Waterlase iPlus™

User Manual

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Contents

Contents

Contents

Contents

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

1 Overview

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. Waterlase iPlus may also be used for specific endodontic and periodontal applications.

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 Optic 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 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 BIOLASE Customer Service at 1-800-321-6717 in the U.S and Canada for any service needs; if the user is located outside the U.S., please contact the BIOLASE-authorized representative.

This device must be installed, operated, and maintained according to the guidelines of CAN/CSA-Z386-14, Safe Use of Lasers in Healthcare.

2 Indications for Use

IMPORTANT: Review all Contraindications, Warnings and Precautions presented in Section 5 before proceeding with using this device on patients.

WATERLASE IPLUS IS INDICATED FOR:

HARD-TISSUE

GENERAL INDICATIONS*

- 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

**For use on adult and pediatric patients*

ROOT CANAL HARD-TISSUE INDICATIONS

- Tooth preparation to obtain access to root canal
- Root canal preparation including enlargement
- Root canal debridement and cleaning

ENDODONTIC SURGERY (ROOT AMPUTATION) INDICATIONS

- Flap preparation – incision of soft-tissue to prepare a flap and expose the bone.
- Cutting bone to prepare a window access to the apex (apices) of the root(s)
- Apicoectomy – amputation of the root end
- Root-end preparation for retrofill amalgam or composite
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex

BONE SURGICAL INDICATIONS

- Cutting, shaving, contouring and resection of oral osseous tissues (bone)
- Osteotomy

LASER PERIODONTAL PROCEDURES

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft-tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium
- Removal of granulation tissue from bony defects
- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft-tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours)
- Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)

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

2 Indications for Use

LASER PERIODONTAL PROCEDURES (CONTINUED)

- Osseous crown lengthening
- Waterlase Er,Cr:YSGG assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).
- Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.

SOFT-TISSUE INDICATIONS INCLUDING PULPAL TISSUES*

- 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
- Hemostasis
- 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

**For use on adult and pediatric patients*

ROOT CANAL DISINFECTION

- Laser root canal disinfection after endodontic instrumentation.

CROWN AND VENEER REMOVAL

- Waterlase laser removal of porcelain and ceramic crowns and veneers.

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 under stood 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 a 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. Surgical procedures related to soft-tissue, osseous, endodontic, or periodontal surgery should only be performed by clinicians who have training and experience in Oral Maxillofacial, Periodontal, or Endodontic Surgery.

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.

3 Contraindications, Warnings and Precautions

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.

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 (700 µs) 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 (60 µs) and (S) long pulse (700 µs). However, the long pulse (S) range is indicated ONLY for soft-tissue applications.

CURETTAGE PROCEDURES

Exercise extreme caution when using this device in areas where critical structures (i.e., nerves and vessels) could be damaged, such as in the apical third of the 3rd molar socket. Do not proceed with using the laser if visibility is limited in these areas.

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.

3 Contraindications, Warnings and Precautions

ROOT CANAL PROCEDURES

The Waterlase iPlus is better suited for straight and slightly curved canals. Great care should be taken during instrumentation of curved canals as the endodontic Tip may break or perforate through the wall of these types of canals. If during insertion the Tip does not advance easily into the canal, do not force the Tip inside. If necessary, pull the Tip out and use an endodontic hand file or a broach to open the path. Do not force the Tip and/or activate the laser while moving the Tip inside a narrow or curved canal, or through the apex. Place the end of the Tip ~2mm from the apex or from being in contact with the wall of a curved canal. Activate the laser and spray only during the outward stroke when the Tip is pulled towards the coronal portion of the canal.

ROOT CANAL DISINFECTION PROCEDURES

The same precautions and warnings stated above are applicable to root canal disinfection procedures. The Tips designed for this indication are the radial emitting RFT2 and RFT3, which have a 200µm and a 300µm diameter, respectively, and come in various lengths to accommodate different root canal lengths. Effective, non-chemical, laser root canal disinfection is performed in a dry canal, with a maximum of 10% air and no water spray. Do not exceed the preset settings (maximum) during laser activation of chemical irrigants.

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.

TISSUE EVALUATION

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

TISSUE CONTACT AND TIP BREAKAGE

Do not contact hard-tissues with the Tip. Hard-tissue cutting occurs in non-contact mode with the Tip ~0.5 mm to 3 mm off the surface (3 to 5 mm for Turbo Handpiece). 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 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.

CROWN AND VENEER MATERIALS

Do not use on crowns that are made from porcelain fused to high noble metals (PFM), or made from gold or other metallic materials.

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 Optic 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:	5A / 8A
• 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:	80 - 120 psi. (5.5 - 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:	± 20%
• Pulse energy:	0 – 600 mJ
• Pulse duration for “H” mode:	60 µs
• Pulse duration “S” mode:	700 µs
• Handpiece head angles:	70° contra-angle
• Gold HP Tip diameter range:	200 – 1200 µm
• Turbo Tip focal diameter range:	500-1100 µm
• Output divergence:	≥ 8° per side
• Mode:	Multi-mode
• Aiming Beam:	635nm (red) laser, 1mW max (safety classification 1)*
• Water Level Sensor Beam:	635nm laser, 1mW max (safety classification 1)
• Nominal Ocular Hazard Distance (NOHD):	5cm
• Maximum Permissible Exposure (MPE):	3.5 x 105 W/m2

5 Equipment Description

SYSTEM PARTS LIST

The Waterlase iPlus laser systems include the following*:

**Additional accessories, including Handpieces and Tips, ordered separately.*

- Waterlase iPlus Laser
- Display Covers (qty. 25)
- Fiber Optic Cable and Fiber support
- Yellow Air Tube
- Protective Laser Eyewear (3)
- (2) Handpieces
- Tip Starter Kit
- Tip Holder
- Tip Cleaning Kit
- Power cord, (1) US, (1) International
- Footswitch
- User Manual
- Laser Warning sign
- Product Registration Card
- Limited Warranty

GENERAL

The Waterlase iPlus dental laser system consists of two modules:

- Main Laser Console (shown in Figures 3.1, 3.2, and 3.3)
- Waterlase iPlus Fiber Delivery System (the Delivery System, shown in Figures 3.1, 3.2, and 3.3, consists of the Fiber Optic Cable, Handpiece, and Tips)

MAIN LASER CONSOLE ELEMENTS

Figures 3.1, 3.2, and 3.3 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 Optic Cable to pull the laser console; this could damage the Fiber Optic 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.

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 (0 = 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 Optic Cable or Handpiece.

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.

5 Equipment Description

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.

TELESCOPIC FIBER OPTIC CABLE SUPPORT ARM

Located at the top of the laser console, it supports the Delivery System (Fiber Optic 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.

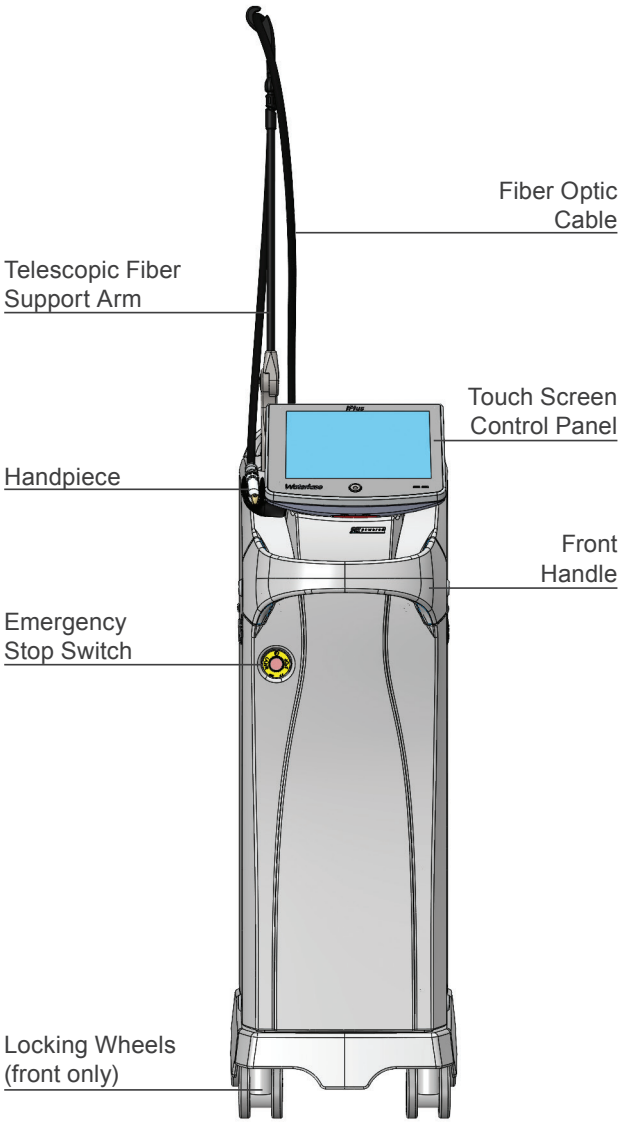


Fig 3.1

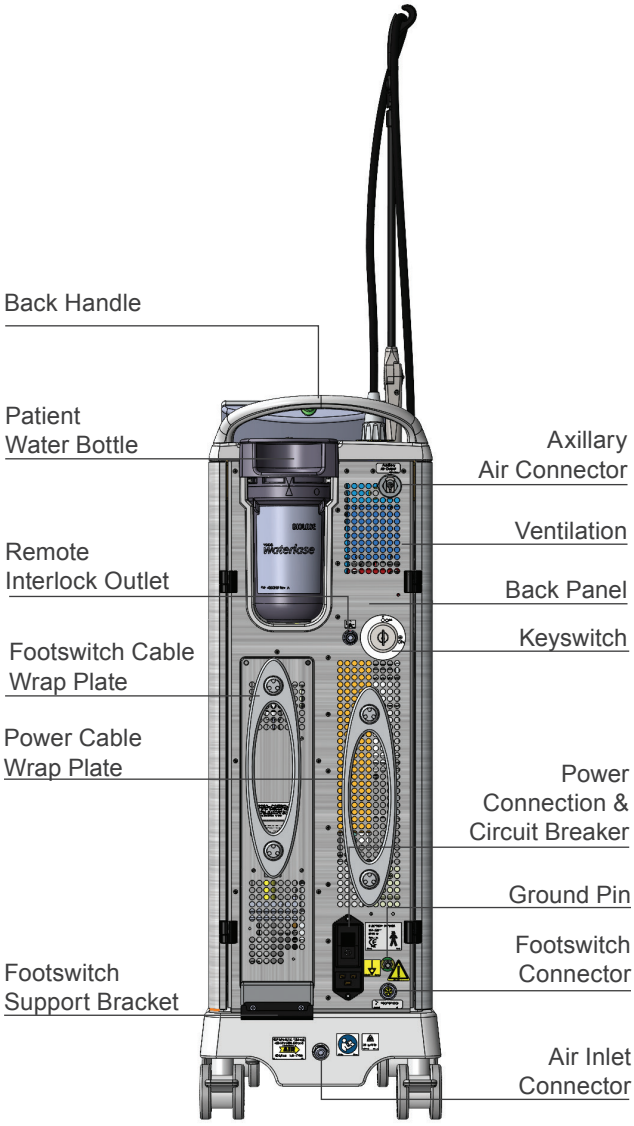


Fig 3.2

5 Equipment Description

NOTE: Proper placement of the Fiber Optic 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.

WATERLASE IPLUS DELIVERY SYSTEM

The Delivery System is comprised of the Fiber Optic Cable, Handpiece, and Tips.

FIBER OPTIC CABLE

A component of the Delivery System: the Fiber Optic Cable, including the illumination waveguides, air tubing, and water tubing, delivers laser radiation from the laser console to the Handpiece.

HANDPIECE

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

TIPS

A Tip is installed in the Handpiece to direct the laser energy. It will focus that energy differently onto the target tissue based on its shape. Tips come in many shapes, materials, and sizes. For more information, refer to Appendix C.

HANDPIECE HOLDER

Cradles the Handpiece when it is not in use.

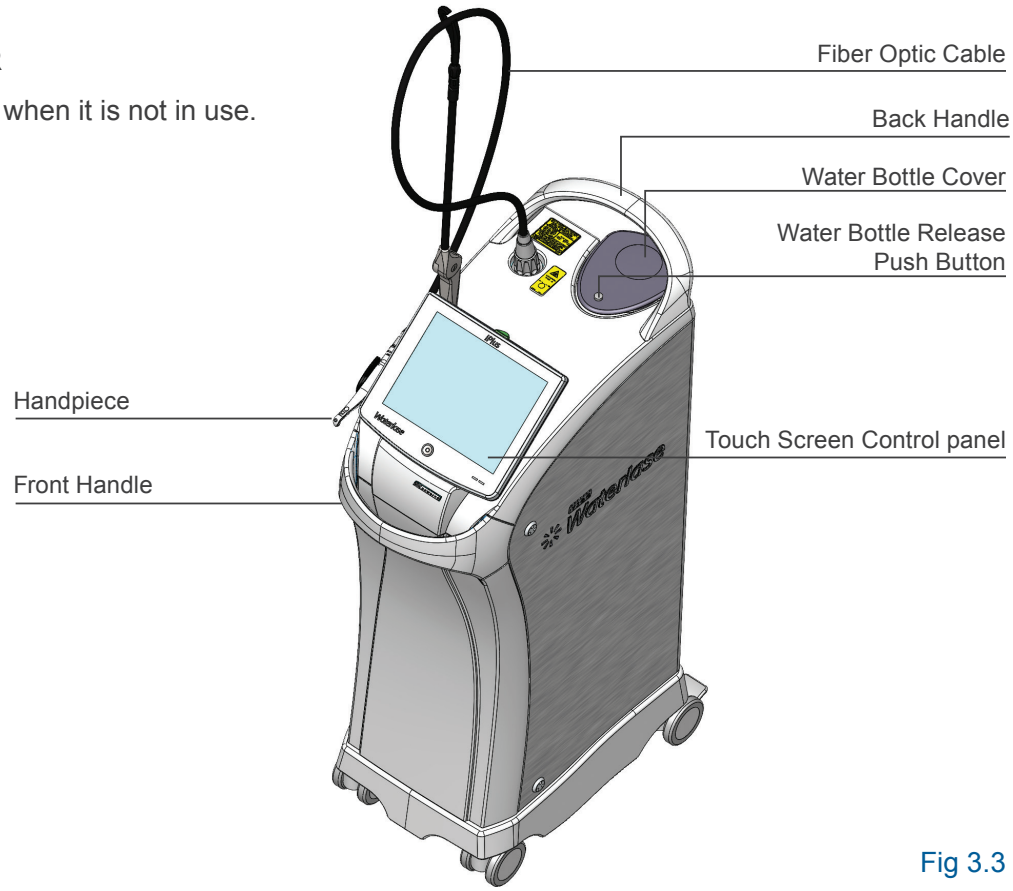


Fig 3.3

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 940nm (if using the iPlus in conjunction with 2,780nm energy (multi-wavelength glasses supplied by BIOLASE, Inc.).
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 BIOLASE Customer Service or the authorized BIOLASE representative.

6. Press the Standby button on the control panel before changing the water in the reservoir and before turning off the laser system.
7. Move the circuit breaker to the OFF (0) 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 representative, or call BIOLASE at **(888) 424-6527**, or BIOLASE Service at **(800) 321-6717 (US only).**

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.

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).

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


Fig 7.1


Fig 7.2


Fig 7.3


Fig 7.4

5. Use the funnel supplied to fill the bottle with distilled or de-ionized water up to ¾ 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 ¾ 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

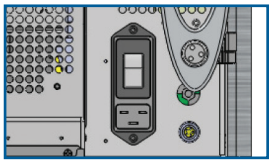


Fig 7.6

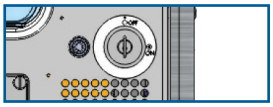


Fig 7.7

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 Optic 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 Optic Cable or Handpiece

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.

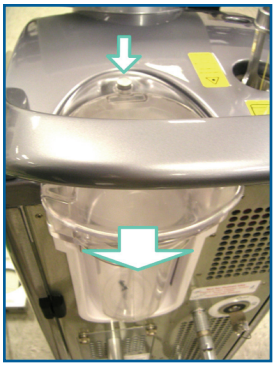


Fig 7.9

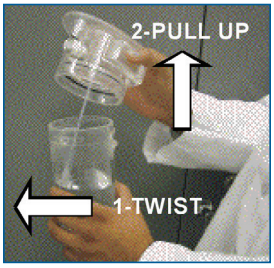


Fig 7.10

5. 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).
6. Attach the bottle back into its holder; make sure the connector is fully engaged.

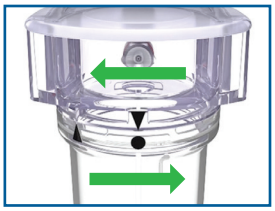


Fig 7.11

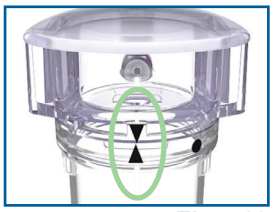


Fig 7.12

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

INSTALLING THE FIBER OPTIC CABLE

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

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


Fig 7.13

2. Remove the Fiber Optic Cable from its packaging (Fig. 7.13).
3. Remove the protective cover from the output (distal) end of the Fiber Optic Cable. Remove the metal cover from the input (proximal) end of the Fiber Optic Cable connector (Fig. 7.14). Point the output end at a bright light source and look into the input end. The fiber in the center should glow yellow, should be flat and clean (Fig. 7.15). Replace the protective cover on the distal (output) end of the Fiber Cable. Keep all protective covers for future use.

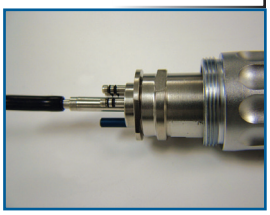


Fig 7.14

4. Remove the black plastic outer cover and the internal red protective cap from the laser head and laser aperture located on the top of the laser console; save these for future use (do not lose them). (Fig 7.16)
5. 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.

   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 7.15


Fig 7.16

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 Optic Cable to the laser console; call BIOLASE, Inc. or the authorized BIOLASE representative for additional support.

6 Align the blue guide of the Fiber Optic 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).

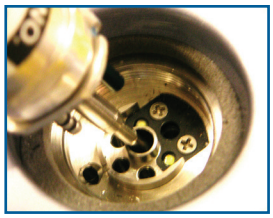


Fig 7.17

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

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

Fig 7.18

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

10. Carefully place the Fiber Optic Cable with its protective cover, or with the Handpiece connected, in the Handpiece Holder. (Fig 7.21)

Fig 7.19

Fig 7.20

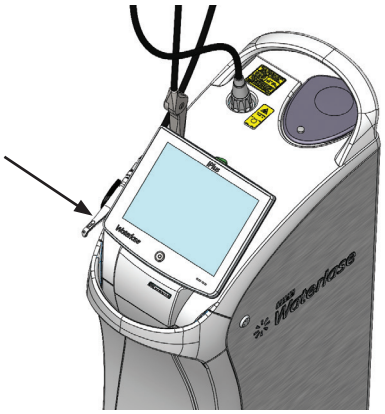


Fig 7.21

7 Installation

CONNECTING THE HANDPIECE TO THE FIBER OPTIC CABLE

CAUTION: Handpieces are not sterile when sold and MUST be sterilized prior to initial use, and cleaned and sterilized between patients. Refer to Section 11 for complete instructions on cleaning and sterilization.

1. Remove the rear plug and the Tip plug from the Handpiece. Be sure to save the plugs, as they will always be required when preparing the Handpiece for cleaning and sterilization.

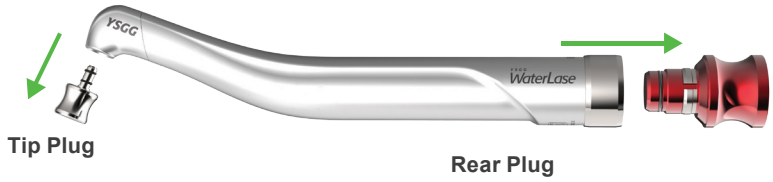


Figure 7.22

2. Hold the Fiber Optic Cable by the metal collar; pull the protective cover from the fiber to remove it. Be sure to save the cover.

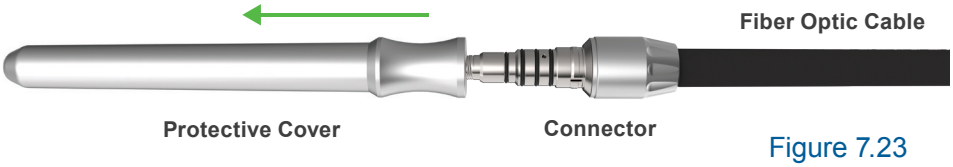


Figure 7.23

3. Check the fiber shaft for any moisture and wipe with a dry, lint free tissue or gauze.

Figure 7.24

4. Carefully slide the Handpiece onto the fiber neck until it sits firmly against the metal collar and there is no gap (do not twist). Handpiece must be completely dry.

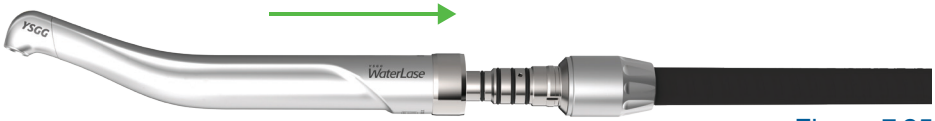


Figure 7.25

DISCONNECTING THE HANDPIECE

1. If the handpiece and fiber cable were previously primed with water, **ALWAYS** purge the handpiece before disconnecting it.
2. To disconnect the Handpiece, hold the Fiber Optic Cable by the metal collar and pull on the Handpiece until it comes completely off the fiber shaft. **DO NOT** pull on the black fiber jacket.

Figure 7.26

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

3. Wipe any moisture off the Fiber Optic Cable shaft with dry tissue.
4. Check that the window at the end of the Fiber Optic Cable is clean and not damaged. If it is not clean, use a dry cotton swab or a tissue to clean it (Fig 7.27). If it is damaged, remove and replace the Protective Window.
5. Carefully attach the Handpiece or Fiber Optic Cable's protective cover until it “clicks” into position.

Fig 7.27

INSTALLING AND CHANGING THE TIP IN THE HANDPIECE

A 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.

CAUTION: Never touch the input (proximal) end of the Tip. If the input surface is contaminated, it may damage the Tip, Handpiece, and Fiber Optic 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).

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

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

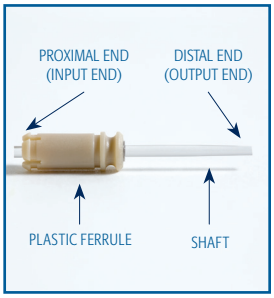


Fig 7.28

NOTE: The Tip must be sterilized before initial use and between patients if it is a reusable sapphire tip. 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. Tips can also be sterilized in the Revolving Tip Holder (Fig. 7.29).

Fig 7.29

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. 7.30).

Fig 7.30

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. 7.31, 7.32).
5. Slide the Handpiece laterally away from the Tip Remover or Tip Holder (Fig. 7.33).

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 Revolving 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 Optic Cable, please follow the table in Section 11, Troubleshooting the Delivery System.

CAUTION: If using the Turbo Handpiece (p/n 6201126), use the same techniques when installing or removing Turbo Tips; however, Turbo Tips do require a different Tip Holder. Note the Turbo Tip Holder/Remover tool (p/n 7200407) ONLY works with Turbo Tips; the tool used for the Gold Handpiece DOES NOT work with Turbo Tips. Refer to the Turbo Handpiece instructions for use for more information.

CAUTION: Do not use the Revolving Tip Holder to remove or store SFT8 tips. The SFT8 handle may be damaged by the Revolver. The standard Tip Remover is compatible with SFT8 tips.

Fig 7.31


Fig 7.32

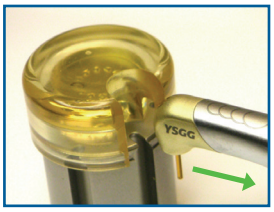


Fig 7.33

8 Operating Instructions

OPERATION

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 Optic Cable Port. Removal of the multi-connector from the Fiber Optic Cable Port may lead to hazardous exposure to laser radiation. Radiation is also emitted from the Fiber Optic Cable shaft when the Handpiece is removed. DO NOT attempt to operate the Waterlase iPlus with the Fiber Optic 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 Optic Cable Shaft (Section 7: Connecting the Handpiece to the Fiber Optic 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 s 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

1. Disconnect the Tip, if required. Install the Tip plug into the Handpiece head.
2. Press and hold the function control button for 2 seconds to turn the system OFF.
3. Turn the key counterclockwise to the OFF position.
4. 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.

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

Fig 8.1

8 Operating Instructions

APPLICATIONS MENU

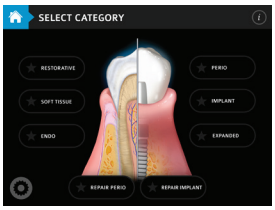


Fig 8.2

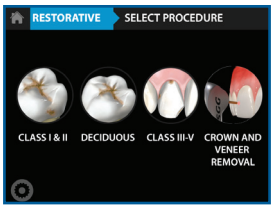


Fig 8.3

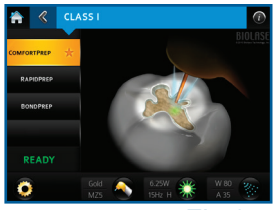


Fig 8.4

Fig 8.5

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 eight operational areas:

- Restorative
- Soft-Tissue
- Periodontics
- Implantology
- Endodontics
- Expanded
- REPAIR Perio™
- REPAIR Implant™

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 20 procedures identified within the eight 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 a 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

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 Optic Cable.
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.

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. 8.6).

Fig 8.6

1. Press the image of the Tip (which may or may not be the recommended Tip);
2. Both Cooling Air and Patient (spray) Air will turn ON;
3. 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 8.7).

Fig 8.7

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 8.8). Mode selection scrolls between ON, OFF and AUTO for both parameters.

Fig 8.8

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 "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.

8 Operating Instructions

SETTINGS / MEMORY MENU

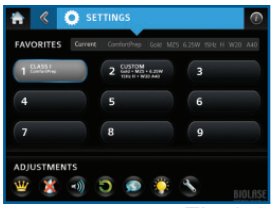


Fig 8.9

The Settings / Memory Menu stores up to 9 "Favorites" (Fig 8.9). 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.

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 Optic 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.).

FUNCTIONS FOR THE SETTING BUTTONS

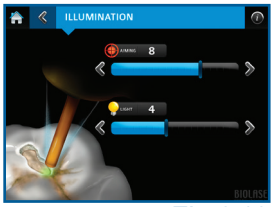


Fig 8.10

- 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 Optic Cable is purged of water.
  - **Prime**: the Fiber Optic 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. 8.10).
- SERVICE – leads to the Service Menu.

8 Operating Instructions

CUSTOM SETTINGS

Fig 8.11

Parameters may be adjusted without any limitations and without any relation to any procedure in the Advanced screen (Fig. 8.11).

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

SYSTEM POWER LIMITS*				
	H - mode		S - mode	
Pulse Rate, Hz	Min Power, W	Max Power, W	Min Power, W	Max Power, W
5	0.10	2.50	0.10	2.50
8	0.10	4.75	0.10	4.75
10	0.10	6.00	0.10	6.00
12	0.10	7.25	0.10	7.25
15	0.10	9.00	0.10	9.00
20	0.10	10.00	0.10	10.00
25	0.25	10.00	0.25	10.00
30	0.25	10.00	0.25	9.00
40	0.25	9.00	0.25	8.00
50	0.25	8.00	0.25	6.00
75	0.50	6.00	0.00	0.00
100	0.50	4.00	0.00	0.00

*These parameters are for all MX, MC, MZ10, MZ8, and MZ6 Tips.

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)

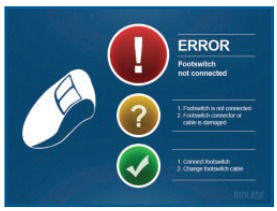


Fig 8.12

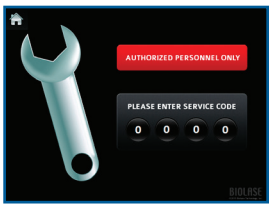
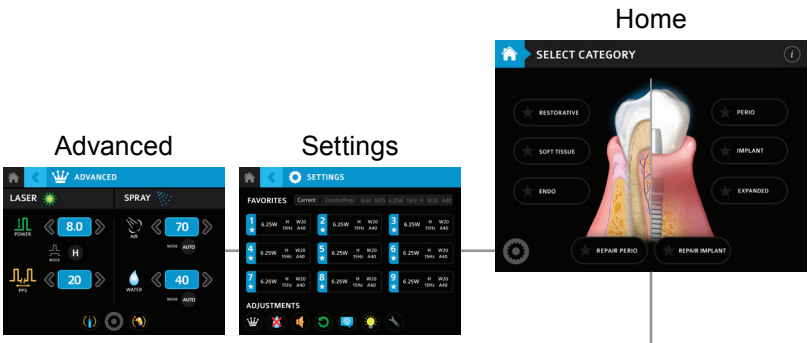
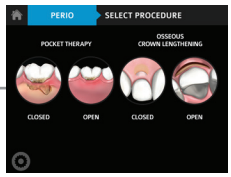


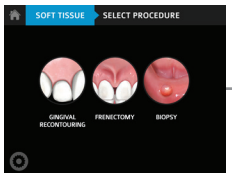
Fig 8.13



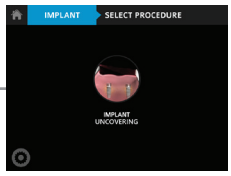
- Class I, II
- Deciduous
- Class III, IV, V
- Crown and Veneer Removal



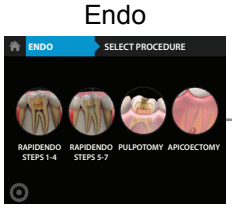
- Pocket Therapy (Closed)
- Pocket Therapy (Open)
- Osseous Crown Lengthening (Closed)
- Osseous Crown Lengthening (Open)



- Gingival Recontouring
- Frenectomy
- Biopsy

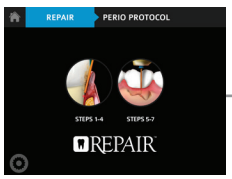


- Implant Uncovering

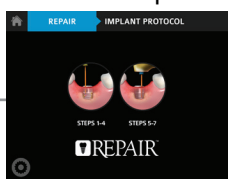


- Rapid Endo Steps 1-4
- Rapid Endo Steps 5-7
- Pulpotomy
- Apicoectomy

- Troughing
- Laser Bandage
- Gingival Depigmentation



- Steps 1-4
- Steps 5-7



- Steps 1-4
- Steps 5-7

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 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.
6. Maintain a distance of 0.1 to 1.5 mm between the Tip and the tissue being treated while moving the Handpiece over the tissue surface as required.

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.

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 place the Handpiece onto the Handpiece Holder on the Laser Console.

10. To remove the Tip from the Handpiece, select the Change Tip icon on the Display, and use the Tip Remover tool. Make sure air is on while replacing the tip to keep the tip and handpiece dry, internally. Place a new Tip in the Handpiece as described in Section 7. If it s 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. Fully purge the Handpiece and Fiber before removing the Handpiece. Select the Settings icon, then select the Water icon, then press and hold Purge button for at least 20 seconds. Clean and sterilize the Handpiece, as outlined in Section 11.
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, distance from the target tissue, and spray configuration. Use clinical judgment to adjust the parameters 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. 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 intended incision. The incision will be noticed immediately after laser activation.

NOTE: Adjust the water spray and / or mode (H and S) to control bleeding. Using S mode, reducing water, or turning water off will increase coagulation.

LASER PARAMETERS

The settings chosen for a procedure will contribute to its overall success. Waterlase iPlus settings must be balanced appropriately to obtain optimal clinical outcomes and positive patient results. Use best clinical judgment and observe the tissue when adjusting settings. For instance, selecting a higher pulse repetition rate (Hz) creates a smoother cut, while increasing power creates a deeper cut. Higher irrigation (water and/or air settings) will cool the tissue. Increase irrigation settings to limit thermal effects. On the other hand, if more coagulation is needed, decrease the irrigation settings, or select S mode (longer laser pulse duration).

Recommended settings for most of the procedures listed in the Indications for Use Section have been pre-programmed in the Waterlase iPlus. Presets may be modified according to best clinical judgment. New or preferred settings can be saved in Favorites (Section 8). If uncertain which parameters are

9 Clinical Application

best for a chosen procedure, please refer to the preset 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.

For more information on clinical procedures, please visit https://www.biolase.com/procedures/dentists/

10 Cleaning and Sterilization

HANDPIECE AND TIP CLEANING AND STERILIZATION

STEP 1—HANDPIECE AND TIP CLEANING

CAUTION: Handpieces and laser Tips are not sterile when sold and must be sterilized prior to initial use (Step 2), Handpieces, and re-usable Sapphire Tips 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. Avoid getting water or chemicals inside of the Handpiece to prevent laser damage. If the inside of the Handpiece is wet, allow it to fully dry before use.

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 Optic 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.
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).

Fig. 10.1


Fig. 10.2

NOTE: Do not use the Revolving Tip Holder to remove or store SFT8 tips. The SFT8 handle may be damaged by the Revolver. The standard Tip Remover is compatible with SFT8 tips.

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 reusable Tip for any residual soil; if any is present, repeat step 13 until all residual soil is removed.

STEP 2—HANDPIECE AND TIP 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; only use FDA-cleared or CE-marked (Europe) sterilization accessories, i.e., sterilization pouch and autoclave tray. 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 Revolving Tip Holder**. Place the individual Tips or the Revolving Tip Holder loaded with Tips into a separate single-wrap self-sealed pouch.
4. Place the pouches on an autoclave tray. Take care when handling the Handpiece and Tip(s).
5. Do not stack other instruments on top of the pouches.
6. 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.

CAUTION: 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. Follow local and national regulations for disposal.

Prior to disposal, the product and accessories must be appropriately reprocessed and cleaned with a disinfectant. 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 Handpiece or Fiber Optic Cable 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

NOTE: If the performance of the Fiber Optic Cable is questionable, but the Tip is in good condition, check the Handpiece mirror for damage or contamination.

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 mirror inside the Handpiece.

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

MIRROR CHECK AND CLEANING

WARNING: Use of a contaminated or damaged Handpiece mirror will cause damage of the Fiber Optic Cable.

Set the system in Standby mode, navigate to the illumination screen (Fig 8.10), 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 (Applies to both Turbo and Gold Handpieces).

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.

Fig. 11.1

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).

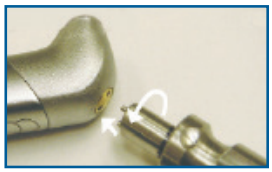


Fig. 11.2

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 2-21/2 full turns. Do not thread all the way into the mirror for easier release of the mirror later (Fig 11.3).


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.

Fig. 11.4

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).

Fig. 11.5

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. 11.6

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.
4. If the mirror has remaining burn marks or scratches, it should be replaced.
5. 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.
6. Install the new or cleaned mirror and check for proper alignment (Fig 11.5, 11.6).

Fig. 11.7

Fig. 11.8

11 Maintenance and Troubleshooting

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 Optic Cable.

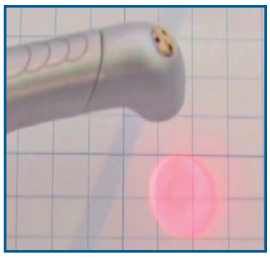


Fig. 11.9

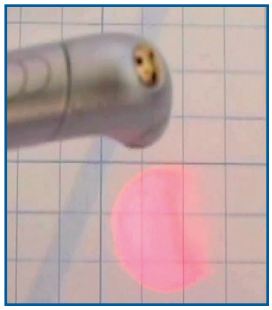


Fig. 11.10

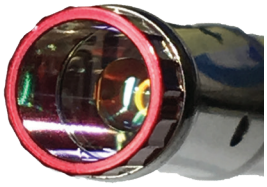
FIBER OPTIC CABLE CHECK

NOTE: Regularly inspect the end of the Fiber Optic Cable. Always inspect and clean the Protective Window at the end of the Fiber Optic 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 Optic Cable.

1. Disconnect the Handpiece following the proper procedure described in Section 7. Never remove the Handpiece from the Fiber Optic Cable without purging properly first.
2. Verify the laser is in Standby mode.
3. The Fiber Optic Cable ships with a pre-installed Protective Window at the distal end of the Fiber Optic Cable. Check the polished reflective surface of the Protective Window (Fig 11.11, 11.12). If the surface is contaminated, clean it with a cotton swab dipped in isopropyl alcohol.

GOOD



Standby Mode

Figure 11.11

GOOD

When Illumination is On

Figure 11.12

REPLACING THE PROTECTIVE WINDOW

The Protective Window may become burned or damaged during use (a crater is visible in the middle of the window). Please follow the steps outlined below, should your Protective Window need to be replaced.

1. Disconnect the Handpiece following the proper procedure described in Section 7.
2. Verify the laser is in Standby mode.
3. To remove the Protective Window from the Waterlase Express Fiber Optic Cable, gently pull the protective window, while unscrewing the protective window counter-clockwise until it is removed. (Figure 11.13).

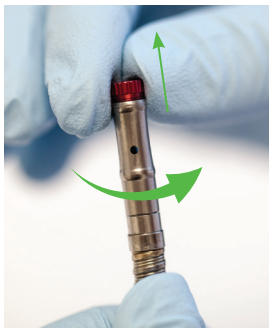


Figure 11.13

4. Gently insert the replacement protective window by aligning it to the circular opening and carefully screwing the replacement protective window clockwise (Figure 11.14).

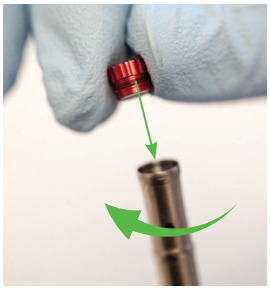


Figure 11.14

> **NOTE:** The protective window will continue to rotate after fully installed. There should be minimal to no gap between the end of the Fiber Optic Cable and protective window. The protective window kit is available for re-order (p/n 7240002).

5. Discard the burned/damaged protective window into a normal waste disposal bin.

REPLACING THE O-RINGS

Inspect the O-rings at the distal end of the Fiber Optic Cable.(Figure 11.15) Replace the O-rings if they appear cracked or damaged, or should you experience water leakage between the Handpiece and the Fiber Optic Cable. Remove and replace the O-rings as follows:

Figure 11.15

O-Ring Removal

1. Disconnect the Handpiece following the proper procedure described in Section 7.
2. Verify the laser is in Standby mode.
3. First remove O-Ring A, pinching and pushing from the proximal end out to the distal end of the Fiber Optic Cable.
4. Repeat for O-Ring B, then O-Ring C and O-Ring D. (Figure 11.16)

Figure 11.16

O-Ring Replacement

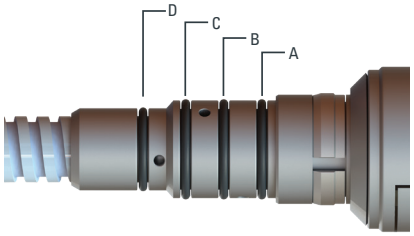


Figure 11.17

1. Slide O-Ring C over spindle
2. Repeat step 1 to install O-Rings B then A, then D.
3. After installation, make sure O-Rings are not twisted, and are installed as shown. (Figure 11.17)

RE-ATTACH THE HANDPIECE

1. Wear protective eyewear and navigate to the illumination screen (Fig 8.10).
2. The visible aiming beam and illumination fibers should be lit (adjust brightness, if necessary); if the aiming beam is not visible, replace the Fiber Optic Cable.
3. Re-attach the Handpiece and prime before using the laser.

11 Maintenance and Troubleshooting

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

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 representative to discuss extended service contracts and annual maintenance options.

DELIVERY SYSTEM

The Fiber Optic Cable and Handpiece represent a sophisticated technology of laser-transmitting components. 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 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 Optic Cable not detected	Fiber Optic Cable not detected	Check Fiber Optic Cable	Properly re-connect the Fiber Optic 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 of 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 of 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 representative.

STORAGE

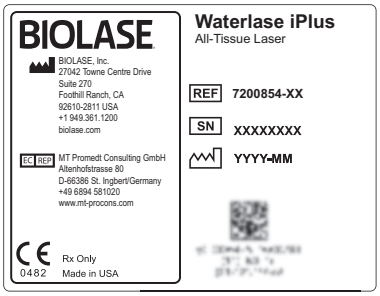
The Waterlase iPlus should be stored in a cool dry place when not in use. Storage temperature should be -20° to 60°C (-4°F to 140°F), relative humidity 10% to 90%, non-condensing. Cover the Laser Console when not in use for extended periods of time. Store the system in a place where it will not be accidentally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

Appendix A Labels

PRODUCT IDENTIFICATION LABEL

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

Location: Back panel, above ventilation channels



MANUFACTURER

CATALOG/PART NUMBER

PRODUCT SERIAL NUMBER

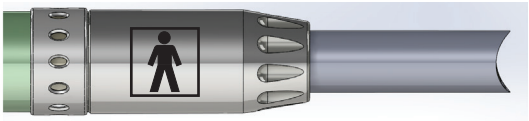
DATE OF MANUFACTURE

REFER TO INSTRUCTION MANUAL

Location: Back panel

TYPE BF APPLIED PART

Location: Distal end of Fiber Optic Cable (one side)



DUTY CYCLE

Location: Distal end of Fiber Optic 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 Optic 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

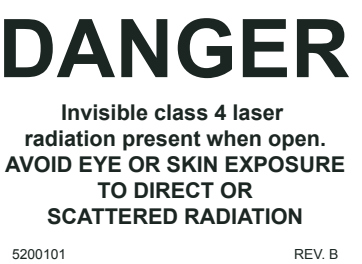
CERTIFICATION

This device complies with FDA laser standards.

Location: Back panel

NON-INTERLOCKED PROTECTION HOUSING WARNING

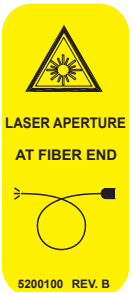
Location: Laser head, access plate
(Accessible only during service proceedings).



LASER APERTURE

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

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



Appendix A Labels

LASER WARNING SIGN

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

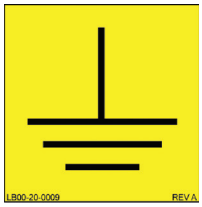
LASER EXPLANATORY LABEL

Provides laser specifications

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

SYSTEM GROUND CONNECTION

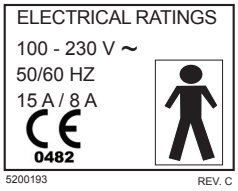
Location: Inside Laser Console, left.



ELECTRICAL SHOCK RATINGS

Type BF Applied Part

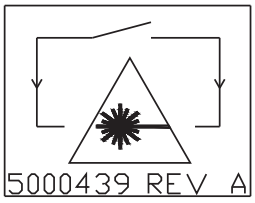
Location: Next to E1 ground terminal, inside Laser Console.



REMOTE INTERLOCK LABEL

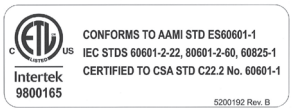
Input for Remote Interlock Connector which, when applied to the access door of the operatory and activated, will shut off the laser.

Location: Back panel



ETL LISTED: UL/CSA CONFORMANCE LABEL

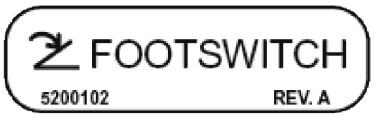
Location: Back panel



FOOTSWITCH LABEL

Connection to Footswitch

Location: Back panel



Appendix A Labels

WEIGHT LABEL

LOCATION: BACK PANEL

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

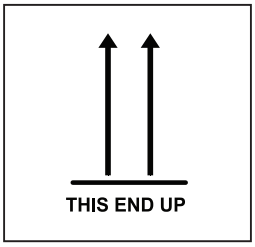
POTENTIAL EQUALIZATION TERMINAL (PEQ)

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

Location: Lower Back Panel

Appendix A Labels

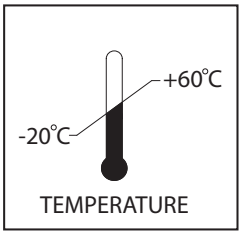
OUTER PACKAGING



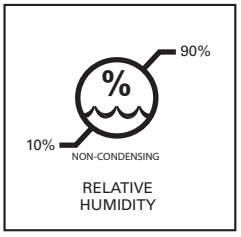
THIS END UP

HANDLE WITH CARE

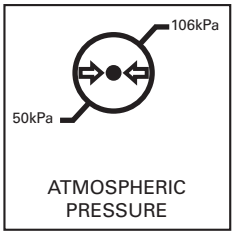
KEEP DRY



TEMPERATURE LIMITATIONS

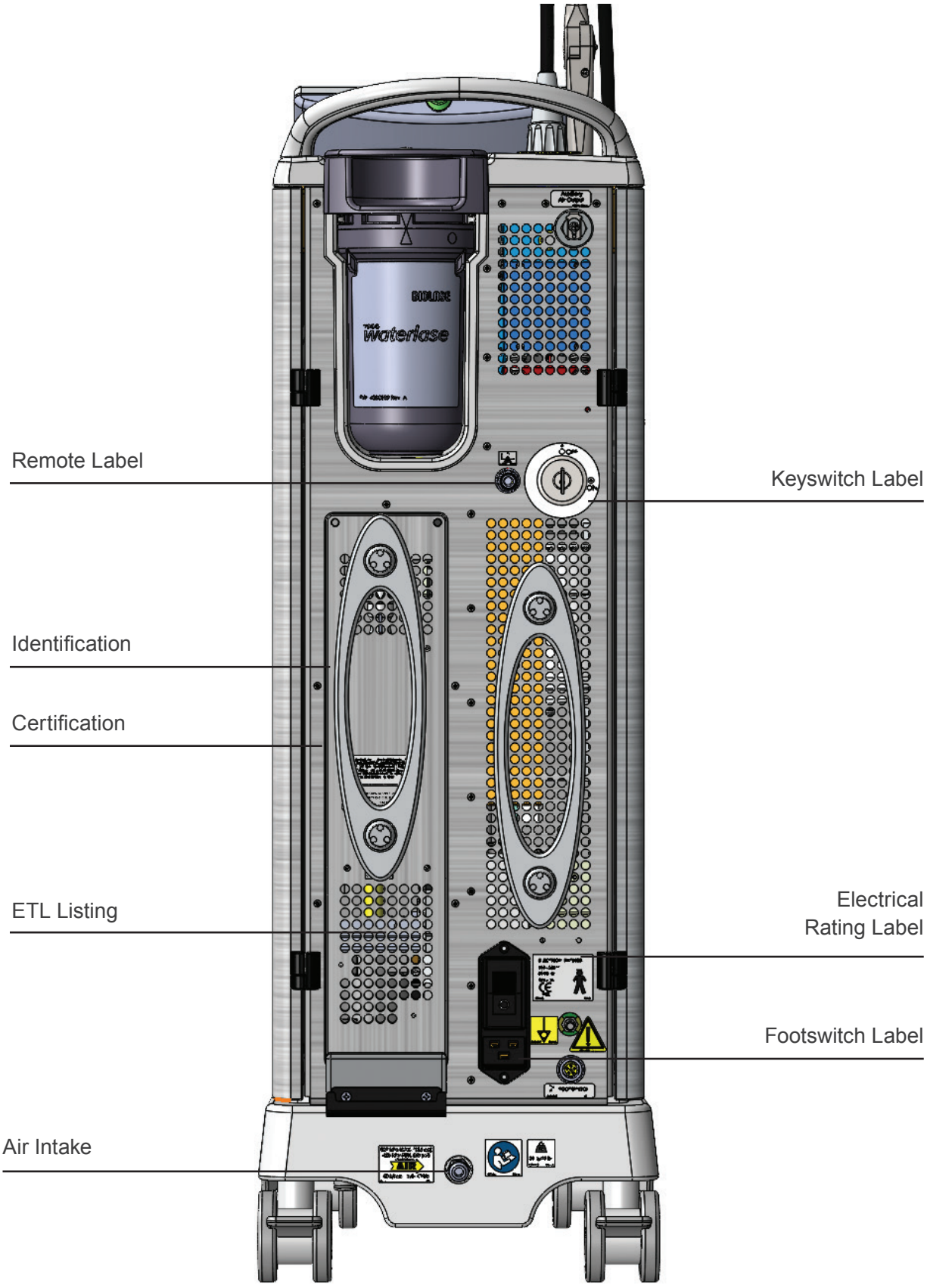


HUMIDITY LIMITATIONS

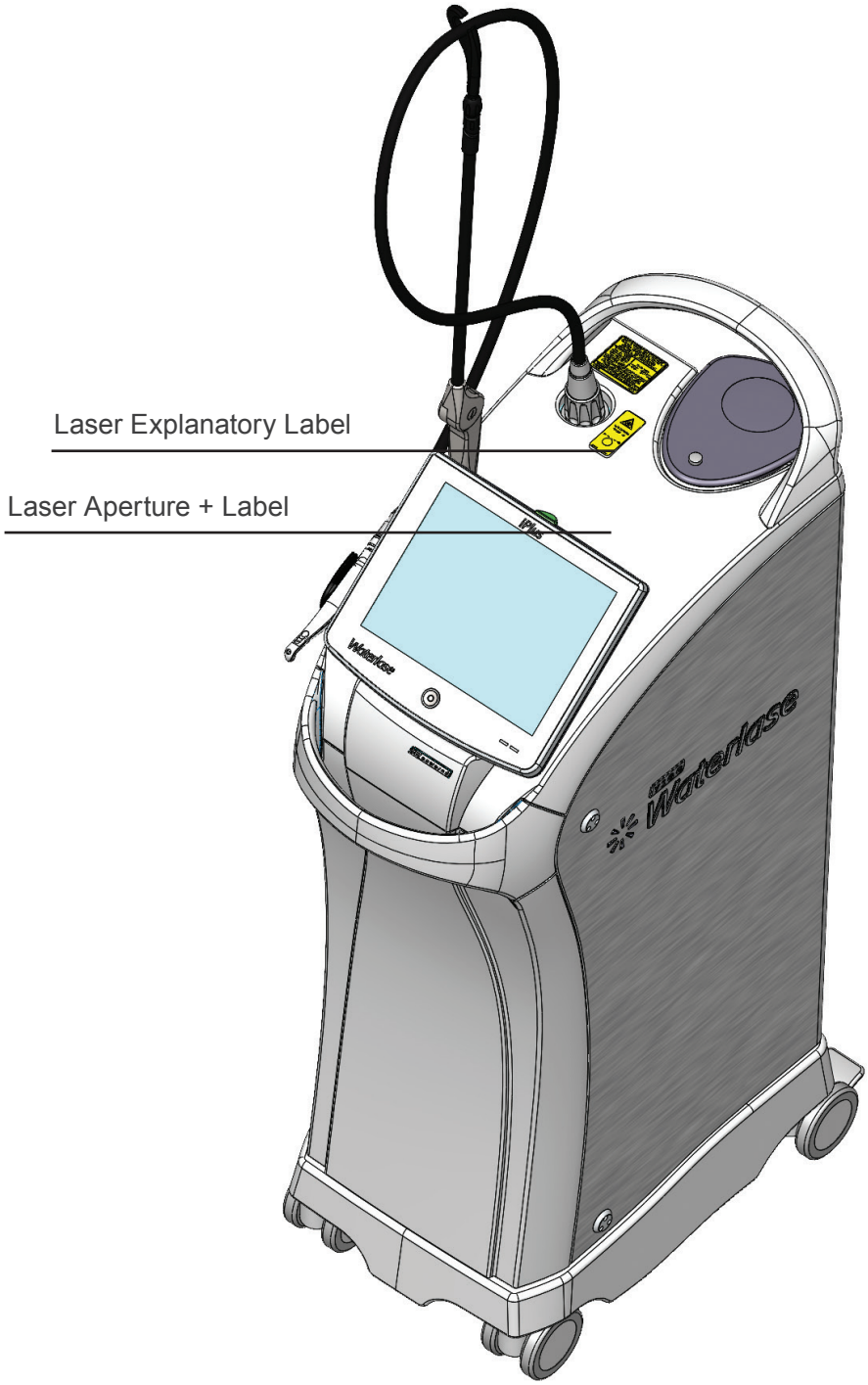


ATMOSPHERIC PRESSURE LIMITATIONS

Appendix A Labels



Appendix A Labels



Appendix B Accessories

ACCESSORIES LIST

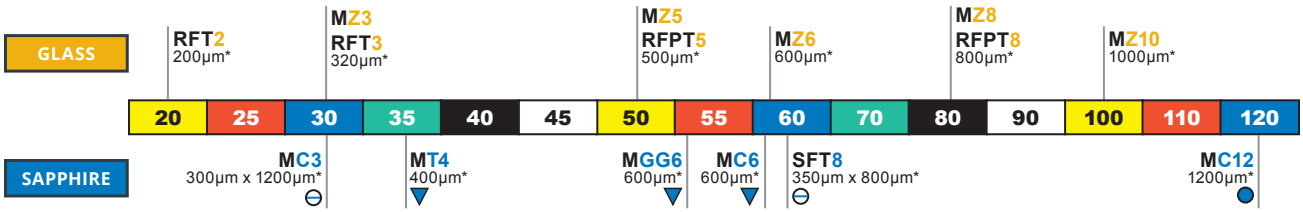
BIOLASE P/N	DESCRIPTION
2200696	Glasses, Protective, Multi Wavelength
2200848	Glasses, Doctor, Multi Wavelength
6201515	Fiber Optic Cable
6200150	Footswitch
2000204	Power Cord, Hospital Grade (U.S.)
2200485	Power Cord, 250VAC (International)
7000414	Waterlase/MD Tip Holder
7000734S	Waterlase Mirror Replacement Kit
7200104	Waterlase/MD Tip Inspection Kit
6200500	Gold Handpiece
6201037	Gold Mirror Refill Kit
6201102	Gold Mirror Single Refill
6201126	Turbo Handpiece
6201133	Turbo Mirror Refill
7200106	MD Gold Mirror Replacement Kit
3200105	Waterlase Mirror Removal Tool
2200706	Waterlase iPlus Display Covers
7200407	Turbo Tip Holder/Remover
5201281	Danger Sign (Laser Warning Sign)
6200317	O Ring A and B Kits
7220002	Waterlase Fractional Handpiece Waterlase iPlus with the Fractional Handpiece is indicated for use in dermatology for skin resurfacing.
6201818	Disposable Applicators for Fractional Handpiece

Appendix C Tips

TIP TYPES

TIP FERRULE COLORS

Tip types following Dental Standard ISO Series Diameter/Color Codes



TIP IDENTIFIERS	TIP TYPES
MGG6	Z Glass Tips
Laser System (MD/iPlus, Radial Firing Tip)	C T G Sapphire Tips
Tip Type	Cylindrical Tips
Tip Diameter	Chisel Tips
	Tapered Tips

*Fiber Output Dimensions

TIP SETTINGS: WATERLASE IPLUS GOLD AND TURBO HANDPIECES

Z - SINGLE USE GLASS (QUARTZ) TIPS

(NOTE: Tips are non-sterile and must be cleaned and sterilized prior to use.)

Tip Type	Ferrule Color/ Output Dimension (µm)*	Lengths (mm)	Gold Handpiece		Tissue Types
			Calibration Factor**	Maximum Power (W)	
RFT2	200	17, 21, 25	0.55	4.0	Root Canal
MZ3	320	9, 14, 18, 22	0.85	4.0	Root Canal, Soft-Tissue
RFT3		17, 21			Root Canal
MZ5	500	3, 6, 9, 14	0.95	4.0	All Types
RFPT5		10, 14		6.0	Bone, Soft-Tissue
MZ6	600	3, 6, 9, 14, 17	1.00	No Limit	Enamel, Bone, Dentin, Soft-Tissue
MZ8	800	6	1.00	No Limit	Enamel, Bone, Dentin, Soft-Tissue
RFPT8		10, 14			Bone, Soft-Tissue
MZ10	1000	6	1.00	No Limit	Enamel, Bone, Dentin, Soft-Tissue

** Calibration Factor: Actual power emitted from the tip = displayed power multiplied by the Calibration Factor.

Appendix C Tips

C, T, G, RE-USABLE SAPPHIRE TIPS

(NOTE: Tips are non-sterile and must be cleaned and sterilized prior to use.)

Tip Type	Ferrule Color/ Output Dimension (µm)*	Lengths (mm)	Gold Handpiece		Tissue Types
			Calibration Factor**	Maximum Power (W)	
MT4	400	6	1.00	2.5	Enamel, Dentin, Soft Tissue
MGG6	600	4, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC3	300 x 1200	9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC6	600	4, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
SFT8	350 x 800	18	1.00	No Limit	Bone, Implant
MC12	1200	9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue

** Calibration Factor: Actual power emitted from the tip = displayed power multiplied by the Calibration Factor.

TURBO TIPS

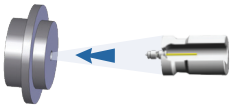
Tip Type	O-Ring Color/	Beam Waist Diameter (µm)	Turbo Handpiece		Tissue Types
			Calibration Factor**	Maximum Power (W)	
MX5	Red	500	1.00	No Limit	Hard Tissues
MX7	Green	700	1.00	No Limit	Hard Tissues
MX9	White	900	1.00	No Limit	Hard Tissues
MX11	Black	1,100	1.00	No Limit	Hard Tissues

** Calibration Factor: Actual power emitted from the tip = displayed power multiplied by the Calibration Factor.

IMPORTANT: 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.

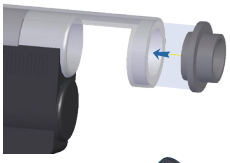
Appendix D Tip Inspection

TIP INSPECTION INSTRUCTIONS

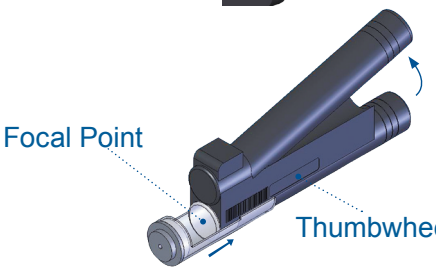


Tip Remover with Tip inside

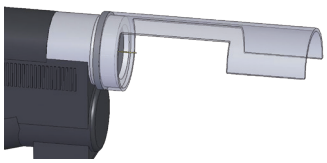
1. Remove the Tip from the Handpiece and insert it into the correct side of the Tip test holder as shown using the Tip Remover.
2. Insert the Tip test holder into the test adapter with the distal (or laser-emitting) end of the Tip toward the microscope.

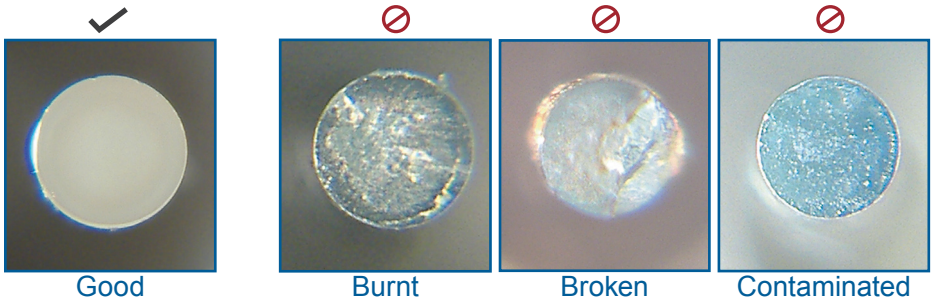


3. Slide the adapter over the microscope to move the Tip surface toward the focal point of the microscope. The focal point lies in the plane at the end of the clear end tube of the microscope.
4. Turn on the microscope's built-in light by gently pulling apart the upper and lower tubes, or hold it up 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.

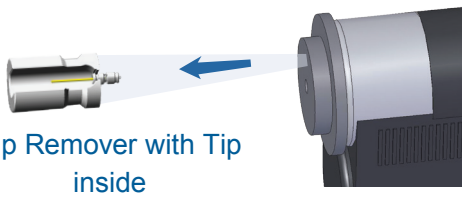


5. To examine the proximal (or Fiber Optic Cable) end of the Tip, remove the adapter from the microscope, and gently fit the other side of the test holder into the clear end tube of the microscope. Refocus the Microscope.





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.



Tip Remover with Tip inside

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

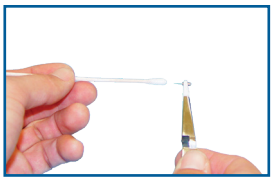


Fig D.1

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)

TURBO TIP INSPECTION

1. Before using the Tip, inspect Tip surfaces for any damage or debris using loupes or a magnifier. Clean or replace as required.
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

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.

CAUTION: Use of damaged or contaminated Tip may cause damage to the Fiber Optic 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.

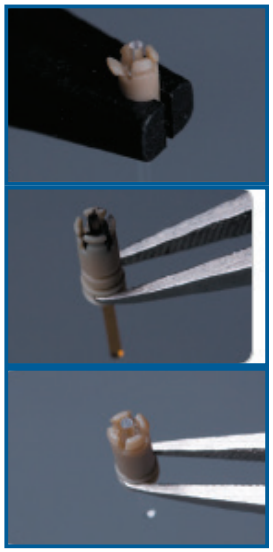


Fig D.2

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

Appendix E 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 accessories, 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 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.		
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	The Waterlase iPlus for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Appendix E 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) IEC 61000-4-2	± 6 kV contact ± 8kV air	± 6 kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines N/A	Main power quality should be that of a typical commercial or hospital environment. Input/output that does not apply because the Footswitch cable length is less than 3 meters.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2kV common mode	± 1 kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% Ur (>95% dip in UT) for 0.5 cycle 40% Ur (60% dip in UT) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 seconds	<5% Ur (>95% dip in UT) for 0.5 cycle 40% Ur (60% dip in UT) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Waterlase iPlus requires continued operation during power mains interruptions, it is recommended that the Waterlase iPlus be powered from an uninterrupted power supply.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to applications of the test level.			

Appendix E 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
Conducted RF IEC 61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 GHz 3V/m 80 MHz to 2.5 GHz	3 V 3Vm	Portable and mobile RF communications equipment should be used no closer to any part of the Waterlase iPlus laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. 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 Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Appendix E 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
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 laser is used exceeds the applicable RF compliance level above, the Waterlase iPlus laser 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 laser. B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE WATERLASE IPLUS

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.

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