YSGG waterlase MD

ALL-TISSUE LASER FOR DENTISTRY

USER MANUAL

BIOLASE®

Biolase YSGG Waterlase® MD™
Laser User Manual.

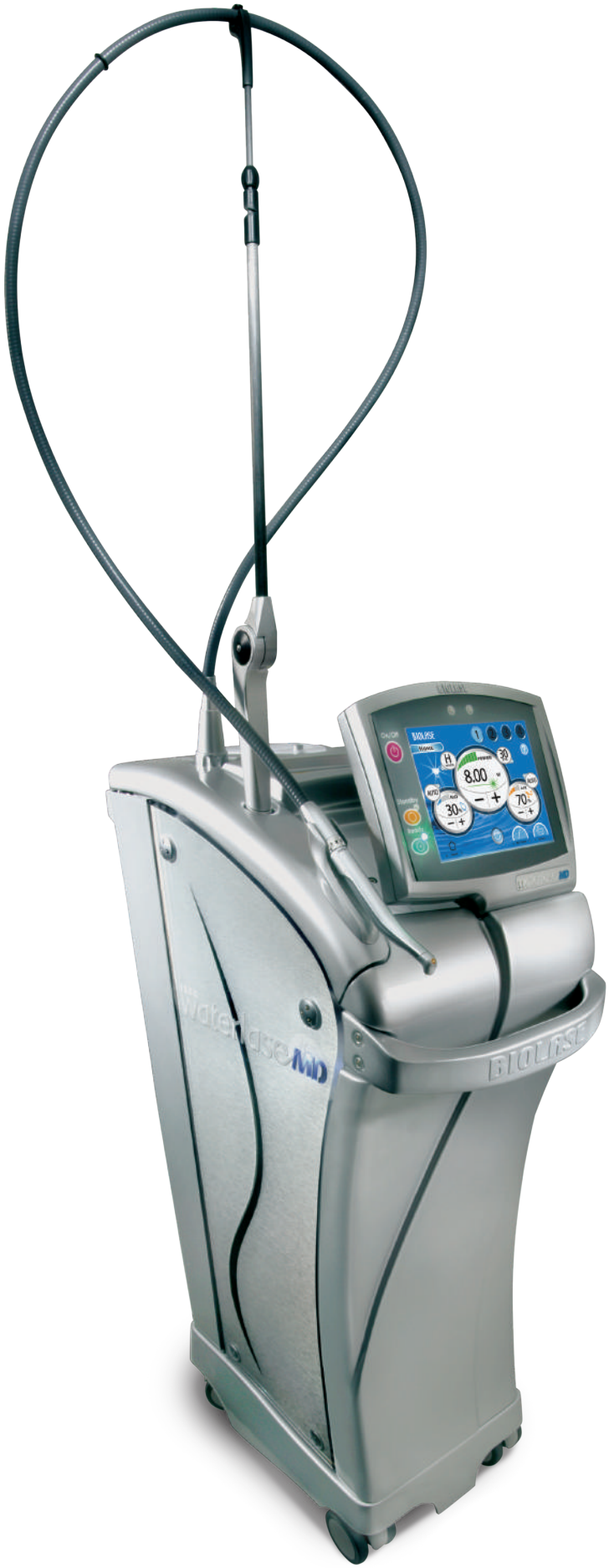
biolase.com

NASDAQ: BLTI

USA

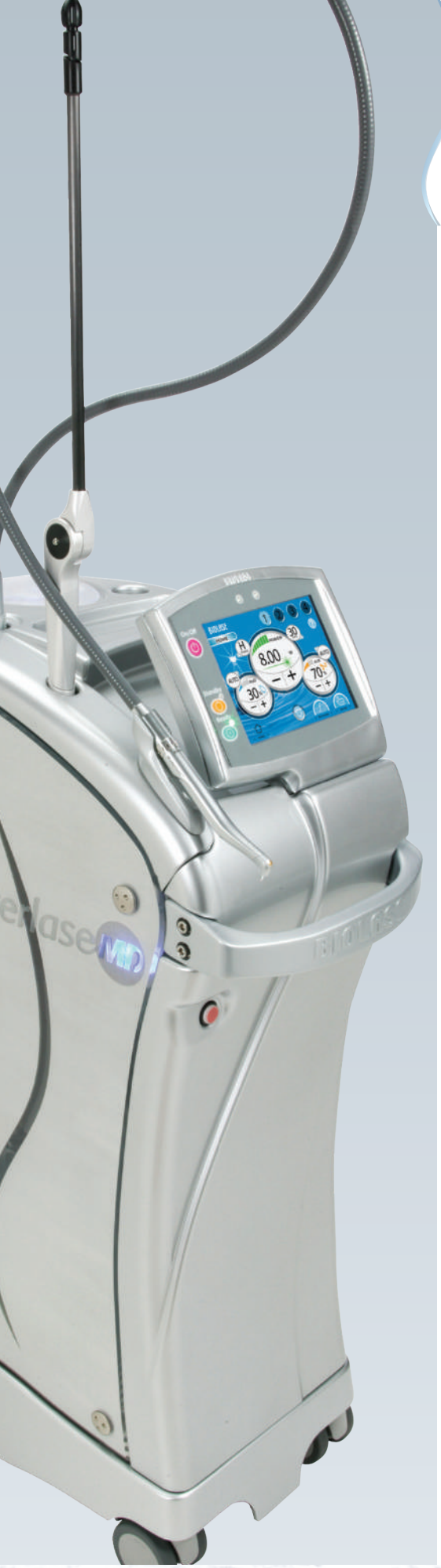
BIOLASE® Technology, Inc.
4 Cromwell
Irvine, CA 92618
949.361.1200

Europe
EC REP MT Promedt Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert/Germany
+49 6894 581020
www.mt-procons.com



5200110 REV. M (01/11)

CONTENTS



INTRODUCTION

The Waterlase MD Er,Cr:YSGG (Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet) tissue cutting system is a unique device with diverse hard and soft tissue dental applications. For hard tissue procedures, the Waterlase MD utilizes advanced laser and water atomization technologies to safely and effectively perform tissue cutting, shaving, contouring, roughening, etching and resection. For soft tissue procedures, the Waterlase MD utilizes direct laser energy to perform tissue removal, incision, excision, ablation and coagulation.

For hard tissue procedures, the YSGG solid-state laser provides optical energy to a user-controlled distribution of atomized water droplets. The water droplets absorb the optical energy, resulting in hydrophotonic cutting effects. The hydrophotonic process refers to the removal of tissues with highly energized water particles. Strong absorption of laser energy by atomized water droplets results in intense yet controlled water particle excitation and micro-expansion. The resulting forces induce mechanical separation of surface material, quickly and cleanly removing hard tissue. A flexible fiber optic with handpiece delivers the unique laser wavelength and atomized distribution of water particles to the target tissue. A red 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 MD is programmed to perform tissue removal, incision, excision, ablation and coagulation using direct laser energy either with or without water for cooling and hydration.

Use of this device requires proper clinical and technical training. This manual provides instructions for use for trained dental surgeons and practitioners.

When used and maintained properly, the Waterlase MD will prove a valuable addition to your practice. Please contact your authorized local Biolase representative if you have any questions or require assistance.

SECTION 1

INSTALLATION OF THE WATERLASE MD

INSTALLATION INSTRUCTIONS

If desired, your local authorized representative will unpack the Waterlase MD and your service representative will install the unit. Please leave all crates and shipping containers unopened until your trained service representative arrives. Complete installation, testing and demonstration requires approximately one full day.

The Waterlase MD must be installed with a qualified Biolase employee or representative; please refer to Section 4, Operating Instructions, for setup instructions.

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

FACILITY REQUIREMENTS

Electrical Supply

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

Compressed Air Supply

- 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 air source.

Connections for air supply must be available in each operatory.

Attach air hose with 1/4” inside diameter male quick connectors on each end between air inlet connector (fig. 3) and operatory air source.

CAUTION: Prior to connection, verify that outlet is for air, not water supply. Connection to water supply may cause damage to the Waterlase MD system. If the unit was connected to the water supply, do NOT turn the system on. Contact your service representative.

SECTION 2

EQUIPMENT DESCRIPTION

GENERAL

The Waterlase MD dental laser system consists of two modules:

- Optical Power Unit (the Unit – shown in Figures 1, 2 and 4)
- Waterlase MD Atomizing Delivery System (the Delivery System – shown in Figure 3 and 4)

OPTICAL POWER UNIT ELEMENTS

Figures 1, 2 and 3 show the front, rear and top views of the unit.

- **Control Panel**—The optical power unit is controlled through a touch-panel control screen. Please see section 4, Operating Instructions, for detailed instructions on using the control panel.
- **Front and Back Handles**—Use the front and back handles to move the unit and lift when necessary.

CAUTION: Prior to lifting, make sure handles are not damaged.

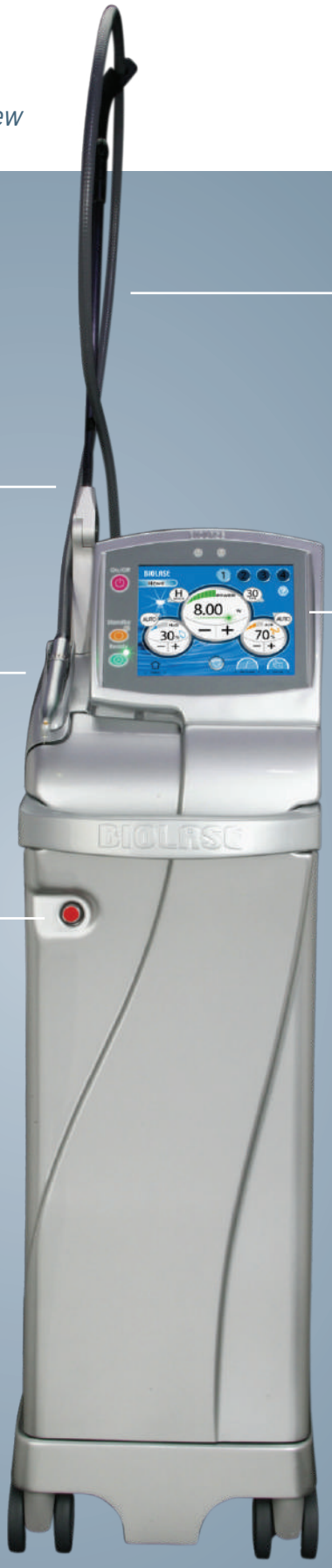
Do not use the delivery system to pull the unit; this could damage the fiber optic and render the unit inoperable.

- **Locking Wheels**—Press down on front tabs to lock the unit. Lift up the tabs to release locking mechanism.
- **Emergency Stop**—Press the red emergency stop button to instantly turn off the unit. 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. If the system was on when the emergency stop was activated, the system will be in standby mode when turned back on. You must push the "Ready" key before using the system again.
- **Keyswitch**—To switch unit ON, turn key to horizontal position. Use the proper key only. The key cannot be removed while in the ON position.
- **Footswitch Connector**—Connect and secure footswitch here.
- **Remote Interlock Outlet**—Each laser has a remote plug and connector on its rear panel. The purpose is to enable a user-provided remote switch (e.g., on the entrance door) to turn OFF the laser. To use it properly requires a normally-closed pair of contacts connected to pins 1 and 5 of the connector. These contacts should have no voltage associated with them and should open on activation.

  Customers may request that the remote interlock be connected to a door switch.

Figure 1: *Front View*



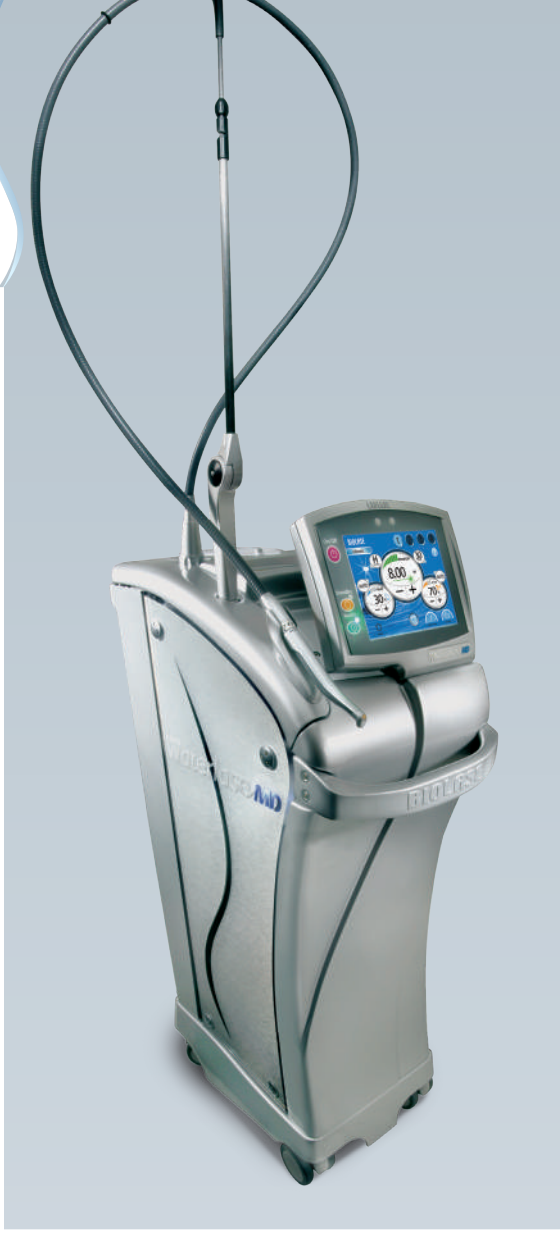


Figure 2: *Rear View*

Back Handle

Self-contained
Water System

Ventilation

Back Panel

Remote
Interlock Outlet

Key Switch

Footswitch Cable
Wrap Plate

Power Cable
Wrap Plate

Power Connection &
Circuit Breaker

Ground Pin

Footswitch Support
Bracket

Footswitch Connector

Air Inlet Connector

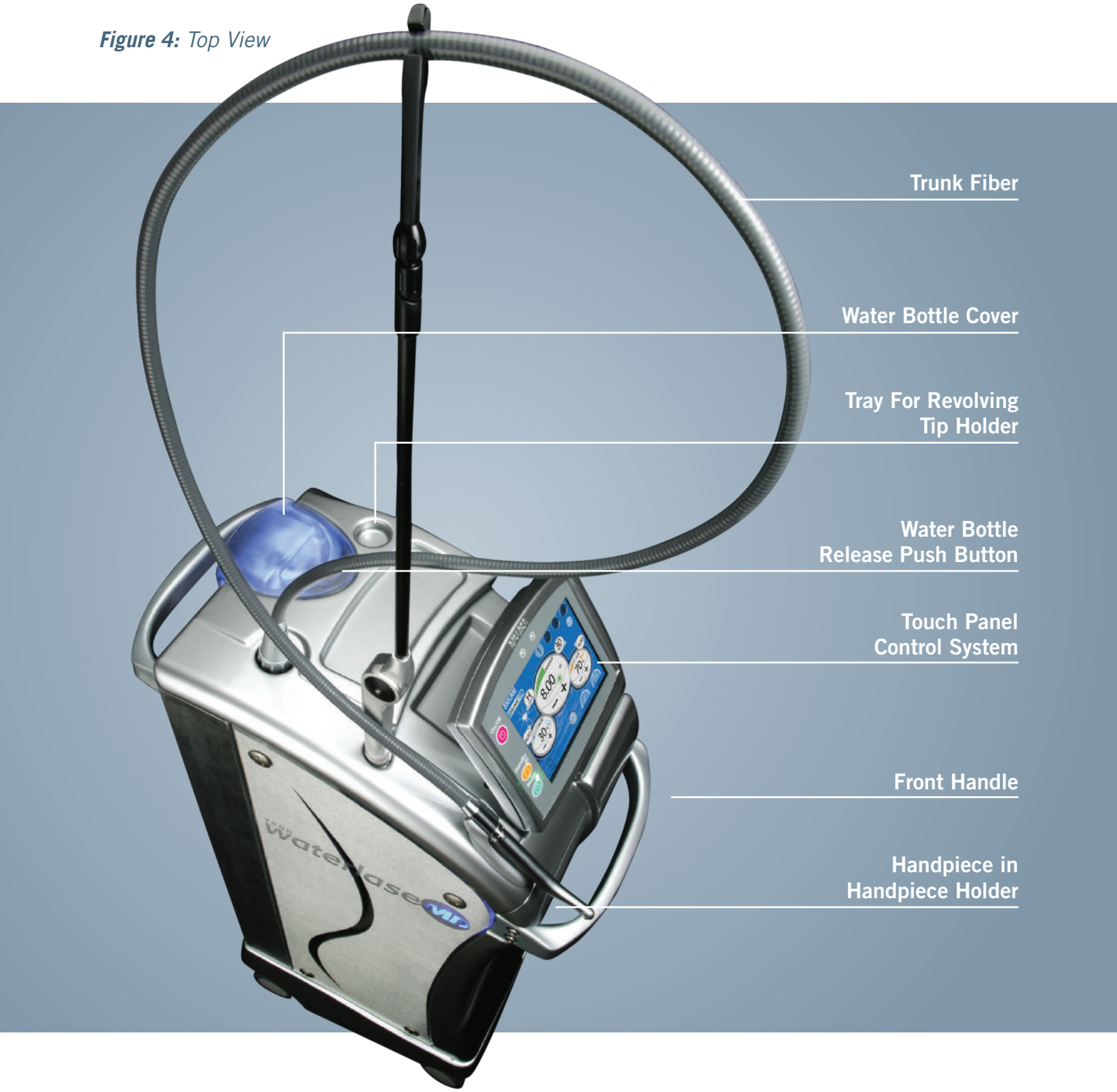
- **Power Connection / Circuit Breaker**—Attach power cord to unit at this location. The circuit breaker serves as a line switch to separate the unit from the main power supply (0 = OFF, 1 = ON). Power cable can be wrapped over the holding plate above the connector when system is not in use or during transportation.
- **Ventilation Channels**—Do not cover or block these channels. They provide an air flow path to cool the system.
- **Air Inlet Connector**—Connect with tubing (included) to compressed dry air outlet at 80-120 psi (5.5 - 8.2 bar)
- **Self Contained Water Bottle**—Provides water supply for handpiece atomization spray. Fill bottle only with distilled or sterile water. Do not use tap water.
- **Water Bottle Release**—When system is in "standby" mode, after bottle is depressurized, push the release button and pull back to remove the water bottle. After refilling the bottle, replace the bottle into its holder and secure the bottle in place.
- **Footswitch Support Bracket**—For storage or moving the unit, the bracket is designed to hold the closed footswitch clamshell. Wrap the footswitch cable around the wrap plate above.
- **Fiber Support Arm**—Supports delivery system on the unit. It extends to support weight of the delivery system when handpiece is pulled forward. Extension comes back when handpiece is released and arm is in vertical position.

Figure 3: *Handpiece in Handpiece Holder*

- **Handpiece Holder**—Supports handpiece when not in use.

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

Figure 4: *Top View*



WATERLASE MD DELIVERY SYSTEM

(see Section 4 for detailed description and instructions)

Delivery System Connection on the Unit

The delivery system attaches to the unit via a multi-connector incorporating air, water, cooling air, illumination waveguides and the optical energy fiber optic.

Fiber Optic Cable

Fiber optic cable contains the optical fiber together with the illumination waveguides, air tubing and water tubing. Laser radiation is delivered from laser unit to the handpiece through the optical fiber.

Protective Black Rubber Cap (for fiber optic connector)

Protects input end of the fiber optic cable when not attached to unit.

Optical Shaft

Contains fiberoptic cable, illumination waveguides and protective window.

Protective Cover (for fiber optic shaft)

Protects optical shaft when handpiece is disconnected.

To disconnect the handpiece or protective cover, pull the handpiece or protective cover off the shaft.

Handpiece

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

Rear Plug

Protects handpiece when disconnected from optical shaft.

Tip Plug

Protects handpiece optical components from damage due to water, steam or debris that could enter through the handpiece fiber tip orifice when tip is not in use.

Tip

The tip is detachable from the handpiece and serves as the optical power conduit to the target tissue. Because the laser energy passes through this tip, your laser unit's proper function depends on the tip's condition. A damaged tip may reflect laser energy back into the handpiece, potentially damaging the handpiece and/or fiber optic.

Clean and inspect the tips before and after every use to maximize their useful life. See Tip Inspection Instruction & Tip Cleaning Instructions in Section 4 for details.

Tip Remover

Tool to remove and insert tips.

Revolving Tip Holder

May hold up to 6 tips, operates as Tip Remover (follow instructions enclosed with tip holder).

SECTION 3

SAFETY WITH THE WATERLASE

PRECAUTIONS

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

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

CAUTION: This unit 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 UNIT IN ANY MANNER OTHER THAN DESCRIBED HEREIN. DO NOT USE THE UNIT 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 2.78µm energy.

CAUTION: Periodically inspect eyewear for pitting and cracking.

NOTE: For replacement or additional protective eyewear, please contact your Waterlase MD representative.

4. Do not look directly into the beam or at specular reflections.
5. Direct the cutting spray toward targeted tissues only.
6. Press STANDBY (Standby button) on the control panel before changing water and before turning off the unit.
7. Press “Change HP” button on the control panel twice before exchanging handpieces, changing water or removing the fiber optic connector from the unit.
8. Move the circuit breaker to OFF (0) position (located on rear panel) and remove the key before leaving unit unattended.

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.

All operatory entrances must be marked with an approved warning sign indicating a laser is in the operatory.

Plume Removal

CAUTION: Laser plume may contain viable tissue particulates.

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

SAFETY FEATURES

Energy Monitor

The energy monitor measures and verifies power output. 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" button on the touch screen. If error messages persist please contact your Representative.

Circuit Breaker

The circuit breaker on the back panel serves as a line switch to separate the unit from the main power supply (0 = OFF, 1 = ON).

Keyswitch

To switch unit ON, turn key to horizontal position. Use the proper key only. The key cannot be removed while in the ON position.

Always remove key when unit left unattended for long time.

Footswitch

The Waterlase MD will not activate until the user presses down on the footswitch. 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. The purpose is to enable a user-provided remote switch (e.g., on the entrance door) to turn OFF the laser. To use it properly requires a normally-closed pair of contacts connected to pins 1 and 5 of the connector. These contacts should have no voltage associated with them and should open on activation.

Your Biolase service engineer can assist you in connecting the remote interlock to a door switch.

Emergency stop

Press the red emergency stop button to instantly turn off the unit. 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. If the system was on when the emergency stop was activated, the system will be in standby mode when turned back on. You must push the “ready” button before using the system again.

Control Panel

The touch screen control panel shows the functional conditions of the system.

Layout of Control Elements

All control functions are located at a safe distance from energy output. Control panel layout and instructions are described in Section 4, Operating Instructions.

NOTE: Please direct any safety questions to your local Biolase representative, or call Biolase at (888) 4-BIOLASE [(888) 424-6527].

SECTION 4

OPERATING INSTRUCTIONS

SETUP

Connect Unit to Operatory

1. Verify circuit breaker is in OFF position.
2. Verify keyswitch is in OFF position.
3. Connect power cord to unit (see fig.2).
4. Verify minimum air pressure of 80 psi (5.5 bar) from air supply.
5. Check air supply for moisture.

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

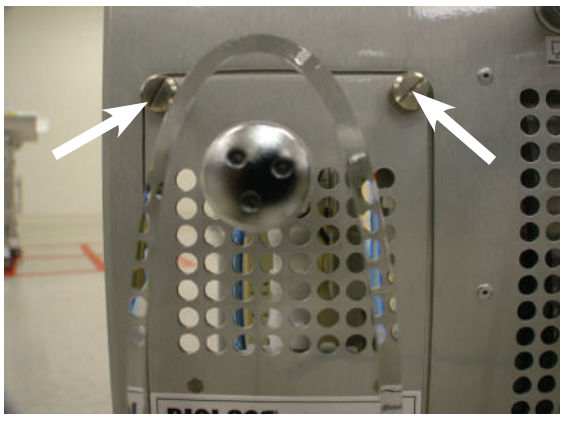
6. Connect to the unit's air inlet connector (see fig. 2).

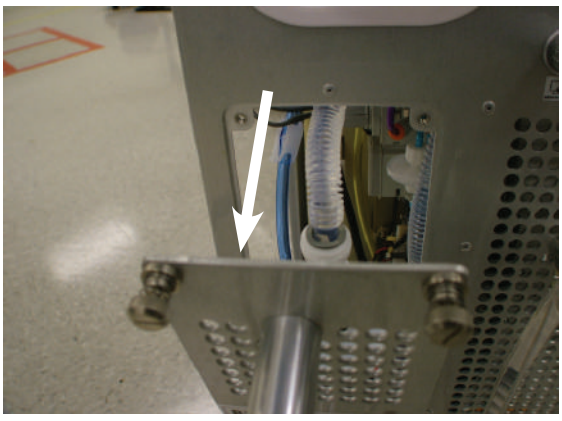
Filling the Internal Cooling Water Reservoir

Your Waterlase MD may have been shipped with a full cooling water reservoir. In the event you need to fill the reservoir please follow the instructions below.

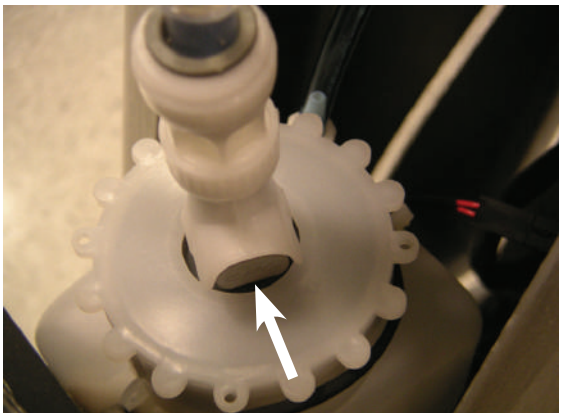
1. Open the back panel door by turning two thumb screws counter clockwise and pull back gently;

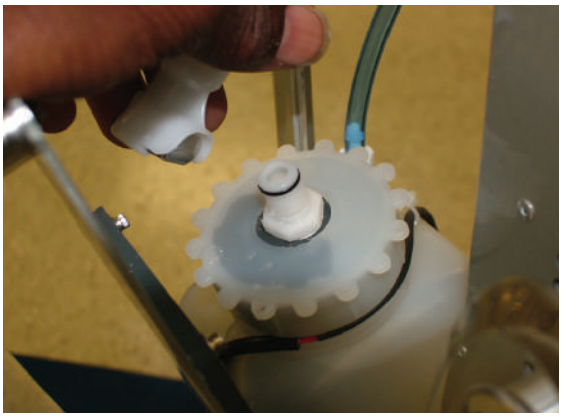
WARNING: Be careful opening the door. Make sure door opens easily and clears the bottle lid and tubing. Door holding bracket is mounted at the bottom hinge. Do not apply excessive force!





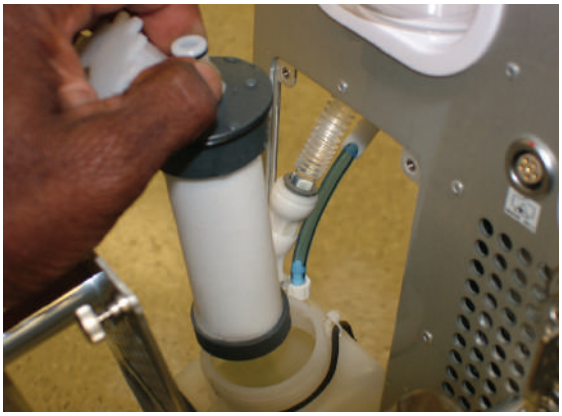
2. Locate internal water reservoir. Verify that white clip on the blue tube that is connected to the side of the water reservoir is closed;
3. Push button on the top connector and disconnect tubing from the lid;



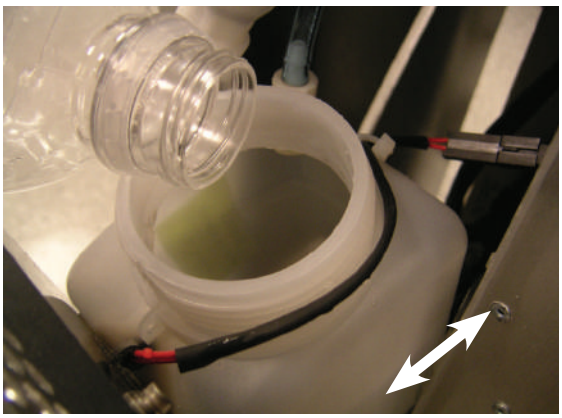


4. Remove lid and filter assembly.

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



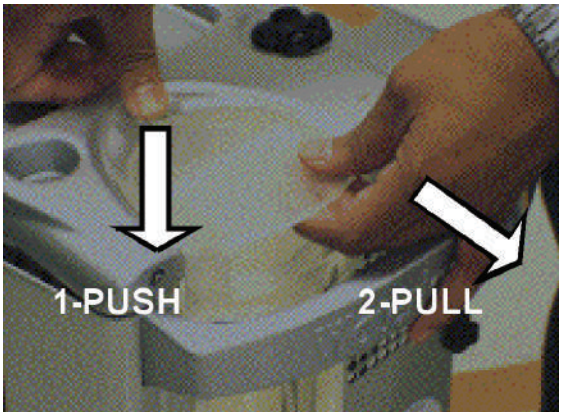
5. Use funnel to fill with distilled or deionized water to ¾'s full;

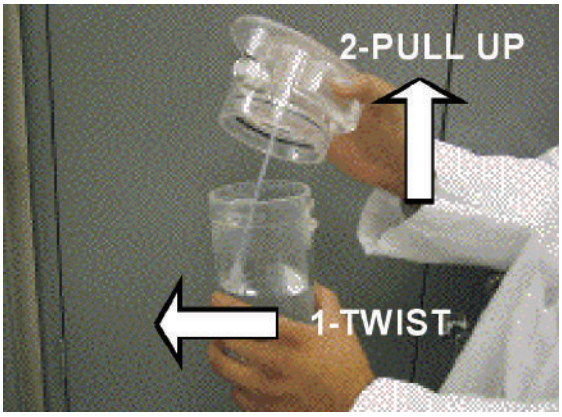


6. Replace filter assembly and close lid tight;
7. Plug in water connector firmly, until it “clicks” in place;
8. Power up the system:
    - Switch the Power Circuit Breaker on the back panel is ON;
    - Turn the Keyswitch to the ON position;
    - When keyswitch is turned ON, the system will begin its boot-up process. Once the system emits second “beep” and the display screen turns dark (about 45 seconds) push the “ON/OFF” key on the front panel;
9. Press “Ready“ key. If “Water level low” error message is shown, turn the system OFF refill the cooling water to ¾ full level.
10. Press “Ready” key again and let 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.

FILL SELF-CONTAINED WATER SYSTEM BOTTLE

1. Make sure that system is in the Standby mode (bottle is de-pressurized);
2. Push the bottle release button and pull the bottle out from the holder towards the back handle;

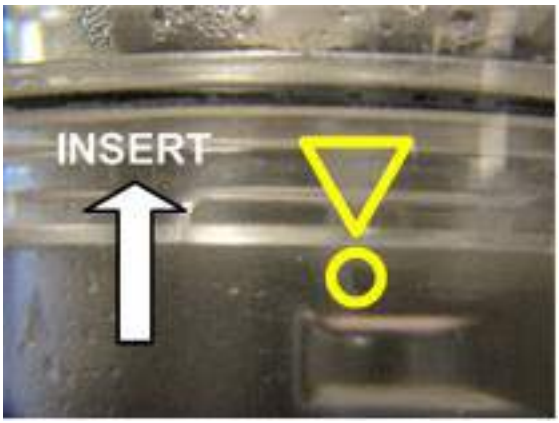


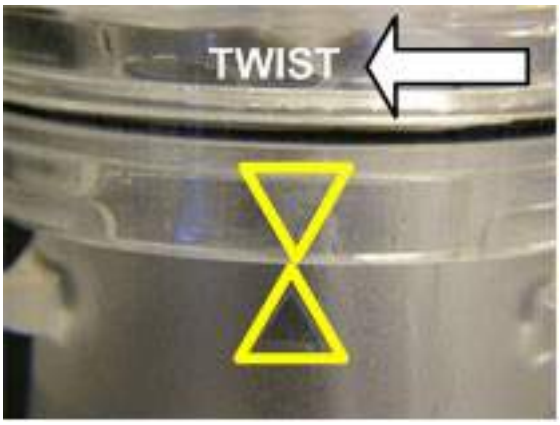


3. Twist the bottle clockwise and pull up the lid to open;
4. Fill bottle with distilled or sterile water only;

WARNING: DO NOT use the tap water or non-authorized solution. If tap water or other non-approved solution is used, system warranty will be voided.

5. Align arrow on the lid and dot on the bottle and insert bottle into the lid;
6. Twist the lid clockwise all the way until the arrows on both parts match;





7. Attach bottle back to its holder; make sure connector is fully engaged.

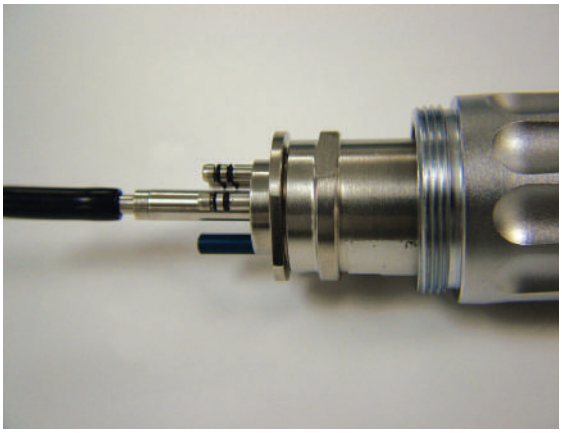
WARNING: Be careful handling the water bottle assembly. Do not drop the parts. Any crack may cause damage when bottle is pressurized.

SECURE FIBER OPTIC ASSEMBLY TO UNIT

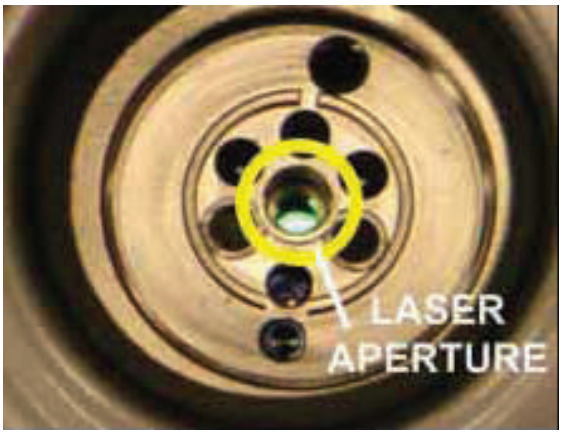
1. Verify the Laser Head is centered to the top cover. If misaligned call Biolase headquarters for additional support;

2. Locate the hole on the left side of top view of laser unit and install telescopic fiber support arm;
3. Take the new trunk fiber from the accessories box and drape it around your neck;

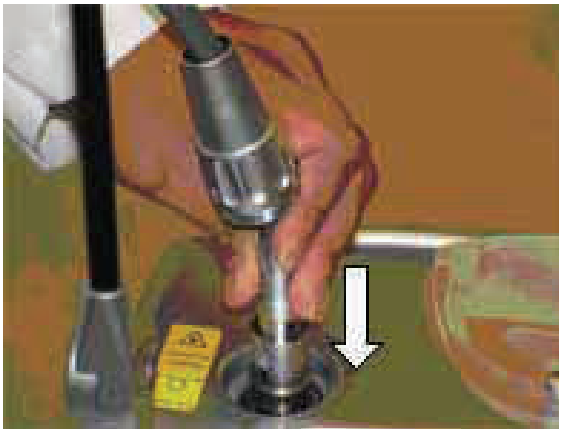
4. Remove protective black rubber cap at the proximal end of fiber;
5. Remove Protective Cover off the Fiber Shaft and place it against any light source. Check proximal end of the fiber – it should glow yellow, be flat and clean.

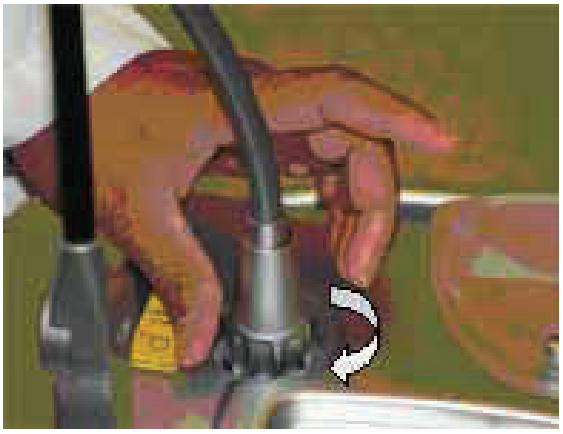


6. Remove black and red protective cups from laser head and aperture (store all the cups for further use, do not loose them);
7. Carefully look inside the laser aperture and check that surface of the protective window is clean, free of water, dirt or damage.
    - If water or dirt found, try to clean by blowing the dry compressed air in the aperture;
    - If this does not help – call for system Service.



8. Align the blue guide of fiber connector to blue dot of laser head interface. Position the middle of the connector to the laser aperture and vertically push down gently all the way;





NOTE: You may need to move connector slightly to the sides to ensure proper engagement of all interfaces. DO NOT APPLY FORCE!

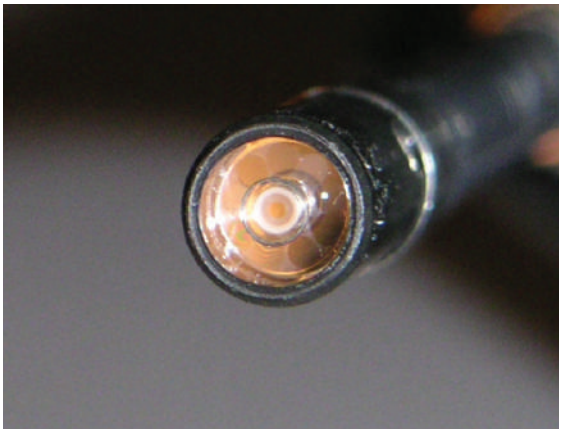
WARNING: Applying force may create metal shavings or shave off the o-rings of the spray connector and cause damage of the laser head components.

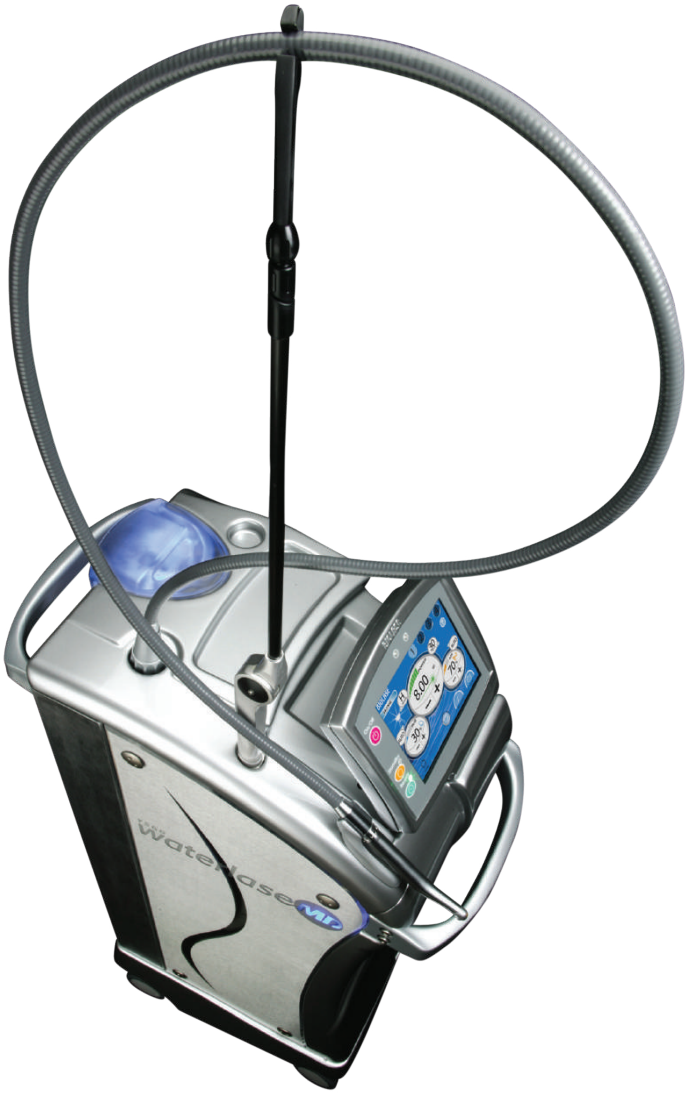
9. Secure retainer ring by turning clockwise until it is snug;

10. Align middle of the fiber to the hook of telescopic arm and push gently to engage;

NOTE: Make sure the black retaining O-ring is in the front side of the hook.

11. Disconnect Protective Cover from the distal end of the Fiber Delivery Cable and verify that it is clean not damaged *(see also Sec. **Fiber Check**);*

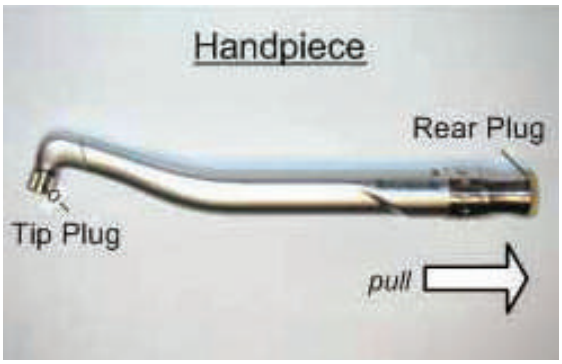




12. Properly align fiber and the Protective Cover (or the handpiece) in the handpiece holder.

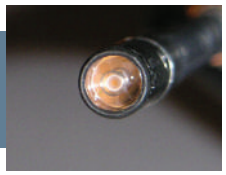
CONNECTING HANDPIECE TO FIBER OPTIC CABLE

1. Remove the Handpiece from the Handpiece Box;
2. Remove the Rear Plug from the handpiece by pulling the plug out and place it in the Handpiece Box to store;



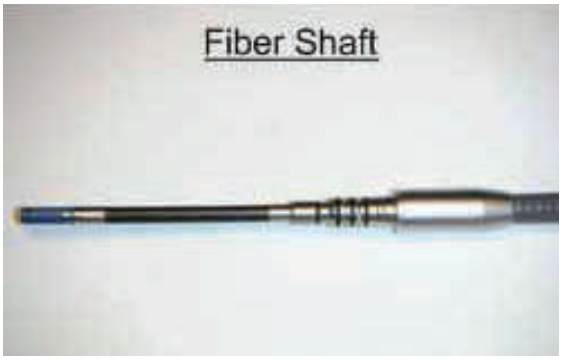
3. Remove the fiber Protective Cover from the Fiber Shaft of the Trunk Fiber by pulling the cover off and place it in the Handpiece Box;
4. Check the Fiber Shaft for any moisture and wipe off any that is found;

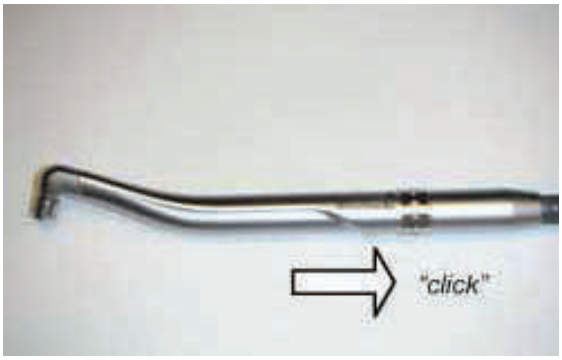
NOTE: Check output end of the Fiber Shaft for any contamination of damage ***(see Sec. Fiber Check).***



WARNING: Do not touch output end of the Fiber Shaft to prevent any contamination and potential further damage. If touched, clean with dry tissue.

5. Carefully insert the Handpiece onto the Fiber Shaft until it “clicks”.





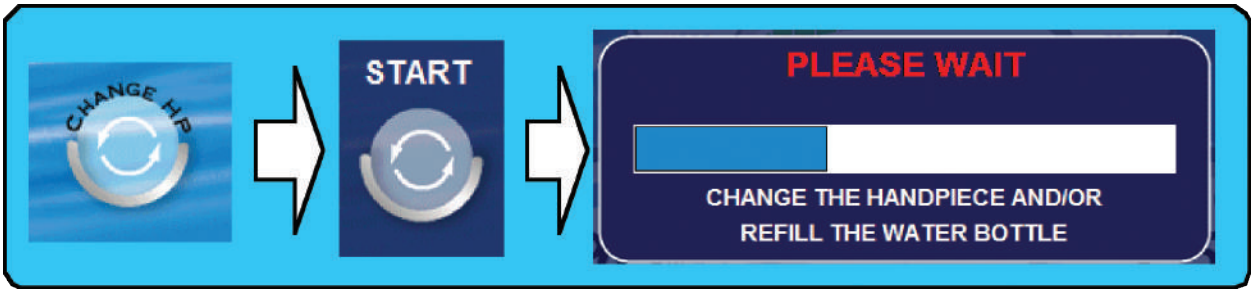
NOTE: Connection and disconnection of the Handpiece and the Protective Cover should be done carefully, without application of excessive force.

WARNING: To prevent the internal fiber from braking, do not bend the flexible part of the Fiber Shaft.

CAUTION: Handpiece should always be connected before turning ON the laser.

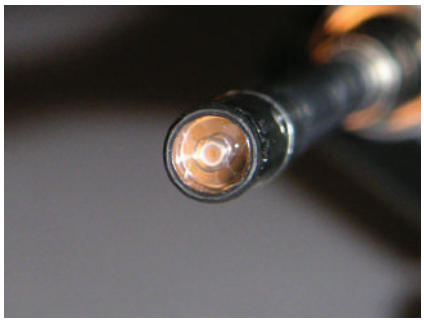
DISCONNECTING THE HANDPIECE

1. Press “Change HP” button on the Touch Screen;
2. Press “Start” button and wait until Delivery System is purged, watching the progress bar on the screen;



WARNING: Failure to purge the handpiece prior to disconnecting may cause damage of the Fiber Delivery system.

3. Remove Tip using Tip Remover or revolving Tip Holder and replace it with the Tip Plug;
4. Pull and disconnect the Handpiece from the Fiber Shaft;
5. Wipe any moisture off the Fiber Shaft with dry tissue;
6. Check that window at the end of the fiber is clean (use dry Q-tip or tissue to clean) and not damaged *(see also Sec. **Fiber Check**)*;
7. Carefully attach new Handpiece or fiber Protective Sheath until it “clicks” on the Fiber Shaft;



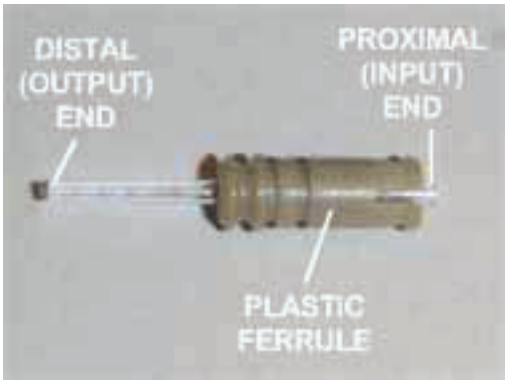
- If new Handpiece is connected press “Done”;
- If Protective Cover is connected or work in complete, turn system OFF.

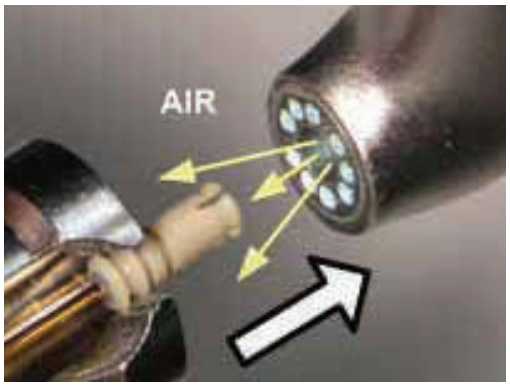
WARNING: Do not press ”Done” button if fiber Protective Cover is attached – water will fill the Cover and may cause damage of the Fiber Shaft. If this happens, take the Cover off and dry out both Fiber Shaft and Protective Cover. Failure to do so may result in damage to the Fiber Shaft.

INSTALLING AND CHANGING TIP IN THE HANDPIECE

1. Set the system in the "Ready" mode;

NOTE: **Always change Tips in "Ready" mode** when cooling air is blowing out from the tip orifice of the handpiece head. This helps clean the input end of the tip from any light dirt or moisture.



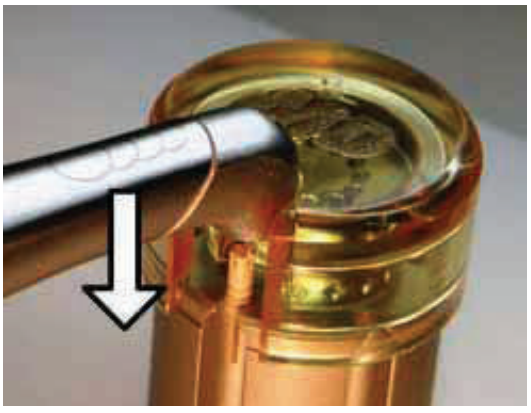


2. Remove the Tip Plug by pulling it out and place it in the Handpiece Box;
3. Remove Tip from the package (for new Tips only) and insert it into the Tip Remover or revolving Tip Holder. Insert by aligning the first groove of the Tip Ferrule against the receiving edges of the Holder, then sliding the Tip in (the use of tweezers is highly recommended);

WARNING: **Never touch the input end of the Tip.** If the input surface is contaminated, it may damage the Tip, Handpiece and the Fiber Delivery System.

Hold the tip only over the plastic ferrule and the output end.

NOTE: Always inspect the Tip prior to use *(see Sec. **Tip Inspection**)* and .

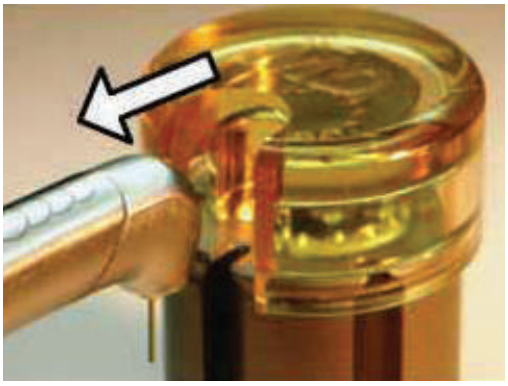


4. Align the tip orifice of the handpiece over the input end of the Tip, placed in the Tip Remover or revolving Tip Holder;

5. Carefully lower the handpiece and insert a clean/inspected Tip *(see: **Tip Inspection**)* all the way until the shoulder of the tip ferrule sits against the handpiece head;

WARNING: Be careful not to hit the proximal end of the Tip against the handpiece head and not to break retaining fingers of the plastic ferrule.

6. Slide the Handpiece laterally away from Tip Remover or Tip Holder.



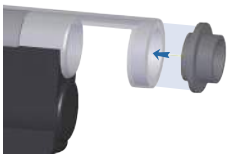
NOTE: To remove the Tip, repeat the whole process in reverse order. Put your thumb against the selected tip slot to prevent Tips from falling out of the Tip Holder when connecting and disconnecting Tips from the Handpiece.

NOTE: If the laser cuts hard and soft tissue after fiber installation slower than expected, please follow the flowchart in Sec. ***Troubleshooting the Delivery System***.

TIP INSPECTION INSTRUCTIONS

[01] Remove the tip from the handpiece and insert it into the correct side of the tip test holder as shown using the tip remover.

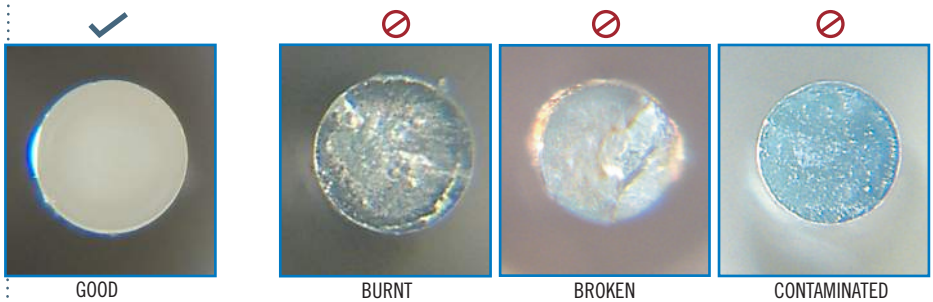
Tip remover with tip inside



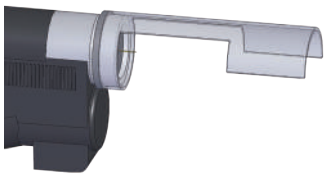
[02] Insert the tip test holder into the test adapter with the distal (or laser-emitting) end of the tip toward the microscope.

[03] 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.

[04] 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.

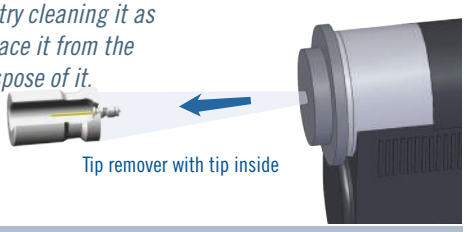


GOOD | BURNT | BROKEN | CONTAMINATED



[05] 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.

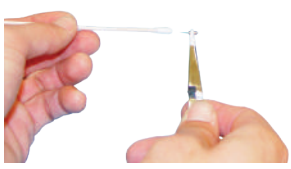
[06] Remove the tip from the test holder using the tip remover.
If the tip is contaminated at either end, try cleaning it as shown below. If the tip is damaged, replace it from the handpiece using the tip remover and dispose of it.



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

OPERATION

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

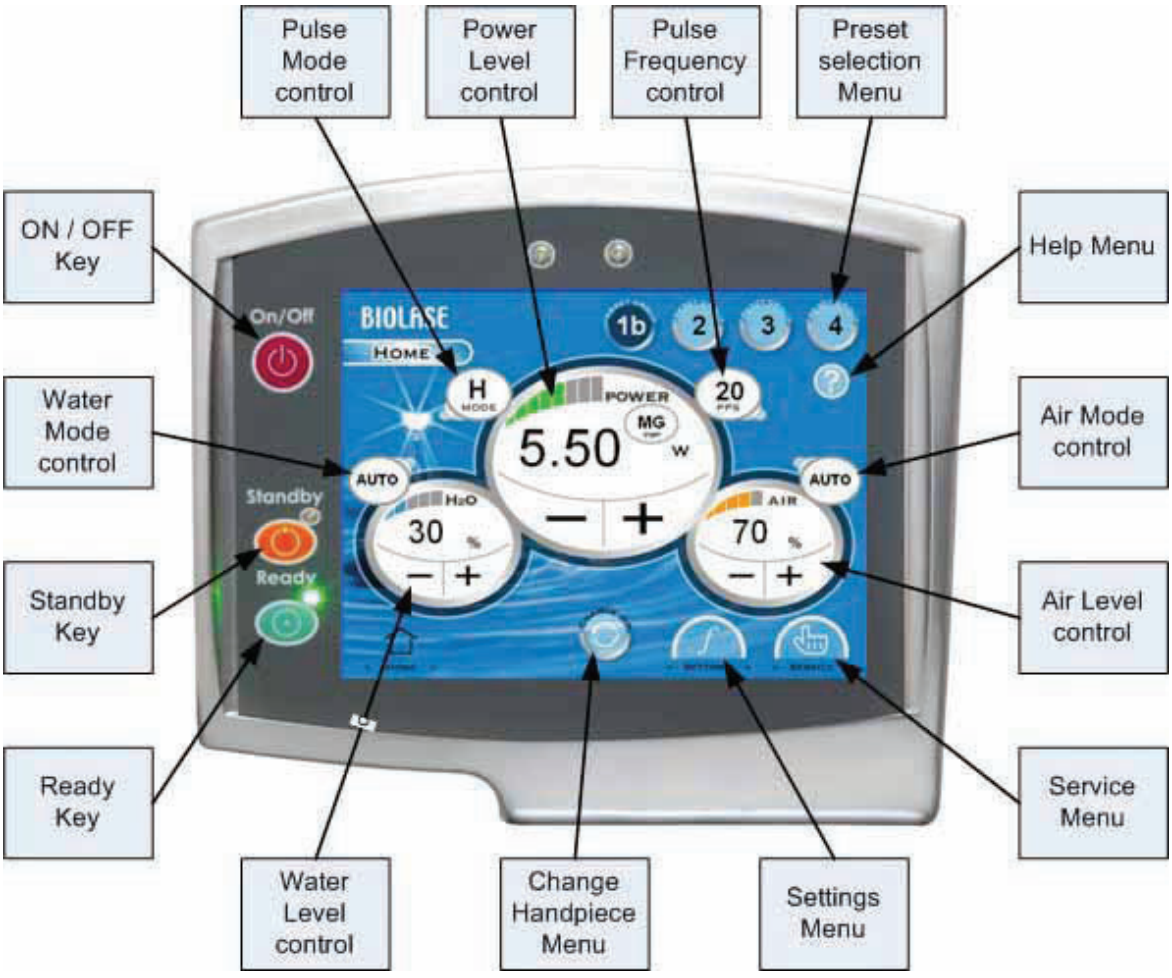
Overview

Before using the Waterlase MD, be sure the system has been started appropriately, as described earlier in this manual. After the system has completed its startup process, turn the unit on by pressing the On/Off button.

The Waterlase MD provides user control for Power, Water and Air parameters. The user may select one of 16 Presets (stored values and modes of operation for Power, Water and Air), or vary the individual values to adjust Power, Pulse Mode, Pulse Rate, Water and Air as appropriate for the procedure.

Operational State Description

System Control Panel consists of the permanently displayed Key Buttons and the Touch Screen Display.



1. KEY BUTTONS:

- **ON/OFF Key**—Turns the Touch Screen Display OFF ("Sleep" mode). System controls are still powered up. Press it when system is not in use overnight.

NOTE: System will automatically switch into the "Sleep" mode, when not in use for 15 minutes.

Standby Key—Turns Touch Screen ON. Main laser controls and cooling system are OFF. Use it all the time when not performing the treatment.

NOTE: System will automatically switch into the "Ready" mode, when not in use for 15 minutes.

- **Ready Key**—Turns all system controls ON. Laser is ready to emit. Use when ready to perform clinical treatment procedure.

2. TOUCH SCREEN CONTROLS.

Each laser control function (Power, Water and Air) has a separate control display, indicating the value of the parameter and its mode. Each mode indicator acts as a control button and when pressed, scrolls through available options. See Sec. 4 ***User Interface*** for navigation algorithm through the Menus.

- **Power level control**—Shows and controls average power of the laser. Maximum power is limited depending on the Pulse Repetition Rate and Pulse Mode. Power adjustment steps are 0.25 Watts.

PPS setting (Hz)	Maximum power setting (W)	
	S mode	H mode
10	3.0	3.0
15	4.5	4.5
20	6.0	6.0
25	7.5	7.5
30	8.0	8.0
35	6.0	7.0
40	6.0	7.0
45	3.0	6.0
50	3.0	6.0

Laser radiation symbol is flashing together with "beep" sound when footswitch is pressed and system emitting laser beam.

- **Pulse Mode control**—The laser pulse has two modes: "H" (hard tissue pulse mode) and "S" (soft tissue pulse mode). These modes control the pulse duration at about 140 µs for "H" mode and about 700 µs for "S" mode.
- **Pulse Frequency control**—Laser pulsed can be delivered at different rates or number of pulses per second, or PPS (also called Hertz, Hz). Press Pulse Frequency Control to change laser pulse repetition rate. Can be selected in the range of 10 – 50 Hz with 5 Hz step.
- **Water and Air Level controls**—Shows and controls relative percentage of water and air in the spray. Controls independently from 1% to 100% with 1% step.
- **Water and Air Mode controls**—When pressed, the Water and Air mode indicators cycle through the OFF, AUTO and ON modes, displaying their current setting. When set ON and system is in "Ready" mode, water or air will start flowing immediately. When set in AUTO mode – after footswitch is pressed.
- **Pre-set Selection Menu**—Allows access to 4 groups of 4 pre-set system operating parameters (total 16 pre-sets). Any change to any pre-set can be memorized.
- **Help Menu**—Accesses to detailed explanation of all controls of the current Menu.
- **Change Handpiece Menu**—Provides access to the automatic purging (drying) of the delivery system in case Handpiece or Fiber Delivery System needs to be disconnected. Allows re-filling (priming) of the spray delivery system when components are connected back.
- **Settings Menu**—System settings like power of the Aiming Beam and Illumination, Sound associated with the touch buttons can be adjusted. Allows access to the Calibration Menu, when power will be limited depending on the selected tip type. Actual output power due to different tip Power Factors are referenced as well.
- **Service Menu**—Provides access to the system calibration and memory. Accessible only for certified Field Service Engineers.

TO START THE WATERLASE MD

1. Verify that all connections have been properly secured
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. The Handpiece should be properly connected
5. Verify that the water bottle is filled more than 1/3 with distilled or sterile water.

DANGER: Laser and collateral radiation are emitted through the fiber optic port. Removal of the multiconnector from the fiber optic port may lead to hazardous exposure. Radiation is also emitted from the fiber shaft when the handpiece is removed. DO NOT attempt to operate the Waterlase MD with the delivery system or the handpiece removed.

6. Switch the circuit breaker ON.
7. Insert the key into the keyswitch and rotate clockwise to the ON position.
8. The emergency stop button must be released (verify by making sure the button is not glowing red, and no error message is displayed).
9. The system will begin its startup process. Once the system emits its second "beep" and the display screen is dark (about 45 – 60 seconds) push the On/Off button.
10. Attach handpiece to the fiber optic cable shaft *(Sec. 4: **Connecting the Handpiece to Fiber Optic Cable**).*
11. Press Ready button and attach tip using the tip remover *(Sec. 4: **Installing and Changing Tip Into Handpiece**)*
12. Select parameters appropriate for the procedure. The mode and value of each parameter may be adjusted by the keys below the associated display. To select a Preset, simply push one of the four preset buttons, labeled 1 through 4. A second screen, showing the four presets within the selected set, will then allow you to select preset a, b, c or d. After a chime, indicating that your selection was accepted, the main screen will display your new preset values.

MODIFY AND SAVE PREFERRED VALUES AS PRESETS

The Waterlase MD has sixteen pre-programmed presets stored on the system. The values of the presets, as well as additional combinations of presets, are presented in appendix D: **Tips: Suggested Clinical Specifications**.

To select and store a new set of values and/or modes for Power, PPS, Water and Air, first select the values you wish to store from the system main menu. Then, select the preset group (1, 2, 3 or 4) in which you wish to save the new values. Push the selected preset button (a, b, c or d) and hold in place for 2-3 seconds until you hear a beep. The new values and modes are now stored. These new values and modes are permanently stored under that preset number and may be recalled at any time by pushing the preset button.

ACTIVATE THE WATERLASE MD

Push the Ready button to enable the Waterlase®, and depress the footswitch when ready.

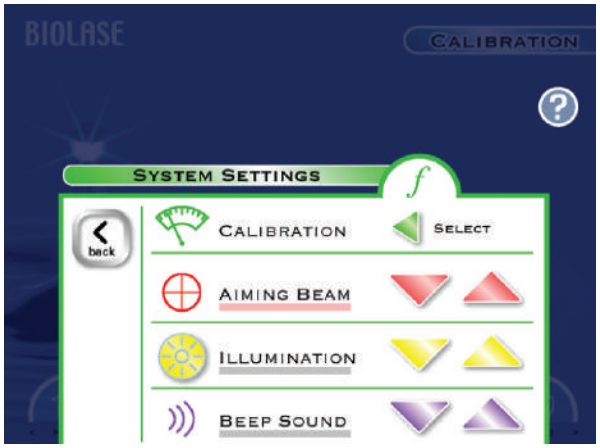
NOTE: The user may evaluate the effect of each parameter setting prior to the procedure by directing the handpiece into a sink or paper cup and adjusting the values as desired

TURN THE WATERLASE MD OFF

- Disconnect tip, if required. Install tip plug.
- Press STANDBY button.
- Push the ON/OFF button.
- Turn key to OFF position
- Turn circuit breaker to OFF.

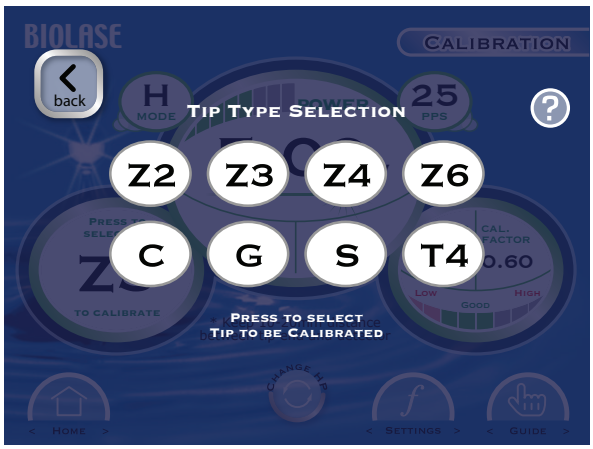
SETTINGS SCREEN

Pressing the "settings" button in the lower right of the main screen will bring up the System Settings screen:



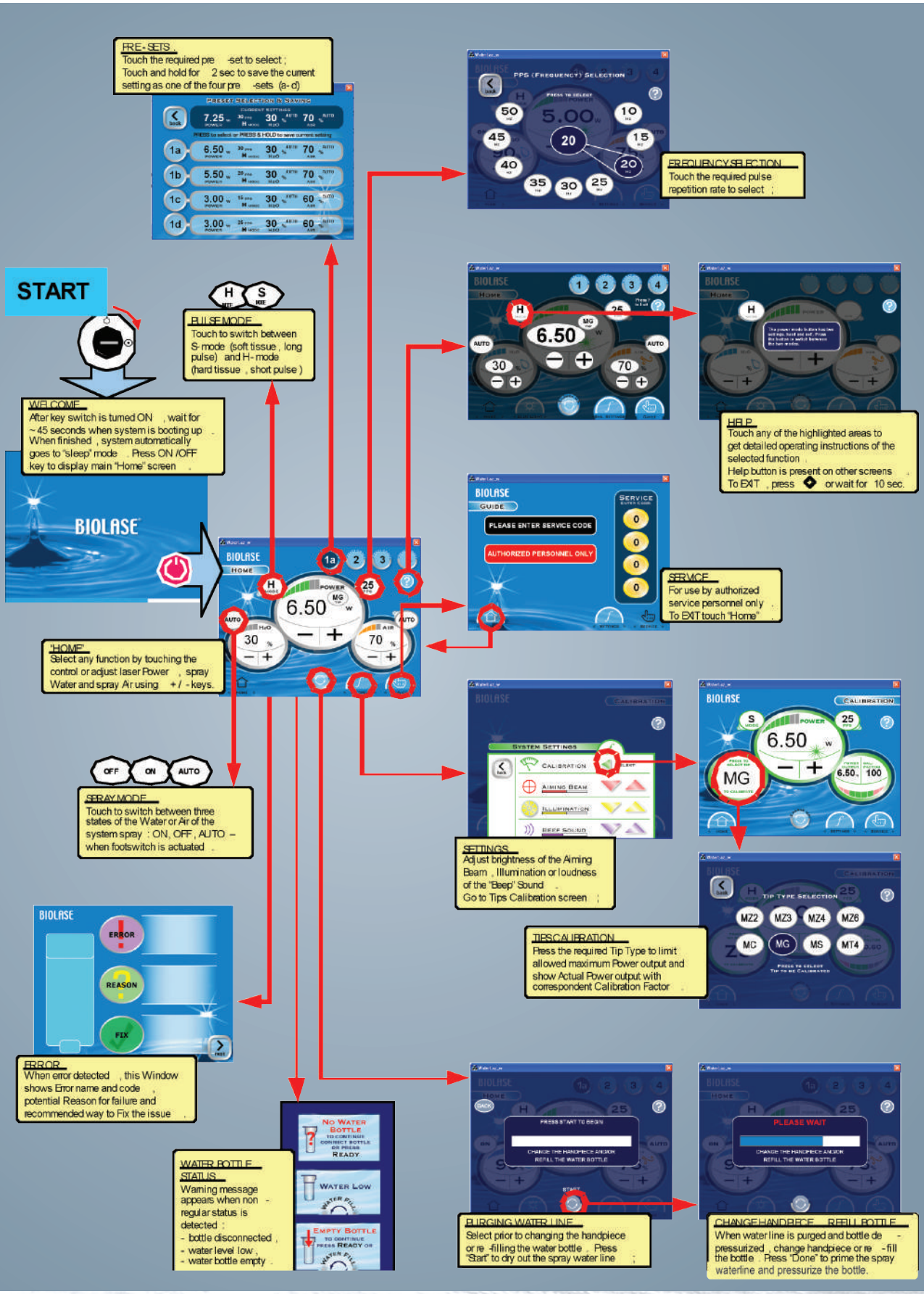
Through this screen, you can adjust the volume of the system speaker, the strength of the illumination, and the intensity of the aiming beam. Use the up and down arrows to make these adjustments.

This screen also has a "calibration" feature – selecting this feature will lead to a screen providing information on the expected power output from each tip. Pressing the "tip type" button on that screen leads to the tip selection screen:



After selecting the tip type, the calibration screen will return, showing the calibration factor and expected power output for the selected tip. Actual power can vary from the expected power by as much as ± 20%. When going back to the Main Screen, selected tip type will be shown within the Power control window.

USER INTERFACE - General Navigation



ERROR MESSAGES

The Waterlase MD constantly monitors its own performance and calibration. If any performance errors occur, the system will be placed in Standby mode and the screen will indicate the cause of the error and provide recommendations on clearing the error.

If you cannot clear an error after following the directions on the error screen, 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	Foot Switch pressed	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	ShutDown temperature condition	System Temperature is high	Allow system to cool down	Let system run in “Ready” mode for 5-10 minutes
18	Emergency switch pressed	Emergency switch pressed	Check Emergency switch	Release the Emergency Stop Button at the front
19	No bottle error	Bottle not detected	Insert bottle or repair sensor	Insert water Bottle and clean the sensors
23	Reservoir fail	Cooling water level is low	Add de-ionized/ distilled water	Add specified water, if trained on that
24	Air pressure failure	Air pressure failure	Check air compressor	Air pressure might be low or disconnected
26	Foot Switch not detected	Foot Switch not detected	Check Foot Switch plugged in	Check connector, footswitch short during standby
29	Fiber not detected	Fiber not detected	Check Fiber	Properly re-connect the Trunk Fiber

SECTION 5

WATERLASE MD SPECIFICATIONS

GENERAL

Dimensions (W x L x H)

- Unit 11 x 19 x 32 in (28 x 48 x 81cm)
- With Fiber 11 x 19 x 40 in (28 x 48 x 102 cm)
- Weight 75 lbs (34 kg)

Electrical

- Operating Voltage: 100 VAC ± 10% / 230VAC ± 10%
- Frequency: 50 / 60 Hz
- Current rating: 15.0 A / 8A
- Main control: Circuit breaker
- On / Off control: Keyswitch
- Remote interruption: Remote interlock connector

Waterlase MD

- Water type: Distilled or Sterile
- External air source: 80 - 120 psi. (5.5 - 8.2 bar)
- Droplet size: 5 - 200 µm
- Max. droplet velocity: 100 m/s
- Interaction zone: 0.5 - 3.0 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: 10 – 50 Hz
- Average power: 0.1 – 8.0 W
- Power accuracy: ± 20%
- Pulse energy: 0 – 300 mJ
- Pulse duration for soft and hard tissue procedures: 140 µs
- Pulse duration range for soft tissue procedures only: 700 µs
- Handpiece head angles: 70° contra-angle
- Tip diameter range: 200 – 1200 µm
- Output divergence: ≥ 8° per side
- Mode: Multimode
- Aiming Beam: 635nm laser, 1mW max (safety classification 1)
- Water level sensor: 635nm laser, 1mW max (safety classification 1)
- Nominal Ocular Hazard Distance (NOHD): 5cm

SECTION 6

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

CONTRAINDICATIONS

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

INDICATIONS, WARNINGS AND PRECAUTIONS

Eyewear

Doctor, patient, assistant, and all others inside the operatory must wear appropriate laser protection eyewear for the 2.78 µm wavelength (OD 4).

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 successfully completed training 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 (650 – 1000 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 (140 µs) and (S) long pulse (a range of 650 – 1000 µs). The long pulse 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 MD 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 MD as are taken when using any air and water emitting cutting device, including the high speed drill.

Root Canal Procedures

Review the clinical procedure and all labeling instructions provided with the endodontic tips and EndoLase™ kits before proceeding with any treatment. Always use air and water spray at the recommended settings to enlarge and remove debris from inside the root canal. Do not exceed the power setting of P= 1.5 W for root canal enlargement with any of the endodontic tips (Z2, Z3 or Z4).

The Waterlase MD 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 the curved canal. If during insertion the fiber tip does not advance easily into the canal, do not force the tip inside. A possibility is to pull the fiber out and use an endodontic hand file or a broach to open the path. The Waterlase MD is an end-cutting device; so to avoid penetration of a canal wall or the apical foramen, 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 away 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. For additional information on laser root canal enlargement, review the recommended clinical procedure presented in Appendix C, or the instructions provided with the EndoLase™ endodontic kits.

Adjacent Structures

Waterlase MD 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) removed with Waterlase MD or conventionally must be submitted to a qualified laboratory for histopathology assessment.

Tissue Contact and Tip Breakage

Do not contact hard tissues with fiber tip. Hard tissue cutting occurs in non-contact mode with the tip ~0.5 to 3 mm off the surface. Also, the tip is 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 accidental biting and breakage of the tip, if necessary.

Tip Changing

Failure to correctly replace the tip could result in damage to the fiber tip or the handpiece. Carefully, review the instructions on how to replace the tip in this User Manual.

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 required to maintain a clear field of vision during treatment. Do not use the Waterlase MD if you cannot clearly see the treatment site.

Plume Removal

CAUTION: 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 laser and minimal or no water spray. Ensure that all appropriate protective equipment (including high-speed suction to remove the plume, appropriately filtered masks, and other protective equipment) is used at all times during procedures with this laser device.

Dental Materials

Do not direct 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 MD tip and delivery system.

Training

Only licensed professionals, who have successfully completed Waterlase MD training, have read and understood this manual, and know how to correctly operate the system, should use this device. Surgical procedures on soft tissue, bone or root apex should only be performed by clinicians who have training and experience in Oral, Maxillofacial or Periodontal and Endodontic Surgery.

SECTION 7

CLINICAL APPLICATIONS

INTRODUCTION

The Waterlase MD device is designed to cut and remove hard and soft tissues within the oral cavity. For hard tissue applications, the Waterlase MD achieves its uniquely diverse capabilities through the process of light absorption by water droplets. The proprietary flexible fiber optic system and handpiece delivers 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 MD device. Waterlase MD operates unlike traditional dental instruments or devices and technique must be practiced and perfected to ensure efficient operation.

Please be aware that the Waterlase MD system removes hard tissues through a hydrophotonic process with the fiber tip applied in a non-contact mode. The fiber tip has to be positioned at approximately 0.5 to 3 mm from the surface and 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 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 MD is presented in the following subsections.

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

HARD TISSUE CUTTING

Hard tissue cutting is achieved through a unique process described as hydrophotonic cutting. This process refers to the removal of tissue with laser energized water particles 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. Step on the footswitch, and water atomization spray and power will be immediately delivered to the tissue site. You will notice a distinct, gentle “popping” noise as water droplets expand from laser energy absorption. At the current position (5 mm away from targeted tissue), 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, hydrophotonic energy are delivered from the very end of the tip. Tissue cutting technique can be characterized as "end cutting," whereas the mechanical drill is known as a "side cutting" instrument.

Gently and slowly move the handpiece tip closer to the targeted tissue site. As you approach the treatment area you may notice a large accumulation of water. Use high speed suction as necessary to keep the field clear. Because of the great differences between traditional dental and Waterlase MD 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 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 highspeed drill. Gently and slowly move the handpiece in a circular, brushing or in-and-out motion as required to remove desired tissues or materials. Unlike traditional dental instruments, with the Waterlase MD, the slower you move the handpiece tip the quicker you will remove tissue.

Cutting efficiency will vary depending upon power setting and spray configuration. If you feel that the system is working slowly at the selected power setting, you can adjust the air and water spray settings. You will notice that clinical efficiency depends upon power as well as spray. As you gain experience with the Waterlase MD you will be able 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 you have completed treatment, release the footswitch and carefully remove the handpiece from the patient's mouth. Do not hit the handpiece tip into 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 *(see **Handpiece and Tip Cleaning and Sterilization** later in this section)*.

SOFT TISSUE INCISION, EXCISION AND ABLATION

Soft tissue procedures are performed with direct laser energy, either with or without the water spray. The water spray settings are generally lower for soft tissue than for hard tissue. During soft tissue cutting, the air and water spray hydrates and cools the target. There are two pulse settings for soft tissue applications: (1) a short pulse setting of 140 µs, and (2) a long pulse setting range of 650 – 1000 µs. The second range of pulses is indicated only for soft tissue applications.

For these procedures, select appropriate settings or presets as shown in Section 7: Presets for Soft and Hard Tissue Procedures. 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. For superficial lesions or hemostasis, the tip must be placed out of contact at approximately 1-3 mm off the surface. Effective hemostasis is achieved when the water spray is turned off.

Procedure Guidelines

For guidelines on specific dental and surgical procedures with the Waterlase MD, please refer to Appendix C.

PRESETS FOR SOFT AND HARD TISSUE PROCEDURES

As described before, Waterlase MD has the option of four user programmable presets stored in the system memory. Examples of pre-programmed values for general hard and soft tissue procedures are presented in Table 2. After deciding on the treatment protocol, select preset settings or adjust the parameters to appropriate values for the procedure. Always start treatment at the lowest power setting recommended, and increase as required using your clinical judgment. The values preprogrammed with the system or recommended in this manual are suggested values only. Use your clinical judgment to adjust any of the individual values for Power, Water and Air in order to compensate for varying tissue composition, density and thickness specific to individual patients. If a particular combination of customized values is especially effective and useful, you can then store these values in the system as a new Preset. Instructions for storing a new group of preset settings are provided in Section 4: Modify and Save Preferred Values as Presets.

Waterlase MD may be used for the applications listed in Section 7: Waterlase MD Indications for Use, Table of Indications for Use. If you are not sure which preset or settings to use for a particular application, please refer to the suggested settings presented in Table 2 from section 7: Presets for Soft and Hard Tissue Procedures, and use your clinical judgment to make appropriate adjustments. Attend training courses and experiment on model tissues before starting a new procedure in your practice.

FIBER TIP CALIBRATION CHART

Refer to Appendix D Tips: Suggested Clinical Specifications to review the different characteristics and calibration factors for the Waterlase MD tips. To calculate the expected power output from different families of tips, follow the instructions below.

- Select the tip for the procedure.
- Review Appendix D Tips: Suggested Clinical Specifications to select appropriate calibration factors for the selected tip.
- Use Calibration Menu to read the actual power coming out of the tip or calculate the power emitted at the tip by multiplying the display power by the calibration factor of the tip type. Remember that for a calibration factor of 1, the emitted power is the same as the display. Also, actual emitted power could vary as much as ±20%.

CALCULATING EMITTED POWER WITH TIP ATTACHMENT:

Example 1:
Tip Type: MT4
Calibration Factor: 0.90

Display Power: 2W
Then the Power Emitted is:
2W x 0.90 = 1.80 W

Example 2:
Tip Type: MZ2
Calibration Factor: 0.30

Display Power: 1W
Then the Power Emitted is:
1W x 0.30 = 0.30 W

PRE-PROGRAMMED PRE-SETS FOR GENERAL HARD AND SOFT TISSUE PROCEDURES

Preset #	Sub-preset letter	Example of Procedure	Power	Pulse Mode	PPS (Hz)	Water		Air	
						%	Mode	%	Mode
1	a	Caries Removal	**3.0**	H	25	30	Auto	60	Auto
	b	Enamel Cutting (sensitive)	**3.0**	H	15	30	Auto	60	Auto
	c	Enamel Cutting	**5.5**	H	20	30	Auto	70	Auto
	d	Enamel Cutting (fast)	**6.5**	H	30	30	Auto	70	Auto
2	a	Root Canal	**1.5**	H	20	20	Auto	30	Auto
	b	Boney Crown Lengthening	**2.5**	H	25	20	Auto	40	Auto
	c	Dentin Cutting	**3.5**	H	30	20	Auto	40	Auto
	d	Bone Removal (bulk)	**6.0**	H	30	30	Auto	70	Auto
3	a	Gingivectomy	**1.5**	S	50	8	Auto	11	Auto
	b	Soft Tissue Cutting (with anesthetic)	**1.5**	H	25	10	Auto	30	Auto
	c	Frenectomy (small incisions, w/o anesthetic)	**1.75**	S	40	8	Auto	11	Auto
	d	Soft Tissue Cutting (big incision, w/anesthetic)	**2.0**	S	30	10	Auto	30	Auto
4	a	Control Sensitivity	**0.25**	H	50	1	**OFF**	1	OFF
	b	Laser “band-aid”, Troughing	**0.5**	H	30	1	**OFF**	20	Auto
	c	Coagulation	**1.5**	S	50	1	**OFF**	20	Auto
	d	Water Priming	**0.1**	S	50	1	**OFF**	100	ON

OPERATING GUIDELINES:

1. Always wear magnifying loupes for better viewing of the operation area;
2. Always first fire the laser outside the mouth for patient comfort and to verify water spray;
3. Always start 10mm away from the target tissue (“de-focused”) at lower power settings and work your way towards the tissue.

TIP INSPECTION

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

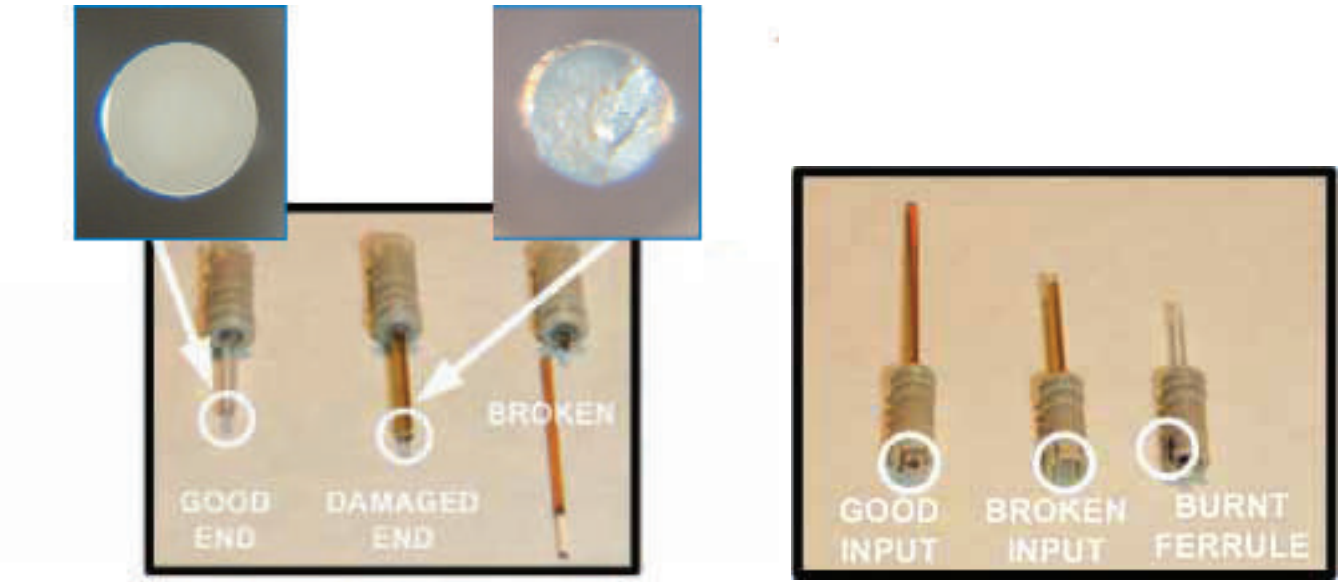
WARNING: Use of the damaged or contaminated Tip may cause damage of the Delivery System and will compromise clinical performance of the Waterlase MD.

Tips can be inspected using magnifying lenses, microscope, laser aiming beam or Biolase Tip Inspection Kit.

NOTE: Use of the Tip Inspection Kit is recommended to learn and differentiate good, damaged and contaminated Tips. See page 27 for Cleaning Instructions.

Visual Inspection.

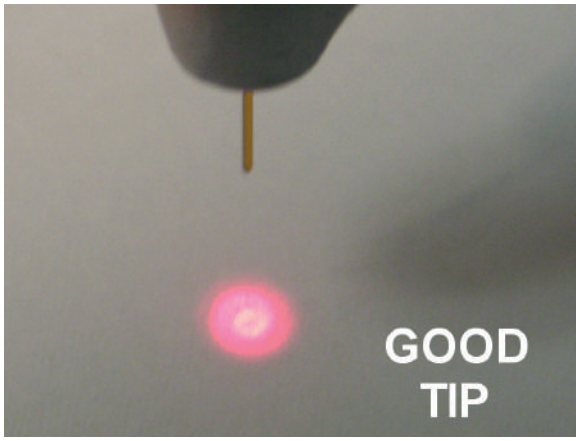
1. Check that both ends of the tip appear flat and have mirror-like reflection of any light source. Look for chips or nicks along the edges;



2. Check the plastic ferrule to ensure it is clean and has no burn marks at the input end. If burn marks are present, check handpiece alignment *(see Sec. **Mirror Alignment Check**)*.

Use of the Aiming Beam.

1. Set system to “Ready” mode and point handpiece towards a white surface. The red spot from the aiming beam should be well confined or have several concentric circles;



2. While still in the “Ready” mode, check that the end of the tip does not “glow.” The red beam should not be visible when observed from the side (end of the tip must be dry);

BASIC MAINTENANCE

NOTE: This will not completely clean or sterilize the handpiece and tip.

- Use standard dental disinfectant to wipe down the handpiece after each procedure (handpiece does not need to be disconnected from the unit). Do not use bleach or abrasive cleaners.
- With the tip still attached, use a q-tip and isopropyl alcohol to wipe the tip and the head of the handpiece after each procedure.

HANDPIECE AND TIP CLEANING AND STERILIZATION

NOTE: To ensure proper sterilization, handpiece must be cleaned and then steam autoclaved prior to each use.

Step 1—Handpiece Cleaning

The cleaning process is intended to remove blood, protein and other potential contaminants from the handpiece surface and crevices. Contamination control should be performed by trained personnel, while wearing protective gear (including gloves masks and shields).

NOTE: Always perform this procedure prior to steam sterilization.

1. Disconnect the handpiece and tip following proper procedures;
2. Insert the Tip Plug and the Rear Plug into the handpiece;
3. Wipe entire handpiece outer surface with cotton gauze and chemical disinfectant;
4. Soak gauze in chemical disinfectant and then wrap the handpiece and tip in gauze;
5. Let sit for ten (10) minutes or as recommended by the disinfectant manufacturer's directions;
6. Remove disinfectant gauze and wipe the handpiece with dry gauze.

Step 2—Handpiece Steam Sterilization

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

NOTE: Always perform this procedure after cleaning and before use.

1. Clean the Handpiece and Tips as described above;
2. Remove Rear Plug and Tip Plug from the Handpiece;
3. Place handpiece and tip(s) inside separate single-wrap, self seal autoclave pouches. Tips can be autoclaved in the revolving Tip Holder;
4. Gently place the autoclave pouches on the autoclave tray. Be careful when handling the handpiece and tip(s). Do not stack instruments on top of the handpiece or pouches;

5. Place the autoclave tray inside the autoclave chamber;
6. Set autoclave cycle to the following parameters: Temperature: 250ºF (121ºC); Pressure: 15 psi (1 bar); Time: 20 minutes;
7. At the time of completion of the autoclave cycle, remove the tray and let items cool;
8. Once cool, remove the handpiece, tips and plugs from the pouches;
9. Connect the handpiece to the system or insert the Tip Plug and Rear Plug and return the handpiece to its box.

MIRROR CHECK AND CLEANING

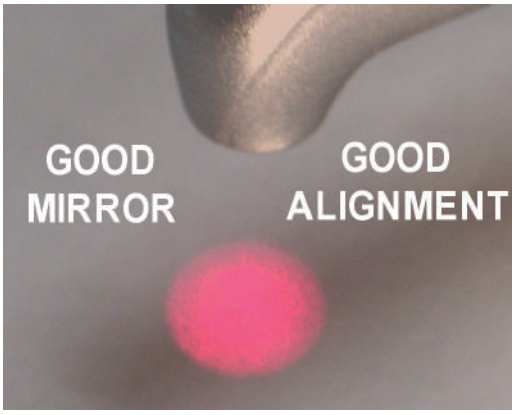
NOTE: If performance of the delivery system is questioned and the Tip is in good condition, check the Handpiece Mirror for damage or contamination.

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

Set system in the "Ready" mode and remove the Tip;

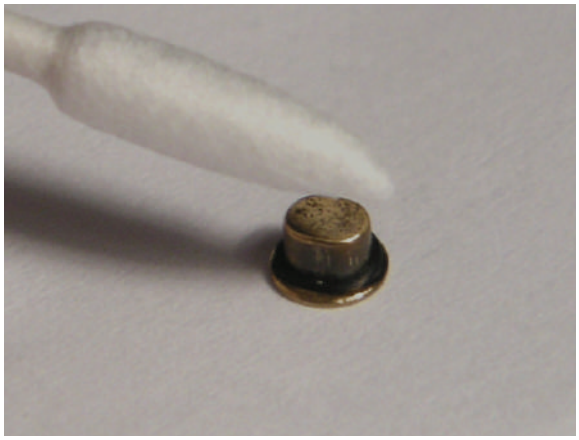
Mirror Inspection and Cleaning

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



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

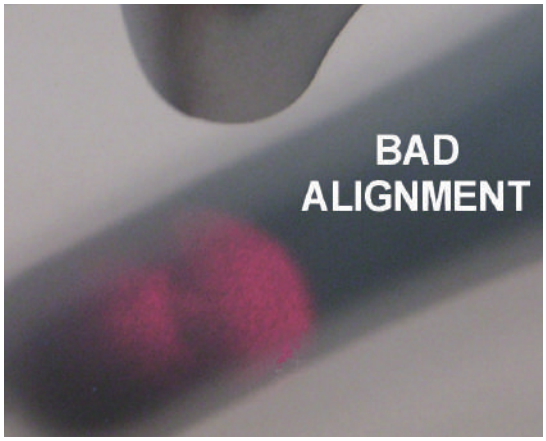
2. To inspect the mirror, remove it following proper procedure *(see:* ***Changing the Waterlase MD Handpiece Mirror****)*;
3. Mirror can be contaminated or damaged;



4. Contaminated mirror can be cleaned and with cotton swab, moistened with optical grade acetone or alcohol:
    - Place wet swab over the mirror surface and wait for ~5sec for solvent to soften the contaminating material;
    - Wipe off the contamination by quick turn and removal of the swab;
    - Repeat several times until all contamination is removed.
5. If mirror has remaining burn marks or scratches, it should be replaced;
6. While mirror is removed and it has contamination or burn marks, clean the internal reflector inside handpiece head with long cotton swab, moistened with acetone or alcohol;
7. Install the new or cleaned mirror and check proper alignment.

Mirror Alignment Check

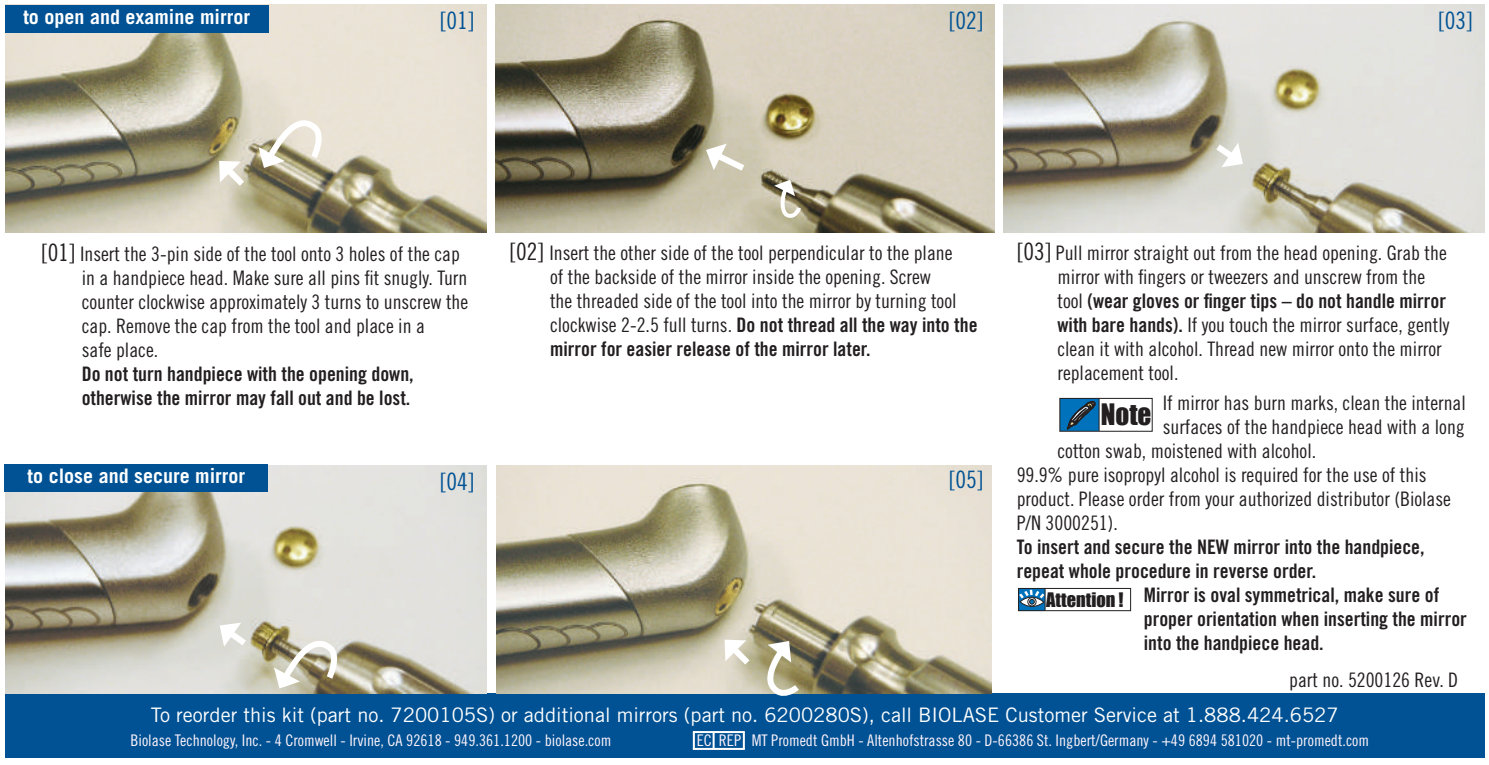
1. Point the Handpiece towards a white surface. The red spot of the aiming beam should be clear, uniform and well confined;
2. If spot is confined on one side and has satellite-type reflection (smile) on the opposite side, mirror alignment is questioned;



3. To improve alignment, remove the mirror and turn it 180 degrees *(see Sec. **Changing the Waterlase MD Handpiece Mirror**)*. If this does not help, replace the handpiece. If that does not help, replace the trunk fiber;

NOTE: If the plastic tip ferrule is continuously getting damaged at the input end, mirror alignment should be questioned.

CHANGING THE WATERLASE MD HANDPIECE MIRROR

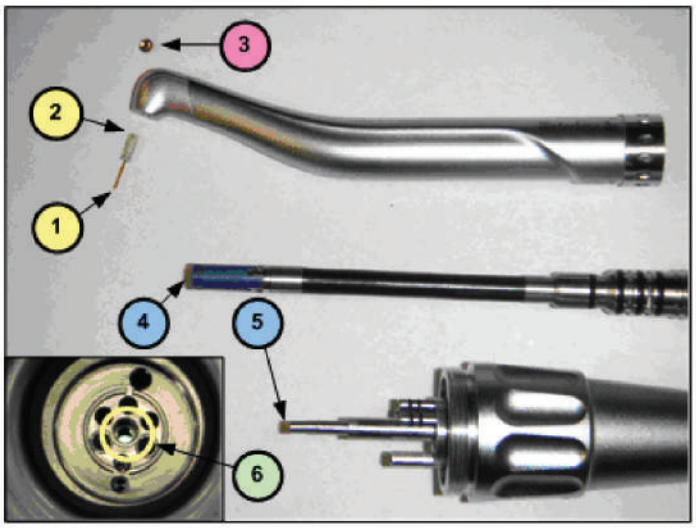


TROUBLESHOOTING THE DELIVERY SYSTEM

When any of the listed Delivery System *Symptoms* are found, inspect the *Checking Areas* following this chart, step by step, and perform recommended *Repair Action*.

NOTE. Refer to the ***Maintenance*** Instructions for detailed information.

WARNING. Early discovery and repair of problems will improve the dependability of the laser system and prevent further problems.



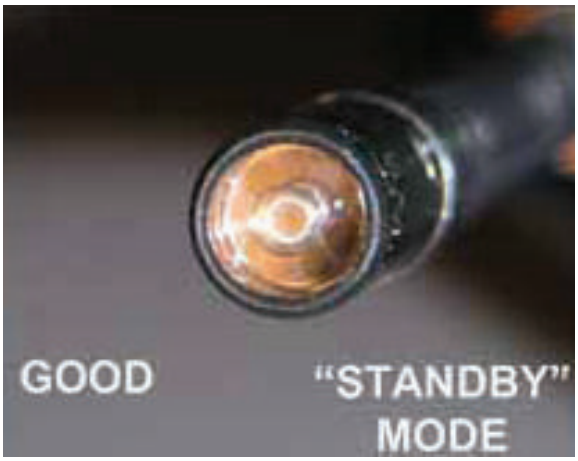
Symptoms	*Checking Areas*		*Repair Actions*
- Slow cutting - No "popping" sound - No red beam - Tip flashing	1. Tip, Distal End	bad	- *Replace Tip*
		good	
- Smell burnt plastic	2. Tip, Proximal End	bad	- *Replace Tip and check Steps 3, 4*
		good	
	3. Handpiece Mirror	bad	- *Clean first, then replace Mirror*
		good	
	4. Fiber Shaft, Window	bad	- *Clean first, then replace Fiber*
		good	
	5. Fiber, Input End	bad	- *Replace Fiber and check Step 6*
		good	
	6. Laser Aperture	bad	- *Blow clean air, Call Service*
		good	
	- *Call Service*		

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 input end of the Tip or Handpiece mirror were damaged.

WARNING: Use of dirty or contaminated Protective Window will cause damage of the Fiber Delivery System.

1. Disconnect the Handpiece following proper procedure;
2. Verify laser is in the “Standby” mode;
3. Check polished reflective surface of the window in the middle of the Fiber Shaft;
4. Clean with q-tip and isopropyl alcohol if surface is contaminated;



- If damage found (crater in the middle of the window), replace Fiber Delivery System;
- If no damage found, switch laser to the “Ready“ mode. Red aiming beam and illumination fibers should lit (adjust brightness, if necessary). If aiming beam is not visible, replace Fiber Delivery System *(see Sec. **Troubleshooting**)*.

WATERLASE MD INDICATIONS FOR USE

IMPORTANT: Review all Contraindications, Warnings and Precautions presented in Section 6 before proceeding with using this device on patients.

Use of Waterlase MD may be 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

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

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.)
- Osseous crown lengthening

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

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

- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

* For use on adult and pediatric patients

SECTION 8

MAINTENANCE

ANNUAL MAINTENANCE

The Waterlase MD should be serviced annually by a qualified, trained and certified technician. During the annual visit the system flash lamp will be inspected and 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 as well. Please contact your local representative to discuss extended service contracts and annual maintenance options.

Delivery System

The fiber delivery system and handpiece represent high technology 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 when the unit is first shipped, as well as when a trained engineer services the unit. Depending on the use of the unit, 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.

DAILY MAINTENANCE

Use standard dental disinfectant to wipe down the handpiece after each procedure. Do not use bleach or abrasive cleansers. Be careful to prevent water from entering the unit, especially around the fiber optic handpiece connectors.

Clean the tips before and after every use to maximize their useful life. *(See **Tip Cleaning Instructions** for details)*

TRANSPORTATION

The Waterlase MD is susceptible to misalignment if not handled

properly. The unit should ALWAYS be packed inside of its shipping crate when transported from one location to another. While the unit is semiportable, and may be rolled from one operatory to another inside of the same office, 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 moving machine for transportation unless it is completely packaged inside of its shipping crate.

Once crated, the unit should be transported by fork lift 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 MD should be stored in a cool dry place when not in use. Storage temperature should be 15° to 30°(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.

The Waterlase MD was shipped inside of a custom shipping crate. Please save and store the crate in a cool dry place. The unit must not be transported unless packaged inside of the crate.

SECTION 9

CALIBRATION

Calibration requires specialized equipment, and is to be performed only by a trained service engineer. The service engineer will follow this procedure:

- Connect an output power meter to the laser, using a test fiber. The power meter head should be 1 to 2 inches from the fiber tip.
- Using the software provided by Biolase, verify the test setup is complete.
- Begin the calibration routine. The software will vary the unit's output power settings and use the power readings from the meter to calibrate the power output monitoring settings.
- If required, the software will revise the unit's internal calibration settings to ensure power remains within ± 20%.

Calibration Schedule:

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

Table 6: 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

APPENDIX A

LABELS

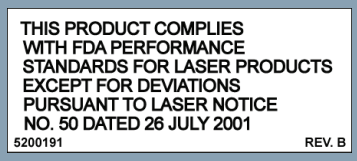
Laser Hazard Symbol

Location: Top cover of Laser head, directly above the Fiber Optic Connector. (Only visible during service)

High Voltage Hazard Symbol
(Only visible during service)

Locations:

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



Certification

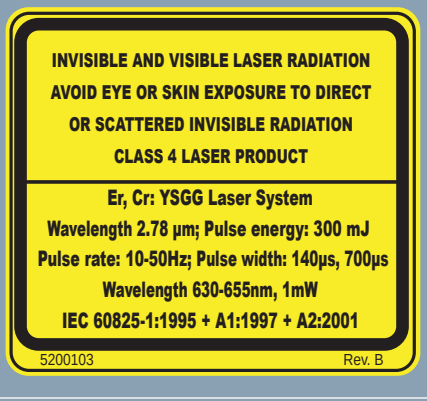
Location: Back Panel

Non-Interlocked Protection Housing Warning

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

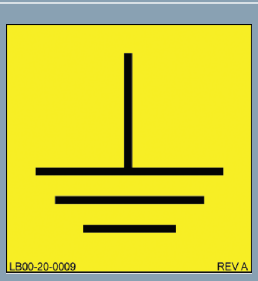
Laser Aperture

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



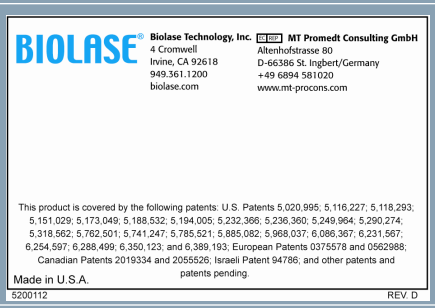
Laser Explanatory Label

Location: On top cover, adjacent to fiber optic connector



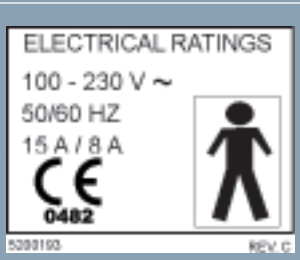
Ground

Location: Next to E1 ground terminal, inside unit.



Identification

Location: Back Panel, above ventilation channels

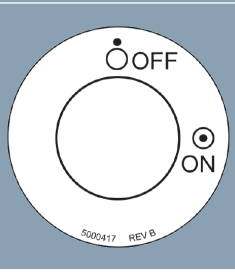


Electrical Ratings

Location: Next to Power cord connection

Air Label

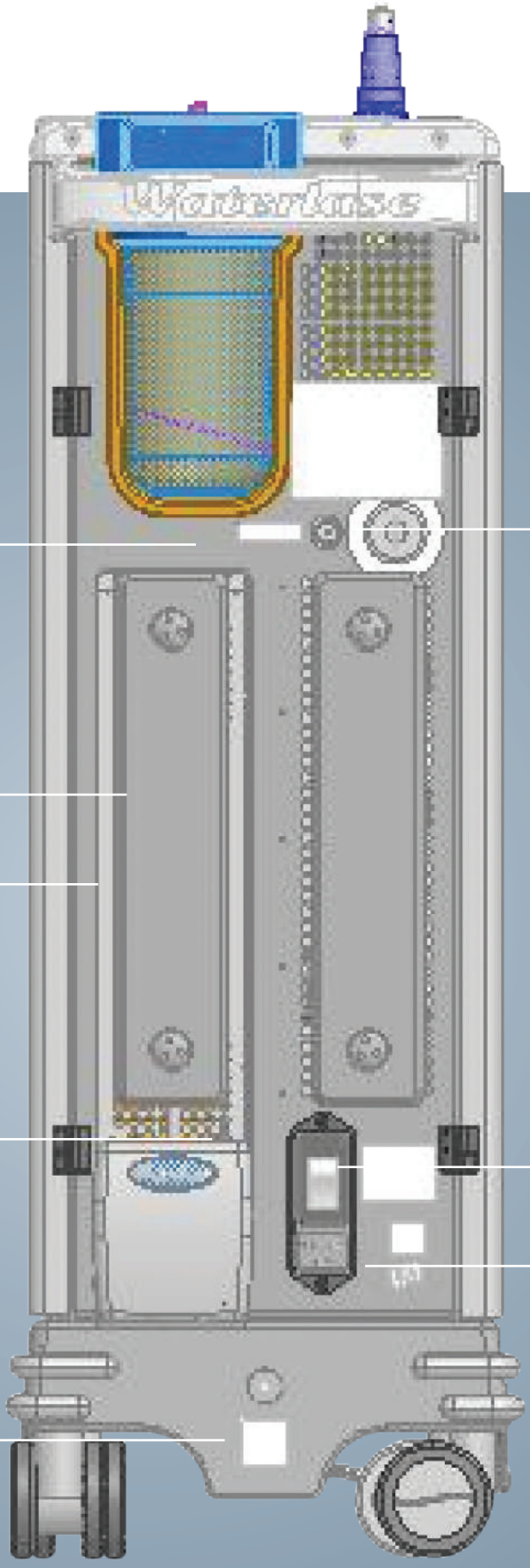
Location: Base, rear of unit



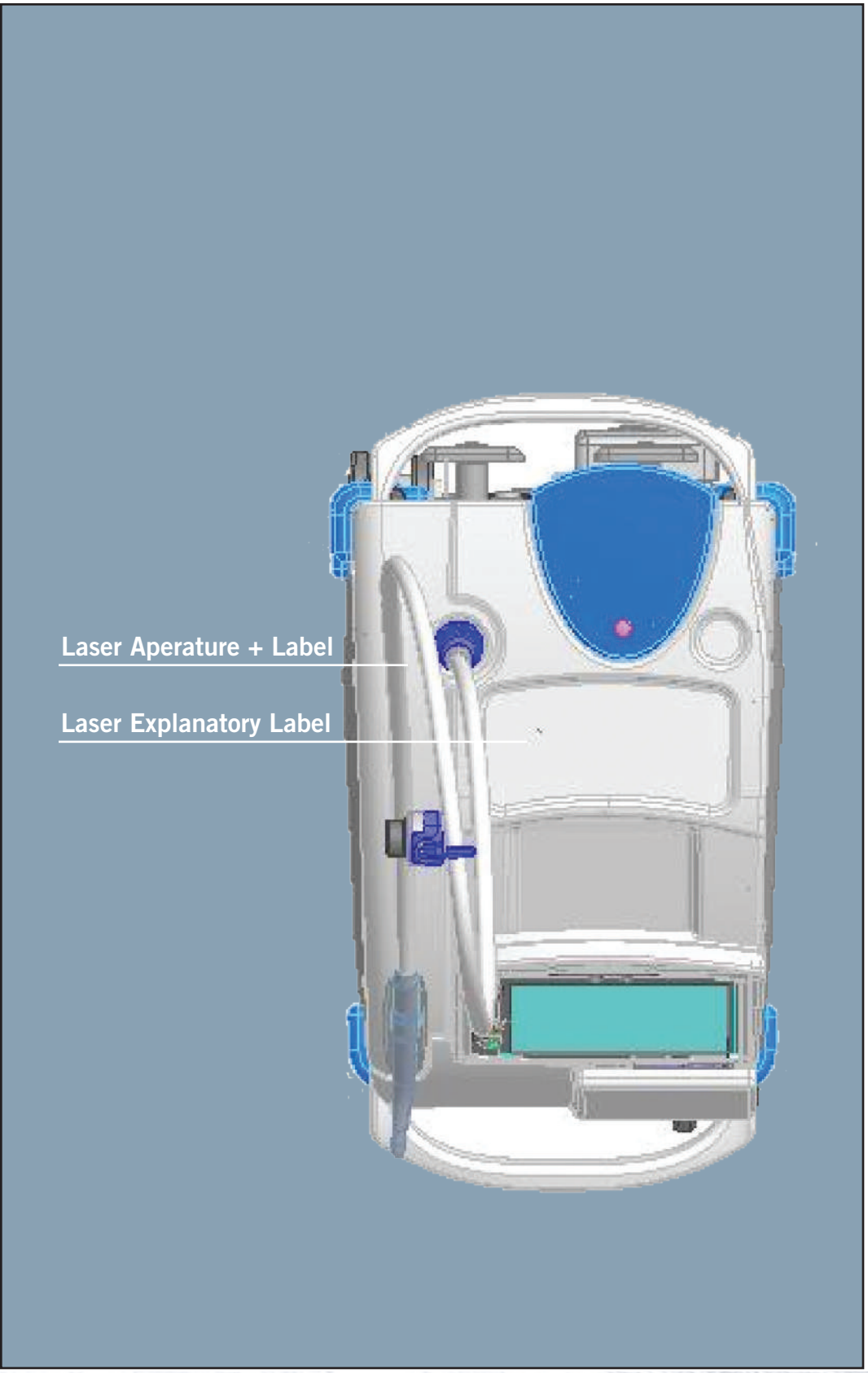
Key Switch

Location: Back panel

	**Remote Interlock Label** Location: Back Panel
	**ETL Listed** Location: Back Panel
	**Footswitch Label** Location: Back Panel
	**Emergency Stop Label** Location: Front Covert
	**Protective Earth Ground** Location: Back Panel
	**Attention (Small)** Location: Back Panel
	**WEEE Label** Location: Back Panel



YSGG Waterlase MD



APPENDIX B

ACCESSORIES

KEYS	
REMOTE INTERLOCK	
FOOTSWITCH	
POWER CORD (USA)	
POWER CORD (EUROPE)	
AIR HOSE	

APPENDIX C

CLINICAL PROCEDURE GUIDELINES

ROOT CANAL CLINICAL PROTOCOL

This modality of treatment uses the Waterlase MD to effectively remove necrotic and infected tissue from root canals, and to enlarge and taper the canal in preparation for obturation. Before proceeding with any endodontic treatment, carefully review the sections of the Waterlase MD User Manual pertaining to Contraindications, Warnings and Precautions, labeling for different endodontic tips, and recommended settings for power and air and water spray. Initial training on extracted teeth is strongly recommended. Start working on patients only after practice of the technique on extracted teeth and training is completed. Select simple cases such as straight canals on anterior teeth first.

Procedure

1. Prepare access to the pulp chamber with the Waterlase MD using a 600 µm fiber tip at the appropriate setting for cutting enamel and dentin.

2. Use the same G6 tip to remove the coronal portion of the infected/necrotic pulp. The recommended range of settings for this procedure is: Power = 0.75 - 1.00 W; Hz = 20; Air = 2 - 11%; Water = 7 - 11%.

3. The initial instrumentation is performed using the small size K files to allow a K#20 or 25 to reach the working length. A Z2 (diameter 200 µm) fiber tip is the thinnest endodontic fiber, which corresponds to a K#20 hand file.

4. Laser root canal enlargement is performed circumferentially starting at the apical third. To start the procedure, select a Z2 (diameter 200 µm) endodontic fiber tip with a length comparable to the established working length. Place fiber tip into the handpiece and select treatment settings. Use the control panel to enter appropriate settings for Power, Water and Air. The parameters suggested for this procedure are: P = 1.50 W, Hertz = 20, Water = 24% (Auto mode) and Air = 34% (Auto mode). These settings can be finely adjusted to better optimize for each patient's care. Power settings should not exceed P = 1.5 W and the procedure should always be conducted using appropriate air and water spray.

5. To measure the working length, insert the Z2 fiber into the canal and mark the length less 2 mm using a waterproof black marker. Use the mark as reference point to insert Z2 approximately 2 mm short of the working length.

6. Activate the system and start moving the fiber upwards, coronally to initiate enlargement. While moving the fiber, apply slight pressure on the side wall of the canal. Take about eight (8) seconds to move the fiber from its apical location to the coronal end of the canal. The motion should feel like painting or sweeping the wall. After completion of the first stroke re-insert the Z2 and proceed with a second stroke. A total of six (6) strokes are suggested for the Z2 instrumentation. Flush debris in between strokes using any conventional irrigation solutions (i.e. NaOCl).

7. Replace the Z2 tip with a Z3 and continue with enlargement and shaping. Use the same protocol and settings to operate the Z3.

8. After six (6) strokes, replace the Z3 with a Z4 tip. Proceed with the Z4 using same settings, techniques and protocol as for Z2 and Z3. A total of eighteen (18) strokes, six (6) with each of the fiber types, are suggested for cleaning and enlargement of most canals. Depending on the case, additional strokes may be necessary.

9. At the end, irrigate thoroughly and check canal dimensions using any graduated endo files. Use any of your preferred techniques and materials to fill the canal and restore the tooth.

It is important to note that sound principles of endodontic treatment have not been affected by using this device and technique. Protocols that constitute correct endodontic treatment such as irrigation, drying, obturation, etc. remain within the scope of the operator's clinical judgment and experience.

NOTE: Clinicians who are conservative of tooth structure and wish to keep the tapered shape of the canal to a minimum may find this laser procedure sufficient for such goals. However, if the goal is to achieve a more tapered shape to accommodate the wide Gutta-Percha points, additional instrumentation may be necessary.

APICOECTOMY CLINICAL PROTOCOL

The same clinical standards as with conventional instrumentation are applied to Waterlase MD for Apicoectomy procedures. Following are procedural steps including laser operating parameters and surgical techniques recommended for Waterlase MD Apicoectomy:

Before starting any procedure, carefully review the Contraindications, Warnings and Precaution section of the User Manual. **Surgical procedures on soft tissue, bone and root apex should only be performed by clinicians who have training and knowledge in Oral, Maxillofacial and Endodontic Surgery.**

1) Preparation of the surgical site:

a. Establish access to the site using cotton rolls, cheek retractors, etc.

b. Apply local anesthesia.

c. Determine location for incision.

* Always start treatment at the lowest power setting for the specific tissue and increase as required. Closely observe the clinical effects and use your judgment to determine the aspects of the treatment (technique, proper power, air and water settings, tip type and duration of operation) and to make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

2) Incision of gingival tissue to prepare the flap:

a. Select Waterlase MD parameters(*) and tip:

1. P = 1.5 W
2. Hz = 20
3. Water = 20%
4. Air = 20%
5. Tip type: T4, 400 µm diameter

b. Apply fiber tip in slight contact with gingival tissue and proceed with the incision following the flap design of your choice (i.e., semilunar, scalloped, triangular, rectangular, etc.).

WARNING: Reduce air and water to a minimum when working on unattached gingiva to avoid any fluid entrapment. Keep a flow of water spray when the cut is approaching the underlying bone.

3) Flap reflection:

a. Reflect flap apically to expose the bone.

4) Bone removal to prepare window access to root apex:

a. Select Waterlase MD parameters (*) and tip:

1. P = 2.50 W
2. Hz = 20
3. Water = 35 %
4. Air = 40%
5. Tip type: G6, 600 µm diameter

b. Place the 600 µm tip at approximately 1.5 – 2.0 mm from tissue. Following a circular motion pattern proceed with bone removal to prepare the window. In most cases a 3 – 4 mm diameter is adequate. Thicker bone may require a power setting as high as P = 3.50 W with Air = 65% and Water = 60%.

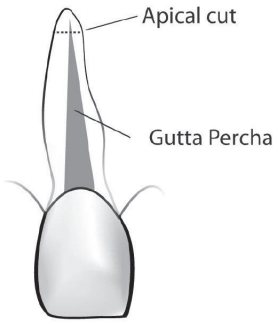
* Always start treatment at the lowest power setting for the specific tissue and increase as required. Closely observe the clinical effects and use your judgment to determine the aspects of the treatment (technique, proper power, air and water settings, tip type and duration of operation) and to make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

5) Amputation of root apex:

a. Select Waterlase MD parameters(*) and tip:

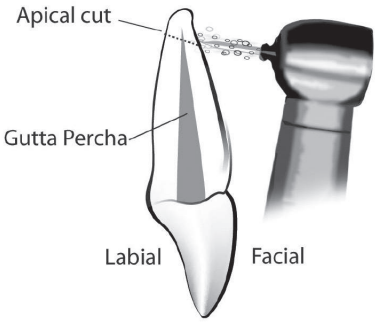
1. P = 2.25 W
2. Hz = 20
3. Water = 30 %
4. Air = 35%
5. Tip type: G6, 600 µm diameter

b. Bring tip approximately 1 mm from the root surface. Direct the tip at slight angle so as to give a bevel effect and proceed with cutting. An example of bevel cut is presented in Fig. 1a and 1b. The angled cut provides better access to the apical Gutta Percha for retrofilling.



Apical Cut Labial View

Fig 1a



Apical Cut Side View

Fig 1b

6) Root end preparation for retrofill:

a. Select Waterlase MD parameters (*) and tip:

1. P = 2.0 W
2. Hz = 20
3. Water = 30 %
4. Air = 35%
5. Tip type: G6, 600 µm diameter

b. Position the tip at approximately 1 mm from the sectioned root. Direct the tip at the sectioned surface and prepare a small pit for placing the sealant.

c. Use any of your preferred materials to seal the end of the root.

* Always start treatment at the lowest power setting for the specific tissue and increase as required. Closely observe the clinical effects and use your judgment to determine the aspects of the treatment (technique, proper power, air and water settings, tip type and duration of operation) and to make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

7) **Pathology and Granulation tissue removal:**

a. Select Waterlase MD parameters(*) and tip:

1. P = 2.25 W
2. Hz = 20
3. Water = 30%
4. Air = 30%
5. Tip type: G6, 600 µm diameter

b. Locate any pathology that has to be removed for lab evaluation. Apply the tip in slight contact with tissue and proceed with the removal. Use any necessary instruments such as forceps, etc., to secure this tissue and with the tip in contact carefully detach the lesion. The tissue must be removed as one piece for histopathological evaluation purposes. In case the lesion is not easily accessible or it is too soft to be removed with the laser use conventional spoon curettes to dislocate and remove.

c. For granulation tissue removal select the following Waterlase MD parameters(*):

1. P = 0.75 W
2. Hz = 20
3. Water = 7 %
4. Air = 11%
5. Tip type: G6, 600 µm diameter

d. With the tip in contact mode, slowly remove any granulation tissue from the periapical area. Use the 600 µm tip in a defocused mode (~2 mm from surface) at settings for bone debridement (P = 2.0 W, W = 30% and A = 35%) to clean bone and remove debris. Surgical curettes can also be use to scrape the bone and remove granulation tissue. To irrigate and rinse the site, use sterile saline.

8) **Irrigation of site:**

Use sterile saline to irrigate and rinse the site before suturing.

9) **Suturing of the flap:**

Use the preferred technique and materials to suture the flap.

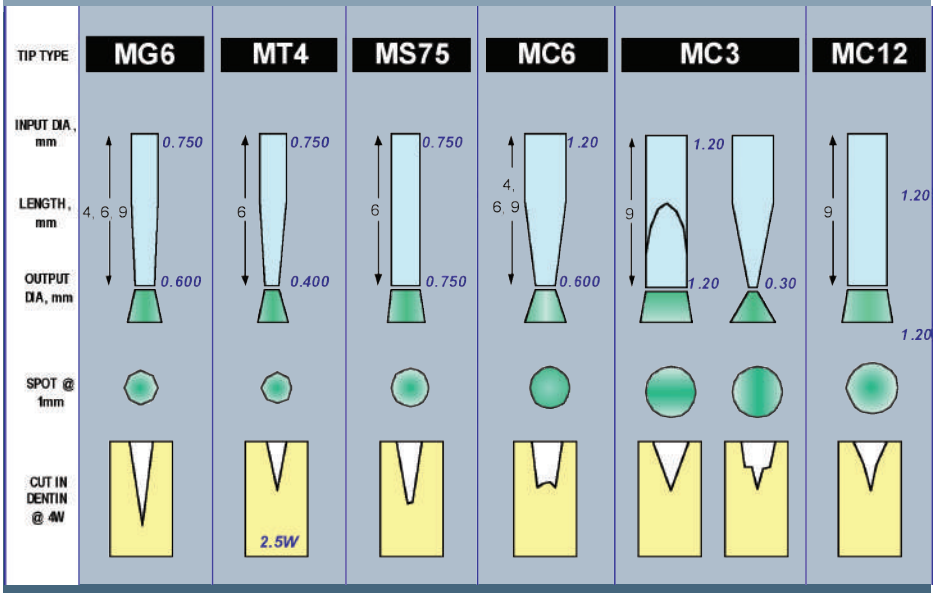
10) **Patient post-operative care instructions and follow-up evaluations:** Provide the patient with take home instructions and the follow-up schedule.

* Always start treatment at the lowest power setting for the specific tissue and increase as required. Closely observe the clinical effects and use your judgment to determine the aspects of the treatment (technique, proper power, air and water settings, tip type and duration of operation) and to make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

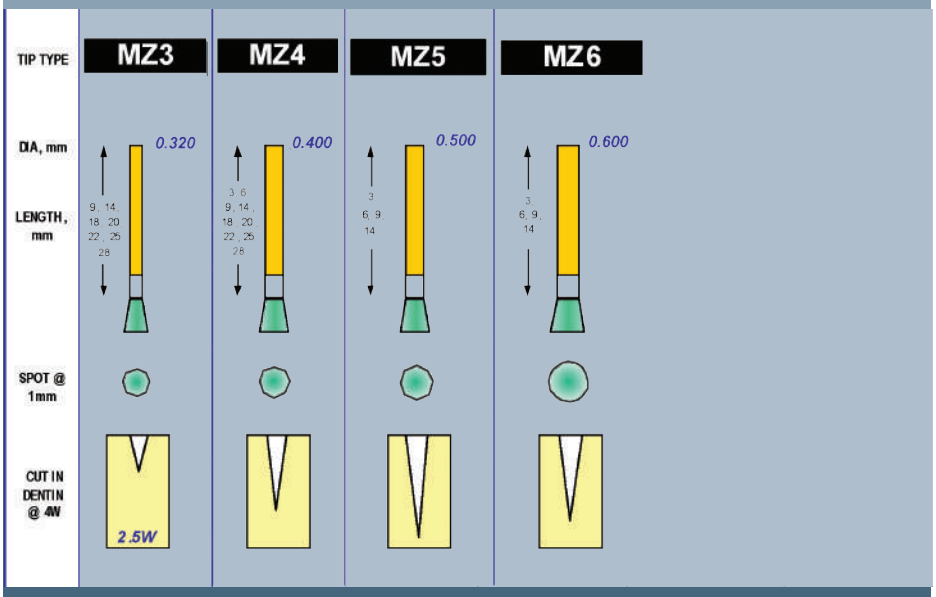
APPENDIX D

TIPS: SUGGESTED CLINICAL SPECIFICATIONS

SAPPHIRE TIPS GUIDE

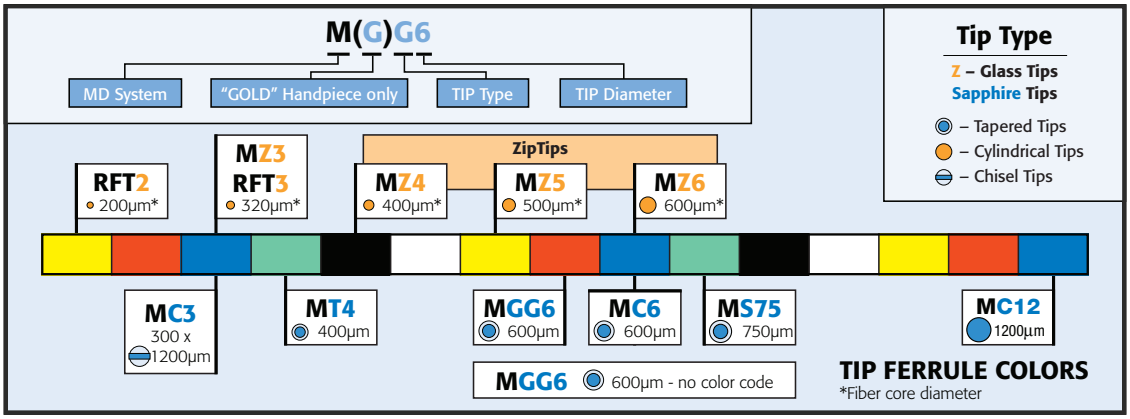


SAPPHIRE TIPS GUIDE



Waterlase MD & MD Gold Tip Guide

MD Tip Types Following Dental Standard ISO Series Diameter / Color Codes



Tip Settings, Waterlase MD & MD Gold Handpieces

Tip Type	Ferrule Color / Diameter (µm)	Lengths (µm)	MD Gold		MD Standard		Tissue Types
			Calibration Factor*	Maximum Power (W)	Calibration Factor*	Maximum Power (W)	
Z – Glass Tips							
RFT2	200	21, 25	0.55	4.0	0.30	2.5	Root Canal
MZ3	320	9, 14, 18, 20, 22, 25, 28	0.85	4.0	0.60	2.5	Root Canal, Soft Tissue
RFT3		17, 21					Root Canal
MZ4	400	9, 14, 18, 20, 22, 25, 28	0.90	4.0	0.75	4.0	All Types
MZ4 Zip		3, 6, 9, 14					
MZ5 Zip	500	3, 6, 9, 14	0.95	No Limit	0.90	5.0	All Types
MZ6	600	6, 9, 14	1.00	No Limit	0.90	No Limit	Enamel, Bone, Dentin, Soft Tissue
MZ6 Zip		3, 6, 9, 14					
Sapphire Tips							
MT4	400	6	1.0	2.5	1.0	2.5	Enamel, Dentin, Soft Tissue
MGG6	600	4, 6, 9	1.0	No Limit	DO NOT USE		Enamel, Bone, Dentin, Soft Tissue
MG6	600	4, 6, 9	DO NOT USE		1.0	No Limit	Enamel, Bone, Dentin, Soft Tissue
MS75	750	6	1.0	No Limit	1.0	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC3	300 x 1200	9	1.0	No Limit	1.0	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC6	600	4, 6, 9	1.0	No Limit	1.0	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC12	1200	9	1.0	No Limit	1.0	No Limit	Bone, Dentin, Soft Tissue

Indications for Use

Tip Type	Soft Tissue	Hard Tissue
Z – Glass Tips		
RFT2	N/A	Root canal debridement, cleaning and disinfection
MZ3	Sulcular debridement; Laser soft tissue currettage	Removal of granulation tissue
RFT3	N/A	Root canal debridement, cleaning and disinfection
MZ4	Same as MT4. Sulcular debridement; Laser soft tissue currettage	Same as MT4
MZ4 Zip		
MZ5 Zip	Combines applications of MZ4 and MZ6 tips	Combines applications of MZ4 and MZ6 tips
MZ6	Same as MGG6 and MG6	Same as MGG6 and MG6
MZ6 Zip		
Sapphire Tips		
MT4	Frenectomy and frenetomy; Gingival troughing; Gingivectomy; Gingivoplasty; Gingival incision and excision; Removal of pathological tissues; Incision and drainage of periapical abscessess; Full, partial and split thickness flap preparation	Excavation of pits and fissures for placement of sealants; Pits and fissures/caries removal
MC3	Most applications are the same as for MT4 and MGG6 tips, taking into consideration "flat" shape of the tip	Cutting, contouring, shaving and resection of oral osseous tissue (bone)
MGG6	Same as MT4; Excisional and incisional biopsies; Exposure of unerupted teeth; Fibroma removal; Hemostasis; Implant recovery; Incision and drainage of abscesses; Leukoplakia; Operculectomy; Oral papillectomy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores; Vestibuloplasty	Cavity preparation I-V; Caries removal; Hard tissue roughening or etching; enameloplasty; Tooth preparation to access to a root canal; Cutting, contouring, shaving and resection of oral osseous tissue (bone); Osteotomy, ostectomy, osteoplasty and osseous recontouring; Cutting bone to prepare a window access to the apex of the root; Apicoectomy; Root end preparation for retrofill
MG6	Same as MGG6, but with Standard MD Handpiece	Same as MGG6, but with Standard MD Handpiece
MS75	Same as MGG6 and MG6	Same as MGG6 and MG6
MC6	Same as MGG6 and MG6, considering more "shallow" cutting profile of tip	Same as MGG6 and MG6, considering more "shallow" cutting profile of tip
MC12	Same as MGG6 and MG6, considering bigger surface area and significantly "shallower" cutting profile of tip	Same as MGG6 and MG6, considering bigger surface area and significantly "shallower" cutting profile of tip

**

Calibration Factor: Actual power emitted from the tip = displayed power multiplied by the Calibration Factor. Applicable to entire range of power settings for the tip type.

Cautions: If a reduction in cutting efficiency is observed, replace the tip. Failure to replace the tip correctly could result in damage of the tip or the handpiece mirror. The tips have limited lifetime therefore damage of the delivery system attributed to overuse of the disposable tip may not be covered by warranty.

IMPORTANT: Federal law restricts this device to sale by or on the order of a dentist or a physician. Only licensed professionals who have successfully completed training should use the laser and accessories. Always start treatment at the lowest power setting and increase as required. Closely observe the clinical effects and use your professional judgment to determine the aspects of the treatment (technique, proper power settings, air and water settings, tip type and duration of the operation) and to make appropriate adjustments to compensate for varying tissue composition, density and thickness.

waterlase dentistry

waterlasedentistry.com Toll-free 888-424-6527

biolase.com NASDAQ: BLTI

USA

Biolase Technology, Inc.
4 Cromwell
Irvine, CA 92618
949.361.1200

Europe

EC REP MT Promedt Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert/Germany
+49 6894 581020
www.mt-procons.com

From BIOLASE

CE 0482

P/N 5200919 Rev. F (11/10)

APPENDIX E

ELECTROMAGNETIC COMPATIBILITY

CAUTION: Medical Electrical Equipment needs special precautions regarding Electro-magnetic 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 Technology as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the model Waterlase MD.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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

Emissions Test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The model Waterlase MD 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 model Waterlase MD 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 model Waterlase MD is intended for use in the electromagnetic environment specified below. The customer or the user of the model Waterlase MD should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines N/A	Mains 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 ±2 kV common mode	±1 kV differential mode ±2 kV 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% U_r (>95% dip in UT) for 0.5 cycle 40% U_r (60% dip in UT) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles <5% U_r (>95% dip in U_r) for 5 seconds	<5% U_r (>95% dip in UT) for 0.5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles <5% U_r (>95% dip in U_r) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Waterlase MD requires continued operation during power mains interruptions, it is recommended that the model Waterlase MD be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_r is the A.C. mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 GHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model Waterlase MD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[A] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones 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 MD is used exceeds the applicable RF compliance level above, the Waterlase MD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Waterlase MD

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

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

The Waterlase MD is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Waterlase MD can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Waterlase MD 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		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

BIOLASE®

biolase.com

NASDAQ: BLTI

USA

BIOLASE® Technology, Inc.
4 Cromwell
Irvine, CA 92618
949.361.1200

Europe

EC REP MT Promedt Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert/Germany
+49 6894 581020
www.mt-procons.com