



WON COSJET ATR S

User Manual
WT-UM-08, v4.4
Issue date: April 14, 2015

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.

- © Unless expressly authorized, forwarding and duplication of this document, and the utilization and communication of its contents are not permitted. Violations will entail an obligation to pay compensation.

All rights reserved in the event of a patent grant or a utility model registration.

EC Representative;
DONGBANG AcuPrime®
1 The Forrest Units, Hennock Road East Exeter
EX2 8RU, UK
TEL: +44 1392 826500 FAX: +44 1392 823232

Manufacturer;
WON TECH Co., Ltd.
64 Techno 8-ro, Yuseong-gu, Daejeon, Korea
TEL: +82 42 934 6800 FAX: +82 42 934 9491

Table of contents

★ SAFETY NOTES.....	5
1. INTRODUCTION	7
1.1 Intended Use	7
1.1.1 Description.....	7
1.1.2 Equipment application specification.....	7
1.2 Applications	8
1.2.1 Side effect	8
1.2.2 Contraindication.....	9
1.3 System Description	9
1.3.1 Laser System.....	9
1.3.2 Classifications	9
1.3.3 Beam Delivery System.....	10
1.4 Specifications and Requirements	10
1.4.1 Technical Specifications	10
1.4.2 Electrical Specifications.....	11
1.4.4 Environmental Requirements.....	11
1.4.4. Indication, Safety and Reference Symbols	12
2. SAFETY	14
2.1 General Safety Rules.....	14
2.2 Laser & Optical Hazards.....	14
2.3 Laser-Induced Risk of Fire	16
2.4 Electrical and Mechanical Hazards.....	17
3. GETTING STARTED	18
3.1 Scope of Delivery	18
3.2 Systems Features.....	21
3.3 Articulated Arm	23
3.4 Handpiece	25
3.5 Explanation of Term	26
3.6 Manu Description.....	27
4. INSTALLATION	28
5. HOW TO USE	30
5.1 Start-up.....	36
6. MAINTENANCE	41

6.1 General Information	41
6.2 Attention	41
6.2.1 General Attention	41
6.2.2 Individual Attention	41
6.3 Cleaning Procedure	42
6.4 Check Points	42
6.5 Technical Customer Service	43
6.6 Notice after Treatment	43
7. LABELING AND PACKAGING	44
7.1 Labeling of WON COSJET ATR S	44
7.2 Laser Operation Danger Labels	46
7.3 Packaging Label	47
7.4 Environment Requirements:	49
8. DISPOSAL	50
9. CONSUMABLES	51
APPENDIX 1	53

★SAFETY NOTES

CAUTION

Lift the device up using handles on the rear and front case of the device to pass over 20mm threshold. Check dangerous obstructions such as pens, medical instruments and etc. to prevent the device falling down.

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 Section 2, and that they are equipped with the correct safety 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 230V, 50Hz. Mains shall be grounded.

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 in contraindications.

WARNING

All people in the operating room should wear the safety goggles supplied by WON TECH and the place should be condemned warning mark at entrance of operating room.

WARNING

Do not touch the internal or connected parts of device because high voltages are used for the device. It may result in an electric shock.

WARNING

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

WARNING

Laser may be radiated 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.

WARNING

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

WARNING

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.

WARNING

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 EN 60825-1:2007.

NOTE

The beam stop according to 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 ATR S laser system is intended 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 ATR S laser system must be operated by a physician with a qualification of dermatology, nurse or any specialist, and who has been trained on the use of the product.

1.1.1 Description

The laser system is an effective treatment for dermal pigment lesion which can generate cancer factors.

1.1.2 Equipment application specification

1.1.2.1 Medical purpose

The WON COSJET ATR S Nd:YAG laser system has extended laser penetration into both epidermis and dermis without any damage to skin cells

1.1.2.2 Patient population

- 1) Age: More than 18 years old
- 2) Weight: Not relevant
- 3) Health: Not relevant
- 4) Nationality: Multiple
- 5) 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:
 - Skin surface
- 2) Condition: intact skin, treated skin

1.1.2.4 Intended operator

- 1) Education:
 - Dermatologist or physician trained by WON TECH
- 2) Knowledge:
 - Understands laser treatment procedures as a physician or dermatologist.
- 3) Language understanding:
 - English
- 4) Experience:
 - Dermatologist or physician trained by manufacturer.
- 5) Permissible impairments:
 - Impaired by 40% resulting in 60% of normal hearing at 500Hz to 2kHz
 - Mild reading vision impairment or vision corrected to log MAR 0.2(6/10 or 20/32)

1.1.2.5 Application

- 1) Environment
 - General:
 - Intended for professional use
 - Use at clean room of hospital for treatment

- Use on horizontal floor
 - There shall be no hazards of the eye. (All persons in an operational room have to put on the safety goggles during treatment.)
 - 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 $\pm 20^\circ$
- 2) Frequency of use:
- Once a week or two weeks for endpoint
- 3) Mobility:
- It has two handles for movement on rear and front part of the device.

1.2 Applications

The WON COSJET ATR S laser system is a 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 applications. This beam is directed to the treatment zone by means of the Articulated arm and specially designed 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; psychiatric disorders; unstable motivations; large fat volumes; and obesity.

1.3 System Description

1.3.1 Laser System

The WON COSJET ATR S laser system consists of an Nd:YAG laser head, a power supply, a cooling system, a delivery system and other electrical components. 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, 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.

The electro-optic modulator with a polarizer (Q-switched module) introduced into the cavity creates the ultra-short (2~40 ns) 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 and sets the treatment parameters and other functions operated by software on the graphical user interface.

1.3.2 Classifications

Under CDRH regulations in US FDA, the WON COSJET ATR S is classified as a Class II medical device. Under the Medical Device Directive, the WON COSJET ATR S is a Class IIb, non-invasive, active device according to Annex IX of Directive 93/42/EE. Under EN60825-1, the WON COSJET ATR S laser system safety level is Class 4.

According to EN60601-1(2006), 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: IPX0 (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 articulated ARM is to deliver the Nd:YAG laser energy and the diode laser aiming beam to the skin surface and handpiece as a distal end for radiation is to radiate the treatment laser and aiming beam. The output of built-in diode laser is a visible low power beam at a wavelength of 650nm. Since the output laser beam is invisible the aiming beam allows the user to see the surgical area to which the treatment laser will be delivered.

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

1.4 Specifications and Requirements

1.4.1 Technical Specifications

Technical Specifications

Laser Type	Q-Switched Nd:YAG Laser	
Wavelength:	1064 nm, 532 nm $\pm$ 10%	
Laser medium:	Nd:YAG	
Pulse energy	Genesis Mode	3500mJ
	PTP mode	1600mJ
	1064nm Mode	1300mJ
	532nm Mode	500mJ
Tolerance of pulse energy:	$\pm$ 20%	
Energy density(Fluenece)	Genesis Mode	0.1J/cm ² to 111J/cm ²
	PTP mode	0.1J/cm ² to 51J/cm ²
	1064nm Mode	0.1J/cm ² to 41J/cm ²
	532nm Mode	0.1J/cm ² to 16J/cm ²
Beam delivery:	Articulated ARM with Handpiece	
Spot size:	Circle, 2mm to 10mm	
Spot size for fractional mode:	5mm x 5mm – 9mm x 9mm	
Pulse width:	Genesis Mode	80 μ s to 480 μ s
	PTP mode	4ns to 48ns
	1064nm Mode	4ns to 48ns
	532nm Mode	4ns to 48ns
Pulse frequency:	1Hz to 10Hz	
Pilot laser:	Laser Diode, 635nm $\pm$ 5nm, <1mW, selectable intensity, CLASS 3A (IEC60825-1)	
User interface:	Touch LCD type	
Physical dimensions:	400x805.2x871mm (WxDxH)	
Weight:	60kg	
Cooling:	Water & Air cooling	

1.4.2 Electrical Specifications

For the WON COSJET ATR S 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 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 may interfere 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 ATR S on a power line that is not consistently within the specification may damage the system and may void the warranty.

WON COSJET ATR S Electrical Specifications

Line power requirements:	230VAC, 50Hz
Electric power consumption	4kVA

Foot Switch

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 ATR S 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 ATR S 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 ATR S laser system.

Sufficient floor space is required for the laser system. Approximately 40 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 ATR S 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 ATR S laser system has been tested and found to comply with the limits for medical devices in EN60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The WON COSJET ATR S laser system 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 ATR S 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:

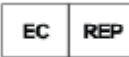
- Reorient or relocate the interfered device.
- Increase the separation between the devices.
- Connect the laser system to a mains outlet-socket not sharing other electrical devices.
- Consult the manufacturer or field service technician.

1.4.4 Indication, Safety and Reference Symbols

A. Indication Symbol

	USB port
---	----------

B. Safety & Reference Symbol

	Manufacturer
	Model name or reference number
	Representative in Europe
	Serial Number
	Follow the disposal procedure in this manual
	Date of manufacture
	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 ATR S LASER SYSTEM CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECAUTIONS ARE NOT TAKEN. CONSEQUENTLY, THE WON COSJET ATR S 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 ATR S 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 ATR S laser system qualifies as a class IIb device.

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

- Ocular (vision) damage resulting from exposure to direct or reflected laser radiation.
- 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 EN 60825-1. 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 ATR S LASER SYSTEM LIES IN THE VISIBLE AND INVISIBLE (NEARINFRARED) REGION OF THE ELECTROMAGNETIC WAVES.

USE ONLY SAFETY GOGGLE THAT IS KNOWN TO HAVE AN OPTICAL DENSITY OF 6.0 OR GREATER AT 1064 NM AND OPTICAL DENSITY OF 7.0 OR GREATER AT 532 NM, THE WAVELENGTH EMITTED BY THIS LASER SYSTEM. SAFETY GOGGLE 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 ATR S laser safety level is class 4.

The laser beam emitted by the WON COSJET ATR S 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 EN 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 Hand-piece. There is a distance from the Hand-piece, 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 laser safety goggles. Laser safety goggles must perform to specifications defined in the technical data.

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 safety goggle, available from WON TECH, provides adequate protection against reflected or scattered laser radiation, or inadvertent brief exposure to the laser beam. Laser safety goggle should be stored away from direct sunlight.

The protective goggle 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 procedures, the patient's eyes must be protected. The patient goggles provided by WON TECH are appropriate for most patients. Even when wearing protective goggle, looking directly into the path of the laser beam may cause permanent eye damage.

The laser beam emitted by the WON COSJET ATR S 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; 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 ATR S 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 and operate in the proper order.
- 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 only trained doctor should use.
- 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 are known to protect against the wavelengths emitted by the WON COSJET ATR S 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.
- Specify the parameter values just before the laser operation.
- Do not use the combustible anesthetic gas.
- Check the Stand-by 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 inside 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 of the laser 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 ATR S laser system was designed to comply with EN 60601-1-2 “Electromagnetic Compatibility Requirements and Tests.” A portion of EN 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 ATR S laser system converts and amplifies the AC line voltage to produce extremely high voltages inside the laser system. These voltages are very dangerous, and possibly even lethal.

It is possible for high-voltage components to retain a charge after the power supplement has been turned off, and even after the WON COSJET ATR S 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 device from moving, all the wheels must be locked. To lock the wheels, press the lever on the wheels down. To unlock the wheels, lift the lever up.

The WON COSJET ATR S 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.

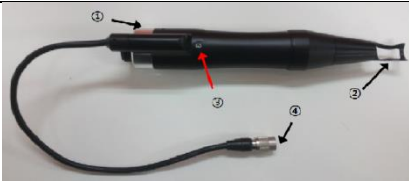
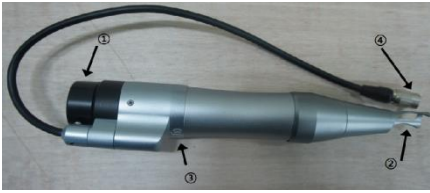
3 GETTING STARTED

3.1 Scope of Delivery

Check the box contents for all supplied accessories according to the packing list enclosed under the top cover of each box.

Carefully inspect the device console and all other accessories for any possible damages.

This device is provided as below. And, the device is installed by technicians qualified by WON TECH.

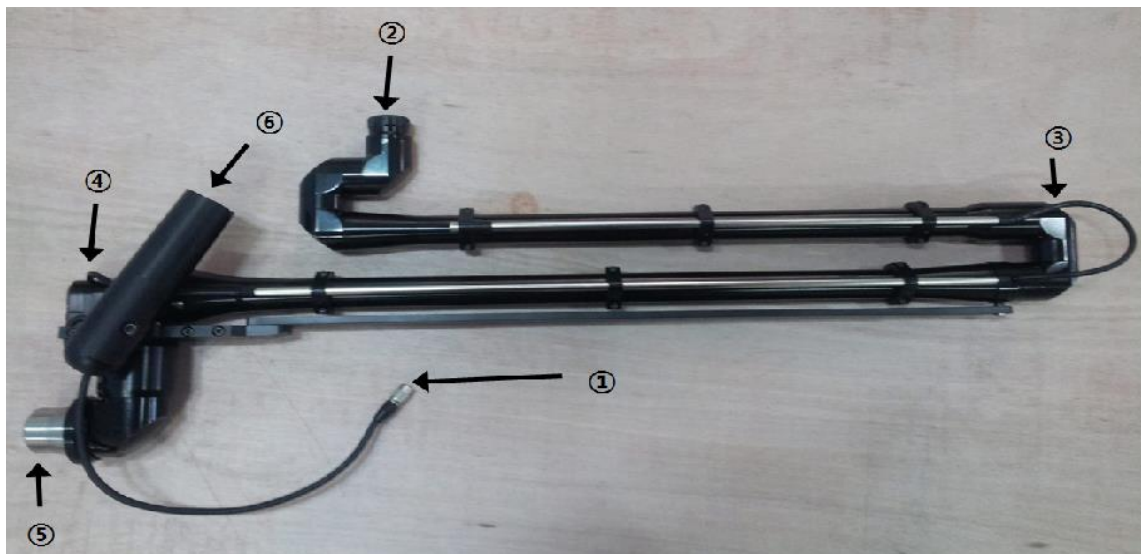
Main unit	Handpiece	
		Spring Type ARM of Zoom HandPiece
		Weight Type ARM of Zoom HandPiece
		Digital ARM of Zoom HandPiece
	 Fractional Handpiece(option) Handpiece (WT-Pastelle-HP-001)	
Foot Switch(WT-Pastelle-FS-001)	Protection Goggles for doctor (YL717C NdYAG2)	Protection Goggles for patient (YL-800W SAFETY EYE GUARD)



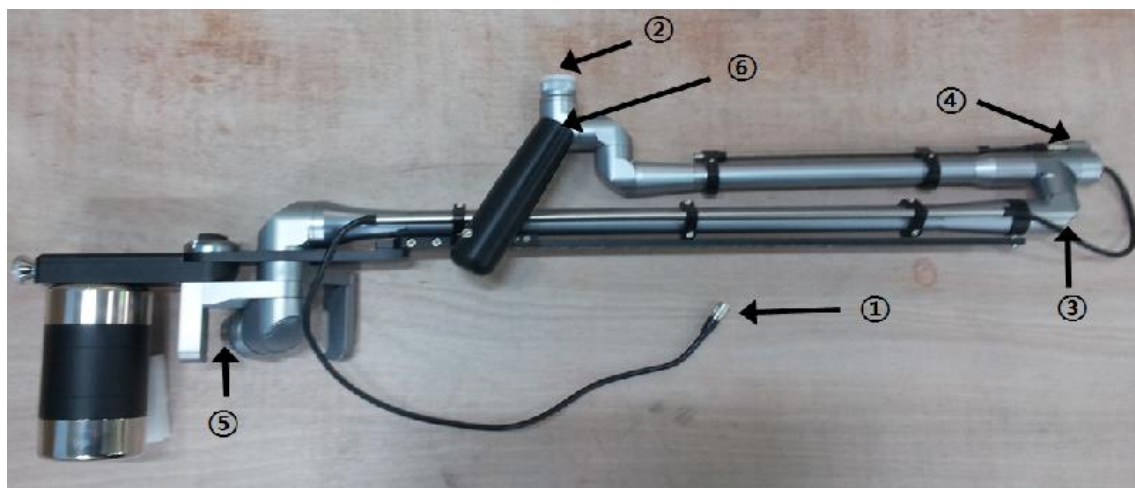
GUI image



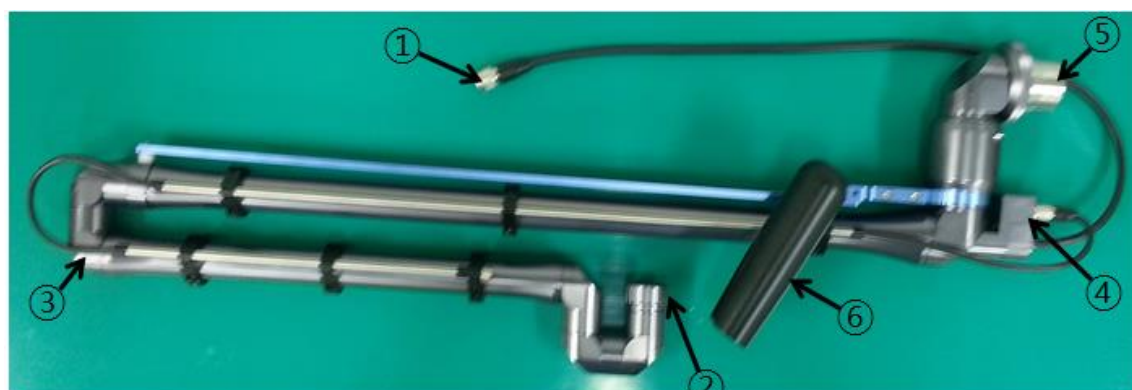
Articulated arm



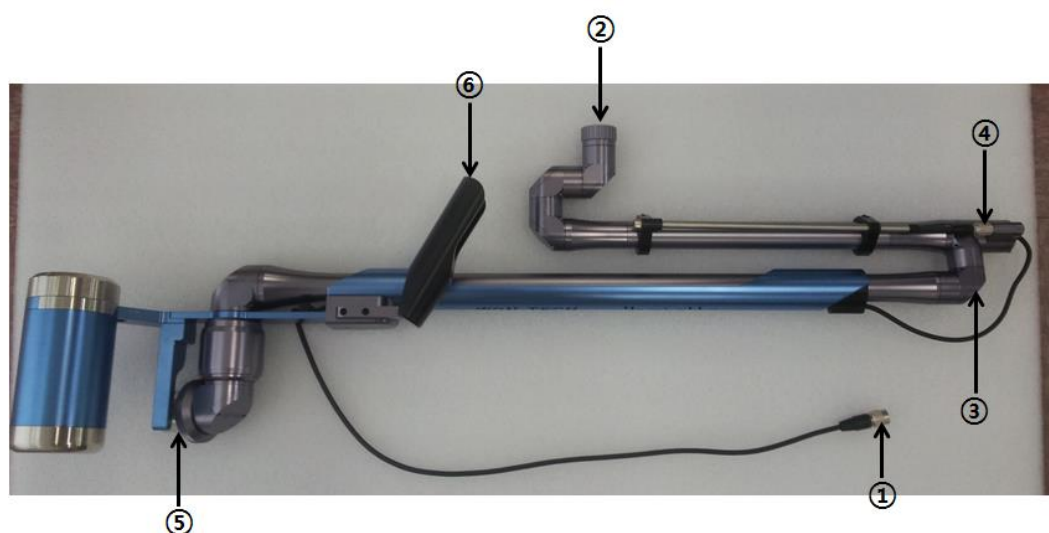
Spring Type ARM - A type



Weight Type ARM



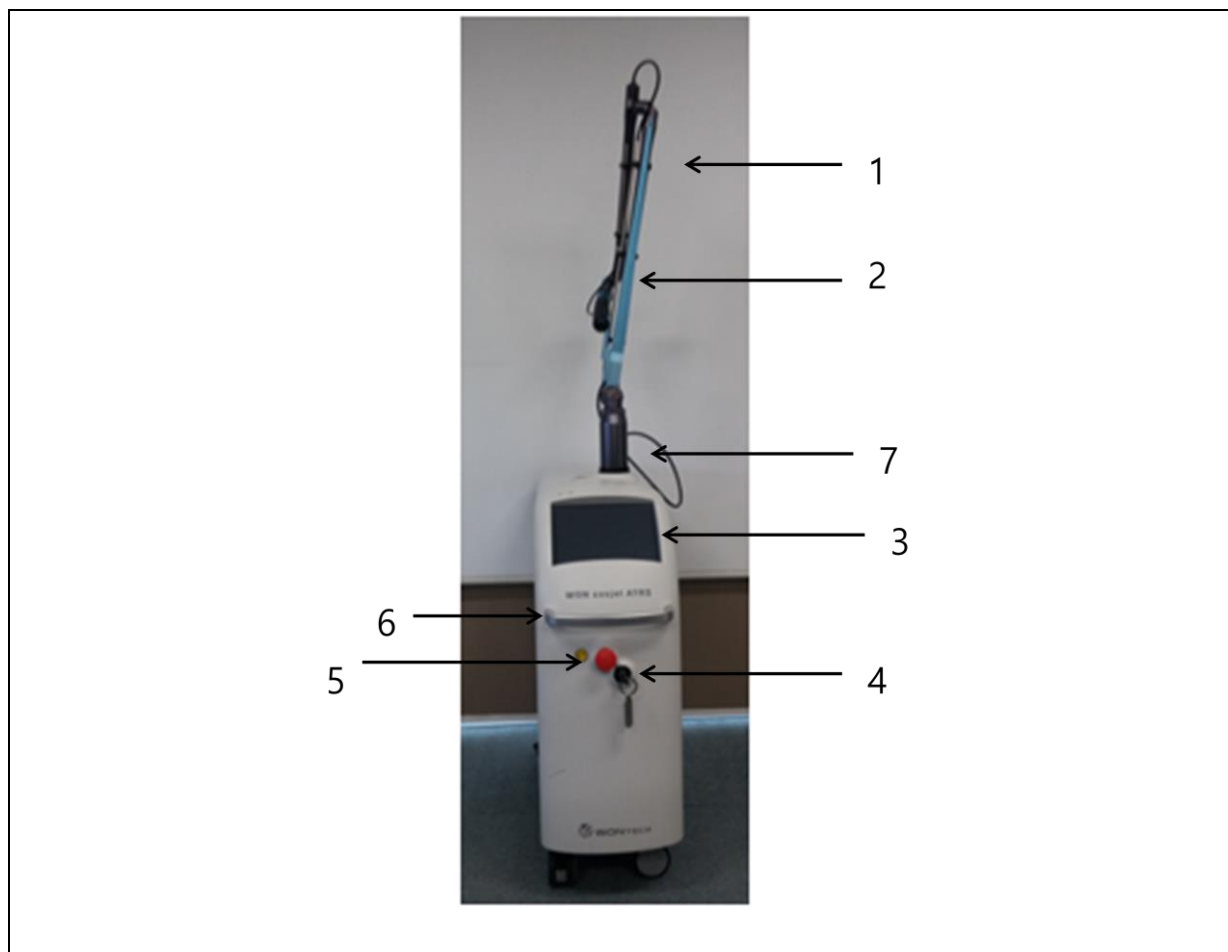
Digital Spring Type ARM



Digital Weight Type ARM

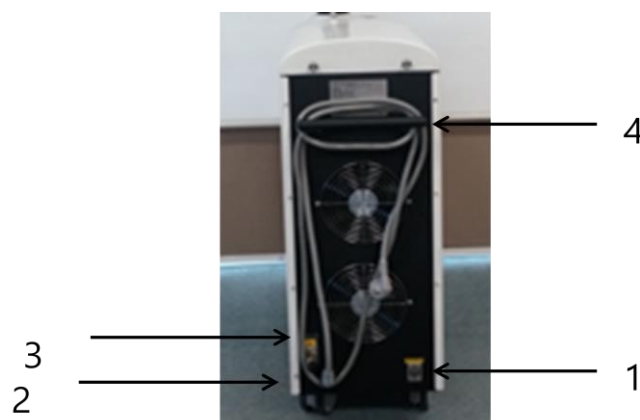
3.2 Systems Features

Front View



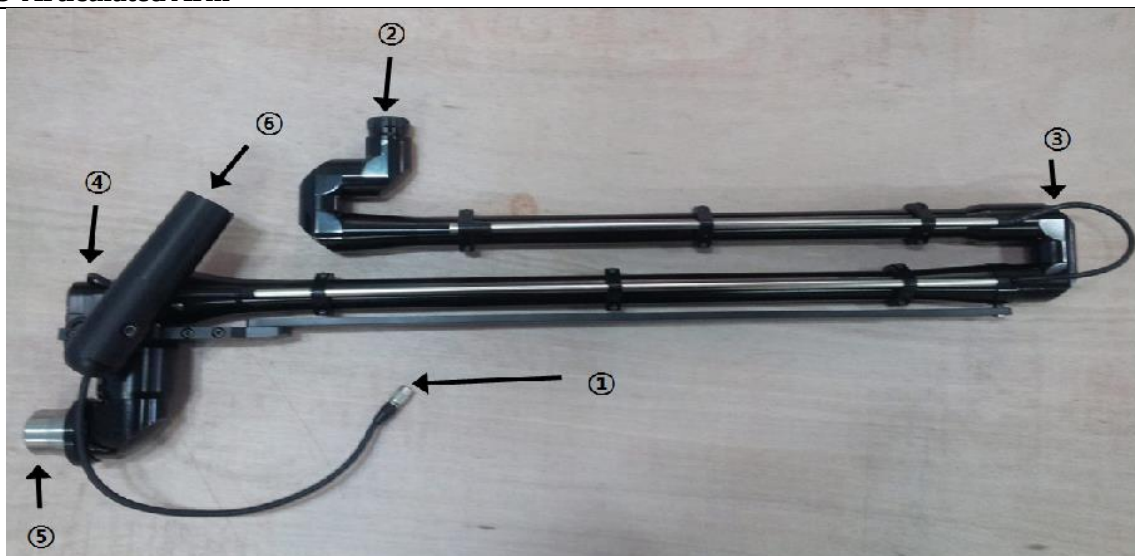
1. Articulate ARM: ARM as a delivery system delivers the treatment laser and aiming beam at the distal end of handpiece. ARM consists of mirrors for delivering lasers and 7 joints for freely moving.
2. Zoom Handpiece: Zoom handpiece controls the spot size of treatment laser turning the dial of handpiece. The spot size depends on the size of lesion.
3. Touch LCD monitor: LCD monitor provides a graphical user interface operators control the treatment parameters and extra functions. The graphical user interface is controlled by software.
4. Key switch: Key switch is turned clockwise to power on the device. Authorized persons shall keep the key of key switch to prevent accidental events.
5. Emergency switch: Emergency switch shuts down the device to prevent hazardous situations. The switch as a protective device shall not be out of reach.
6. Handle: Handle moves the device due to the device is heavy unit. Device falling should be careful.
7. Articulate ARM connection part : Articulate ARM connection and separation part at main body. Connection part radiates the treatment laser with aiming beam.

Rear View

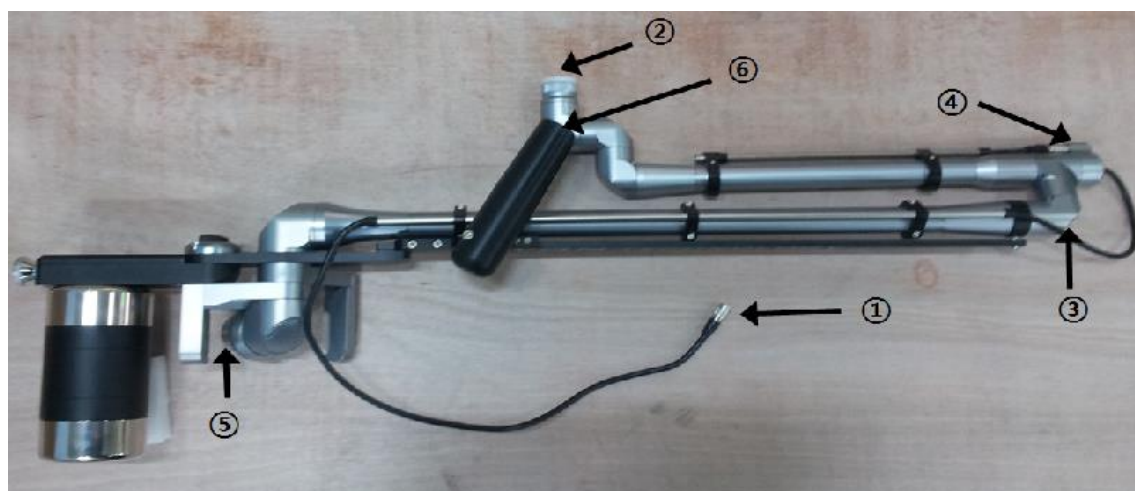


1. Foot switch terminal: Foot switch connector is connected the terminal to control the treatment laser. The foot switch connector shall be firmly connected to the terminal.
2. Power cable: Power cable supplies electrical energy from mains. The cable shall be connected to mains outlet-socket not sharing with other heavy power-load devices such as refrigerators or air conditioners.
3. Interlock terminal: Interlock connector as a protective device to stop radiating when the door of operating room opens during radiation is connected to the terminal.
4. Handle: Handle moves the device due to the laser console is heavy unit. Device falling should be careful.

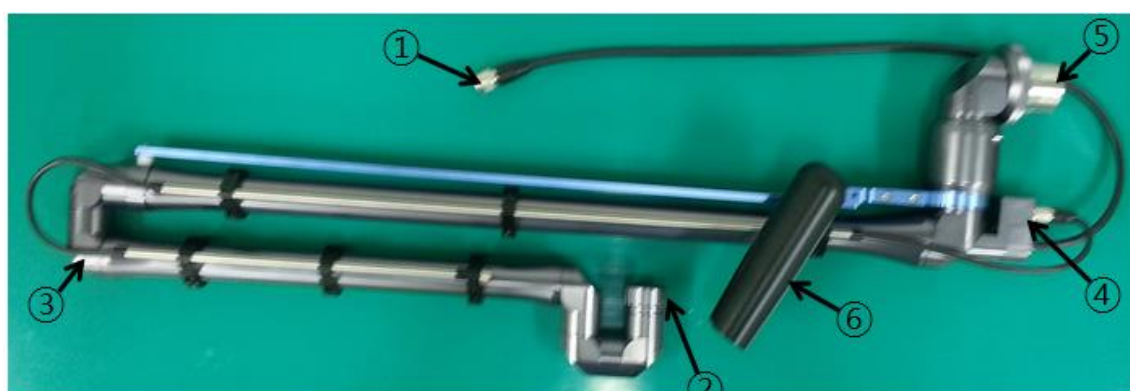
3.3 Articulated Arm



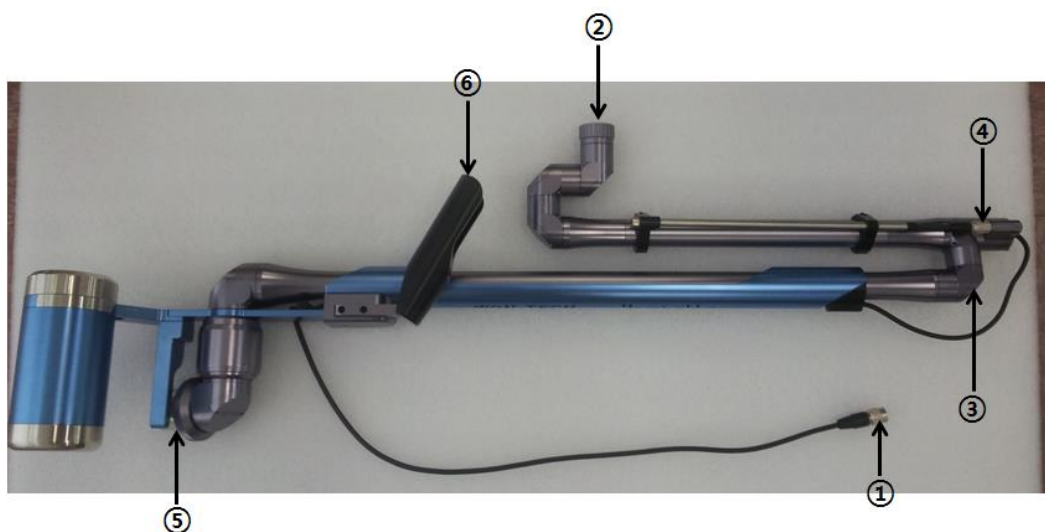
Spring Type ARM - A type



Weight Type ARM



Digital Spring Type ARM



Digital Weight Type ARM

- ① Auto spot cable: The auto spot cable controls the spot size that is indicated on the screen. Tuning the dial of handpiece for spot size change sends a signal indicating the spot size on the graphical user interface.
- ② Connection part for handpiece: A handpiece is connected with the connection part for the treatment laser radiation. The connection part shall be firmly screwed with handpiece.
- ③ Joint of Articulated ARM: The 7 joints of Articulated ARM make the handpiece operation during treatment convenient. Reflection mirrors are equipped at each joint.
- ④ Aiming beam: A laser diode provides the aiming beam to indicate the treatment zone.
- ⑤ Articulated ARM connector: The connector is connected with the terminal on the top case of device. The connector is connected with a laser head of the laser console.
- ⑥ Handpiece pocket: The pocket holds the handpiece not in use.

3.4 Handpiece



Spring Type ARM of Zoom HandPiece



Weight Type ARM of Zoom HandPiece



Digital ARM of Zoom HandPiece

- ① Connector connecting to the ARM: The connector is connected with Articulated ARM.
- ② Handpiece tip: The treatment laser is radiated with aiming beam from the distal end of handpiece. Operator shall not contact the handpiece tip to the skin surface of patient.
- ③ Spot size dial: The dial adjusts the spot size.
- ④ Auto Spot cable: The cable sending a signal to indicate the spot size on the screen is connected with the terminal of Articulated ARM.

3.5 Explanation of Term

Emergency Switch:

A switch for shutting down the device in hazardous situations

Key Switch:

A switch for supplying an electrical energy to the device

Foot Switch:

A trigger for radiating the treatment laser in Ready mode

All people in the operating room for treatment should wear the safety goggles supplied by WON TECH, and there should be a warning mark on the entrance of the place.

3.6 Manu Description



1. LOAD: Loads a saved treatment parameters on the screen.
2. SAVE: Saves the current treatment parameters on the screen.
3. User Mode: Indicates general information of the laser system on the screen.
4. Engineer Mode: Calibrates technical parameters. Authorized persons like technicians of WON TECH shall access the mode.
5. Standby: Changes from Ready mode to Standby mode or vise versa.
6. Reset: Reset the count to zero.
7. Calibration: Automatically calibrates the output energy of treatment laser.
8. Fluence(Energy density): Adjusts the value of energy density (0.1~64J/cm²).
9. Frequency: Adjusts the value of frequency (1~10Hz).
10. Spot Size: Indicates a spot size set from the dial of handpiece (2~10mm).
11. Up: Increases the treatment parameters.
12. Down: Decreases the treatment parameters.
13. 1064nm: Turns into 1064nm mode.
14. 532nm: Turns into 532nm mode
15. Genesis: Turns into long pulse mode at 1064nm.
16. PTP: Turns into PTP mode for double pulse laser.

- 1064nm mode: 1064nm laser is radiated Q-switching with pulse duration.(4-48ns)
- 532nm mode: 532nm laser is radiated Q-switching with pulse duration.(4-48ns)
- Genesis: 1064nm laser is radiated without Q-switching with long pulse duration.(80-480μs)
- PTP: Double pulse laser is radiated without Q-switching with double pulse duration.(4-48ns)

4 INSTALLATION

- 1) All components shall be installed by technicians of WON TECH. If you want to reinstall, please call the service center of WON TECH.
- 2) Connect the Articulated ARM to the mounting hole on the top.

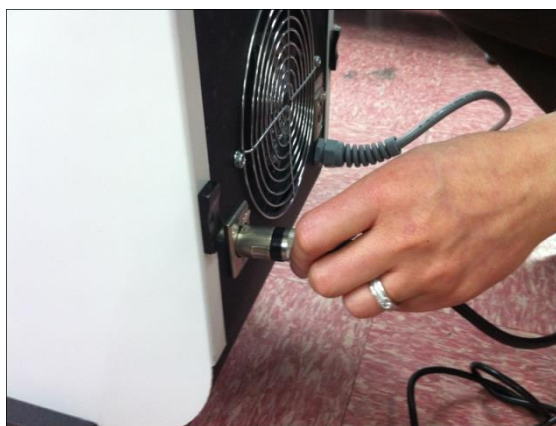
WARNING

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.

- 3) Plug the foot switch connector to the rear of the device. Be sure to connect between interlock of the connection part which is located the back and entrance hole and be regulate the access.

NOTE

FIRMLY CONNECT THE FOOT SWITCH CONNECTOR TO THE TERMINAL ON THE REAR OF DEVICE.



- 4) The lever on the wheels locks the wheels during treatment to prevent hazardous situations from the device movement. Press the lever down to lock the wheel. To unlock the wheels, lift the lever up.

**NOTE**

PLEASE MAKE SURE THAT THE EMERGENCY BUTTON IS WITHIN A REACH.

5 HOW TO USE

■ Instruction for Use

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

NOHD Calculation (WON COSJET ATR S)

1. Genesis mode (1064nm, 0.48ms)
2. Q-switching mode (1064nm, 48ns)
3. Q-switching mode (532nm, 48ns)

1. For the WON COSJET ATR S laser system, determine the intra-beam MPE for direct ocular exposure to the radiation from a Nd:YAG laser($\lambda = 1\,064\text{ nm}$) operating at a frequency of $F = 1\text{ Hz}$ with a pulse width of $t = 0.48\text{ ms}$ 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:

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

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:

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

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:

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

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

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

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 $C_5 = N^{-1/4}$). For the $N = 10$ pulses in the 1 s period, the radiant exposure under these criteria would be:

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

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 $0.115 \text{ J}\cdot\text{m}^{-2}$. The MPE could also be expressed in terms of irradiance as:

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

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):

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

Where:

NOHD is the Nominal Ocular Hazard Distance, in meters.

ϕ is the beam divergence, in radians. 0.005 radians

P_o is the laser output radiant energy, in joules. 3.5J at 1064nm

H_{MPE} is the appropriate per pulse Maximum Permissible Exposure, in joules/m². 0.115 Joules/m²

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, $H_{MPE} = 0.115 \text{ J} \cdot \text{m}^{-2}$ 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,

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

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

The NOHD for the rangefinder is therefore 149 m.

2. For the WON COSJET ATR S laser system, determine the intra-beam MPE for direct ocular exposure to the radiation from a Nd:YAG laser ($\lambda = 1064 \text{ nm}$) operating at a frequency of $F = 1 \text{ Hz}$ with a pulse width of $t = 20 \text{ ns}$ at Q-switching mode.

Wavelength = 1064 nm;

Peak power per pulse $P_p = 65 \text{ MW}$;

Energy per pulse $P_o = 1.3 \text{ J}$;

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

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

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

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

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

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

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

Average irradiance assessment (condition 13.3b))

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

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

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

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

Multiple-pulse assessment (condition 13.3c))

The maximum exposure duration for which requirement c) should be applied is T_2 in the wavelength range 400 nm to 1400 nm, where $T_2 = 10 \text{ s}$ for $\alpha \leq \alpha_{\min}$. Therefore, the correction factor $N^{-1/4} = (10)^{-1/4} = 0.56$ is used to calculate $H_{\text{MPE, train}}$:

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

The conclusion is that condition 13.3c) produces the most restrictive MPE per pulse and therefore, $H_{\text{MPE}} = 2.8 \times 10^{-2} \text{ J} \cdot \text{m}^{-2}$ 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,

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

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

The NOHD for the rangefinder is therefore 243 m.

3. For the WON COSJET ATR S laser system, determine the intra-beam MPE for direct ocular exposure to the radiation from a Nd:YAG laser($\lambda = 532$ 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

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

where $C_6 = 1$, therefore

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

Average irradiance assessment (condition 13.3b))

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

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

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

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

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 $H_{\text{MPE, train}}$:

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

The conclusion is that condition 13.3c) produces the most restrictive MPE per pulse and therefore, $H_{MPE} = 2.8 \times 10^{-3} \text{ J} \cdot \text{m}^{-2}$ 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,

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

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

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: 1mm Tolerance: $\pm 20\%$ Aiming Beam: 3mm $\pm 20\%$			
Pulse duration	Genesis Mode	PTP Mode	1064nm Mode	532nm Mode
	Max: 480 μs Min: 80 μs Tolerance: $\pm 20\%$	Max: 48 μs Min: 4 μs Tolerance: $\pm 20\%$	Max: 48ns Min: 4ns Tolerance: $\pm 20\%$	Max: 48ns Min: 4ns Tolerance: $\pm 20\%$
Maximum Energy	Genesis Mode: 3500mJ PTP Mode: 1600mJ 1064nm Mode: 1300mJ 532nm Mode: 500mJ			

-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 pulsed laser energy.

1. As the main power 230VAC is supplied to the system, and 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 keeps monitoring whether fan, pump, thermometer and other sensors properly work.
4. In Ready mode, when user steps on the foot switch, the setting energy on screen will be radiated at the distal end of the handpiece.

- After finishing the operation of the device, it should remove the key from the key switch. Unauthorized persons shall not turn on the key switch to prevent hazardous situations.
- 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 handpiece connecting with 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 Start-up

- 1) Put on the safety goggles for eye protection. Turn on the key switch. Wait a few seconds until the main menu appears on the screen.

NOTE

IT WOULD BETTER TO PRESS THE MONITOR BUTTON USING NAIL BETTER THAN FINGER TIP.

- 2) During booting, the logo of company appears on the screen. The main menu appears on the screen if there is no problem after self-check. After that, the device is in Ready mode. If the device has a technical problem during self-check, an error message appears on the screen with buzzer. This device provides the graphical user interface to control the treatment parameters and extra functions.



- 3) After the above the initiation process, the below display appears.



- 4) In Standby mode, operator controls the treatment parameters and extra functions. After pressing the Standby button to enter in Ready mode, step on the foot switch for radiating the treatment laser. For again entering in Standby mode, press the Ready button. Operator cannot adjust any parameters in Standby mode.



- 5) Change the treatment parameters at each treatment mode depending on each treatment session.



- 6) Press the Reset button to return the counter to zero.



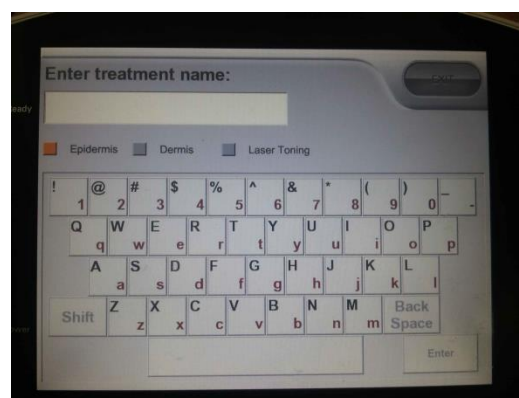
- 7) Depending on the size of treatment zone of patient, set the spot size of zoom handpiece. The spot size on the screen shall be set with matching the spot size adjusted by the dial of zoom handpiece.



- 8) Pressing the Load button loads treatment parameters saved on the screen. Operator uses the load function for the effective treatment in clinical treatment parameters.



- 9) Pressing the Save button saves the current treatment parameters. Save clinical parameters for the future treatment session of your patients.

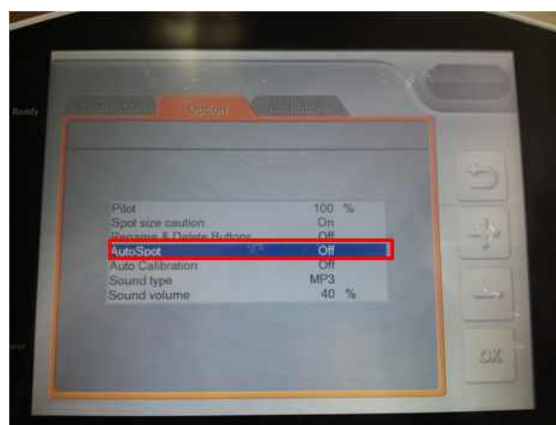


- 10) During radiation of treatment laser with aiming beam, if hazardous situations occurred, press the emergency switch to shut down the device. An alarm message appears on the screen. For returning in Standby mode, release the emergency switch. After that, press the ☒ button for returning to Standby mode.



11) Extra functions

The fractional handpiece as an optional component is connected with Articulated ARM after separating the zoom handpiece from ARM. After connecting the fractional handpiece, turn off the device after setting the off mode of Auto spot in the option of User mode. Operator shall purchase the fractional handpiece from WON TECH. Any fractional handpiece other than the fractional handpiece of WON TECH shall not used for treatment.



After turning on the device again, pressing the fractional button on the screen indicates the spot size of fractional handpiece.



12) Power off the device turning the key counterclockwise.

6 MAINTENANCE

6.1 General Information

- (1) After use, wipe the tip of handpiece which was contacted with the patient with alcohol according to the procedure indicated 6.3 section. Isopropyl alcohol can be purchased at any local store.
- (2) Once a week, wipe the exterior sides of WON COSJET ATR S 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 ATR S laser system is not in use.
- (5) Handle the Articulated 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 ATR S laser system is not in use for a period longer than one day, unplug power plug.
- (8) Follow local governing ordinances and recycling plans regarding the disposal or recycling of device components.
- (9) Routine cleaning of the Handpiece safety glass and tip instruction is explained in the following sections for user (Operator as trained doctor).
- (10) All other maintenance and service must be performed by a qualified service representative.

6.2 Attention

6.2.1 General Attention

- Do not operate the laser without a skilled doctor or designated specialist indicated in intended use part. Check the device working before operation.
- Call a technical engineer when the laser shows unusual signals or troubles.
- Do not put any foreign parts to the unit or remove any components from the unit.
- Check the device not in use before operating.

6.2.2 Individual Attention

- Do not look at the laser aperture directly.
- While the laser is in use, all people in the treatment area should wear the safety goggles.
- Do not use the laser with the flammable anesthetic or in the volatility matter areas.

- Use the laser carefully in the high voltage.
- Please allow at least 20 cm between the device and the wall.
- Use appropriate anesthesia cream.
- Do not touch the device with wet hand.

6.3 Cleaning Procedure

Operator (Dermatologist or Physician) or nurse must clean Handpiece tip and safety glass after treatment for patient. Hand-piece 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 below.

1. Unscrew the handpiece from the Articulated ARM.

2. Pull out tip to detach it from Handpiece

3. Prepare a swab with isopropyl alcohol to clean the handpiece tip.

4. Clean any dust on the safety glass to prevent an optical damage of the delivery system.

5. After each treatment, for health of patient, clean the Handpiece tip (contacted part to patient) using a cotton swab moistened with isopropyl 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 safety glass with alcohol swab or lens paper.

6.4 Check Points

When the device does not give any particular response.

- Please check the power cord connected to mains.
- Please check the mains power is inappropriate.
- Please check the key switch and emergency switch are activated.

When the laser beam is not generated, despite of stepping on the foot switch.

- Please make sure the device is in Ready Mode.
- Please make sure the foot switch cable is firmly connected to the terminal of device. An error message appears on the screen if it is not firmly connected.

6.5 Technical Customer Service

WON TECH Co., Ltd.
64 Techno 8-ro, Yuseong-gu, Daejeon, Korea
Website: <http://www.wtlaser.com/>
TEL: +82 42 934 6800
FAX: +82 42 934 9491

If the device seems to be defective or not operated, please contact the service team immediately. Do not try to repair the device by yourself. No modification or dismantle is permitted.

WON TECH will not be responsible for any damage that is caused by other than WON TECH certified service team.

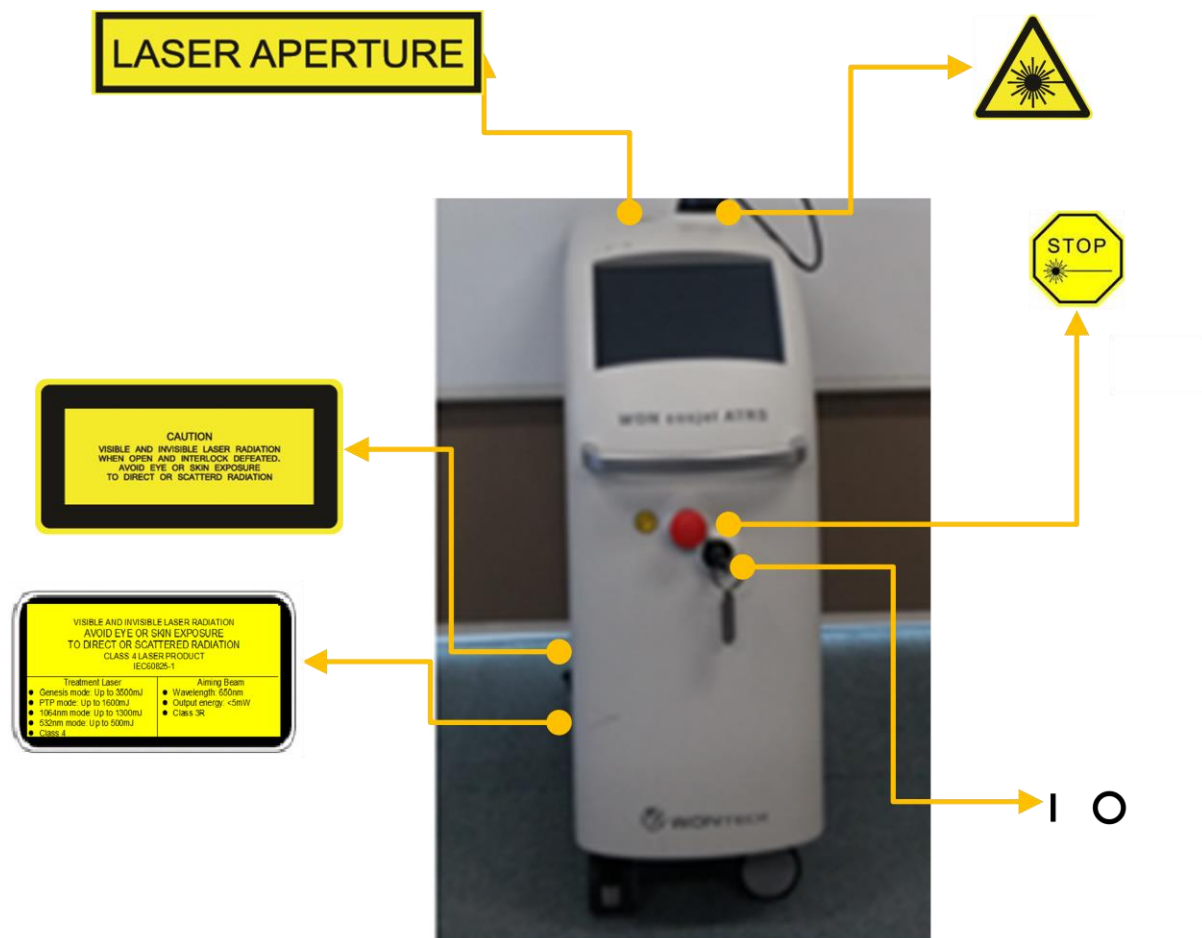
6.6 Notice after Treatment

- Although simple shower or washing the face on the day of operating after the treatment is possible, we recommend to wash the treated areas after couple of days. If the patient needs to wash the face, we recommend that the patient gently sprinkle water on the face, use the foam of the soap, then massage gently. When the patient rinse, he/she should not rub, scrub or press the skin.
- Patients should avoid any strenuous exercise that can cause sweating or contacts with water such as swimming. Patients should avoid any humid or wet places like sauna.
- Patients can put on make up after the treated areas form scabs. However, we recommend that patients do not put on make up until the scabs fall off naturally.
- Scabs generally peel off after 7-10 days. If the scabs are picked off or fall off prematurely from being soaked (i.e. sauna), the treated areas can become red and pigments can build up after a few days. It is highly recommended to let the scabs to fall off naturally.
- To prevent pigmentations on the treated areas, patients must put on sunscreen even when indoors during the daytime or on cloudy days.

7 LABELING AND PACKAGING

7.1 Labeling of WON COSJET ATR S

Package & Label according to ISO15223-1(2012) and IEC60825



 : WON TECH Co., Ltd.
64 Techno 8-ro, Yuseong-gu, Daejeon, Korea

REF : **WON COSJET ATR S** (Q-switched Nd:YAG Laser)

EC REP : DONGBANG AcuPrime®
1 The Forrest Units, Hennock Road East
Exeter, EX2 8RU, UK
Tel. +44 1392 826500 Fax. +44 1392 823232

SN :

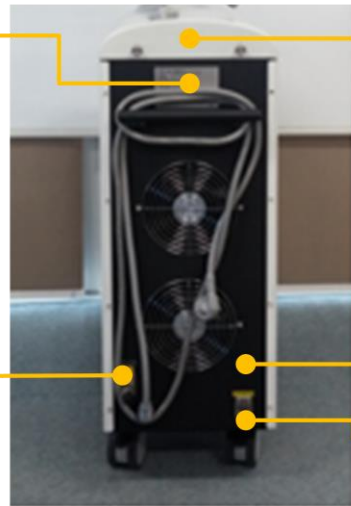
Input Power : 230V ~, 50Hz, 4.0KVA

 Please read user's manual before using this equipment!!

CE 0476



FOOT SWITCH



 : WON TECH Co., Ltd.
64 Techno 8-ro, Yuseong-gu, Daejeon, Korea

REF : **WON COSJET ATR S** (Q-switched Nd:YAG Laser)

EC REP : DONGBANG AcuPrime®
1 The Forrest Units, Hennock Road East
Exeter, EX2 8RU, UK
Tel. +44 1392 826500 Fax. +44 1392 823232

SN :

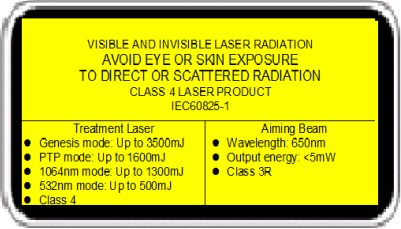
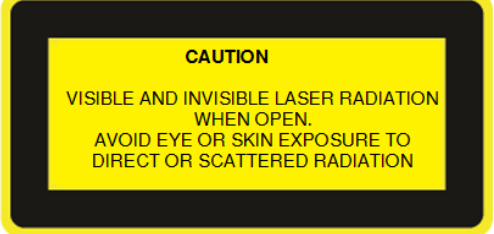
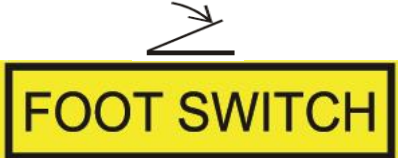
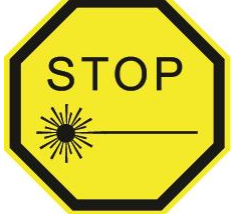
Input Power : 230V ~, 50Hz, 4.0kVA

 Please read user's manual before using this equipment!!

CE 0476

7.2 Laser Operation Danger Labels

Laser warning labels according to IEC60825-1

 VISIBLE AND INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT IEC60825-1 <table border="1"> <tr> <td>Treatment Laser</td> <td>Aiming Beam</td> </tr> <tr> <td>• Genesis mode: Up to 3500mJ</td> <td>• Wavelength: 650nm</td> </tr> <tr> <td>• PTP mode: Up to 1600mJ</td> <td>• Output energy: <5mW</td> </tr> <tr> <td>• 1064nm mode: Up to 1300mJ</td> <td>• Class 3R</td> </tr> <tr> <td>• 532nm mode: Up to 500mJ</td> <td></td> </tr> <tr> <td>• Class 4</td> <td></td> </tr> </table> This label informs about the dangers, the maximum values of energy emitted by, and the classification of, the laser source.	Treatment Laser	Aiming Beam	• Genesis mode: Up to 3500mJ	• Wavelength: 650nm	• PTP mode: Up to 1600mJ	• Output energy: <5mW	• 1064nm mode: Up to 1300mJ	• Class 3R	• 532nm mode: Up to 500mJ		• Class 4		 CAUTION VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION Indicating the interlock location
Treatment Laser	Aiming Beam												
• Genesis mode: Up to 3500mJ	• Wavelength: 650nm												
• PTP mode: Up to 1600mJ	• Output energy: <5mW												
• 1064nm mode: Up to 1300mJ	• Class 3R												
• 532nm mode: Up to 500mJ													
• Class 4													
 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 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 Foot switch attached to connection part	 Interlock Notified for Interlock												
 Protection ground connection indication. EN60601-1	 Power ON/OFF EN60601-1												
 STOP EN60601-2-22 Emergency stop Remarked on the front, Emergency switch indication. This sign designates the EMO pushbutton for express shutdown of laser emission.	 DANGER LASER OPERATING Laser warning label (US) This label informs about the dangers, the maximum values of energy emitted by the laser source.												

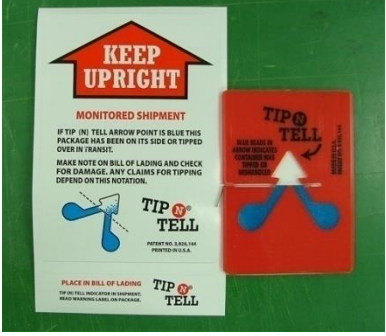
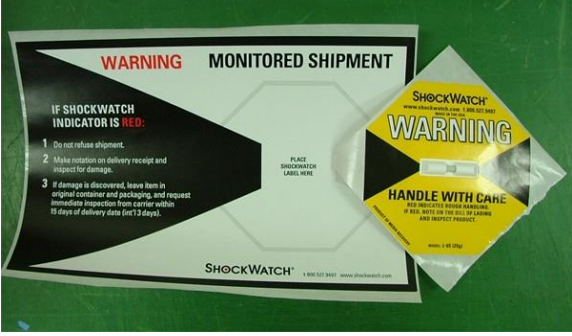
 60417-5264(DB:2002-10) "ON" for a part of equipment	
---	--

7.3 Packaging Label

Package & Label according to ISO15223-1(2012)



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

	
Keep-upright indicator	Shock Watch indicator

 	WON TECH BOX WON COSJET ATR S (Nd:YAG Laser System) SN: xx(xxx)xxx-xxx 
Precaution Mark	Company name & Product Serial Number

7.4 Environment Requirements:

- **Transport and Storage Condition**

Temperature: - 20 °C to 60 °C

Humidity: 0 % to 90 %,

Pressure: 70 kPa to 106 kPa

- **Operation condition**

Temperature: +10 °C to 40 °C,

Humidity: 30 % to 75 %,

Pressure: 70 kPa to 106 kPa

8 DISPOSAL

The WON COSJET ATR S laser system must be disposed in accordance with WEEE Directive 2012/19/EU 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 contact our Technical Customer Service on questions of any kind.

9 CONSUMABLES

1) Protection Goggles for doctor (2ea)-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 goggle 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 two Protection Goggles for operating doctor.)
- After using and washing the Protection goggles, you should clean this one with the clean towel in the Goggles pocket.
- If you consumed all of goggles, you should buy the Protection Goggle 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 Protection Goggle.**
- **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**

2) Protection Goggle for patient (YL-800W SAFETY EYE GUARD)



- Notified body 1096(CE mark)
- Luminous Transmittance: 0%
- This laser goggle protects the eyes 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 goggle shall be stored at a temperature between -10°C and +55°C 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 Protection goggles, you should clean this one with the clean towel in the Goggle pocket.
- If you consumed all of goggles, you should buy the Protection Goggle it has a precise effect and qualified from manufacturer. Call to the service center (+82 42 934 6800).
- **Warning: Do not look directly into the laser beam even if you are wearing this goggles.**
- **This product shall only be used for the indicated lasers, not for others.**

APPENDIX 1

Guidance and manufacturer's declaration – electromagnetic immunity

Standards		Test level	Compliance level	Electromagnetic environment-guidance
EN 55011: 2009 + A1: 2010(Class A, Group 1)	Mains terminals continuous disturbance voltage	0.15MHz~30M Hz	0.15MHz~30M Hz	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.
	Radiated electromagnetic field	30MHz~1000M Hz	30MHz~1000M Hz	The radiated 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.
EN 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 $Z=0.4+J0.25\text{ohm}$. The short-term flicker values are measured during a time interval of 10 minutes.
EN 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 $Z=0.4+J0.25\text{ohm}$. The short-term flicker values are measured during a time interval of 10 minutes.
EN 60601-1-2: 2007	Electrostatic discharge immunity	Contact discharge: 2/4/6kV Air discharge: 2/4/8kV	Contact discharge: 2/4/6kV Air discharge: 2/4/8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Radiated 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 WON COSJET ATR S, 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, 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 main)	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.
	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 WON COSJET ATR S, 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, 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 30% Short interruption: 5 secs at >95%	Dips: 0.5 Cycle at >95% 5 Cycle at 60% 25 Cycle at 30% Short interruption: 5 secs at >95%	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WON COSJET ATR S system requires continued operation during power mains interruptions, it is recommended that WON COSJET ATR S be powered from an uninterruptible power supply.