▶ Vestibuloplasty
- ▶ Tissue retraction for impression

Laser periodontal procedures, including:

- ▶ Laser soft tissue curettage
- ▶ 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, probing depth, attachment loss, and tooth mobility).

1.3 CONTRAINDICATIONS

All clinical procedures performed with the iLase 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. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, and 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 patient's physician is advisable when doubt exists regarding treatment.

2 Precautions and Warnings

2.1 CLINICAL

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

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

CLINICAL USE: 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 pulse interval settings, mode of operation as well as the tip type and other procedural requirements. Always start treatment at the lowest power setting for that specific indication and increase as required. Closely observe and monitor clinical effects and use your judgment to determine clinical parameters and approach for the treatment. Make appropriate power and settings adjustments to compensate for varying tissue compositions, density and thickness. Cutting with the iLase is a thermal process and any transfer or accumulation of heat into adjacent structures may result in a burn and tissue damage. Always start treatment at the lowest power setting for that specific indication and increase as required. Be aware of the underlying and adjacent structures such as nerves and blood vessels when cutting with this device. Do not direct laser energy towards hard tissues such as tooth or bone or any metallic restorations. Do not direct laser energy towards metallic restorations, cements or other dental materials. Exercise extreme caution when using this laser inside the pocket, 3rd molar sockets, channels and other openings where visibility is limited.

ANESTHESIA: When treating soft tissue, anesthesia may not be necessary; patients should be closely monitored for signs of pain or discomfort at all times. If such signs are present, adjust settings, apply anesthesia, or cease treatment if required.

INEFFECTIVE REMOVAL OF TISSUE: Ineffective removal of tissue may be caused by improper tip initiation (see Section 4.7) or reduction in the power output. Check with a Biolase service representative to make sure that the iLase is functioning properly.

TIP BREAKAGE: Use a bite block to prevent accidental biting and breakage of the tip; use high-speed suction to prevent patient inadvertently swallowing a broken tip and choking.

iLASE WINDOW: Check and clean the protective window of the fiber optic shaft with a cotton swab moistened with isopropyl alcohol. **CAUTION:** Failure to check and clean the window will lead to reduced optical power efficiency and permanent damage to the system (refer to Section 7 for maintenance information).

2.2 LASER SAFETY



DANGER

Do not look directly into the beam or at specular reflections. Never direct or point the beam at anyone's eyes.



WARNING

Do not use this device if you suspect it is functioning improperly or other than described herein.



WARNING

No modification of this equipment is allowed.



CAUTION

All persons present in the operatory must wear protective laser eyewear for the laser wavelength of 940nm.



CAUTION

Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. Laser beam reflections from these surfaces create a potential hazard.



CAUTION

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



CAUTION

Instrument should be installed and operated according to CAN/CSA-Z386-08: Laser safety in health care facilities.

2.3 ELECTRICAL SAFETY



CAUTION

Do not look directly into the beam or at specular reflections. Never direct or point the beam at anyone's eyes.



CAUTION

Plug the power supply into a grounded receptacle only. Connection to an ungrounded receptacle may create hazardous conditions.

2.4 FIRE SAFETY



DANGER

Do not operate this device in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen (O₂) should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser is used. Attention should also be drawn to the danger of ignition of endogenous gases.

2.5 CLEANING AND STERILIZATION



WARNING

The single-use tips are supplied non-sterile and must be sterilized before use. The iLase Cover is another component that requires sterilization. Refer to Chapter 6 "Cleaning and Sterilization" for instructions on sterilizing tips and the iLase cover.

2.6 PERSONAL PROTECTIVE EQUIPMENT



PROTECTIVE EYEWEAR REQUIRED

Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the laser wavelength of 940nm. Periodically inspect laser eyewear for pitting and cracking. For replacement or additional protective laser eyewear, please contact Biolase or your authorized dealer.



LASER PLUME

Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue. Use high speed suction and clinical masks for protection at all times during the laser procedure.

3 Installation

3.1 UNPACKING

Carefully unpack the shipping container and inspect the contents. If any parts are damaged or missing, do not use the iLase and contact your Biolase representative immediately.

Inside the shipping container you will find the following items:

<i>Description</i>	<i>Model 7400040-01</i>
Charging Station	1
Power Supply – Charging Station	1
iLase Main Body	1
iLase Cover	1
Single-Use Tips	1 Kit
iLase Cover Grips	1 Pkg
Tip Initiation Blocks	1 Pkg
iLase Rechargeable Battery	2
Laser Safety Signs	1
Laser Safety Glasses (Clinician)	2
Laser Safety Glasses (Patient)	1
iLase Cleaning Kit	1
User Manual	1

Retain the shipping container and store it in a cool dry place. Use this container if it becomes necessary to ship the iLase to Biolase or a Biolase Authorized Service Center.



3.2 CLEANING AND STERILIZATION BEFORE USE ON PATIENTS

The iLase and accessories are provided non-sterile. The cover is reusable and must be cleaned and sterilized between patients to avoid cross-contamination. The tips are single-use only to avoid cross-contamination and are designed to withstand a single sterilization cycle only; they must be disposed of after single use in a biohazard medical waste Sharps container. Refer to section 6 “Cleaning and Sterilization for complete instructions.

3.3 BATTERY CHARGING

You must charge the batteries before using the device.

► Plug in the charging station power supply to an AC power receptacle and connect it to the charging station as shown below. Place the charging station on a surface where it will not be disturbed or come in contact with liquids or contaminants.

IMPORTANT: Use only Biolase approved power supplies, P/N 6400422

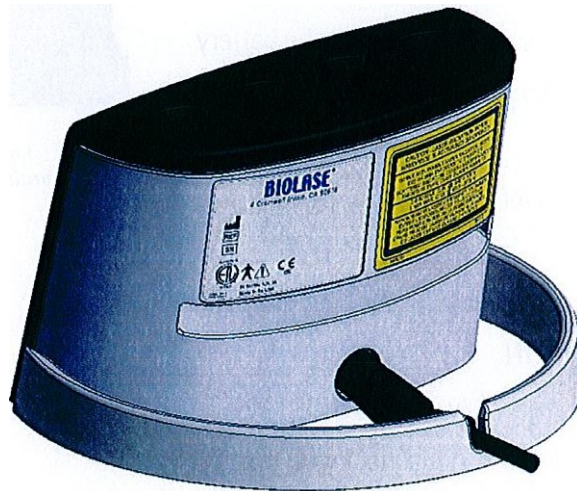


Figure 3 - 1: Power Supply Attachment

► Place the batteries, either end first, in any one of the battery charging receptacles at the top of the charging station. iLase batteries have contacts on both ends and allow placement into the receptacle in either orientation. The batteries will connect automatically to the charging contacts when inserted, and the charging indicator will illuminate with an amber color to indicate that the charging has started. If the indicator illuminates with a green color, the battery is already charged and is ready for use. Attaching the main body to the battery is optional, but not required to charge a battery.

The battery charging indicator on the front of the charger will display the charge condition of each of the batteries placed in the charger. If no battery is installed, the charging indicator will be off.

Allow the batteries to charge for a minimum of two hours before first use. If the battery has been charging for more than two hours and the indicator has not turned green, the battery might be damaged and may need to be replaced. When the battery charging indicator turns green, the battery is fully charged and you may prepare the device for use.

NOTE: Charge spare batteries for a minimum of 2 hours before use.

3.4 BATTERY INSTALLATION

Slide a fully charged battery assembly into the socket at the end of the main body of the iLase. A magnet inside the main body will grip and hold the battery in place. (Battery assemblies have contacts on both ends; it is not necessary to orient the end of the battery when installing it). To remove a battery, gently pull the battery from the socket until the magnet releases the battery assembly.

3.5 ATTACHING A TIP

To install a tip, slide a sterile iLase cover onto the handpiece. Make sure the cover is properly oriented and fits snug against the button on the main body as shown in FIGURE 3-3.

Insert a sterile tip into the open end of the cover. Tighten the tip by turning clockwise until snug. Once installed, verify that the tip appears to extend straight from the cover.

If it appears angled, remove and re-install the tip until it appears straight. Once properly installed, bend the metal cannula as appropriate for the planned procedure.

CAUTION: Do not bend the tip at a sharp angle as it may break.



Figure 3-2: Charging Indicators



Figure 3-3:
iLase Cover Attachment



Figure 3-4:
Tip properly installed



Figure 3-5: Bending the tip cannula

4 Operating Instructions

4.1 PERSONAL PROTECTIVE EQUIPMENT



PROTECTIVE EYEWEAR REQUIRED

Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the laser wavelength of 940nm. Periodically inspect laser eyewear for pitting and cracking. For replacement or additional protective laser eyewear, please contact Biolase or your authorized dealer.



LASER PLUME

Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue. Use high speed suction and clinical masks for protection at all times during the laser procedure.

4.2 PREPARATION FOR USE

Before using the iLase, make sure the following conditions have been met:

- ▶ The iLase charging station power supply is plugged into working AC power receptacle, and at least one battery is connected to the charging station and charged for at least 2 hours.
- ▶ The iLase cover has been sterilized using the sterilization instructions noted in Chapter 6 "Cleaning and Sterilization."
- ▶ The tips that you plan to use have been sterilized using the sterilization instructions noted in Chapter 6 "Cleaning and Sterilization."
- ▶ The iLase main body and battery have been disinfected by following the cleaning and disinfecting instructions noted in Chapter 6 "Cleaning and Sterilization."
- ▶ The iLase has been assembled, including the cover and a fully charged battery assembly.
- ▶ A tip appropriate for the planned procedure has been installed in the iLase cover.

4.3 STARTING THE ILASE

Turn on the iLase by installing the battery.

NOTE: To avoid Error message, do not hold the handpiece over the rubber finger grip area at any time in *STANDBY* mode. If an error message occurs, simply remove your fingers from the rubber grip and wait until message clears.

The iLase Welcome Screen is displayed.



Figure 4-1: Welcome Screen .

Safety operation of laser electronic devices requires prevention of the unauthorized use of the devices. An electronic key is implemented in the iLase for that purpose. When PLEASE ENTER KEY appears, there is a progression bar shown for 3 seconds. Triple click the selector switch (rapidly press three times) to advance to the next screen, Procedures Menu. If the key is not entered, the system remains on the Welcome screen. To get back to the PLEASE ENTER KEY screen, press the selector switch once.



Figure 4-2: Key Enter Screen .

4.4 INITIAL SELECTION OF A PROCEDURE

The SELECT PROCEDURE screen will appear once the key is properly entered. Eleven preset procedures are available; to select a procedure, scroll up or down using the Selector Switch and press the switch in on the desired procedure (refer to section 5.1 for a listing of procedure presets).

When you have selected a procedure by pressing the selector switch, the Tip Initiation screen will appear with the preset values for that operation: 1.4 W, continuous or CW mode.

After two seconds, the system will enter Ready mode and the laser will be ready for firing by pressing on the rubber grip to initiate the tip. After completing the initiation of the tip, press down the selector switch to start the procedure using the selected presets.

4.5 SYSTEM MODES

STANDBY MODE: For all operations leading up to the firing of the laser, the system has remained in STANDBY Mode (as noted by the amber LED in the iLase display). In STANDBY Mode, the user has the ability to select a new procedure, modify settings for the procedure, and make any other changes necessary. In this mode, the laser is disabled from accidental firing. Actuation of the finger switch will be indicated by the error symbol E05 (refer to section 8.2 for a full listing of error messages). If the selector switch is pressed in for longer than 1.5 seconds or if the iLase is inactive for more than three (3) minutes, it will go into SLEEP mode.

READY MODE: When a procedure is selected or when you have made any needed adjustments and are ready to perform a procedure, place the system into READY mode by pressing down the selector switch. When the iLase is in READY mode, the LED will be green. Only in this mode is the red aiming beam activated and the laser can be fired. While in READY mode, you may adjust the power only. In order to save modified settings to a pre-set procedure, press in and hold the selector switch for

1.5 seconds. SAVED will appear on the screen indicating that your modifications are saved under the current procedure name. You must ensure that all safety precautions have been followed prior to entering READY mode. (See Section 2 “Precautions and Warnings”). The system will return to STANDBY mode when it is inactive for more than three (3) minutes.

SLEEP MODE: The system is placed in a low power state to conserve battery power. All LED's and the Display panel are turned off in this mode. The system will enter STANDBY mode with the last settings used when the Selector Switch or Finger Switch is pressed.

4.6 FIRING THE LASER



**EMERGENCY
STOP**

To immediately stop laser emission, pull the battery from the iLase main body.

NOTE Most procedures require tip initiation before using the iLase. For those procedures that require tip initiation, you must complete the tip initiation steps before using the iLase in a procedure on a patient. If tip initiation is not required or has already been initiated, press the selector switch to bypass this operation.

- 1 Make sure the iLase has a tip installed that is appropriate for the planned procedure.
- 2 Make sure that all personnel in the operatory are wearing laser protective eyewear.
- 3 After the user enters READY mode, the LED on the iLase will be green. The red aiming beam will also appear at this time. The laser is now ready to fire.
- 4 Prior to firing, verify that the tip is installed correctly into the iLase cover by shining the red aiming beam onto a bright surface, such as a white table top. If using a tip that requires initiation (not pre-initiated), make sure the aiming beam image appears as in the example below:



Figure 4-3: Aiming beam pattern.

WARNING: When the aiming beam is not present or has a significantly different shape, change the tip and inspect / clean the protective window until the image appears as shown above.

- 5 Use the aiming beam to position the tip over the target treatment area. Place the laser tip on the treatment area and press the finger switch (or gently squeeze the finger grip) on the iLase to fire the laser. Actuation will occur when the finger grip is pressed over any one of the six ridges anywhere along the whole length of the switch.

6 The iLase will immediately emit a "beep" tone, then after a 0.3 second delay, the laser will fire. Laser firing is indicated by a blinking green LED and pulsing beep sound.

7 Release the finger switch to stop laser emission.

4.7 TIP INITIATION INSTRUCTIONS

VERIFYING THE TIP

Prior to initiating the tip, verify that it is installed correctly into the iLase cover (see previous section).

The Tip Initiation Aid screen appears as you enter Ready Mode [1.4W / CW]. You will need to have the Tip Initiation Block handy to perform this step.

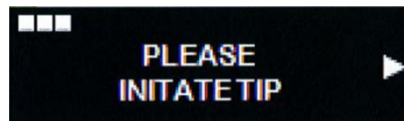


Figure 4-4: Tip Initiation Screen.

Touch the tip to the surface of the tip initiation block, without firing. Fire the laser by gently squeezing the finger grip, allowing the tip to sink into the block. Pull the tip out when the metal cannula touches the block, still firing until just before the tip is out of the block. Fire the laser into the air once. You will see a white flash or a glowing tip. A glowing tip indicates that the tip is ready for use. During a procedure, there is a chance the tip can lose its initiation; repeat the tip initiation procedure, if necessary.

When you have finished the tip initiation, you are ready to begin the procedure. Press the Selector Switch to move to the Main Screen while keeping the system in Ready Mode.

4.8 MAIN SCREEN

The Main screen shows the current settings of the iLase.

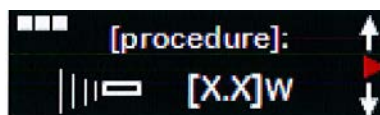


Figure 4-5: Main Screen in Standby mode

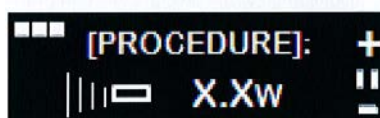


Figure 4-6: Main Screen in Ready mode

- ▶ The top left corner of the screen displays the battery power level.
- ▶ The top center of the screen displays the name of the currently selected procedure.
- ▶ The Pulse Mode icon (lower left) indicates the currently selected pulse mode.
- ▶ The Power icon (lower center) indicates the current laser power setting (average output power).

While in READY mode, you may adjust the *power level* at any time during the procedure by toggling up (+) or down (-) the selector switch; however, the *pulse mode* may not be changed in READY mode. You must return to STANDBY to change the pulse mode.

When your procedure is complete, press the selector switch on the iLase to enter STANDBY mode. The LED on the iLase will turn an amber color. The system is now in STANDBY mode. You can modify and save new settings for the Procedure by changing power values and pressing and holding the selector switch for approximately 1.5 seconds while in READY mode.

NOTE: Pressing the finger switch for 60 seconds while firing will cause the laser to stop firing. To continue firing, release the finger switch and then press again.

4.9 SELECTING A DIFFERENT PROCEDURE

While in Standby mode in the Main Screen, highlight the Procedure Name using the up (+) motion of the selector switch, and make your selection by pressing the finger switch. The procedure screen will be displayed.

Scroll up (+) or down (-) to select a new procedure, or select your own Custom setting.

After a new procedure is selected, the system will go to the Tip Initiation and Main screens in READY mode. Switch to STANDBY mode If you need to continue modifying the preset.

4.10 SELECTING A PULSE MODE

While in Standby mode in the Main Screen, highlight and select the pulse mode icon to access the Pulse Mode menu; one of three available pulse modes can be chosen from that menu by using the selector switch.

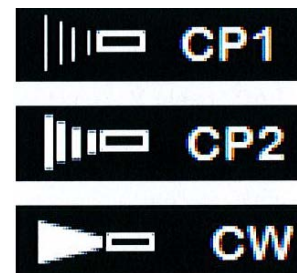


Figure 4-7: Pulse Mode Selection Screen.

For a pulse that is 0.1ms on, followed by 0.2ms off, select CP1.

For a pulse mode that is 1.0ms on, followed by 1.0ms off, select CP2.

For continuous wave output (not pulsed), select CW.



Return to the main screen by selecting one of the available pulse modes.

4.11 ADJUSTING LASER POWER

If you wish to change the power setting, highlight and select the power icon in the Main Screen in STANDBY mode to display the Power Setting screen. The figure below does not show a power setting, but rather has "[X.X] W" to indicate the numeric format of the average power setting.

The Power Setting screen displays the current laser output power setting in both Peak and Average Power values and allows you to adjust the power up (+) or down (-).

Using the selector switch, scroll up to the "+" sign to *increase* the power; scroll down to the "-" sign to *decrease* the power. The power setting increases or decreases by one increment each time the selector switch is scrolled. When the power setting has reached its upper or lower limit, the value will remain at the limit.



Figure 4-8: Power Setting Screen.

Press the selector switch to return to the main screen. You can also access the Settings Menu from this screen. For further details of the Settings Menu refer to the Maintenance section of this manual.

5 Clinical

5.1 PRESETS

iLase has 11 pre-programmed settings, plus 2 open slots to allow the user to set and store customized settings.

	<i>Preset Name</i>	<i>Tip Initiation*</i>	<i>Peak Power</i>	<i>Average Power</i>	<i>Pulse Length</i>	<i>Pulse Interval</i>
1	Gingivectomy	Yes	3.00W	1.00W	CP1 (0-10ms)	0.20ms
2	Troughing	Yes	2.00W	1.00W	CP2 (1.00ms)	1.00ms
3	Excision	Yes	1.80W	0.90W	CP2 (1.00ms)	1.00ms
4	Frenectomy	Yes	2.00W	1.00W	CP2 (1.00ms)	1.00ms
5	Implant Recovery	Yes	2.40W	1.20W	CP2 (1.00ms)	1.00ms
6	Crown Lengthening	Yes	1.80W	0.90W	CP2 (1.00ms)	1.00ms
7	Perio Pockets	Yes	1.60W	0.80W	CP2 (1.00ms)	1.00ms
8	Exposure of Unerupted Teeth	Yes	1.80W	0.90W	CP2 (1.00ms)	1.00ms
9	Aphthous Ulcer	No	0.70W	0.70W	CW	
10	Hemostasis	No	0.50W	0.50W	CW	
11	Endo (*)		0.10W	0.10W	CW	
12	Custom 1 (*)		0.10W	0.10W	CW	
13	Custom 2 (*)		0.10W	0.10W	CW	

- **Not required for pre-initiated tips**

(*) Minimum defaults provided for user setting of Endodontic Procedures such as Pulpotomy and Pulpotomy as an adjunct to root canal therapy

- The first 8 procedures listed are performed in contact mode. Aphthous Ulcer and Hemostasis require a defocused mode of application.

- ▶ 300µm tips are recommended for removing less fibrous tissue types. 400µm tips are recommended for removing fibrous tissue and inside the pocket.
- ▶ All of the procedures listed require tip initiation except for Hemostasis and Aphthous Ulcer.
- ▶ For information on how to initiate the tips that are not pre-initiated, please refer to the Tip Initiation Instructions provided in Section 4.

6 Cleaning and Sterilization

6.1 CLEANING AND DISINFECTION

CAUTION: During use the internal components of the iLase under the cover may become hot to the touch. Allow the iLase to cool for a few minutes before removing the cover for cleaning and sterilization.

The iLase must be cleaned prior to use on each patient. **Cleaning must be performed within a maximum of one (1) hour after the procedure, and prior to sterilization.** Manual cleaning is recommended.

Prepare a cleaning solution per the manufacturer's instructions. Use a commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol®, or a similar enzymatic presoak and cleaner. Follow the instructions for disposal of used solution.

To disinfect the iLase main body and battery, perform the following steps in the indicated order:

- 1 Place the iLase in STANDBY mode.
- 2 Wear protective gloves and eyewear when handling the contaminated main body and battery.
- 3 Remove the used tip from the cover (if present) and dispose of in a biohazard medical waste Sharps container.
- 4 Remove the battery from the main body and set it aside.
- 5 Pull the iLase cover forward and slide it off the body of the main body.
- 6 To disinfect the main body, wipe with an appropriate disinfecting solution, such as Cavidice® or a similar quaternary ammonium compound product (containing 20% alcohol or less) and follow the manufacturer's instructions.

CLEANING THE COVER

- 1 Rinse the cover under lukewarm water (22 - 43° C) for a **minimum of 10 seconds** to remove gross soil.
- 2 Soak a piece of gauze in the cleaning solution and wrap the handpiece cover. Leave it wrapped for a minimum of 10 minutes. Unwrap, and using a soft-bristled brush dipped in the cleaning solution, gently brush the cover for **at least 15 seconds**.
- 3 Rinse the cover under lukewarm running tap water (22 - 43° C) for a minimum of 10 seconds and dry with a lint-free cloth.
- 4 Visually inspect the cover for any residual soil. If present, repeat steps 1 through 3 until residual soil is removed.



Figure 6–1: Disassembly for Disinfection, Cleaning, and Sterilization

6.2 STEAM STERILIZATION OF HANDPIECE COVER AND TIPS

The steam sterilization process is intended to destroy infectious microorganisms and pathogens.

NOTE: Always perform the procedure immediately after cleaning and prior to use and only use FDA-cleared (USA) or CE-marked (Europe) sterilization accessories, i.e., sterilization pouch and autoclave tray.

- 1 Place the handpiece cover and/or tips inside separate single-wrap, self-sealed sterilization pouch(es).
- 2 Place the pouch(es) on an autoclave tray. Do not stack other instruments on top of the pouches.
- 3 Place the tray into the autoclave chamber and set appropriate cycle as recommended below:

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

- 4 When cycle is complete, the handpiece cover and tips must remain in the sterilization pouches until used to maintain sterility.
- 5 To assemble the components when ready to use, slide the cover over the handpiece main body and push it toward the window until you it 'clicks' into position. Install the tip and connect the battery as detailed in Section 3 of this User Manual.

6.3 DISPOSAL

TIPS

Tips are designed to be used one time only and must be sterilized prior to each use. Proper tip disposal in a biohazard medical waste Sharps container is required. Do not reprocess tips.

BATTERIES

Lithium ion batteries contain toxic materials and should not be disposed of in landfills or incinerators. Dispose of depleted batteries as directed by your local solid waste handling regulations. If you have questions or need advice about safe disposal of used batteries, contact Biolase or your Biolase Authorized Service Representative.

DEVICE AND PARTS

The iLase is a medical device subject to regulations governing its disposal. Contact Biolase or your Biolase Authorized Service Representative for instructions on returning the device to Biolase for disposal. Do not dispose of an iLase or its parts in landfills or incinerators.

7 Maintenance

7.1 REGULAR MAINTENANCE

Do not use bleach or abrasive cleansers on any surfaces of the main body.

Return the iLase to the charging station for recharging between procedures or when the low-battery indicator is illuminated.

Periodically check the laser aperture for contamination. If the aperture appears contaminated, wipe with a cotton swab moistened with isopropyl alcohol until clean. The iLase cover must be removed from the main body to be able to access the laser aperture for cleaning.



WARNING: Failure to clean the aperture when contaminated, will lead to reduced optical power efficiency and permanent damage to the system. To prevent aperture contamination, please keep the tip plug or protective cover attached to the handpiece when not in use.

7.2 iLASE COVER GRIP REPLACEMENT

Although the iLase cover is designed to survive repeated autoclave sterilization cycles, its rubber grip may become worn or damaged through repeated use. The grip has been designed to be replaceable by the user if it becomes necessary. The iLase system is shipped with two additional grips for this purpose.

To replace the rubber grip, remove the iLase cover from the main body. Slide the old grip off of the small end of the cover and slide a new rubber grip onto the same end with the large end of the grip first. Ensure that the grip alignment tabs on the grip snap into the grip alignment holes on the cover, as shown below:

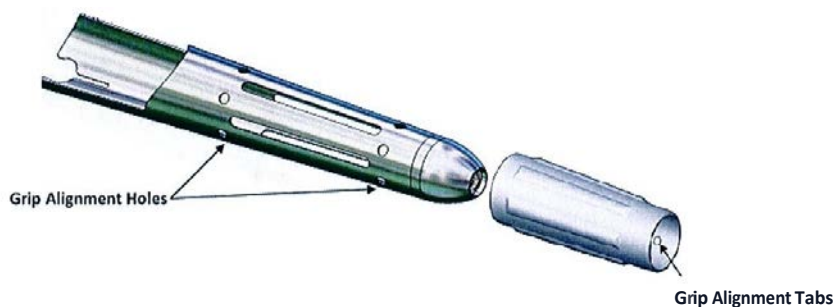


Figure 7-1: Cover Grip Alignment

7.3 SYSTEM CONFIGURATION

The Settings Menu screen allows you to adjust the settings of the user interface. The Settings Menu is entered by pressing and holding down the selector switch for approximately 1.5 seconds when in the Main Screen while in Standby mode.



Figure 7-2: Settings Screen (Aiming beam currently shown)

The following screens are available in the Settings Menu:

- ▶ Aiming Beam: To modify the aiming beam brightness.
- ▶ Restore All: To restore all procedures and preferences to their default settings.
- ▶ Language: To select from the available languages.
- ▶ Exit: To exit the Settings Menu

Aiming Beam allows you to adjust the brightness of the aiming beam. To change the brightness, select the **Increase** or **Decrease** arrow icons. The aiming beam has 3 brightness settings: level 1 is the lowest setting and level 3 is the highest at 1mW output. Level 2 is the default setting.

The Restore All button will reset the aiming beam brightness, preset values, and language selection to their default settings.

The Language selection will enable selection from up to 10 different languages.

- | | | | |
|-----------|--------------|-----------|----------------------|
| • English | • French | • German | • Russian |
| • Italian | • Portuguese | • Spanish | • Chinese (Mandarin) |
| • Korean | • Japanese | | |

8 Troubleshooting and Repairs

8.1 TROUBLESHOOTING

















The following tables list warning and error messages which indicate conditions that can usually be remedied by the user. If the recommended corrective action does not solve the problem and the message persists, restart the iLase by removing the battery, waiting 5 seconds, and then re-installing the battery. If the error message reappears after restarting the iLase, the system cannot be used until the cause of the error has been remedied. Call Biolase Service at (800) 321-6717 or your Biolase Authorized Service Representative.

8.2 WARNING AND ERROR MESSAGES

The Warning and Error screens display codes and recommended corrective actions. If a Warning or Error message is displayed, perform the indicated corrective action.

Figure 8-1: Finger Switch Actuated.



Error/Warning Code	Error/Warning Description	Action
 E 01	E01 Temperature Sensor open (check at start up)	Call Service
 E 02	E02 Temperature Sensor short (check at start up)	Call Service
  T°	E03 Laser system overheated	Wait to cool off
 E 04	E04 Laser current is outside of allowed range	Call Service
 	E05 Finger switch actuated in STANDBY mode	Release Finger Switch
 	E06 Up/down/select switch stuck	Call Service
 E 07	E07 Check Sum Error (memory integrity)	Call Service
  T° 	W01 Warning temperature	Wait to cool off
  	W02 Warning low battery level	Battery replacement may be necessary

8.3 REPAIRS

There are no user-serviceable parts in the iLase. Do not open any part of the device or attempt to make repairs. Doing so may expose the user to unsafe voltages, high temperatures, or laser energy and may void the product's limited warranty.

To obtain repair service for your iLase, call Biolase Service at 1-800-321-6717 or your Biolase Authorized Service Representative.

9 Laser Calibration

9.1 LASER CALIBRATION

Biolase recommends that a laser calibration be performed every 12 months to ensure that the laser output power corresponds accurately to the displayed power. Annual calibrations can be performed at a Biolase Authorized Service Center.

Call Biolase Service at 1-800-321-6717 or contact your Biolase Authorized Service Representative to schedule an appointment.

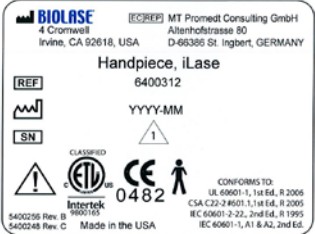



10 Specifications

<i>Dimensions</i>	
Charging Station (W X D X H)	4.7" X 4.0" X 2.8" / 11.9 cm X 10.2 cm X 7.1 cm
iLase Handpiece with surgical tip and battery attached (Length X Diameter)	8.1" X 0.75" / 20.5 cm X 1.90 cm
Power Supply (W X D X H)	1.77" X 2.36" X 2.26" / 4.5 cm X 6.0 cm X 6.0 cm
<i>Weight</i>	
iLase Complete System	1.89 lbs / 0.86 kg
iLase Charging Station	0.87 lbs / 0.34 kg
iLase with Battery attached	0.22 lbs / 0.10 kg
iLase Charging Station PowerSupply and cord/plug set	0.62 lbs / 0.28 kg
<i>Electrical</i>	
Voltage (to power supply)	90 – 230 VAC
Amperage (max)	0.8A
Frequency	50 – 60 Hz
Electrostatic Discharge Immunity	Up to 10 KV (per IEC 60601)
Battery	Lithium ion 3.7 V 800 mAh
Recharge Time (fully discharged)	2 hours
Safety	Discharge over current sensor and resettable circuit breaker
<i>Laser</i>	
Laser Class	IV (4)
Wavelength	940 nm ± 10nm
Output Power	3.0 W Max CW / 5.0 W Peak Power (Pulse Mode)
Power Accuracy	± 20%
Pulse Duration	Continuous 0.1 ms 1 ms
Pulse Interval	----- 0.2 ms 1 ms
Aiming Beam	Laser diode, max 1 mW, 625-670nm, Class 1
N.O.H.D.	2.61 meters
<i>Environmental</i>	
Temperature - Operating	68° – 77° F (20° – 25° C)
Temperature - Storage	59° – 90° F (15° – 35° C)
Humidity - Operating	15 – 95 % non-condensing
Humidity - Storage	10 – 70 % non-condensing
Altitude - Operating	maximum 10,000 ft (3048 m)
Altitude - Storage	maximum 12,000 ft (3658 m)

11 Labels

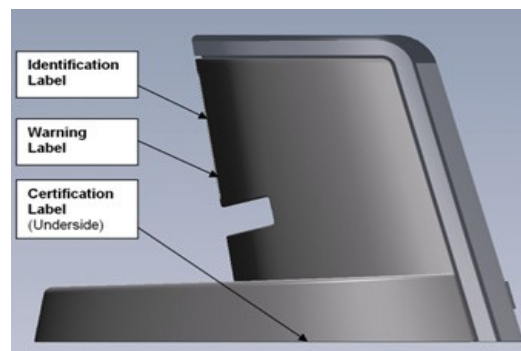
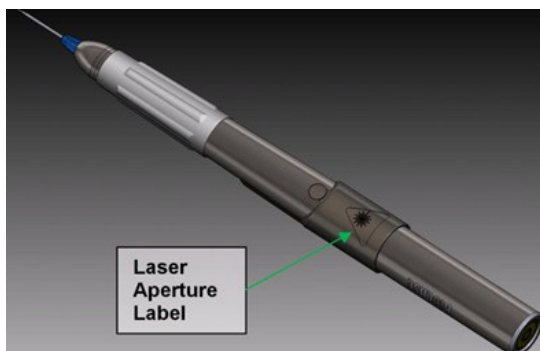
11.1 LABELS

The iLase is labeled as indicated in the following table. Refer to Figures 11-2 for label locations.

Label	Description	Location
	Product ID Label	Charging Station, rear. Refer to Section 11-2.
	Certification Label	Charging Station, underside. Refer to Section 11-2.
	Laser Warning Label	Charging Station, rear. Refer to Section 11-2.
	Laser Aperture	Handpiece near battery end. Refer to Section 11-2.

11.2 LOCATION OF LABELS

Instruction and warning labels are affixed to the device in the locations shown.





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About BIOLASE

Founded in 1986, BIOLASE, Inc. specializes in lasers for medicine and dentistry that feature proprietary and patented technologies for minimally invasive surgeries, reducing pain and improving clinical results.

Only BIOLASE combines the leading laser technology – continuously improved through ongoing clinical R&D and engineering – with unmatched training, practice integration support and service.

BIOLASE leads the global dental laser market with over 21,000 lasers in use today and the most complete family of dental lasers – from diode lasers to the most advanced all-tissue laser, the WaterLase iPlus™.



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