WONTECH

PICOCARE

USER MANUAL

WT-UM-36, v1.0
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***Caution**
Federal law restricts this device to sale by or on the order of a physician.

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.

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* 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 etc. to prevent the device falling down.

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 230 V~, 50Hz. Mains shall be grounded.

CAUTION

Do not draw the device on the threshold or obstacle when moving the device. Carefully use the handles of the device and watch your step..

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.

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.

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 exposed 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

Do not use combustible anesthetics (ex: flammable gas anesthetic or anesthesia such as halothane or enflurane gas.), which might cause the ignition by laser beams.

WARNING

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

WARNING

The smoke caused from the device during the operation can be harmful to the body. It is recommended to install the ventilator if you use the device for a long period.

WARNING

The tip of the handpiece shall not be in contact with intact skin of the therapeutic part.

WARNING

To avoid the risk of electric shock, connect the device only to a main power supply with a protective earth ground.

WARNING

Device could interference with other electric devices.

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.

NOTE

In the context of this Standard, "laser" radiation is understood to cover optical radiation as specified in EN 60825-1.

NOTE

The beam stop (attenuator) according to 4.8 of EN 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 INDICATION FOR USE

Picocare is indicated for use in aesthetic applications at the specified wavelength:

532 nm – removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

1064 nm – removal of tattoos for all skin types (Fitzpatrick I-VI) to treat tattoo colors: black, brown, green, blue and purple.

*** Nd:YAG Laser system**

A certain amount of electric power set by the LCD monitor is permitted to the laser resonator by the power supply.

Then, the laser resonator delivers the electrical energy to the flash lamp which converts the electrical energy into the light source. This concentrated light source is radiated on the medium of Nd:YAG, resulting in the ultimate laser energy source.

The laser energy generated by the medium of Nd:YAG is converted to the heat energy once it gets to human skin surface and used for a variety of medical purpose such as an ablation, incision and removal of targeted tissue.

WARNING

A physician or a dermatologist who has been trained on the use of the product must operate the device.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

1-2 APPLICATION SPECIFICATION

a. Medical purpose

The PICOCARE Nd:YAG laser system provides extended laser penetration into both epidermis and dermis without any damage to skin cells. It is an effective aesthetic treatment for tattoo removal.

b. Patient population

① Age: More than 22 years old
② Weight & Height: Not relevant
③ Nationality: Multiple
④ Patient State: Patient is not operator: not relevant, unless patient is agitated.

c. Part of the body or type of tissue applied to or interacted with

① Treatment site: Skin surface
② Condition of skin: intact or previously treated.

d. Operator Qualification

① Education: Dermatologist or physician trained by WON TECH, who understands las er tre atment procedures.
② Language of understanding: English
③ 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)

e. Clinical Environment

① Intended for professional use at all times.
② Use the device always at a clean room of the hospital and on the horizontal floor.
③ There shall be no damage to the eyes. (All of persons in an operational room have to put on the goggle for safety during laser radiation)
④ Conditions of visibility: Ambient luminance range;300~750lux / Viewing distance; 20cm to 40cm / Viewing angle; normal to the display ± 20°
⑤ Frequency of clinical application: Once a week or two weeks to the endpoint
⑥ Equipment mobility: The device has two handles for movement on rear and front part of the body.

1-3 CLINICAL APPLICATIONS

The PICOCARE laser system is a flash lamp pumped, Q-Switched Nd:YAG(Neodymium- doped Yttrium Aluminum Garnet). It has both near infrared (1064 nm) and visible (532 nm) pulsed laser. 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 .
It is a high performance Q-Switched Nd:YAG laser system designed for tattoo removal in aesthetic dermatology. It has an extremely uniform beam profile that allows the user to raise the fluence without creating hot spots on the skin.

The user of this equipment should review the published literature concerning Nd:YAG laser infrared (IR) dermatological administration of laser energy for a more detailed description of the laser-initiated photothermolysis process.

1-4 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 scrapped. 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 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 can be prescribed.

Ink darkening: When the laser is applied on cosmetic tattoos, it can worsen or darken the color. This is most likely 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. In spite of that, complications of laser treatment are rare. A few individuals do develop thickening of the skin. This thickening known as granuloma is most like ly due to ink particles embedded in scavenging cells. The granuloma may be seen as small bumps on the skin. When lasers are used near the eye, hair loss and anatomical distortion of the eye lids have been known to occur

1-5 CONTRAINDICATION

Picocare laser therapy is contraindicated for individuals who has:

1. Pregnancy
2. Bleeding disorders
3. Immune deficits
4. Heart, liver, and kidney insufficiency
5. Allergies to local anesthetics
6. Pacemaker and serious heart rhythm disorders
7. Psychiatric disorders or unstable motivations
8. Obesity or large fat volumes
9. Keloid skin - Persons known to form skin keloids may be more prone to scarring after any skin trauma, including laser administration to the skin.
10. Cancerous lesion - Treatment of lesions or treatment near lesions that are known to be or suspected of being cancerous are contraindicated.
11. Dark skin - Persons with dark skin may be at increased risk of hypopigmentation. Hypo and hyper-pigmentation are a common risk of treatment.
12. Treatment around the eyes - Any treatment around the eyes is contraindicated due to the risk of laser light induced eye injury. The PICOCARE Nd:YAG laser system is a Class IV laser product and both the direct and reflected beam can cause damage to eyes or the skin. Proper precautions should always be taken to prevent injury. Always observe ALL safety issues outlined later in this section.

1-6 SYSTEM DESCRIPTION

a. Operation Principle

The electro-optic modulator with a polarizer (Q-switched module) introduced into the cavity creates the picoseconds pulse 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.

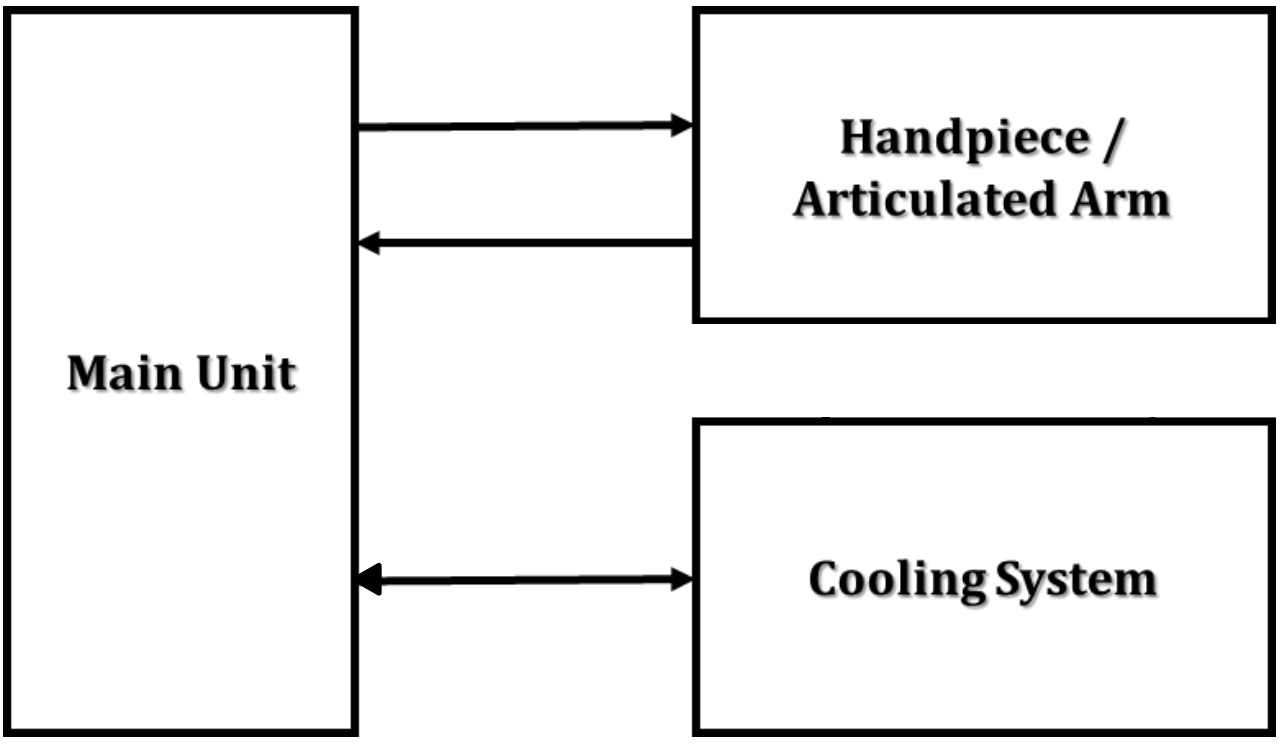
The system delivers laser energy at a wavelength of 1064 nm, 532nm. The output of the laser is delivered to the area of treatment through an articulated ARM with a handpiece. A trigger (foot switch) controls the delivery of pulses.
The user selects and sets the treatment parameters and other functions operated by software on the graphical user interface.

•Function and Operating Principle

The Main Unit of Picocare is electrically connected to the facility power source. Laser energy produced by the Main Unit is delivered to the tissue through the articulated arm and handpiece. The Foot Switch is used to commence operation of the laser. The Picocare is operated with the software by controlling the main program. The software controls all the treatment parameters and extra functions to perform all treatment procedures.

Item	Description
Main Unit	Picocare is capable of emitting wavelengths of light, 1064 nm and 532 nm. This Main Unit controls the fluence (energy density) and frequency, and also provides visual feedback of the number of pulses and spot size.
Handpiece/ Articulated Arm	The Zoom handpiece is used at either 1064 or 532 nm and allows the spot size on the skin to be adjusted from 2 to 10 mm in steps of 1 mm. The Optional Fractional handpiece is used at 1064 nm/532 nm and allows the spot size on the skin to be adjusted from 5 x 5 to 9 x 9 mm in steps of 1 x 1 mm. The Optional Dye handpiece is used to provide 585 nm treatment capability. In addition, these handpieces do not contain any parts which be contacted with the body of patient. The handpiece shall be connected to an articulated ARM for the output of the laser to be delivered to the area of treatment.
Cooling System	This part consists of the internal water flow circuit together with water to air heat exchanger.

[Function Diagram]



b. Classifications

This device is designated as Class I, Type B equipment per 60601-1. There are no special provisions to protect the system from flammable anesthetics or ingress of liquids.

FDA : This laser is classified by the as a Class IV laser product. This means that the invisible laser light produced is considered hazardous to the eyes and skin when viewed directly or indirectly.

According to IEC 60601-1(2012), 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), IP68 (Foot Switch)
4. Method of sterilization: Not Applicable
5. Suitability for use in an oxygen rich environment: Not Applicable
6. Mode of operation: Continuous

c. Beam Delivery System

The articulated ARM is to deliver the Nd:YAG laser energy and the guide beam. The articulated ARM consists of seven high reflection mirrors mounted at the special joint ARM, freely rotated in different directions.

Since the output laser beam is invisible, the guide beam allows the user to see the surgical area to which the treatment laser should be delivered. The output of diode laser built-in the guide beam is a visible low power beam at a wavelength of 635nm.

The handpiece with the focusing lens is mounted at the end of the ARM. The handpiece as a distal end for radiation is to radiate the treatment laser and guide beam. 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.

1-7 SPECIFICATIONS AND REQUIREMENT

a. Technical Specifications

Irradiation type	Nd:YAG
Wavelength	1064nm, 532nm,
Max. energy	600mJ(1064nm), 300mJ(532nm)
Pulse duration	600~800ps(1064nm), 600~800ps(532nm)
Peak power	~0.8GW(1064nm), ~0.4GW(532nm)
Spot size	Max. 10mm
Repetition rate	Single, 1~10Hz
Delivery	Articulated arm
Optional handpiece	Fractional Handpiece (1064nm or 532nm) Dye Handpiece (585nm)
Dimension	450x940x908(WxDxH)mm
Weight	80Kg

b. Environment requirements

Before installation of the PICOCARE 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 PICOCARE 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 PICOCARE laser system.

Sufficient floor space is required for the laser system. Approximately 20 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 PICOCARE laser system is not suitable for use in the presence of a flammable mixture with air or with oxygen or nitrous oxide.

The PICOCARE laser system has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The PICOCARE 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 PICOCARE 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:

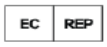
- Reorient or relocate the interfered device.
- Increase the separation between the devices.
- Connect the laser system to a mains outlet-socket not sharing other electrical devices.
- Consult the manufacturer or field service technician.

c. Indication, safety and reference symbols

A. Indication Symbol

Symbols	Description
	USB port

B. Safety & Reference Symbol

Symbols	Description
	Manufacturer
REF	Model name or reference number
	Representative in Europe
SN	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
IP68	Protected against the effects of continuous immersion in water
	Foot switch
	“ON” (power)
	“OFF” (power)
	Protective earth (ground)
	Dangerous voltage
	Caution
	Warning

2. SAFETY

2-1. General Safety Rules

WARNING

THE ELECTRICAL AND LASER RADIATION HAZARDS PRESENT DURING SERVICING OF TH E PICOCARE LASER SYSTEM CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECA UTIONS ARE NOT TAKEN. CONSEQUENTLY, THE PICOCARE LASER SYSTEM IS TO BE SERV ICED ONLY BY THOSE QUALIFIED TECHNICIANS WHO HAVE RECEIVED APPROPRIATE TR AINING, AND WHO ARE FAMILIAR WITH THE SAFETY CONSIDERATIONS DISCUSSED IN TH IS SECTION.

However, any laser system can cause injury if it is not properly installed, operated, moved or serviced. The potential hazards associated with the PICOCARE 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 Hazard / Optical Safety Precaution

For fundamental rules on the handling of laser devices, you are referred to the international standard IEC60825-1.
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.

NOTE

Refer to IEC 60825-1.

⚠ WARNING

LASER BEAM ENERGY EMITTED BY THE PICOCARE LASER SYSTEM LIES IN THE VISIBLE AND INVISIBLE (NEAR INFRARED) 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, OPTICAL DENSITY OF 7.0 OR GREATER AT 532 NM, OPTICAL DENSITY OF 2.0 OR GREATER AT 585 NM. SAFETY GOGGLE THAT IS DE SIGNED FOR USE WITH OTHER LASER SYSTEMS MAY NOT PROVIDE ADEQUATE PROTECTION.

Lasers are classified in accordance with their potential for danger. The PICOCARE laser safety level is class 4.
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).
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.

WARNING

EVERYONE WITHIN THE NOHD WHERE THE LASER SYSTEM IN OPERATING, INCLUDI NG DURING SERVICE PROCEDURE, MUST WEAR APPROPRIATE EYE PROTECTION TO AVOID THESE VISION HARZARDS. SAFETY GOGGLE, AVAILABLE FROM WON TECH P ROVIDES ADEQUATE PROTECTION AGAINST REFLECTED OR SCATTERED LASER RA DIATION, OR INADVERTENT BRIEF EXPOSURE TO THE LASER BEAM.

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, an optical density of 7.0 or greater at 532 nm and an optical density of 2.0 or greater at 585nm. Laser safety goggle should be stored away from direct sunlight.

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 PICOCARE 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 PICOCARE 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 goggle whenever the laser system is on. Verify that the protective goggle used is known to protect against the wavelengths emitted by the PICOCARE laser system.
- Never look directly into the laser beam coming from the laser system, or reflected from a surface, even when wearing protective goggle.
- 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 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 anesthesia, 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 Hazard

The PICOCARE laser system was designed to comply with IEC 60601-1-2 “Electromagnetic Compatibility Requirements and T ests.” A portion of IEC 60601-1-2 deals with measurements of unwanted radio frequency emissions generated from a product. B oth radiated emissions (radiated through the air) and conducted emissions (conducted into the AC mains) are measured.

The PICOCARE 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 PICOCARE 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 PICOCARE laser system weights more than 80 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.

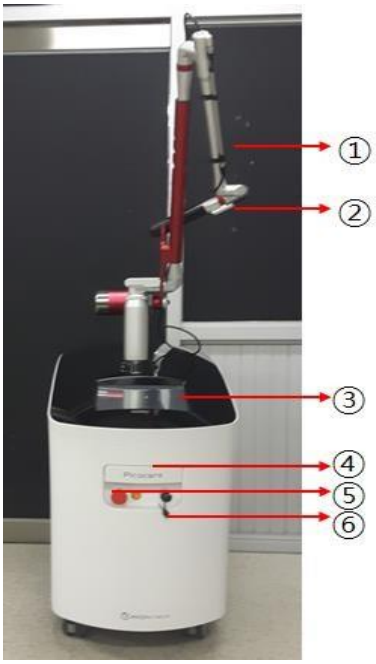
This device is provided as below. And, the device is installed by technicians qualified by WON TECH.

<table>
<tr><td colspan="4">Articulated arm
(WT-PC-AM-001)</td></tr>
<tr><td colspan="4">  </td></tr>
<tr><td>Main unit
(WT-PC-CS-001)</td><td colspan="3">Handpiece</td></tr>
<tr><td>  </td><td> 
Zoom Handpiece
(WT-PC-HP-001)</td><td> 
(Optional)
Fractional Handpiece
(WT-PC-HP-002)</td><td> 
(Optional)
Dye Handpiece
(WT-PC-FS-001)</td></tr>
<tr><td>Foot switch
(WT-PC-FS-001)</td><td colspan="2">Goggles for doctor
(WT-PC-GG-001)</td><td>Goggles for patient
(WT-PC-GG-002)</td></tr>
<tr><td>  </td><td colspan="2">  </td><td>  </td></tr>
</table>

3-2. System Features

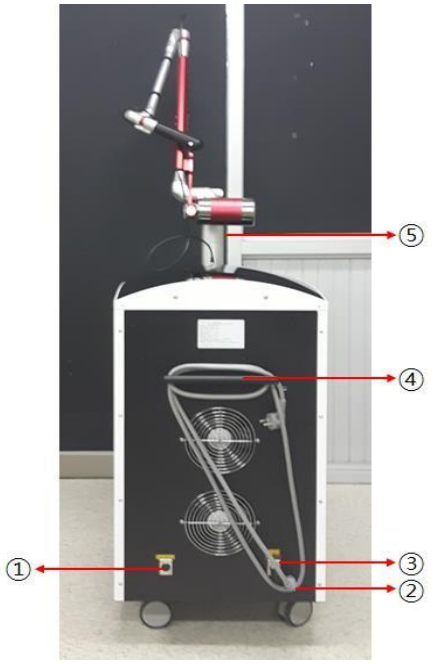
Front View

1. Articulated ARM: A delivery system for the treatment la ser up to the handpiece.
2. Handpiece: A delivery system as a distal end of the artic ulated arm for the laser radiation onto the treatment zone.
3. LCD and Touch pad: A touchable- graphical user interface for controlling the treatment parameters and extra functions.
4. Handle: For moving the device.
5. Emergency Switch: The stop-switch for shutting down the device in any hazard ous situations.
6. Key Switch: A switch for turning the device on and off.

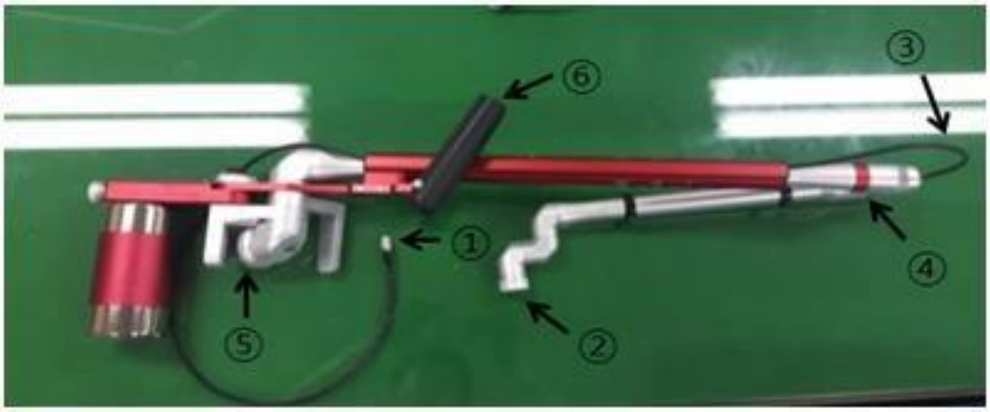


Rear View

1. Foot switch terminal: A terminal for connecting with a foot switch.
2. Power Supply cord: A cable for supplying electrical power to operate the device.
3. Interlock switch terminal: A terminal for connecting with an interlock switch.
4. Handle: A handle for moving the device.
5. Articulated ARM terminal: A terminal for connecting with an articulated ARM.



3-3. Articulated Arm



1. Handpiece cable: It connects to SPU board through the connector of Top Case, in order to realize the function of the Handpiece .

2. Connection part for handpiece: A handpiece is connected with the connection part for the treatment-laser to be emitted.

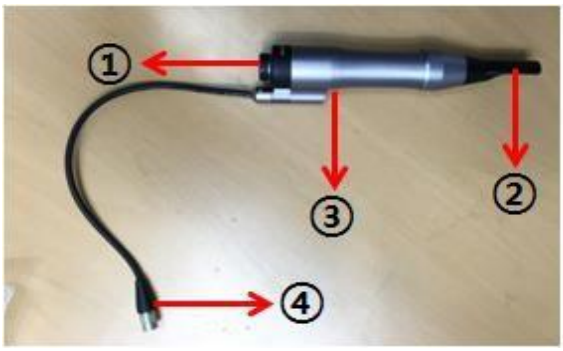
3. Joint of articulated ARM: As a joint-part of the Arm, it is compose of 7 different joints to facilitate movements of the Arm. Each joint has a reflective mirror that reflects the laser energy all the way to the handpiece.

4. Guide beam: A diode laser is emitted by the aiming beam in order to indicate the treatment zone.

5. Articulated ARM connector: This is the part connects the Arm into the top-case of the main body of the device by combining with the mount

6. Handpiece pocket: The pocket holds the handpiece when not in use.

3-4. Handpiece

Zoom Handpiece	Fractional Handpiece	Dye Handpiece
		
Picocare uses Zoom handpiece for operation at either 1064nm or 532nm. It provide a range of spot sizes by rotating the barrel of the handpiece and it overrides the spot size setting indicated on the screen.	(Optional) Picocare can be optionally supplied with Fractional handpiece at1064nm or 532nm It could be used in wider treatment section.	(Optional) Picocare can be optionally supplied with Dye handpiece. This handpiece is used to provide 585nm only. This wavelength is very useful when removing blue or green ink tattoos.

1. Connection part for handpiece: The ARM is connected with the connection part of the handpiece.
2. Laser output port: The laser source will come out through the port by aiming on the treatment area.
3. Spot size display: It displays the value of spot (2 to 10 mm) when it's rotated.
4. Handpiece connector: It is the cable connected with the Arm for the treatment-laser to be emitted.

3-5. Terminology

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

⚠ WARNING

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

3-6. Menu Description

Monitor Display	Description
	1. Load: It brings out the treatment parameters saved previously on the screen. 2. Save: Saves the current treatment parameters on the screen. 2. User Mode: Indicates general information or options of the laser system on the screen. 4. Standby-Ready: Changes from Ready mode to Standby mode and vice versa. 4. Fluence(Energy density): Adjusts the value of energy density. 4. Frequency: Adjusts the value of frequency. 7. Spot Size: Indicates a spot size set from the dial of handpiece (2~10mm). 8. Fluence Up: Increases the value of the fluence of the laser. 9. Fluence Down: Decreases the value of the fluence of the laser. 10. Frequency Up: Increases the value of the frequency of the laser. 11. Frequency Down: Decreases the value of the frequency of the laser. 12. Wavelength: Able to select the 1064nm or 532nm with Zoom (or fractional) Handpiece. (Optional Dye handpiece is used with 585nm only) 13. Reset: Reset the count of shots to zero.

4. INSTALLATION

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

> ⚠ **WARNING**
>
> **DURING THE CONNECTION OR DISCONNECTION OF ARTICULATED ARM, BE EXTR EMELY CAREFUL TO PROTECT THE OPTICAL SURFACES OF THE LASER HEAD. AL WAYS PLUG THE PROTECTION PLASTIC CAPS WHEN THEY ARE NOT IN USE AND K EEP THEM IN A SAFE PLACE. KEEP HANDPIECE AND ARTICULATED ARM AWAY FR OM DUST AT ALL TIMES.**

3) Plug the foot switch connector into the terminal on 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

5-1. Start-up

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

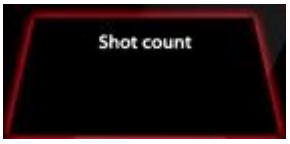
> **NOTE**
>
> **IT WOULD BETTER TO PRESS THE MONITOR BUTTON USING NAIL BETTER THAN FINGER TIP.**

3) 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.

4) After the above the initiation process, the below display appears.

5) 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.

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.

11) Replacing the handpiece

		
1. Remove the connector	2. Disconnect the previous handpiece by turning it count erclockwise	3. Connect the new hand piece by turning it clockwise.

12) Power off the device by turning the key counterclockwise.

6. MAINTENANCE

6-1. General Information

(1) After use, wipe the tip of the handpiece with a dry towel, according to the cleaning procedure indicated in section6-3.

(2) Once a week, wipe the exterior of PICOCARE Laser System with a dry towel. In particular, clean the LCD display/Touch Pad gently not to scratch the surface.

(3) Do not drop any food or liquid on the device. It may affect the electrical parts of the device and causes damages. .

(4) Do not place anything on the base frame or apply any pressure onto it even when the system is not in use.

(5) You need to be very careful, handling the articulated ARM. It might get severe damages on the joint part of the connection.

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

(7) Unplug the power cable when the system is not in use for a period time.

(8) Provide a routine cleaning of the handpiece tip and safety glasses instructed by the cleaning procedure indicated in section6-3.

(9) All other maintenance service shall be performed by a qualified service representative from WONTECH.

6-2. Attentions

a. General Attentions

- Do not operate the laser without a physician or dermatologist . Check the device working before operation.
- Call a technical engineer of WONTECH when the laser shows unusual signs or troubles.
- Do not add any foreign parts to the unit or remove any components from the unit.
- Check the device if it works before the treatment gets started..

b. Individual Attentions

- Do not look at the laser aperture directly.
- While the laser is in use, everyone in the treatment area should wear the safety goggles.
- Do not use the laser with the flammable anesthetic (ex: flammable gas anesthetic or anesthesia such as halothane or enflurane gas.), which might cause the ignition by laser beams.
- Use the laser carefully in the high voltage.
- Please allow at least 20cm distance between the device and the wall.
- Do not touch the device with wet hand.

6-3. Cleaning Procedure

Operator (Dermatologist or Physician) or nurse must clean handpiece-tip and safety glasses after the treatment for each patient. Hand-piece maintenance is directly related to lifespan of the device and patients' health. Maintain optimal condition of the device by following next steps of cleaning as shown below.

1. Unscrew the handpiece from the Articulated ARM.

2. Pull out the tip from the handpiece.

3. After the treatment of each patient, clean the handpiece tip with a dry towel.

4. Clean any dust on the safety goggles to prevent an optical damage from the delivery system.

5. 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 thinneror benzene)

6. After using the device, clean the safety glasses as well with a dry towel.

6-4. 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.

6-5. Notice before and after Treatment

NOTICE BEFORE TREATMENT

During the initial visit, inform patients about the treatment.

- It is possible for simply shower or washing face on the day of operating, but it is better to wash the operation part a couple of days after.
- If you need to wash your face, gently sprinkle water on your face by making enough foam of soap, and then gently massage. when you clean with the water, do not rub or press the skin.
- Avoid heavy exercise such as swimming, sweaty exercise which enough to wet shirt, or sauna.
- Make-up is available after scab of forms. However, it had better not to do if possible.
- A scab generally peels away around 7~10days. In case of taking off the scab constrainedly, or being in soaked condition due to sauna, scab part becomes red and moreover pigment builds up after a few days. So it is better to remain it until it falls off naturally.
- To prevent pigmentation, surely put sunscreen on sunscreen whenever cloudy day or indoors during the daytime. By applying sun block on your face, avoid side effects such as aging of the skin or pigmentation.

NOTICE AFTER TREATMENT

After each treatment session, physicians should advise their patients on the proper care of the treated area.

6-6. Trouble Shooting

When the device is not working properly:

- Please check the power code whether plugged or unplugged.
- Please check the AC power supply is interrupted.
- Please check the key switch and emergency switch..

If the device is regarded as defective or is not operated, please contact us immediately. Don't try to repair the device by yourself.

No modification or dismantle is permitted.

Error messages of displaying:

Item	Check point
No power	Check the power cable
	Check the key switch
	Disengage the emergency switch by rotating towards the direction of the arrow indicated
	Notify us
Key pads are none responsive	Please contact us.
System failed to initialize	Not enough power, please check main power supply.
	Please contact us.
NOTE If any problems occur that are not covered in the troubleshooting chart, or the suggested solutions do not work, please contact WON TE CH or your local representative.	

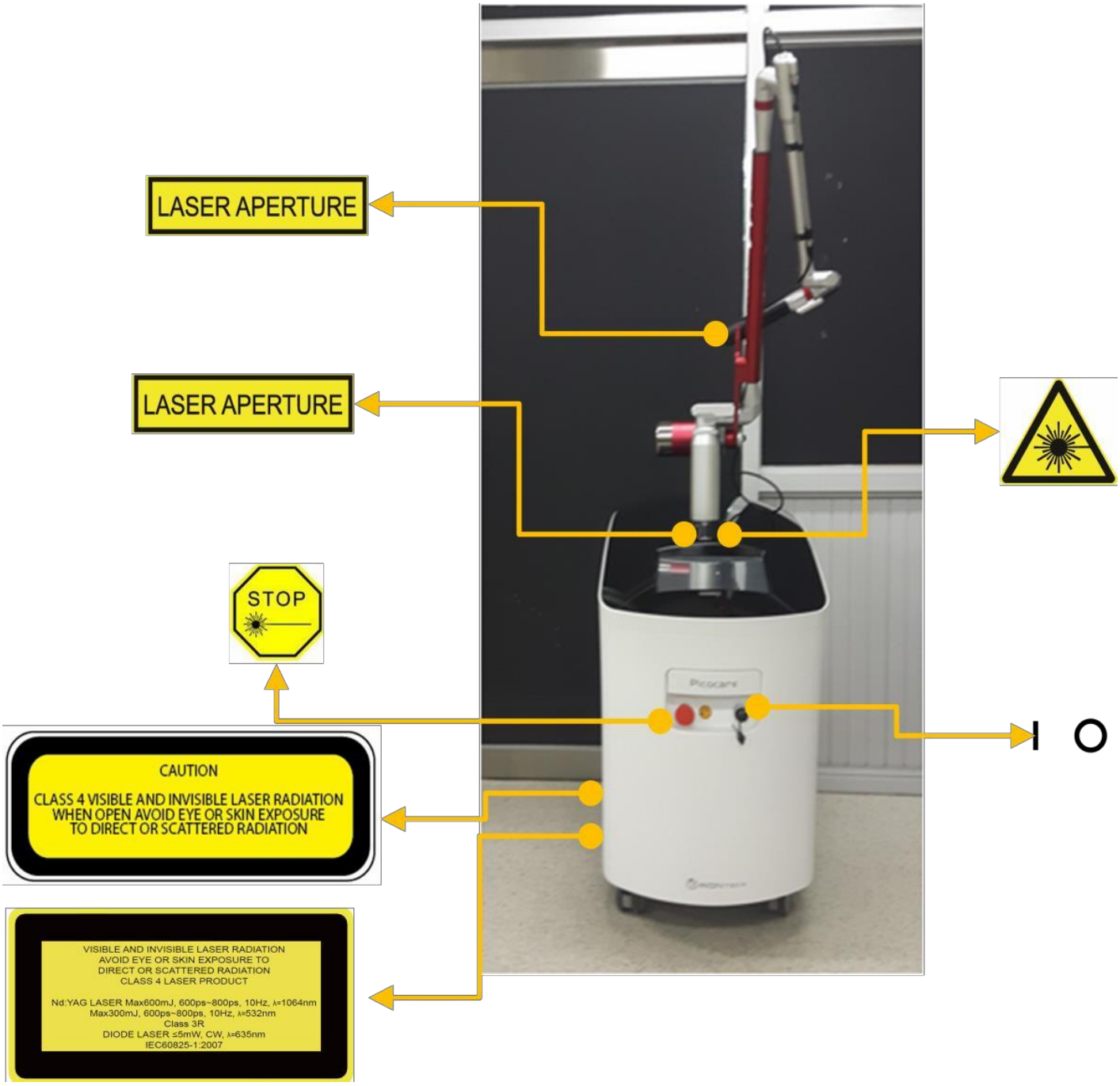
If the device is regarded as defective or is not operated, please contact us immediately. Don't try to repair the device by yourself.
No modification or dismantling is allowed.

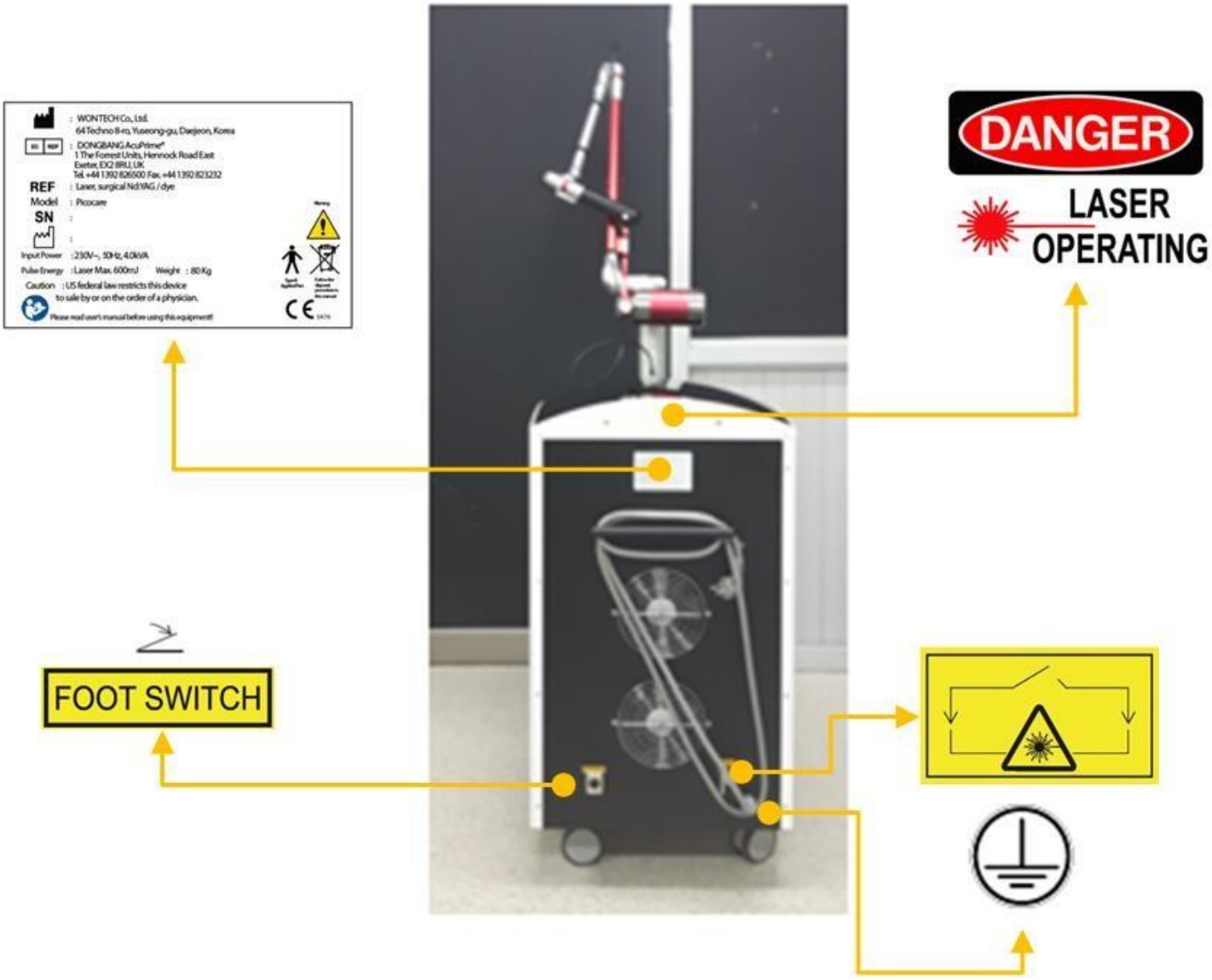
Message	Description	Message	Description
PS Input Over Voltage	Input power malfunction	PS RS232 Checksum	Signal malfunction
PS Input Low Voltage	Input power malfunction	PS Voltage#1 Set Timeout	Input power malfunction
No simmer	Simmer malfunction	PS No Connect	Input power malfunction
Emergency button	Emergency button pressed	PS Over-Temperature"	Over temperature malfunction
Interlock	Interlock switch opened	Timer full	Signal malfunction
PS Capacitor Over Voltage	Input power malfunction	FRAM i2c error	Signal malfunction
Contactor Malfunction	Contactor Malfunction	PS Capacitor Low Voltage	Input power malfunction

7. LABELING AND PACKAGING

7-1. Labeling

Package & Label according to ISO15223-1(2012)

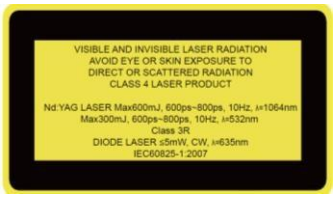


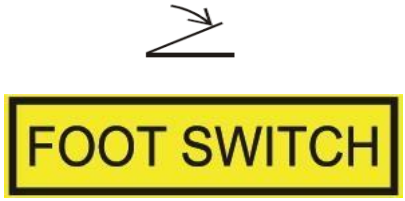

: WONTECH Co., Ltd.
64 Techno 8-ro, Yuseong-gu, Daejeon, Korea
: DONGBANG AcuPrime®
1 The Forrest Units, Hennock Road East
Exeter, EX2 8RU, UK
Tel. +44 1392 826500 Fax. +44 1392 823232
REF : Laser, surgical Nd:YAG / dye
Model : Picocare
SN :
:
Input Power : 230V~, 50Hz, 4.0kVA
Pulse Energy : Laser Max. 600mJ Weight : 80 Kg
Caution : US federal law restricts this device
to sale by or on the order of a physician.
Please read user's manual before using this equipment!
DANGER
LASER
OPERATING
FOOT SWITCH

7-2. Name Plate

7-3. Warning Labels of Laser Operation

Laser warning labels according to IEC60825-1

 This label informs about the dangers, the maximum values of ene rgy emitted by, and the classification of, the laser source.	 Indicating the interlock location
 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 to connection part	 Notified for Interlock
 Protection ground connection indication. IEC 60601-1	 Power ON/OFF IEC 60601-1
 IEC 60601-2-22 Emergency stop Remarked on the front of the Emergency switch This sign designates the EMO pushbutton to 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.
 60417-5264(DB:2002-10) "ON" for a part of equipment	

7-4. Packaging Labels

Package & Label according to ISO15223-1(2012)

Box for Packaging

	
Keep-upright indicator	Shock Watch indicator
	WON TECH BOX Picocare (Nd:YAG Laser System) SN: xx(xxx)xxx-xxx CE 0476
Precaution Mark	Company name & Product Serial Number

7-5. 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

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.

The PICOCARE laser system must be disposed in accordance with WEEE Directive 2012/19/EU of the European Council on Waste Electrical and Electronic Equipment [WEEE].

9. CONSUMABLES

a. Protection goggles for doctor

- Notified body 0196(CE mark)
- Luminous transmittance: 40%
- Optical Density:6.0(1064nm), 4.0(532nm)
- 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 cover with the towel in the Goggles pocket.

b. Protection goggles for patient

- Notified body 1096(CE mark)
- Luminous Transmittance: 0%
- This laser goggle protects the eyes of patient against scattered light and diffusion of the laser beam.
- It gives the protection against the laser beam within a certain period of time (max. 10 sec resp. 100 pulse).
- All parts can be cleaned with running water. A soft cloth shall be used for drying the laser filters on the goggles.
- After using and washing the Protection goggles, you should cover with the towel in the Goggle pocket.
- If you consumed all of the goggles, you can purchase from the qualified manufacturer.
  Call to the service center (+82 42 934 6800).

- **Warning: Do not look directly into the laser beam even though you are wearing this goggles.**
  This product shall only be used for the indicated lasers, not for others

APPENDIX 1 - Guidance and Declaration of Manufacturer – 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~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 l ines were filtered from ambient.
	Radiated electromagnetic field	30MHz~1000MHz	30MHz~1000MHz	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 47000-3-2:2006 + 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 minutes.
EN 47000-3-3: 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 minutes.

IEC 60601-1-2	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 PICOCARE, 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 immuniy	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 PICOCARE, 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 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 PICOCARE system requires continued operation during power mains interruptions, it is recommended That PICOCARE be powered from an uninterruptible power supply.