WaterLase iPlus™

User Manual

5200158 Rev F

BIOLASE

WaterLase iPlus™

User Manual

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NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED

Introduction

The WaterLase iPlus tissue cutting system is a unique device with diverse, hard and soft tissue dental applications. It utilizes advanced laser and water atomization technologies to safely and effectively cut, shave, contour, roughen, etch, and resect oral hard tissue, and direct laser energy to perform oral soft tissue removal, incision, excision, ablation and coagulation. WaterLase iPlus may also be used for specific endodontic and periodontal applications.

When used for hard tissue procedures, the YSGG solid-state laser provides optical energy to a user-controlled distribution of atomized water droplets and hydrated surface layer of hard tissue. Water in the spray, on the tissue surface and within the surface tissue layer, absorbs laser radiation, resulting in explosive water expansion. Strong mechanical forces from rapid water expansion induce separation of surface material, quickly and cleanly removing hard tooth tissue. A flexible Fiber optic cable with a Handpiece delivers the unique laser wavelength and atomized distribution of water particles to the target tissue. A visible light emitted from the Handpiece distal end pinpoints the area of treatment. The optical power output and atomized water spray may be adjusted to specific user requirements for both soft and hard tissue applications.

In soft tissue mode, the WaterLase iPlus is programmed to perform tissue removal, incision, excision, ablation and coagulation using direct laser energy, either with or without water, for cooling and hydration.

In addition, with the WaterLase iPlus laser system there is the option to include the iLase diode laser, a hand-held, self-contained surgical device designed for a wide variety of dental soft tissue procedures. Detailed information on the iLase can be found in the iLase User Manual, Biolase P/N 5400230.

WaterLase iPlus is indicated for professional use on adult and pediatric patients. Procedures must be performed only by licensed dental and medical practitioners in a dental or medical facility. Use of this device requires proper clinical and technical expertise, and this 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 your practice. Please contact Biolase Customer Service at **1-800-321-6717** in the U.S. for any service needs; if you are located outside the U.S., please contact your Biolase-authorized representative.

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 you suspect it is functioning improperly.

SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

1. Remove or cover all highly reflective items in the treatment area, if possible.
2. Do not operate in the presence of explosive or flammable materials.
3. All persons present in the operatory must wear protective eyewear suitable for blocking 940nm (if using the iPlus in conjunction with the iLase) and 2,780nm energy (multi-wavelength glasses supplied by BIOLASE).
4. Do not look directly into the beam or at specular reflections.
5. Direct the cutting spray toward targeted tissues only.

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

6. Press the Standby button on the control panel before changing the water in the reservoir and before turning off the laser system.
7. Move the circuit breaker to the OFF (0) position (located on the rear panel) and remove the key before leaving the unit 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 your 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 Unit - 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.

2 Equipment Description

SYSTEM PARTS LIST

The iPlus laser systems include the following*:

- iPlus laser
- Display covers (qty. 25)
- Trunk Fiber and Fiber support
- Yellow air tube
- Protective laser eyewear (3)
- Handpieces, (1) Gold, (1) Turbo
- Tip holder
- Tip cleaning kit
- Power cord, (1) US, (1) International
- Footswitch
- User Manual
- Laser Warning sign
- Product registration card
- Limited warranty
- iLase Laser (Optional)

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

GENERAL

The WaterLase iPlus dental laser system consists of three modules:

- Main Unit (the Unit – shown in Figures 2.1, 2.2, and 2.3)
- WaterLase iPlus Fiber Delivery System (the Delivery System, shown in Figures 2.1, 2.2, and 2.3, consists of the Fiber, Handpiece, and Tips)
- (Optional) iLase soft tissue diode laser

MAIN UNIT ELEMENTS

Figures 2.1, 2.2, and 2.3 show the front, rear and top views of the unit.

CONTROL PANEL

The main unit is controlled through a touch screen control panel. See section 5, 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.

ENERGY MONITOR

The energy monitor measures and verifies power output.

Safety Features

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

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 to pull the unit; this could damage the Fiber optic and render the laser inoperable.

LOCKING WHEELS

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

EMERGENCY STOP

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

Safety Features

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

KEY SWITCH

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

FOOTSWITCH, FOOTSWITCH CONNECTOR

Activates the laser; the WaterLase iPlus laser will not activate until the user presses down on the footswitch. Connect and secure the footswitch to the footswitch connector located on the back panel of the console.

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

REMOTE INTERLOCK OUTLET

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

Safety Features
Turns 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 unit from the main power supply (0 = OFF, 1 = ON). The power cable can be wrapped over the holding plate above the connector when the system is not in use or when it is being transported.

VENTILATION CHANNELS

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

AIR INLET CONNECTOR

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

SELF-CONTAINED WATER BOTTLE

Located on the rear of the laser, this detachable bottle provides the water supply for Handpiece atomization spray. Fill the bottle only with distilled, purified or sterile water. **DO NOT use tap water.**

WATER BOTTLE RELEASE

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

FOOTSWITCH SUPPORT BRACKET

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

TELESCOPIC FIBER SUPPORT ARM

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

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

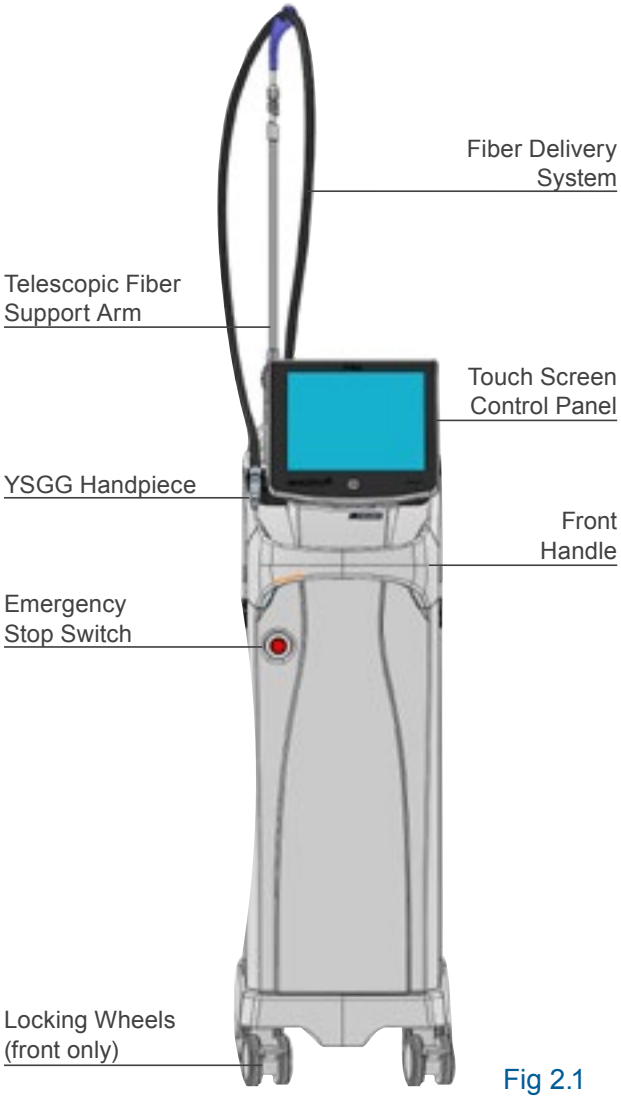


Fig 2.1

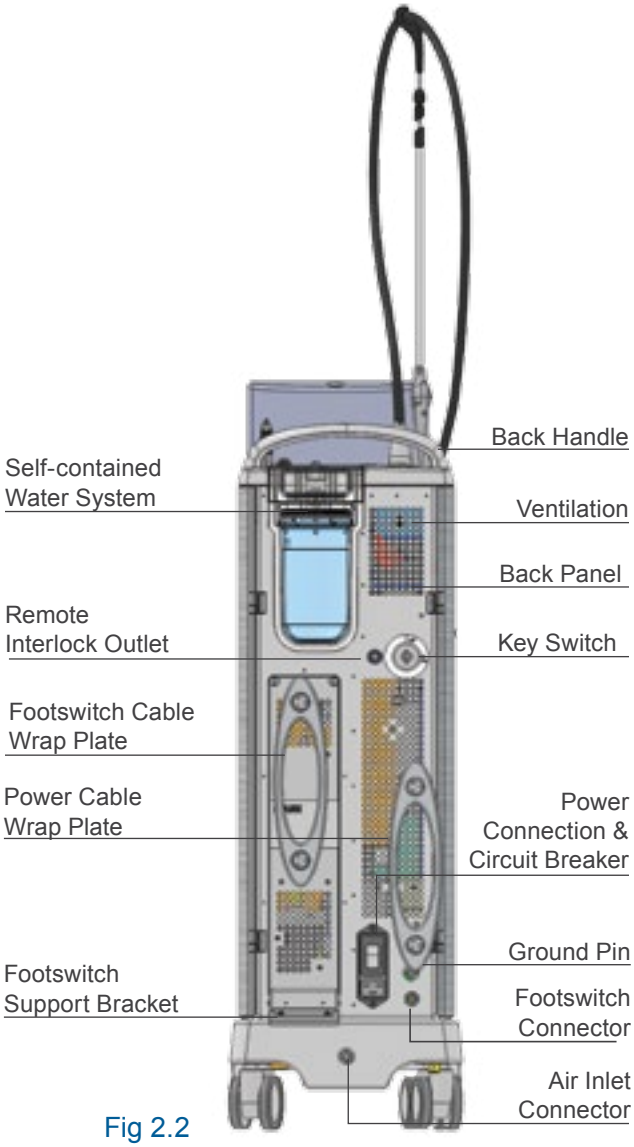


Fig 2.2

WATERLASE IPLUS DELIVERY SYSTEM

(See Section 4 for detailed description and instructions)

DELIVERY SYSTEM CONNECTION ON THE UNIT

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

HANDPIECE HOLDER

Cradles the YSGG Handpiece when it is not in use.

FIBER OPTIC CABLE

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

HANDPIECE

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

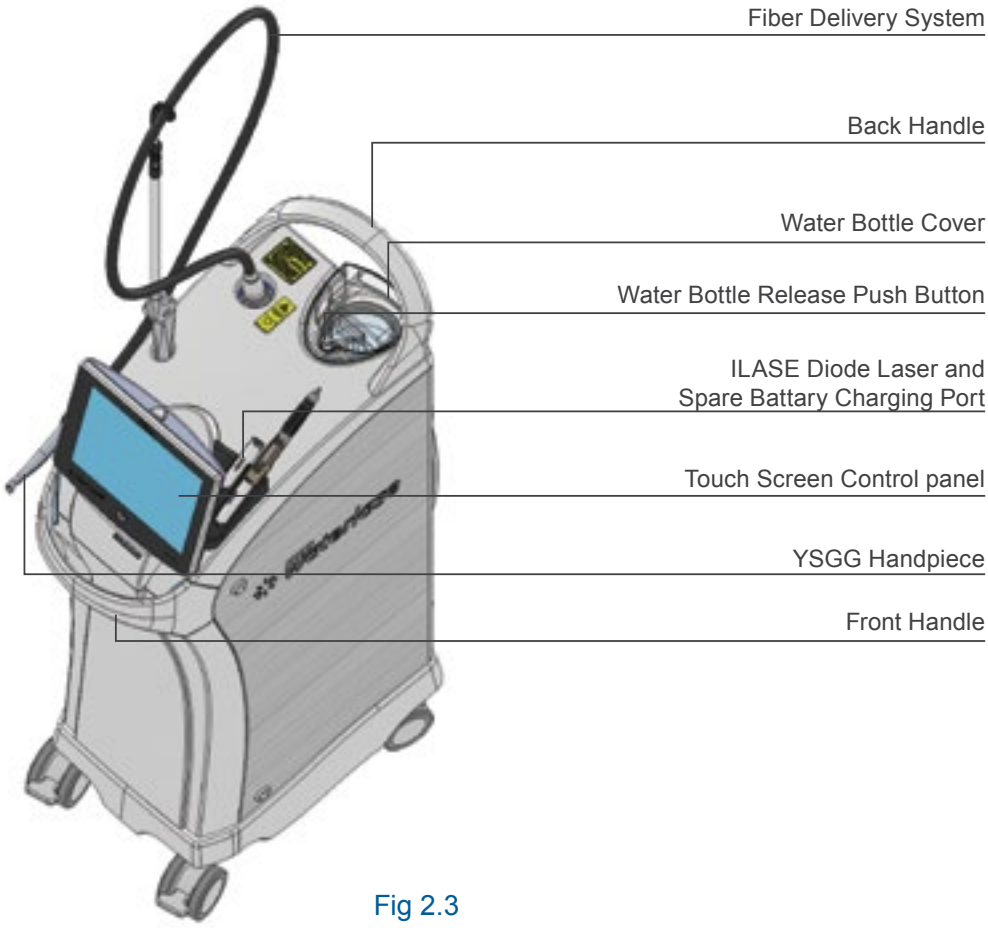


Fig 2.3

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 your trained representative arrives. Complete installation, testing, and demonstration require approximately one full day. Please refer to Section 4, Setup Instructions, for further details.

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

FACILITY REQUIREMENTS

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

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

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

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

ENVIRONMENTAL REQUIREMENTS

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

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

CAUTION: Prior to connection, verify that the outlet is for the air, NOT the water supply. Connection to the water supply may cause damage to the WaterLase iPlus system. If the unit is connected to the water supply, DO NOT turn the system on; contact your 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.

SETUP

CONNECTING THE UNIT 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 unit (Fig 2.2).
4. Verify a minimum air pressure of 80 psi (5.5 bar) is emitted from the air supply.
5. Check the air supply for moisture.
6. Connect the air supply to the unit's air inlet connector at the rear of the console (Fig 2.2).

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

FILLING THE INTERNAL COOLING WATER RESERVOIR

Your WaterLase iPlus may have been shipped with a full cooling water reservoir. In the event you need 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 4.1);

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

2. Locate the internal water reservoir and verify that the white clip on the blue tube connected to the side of the water reservoir is closed;
3. Push the button on the top connector and disconnect the tubing from the lid (Fig 4.2);


Fig 4.1


Fig 4.2


Fig 4.3


Fig 4.4

4. Remove the lid and filter assembly (Fig 4.3, 4.4);

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

5. Use the funnel supplied to fill the bottle with distilled, purified or sterile water up to ¾ full (Fig 4.5);
6. Replace the filter assembly and close the lid tight;
7. Plug in the water connector firmly, until it “clicks” in place;
8. Power up the system:
   - Switch the Power Circuit Breaker on the back panel to the ON position (Fig 4.6);
   - Turn the Keyswitch to the ON position (Fig 4.7);
   - When the keyswitch is turned ON, the system will begin its boot-up process. The system will load the software (approximately 30 seconds).
9. Press the Ready key (Fig 4.8). If the “Water level low” error message appears, turn the system off and refill the cooling water container ¾ full;
10. Press the Ready key again and let the system run for 1-2 minutes to clear the air bubbles from all components of the cooling system;
11. Close the back door and tighten the two captive screws.


Fig 4.5


Fig 4.6


Fig 4.7


Fig 4.8

FILLING THE SELF-CONTAINED WATER SYSTEM BOTTLE

> **CAUTION:** Use only distilled, purified or sterile water with no less than 20µ Siemens/meter conductance.

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 4.9);
3. Twist the bottle clockwise and pull up the lid to open (Fig 4.10);
4. Fill the bottle with distilled, purified or sterile water only. DO NOT use tap water;
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 4.11, 4.12);


Fig 4.9

Fig 4.10

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


Fig 4.11


Fig 4.12

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

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

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

SECURING THE FIBER OPTIC ASSEMBLY TO THE UNIT

1. Looking down to the top of the console, locate the small hole on the lower left side and install the telescopic Fiber support arm (Fig 2.1);

NOTE: Take the new trunk Fiber from the accessories box and drape it around your neck (for convenience)

2. Remove the protective silver cap from the proximal end of the Fiber (Fig 4.14);


Fig 4.13

4. Remove the protective cover of the Fiber shaft (distal end) and hold it against any light source; look into the proximal end of the Fiber – it should glow yellow, be flat and clean. Replace the cover.

5. Remove the black plastic outer cover and the internal red protective cap from the laser head and laser aperture; save these for future use (do not lose them);

6. After removing the red protective cap, carefully look inside the laser aperture and check that the surface of the protective window is clean, free of water, dirt, or damage (Fig 4.15)

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

   If this does not help, call for Service.


Fig 4.14

NOTE: If the laser head is not positioned properly within the cover of the laser console, it will not be possible to connect the Fiber to the unit; call Biolase or your authorized Biolase representative for additional support.


Fig 4.15

7. Align the blue guide of the Fiber 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 4.17);

WARNING: DO NOT APPLY FORCE! Applying force may create metal shavings or shave off the o-rings of the spray connector and cause damage of the laser head components.

9. Secure the retainer ring by turning it clockwise until it is snug (Fig 4.19);
10. Align the middle length of the Fiber to the hook of the telescopic arm and push it in gently to secure it;

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

11. Remove the protective cover from the distal end of the Fiber again and verify that it is clean and not damaged (see Section 11, Maintenance and Troubleshooting) (Fig. 4.20);
12. Carefully place the Fiber with its protective cover or with the Handpiece connected in the Handpiece holder (Fig 4.21).

Fig 4.16

Fig 4.17

Fig 4.18

Fig 4.19

Fig 4.20

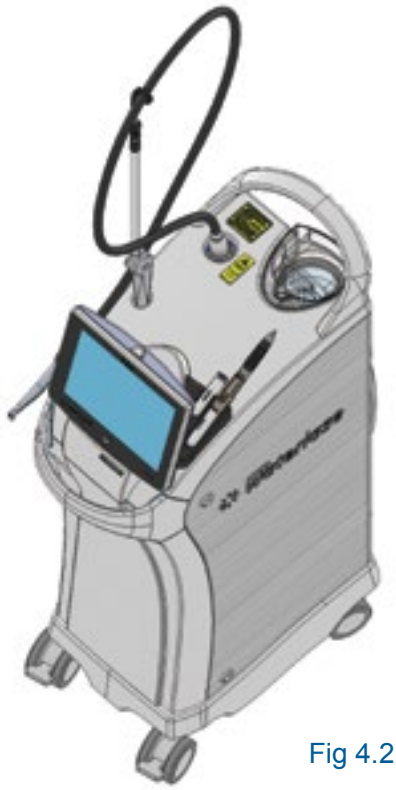


Fig 4.21

CONNECTING THE YSGG HANDPIECE TO THE FIBER OPTIC CABLE

This procedure applies to the Gold and Turbo Handpieces.

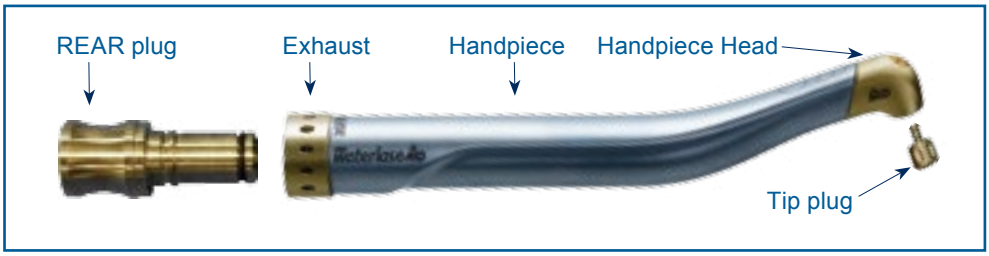


Fig 4.22

1. Remove the Handpiece from the Handpiece box;
2. Remove the rear plug from the Handpiece by pulling; place the plug in the Handpiece box to store;
3. Remove the Fiber protective cover from the Fiber shaft of the trunk Fiber by pulling; place it in the Handpiece box to store;
4. Check the Fiber shaft for any moisture and wipe off any that is found with a dry tissue;
5. Carefully insert the Fiber shaft into the Handpiece until it “clicks” (Fig 4.23, 4.24, 4.25);

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

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

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

Fig 4.23

Fig 4.24

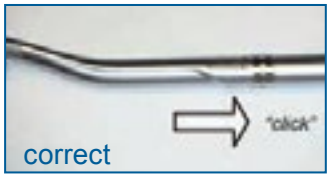


Fig 4.25

DISCONNECTING THE HANDPIECE

1. Purge the Handpiece by following the instructions described in Section 5, Level 2 Description;
2. Pull and disconnect the Handpiece from the Fiber Shaft;

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

3. Wipe any moisture off the Fiber shaft with dry tissue;
4. Check that the window at the end of the Fiber is clean and not damaged; if it's not clean, use a dry cotton swab or a tissue to clean it (Fig 4.26);
5. Carefully attach a new Handpiece or Fiber protective sheath until it "clicks" into position;

Fig 4.26

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

INSTALLING AND CHANGING THE TIP IN THE HANDPIECE

This procedure applies to the Gold and Turbo Handpieces.

1. Place the system in the **Standby** mode;
2. Proceed to **Advanced** screen (Fig 5.11) and press the Tip change button at the bottom of the screen.

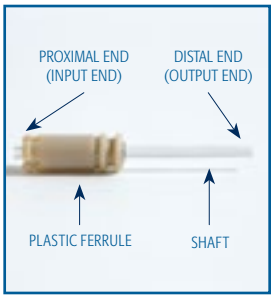


Fig 4.27

NOTE: Always change Tips after pressing the Tip change button to turn on patient air and cooling air. This helps clean the input end of the Tip from any light dirt or moisture.

Fig 4.28

3. Remove the Tip plug from the Handpiece head by pulling it out and place it in the Handpiece box;
4. Remove the Tip from its package and insert it into the Tip Remover or revolving Tip holder by aligning the first groove of the Tip ferrule against the receiving edges of the holder, then sliding the Tip in (the use of tweezers is highly recommended);

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

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

5. Align the Tip orifice in the Handpiece head over the input (proximal) end of the Tip in the Tip Remover or revolving Tip holder;
6. Carefully lower the Handpiece and insert a clean/inspected Tip all the way in until the shoulder of the Tip ferrule sits against the Handpiece head;

WARNING: 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.

7. Slide the Handpiece laterally away from Tip Remover or Tip holder.
8. Press the “Tip Change” button again on the Advanced screen to stop patient air and cooling air.

NOTE: To remove the Tip, repeat the process described in reverse order. Put your thumb against the selected Tip slot to prevent Tips from falling out of the Tip holder when connecting and disconnecting Tips from the Handpiece.

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

Caution: Use the same techniques when operating the MD Turbo Handpiece and MX Tips. Also, note that (1) the Turbo Tip holder/remover tool is different than the regular Tip holder/remover; (2) the Turbo tool works ONLY with Turbo Tips; (3) the regular tool does NOT work with Turbo Tips. Refer to the Turbo Handpiece Instructions for Use for more information. (p/n 5200147)


Fig 4.29

Fig 4.30


Fig 4.31


Fig 4.32


Fig 4.33

OPERATION

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

OVERVIEW

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

STARTING THE WATERLASE IPLUS

1. Verify that all connections have been properly secured and the Fiber cable properly attached
2. The air supply must be connected and the external air pressure must be at 80 PSI (5.5 bar) or more.
3. Electrical input should be at least 100 VAC, maximum 15 amperes, to 230VAC, 8 amperes.
4. Verify that the water bottle is more than 1/3 filled with distilled, purified or sterile water.

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

5. Switch the circuit breaker ON.
6. Insert the key into the keyswitch and rotate it clockwise to the ON position.
7. Verify the emergency stop button is not engaged, the button is not glowing red and no error message is displayed on the screen.
8. The system will begin its startup process; as the software is loaded (about 45 seconds).
9. Attach the Handpiece to the Fiber optic cable shaft (Section 4: Connecting the YSGG Handpiece to the Fiber Optic Cable).
10. Place the system into **Standby** mode and attach a Tip using the Tip remover (Section 4: Installing and Changing the Tip in the Handpiece).

ACTIVATING THE WATERLASE IPLUS

Push the Ready button to enable the WaterLase iPlus, and depress the footswitch when Ready.

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

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

TURNING THE WATERLASE IPLUS OFF

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

USER INTERFACE / GENERAL NAVIGATION

INTRODUCTION

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

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

CONTROLS AND INDICATORS.

The control panel (Fig. 5.1) has one function control button for turning the system ON and OFF, and for switching between Standby and Ready modes. Pressing and holding the button for more than 2 seconds will turn the system ON / OFF. When the system is ON, pushing the button will switch the system between Standby and Ready modes.

The control panel also has one LED indicator for system status and laser power actuation (Fig 5.1):

- Amber - indicates that the system is in Standby mode.
- Green - indicates Ready mode
- Blinking green – indicates the laser is firing.


Fig 5.1

There are also two status indicators for the iLase batteries:

- Amber – charging mode
- Green – fully charged


Fig 5.2

APPLICATIONS MENU

LEVEL 0 DESCRIPTION

After the system is powered up, it takes approximately 45 seconds for the software to load. Touch the screen to access the Level 0 Home Menu. (Fig 5.2 and Flow Chart in Fig 5.14) This screen offers a choice of one of seven operational areas:

- Restorative
- Soft Tissue
- Periodontics
- Implantology
- Endodontics
- Expanded
- REPaiR

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


Fig 5.3

NOTE: The system is in Standby mode and cannot be changed to Ready mode while the Home menu is displayed.

LEVEL 1 DESCRIPTION

Once a procedure category is selected, the system goes to Level 1, which offers the clinical applications within the selected category that have been tested and cleared for use with our WaterLase technology (Fig 5.3).

There are currently 18 procedures identified within the 7 procedure categories offered in Level 0 (See the Flow Chart, Fig. 5.14).

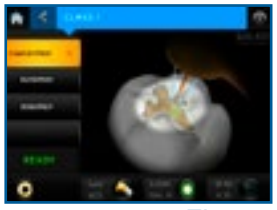


Fig 5.4

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

LEVEL 2 DESCRIPTION

When selection is made from the Level 1 menu, the system proceeds to a Level 2 (See Fig. 5.4). Here all laser operating parameters are identified as pre-sets for the selected step within the procedure, as well as several steps


Fig 5.5

recommended for the procedure. Each step has its own name and its own recommended settings.

Changing the Water in the bottle

When the system detects that the water level in the self-contained bottle is low, a blinking button with a low water level symbol will appear next to the Settings button. Place the system into **Standby** mode and follow the steps outlined in Section 4: Filling the Self-Contained Water System Bottle. To return to **Ready** mode, press the main Function button below the touchscreen.

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

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

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

Handpiece

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

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

4. Once a new Tip is attached to the Handpiece, press the Handpiece image again; a progress timer will again appear for 3-4 seconds, and the Handpiece will be primed with water.

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


Fig 5.6

Tips

Tip selection will always correspond to the selected Handpiece. The names of the respective Tips are shown below each image for reference. When Tip Selection is active, the recommended Tip is highlighted, preferred Tips for the Handpiece are outlined, and all the Tips allowed for the specific application are shown on the screen (Fig. 5.6).


Fig 5.7

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

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


Fig 5.8

Laser Power

Laser power settings, as well as pulse repetition rate and laser pulse mode, are always defined by the procedure type and the selected Tip (Fig 5.7). The Pulse Mode button switches the system between S (long pulse) and H (short pulse) modes. Laser parameters can be changed at any time in **Ready** or **Standby** modes. After adjusting these settings, press the back or Laser button at the bottom of the display to return to the Procedure screen.

Spray

Spray settings for air and water percent can also be adjusted while in **Ready** or **Standby** (Fig 5.8). Mode selection scrolls between ON, OFF and AUTO for both parameters.

CHANGING AND SAVING THE PRE-SETS

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

To save modifications to any settings, press and hold the specific procedure mode for 2 seconds. The “unlocked lock” symbol will change to a “locked lock” symbol, indicating that the settings have been saved. Otherwise, the

modifications will be lost when proceeding to a different screen.

To restore the factory pre-programmed settings for the customized procedure mode (indicated by a “locked lock” symbol), press and hold the corresponding name of the step for 2 seconds. The “star” symbol will re-appear in place of the “locked lock” symbol, confirming that the settings have been changed back to factory pre-set values.

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

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

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

De-fault settings for Illumination (both Aiming Beam and Light) are in the middle of the adjustment range. The same is true for the Sound Tone.

SETTINGS / MEMORY MENU

The Settings / Memory Menu stores up to 9 “Favorites” (Fig. 5.9). It can correspond to a particular step of the procedure described in the Main Application Menu, or it can be completely independent, if selected by the user and stored from the Advanced Menu.

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

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

When switching to the Settings/Memory Menu from the Procedure screen or the Advanced screen, the latest settings and name of the procedure step are displayed at the top of the display. To save the current settings into one of the “Favorites,” press and hold one of the nine buttons for 2 seconds; the name of

the procedure and step will appear inside the button (in the Advanced screen, the name for the button will be given as “Custom 1,” “Custom 2,”etc.).


Fig 5.9


Fig 5.10


Fig 5.11

FUNCTIONS FOR THE SETTING BUTTONS

- ADVANCED - switches the system to the Advanced screen;
- DRAIN WATER - used only when replacing the Fiber; when pressed, “Purge” and “Prime” buttons appear.

  – Purge - the Fiber is purged of water.
  – Prime - the Fiber is primed with water.
- SOUND - allows adjustment of sound setting within the range 0 to 15.
- RESTORE - leads to a dialogue screen asking “Do you want to restore all factory pre-sets?” Offers options for “YES” and “Exit.”

  – If YES is selected, all factory pre-sets are restored.
- LANGUAGE - gives an option of selecting one of mulTiple languages.
- ILLUMINATION – allows the adjustments for the visible aiming beam and light illumination for the Handpiece within a range 0 to 9.
- SERVICE - leads to the Service Menu.

CUSTOM SETTINGS

Parameters may be adjusted without any limitations and without any relation to any procedure in the Advanced screen (Fig. 5.11).

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

SYSTEM POWER LIMITS*				
	H - mode		S - mode	
Pulse rate, Hz	Min power, W	Max Power, W	Min power, W	Max Power, W
5	0.10	2.50	0.10	2.50
8	0.10	4.75	0.10	4.75
10	0.10	6.00	0.10	6.00
12	0.10	7.25	0.10	7.25
15	0.10	9.00	0.10	9.00
20	0.10	10.00	0.10	10.00
25	0.25	10.00	0.25	10.00
30	0.25	10.00	0.25	9.00

*These parameters are for all MX, MC Tips and MZ10, MZ8, MZ6 and MS75 Tips.

SYSTEM POWER LIMITS*				
	H - mode		S - mode	
Pulse rate, Hz	Min power, W	Max Power, W	Min power, W	Max Power, W
40	0.25	9.00	0.25	8.00
50	0.25	8.00	0.25	6.00
75	0.50	6.00	0.00	0.00
100	0.50	4.00	0.00	0.00

Fig 5.12


Fig 5.13

DESCRIPTION OF FUNCTIONAL BUTTONS:

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

OTHER SCREENS

- Help “i” icon – found on every screen, accesses an Information/ Recommendations Screen.
- Error screen - appears when a system error is detected. It will give the Error name and recommendations for correcting the error (Fig 5.12).
- Service - provides a pass code to allow entry to authorized Service personnel only (Fig 5.13).

SYSTEM FLOW CHART:

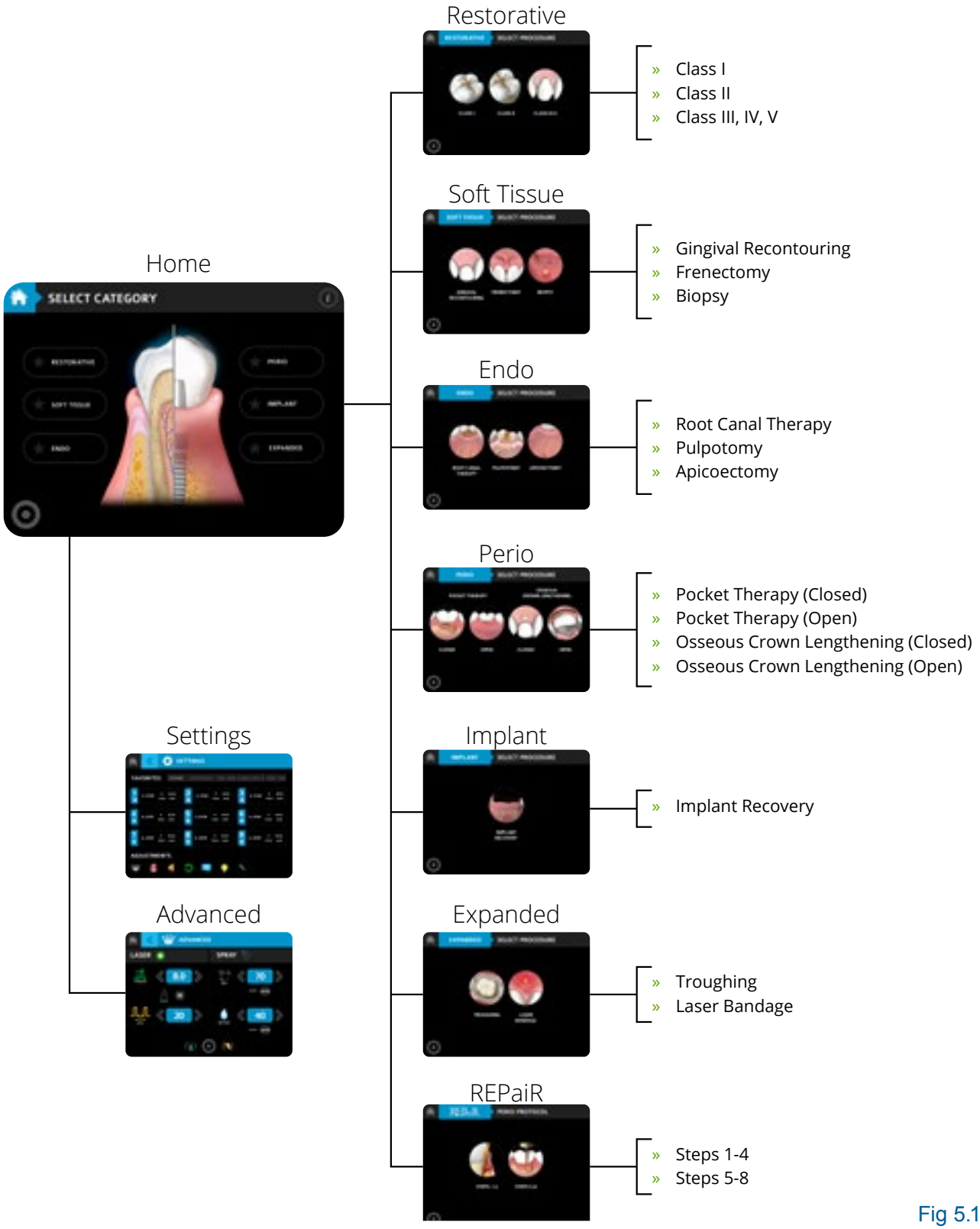


Fig 5.14

6 Specifications

DIMENSIONS (W X L X H)

• Unit	11 x 19 x 33 in (28 x 48 x 84cm)
• With Fiber	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 VAC ± 10% / 230VAC ± 10%
• Frequency:	50 / 60 Hz
• Current rating:	5.0 A / 8A
• Main control:	Circuit breaker
• On / Off control:	Keyswitch
• Remote interruption:	Remote interlock connector

WATER SPRAY

• Water type:	Distilled, De-ionized, or Sterile
• External air source:	80 - 120 psi. (5.5 - 8.2 bar
• Water:	0 - 100%
• Air:	0 - 100%
• Interaction zone:	0.5 - 5.0 mm from Handpiece Tip to target

OPTICAL

• Laser classification:	4
• Medium:	Er,Cr:YSGG (Erbium, Chromium:Yttrium, Scandium,Gallium, Garnet)
• Wavelength:	2.78 µm (2780nm)
• Frequency:	5 – 100 Hz
• Average power:	0.1 – 10.0 W
• Power accuracy:	± 20%
• Pulse energy:	0 – 600 mJ
• Pulse duration for “H” mode:	60 µs
• Pulse duration “S” mode:	700 µs
• Handpiece head angles:	70° contra-angle
• Gold HP Tip diameter range:	200 – 1200 µm
• Turbo Tip focal diameter range:	500-1100 µm
• Output divergence:	≥ 8° per side
• Mode:	Multimode
• Aiming Beam:	635nm (red) laser, 1mW max (safety classification 1)*
• Water Level Sensor Beam:	635nm laser, 1mW max (safety classification 1)
• Nominal Ocular Hazard Distance (NOHD):	5cm
• Maximum Permissible Exposure (MPE):	3.5 x 105 W/m2

**See separate specifications for the iLase Diode Laser Handpiece in the iLase User Manual Biolase P/N 5400230*

7 Indications for Use

IMPORTANT: Review all Contraindications, Warnings and Precautions presented in Section 8 before proceeding with using this device on patients.

WATERLASE IPLUS IS INDICATED FOR:

HARD TISSUE

GENERAL INDICATIONS*

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

** For use on adult and pediatric patients*

ROOT CANAL HARD TISSUE INDICATIONS

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

ENDODONTIC SURGERY (ROOT AMPUTATION) INDICATIONS

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

BONE SURGICAL INDICATIONS

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

LASER PERIODONTAL PROCEDURES

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and 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.

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 soft tissue to prepare a flap and expose unerupted teeth (hard and 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.

8 Contraindications, Warnings, and Precautions

CONTRAINDICATIONS

All clinical procedures performed with the WaterLase iPlus must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully under stood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions which might contraindicate a local procedure. Such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease (e.g. pacemakers, implantable defribulators), 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 physician or other licensed medical practitioner.

EYEWEAR

Doctor, patient, assistant, and all others inside the operatory must wear appropriate laser protection eyewear for the 2780nm and 940nm wavelengths (OD 4 or greater).

ANESTHESIA

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

TREATMENT, TECHNIQUE AND SETTINGS

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

HARD TISSUE PROCEDURES

All hard tissue (i.e. enamel, dentin, cementum and bone) procedures must be performed using air and water spray at appropriate settings. Failure to use the spray will result in tissue thermal damage. The long pulse settings (700 µs) are indicated only for soft tissue applications. Do not use long pulse settings to perform hard tissue procedures.

SOFT TISSUE PROCEDURES

Soft tissue procedures can be performed using two pulse duration settings: (H) short pulse (60 µs) and (S) long pulse (700 µs). However, the long pulse (S) range is indicated ONLY for soft tissue applications.

CURETTAGE PROCEDURES

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

FLUID ENTRAPMENT AND AIR EMBOLISM

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

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 Fiber Tip may break or perforate through the wall of these types of canals. If during insertion the Fiber Tip does not advance easily into the canal, do not force the Tip inside. If necessary, pull the Fiber 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 Fiber 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 Fiber Tips designed for this indication are the radial emitting RFT2 and RFT3, which have a 200µm and a 300µm diameter, respectively, and come in various lengths to accommodate different root canal lengths. Effective laser root canal disinfection is performed with air and no water spray. Do not exceed the maximum air setting for this procedure (10%).

ADJACENT STRUCTURES

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

CLINICAL CONDITIONS

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

TISSUE EVALUATION

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

TISSUE CONTACT AND TIP BREAKAGE

Do not contact hard tissues with the Fiber 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 Fiber Tip, Handpiece, or affect the emission of laser energy around the Tip. A careful review of the instructions on how to replace the Tip is recommended.

WATER SPLASHING

Water from spray may splash during treatment. Use protective eyewear and/or a face shield to protect from splashing. Use high-speed suction, as needed, to maintain a clear field of vision during treatment. Do not use the WaterLase iPlus if you 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. Do not direct energy towards dental cements or other similar filling materials. Doing so may damage the WaterLase iPlus Tip and delivery system.

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.

INTRODUCTION

The WaterLase iPlus device is designed to cut and remove hard and soft tissues within the oral cavity. For hard tissue applications, the WaterLase iPlus achieves its uniquely diverse capabilities through the process of light absorption by water. The proprietary flexible Fiber optic system and Handpiece deliver both optical energy and atomized water to the treatment site for precise hard tissue removal.

To efficiently remove hard and soft tissues it helps to understand the unique nature of the WaterLase iPlus device. WaterLase iPlus operates unlike traditional dental instruments or devices and technique must be practiced and perfected to ensure efficient operation.

Please be aware that the WaterLase iPlus system removes hard tissues with the Fiber Tip applied in a non-contact mode. Great care must be taken not to brush or push the Tip into tissue during treatments. The Tip is fragile and may break if knocked or pressed into the tooth or other instruments.

For soft tissue applications, cutting is achieved in both a contact or non-contact mode by application of direct laser energy, either with or without water cooling and hydration spray. A detailed description of the techniques for cutting hard and soft tissues with WaterLase iPlus is presented in the following subsections.

Please study this Section carefully, practice on tissue models and attend a WaterLase iPlus training seminar before using this device in a clinical situation.

HARD TISSUE CUTTING

Hard tissue cutting is achieved through a unique process that utilizes laser-energized water and results in quick and clean hard tissue removal.

Once settings have been selected for enamel, dentin or cementum cutting, carefully position the Fiberoptic Tip approximately 5 mm away from the targeted tissue site to test the laser system. Step on the footswitch, and water spray and power will be immediately delivered to the tissue site. You will notice a distinct, gentle “popping” noise as water expands from laser energy absorption. From this position (5 mm away from targeted tissue, or slightly more if using the Turbo Handpiece), there will be minimal to no cutting effect. If the water spray is not flowing, or no distinct popping noise is present, stop the system immediately. Refer to the troubleshooting section of this Manual for instructions or call your local representative for assistance.

NOTE: Always remember that laser power, and therefore energy, is delivered from the very end of the Tip. Laser tissue cutting technique can be characterized as “end cutting,” whereas the mechanical drill is known as a “side cutting” instrument.

If the water flow and laser energy (“popping” sound) are satisfactory, gently and slowly move the Handpiece Tip closer to the targeted tissue site. A large accumulation of water may be noticeable when approaching the treatment area. Use high speed suction as needed to keep the field clear. Due to the

great differences between traditional dental drill and WaterLase iPlus cutting techniques, it is very important to have the exact treatment location visually identified before and during treatment.

Maintain a distance of 0.5 to 3 mm between the Fiber Tip and the treatment tissue (3 to 5 mm for Turbo Handpiece) while moving the Handpiece over the tissue surface as required. Keep in mind that cutting speed is determined primarily by parameter settings and distance from tissue, not by rapid hand movement as with the high-speed drill. Gently and slowly move the Handpiece in a circular, brushing, or in-and-out motion as required to remove the desired tissues or materials. Unlike traditional dental instruments, the WaterLase iPlus will remove tissue more effectively the slower the Handpiece Tip is moved over the treatment site.

Cutting efficiency will vary depending upon the power setting, Tip diameter, and spray configuration. If the system is working slowly for the selected application at the selected power level, the air and water spray settings can be adjusted. Clinical efficiency depends upon power as well as spray. Increased experience with the WaterLase iPlus will make it easier to determine spray and power efficiency from the sound of the popping water droplets. A sharper, more distinct popping sound represents a higher cutting rate.

After completing the treatment, release the footswitch and carefully remove the Handpiece from the patient's mouth. Do not hit the Handpiece Tip on teeth or other instruments while removing the Handpiece or the Tip may break. To remove the Tip, use the Tip remover tool. Place a new Tip on the Tip plug to avoid contamination and damage to the Handpiece. At the end of the treatment, the Handpiece and Tip must be autoclaved (Section 10: Cleaning and Sterilization), except for single-use Tips (such as ZipTips, RFPT, RFT, and some others) which must be disposed of in a biohazard medical waste Sharps container after use. **Single-use Tips should not be reused to prevent cross-contamination.**

SOFT TISSUE INCISION, EXCISION, AND ABLATION

Soft tissue procedures are performed with direct laser energy, either with or without water spray. Water spray settings are generally lower for soft tissue than for hard tissue. During soft tissue cutting, the air and water spray hydrate and cool the targeted tissue. There are two pulse settings for soft tissue applications: (1) a short pulse setting of 60 µs, and (2) a long pulse setting range of 700 µs. The second range of pulses is indicated only for soft tissue applications.

For these procedures, select appropriate settings or presets as described in the GUI instructions (Section 5: Operating Instructions). Once settings or presets have been selected, carefully place the Tip in contact with the tissue to be incised. Step on the footswitch and start moving the Tip along the tissue surface by applying light pressure. The incision will be noticed immediately after laser activation. Bleeding is controlled through reduction of the water setting or changing to S mode. For superficial lesions or hemostasis, the Tip must be placed out of contact at approximately 1-3 mm off the surface. The most effective hemostasis is achieved when the water spray is turned off.

PRESETS FOR SOFT AND HARD TISSUE PROCEDURES

As described before, WaterLase iPlus has the option of nine user programmable presets stored in the system memory. There are about 50 pre-set settings to select from or adjust to appropriate values for the procedure. Always start treatment at the lowest recommended power setting and increase as necessary using clinical judgment. The values pre-programmed with the system are suggested values only. Use your clinical judgment to adjust individual values for Power, Water, Air, Pulse Repetition Rate, and Mode S/H in order to compensate for variations in tissue composition, density and, or thickness. When a particular combination of customized values is especially effective and useful, you have the option to store them as a new Preset (Section 5: Settings/Memory Menu).

The WaterLase iPlus may be used for the applications listed in Section 7: Indications for Use. If you are not sure which preset or settings are best for a chosen procedure, please refer to the suggested settings on the device or use your clinical experience to make the appropriate adjustments. Attend training courses and experiment on model tissues before using the WaterLase iPlus on patients.

Refer to the WaterLase Clinical Manual for a list of pre-sets programmed into the WaterLase iPlus.

HANDPIECE AND TIP CLEANING AND STERILIZATION

CAUTION: Handpieces and laser Tips MUST be sterilized prior to initial use and cleaned and sterilized between patients. Disposable single-use Tips must be disposed of in a biohazard medical waste Sharps container. To clean the Fiber, wipe with alcohol.

CAUTION: Cleaning must be performed within a maximum of 1 hour after the procedure and prior to sterilization.

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

STEP 1—CLEANING PROCESS

The cleaning process is intended to remove blood, protein and other potential contaminants, and 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 office personnel trained to perform the procedure and handle the laser Handpiece and Tips while wearing goggles, masks, gloves, and shields.

1. Upon completion of the clinical procedure detach the Handpiece from the Fiber; ensure that the laser Tip remains installed in the Handpiece. Do not remove the Tip.
2. Insert the Rear Plug into the Handpiece; during the cleaning procedure care must be taken to prevent the cleaning solution and rinse water from entering the portals of the exhaust ring.
3. Rinse the Handpiece with the Tip still installed under lukewarm water (22 – 43°C) for 10 seconds to remove gross soil.
4. Prepare a cleaning solution per the manufacturer's instructions. Use a commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol®, or a similar enzymatic presoak and cleaner. Follow instructions for disposal of used solution.
5. Soak a piece of gauze large enough to wrap the Handpiece in the cleaning solution. Squeeze out the excess liquid and wrap the Handpiece with the Tip still installed and leave it wrapped for a minimum of 10 minutes.
6. Unwrap the Handpiece and Tip and, 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. Avoid contact with the exhaust ring and portals.
7. Rinse the Handpiece under lukewarm running tap water (22-43°C) for 10 seconds.
8. Dry the Handpiece with a lint-free cloth.

9. Visually inspect the Handpiece for any residual soil. If any residual soil is still present, repeat steps 5 through 8 until it is removed.
10. Using the Tip Remover or Revolving Tip holder, remove the Tip from the Handpiece per the steps outlined below.
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.

Tip removal using the Tip Remover or Revolving Tip Holder

- Slide the Handpiece laterally toward the Tip Remover or Revolving Tip Holder (Fig 10.1)
- Place your thumb against the selected Tip slot to prevent the laser Tip from falling out of the Tip holder when disconnecting it from the Handpiece
- Carefully lift the Handpiece to disengage the Tip ferrule from the Handpiece head
- Use tweezers to slide the Tip out from the Tip holder or Tip Remover (Fig 10.2)

Fig 10.1

Fig 10.2

12. If the Tip is a single-use accessory, dispose of in a biohazard medical waste Sharps container. If the Tip is reusable, rinse it with distilled, purified or sterile water for 10 seconds and then dry with a lint-free cloth.
13. Visually inspect the Tip for any residual soil. If any is present, repeat step 12 until all residual soil is removed.

STEP 2—HANDPIECE STERILIZATION PROCESS

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

The Handpiece can be sterilized with no loss of functionality up to 100 autoclave cycles.

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

1. Prior to sterilization, remove the Rear and Tip plugs, if installed.
2. Place the Handpiece inside a single-wrap, self-sealed pouch.

3. **The Tips may be autoclaved in the Tip holder.** Place the individual Tips or the Tip holder loaded with Tips into a separate single-wrap self-sealed pouch.
4. Place the pouches on an autoclave tray. Take care when handling the Handpiece and Tip(s).
5. Do not stack other instruments on top of the pouches.
6. Place the tray into the autoclave chamber and set the autoclave to the appropriate cycle, as recommended below.

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 (EU only)	4 minutes	20 - 30 minutes

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 4, Installing and Changing the Tip in the Handpiece.

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

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

DAILY MAINTENANCE

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

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

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

MIRROR CHECK AND CLEANING

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

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

Set the system in **Standby** mode, navigate to the illumination screen (Fig 5.10), and remove the Tip.

MIRROR INSPECTION AND CLEANING

Point the Handpiece towards a white surface. The visible spot of the aiming beam should be clear, uniform, and well confined. If dark areas and irregularities are present, inspect the mirror (Applies to both Turbo and Gold Handpieces).

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

Fig 11.1

REMOVING THE HANDPIECE MIRROR

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

Fig 11.2

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

2. Insert the other side of the tool perpendicular to the plane of the backside of the mirror inside the opening. Screw the threaded side of the tool into the mirror by turning the tool 2-2½ full turns. Do not thread all the way into the mirror for easier release of the mirror later (Fig 11.3);

Fig 11.3

3. Pull the mirror straight out from the head opening (Fig 11.4). Wear gloves or finger-Tips — Do not handle the mirror with bare hands. Grab the mirror with fingers or tweezers and unscrew it from the tool. If you touch the mirror surface, gently clean it with a cotton swab moistened with alcohol.

Fig 11.4

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

Fig 11.5

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

Fig 11.6

CHANGING THE HANDPIECE MIRROR

1. To inspect the mirror, remove it following the proper procedure as illustrated above;
2. Mirror can be contaminated or damaged (Fig 11.7);

Fig 11.7

3. A contaminated mirror can be cleaned with a cotton swab moistened with optical grade acetone or alcohol, as follows (Fig 11.8):
   - Place the wet swab over the mirror surface and wait for approximately 5 seconds for the solvent to soften the contaminating material;
   - Wipe off the contamination by a quick turn and removal of the swab
   - Repeat several times until all contamination is removed.
5. If the mirror has remaining burn marks or scratches, it should be replaced;
6. While the mirror is removed, and if it has contamination or burn marks, clean the internal reflector inside the Handpiece head with a long cotton swab moistened with acetone or alcohol;
7. Install the new or cleaned mirror and check for proper alignment (Fig 11.5, 11.6).


Fig 11.8

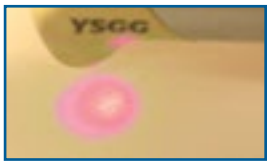


Fig 11.9


Fig 11.10

MIRROR ALIGNMENT CHECK

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

FIBER CHECK

NOTE: Regularly inspect the end of the Fiber Shaft. Always inspect and clean the Protective Window at the end of the Fiber Shaft 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 Delivery System.

1. Disconnect the Handpiece following the proper procedure described in Section 4: Set Up Instructions;
2. Verify the laser is in **Standby** mode;
3. Check the polished reflective surface of the window at the distal end of the Fiber Shaft (Fig 11.10, 11.12);
4. If the surface is contaminated, clean the window with a cotton swab dipped in isopropyl alcohol; if the window is damaged (a crater is visible in the middle of the window), replace it, as follows:
   - Using a small pin, push the tab of the window holder (Fig 11.13);
   - Pull out the window holder from the metal bearing (Fig 11.14);
   - Immediately insert the new window holder by aligning the tab to the rectangular hole; the tab should snap into the hole (Fig 11.15).
5. Wear protective eyewear and navigate to the illumination screen (Fig 5.10);
6. The visible aiming beam and illumination Fibers should be lit (adjust brightness, if necessary); if the aiming beam is not visible, replace the Fiber Delivery System.

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

Fig 11.10

Fig 11.12

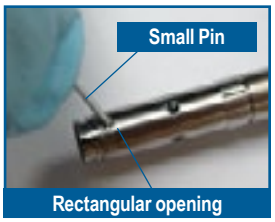


Fig 11.13


Fig 11.14

Fig 11.15

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 your local representative to discuss extended service contracts and annual maintenance options.

DELIVERY SYSTEM

The Fiber and Handpiece represent a sophisticated technology of laser-transmitting components. Depending on use, and due to the precision involved in the manufacture and alignment of the laser beam and internal optics, the components may need to be periodically replaced to maintain tissue cutting efficiency. Properly following the operating and maintenance instructions of this 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 unit will usually deliver lower power than normal if this is the case. Please contact your service representative for assistance.

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 your local service representative for assistance.

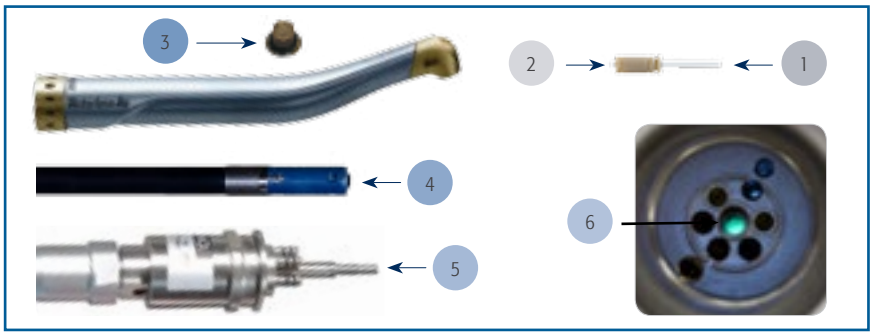
Error Number	Error	Reason	Fix	Corrective Action
6	All bottle sensors off	Possible error in light source	Check bottle sensor light source	Check bottle straw, clean sensors
7	Bottle sensor 1 off, 2 on	Possible defective sensor 1	Check Bottle sensor	Check bottle straw, clean sensors
8	All bottle sensors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

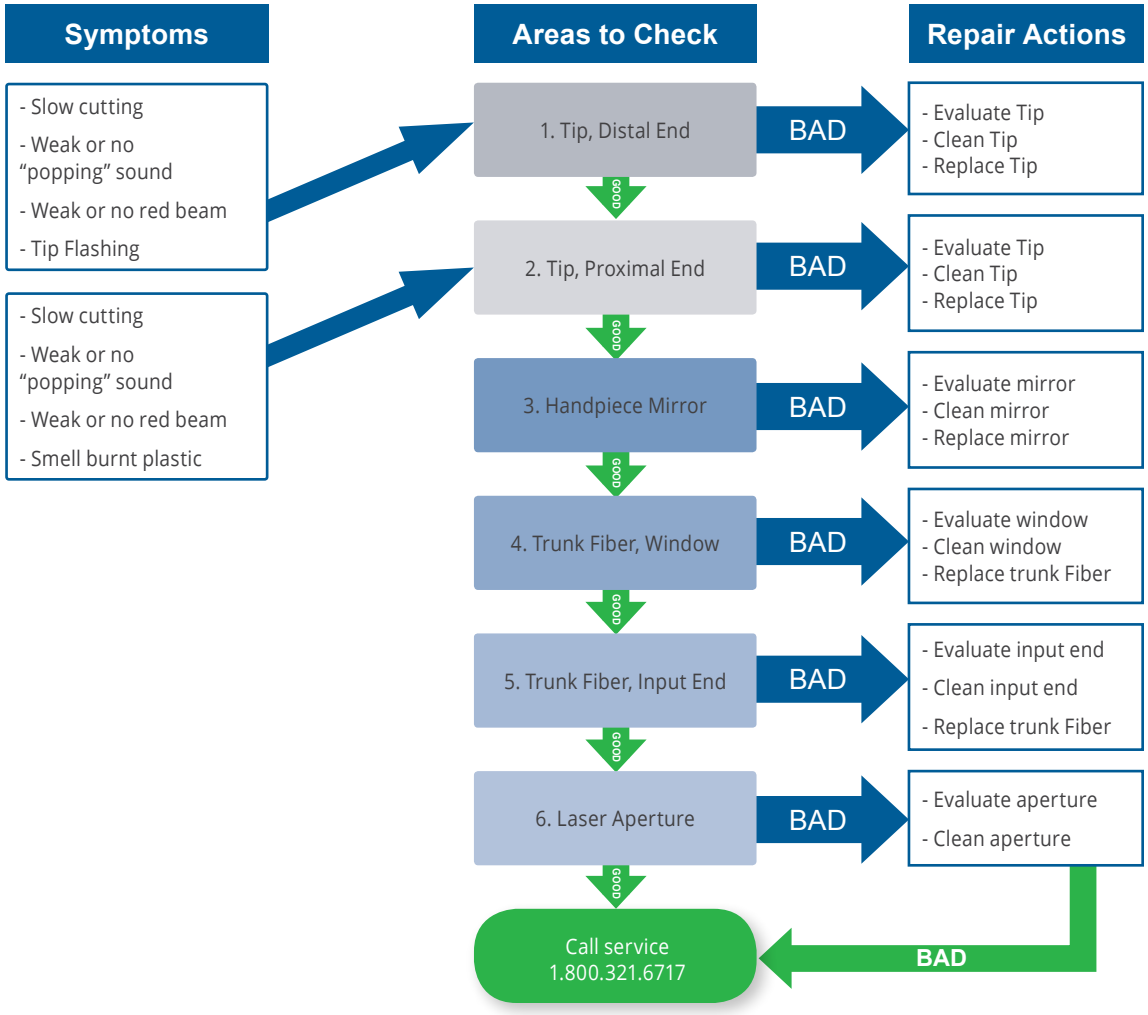
TROUBLESHOOTING THE DELIVERY SYSTEM

USING THE FLOWCHART:

- Find the Symptom (left);
- Inspect the Areas to Check (middle);
- Perform the recommended Repair Action (right).

Use the Repair Actions to direct you to the appropriate corrections in this reference guide.





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 unit 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 unit 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 unit over doorway thresholds and other bumps or objects on the ground.

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

Once crated, the unit should be transported by forklift or pallet jack, and should never be laid on its side, dropped, or banged. If you have any questions regarding transportation please call your local representative.

STORAGE

The WaterLase iPlus should be stored in a cool dry place when not in use. Storage temperature should be 15° to 30°C (59°F to 86°F), relative humidity 20% to 80%. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged

13 Calibration

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.

CALIBRATION SCHEDULE:

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:

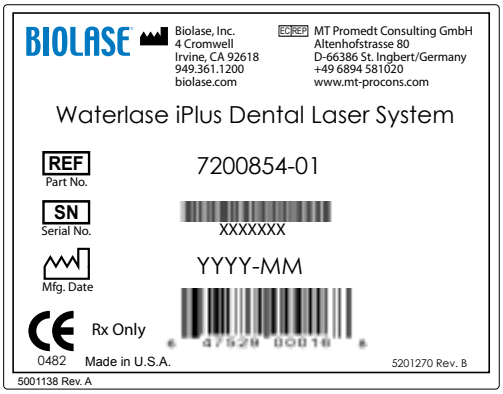
INSTALLATION AND CALIBRATION DATES:

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:

PRODUCT IDENTIFICATION LABEL

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

Location: Back Panel, above ventilation channels



MANUFACTURER

CATALOG/PART NUMBER

PRODUCT SERIAL NUMBER

DATE OF MANUFACTURE

REFER TO INSTRUCTION MANUAL

Location: Back panel

TYPE BF APPLIED PART

Location: Distal end of trunk Fiber (one side)

DUTY CYCLE

Location: Distal end of trunk Fiber (opposite side)

LASER HAZARD SYMBOL

Indicates the system contains a laser.

Location: Top cover of Laser head, directly above the Fiber Optic 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

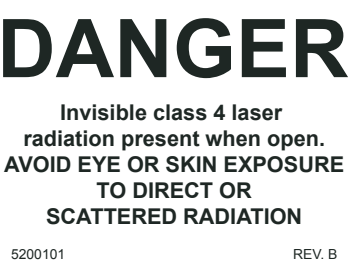
CERTIFICATION

This device complies with FDA laser standards.

Location: Back Panel

NON-INTERLOCKED PROTECTION HOUSING WARNING

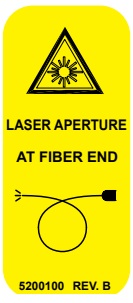
Location: Laser head, access plate
(Accessible only during service proceedings).



LASER APERTURE

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

Location: On the top cover, adjacent to Fiber Optic Connector



LASER EXPLANATORY LABEL

Provides laser specifications

Location: On top cover, adjacent to Fiber optic connector

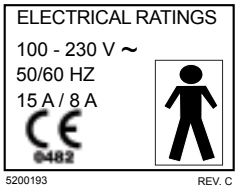
SYSTEM GROUND CONNECTION

Location: Inside unit, left.

ELECTRICAL SHOCK RATINGS

Type BF Applied Part

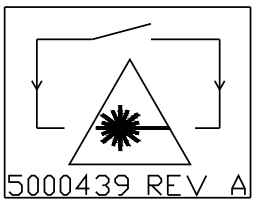
Location: Next to E1 ground terminal, inside unit.



REMOTE INTERLOCK LABEL

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

Location: Back Panel



ETL LISTED: UL/CSA CONFORMANCE LABEL

Location: Back Panel

FOOTSWITCH LABEL

Connection to footswitch

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 unit.

ATTENTION (SMALL)/GENERAL WARNING

Location: Back Panel

AIR LABEL

Indicates minimum and maximum air pressure

Location: Wall & Back Panel

KEY SWITCH LABEL

Turns laser on and off when key inserted.

Location: Back panel

WEEE (WASTE ELECTRICAL AND ELECTRONIC)

Do not throw in trashbin. Dispose of as regulated.

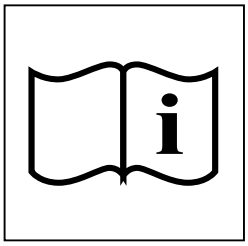
Location: Back Panel

POTENTIAL EQUALIZATION TERMINAL (PEQ)

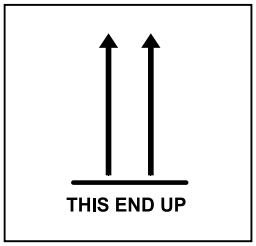
Potential equilization conductor used to connect the GND terminal of the operatory.

Location: Lower back panel

OUTER PACKAGING



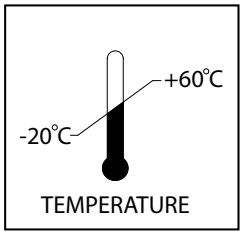
SEE INSTRUCTIONS FOR USE



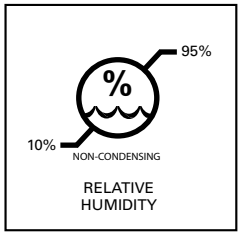
THIS END UP

HANDLE WITH CARE

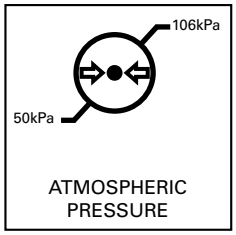
KEEP DRY



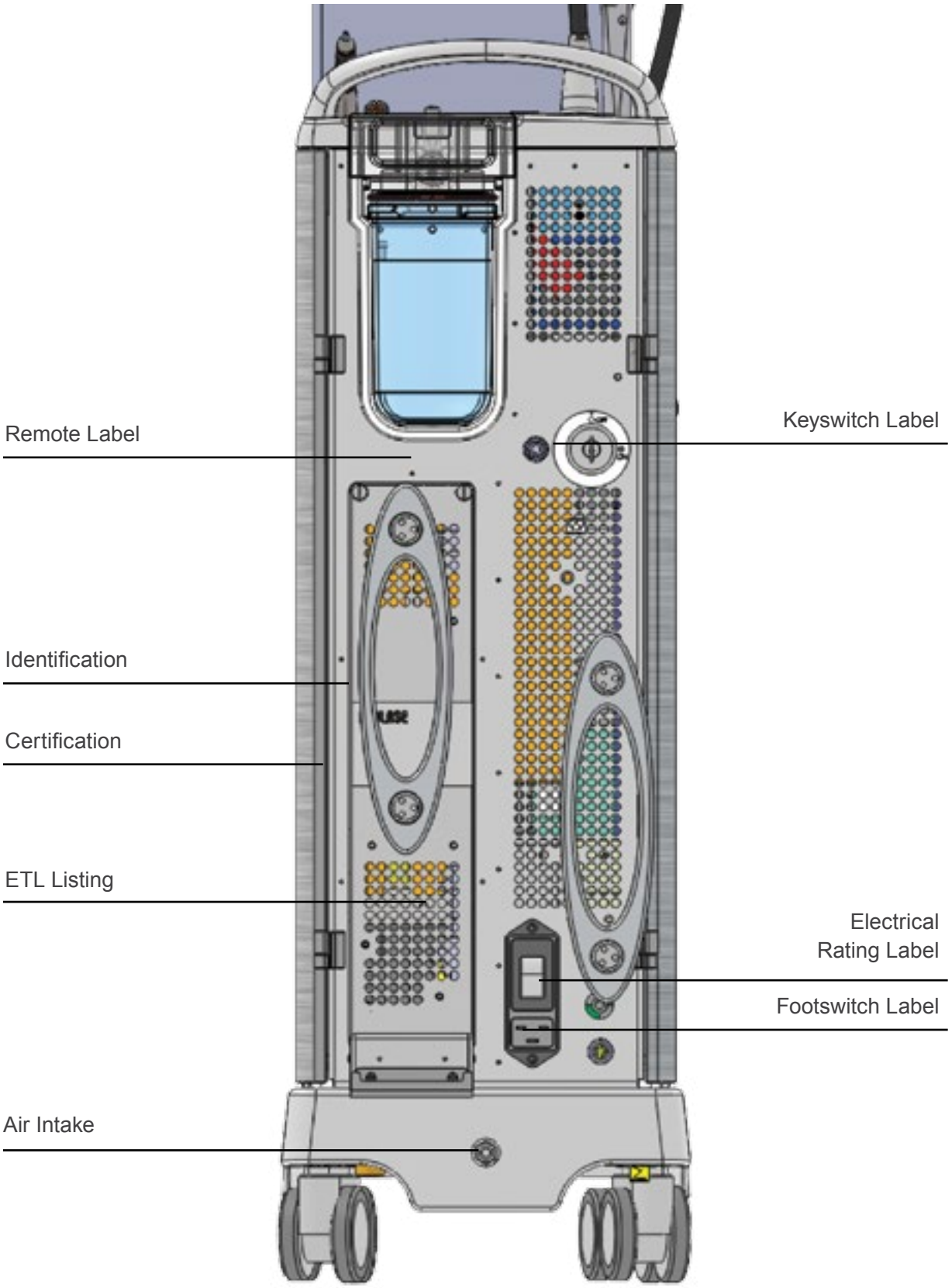
TEMPERATURE LIMITATIONS

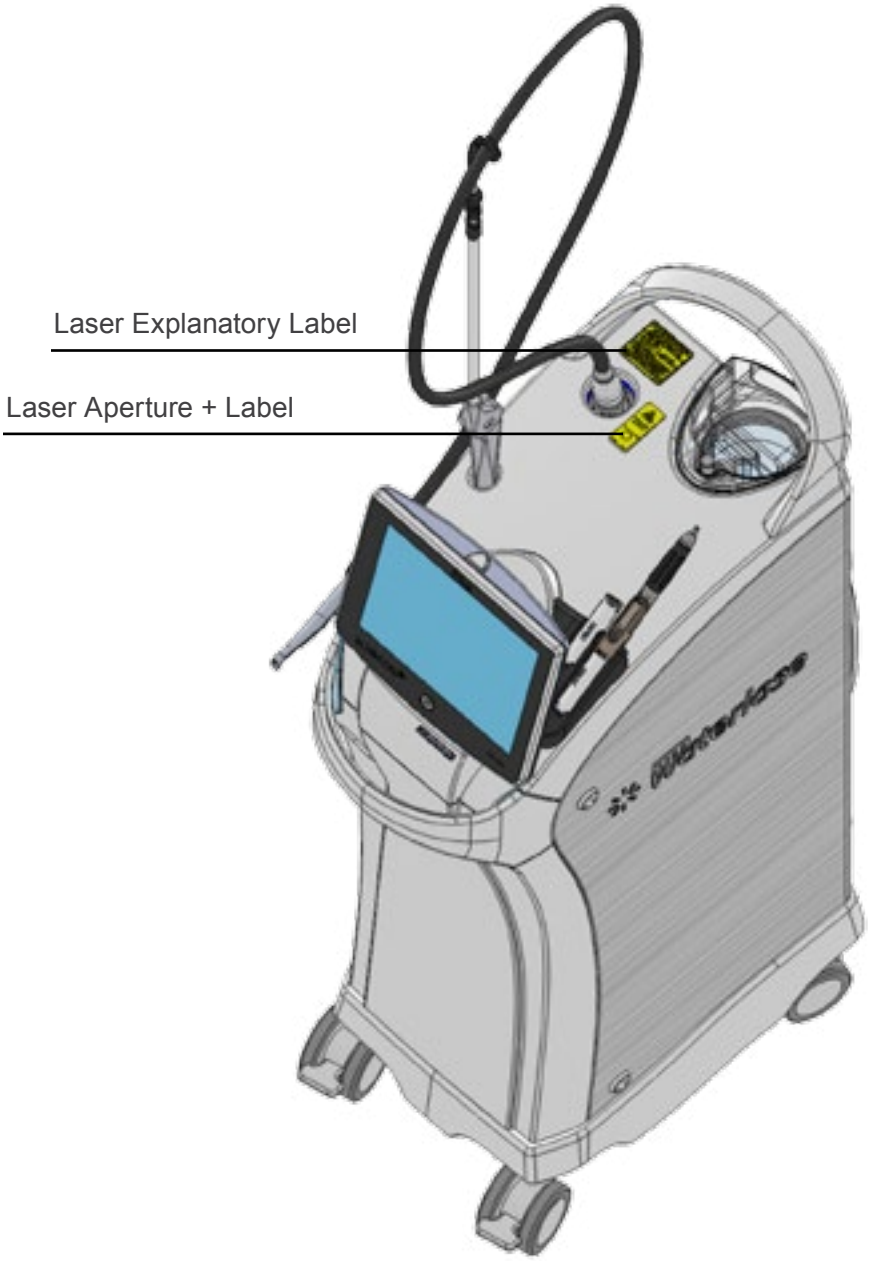


HUMIDITY LIMITATIONS



ATMOSPHERIC PRESSURE LIMITATIONS


Remote Label
Keyswitch Label
Identification
Certification
ETL Listing
Electrical
Rating Label
Footswitch Label
Air Intake


Laser Explanatory Label
Laser Aperture + Label

Appendix B Accessories

ACCESSORIES LIST

BIOLASE P/N	DESCRIPTION
2200479	Keys
6200238	Remote interlock
6200150	Footswitch
2200798	Glasses (YSGG protection)
2200696	Glasses (Multi-wavelength protection)
2000204	Power cord (USA)
2200485	Power cord (International)
6001029	Air hose
6201074	Trunk Fiber
6200500	Contra-angle gold Handpiece
6201126	Contra-angle turbo Handpiece
6200502	O-rings, Turbo Tip MX11 (qty. 4)
6200503	O-rings, Turbo Tip MX9 (qty. 4)
7000414	Tip holder/Remover (Gold HP)
7200407	Tip holder/Remover (Turbo HP)
7200831	Tip starter kit*
7200104	Tip inspection kit
2200706	Display covers (qty. 25)
5201281	Danger sign

*TIP STARTER KIT

Qty	DESCRIPTION
1	MC3-9mm flat Tip
2	MZ10-6mm ZIPTIP 1000 µm
3	MZ8-6mm ZIPTIP 800 µm
4	MZ5-6mm ZIPTIP 500 µm
2	MZ5-9mm ZIPTIP 500 µm
2	MZ6-6mm ZIPTIP 600 µm
1	MZ6-9mm ZIPTIP 600 µm
1	MT4-6mm Tip

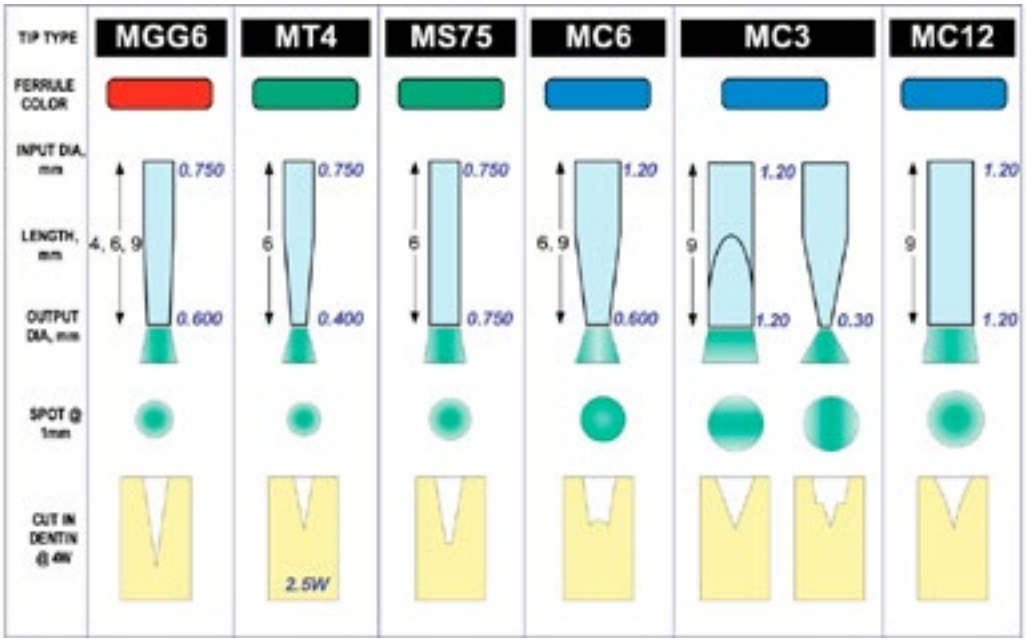
TIP SETTINGS: WATERLASE IPLUS GOLD HANDPIECES

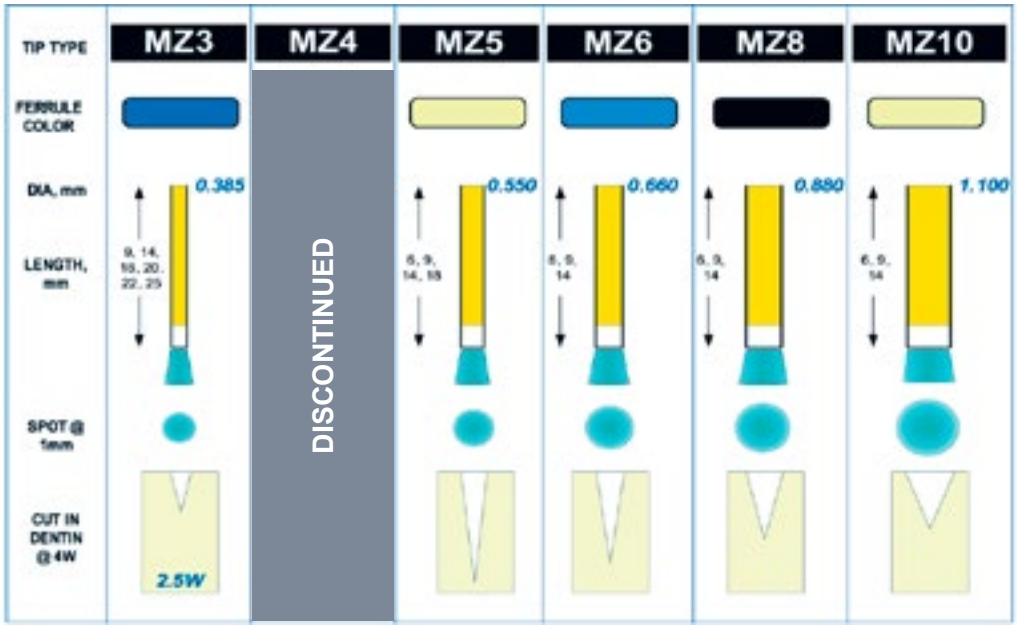
Z - GLASS TIPS

Tip Type	Ferrule Color/ Diameter (µm)	Lengths (µm)	Gold Handpieces		Tissue Types
			Calibration Factor*	Maximum Power (W)	
RFT2	200	21, 25	0.55	4.0	Root Canal
MZ3	320	9, 14, 18, 20, 22, 25, 28	0.85	4.0	Root Canal, Soft Tissue
RFT3		17, 21			Root Canal
MZ5	500	3, 6, 9, 14	.95	4.0	All Types
RFPT5		10, 14		6.0	Bone, Soft Tissue
MZ6	600	3, 6, 9, 14	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MZ8	800	3, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MZ10	1000	3, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue

SAPPHIRE TIPS

Tip Type	Ferrule Color/ Diameter (µm)	Lengths (µm)	Gold Handpieces		Tissue Types
			Calibration Factor*	Maximum Power (W)	
MT4	400	6	1.00	2.5	Enamel, Dentin, Soft Tissue
MGG6	600	4, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MS75	750	6	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC3	300 x 1200	9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC6	600	4, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC12	1200	9	1.00	No Limit	Bone, Dentin, Soft Tissue





CALCULATING EMITTED POWER WITH TIP ATTACHMENT:

EXAMPLE 1:

- Tip Type: MZ5
- Calibration Factor: 0.95
- Display Power: 4W

Then the Power Emitted is: 4W x 0.95 = 3.80 W

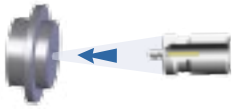
EXAMPLE 2:

- Tip Type: RFT2
- Calibration Factor: 0.55
- Display Power: 1W

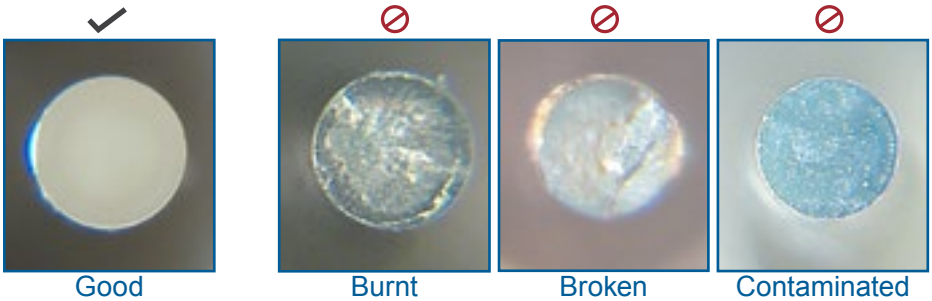
Then the Power Emitted is: 1W x 0.55 = 0.55 W

TIP INSPECTION INSTRUCTIONS

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

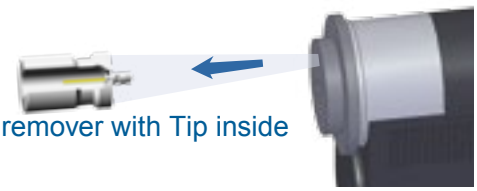


Tip remover with Tip inside



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.

TIP CLEANING INSTRUCTIONS

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

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 you suspect that part of the O-ring still remains inside the Handpiece, blow dry, clean air through the Handpiece.

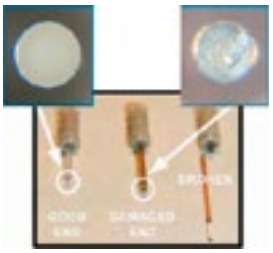


Fig D.1

FIBER TIP INSPECTION

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

Fig D.2

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

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

   Look for chips or nicks along the edges (Fig. D.1).

2. Check the plastic ferrule to ensure it is clean and has no burn marks at the input end (Fig. D.2). If burn marks are present, check the Handpiece alignment (see Section 11).

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 EMISSIONS

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

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	**Group 1**	The WaterLase iPlus laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	**Class A**	The WaterLase iPlus laser is suitable 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**	

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: Ur is the A.C. mains voltage prior to applications of the test level.			

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 maxi mum 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.			

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 EPIC DIODE LASER			
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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