



Laser apparatus for medical use

PICOCAREMAJESTY

Nd:YAG Laser System

User Manual

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WON TECH Co., Ltd.

This manual applies to PICOCAREMAJESTY laser system

Rx only

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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.

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The document will be remained for 10 years since release of the products.

As for the commercializing PICOAREMAJESTY product with Linguistic variants, the English is only available as it is a global language and most of countries may not have any problem with communication in English.

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Operator shall read this user manual before using
PICOAREMAJESTY

Rx only

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CAUTIONS

“Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner by the law of the state in which he/she practices to use or order the use of the device.”

CAUTION

Use medical device only as intended.

CAUTION

All people in the operating room for laser treatment should wear safety goggles which are certificated and the place should be condemned warning mark at entrance of operating room.

CAUTION

Lift the device up using handles on the rear and front of laser console to pass over 20mm threshold. Check the floor condition of operating room to prevent the device falling when the laser system is moved.

CAUTION

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

CAUTION

Laser plume may contain viable tissue particulate.

CAUTION

Power supplier should be used the independent 220-230 VAC, 50/60 Hz. Mains must be grounded.

CAUTION

No modification of this medical device is allowed.

CAUTION

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



WARNINGS

WARNING

Do not contact directly the laser module the patient who has a skin allergy. Diagnose the allergy reaction of patient on medical history and body characteristic before treatment.

WARNING

Do not use the medical device the patient who has a skin allergy. Diagnose the allergy reaction of patient on medical history and body characteristic before treatment.

WARNING

Improper use of the medical device or use of a damaged device may result in severe eye or tissue damage, fire in the treatment room and accidental laser exposure to the treatment room personnel or patient.

WARNING

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, and that they are equipped with the correct safety goggles.

WARNING

Do not touch the medical device and its connections, because high voltage is used for the device. It may cause an electric shock in that case.

WARNING

Avoid direct contact of the distal end with body tissue or flammable materials, such as drapes, as it can cause burns and fires.

WARNING

Follow the cleaning procedure herein to prevent the second infection.

WARNING

Laser should not be exposure directly of the naked eye because it emits the invisible light. Wear the protective glasses or goggles before operating the device.

WARNING

Do not use Combustible anesthetics that can cause ignition by laser. (Note: Do not use flammable gas anesthetic or anesthesia such as halothane or enflurane gas)

WARNING

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

 WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

 WARNING

While specific diagnosis or treatment of interference caused by ME devices can lead to serious danger.

 WARNING

Before wearing the safety goggles, check the damages of goggles. If a damage of safety goggles is found, wear new safety goggles having met with same specifications. (Refer to Section 8 for detail)

 WARNING

Check the device electrical specifications (220-230 VAC, 50/60 Hz) before installing to a switch board. Switchboard specifications shall be met with the following;

1 SAFETY

1.1 General safety

WARNING

THE ELECTRICAL AND LASER RADIATION HAZARDS PRESENT DURING SERVICING OF THE PICOAREMAJESTY LASER SYSTEM CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECAUTIONS ARE NOT TAKEN. CONSEQUENTLY, THE PICOAREMAJESTY 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 PICOAREMAJESTY laser system has been designed to comply with the requirements of the EC Directive on Medical Products (93/42/EEC). PICOAREMAJESTY is classified as a Class II medical device per FDA 21 CFR 878.4810.

However, any laser system can cause injury if it is not properly installed, operated, moved or serviced. The potential hazards associated with the PICOAREMAJESTY 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.

1.2 Laser & Optical hazard

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.

WARNING

LASER BEAM ENERGY EMITTED BY THE PICOCAREMAJESTY 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 5.0 OR GREATER AT 1064 NM AND OPTICAL DENSITY OF 4.0 OR GREATER AT 755 NM. 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 PICOCAREMAJESTY laser safety level is class 4.

The laser beam emitted by the PICOCAREMAJESTY 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 IEC 60825-1.

The beam emitted from the Handpiece is expanding with a full-angle beam divergence. This means that the spot size enlarges as the distance from the 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 5.0 or greater at 1064 nm and an optical density of 4.0 or greater at 755 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 PICOAREMAJESTY 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.

NOHD Calculation (PICOARE MAJESTY)

Q-switching mode (1064nm, 350ps)

Q-switching mode (532nm, 280ps)

1. For the PICOAREMAJESTY laser system, determine the intra-beam MPE for direct ocular exposure to the radiation from a Nd:YAG laser($\lambda = 1064$ nm) operating at a frequency of $F = 1$ Hz with a pulse width of $t = 350$ ps at 1064nm mode.

Wavelength = 1064 nm;

Peak power per pulse $P_p = 1,429$ GW;

Energy per pulse $P_o = 500$ mJ;

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

$$P_p \times t_p = P_o \text{ by } 1,429 \times 10^9 \times t_p = 0.6$$

giving $t_p = 350 \text{ ps}$ (i.e. $10^{-13} < t_p < 10^{-11} \text{ s}$). 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

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:

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

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

Single-pulse assessment (condition 13.3a))

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

$$H_{MPE} = 1.5 \times 10^{-3} C_6 C_7 \text{ J}\cdot\text{m}^{-2}$$

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

$$H_{MPE, \text{ single}} = 1.5 \times 10^{-3} \text{ J}\cdot\text{m}^{-2}$$

Average irradiance assessment (condition 13.3b))

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

$$H_{MPE} = 2.7 \times 10^5 \times t^{0.75} C_6 C_7 \text{ J}\cdot\text{m}^{-2}$$

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

$$H_{MPE, \text{ exposure}} = \frac{2.7 \times 10^5 \times 10^{0.75}}{10} = 151,852.1 \text{ J}\cdot\text{m}^{-2}$$

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_{MPE} , train:

$$\text{HMPE, train} = \text{HMPE, single N-1/4} = 1.5 \times 10^{-3} \times 0.56 = 8.4 \times 10^{-4} \text{ J}\cdot\text{m}^{-2}$$

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

$$\text{NOHD} = \frac{1}{\phi} \left[\sqrt{\frac{4 \times 2.5 \times P_0}{\pi \times \text{HMPE, train}}} - a \right]$$

$$\text{NOHD} = \frac{1}{5 \times 10^{-2}} \left[\sqrt{\frac{4 \times 2.5 \times 0.6}{\pi \times 8.4 \times 10^{-4}}} - 0.01 \right] = 954 \text{ m}$$

The NOHD for the rangefinder is therefore 954 m.

1.3 Optical safety precautions

- 1) Identify the laser room clearly. Post appropriate warning signs in prominent locations at all entrances to the laser room.
- 2) Cover all windows, portholes, etc. with opaque material to prevent unintended viewing or laser light escaping from the laser room.
- 3) Restrict entry to the laser room when the PICOCAREMAJESTY 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.
- 4) Check the safety before operating the laser and operate in the proper order.
- 5) 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.
- 6) Appoint one person to be responsible for the laser system controls during the procedure.
- 7) Laser can cause fatal harm to human, so only trained doctor should use.
- 8) 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 PICOAREMAJESTY laser system.

- 9) Never look directly into the laser beam coming from the laser system, or reflected from a surface, even when wearing protective goggle.
- 10) 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).
- 11) Never permit reflective objects such as jewelry, watches, instruments or mirrors to intercept the laser beam.
- 12) Specified the parameter values just before the laser operation.
- 13) Do not use the combustible anesthetic gas.
- 14) Check the Stand-by or Ready state before using.
- 15) Never leave the key in an unattended laser system.

1.4 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.

1.5 Electrical and Mechanical Hazards

The PICOAREMAJESTY laser system was designed to comply with IEC 60601-1-2 “Electromagnetic Compatibility Requirements and Tests.”

The PICOAREMAJESTY 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 PICOAREMAJESTY 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 PICOAREMAJESTY laser system weights more than 110 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.

1.6 Relocation

The PICOAREMAJESTY laser system should always take care when moving. Before moving the device, disconnect the footswitch from the connector located on the rear panel of the device. Take special care when elevator doors and other uneven or sloping floor surfaces. A severe physical shock could cause device to be damaged resulting in personal injury or physical damage.

1.7 Mobile Use

The PICOAREMAJESTY laser system is not designed for mobile use.

2 INTRODUCTION

2.1 Indications for Use

The PICOCAREMAJESTY system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures.



WARNING: Basically, the PICOCAREMAJESTY must be operated by a physician with a qualification of dermatology, and who has been trained on the use of the device.

2.1.1 Description

The PICOCAREMAJESTY laser system consists of laser resonator, touch screen monitor, optical fiber with hand piece, and foot switch.

1) Nd:YAG Laser

Power supply and the laser resonator to the laser resonator is calculated from a power supply to the laser energy is set via the LCD monitor is a certain amount of power.

In the laser resonator is a certain amount of electrical energy to the flash lamp by changing the electrical energy into light Nd:YAG broiling to momentarily strong light in the laser medium to generate a laser.

The generated laser is a laser return to convert heat energy reaches the surface tissue.

2.1.2 Device applications specification

1) Medical purpose

The PICOCAREMAJESTY laser system has extended laser penetration into both epidermis and dermis without any damage to skin cells.

2) Patient population

- ① Age: More than 18 years old
- ② Weight: Not relevant
- ③ Health: Not relevant
- ④ Nationality: Multiple
- ⑤ Patient State: Not relevant

3) Part of the body or type of tissue applied to or interacted with

- ① Treatment site: Skin Tissue

- ② Condition: Intact skin, Treated skin

4) Intended operator

- ① Education: Dermatologist or physician trained by WON TECH
- ② Knowledge: Understands the laser treatment as a surgeon or dermatologist.
- ③ Language understanding: English
- ④ Experience: Dermatologist and surgeon who have been qualified to use a laser medical device.
- 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)

5) Application

- ① Environment
 - General:
 - Intended for prescription use
 - Use at the clean room of hospital for treatment
 - Use on the horizontal floor
 - There shall be no safety hazard of eyes. (All persons in the operating room shall put on the safety goggles during treatment.)
 - 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.
- ④ Storage/operation condition:
 - Transport and Storage Condition
 - Temperature range: -20 to 60 °C
 - Relative Humidity range: 0 to 90 % R.H
 - Atmospheric Pressure range: 80 to 106 kPa
 - Operation Condition
 - Temperature: 10°C to 40°C
 - Humidity: 30 % to 75 %,
 - Pressure: 80kPa to 106kPa

2.1.3 Side effect

- 1) **Skin lightening** (depigmentation): Some dark skin 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.
- 2) **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.

- 3) **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.
- 4) **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.
- 5) **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.
- 6) **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.
- 7) **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.
- 8) **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.

2.1.4 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.

2.1.5 Forbidden group

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.

2.2 System Description

2.2.1 Laser system

The PICOAREMAJESTY 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 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, 532 nm. 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.

2.2.2 Classifications

PICOAREMAJESTY is classified as a Class II medical device per FDA 21 CFR 878.4810, and a Class IIb (Rule 9), non-invasive, active device according to Annex IX of the European Medical Device Directive (MDD) 93/42/EEC.

2.2.3 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 635nm. 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.

2.2.4 Epidermal Cooling

The PICOAREMAJESTY laser system offers two cooling system with its delivery systems:

- Skin Cooling System (SCS)

This part consists of the internal water flow circuit with water to air heat exchanger.

2.3 Specifications and Requirements

2.3.1 Specification

No.	Item	Specification			
1	Laser wavelength	Treatment beam		1064 nm $\pm$ 10% , 532 nm $\pm$ 10%,	
		Aiming beam		635 nm $\pm$ 10%	
2	Laser material	Treatment beam		Nd:YAG, Solid state Dye	
		Aiming beam		InGaAlP	
3	Laser delivery type	Articulated Arm			
4	Radiation diameter	Normal mode	Treatment beam	Radiation diameter	2 mm-10 mm (Step : 1 mm)
				Radiation type	Circle
			Guide beam	Radiation diameter	1.5 mm
				Radiation type	Circle
		Collimation Mode	Treatment beam	Radiation diameter	7mm $\pm$ 20%

				Radiation type	Circle	
			Guide beam	Radiation diameter	1.5 mm ± 20%	
				Radiation type	Circle	
4	Radiation diameter	MLA & DOE Mode	Treatment beam	Radiation diameter	MLA	3~10mm ± 20%, (step 1 mm)
					1064nm DOE	5mm X 5mm ~ 9mm X 9mm ± 20% (Step : 1mm x 1mm)
					532nm DOE	6mm X 6mm ± 20% (Step : 1mm x 1mm)
				Radiation type	MLA	Circle
					1064nm DOE	Square
					532nm DOE	Square
			Guide beam	Radiation diameter	MLA(1.5mm ±20 %) 1064nm DOE(5mmX5mm ±20%), 532nm DOE(6mm X6nn ±20%),	
				Radiation type	MLA : Circle DOE : Square	
5	Laser output power	Treatment beam	1. 1064nm Mode : 30 ~ 500 mJ ±10% 2. 532nm Mode : 10 ~ 250 mJ ±10% 3. 1064nm Collimation Mode : 38 ~500 mJ ±10% 4. 1064nm MLA Mode : 30 ~ 500 mJ ±10%			

			5. 532nm MLA Mode : 10 ~ 250 mJ $\pm 10\%$ 6. 1064nm DOE Mode : 30 ~ 450 mJ $\pm 10\%$ 7. 532nm DOE Mode : 20 ~ 200 mJ $\pm 10\%$
		Guide beam	≤ 5 mW
6	Pulse Width	1064nm mode : 250-350 ps, 532nm mode : 180~280ps	
7	Pulse repetition rate	1. 1064nm Mode : 1 ~ 10 Hz $\pm 10\%$ 2. 532nm Mode : 1 ~ 10 Hz $\pm 10\%$ 3. 1064nm Collimation Mode : 1 ~ 10 Hz $\pm 10\%$ 4. 1064nm MLA Mode : 1 ~ 10 Hz $\pm 10\%$ 5. 532nm MLA Mode : 1 ~ 10 Hz $\pm 10\%$ 6. 1064nm DOE Mode : 1 ~ 10 Hz $\pm 10\%$ 7. 532nm DOE Mode : 1 ~ 10 Hz $\pm 10\%$	
8	Laser class by EN 60825-1	Treatment beam	CLASS 4
		Guide beam	CLASS 3R
9	Protection on electronic shock	Class 1 / Type B	
10	User Interface	Touch LCD type	
11	Size(mm)	500 * 960 * 900 (W * D * H)	
12	Weight	108 kg	
13	Cooling method	Water-cooled, air-cooled	
14	Electrical Ratings	Single phase 220-230 VAC, 50/60 Hz Power Consumption : 4 kVA	

2.3.2 Environmental requirement

Before installation of the PICOAREMAJESTY 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 PICOAREMAJESTY 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 PICOAREMAJESTY 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 PICOAREMAJESTY laser system is not suitable for use in the presence of a flammable mixture with air or with oxygen or nitrous oxide.

The PICOAREMAJESTY 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 PICOAREMAJESTY laser system, 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 PICOAREMAJESTY 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.

2.3.3 Indication, Safety and Reference Symbols

SYMBOL	DEFINITION
	Manufacturer
	Date of manufacture
REF	Catalogue number
LOT	Batch code
SN	Serial number
EC REP	Representative in Europe
	Emitting Laser Hazard
LASER APERTURE	Laser aperture
	Emergency Stop
	Type B Applied Part
	Protective earth (ground)
	Dangerous voltage
	Alternate Current
	“ON” (power)
	“OFF” (power)
IPX8	Protected against the effects of continuous immersion in water
	Foot switch
	Do not use if package is damaged
	Follow the disposal procedure in this manual
	Follow operating instructions
	Caution
	Warning
	Temperature limitation
	Non-ionizing Radiation

2.4 Pre-treatment Preparation

Patient selection should be based upon the physician's assessment of the individual patient, including a detailed medical history. The treatment protocol should be discussed in detail including risks and benefits, side effects, and expected results, alternative or concurrent therapies and follow-up care. The physician should set proper expectations based upon their clinical experience. Informed consent and photographs should be obtained. Individual patient characteristics such as skin condition and type, sex, age and medications may influence the response to and efficacy associated with treatment. The response to treatment may vary on subsequent visits and the skin reaction must be carefully assessed on each visit. These guidelines are intended for use by providers who are knowledgeable in laser tissue interactions.

2.5 Pre-Treatment Patient Recommendations

- Stop use of the following 2 weeks prior to treatment;
 - 1) Tanning or sun exposure
 - 2) Complementary/supplementary non-ablative laser treatments (i.e. IPL, Hair Removal, etc.)
- Stop use of the following 7-10 days prior to treatment;
 - 1) Waxing
 - 2) Abrasive scrubs
 - 3) Microdermabrasion treatments

2.6 Pre-Operative Inspection

Do not use the PICOAREMAJESTY Laser system on patients meeting the contraindication criteria.

The physician should set proper expectations based upon their clinical experience. Individual patient characteristics such as skin condition and type, sex, age and medications may influence the response to and efficacy associated with treatment.

WARNING

Physician should make their own assessment of and decision on the use of any of the information in this user manual.

2.7 Treatment intervals

Everyone has different skin condition, but clinical studies of predicate device suggest that for most patients, maximum results can be achieved in 1-3 sessions with the 1064 nm and 532 nm wavelength. Treatments are usually spaced 2-12 weeks apart, at symptoms and physician's discretion.

2.8 Laser Treatment Considerations

- Position patient comfortably and confirm that the patient and everyone in the treatment room are wearing the correct protective eyewear.
- Always hold the laser handpiece perpendicular, flat and in contact to the skin to apply laser energy.

- The aiming beam and laser beam are dimensionally identical, so the aiming beam can be used to accurately scan the treatment area.
- Always observe the epidermal response throughout the treatment and adjust the fluence and epidermal cooling (SCS) as needed.

2.9 Preventing Untoward Effects and Decreasing Discomfort

- Cool compress or cold gel packs may be applied immediately after treatment to decrease discomfort.
- After each laser pulse, a gentle rub of the area with a dry gauze pad or gentle rub with a gloved hand may minimize discomfort.

2.10 Post- Operative Information

- Skin protection: Patient should put sun-block on the treatment area, at least 30 SPF.
- Routine Skin Care: Most skin care products can be used 3 weeks after treatment. Avoid the use of retinoids and topical corticosteroids for 1-2 weeks following treatment.
- Expected Responses to Treatment: Edema, Erythema, Itching, Dryness of treated area, Pain or discomfort, Petechiae and Pinpoint Bleeding.

3 Overview of the PICOAREMAJESTY Laser System

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.

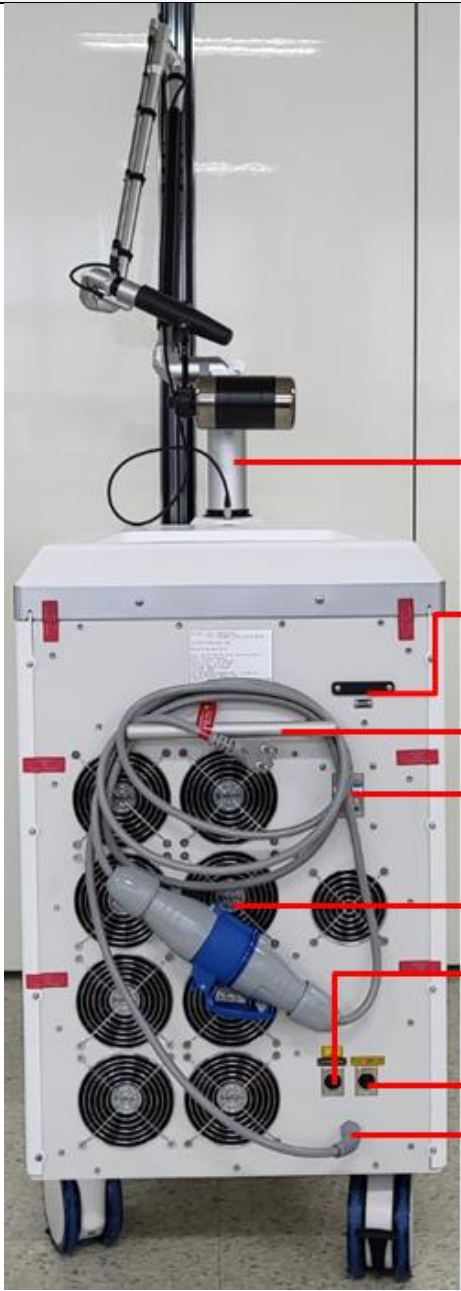
Main Body		
		
A Type Articulated Arm		
		
B Type Articulated Arm		
		
Handpiece		
		
Zoom Handpiece	Collimated Handpiece	MLA Handpiece

	
1064nm DOE Handpiece	532nm DOE Handpiece
Accessories	
	
Footswitch	Goggles (1064nm, 532nm)
	
InterLock	
	Power Cable
Key	

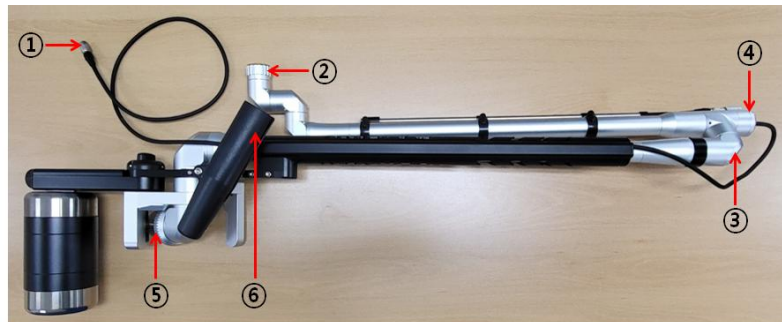
System Features

1) Device description

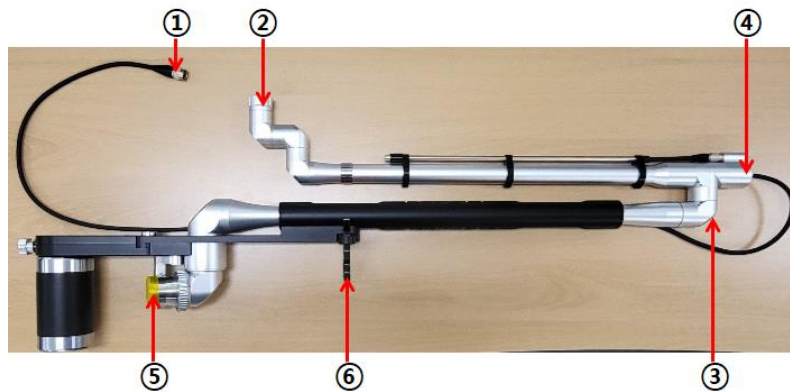
Front view	Description
 The image shows the front view of a medical laser device. It has a white base with a control panel and a silver articulated arm extending upwards. Red arrows point to specific parts: 1 points to the articulated arm, 2 points to the handpiece at the end of the arm, 3 points to the LCD and touch pad on the control panel, 4 points to a handle on the front of the base, 5 points to a key switch, and 6 points to an emergency stop button.	1. Articulated Arm: A delivery system for delivering the treatment laser to the handpiece. 2. Handpiece: A delivery system as a distal end of laser radiation for radiating the treatment laser to treatment zone. When Handpiece is separated from Articulated Arm, lasers are radiated from the distal end of Articulated Arm. 3. LCD and Touch pad: A graphical user interface for controlling the treatment parameters and extra functions. 4. Handle: A handle for moving the device. 5. Key Switch: A switch for turning the device on and off. 6. Emergency Switch: A laser stop switch for shutting the device down in hazardous situations.

Rear view	Description
 The image shows the rear of a white, wheeled medical device. An articulated arm is mounted on top. Red arrows point from numbered circles to specific features: 1 points to the arm's terminal; 2 points to a USB port on the top panel; 3 points to a handle on the top edge; 4 points to a power switch; 5 points to a large blue interlock connector; 6 points to a foot switch connector; 7 points to a foot switch connector; and 8 points to a power cable at the bottom.	1. Articulated Arm Terminal: A terminal for connecting with an articulated Arm. When Articulated Arm is separated, lasers are radiated from the distal end of the terminal. 2. USB port: The port for the software update.(Lock is applied) 3. Handle: A handle used to move the device. 4. Power Switch: A Switch to turn the device on 5. FAN: Fan to move the heat from inside of the device to outside. 6. Interlock Connector: A connector to connect interlock with device. 7. Foot Switch Connector: A connector to connect foot switch with the device. 8. Power Cable: A cable which provides power to the device.

2) Articulated Arm



A type

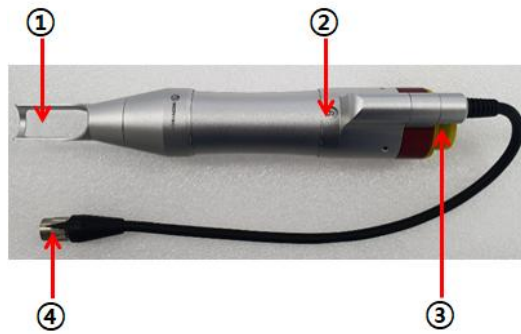


B Type

1. Auto spot cable: The auto spot cable controls the spot size that is indicated on the screen.
2. Connection part for handpiece: A handpiece is connected by the connection part for the treatment laser radiation. When Handpiece is separated from Articulated Arm, lasers are radiated from the distal end of Articulated Arm.
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 by the terminal on the top case of device.
6. Handpiece pocket: The pocket holds the handpiece not in use.

* The only difference between A and B type arm is the manufacturer of the arm. Functions and internal design is same.

3) Handpiece



Zoom handpiece

1. Connection part for handpiece: Articulated Arm is connected by the connection part for the treatment laser radiation.
2. Laser output part: The output will come out, bring to the actions by aiming the treatment area.
3. Spot size display part: If when the handpiece rotate, displays the value of spot. (2 to 10 mm).
4. Auto spot connector: The connector is connected by controller.

The description of the part is applied in same to Collimated, MLA, and DOE handpiece, too.

Footswitch description



When user pushes foot switch, the setting energy on screen will be radiated at the end of the handpiece.

4) Goggles description



Wear the protective goggles before operating the device.

5) Monitor indicator description

Normal Mode		
①	User Mode	Indicates general information of the laser system on the screen.
②	Mode Change	The ability to select the handpiece that you want to use switched to the available screen for the selected handpiece
③	Save & Load	Saves the set parameters in the Display window or recalls the stored parameters.
④	Reset	Reset the count to zero.
⑤	Spot Size	Indicates a spot size set from the dial of handpiece (2~10mm)
⑥	Fluence	Adjusts the value of energy density.
⑦	Frequency	Adjusts the value of frequency
⑧	Spot Size	Indicates a spot size set from the dial of handpiece (2~10mm).
⑨	Fluence Up	Increases the treatment fluence.
⑩	Fluence Down	Decreases the treatment fluence.
⑪	Frequency Up	Increases the treatment frequency.
⑫	Frequency Down	Decreases the treatment frequency.
⑬	Standby	Changes from Ready mode to Standby mode or vise versa.

Collimation Mode		
①	User Mode	Indicates general information of the laser system on the screen.
②	Reset	Reset the count to zero.
③	Spot Size	Indicates a spot size set from the dial of handpiece (2~10mm)
④	Fluence	Adjusts the value of energy density.
⑤	Frequency	Adjusts the value of frequency
⑥	Spot Size	Indicates a spot size set from the dial of handpiece (2~10mm).
⑦	Fluence Up	Increases the treatment fluence.
⑧	Fluence Doen	Decreases the treatment fluence.
⑨	Frequency Up	Increases the treatment frequency.
⑩	Frequency Down	Decreases the treatment frequency.
⑪	Standby	Changes from Ready mode to Standby mode or vise versa.

MLA Mode		
①	User Mode	Indicates general information of the laser system on the screen.
②	Mode Change	The ability to select the handpiece that you want to use switched to the available screen for the selected handpiece
③	Reset	Reset the count to zero.
④	Spot Size	Indicates a spot size set from the dial of handpiece (2~10mm)
⑤	Fluence	Adjusts the value of energy density.
⑥	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 treatment fluence.
⑨	Fluence Doen	Decreases the treatment fluence.
⑩	Frequency Up	Increases the treatment frequency.
⑪	Frequency Down	Decreases the treatment frequency.
⑫	Standby	Changes from Ready mode to Standby mode or vise versa.

DOE Mode		
DOE1064 User mode ① ② M1 M2 M3 Parameter ③ Shot count ④ 5 mm ⑤ Fluence 0.15 Energy=0.030 J J/cm² ⑥ 6 Hz ⑦ - + ⑧ ⑨ - + ⑩ ⑪ Standby Handpiece Guide beam - 100% +		
DOE532 User mode ① ② M1 M2 M3 Parameter ③ Shot count ④ 6 mm ⑤ Fluence 0.40 Energy=0.113 J J/cm² ⑥ 1 Hz ⑦ - + ⑧ ⑨ - + ⑩ ⑪ Standby Handpiece Guide beam - 100% +		
①	User Mode	Indicates general information of the laser system on the screen.

②	Reset	Reset the count to zero.
③	Spot Size	Indicates a spot size set from the dial of handpiece (2~10mm)
④	Fluence	Adjusts the value of energy density.
⑤	Frequency	Adjusts the value of frequency
⑥	Spot Size	Indicates a spot size set from the dial of handpiece (2~10mm).
⑦	Fluence Up	Increases the treatment fluence.
⑧	Fluence Doen	Decreases the treatment fluence.
⑨	Frequency Up	Increases the treatment frequency.
⑩	Frequency Down	Decreases the treatment frequency.
⑪	Standby	Changes from Ready mode to Standby mode or vise versa.

4 INSTALLATION

4.1 Set-up before Use

- 1) Check the packing to be sure there is no cosmetic damage.
- 2) Check the kit to be sure there is no missing components
- 3) Make sure there is no damage of the device during the Shipping & handling.

4.2 Unpacking Procedures

All components shall be installed by technicians of WON TECH. If you want to reinstall, please call the service center of WON TECH.

1. 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.

2. Plus the foot switch connector to 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 regulated the access.

NOTE

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



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

NOTE

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

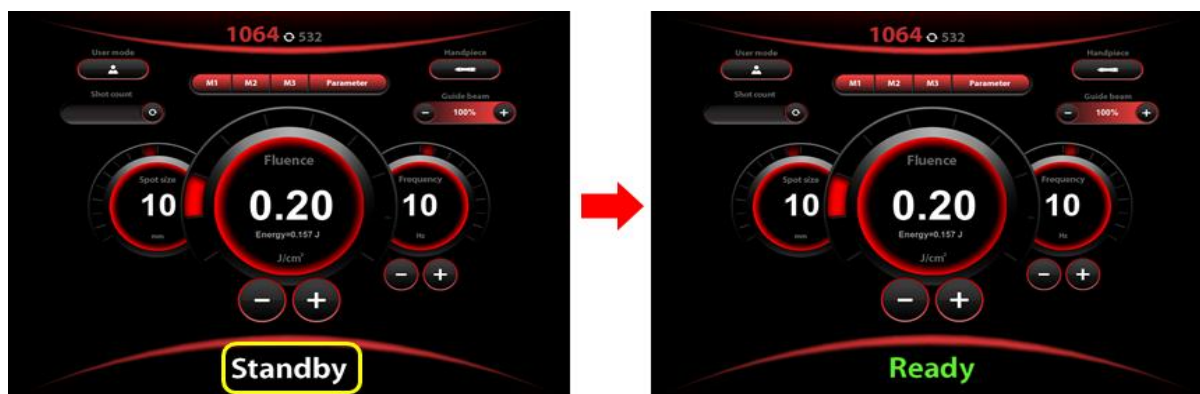
4.3 Using the device

* Please wear the safety goggle before use the device for eye protection.

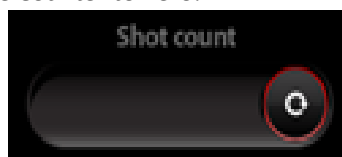
- 1) Turn the key switch clockwise to the ON position and the power is applied. Wait a few seconds until the main menu appears on the screen.\
- 2) During booting, the logo of company appears on the screen. The main menu appears on the screen if there is no problem after self-check. After that, the device 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(GUI) to control the treatment parameters and extra functions. After the above the initiation process, the below display appears.



- 3) 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.



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



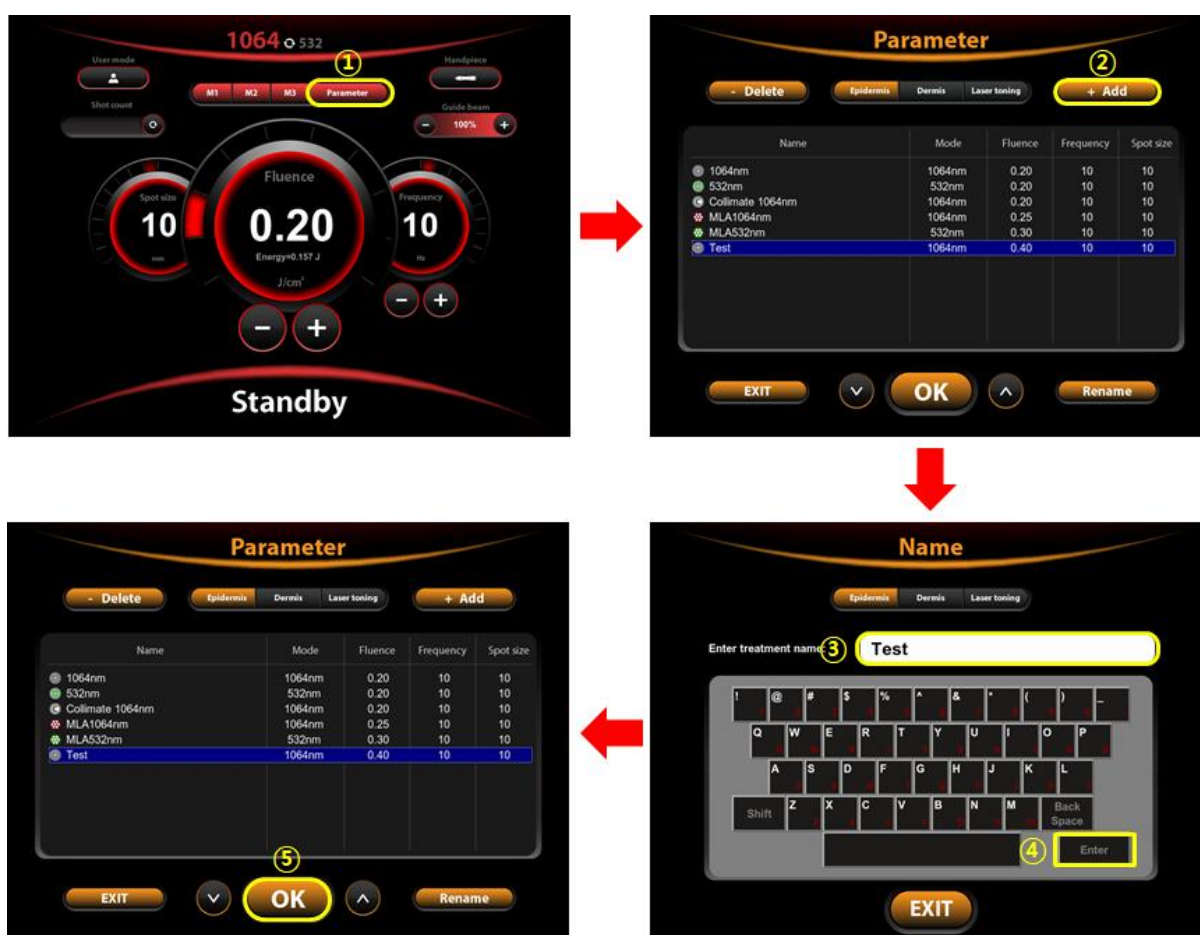
- 5) Depending on the size of treatment zone of patient, set the spot size of zoom handpiece. The spot size on the screen shall be set with matching the spot size adjusted by the dial of zoom handpiece.



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



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



- 8) 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.



- 9) Power off the device turning the key counterclockwise.

⚠CAUTION: If the patient complained of discomfort, press the Emergency Stop switch to stop the system operation immediately.

4.4 Attention

1) Warning

- Device must be operated by trained expert.
- Read and follow all the instructions, procedures, and messages provided in user manual.
- Maintenance and service must be performed by a qualified service representative.
- This device must be medical use.

- 2) There is no age and gender limit but using the device are available depending on patient condition.

3) Caution for use

- Monitoring the state of patient and device
- If an abnormality patient or device, keep patient safety and take proper action.
- Avoid contact with the device.
- Do not look into end of the hand piece or any other laser output while device is in use. Ocular damage resulting from exposure to direct or reflected laser radiation will result.
- Expose to focused laser beam for a long time will potential burning of patients.

4) Universal precautions

- Do not operate the laser without a skilled doctor or designated specialist indicated in intended use part. Check the device working before operation.
- To prevent other people from being exposed to laser light, work in a closed room and/or place warning signs in the area.
- Please check the interlock switch and emergency switch to make sure it will work well.
- Please read and understand user manual and operator should think about possible dangers.

5) Interaction

- In case use with other device, it can make inaccurate diagnosis and danger.

6) 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.
- Do not use the device if the product is damaged.
- Transport and Storage Condition
 - Temperature range: -20 to 60 °C
 - Relative Humidity range: 0 to 90 % R.H
 - Atmospheric Pressure range: 80 to 106 kPa
- Operation Condition
 - Temperature: 10°C to 40°C
 - Humidity: 30 % to 75 %,
 - Pressure: 80kPa to 106kPa

5 MAINTENANCE

5.1 General Information

- Once a week, wipe the exterior sides of device with a dry towel. In particular, clean the LCD display/Touch Pad, using gentle care not to scratch the surface.
- Do not drop any food or liquid on the equipment. It may affect the electrical parts in the equipment or cause damage.
- Do not place anything on the base frame or apply any pressure onto it when the device is not in use.
- Carefully handle the optical fiber cable not broken or twisted. It may induce laser hazards or physical injury.
- Do not move or relocate the device during treatment.
- Follow local governing ordinances and recycling plans regarding the disposal or recycling of device components.
- All other maintenance and service must be performed by a qualified service representative.

5.2 Check Points

When the device doesn't give any particular response;

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

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

- Please check the device is on Ready mode.
- Please make sure that 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.

5.3 Cleaning procedure of Device

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

- 1. Unscrew the handpiece from the Articulated Arm.**
- 2. Prepare a swab with isopropyl alcohol (70%) to clean the handpiece tip.**
- 3. Clean any dust on the safety glass to prevent an optical damage of the delivery system.**
- 4. After each treatment, for health of patient, clean the Handpiece tip (contacted part to patient) using a cotton swab moistened with isopropyl alcohol (70%)**

***Caution: The concentration of isopropyl alcohol used for cleaning must be 70%.**

Even after cleaning the handpiece tip, you should check the cleaning result with the naked eye. If you see foreign substances or dust that have not been washed, do a new cleaning to ensure that there are no foreign substances.

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.

 **Caution:** This section corresponds to exteriors of device, handpiece, LCD and other plastics.

5.4 Cleaning procedure of Safety Goggles for patient

Operator or nurse must clean safety goggle for patient. Maintain optimal condition of safety goggles for patient as shown below.

- 1) All parts can be cleaned under running water with a normal washing-up liquid.
- 2) A soft cloth shall be used for drying the laser filters.
- 3) After using and washing the Protection goggles, you should clean this one with the clean towel in the Goggle pocket.

5.5 Cleaning procedure of handpiece tip

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

- 1) Prepare a soaking container with chlorine bleach, suitable for disinfecting and cleaning. The bleach should not contain any other chemicals or softeners. Add tap water (distilled water is not necessary) to make a solution.
- 2) Place the handpiece tip into a container and soak overnight.
- 3) Scrub all surfaces of the handpiece tip body with a toothbrush and rinse with clean water.
- 4) Let the handpiece tip "air dry".

 **Caution:** After each treatment, for health of patient, clean the handpiece tip.

 **Caution:** Even after cleaning the handpiece tip, you should check the cleaning result with the naked eye. If you see foreign substances or dust that have not been washed, do a new cleaning to ensure that there are no foreign substances.

5.6 Troubleshooting

When the device is not working properly:

- Please check the AC power supply is interrupted.

- Please check the key switch and emergency switch to make sure it will work well.
- Please check the power cord whether plugged or unplugged.

If the device is regarded as defective or is not operated, please contact us immediately. Do not try to repair the device by yourself. No modification or dismantle is permitted.

Item	Check point
No power	Check power cable
	Check key switch
	Disengage the emergency cut off switch by rotating towards the direction of the arrows 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, contact WON TECH or your local representative.	

Error message of displaying:

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.

Message	Description
Queue Full	Queue is a memory space for events from communication. If memory in SPU board is full of events, system displays alarm.
Charger Power Fault	Internal temperature exceeds a safety operating level, DC bus voltage drops below the specified value, Fan failure, or Aux power sag.
Charger Load Fault	The Power module output is shorted or open
Charger over-voltage	It means over-charging to the capacitor.
Charger is off	SPU board sends Charging command to charge board. But no response
Charge too slow	In case charging time is longer than limited maximum value.

No Simmer 1	At the end of booting, simmer B/D generates high voltage in order to make a high peak ignition voltage. By ignition voltage, lamps are on and simmer unit supplies the lamp with low current.
No Simmer 2	At the end of booting, simmer B/D generates high voltage in order to make a high peak ignition voltage. By ignition voltage, lamps are on and simmer unit supplies the lamp with low current.
No Flow	No flow alarm is detected by flow sensor. If water doesn't flow through cooling system, system displays the alarm.
Over-temperature	During operation, system needs to cool down flash lamp by cooling system. Otherwise, optical parts in cavity will be burnt. To protect the over-temperature of cavity, system is checking the current temperature of cavity at the right below laser head. The max. temperature of cavity is 50 °C.
Interlock	Interlock is installed at the door in laser room for safety. When opening the door during treatment, system is down and displaying alarm.
Emergency button	In case of emergency, system is down by pushing emergency button and main power is off.
Timer Full	If total timer event in SPU memory is over 8, displayed the alarm.
Unexpected Command	CP program error For example, in error state, cp board sends the ready signal
FRAM i2c error	In SPU board, FRAM IC is for saving important data like total pulse. Communication error between SPU board and FRAM IC.
Contactors sealing	Before contactor powers up, SPU board checks the contactor status by the signal CONT-OK (A1 & A2). CONT-OK signal must be opened electrically. If it's on during power-up, displayed alarm.

Contactor malfunction	Using contactor, system turns on or off 220Vac main voltage. Once system is powered up, SPU board switches on contactor. By checking CONT-ON signal, SPU board detects the condition of Contactor. For more, refer to Reference #4. Contactor
RS232 control sum error	It's kind of communication protocol. Basically, communication is started with 0xAA, finished with 0xAB. At the end of the data, there is checksum byte for checking wrong data. For example, Data will be like: 0xAA(start) / 0x01(data) / 0x10(data) / 0x00(checksum) / 0xAB(end) We can find the checksum data by Exclusive-or calculation. $0x01(data) \text{ xor } 0x10(data) = 0x00 \text{ (checksum)}$ If the received checksum is something wrong, displayed alarm.
RS232 overflow	In serial communication, Maximum memory space is 256 byte for receiving data. Receiving data is over 256 byte, displayed alarm.
No discharging	Capacitor energy can't be discharged by thyristor (SCR). If the voltage is over 200V (PICOAREMAJESTY: 330V) right after discharging, displayed alarm at the next shot.
Flow Sensor malfunction	In case water is flowing through water tube, sensor is automatically shorted. SPU board keeps sensing this signal. Usually this signal must be open state before system boot. This alarm means flow sensor is shorted electrically before system boot.
H/P malfunction	System detects the spot change and displays the setting spot size on screen.

	If something wrong in h/p or wires, it's out of range and finally display "X" on spot area or h/p malfunction. Most of case, the problem is from the h/p or wires. By replace the h/p or arm set, we can solve the problem.
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5.7 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

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

Handpiece

LASER APERTURE

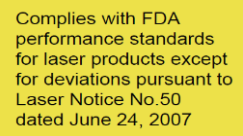


6.2 Nameplate

Device nameplate	 : WONTECH Co., Ltd. 64 Techno 8-ro, Yuseong-gu, Daejeon, Korea  : Nd:YAG Laser System Model : PICOAREMAJESTY Australian Sponsor Compliance Management Solutions Pty Ltd 3/85 Curzon Street, North Melbourne, Victoria 3051 Australia  :  : Input Power : 220V~,50/60Hz,4.0kVA Power : Max. 500mJ weight: 108kg     Please read user's manual before using this equipment!!
Footswitch nameplate	
Goggles nameplate	 Manufacturer : LASERVISION Address : 595 Phalen Blvd, Saint Paul, MN55130  Serial No. : "Indicated on surface of product" Country of origin : Made in USA Product Name : Laser Protective Goggles Model : P1L02  Date of manufacturer : "Indicated on surface of product" Indication for use : To protect eyes from reflection of laser emitting during the laser treatment. Note : For more information such as IFU and Cautions, refer to User Manual

6.3 Laser Operation Danger Labels

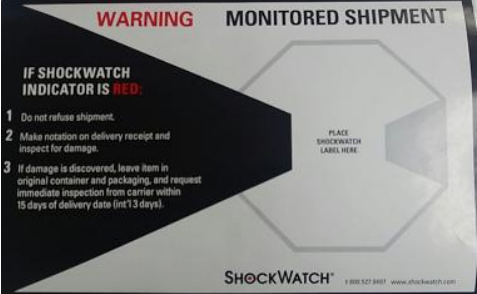
Laser warning labels according to IEC60825-1

	This label informs about the dangers, the maximum values of energy emitted by, and the classification of, the laser source.
	Indicating the laser radiation of top case 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.
	Selected requirements under CDRH 21 CFR 1040.10 & 1040.11 were waived for comparable IEC requirements as allowed by Laser Notice 50.
 	Foot switch attached to connection part
	Notified for Interlock
	Protection ground connection indication.
	Power ON/OFF
	IEC 60601-2-22 Emergency stop Remarked on the front, Emergency switch indication. This sign designates the EMO pushbutton for express shutdown of laser emission.
	Laser warning label (US) This label informs about the dangers, the maximum values of energy emitted by the laser source.

6.4 Packaging Label

Box for Packaging



Keep-upright indicator	Shock Watch indicator
	
Storage	Company name & Product Serial Number
	WON TECH CO. LTD. BOX[1/1] PICOCAREMAJESTY S/N:
EC Representative	Manufacturer
REP WONTECH LLC. 500 W. Office Center Dr. Suite # 400 Fort Washington, PA 19034 Tel: +1 267 342 8890	 Manufacturer; WON TECH Co., Ltd. 64 Techno 8-ro, Yuseong-gu, Daejeon, Korea TEL: +82 42 934 6800 FAX: +82 42 934 9491

Detail description of precaution mark

Symbol	Description
	Fragile
	Use no hooks
	Keep dry
	This way up
	Fragile

7.5 Environment Requirements

Transport and Storage Condition	Operation condition
• Temperature range: -20 to 60 °C • Relative Humidity range: 0 to 90 % • Atmospheric Pressure range: 70 to 106 kPa	• Temperature: 10°C to 40°C • Humidity: 0 % to 80 % • Pressure: 80 to 106 kPa

7 DISPOSAL

The PICOCAREMAJESTY 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.

8 CONSUMABLES

1) Protection Goggles for doctor

1064nm	532nm
 (For 1064 nm and 532 nm)	

- Luminous transmittance: 40%
- Optical Density:
 - For 1064 nm and 532 nm: 7.0(1064 nm), 7.0(532 nm)
- LB Rating:
 - For 1064 nm and 532 nm: D LB6 + IRM LB7(940-1070 nm), D LB6 + IRM LB7(532 nm)
- Storing: The goggle shall be stored at a temperature between -10°C and +55°C and a relative humidity of <80%
- Doctor should wear the goggle when operating this device to radiate Laser for treatment. (Manufacturer supplies two Protection Goggles for operating doctor.)
- After using and washing the goggle, you should clean this one with the clean towel in the goggles pocket.
- If you consumed all of goggles, you should buy the safety goggles it has a precise effect and qualified from manufacturer. Call to the service center (+82 42 934 6800).
- The manufacturer and design of the safety goggles(CE marking) could be changed depending on internal situation of WON TECH.

2) Protection Goggles for patient



- 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).
- The manufacturer and design of the safety goggles(CE marking) could be changed depending on internal situation of WON TECH.

⚠ WARNING: Before wearing the safety goggles, check the damages of goggles. If a damage of safety goggles is found, wear new safety goggles having met with specifications above.

⚠ CAUTION: 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 Emissions & Immunity

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

Guidance and manufacturer's declaration—electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. You should assure that the device is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic Emissions EN 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions EN 61000-3-3	Complies	



WARNING

- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.

Guidance and manufacturer's declaration – electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. You should assure that the device is used in such an environment.

Immunity test	EN 60601-1-2 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% Ut (100% dip in Ut) for 0.5 cycle 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles 0% Ut (100% dip in Ut) for 25 cycles	0% Ut (100% dip in Ut) for 0.5 cycle 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles 0% Ut (100% dip in Ut) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If you need continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF EN 61000-4-6	Professional Healthcare- 3 V @ 150 kHz ~ 80 MHz 6 V @ ISM bands @ 150 kHz ~ 80 MHz Home Healthcare- 3 V @ 150 kHz ~ 80 MHz 6 V ISM and amateur radio bands @ 150 kHz ~ 80 MHz	Professional Healthcare- 3 V @ 150 kHz ~ 80 MHz 6 V @ ISM bands @ 150 kHz ~ 80 MHz Home healthcare- 3 V @ 150 kHz ~ 80 MHz 6 V ISM and amateur radio bands @ 150 kHz ~ 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. 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).

Radiated RF EN 61000-4-3	Professional healthcare - 3 V/m @ 80 MHz ~ 2.7 GHz Home healthcare - 10 V/m @ 80 MHz ~ 2.7 GHz (9 ~ 28) V/m @ 385 MHz ~ 6.0 GHz	Professional healthcare - 3 V/m @ 80 MHz ~ 2.7 GHz Home healthcare - 10 V/m @ 80 MHz ~ 2.7 GHz (9 ~ 28) V/m @ 385 MHz ~ 6.0 GHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
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- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V or 6V.

Notes:

- U_t is the AC mains voltage prior to application of the test level.
- At 80 MHz and 6000 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.