Waterlase iPlus®

USER MANUAL

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NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

1 Overview

The Waterlase iPlus laser 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. In addition, this direct laser energy is also able to perform oral soft-tissue removal, incision, excision, ablation, and coagulation. These same wavelength properties further allow for Waterlase utilization in specific endodontic and periodontal applications.

When used for oral hard-tissue procedures, the Er,Cr:YSGG solid-state laser provides optical energy to a user-selected distribution of atomized water droplets and hydrated surface layer of hard-tissue. Water present in the target tissue absorbs laser radiation (non-ionizing), resulting in explosive molecular expansion and ablation of hard-tissue. The water spray simultaneously provides cooling and hydration for the target tissue. For oral soft-tissue procedures, the Waterlase iPlus laser works similarly, applying optical energy to the soft-tissue for tissue removal, incision, excision, and coagulation. In soft-tissue, laser energy can be combined with water spray for cooling and hydration, or it can be used without water spray for enhanced coagulation.

A flexible Fiber Optic Cable connects at one end to the laser console 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. An aiming beam also emits from the tip, providing a visual example of where the laser energy will be interacting with target tissues. 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 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 3 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
- 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.

SKIN RESURFACING

- Waterlase iPlus with the Fractional Handpiece** is indicated for use in dermatology for skin resurfacing.

*(**Refer to the Waterlase Fractional Handpiece User Manual (PN 5201516) regarding Instructions for Use.)*

3 Contraindications, Warnings, and Precautions

CONTRAINDICATIONS

All clinical procedures performed with the Waterlase iPlus must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions which might contraindicate a local procedure. Such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease (e.g. pacemakers, implantable defibrillators), lung disease, bleeding disorders, or an immune system deficiency. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

WARNINGS AND PRECAUTIONS

PRESCRIPTION STATEMENT

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

EYEWEAR

Doctor, patient, assistant, and all others inside or entering the operatory must always wear appropriate laser protection eyewear for the 2780nm wavelength, OD4 (DI LB4) or greater. **Always check the eyewear specifications imprinted on the frame of the glasses to ensure they offer the required protection for the specific laser wavelength.** Prior to use, inspect eyewear for pitting 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.

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, S mode) 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 (e.g., 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 handpiece.

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 have a 200µm and a 320µm diameter fiber core, 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.

3 Contraindications, Warnings, and Precautions

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 34 in (28 x 48 x 86cm)
• Laser System, Fully Assembled	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:	15A / 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:	60 - 120 psi. (4.2 - 8.2 bar) (420 - 827 kPa)
• 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, 110° reverse contra-angle, straight
• 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)
• Nominal Ocular Hazard Distance (NOHD):	5cm
• Maximum Permissible Exposure (MPE):	3.5×10^5 W/m^2

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
- Fiber Optic Cable and Fiber support
- Yellow Air Tube
- Protective Laser Eyewear (3)
- Handpieces (2)
- Tip Starter Kit with Handpiece Mirror Tool
- Handpiece Holder
- Remote Interlock Connector
- Revolving Tip Holder
- Tip Cleaning Kit
- Power cord, (1) US, (1) International
- Footswitch
- Keys
- User Manual
- Laser Warning sign
- Limited Warranty

GENERAL

The Waterlase iPlus dental laser system consists of two modules:

- Main Laser Console
- Waterlase iPlus Fiber Delivery System (the Delivery System consists of the Fiber Optic Cable, Handpiece, and Tips)

MAIN LASER CONSOLE ELEMENTS

Figures 5.1 through 5.4 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 power 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.

EMERGENCY STOP

The emergency stop (red) button is located on the front panel of the laser console.

Safety Features

Pressing this button instantly stops the emission of laser energy. The button will glow red to indicate an emergency stop has taken place and the screen will display the message “Emergency Stop Pressed.” To operate the laser system, press the button a second time (the system will return to **Standby** mode).

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 tabs on the wheels to lock the console. Lift up the tabs to release the locking mechanism.

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.

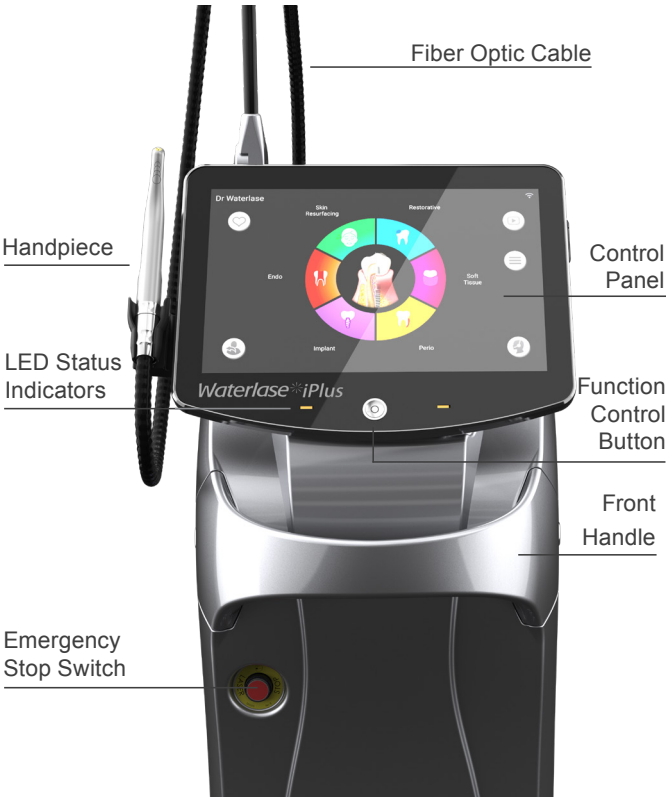


Fig 5.1

5 Equipment Description

FOOTSWITCH, FOOTSWITCH CONNECTOR

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

Safety Features

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

REMOTE INTERLOCK OUTLET

Each laser has a remote interlock outlet and connector on the 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. The interlock connector must be plugged in to the outlet to operate the Waterlase iPlus.

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.

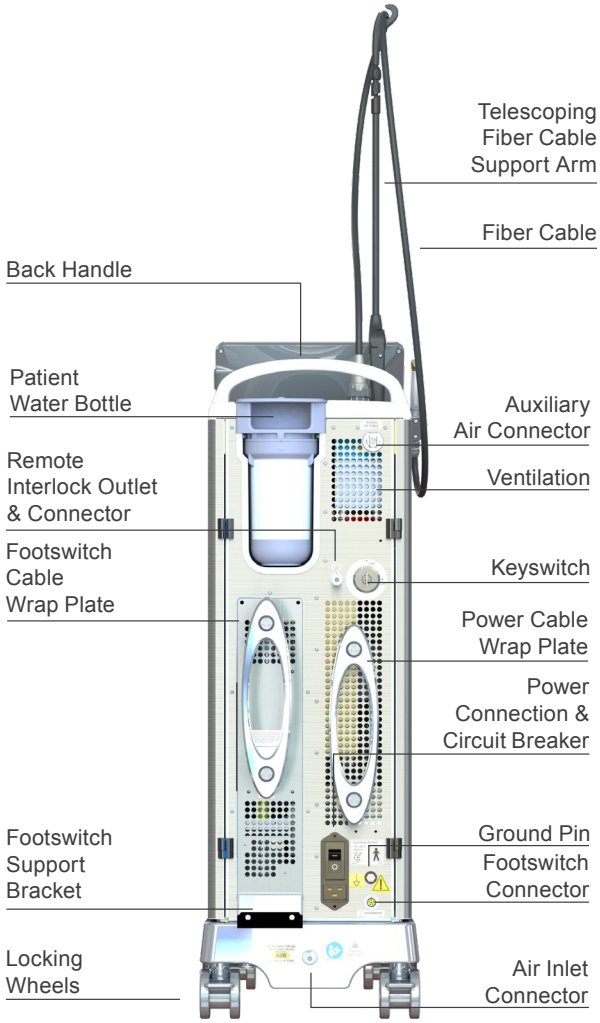


Fig 5.2

5 Equipment Description

AIR INLET CONNECTOR

Connects the laser to a compressed dry air outlet at 60-120 psi (4.2 - 8.2 bar) using the tubing provided.

PATIENT 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. The Patient Water Bottle should only be removed when the system is off, or in Standby mode.

FOOTSWITCH SUPPORT BRACKET

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

Fig 5.3

NOTE: Only official Biolase SD Cards may be used. Any other SD card will cause an "Invalid SD Card" error, which will prevent system operation until the invalid SD card is removed. An SD card may be used during during a service update, for instance.

5 Equipment Description

TELESCOPING 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. The support arm locks at incremental angles from vertical to horizontal. To release the locking mechanism, rotate the support arm to horizontal position, and the arm will automatically return to vertical position.

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 delivers laser energy from the laser console to the Handpiece. The Fiber Cable includes the illumination waveguides and air and water tubing.

HANDPIECE

The Handpiece is rotatable and detachable from the Fiber Cable. It delivers laser 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. Holder may be installed on either side of the control panel.

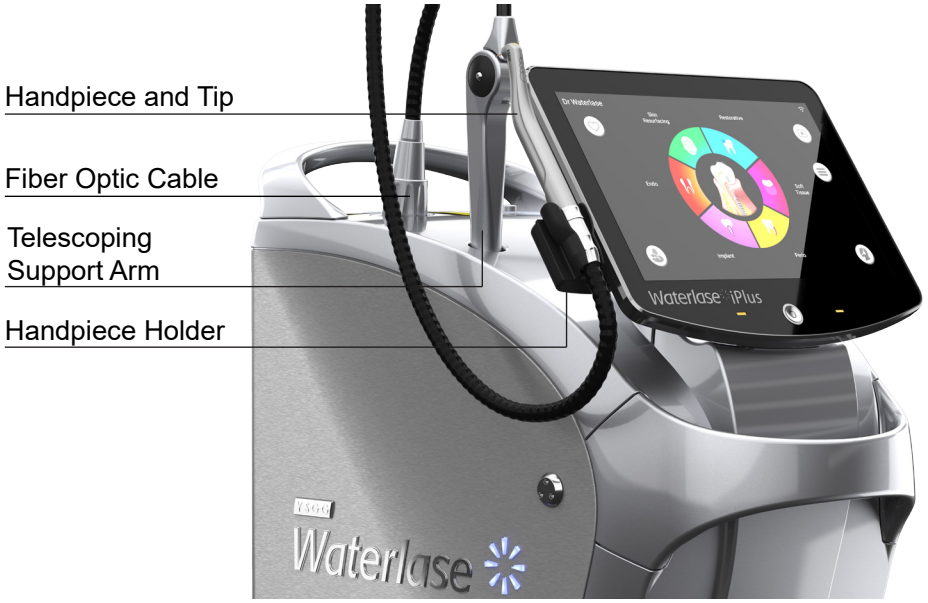


Fig 5.4

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 for the 2780nm wavelength, OD4 (DI LB4) or greater (safety glasses supplied by BIOLASE, Inc.).

CAUTION: Periodically inspect eyewear for pitting and cracking. For replacement or additional protective eyewear, please contact BIOLASE Customer Service or the authorized BIOLASE representative.

4. Do not look directly into the beam or at specular reflections.
5. Direct the Laser Tip toward targeted tissues only.
6. Do not remove the Patient Water Bottle while the system is in **Ready** mode. Make sure the system is in **Standby** mode and the bottle is not pressurized.
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

COMPRESSED AIR SUPPLY: 60 - 120 psi (420 - 827 kPa)

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 5.2).
4. Install the Remote Interlock Connector.
5. Verify a minimum air pressure of 60 psi (4.2 bar) is emitted from the air supply.
6. Check the air supply for moisture.
7. Connect the air supply to the laser console's air inlet connector at the rear of the console (Fig 5.2).

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

Fig 7.1

Fig 7.2

Fig 7.3

Fig 7.4

FILLING THE INTERNAL COOLING WATER RESERVOIR

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

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

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

2. Locate the internal water reservoir and verify that the valve on the blue tube connected to the side of the water reservoir is closed (blue handle is perpendicular to the tubing line).
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.

7 Installation

5. 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 tightly.
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.

Fig 7.5

Fig 7.6

9. Navigate to a Procedure settings screen (Fig. 8.13) and press the Function Control Button (Fig 7.8) to transition into Ready mode. Let the system run for 1-2 minutes.

NOTE: If filling an empty cooling water reservoir, open the blue valve on the tubing connected to the reservoir before placing the system into Ready mode for 1-2 minutes. After the air bubbles have cleared, close the blue valve. If refilling a partially-full cooling water reservoir, the blue valve can remain closed throughout this process. (The valve is perpendicular to the tubing line when closed, and parallel to the tubing line when open.)

Fig 7.7

10. If the "Water Level Low" error message appears, turn the system off by pressing the power circuit breaker and turning the Keyswitch to the OFF position. Refill the cooling water bottle to 3/4 full. Repeat steps 3-9.

11. Close the back panel door and tighten the two captive screws (Fig. 7.1)

Fig 7.8

7 Installation

INSTALLING THE HANDPIECE HOLDER

The Handpiece Holder is packaged as a separate item in the system packaging. Attach it to the back of the Display using the screw and hex key Allen wrench provided (Figure 7.9):

1. Hold the Handpiece Holder with the wider portion of the cradle facing upwards (Figure 7.9).

2. Slide the Handpiece Holder into the slot at the back of the Display (Figure 7.10) until the holes in both pieces are aligned.

3. Insert the screw provided and tighten with the Allen wrench.

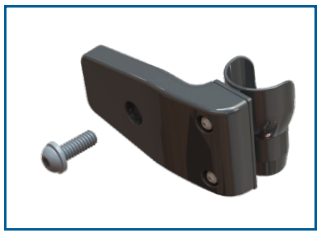


Fig 7.9

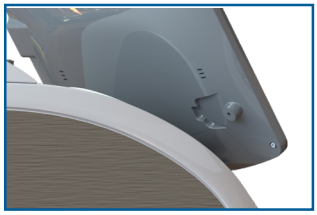


Fig 7.10

NOTE: The Handpiece Holder can be installed on either the left or the right side of the Display. To install on the opposite side, the cradle must be rotated. To do so, remove the two screws holding the cradle to the flat surface of the Handpiece Holder, rotate it 180 degrees, and then reattach it using the same two screws.

FILLING THE PATIENT WATER 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.

Fig 7.11

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 7.11).
3. Hold the bottle, rotate the lid counterclockwise, and pull the lid up to open (Fig 7.12). It is suggested to hold the bottle near the arrow and push the lid up with your thumbs to release the seal.
4. Fill the patient water bottle with only distilled or de-ionized water.

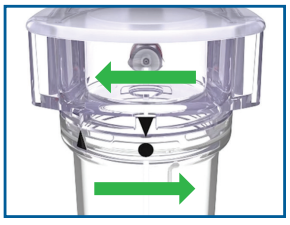


Fig 7.12

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.

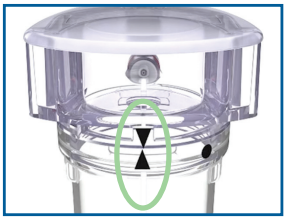


Fig 7.13

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 7.12, 7.13).
6. Attach the bottle back into its holder; make sure the connector is fully engaged.

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 patient water 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 Fiber Optic Cable support arm (Fig 5.4).

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.

2. Remove the Fiber Optic Cable from its packaging (Fig. 7.14).
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. 7.15). Point the output end at a bright light source and look into the input end. The fiber in the center should glow yellow, and be flat and clean (Fig. 7.16). Replace the protective cover on the distal (output) end of the Fiber Cable. **Keep all protective covers for future use.**
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 7.17)
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.

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.


Fig 7.14

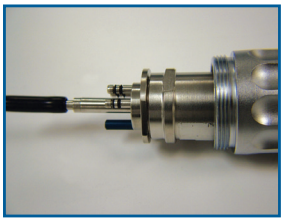


Fig 7.15


Fig 7.16


Fig 7.17

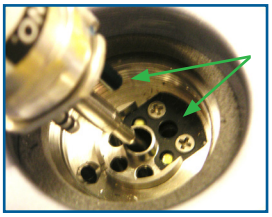


Fig 7.18


Fig 7.19

7 Installation

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 7.18, 7.19).

Fig 7.20

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 7.20)
8. Align the middle length of the Fiber Optic Cable to the hook of the telescoping arm and push it in gently to secure it. The black O-ring on the Fiber Cable can be positioned before the hook of the telescoping arm to prevent the Fiber Cable from slipping forward.

Fig 7.21

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. 7.21).
10. Carefully place the Fiber Optic Cable with its protective cover, or with the Handpiece connected, in the Handpiece Holder. (Fig 7.22)

Fig 7.22

FIRST TIME STARTUP

1. Make sure the air supply is connected and fill the Patient Water Bottle with distilled or de-ionized water.
2. Power up the system by toggling the main power switch at the back of the console to ON; insert the key into the Keyswitch and rotate it clockwise to the ON position. (ON position is marked with a dash, and OFF is marked with a circle.)
3. The system software will begin to load.
4. When prompted, enter the user account details, Figure 7.23. Additional users can be added through the Settings Menu.
5. (Optional) Press the Set-Up WiFi button; the system will begin to scan for Wi-Fi networks Select a Wi-Fi network, enter the password for the network selected, then press OK.
6. The system will proceed to the Daily Startup screen, Section 8.

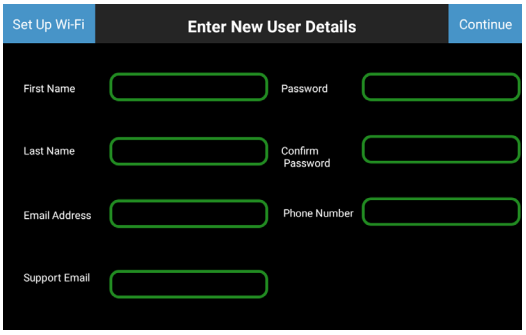


Fig 7.23

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 10 for complete instructions on cleaning and sterilization.
Always hold and move the Handpiece or Protective Cover along the same axis as the Fiber Shaft. Do not install or remove at an angle, as this may damage the Fiber.

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.

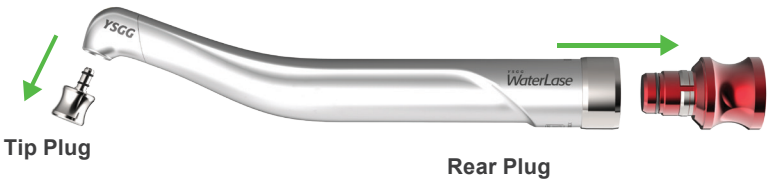


Figure 7.24

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.

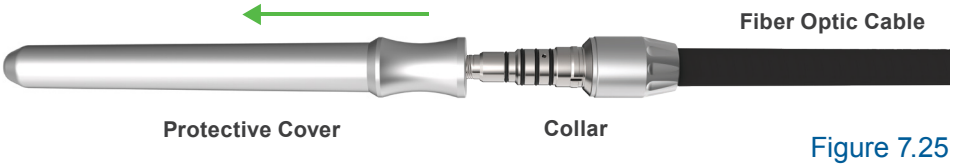


Figure 7.25

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

Figure 7.26

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.

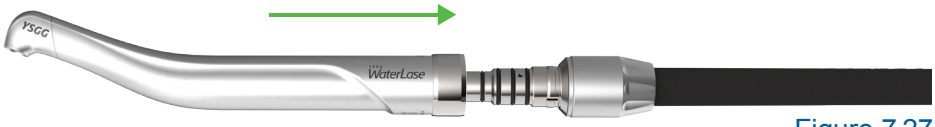


Figure 7.27

7 Installation

DISCONNECTING THE HANDPIECE

1. If the handpiece and fiber cable were previously primed with water, **ALWAYS** purge the handpiece before disconnecting it. Make sure you have a handpiece connected and a tip inserted before purging.
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 7.28

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

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.

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.

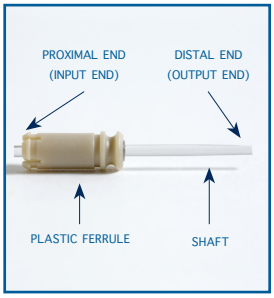


Fig 7.29

7 Installation

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. 7.30).

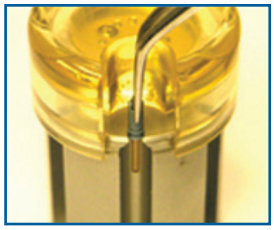


Fig 7.30

3. Align the Tip orifice of the Handpiece over the input end of a clean Tip placed in the Tip Remover or Revolving Tip Holder. (Fig. 7.31, 7.32).
4. Carefully lower the Handpiece and insert the tip all the way until the shoulder of the Tip ferrule sits against the Handpiece head (Fig. 7.33).
5. Slide the Handpiece laterally away from the Tip Remover or Tip Holder (Fig. 7.34).

Fig 7.31

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

Fig 7.32

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.

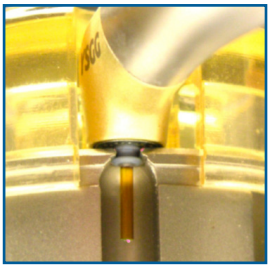


Fig 7.33

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.

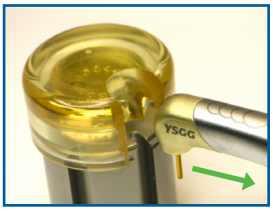


Fig 7.34

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.

8 Operating Instructions

OPERATION OVERVIEW

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

CAUTION: Post the laser warning sign provided with the Waterlase outside the operatory when the laser is in use. Everyone entering or present in the room must wear appropriate laser eyewear for the 2780 nm wavelength. Prior to use, always inspect eyewear for pitting and cracking. Replace if damaged.

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.

Before using the Waterlase iPlus, be sure the system has been installed properly, as described in Section 7 of this user manual, to ensure safe and efficient function.

DAILY STARTUP

1. Make sure the air supply is connected and fill the Patient Water Bottle with distilled or de-ionized water. It is suggested to fill the Patient Water Bottle at the start of the day and to empty it at the end of each day.

Fig 8.1

2. Power up the system by toggling the main power switch at the back of the console to ON; insert the key into the Keyswitch and rotate it clockwise to the ON position. (ON position is marked with a dash, and OFF is marked with a circle.)
3. The system software will begin to load.
4. Remove the Protective Cover from the Fiber Cable. Check the Fiber shaft for any moisture and wipe dry with a lint free gauze.
5. Check that the Fiber Cable O-rings are in good condition, Figure 8.1. If any O-rings are frayed, cracked, cut, or loose, replace all 4 O-rings following instructions in Section 11. O-rings should be replaced every 6 months.

Fig 8.2

6. Once the system software has initiated, a screen will appear offering the Startup Checklist, Figure 8.2. The Checklist leads the user through a series of simple steps to inspect and properly set up the Waterlase iPlus. Select the Startup Checklist and follow the instructions on the screen.
7. After completing the checklist, the system will display the Main Procedures Screen and will be in **Standby** mode.

NOTE: Priming forces water from the patient water bottle to the Handpiece. If priming does not take place, no water will spray from the Handpiece during the procedure. Point the Handpiece away from the console during priming to avoid wetting the system.

8 Operating Instructions

CONTROLS AND INDICATORS

The control panel has one Function Control Button, Figure 8.3.

When in a procedure settings screen with laser parameters selected, pressing the Function Control Button will switch the system between **Standby** and **Ready** modes.

The control panel also has two LED indicators on either side of the Function Control Button. The LED color indicates for system status and laser power actuation:

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

Fig 8.3

WAKING THE SYSTEM FROM SLEEP MODE

When the Waterlase is not shut OFF at the power switch, the laser and Display will go into **Sleep** mode after 10 minutes of inactivity. To “wake” the system, press and hold the Function Control Button for at least 2 seconds. The laser system can be placed into **Sleep** mode by holding the Function Control Button for more than 2 seconds.

ACTIVATING THE WATERLASE IPLUS

After selecting a procedure step and settings, place the system into **Ready** mode by pressing the Function Control Button. Press down on the Footswitch when ready to fire the laser.

IN BETWEEN PROCEDURES

After completing a procedure, Purge the Handpiece and Fiber Cable.

NOTE: The transition from Standby to Ready mode requires approximately 5 seconds. Approximately 2 seconds will elapse between the time the Footswitch is pressed and when the laser activates. This delay is designed to help prevent the unintentional activation of the laser.

If moving to the next patient directly:

1. From the Procedure Settings screen, Select Change Handpiece, Figure 8.4.
2. Select the image corresponding to the next Handpiece, Figure 8.5. The system will purge the Handpiece and Fiber Cable. Point the Handpiece away from the laser console.
3. Remove the Handpiece, dry the Fiber Cable shaft with a lint free gauze, and install the new, sterile Handpiece. Install a sterile, dry Tip. Confirm the tip selection on the screen.
4. The used Handpiece can be cleaned and sterilized (instruction in Section 10).
5. Select Prime and point the Handpiece away from the laser console.

8 Operating Instructions

If anticipating a pause between scheduled patients:

1. From the Procedure Settings screen, Select Change Handpiece, Figure 8.4.
2. Select Purge (Figure 8.5) and point the Handpiece away from the laser console.

3. Remove the Handpiece, dry the Fiber shaft with a lint free gauze, and place the Protective Cover on the Fiber Cable.
4. The used Handpiece can now be cleaned and sterilized (instruction in Section 10).
5. Before the next procedure, navigate to the Procedure Settings screen and select Change Tip, Figure 8.4.
6. While the air is on, remove the Protective Cover and install a sterile, dry Handpiece onto the Fiber Cable. Install a sterile, dry Tip. Confirm the tip selection on the screen.
7. Prime the Handpiece: From the Tip Change or Handpiece Change screen, select Prime (Figure 8.5) and point the Handpiece away from the console.

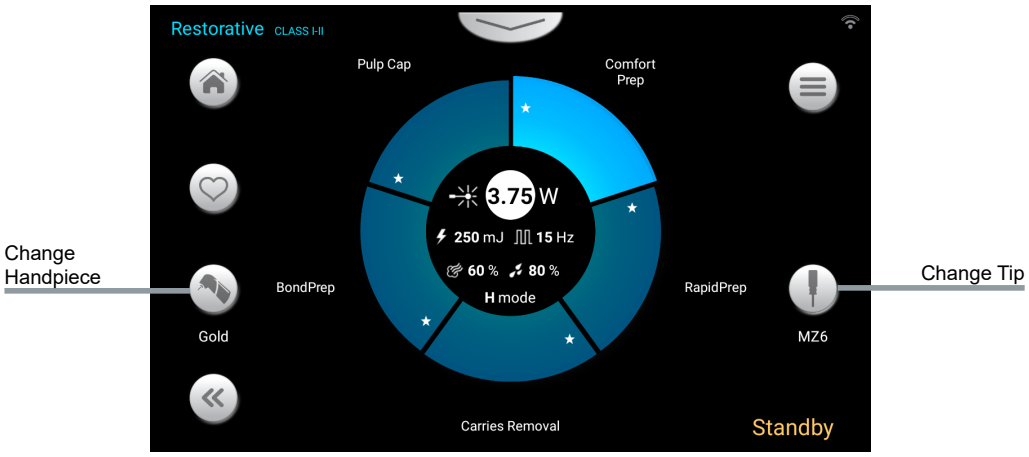


Fig 8.4

Fig 8.5

CAUTION: A Tip must be installed before priming or purging. If a tip is not installed, water is likely to enter the Handpiece and damage the optics. A Tip seals the Handpiece Head and helps to protect the optics. All components must be dry. Do not prime or purge while the Protective Cover is installed.

8 Operating Instructions

CHANGING THE WATER IN THE PATIENT WATER BOTTLE

When the system detects that the water level in the Patient Water Bottle is low, a yellow warning icon with will appear. Place the system into **Standby** mode, wait about 10 seconds for the Bottle to de-pressurize, and follow the steps outlined in Section 7: Filling the Patient Water Bottle. To return to **Ready** mode, press the Function Control Button.

TURNING THE WATERLASE IPLUS OFF

1. Press the Exit / Switch User icon, Figure 8.6.
2. The shutdown checklist is available to help properly care for the system and accessories. Select the shutdown checklist and follow the instructions on the screen.

> **NOTE:** When the bottle is disconnected, an Error screen will appear. When the bottle is reattached, the Error screen will clear automatically.

3. The Fiber Cable must be purged before the Waterlase is turned off. While the system is purging, make sure that air bubbles can be seen in the Patient Water Bottle. If no air bubbles are observed, purge again.
4. When prompted, disconnect the Handpiece. Inspect the Fiber shaft for water and dry with a lint-free gauze. Install the Protective Cover over the Fiber Optic Cable.
5. Place the rear plug into the Handpiece. Clean and disinfect the Handpiece with Tip and rear plug installed. (Instruction in Section 10)
6. Remove the Tip and Rear plug from the Handpiece. Sterilize the Handpiece and reusable Tips. Discard single use Tips in a medical sharps container. Cleaning, disinfecting, and sterilization instructions are detailed in Section 10.
7. Remove and empty the Patient Water Bottle.
8. Turn the Key to the OFF position and toggle the power switch to the OFF position.

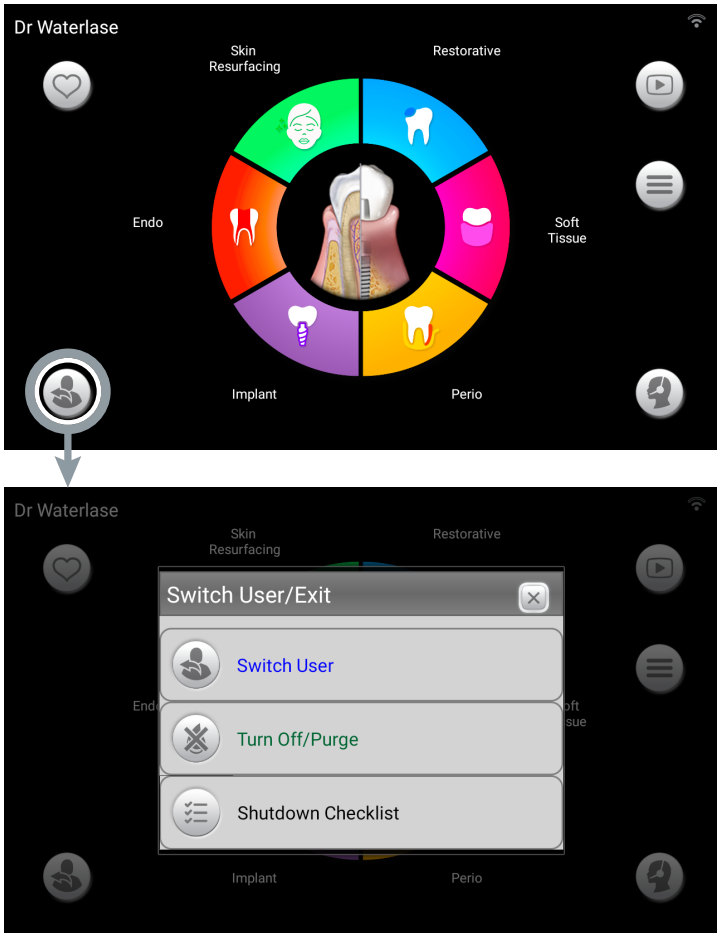


Fig 8.6

8 Operating Instructions

USER INTERFACE NAVIGATION

INTRODUCTION

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

The system automatically applies the recommended preprogrammed 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.

PROCEDURE MENU NAVIGATION

HOME SCREEN

The home screen offers a choice of the following procedure categories, plus the favorites list.
The selection is organized in a radial menu, Figure 8.7. To select a procedure category, press the corresponding radial menu segment.

- Restorative
- Soft Tissue
- Periodontics
- Implantology
- Endodontics
- Skin Resurfacing

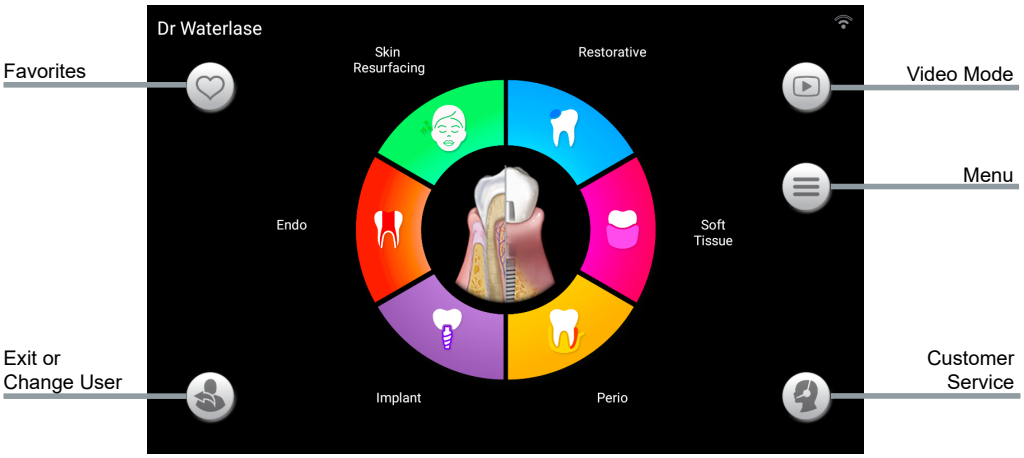


Fig 8.7

To play a video summary of the procedure category, select the Video Mode icon first, and then select the procedure category. When active, the Video Mode icon will appear blue, Figure 8.8. Video Mode is active for one video at a time. To play a second video, press the Video Mode icon again.

NOTE: Performing Skin Resurfacing requires an additional accessory, sold separately. Fractional Handpiece PN 7220002. Do not perform Skin Resurfacing without a Fractional Handpiece and training. Contact your local Biolase representative.

8 Operating Instructions

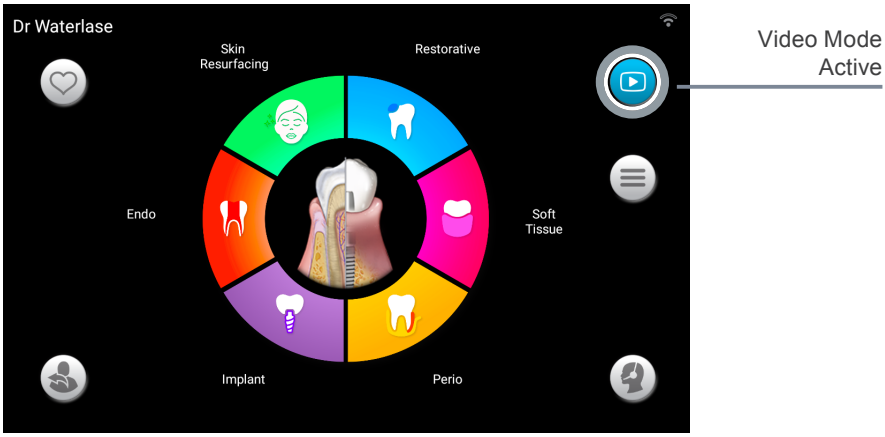


Fig 8.8

PROCEDURE SCREEN

Once a procedure category is selected, the next screen displays the list of procedures available for that category, Figure 8.9. To select a procedure, press the radial menu segment first, and then press the illustration in the center of the screen, Figure 8.10.

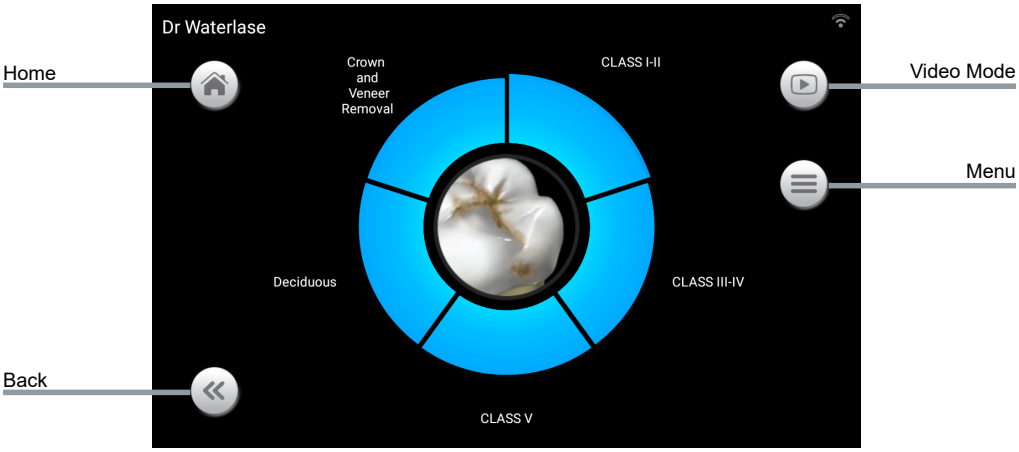


Fig 8.9

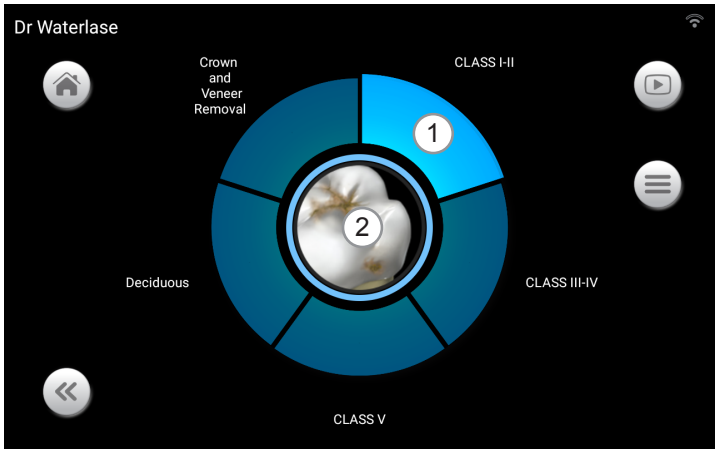


Fig 8.10

8 Operating Instructions

The Waterlase iPlus contains detailed animations of each procedure to help illustrate the tip positioning and best practices throughout each protocol. To view the videos, press the Video Mode icon. Then, select the procedure the user would like to view. When active, the Video Mode icon will appear blue. Video Mode is active for one video at a time. To play a second video, press the Video Mode icon again.

PROCEDURE STEPS AND OPTIONS SCREEN

Once a procedure is selected, the next screen displays the list of procedure steps or options for that procedure.

Some procedures include options, such as Rapid or Comfort, Figure 8.11. Rapid settings are typically higher in energy dosage and may require anesthesia. Comfort settings are typically lower energy dosage, may be slower and smoother, and may be more tolerable without anesthesia.

Other procedures, such as Repair, include a series of sequential steps. The steps are arranged clockwise from the top right, with the first step at the one o'clock, position. Figure 8.12.

To select a step, press the corresponding radial menu segment.

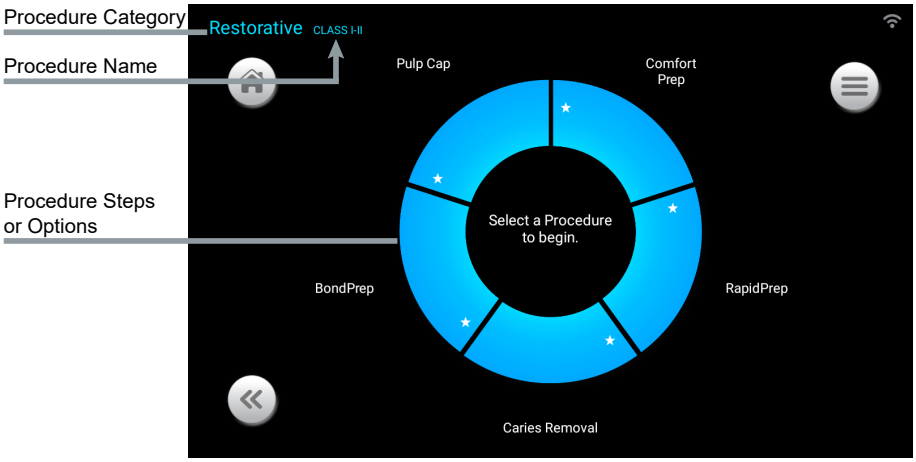


Fig 8.11

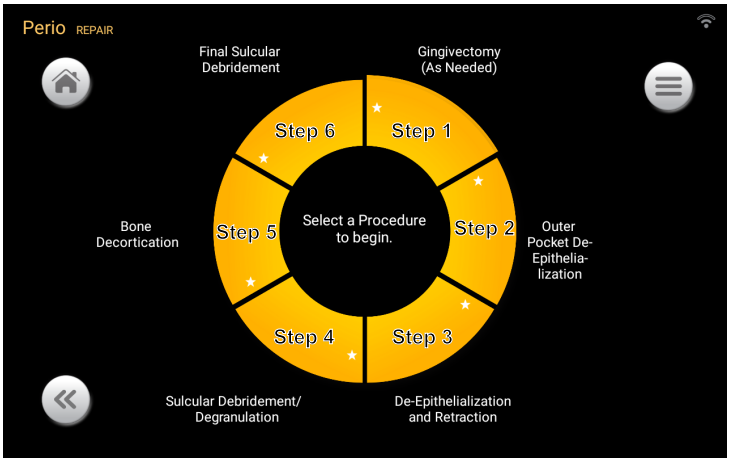


Fig 8.12

8 Operating Instructions

PROCEDURE SETTINGS SCREEN

Once a step is selected, the next screen displays the factory preset parameters, Figure 8.13. These parameters are chosen based on testing, published research, or expert clinician experience. Settings can be adjusted by pressing the pull-down menu at the top of the screen, which displays the Custom Settings screen. Press the next radial menu segment to move to the next procedure step or option.

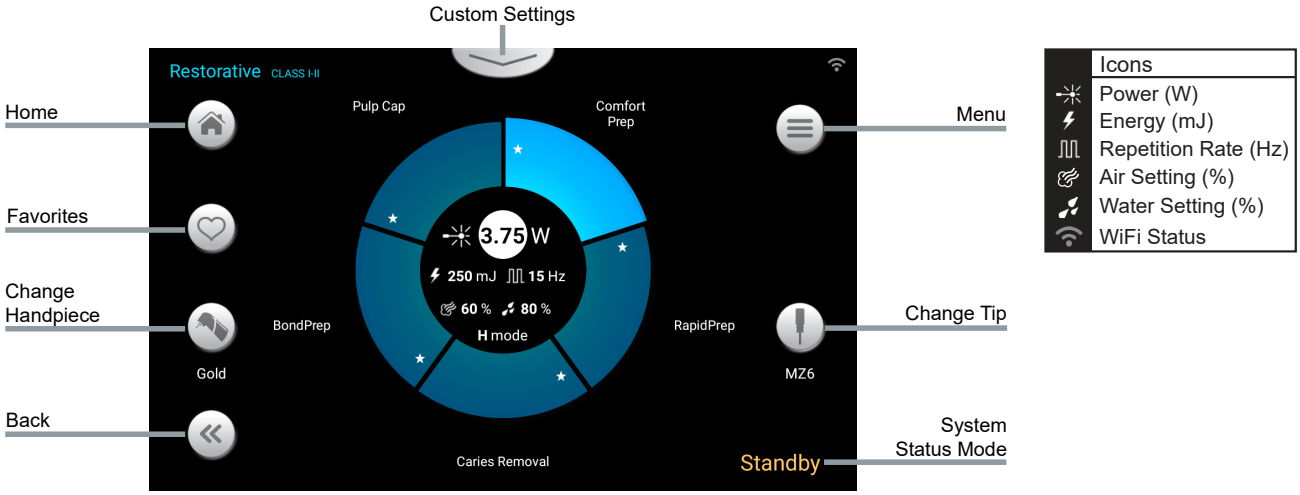


Fig 8.13

Press the Function Control button to transition from Standby to Ready mode, and then press the Footswitch to fire the laser when ready.

When firing the Waterlase with the water irrigation spray on, a fast “popping” sound should be heard. This sound corresponds to the laser energy creating sound pressure waves. If no “popping” sound is audible, follow instructions in Section 11 to troubleshoot. Running the Startup Checklist is also recommended to identify the cause. To access the Startup Checklist, restart the system after purging the Handpiece and Fiber Cable.

ADJUSTING CUSTOM SETTINGS

Adjust individual parameters on the Custom Settings screen, Figure 8.14. To access, press the Custom Settings pull down menu at the top of the Procedure Settings screen.

To adjust power (W), pulse repetition rate (Hz), water, or air, select the corresponding quadrant in the center of the screen. Then, adjust the level using either the radial slider or the plus (+) or minus (-) icons. Toggle switches on the left of the screen control the air and water spray from the Handpiece and the laser pulse duration (H or S Mode).

Always use best clinical judgment when adjusting parameters. Adjusted settings can be saved by pressing the save icon on the bottom right of the screen. To close the Custom Settings screen, press the up-arrow icon at the bottom of the screen.

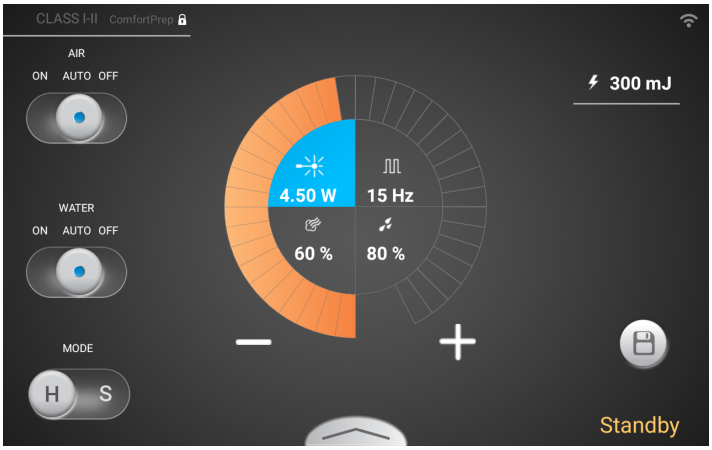
8 Operating Instructions

Air & Water Modes:
Auto: Footswitch Control

On: Always On in Ready Mode

Off: Always Off

Laser Pulse Duration:
H Mode: 60µs
S Mode: 700µs



Icons
Power (W)
Energy (mJ)
Repetition Rate (Hz)
Air Setting (%)
Water Setting (%)
WiFi Status
Factory Setting
Temporary Custom Setting
Saved Custom Setting

Fig 8.14

SAVE CUSTOM SETTINGS AND FAVORITES

To save a custom setting from the Settings screen, press and hold the radial menu segment corresponding to the selected procedure step. The pop up menu (Figure 8.15) directs the user to save the custom setting for the selected step, to save the setting as a Favorite, or to clear the custom setting and return to the factory setting. Each Procedure Step displays an icon corresponding to the status of the settings displayed, Figure 8.16.

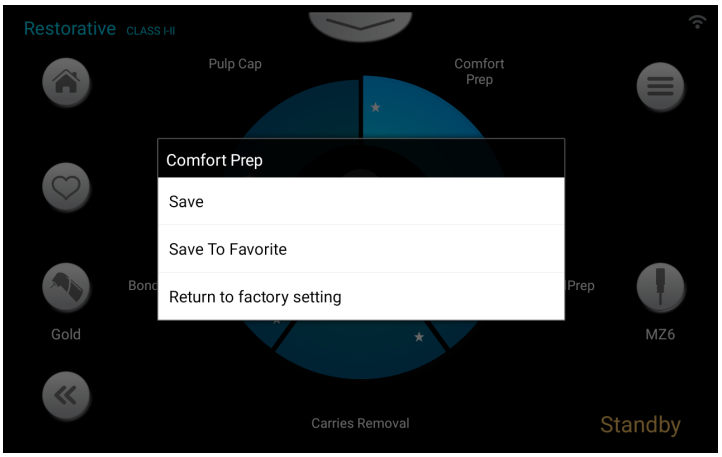
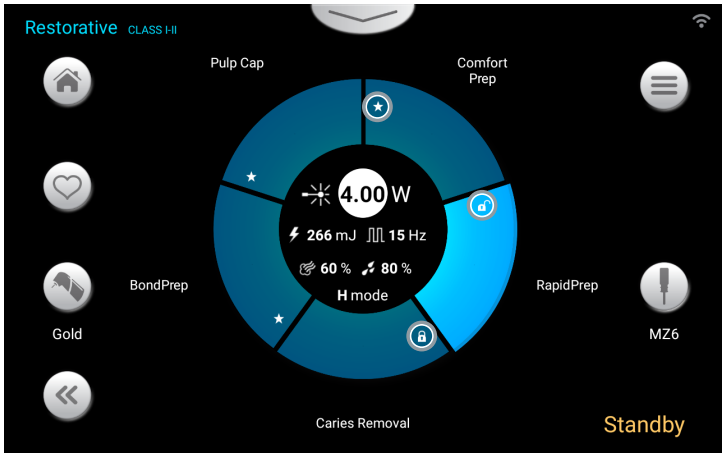


Fig 8.15



Icons
Factory Setting
Temporary Custom Setting
Saved Custom Setting

Fig 8.16

8 Operating Instructions

The Waterlase iPlus can store up to 12 favorite procedure or step settings. Saved Favorites (Fig. 8.17) can be accessed by pressing the heart icon on the left side of the Main or Procedure screens. To rename or delete a Favorite, press and hold the chosen favorite for about 2 seconds – a pop up menu will display with “Rename” and “Delete” options.

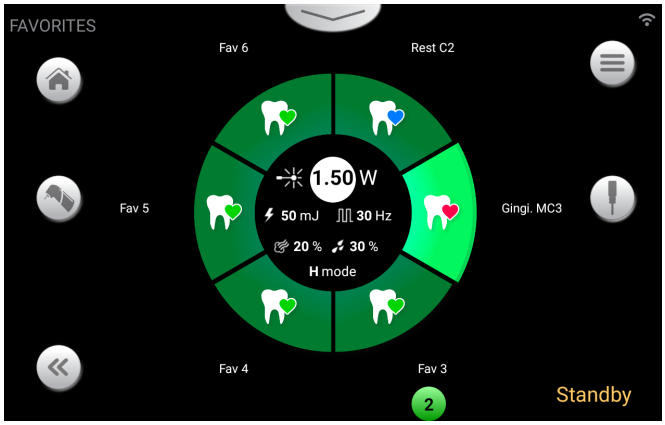


Fig 8.17

SYSTEM MENU

Press the Menu button at the right side of any screen to access a number of key features included with the Waterlase iPlus, Figure 8.18. To return to the Home screen, press the Home button at the top left of the screen. To review the startup checklist tutorial, select the checklist button on the bottom right.

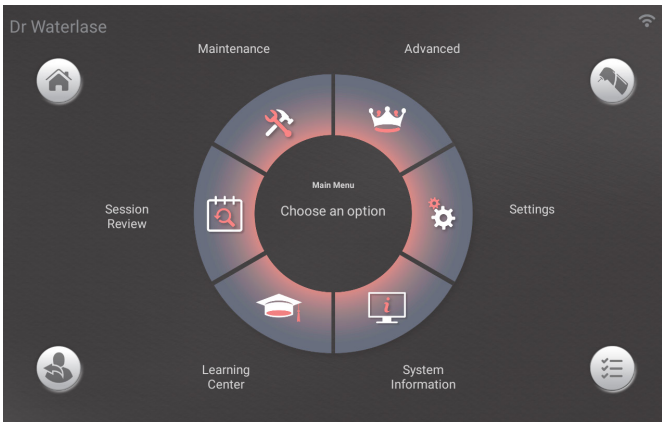


Fig 8.18

System Menu categories:

- Advanced
- Settings
- System Informtion
- Learning Center
- Session Review
- Maintenance

NOTE: Selecting the Handpiece Change icon on the Favorites, System Menu, or Advanced screens will purge the Handpiece. After changing the Handpiece and installing a Tip, select the icon again to prime the new Handpiece. Be sure to install a Tip before priming to prevent water from entering the Handpiece.

8 Operating Instructions

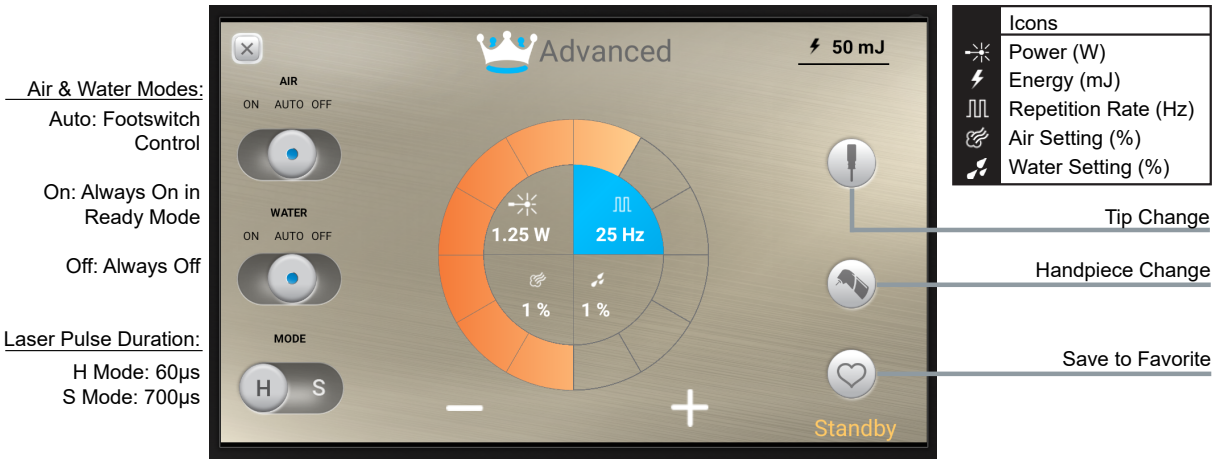


Fig 8.19

ADVANCED

Advanced allows full customization of all Waterlase iPlus parameters over the full settings range, Figure 8.19. To adjust power (W), pulse repetition rate (Hz), water, or air, select the corresponding quadrant in the center of the screen. Then, adjust the level using either the radial slider or the plus (+) or minus (-) icons. Always use best clinical judgment when adjusting parameters. Toggle switches on the left of the screen control the air and water spray from the Handpiece and the laser pulse duration (H or S Mode).

Always use the Change Tip or Change Handpiece options on the right side of the screen before removing and changing the accessories. A new Favorite can be saved by selecting the corresponding heart icon on the right of the screen.

SYSTEM POWER LIMITS*				
	H-Mode		S-Mode	
Pulse Rate	Min Power	Max Power	Min Power	Max Power
Hz	W	W	W	W
5	0.1	2.5	0.1	2.5
8	0.1	4.75	0.1	4.75
10	0.1	6	0.1	6
12	0.1	7.25	0.1	7.25
15	0.1	9	0.1	9
20	0.1	10	0.1	10
25	0.25	10	0.25	10
30	0.25	10	0.25	9
40	0.25	9	0.25	8
50	0.25	8	0.25	6
75	0.5	6	0	0
100	0.5	4	0	0

*Not all Tips are compatible with the full settings range. Consult the Tip guide in Appendix C for details.

8 Operating Instructions

SETTINGS

This category allows the user to personalize the laser system in the following areas:

- Initial Setup
  - Repeat initial setup
  - Perform Factory Reset
  - Enable / Disable Mandatory Checklist, Figure 8.21
- User
  - Add, change, or delete a user
  - Clear or restore user data
- Language
  - Change the system language
- Wi-Fi
  - Enable Wi-Fi, change network, disable Wi-Fi
- Volume
  - Change system volume
- Handpiece Illumination
  - Change aiming beam and Handpiece illumination brightness, Figure 8.22

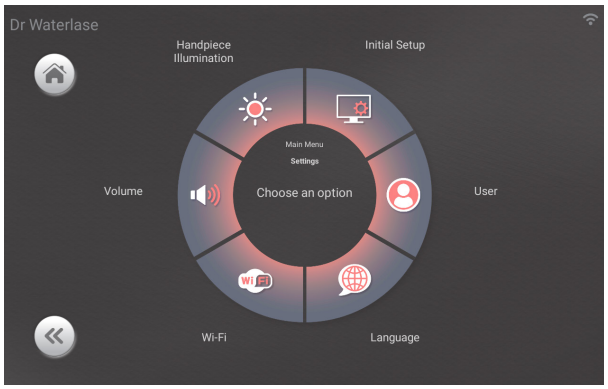


Fig 8.20

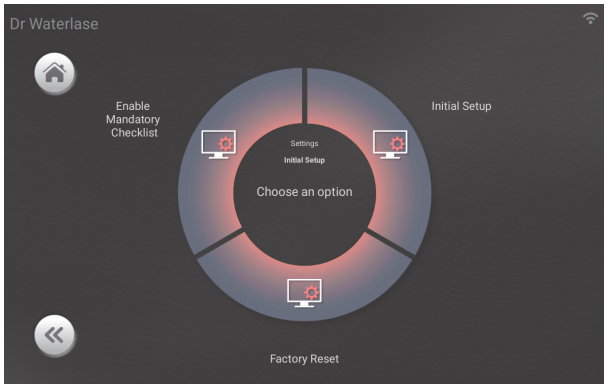


Fig 8.21

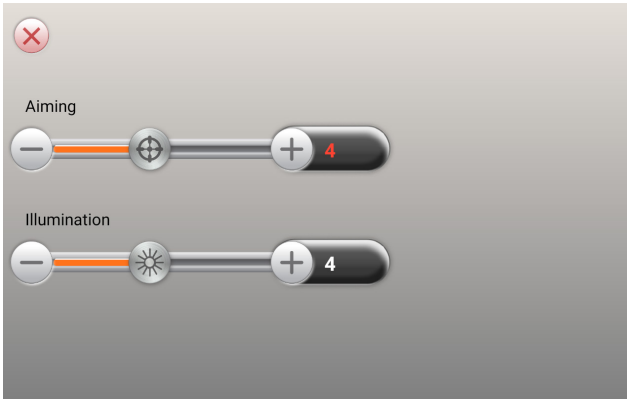


Fig 8.22

NOTE: The Startup and Shutdown Checklists guide the user through the best practices of how to inspect, set up, clean and store the Waterlase system at the beginning and end of the day. The Checklists can be made either optional or mandatory for all users. As the Admin user, select Enable Mandatory Checklist under the Initial Setup menu to make the Startup Checklist compulsory when the system is turned on.

8 Operating Instructions

SYSTEM INFORMATION

System Information provides the user with the following data (Figure 8.23):

- Laser serial number
- Memory
- Software Versions
- Background Color (The user interface can be displayed in Dark mode or Light mode. Dark mode is default.)
- Set Date and Time

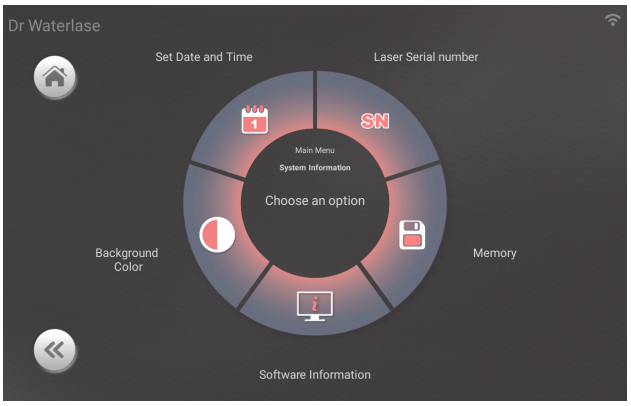


Fig 8.23

LEARNING CENTER

The Learning Center offers Practice Guides for various procedures, Figure 8.24.

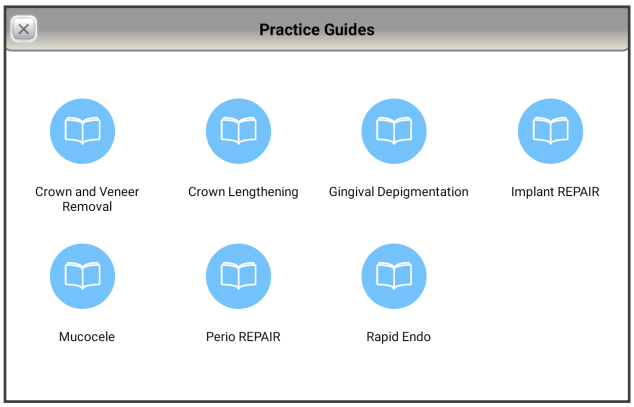


Fig 8.24

SESSION REVIEW

Waterlase iPlus stores all session information (Figure 8.25), including procedure settings and duration, and allows the user to sort by Date, Procedure, or by Doctor. Session information can be emailed to the user's registered account email.

NOTE: No patient information is stored in the laser software.

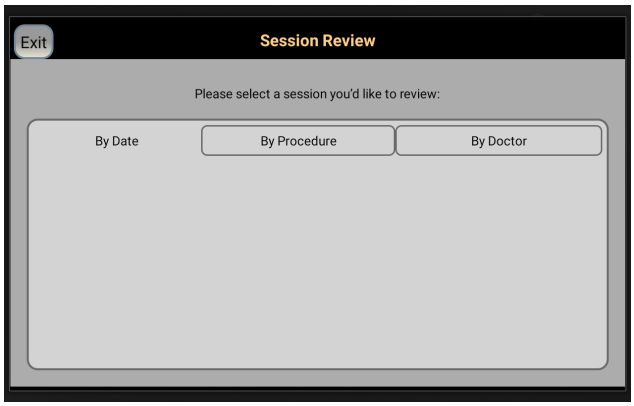


Fig 8.25

8 Operating Instructions

MAINTENANCE

The Maintenance selection offers the user the following options (Figure 8.26):

- Purge/Prime
  - Starts the Handpiece and Fiber Cable purge or prime processes
- Service
  - Entry for authorized service personnel only
- Helpful Videos
  - Stores how-to videos for daily maintenance activities, Figure 8.27
- User Manual
- Contact Customer Support
  - If Wi-Fi is enabled, the user can send an automated email requesting support to BIOLASE

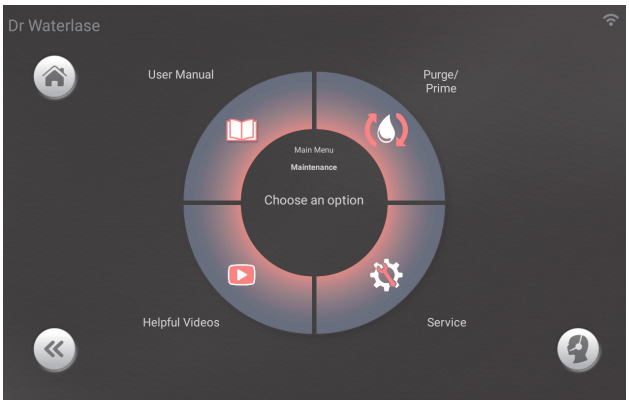


Fig 8.26

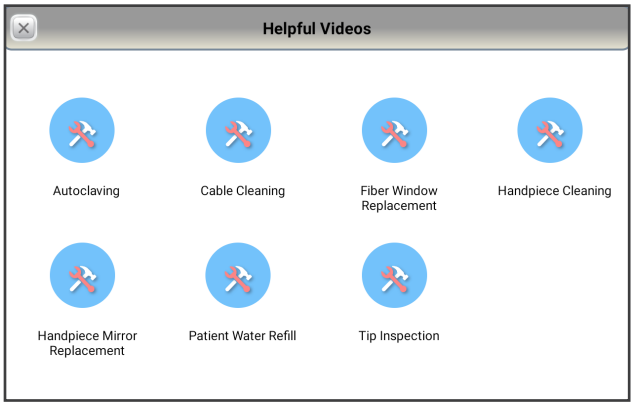


Fig 8.27

8 Operating Instructions

CAUTION: Connection to IT-networks including other equipment could result in previously unidentified risks to patients, operators or third parties. The responsible organization should identify, analyze, evaluate and control these risks.

Changes to the IT-network could introduce new risks that require additional analysis.
Changes to the IT-network include:
- Changes in network configuration
- Connection of additional items
- Disconnection of items
- Update of equipment
- Upgrade of equipment

CHANGE TIP OR HANDPIECE

Before changing the Tip or the Handpiece during or in between procedures, press the Change Tip or Change Handpiece icon on the Procedure Settings screen (Figure 8.13) or Advanced settings screen (Figure 8.19).

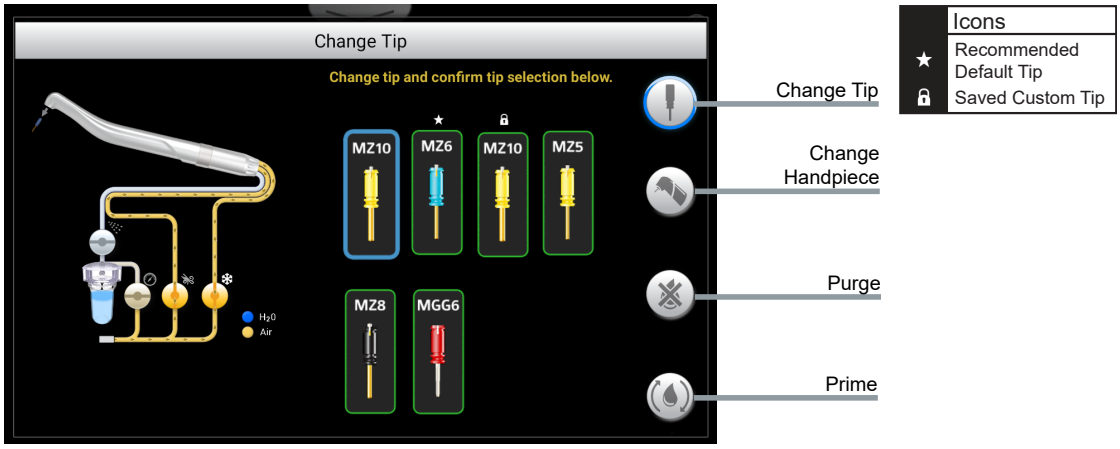


Fig 8.28

When changing the Tip (Figure 8.28), cooling air will be automatically on and flowing through the Handpiece head. The air keeps the internal components of the Handpiece dry during Tip change to prevent water from entering the Handpiece and causing damage. Select the new tip to exit.

When changing the Handpiece (Figure 8.29):

1. Press the Change Handpiece icon, and then select the next Handpiece on the screen.
2. The system will purge the Handpiece and Fiber.

CAUTION: Do not remove the Handpiece before purging is complete. Water on the Fiber Optic Cable will damage it.

3. Once purge is complete, change the Handpiece (Section 7). Press the Tip icon in the middle of the screen to select the new tip.
4. Install a new, sterile Tip and select the corresponding Tip on the screen.
5. Press the Prime icon in the middle of the screen.
6. The system will prime the Fiber and Handpiece.
7. Press the check mark icon to exit.

CAUTION: A Tip must be installed before priming the Handpiece.

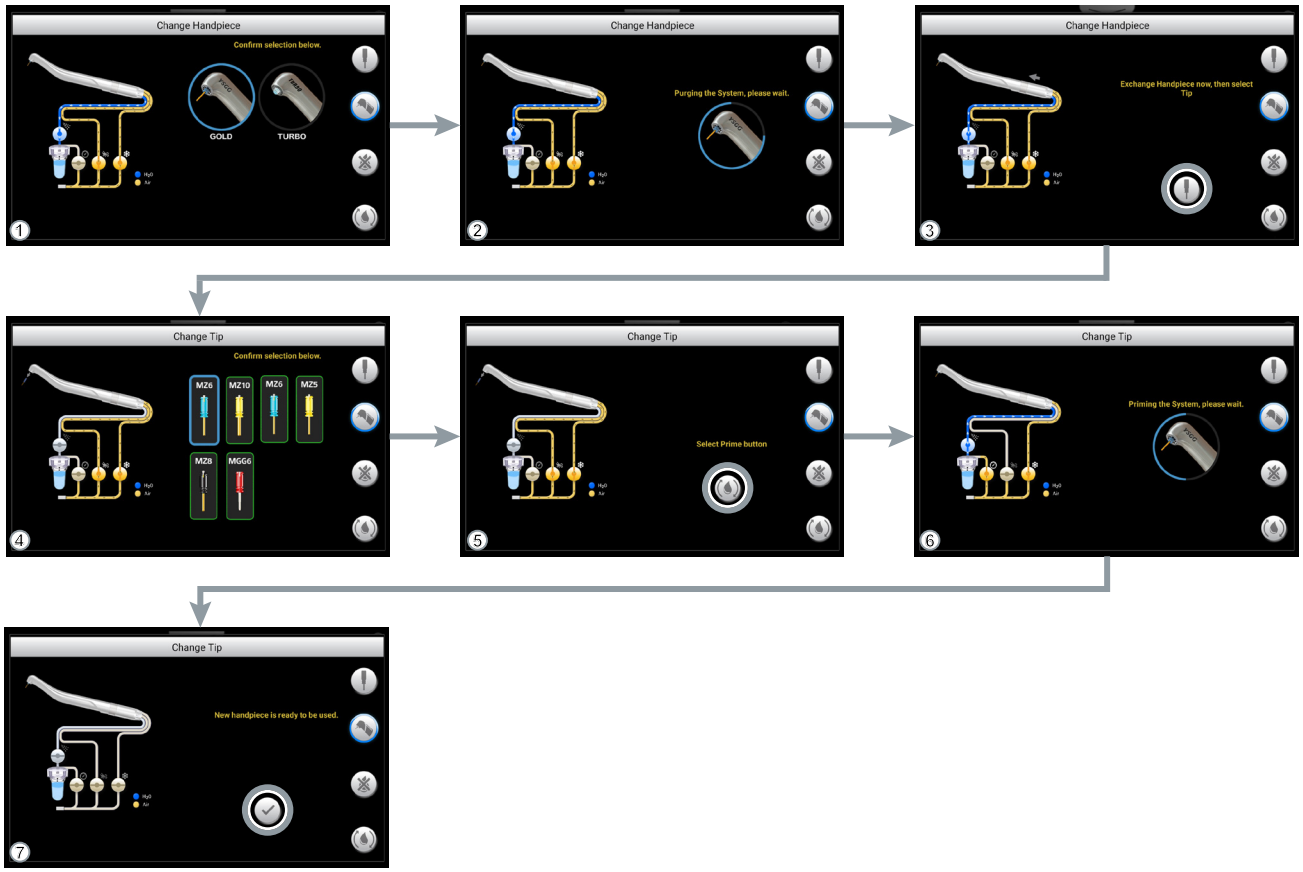


Fig 8.29

8 Operating Instructions

BIOLASE CONNECT

NOTE: An active wireless connection is necessary to implement this feature on the Waterlase. Wi-Fi may be enabled during first-time start-up, or at any later time by going to the main menu and selecting the Wi-Fi option. BIOLASE is not responsible for any internet connectivity issues; these must be reported to the local internet service provider or similar personnel for resolution.

Waterlase iPlus includes a set of features which allow the user to interact with BIOLASE utilizing Wi-Fi. These features provide email contact with Customer Support for clinical and/or technical support, automated software and content updates. However, **no individually identifiable patient data of any kind is accessed or stored on the system itself.**

ENABLING BIOLASE CONNECT

BIOLASE Connect may be enabled during first-time set-up, or at any later time by going to the main Menu and selecting the Wi-Fi option. An active wireless connection is necessary to implement this feature on the Waterlase iPlus.

NOTE: To contact BIOLASE for technical or clinical assistance, press the Call Customer Support button located on the bottom right of the Home and Menu screens. This will automatically generate an email request to BIOLASE Customer Support. A representative will respond as soon as possible (within business hours).

SOFTWARE AND CONTENT UPDATES

From time-to-time, Waterlase iPlus will update the system Software, or refresh the digital content, adding new videos, animations, practice guides, etc. Users will be notified of upcoming updates, along with a summary of the enhancements included with each update.

Users who are utilizing BIOLASE Connect will be able to execute updates through their Wi-Fi connection.

The screen will display easy-to-follow step-by-step instructions throughout the implementation process. For systems that have not enabled the Wi-Fi feature, one or more SD cards will be provided via mail, along with detailed instructions.

Software updates are downloaded automatically, but not installed until the user chooses to do so. When download is complete, a message is displayed prompting the user to install or postpone. If postpone is selected, a message is displayed the next time the system is turned on.

9 Clinical Application

OVERVIEW

The Waterlase iPlus laser system 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 optimal 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. (If using the Turbo handpiece, maintain a distance of 3-5mm.)

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 is not immediately needed, use the Tip plug to avoid contamination and damage to the Handpiece until it can be cleaned and sterilized for the next patient.
11. 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 10.
12. Disposable, single-use, quartz (glass) Tips must be disposed of in a biohazard medical waste sharps container. Single-use Tips should not be reused. Reusable Sapphire Tips must be cleaned and sterilized between patients to prevent cross contamination.

Cutting efficiency will vary depending upon the power setting, tip diameter, 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 optimal 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/ or https://www.biolase.com/education/waterlase-academy/

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. (Figure 10.1)
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. (Figure 10.2)
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. (Figure 10.3)

Fig. 10.1

Fig. 10.2


Fig. 10.3

10 Cleaning and Sterilization

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. (Figure 10.4)
7. Rinse the Handpiece under lukewarm running tap water (22-43°C) for 10 seconds. (Figure 10.1)
8. Dry the Handpiece with a lint-free cloth. (Figure 10.5)
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 10.6)
    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; (Figure.10.7)
    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. 10.4


Fig. 10.5


Fig. 10.6


Fig. 10.7

> **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.

10 Cleaning and Sterilization

STEP 2—HANDPIECE AND REUSEABLE 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.
(Figure 10.8)
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. (Figure 10.9)
4. Place the pouches on an autoclave tray. Take care when handling the Handpiece and Tip(s).

Fig. 10.8

Fig. 10.9

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 Figure 10.10.

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. 10.10

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 of the User Manual, Installing and Changing the Tip in the Handpiece.

10 Cleaning and Sterilization

STEP 3—DISINFECTING THE FIBER OPTIC CABLE

Fig. 10.11

Always disinfect the Fiber Cable between patients. Use 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. Wipe the full length of the Fiber Cable. Remove the Handpiece or Protective Cover and wipe the Fiber Cable flexible neck and metal spindle. **DO NOT wipe the output end**, which includes optical components and the protective window. **DO NOT autoclave.** Make sure the Fiber Cable neck is dry before placing the Handpiece or Protective Cover.

Inspect the O-rings on the distal end of the Fiber Optic Cable (Figure. 10.11) regularly for signs of wear or tear. Replace as needed (PN 6200317).

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. Please refer to the User Manual for Tip Inspection instructions.

11 Maintenance and Troubleshooting

DAILY MAINTENANCE

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 liquid to enter the Laser System, especially where the Fiber Optic Cable connects to the Console and where it connects to 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 8.22), 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). (Fig. 11.1)

NOTE: If a Tip is damaged at the input end after use, check the mirror and the Fiber Cable Protective Window for contamination or damage.

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. 11.1

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

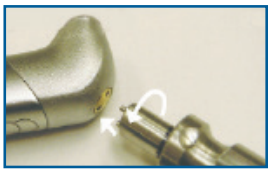


Fig. 11.2

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 (Fig 11.3).
3. Pull the mirror straight out from the head opening (Fig 11.4). Wear gloves - DO NOT handle the mirror with bare hands. Grab the mirror with 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. 11.3

11 Maintenance and Troubleshooting

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

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

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).

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).


Fig. 11.4


Fig. 11.5


Fig. 11.6

Fig. 11.7


Fig. 11.8

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.

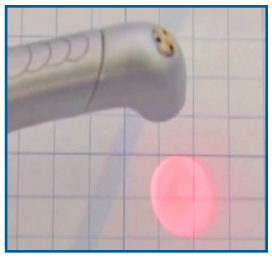


Fig. 11.9

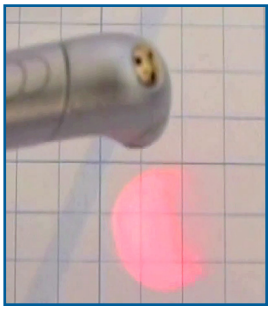


Fig. 11.10

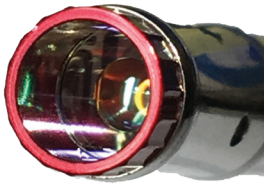
FIBER OPTIC CABLE CHECK

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. Allow to dry.

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 Fiber Optic Cable, gently pull the protective window, while unscrewing the protective window counter-clockwise until it is removed. (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).

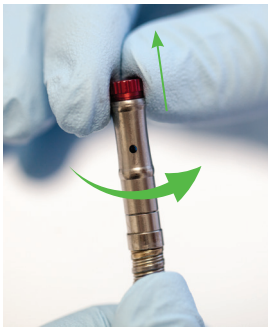


Figure 11.13

11 Maintenance and Troubleshooting

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).

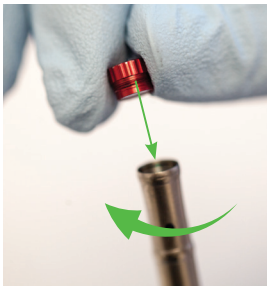


Figure 11.14

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:

O-Ring Removal

Figure 11.15

1. Confirm that the Fiber Cable had been purged before removing the Handpiece or Protective Cover.
2. Continue with the Waterlase iPlus Off or 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. (Figure 11.16)
4. Repeat for O-Ring B, then O-Ring C and O-Ring D. (Figure 11.17)

Figure 11.16

O-Ring Replacement

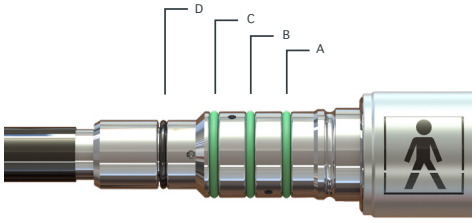


Figure 11.17

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.

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

11 Maintenance and Troubleshooting

ANNUAL MAINTENANCE

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

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

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

An annual service reminder may appear to aid the user in scheduling the maintenance visit. Select the pop up icon on left of the screen (Figure 11.18) and press Continue to send an automatic message to Biolase customer service. A representative will contact the user at the registered email or phone number to complete the process.

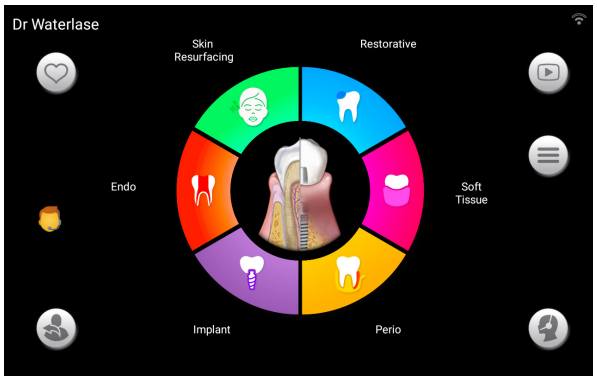


Fig. 11.18

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.

Number	Error	Reason	Fix / Corrective Action
3	Serial command failed	The system has detected a communication error	Restart the system. Contact Customer Service if error persists.
4	SBC Data Corruption Error	The system has detected an error relating to internal database	
5	Laser Failed to Respond	Serial Port timed out, System error	
6	High voltage temperature	HV supply temperature too high	Turn the system OFF. Allow at least 10 minutes for the system to cool down before turning it ON. Contact Customer Service if error persists.
9	VFeedBack error	VFeedBack voltage is out of specification	Contact Customer Service to schedule system calibration.
12	Internal Shutter Error	The system has detected an internal shutter error	Restart the system. Contact Customer Service if error persists.
14	Thermistor failure	Thermistor failure	
15	Control Button Error	The system has detected a problem with the front Function Control Button	Press and release the Function Control Button, then restart the system. Remove any debris or foreign object that may be present. Contact Customer Service if error persists.
17	Shut down temperature condition	System temperature is high	Leave the system ON. This error will automatically clear once system temperature is within limits.
18	Emergency Switch pressed	Emergency Switch pressed	Press the Emergency Switch again to return system to Standby mode.
22	Water flow failure	Internal cooling water flow is not detected	Restart the system. Contact Customer Service if error persists.
23	Reservoir fail	Internal cooling reservoir water level is low	Add de-ionized or distilled water to the internal cooling reservoir.
24	Air pressure failure	Air pressure is not within required range (60-120 psi or 420-827 kPa)	Check air tubing connector and air compressor.
26	Footswitch not detected	Footswitch disconnected	Connect Footswitch
28	Remote interlock open	Remote interlock open	Check remote interlock pin.
29	Fiber not detected	Fiber not detected	Install the Fiber Cable. Check that the connector is seated properly and that the metal retaining ring is fully tightened.
31	Patient Water Bottle is empty or missing	Patient Water Bottle is empty or missing	Add distilled or de-ionized water to Patient Water Bottle and install it. Contact Customer Service if error persists.
-	Invalid SD Card	The system has detected the insertion of an invalid SD card.	Remove the invalid memory card. Insert a valid SD card and press OK. Contact Customer Service for assistance.
-	The system has detected a condition which requires a display reset. This can be accomplished by pressing the OK button. The display will restart automatically. If the error persists, please contact Customer Service.		

11 Maintenance and Troubleshooting

Number	Warning	Reason	Fix / Corrective Action
13	Footswitch pressed in Standby mode	System was not in Ready mode when footswitch was pressed	Place the system in Ready mode, and then press the footswitch.
100	Patient Water Bottle level low	Approximately 5 minutes of water remain in the Patient Water Bottle	Add distilled or de-ionized water to the Patient Water Bottle.

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

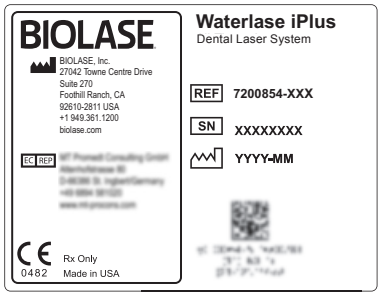
The Waterlase iPlus should be stored in a cool dry place when not in use. Storage temperature should be -20° to 60°C (-4°F to 140°F), relative humidity 10% to 90%, non-condensing. Cover the Laser Console when not in use for extended periods of time. Store the system in a place where it will not be accidentally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

REF

PRODUCT SERIAL NUMBER

SN

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.

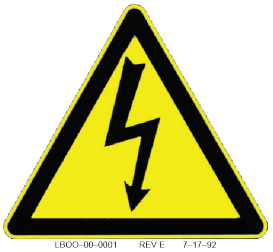
Location: Top cover of laser head, directly above the Fiber Optic Cable connector. (Only visible during service)

HIGH VOLTAGE HAZARD SYMBOL

Warning - Dangerous voltage (Only visible during service).

Locations:

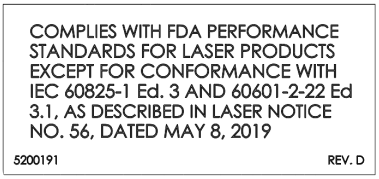
- Top cover of laser head, directly above the High Voltage input.
- PFN Board Capacitor
- Front Capacitor Bracket



CERTIFICATION

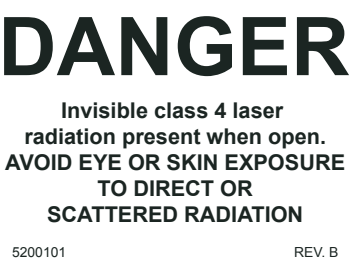
This device complies with FDA laser standards.

Location: Back panel



NON-INTERLOCKED PROTECTION HOUSING WARNING

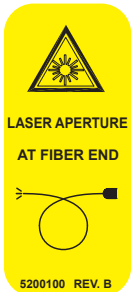
Location: Laser head, access plate
(Accessible only during service proceedings).



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.

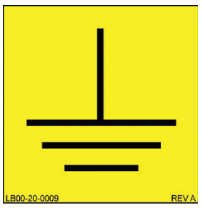
LASER EXPLANATORY LABEL

Provides laser specifications

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

SYSTEM GROUND CONNECTION

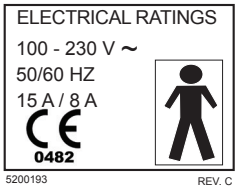
Location: Inside Laser Console, left.



ELECTRICAL SHOCK RATINGS

Type BF Applied Part

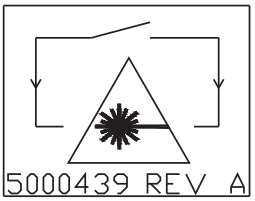
Location: Back Panel



REMOTE INTERLOCK LABEL

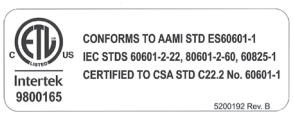
Input for Remote Interlock Connector which, when applied to the access door of the operatory and activated, will shut off the laser.

Location: Back panel



ETL LISTED: UL/CSA CONFORMANCE LABEL

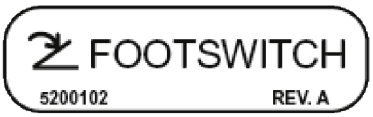
Location: Back panel



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

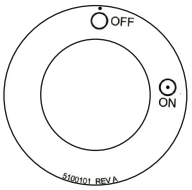
Indicates minimum and maximum air pressure

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

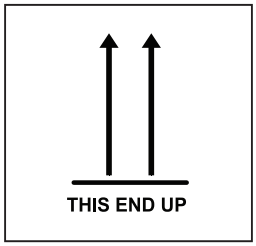
POTENTIAL EQUALIZATION TERMINAL (PEQ)

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

Location: Lower Back Panel

Appendix A Labels

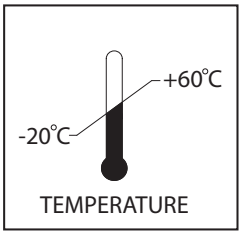
OUTER PACKAGING



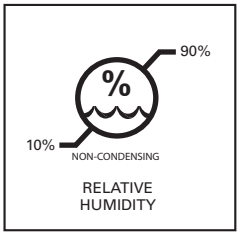
THIS END UP

HANDLE WITH CARE

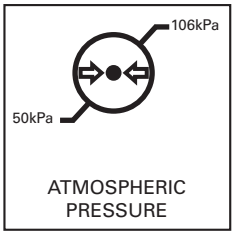
KEEP DRY



TEMPERATURE LIMITATIONS



HUMIDITY LIMITATIONS



ATMOSPHERIC PRESSURE LIMITATIONS

Appendix B Accessories

ACCESSORIES LIST

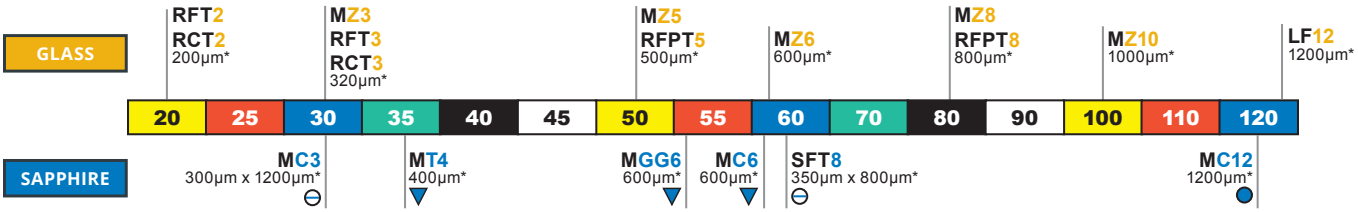
BIOLASE P/N	DESCRIPTION
2200696	Glasses, Protective, Multi Wavelength
2200848	Glasses, Doctor, Multi Wavelength
6201515	Fiber Optic Cable
6200150	Footswitch
2000204	Power Cord, Hospital Grade (U.S.)
2200485	Power Cord, 250VAC (International)
7000414	Waterlase/MD Tip Holder
7000734S	Waterlase Mirror Replacement Kit
7200104	Waterlase/MD Tip Inspection Kit
6200500	Gold Handpiece
6201037	Gold Mirror Refill Kit
6201102	Gold Mirror Single Refill
6201126	Turbo Handpiece
7220005	LaserFresh Handpiece Kit
6201133	Turbo Mirror Refill
7200106	MD Gold Mirror Replacement Kit
3200105	Waterlase Mirror Removal Tool
7200407	Turbo Tip Holder/Remover
5201281	Danger Sign (Laser Warning Sign)
6200317	Replacement O-Ring Kit
7220002	Waterlase Fractional Handpiece
6201818	Disposable Applicators for Fractional Handpiece
6200377	Replacement handpiece holder

Appendix C Tips

TIP TYPES

TIP FERRULE COLORS

Tip types following Dental Standard ISO Series Diameter/Color Codes



TIP IDENTIFIERS	TIP TYPES
MGG6-6 (Laser System (MD/iPlus, Radial Firing Tip); Tip Type; Tip Diameter; Tip Length)	Z RF Glass Tips
	CTG SF Sapphire Tips
	● Cylindrical Tips
	⊖ Chisel Tips
	▼ Tapered Tips

*Fiber Output Dimensions

SINGLE USE GLASS (QUARTZ) TIPS

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

Tip	Ferrule Color / Output Dimension (µm)	Lengths (mm)	Tip Type	Maximum Energy Setting *	Tissue Types
RFT2 **	200	17, 21, 25	Radial Firing	100mJ	Root Canal
RCT2 **	200	17, 21	Cylindrical, Flat	100mJ	Root Canal
RFT3 **	320	17, 21	Radial Firing	200mJ	Root Canal
RCT3 **	320	17, 21	Cylindrical, Flat	200mJ	Root Canal
MZ3	320	9, 14, 18, 22	Cylindrical, Flat	200mJ	Soft Tissue
RFPT5	500	10, 14	Radial Firing, Perio	400mJ	Bone, Soft Tissue
MZ5	500	3, 6, 9, 14	Cylindrical, Flat	400mJ	All Types
MZ6	600	3, 6, 9, 14, 17	Cylindrical, Flat	500mJ	All Types
RFPT8	800	10, 14	Radial Firing, Perio	No Limit	Bone, Soft Tissue
MZ8	800	6	Cylindrical, Flat	No Limit	All Types
MZ10	1000	6	Cylindrical, Flat	No Limit	All Types
LF12	1,200	2	Cylindrical, Flat	100mJ	Soft Tissue

* Damage to the Tip is likely above specified threshold.

** Energy output from RFT3 tip is significantly higher than the output from RFT2. System preset settings account for tip energy output. Do not exceed presets.

Appendix C Tips

RE-USABLE SAPPHIRE TIPS

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

Tip	Ferrule Color / Output Dimension (µm)	Lengths (mm)	Tip Type	Maximum Energy Setting *	Tissue Types
MT4	400	6	Tapered	200mJ	All Types
MGG6	600	4, 6, 9	Tapered	No Limit	
MC6	600	4, 6, 9	Tapered		
MC3	300 x 1,200	9	Chisel		
SFT8	350 x 800	18	Side Firing, Chisel		
MC12	1,200	9	Cylindrical, Flat		

* Damage to the Tip is likely above specified threshold.

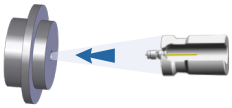
TURBO TIPS

Tip	O-Ring Color	Output Beam Waist (µm)	Tissue Types
MX5	Red	500	All Hard Tissues
MX7	Green	700	
MX9	White	900	
MX11	Black	1,100	

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.

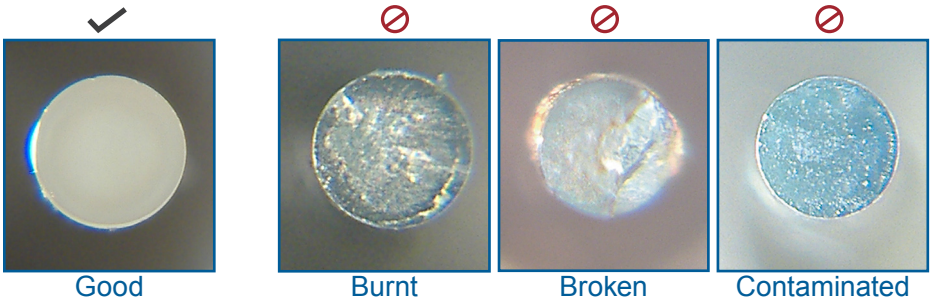
Appendix D Tip Inspection

TIP INSPECTION INSTRUCTIONS



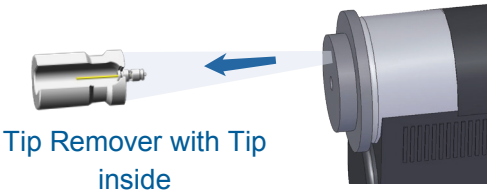
Tip Remover with Tip inside

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.



Good Burnt Broken Contaminated

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

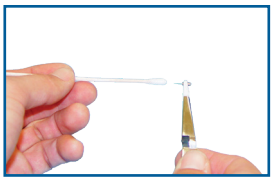


Fig D.1

1. Hold Reuseable 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)

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.

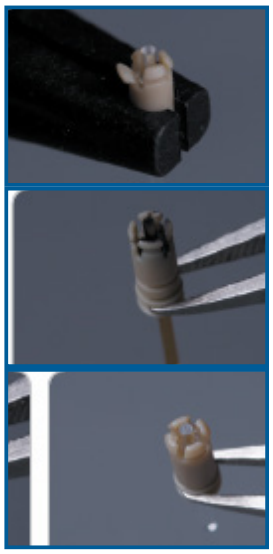


Fig D.2

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).

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

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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Conforms to:
AAMI
ES60601-1
IEC60601-1
IEC60601-2-22
IEC62366
IEC80601-2-60
IEC60825-1
Certified to:
CSA C22.2
No. 60601-1

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