



WaterLase
BIOLASE

Waterlase**iPlus*[™]
User Manual

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NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

1 Introduction

The Waterlase iPlus tissue cutting system is a unique device with diverse, hard- and soft-tissue dental applications. It utilizes advanced laser and water atomization technologies to safely and effectively cut, shave, contour, roughen, etch, and resect oral hard-tissue, and direct laser energy to perform oral soft-tissue removal, incision, excision, ablation and coagulation.

When used for oral hard-tissue procedures, this YSGG solid-state laser provides optical energy to a user-controlled distribution of atomized water droplets and hydrated surface layer of hard-tissue. Water present in the target tissue absorbs laser radiation, resulting in explosive molecular expansion and ablation of hard-tissue. The water in the spray provides cooling and hydration for the target tissue.

For oral soft-tissue procedures, the Waterlase iPlus laser applies optical energy to the soft-tissue for tissue removal, incision, excision, ablation, and coagulation using direct laser energy, either with water for cooling and hydration, or without water for coagulation.

A flexible Fiber Cable connects at one end to the laser and at the other to a Handpiece that delivers laser energy to the target tissue through a Fiber Tip. A visible light emitted from the Handpiece head illuminates the area of treatment. The optical power output and atomized water spray may be adjusted to specific user requirements for both soft- and hard-tissue applications.

Waterlase iPlus is indicated for professional use on adult and pediatric dental patients. Procedures must be performed only by licensed dental practitioners in a dental facility. Use of this device requires proper clinical and technical proficiency, and this User Manual provides instructions for use for those professionals who have completed the appropriate training.

When used and maintained properly, the Waterlase iPlus proves a valuable addition to a practice.

Please contact your BIOLASE-authorized representative for any service needs, or contact BIOLASE directly at waterlaseservice@biolase.com.



2 Indications for Use



IMPORTANT: Review all Contraindications, Warnings and Precautions presented in Section 3 before proceeding with using this device on patients.

WATERLASE IPLUS IS INDICATED FOR:

HARD-TISSUE

GENERAL INDICATIONS*

** For use on adult and pediatric patients*

- Class I, II, III, IV and V cavity preparation
- Caries removal
- Hard-tissue surface roughening or etching
- Enameloplasty, excavation of pits and fissures for placement of sealants

SOFT-TISSUE INDICATIONS INCLUDING PULPAL TISSUES*

** For use on adult and pediatric patients*

- Incision, excision, vaporization, ablation and coagulation of oral soft-tissues, including:
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Flap preparation – incision of soft-tissue to prepare a flap and expose the bone.
- Flap preparation – incision of hard- and soft-tissue to prepare a flap and expose unerupted teeth (soft-tissue impactions).
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty

- Gingival incision and excision
- Implant recovery
- Incision and drainage of abscesses
- Laser soft-tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
- Root canal debridement and cleaning
- Reduction of gingival hypertrophy
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex
- Soft-tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty



NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.

3 Contraindications, Warnings, and Precautions

CONTRAINDICATIONS

All clinical procedures performed with the Waterlase iPlus 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 which might contraindicate a local procedure. Such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease (e.g. pacemakers, implantable defibrillators), lung disease, bleeding disorders, or an immune system deficiency. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

WARNINGS AND PRECAUTIONS

PRESCRIPTION STATEMENT

Federal Law restricts this device to sale by or on the order of a dentist or other licensed dental practitioner.

EYEWEAR

Doctor, patient, assistant, and all others inside or entering the operatory must always wear appropriate laser protection eyewear for the 2780nm wavelength, OD4 (DI LB4) or greater. Always check the eyewear specifications imprinted on the frame of the glasses to ensure they offer the required protection for the specific laser wavelength. Prior to use, inspect eyewear for pitting or cracking. Replace if damaged; do not use.

TRAINING

Only licensed professionals who have reviewed and understood this user manual, and have been trained on how to correctly operate the system should use this device.

ANESTHESIA

Although in most cases anesthesia may not be required, patients should be closely monitored for signs of pain or discomfort. If such signs are present, adjust settings, apply anesthesia or cease treatment, if required.

TREATMENT, TECHNIQUE AND SETTINGS

Only licensed professionals who have reviewed and understood this user manual should use this device. Always start treatment at the lowest power setting for the specific tissue and increase as required. Observe clinical effects and use judgment to determine the aspects of the treatment (technique, proper power, pulse mode, air and water settings, tip type and duration of operation) and make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

3 Contraindications, Warnings, and Precautions

HARD-TISSUE PROCEDURES

All hard-tissue (i.e. enamel, dentin, cementum and bone) procedures must be performed using air and water spray at appropriate settings. Failure to use the spray will result in tissue thermal damage. The long pulse settings (1.0 - 1.3 ms) are indicated only for soft-tissue applications. Do not use long pulse settings to perform hard-tissue procedures.

SOFT-TISSUE PROCEDURES

Soft-tissue procedures can be performed using two pulse duration settings: (H) short pulse (70 - 100 μ s) and (S) long pulse (1.0 - 1.3 ms). However, the long pulse (S) range is indicated ONLY for soft-tissue applications.

FLUID ENTRAPMENT AND AIR EMBOLISM

Do not direct air or spray toward tissues that may trap air or water. For example, when performing surgical procedures, the clinician should be aware of adjacent soft-tissue pockets, cavities, or channels that may collect or entrap air. Always use high-speed suction to remove any excess fluid and avoid directing the spray into deep pockets, cavities or channels such as the crevice resulting from the extraction of a molar. Also, for example, avoid working through soft-tissues adjacent to the roots of molars, especially the third inferior molars, which communicate directly with the sublingual and submandibular spaces. Do not use the Waterlase iPlus if it is not possible to access the treatment site without directing air into an area that may collect or entrap air. In general, the same care and precautions should be taken when using the Waterlase iPlus as are taken when using any air and water emitting cutting device, including the high speed drill.

ADJACENT STRUCTURES

Waterlase iPlus can remove both hard- and soft-tissues. Therefore, always be aware of adjacent structures and substructures during treatments. Be extremely careful not to inadvertently penetrate or ablate through the apex, the root canal wall, or underlying/adjacent tissues. Also, be aware and use extreme caution working on tissue (i.e., bone, root apex, etc.) adjacent to the following structures: maxillary sinus, mental foramen and mandibular canal, or any other major anatomical structures (i.e., nerves). Exercise extreme caution when using this device in areas such as pockets, cavities, or channels, where critical structures (i.e. nerves, vessels) could be damaged. Do not proceed with using the laser if visibility is limited in these areas.

CLINICAL CONDITIONS

Use a sterile field and aseptic technique with all procedures, especially for surgical interventions.

3 Contraindications, Warnings, and Precautions

TISSUE EVALUATION

Any tissue growth (i.e. cyst, neoplasm and other lesions), whether removed with Waterlase iPlus or conventionally, should always be submitted to a qualified laboratory for histopathology assessment.

TISSUE CONTACT AND TIP BREAKAGE

Do not contact hard-tissues with the Fiber Tip. Hard-tissue cutting occurs in non-contact mode with the Tip ~0.5 mm to 3 mm off the surface. Tips are very brittle and fragile, and could break if pressed against tooth or bone tissues or if forced through a narrow or curved path or root canal. Use a bite block to prevent breakage or swallowing of the Tip from biting. High-speed suction is required to remove any excess fluid and materials resulting from accidental Tip breakage.

TIP CHANGING

Failure to correctly replace the Tip could result in damage to the Fiber Tip, Handpiece, or affect the emission of laser energy around the Tip. A careful review of the instructions on how to replace the Tip is recommended.

WATER SPLASHING

Water from spray may splash during treatment. Use protective eyewear and/or a face shield to protect from splashing. Use high-speed suction, as needed, to maintain a clear field of vision during treatment. Do not use the Waterlase iPlus if the user cannot clearly see the treatment site.

PLUME REMOVAL

Laser plume may contain viable tissue particulates. Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue during procedures done with the laser and minimal or no water spray. Ensure that all appropriate protective equipment (including high-speed suction to remove the plume, appropriate masks, and other protective equipment) is used at all times during procedures with this laser device.

DENTAL MATERIALS

Do not direct laser energy towards amalgam, gold, or other metallic surfaces; doing so may damage the Waterlase iPlus delivery system.

4 Specifications

DIMENSIONS (W X L X H)

- Laser Console 11 x 19 x 33 in (28 x 48 x 84cm)
- Laser Console with Fiber Cable 11 x 19 x 40 in (28 x 48 x 102 cm)
- Weight 75 lbs. (34 kg)

ELECTRICAL

- Class I Medical Electrical (ME) Equipment
- Operating Voltage: 100 - 230 VAC
- Frequency: 50 / 60 Hz
- Current rating: 8A / 15A
- Main control: Circuit breaker
- On / Off control: Keyswitch
- Remote interruption: Remote interlock connector

AIR AND WATER OUTPUT

- Water type: Distilled or De-Ionized only
- External air source: 60 - 120 psi. (4.1 - 8.2 bar)
- Water: 0 - 100%
- Air: 0 - 100%
- Interaction zone: 0.5 - 5.0 mm from Handpiece Tip to target

OPTICAL

- Laser classification: IV (4)
- Medium: Er,Cr:YSGG
(Erbium, Chromium:Yttrium, Scandium, Gallium, Garnet)
- Wavelength: 2.78 μm (2780nm)
- Frequency: 5 – 100 Hz
- Average power: 0.1 – 10.0 W
- Power accuracy: $\pm 20\%$
- Pulse energy: 0 – 600 mJ
- Pulse duration for “H” mode: 70 - 100 μs
- Pulse duration “S” mode: 1.0 -1.3 ms
- Handpiece head angles: 70° contra-angle
- Gold HP Tip diameter range: 200 – 1200 μm
- Output divergence: $\geq 8^\circ$ per side
- Mode: Multimode
- Aiming Beam: 625-670 nm (red) laser, 1mW max (Laser Class 1)
- Nominal Ocular Hazard Distance (NOHD): 5cm
- Maximum Permissible Exposure (MPE): $3.46 \times 10^5 \text{ W/m}^2$

5 Equipment Description

SYSTEM PARTS LIST

The Waterlase iPlus laser systems include the following :

- Waterlase iPlus Laser
- Display Covers (25)
- Trunk Fiber and Fiber support
- Yellow Air Tube
- Protective Laser Eyewear (3)
- Handpieces (2)
- Tip Starter Kit
- Tip Holder
- Tip Cleaning Kit
- Power cord
- Footswitch
- User Manual
- Laser Warning sign
- Limited Warranty

GENERAL

The Waterlase iPlus dental laser system consists of two modules:

- Main Laser Console (shown in Figures 5.1, 5.2, and 5.3)
- WaterLase iPlus Fiber Delivery System (the Delivery System, shown in Figures 5.1, 5.2, and 5.3, consists of the Fiber Cable, Handpiece, and Tips)

MAIN LASER CONSOLE ELEMENTS

Figures 5.1, 5.2, and 5.3 show the front, rear and top views of the laser console.

CONTROL PANEL

The main laser console is controlled through a touch screen control panel. See section 8, Operating Instructions, for details and instructions.

Safety Features

All control functions accessed through the Control Panel are located at a safe distance from the energy output.

5 Equipment Description

ENERGY MONITOR

The energy monitor measures and verifies power output.

Safety Features

Power deviations of more than 20% from the selected value will cause the display to show an error message; the laser console will not operate until the system is reset by pressing the "Next" arrow at the top of the touch screen. If the error message persists, please contact BIOLASE Service or the authorized BIOLASE representative for your area.

FRONT AND BACK HANDLES

Use the front and back handles to move and/or lift the laser console when necessary.



CAUTION: Prior to lifting, make sure the handles are not damaged. DO NOT use the Fiber Cable to pull the laser console; this could damage the Fiber Cable and render the laser inoperable.

LOCKING WHEELS

Allow easy transport of the laser from operatory to operatory. Press down on the front tabs on the wheels to lock the console. Lift up the tabs to release the locking mechanism.

EMERGENCY STOP

The red button located on the front panel of the laser console, instantly turns off the laser when pressed.

Safety Features

The button will glow red to indicate an emergency stop, and the control panel will display an error message; press the button again to restart the system. The system will be in **Standby** mode when turned back on, even if it was in **Ready** mode at the time the Emergency Stop was activated. Push the **Ready** button before using the system.

KEYSWITCH

Use to switch the laser system ON by turning the key to the horizontal position; always use only the key provided. The key cannot be removed while it is in the ON position. Always remove the key when the laser is left unattended.

5 Equipment Description

FOOTSWITCH, FOOTSWITCH CONNECTOR

The Footswitch activates the laser; the Waterlase iPlus laser will not activate until the user presses down on the Footswitch. Connect and secure the Footswitch to the Footswitch connector located on the back panel of the console.

Safety Features

A protective cover prevents unintentional pressing of the Footswitch. The protective cover can be opened or closed by pressing it from the top.

REMOTE INTERLOCK OUTLET

Each laser has a remote plug and connector on its rear panel that enables the laser to be connected to the remote sensor. Customers may request that the remote interlock be connected to a door switch.

Safety Features

The Safety Features turn the laser OFF when a user-provided remote switch (e.g., on the entrance door) is triggered, protecting anyone entering the operatory while the laser is in use from inadvertent exposure to laser radiation. To use it properly requires a normally closed pair of contacts to be connected to pins 1 and 5 of the connector. These contacts should have no voltage associated with them and should open on activation.

POWER CONNECTION / CIRCUIT BREAKER

Located on the back panel, allows the power cord to be attached to the laser console. The circuit breaker serves as a line switch to separate the laser console from the main power supply (O = OFF, 1 = ON). The power cable can be wrapped over the holding plate above the connector when the system is not in use or when it is being transported.

VENTILATION CHANNELS

These provide an air flow path to cool the system; do not cover or block.

AIR INLET CONNECTOR

Connects the laser to a compressed dry air outlet at 80-120 psi (5.5 - 8.2 bar) using the tubing provided.

SELF-CONTAINED WATER BOTTLE

Located on the rear of the laser, this detachable bottle provides the water supply for Handpiece atomization spray. Fill the self-contained water bottle with only distilled or de-ionized water. **DO NOT USE TAP OR FILTERED WATER**, which can leave deposits that may damage the fiber cable or Handpiece.

5 Equipment Description

WATER BOTTLE RELEASE

A push button release on the top of the self-contained water bottle that allows its removal from the console for refilling.

FOOTSWITCH SUPPORT BRACKET

This bracket on the rear bottom of the laser console is designed to hold the closed Footswitch clamshell when storing or moving the laser system. Wrap the Footswitch cable around the wrap plate above the bracket.

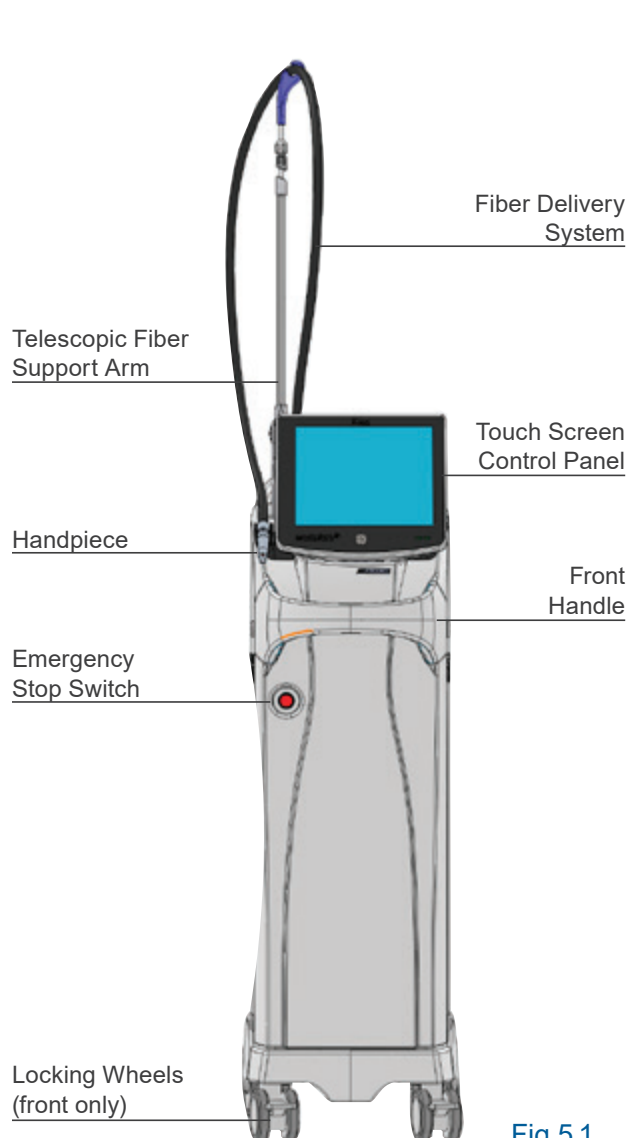


Fig 5.1

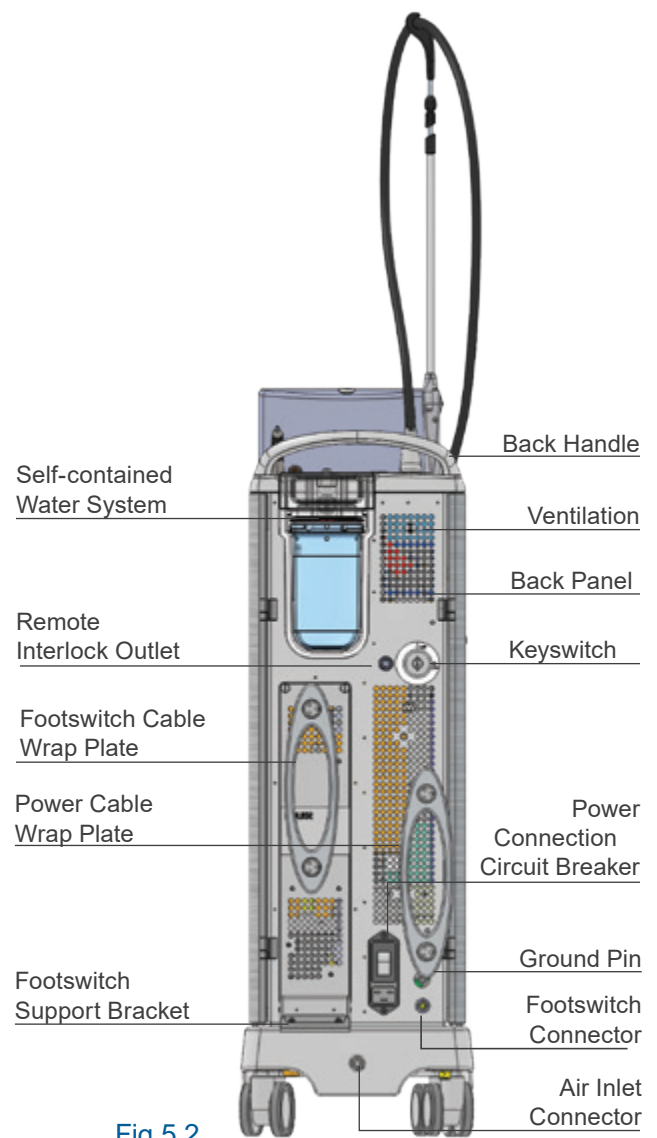


Fig 5.2

5 Equipment Description

TELESCOPIC FIBER CABLE SUPPORT ARM

Located at the top of the laser console, it supports the Delivery System (Fiber Cable), and extends to bear its weight when the Handpiece is pulled forward; extension releases when the Handpiece is let go and the arm is in a vertical position.



NOTE: Proper placement of the Delivery System Cable in the Support Arm and of the Handpiece in the Handpiece holder is important for the convenient and safe handling of the delivery system.

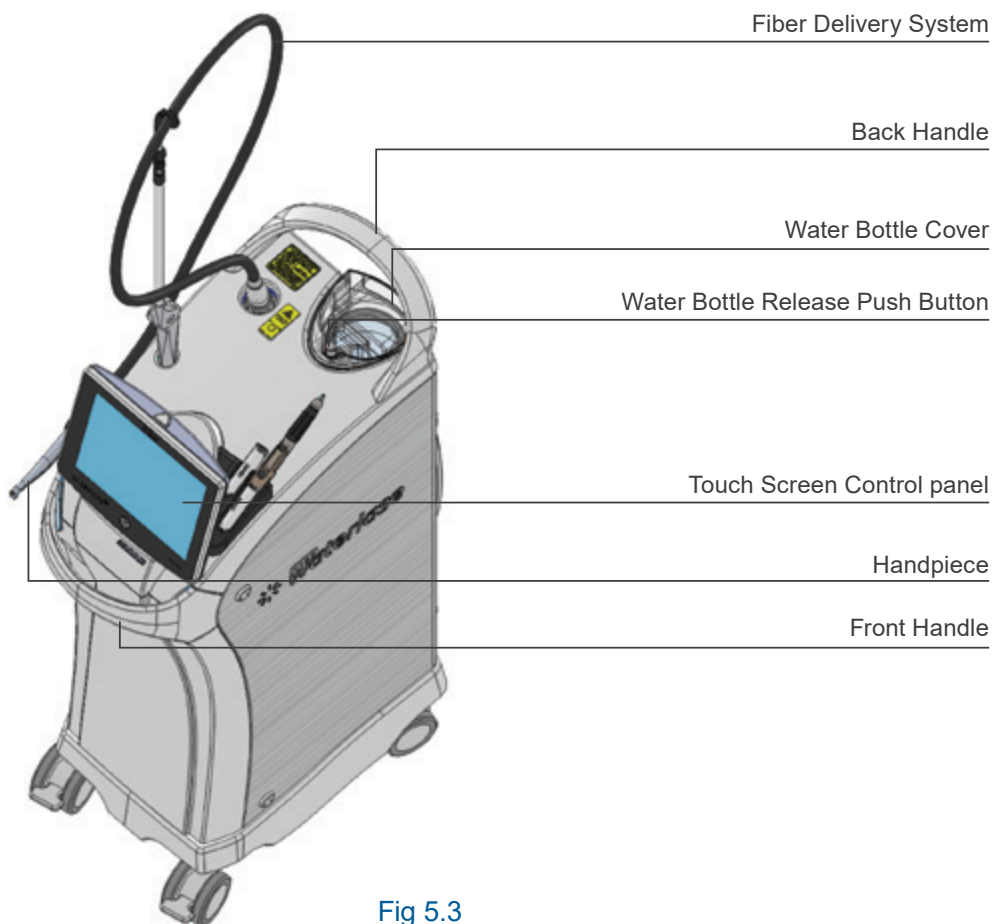


Fig 5.3

5 Equipment Description

DELIVERY SYSTEM CONNECTION ON THE LASER CONSOLE

The delivery system attaches to the top of the console via a multi-connector that incorporates air, water, cooling air, illumination waveguides, and the optical energy Fiber Cable.

HANDPIECE HOLDER

Cradles the Handpiece when it is not in use.

FIBER CABLE

A component of the delivery system: contains the optical Fiber Cable, together with the illumination waveguides, air tubing, and water tubing. Delivers laser radiation from the laser console to the Handpiece.

HANDPIECE

The Handpiece is rotatable and detachable from the optical shaft. It delivers optical energy, illumination, and atomized water spray to the treatment area.

6 Safety with the Waterlase

PRECAUTIONS

Failure to comply with these precautions and warnings may lead to exposure to dangerous voltage levels or optical radiation sources. Please comply with all safety instructions and warnings.



CAUTION: Use of controls or adjustments or performance of procedures other than those specified in this user manual may result in hazardous radiation exposure.



DANGER: Invisible and/or visible laser radiation when the laser is fired. Avoid eye or skin exposure to direct or scattered radiation. Class IV.



CAUTION: This laser system has been designed and tested to meet or exceed the requirements of severe electromagnetic, electrostatic and radio frequency interference testing. However, the possibility of electromagnetic or other interference may still exist.



DANGER: Do not use this laser system in any manner other than described in this user manual. Do not use the laser system if it is suspected as functioning improperly.

SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

1. **Remove or cover** all highly reflective items in the treatment area, if possible.
2. **Do not** operate in the presence of explosive or flammable materials.
3. All persons present in the operatory **must wear protective eyewear** suitable for blocking the 2780nm wavelength, OD4 (DI LB4) or greater. Refer to the OD specification imprinted on the glasses.
4. **Do not** look directly into the beam or at specular reflections.
5. Direct the cutting spray toward targeted tissues only.



CAUTION: Periodically inspect eyewear for pitting and cracking. For replacement or additional protective eyewear, please contact your BIOLASE-authorized representative or contact BIOLASE directly at waterlaseservice@biolase.com.

6. Press the Standby button on the control panel before changing the water in the reservoir and before turning off the laser system.

6 Safety with the Waterlase

7. Move the circuit breaker to the OFF (O) position (located on the rear panel) and remove the key before leaving the laser console unattended.
8. All operatory entrances must be marked with an approved warning sign (provided) indicating a laser is in use.
9. Take special care to contain the laser plume (particles produced by the vaporization of virally or bacterially infected tissue during procedures utilizing the laser and minimal or no water spray); ensure that all appropriate protective equipment (including high-speed suction to remove the plume, appropriate masks, and other protective equipment) is used at all times during the procedure.



DANGER: DO NOT open system side doors. These are to be used by authorized service personnel only. Danger from radiation exposure and high voltage may exist.



NOTE: Please direct any safety questions to the local BIOLASE authorized representative, or email waterlaseservice@biolase.com.

SAFETY CLASSIFICATION

The following safety classifications are applicable to this device:

- Laser Radiation - Class 4
- Aiming Beam - Class 1
- Type of protection against electrical shock - Type BF Applied Part: Laser Handpiece
- Not protected against water ingress - Ordinary Equipment
- Main Laser Console - IPX0
- Footswitch - IPX8
- Not suitable for use in the presence of flammable anesthetic
- Not suitable for use in oxygen-rich environments
- Operation Mode - Non-continuous with duty cycle of max 2 minutes ON, min 30 seconds OFF at maximum power output



CAUTION: High temperatures produced in the normal use of this laser equipment may ignite some materials (e.g., cotton wool when saturated with oxygen); solvents of adhesive and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.

7 Installation

INSTALLATION INSTRUCTIONS

The Waterlase iPlus laser system must be installed by a qualified BIOLASE employee or representative who will unpack and install the laser. Please leave all crates and shipping containers unopened until the trained representative arrives. Complete installation, testing, and demonstration require approximately one full day.

Please contact the representative before transporting the laser system to a different location. Misalignment of optical components may occur during transportation if the laser is not properly packaged.

FACILITY REQUIREMENTS

ELECTRICAL SUPPLY: 100 VAC @ 15.0 Amps to 230 VAC @ 8.0 Amps, 50/60 Hz



NOTE: The main power supply of the iPlus laser system has an isolation transformer that complies with a Transient Voltage of 4kV.

COMPRESSED AIR SUPPLY: 80 - 120 psi (5.5 - 8.2 bar)



CAUTION: Moisture in the air supply line may damage the laser system. Please provide proper filtration to eliminate all moisture from the air source.

ENVIRONMENTAL REQUIREMENTS

TEMPERATURE: 15 - 30 °C **HUMIDITY:** 20% - 80%, non-condensing

AIR SUPPLY: Connections for an air supply must be available in each operatory. Attach an air hose with 1/4" inside diameter male quick connectors on each end between the air inlet connector and the operatory air source.



CAUTION: Prior to connection, verify that the outlet is for the air, NOT the water supply. Connection to the water supply may cause damage to the Waterlase iPlus system. If the laser console is connected to the water supply, DO NOT turn the system on; contact the service representative.



CAUTION: DO NOT position this equipment so that it is difficult to pull the plug from the power source.



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

7 Installation

SET-UP REQUIREMENTS

CONNECTING THE LASER CONSOLE TO THE OPERATORY

1. Verify the circuit breaker is in the OFF position.
2. Verify the keyswitch is in the OFF position.
3. Connect the power cord to the rear of the laser console (Fig 3.2).
4. Verify a minimum air pressure of 80 psi (5.5 bar) is emitted from the air supply.
5. Check the air supply for moisture.
6. Connect the air supply to the laser console's air inlet connector at the rear of the console (Fig 3.2).



CAUTION: Do not connect the operatory air supply to the laser console if water or oil is present. The air compressor may need to be drained or cleaned and air filters installed if moisture appears. Wet air will damage the laser system. Check the air supply weekly to verify the absence of water and oil.



Fig 7.1



Fig 7.2



Fig 7.3



Fig 7.4

FILLING THE INTERNAL COOLING WATER RESERVOIR

The Waterlase iPlus may have been shipped with a full cooling water reservoir. In the event the user needs to fill the reservoir, please follow the instructions below.

1. Open the back panel door by turning two thumb screws counter clockwise and pull back gently (Fig 7.1).



WARNING: Be careful when opening the door. Make sure it opens easily and clears the lid and tubing of the bottle. The bracket holding the door is mounted at the bottom hinge. Do not apply excessive force.

2. Locate the internal water reservoir and verify that the white clip on the blue tube connected to the side of the water reservoir is closed.
3. Push the button on the top connector and disconnect the tubing from the lid (Fig 7.2).
4. Remove the lid and filter assembly (Fig 7.3, 7.4).

7 Installation



WARNING: Be careful when handling the water filter assembly. Do not touch the white filter material to prevent contamination and potential damage.

5. Use the funnel supplied to fill the bottle with distilled or de-ionized water up to $\frac{3}{4}$ full (Fig 7.5). **DO NOT USE TAP OR FILTERED WATER.**
6. Replace the filter assembly and close the lid tight.
7. Plug in the water connector firmly, until it “clicks” in place.
8. Power up the system:
 - Switch the Power Circuit Breaker on the back panel to the ON position (Fig 7.6);
 - Turn the Keyswitch to the ON position (Fig 7.7);
 - When the Keyswitch is turned ON, the system will begin its boot-up process. The system will load the software (approximately 30 seconds).
9. Press the Ready key (Fig 7.8). If the “Water Level Low” error message appears, turn the system off and refill the cooling water container $\frac{3}{4}$ full.
10. Press the Ready key again and let the system run for 1-2 minutes to clear the air bubbles from all components of the cooling system.
11. Close the back door and tighten the two captive screws.



Fig 7.5



Fig 7.6



Fig 7.7

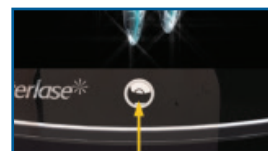


Fig 7.8

FILLING THE SELF-CONTAINED WATER SYSTEM BOTTLE



CAUTION: Use only distilled or de-ionized water. **DO NOT USE TAP WATER OR FILTERED WATER**, which can leave deposits that may damage the Fiber Cable or Handpiece.

1. Make sure that the system is in **Standby** mode; this allows the bottle to de-pressurize.
2. Push the bottle release button and pull the bottle straight back from the holder (Fig 7.9).
3. Twist the bottle clockwise and pull up the lid to open (Fig 7.10).
4. Fill the self-contained water bottle with only distilled or de-ionized water. **DO NOT USE TAP WATER OR FILTERED WATER**, which can leave deposits that may damage the Fiber Cable or Handpiece.

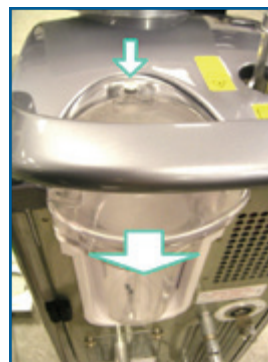


Fig 7.9

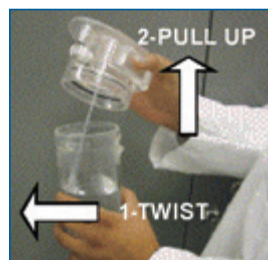


Fig 7.10

7 Installation

- Align the arrow on the lid to the dot on the bottle and insert the bottle into the lid, then twist the lid clockwise until the arrows on both parts are lined up (Fig 7.11, 7.12).
- Attach the bottle back into its holder; make sure the connector is fully engaged.



WARNING: DO NOT use tap water or any non-approved solution. If anything other than distilled or de-ionized water is used, the system warranty will be voided.



WARNING: Be careful handling the water bottle assembly. Do not drop the parts; even a small crack may cause damage when the bottle is pressurized.



NOTE: BIOLASE recommends replacing the self-contained water system bottle once every 5 years. Refer to the expiration date noted on the bottle label.

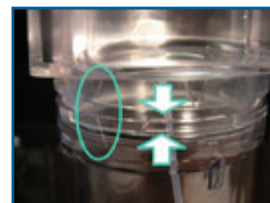


Fig 7.11

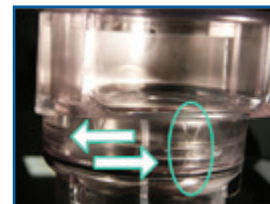


Fig 7.12

INSTALLING THE SUREFIRE DELIVERY SYSTEM

- Looking down to the top of the console, locate the small hole on the lower left side and install the telescopic Fiber Cable support arm (Fig 3.1).



Fig 7.13



NOTE: It may help to drape the Fiber Cable around the user's neck for ease of handling as they prepare it for installation.

- Remove the Fiber Cable from its packaging (Fig. 7.14).
- Remove the protective cover of the Fiber Cable shaft (distal end) and hold it against any light source; look into the proximal end of the Fiber Cable – it should glow yellow, be flat and clean. Replace the cover.
- Remove the black plastic outer cover and the internal red protective cap from the laser head and laser aperture; save these for future use (do not lose them).
- After removing the red protective cap, carefully look inside the laser aperture and check that the surface of the protective window is clean, free of water, dirt, or damage (Fig 7.16).

If water or dirt is visible, try to remove it by blowing dry, compressed air in the aperture.

If this does not help, call for Service.



Fig 7.14



Fig 7.15



Fig 7.16

7 Installation



NOTE: If the laser head is not aligned properly within the cover of the laser console, it will not be possible to connect the Fiber Cable to the laser console; call your BIOLASE-authorized representative or contact BIOLASE directly at waterlaseservice@biolase.com.

7. Align the blue guide of the Fiber Cable connector (proximal end) to the blue dot on the laser head interface. Position the middle of the connector to the laser aperture and vertically push down, gently, as far as the connector will go (Fig 7.17, 7.18).



WARNING: DO NOT APPLY FORCE when installing the Fiber Cable. Applying force may damage the laser head components.

8. Secure the retainer ring by turning it clockwise until it is snug (Fig 7.19).
9. Align the middle length of the Fiber Cable to the hook of the telescopic arm and push it in gently to secure it.
10. Remove the protective cover from the distal end of the Fiber Cable again and verify that it is clean and not damaged (see Section 11, Maintenance and Troubleshooting) (Fig. 7.20).



NOTE: Make sure the black retaining o-ring on the Fiber Cable is on the front side of the hook to keep the Fiber Cable in place.

11. Carefully place the Fiber Cable with its protective cover, or with the Handpiece connected, in the Handpiece holder (Fig 7.21).



Fig 7.17



Fig 7.18



Fig 7.19



Fig 7.20

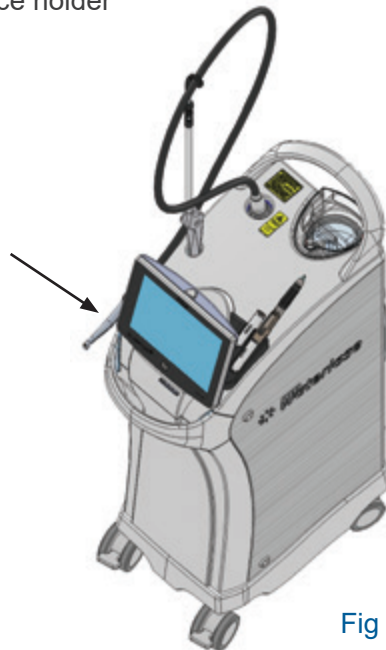


Fig 7.21

7 Installation

CONNECTING THE HANDPIECE TO THE FIBER CABLE

The Handpiece is designed to operate with the Waterlase all-tissue laser system and uses Quartz (single-use) and Sapphire (reusable) Tips. It is used in all soft-tissue procedures and most hard-tissue procedures that do not require bulk removal of tissue.

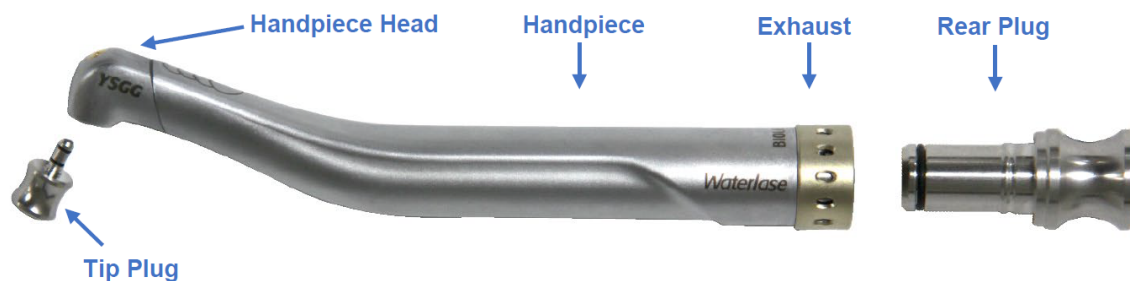


Fig 7.22

1. Remove the Handpiece from the Handpiece box.
2. Remove the rear plug from the Handpiece by pulling; place the plug in the Handpiece box to store.
3. Remove the protective cover from the shaft of the Fiber Cable by pulling; place it in the Handpiece box to store.
4. Check the Fiber Cable shaft for any moisture and wipe off any that is found with a dry tissue.
5. Carefully insert the Fiber Cable shaft into the Handpiece until it “clicks” (Fig 7.23, 7.24, 7.25).



Fig 7.23



Fig 7.24

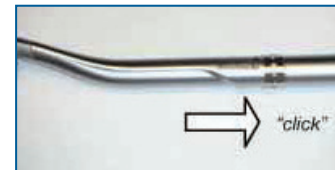


Fig 7.25



CAUTION: Check the output end of the Fiber Cable shaft for any contamination or damage (see Section 11, Maintenance and Troubleshooting). DO NOT touch the output end to prevent contamination and/or potential further damage. If touched, clean with a dry tissue.



NOTE: Connecting and disconnecting the Handpiece and removal of the protective cover should be done carefully, without applying excessive force.



WARNING: To prevent the internal Fiber Cable from breaking, do not bend the flexible part of the Fiber Cable shaft.

7 Installation

DISCONNECTING THE HANDPIECE

1. Purge the Handpiece
2. Pull and disconnect the Handpiece from the Fiber Cable shaft.



WARNING: Failure to purge the Handpiece prior to disconnecting may damage the Fiber Cable.

3. Wipe any moisture off the Fiber Cable shaft with dry tissue.
4. Check that the window at the end of the Fiber Cable is clean and not damaged; if it's not clean, use a dry cotton swab or a tissue to clean it (Fig 7.26).
5. Carefully attach the Handpiece or Fiber Cable's protective sheath until it "clicks" into position.



WARNING: Do not press "Done" if the Fiber Optic Cable's protective cover is attached, as water will fill the cover and may cause damage to the Fiber Cable shaft. If this happens, take the cover off and dry out both the Fiber Cable shaft and the protective cover; failure to do so may result in damage to the Fiber Optic Cable.



Fig 7.26

INSTALLING AND CHANGING THE TIP IN THE HANDPIECE

A Fiber Tip is installed in the Handpiece to direct the electromagnetic energy generated by the laser; based on its shape and length, it will focus that energy differently onto the target tissue.



WARNING: Never touch the input (proximal) end of the Tip. If the input surface is contaminated, it may damage the Tip, Handpiece, and Fiber Cable. Hold the Tip only by the plastic ferrule and the output (distal) end.



NOTE: Always inspect the Tip prior to use (See Appendix D, Tip Inspection).



WARNING: Be careful not to hit the input (proximal) end of the Tip against the Handpiece head and not to break the retainers of the plastic ferrule.

1. Place the system into Standby.
2. Remove the Tip plug from the Handpiece head.

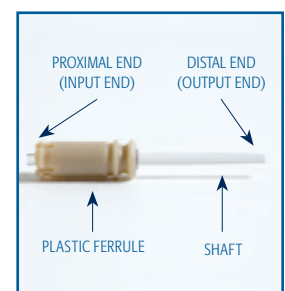


Fig 7.27

7 Installation



NOTE: The Tip must be sterilized before initial use and between patients. If not sterilized in the Tip Holder, remove the Tip from its sterilization pouch and insert it into the Tip Remover or the revolving Tip Holder by aligning the first groove of the Tip ferrule against the receiving edges of the holder, then sliding the Tip in; using tweezers facilitates this process (Fig. 7.28).

3. Align the Tip orifice of the Handpiece over the input end of the Tip placed in the Tip Remover or revolving Tip Holder (Fig. 7.29).
4. Carefully lower the Handpiece and insert a clean/inspected tip all the way until the shoulder of the Tip ferrule sits against the Handpiece head (Fig. 7.30, 7.31).
5. Slide the Handpiece laterally away from the Tip Remover or Tip Holder (Fig. 7.32).

To remove the Tip, repeat this process in reverse order.

1. Slide the Handpiece laterally toward the Tip Remover or revolving Tip Holder.
2. Place your thumb against the selected Tip slot to prevent laser Tip from falling out of the Tip Holder when disconnecting it from the Handpiece.
3. Carefully lift the Handpiece to disengage the Tip ferrule from the Handpiece head.
4. Use tweezers to slide the Tip out from the Tip Holder or Tip Remover; dispose of the used Tip in a medical waste sharps container.



NOTE: If the laser cuts hard- and soft-tissue slower than expected after installing the Fiber Cable, please follow the table in Section 11, Troubleshooting the Delivery System.



Fig 7.28

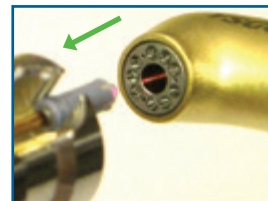


Fig 7.29

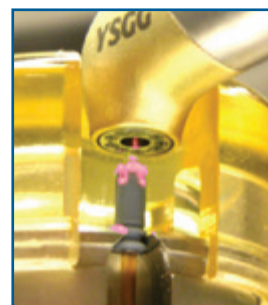


Fig 7.30



Fig 7.31



Fig 7.32

8 Operating Instructions



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

OVERVIEW

Before using the Waterlase iPlus, be sure the system has been installed properly, as described previously in this User Manual.

STARTING THE WATERLASE IPLUS

1. Verify that all connections have been properly secured and the Fiber Optic Cable properly attached.
2. The air supply must be connected and the external air pressure must be at 80 psi (5.5 bar) or more.
3. Electrical input should be at least 200 VAC, maximum 15 amperes, to 230 VAC, 8 amperes.
4. Verify that the water bottle is more than 1/3 filled with distilled or de-ionized water.



DANGER: Laser and collateral radiation are emitted through the Fiber Cable Port. Removal of the multi-connector from the Fiber Cable Port may lead to hazardous exposure to laser radiation. Radiation is also emitted from the Fiber Cable shaft when the Handpiece is removed. **DO NOT** attempt to operate the Waterlase iPlus with the Fiber Cable or the Handpiece not attached.

5. Switch the circuit breaker ON.
6. Insert the key into the keyswitch and rotate it clockwise to the ON position.
7. Verify the emergency stop button is not engaged, the button is not glowing red and no error message is displayed on the screen.
8. The system will begin its startup process as the software is loaded (about 45 seconds).
9. Attach the Handpiece to the Fiber Cable Shaft (Section 7: Connecting the Handpiece to the Fiber Cable).
10. Place the system into **Standby** mode and attach a Tip using the Tip Remover (Section 7: Installing and Changing the Tip in the Handpiece).

8 Operating Instructions

ACTIVATING THE WATERLASE IPLUS

Push the **Ready** button to enable the Waterlase iPlus, and depress the Footswitch when ready.



NOTE: It is possible to evaluate the effect of each parameter setting prior to a procedure by directing the Handpiece into a sink or paper cup and adjusting the values as desired.



NOTE: To help prevent inadvertent laser activation, there is a 0.5 second delay between the time the Footswitch is depressed and the laser actually emits energy.

TURNING THE WATERLASE IPLUS OFF

- Disconnect the Tip, if required. Install the Tip plug into the Handpiece head.
- Press and hold the function control button for 2 seconds to turn the system OFF.
- Turn the key counterclockwise to the OFF position.
- Turn the circuit breaker to the OFF position.

USER INTERFACE / GENERAL NAVIGATION

INTRODUCTION

The Graphical User Interface (GUI) is the main part of the system control. It communicates with the user through the interactive touch screen display and is designed to provide easy and intuitive interaction with the laser system while performing clinical procedures.

The system automatically selects the recommended pre-programmed settings corresponding to a selected clinical application. It minimizes any potential error in setting laser parameters and creates a more satisfactory experience for both the user and the patient.

CONTROLS AND INDICATORS.

The control panel (Fig. 8.1) has one function control button for turning the system ON and OFF, and for switching between Standby and Ready modes. Pressing and holding the button for more than 2 seconds will turn the system ON / OFF. When the system is ON, pushing the button will switch the system between Standby and Ready modes.

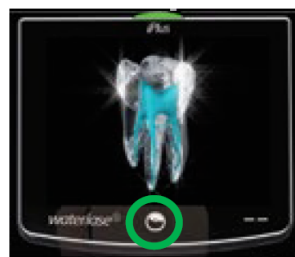


Fig 8.1

8 Operating Instructions

The control panel also has one LED indicator for system status and laser power actuation (Fig 8.1):

- Amber - indicates Standby mode
- Green - indicates Ready mode
- Blinking Green – indicates Firing mode

APPLICATIONS MENU

HOME SCREEN

After the system is powered up, it takes approximately 45 seconds for the software to load. Touch the screen to access the Home Menu (Fig 8.2 and Flow Chart in Fig 8.14). This screen offers a choice of one of two operational areas, plus a shortcut to Favorites, and Advanced:

- Restorative
- Soft tissue
- Advanced
- Favorites

To select a procedure category, press the name of the category on the touch screen.

CLINICAL APPLICATIONS

Once a procedure category is selected, the system goes to a Clinical Applications Menu, which offers the clinical applications within the selected category that have been tested and cleared for use with Waterlase technology (Fig 8.3).

There are currently 6 procedures identified within the two procedure categories offered on the Home Screen (Flow Chart, Fig. 8.14).

To select a procedure, touch the corresponding name or image.

OPERATING PARAMETERS

When selection is made from the Clinical Applications Menu, the system proceeds to the Operating Parameters Menu (Fig. 8.4). Here all laser operating parameters are identified as pre-sets for the selected step within the procedure, as well as several steps recommended for the procedure. Each step has its own name and its own recommended settings.

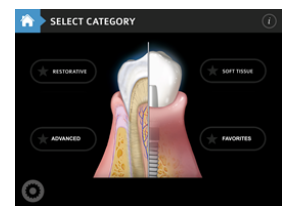


Fig 8.2

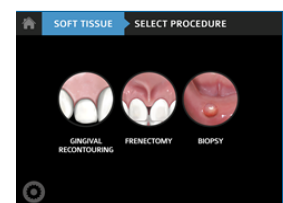
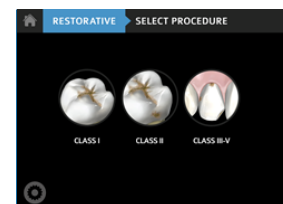


Fig 8.3

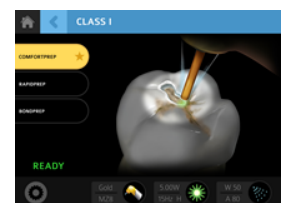


Fig 8.4

Fig 85

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Changing the Water in the Bottle

When the system detects that the water level in the self-contained bottle is low, a blinking button with a low water level symbol will appear next to the Settings button. Place the system into **Standby** mode and follow the steps outlined in Section 7: Filling the Self-Contained Water System Bottle. To return to **Ready** mode, press the Main Function button below the touchscreen.



NOTE: When the bottle is disconnected, an Error screen will appear. When the bottle is re-attached, the Error screen will clear automatically when the system checks the bottle status (approximately 5 seconds).

Three setting categories are shown at the bottom of the screen, i.e., Handpiece and Tip, Laser, and Spray. From here, adjustments can be made to the following parameters:

- **Handpiece** type and **Tip** type (only the Tips which are allowed for this procedure)
- **Laser Power**, Pulse Repetition Rate, and Pulse Mode
- **Water Spray** and Air Percentage setting

Handpiece

The Handpiece recommended for the current procedure step appears at the bottom of the screen. However, the Handpiece can be changed by taking the following steps:

1. Press the image of the Handpiece that the user wants to install; a progress timer will appear in the form of a segmented circle outside of the Handpiece icon and the system will automatically purge the water from the installed Handpiece (Patient Air 100% ON, air pressure in the bottle OFF, Patient Water 100% ON). This step will take 3 – 4 seconds.
2. When the water is purged from the Handpiece, a new message will appear on the screen: “Exchange Handpiece now and then select Tip.” Attach the new Handpiece to the Fiber Delivery System.
3. Press the image of the Tip chosen for the procedure; patient air (and internal cooling air) will be activated through the Handpiece, and a new Tip may now be inserted.
4. Once a new Tip is attached to the Handpiece, press the Handpiece image again; a progress timer will again re-appear for 3-4 seconds, and the Handpiece will be primed with water.

To return to the Procedure screen, press either the Back or Handpiece button located at the bottom of the display.

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Tips

Tip selection will always correspond to the selected Handpiece. The names of the respective Tips are shown below each image for reference. When Tip Selection is active, the recommended Tip is highlighted, preferred Tips for the Handpiece are outlined, and all the Tips allowed for the specific application are shown on the screen (Fig. 8.5).

- Press the image of the Tip (which may or may not be the recommended Tip);
- Both Cooling Air and Patient (spray) Air will turn ON;
- Replace the Tip.

To return to the Procedures screen once the Tip is installed, press either the back or Handpiece button located at the bottom of the display.

Laser Power

Laser Power settings, as well as pulse repetition rate and laser pulse mode are always defined by the procedure type and the selected Tip (Fig 8.6).

The Pulse mode button switches the system between S (long pulse) and H (short pulse) modes. Laser parameters can be changed at any time in **Ready** or **Standby** modes. After adjusting these settings, press the Back or Laser button at the bottom of the display to return to the Procedure screen.

Spray

Spray settings for air and water percent can also be adjusted while in **Ready** or **Standby** (Fig 8.7). Mode selection scrolls between ON, OFF and AUTO for both parameters.



Fig 8.5



Fig 8.6



Fig 8.7

CHANGING AND SAVING THE PRE-SETS

When system parameters are changed from the factory pre-sets, the "star" symbol visible in the highlighted procedure mode on the left side of the screen changes to an "unlocked lock" symbol, indicating that the system pre-set parameters have been modified but not saved.

To save modifications to any settings, press and hold the specific procedure mode for 2 seconds. The "unlocked lock" symbol will change to a "locked lock" symbol, indicating that the settings have been saved. Otherwise, the modifications will be lost when proceeding to a different screen.

To restore the factory pre-programmed settings for the customized procedure mode (indicated by "locked lock" symbol), press and hold the corresponding name of the step for 2 seconds. The "star" symbol will re-appear in place of the

8 Operating Instructions

"locked lock" symbol, confirming that the settings have been changed back to factory pre-set values.

Factory recommended settings and modified settings can be saved as one of the "Favorites," if desired.

The entire original factory pre-sets can be restored, as well, when the Settings Menu RESTORE ALL icon is selected.

No parameters can be changed while the system is in **Firing** mode.

Default settings for illumination (both Aiming Beam and Light) are in the middle of the adjustment range. The same is true for the Sound Tone.

SETTINGS / MEMORY MENU

The Settings / Memory Menu stores up to 9 "Favorites" (Fig 8.8). It can correspond to a particular step of the procedure described in the Main Application Menu, or it can be completely independent, if selected by the user and stored from the Advanced Menu.

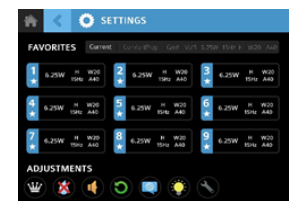


Fig 8.8

This Menu also provides access to supplementary functions that allow the user to perform the following activities:

- Access the Custom operational menu, Advanced Menu, not associated with any clinical procedure;
- Purge and prime the Fiber Cable;
- Adjust sound;
- Restore factory pre-sets;
- Select language;
- Adjust the Aiming beam and Illumination;
- Access the Service Screen.

When switching to the Settings/Memory Menu from the Procedure screen or the Advanced screen, the latest settings and name of the procedure step are displayed at the top of the display. To save the current settings into one of the "Favorites," press and hold one of the nine buttons for 2 seconds; the name of the procedure and step will appear inside the button (in the Advanced screen, the name for the button will be given as "Custom 1", "Custom 2", etc.).

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FUNCTIONS FOR THE SETTING BUTTONS

- **ADVANCED** - switches the system to the Advanced screen;
- **DRAIN WATER** - used only when replacing the Fiber; when pressed, “Purge” and “Prime” buttons appear.
 - Purge - the Fiber Cable is purged of water.
 - Prime - the Fiber Cable is primed with water.
- **SOUND** - allows adjustment of sound setting within the range 0 to 15.
- **RESTORE** - leads to a dialogue screen asking “Do you want to restore all factory pre-sets ” Offers options for “YES” and “Exit”.
 - If YES is selected, all factory pre-sets are restored.
- **LANGUAGE** - gives an option of selecting one of multiple languages.
- **ILLUMINATION** – allows the adjustments for the visible aiming beam and light illumination for the Handpiece within a range 0 to 9 (Fig. 8.9).
- **SERVICE** - leads to the Service Menu.



Fig 8.9

CUSTOM SETTINGS

Parameters may be adjusted without any limitations and without any relation to any procedure in the Advanced screen (Fig. 8.10).

When selecting the “Advanced” screen, the system proceeds to that screen with all parameters shown and without referencing any particular procedure or limiting any range of adjustments.



Fig 8.10

Frequency (Hz)	Minimum Power for H&S Modes (W)	Max Power H-mode (W)	Max Power S-mode (W)
5	0.1	2.50	2.50
8	0.1	4.75	4.75
10	0.1	6.00	6.00
12	0.1	7.25	7.25
15	0.1	9.00	9.00
20	0.1	10.00	10.00
25	0.25	10.00	10.00
30	0.25	10.00	9.00
40	0.25	9.00	8.00
50	0.25	8.00	6.00
75	0.5	6.00	0.00
100	0.5	4.00	0.00

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DESCRIPTION OF FUNCTIONAL BUTTONS:

- Change Handpiece - selection will automatically purge the water from the Handpiece, with a progress timer displayed (3-4 second). See “Handpiece” section, above.
- Change Tip Selection - turns both Internal Cooling Air and Patient Air ON. Press again, and the system returns to the Advanced screen.
- Settings - leads to the Settings screen.

OTHER SCREENS

- Help “i” icon – found on every screen, accesses an Information/ Recommendations Screen.
- Error screen - appears when a system error is detected. It will give the Error name and recommendations for correcting the error (Fig 8.12).
- Service - provides a pass code to allow entry to authorized Service Personnel only (Fig 8.13).



Fig 8.12



Fig 8.13

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SYSTEM FLOW CHART:

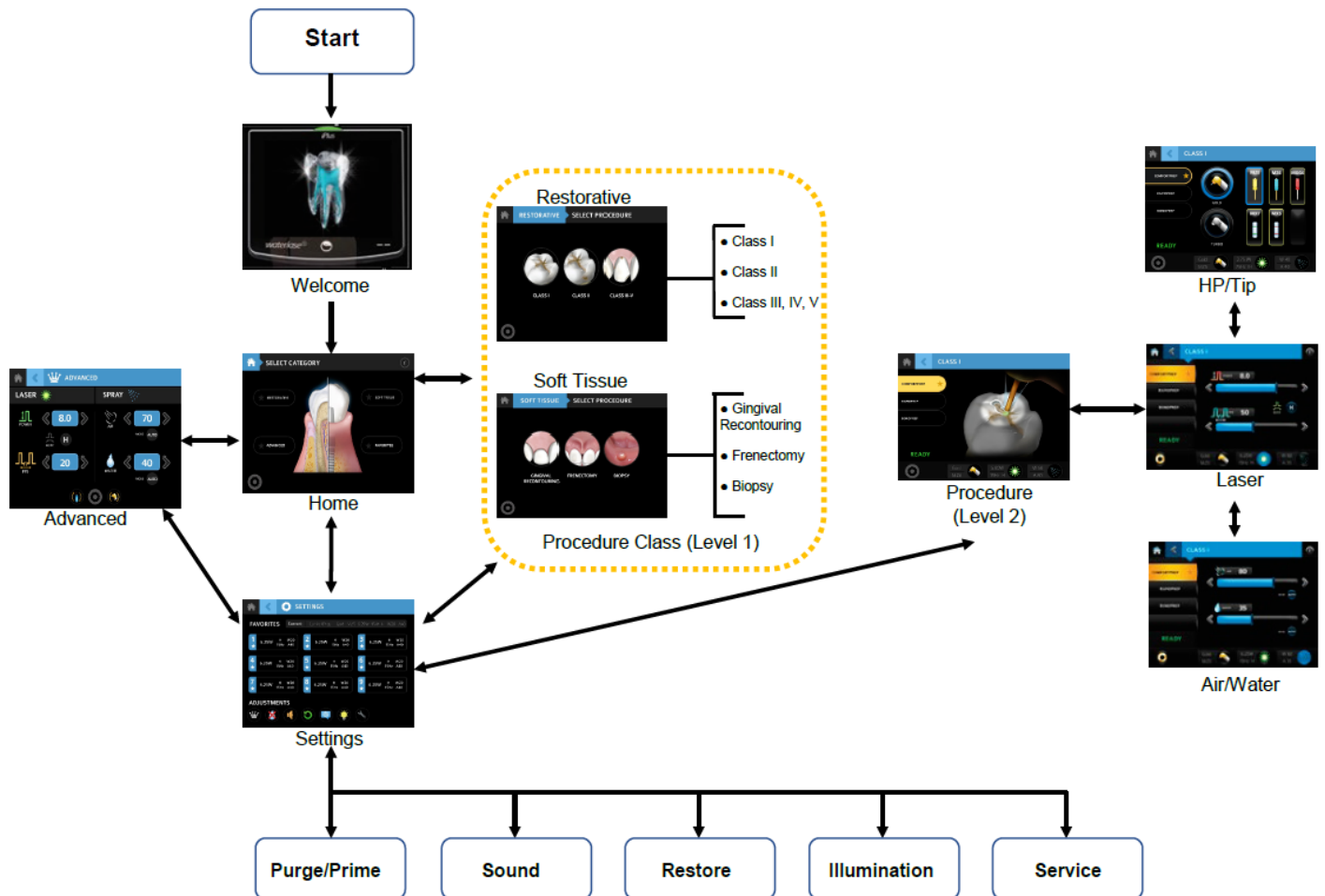


Fig 8.14

9 Clinical Application

Overview

The Waterlase iPlus laser is designed to cut and remove hard and soft tissues. Cutting is achieved in a contact or non-contact mode by application of direct laser energy either with water for cooling and hydration, or without water for coagulation. To efficiently remove tissues it helps to understand the unique nature of the Waterlase iPlus laser. Waterlase iPlus operates unlike traditional medical instruments or devices, and a proper technique must be practiced and perfected to ensure efficient operation.

BIOLASE recommends anyone using Waterlase iPlus to study this section carefully, practice on tissue models, and attend a company-sponsored training seminar before using this laser in a clinical situation.

HARD-TISSUE CUTTING

Hard-tissue cutting is achieved through the removal of tissue with laser-energized water.

1. Select the desired procedure from the Home (Procedures Main) screen (Section 8).
2. Begin the procedure with Step 1; the optimum settings for each step of each procedure have been preset at the factory.
3. Point the Tip away from the patient and Laser Console, and step on the Footswitch. The user will see water spray flow from the Handpiece and hear a gentle “popping” sound.
4. If the water flow and “popping” sound are both present, stop firing the laser and move the Handpiece Tip to the targeted tissue site. Press on the Footswitch to fire the laser and begin cutting tissue.
5. Use high speed suction as necessary to keep the field clear. There is a pronounced difference in cutting techniques between a traditional dental drill and Waterlase iPlus; it is very important to have the exact treatment location visually identified before and during the procedure.



CAUTION: If no water spray or distinct popping sound is present, stop the laser immediately. Refer to the Troubleshooting section of this User Manual for instructions, or call the local representative for assistance.

6. Maintain a distance of 0.1 to 1.5 mm between the Fiber Tip and the tissue being treated while moving the Handpiece over the tissue surface as required.
7. Cutting speed is determined primarily by parameter settings and distance from tissue, not by rapid hand movement as with the high-speed drill.
8. Gently and slowly move the Handpiece in a circular, brushing, or in-and-out motion, as required, to remove desired tissues or materials. Unlike with traditional dental instruments, with the Waterlase iPlus, the slower the user moves the Handpiece Tip the quicker they will remove tissue.
9. Once treatment is completed, release the Footswitch and remove the Handpiece from the patient's mouth. Be careful not to hit the Handpiece Tip against teeth or other instruments, or the Tip may break.

9 Clinical Application

10. To remove the Tip from the Handpiece, use the Tip Remover tool; place a new Tip in the Handpiece as described in Section 7. If it is not immediately needed, use the Tip plug to avoid contamination and damage to the Handpiece until it can be cleaned and sterilized for the next patient.
11. Clean and sterilize the Handpiece, as outlined in Section 10.
12. Disposable, single-use, quartz (glass) Tips must be disposed of in a biohazard medical waste sharps container. Single-use Tips should not be reused. Reusable Sapphire Tips must be cleaned and sterilized between patients to prevent cross contamination.

Cutting efficiency will vary depending upon the power setting, tip diameter, and spray configuration. If the system appears to be working slowly at the preset power setting, the air and water spray settings can be adjusted; tap the pull down arrow at the top of the screen and then use the sliders to increase or decrease the air and water values as needed. Note that clinical efficiency depends on power as well as spray; with experience, the user will be able to gauge spray and power efficiency from the sound of the popping water droplets. A sharper, more distinct popping sound represents a higher cutting rate. Use clinical judgment to adjust the air and water spray to compensate for variations in tissue composition, density and/or thickness.

SOFT-TISSUE CUTTING

Soft-tissue procedures are performed with direct laser energy, either with or without water spray.

- A. Select the desired procedure from the Home (Procedures Main) screen.
- B. Begin the procedure with Step 1; the optimum settings for each step of each procedure have been preset at the factory.
- C. Carefully place the tip approximately 1-2 mm from the targeted tissue.
- D. Step on the Footswitch and slowly move the tip along the tissue surface. The incision will be noticed immediately after laser activation.



NOTE: Bleeding is controlled by lowering the water setting as much as possible..

9 Clinical Application

Laser Parameters

The settings chosen for a procedure will contribute to its overall success. Waterlase iPlus uses a spray combining air and water to effectively cut tissue, in conjunction with pulse repetition rate and mode, which must be balanced appropriately to obtain optimal clinical outcomes and positive patient results.

As examples, a greater percentage of water is good for cooling targeted tissue, but too much water will reduce the power delivered because the laser radiation is absorbed by the water; more air in the mix will generate a finer spray, making it easier for the water molecules to penetrate the tissue, facilitating cutting; a higher pulse repetition rate will allow faster, smoother cutting of hard tissue, but could result in a higher tissue temperature, possibly making the procedure more painful for the patient, while a longer pulse (S mode) works well for soft tissue because it increases tissue temperature, reducing bleeding.

If uncertain which parameters are best for a chosen procedure, please refer to the suggested settings on the device or make the appropriate adjustments based on prior clinical experience. Attend training courses and experiment on model tissues before using the Waterlase iPlus on patients.

PRESETS FOR SOFT- AND HARD-TISSUE PROCEDURES

Recommended settings for most of the procedures listed in Section 2 (Indications for Use) have been pre-programmed in the Waterlase iPlus. These suggested values only and may be modified as needed to compensate for variations in tissue composition, density and/or thickness; always use clinical judgment when doing so. A favorite combination of customized values can be saved as a new Preset (Section 8: Settings/Memory Menu).

Refer to the Appendix E for a list of programmed pre-sets available in the Waterlase iPlus.

Always use clinical judgment when adjusting these individual values; as noted, preferred settings can be saved as new Presets.

10 Cleaning and Sterilization

HANDPIECE AND TIP CLEANING AND STERILIZATION

STEP 1—CLEANING PROCESS



CAUTION: Handpieces and laser Tips are not sterile when sold and must be sterilized prior to initial use, and Handpieces must be cleaned and sterilized between patients. Disposable, single-use Quartz (glass) Tips must be disposed of in a biohazard medical waste sharps container. Cleaning must be performed within a maximum of 1 hour after the procedure and prior to sterilization.

Use only the MANUAL cleaning process described below. Other cleaning methods should be avoided since water entering the portals of the exhaust ring may damage the fiber optics inside the Handpiece.



CAUTION: The Fiber Cable cannot be autoclaved; doing so will make it unusable. However, the Fiber Optic Cable must always be disinfected between patients by following the procedure outlined in Step 3 of this section.

The cleaning process is intended to remove blood, protein and other potential contaminants, as well as to reduce the quantity of particles, microorganisms and pathogens present from the Handpiece, laser Tip surfaces and crevices. Cleaning should be performed prior to sterilization and must be conducted only by qualified personnel trained in the process who know how to handle the laser Handpiece and Tips, and wearing goggles, masks, gloves, and shields.

1. After each clinical procedure, detach the Handpiece from the Fiber Cable with the Tip still attached. Do not remove the Tip.
2. Insert the rear plug into the Handpiece; during the cleaning procedure ensure the cleaning solution and rinse water does not enter the portals of the exhaust ring.
3. Rinse the handpiece with the Tip still installed under lukewarm water (22 – 43°C) for 10 seconds to remove gross soil.
4. 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 similar enzymatic presoak and cleaner. Follow instructions for the disposal of used solution.
5. Soak a piece of gauze large enough to wrap the Handpiece in the cleaning solution. Squeeze out the excess liquid and wrap the Handpiece with the Tip still installed and leave wrapped for a minimum of 10 minutes.
6. Unwrap the Handpiece and Tip. Using a soft-bristled brush dipped in the cleaning solution, gently brush around the Tip ferrule, crevices, and other hard-to-clean areas for 15 seconds. The brush should be wet, but not dripping.

10 Cleaning and Sterilization

7. Rinse the Handpiece under lukewarm running tap water (22-43°C) for 10 seconds.
8. Dry the Handpiece with a lint-free cloth.
9. Visually inspect the Handpiece for any residual soil. If any is still present, repeat steps 5 through 8 until any residual soil is removed.
10. Using the Tip Remover or revolving Tip Holder, remove the Tip from the Handpiece:
 - a. Slide the Handpiece laterally toward the Tip Remover or revolving Tip Holder (Figure 10.1);
 - b. Place thumb against the selected Tip slot to prevent laser Tip from falling out of the Tip Holder when disconnecting it from the Handpiece;
 - c. Carefully lift the Handpiece to disengage the Tip ferrule from the Handpiece head;
 - d. Use tweezers to slide the Tip out from the Tip Holder or Tip Remover; dispose of the used Tip in a medical waste sharps container (Fig.10.2).
11. Gently wipe the orifice of the Handpiece head with a dry lint-free cloth, making sure to remove any soil/debris that may have accumulated in the crevice between the laser tip and the Handpiece.
12. Once removed from the Handpiece, single-use Tips must be disposed of in a biohazard medical waste sharps container; if the Tip is meant to be reusable, rinse with distilled, or de-ionized water for 10 seconds and then dry with a lint-free cloth. Sterilize per the procedure outlined below.
13. Visually inspect the Tip for any residual soil; if any is present, repeat step 13 until all residual soil is removed.



Fig. 10.1



Fig. 10.2

STEP 2—HANDPIECE STERILIZATION PROCESS

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



NOTE: Always perform the procedure immediately after cleaning and prior to use. The product packaging is **NOT** suitable for steam sterilization.

1. Prior to sterilization, remove the Rear and Tip plugs, if installed.
2. Place the Handpiece inside a single-wrap, self-sealed pouch.
3. The Tips may be autoclaved in the Tip Holder. Place the individual Tips or the Tip Holder loaded with Tips into a separate single-wrap self-sealed pouch.

10 Cleaning and Sterilization

3. Place the pouches on an autoclave tray. Take care when handling the Handpiece and Tip(s).
4. Do not stack other instruments on top of the pouches.
5. Place the tray into the autoclave chamber and set the autoclave to the appropriate cycle, as noted in Fig. 10.3.

Type of Sterilizer	Temperature	Minimum Time	Drying Time
Gravity Displacement	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 (273°F)	3 minutes	20 minutes

Fig. 10.3

7. Upon completion of the cycle, the Handpiece and Tips must remain in the sterilization pouches prior to use to ensure sterility.
8. To reassemble, remove the Tip from the sterilization pouch with tweezers and insert it into the Tip Remover or Tip Holder (if not already in the Tip Holder). Follow the instructions outlined in Section 7, Installing and Changing the Tip in the Handpiece.

STEP 3—DISINFECTING THE FIBER OPTIC CABLE

Always disinfect the Fiber Optic Cable between patients by wiping it completely with an appropriate disinfecting solution such as Cavicide or a similar quaternary ammonium compound product (containing 20% alcohol or less), and follow the manufacturer's instructions. Avoid getting any liquid or debris near the laser head. **DO NOT AUTOCLAVE.**



WARNING: Repeated processing of the Handpiece and reusable Tips may reduce the useful life of these devices. Check the Handpiece for damage or wear prior to each use. The Handpiece should be free of nicks, distortion, corrosion or other signs of mechanical degradation. If damage or wear is observed, discard the Handpiece as required by local Waste Electrical and Electronic Equipment (WEEE) laws. Used or damaged Tips must be disposed of in a biohazard medical waste Sharps container.

Use of damaged or worn Tips may cause damage to the delivery system and will compromise the clinical performance of the Waterlase iPlus Laser System. The Tips must be inspected prior to each use for damage or wear as described in Appendix D:
TIP INSPECTION

11 Maintenance and Troubleshooting

DAILY MAINTENANCE

Use the display covers supplied with the system to cover/protect the screen console. Use disinfectant to wipe down the front of the laser and the Handpiece holder after each procedure. Do not use bleach or abrasive cleaners.



CAUTION: DO NOT allow water to enter the Laser Console, especially where the Fiber Optic Cable and Handpiece connect; any water entering the portals of the exhaust ring may damage the fiber optics inside the Handpiece.

Single-use Tips must be discarded after one use in a medical waste Sharps container.

MIRROR CHECK AND CLEANING



NOTE: If the performance of the delivery system is questionable, but the Tip is in good condition, check the mirror for damage or contamination.



WARNING: Use of a contaminated or damaged mirror will cause damage of the Fiber Delivery System.

Set the system in Standby mode, navigate to the illumination screen (Fig 8.9), and remove the Tip.

MIRROR INSPECTION AND CLEANING

Point the Handpiece towards a white surface. The visible spot of the aiming beam should be clear, uniform, and well-confined. If dark areas and irregularities are present, inspect the mirror.



NOTE: If the plastic Tip ferrule is continuously getting damaged at the input end, the mirror should be checked and cleaned, and mirror alignment should be checked.

11 Maintenance and Troubleshooting

REMOVING THE HANDPIECE MIRROR

1. Insert the 3-pin side of the tool into the 3 holes of the cap in the Handpiece head. Make sure the user sees all the pins fit snugly. Turn counter-clockwise approximately 3 turns to unscrew the cap. Remove and store the cap in a safe place (Fig 11.2).



NOTE: Do not turn the headpiece with the opening facing down to avoid the mirror falling out and becoming lost.

2. Insert the other side of the tool perpendicular to the plane of the backside of the mirror inside the opening. Screw the threaded side of the tool into the mirror by turning the tool 2-2½ full turns. Do not thread all the way into the mirror for easier release of the mirror later (Fig 11.3).
3. Pull the mirror straight out from the head opening (Fig 11.4). Wear gloves or fingertips - DO NOT handle the mirror with bare hands. Grab the mirror with fingers or tweezers and unscrew it from the tool. If the user touches the mirror surface, gently clean it with a cotton swab moistened with alcohol.



IMPORTANT: The mirror is oval symmetrical, make sure of proper orientation when inserting the mirror into the opening in the Handpiece head (Fig. 11.5, 11.6).



NOTE: If the mirror has burn marks, clean the internal surfaces of the Handpiece head with a long cotton swab moistened with alcohol. 99% pure isopropyl alcohol is required for the use of this product.



Fig. 11.1



Fig. 11.2



Fig. 11.3



Fig. 11.4



Fig. 11.5



Fig. 11.6

CHANGING THE HANDPIECE MIRROR

1. To inspect the mirror, remove it following the proper procedure as illustrated above.
2. Mirror can be contaminated or damaged (Fig. 11.7).
3. A contaminated mirror can be cleaned with a cotton swab moistened with optical grade acetone or alcohol, as follows (Fig 11.8):
 - Place the wet swab over the mirror surface and wait for approximately 5 seconds for the solvent to soften the contaminating material;
 - Wipe off the contamination by a quick turn and removal of the swab;
 - Repeat several times until all contamination is removed.
5. If the mirror has remaining burn marks or scratches, it should be replaced.

11 Maintenance and Troubleshooting

6. While the mirror is removed, and if it has contamination or burn marks, clean the internal reflector inside the Handpiece head with a long cotton swab moistened with acetone or alcohol.
7. Install the new or cleaned mirror and check for proper alignment (Fig 11.5, 11.6).

MIRROR ALIGNMENT CHECK

1. Point the Handpiece towards a white surface. The visible spot of the aiming beam should be clear, uniform, and well confined (Fig 11.9).
2. If the spot is confined on one side and has a satellite-type reflection (smile) on the opposite side, the mirror alignment is questionable (Fig 11.10).
3. To improve alignment, remove the mirror and turn it 180 degrees. If this does not help, replace the Handpiece. If that does not help, replace the Fiber Cable.

FIBER CHECK



NOTE: Regularly inspect the end of the Fiber Cable. Always inspect and clean the Protective Window at the end of the Fiber Cable after the input end of the Tip or Handpiece mirror were damaged.



WARNING: Use of a dirty or contaminated Protective Window will cause damage of the Fiber Cable.

1. Disconnect the Handpiece following the proper procedure described in Section 7.
2. Verify the laser is in Standby mode.
3. Check the polished reflective surface of the window at the distal end of the Fiber Optic Cable (Fig 11.11, 11.12).



Fig. 11.7



Fig. 11.8



Fig. 11.9

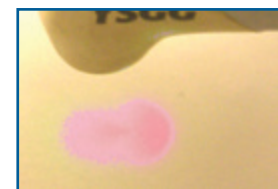


Fig. 11.10



Fig 11.11

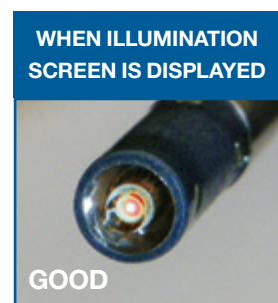


Fig 11.12

11 Maintenance and Troubleshooting

1. If the laser is not firing, check the following:

- Verify the laser is powered on. Check the power switch and the power cord connection.
- Verify the laser is focused. Adjust the focus wheel (see Fig 11.14).
- Check the laser output. The laser output should be visible through the rectangular opening. If not, check the protective window and the rectangular opening alignment.



DANGER: Invisible and/or visible laser radiation when the laser is firing - avoid eye or skin exposure to direct or scattered radiation.



Fig 11.13

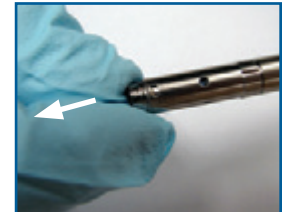


Fig 11.14



Fig 11.15

11 Maintenance and Troubleshooting

ANNUAL MAINTENANCE

The Waterlase iPlus should be serviced annually by a qualified, trained BIOLASE-certified technician. As part of the annual maintenance, the following will take place:

- The system flash lamp will be inspected;
- The system will be calibrated
- The entire laser cavity and optical train will be cleaned;
- All relevant electronic circuits will be calibrated;
- Filters and cooling fluid will be changed.

Please contact the local BIOLASE representative to discuss extended service contracts and annual maintenance options.

DELIVERY SYSTEM

The Fiber Cable and Handpiece represent a sophisticated technology of laser-transmitting components. Depending on use, and due to the precision involved in the manufacture and alignment of the laser beam and internal optics, the components may need to be periodically replaced to maintain tissue cutting efficiency. Properly following the operating and maintenance instructions of this User Manual will increase the delivery system's lifetime.

LASER CONSOLE

The Laser Console contains electronic and mechanical components that are thoroughly checked prior to shipment, as well as when a trained engineer services the unit. Depending on usage, some of these components may require periodic servicing and/or replacement between annual maintenances. The Laser Console will usually deliver lower power than normal if this is the case. Please contact the BIOLASE service representative for assistance.

11 Maintenance and Troubleshooting

CALIBRATION SCHEDULE:

Calibration requires specialized equipment, and is to be performed only by a BIOLASE-trained service engineer who is provided with the proper calibration procedure and necessary circuit diagrams, component parts list and descriptions, etc.

Power calibration is to be performed annually. The Service Engineer will write the date of installation and subsequent power calibration dates in the table provided below:

INSTALLATION AND CALIBRATION DATES:

Installation Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:
Calibration Date:	Technician:

11 Maintenance and Troubleshooting

TROUBLESHOOTING

The Waterlase iPlus constantly monitors its own performance and calibration. If any performance errors occur, the system will automatically go into **Standby** mode and the screen will show a message indicating the cause of the error and the recommendation for clearing it.

If, after following the directions on the screen, the error does not clear, please call the local service representative for assistance.

Error Number	Error	Reason	Fix	Corrective Action
6	All bottle sensors off	Possible error in light source	Check bottle sensor light source	Check bottle straw, clean sensors
7	Bottle sensor 1 off, 2 on	Possible defective sensor 1	Check Bottle sensor	Check bottle straw, clean sensors
8	All bottle sensors on	Error in bottle sensor system	Check out bottle sensor system	Check bottle straw, clean sensors
13	Footswitch pressed in Standby Mode	Footswitch pressed in Standby Mode	Release the Footswitch	Check connector, Switch to "Ready" mode
15, 28	Interlock is open	Interlock is open	Check Interlock	Check Remote Interlock connector at back panel
17	Shut Down temperature condition	System Temperature is high	Allow system to cool down	Let system run in "Ready" mode for 5-10 minutes
18	Emergency switch pressed	Emergency switch pressed	Check Emergency switch	Release the Emergency Stop button at the front
19	No bottle error	Bottle not detected	Insert bottle or repair sensor	Insert water bottle and clean the sensors
23	Reservoir fail	Cooling water level is low	Add de-ionized/ distilled water	Add specified water, if trained on that
24	Air pressure failure	Air pressure failure	Check air compressor	Air pressure might be low or disconnected
26	Footswitch not detected	Footswitch not connected	Connect Footswitch	Check connector, Footswitch short during Standby
29	Fiber Cable not detected	Fiber Cable not detected	Check Fiber Cable	Properly re-connect the Fiber Cable
31	No water	No water in bottle	Add de-ionized/ distilled water	Add specified water to bottle

11 Maintenance and Troubleshooting

TRANSPORTATION

The Waterlase iPlus ships inside a custom shipping crate. Please save and store the crate in a cool, dry place for future use. The Laser Console must not be transported from facility to facility unless packaged inside the crate.

the Waterlase iPlus is susceptible to misalignment if not handled properly. The Laser Console should ALWAYS be packed inside its shipping crate when transported from one facility to another. While the laser is semi-portable and may be rolled from one operatory to another inside the same facility, care should be taken when pushing the Laser console over doorway thresholds and other bumps or objects on the ground.

Do not roll the Laser Console outside of the office building, across a road, or over any other rough surface. Do not place the Laser Console into a pick-up truck, van, or other means of transportation unless it is completely packaged inside its shipping crate.

Once crated, the Laser Console should be transported by forklift or pallet jack, and should never be laid on its side, dropped, or banged. If the user has any questions regarding transportation, please call the local BIOLASE representative.

STORAGE

The Waterlase iPlus should be stored in a cool, dry place when not in use. Storage temperature should be -20° to 60°C (-4° to 140°F), relative humidity 10% to 90%, non-condensing. Cover the Laser Console when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged.

Appendix A Labels

PRODUCT IDENTIFICATION LABEL

Identifies product part number, serial number, manufacturer, manufacturing date.

Location: Back panel, above ventilation channels and outer shipping box.



MANUFACTURER



CATALOG/PART NUMBER



PRODUCT SERIAL NUMBER



DATE OF MANUFACTURE



REFER TO INSTRUCTION MANUAL

Location: Back panel



TYPE BF APPLIED PART

Location: Distal end of Fiber Cable (one side)



DUTY CYCLE

Location: Distal end of Fiber Cable (opposite side)



Appendix A Labels

LASER HAZARD SYMBOL

Indicates the system contains a laser.

Location: Top cover of laser head, directly above the Fiber Cable connector. (Only visible during service)



HIGH VOLTAGE HAZARD SYMBOL

Warning - Dangerous voltage (Only visible during service).

Locations:

- Top cover of laser head, directly above the High Voltage input.
- PFN Board Capacitor
- Front Capacitor Bracket



CERTIFICATION

This device complies with FDA laser standards.

Location: Back panel

Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice 56, dated May 8, 2019.

5400341

Rev. C

NON-INTERLOCKED PROTECTION HOUSING WARNING

Location: Laser head, access plate
(Accessible only during service proceedings).

DANGER

Invisible class 4 laser
radiation present when open.
AVOID EYE OR SKIN EXPOSURE
TO DIRECT OR
SCATTERED RADIATION

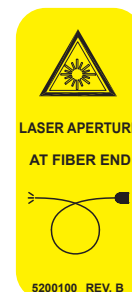
5200101

REV. B

LASER APERTURE

Indicates the laser aperture is at the end of the Fiber.

Location: On the top cover, adjacent to Fiber Cable connector



LASER WARNING SIGN

Included in the Welcom Kit; must be placed outside of the operatory whenever the laser system is in use.



Appendix A Labels

LASER EXPLANATORY LABEL

Provides laser specifications

Location: On top cover, adjacent to Fiber Optic Cable connector



SYSTEM GROUND CONNECTION

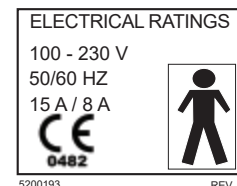
Location: Inside Laser Console, left.



ELECTRICAL SHOCK RATINGS

Type BF Applied Part

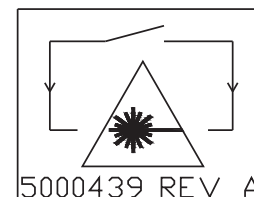
Location: Next to E1 ground terminal, inside Laser Console.



REMOTE INTERLOCK LABEL

Input for Remote Interlock Connector which, when applied to the access door of the operatory and activated, will shut off the laser.

Location: Back panel



ETL LISTED: UL/CSA CONFORMANCE LABEL

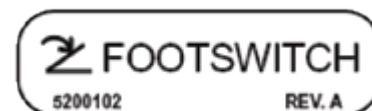
Location: Back panel



FOOTSWITCH LABEL

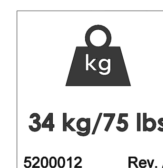
Connection to Footswitch

Location: Back panel



WEIGHT LABEL

Location: Back panel



Appendix A Labels

EMERGENCY STOP

The button used in emergencies to stop laser output.

Location: Front Cover



PROTECTIVE EARTH GROUND

Location: Next to E1 ground terminal, inside laser console.



ATTENTION (SMALL)/GENERAL WARNING

Location: Back Panel



AIR LABEL

Indicates minimum and maximum air pressure

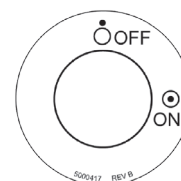
Location: Wall Back Panel



KEYSWITCH LABEL

Turns laser on and off when key inserted.

Location: Back Panel



WEEE (WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT)

Do not throw in trash bin. Dispose of as regulated.

Location: Back Panel



POTENTIAL EQUALIZATION TERMINAL (PEQ)

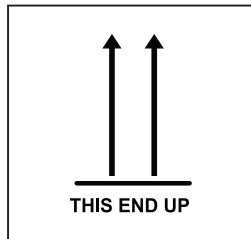
Potential equalization conductor used to connect the GND terminal of the operator.

Location: Lower Back Panel



Appendix A Labels

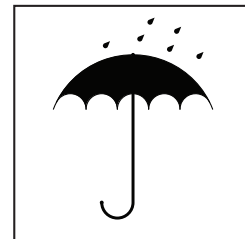
OUTER PACKAGING



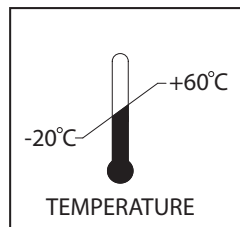
THIS END UP



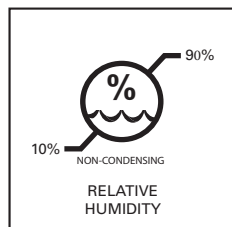
**HANDLE
WITH CARE**



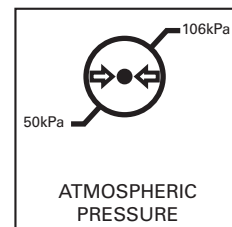
KEEP DRY



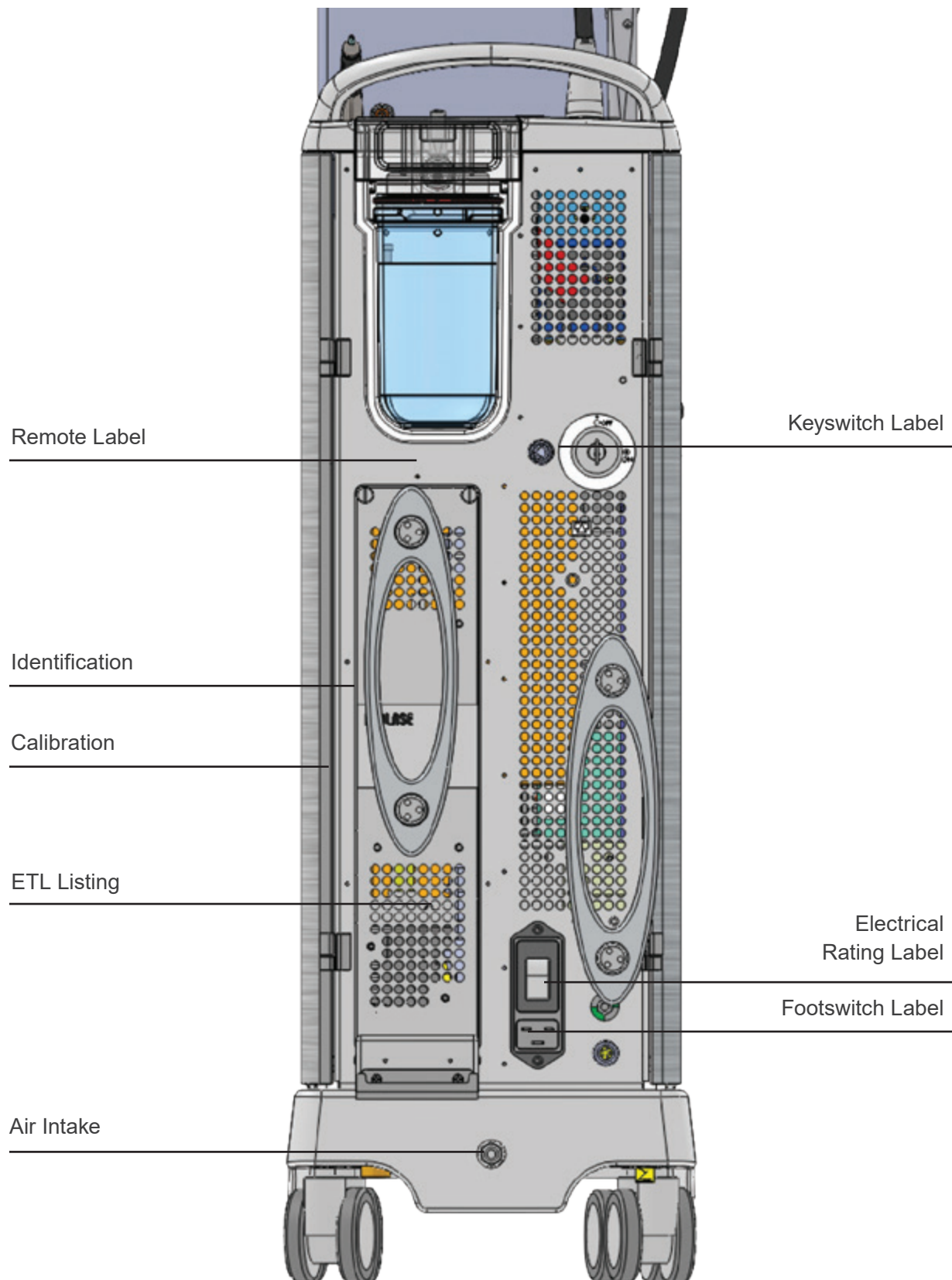
**TEMPERATURE
LIMITATIONS**



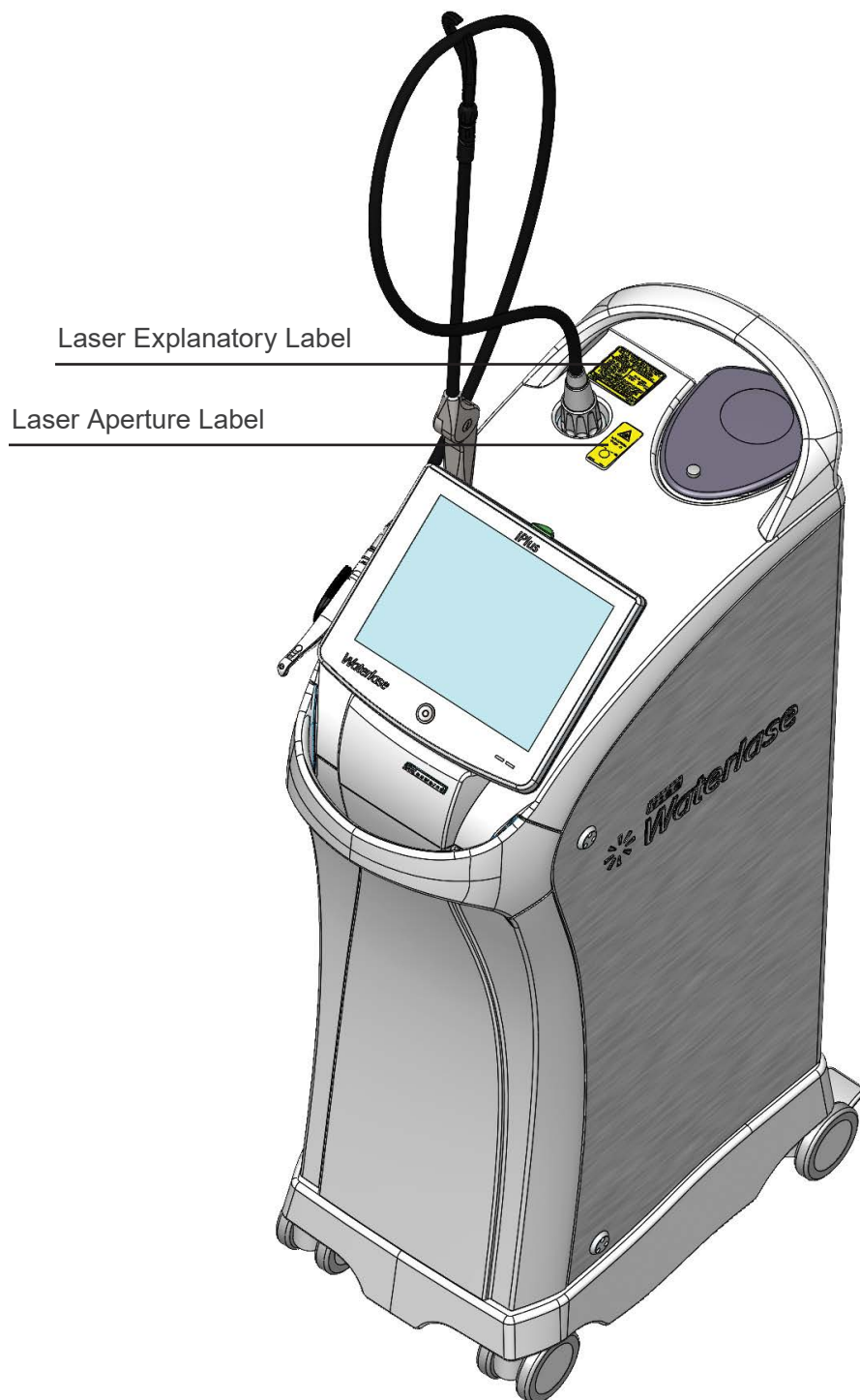
**HUMIDITY
LIMITATIONS**



**ATMOSPHERIC
PRESSURE
LIMITATIONS**



Appendix A Labels



Appendix B Accessories

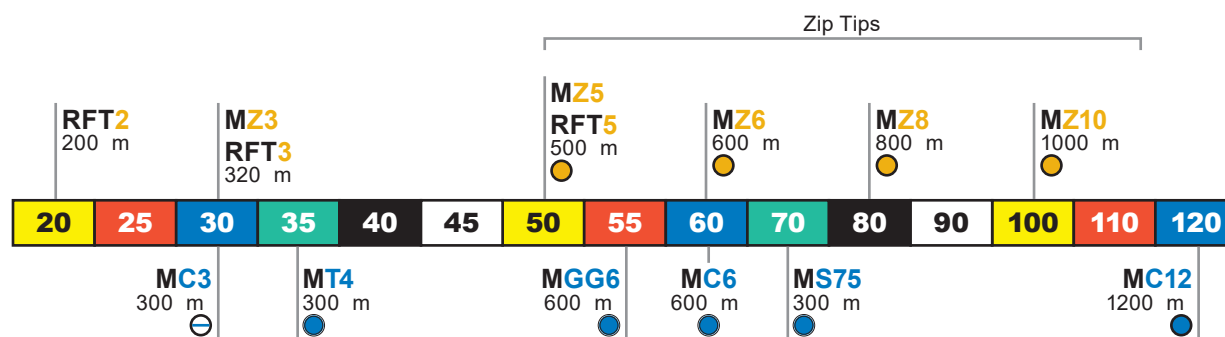
BIOLASE P/N	DESCRIPTION
2200696	Glasses, Protective, Multi Wavelength
2200848	Glasses, Doctor, Multi Wavelength
6201515	Fiber Optic Cable
6200150	Footswitch
2000204	Power Cord, Hospital Grade (U.S.)
7000414	Waterlase/MD Tip Holder
7000734S	Waterlase Mirror Replacement Kit
7200104	Waterlase/MD Tip Inspection Kit
6200500	Gold Handpiece
6201037	Gold Mirror Refill Kit
6201102	Gold Mirror Single Refill
7200106	MD Gold Mirror Replacement Kit
3200105	Waterlase Mirror Removal Tool
2200706	Waterlase iPlus Display Covers
5201281	Danger Sign (Laser Warning Sign)

Appendix C Tips

TIP TYPES

TIP FERRULE COLORS

Tip types following Dental Standard ISO Series Diameter/Color Codes



TIP IDENTIFIERS			TIP TYPES	
			Z	Glass Tips
			C	Sapphire Tips
			●●	Cylindrical Tips
			⊖	Chisel Tips
			●	Tapered Tips

Fiber Core Diameter

TIP SETTINGS: WATERLASE IPLUS HANDPIECE

Z - GLASS (QUARTZ) TIPS - SINGLE USE

Tip Type	Ferrule Color/ Diameter (µm)	Lengths (mm)	Gold Handpiece		Tissue Types
			Calibration Factor*	Maximum Power (W)	
RFT2	200	21, 25	0.55	4.0	Root Canal Cleaning
MZ3	320	9, 14, 20, 25, 28	0.85	4.0	Soft-Tissue
RFT3		17, 21			Root Canal Cleaning
MZ5	500	3, 6, 9, 14	0.95	4.0	All Types
RFPT5		10, 14		6.0	Soft-Tissue
MZ6	600	3, 6, 9, 14	1.00	No Limit	Enamel, Bone, Dentin, Soft-Tissue
MZ8	800	3, 6, 9	1.00	No Limit	Enamel, Dentin, Soft-Tissue
MZ10	1000	3, 6, 9	1.00	No Limit	Enamel, Dentin, Soft-Tissue

Appendix C Tips

SAPPHIRE TIPS - RE-USABLE

Tip Type	Ferrule Color/ Diameter (µm)	Lengths (mm)	Handpiece		Tissue Types
			Calibration Factor*	Maximum Power (W)	
MT4	400	6	1.00	2.5	Enamel, Dentin, Soft-tissue
MS75	750	6	1.00	No Limit	Enamel, Dentin, Soft-tissue
MC3	300 x 1200	9	1.00	No Limit	Enamel, Dentin, Soft-tissue
MC6	600	9	1.00	No Limit	Enamel, Dentin, Soft-tissue
MGG6	600	4, 6, 9	1.00	No Limit	Enamel, Dentin, Soft-tissue
SFT8	800	18	0.95	2.4	Soft-tissue
MC12	1200	9	1.00	No Limit	Dentin, Soft-tissue

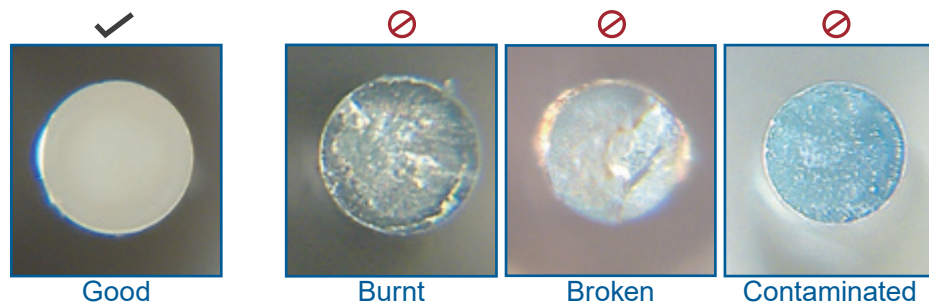
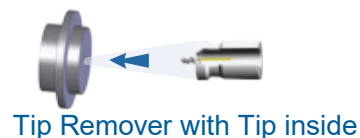


CAUTION: Tips are shipped non-sterile and require sterilization before use. If a reduction in cutting efficiency is observed, replace the Tip. Failure to replace the Tip correctly could result in damage of the Tip or the Handpiece mirror. The Tips have a limited lifetime, therefore damage of the cable attributed to overuse of the Single-Use Tips may not be covered by warranty.

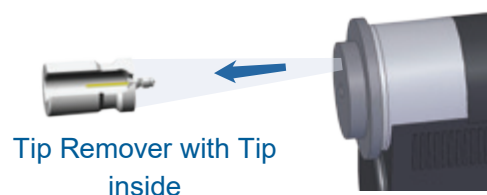
Appendix D Tip Inspection

TIP INSPECTION INSTRUCTIONS

1. Remove the Tip from the Handpiece and insert it into the correct side of the Tip test holder as shown using the Tip Remover.
2. Insert the Tip test holder into the test adapter with the distal (or laser-emitting) end of the Tip toward the microscope.
3. Slide the adapter over the microscope to move the Tip surface toward the focal point of the microscope. The focal point lies in the plane at the end of the clear end tube of the microscope.
4. Turn on the microscope's built-in light by gently pulling apart the upper and lower tubes, or hold it up to another light source, and bring the surface of the Tip into focus using the thumbwheel. Examine the Tip surface carefully for damage or contamination.
5. To examine the proximal (or Fiber Cable) end of the Tip, remove the adapter from the microscope, and gently insert the other side of the test holder into the clear end tube of the microscope. Refocus the Microscope.



6. Remove the Tip from the test holder using the Tip Remover. If the Tip is contaminated at either end, try cleaning it as shown below. If the Tip is damaged, replace it from the Handpiece using the Tip Remover and dispose of it.



To replace the batteries for the built-in microscope light, gently pull apart the upper and lower tubes of the microscope. Locate the battery cover marked with "OPEN", slide the cover in the direction of the arrow, remove the old batteries and replace with two size AA 1.5 volt (Europe size M) batteries.

Appendix D Tip Inspection

TIP CLEANING INSTRUCTIONS

1. Hold Tip with tweezers.
2. Moisten cotton swab with 100% isopropyl alcohol drops.
3. Push Tip into cotton swab.
4. Twirl cotton swab while maintaining pressure on Tip. (Fig. D.1)



Fig D.1

FIBER TIP INSPECTION



NOTE: Prior to each use always check the distal end of the Tip for damage or contamination. Check both ends of the Tip when replacing.



WARNING: Use of damaged or contaminated Tip may cause damage to the Fiber Cable and will compromise clinical performance of the Waterlase iPlus. Tips can be inspected using magnifying lenses, a microscope, laser aiming beam, or the BIOLASE Tip Inspection Kit.

1. Check that both ends of the Tip appear flat and present a mirror-like reflection of any light source.

Look for chips or nicks along the edges (Fig D.2).
2. Prior to insertion of the Tip, inspect the o-rings for any damage or debris. Replace damaged o-rings; if it is suspected that part of the o-ring still remains inside the Handpiece, blow dry, clean air through the Handpiece

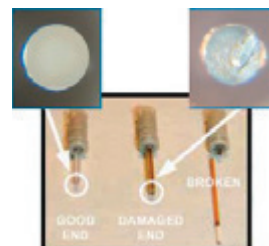


Fig D.2

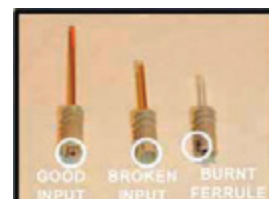


Fig D.3

Appendix E Pre-Programmed Settings

The table below lists the settings pre-programmed for each of the procedures offered available with the Waterlase iPlus; the highlighted settings are the default values for each procedure step.

PROCEDURE	PROCEDURE STEP	HAND PIECE	TIP TYPES	POWER	PPS	MODE		SPRAY %	
			(Default: yellow)	W	Hz	H	S	WATER	AIR

Restorative

Class I	ComfortPrep	Gold	MZ10	9.00	15	H		70	90
			MZ8	5.00	15	H		50	80
			MZ6	3.75	15	H		50	60
			MZ5	3.00	15	H		50	60
			MT4	2.00	15	H		50	60
			MGG6	3.75	15	H		50	60
			MC6	3.75	15	H		50	60
			MS75	5.50	15	H		50	80
	RapidPrep	Gold	MZ10	10.00	20	H		70	90
			MZ8	8.00	20	H		70	90
			MZ6	5.00	20	H		50	80
			MZ5	4.00	20	H		40	60
			MT4	2.50	20	H		40	60
			MGG6	5.00	20	H		50	80
			MC6	5.00	20	H		50	80
			MS75	7.25	20	H		50	80
	BondPrep	Gold	MZ10	7.00	50	H		50	80
			MZ8	4.50	50	H		40	60
			MZ6	2.50	50	H		40	60
			MZ5	2.00	50	H		40	60
			MT4	1.25	50	H		40	60
			MGG6	2.25	50	H		40	60
			MC6	2.50	50	H		40	60
			MS75	3.75	50	H		40	80

Appendix E Programmed Settings

PROCEDURE	PROCEDURE STEP	HAND PIECE	TIP TYPES	POWER	PPS	MODE		SPRAY %	
			(Default: yellow)	W	Hz	H	S	WATER	AIR
Class II	ComfortPrep	Gold	MZ10	9.00	15	H		70	90
			MZ8	6.00	15	H		50	80
			MZ6	3.75	15	H		50	60
			MZ5	3.00	15	H		50	60
			MT4	2.00	15	H		50	60
			MGG6	3.75	15	H		50	60
			MC6	3.75	15	H		50	60
			MS75	5.50	15	H		50	80
	RapidPrep	Gold	MZ10	10.00	20	H		70	90
			MZ8	8.00	20	H		70	90
			MZ6	5.00	20	H		50	80
			MZ5	4.00	20	H		30	60
			MT4	2.50	20	H		40	60
			MGG6	5.00	20	H		50	80
			MC6	5.00	20	H		50	80
			MS75	7.25	20	H		50	80
	BondPrep	Gold	MZ10	7.00	50	H		50	80
			MZ8	4.50	50	H		30	60
			MZ6	2.50	50	H		30	60
			MZ5	2.00	50	H		30	60
			MT4	1.25	50	H		30	60
			MGG6	2.25	50	H		30	60
			MC6	2.50	50	H		30	60
			MS75	3.75	50	H		50	80

Appendix E Pre-Programmed Settings

PROCEDURE	PROCEDURE STEP	HAND PIECE	TIP TYPES	POWER	PPS	MODE		SPRAY %	
			(Default: yellow)	W	Hz	H	S	WATER	AIR
Class III-V	ComfortPrep	Gold	MZ8	4.00	15	H		40	60
			MZ6	2.50	15	H		40	60
			MZ5	2.00	15	H		40	60
			MT4	1.25	15	H		40	60
			MGG6	2.50	15	H		40	60
			MC6	2.50	15	H		40	60
			MS75	3.50	15	H		40	60
	Rapid Prep	Gold	MZ8	5.25	20	H		50	80
			MZ6	3.25	20	H		50	60
			MZ5	2.50	20	H		50	60
			MT4	1.75	20	H		50	60
			MGG6	3.25	20	H		50	80
			MC6	3.25	20	H		50	80
			MS75	4.75	20	H		50	80
	BondPrep	Gold	MZ8	4.50	50	H		40	60
			MZ6	2.50	50	H		40	60
			MZ5	2.00	50	H		40	60
			MT4	1.25	50	H		40	60
			MGG6	2.25	50	H		40	60
			MC6	2.50	50	H		40	60
			MS75	3.75	50	H		40	80

Appendix E Programmed Settings

PROCEDURE	PROCEDURE STEP	HAND PIECE	TIP TYPES	POWER	PPS	MODE		SPRAY %	
			(Default: yellow)	W	Hz	H	S	WATER	AIR

Soft Tissue

Gingivectomy	Rapid Cut	Gold	MT4	2.5	75	H		30	20
			MZ6	3.25	75	H		30	20
			MGG6	3.25	75	H		30	20
			MZ5	2.75	75	H		30	20
	Smooth Cut	Gold	MT4	2.5	50		S	20	20
			MZ6	4	50		S	20	20
			MGG6	4	50		S	20	20
			MZ5	3.5	50		S	20	20
	Tissue Plasty	Gold	MZ6	2.25	50	H		10	10
			MZ5	2	50	H		10	10
			MGG6	2.25	50	H		10	10
			MC3	2	50	H		10	10
Frenectomy	Rapid Cut	Gold	MZ6	2.75	75	H		30	20
			MT4	2.5	75	H		30	20
			MC3	2.75	75	H		30	20
	Smooth Cut	Gold	MZ6	3.5	50		S	20	20
			MT4	2.5	50		S	20	20
			MC3	3.5	50		S	20	20
	Tissue Plasty	Gold	MZ6	2	50	H		10	10
	Laser Bandage* (Dry)	Gold	MZ6	0.5	50		S	OFF	20
Biopsy	Rapid Cut	Gold	MZ6	2.75	75	H		40	20
			MT4	2.5	75	H		40	20
			MC3	2.75	75	H		40	20
	Smooth Cut	Gold	MZ6	3.5	50		S	20	20
			MT4	2.5	50		S	20	20
			MC3	3.5	50		S	20	20
	Tissue Plasty	Gold	MZ6	2	50	H		10	10
			MC3	2	50	H		10	10
	Laser Bandage* (Dry)	Gold	MZ6	0.5	50		S	OFF	20

* **Laser Bandage** is a term generally used to describe using the laser in the lowest settings to put a coating on the tissue either to decrease pain from an oral lesion or to make small alterations to a soft-tissue surgery.

Appendix F Electromagnetic Compatibility



CAUTION: Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment.

Accessories: Medical grade power cord, maximum length 10ft (2.44 meters) (BIOLASE part number 2000204).

Footswitch: includes shielded, coiled Footswitch cable, Footswitch, 5 conducting wires. (BIOLASE part number 6200150)



WARNING: The use of accesories, other than those specified, except those supplied or sold by BIOLASE as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the model Waterlase iPlus.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS


The Waterlase iPlus is intended for use in the electromagnetic environment specified below. The customer or the user of the Waterlase iPlus should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF radiated emissions CISPR 11	Group 1, Class A/B	The Waterlase iPlus 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 conducted emissions CISPR 11	Group 1, Class A/B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	

Appendix F Electromagnetic Compatibility

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Waterlase iPlus is intended for use in the electromagnetic environment specified below. The customer or the user of the Waterlase iPlus should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Continuous level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	$\pm 2, \pm 4, \pm 8$ kV contact	$\pm 2, \pm 4, \pm 8$ kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 50%.
IEC 61000-4-2	$\pm 2, \pm 4, \pm 8, \pm 15$ kV air	$\pm 2, \pm 4, \pm 8, \pm 15$ kV air	
Electrical fast transient/burst	100 kHz repetition ± 2 kV for power supply lines	100 kHz repetition ± 2 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	100 kHz repetition ± 1 kV for input/output lines	N/A	Input/output that does not apply because the footswitch cable length is less than 3 meters.
Surge	± 1 kV differential mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	± 2 kV common mode	± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines.	0% U_T for 0.5 cycle	0% U_T for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Waterlase iPlus requires continued operation during power mains interruptions, it is recommended that the model Waterlase iPlus be powered from an uninterrupted power supply.
	0% U_T for 1.0 cycle	0% U_T for 1.0 cycle	
	70% U_T for 25 cycles (50 Hz/60 Hz)	70% U_T for 25 cycles (50 Hz/60 Hz)	
IEC 61000-4-11	0% U_T for 250 sec/300 cycles (50 Hz/60 Hz)	0% U_T for 250 sec/300 cycles (50 Hz/60 Hz)	
Power frequency (50-60 Hz) magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			
NOTE: U_T is the A.C. mains voltage prior to applications of the test level.			

Appendix F Electromagnetic Compatibility

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (Continued)			
The Waterlase iPlus is intended for use in the electromagnetic environment specified below. The customer or the user of the Waterlase iPlus should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Continuous level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz	3 Vrms 150 kHz to 80 GHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the model Waterlase iPlus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC61000-4-3	6Vrms At the standard specified ISM band	6Vrms At the standard specified ISM band	
	9 V/m to 28 V/m 385 to 5785 MHz		
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.			
<p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone 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 Waterlase iPlus is used exceeds the applicable RF compliance level above, the Waterlase iPlus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Waterlase iPlus.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</p>			

Appendix F Electromagnetic Compatibility

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE XXX 10			
The Waterlase iPlus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Waterlase iPlus can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Waterlase iPlus 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)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For 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.			



biolase.com

NORTH AMERICA



BIOLASE MG LLC

27042 Towne Centre Drive, Suite 270
Foothill Ranch, CA 92610-2811 USA

Toll Free: (833) BIOLASE
Telephone: (949) 361-1200
Fax: (949) 273-6687
Service: (800) 321-6717

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