



Er:YAG Laser for Dentistry
AdvErL EVO

INSTRUCTIONS FOR USE
for Taiwan

CE
0197



Thank you for purchasing the AdvErL EVO.

For optimum safety and performance, read this manual thoroughly before using the unit and pay close attention to the warnings, cautions and notes.

Keep this manual in a handy place for ready reference.

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Table of Contents






	Page
PREVENT ACCIDENTS	4
1. EQUIPMENT DESCRIPTION.....	6
2. PARTS IDENTIFICATION AND ACCESSORIES.....	9
(1) Parts Identification	9
(2) Accessories.....	11
(3) Labels	13
(4) Symbols.....	14
3. OPERATION	15
(1) Set Up.....	15
(2) Turn the Unit On	17
(3) Handpiece and Contact Tip Attachment	19
(4) Operation Procedure.....	21
1) Set Laser Irradiation Conditions	21
2) Laser Emission Procedure.....	24
3) Emergency Stop.....	25
4) Memory.....	27
5) Turn Unit Off	32
6) Moving the Unit.....	33
7) Make Other Settings and Check Information	34
4. STERILIZATION, REPLACEMENT PARTS, AND STORAGE	41
(1) Handpiece grips, Hanger, Tips and Tip stand Cleaning and Sterilization.....	42
1) Cleaning (Always perform this procedure prior to sterilization)	42
2) Autoclaving (sterilization) (Always perform this procedure after cleaning and before use)	43
(2) Cleaning the Main Unit	44
(3) Maintenance	45
1) Grease Handpiece Grips	45
2) Lens Cleaning	46
3) Spray Water Bottle (Distilled Water for Spray) Replacement.....	47
(4) Storage.....	48
(5) Replacement Parts	49
5. INSTALLATION	50
< Cautionary Remarks on Installation >	50
1) Connect Water Tube.....	50
2) Foot Switch.....	51
3) Remote Interlock.....	51

	Page
6. MAINTENANCE, INSPECTION AND CALIBRATION	52
Annual Maintenance	52
1) Outline	52
2) Function check (Interlock).....	52
3) Replacement	52
4) Other Parts	52
5) Calibration of Laser Output	52
7. CLINICAL APPLICATIONS	53
(1) Introduction	53
(2) Er:YAG Laser Ablation	53
2.1) Tissue Interaction.....	53
2.2) Parameter of Laser Ablation	53
(3) Warnings and Notes.....	54
(4) Adverse Effects	54
(5) AdvErL EVO INDICATIONS FOR USE	54
(6) Clinical Procedure	55
6.1) General.....	55
6.2) Tissue Effects of Er:YAG Laser.....	55
6.3) Pulse Energy (Energy Level Setting: mJ)	55
6.4) PPS (Hz)	55
6.5) Laser Energy Density.....	55
6.6) Type of Tips	57
8. TROUBLESHOOTING	59
Explanation of Error and Caution Messages.....	59
Troubleshooting for Problems Other than Error Messages.	62
9. TECHNICAL DESCRIPTION	65
10. ELECTROMAGNETIC DISTURBANCES (EMD)	67

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 the unit 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 the equipment 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 equipment 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.

- 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 instrument 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 instrument to operate erratically. Turn off all communication devices of this type in the operating area.*
- *As far as possible do not use this laser unit 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.*

To access the warranty information for this product, scan the following QR code and visit our website.



1. Equipment Description

1. Operational Principles

The AdvErL EVO consists of a combination of four systems plus the laser transmission apparatus.

(1) Laser Beam Production Apparatus

1) Laser Beam Emitter System

An Er:YAG laser beam (2.94 μm) is emitted from the condenser assembly when it is excited by a flash lamp. The laser beam emitted from the laser resonator's mirror is partially reflected by a beam splitter, and the sensor for the power monitor detects the output, which is then adjusted. The safety shutter (beam shutter) opens after the Ready button has been pressed and the foot switch depressed as long as all other operational conditions have been satisfied, and the laser beam reaches the coupler for the transmission apparatus. At this point the laser beam is mixed with an aiming beam (650 nm) and goes on to the hollow waveguide.

2) Electrical System

The electrical system consists of the laser power supply, the control unit, the calibrator, the touch panel display, the key switch and the foot switch. The laser power supply is made up of a high voltage power supply, a high voltage trigger control board, and other components. The high voltage power is used to produce a light beam with 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 buttons on the touch panel display. Once the unit is in its Ready condition, the laser beam is emitted by depressing the foot switch.

Safety is constantly being monitored. If anything abnormal is detected, laser irradiation is terminated and an error message is displayed.

4) Cooling System

The AdvErL EVO is water cooled. Water circulates to cool the unit and then the water is cooled by a water-and-air heat exchanger. Water is stored in a tank inside the unit and circulates through the unit. The heated water is then cooled by the heat exchanger and returns to the water tank.

(2) Hollow Waveguide and Spray System

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 site. 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 grips, and the hollow waveguide are applied parts.

2. Biological Effects

An Er:YAG laser emits an infrared beam with a wavelength of 2.94 μm 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 a Laser Surgical Equipment

For the safety procedures written below, use Bundled "danger plate" or "warning plate".

(1) Safety measures to protect the 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 operation 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 equipment, always put on the protective goggles. Furthermore, never allow the laser beam to shine directly on the eyes even if Laser Safety Glasses are worn.
- 3) Regularly inspect the protective goggles to make sure there are no holes or fine cracks and make sure that they are physically sound.
- 4) Before using this equipment, 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 two 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 the patient

The doctor must explain to the patient all crucial points regarding treatment involving the laser surgery equipment.

When using the laser surgery equipment, 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 the equipment and the patient at the same time.

(3) Safety measures to protect people other than the user and the patient (observers etc)

- 1) The user must prohibit people other than the user and the patient from being in the area where the laser surgery equipment is used. If it is necessary to allow a person to enter the operation area, it should be limited to cases where the person is undertaking instruction and training. When the user is using the laser surgery equipment, 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 the equipment.
- 3) The user of this equipment must have complete proficiency in the operational procedures of the equipment.
- 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 operation area of the equipment must receive a comprehensive explanation on the hazards of laser beams.
- 6) The user of this equipment must never direct the laser beam to reflective surfaces or people other than the patient being treated.
- 7) The key of the equipment's key switch must be taken care of and kept by the person assigned that task and when the equipment is not in use, the key must always be removed from the equipment.
- 8) Wear only Laser Safety Glasses that have been regularly inspected.

(4) Prevention of Laser Beam Reflection off other Equipments and Equipment

As far as possible, remove all reflective equipments from the treatment area.

Take reflection protection measures by covering items that could reflect a laser beam such as surgical equipments and equipment with wet gauze or some other suitable material.

Look out for the possibility of the laser beam being reflected by metal objects and use surgical equipments that have undergone processing to eliminate reflectivity.

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 equipments and equipment such as forceps and suction tubes have undergone processing to prevent reflection and take all possible measures to reduce the chance of laser rays being reflected.
- 2) Never perform laser beam emission 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 equipment 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 operation area.

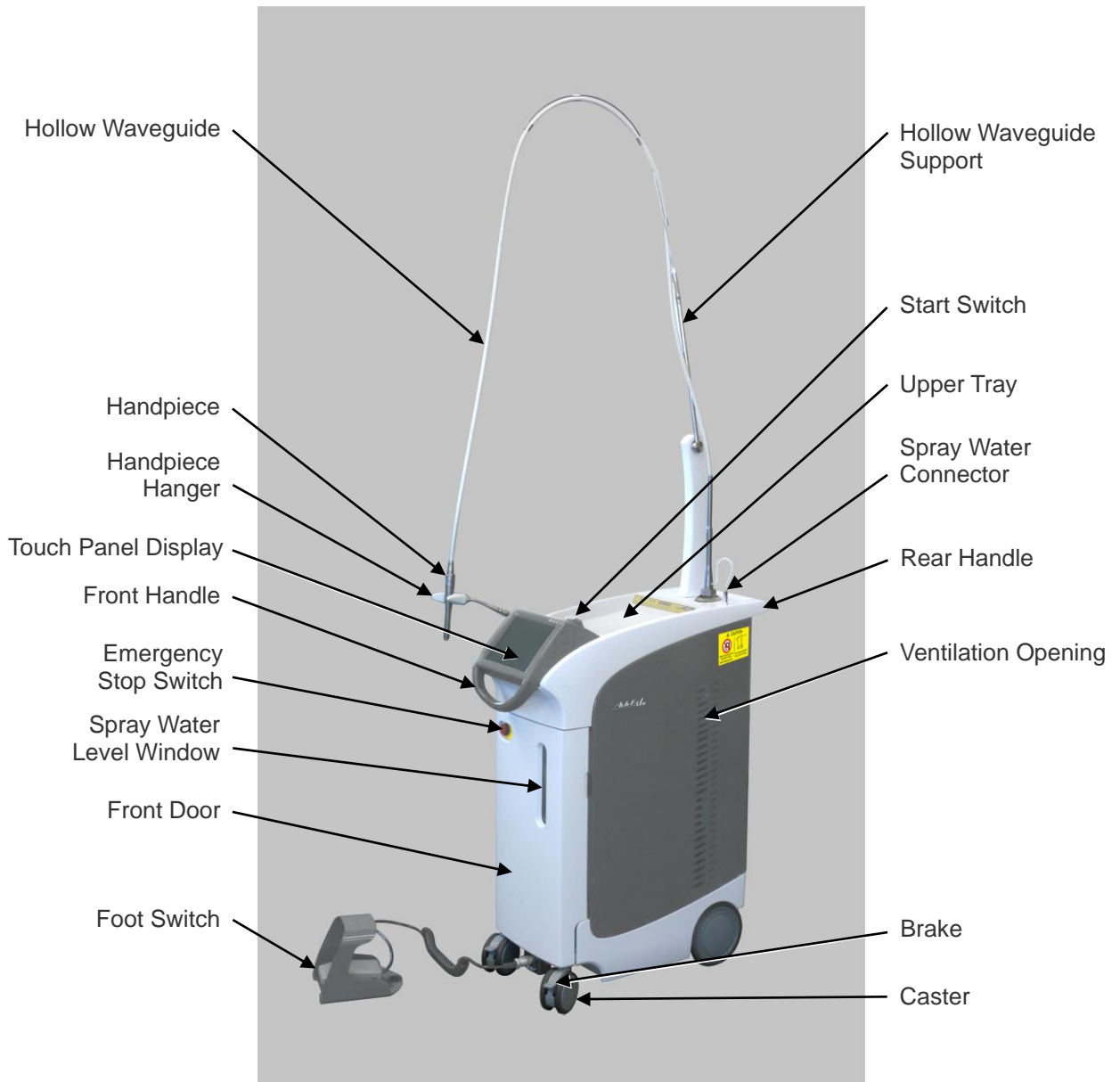
(6) Accidental Irradiation Precautions

- 1) Before performing laser beam emission, living body tissue that could be exposed to laser beam emission 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 emission time required for treatment and avoid excessive laser beam emission.
- 3) Both patient and laser surgeon must wear Laser Safety Glasses. If the laser beam (direct rays or diffused rays) strikes the eyes, it could cause blindness. Even when wearing Laser Safety Glasses, never allow the beam to strike the eyes directly.

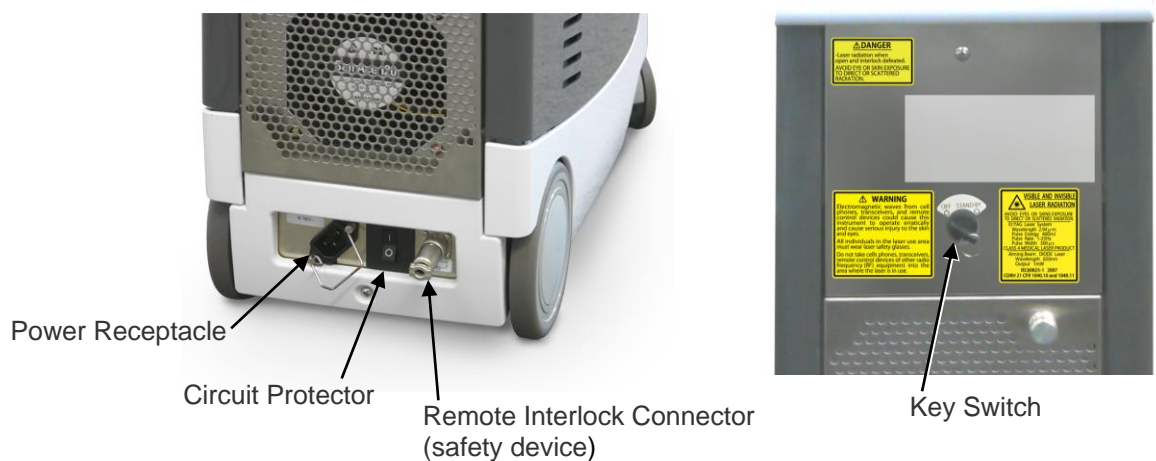
2. Parts Identification and Accessories

(1) Parts Identification

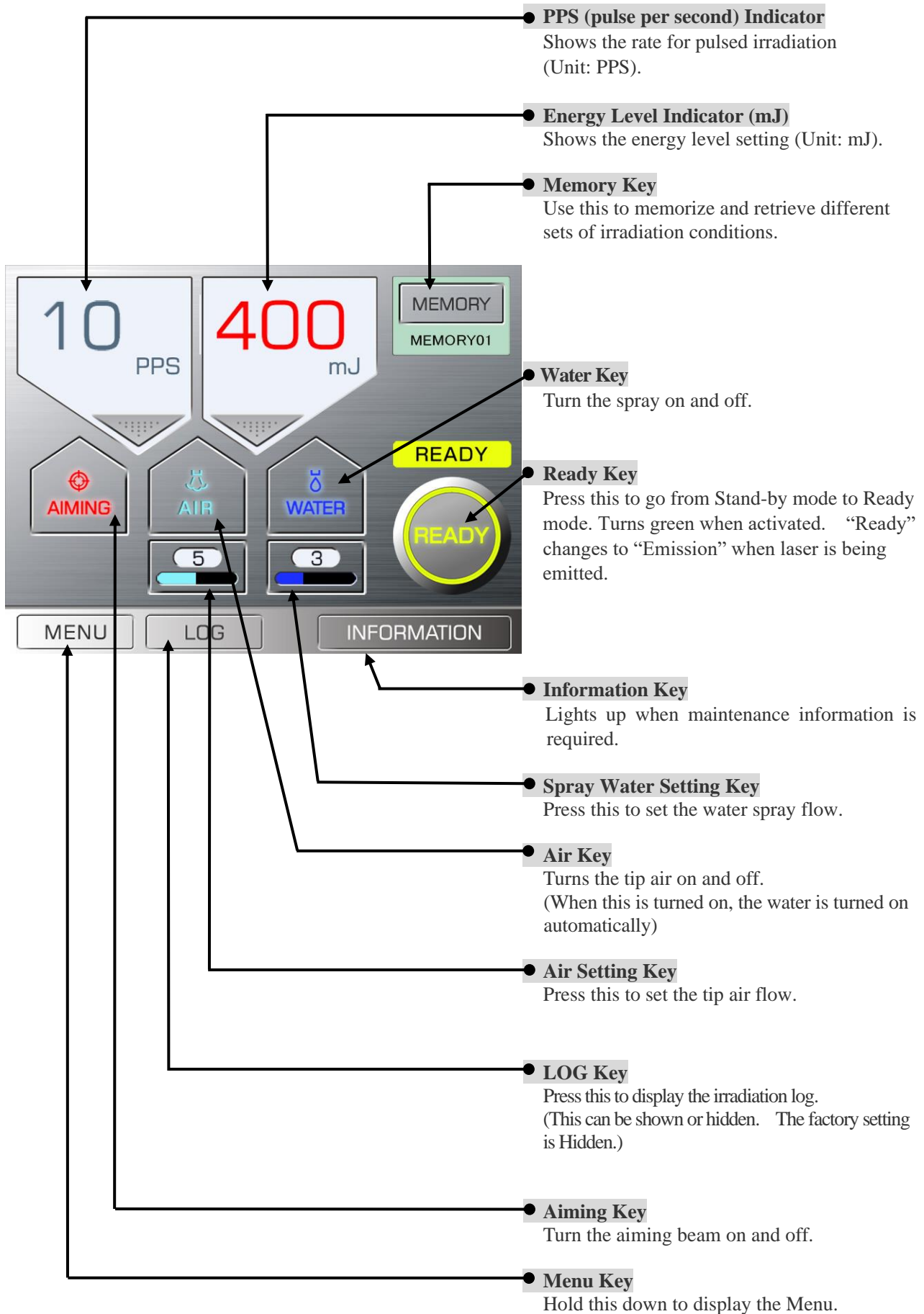
Main Unit



Back














Touch Panel Display(Main panel)










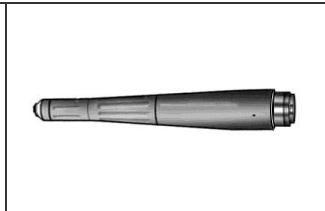
(2) Accessories



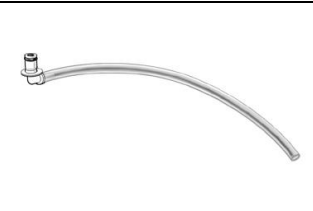

Contact Tips

			
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 Hanger (2)	Handpiece Grips (2)

			
Deionized Water Tank for Cooling, 2.5-liters	Deionization Filter Cartridge (1)	Drain Tube (1)	Wheel locking device (1)

WARNING
★ To Patients ★
This is a designated laser surgery area.
Follow the following rules:

1. Follow the instructions of doctors and nurses.
2. Do not touch or handle any of the instruments and equipment in this area.

Surgical Laser Supervisor

Patient warning plate

WARNING
To Operators of Laser Surgical Equipment

1. This laser surgical equipment may be operated only by those individuals whose name appears in the list of registered users.
2. Before use, record the date and time of use, the purpose and the surgeon's name in the Surgical Laser Log, and then request the key for the instrument from the supervisor of surgical laser equipment.
3. Before use, post a warning notice such as "Laser In Use" outside the surgical laser room.
4. If the laser equipment does not operate properly, stop using it immediately and report to the supervisor.
5. After use, inspect the equipment and perform all necessary maintenance procedures.
6. After use, immediately return the key to the supervisor, and record the length of time the equipment was used and other pertinent facts in the Surgical Laser Log.

Operator warning plate

WARNING

Laser In Use

Eye Protection Required

Eye warning plate

DANGER

LASER RADIATION
AVOID EYE OR SKIN EXPOSURE
TO DIRECT OR SCATTERED
RADIATION

Er:YAG LASER System
Wavelength 2.94 μm Pulse Energy 400mJ
Pulse Rate 1-25Hz Pulse Width 300 μs

CLASS 4 LASER

Laser Danger plate

DANGER

Laser Light and Equipment Dangers

The laser emitted by this equipment could cause serious injury to eyes and skin; put on safety glasses or take other suitable safety measures before use.

- Do not apply excessive force to the tip; it could break and cut the patient or fragments could be left in the surgical area. Handle the tips carefully.
- Keep output power within the specified limit for the tip.
- When not in use, do not leave the equipment in a place where it might freeze.

Tip Air Dangers


- Tip air for spray is emitted when the spray and air switches are turned on.
- Take care when performing operations inside body cavities and lumens; tip air could cause emphysema or a gas embolism.
- Take care that tip air does not injure tissues.
- Also take care that critical tissues such as nerves and blood vessels are not injured by the heat produced by the laser.

Combustion and Explosion Dangers


- Never direct the laser beam at combustible objects such as tracheal tubes, fabrics, surgical gowns etc.; this could cause these objects to catch on fire.
- Never use this laser in the presence of flammable anesthetics or in environments with a high oxygen concentration; this could result in a fire or explosion.
- Do not use standard, combustible tracheal tubes made of plastic or rubber.
- Avoid contamination and infection; take care that fumes and particulates produced by laser irradiation are not inhaled and do not get in anyone's eyes.

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

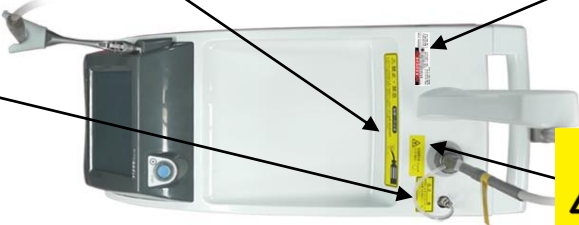
(3) Labels

Read All Warning and Caution Labels

WARNING SUBCUTANEOUS EMPHYSEMA
 Use with care. Cooling air from the contact tip can cause subcutaneous emphysema or air embolism.

DANGER
 LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION
 Er:YAG LASER System
 Wavelength 2.94 μm Pulse Energy 400mJ
 Pulse Rate 1-25Hz Pulse Width 300 μs
 CLASS IV LASER PRODUCT

CAUTION
 Before use, do not fail to connect the water tube for spray delivery



LASER APERTURE AT FIBER END

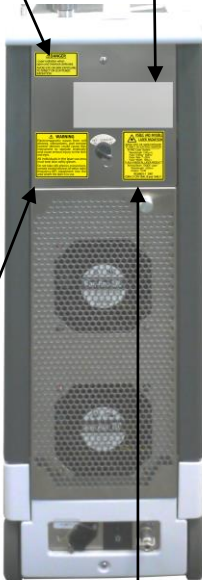
CAUTION
 Do not apply excessive force or stress to the transmission cable. Never bend it into a curve with a radius of less than 6 cm

CAUTION (inside of the device)

LASER STOP

DANGER
 -Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.

Rating Label



CAUTION
 Risk of overbalance, DO NOT PUSH side of equipment.
 Push rear end first to go over bumps.











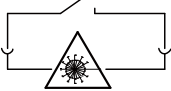






CAUTION
 Be sure to use distilled water. Using tap water or a saline solution could plug up the water lines.

WARNING
 Electromagnetic waves from cell phones, transceivers, and remote control devices could cause this instrument to operate erratically and cause serious injury to the skin and eyes.
 All individuals in the laser use area must wear laser safety glasses.
 Do not take cells phones, transceivers, remote control devices of other radio frequency (RF) equipment into the area where the laser is in use.

VISIBLE AND INVISIBLE LASER RADIATION
 AVOID EYES OR SKINS EXPOSURE TO DIRECT OR SCATTERED RADIATION
 Er:YAG Laser System
 Wavelength 2.94 μm
 Pulse Energy 400mJ
 Pulse Rate 1-25Hz
 Pulse Width 300 μs
 CLASS 4 MEDICAL LASER PRODUCT
 Aiming Beam DIODE Laser
 Wavelength 650nm
 Output 1mW
 IEC60825-1 2007
 CDRH 21 CFR 1040.10 and 1040.11

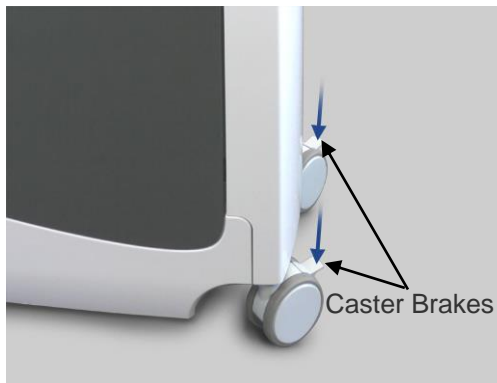
(4) Symbols

* Some symbols may not be used.

	Serial number		Unique device identifier
	Medical device		CE(0197) marking Conforms with the European Directive, 93/42/EEC. CE marking Conforms with the European Directive, 2011/65/EU.
	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
	Authorized representative in the European Community		

3. Operation

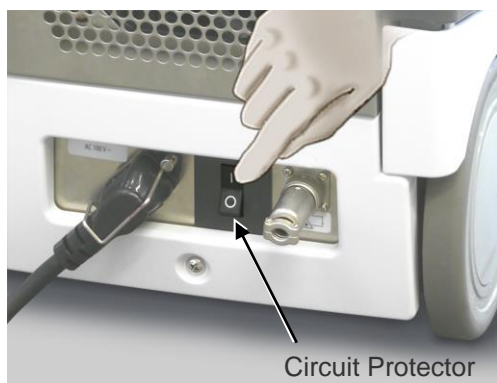
(1) Set Up



- (1) Put the unit in position and then step on the tabs to lock 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 unit.



- (4) Pull the handpiece hanger forward.

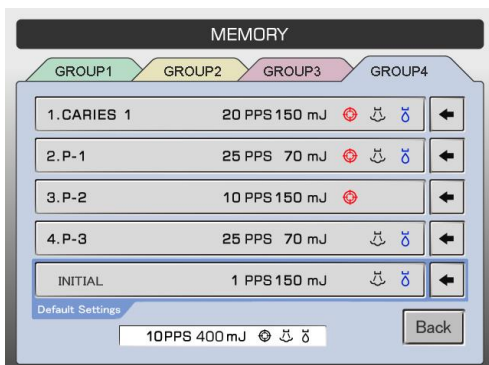
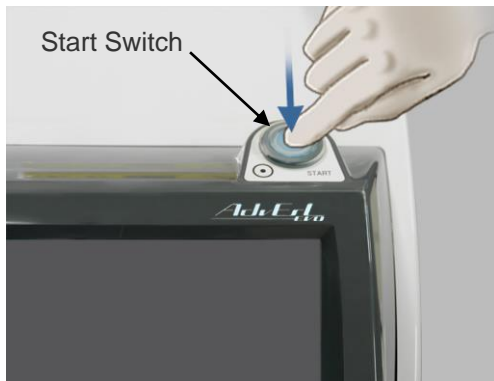
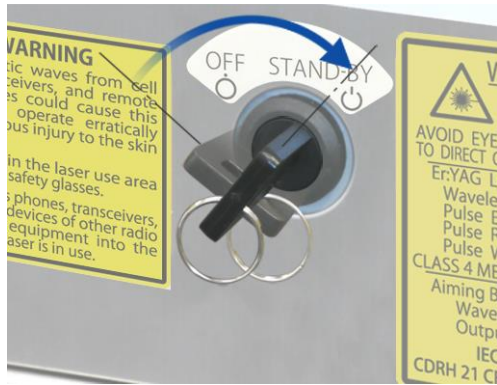
 **WARNING**

- *When the unit is not in use, always take out the key and give it to the person in charge.*
- *Never use this laser, modify it, or calibrate it in any way other than as described in the user manual. Inadvertent laser emission could be extremely dangerous.*
- *Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.*

 **CAUTION**

- *Do not apply excessive force or stress to the hollow waveguide. Never bend in into a curve with a radius of less than 6 cm.*
- *Do not let anyone go between the patient and the laser unit. Do not let personnel not involved with the treatment stand near the laser unit.*
- *If an error occurs, stop using the laser unit immediately and turn it off.*
- *Do not put the laser unit on a surface that is not level; it could tip over. Make sure the brakes on the casters are on.*
- *Never tip the laser unit more than 10° when moving it; it could tip over.*
- *Make sure there is enough water in the spray bottle.*
- *To avoid accidentally stepping on the foot switch, decide where it should be and always leave it in exactly the same place.*

(2) Turn the Unit On



- (1) Put on laser safety glasses.
- (2) Put in the key and turn it to the Stand-by position.

- (3) Push the Start Switch.
 - The warm-up procedure will run for 20 seconds.
 - * The warm-up countdown number will appear in the operation panel.
 - After warm-up is completed, the LCD panel will show the Laser Setting panel and the equipment will be in Stand-by mode.
 - * **If the water temperature is less than +15°C (+59°F), the “D” interlock lamp may light up. 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) Press the “Confirm” switch.

- (5) The main panel will appear.
The settings for the Initial Memory will appear.

Initial Settings

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

These settings can be changed in the same way as all the others. Even the name “Initial” can be changed if you like.

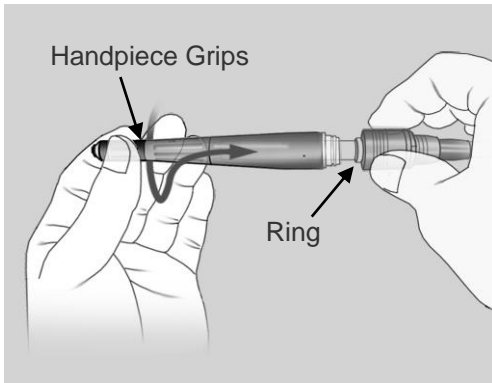
 **WARNING**

- *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 the AdvErL EVO. The Laser safety glasses has an OD of 3.5 (or greater) at 2.94 μ m. 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 safety glasses, never look directly into the aperture where the laser comes out; you could be blinded by the laser. Both the main laser and the guide light are dangerous. The safety glasses provided only temporary 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 CO₂ laser, for example.*

(3) Handpiece and Contact Tip Attachment

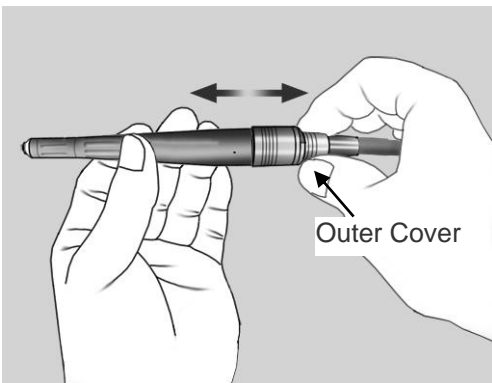


- (1) Hold the ring in one hand and then put the handpiece Grips on by turning it until it clicks into place.

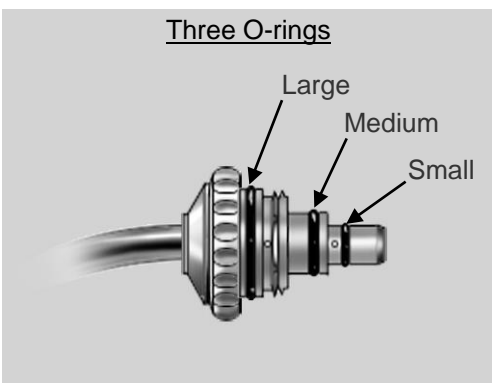
* To remove it, hold the ring and pull it off.

NOTE

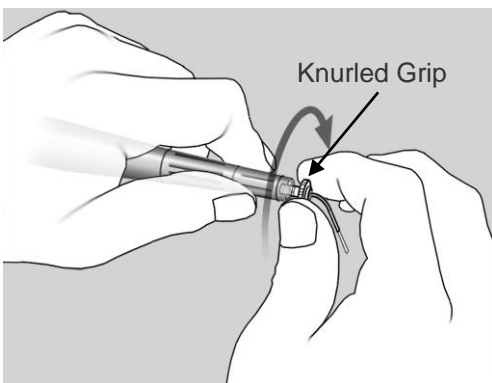
- ◆ *If you do not hold the tip end of the handpiece Grips and turn when you put it on, the o-ring will be damaged.*
- ◆ *Grease the end of the handpiece periodically to prevent damage to the o-ring.*
(See page 45.)



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



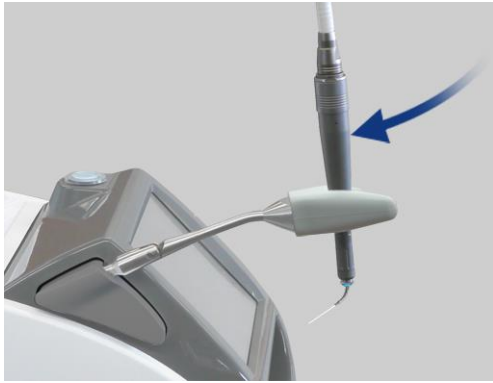
- (3) Make sure the contact tip is clean and free of blood and other contaminants. Make sure all three o-rings are in place.



- (4) Grip the knurled part of the contact tip and screw it onto the handpiece Grips.

NOTE

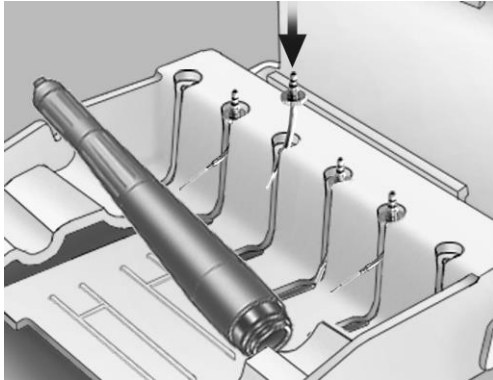
- ◆ *Only hold the knurled grip. Never grip the pipe; this could damage the tip.*
- ◆ *R200T and R300T tips are required to attach to the R Handpiece Grips.*



(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 tip, place the handpiece so that the tip faces the laser unit.*



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

NOTE

- ◆ *The actual contact tip could be damaged if it is sticking up when the top of the stand is closed.*

⚠ WARNING

- *The contact tip could come off if it is not screwed all the way on, and this could cause an injury if it happened during treatment.*

⚠ CAUTION

- *Contact tips wear out and must be replaced periodically. Inspect tips carefully before using them (see below). Worn tips could overheat and injure the patient.*
 - *Do not use chipped or worn tips.*
 - *Do not use tips if the output seems lower than normal.*
 - *If the guide light is dim or does not appear at all, the tip may be damaged.*
- *Tips are sharp and can cause injury; handle them with care.*
- *Use only contact tips specified for use with the AdvErL EVO laser system.*
- *When putting tips on and taking them off, turn the key off or put the unit in standby mode.*
- *Always hold the knurled part of the tip to screw it on or off; never grip the metal pipe, which could damage the tip..*
- *Never emit a laser beam without having the handpiece and a contact tip installed.*
- *Check the ends of 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 are turned off. Overheated tips could injure the patient.*

(4) Operation Procedure

1) Set Laser Irradiation Conditions



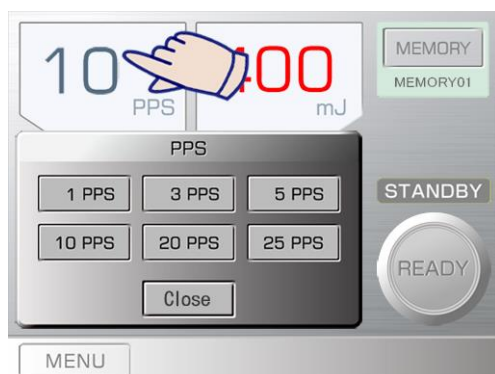
(1) Energy Level

- Press the “mJ” part of the panel; a window to make this setting will appear.
- Press a number to make the setting.
- You can also press the plus and minus signs.
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: 10pps — 30 mJ to 400 mJ
20pps — 30 mJ to 170 mJ
25pps — 30 mJ to 80 mJ

Press “Close” after making the setting.

PPS means pulses (laser shots) per second.

- 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.)

The total amount of energy delivered in one second can be found by multiplying the energy level setting by the setting for the pulse rate.



(3) Turn Aiming Beam On or Off

A red aiming beam is emitted from the handpiece.

- Press the Aiming key to turn the aiming beam on or off.
- The aiming beam is turned on when the unit starts up.
* The Aiming Key will be lit up.
- Turn the aiming beam off if you don't need it.
- The aiming beam is emitted when the unit is in Ready mode as well as during laser emission.



(4) Turning the Spray Water On and Off

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

- Press the Water Key to turn the spray water on and off.
- The spray is set for on when the unit is turned on, and the Water Key lights up to show this.
- Press the Water Key to turn the spray water off if it is not needed; the key light will go out.
 - * The light for the Air key will also go out.



(5) Turning the Tip Air On and Off

A mixture of air and water produces a spray that comes out of the end of the contact tip.

- Press the Air key to turn the tip air on and off. The Tip Air is set for on when the key is turned on, and the Air key lights up to show this.
- Press the Air key to turn the Tip Air off if it is not needed.
 - * 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 (<) buttons to adjust the flow of the water or air.
- Press the “Close” switch 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 a gas 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 gas embolism or subcutaneous emphysema.*
- *Never look directly in the aperture where the guide light comes out or let it strike anyone in the eye; this could result in blindness.*

 **CAUTION**

- *Irradiating hard tooth tissue without using spray could cause carbonization. When irradiating hard tissue, make sure the spray 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 tip.*
- *Before using the laser, check if the spray is on or off and what the volume adjustment is. Depress the foot switch to the first level only to check the spray.*
- *Make sure tip air flow is not so great 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 tip to make contact with body tissue for more than 1 minute.*

2) Laser Emission Procedure



- (1) Press the Ready Key.



- The Ready lamp will light up to show that the unit will not emit a laser beam.
- The aiming beam will be emitted when you press the Ready Key.

- (2) Before using the laser, make sure the aiming beam is clear and bright. (See page 21.)



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



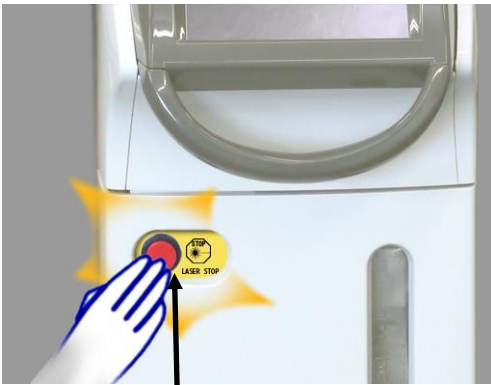
- (4) Depress the foot switch all the way down to emit the laser beam. The Ready lamp will change to Emission, and beeps will sound continuously.

This photo shows the panel when the foot switch is depressed all the way down and a laser beam is being emitted. If you depress the foot switch only part of the way down, the spray and the air will be emitted but the laser beam will not. Depress the foot switch all the way down to emit the laser beam.



- (5) Press the Ready Key when you finish. Check that the light for the Ready Key goes out and the unit goes to Standby mode.

3) Emergency Stop



Emergency Stop Switch

(1) Emergency Stop

- In an emergency, press the Emergency Stop Switch; this will immediately turn off the laser beam.

(2) Restore Operation

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

If the unit is not restored to safe and normal operation, or if it 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. 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 safety glasses, never look directly into the aperture where the laser comes out; you could be blinded by the laser. Both the main laser and the guide light are dangerous. The safety glasses provided only temporary protection.*
- *Take great care to avoid overheating in the vicinity of critical tissues such as nerves and blood vessels.*
- *A pulse speed 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.*
- *Keep combustible tubes, gases and other materials well away from the laser beam. Never irradiate combustible materials such as trachea tubes, non-woven cloth, and surgical gloves with a laser beam. 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 the laser irradiating the treatment area or get them in your eyes. Because the laser plume may contain infectious viral particles and 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 instrument 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.*

 **CAUTION**

- *The output depends somewhat on the diameter of the contact tip; a larger diameter will deliver more energy. Keep this in mind to make irradiation settings.*
- *This equipment must not be used for any purpose other than vaporization, coagulation, hemostasis and resection of biological tissues. Never direct the laser beam to anything except the treatment area.*
- *Handle contact tips with great care; they break easily. A piece of a broken tip could cut the patient and cause bleeding or might be left in the tissue being treated. Never bend or apply force to the tip. Thin tips 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 chance that the tip might get broken during treatment.*
- *Before emitting a laser beam, check the aim with the guide light or by touching the target with the tip.*
- *Never shine the laser beam 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 light.*
- *Always leave the unit in Stand-by mode when it is not required to actually emit a laser beam.*

4) Memory

Twenty combinations of settings can be memorized and retrieved.
Press the Memory Key on the Main Panel to show what has been memorized.

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 names of the group tabs can be changed for convenience.

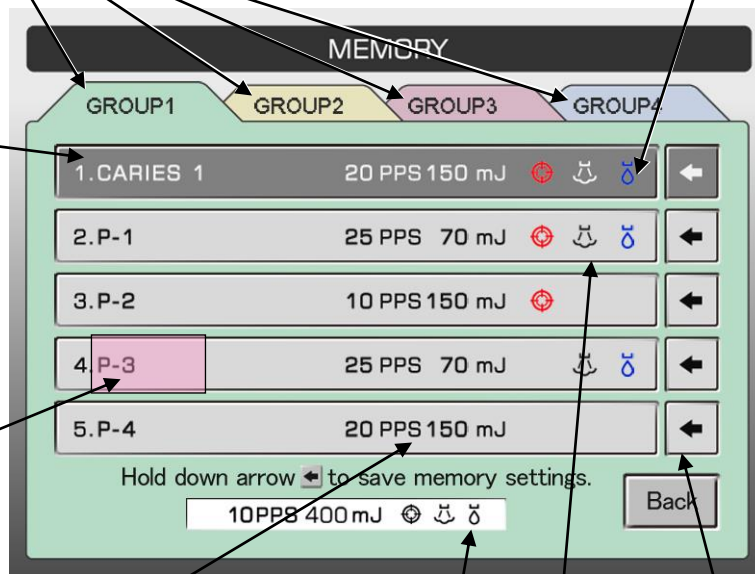
The color of the switch for the memory previously selected is different.

Memory Keys

There are 5 memory switches for each group.
Press one of the switches to use the setting combination for it.

Memory Name

You can name each memory for your convenience.



Settings

The settings for each memory are shown on the switch.

Current Setting

Memorize Keys

Press one of these switches to memorize the current settings.

Icons for Aiming, Water and Air

These icons appear if their associated function is turned on.

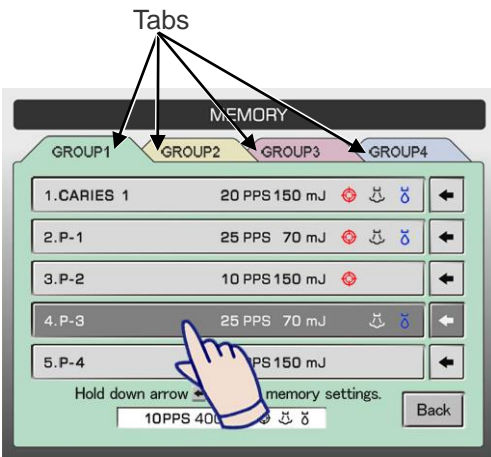
Retrieve a Memory

(1) Press the Memory key to go to the memory display.



(2) Press one of the group tabs.

(3) Press a memory number from 1 to 5.



Press the number of the memory

(4) This will select the settings for that memory.



Memory Name
(Up to 8 characters)

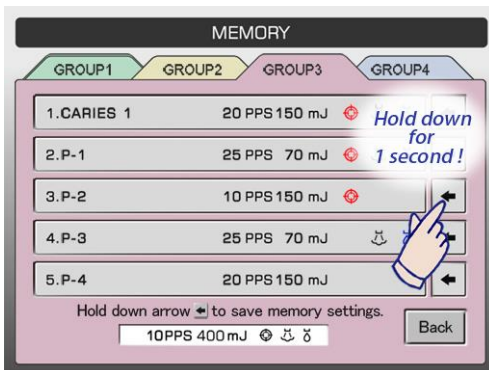
CAUTION

- *Always check settings before using the laser.*

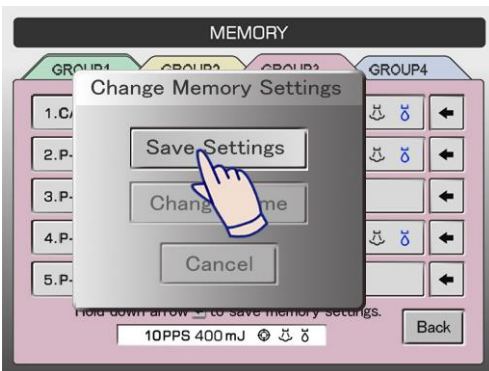
Memorize New Settings Combination



- (1) Make the desired settings on the main display.
- (2) Press the Memory key to go to the memory display.



- (3) Hold down the Memorize Key for one of the Memory keys for 1 second.



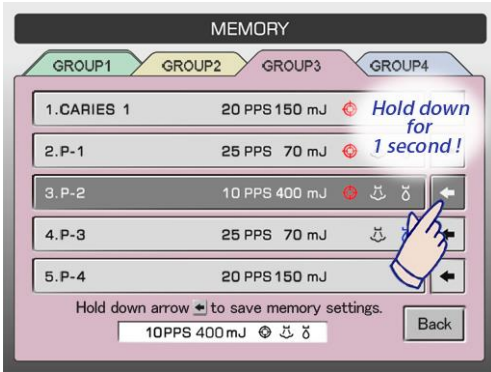
- (4) A pop-up menu will appear. Press Save Settings.



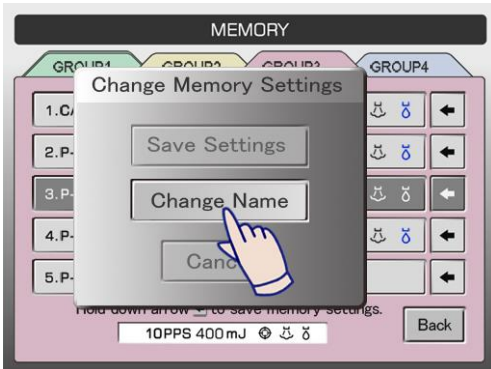
- (5) The new setting combination is now memorized.

Change Names of Memories

(1) Press the Memory Key to go to the memory display.



(2) Hold down the Memorize Key for one of the Memory Keys for 1 second.



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



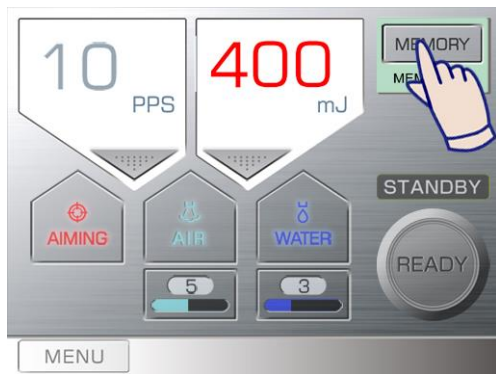
(4) A keyboard will appear. Enter the name. You may use up to 10 characters. Press Back Space to erase the last character. Press Delete All to erase the whole field.



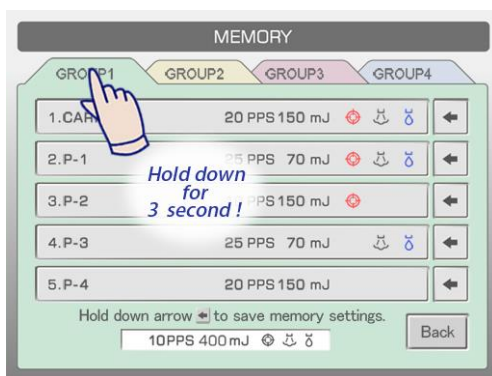
(5) Press Enter to complete the name change. Changing the name will not change any of the settings for that memory.

Change Name of Group Tab
Name the tabs for your convenience.

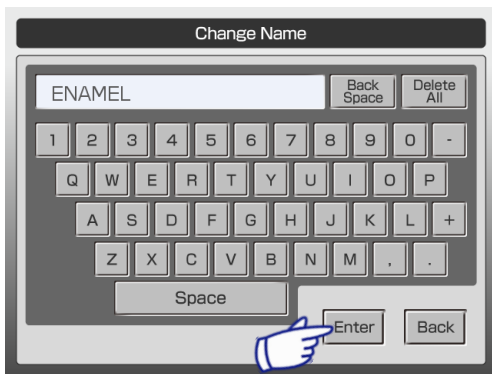
(1) Press the Memory Key to go to the memory display.



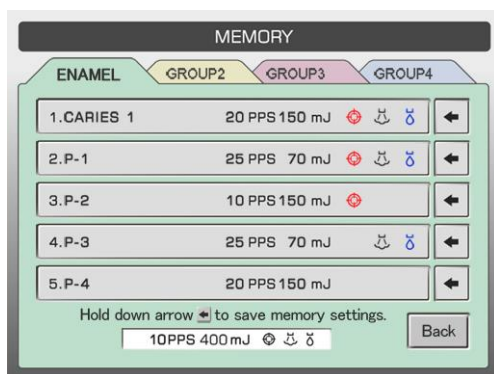
(2) Hold down the tab for one of the groups for 3 seconds.



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



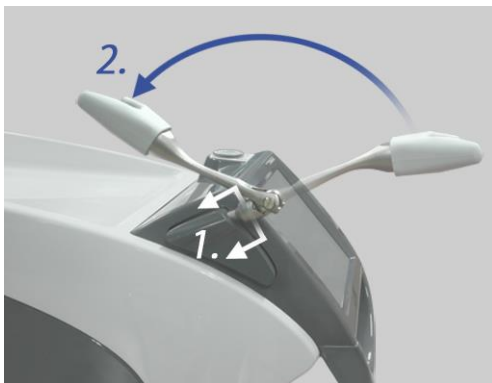
(4) Press Enter to complete the name change.



6) Moving the Unit



- (1) Hang up the foot switch.
- (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) Grip the handle to move the unit.



NOTE

- ◆ *Do not leave the handpiece in the hanger to push the hanger back; it could fall out.*
- ◆ *Remove the tip before moving the unit; it could get broken.*
- ◆ *Never push or pull on the hollow waveguide support or the transmission cable or the handpiece hanger.*



⚠ WARNING

Risk of overbalance;

- *Do not push side of the equipment to prevent any unwanted movement.*
- *In transport position lock the front casters and lock rear wheel by using the wheel locking device.*

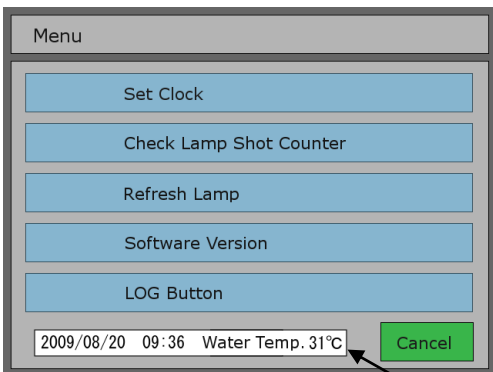
⚠ CAUTION

- *When passing over threshold, go from backside first.*
- *Push rear end first to go over bumps.*

7) Make Other Settings and Check Information



Hold down the Menu key.

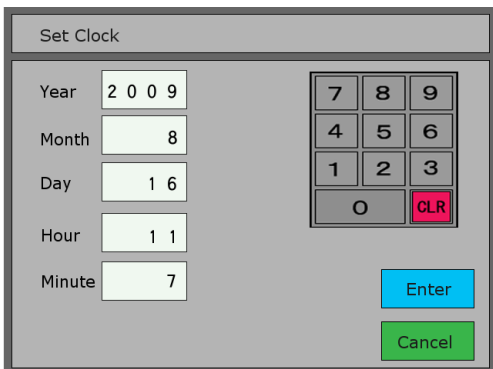


The Menu will appear.

Press the key for the category you wish to view.

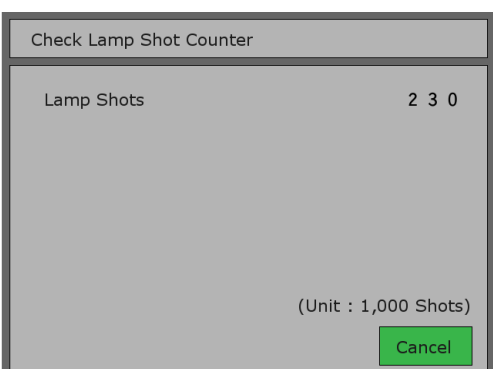
The clock and temperature of the cooling water appear here.
Water temperature range for operation:
15 – 45 °C (59 – 113 °F).

Set Clock



Select each item (year, month, day, hour and minute) and then use the key board to enter the number. Press Enter to finish.

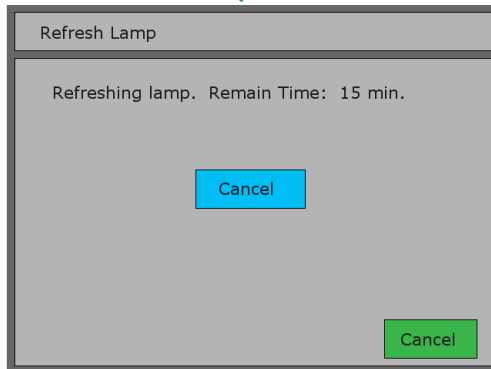
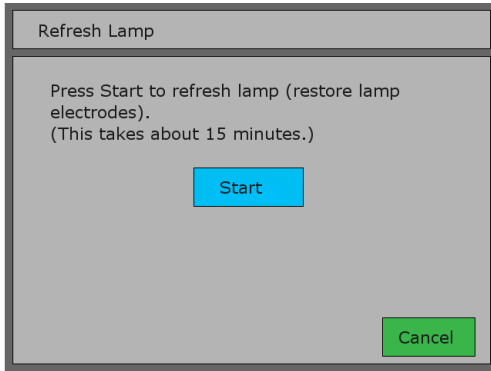
Check Lamp Shot Counter



Check the total number of shots for the flash lamp. See page 49.

Refresh Flash Lamp

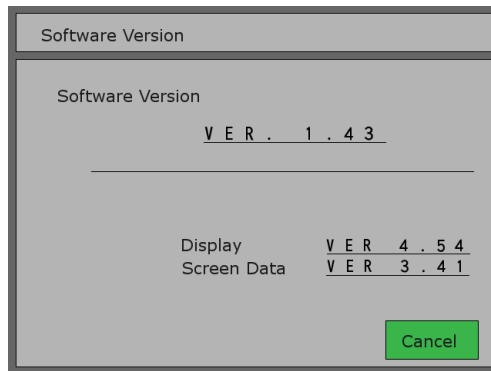
After considerable use, the flash lamp may no longer work so well and cause errors to occur. This procedure may rectify the problem. It takes about 15 minutes.



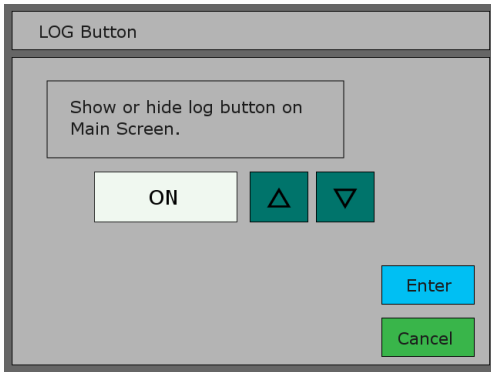
If the unit is use at low power for a long time, the terminals may get dirty and interfere with ignition. Operating the lamp at high power can clean the terminals. The procedure stops after 15 minutes or you can stop it anytime by pressing Cancel.

Check Software Version

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



Show or Hide Log key and Copy Log



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

Press "ON" switch to show the Log key.
Using the Up and Down, or switch to turn it on or off and then press Enter.

It is turned off at the time of factory shipping.



The Log key appears on the main display when it is turned on.

(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 Procedure

Press the Log switch. Go to the Menu if the Log switch is not currently displayed and turn it on.

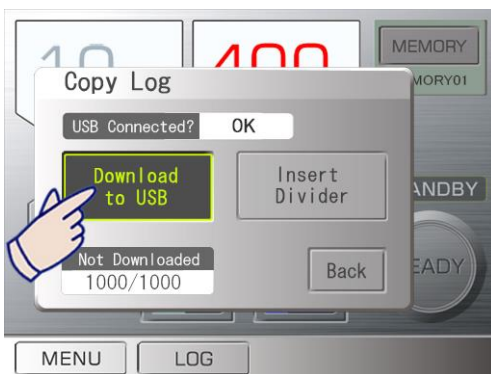


(3) Copy Data to USB Flash Drive

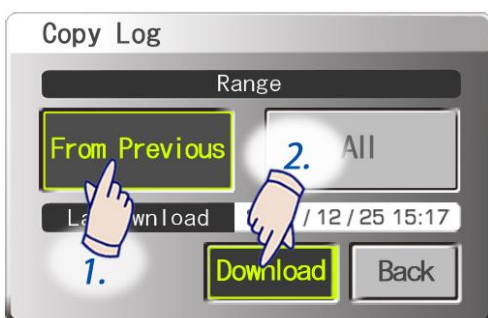
- Take off the handpiece hanger cover.
- Plug the USB flash drive in.



- 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.





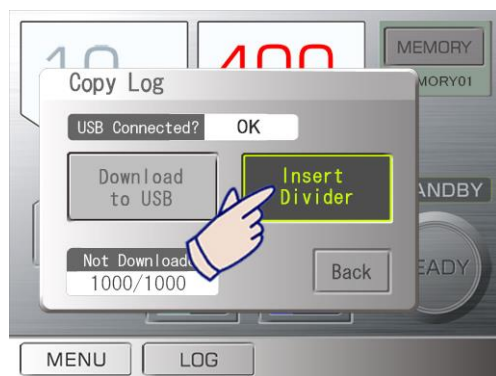
- Press the Download key; the data will then be copied onto the USB flash drive.



- 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” switch.
- 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.

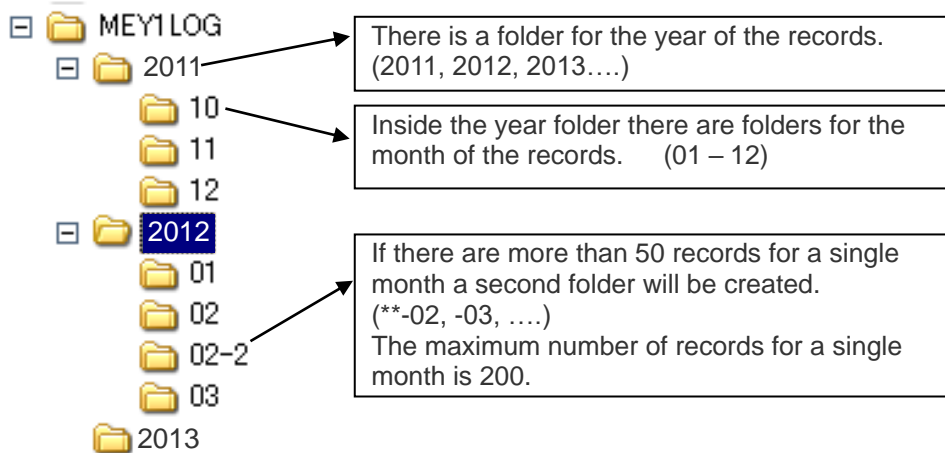
(3)-2 Number of Log Records

Out of a maximum of 1,000 records, the number of log records not yet copied is shown. If this number is more than 900, the Log key will start blinking.

(4) Data Files

The data files will be saved in the MEY1LOG folder on the USB flash drive. This folder is created automatically.

MEY1LOG Folder and its Contents



The record files inside the folders will be named like this: 0715-01.csv

- * The date for the file name is the date the file was copied.
- * The .csv extension represents text data files. These can be used with software applications such as 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. Sterilization, Replacement Parts, and Storage

⚠ WARNING

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

<All information about cleaning and sterilization (Autoclaving) >

	Cleaning and Sterilization	Detail
Tips	Immerse the tip fiber in tap water and emit the laser. Use the enzymatic detergent (CIDEZYME Johnson & Johnson company: for example) provided to clean off blood and other contaminants. ↓ Immerse the tip in an available chemical disinfectant <ul style="list-style-type: none"> • Chlorhexidine gluconate • Ethanol for disinfection (Ethanol 70 vol% to 80 vol%) ↓ Autoclaving (+135°C (+275°F) 10 to 15 min)	Refer to pp. 42-43
Handpiece grips	Wipe entire handpiece grips outer surface with a soft cloth and ethanol for disinfection (Ethanol 70 vol% to 80 vol%). ↓ Autoclaving (+135°C (+275°F) 10 to 15 min)	Refer to pp. 42-43
Hanger	Wipe the hanger with a soft cloth and ethanol for disinfection (Ethanol 70 vol% to 80 vol%). ↓ Autoclaving (+135°C (+275°F) 10 to 15 min)	Refer to pp. 42-43
Tip stand	Wipe the tip stand with a soft cloth and ethanol for disinfection (Ethanol 70 vol% to 80 vol%). ↓ Autoclaving (+135°C (+275°F) 10 to 15 min)	Refer to pp. 42-43

	Cleaning only	Detail
Main unit	Wipe the outside of the main unit with ethanol for disinfection (Ethanol 70 vol% to 80 vol%) or neutral detergent	Refer to p. 44

* We recommend autoclaving time longer than 10 minutes.

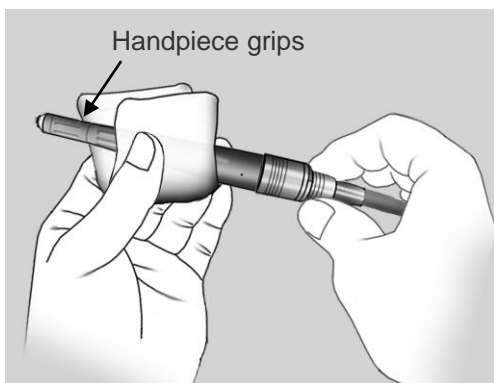
(1) Handpiece grips, Hanger, Tips and Tip stand Cleaning and Sterilization

1) Cleaning (Always perform this procedure prior to sterilization)

The cleaning process is intended to remove blood, protein and other potential contaminants from tips, handpiece grips and hanger. This will not sterilize them. Contamination control should be performed by trained personnel, while wearing protective gear (including masks gloves and shields).

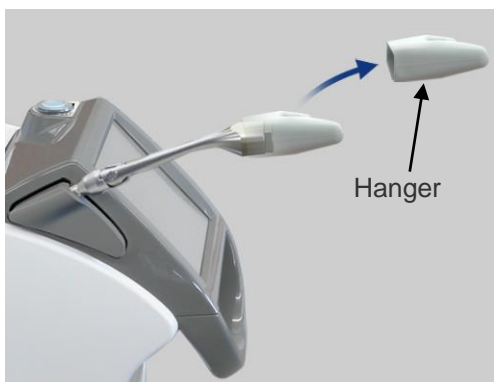
<Tip>

- (1) After use the tip, immerse the fiber part of the tip in tap water and emit the laser for 3 to 5 seconds. **Use the enzymatic detergent (CIDEZYME Johnson & Johnson company: for example) provided to clean off blood and other contaminants.**
- (2) Immerse the tip in an available chemical disinfectant for recommended time by the disinfectant's manufacturer's directions.
Use one of the disinfectants listed below at the concentration specified for medical instruments for cleaning solution.
 - Chlorhexidine Gluconate (Hibiten, for example)
 - Ethanol for disinfection (Ethanol 70 vol% to 80 vol%)
 - **Do not use ultra sonic cleaning methods; this could break the tip or cause its connector to fall off.**
 - **Contact tips will wear out and must be replaced periodically. Replace damaged tips and those that cannot be adequately cleaned.**
- (3) Wash tips thoroughly with tap water after using the cleaning solution.
- (4) Wipe the contact tip with cotton. Take care not to pull out the hollow waveguide.



<Handpiece grips>

Wipe entire handpiece grips outer surface with a soft cloth dampened with ethanol for disinfection (Ethanol 70 vol% to 80 vol%).



<Hanger>

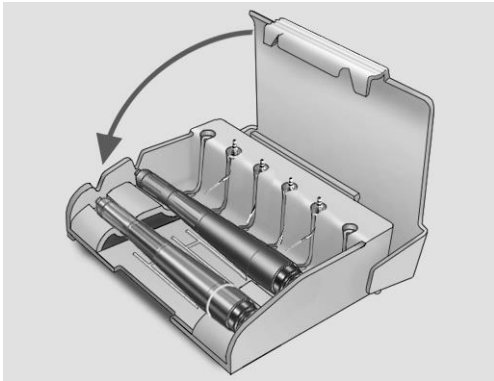
- (1) Take the hanger off its arm.
- (2) Wipe entire hanger outer surface with a soft cloth dampened with ethanol for disinfection (Ethanol 70 vol% to 80vol%).

<Tip stand>

Wipe entire tip stand outer surface with a soft cloth dampened with ethanol for disinfection (Ethanol 70 vol% to 80 vol%).

2) Autoclaving (sterilization) (Always perform this procedure after cleaning and before use)

The autoclaving process is intended to destroy infectious microorganisms and pathogens.



- (1) Put the handpiece grips, hanger and tips in sterilization pouches or the tip stand for autoclaving.

NOTE

- ◆ *The contact tip could be damaged if it is sticking up when the top of the stand is closed.*

- (2) Place them inside the autoclave chamber.

NOTE

- ◆ *Tips are easily broken. Take care that 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.*

- (3) Set autoclave cycle to the following parameters:

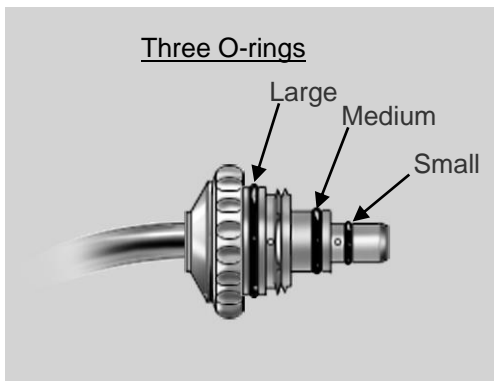
Temperature: +135°C (+275°F)

Time: 10 to 15 minutes

Dry Time: 0 min (dry naturally)

NOTE

- ◆ *Do not use any washer disinfectors as well as Class B Autoclave equipments.*
- ◆ *Do not use the drying stage if the autoclave has one. The temperature might be too high.*



- (4) At the time of completion of the autoclave, let them cool.

NOTE

- ◆ *Make sure all 3 o-rings of 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) Cleaning the Main Unit

Prevent contagion and contamination by cleaning the unit regularly.

Wipe the outside of the main unit with ethanol for disinfection (Ethanol 70 vol% to 80 vol%) or a neutral detergent.

Do not use ozone or ultra violet light to disinfect the treatment area. This could damage plastic, rubber or other materials.

- Use only ethanol for disinfection (Ethanol 70 vol% to 80 vol%) or a neutral detergent. Alkaline and acidic cleaners, liquid cresol soap, and other chemicals may damage or discolor the surface. Do not use solutions that contain cresols, triclosans, hypochlorite, aldehydes, or quaternized ammonium salts. (Check the ingredients for disinfectants.)
- Immediately wipe off any chemicals that are spilled on the unit with ethanol for disinfection (Ethanol 70 vol% to 80 vol%).
- Do not press down too hard to wipe the surface; this could cause peeling.

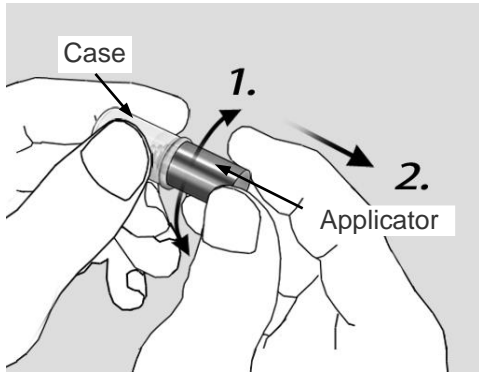
 CAUTION
<ul style="list-style-type: none">• <i>Prevent contagion and contamination by cleaning the unit regularly.</i>

(3) Maintenance

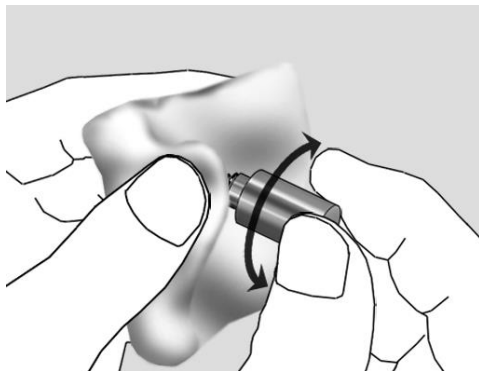
For optimum performance follow the maintenance procedures described below.

1) Grease Handpiece Grips

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

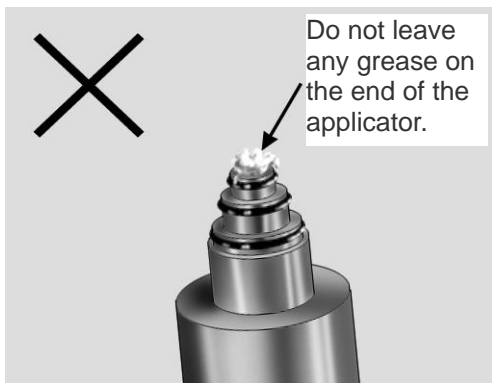


- (1) Rotate the applicator to get some grease on it and then pull it out of its case.



- (2) Use a piece of gauze to wipe off excess grease.

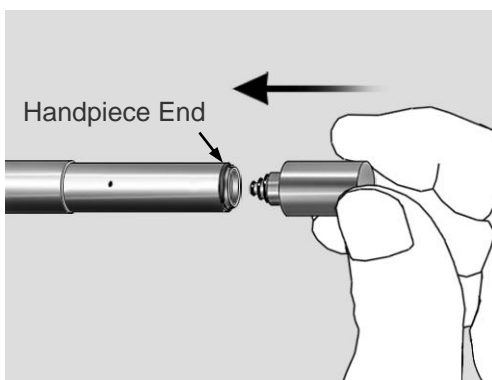
* Do not wipe off too much grease; leave enough to lubricate the handpiece grips.



NOTE

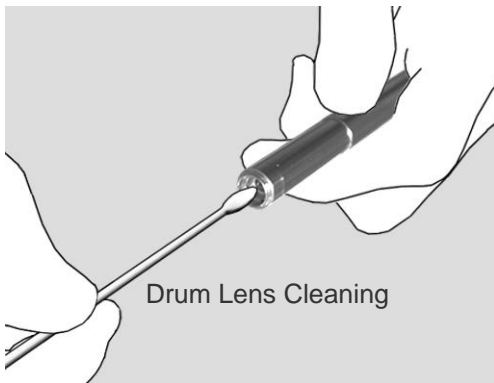
- ♦ *Carefully remove all the grease on the end of the applicator; otherwise it might get on the drum lens inside the handpiece grips.*

(If any grease accidentally gets on the drum lens, wipe it off with a piece of cotton dampened with ethanol for disinfection (Ethanol 70 vol% to 80 vol%))



- (3) Insert the 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.

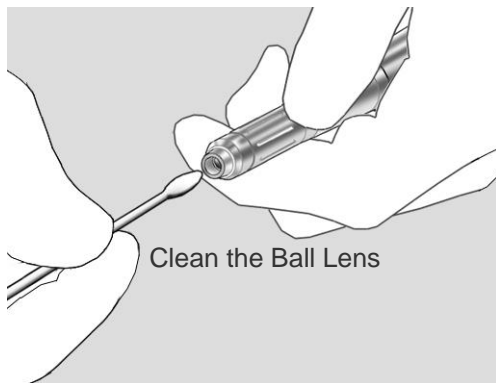
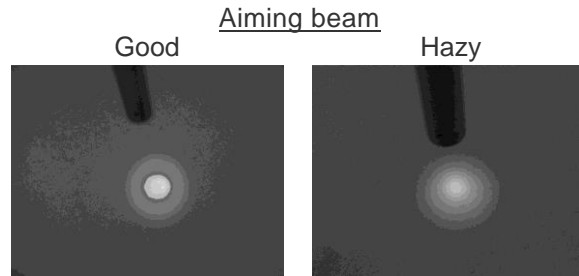
2) Lens Cleaning



<< 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 cleaner with ethanol for disinfection (Ethanol 70 vol% to 80 vol%) and lightly wipe the lens with it.



<< Ball Lens >>

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

Dampen the end of the cleaner with ethanol for disinfection (Ethanol 70 vol% to 80 vol%) and lightly wipe the lens with it.

NOTE

- ◆ *Use only the special tool 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 (Distilled Water for Spray) Replacement



Before use, check the level of the spray water bottle. If air gets in the lines 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 cover.*

⚠ CAUTION

- *Use only distilled water. Do not use tap water or saline solution.*
- *Do not pinch your fingers when you close the front cover.*

(4) Storage

Notes on storage

- (1) After use turn off the key and the circuit protector.
- (2) Take out the key and give it to the individual responsible for the unit.
- (3) Lock the casters.
- (4) Take the contact tip off the handpiece after use and put it in its case to keep it clean.
- (5) Unit must be level and not subject to vibrations or bumping.



If the unit is left on a slanted surface, it could start moving. Block one of the rear casters with the wheel locking device provided.

- (6) Store the unit where it will not get wet.
- (7) If the unit 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 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 the unit.*
- ◆ *Even if the unit 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 back up battery once every six months. Leave the key switch off and turn on the main and start switches. Leave the unit like this for 8 hours. (Never turn the key switch to the Standby position when there is no cooling water inside. This will damage the pump.)*

About Tip Cases



- Tip cases are not used after the tip has been taken out. Throw them away after taking the tips out. Follow normal procedures for disposing of 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.



(5) 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 pulses; after this, errors may occur. After 20,000,000 pulses, 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 pulses 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 unit in any way other than specified in the user manual.*

⚠ CAUTION

- *Do not apply excessive force or stress to the hollow waveguide. Never bend in into a curve with a radius of less than 6 cm.*
- *Do not put the laser unit on a surface that is not level; it could tip over. Make sure the brakes on the casters are locked.*
- *Never tip the laser unit more than 10° when moving it; it could tip over.*
- *Do not fail to connect the ground lead.*
- *Use only at the specified voltage. The wrong voltage could damage the unit. It could also cause the unit to start smoking and catch on fire.*
- *Do not pinch your fingers or catch your clothing in the casters when moving the unit.*

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 Amps to 240 V 7 Amps 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

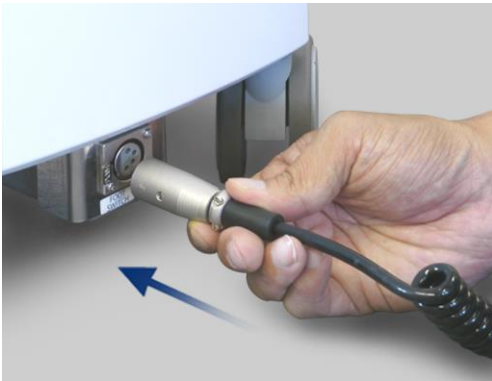
- ◆ *Keep the unit where the cooling water will never freeze.*

1) Connect Water Tube

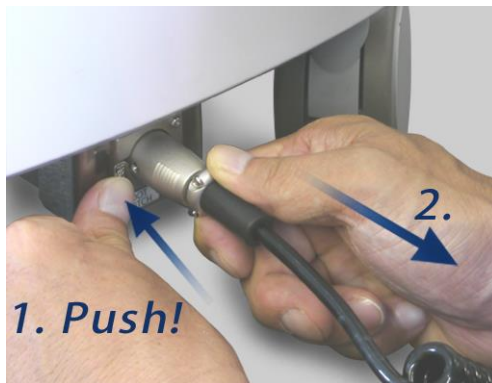


If the tube is not connected, plug it in until it clicks into place.

2) Foot Switch



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

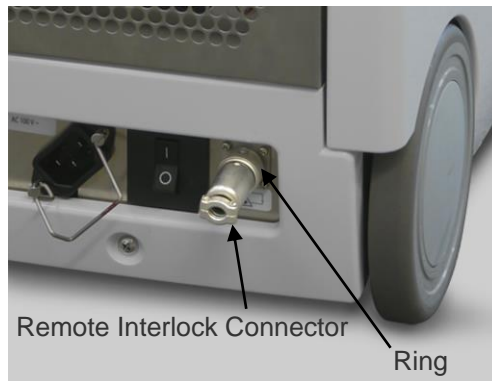


* To unplug it, push the lever in to unlock it and then pull it out.

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 the unit to avoid getting the cable caught in the casters.*

3) Remote Interlock



- The remote interlock connector is on the back near the connector for the power cord.
- It can be used in various ways to enhance safety and avoid risk.
 - * Use it as an emergency shut down device.
 - * Connect it to a door.
 - * Any other interlock function.

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

6. Maintenance, Inspection and Calibration

WARNING

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

CAUTION

- *Check laser output annually.*
- *A laser beam could be emitted if the top is removed and the safety interlocks are disabled. Never look into the aperture where the laser comes out or touch it.*

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 $\pm 10\%$
- 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

- Cooling water and Deionization Filter Cartridge
Replace all the cooling water and deionization filter cartridge.
- Flash Lamp
Check flash lamp usage. Replace after 10 million shots.(recommend)

4) Other Parts

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

5) Calibration of Laser Output

- Laser Output Level
Output level is $\pm 20\%$ 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.
- * Contact your local dealer or J. MORITA OFFICE for repairs.
- * High voltage circuits are inside the unit; do not try to perform servicing or adjustments yourself.

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.

(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 2.94um laser.

It was selected because of the wavelength matching with vibrational absorption of water molecules in the tissue.

Figure 1 shows that absorption coefficient of water.

Er:YAG laser wavelength (2.94um) is near the peak of absorption coefficient of water.

When laser are absorbed by tissues, it excite the movement of tissue molecules and causes tissue coagulation and vaporization, in both hard and soft oral tissues.

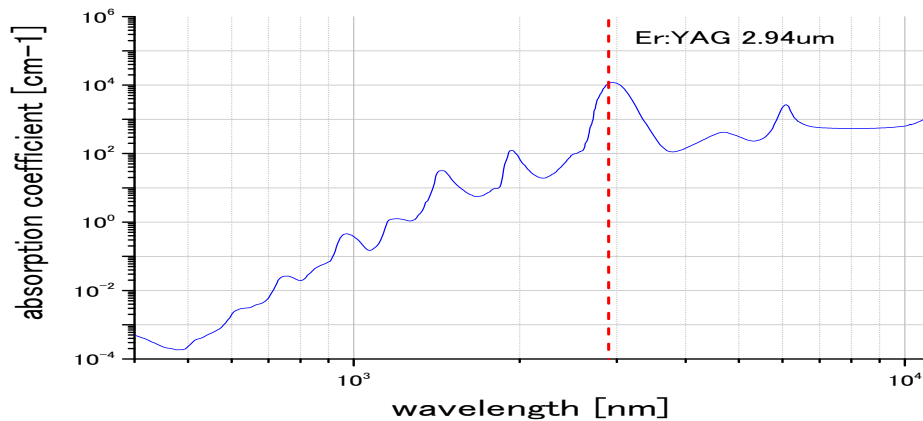


Figure 1 Absorption coefficient of water.

[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 laser tip, such as diameter and distance from the tissues, are all important for the laser ablation procedure.

For more detail, see later section.

■Reference

- | | |
|---|--------------------|
| 1) Tissue Ablation: Devices and Procedures | John. G XVeberster |
| 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 instrument 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 a gas 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 gas embolism or subcutaneous emphysema.

Combustion Danger due to Elevated Level of Oxygen

Do not use this instrument 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. 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 safety glasses, never look directly into the aperture where the laser comes out; you could be blinded by the laser. Both the main laser and the guide light are dangerous. The safety glasses provided only temporary 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:

Hard Tissue

Cavity preparation

Soft Tissue

Gingival application

(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 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 170mJ.

At 25 Hz, the maximum energy is 80mJ.

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 tip end spreads out, as detailed at **6.6) Type of Tips**.

Therefore, the best cutting efficiency is achieved when the tip is very close to the target.

In order to get the best cutting efficiency and longest tip lifetimes, be separately used from the hard tissue approximately 1/2mm.

Another, diameter of tip is important. Treatment by small diameter tips will be more effective on ablation than lager diameter tip, but irradiated area is smaller















 **WARNING**








- *The contact tip could come off if it is not screwed all the way on, and this could cause an injury if it happened during treatment.*

 **CAUTION**

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

6.6) Type of 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	
	R200T		TAPER	200	Hard Tissue	
	R300T		TAPER	300	Hard Tissue	
	R600T		TAPER	600	Perio	
CS Series 	CS600F		FLAT	600	Hard Tissue	

*1 These tips require R Handpiece Grips.

8. Troubleshooting

Explanation of Error and Caution Messages

Error and caution messages appear in the touch panel display. Follow the instructions which appear.

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.
- Updating the V-J table (calibrating output power)
- Cleaning the internal filter
- Frequent or repeated errors

A message appears in the operation panel when the following errors occur.

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.

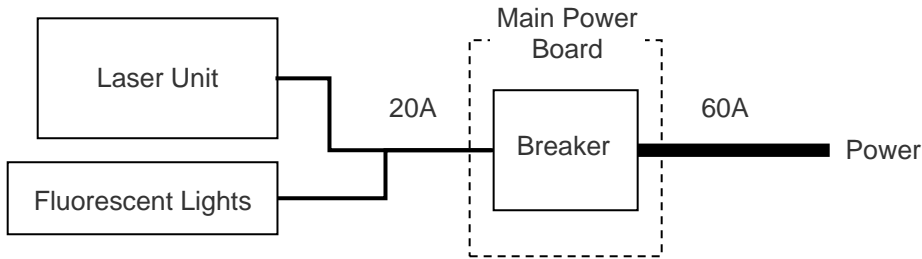
Problem	Cause	Response
Does not turn on.	Circuit Protector may be opened	Check the Circuit breaker, on the back of the unit. It may be off.
Low laser output or Aiming beam is not emitted or Aiming beam is dim or hazy	Water leaks inside the handpiece.	Water may seep inside the handpiece if the o-rings on the tip or the handpiece are worn out. This can interfere with the output of the laser or its aiming beam or both. Try using a different handpiece or a new tip. Apply a little grease to the o-rings occasionally to keep them from wearing out.
	Tip may be worn out.	Wear or damage (chipping etc.) will lower the transparency of the tip. If the tip is worn down completely inside the metal sleeve, it will not transmit the laser effectively and the laser output will drop. Replace the tip.
	Poor assembly of hollow waveguide	Take off the handpiece grips. Check the drum lens. Make sure the hollow waveguide is lined up with the hollow waveguide support. Loosen the ring for the hollow waveguide and rotate the hollow waveguide until the Aiming beam shines properly. Then retighten the ring.
	Lens of Handpiece or R handpiece grips is dirty.	Clean the drum lens for the handpiece and the ball lens for R handpiece grips with a cotton swab occasionally. A dirty lens will interfere with the laser output power and spoil its focus. Replace the lens if it is extremely dirty, scratched or otherwise damaged.
	Hollow waveguide is broken	Contact your local dealer or J. MORITA OFFICE.
Spray is not emitted from tip.	Spray water bottle is empty.	Replace the spray water bottle.
	No spray after replacing the spray water bottle.	After the spray water bottle is replaced or after the unit has not been used for a long time, there may be some air in the water line. Put the unit in Ready mode and depress the foot switch to its first level to run the water pump until spray starts coming out.
	Tip is plugged up	The tip may be worn out or plugged up. Or the water line in the tip may be plugged. Replace the tip and see if spray comes out normally.
	Water connection for the hollow waveguide may not be properly inserted.	Reconnect the hollow waveguide. Plug it in until there is an audible click.

Problem	Cause	Response
No air emitted from tip	Air may be leaking inside the handpiece	Water may seep inside the handpiece if the o-rings on the tip or the handpiece are worn out. This can interfere with the output of the laser or its guide light or both. Try using a different handpiece or a new tip. Apply a little grease to the o-rings occasionally to keep them from wearing out.
Water collects inside the handpiece	Water may be leaking inside the handpiece.	Water may seep inside the handpiece if the o-rings on the tip or the handpiece are worn out or if the tip is worn out. Try using a different handpiece or a new tip. Apply a little grease to the o-rings occasionally to keep them from wearing out.
Water does not stop when foot switch is released or water drips from the tip.	There is air in the water line	Put the unit in Ready mode and depress the foot switch to the first level for about 30 seconds to clear the water line of air.
Log switch does not appear on operation panel	The switch is set for Hidden.	This is the factory settings. Go to the Menu to change the setting to Show.
Log switch 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 switch starts blinking. Copy the log onto a USB flash drive.
Cooling fan is often too noisy.	Poor heat dissipation	Leave plenty of space behind the unit so that the cooling fan is effective
	Poor heat dissipation due to a clogged filter for the cooling radiator.	The laser emitter will not be properly cooled if the filter for the radiator behind that fan is clogged with dust. This will result in the water heating up and the cooling fan being activated frequently. For proper cleaning of the inside of the unit, contact your local dealer or J. MORITA OFFICE.
The cooling water inside the tank is cloudy.	Water quality has been degraded.	If the cooling water is cloudy or otherwise degraded, replace the cooling water without turning the unit on. Otherwise, the laser emitter 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 water from degrading, especially when the unit is not being used frequently, turn the power on and allow the water to circulate through the filter and the deionization filter cartridge for 15 minutes at least once a month.
Touch panel does not respond while log is being copied onto a USB flash drive.	Something is wrong with the USB flash drive.	Take the USB flash drive.

Problem	Cause	Response
Fluorescent lights in the room flicker when the laser beam is emitted.	The main power source may not be good enough.	<ul style="list-style-type: none"> • Plug the unit into another receptacle. • Plug the fluorescent light into another receptacle. • Use separate circuits for the laser unit and the lights. • Replace the lights with inverter type fluorescent lights.

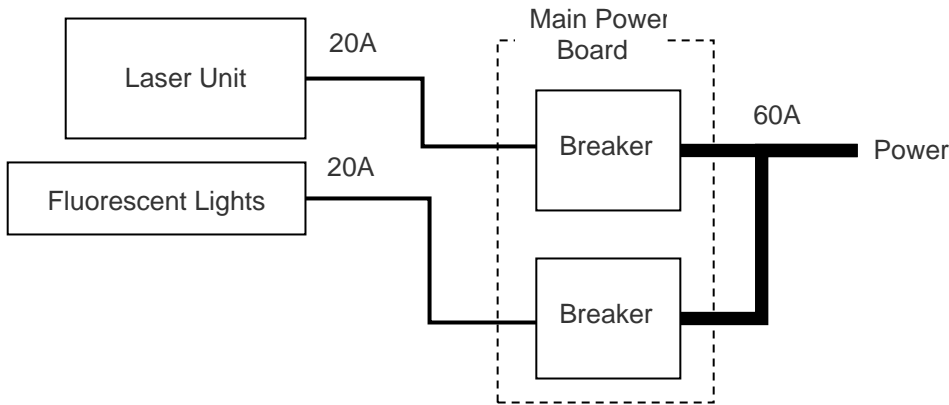
Example of circuit that can cause fluorescent lights to flicker.

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 the laser unit and the lights.



9. Technical Description

Name	AdvErL EVO
Model	MEY-1-A
Type	EX-2
Rating	AC 100 V to 240 V \pm 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 μ m
Beam Spread Angle	\geq 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 \times (Depth) 469 mm \times (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	10% to 85% (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	
Temperature	-10°C to +70°C (+14°F to +158°F)
Humidity	10% to 85% (without condensation)
Atmospheric Pressure	70 kPa to 106 kPa

* This instrument conforms to EMC standard IEC60601-1-2:2014.
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 equipment 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 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.
Radiated disturbance CISPR 11	Group 1 Class B	
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 equipment 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	<u>AC/DC power</u> ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth <u>Signal input/output</u> ±2 kV line(s) to earth	<u>AC/DC power</u> ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth <u>Signal input/output</u> —*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	<u>dips</u> 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) <u>short interruptions</u> 0% U_T : 250/300 cycles 250 (50 Hz)/300 (60 Hz)	<u>dips</u> 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) <u>short interruptions</u> 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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V ISM^(c) frequency band: 6 V 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.7 GHz</p> <p>27 V/m 385 MHz</p> <p>28 V/m 450 MHz</p> <p>9 V/m 710, 745, 780 MHz</p> <p>28 V/m 810, 870, 930, MHz</p> <p>28 V/m 1720, 1845, 1970 MHz</p> <p>28 V/m 2450 MHz</p> <p>9 V/m 5240, 5500, 5785 MHz</p>	<p>3 V ISM^(c) frequency band: 6 V 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.7 GHz</p> <p>27 V/m 385 MHz</p> <p>28 V/m 450 MHz</p> <p>9 V/m 710, 745, 780 MHz</p> <p>28 V/m 810, 870, 930, MHz</p> <p>28 V/m 1720, 1845, 1970 MHz</p> <p>28 V/m 2450 MHz</p> <p>9 V/m 5240, 5500, 5785 MHz</p>	<p>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.</p> <p>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</p> <p>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).</p> <p>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).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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

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

^(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which 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 or 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 $\pm 20\%$ / -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

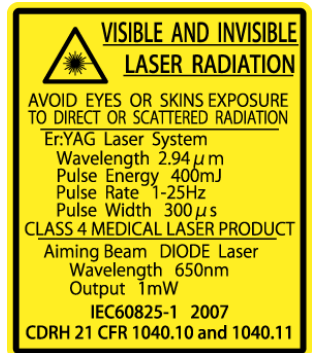
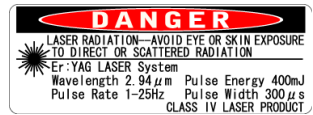
If the essential performance is lost or degraded due to electromagnetic disturbance, unexpected operation mode change or error will be occurred.

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

Memo

Memo



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