Er:YAG Laser for Dentistry

AdvErL EVO

INSTRUCTIONS FOR USE

CE
0197

2024-03-21 Pub. No.: K240-91101-503 (en)

Thank you for purchasing the AdvErL EVO.
For optimum safety and performance, read this manual thoroughly before using this device and pay close attention to the warnings, cautions and notes.
Keep this manual in a handy place for ready reference.

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PREVENT ACCIDENTS

Most operation and maintenance problems result from insufficient attention being paid to basic safety precautions and not being able to foresee the possibilities of accidents. Problems and accidents are best avoided by foreseeing the possibility of danger and operating this device in accordance with the manufacturer's recommendations. First thoroughly read all precautions and instructions pertaining to safety and accident prevention; then, operate the equipment with the utmost caution to prevent either damaging this device itself or causing bodily injury.

The following symbols and expressions indicate the degree of danger and harm that could result from ignoring the instructions they accompany:

⚠DANGER This warns the user of the extremely serious injury or complete destruction of the equipment as well as other property damage including the possibility of fire.

⚠WARNING This warns the user of the possibility of extremely serious injury or complete destruction of the equipment as well as other property damage including the possibility of fire.

⚠CONTRAINDICATION
This identifies methods which must not be used or purposes which the equipment is not suited for.

⚠CAUTION This warns the user of the possibility of mild injury or damage to the equipment.

NOTE This alerts the user of important points concerning operation or the risk of equipment damage.

The user (e.g., healthcare facility, clinic, hospital etc.) is responsible for the management, maintenance, and use of medical devices.

This device must not be used for any purpose other than incision, hemostasis, coagulation and vaporization of biological tissues.

Federal law restricts this device to sale by or on the order of a dentist (valid only for U.S.A.). Only licensed professionals who have successfully completed training should use the laser and accessories.

Disclaimer

- J. MORITA MFG. CORP. will not be responsible for accidents, instrument damage, or bodily injury resulting from:
  - (1) Repairs made by personnel not authorized by J. MORITA MFG. CORP.
  - (2) Any changes, modifications, or alterations of its products.
  - (3) The use of products or instrument made by other manufacturers, except for those procured by J. MORITA MFG. CORP.
  - (4) Maintenance or repairs using parts or components other than those specified by J. MORITA MFG. CORP. and other than in their original condition.
  - (5) Operating the instrument in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being observed.
  - (6) Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
  - (7) Fires, earthquakes, floods, lightning, natural disasters, or acts of God.
- The useful life of the AdvErL EVO is 8 years from the date of installation provided it is regularly and properly inspected and maintained.
- J. MORITA MFG. CORP. will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued.

⚠WARNING

- ***Never use this device for patients who have a pacemaker or an implantable cardioverter defibrillator (ICD); it could cause these devices to operate erratically.***

⚠CAUTION

- ***Electromagnetic waves from cell phones, transceivers, and remote control devices could cause this device to operate erratically. Turn off all communication devices of this type in the operating area.***
- ***As far as possible do not use this device near or at the same time as other devices. If this cannot be avoided, make sure both units operate properly before using them for treatment.***

1. Device Description

1. Operational Principles

The AdvErL EVO consists of a combination of 4 systems and the Hollow Waveguide.

(1) Main Unit

1) Laser Oscillator System
The Er:YAG laser (2.94 μm) is generated by exciting the Er:YAG rod by the light of a flash lamp in the resonator, and is emitted from a half reflection mirror. The laser beam is partially reflected by a beam splitter, and is read by a laser sensor for power monitoring, and laser power control.
The safety shutter (beam shutter) opens after the Ready key is in the on state and the foot switch is depressed under no error condition, and the laser beam is emitted to the laser aperture.
After the shutter, the laser beam is mixed with an aiming beam (650 nm) and goes on to the Hollow Waveguide via the laser aperture.

2) Electrical System
The electrical system consists of the laser power supply, control unit, LCD touch screen control panel, key switch, and foot switch. The laser power supply consists of a high voltage circuit, trigger circuit, and other components, and is used to light the flash lamp.

3) Software
The software for the AdvErL EVO controls all its operations, maintains its safety, and makes sure that the output is accurate and exact.
The Laser output conditions including output power, number of repetitions etc. is set with the various keys on the touch panel display. Once the device is in its Ready condition, the laser beam is emitted by depressing the foot switch.
In this process, safety parameters are checked, and if anything abnormal is detected, an error is displayed and laser irradiation is stopped.

4) Cooling System
The AdvErL EVO is a water-cooled device.
Water is stored in a tank inside the Main unit, and circulates between the resonator and heat exchanger.
The heated water is cooled by the water-and-air heat exchanger and returns to the water tank.

(2) Hollow Waveguide

The hollow waveguide transmits the laser beam to the contact tip attached to the end of the handpiece. There are also water and air lines that provide spray to cool the treatment tissue. When the foot switch is depressed, the laser beam, water and air are all emitted from the end of the contact tip.
Contact tips, handpiece grip, and the hollow waveguide are applied parts.

2. Biological Effects

An Er:YAG laser emits an infrared beam with a wavelength of 2.94μm which is readily absorbed by water contained by both hard and soft tissues. As a result, the energy of the laser beam instantly vaporizes the water molecules in hard tooth tissue causing the tissue to crumble away.

These beams can also resect soft tissue.

3. Safety Procedures for Use of Laser Surgical Device

Post or display a “danger notice plate” or “warning notice plate” in an easily visible place outside the laser surgery area.

(1) Safety Measures to Protect Eyes, Skin, etc.

1) A serious injury will result if the laser beam directly strikes the eyes or skin. It is particularly essential to avoid damage to eyes (such as injuring the cornea, etc.).
The user, patient and all other people inside the laser surgery area must always wear Laser Safety Glasses to protect their eyes from the laser beam.
In all testing, instruction or training situations, the laser surgeon, instructors and students also must wear Laser Safety Glasses.

2) When entering the operation area of this device, always put on the Laser Safety Glasses. Furthermore, never emit the laser beam directly towards your eyes even if Laser Safety Glasses are worn.
3) Regularly inspect the Laser Safety Glasses to make sure there are no holes or fine cracks and make sure that they are physically sound.
4) Before using this device, the user must undergo a dermatology and ophthalmology examinations. Moreover, the user must undergo regular dermatology and ophthalmology examinations.
5) Due to the harmful effects laser beam emission can have on eyes and skin, it is necessary to undergo an ophthalmology and dermatology examinations. There are 2 reasons for this.
   1. To ascertain the state of the skin and eyes before performing laser beam emission.
   2. To detect damage to eyes or skin at an early stage.
6) If the user has suspected damage to eyes or skin, they must be examined by a doctor as soon as possible.

(2) Safety Measures to Protect Patient

The doctor must explain to the patient all crucial points regarding treatment involving the laser surgery device.
When using the laser surgery device, no matter what the circumstances, the doctor must always have the patient wear Laser Safety Glasses to protect the patient's eyes. The patient must follow the directions of the doctor.
Do not touch any terminals of this device and the patient at the same time.

(3) Safety Measures to Protect People other than User and Patient (Observers, etc.)

1) The user must prohibit people other than the user and patient from being in the area where the laser surgery device is used. If it is necessary to allow a person to enter the laser surgery area, it should be limited to cases where the person is undertaking instruction and training.
   When the user is using the laser surgery device, a notice stating laser surgery is in progress should be placed where all people visiting the area will notice it such as outside the entrance of the laser surgery room.
2) Only people recognized as authorized users may operate this device.
3) The user of this device must have complete proficiency in the operational procedures of this device.
4) The user must have received comprehensive instruction and training on the hazards of laser beams.
5) Any dentists, doctors, nurses or dental hygienists who might have to enter the laser surgery area must receive a comprehensive explanation on the hazards of laser beams.
6) The user of this device must never direct the laser beam to reflective surfaces or people other than the patient being treated.
7) The key for this device must be taken care of and kept by a supervisor and when this device is not in use, the key must always be removed.
8) Wear only Laser Safety Glasses that have been regularly inspected.

(4) Prevention of Laser Beam Reflection by Surgical Instruments, Equipment, etc.

As far as possible, remove all reflective instruments from the laser surgery area.
Take reflection protection measures by covering items that could reflect a laser beam such as surgical instruments and equipment with wet gauze or some other suitable material.
Pay attention to the reflection of the laser by metal objects, and use anti-reflection treated surgical instruments.
This laser beam is dangerous to eyes, skin, mucous membranes etc. even when reflect from a diffusing surface.
Ensure the measures to eliminate the hazard of reflected light outlined below are comprehensively followed.

1) Make sure the surgical instruments and equipment such as forceps and suction tubes have undergone processing to prevent reflection and take all possible measures to reduce reflection of the laser beam.
2) Never irradiate laser on a reflective surface.
3) Take care to prevent reflection by dental prosthetics etc.
4) No one should stand behind the patient or laser surgeon.
5) When using a surgical instruments that has not undergone processing to prevent reflection, cover it with gauze soaked with physiological saline.

(5) Measures to Prevent Fire

The heat generated by the laser beam could cause significant fire damage. Make sure the laser beam will not strike any combustible substances within the laser surgery area.

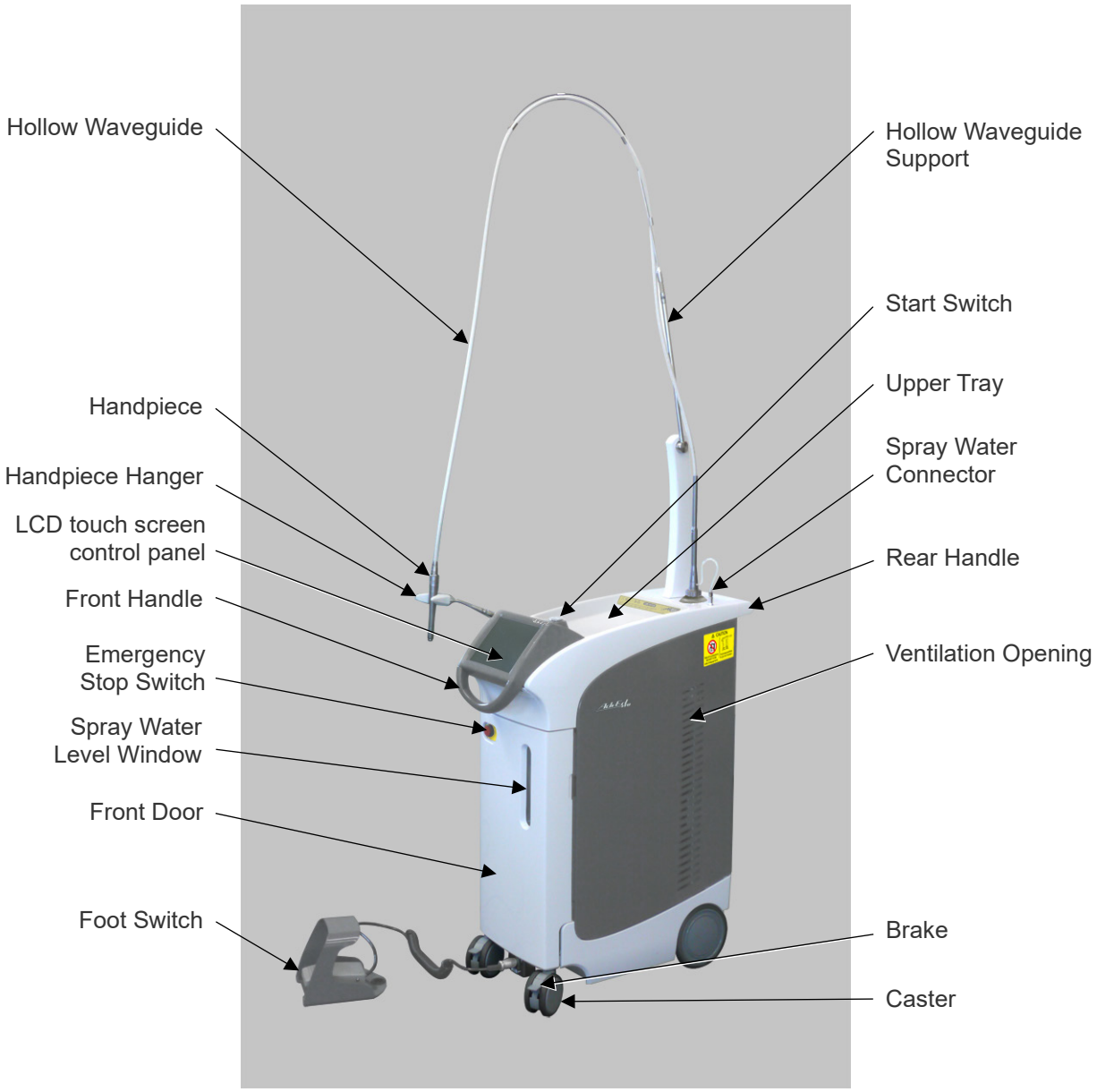
(6) Accidental Irradiation Precautions

1) Before irradiating a laser, biotissue that could be exposed to laser irradiation should be well-covered with gauze that has been soaked in a saline solution so that it cannot be harmed by accidental laser irradiation.
2) Always carefully consider the output power and irradiation time required for treatment and avoid excessive laser irradiation.
3) Both patient and laser surgeon must wear Laser Safety Glasses. If the laser beam (direct beam or diffused beams) strikes the eyes, it could cause blindness. Even when wearing Laser Safety Glasses, never allow the beam to strike the eyes directly.

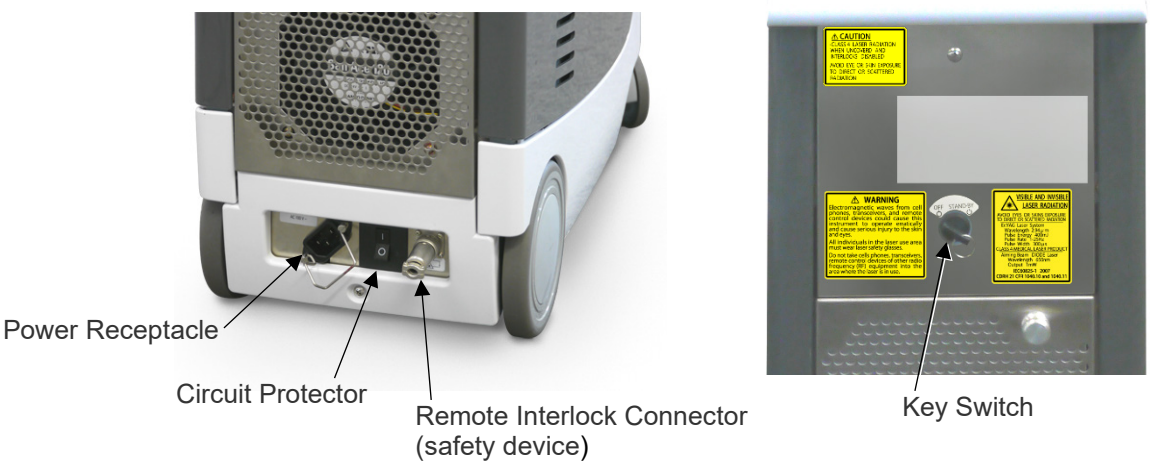
2. Parts Identification and Accessories

(1) Parts Identification

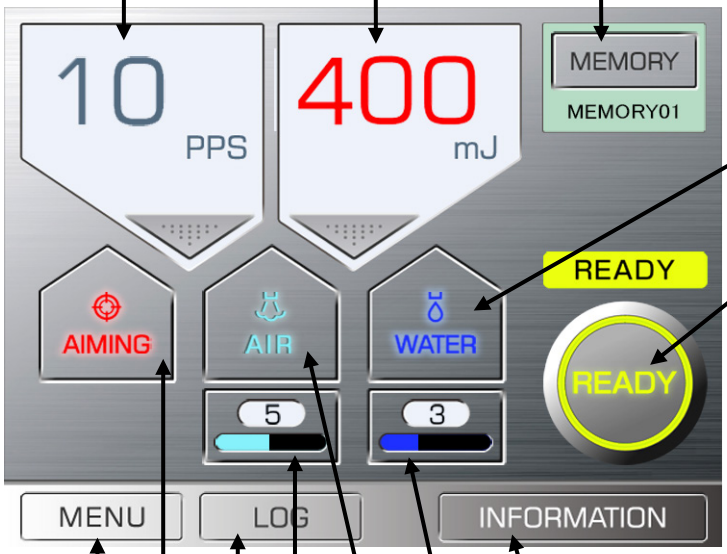
Main Unit



Back



LCD Touch Screen Control Panel (Main Panel)



PPS (pulse per second) Indicator
Shows the rate for pulsed irradiation (Unit: PPS).

Energy Level Indicator (mJ)
Shows the energy level setting (Unit: mJ).

Memory Key
Use this to memorize and retrieve different sets of irradiation conditions.

Water Key
Turn the spray on and off.

Ready Key
Press this to change the mode from Stand-by to Ready.
The key turns green in Ready mode. "Ready" changes to "Emission" and turns orange when laser is emitted.

Information Key
Lights up when there is maintenance information requiring attention.

Spray Water Setting Key
Press this to set the water spray flow.

Air Key
Turns the tip air on and off.
(When this is turned on, the water is turned on automatically)

Air Setting Key
Press this to set the tip air flow.

LOG Key
Press this to display the irradiation log.
(This can be shown or hidden. The factory setting is hidden.)

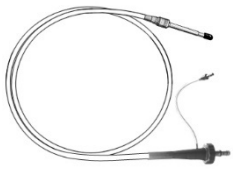
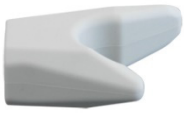
Aiming Key
Turn the aiming beam on and off.

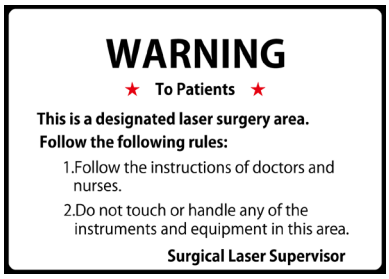
Menu Key
Hold this down to display the Menu.

(2) Accessories

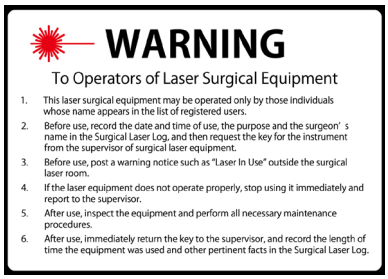
Contact Tips

			
C400F (1)	C600F (1)	C800F (1)	
			
S600T (1)	PS400TS (2)	PS600TS (1)	PS600T (1)

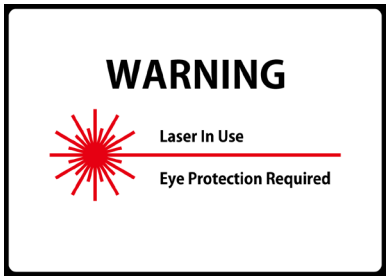
			
Keys (2)	Grease Applicator (1)	Laser Safety Glasses (3 pairs)	Lens Cleaner (1)
			
Tip Stand (1)	Foot Switch (1)	Remote Interlock Connector (1)	Hollow Waveguide (1)
			
Hollow Waveguide Support (1)	Power Cord (1)	Handpiece Hangers (2)	Handpiece Grips (2)
			
Deionized Water Tank for Cooling, 2.5-liters	Deionization Filter Cartridge (1)	Drain Tube (1)	Wheel Locking Device (1)



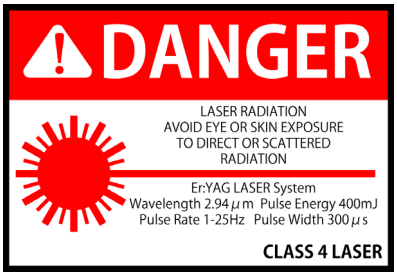
Patient Warning Plate



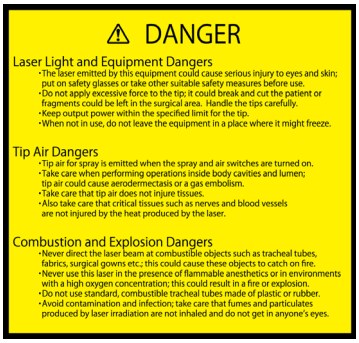
Operator Warning Plate



Eye Warning Plate

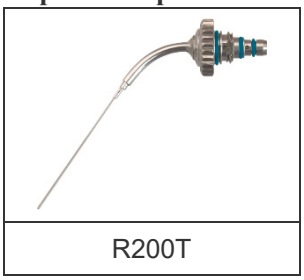


Laser Danger Plate

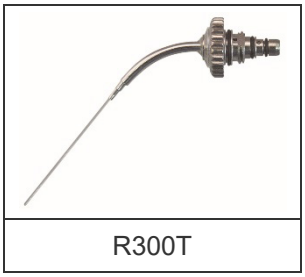


Operation Danger Plate

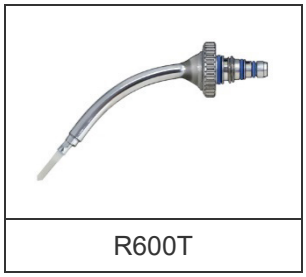
Optional Tips and Parts



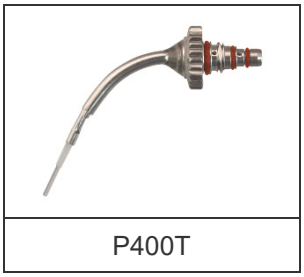
R200T



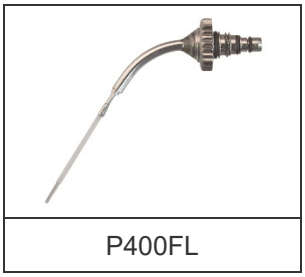
R300T



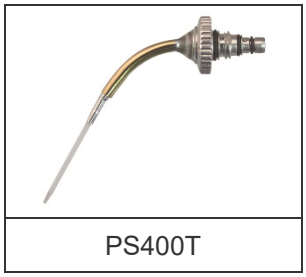
R600T



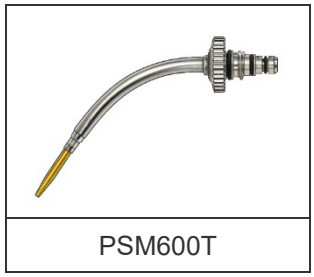
P400T



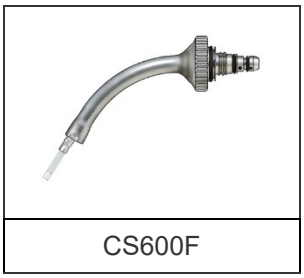
P400FL



PS400T



PSM600T



CS600F

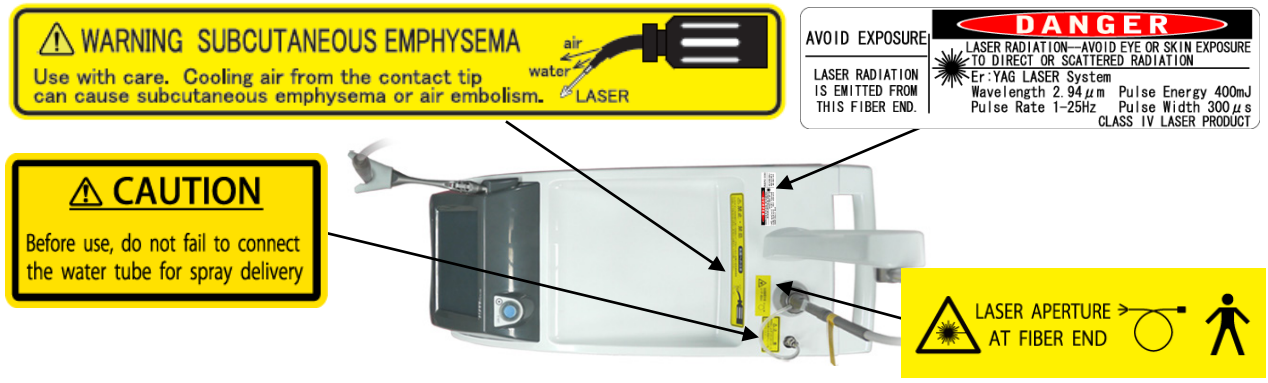
* Only for R200T and R300T

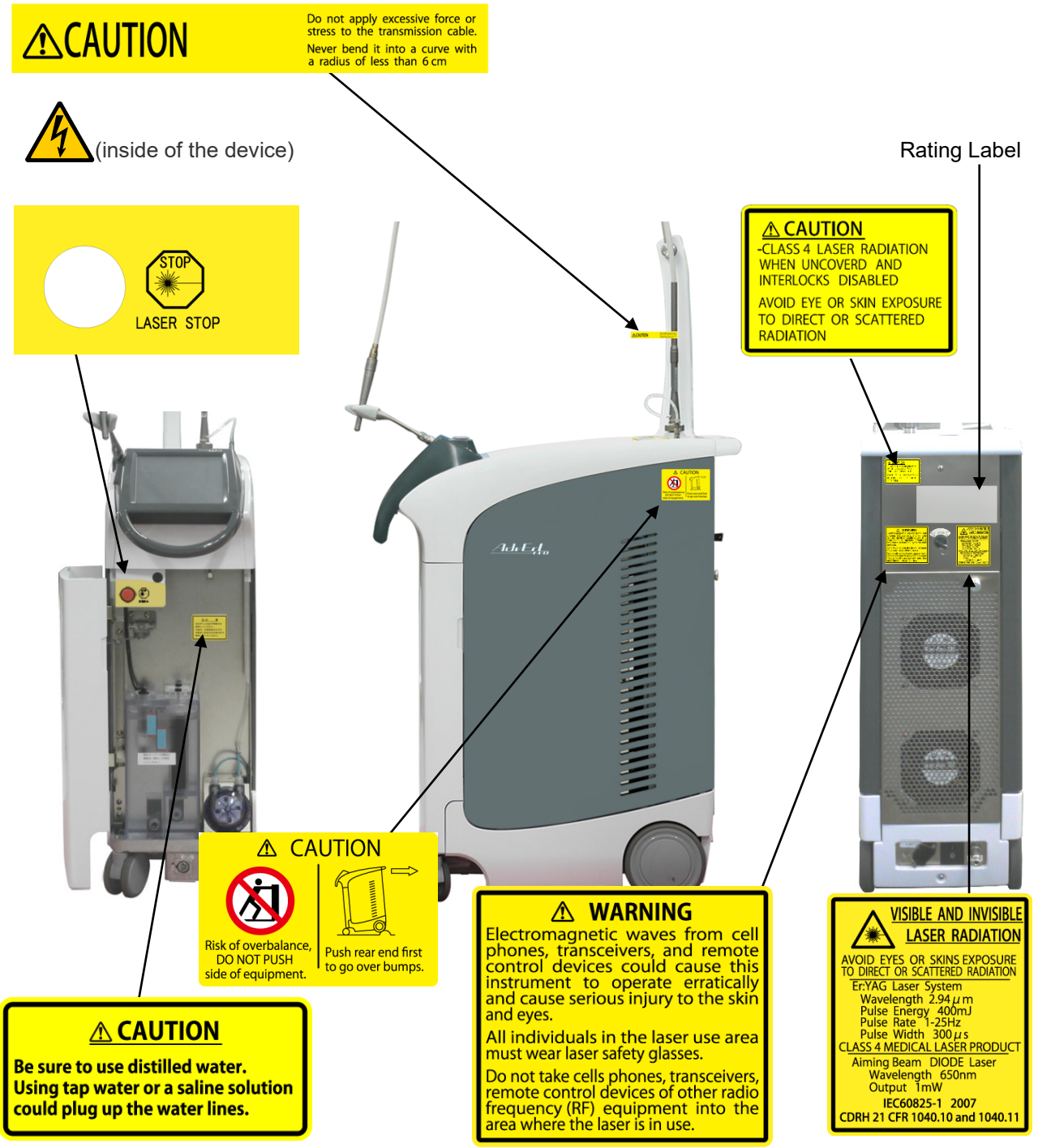
R Handpiece Grips

Touch Panel
Protective Sheet

(3) Labels

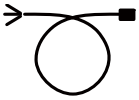
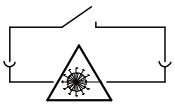
Read All Warning and Caution Labels





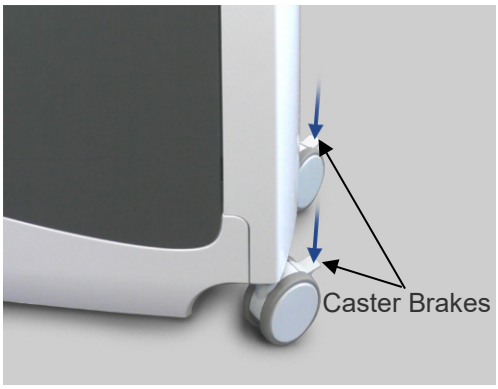
(4) Symbols

* Some symbols may not be used.

	Serial number		CE(0197) marking Conforms with the European Directive, 93/42/EEC. CE marking Conforms with the European Directive, 2011/65/EU.
	Unique device identifier		Medical device
	Manufacturer		Date of manufacture
	Refer to instructions for use		Attention, consult accompanying documents
	Type B applied part		Marking of electrical equipment in accordance with the European Directive 2012/19/EU (WEEE)
	cTUVus certification mark (Valid only for U.S.A. and Canada)		DANGER
	No pushing		Caution
	Caution: Laser		Caution: High Voltage
	Emergency laser stop		Optical fiber applicator
	Alternating current		“ON” / “OFF” (push push)
	“ON” for part of equipment		“OFF” for part of equipment
	Remote interlock connector, as defined in 3.74 of IEC60825-1		GS1 DataMatrix
	This way up		Fragile
	Keep away from rain		Temperature limitation
	Humidity limitation		Atmospheric pressure limitation
	Authorized representative in the European Community		Authorized representative in Switzerland

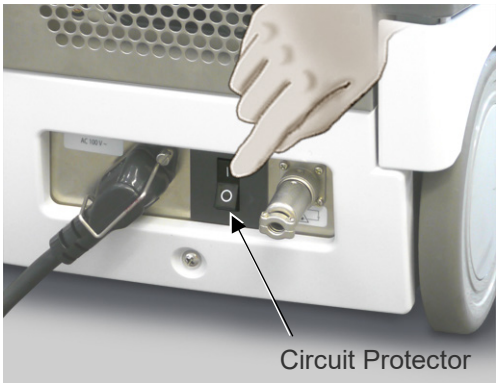
3. Operation

(1) Set Up



(1) Put the Main unit in position and lock the casters with the caster brakes.

(2) Take the foot switch off its hook and place it on the floor.



(3) Turn on the circuit protector on the back of Main unit.

(4) Pull the handpiece hanger forward.

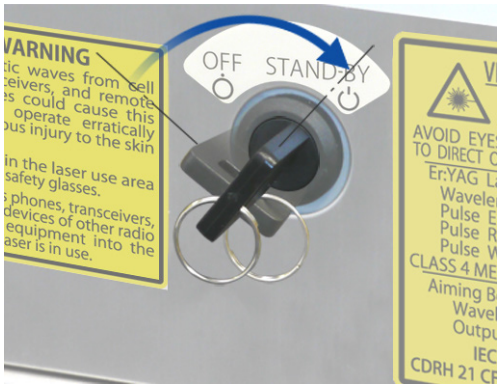
⚠WARNING

- ***When this device is not in use, always remove the key and return it to a supervisor.***
- ***Never use, modify, or calibrate this device in any way other than as described in this user manual. Accidental laser irradiation may occur.***
- ***Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser irradiation.***
- ***When a lightning strike occurs, stop using this device and do not touch this device or the power cord. There is a risk of electric shock.***

⚠CAUTION

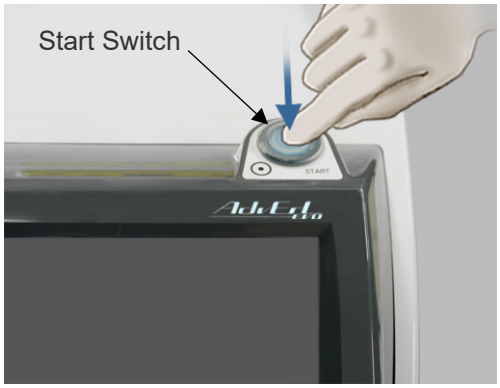
- ***Do not apply excessive force or stress to the hollow waveguide. Never bend it into a curve with a radius of less than 6 cm.***
- ***Do not let anyone go between the patient and this device. Do not let personnel not involved with the treatment stand near this device.***
- ***If an error occurs, stop using this device immediately and turn it off.***
- ***If an error is indicated on the LCD touch screen, stop using this device immediately and turn it off.***
- ***Do not put this device on a surface that is not level; it could tip over. Make sure the brakes on the casters are on.***
- ***Never tilt this device more than 10°when moving it; it could tip over.***
- ***Make sure there is enough water in the spray bottle.***
- ***When replacing the spray water bottle, disinfect the connecting needle with Dürr FD 333 forte or ethanol (70vol% to 80vol%).***
- ***To avoid stepping on the foot switch accidentally, decide where it should be and always place it in exactly the same place.***
- ***Depress the foot switch to the first level to drain residual water in the spray water line for at least 3 minutes before daily use of this device. (Implementation of flushing)***
  In addition, please drain the residual water especially carefully the day after a holiday.
- ***After the use of this device for each patient, depress the foot switch to the first level to drain residual water in the spray water line for at least 10 seconds.***

(2) Starting Device



(1) Put on Laser Safety Glasses.

(2) Insert the key and turn it to the Stand-by position.



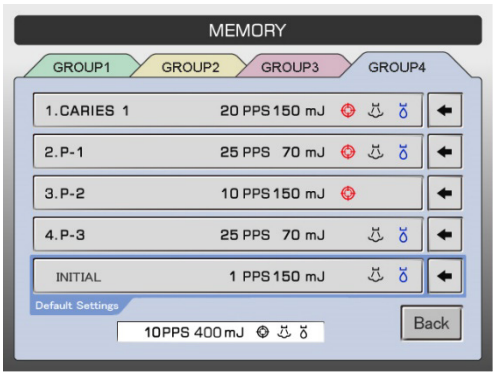
(3) Press the Start Switch.

- The warm-up procedure will run for 20 seconds.
  * The warm-up countdown number will appear on the LCD touch screen.
- After the warm-up is completed, the LCD touch screen will show a Warning message.

* **If the water temperature is less than +15°C (+59°F), the "D" interlock message will appear. In this case, wait for the water to warm up.**
* **If the cooling water gets too warm, the fan will speed up and make a louder noise.**

(4) Make sure you are wearing Laser Safety Glasses then press the "Confirm" key.

(5) The LCD touch screen will show the Main panel and the device will be in Stand-by mode.
The values of the Default Settings will be shown when starting up the device.



Default Settings

The fifth set in Group 4 (blue tab) are the Default Settings. These are the values set when the device is first turned on.

These settings can be changed as well as others. Even the set name "INITIAL" can be changed to the user's desired name.

(See page 27).

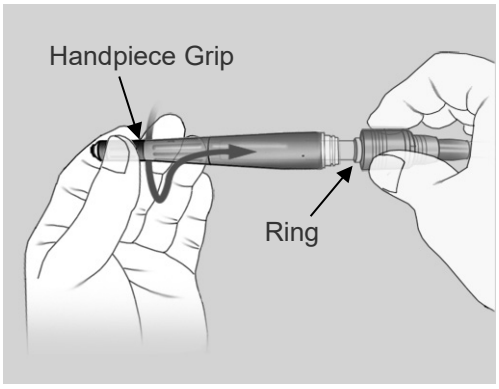
⚠WARNING

- ***A direct, reflected or scattered laser beam can cause permanent blindness. All individuals in the laser use area must wear Laser Safety Glasses supplied with this device. The Laser safety glasses has an OD of 3.5 (or greater) at 2.94 µm. Other parts of the body should also be protected. The laser beam can cause serious injury to the skin and eyes.***
- ***Even if you are wearing Laser Safety Glasses, never look directly into the aperture where the laser comes out; there is a risk of blindness. Both the main laser and the guide light are dangerous. The Laser Safety Glasses provide only limited protection.***

⚠CAUTION

- ***Use only Laser Safety Glasses specifically designed for the Er:YAG laser. Do not use Laser Safety Glasses meant for use with other types of lasers, the CO_2 laser, for example.***
- ***Before use, inspect the Laser Safety Glasses to make sure they are free of holes and cracks and are mechanically safe.***

(3) Attaching Contact Tip to Handpiece

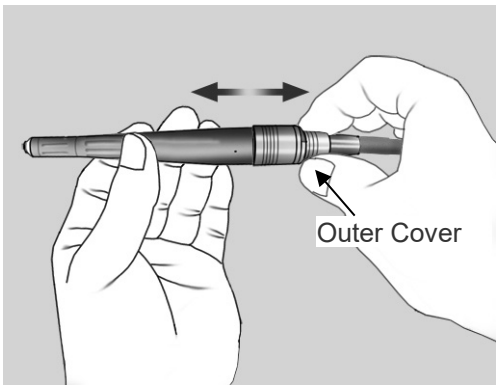


(1) Hold the ring in one hand and then put the Handpiece Grip on by turning it until it clicks into place.

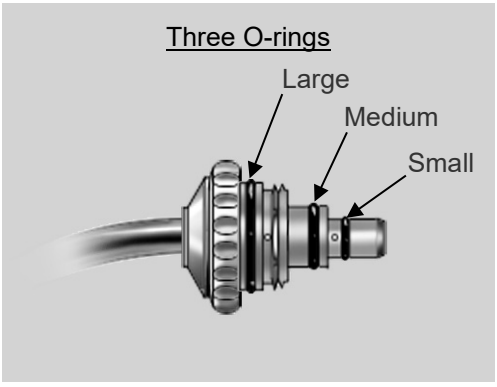
* To remove it, hold the ring and pull it off.

NOTE

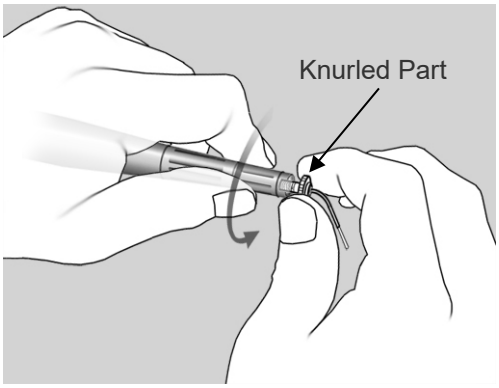
- ***When inserting the Handpiece Grip, hold the end of the Handpiece Grip and insert it while turning, or the internal O-ring may be damaged.***
- ***Grease the end of the handpiece periodically to prevent damage to the O-ring.***
  (See page 47.)



(2) Hold onto the outer cover of the hollow waveguide and give the Handpiece Grip a light tug to make sure it will not come off.



(3) Make sure the contact tip is clean and free of blood and other contaminants. Make sure all 3 O-rings are in place.

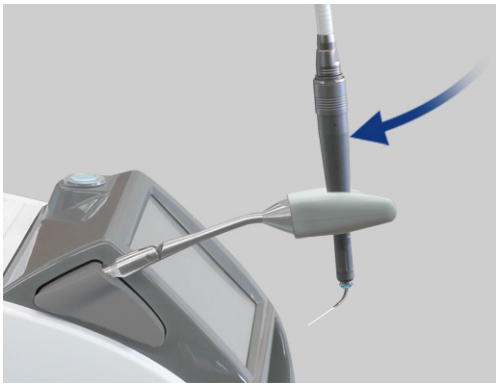


(4) Grip the knurled part of the contact tip and screw the Handpiece Grip.

⚠CAUTION
• ***Always hold the knurled part of the contact tip to screw it on or off; never grip the metal pipe of the contact tip, which could damage the contact tip.***

NOTE

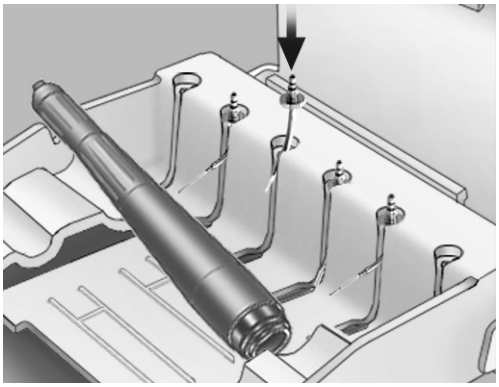
- ***R Handpiece Grip is required for R200T and R300T.***



(5) Put the handpiece in its hanger.

NOTE

- ♦ ***Be careful not to damage a contact tip when you put the handpiece in its hanger.***
- ♦ ***To avoid damaging the contact tip, place the handpiece so that the contact tip faces the Main unit.***



* Put the contact tips in the Tip Stand after taking them out of their cases.

NOTE

- ♦ ***The contact tip could be damaged if it is placed upward when closing the top cover of the stand.***

⚠WARNING

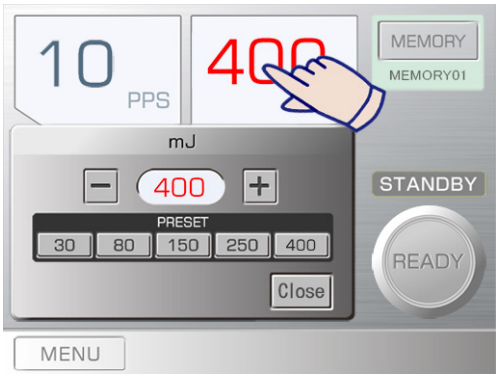
- ***Screw the contact tip into the handpiece grip all the way otherwise the contact tip may come off during use, causing incorrect laser irradiation or swallowing of the contact tip.***

⚠CAUTION

- ***Contact tips are consumable and must be replaced periodically. Inspect contact tips carefully before use (see below). Worn tips could overheat and injure the patient.***
  - ***・ Do not use chipped or worn contact tips.***
  - ***・ Do not use contact tips if the laser output seems lower than normal.***
  - ***・ If the guide light is dim or does not appear at all, the contact tip may be damaged.***
- ***End of contact tips are sharp and can cause injury; handle them with care.***
- ***Use only contact tips specified for AdvErL EVO.***
- ***When putting contact tips on and taking them off, turn the key off or put this device in Stand-by mode.***
- ***Never emit a laser without having the handpiece and a contact tip installed.***
- ***Check the end of contact tips and make sure they are free of blood and other contamination or debris. Otherwise, they could overheat, especially if the tip air and spray water are turned off. Overheated contact tips could injure the patient.***

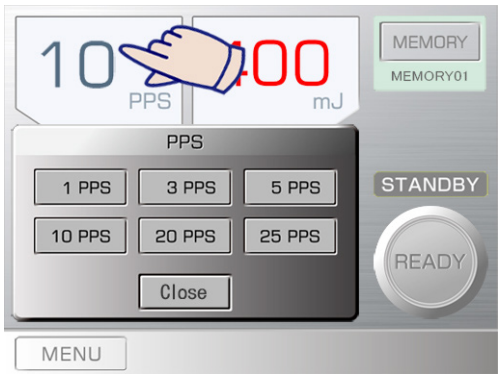
(4) Operation Procedure

1) Set Laser Irradiation Conditions



(1) Energy Level

- Press the “mJ” part of the panel; a window to make this setting will appear.
- Press a preset number to change the energy level.
- You can also press the plus or minus key to adjust the energy level.
  For less than 100 mJ, values can be set in 5 mJ steps.
  For more than 100 mJ, values can be set in 10 mJ steps.
  Setting Ranges: 10 pps — 30 mJ to 400 mJ
  20 pps — 30 mJ to 170 mJ
  25 pps — 30 mJ to 80 mJ
  Press “Close” after making the setting.
- Press one of the numbers to make this setting.
- The mJ display turns red if mJ is set at 150 or higher.



(2) PPS (pulses per second) Setting

- Press the “PPS” part of the panel; a window to make this setting will appear.
- Press one of the numbers to make this setting.
  (3 PPS is actually 3.3 pulses per second.)

  PPS means pulses (laser shots) per second.
  The total amount of energy delivered in 1 second can be found by multiplying the energy level by the PPS.

(3) Turning Aiming Beam On and Off

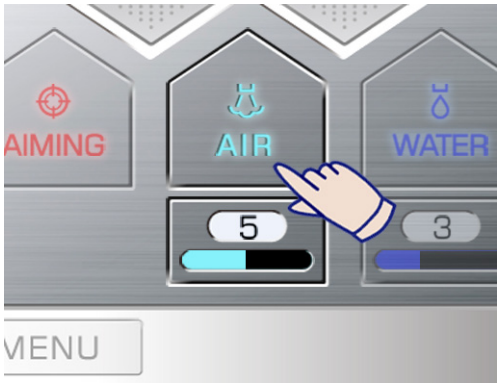
A red aiming beam is emitted from the handpiece.

- The aiming beam is emitted when the device is in Ready mode and during laser emission.
- Press the Aiming key to turn the aiming beam on or off.
- Initial setting is on.
  * The Aiming Key lights up.
- Press the Aiming Key to turn off the aiming beam if it is not needed; the key light will go out.

(4) Turning Spray Water On and Off

Spray Water is emitted from the end of the contact tip to cool the area being irradiated.

- Press the Water Key to turn the spray water on and off.
- Initial setting is on.
  * The Water Key lights up.
- Press the Water Key to turn the spray water off if it is not needed; the key light will go out.
  * The Air Key will turn off automatically when the Water Key is turned off.

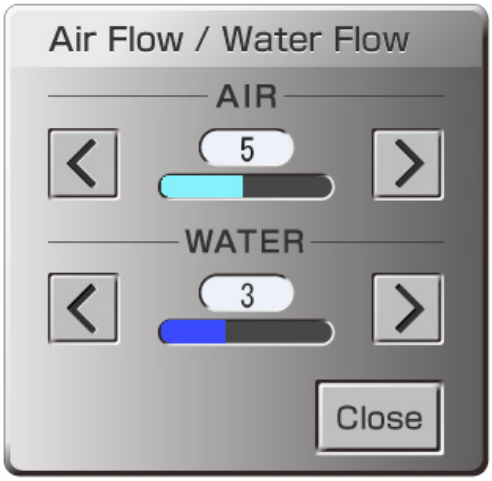


(5) Turning Tip Air On and Off

A mixture of air and water produces a mist and is emitted from the end of the contact tip.

- Press the Air Key to turn the tip air on and off.
- Initial setting is on.
  * The Air Key lights up.
- Press the Air Key to turn the Tip Air off if it is not needed; the key light will go out.

* The Water Key will turn on automatically when the Air Key is turned on.



(6) Spray Water and Tip Air Adjustment

- Press the setting key under either the Water or Air Key; a window to make these settings will appear.
- Press the increase (>) or decrease (<) Key to adjust the flow of the water or air.
- Press the “Close” Key when you finish.
- The air and water flows can be adjusted even when the laser beam is being emitted.

⚠WARNING

- ***Take great care when using the tip air inside a body cavity or tubular lumen. Raising the air pressure inside a cavity or lumen could force air into a blood vessel through an open wound and result in an air embolism. Also take great care when using the tip air in areas of the oral cavity where it could increase the pressure; this could result in a severe air embolism or subcutaneous emphysema.***
- ***Never look at the guide light directly; this could result in blindness.***

⚠CAUTION

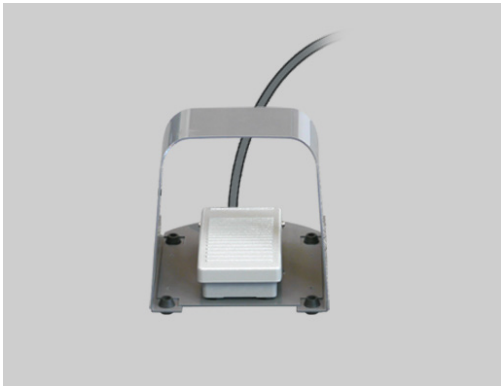
- ***Irradiating hard tooth tissue without using spray water could cause carbonization. When irradiating hard tissue, make sure the spray water is turned on and that enough water is being delivered to the treatment area.***
- ***Do not set output powers greater than that specified for the contact tip; this could overheat the contact tip.***
- ***Before irradiating the laser, check if the spray water is on or off and what the volume is. Depress the foot switch to the first level to check the water.***
- ***Make sure the tip air flow is not so strong that it damages tissue.***
- ***When the spray water setting is off, the contact tip temperature may rise up to +50°C (+122°F). Do not allow the contact tip to make contact with body tissue for more than 1 minute.***

2) Laser Emission Procedure

(1) Press the Ready Key.

- When the preparation for laser emission is completed, the device will be in the Ready mode and the Ready Key will turn green.
- If the Aiming key is in the on state, the aiming beam will be emitted.

(2) Before using the laser, make sure the aiming beam is clear and bright. (See page 48)



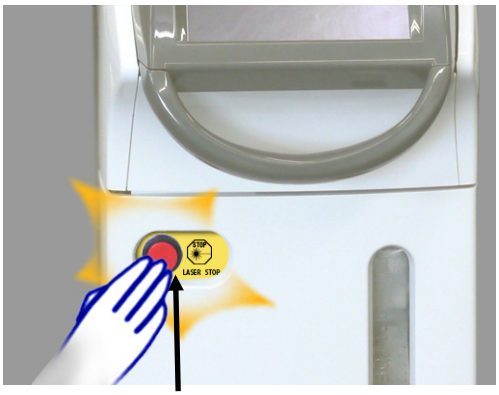
(3) Depress the foot switch to its first level to check that spray is properly emitted from the end of contact tip.

(4) Depress the foot switch all the way down to emit the laser. The Ready Key will change to Emission, and the device will make a continuous beeping sound.

This photo shows the panel when the foot switch is depressed all the way down and laser is being emitted. If you depress the foot switch to first level, spray water and air will be emitted but laser will not.
Depress the foot switch all the way down to emit the laser.

(5) Press the Ready Key when you finish laser emission. Check that the Ready Key goes out and the device goes to Stand-by mode.

3) Emergency Stop



Emergency Stop Switch

(1) Emergency Stop

- In an emergency, press the Emergency Stop Switch; this will immediately stop the laser emission.

(2) Restore Operation

- Press the Start Switch to turn the device off.
- Press the Emergency Stop Switch again to release it.
- Press the Start Switch.
- The device will go into Stand-by mode if it passes the automatic self-diagnostic test.

If the device cannot be restored to safe and normal operation, or will not operate, contact your local dealer or
J. MORITA OFFICE.

⚠WARNING

- ***A direct, reflected or scattered laser beam can cause permanent blindness. All individuals in the laser use area must wear Laser Safety Glasses supplied with this device. Other parts of the body should also be protected. The laser beam can cause serious injury to the skin and eyes.***
- ***Even if you are wearing Laser Safety Glasses, never look directly into the aperture where the laser comes out; there is a risk of blindness. Both the main laser and the guide light are dangerous. The Laser Safety Glasses provide only limited protection.***
- ***Do not polish or cut the end of the contact tip. It may cause contact tip damage.***
- ***Take great care to avoid overheating in the vicinity of critical tissues such as nerves and blood vessels.***
- ***A pulse rate of 20 or 25 pps will tend to heat up the target area more than one of 10 pps or less. Keep this in mind to set the power and adjust the flow of the spray water.***
- ***Keep combustible tubes, gases and other materials well away from the laser beam. Never irradiate a laser to combustible materials such as trachea tubes, non-woven cloth, or surgical gloves. These could suddenly ignite. Also watch out for combustible medical solutions and gases inside the patient's body.***
- ***Do not inhale laser plume produced by laser irradiation to the treatment area or get them in your eyes, because the laser plume may contain infectious viral particles or bacteria. Use high-speed suction to remove all smoke and particulates in the laser plume. Also use clinical masks for protection.***
- ***Do not use this device in the presence of a combustible anesthetic or an elevated concentration of oxygen; this could result in ignition or explosion. A laser beam will readily ignite a tracheal tube such as those made of silicon rubber in the presence of a high concentration of oxygen or an anesthetic gas mixed with oxygen. For example, a laser beam will instantly ignite the tube if the oxygen concentration is 48%.***
- ***If use of oxygen is absolutely essential, the oxygen delivery tube must be protected with a non-combustible cuff and steps must be taken to insure that there is no leakage of oxygen.***
- ***Handle contact tips with great care; they break easily. A piece of a broken contact tip could cut the patient and cause bleeding or might be left in the tissue being treated. Never bend or apply force to the contact tip. Contact tips with a small fiber diameter are especially delicate and will break very easily if some force is applied to the part coming out of the pipe. Use a rubber dam if there is a case that the contact tip might get broken during treatment.***

⚠CAUTION

- ***The output depends on the diameter of the contact tip; a larger diameter will deliver more energy. Keep this in mind when modifying irradiation settings.***
- ***This device must not be used for any purpose other than vaporization, coagulation, hemostasis and resection of biological tissues. Never irradiate the laser to anything except the treatment area.***
- ***Before irradiating the laser, check the aim with the guide light or by touching the target with the contact tip.***
- ***Never irradiate the laser on prosthetic devices, mirrors or anything that will reflect it or scatter it. Cover the treatment area with damp gauze or find some other way to avoid the risk of reflected laser.***
- ***Always leave this device in Stand-by mode when it is not required to emit laser.***

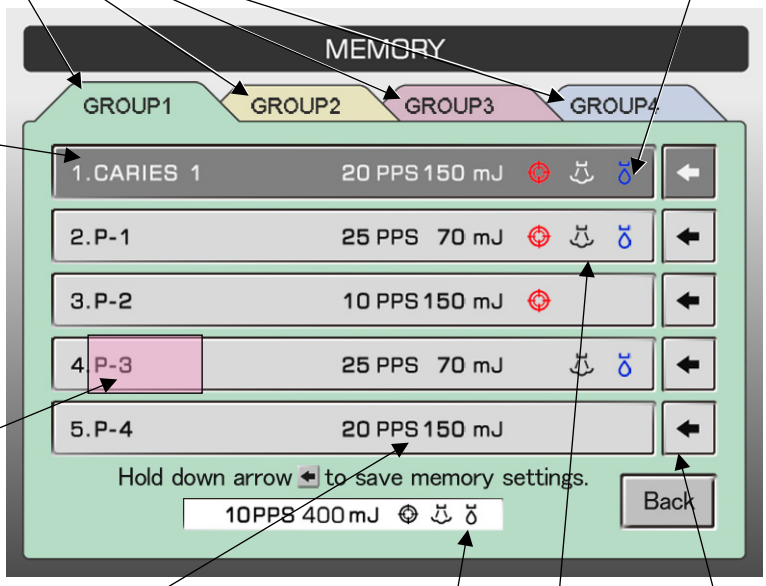
4) Memory

20 combinations of settings can be saved and restored.
Press the Memory key on the Main panel to go to the Memory Display Panel to show the saved settings.

Memory Display Panel

Group Tabs
There are 4 groups of memories, each of which has 5 sets of memorized settings, for a total of 20 sets of settings.
The name of the group tab can be changed for your convenience.

The background color of the previously selected setting differs from others.



Memorized Keys
There are 5 Memorized Keys for each group.
Press the key to restore the memorized setting.

Memory Name
Each Memorized Key can be named for your convenience.

Settings
The saved setting is shown on the Memorized Key.

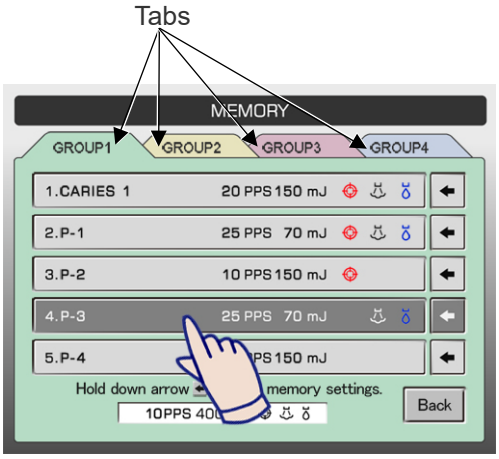
Current Setting

Memorize Keys
Hold down one of the Memorize Keys to save the current setting.

Icons for Aiming, Air, and Spray Water
The icon appears if the associated function is turned on.

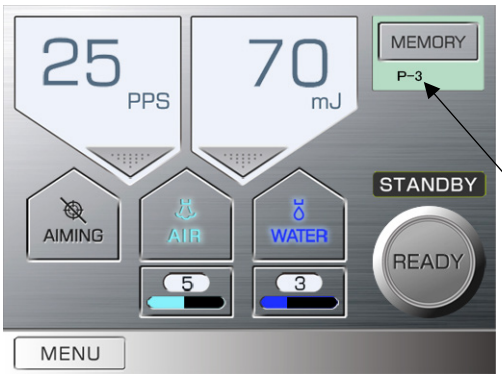
Restoring Memory

(1) Press the Memory key to go to the Memory Display Panel.



Press the memorized key.

(2) Press the group tab to use.
(3) Press the memorized key to restore.



Memory Name
(Up to 8 characters)

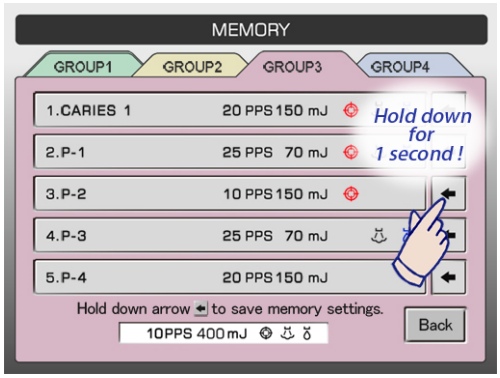
(4) The selected setting is restored.

⚠CAUTION
• ***Always check settings before using the device.***

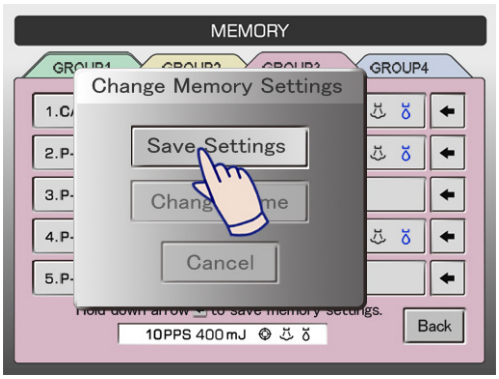
Saving New Settings

(1) Display the desired setting on the Main panel.

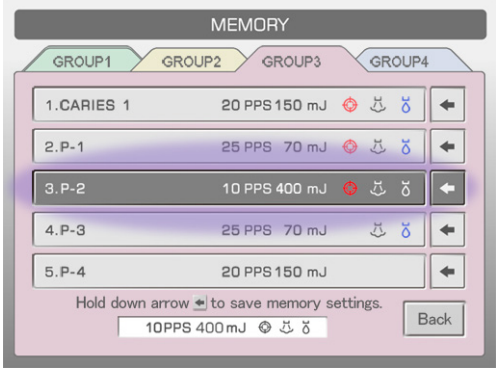
(2) Press the Memory Key to go to the Memory Display Panel.



(3) Hold down a Memorize Key for a memory for 1 second.

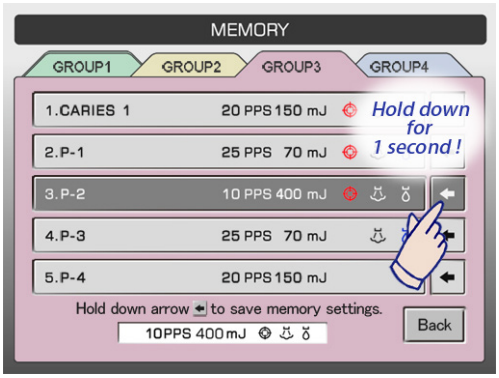


(4) A pop-up menu will appear. Press Save Settings.



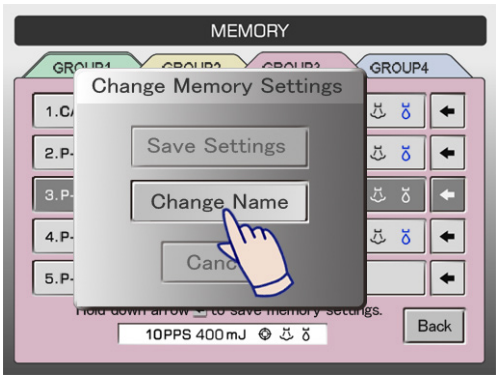
(5) The new setting combination is now saved.

Changing Memory Name

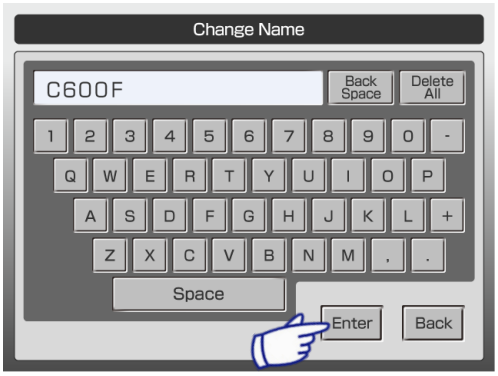


(1) Press the Memory Key to go to the Memory Display Panel.

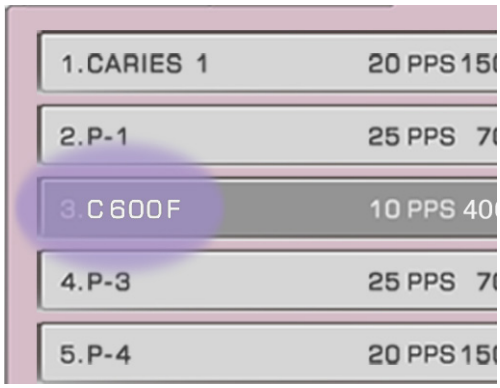
(2) Hold down the Memorize Key for the memory for 1 second.



(3) A pop-up menu will appear. Press Change Name.



(4) A keyboard will appear. Enter the desired name. You may use up to 10 characters. Press Back Space to erase the last character. Press Delete All to erase the whole field.

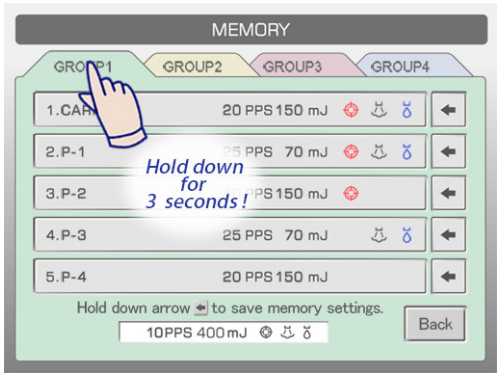


(5) Press Enter to complete the name change.
Changing the name will not change any of the settings for that memory.

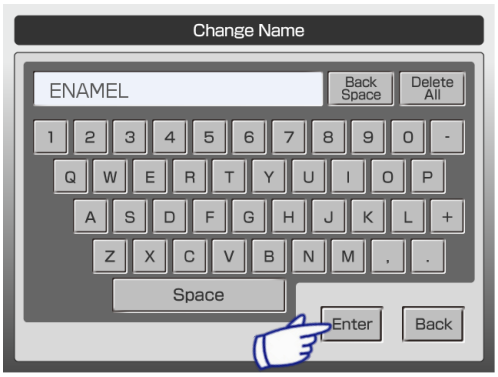
Changing Group Tab Name

Name the tabs for your convenience.

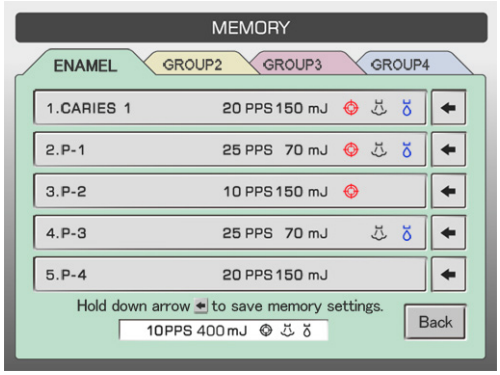
(1) Press the Memory Key to go to the Memory Display Panel.



(2) Hold down the Tab for the name change for 3 seconds.



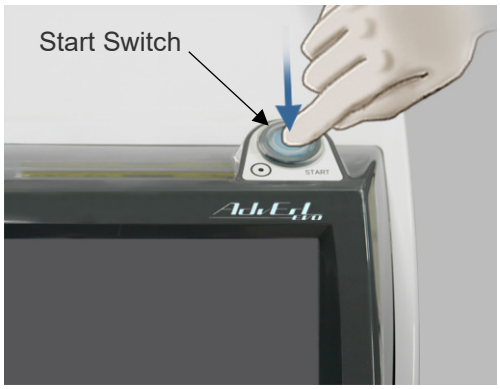
(3) A keyboard will appear. Enter the desired name. You may use up to 6 characters. Press Back Space to erase the last character. Press Delete All to erase the whole field.



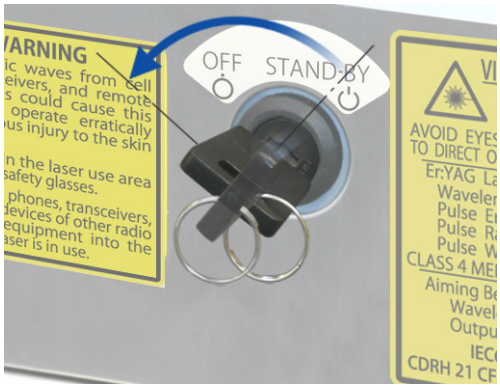
(4) Press Enter to complete the name change.

(5) Stopping Device

(1) Check if the device is in Stand-by mode.
If it is in Ready mode, press the Ready key.
The ready key will go out and the device will go into Stand-by mode.



(2) Press the Start switch.
The device will turn off.



(3) Turn the key off.

(4) Remove the key and return it to a supervisor.

(5) Turn off the circuit protector at the bottom of the back of the Main unit.

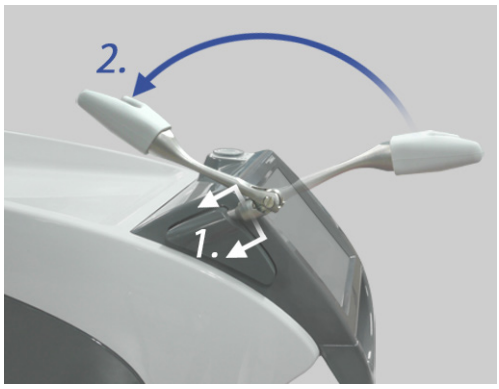
(6) Moving Device

(1) Hang the foot switch on the hook on the rear of the device.

(2) Push the handpiece hanger back and put the handpiece in it.

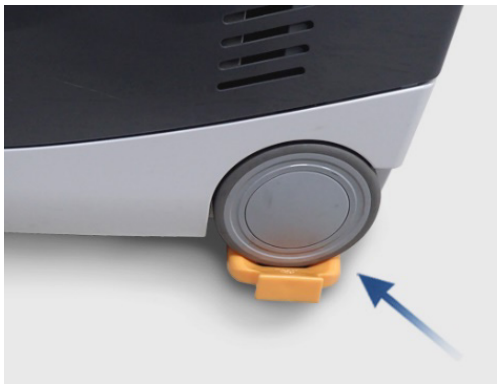
1. Push down the ring on the joint.
2. Push the hanger back.

(3) Use the front or rear handle to move the device.



NOTE

- ***Do not leave the handpiece in the hanger when pushing the hanger back; it could fall out.***
- ***Remove the contact tip before moving this device; it could get broken.***
- ***Never push or pull on the hollow waveguide support or the handpiece hanger.***

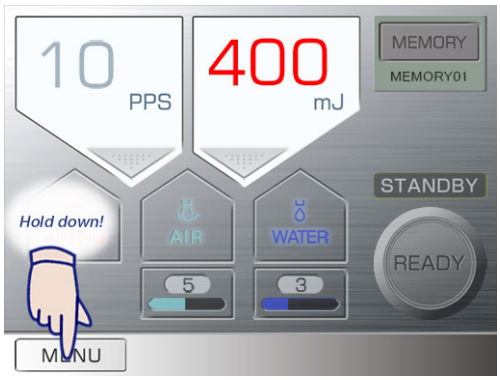


⚠CAUTION

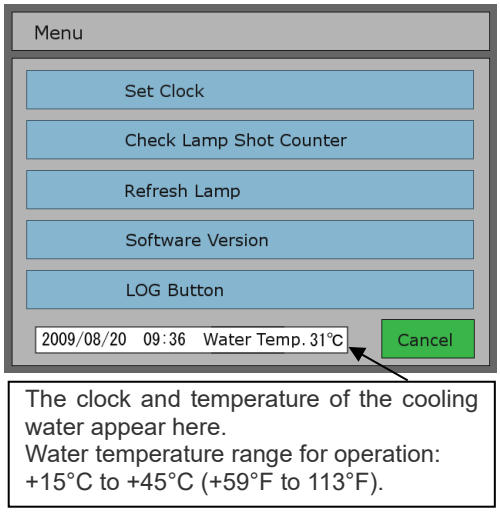
Risk of overbalance;

- ***Do not push side of the equipment to prevent any unwanted movement.***
- ***When moving the device on a slope, lock the front casters and lock the rear wheels by using the wheel locking device.***
- ***Push rear end first to go over bumps.***
- ***Never tilt this device more than 10°when moving it; it could tip over.***
- ***When moving the device, keep a safe distance away from the casters and wheels to avoid entanglement of fingers or clothes, etc.***

(7) Making Other Setting and Checking Information



Hold down the Menu key.

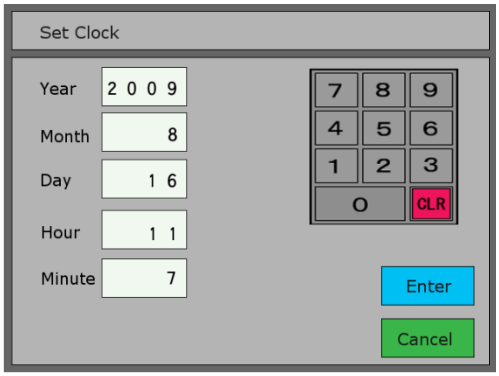


The Menu will appear.

Press the key for the category you wish to view.

The clock and temperature of the cooling water appear here.
Water temperature range for operation: +15°C to +45°C (+59°F to 113°F).

Set Clock

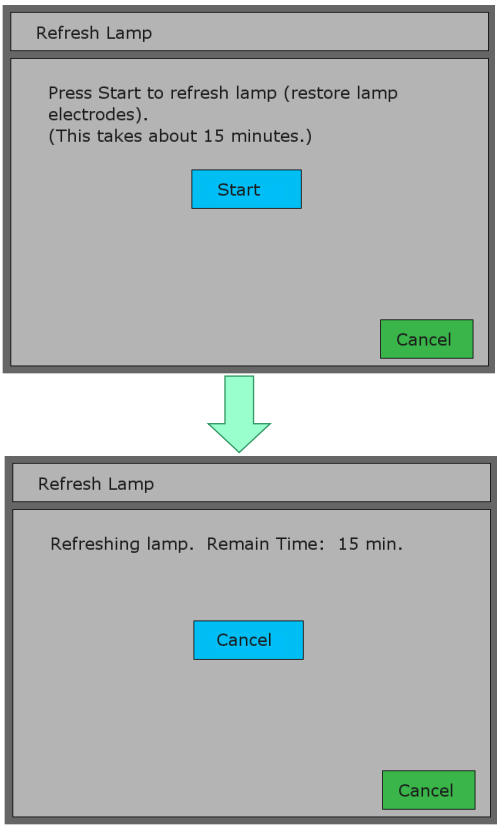


Select Year, Month, Day, Hour, or Minute and then use the numeric keyboard to enter the number.
Press Enter to finish.

Check Lamp Shot Counter

Check the total number of shots for the flash lamp.
(See page 51)

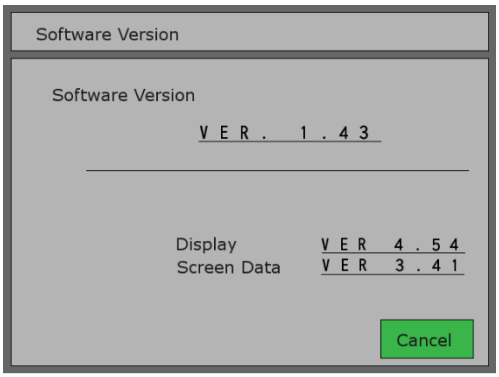
Refresh Lamp



After considerable use, the condition of the flash lamp may get deteriorate, and cause errors to occur. (Interlock 1 or error 104) The procedure described below may rectify the problem. It takes about 15 minutes.

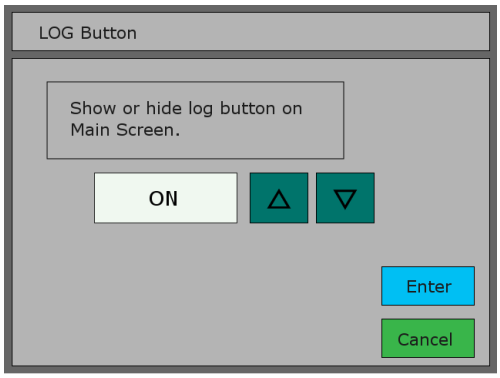
Comment
If the device is used at low power for a long time, the terminals of the flash lamp may get dirty and interfere with ignition. Operating the flash lamp at high power by executing the "Refresh Lamp" will clean up the terminals.
The procedure stops after 15 minutes or you can stop it anytime by pressing Cancel.

Check Software Version



Check the software versions for the control system, display, and screen.

LOG Button



Use the LOG Button to show or hide the Log key on the main panel.

Select the “ON” state to show the Log key.
Use the Up and Down key to switch to “ON” and “OFF” and then press Enter.

The default setting is the “OFF” state.

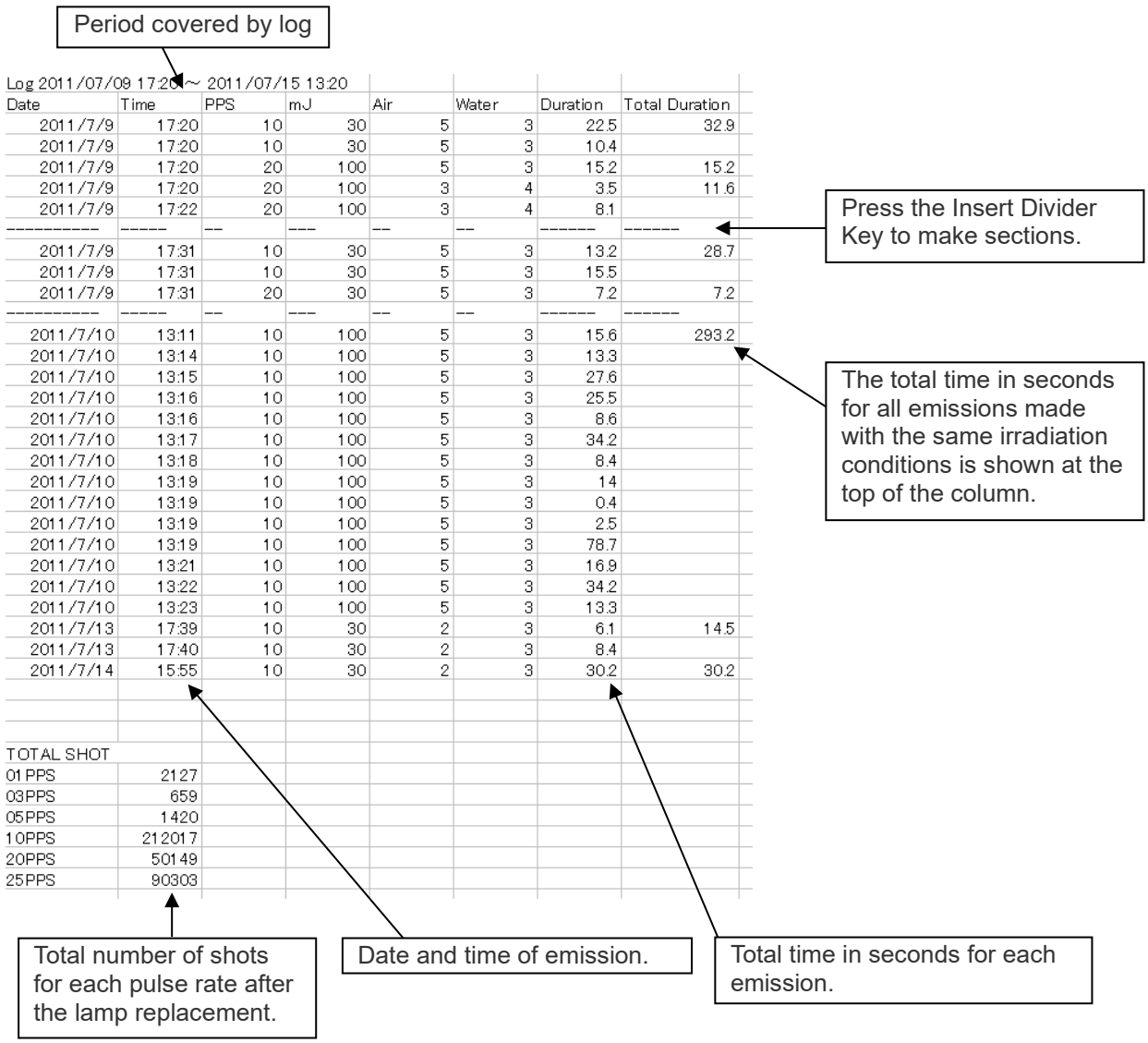
The Log key appears on the Main panel when it is in the “ON” state.

(1) Irradiation Log

This shows the irradiation history of the device.
A log entry is created every time the device emits a laser.
The log can be copied onto a USB flash drive and used with applications such as Microsoft Excel.
The log records up to 1,000 laser emissions. If you go over this limit, earlier records will be deleted in order.
Keep all the records by copying them onto a USB flash drive if necessary.

Example

- This shows a log that was copied onto a USB flash drive and then opens with Microsoft Excel.

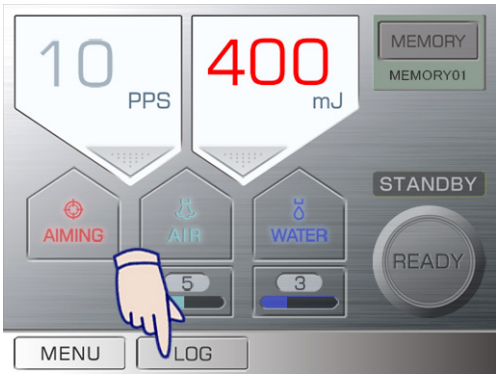


(2) USB Flash Drives

The format for USB flash drive must be at least FAT16/32, 128 MB.
Some USB flash drives may not recognize the log data.

NOTE

- ***Some USB flash drives have a format that will not recognize the data. These can be reformatted using Windows. (All data will be lost when the USB flash drive is reformatted.)***
- ***Never take the USB flash drive out while data is being copied onto it. This could destroy all the data on the flash drive. You can take the USB flash drive out anytime data is NOT being copied onto it.***

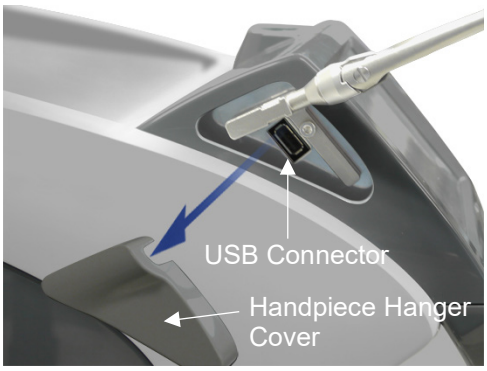


Data Transfer Preparation

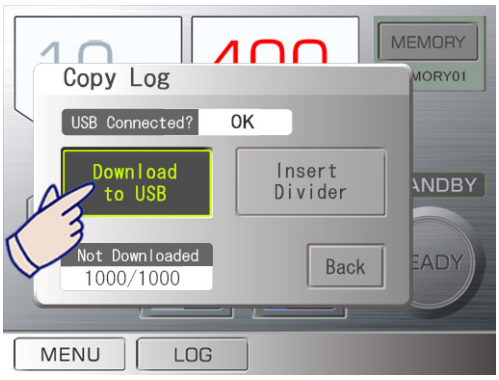
Press the LOG Key. If the LOG Key is not displayed, go to the Menu to enable the LOG Key function.

(3) Copy Data to USB Flash Drive

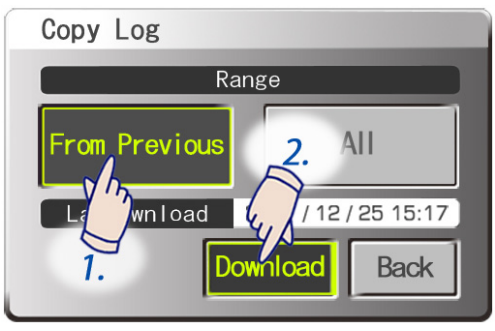
- Take off the handpiece hanger cover.
- Plug a USB flash drive in.



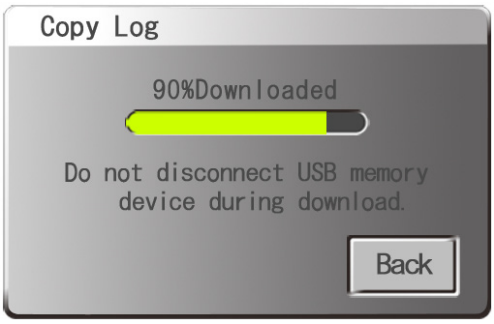
- If the USB flash drive is recognized, “OK” will appear in the display.
  Press the “Download to USB” key.



- Specify the Part for Copying
  Press “From Previous” to copy the part of the log created since the last time it was copied.
  Press “All” to copy the whole log (up to 1,000 records).
  Then press the Download key.



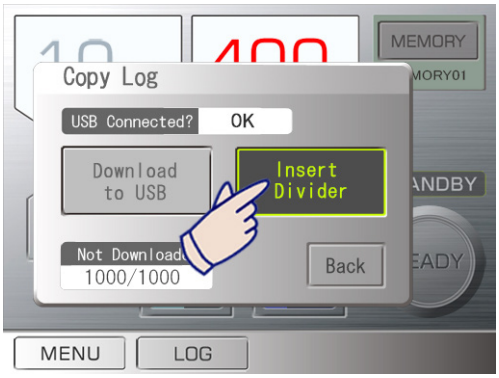
- Press the Download key; the data will then be copied onto the USB flash drive.



- A progress bar will show how much has been copied so far.

- Never unplug the USB flash drive while data is being copied onto it; this could destroy all the data.
- After all the data has been copied to the USB flash drive, press the Back key and pull the USB flash drive out.
- Press the “Back” key.
- If the copy procedure stops before finishing, press the Back key and do it again.

(3)-1 Put Dividers in Log Record



- Divider lines can be put in the log.
- These can be put in between patients or types of treatment for your later convenience.
- Press the Log key and then press the Insert Divider key. A divider will be inserted each time you press the key.

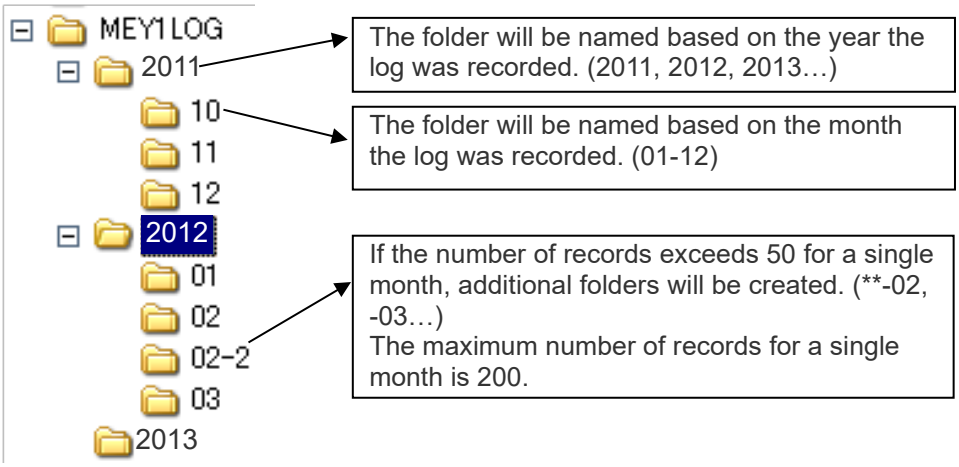
(3)-2 Number of Log Records

Out of a maximum of 1,000 records, the number of log records not yet copied is shown.
The Log key will start blinking after this number has exceeded 900.

(4) Data Files

The data files will be saved in a folder named “MEY1LOG” on a USB flash drive. This folder is created automatically.

MEY1LOG Folder and its Contents



A log file, named like “0715-01.csv”, will be saved inside the folders.
0715-01.csv, for example, is interpreted as July 15th and consecutive number in a single day (01, 02, 03…)

* The date used in the file name is the date the file was copied.
* CSV files are text files. These can be opened with software applications such as Microsoft Excel.

NOTE

- ***Periodically back up all data so that it cannot be accidentally lost.***
- ***If there is a power failure while data is being copied onto the USB flash drive, all the files on the USB flash drive could be lost. Do not keep any other important files on the USB flash drive.***

4. Reprocessing, Storage and Replacement

⚠WARNING

- ***To prevent the spread of serious, life-threatening infections, the handpiece grip and its hanger, contact tips and tip stand must be cleaned and sterilized between patients.***
- ***All the handpiece grip and its hanger, contact tips and tip stand are delivered in non-sterile condition. Clean and sterilize them prior to initial use.***

(1) Reprocessing

< Parts to be Sterilized >

	Procedure		Detail
Contact Tips	Pre-treatment ↓ Cleaning & Disinfection ↓ Packaging ↓ Sterilization	Immerse the contact tip fiber in tap water and emit the laser. Use the enzymatic detergent (CIDEZYME Johnson & Johnson company: for example) to clean off blood and other contaminants. Immerse the contact tip in an available chemical disinfectant ・Chlorhexidine Gluconate ・Dürr FD 333 forte ・Ethanol (70 vol% to 80 vol%) Put components in individual sterilization pouches. Autoclaving ・Dynamic Air Removal type (+134°C (+273.2°F) 5 min) ・Gravity type (+135°C (+275°F) 5 min)	Refer to pp. 42-45
Handpiece Grip	Cleaning & Disinfection ↓ Packaging ↓ Sterilization	Wipe entire handpiece grip outer surface with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%). Put components in individual sterilization pouches. Autoclaving ・Dynamic Air Removal type (+134°C (+273.2°F) 5 min) ・Gravity type (+135°C (+275°F) 5 min)	Refer to pp. 43-45
Hanger	Cleaning & Disinfection ↓ Packaging ↓ Sterilization	Wipe the hanger with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%). Put components in individual sterilization pouches. Autoclaving ・Dynamic Air Removal type (+134°C (+273.2°F) 5 min) ・Gravity type (+135°C (+275°F) 5 min)	Refer to pp. 43-45
Tip Stand	Cleaning & Disinfection ↓ Packaging ↓ Sterilization	Wipe the tip stand with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%). Put components in individual sterilization pouches. Autoclaving ・Dynamic Air Removal type (+134°C (+273.2°F) 5 min) ・Gravity type (+135°C (+275°F) 5 min)	Refer to pp. 43-45

< Parts to be Disinfected >

	Procedure		Detail
Main Unit	Cleaning & Disinfection	Wipe the outside of the Main unit with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%).	Refer to p. 46

1) Parts to be Sterilized

(1) Pre-treatment (Always perform this procedure prior to cleaning & disinfection)

The pre-treatment process is intended to remove blood, protein and other potential contaminants from contact tips. Contamination control should be performed by trained personnel, while wearing protective gear (including masks gloves and shields).

<Contact Tip>

① After using the contact tip, immerse the fiber part of the contact tip in tap water and emit the laser for 3 to 5 seconds. If there are many contaminants, emit the laser for 20 to 30 seconds. (Recommended setting is 25 PPS 50 mJ Air 10 Water 7)

② Use enzymatic detergent (CIDEZYME Johnson & Johnson company: for example) according to the detergent's manufacturer's directions to clean off blood and other contaminants.

NOTE

♦ ***Do not use an ultrasonic washer to clean the contact tip as it may chip the contact tip or remove the adhesive.***

(2) Cleaning & Disinfection (Always perform this procedure prior to packaging.)

<Contact Tip>

① Wash the contact tip thoroughly with tap water.

② Wipe the contact tip with cotton.

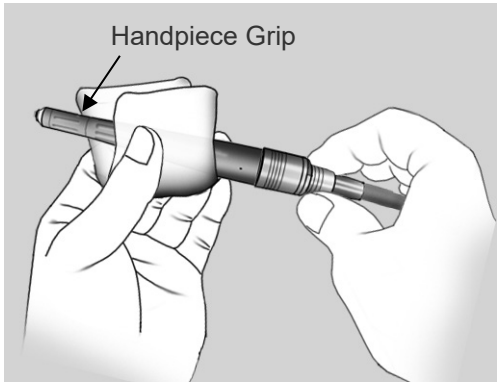
③ Immerse the contact tip in an available chemical disinfectant for recommended time by the manufacturer's directions.
Use one of the disinfectants listed below at the concentration specified for medical instruments for disinfectant solution.

- **Chlorhexidine Gluconate (Hibiten, for example)**
- **Dürr FD 333 forte**
- **Ethanol (70 vol% to 80 vol%)**

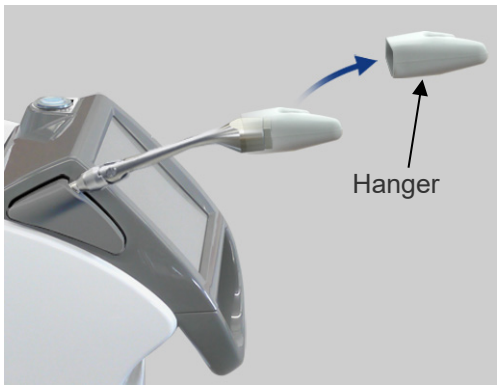
④ Wipe the contact tip with cotton.

NOTE

- ***When wiping the contact tip with cotton, be careful as the fiber may come off if you pull the fiber with a strong force.***
- ***Contact tips are consumables. If a contact tip is damaged or cannot be cleaned adequately, replace it with a new one***
- ***Do not use washer disinfectors.***



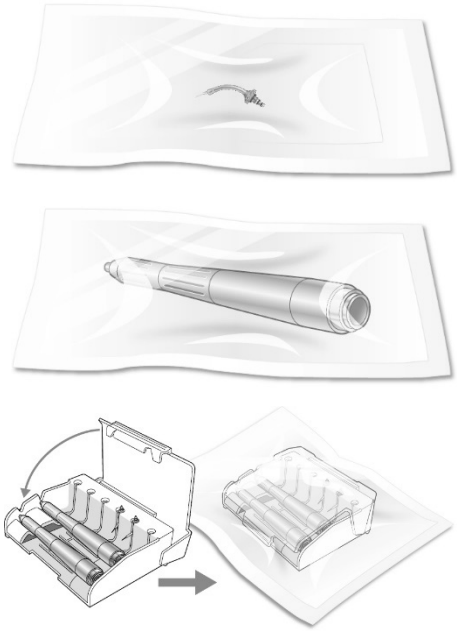
<Handpiece Grip>
Wipe the entire handpiece grip outer surface with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%).



<Hanger>
① Take the hanger off its arm.
② Wipe the entire hanger outer surface with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%).

<Tip Stand>
Wipe the tip stand with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%).

(3) Packaging (Always perform this procedure prior to sterilization.)



<Contact Tip, Handpiece Grip, Hanger, Tip Stand>
Put components individually in sterilization pouches or set components in a tip stand and put in sterilization pouches.

NOTE

- ***When using the tip stand, the contact tip could be damaged by closing the top of the tip stand, if the contact tip is sticking up.***
- ***Use sterilization pouches that conform to ISO 11607***
- ***Do not use any sterilization pouches that contain hydrosoluble adhesive ingredients such as PVA (polyvinyl alchol).***
  Note that even ISO 11607 conformable sterilization pouches may contain PVA.

(4) Autoclaving (sterilization) (Always perform this procedure after packaging and before use)
The autoclaving process is intended to destroy infectious microorganisms and pathogens.

① Autoclave the components.
Recommednded Temperature and Time

Dynamic Air Removable type
Temperature: +134°C (+273.2°F)
Time: 5 minutes
Dry Time: 10 minutes

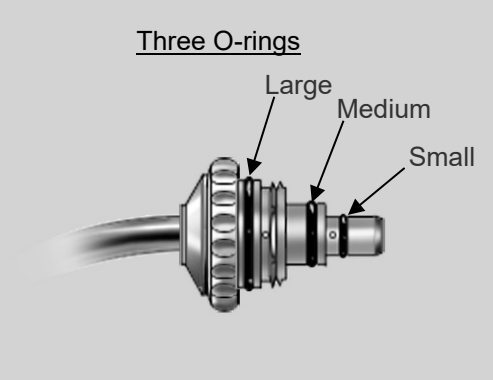
Gravity type
Temperature: +135°C (+275°F)
Time: 5 minutes
Dry Time: 0 min (dry naturally)

② At the time of completion of the autoclave, let them cool.

⚠CAUTION
• ***After the autoclave sterilization, store the components with care to prevent contamination.***

NOTE

- **Contact tips are easily broken. Take care that contact tips do not bump against each other or against other instruments when putting them into the autoclave. Do not drop or bump them against anything when handling them.**
- **Do not perform sterilizations other than the autoclave sterilization.**
- **The setting temperature for sterilization and drying process must be +135°C (+275°F) or lower. If the temperature is set at beyond +135°C (+275°F), it may cause a malfunction or stain on the parts.**
- **Make sure all 3 O-rings of contact tips are intact and not damaged in any way. Pay special attention to the smallest one. If this is missing or damaged, water could seep into the handpiece and damage it or cause the laser to lose power. It also might harm the drum lens.**



2) Parts to be Disinfected

(1) Cleaning & Disinfection

< Main Unit >

Wipe the outside of the Main unit with a soft cloth dampened with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%).

- Immediately wipe off any chemicals that are spilled on the unit with Dürr FD 333 forte or ethanol (70 vol% to 80 vol%).

⚠WARNING

- ***Always turn off the key and the circuit protector before cleaning. This will avoid the risk of burns and electric shocks as well as accidents that could results from accidentally pressing a switch.***

⚠CAUTION

- ***Prevent contagion and contamination by cleaning the Main unit regularly.***

NOTE

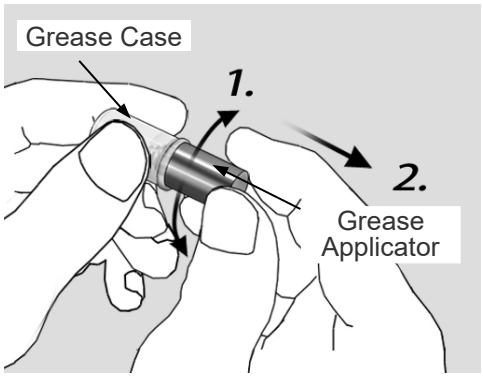
- **Do not use ozone or ultra violet light to disinfect the clinic. This could damage this device (plastic, rubber or other materials).**
- **Use only Dürr FD 333 forte or ethanol (70 vol% to 80 vol%). Alkaline and acidic cleaners, liquid cresol soap, and other chemicals may damage or discolor the surface. Do not use solutions that contain cresols, triclosan, hypochlorite, or aldehydes. (Check the ingredients for disinfectants.)**
- **Do not press down too hard to wipe the surface; this could cause peeling.**

(2) Maintenance

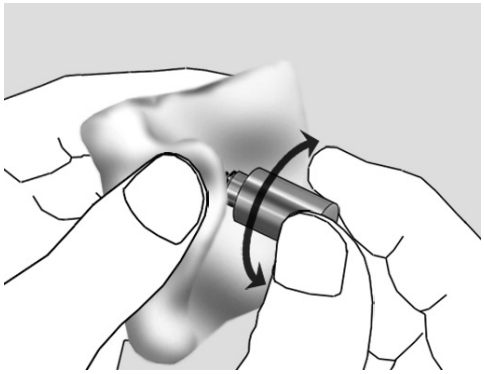
For optimum performance follow the maintenance procedures described below.

1) Grease Handpiece

Grease the handpiece every day before use or after putting handpiece grip on and taking it off more than 50 times. The O-rings will be damaged if they are not properly lubricated and this can lead to water and air leakage inside the handpiece grip.



(1) Rotate the grease applicator to apply grease (lubricating oil) to the end of the grease applicator.



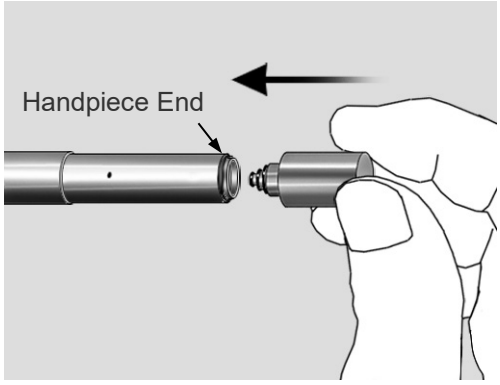
(2) Wipe the end of the grease applicator including O-ring with gauze to remove excess grease.

* Even if the grease applicator is wiped off with gauze, there is enough grease on the handpiece side.

NOTE

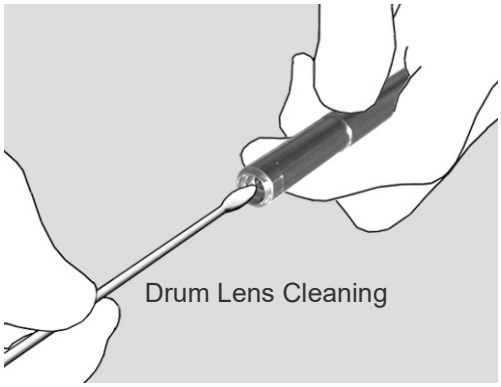
♦ ***Carefully remove all the grease on the end of the grease applicator; otherwise it might get on the drum lens inside the handpiece.***

If any grease accidentally gets on the drum lens, clean it. (See page 48)



(3) Insert the grease applicator into the handpiece as far as it will go and rotate it; then take it out.
Put the applicator back in its case when you are finished using it.

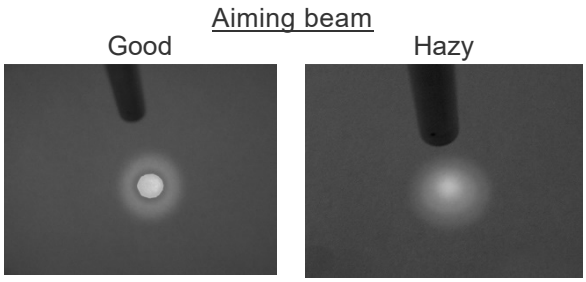
2) Lens Cleaning

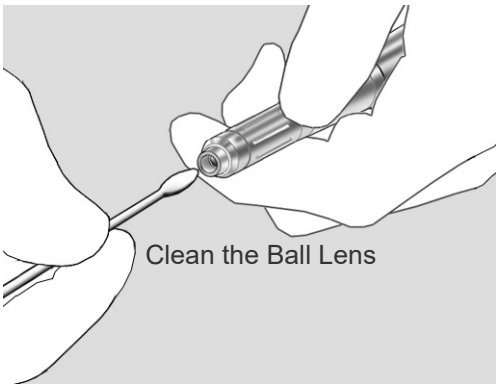


<< Drum Lens >>

Disconnect the handpiece grips and clean the drum lens on the end of the handpiece with the lens cleaner provided.

Dampen the end of the lens cleaner with ethanol or isopropyl alchol (≧70%) and lightly wipe the lens with it.
The recommended is ethanol (≧99%) or isopropyl alchol (≧99%)
Make sure that no stain or dirt remains on the lens surface.





<< Ball Lens >>

Clean the ball lens on the end of the R Handpiece grip after each patient.

Dampen the end of the lens cleaner with ethanol or isopropyl alchol (≧70%) and lightly wipe the lens with it.
The recommended is ethanol (≧99%) or isopropyl alchol (≧99%)
Make sure that no stain or dirt remains on the lens surface.

NOTE

- ***Use only the dedicated lens cleaner provided to clean the drum and ball lenses.***
- ***If the aiming beam is hazy even after cleaning the drum lenses, these lenses might need to be replaced. In this case, contact your local dealer or J. MORITA OFFICE.***

3) Spray Water Bottle (Sterile Water for Spray) Replacement

Before using the device, check the level of the spray water bottle.
Replace the bottle when the remaining water in the bottle is low.
If air gets in the tube when the bottle is replaced, depress the foot switch to its first level to force the air out.

NOTE

- ***Do not step on the foot switch before connecting the tube to the spray water bottle. This will cause the pump to start up and could damage the tube.***
- ***Do not pinch the water tube when you close the front door.***

⚠CAUTION

- ***Use only sterile water. Do not use tap water or saline solution.***
- ***When replacing the spray water bottle, disinfect the connecting needle with Dürr FD 333 forte or ethanol (70vol% to 80vol%).***
- ***Do not pinch your fingers when you close the front door.***

(3) Storage

Notes on Storage

(1) After using the device, turn off the key switch and the circuit protector.
(2) Take out the key and give it to a supervisor.
(3) Lock the casters.
(4) Take the contact tip off the handpiece after use and keep it clean.
(5) The device must be level and not subject to vibrations or bumping.
(6) Store the device where it will not get wet.
(7) If the device has not been used for 3 months, check that it operates normally before using it again.
(8) Storage Environments

Temperature:	+5°C to +40°C (+41°F to +104°F)
Humidity:	10% to 85% (without condensation)
Atmospheric Pressure:	70 kPa to 106 kPa

⚠WARNING

- ***Store contact tips safely and securely in a place where they will not be accidentally swallowed.***

NOTE

- ***Storage area must not be subject to freezing. If the water freezes, the resulting expansion will ruin this device.***
- ***Even if this device is not being used, turn it on and circulate the cooling water once a month. This will filter the cooling water and keep it from degrading.***
- ***Charge the backup battery once every 6 months. Leave the key switch off and turn on the circuit protector and start switch. Leave this device like this for 8 hours. (Never turn the key switch to the Stand-by position when there is no cooling water inside. This will damage the pump.)***

About Tip Cases

- The tip case is designed for transportation purpose only until the contact tip is used. Remove the contact tip from the tip case and store it, and dispose of the tip case (it can be treated as waste plastic).
- Store the tips cases in a cool, dark place which is well ventilated. Avoid high temperatures, humidity, exposure to direct sunlight and proximity to sources of ignition.
- Tip cases that are made with biodegradable plastic are identified with a logo, shown to the right, inside the case.

- Tip cases that are made of environmentally-friendly biodegradable plastic are easily degraded by humidity, alcohol fumes and similar air-borne substances.

(4) Replacement Parts

* Replace the cooling water once a year.
* Replace the deionization filter cartridge once a year.
* We recommend replacing the flash lamp after it has exceeded 10,000,000 shots; after this, errors may occur. After 20,000,000 shots, the lamp is at the end of its working life and must be replaced; otherwise, various errors will occur with increasing frequency. See page 34 for how to check the total number of shots for the flash lamp by using the Menu.
* Order parts through your local dealer or J. MORITA OFFICE.

5. Installation

⚠WARNING

- ***Never assemble or disassemble the device in any way other than specified in this user manual.***

⚠CAUTION

- ***Do not apply excessive force or stress to the hollow waveguide. Never bend it into a curve with a radius of less than 6 cm.***
- ***Do not put this device on a surface that is not level; it could tip over. Make sure the brakes on the casters are locked.***
- ***Never tilt this device more than 10°when moving it; it could tip over.***
- ***Do not fail to connect the ground lead.***
- ***Use only at the specified voltage. Connecting this device to the wrong voltage could damage the device and also cause smoke or a fire.***
- ***When moving the device, keep a safe distance away from the casters and wheels to avoid entanglement of fingers or clothes, etc.***

The AdvErL EVO must be installed with a qualified employee or representative; refer to “Installation Instructions” for setup instructions.

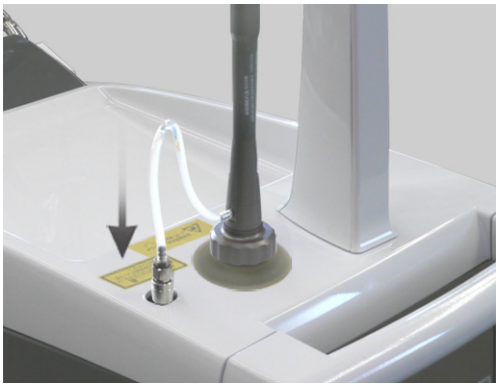
< Cautionary Remarks on Installation >

- Electrical Supply Requirement 100 VAC 15 A to 240 V 7 A 50/60 Hz
- Never cover or block the ventilation opening with anything.
- Use this laser in a specially designated area and identify the area clearly with a sign by using Bundled danger plate” or “warning plate”.

NOTE

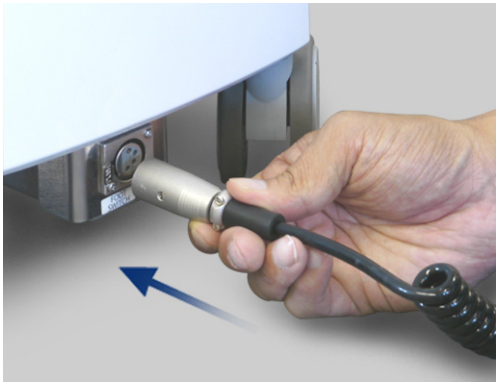
♦ ***Keep this device where the cooling water will never freeze.***

1) Water Tube

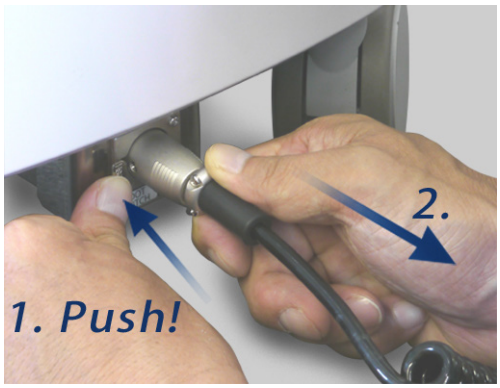


If the water tube is not connected to the spray water connector, plug it in until it clicks into place.

2) Foot Switch



Plug the cord for the foot switch into its mate on the Main unit. Make sure it clicks securely into place.



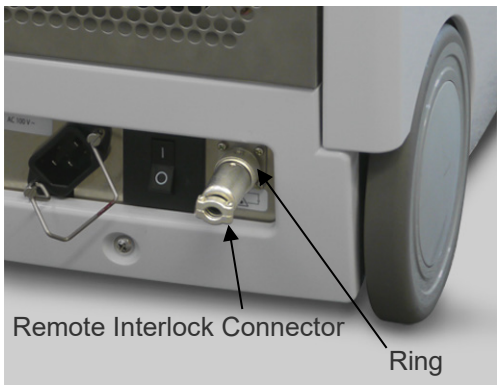
* To unplug it, push the lever in to unlock it and then pull it out.

NOTE

♦ ***To avoid breaking the cable wire or damaging the connectors, pay attention to the following points:***

- ***Do not give a strong tug or apply excessive force to the foot switch cable or remote interlock connector.***
- ***Make sure that the connector does not make contact with bumps on the floor when moving this device to avoid getting the cable caught in the casters.***

3) Remote Interlock Connector



- The remote interlock connector is on the back of the Main unit.
  The remote interlock connector is internally shorted.
- It can be used in various ways to enhance safety and avoid risk.
  * Emergency shut down
  * Door interlock
  * Other interlock functions

Plug in the connector and turn the ring to secure it.

6. Annual Maintenance, Inspection and Calibration

⚠WARNING

- ***This device must not be taken apart by anyone except for specially trained MORITA service personnel. High voltage circuits inside the Main unit could cause death by electric shock. For disassembly and servicing, rely only on J. MORITA OFFICE personnel.***

⚠CAUTION

- ***Check laser output annually.***
- ***Laser can be emitted from the laser aperture when the top cover is opened and interlock is defeated. Never look into or touch the laser aperture.***

Annual Maintenance

* The AdvErL EVO should be maintained annually in accordance with the following maintenance and inspection items.
Maintenance should be done by specially trained service personnel.

1) Outline

- Screw Tightness of all screws, bolts etc.
- Floor level and casters are stable
- Main Power Supply Within: 100 V to 240 V ±10%
- Electric Circuits wiring and Cables for foot switch and power.

2) Function Check (Interlock)

- Emergency Stop
- Hollow Waveguide disconnected.
- Remote Interlock connector disconnected.
- Interlock messages are not displayed before use
- Foot Switch
- Key Switch
- Spray Water
- Tip Air

3) Replacement

- Cooing water and Deionization Filter Cartridge
  Replace all the cooling water and deionization filter cartridge.
- Flash Lamp
  Check the total number of shots for the flash lamp. Replace after 10 million shots. (recommended)

4) Other Parts

- Aiming beam emission
- Laser Safety Glasses are not damaged.
- Contact tips are not damaged or dirty.
- Handpiece O-ring
- Handpiece is securely attached

5) Calibration of Laser Output

- Laser Output Level
  Output level is ± 20% of displayed value.
  Calibration is to be performed only by a trained service engineer.

* For repair or other types of service contact your local dealer or J. MORITA OFFICE.

7. Clinical Applications

(1) Introduction

The AdvErL EVO Laser System is intended for use only by dentists trained in the safe handling of the laser.
Please read and understand this user manual, and use the laser system in vitro prior to using it on patients.
Observe all of the safety precautions described in this user manual.
Hygienists or other health professionals handling lasers should also read and understand this user manual of the system (INSTRUCTIONS FOR USE).

(2) Er:YAG Laser Ablation

2.1) Tissue Interaction

AdvErL EVO is an Er:YAG laser system.
Er:YAG is Erbium doped Yttrium Aluminum Garnet crystal, and system generate 2.94 um laser.
It was selected because the wavelength matches the vibrational absorption of water molecules in the tissue.
Figure l shows that absorption coefficient of water.
Er:YAG laser wavelength (2.94 um) is near the peak of absorption coefficient of water.
When the laser is absorbed by tissues, it excites the movement of tissue molecules and causes tissue coagulation and vaporization, in both hard and soft oral tissues.

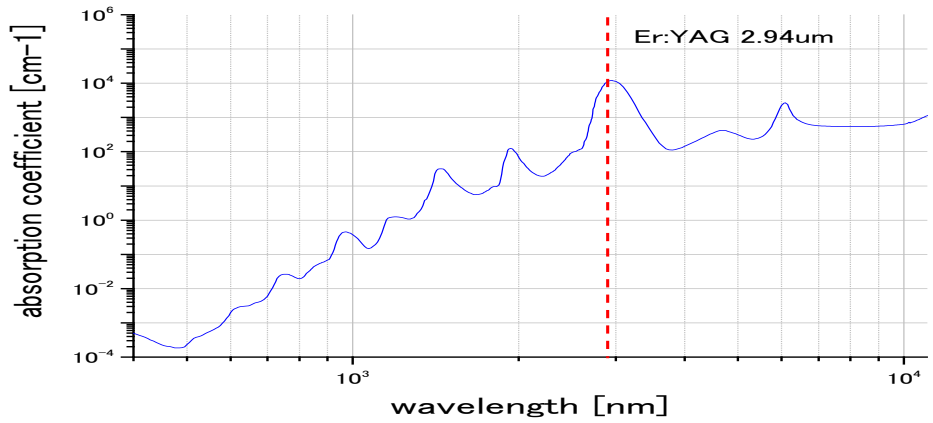


Figure l Absorption coefficient of water.
[Data from D. J. Segelstein, “The complex refractive index of water”, University of Missouri-Kansas City, (1981)]

2.2) Parameter of Laser Ablation

There are many important parameters for laser ablation procedures.
Parameter of laser output, such as pulse frequency, energy density, total irradiation time, etc., parameters of contact tip, such as diameter and distance from the tissues, are all important for the laser ablation procedure.
For more detail, see later section.

■Reference

l) Tissue Ablation: Devices and Procedures — John. G XVebster
2) Dent. Clin. N. Am. 48 (2004)1017-1059 — Glenn van As
3) Laser-Tissue Interactions: Fundamentals and Applications — Markolf H. Niemz

(3) Warnings and Notes

Never use this device for patients who have a pacemaker or an implantable cardioverter defibrillator (ICD); it could cause these devices to operate erratically.

Tip Air

Take great care when using the tip air inside a body cavity or tubular lumen. Raising the air pressure inside a cavity or lumen could force air into a blood vessel through an open wound and result in an air embolism. Also take great care when using the tip air in areas of the oral cavity where it could increase the pressure; this could result in a severe air embolism or subcutaneous emphysema.

Combustion Danger due to Elevated Level of Oxygen

Do not use this device in the presence of a combustible anesthetic or an elevated concentration of oxygen; this could result in ignition or explosion. A laser beam will readily ignite a tracheal tube such as those made of silicon rubber in the presence of a high concentration of oxygen or an anesthetic gas mixed with oxygen. For example, a laser beam will instantly ignite the tube if the oxygen concentration is 48%.
If use of oxygen is absolutely essential, the oxygen delivery tube must be protected with a non-combustible cuff and steps must be taken to insure that there is no leakage of oxygen.

A direct, reflected or scattered laser beam can cause permanent blindness. All individuals in the laser use area must wear Laser Safety Glasses supplied with this device. Other parts of the body should also be protected. The laser beam can cause serious injury to skin and eyes.
Even if you are wearing Laser Safety Glasses, never look directly into the aperture where the laser comes out; there is a risk of blindness. Both the main laser and the guide light are dangerous. The Laser Safety Glasses provide only limited protection.

Read and understand all safety Warnings and Precautions described in the each section.

(4) Adverse Effects

There are no known adverse effects in treating soft or hard tissue applications.

(5) AdvErL EVO INDICATIONS FOR USE

This device is intended for the incision, excision, vaporization, ablation and coagulation of soft tissue in oral and dentistry and for the ablation and vaporization of hard tissue in dentistry.

Use of AdvErL EVO is indicated for:

Hard Tissue
- Caries removal
- Surface ablation of wedge shaped defect

Perio
- Irradiation to the periodontal pocket
- Scaling
- Periodontal curettage
- Gingivoplasty
- Gingival flap operation

Soft Tissue
- Frenectomy
- Gingival incision and excision
- Coagulation of stomatitis
- Removal of pigmentation

(6) Clinical Procedure

6.1) General

Begin treatment with the lowest energy possible. If more tissue reaction is desired, increase the energy level in small increments until the desired tissue effect is observed.
Stop frequently to observe the treated area and adjust the laser settings accordingly.
Patients will usually respond more favorably if lower settings are used in the beginning of the treatment.
The ablation effect of the laser energy remove the target tissue structure is not any mechanical action of the contact tip.

6.2) Tissue Effects of Er:YAG Laser

Er:YAG laser beam is well absorbed by water.
The rate of tissue removal strongly depends on the water content of the target tissue.
So the percentage of water in target tissue is very important.
Enamel has a few percentage of water, caries and healthy dentin is more than enamel, so that caries and dentin will be removed much faster than healthy enamel. Soft tissue contains water with much more percentages, and can be ablated very rapidly.

6.3) Pulse Energy (Energy Level Setting: mJ)

Pulse energy is very important because higher pulse energy is effective for tissue ablation.
The energy of pulse is varied from 30 mJ.
Under 10 Hz, the maximum energy is 400 mJ.
At 20 Hz, the maximum energy is 170 mJ.
At 25 Hz, the maximum energy is 80 mJ.
In case of using high energy per pulse settings, consider about patient discomfort and adverse effects on tissues. .
The duration of each individual pulse is a duration of approximately 300 microseconds.
This duration is very short compared to a whole second.
The time between irradiation, tissue is cooled properly with spray water.

6.4) PPS (Hz)

This is irradiation number of times in a second. The PPS setting can be adjusted from 1 to 25 Hz.
It can influence patients' comfort level.

Generally, higher PPS irradiation of tissue surface will be smooth in enamel and dentin.
In soft tissue, the finish line of the cut can be better controlled.
Lower PPS setting is better to improving patient’s comfort level.

6.5) Laser Energy Density

The threshold for ablation depends not only on the energy per pulse, but also depends on the density of the energy per pulse.
When the laser energy is irradiated on tissues, a higher energy density will have a greater effect.
The laser emission from the contact tip end spreads out, as detailed at **6.6) Type of Contact Tips**.
Therefore, the best cutting efficiency is achieved when the contact tip is very close to the target.
In order to get the best cutting efficiency and longest contact tip lifetimes, be separately used from the hard tissue approximately 1/2 mm.
Another, diameter of contact tip is important. Treatment by small diameter contact tips will be more effective on ablation than lager diameter tip, but irradiated area is smaller.

⚠WARNING

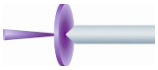
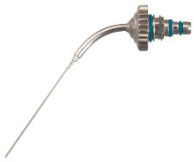
- ***Screw the contact tip into the handpiece grip all the way otherwise the contact tip may come off during use, causing incorrect laser irradiation or swallowing of the contact tip.***

⚠CAUTION

- ***Contact tips are consumable and must be replaced periodically. Inspect contact tips carefully before using them (see below). Worn contact tips could overheat and injure the patient.***
  - ***・ Do not use chipped or worn contact tips.***
  - ***・ Do not use contact tips if the laser output seems to be lower than the usual.***
  - ***・ If the guide light is dim or does not appear at all, the contact tip may be damaged.***
- ***End of contact tips are sharp and can cause injury; handle them with care.***
- ***Use only contact tips specified for AdvErL EVO.***
- ***When putting contact tips on and taking them off, turn the key off or put this device in Stand-by ode.***
- ***Always hold the knurled part of the contact tip to screw it on or off; never grip the metal pipe, which could damage the contact tip.***
- ***Never emit a laser without having the handpiece and a contact tip installed.***
- ***Check the end of contact tips and make sure they are free of blood and other contamination or debris. Otherwise, they could overheated, especially if the tip air and spray water are turned off. Overheated contact tips could injure the patient.***

6.6) Type of Contact Tips

Series	Type	Outline	End Shape	Diameter (μm)	Tissue Type	Remarks
C Series 	C400F		FLAT	400	Hard Tissue Perio	
	C600F		FLAT	600	Hard Tissue Perio	
	C800F		FLAT	800	Hard Tissue Perio	
P Series 	P400FL		FLAT	400	Hard Tissue Perio	
	P400T		TAPER	400	Hard Tissue Perio	
PS Series (PERIO SURGERY TIP) 	PS400T		TAPER-FLAT	400	Hard Tissue Perio Soft Tissue	
	PS400TS		TAPER-FLAT SHORT	400	Hard Tissue Perio Soft Tissue	
	PS600T		TAPER-FLAT	600	Perio	
	PS600TS		TAPER-FLAT SHORT	600	Perio	
PSM Series 	PSM600T		FLAT	400	Perio	

Series	Type	Outline	End Shape	Diameter (μm)	Tissue Type	Remarks
S Series (SURGICAL TIP) 	S600T		TAPER	600	Soft Tissue	
R Series 	R200T		TAPER	200	Hard Tissue	*1
	R300T		TAPER	300	Hard Tissue	
	R600T		TAPER	600	Perio	
CS Series 	CS600F		FLAT	600	Hard Tissue	

*1 These contact tips require R Handpiece Grip.

8. Troubleshooting

Explanation of Error and Caution Messages

If an error message appears in the LCD touch screen, follow the message and instruction in the table below. Contact your local dealer or J. MORITA OFFICE in the following cases:

- Repairs are required
- Replacement of parts such as the flash lamp, cooling water, deionization filter cartridge etc.
- Calibrating laser output (updating the V-J table)
- Cleaning the internal filter
- Frequent or repeated errors

A message appears in the LCD touch screen when one of the following errors occurs.

No.	Type	Explanation and Response	Reference
Interlock 1.	Flash lamp defect.	Lamp is defective or doesn't light up. Response: Flash lamp is old and not working properly. Go to Menu and use Refresh Lamp. If this does not work, contact your local dealer or J. MORITA OFFICE.	
Interlock 2	Main power supply is abnormal.	Cannot charge Up. Response: Restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	
Interlock 4	Cooling water problem	Cooling water is not circulating. Response: Either the pump is not working or there is no cooling water in the unit. Turn the power off, wait about 10 seconds, and then turn the power on again. Open the front cover and see if there is enough cooling water.	
Interlock 5	Shutter error	Shutter is not working properly. Response: Restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	
Interlock A	Hollow waveguide is not connected.	The hollow waveguide is not connected. Response: The hollow waveguide may be loose. Tighten the connection ring and restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	
Interlock B	Not enough cooling water.	Not enough cooling water. Contact your local dealer or J. MORITA OFFICE.	
Interlock C	Cooling water is too hot	Cooling water is too hot, over +45°C (+113°F). Response: Wait until the water cools down to below +45°C (+113°F). Check current temperature. This will happen less often if there is plenty of open space in back of the unit.	If this happens frequently, the filter inside the unit may be plugged up. Contact your local dealer or J. MORITA OFFICE to have the filter cleaned.

No.	Type	Explanation and Response	Reference
Interlock D	Cooling water too cold	Cooling water is too cold, less than +15°C (+59°F). Wait for it to warm up. Response: Leave the unit on and wait for the water to warm up; it will then automatically start to operate normally. Check current temperature.	This commonly happens in the winter when the room is cold.
Interlock F	Cover Interlock	Cover interlock activated. Response: Restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	
Interlock G	Remote Interlock	Remote interlock activated. Response: Check the door for the remote interlock. Or check the remote interlock connection on the back of the unit.	
100	Emergency Stop Alarm	The emergency stop switch has been pressed. Response: Turn off the main power and release the emergency switch. Then restart the unit.	Push the emergency switch again after it has been activated to release it.
101	Watch Dog Timer	Watch Dog Timer activated. Response: Restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	
102	Switch error	A switch error was detected when the unit was turned on. Response: This happens if the foot switch is depressed when the unit is turned on. Let the foot switch up and restart the unit.	The foot switch is checked for safety when the unit is turned on.
103	Memory Back-up Error (SRAM)	Battery for memory is low. To recharge the back-up battery, turn on the power and leave it on for 30 minutes. Then reset the clock and rewrite the names for the memories.	A rechargeable battery is used to maintain the clock and other functions. Turn the unit on once every 6 months to recharge the battery.
104	Laser output Error	Laser output does not match set value. Response: The flash lamp is probably old and not working right. Go to Menu and use Refresh Lamp. If this does not work, contact your local dealer or J. MORITA OFFICE.	
105	Energy Setting Error	Energy level cannot be properly set. Response: Probably needs calibration. Contact your local dealer or J. MORITA OFFICE.	This happens if the laser has not been calibrated for some time.
106	Voltage limit stop	Cannot produce the output power that has been set. Response: Lower the output power (mJ), or replace the flash lamp. If an error occurs even after the power has been lowered, a mirror may be damaged; in this case, contact J. MORITA OFFICE.	This happens if the flash lamp is in poor condition
110	Temporary power failure	Temporary power failure error. Response: Restart the unit. Check the socket for the main power cord.	Happens when main AC power source is temporarily lost.

No.	Type	Explanation and Response	Reference
113	Memory back-up error (EEPROM)	Memory for EEPROM has been erased. Response: For proper laser output, the characteristic values must be reset. Contact J. MORITA OFFICE.	
201	Pulse misses	Laser is skipping pulses Response: The flash lamp is probably old and not working right. Go to Menu and use Refresh Lamp. If this does not work, contact your local dealer or J. MORITA OFFICE.	
202	Communication error	Communication failure from panel to laser control unit. Response: Restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	
204	Purge air error	Cooling air for the hollow waveguide not detected. Response: The hollow waveguide may be loose. Tighten the connection ring and restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE. Cable could be damaged if used as is.	
205	Laser output too high	Laser output does not match set value. Response: Restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	This happens if the laser has not been calibrated for some time.
206	Sudden laser output anomaly	Sudden deviation of laser output. Response: Restart the unit. If this does not work, contact your local dealer or J. MORITA OFFICE.	
208	Sudden output drop	Output suddenly dropped. Response: Possible mirror damage. Contact J. MORITA OFFICE.	Detected during start up.
501	Time to replace cooling water and deionization filter cartridge.	Time to replace the cooling water and the deionization filter cartridge. Response: contact your local dealer or J. MORITA OFFICE. The AdvErL EVO could be damaged if the both are not replaced on time. Replace them as soon as possible, within 1 or 2 months.	Replace the cooling water and the deionization filter cartridge once a year.
502	Flash Lamp is worn out.	After 10 million shots the flash lamp should be replaced as its performance will start to deteriorate. After 20 million shots the lamp has reached the end of its working life. Although it can still be used errors will occur more and more frequently; replace it right away. Go to the Menu to check the total shot number for the lamp.	Go to the Menu and check Lamp Shot Number.

Troubleshooting for Problems Other than Error Messages.

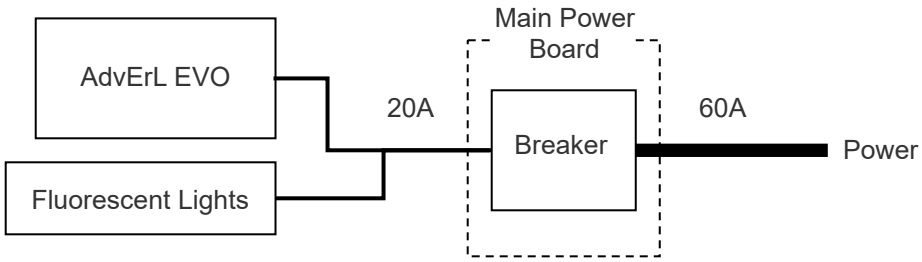
If the procedures described below do not solve the problem, please contact your local dealer or J. MORITA OFFICE.

Problem	Cause	Response
The device does not start.	Circuit Protector may be in the off position.	Make sure the Circuit protector on the back of the Main unit is not in the off position.
Low laser output or Aiming beam is not emitted or Aiming beam is dim or hazy	Contact tip is damaged.	Wear or damage (such as chipping) will reduce the efficiency of the contact tip, and lower the laser output. When the contact tip wears down to the metal sleeve, the laser output is significantly deteriorated. Replace the contact tip.
	Lens of Handpiece (Drum Lens) or lens of R handpiece grip (Ball lens) is dirty or damaged.	Clean the Drum lens or the Ball lens. (See page 48) This will lower the laser output and cause aiming beam trouble. Replace the lens if it is extremely dirty, scratched or otherwise damaged.
	Water leaks inside the handpiece.	Water leaks inside the handpiece if the O-rings on the contact tip or handpiece are damaged. This will lower the laser output and cause aiming beam trouble. Try using another handpiece or a new contact tip. Grease the handpiece grip every day before use or after putting it on and taking it off more than 50 times. (See page 47)
	Poor assembly of hollow waveguide	Make sure the hollow waveguide is neatly parallel to the hollow waveguide support.
	Hollow waveguide is broken	Replace the Hollow waveguide. Contact your local dealer or J. MORITA OFFICE.
Spray water is not emitted from the contact tip.	Spray water bottle is empty.	Replace the spray water bottle.
	Air got in the tube when replacing the spray water bottle.	When the bottle is replaced or the device is not used for a long time, some air will get in the water tube. Set the device to Ready mode and depress the foot switch to its first level to run the spray water pump until water is coming out.
	The water flow path of the contact tip is plugged.	Replace the contact tip and make sure the spray water is coming out.
	The spray water connector is not properly plugged in.	Reconnect the connector. (See page 52)

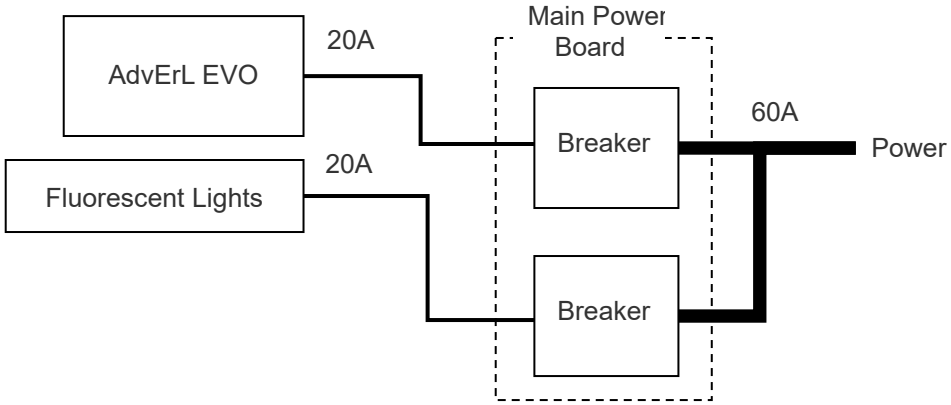
Problem	Cause	Response
Spray air is not emitted from the contact tip.	Air is leaking inside the handpiece	Air will leak inside the handpiece if the O-rings on the contact tip or handpiece are damaged. Try using another handpiece or a new contact tip. Grease the handpiece grip every day before use or after putting it on and taking it off more than 50 times. (See page 47)
Water collects inside the handpiece	Water is leaking inside the handpiece.	Water will leak inside the handpiece if the O-rings on the contact tip or handpiece are damaged. This will lower the laser output and cause aiming beam trouble. Try using another handpiece or a new contact tip. Grease the handpiece grip every day before use or after putting it on and taking it off more than 50 times. (See page 47)
Water does not stop immediately when the foot switch is released or drips from the end of the contact tip.	There is air in the water tube.	Put the device in Ready mode and depress the foot switch to the first level for about 30 seconds to clear the water tube of air.
Log key does not appear on operation panel	The key is set for Hidden.	This is the factory settings. Go to the Menu to change the setting to Show.
Log key starts blinking.	More than 900 log records have not yet been copied.	The log saves up to 1,000 records. If more than 900 records have not yet been copied onto a USB flash drive, the Log key starts blinking. Copy the log onto a USB flash drive.
Sound of fans is frequently noisy.	Lack of space for air ventilation to cool the device.	Make space on the sides and back of the device for air ventilation.
	Lack of cooling air due to clogged air filter.	Cleaning of air filter is needed. The cooling water not properly cooled if the air filter of the heat exchanger is clogged with dust, causing the fans to run high speed. Contact your local dealer or J. MORITA OFFICE.
The cooling water inside the tank is cloudy.	The quality of the cooling water is degraded.	Replacement of the cooling water is needed. If the cooling water is cloudy or degraded, stop using the device and replace the cooling water. Otherwise, the device could malfunction. Contact your local dealer or J. MORITA OFFICE for instructions on how to replace the cooling water. To keep the quality of the cooling water from degrading, especially when the device is not being used for a long time, turn the power on and circulate the cooling water through the deionization filter cartridge for 15 minutes at least once a month.
LCD touch screen does not respond while log is being copied onto a USB flash drive.	Something is wrong with the USB flash drive.	Remove the USB flash drive.

Problem	Cause	Response
Fluorescent lights in the room flicker when the laser is emitted.	The main power source may not be good enough.	•Plug the device into another receptacle. •Plug the fluorescent light into another receptacle. •Use separate circuits for the device and fluorescent lights. •Replace the lights with inverter type fluorescent lights.

Example of circuit that can cause fluorescent lights to flicker.
Rather low (20 amps) breaker current capacity can cause lights to flicker.



Example of circuit that is not likely to cause fluorescent lights to flicker.
Use separate breakers for this device and fluorescent lights.



9. Technical Description

Name	AdvErL EVO
Model	MEY-1-A
Type	EX-2
Rating	AC 100 V to 240 V ±10%
Frequency	50/60 Hz
Power Consumption	1.5 kVA
Electric Shock Protection Class	Class I
Electric Shock Protection Type	Type B with applied component
Laser Classification	Class 4 < Er:YAG Laser >
Laser Stimulation Method	Pulsed Stimulation
Laser Medium	Er:YAG
Laser Energy	30 mJ to 400 mJ per pulse (at handpiece tip) For a pulse rate higher than 10 pps: 20 pps: 30 mJ/pulse to 170 mJ/pulse 25 pps: 30 mJ/pulse to 80 mJ/pulse
Pulse Rate	1, 3.3, 5, 10, 20, 25 pps
Wavelength	2.94 μm
Beam Spread Angle	≥8° (full width at handpiece tip)
Nominal Ocular Hazard Distance	41 cm from handpiece tip
Aiming beam	Wavelength 650 nm
Transmission Method	Hollow Waveguide System
Outer dimensions	(Width) 246 mm × (Depth) 469 mm × (Height) 732 mm
Weight	Approx. 49 kg
IP	IPX8 (Foot Switch)
Operation Environments	
Temperature	+10°C to +35°C (+50°F to +95°F)
Humidity	30% to 75% (without condensation)
Atmospheric Pressure	70 kPa to 106 kPa
Storage Environments	
Temperature	+5°C to +40°C (+41°F to +104°F)
Humidity	10% to 85% (without condensation)
Atmospheric Pressure	70 kPa to 106 kPa
Transport Environments (without cooling water and spray water)	
Temperature	-10°C to +70°C (+14°F to +158°F)
Humidity	10% to 85% (without condensation)
Atmospheric Pressure	70 kPa to 106 kPa

* Specifications may be changed without notice due to improvements.

■ Disposal of Medical Devices

Any medical devices which could possibly be contaminated must be first decontaminated by the responsible doctor or medical institution and then be disposed by an agent licensed and qualified to handle medical and industrial waste.

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Material must be disposed according to the relevant national legal regulations. Consult specialized disposal companies for this purpose. Please inquire of the local city/community administrations concerning local disposal companies.

■ Service

AdvErL EVO may be repaired and serviced by:

- The technicians of J. MORITA's subsidiaries all over the world.
- Technicians employed by authorized J. MORITA dealers and specially trained by J. MORITA.
- Independent technicians specially trained and authorized by J. MORITA.

10. Electromagnetic Disturbances (EMD)

The AdvErL EVO (hereafter “this device”) conforms to IEC 60601-1-2:2014 Ed. 4.0, the relevant international standard for electromagnetic disturbances (EMD).
The following is the “Guidance and Manufacturer's Declaration” which is required by IEC 60601-1-2:2014 Ed. 4.0, the relevant international standard for electromagnetic disturbances.

This is a Group 1, Class B product according to EN 55011 (CISPR 11).
This means that this device does not generate and/or use internationally radio-frequency energy, in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material or inspection/analysis purpose and that it is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings use for domestic purposes.

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions		
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
Conducted disturbance CISPR 11	Group 1 Class B	This device 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.
Radiated disturbance CISPR 11	Group 1 Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current IEC 61000-3-2	Class A	
Voltage fluctuations and flicker IEC 61000-3-3	Clause 5	

⚠WARNING

- ***The use environment of this device is the Professional healthcare facility environment.***
- ***This device needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the ACCOMPANYING DOCUMENTS.***
- ***Use of parts other than those accompanied or specified by J. MORITA MFG. CORP. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.***
- ***Do not use this device as adjacent or stacked as possible with other.***
  When adjoining or stacking is necessary, use it after observing whether this device and other equipment work properly.
- ***Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the MEY-1-A, including cables specified by the manufacturer.***

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth Signal input/output ±2 kV line(s) to earth	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth Signal input/output —[*1]	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (r.m.s.) 50 Hz or 60 Hz	30 A/m (r.m.s.) 60 Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level. r.m.s.: root mean square			

[*1] Not applicable because it does not connect directly to outdoor cable.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device 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 V ISM[(c)] frequency band: 6 V 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	3 V ISM[(c)] frequency band: 6 V 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the compliance level in V/m 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 ratio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated 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 this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating this device.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

(c) The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

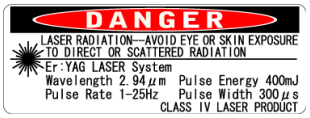
Essential Performance

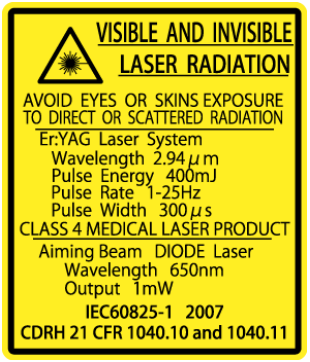
- Laser output level shall be within ±20% / -30% of output set level.
- No loss of operation and control of the unit
- No operation mode change (change to safe side is acceptable)
- No back up data destruction

If the essential performance is lost or degraded due to electromagnetic disturbance, unexpected operation mode change or error will be occurred.

Cable List

No.	Interface(s):	Max. Cable Length, Shielding	Cable Classification
1.	AC Mains	3 m, Un-shielded	AC Power Line
2.	Foot Switch Cable	0.8 m, Shielded	Signal Line
3.	Remote Interlock Cable	5 m, Shielded	Signal Line
4.	Laser Transmission Cable	2 m, Un-shielded	Signal Line (Patient-Coupled cable)
5.	USB Port (USB flash drive only)	Direct Plug-in	Signal Line





Development and Manufacturing

J. MORITA MFG. CORP.
680 Higashihama Minami-cho, Fushimi-ku, Kyoto 612-8533, Japan
T +81. (0)75. 611 2141, F +81. (0)75. 622 4595

Morita Global Website ***www.morita.com***

Distribution

J. MORITA CORP.
3-33-18 Tarumi-cho, Suita-shi, Osaka 564-8650, Japan
T +81. (0)6. 6380 1521, F +81. (0)6. 6380 0585

J. MORITA USA, INC.
9 Mason, Irvine CA 92618, USA
T +1. 949. 581 9600, F +1. 949. 581 8811

J. MORITA EUROPE GMBH
Justus-von-Liebig-Strasse 27b, 63128 Dietzenbach, Germany
T +49. (0)6074. 836 0, F +49. (0)6074. 836 299

MORITA DENTAL ASIA PTE. LTD.
150 Kampong Ampat #06-01A KA Centre, Singapore 368324
T +65. 6779. 4795, F +65. 6777. 2279

J. MORITA CORP. AUSTRALIA & NEW ZEALAND
Suite 2.05, 247 Coward Street, Mascot NSW 2020, Australia
T +61. (0)2. 9667 3555, F +61. (0)2. 9667 3577

J. MORITA CORP. MIDDLE EAST
4 Tag Al Roasaa, Apartment 902, Saba Pacha 21311 Alexandria, Egypt
T +20. (0)3. 58 222 94, F +20. (0)3. 58 222 96

J. MORITA CORP. INDIA
Filix Office No.908, L.B.S. Marg, Opp. Asian Paints,
Bhandup (West), Mumbai 400078, India
T +91-82-8666-7482

J. MORITA MFG. CORP. INDONESIA
28F, DBS Bank Tower, Jl. Prof. Dr. Satrio Kav. 3-5, Jakarta 12940, Indonesia
T +62-21-2988-8332, F + 62-21-2988-8201

SIAMDENT CO., LTD.
71/10 Moo 5 T. Tharkham A. Bangpakong Chachuengsao 24130 Thailand
T +66 (0) 3857 3042, F +66 (0) 3857 3043 www.siamdent.com

EU Authorized Representative under the European Directive 93/42/EEC

EC REP **Medical Technology Promedt Consulting GmbH**
Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany T +49. 6894 581020, F +49. 6894 581021

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