WON-COSJET ATR

User Manual

WT-UM-10, Revision 2.1

Copyright

Knowledge of this User Manual is necessary for system operation. You are therefore requested to familiarize yourself with its contents and follow all notes or references regarding the safe handling of the system.

The specifications are subject to change; the manual is not covered by an update service.

EC REP

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CE 0476

Devices compliant with European Communities Directive 93/42/EEC.
Medical Device Directive.

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✶ SAFETY NOTES

⚠ CAUTION

Lift the device up using handles of rear and front part of the device to pass over 20mm threshold. Check dangerous obstructions (pen, medical instrument and etc) it can damage to device on the floor of operating room.

⚠ CAUTION

Before starting up the laser system for any reason, the operator must ensure that all personnel in the area are familiar with the safety concerns outlined in Chapter 2, and that they are equipped with the appropriate protective goggles.

⚠ CAUTION

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

⚠ CAUTION

Laser plume may contain viable tissue particulate

⚠ CAUTION

Power supplier should be used the independent 220~230V, 50/60Hz, and it should be a stable one by ground connection.

⚠ CAUTION

Do not use or keep the device in the place which has much dust and moisture, in the place reflected by direct rays, or in the place at under 10 °C to 40 °C.

⚠ CAUTION

Do not use to the patient who is on treatment or has allergy.

Do not touch the device and its connections because high voltage is used for the device. It can cause an electric shock in this case.

Laser should not be exposure directly to the eyes and skin because the laser emits the visible and invisible ray. Wear the protective glasses or goggles before operating the device.

All people who in laser operating area should wear Protective goggles which are certificated and the place should be condemned warning mark at entrance of operating room.

Laser can be generated onto unexpected place by reflecting and scattering, so do not use mirror or lustrous metal together with laser which can reflect and scatter the laser beam.

To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.

Power plug is used as the isolation means electrically from the power source on all poles simultaneously. Do not place the equipment to the difficult position for disconnection.

No modification of this equipment is allowed.

NOTE

In the context of this Standard "light" radiation is understood to cover optical radiation as specified in IEC 60825-1:2007.

NOTE

The beam stop according to 4.7 of IEC 60825-1:2007 is replaced by the requirement for a STAND-BY/READY device.

A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment". The high temperatures produced in NORMAL USE of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

1 INTRODUCTION

1.1 Intended Use

The WON-COSJET TR laser system presents for the non-invasive Incision, Excision, Ablation and Vaporization of Soft Tissue for General Surgical Procedures for Coagulation and Hemostasis.

WARNING: Basically, the WON-COSJET TR laser system must be operated by a physician with a qualification of dermatology and who has been trained on the use of the product.

1.1.1 Description

WON-COSJET TR is an effective treatment for dermal pigment lesion which can generate cancer factor.

1.1.2 Equipment application specification

1.1.2.1 Medical purpose

WON-COSJET TR laser system has extended laser penetration into both epidermis and dermis without any damage to skin cells

1.1.2.2 Patient population

- Age: newborn to geriatric
- Weight: Not relevant
- Health: Not relevant
- Nationality: Multiple
- Patient State: Patient is not operator: not relevant, unless patient is agitated.

1.1.2.3 Part of the body or type of tissue applied to or interacted with

1) Treatment site:

- Whole body exempt of eyelids.

2) Condition: intact skin, treated skin

1.1.2.4 Intended operator

1) Education:

- Dermatologist or physician trained who can use the laser medical device.

2) Knowledge:

- Read and understand English
- Understands laser and human body and skin as doctor

3) Language understanding:

- English

4) Experience:

- Dermatologist or surgeon trained by manufacturer.

5) Permissible impairments:

- impaired by 40% resulting in 60% of normal hearing at 500Hz to 2kHz
- One arm/hand system capable of guiding and holding.
- Mild reading vision impairment or vision corrected to log MAR 0.2(6/10 or 20/32)

1.1.2.5 Application for device operating

1) Environment

General:

- Intended for professional use
- Use at a clean room of hospital for treatment
- Use on the horizontal floor
- There shall be no hazard of eyes. (All of persons in an operational room have to put on the goggles for safety during laser radiation.)
- When it is functioning, it shall keep its precision.

Conditions of visibility:

- Ambient luminance range: 300~750lux
- Viewing distance: 20cm to 40cm
- Viewing angle: normal to the display ± 20°

2) Frequency of use:

- Once a week or two weeks for endpoint

3) Mobility:

- Two handles on the front and rear for moving device.

1.2 Applications for treatment

The WON-COSJET TR laser system is flash lamp pumped, Q-Switched Nd:YAG(Neodymium-doped Yttrium Aluminum Garnet) laser is near infrared (1064 nm) and visible (532 nm) pulsed laser output energy are used in these application.

This beam is directed to the treatment zone by means of an Articulated Arm and a specially designed zoom Handpiece. When the laser beam contacts human tissue, the energy in the beam is absorbed surrounding skin structures. The physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam.

1.2.1 Side effect

Skin lightening (depigmentation): Some dark skinned individuals can develop fading of the skin color. This complication is temporary and usually resolves within 10-14 weeks. However, there are times when the complication is permanent.

Skin darkening (hyperpigmentation): In fair skinned people, lasers can sometimes cause darkening of the skin. Over time this fades and recovers; but in some cases a bleaching agent has to be used to erase the dark color.

Infections: Sometimes an infection can occur at the site of the tattoo removal. The infection may be superficial and resolves but in some cases, deep skin infections can occur and result in a scar.

Skin Texture: After laser treatment, most individuals will have a rough skin texture. The skin will feel like it has been scraped. These changes are transient and usually resolve in 1-3 months. Thick skin usually resolves better than thin skin. The facial skin is more sensitive to texture changes than skin elsewhere on the body.

Allergic reactions: Rarely when the laser disrupts the ink particles some individuals may have an allergic type reaction. It is not known why the reaction occurs and to what ink. The skin usually becomes red, dry and it itchy. Application of topical corticosteroids will suffice.

Ink darkening: When the laser is applied on cosmetic tattoos, it can worsen or darken the color. This is most likely felt to be due to the heat of the laser reacting with the cosmetic chemicals. The changes can be permanent. So before a cosmetic tattoo is treated, a brief test is done to look at the response. Many an individual has had permanent tattooing of their eye liners.

Sun burn: After every laser procedure, a sunburn effect occurs. The skin appears red and fiery in some cases. This is a normal and transient- it does resolve within a few weeks. Besides keeping the area clean, there is no need to apply any ointments or creams, except the sunscreen

Miscellaneous: Many of the tattoo dyes are unregulated and their exact contents unknown. Despite this the, complications of laser are rare. A few individuals do develop thickening of the skin. This thickening known as granuloma is felt to be due to ink particles embedded in scavenging cells. The granuloma may be small bump on the skin. When lasers are used near the eye, hair loss and anatomical distortion of the eye lids have been known to occur

1.2.2 Contraindication

Pregnancy, bleeding disorders; immune deficits; heart, liver, and kidney insufficiency; allergies to local anesthetics; pacemaker and serious heart rhythm disorders; psychiTRic disorders; unstable motivations; large fat volumes; and obesity.

1.3 System Description

1.3.1 Laser System

The WON-COSJET TR laser system consists of an Nd:YAG Laser head, a power supply and a cooling system. The laser head contains two Nd:YAG laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed in the special adjustable holders composed the laser cavity.

To provide energy to the flash lamp, a high voltage power supply charges a storage capacitor. Then, a trigger pulse applied to the flash lamps causes the capacitor to discharge through the flash lamps. The resulting flash excites the Nd:YAG laser rod, causing the emission of a pulse of laser energy.

The electro-optic modulator with a polarizer (Q-switched module) introduced into the cavity creates the ultra-short irradiation pulses. The basic frequency of 1064 nm can be doubled by a KTP crystal, which can be inserted to a working area. The sealed top metal cover protects all optical components from dust and humidity and

blocks the visible and invisible scattering light from the laser head.

The system delivers laser energy at a wavelength of 1064 nm and 532nm. The output of the laser is delivered to the area of treatment through an articulated arm with a Handpiece. A trigger (Foot switch) controls the delivery of pulses. The user selects the desired energy density (fluence), and enables or disables the laser at the touched LCD panel.

1.3.2 Classifications

Under CDRH regulations in US FDA, the WON-COSJET TR is classified as a Class IV laser. Under the Medical Device Directive, the WON-COSJET TR is a Class IIb, non-invasive, active device according to Annex IX of Directive 93/42/EEC. Under IEC60825-1, the WON-COSJET TR laser level is classified as a Class 4 laser.

According to IEC60601-1: 2007, following classifications are applied:

1. Protection against electric shock: Class I ME equipment
2. Type of Applied Part: B
3. Protection against harmful ingress of water: IPXO (Main Equipment), IPX8 (Foot Switch)
4. Method of sterilization: Not Applicable
5. Suitability for use in an oxygen rich environment: Not Applicable
6. Mode of operation: Continuous

1.3.3 Beam Delivery System

The delivery system, the articulated arm functions as to deliver the Nd:YAG laser energy and the diode laser aiming beam to the skin surface. The output of built-in diode laser is a visible low power beam at a wavelength of 650 nm. Since the output laser beam is invisible the aiming beam allows the user to see the surgical area to which the laser beam will be delivered.

It consists of seven high reflection mirrors mounted at the articulated arm freely rotated in different directions. The Handpiece with the focusing lens is mounted at the end of the arm. It provides the adjustability of the beam spot size. The spot size of Handpiece is automatically detected by change the Handpiece dial. The articulated arm with Handpiece unit must always be perfectly aligned.

1.4 Specifications and Requirements

1.4.1 Technical Specifications

WON-COSJET TR Specifications

Laser Type	Q-Switched Nd:YAG Laser
Wavelength:	1064 nm, 532 nm
Laser medium:	Nd:YAG
Pulse energy	Free Mode 1800mJ 1064nm Mode 1000mJ 532nm Mode 500mJ
Tolerance of pulse energy:	±20%
Beam delivery:	Articulated ARM with Handpiece
Spot diameter:	Circle, 2mm to 10mm
Pulse frequency:	0Hz to 10Hz
Pilot laser:	Laser Diode, 650nm±5nm, 1mW
User interface:	Touch LCD type
Physical dimensions:	288 * 578 * 751mm (W x D x H)
Weight:	60kg
Cooling:	Water & Air cooling

1.4.2 Electrical Specifications

For WON-COSJET TR laser system shipped internationally, customers must supply a suitable plug and receptacle. The power receptacle must be within two meters of the intended laser system location, and must be earth-grounded. The safety ground wire of the power system (green or green with a yellow stripe) is an acceptable ground for the laser system, provided that it is terminated only to an earth ground stake or dedicated ground grid. Poor grounding could interrupt with the operation of the laser system.

⚠ WARNING

THE POWER PLUG MUST BE INSTALLED BY A QUALIFIED PERSON, IN ACCORDANCE WITH IEC REQUIREMENTS AND THE APPROPRIATE NATIONAL ELECTRICAL CODE.

The input power line should be free of transients (spikes, sags and/or surges). A dedicated branch circuit is recommended.

Operation of the WON-COSJET TR on a power line that is not consistently within the specification may damage the system and may void the warranty.

WON-COSJET TR Electrical Specifications

Line power requirements:	220~230VAC, 50/60Hz
Electric power consumption:	1.5kVA

Foot Switch specification

After the desired treatment parameters are selected and READY is activated by pushing ready button, the function of the foot switch, when pressed, allows the Nd:YAG laser to start, generating laser pulses with the selected properties (fluence/energy, repetition rate etc).

Water resistant:	Ordinary equipment	IPX 0
	Foot Switch	IPX 8

Continuous operation with intermittent loading

1.4.3 Environmental Requirements

Before installation of the WON-COSJET TR laser system, the intended site must be prepared as described in this section. The site must have sufficient space to accommodate the laser system, must provide the proper electrical power configuration and receptacles, and must meet the additional environmental specifications given in the following paragraphs.

Installation of the WON-COSJET TR laser system is performed by a service representative. Following installation, a Nurse Consultant instructs designated personnel on the basic operation and care of the laser. This instruction supplements the more detailed information presented in this manual. Such instruction is not a substitute for the in-depth clinical training required of a physician to become proficient in the use of the WON-COSJET TR laser system.

Sufficient floor space is required for the laser system. Approximately 10 cm of clearance is required between the rear panel of the laser system and the wall behind it, to allow room for the power cord and circulation of air from the cooling vents.

Ensure that the atmosphere is non-corrosive, with no salts or acids in suspension in the air.
Acids, corrosives, and volatile materials are likely to attack electrical wiring and the surfaces of optical components.

Keep air-borne dust particles to a minimum. Dust particles can cause permanent damage to optical surfaces. Metallic dust can be destructive to electrical equipment.

The WON-COSJET TR laser system is not suitable for use in the presence of a flammable mixture with air or with oxygen or nitrous oxide.

The WON-COSJET TR laser system has been tested and found to comply with the limits for medical devices in IEC60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The WON-COSJET TR laser system generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

If the WON-COSJET TR laser system does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving device.

- Increase the separation between the equipment.

- Consult the manufacturer or field service technician for help.

1.4.4 Indication, Safety and Reference Symbols

A. Indication Symbol

	USB port

B. Safety & Reference Symbol

	Manufacturer
REF	Model name or reference number
EC REP	Representative in Europe
SN	Serial Number
	Follow the disposal procedure in this manual
	Date of manufacturer
	Follow operating instructions
	Emergency Stop (Emergency Stop switch)
	Alternate Current
	Type B Applied Part
IPX8	Protected against the effects of continuous immersion in water
	Foot switch
	"ON" (power)
	"OFF" (power)
	Protective earth (ground)
	Dangerous voltage
	Caution
	Warning

	Pushing prohibited
	Sitting prohibited
⚠ **Refer to the chapter 7.1 and 7.2 for the more marking and symbols related to the laser.**	

2. SAFETY

2.1 General Safety Rules

WARNING

THE ELECTRICAL AND LASER RADIATION HAZARDS PRESENT DURING SERVICING OF THE WON-COSJET TR LASER SYSTEM CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECAUTIONS ARE NOT TAKEN. CONSEQUENTLY, THE WON-COSJET TR LASER SYSTEM IS TO BE SERVICED ONLY BY THOSE QUALIFIED TECHNICIANS WHO HAVE RECEIVED APPROPRIATE TRAINING, AND WHO ARE FAMILIAR WITH THE SAFETY CONSIDERATIONS DISCUSSED IN THIS SECTION.

The WON-COSJET TR laser system has been designed to comply with the requirements of the EC Directive on Medical Products (93/42/EEC). In accordance with this EC Directive, the WON-COSJET TR laser system qualifies as a class IIb device.

However, any laser system can cause injury if not properly installed, operated, moved or serviced. The potential hazards associated with the WON-COSJET TR laser system are:

- Ocular (vision) damage resulting from exposure to direct or reflected laser irradiation.

- Electrical shock from contact with electrical components inside the system.

- Physical injury incurred while moving the system.

In handling medical laser devices, observe the relevant national regulations on the prevention of accidents by laser radiation, as amended. To avoid these hazards, when installing, operating, moving or servicing the system, always observe the precautions discussed in this section. Our service technician will assist you in filling it in as part of the startup procedure.

2.2 Laser & Optical Hazards

For fundamental rules on the handling of laser devices, you are referred to the international standard IEC 60825-1:2007. It is complemented by national regulations providing general protection from dangerous laser radiation. Their purpose is to protect operating personnel and patients present in medical application.

⚠ WARNING

LASER BEAM ENERGY EMITTED BY THE WON-COSJET TR LASER SYSTEM LIES IN THE VISIBLE AND INVISIBLE (NEARINFRARED) REGION OF THE ELECTROMAGNETIC WAVES.
USE ONLY THE PROTECTIVE GOGGLES THAT IS KNOWN TO HAVE AN OPTICAL DENSITY OF 6.0 OR MORE AT 1064 NM AND OPTICAL DENSITY OF 7.0 OR MORE AT 532 NM, THE WAVELENGTH EMITTED BY THIS LASER SYSTEM. PROTECTIVE GOGGLES THAT IS DESIGNED FOR USE WITH OTHER LASER SYSTEMS MAY NOT PROVIDE ADEQUATE PROTECTION.

Lasers are classified in accordance with their potential for danger. The WON-COSJET TR laser system is a class 4 product.

The laser beam emitted by the WON-COSJET TR laser system is capable of causing loss of vision. Laser beam energy emitted by this system lies in the visible and invisible, near-infrared region of the electromagnetic waves.

Remember this and take precautions to avoid inadvertent exposure. The cornea and lens of the eye are transparent to the invisible 1064 nm wavelength emitted from this laser, and therefore will focus the beam directly onto the retina. Such direct impingement of the laser beam on the retina can result in temporary clouded vision, retinal lesions, long-term scotoma (vision absence in an isolated area), and long-term photophobia (sensitivity to light).

NOTE

REFER TO 10.8 OF IEC 60825-1.

The beam emitted from the Handpiece is expanding with a full-angle beam divergence. This means that the spot size enlarges as the distance from the Handpiece. There is a distance from the Handpiece, called the NOHD (Nominal Ocular Hazard Distance), at which the beam is so big that it is no longer dangerous to the unprotected eye.

Personal eye protection: Everyone present in the laser room during a treatment session must wear protective goggles. The protective goggles must perform to specifications defined in the technical data section 1.4.1.

To avoid these vision hazards, everyone within the NOHD where the laser system is operating, including during service procedures, must wear appropriate eye protection. Such protective goggles, available from WON Technology, provides adequate protection against reflected or scattered laser radiation, or inadvertent brief exposure to the laser beam. Protective goggles should be stored away from direct sunlight.

The protective goggles recommended for use with this laser system by all personnel is either goggles or spectacles (with side shields) that have an optical density of 6.0 or greater at 1064 nm and an optical density of 7.0 or greater at 532 nm.

During laser treatment procedures, the patient's eyes must be protected. The patient goggles provided by WON Technology is appropriate to most patients. Even when wearing protective goggles, looking directly into the path of the laser beam may cause permanent eye damage.

The laser beam emitted by the WON-COSJET TR laser system should never be directed at any part of the body other than the intended site of treatment or testing. Care should be taken to avoid unintended exposure of any part of the patient or other personnel to the laser beam.

Removal of any of the exterior panels of the laser system cabinet could allow access to hazardous levels of laser radiation. For this reason, these panels are designed not to be easily removable without a use of tool; they must not be removed except by authorized, trained service engineer.

Optical Safety Precautions;

- Identify the laser room clearly. Post appropriate warning signs in prominent locations at all entrances to the laser room.

- Cover all windows, portholes, etc. with opaque material to prevent unintended viewing or laser light escaping from the laser room.

- Restrict entry to the laser room when the WON-COSJET TR laser system is in operation. Limit access to the laser room only to those personnel both essential to the procedure and well trained in laser safety precautions.

- Check the safety before operating the laser that may cause a hazardous situation.

- Make sure that all laser room personnel are familiar with the laser system controls and know how to shut down the laser system instantly in an emergency.

- Appoint one person to be responsible for the laser system controls during the procedure.

- Laser can cause fatal harm to human, so authorized doctor only should use following safety instructions in this user manual.

- Avoid accidental exposure to the laser beam either directly, or by reflection, by ensuring that all personnel wear appropriate safety goggles whenever the laser system is on. Verify that the protective goggles used is known to protect against the wavelengths emitted by the WON-COSJET TR laser system.

- Never look directly into the laser beam coming from the laser system, or reflected from a surface, even when wearing protective goggles.

- Never allow the laser beam to be directed at anything other than the targeted area, the calibration port or a safe beam stop (used when servicing the system).

- Never permit reflective objects such as jewelry, watches, instruments or mirrors to

intercept the laser beam.

- Specified the parameter values just before the laser operation.

- Do not use the combustible anesthetic gas.

- Check the Standby or Ready state before using.

- Never leave the key in an unattended laser system.

2.3 Laser-Induced Risk of Fire

A surface hit by the laser beam will absorb laser energy causing its temperature to rise, regardless of whether the surface belongs to skin, hair, clothing or other flammable substances.

Operators should take the following precautionary measures, in order to prevent cases of laser-induced fire:

- Use non-flammable substances for anaesthesia, preparation for treatment, cleaning and disinfection of instruments.

- Refrain from the use of oxidizing gases such as nitrogen oxide (N2O) or oxygen. Proceed with particular care when using oxygen. Oxygen increases the intensity and the scope of fire.

- Keep only a minimum in flammable materials in the treatment room. Where a flammable material is required for a given therapy, this material should first be moistened.

- Keep clothing away from the zone of treatment as much as possible.

- Always keep a small fire extinguisher and water ready for use in the treatment room.

- Some materials like cotton may ignite at high temperatures prevailing during normal use if penetrated by oxygen.

- Let solvent constituents of adhesives and flammable solutions used for cleaning or disinfection evaporate before you apply the laser.

2.4 Electrical and Mechanical Hazards

The WON-COSJET TR laser system was designed to comply with IEC 60601-1-2 "Electromagnetic Compatibility Requirements and Tests." A portion of IEC 60601-1-2 deals with measurements of unwanted radio frequency emissions generated from a product. Both radiated emissions (radiated through the air) and conducted emissions (conducted into the AC mains) are measured.

The WON-COSJET TR laser system converts and amplifies the AC line voltage to produce extremely high voltages in the laser system. These voltages are very dangerous, and even lethal.

It is possible for high-voltage components to retain a charge after the power supply has been turned off, and even after the WON-COSJET TR laser system has been disconnected from the line voltage. Therefore, no part of the exterior housing should be removed, except by a trained and authorized technician.

To prevent the laser from moving, whole of the wheels must be locked. To lock the wheels, press the tab of the wheels down. To unlock, pull the extending tab up.

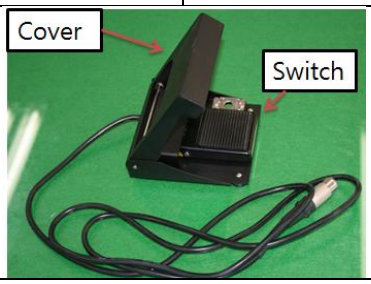
The WON-COSJET TR laser system weighs more than 60 kg and may cause injury if proper care is not used when it is moved. The system is well balanced and is designed to be moved, but it should always be moved carefully and slowly.

3. GETTING STARTED

3.1 Scope of Delivery

Check the box contents for all supplied accessories according to the packing list enclosed under the top cover each of box. Carefully inspect the device console and all other accessories for any possible damages.

This device is provided as below. And, it should be installed by technician qualified.

<table>
<tr><td rowspan="2">  </td><td>  </td><td>  </td></tr>
<tr><td>Articulated ARM
(WT-TR-ARM-001)</td><td>Handpiece
(WT-TR-ARM-001)</td></tr>
<tr><td>Main unit</td><td colspan="2"> 

Foot Switch(WTFS000)</td></tr>
</table>

	
Protection Goggles for doctor (YL717C NdYAG2)	Protection Goggles for patient (YL-800W SAFETY EYE GUARD)

3.2 Systems Features

① Laser Arm
It is the device to transmit the laser into the required place.

② Handpiece
It irradiates laser through the Articulated ARM.

③ LCD and Touch pad
LCD shows the present condition of device, and Touch Panel is a controlling part of device.

④ Emergency Switch (Reset button)
It can stop the device working in the unexpected situation.

⑤ Key Switch
It controls the power by ON/OFF and it protects the device being defected by outsiders

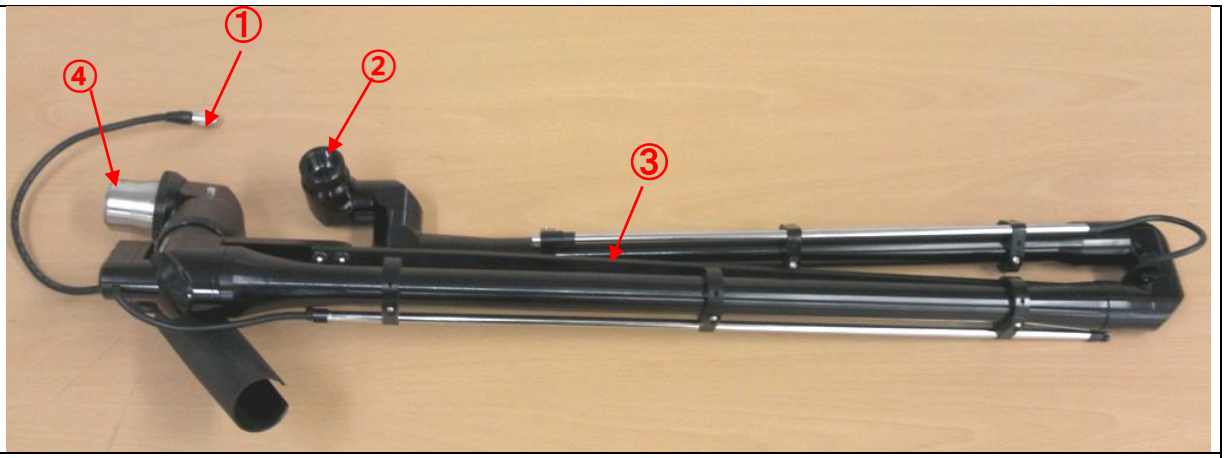
⑥ Foot Switch Connector
It connects to the Foot Switch which controls the generating of laser.

Front View

① Connection to the ARM It connects to the articulated ARM. ② Handle Moving, pulling and lifting the device ③ Interlock Connector It is external interlock equipment ④ Power Supply Cable It is a cable for AC220~230V which supplies power to the device	

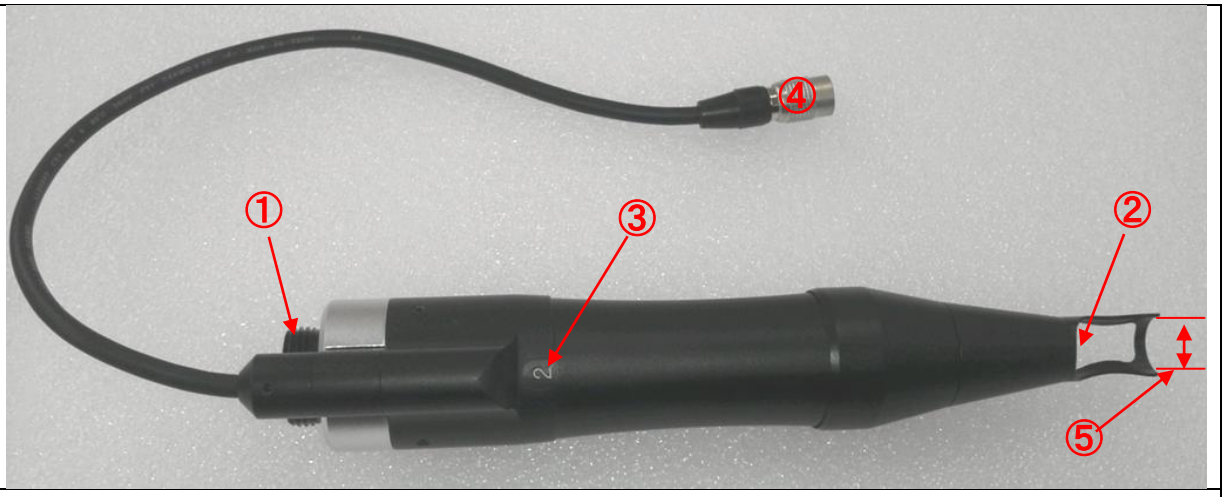
Rear View

3.3 Articulated ARM



① Auto Spot Cable that is a cable for auto spot control function.
② Connector connecting to the Handpiece.
③ Joints of Articulated ARM which can freely move with seven joints.
④ Connector connecting to the top case socket.

3.4 Handpiece



① Connecting part to the Articulated ARM.

② Laser aperture Collimated beam out to the operation sites.

③ Rotary dial which can control the spot size.

④ Connector connecting to the Articulated ARM for auto spot control function.

⑤ Handpiece Tip (Designation of Applied Part): Contacted part with the patient during treatment.

3.5 Explanation of Term

Emergency Switch:

Stops operating the device when occurring unexpected situation.

Key Switch:

Supplies power to the system for operating of device.

(Prohibits access by unauthorized person.)

Foot Switch:

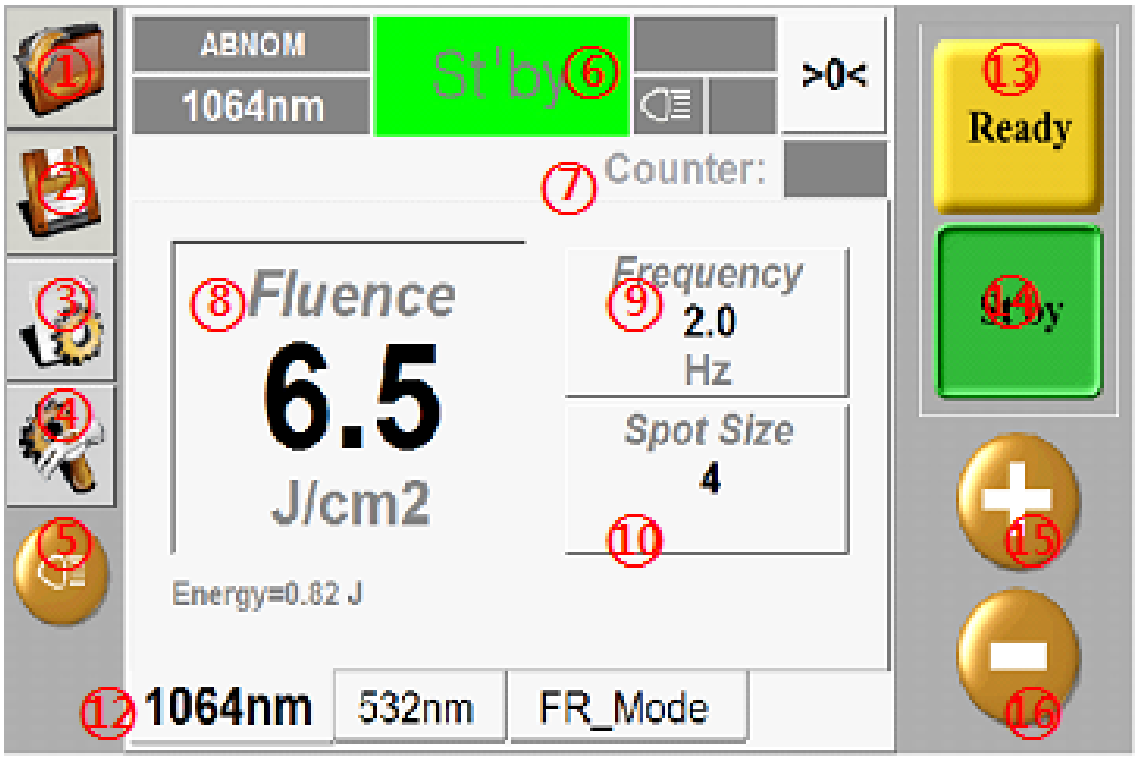
Irradiates laser on Ready mode.

All people who are in application area of the device should wear the certificated protective goggles, and there should be warning mark on the entrance of the place.

Foot Switch

Goggles

3.6 Manu Description



No	Title	Function
1	Load	Loads saved parameters
2	Save	Saves setting parameters
3	Information	Device Information
4	Engineer Mode	Do not use unless supervised by engineer
5	Guide Beam	Pilot beam On/Off
6	Device Status	Indicates current Mode.
7	Counter	Pulse shot counter
8	Fluence	Controls pulse energy density(J/㎠)
9	Frequency	Controls pulse duration
10	Spot size	Controls laser beam diameter(mm)
11	Energy	Controls pulse energy level(J)
12	Mode	Selects treatment wavelengths(532nm/1064nm/FR Mode) - 1064nm mode: 1064nm laser is radiated using Q-switch.

		- 532nm mode: 532nm laser is radiated using Q-switch. - 1064 Free mode: 1064nm laser is radiated without using Q-switch.
13	Ready	Changes to Ready mode.
14	ST'BY	Changes to Standby mode.
15	Up	Increases the parameters.
16	Down	Decreases the parameters.

4. UNPACKING AND CONNECTIONS

※ Accessories

- Articulated ARM with handpiece
- Foot Switch
- Interlock
- Protective Goggles for patient and operator
- Carbon Cream

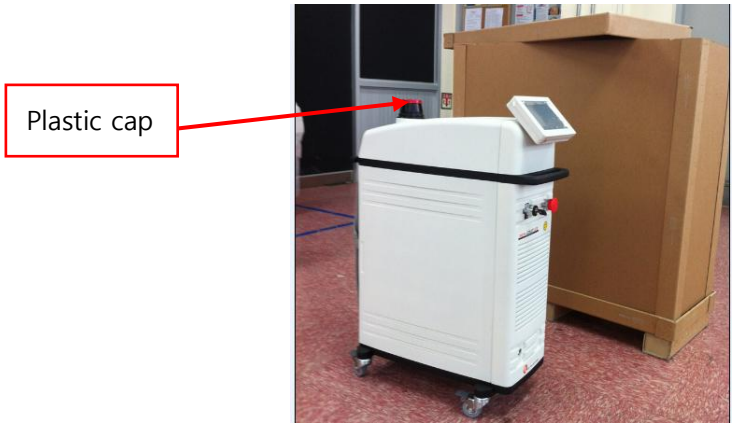
1) Unpack the articulated arm from the box.

→

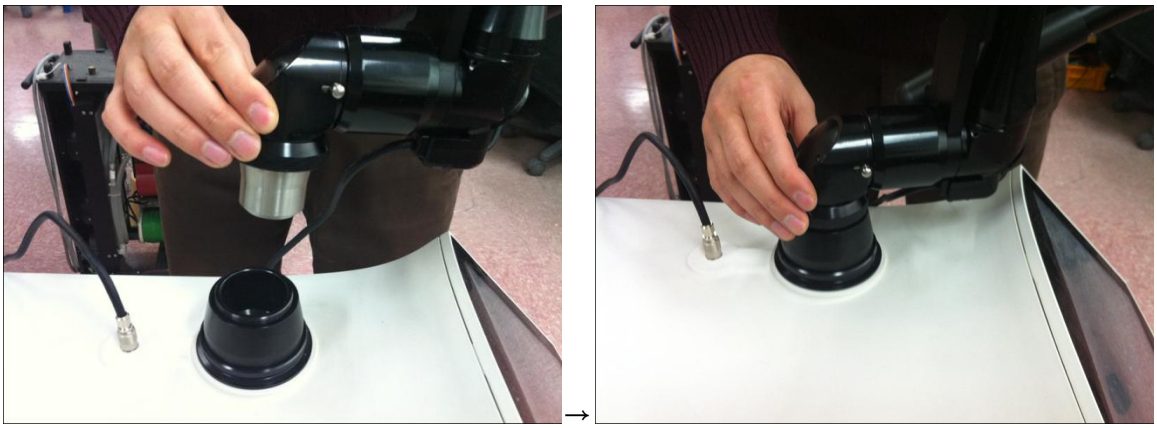

→


2) Check the package condition that has a defect and destruction.

3) Uncover a plastic cap for safety from the device top cover.



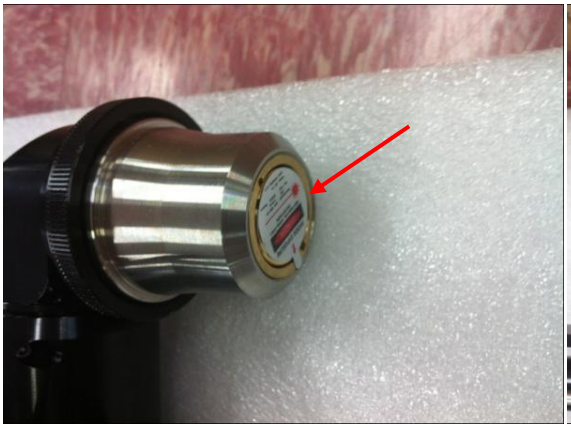
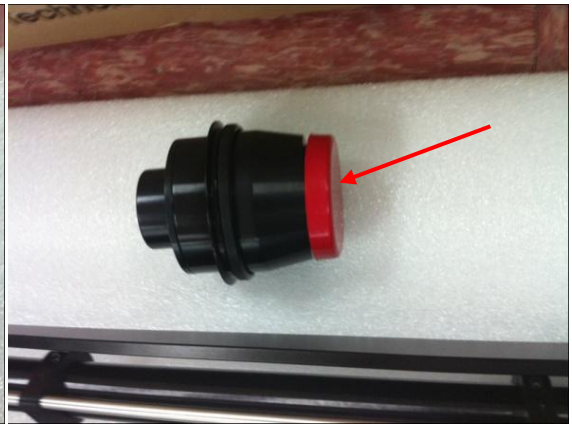
4) Attach the Articulated ARM to the Mounting hole.

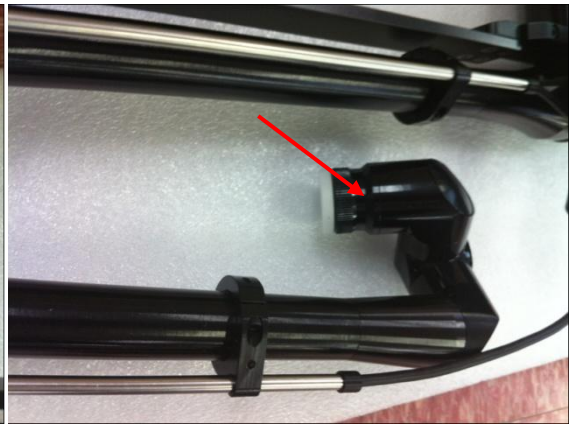


⚠ WARNING

DURING THE CONNECTIONS AND DISCONNECTIONS OF ARTICULATED ARM, BE EXTREMELY CAREFUL TO PROTECT THE OPTICAL SURFACES OF THE LASER HEAD, HANDPIECE AND ARTICULATED ARM FROM DUST. ALWAYS PLUG THE PROTECTION PLASTIC CAPS WHEN THEY ARE NOT IN USE AND KEEP THEM IN A SAFE PLACE.

5) The Laser Beam Safety Sticker and Plastic Cap are removed from Main unit, Articulated ARM and Handpiece for assembly.



6) Connect the Handpiece to the Articulated ARM.

Plug the Guide Beam Connector to the Handpiece.


7) Plug the Guide Beam Connector to the socket on the rear case of the Main unit.

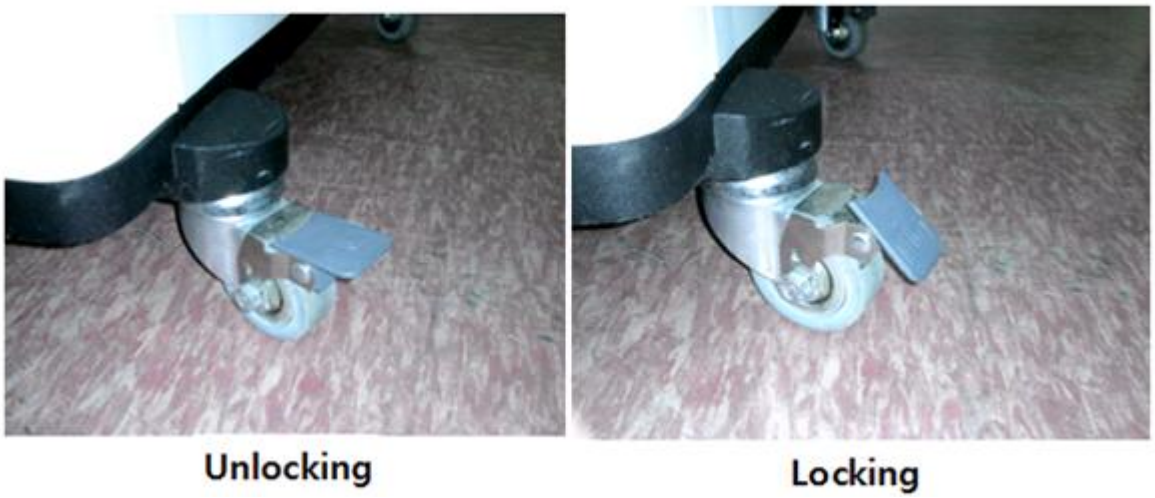
8) Plug the Foot Switch connector to the socket on the front of the Instrument.

Plug the Power cord to the mains.

Be sure to connect between Interlock of connection part which is located the back and entrance hole and be regulate the access.

> **NOTE**
>
> Connect the foot switch connector tightly, not moved.
>
> Carefully connect the foot witch connector to the socket on the front of device in care of terminal of the connector, until hearing equipping sound.

9) Check the wheel locks to ensure that unintended movement is prevented.



> **NOTE**
> **PLEASE MAKE SURE THE WHEEL LOCKS DURING OPERATING.**

5. HOW TO USE

■ Intruction for Use

- Information on the NOMINAL OCULAR HAZARD DISTANCE (NOHD) for the laser equipment in NORMAL USE with each appropriate ACCESSORY.

NOHD Calculation

1. Free Running mode (1064nm, 0.3ms)
2. Q-switching mode (1064nm, 20ns)
3. Q-switching mode (532nm, 20ns)

1. For the WON-COSJET TR laser system, determine the intra-beam MPE for direct ocular exposure to the radiation from a Nd:YAG laser(λ = 1 064 nm) operating at a frequency of F = 1 Hz with a pulse width of t = 0.3 ms at free running mode.

As the laser does not operate in the visible part of the spectrum, protection is not afforded by the blink reflex. A reasonable estimate of a hazardous chance exposure time can be taken as 10 s. For this time period, the total number of pulses is:

$$N = T \times F = 10\ s \times 1\ Hz = 10$$

At IEC60825-1:2001, subclause 13.3 includes three criteria which must be considered, and the most restrictive one applies to this evaluation. The value of C_6 is 1 in these calculations since the beam is emitted from a small source. The value of C_7 from notes to tables 1 to 4 is also 1 for the 1 064 nm wavelength.
From 13.3a), the exposure from any single pulse shall not exceed the single pulse MPE. Thus the radiant exposure from table 6 for the time period of 0.3ms is:

$$H_{single} = 90\ t^{0.75}\ C_6\ C_7\ J{\cdot}m^{-2} = 90 \times 0.0003^{0.75} \times 1 \times 1\ \ J{\cdot}m^{-2} = \ 0.205\ J{\cdot}m^{-2}$$

From 13.3b), the average exposure for a pulse train of exposure duration T shall not exceed the MPE for a single pulse of exposure duration T. For the 10 s duration (the total exposure time), table 6 limits the radiant exposure to:

$$H_{single}=90\ t^{0.75}\ C_6\ C_7\ J{\cdot}m^{-2}=90\times 10^{0.75}\times 1\times 1\ \ J{\cdot}m^{-2}=\ \ 506\ J{\cdot}m^{-2}$$

Since there are N = 10 pulses in the 10 s period, the average irradiance criteria results in a single pulse radiant exposure of:

$$H_{single,\ avg}\ =\ \frac{H_T}{N}=\ \frac{506}{10}\ J{\cdot}m^{-2}\ =\ 50.6\ \ J{\cdot}m^{-2}$$

From 13.3c), the average exposure from pulses within a pulse train shall not exceed the MPE for a single pulse multiplied by the correction factor C_5 (where C5 = $N^{-1/4}$). For the N = 10 pulses in the 1 s period, the radiant exposure under these criteria would be:

$$H_{MPE,\ train}\ =\ H_{MPE,\ single}\times N^{-0.25}\ =\ 0.205\times(10)^{-0.25}\ \ J{\cdot}m^{-2}\ =\ 0.115\ J{\cdot}m^{-2}$$

Since the limit from the repetitive pulse criteria of 13.3 c) is the most restrictive, the single pulse MPE for this system would be 0.115 $J\cdot m^{-2}$. The MPE could also be expressed in terms of irradiance as:

$$E_{MPE}\ =\ \frac{H_{train}}{t}\ =\ \frac{0.115\ J{\cdot}m^{-2}}{0.3{\times}10^{-3}\ s}\ =\ 385\ W{\cdot}m^{-2}$$

The NOHD (Nominal Ocular Hazard Distance) represents that range at which under ideal conditions, the irradiance and the radiant exposure fall below the appropriate MPE.

The appendix of the ANSI z136.1:2000 standard presents the following formula for determining the range of the NOHD for unaided viewing conditions (specific for pulsed lasers):

$$NOHD\ =\ \frac{\sqrt{4\ P_o\ /\ \pi\ E_{MPE}}\ -\ a}{\varphi}$$

Where:

NOHD is the Nominal Ocular Hazard Distance, in meters.

ϕ is the beam divergence, in radians. 0.005radians

P_o is the laser output radiant energy, in joules. 2J at 1064nm

H_{MPE} is the appropriate per pulse Maximum Permissible Exposure, in joules/m^2. 0.115 Joules/m^2

a is the output beam diameter at the laser, 10 mm diameter

The conclusion is that condition 13.3c) produces the most restrictive MPE per pulse and therefore, H_{MPE} = 0.115 J·m^{-2} for intra-beam viewing. The range equation of the previous example can be used to calculate NOHD; however, because the mode structure of this solid-state laser is not specified, the pulse energy should be increased by a factor 2.5. Therefore,

$$NOHD = \frac{1}{\varphi}\left[\sqrt{\frac{4\times 2.5\times P_o}{\pi\times H_{MPE,\ train}}} - a\right]$$

$$NOHD = \frac{1}{5\times 10^{-2}}\left[\sqrt{\frac{4\times 2.5\times 2}{\pi\times 0.115}} - 0.01\right] = 149\ m$$

The NOHD for the rangefinder is therefore 149 m.

2. For the WON-COSJET TR laser system, determine the intra-beam MPE for direct ocular exposure to the radiation from a Nd:YAG laser(λ = 1 064 nm) operating at a frequency of F = 1 Hz with a pulse width of t = 20 ns at Q-switching mode.

Wavelength = 1064 nm;
Peak power per pulse P_p = 65 MW;
Energy per pulse P_o = 1.3 J;
Pulse repetition rate = 1 per second;
Exit aperture beam diameter = 10 mm;
Beam divergence angle = 50 mrad.

What is the effective NOHD on the basis of the single-pulse threshold (a) for exposure of the unaided eye, and (b) when intra-beam viewing through 50 mm diameter optics is involved?
(Effects of beam attenuation or refractive focusing due to atmospheric transmission are neglected in these calculations.)

The pulse width t_p can be calculated from the condition

$P_p \times t_p = P_o$ by $65 \times 10^6 \times t_p = 1.3$

giving $t_p = 20$ ns (i.e. $10^{-9} < t_p < 5 \times 10^{-5}$ s). The pulse repetition frequency F is 1/1 = 1 Hz.

In this example, it is assumed that $\alpha \leq \alpha_{min}$ and for a small source $C_6 = 1$. If there is no intentional viewing, the exposure duration to be used is 10 s; during this time, the number of pulses is

$N = F \times t = 1$ Hz $\times$ 10 s = 10

The intra-beam MPE is taken as the most restrictive calculated from the application of 13.3.

Single-pulse assessment (condition 13.3a))

From table 6, the MPE for a single-pulse exposure from this laser is

$H_{MPE} = 5 \times 10^{-2} C_6 C_7$ J·m^{-2}

where $C_6 = 1$ and $C_7 = 1$, therefore

$H_{MPE, single} = 5 \times 10^{-2}$ J·m^{-2}

Average irradiance assessment (condition 13.3b))

From table 6, the MPE for the exposure duration of 10 s is

$H_{MPE} = 90 \times t^{0.75} C_6 C_7$ J·m^{-2}

where $C_6 = 1$ and $C_7 = 1$. There are 10 pulses in 10 s, therefore the average MPE per pulse is

$$H_{MPE, exposure} = \frac{90 \times 10^{0.75}}{10} = 50.6 \text{ J·m}^{-2}$$

Multiple-pulse assessment (condition 13.3c))

The maximum exposure duration for which requirement c) should be applied is T2 in the wavelength range 400 nm to 1400 nm, where T2 = 10 s for $\alpha \leq \alpha_{min}$. Therefore, the

correction factor $N^{-1/4} = (10)^{-1/4} = 0.56$ is used to calculate H_{MPE}, train:

$$H_{MPE,\ train} = H_{MPE,\ single}\ N^{-1/4} = 5 \times 10^{-2} \times 0.56 = 2.8 \times 10^{-2}\ J \cdot m^{-2}$$

The conclusion is that condition 13.3c) produces the most restrictive MPE per pulse and therefore, $H_{MPE} = 2.8 \times 10^{-2}\ J \cdot m^{-2}$ for intra-beam viewing. The range equation of the previous example can be used to calculate NOHD; however, because the mode structure of this solid-state laser is not specified, the pulse energy should be increased by a factor 2.5.
Therefore,

$$NOHD = \frac{1}{\varphi}\left[\sqrt{\frac{4\times 2.5\times P_o}{\pi\times H_{MPE,\ train}}} - a\right]$$

$$NOHD = \frac{1}{5\times 10^{-2}}\left[\sqrt{\frac{4\times 2.5\times 1.3}{\pi\times 2.8\times 10^{-2}}} - 0.01\right] = 243\ m$$

The NOHD for the rangefinder is therefore 243 m.

3. For the WON-COSJET TR laser system, determine the intra-beam MPE for direct ocular exposure to the radiation from a Nd:YAG laser(λ = 532 nm) operating at a frequency of F = 1 Hz with a pulse width of t = 20 ns at Q-switching mode.

Wavelength = 532 nm;
Peak power per pulse P_p = 25 MW;
Energy per pulse P_o = 0.5 J;
Pulse repetition rate = 1 per second;
Exit aperture beam diameter = 10 mm;
Beam divergence angle = 50 mrad.

What is the effective NOHD on the basis of the single-pulse threshold (a) for exposure of the unaided eye, and (b) when intra-beam viewing through 50 mm diameter optics is involved?
(Effects of beam attenuation or refractive focusing due to atmospheric transmission are neglected in these calculations.)

The pulse width t_p can be calculated from the condition

$$P_p \times t_p = P_o \text{ by } 25 \times 10^6 \times t_p = 0.5$$

giving t_p = 20 ns (i.e. $10^{-9} < t_p < 5 \times 10^{-5}$ s). The pulse repetition frequency F is 1/1 = 1 Hz.

In this example, it is assumed that $\alpha \leq \alpha_{min}$ and for a small source C_6 = 1. If there is no intentional viewing, the exposure duration to be used is 10 s; during this time, the number of pulses is

$$N = F \times t = 1 \text{ Hz} \times 10 \text{ s} = 10$$

The intra-beam MPE is taken as the most restrictive calculated from the application of 13.3.

Single-pulse assessment (condition 13.3a))

From table 6, the MPE for a single-pulse exposure from this laser is

$$H_{MPE} = 5 \times 10^{-3} C_6 \text{ J·m}^{-2}$$

where C_6 = 1, therefore

$$H_{MPE, single} = 5 \times 10^{-3} \text{ J·m}^{-2}$$

Average irradiance assessment (condition 13.3b))

From table 6, the MPE for the exposure duration of 10 s is

$$H_{MPE} = 90 \times t^{0.75} C_6 C_7 \text{ J·m}^{-2}$$

where C_6 = 1 and C_7 = 1. There are 10 pulses in 10 s, therefore the average MPE per pulse is

$$H_{MPE, exposure} = \frac{90 \times 10^{0.75}}{10} = 50.6 \text{ J·m}^{-2}$$

Multiple-pulse assessment (condition 13.3c))

The maximum exposure duration for which requirement c) should be applied is T2 in the wavelength range 400 nm to 1400 nm, where T2 = 10 s for $\alpha \leq \alpha_{min}$. Therefore, the correction factor $N^{-1/4} = (10)^{-1/4} = 0.56$ is used to calculate H_{MPE}, train:

$$H_{MPE,\ train} = H_{MPE,\ single}\ N^{-1/4} = 5 \times 10^{-3} \times 0.56 = 2.8 \times 10^{-3}\ J \cdot m^{-2}$$

The conclusion is that condition 13.3c) produces the most restrictive MPE per pulse and therefore, $H_{MPE} = 2.8 \times 10^{-3}\ J \cdot m^{-2}$ for intra-beam viewing. The range equation of the previous example can be used to calculate NOHD; however, because the mode structure of this solid-state laser is not specified, the pulse energy should be increased by a factor 2.5.

Therefore,

$$NOHD = \frac{1}{\varphi}\left[\sqrt{\frac{4 \times 2.5 \times P_o}{\pi \times H_{MPE,\ train}}} - a\right]$$

$$NOHD = \frac{1}{5 \times 10^{-2}}\left[\sqrt{\frac{4 \times 2.5 \times 0.5}{\pi \times 2.8 \times 10^{-3}}} - 0.01\right] = 476\ m$$

The NOHD for the rangefinder is therefore 476 m.

– A statement in SI units of BEAM DIVERGENCE, PULSE DURATION, maximum LASER OUTPUT of the LASER RADIATION, with the magnitudes of the cumulative measurement uncertainty and any expected increase in the measured quantities at any time after manufacture added to the values measured at the time of manufacture.

Spot Size	Max: 10mm Min: 2mm Variation: 2,3,4,5,6,7,8,9,10mm Tolerance: ± 20% Aiming Beam: 3mm ± 20%
Maximum Energy	Free Mode: 1800mJ 1064nm Mode: 1000J 532nm Mode: 500J

-Information and guidance for regular calibration of the LASER OUTPUT in accordance

with 201.12.1 of this standard. The information shall include a specification for the measuring equipment and frequency of calibration and clarification requirements concerning regular calibration of LASER OUTPUT

Only engineer qualified by manufacturer shall have a calibration of Laser output on Engineer mode. User should call the service center (*TEL: +82 42 934 6800) when laser output is decreased.*

– A description of the BEAM DELIVERY SYSTEMS including the characteristics of the LASER OUTPUT.

To provide energy to the flash lamp, high voltage power supply charges to a storage capacitor. Then, a trigger pulse applied to the flash lamps causes the capacitor to discharge through the flash lamps. The resulting flash excites the Nd:YAG laser rod, causing the emission of a pulse of laser energy.

1. As the main power 220-230VAC is supplied to the system, charge board, simmer board and SMPS, the device starts to convert the main power to respective voltage for the system operation.
2. Main board gets the data on LCD screen whenever user touches the screen and displays the setting value on the screen.
3. While a system operates, the system keep monitoring whether fan, pump, thermometer and other sensors are wrong or not.
4. In case of ready state, when user pushes foot switch, the setting energy on screen will be radiated at the end of the articulated arm.

– After finishing the operation of the device, it should remove the key from the key switch. No one turns the key switch on and off exempt of qualified persons (Dermatologist or Physician trained by manufacturer).

– Avoid the fiber optics to be exposed to inserting, sharply bending or improperly occurring, the damage can cause harm to the patient or laser operator;

– As the aiming beam passes down the same Articulated Arm as the working beam, it provides a good means of checking the integrity of the Articulated Arm. If the aiming beam is not present at the distal end of the Articulated Arm, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning delivery system.

– A risk of fire and/or explosion exists when the laser output is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment. The high temperatures produced in normal use of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen. The alcohol used for cleaning must be allowed to evaporate before the laser equipment is used.

5.1 Power On

1) Put on protective goggles for your safety.
Turn on the key switch clockwise.
Wait a few seconds until the main menu appears on the screen.

> **NOTE**
> **PRESS THE MONITOR BUTTON USING NAIL BETTER THAN FINGER TIP.**

2) After WON Technology logo briefly appears, the main menu appears to control.

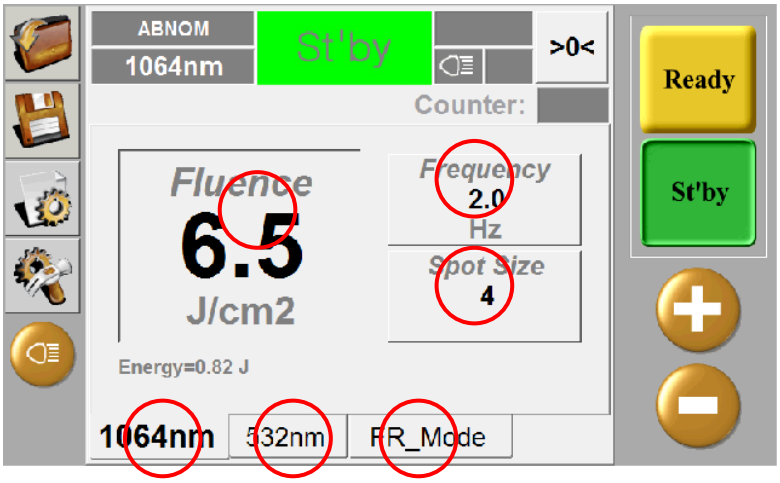
→


5.2 Select Indication and Setting

1) Press the Load button in the red circle of the picture below.
The parameter list saved as treatment parameters appears as shown picture below.
You choose the parameter saved each of treatment.

→


2) Besides written indications, setting treatment parameters using Fluence, Frequency, 1064 nm & 532 nm & Genesis based on Energy as shown picture below.
In case of Spot size, adjust Spot size as turning a dial of Handpiece.

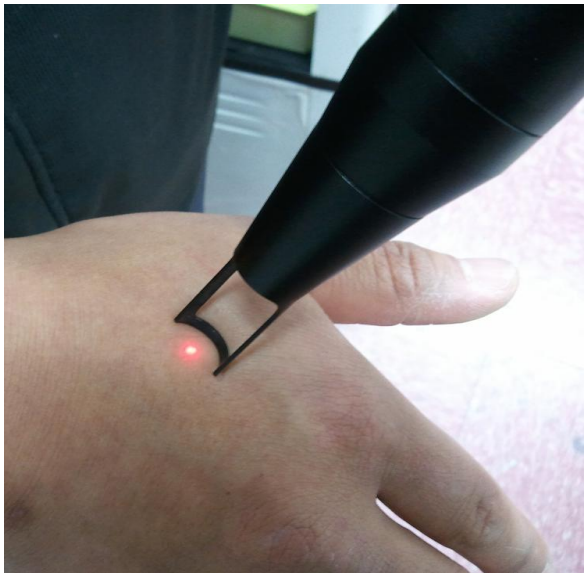


3) You can save setting parameters with new name for treatment convenience.
Press the Save button in the red circle of the picture below to save a new parameters.

5.3 Laser Procedure

1) If you finish selecting of treatment parameters, push the Ready button on the picture below.
Check again the spot size and other parameters for laser irradiation.
You press the Ready button, you can see the screen that changes to the Ready mode.
The Ready and Standby LED are light on the Ready mode at the same time.

2) Check the guide beam for indication of a treatment region as shown picture below.
Press the Foot Switch for laser irradiation on Ready mode.

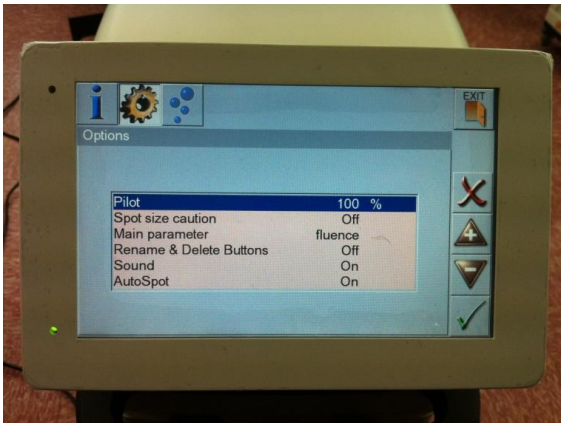


3) See the Counter for laser shot frequency. When you press the Reset button on the picture below, shot count number will be reset to '0'. The Ready LED is light.

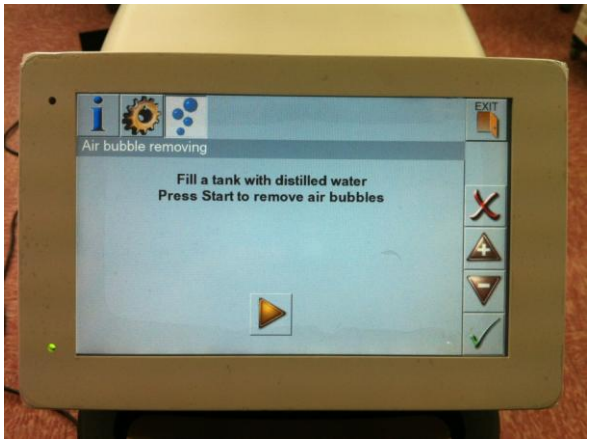
5.4 Laser Information and Setting

1) You can see information such as model name, S/N, pulse, Manufacturing date and software version as shown picture below.

2) As the picture below, you can adjust brightness of Pilot (Guide beam), ON/Off of spot size caution, Rename& Delete buttons and etc.



3) Air bubble removing button is to remove air in water pump flowing distilled water. Do not turn off the device during air bubble removing.



5.5 Power Off

Press the Standby button which makes sure not irradiating laser.

To turn off the device, turn the Key Switch counter-clockwise.

Remove the key to prevent used by unauthorized user.

6. MAINTENANCE

6.1 General Information

(1) After using, wipe the tip of Handpiece which was contacted with the patient with alcohol according to the procedure indicated 6.3 section. The alcohol can be purchased at any local store.

(2) Once a week, wipe the exterior sides of WON-COSJET TR Laser System with a dry towel. In particular, clean the LCD display/Touch Pad, using gentle care not to scratch the surface.

(3) Do not drop any food or liquid on the equipment. It may affect the electrical parts in the equipment or cause damage.

(4) Do not place anything on the base frame or apply any pressure onto it when the WON-COSJET TR laser system is not in use.

(5) Handle the laser arm with care. It can cause damage in joint part for connection.

(6) Do not move or relocate the device while the power is on

(7) When the WON-COSJET TR laser system is not in use for a period longer than one day, unplug power line.

(8) Follow local governing ordinances and recycling plans regarding the disposal or recycling of device components.

NOTE

ROUTINE CARE OF THE HANDPIECE TIP AND LENS CLEANING OF THIS LASER SYSTEM IS COVERED IN THE FOLLOWING SECTIONS (DOCTOR SHOULD CLEAN THIS PART AFTER TREATMENT.).
ALL OTHER MAINTENANCE AND SERVICE MUST BE PERFORMED BY A QUALIFIED SERVICE REPRESENTATIVE (ENGINEER QUALIFIED BY MANUFACTURER).

6.2 Attention

6.1.1 General Attention

- Do not operate the laser **without a skilled doctor or designated specialist indicated in intended use**. Check the laser system before operating.

- **Call a technical engineer** when the laser occurs unusual signal or trouble.

- Do not put or remove any components in the unit.

- **Check the laser system before use** when the device is not used for a long time.

6.1.2 Individual Attention

- Do not see the laser aperture directly.

- While the laser works, all people attending treatment wear **the Protective goggles**.

- Do not use the laser in the **Flammable anesthetic** or **Volatility** matter area.

- Use the laser carefully due to **High voltage** inside.

- Keep the distance approximately 20 cm between laser system and wall.

- Use an **Anesthesia cream** which uses for reducing pain during laser treatment.

- Do not touch the unit with **wet hands**.

6.3 Cleaning Procedure

Operator (Dermatologist or Physician) or nurse must clean Handpiece tip and lens after treatment for patient. Handpiece maintenance is directly related to device life span and patient's health. Maintain optimal condition of device by following easy steps of cleaning as shown pictures below.

1) Twist out Handpiece from articulated arm

2) Full out tip to detach it from Handpiece

3) Preparing the cotton swab with alcohol

4) Clean dusty on the lens.

5) After each treatment, for prevention of infection, clean the Handpiece tip (applied part to patient) using a cotton swab moistened with alcohol.

- If the device is dirty with dusts or any stain, clean it with soft and dried cloth. (Do not use strong chemistry solution such as thinner or benzene)

- After using the device, clean the Handpiece Tip following to the cleaning procedure above. The cleaning procedure is very significant for prevention of infection.

-Clean and disinfect the device exterior. Turn off the device when cleaning the exterior of device.

> **⚠ WARNING**
>
> DO NOT IMMEDIATELY TREAT AFTER CLEANING HANDPIECE TIP UNTIL ALCOHOL IS EVAPORATED. ALCOHOL MAY INDUCE FIRE.

6.4 Check Points

When the device doesn't give any particular response;

- Please check the power code connected to power or not.
- Please check the main power is too low or not. (Check the voltage level of the wire, and connect power cord to the other socket-outlet.)
- Please check the operating of key switch and emergency switch
- Please request the service in case that CPU board is not supplied with the power, because it may be damage the key switch, emergency switch, or CPU board.

When the laser beam is not generated despite pressing on the foot switch;

- Please check the device is on Ready mode.
- Please check the Foot switch cable is connected to the connection devices. An error message is shown up on screen.

6.5 Technical Customer Service

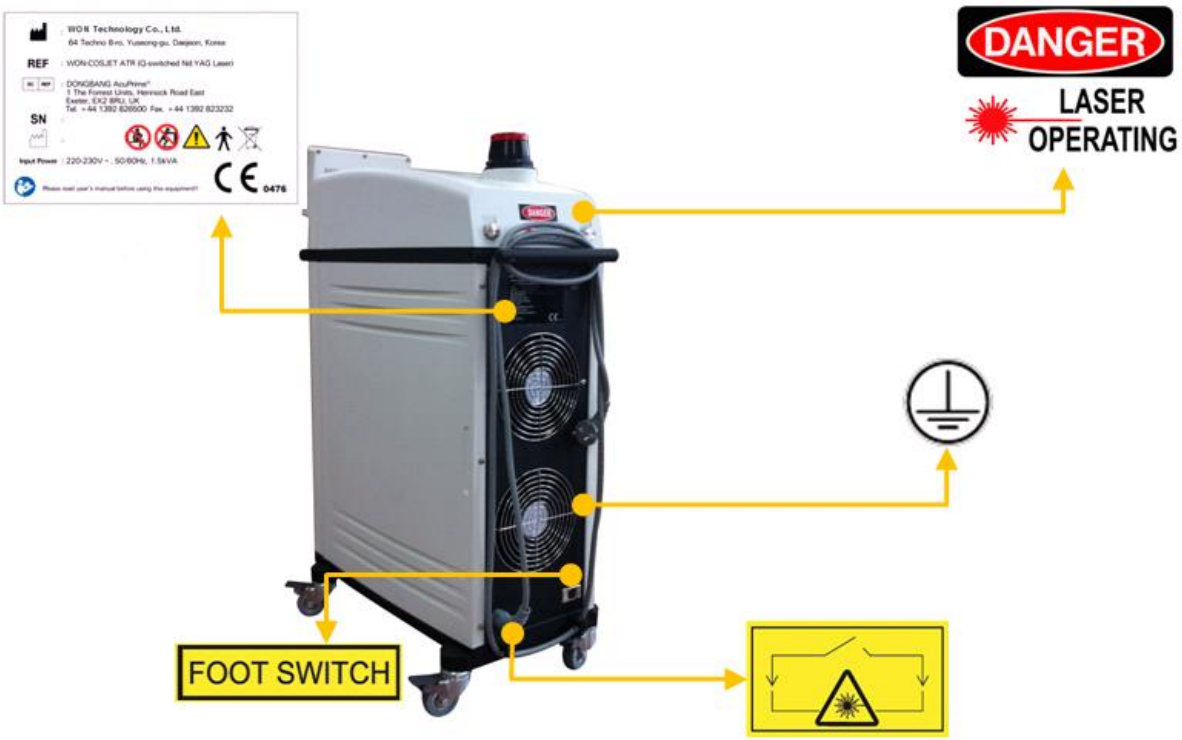
WON Technology Co., Ltd.
64 Techno 8-ro, Yuseong-gu, Daejeon, Korea
Email: wtlaser@wtlaser.com
Website: http://www.wtlaser.com/

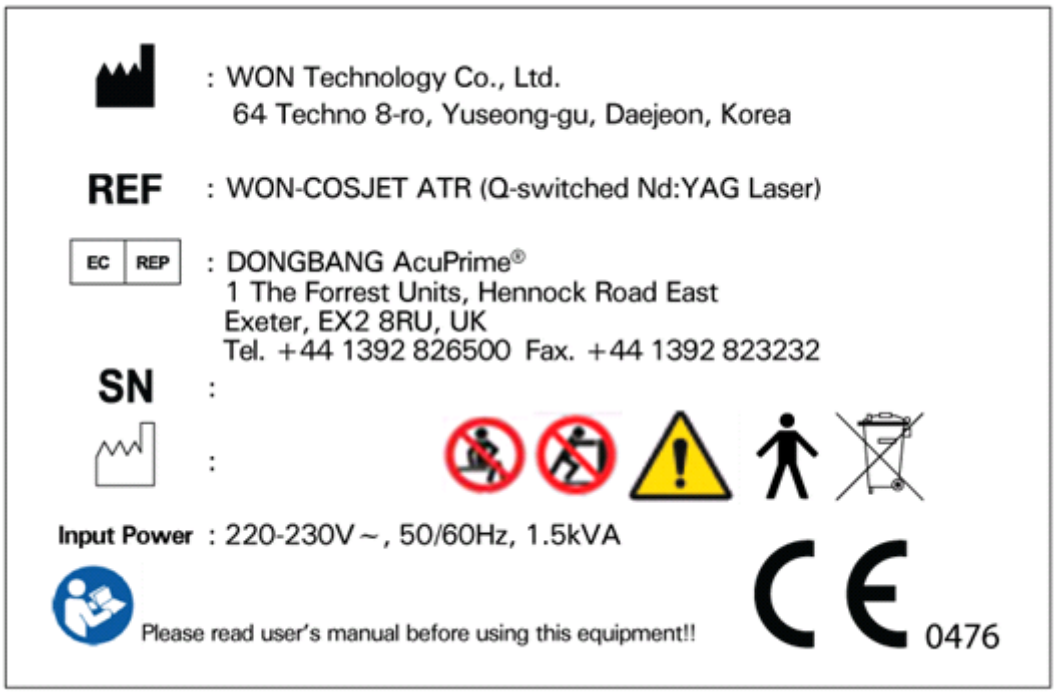
TEL: +82 42 934 6800
FAX: +82 42 934 9491

If the device is regarded with defective situations above, please contact immediately. Do not repair the device by yourself or unauthorized engineer. No modification or dismantle is allowed to unauthorized engineer.

7. LABELING AND PACKAGING

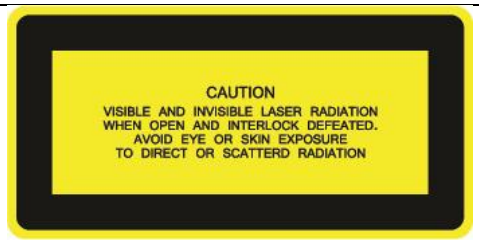
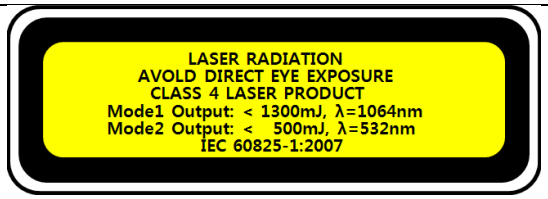
7.1 Labeling of WON-COSJET TR

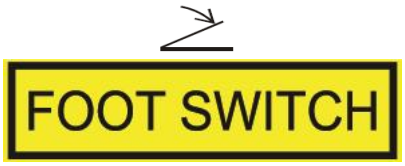




WON-COSJET TR nameplate

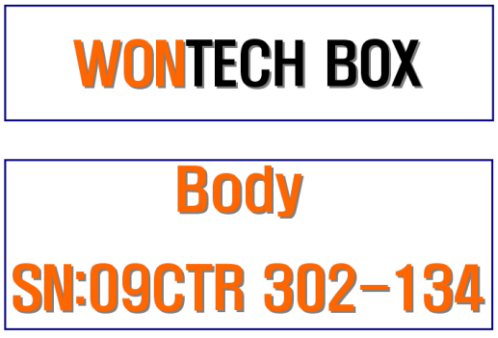
7.2 Laser Operation Danger Label

 Indicating laser beam exit location	 This label informs about the dangers, the maximum values of energy emitted by, and the classification of, the laser source.
 Part of Emitting Laser Hazard symbol. This symbol is intended to alert the operator to the danger of exposure to hazardous visible and invisible radiation.	 Laser aperture remarked on the top Notified Beam outlet opening (Laser Aperture) This label marks the location where laser radiation emerges from the beam delivery system.

 Foot switch attached connection part	 Interlock Notified for Interlock
 Protection ground connection indication. IEC60601-1	 Power ON/OFF IEC60601-1
 IEC60601-2-22 Emergency stop Remarked on the front, Emergency switch indication. This sign designates the EMO pushbutton for express shutdown of laser emission.	 Laser warning label (US) This label informs about the dangers, the maximum values of energy emitted by the laser source.

7.3 Label of package

Box for Packaging (Dimensions: W 40cm X H 110cm X L 105cm)

	
Keep-upright indicator	Shock Watch indicator
	
Precaution Mark	Company name & Product S/N

7.4 Transport and Storage Condition

■ Transport and Storage Condition

Temperature: - 20 °C to 60 °C

Humidity: 0 % to 90 %,

Pressure: 700 hPa to 1060 hPa

■ Operation condition

Temperature: +10 °C to 40 °C,

Humidity: 30 % to 75 %,

Pressure: 700 hPa to 1060 hPa

8. DISPOSAL

The WON-COSJET TR laser system must be disposed in accordance with Directive 2002/96/EC of the European Council on Waste Electrical and Electronic Equipment [WEEE].

Please contact our Technical Customer Service Department for help or consultation if required.

For disposal of replaceable filters locally binding waste removal regulations must be observed.

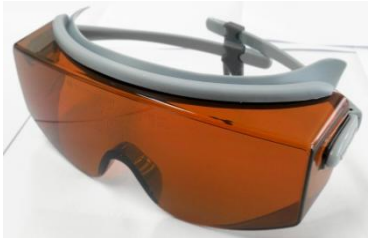
You are advised to dispose filters together with other items of medical waste, typically resulting from operation of physician's practices or clinics, such as single-use syringes, gauze bandages, etc. as special medical waste.

Please refer to the signed Warranty information detailed in the Terms and Condition of your Sales Contract. If you really wonder about more detail warranty information, please freely call the service center of WON Technology.
(*+82 42 934 6800)*

Please contact our Technical Customer Service on questions of any kind.

9. CONSUMABLES

9.1 Protective Goggles for doctor(YL717C NdYAG2)




- Notified body 0196(CE mark)
- Luminous transmittance: 40%
- Optical Density:6.0(1064nm), 4.0(532nm), 10.0(355nm), 10.0(266nm)
- Storing: The goggles shall be stored at a temperature between -10℃ and +55℃ and a relative humidity of <80%
- Doctor should wear the goggles when operating this device to radiate Laser for treatment. (Manufacturer supplies the Protective Goggles for operator.)
- After using and washing the Protective Goggles, you should clean this one with the clean towel in the Goggles pocket.
- If you consumed all of goggles, you should buy the Protective goggles it has a precise effect and qualified from manufacturer. Call to the service center (*+82 42 934 6800).*
- **Warning**: **Do not see laser directly even though you wear the Protective Goggles.**
- **Caution: Please put on or take off your glasses with both hands carefully. If you take off the glasses with one hand, the lenses and frames may become damaged**
- **This product shall not be used to range than the indicated wavelengths.**

9.2 Protective Goggles for patient (YL-800W SAFETY EYE GUARD)

- Notified body 1096(CE mark)
- Luminous Transmittance: 0%
- This laser goggles protects the eye of patient against scattered light and diffuse reflection of a laser beam and it gives the user the possibility to protect the laser beam within a certain period of time (max. 10 sec resp. 100 pulse).
- Storing: The goggles shall be stored at a temperature between -10℃ and +55℃ and a relative humidity of <80%.
- Cleaning: All parts can be cleaned under running water with a normal washing-up liquid. A soft cloth shall be used. For drying the laser filters.
- After using and washing the Protective goggles, you should clean this one with the clean towel in the Goggle pocket.
- If you consumed all of goggles, you should buy the Protective Goggles it has a precise effect and qualified from manufacturer. Call to the service center (*+82 42 934 6800).*
- **Warning: Do not be exposure directly to the laser beam even if patient is wearing the protective goggles.**
- **This product shall not be used to range other than the indicated wavelengths.**

Appendix 1(Error message)

Message	Description
Queue Full	Queue is a memory space for events from communication. If memory in SPU board is full of events, system displays alarm.
Charger i2c error	Communication connection between SPU and Charger board is something wrong
Charger over-temperature	This alarm is for protecting IGBT in charge board from over-temperature. The temperature of IGBT in charger board must be lower than 85 °C. A temperature sensor is attached in the heat sink for detecting temperature.
Charger over-voltage	It means over-charging to the capacitor. SR, Mercury : capacitor voltage > 550V, TR : capacitor voltage > 1100V
Charger is off	SPU board sends Charging command to charge board. But no response.
Charger in test mode	"Charger in test mode" is manual mode for tuning the charging voltage. This mode is only for manufacturer.
Charger unknown Fault	SPU board received FAULT_CC signal from charge-board. Then, SPU board checks the charge board, but can't find any problem in charge board.
Charge too slow	In case charging time is longer than limited maximum value. TR maximum charging time : 200ms SR & Mercury maximum charging time : 10 seconds

No Simmer 1	At the end of booting, simmer B/D generates high voltage in order to make a high peak ignition voltage. By ignition voltage, lamps are on and simmer unit supplies the lamp with low current.
No Simmer 2	At the end of booting, simmer B/D generates high voltage in order to make a high peak ignition voltage. By ignition voltage, lamps are on and simmer unit supplies the lamp with low current.
No Flow	No flow alarm is detected by flow sensor. If water doesn't't flow through cooling system, system displays the alarm.
Over-temperature	During operation, system needs to cool down flash lamp by cooling system. Otherwise, optical parts in cavity will be burnt. To protect the over-temperature of cavity, system is checking the current temperature of cavity at the right below laser head. The max. temperature of cavity is 50 °C.
Interlock	Interlock is installed at the door in laser room for safety. When opening the door during treatment, system is down and displaying alarm.
Emergency button	In case of emergency, system is down by pushing emergency button and main power is off.
Timer Full	If total timer event in SPU memory is over 8, displayed the alarm.
Step motor malfunction	KTP crystal Mount for changing wavelength is moving on the rail by stepping motor. Micro-button is located respectively at the front and end of rail. When KTP crystal Mount pushes the micro-button, stepping motor stops and SPU sends ready message to cp-board. When pressing ready button, stepping motor begins moving and have to push the micro-button on time.

RS232 unexpected start bit	RS232 is a kind of communication protocol. Basically, communication is started with 0xAA, finished with 0xAB. For example, Data will be like: 0xAA(start) / 0x01(data) / 0x10(data) / 0x00(checksum) / 0xAB (end) if start byte is not 0xAA, displayed Alarm
Unexpected Command	CP program error For example, in error state, cp board sends the ready signal
FRAM i2c error	In SPU board, FRAM IC is for saving important data like total pulse. Communication error between SPU board and FRAM IC.
Contactor sealing	Before contactor powers up, SPU board checks the contactor status by the signal CONT-OK (A1 & A2). CONT-OK signal must be opened electrically. If it's on during power-up, displayed alarm.
Contactor malfunction	Using contactor, system turns on or off 220Vac main voltage. Once system is powered up, SPU board switches on contactor. By checking CONT-ON signal, SPU board detects the condition of Contactor. For more, refer to Reference #4. Contactor
Charger in boot loader mode	The charge B/D is reset by something during the operation.
Charging don't start	System tries to charge the capacitor. But can't. If the capacitor voltage is less than limited minimum value. TR: minimum voltage 150V SR , Mercury : maximum voltage 75V
Charger over-voltage Mid	Charger could not reach to setting voltage. Refer to the Reference #1. Charger problem.

Charger Thermometer malfunction	The temperature sensor is in heat sink of charge board. Temp. Sensor is detecting current temperature for IGBT to protect IGBT from defect by over-heat. In case the sensor is broken, system displays alarm.
RS232 control sum error	It's kind of communication protocol. Basically, communication is started with 0xAA, finished with 0xAB. At the end of the data, there is checksum byte for checking wrong data. For example, Data will be like: 0xAA(start) / 0x01(data) / 0x10(data) / 0x00(checksum) / 0xAB (end) We can find the checksum data by Exclusive-or calculation. 0x01(data) xor 0x10(data) = 0x00 (checksum) If the received checksum is something wrong, displayed alarm.
RS232 overflow	In serial communication, Maximum memory space is 256 byte for receiving data. Receiving data is over 256 byte, displayed alarm.
No discharging	Capacitor energy can't be discharged by thyristor (SCR). If the voltage is over 200V right after discharging, displayed alarm at the next shot.
Flow Sensor malfunction	In case water is flowing through water tube, sensor is automatically shorted. SPU board keeps sensing this signal. Usually this signal must be open state before system boot. This alarm means flow sensor is shorted electrically before system boot.
Connection with CPU lost	After booting, cp board sends the alive-signal to the SPU board every 2second. No data from the cp board.
Communication error	During boot loader mode, CPU board sends the data to SPU board. SPU board checks the

	checksum for purity. If the checksum is something wrong, displayed alarm.
Wrong command	During boot loader mode, There is no kind of command in SPU and Charge board communication protocol.
Wrong device address	During boot loader mode, CPU board has only address for SPU board and charge board in communication protocol. The board address is out of range.
Wrong memory address	During boot loader mode, CPU sends the address to SPU board and Charge board in order to write the data to the flash memory and eeprom. If the memory address is over setting value, displayed alarm.
Write error	During boot loader mode, Wrong data is written in flash memory and eprom.
No connect	During boot loader mode, System can't communicate between SPU board and Charge board.
Wrong answer	During boot loader mode, Charge board sends wrong answer to SPU board.
Timeout	Communication error between CPU and SPU boards If there is no answer for 60 seconds after sending command, displayed alarm
No connect	During boot loader mode, No Serial communication between CPU board and spu board
Bad packet answer	During boot loader mode, SPU board sends wrong command to CPU board.
CRC mismatch	During boot loader mode, CRC SPU board error after upload or CRC Charge board error after upload

HEX Files error	Hex file for firmware is in flash memory of cp board. It's not Hex file format in flash memory.
No Cable	In boot loader mode, No cable connection between CPU board and SPU board.
Hex file not found	The hex file for auto-self programming is in flash memory in CPU board. When booting, CPU need hex file to update the program. If there is no hex files, displayed alarm.
SP board in bootloader mode	During operation, SPU board is reset. Finally, sp board goes into boot loader mode.
Connection with SPU lost	During operation, there is something wrong in connection.
Temperature sensor broken	During operation, system needs to cool down flash lamp by cooling system. Otherwise, optical parts in cavity will be burnt. To protect the over-temperature of cavity, system is checking the current temperature of cavity at the right below laser head. The maximum temperature of cavity is 50 °C. If temperature sensor is broken, system can't control the fan speed by temperature sensor. Instead of system shutdown, system set the fan speed as max 100% not to go up 50 °C. User can use the system without system downtime until engineer visit to repair the senor.
H/P malfunction	System detects the spot change and displays the setting spot size on screen. If something wrong in h/p or wires, it's out of range and finally displays "bad" on spot area or h/p malfunction. Most of case, the problem is from the h/p or wires. By replace the h/p or arm set, we can solve the problem.

Appendix 2(Electromagnetic immunity)

Guidance and manufacturer's declaration – electromagnetic immunity

Standards		Test level	Compliance level	Electromagnetic environment-guidance
IEC 55011: 2009 + A1: 2010(Class A, Group 1)	Mains terminals continuous disturbance voltage	0.15MHz~ 30MHz	0.15MHz~ 30MHz	The EUT was placed on a wooden table, 0.1m height above the floor. The EUT was connected to adaptor and the power of adaptor was fed to the EUT through a 50Ω/ 50μH + 5Ω Artificial Mains Network(AMN) The ground plane was electrically bonded to the reference ground system and all power lines were filtered from ambient.
	Irradiated electromagnetic field	30MHz~1000MHz	30MHz~ 1000MHz	The irradiated emissions measurements were on the ten-meter, open-field test site. The EUT was placed on a non-conductive turntable approximately 0.1 meters above the ground plane.
IEC 61000-3-2:2006 + A2:2009	Voltage changes, voltage fluctuations and flicker	220V-230VAC	220V-230VAC	The voltage changes at the supply terminals were measured across the complex reference impedance Z=0.4+J0.25ohm. The short-term flicker values are measured during a time interval of 10 mintutes.
IEC 61000-3-3: 2008	Voltage changes, voltage fluctuations and flicker	220V-230VAC	220V-230VAC	The voltage changes at the supply terminals were measured across the complex reference impedance Z=0.4+J0.25ohm. The short-term flicker values are measured during a time interval of 10 mintutes.
IEC 60601-1-2: 2007	Electrostatic discharge immunity	Contact discharge: 2/4/6kV Air	Contact discharge: 2/4/6kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

		discharge: 2/4/8kV	discharge: 2/4/8kV	
	Irradiated RF E-Field (80 to 2500MHz)	80~2500MHz	80~2500MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Model 006, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\ P$ $d = 1.2\ P$ 80 MHz to 800 MHz $d = 2.3\ P$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range
	Electrical fast transient/Burst immunity	5kHz	5kHz	Mains power quality should be that of a typical commercial or hospital environment.
	Surge immunity	1kV(Line-Line of AC main) 2kV(Line-PE of AC	1kV(Line-Line of AC main) 2kV(Line-PE of AC main)	Mains power quality should be that of a typical commercial or hospital environment.

		main)		
	Conducted disturbance induced by RF fields immunity	3V	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Model 006, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\ P$ $d = 1.2\ P$ 80 MHz to 800 MHz $d = 2.3\ P$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range
	Power frequency	0.15~80MHz	0.15~80MHz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
	Voltage dips and short interruptions	Dips: 0.5 Cycle at >95% 5 Cycle at 60% 25 Cycle at	Dips: 0.5 Cycle at >95% 5 Cycle at 60% 25 Cycle at	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ultra Skin system requires continued operation during power mains interruptions, it is recommended that Ultra Skin be powered from an

		30% Short interruption: 5 secs at >95%	30% Short interruption: 5 secs at >95%	uninterruptible power supply.