

Q-Switch ND YAG Laser

User Manual

Model No.: FG 2014



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PREFACE

Welcome to use the ND YAG Q-switched laser machine produced by ADSS. Nd yag Q-siwhe is our independent research and development, high-tech products with independent intellectual property rights. This manual for FG 2015, ND YAG Q-switched laser treatment instrument.

First identified by packaging please check accessories, if accessories are not complete, please contact with us.

Notes to users:

1. If you are using the laser treatment instrument for the first time, please read this user manual carefully before you power on.
2. Proposals not in the presence of electromagnetic interference, vibration and other disturbances of the environment under the conditions of use of the instrument, while the apparatus is in the process of running will not cause interference to other equipment/instrument.
3. Must be avoided in case of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen using the hair removal device. Of certain material, such as cotton and wool, in oxygen-rich of laser equipment that will be used when high temperatures ignited. For
4. Cleaning and disinfection of solvents and flammable liquid before using the laser equipment to volatilize.
5. This apparatus scrap or replace obsolete components referred to the designated agency or manufacturer to focus on, so as not to pollute the environment.



CAUTION

FG2015 ND YAG Q-switched laser machine Launch high-intensity laser beam, in order to protect the eyes, according to (NOHD) standards, use and patients wear suitable protective glasses.

Prohibit the following behavior:

- ※ Do not point the laser directly to eyes and skin;
- ※ Do not cut off the power supply during the laser operation;
- ※ Before use, make sure you are familiar with laser all construction and instruction.

Note: ND: YAG q-switched laser allows only after adequate security and training of personnel.

1.1 Machine parts

1.1.1. Machine Packages



Main machine packing box



Handpiece packing box

1.1.2 The accessories



Handpiece *1 pc



Power line*1 pc



Pedal*1 pc



Eye patch*1 pc



Glasses*1 pair



Funnel*1 pc

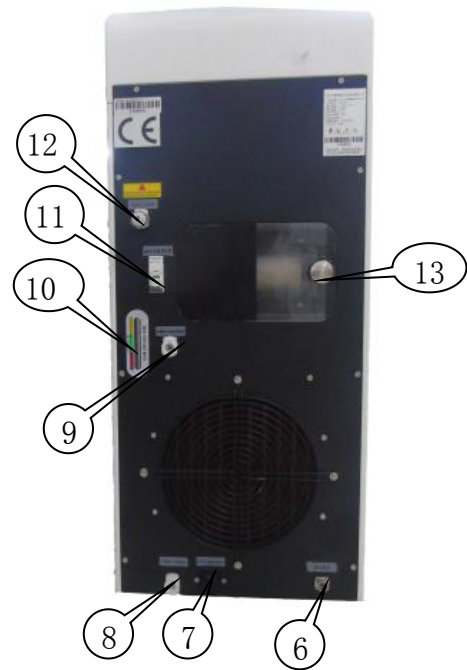
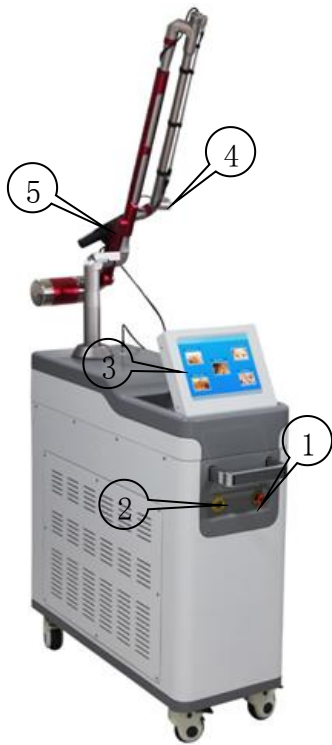


Nozzle*2 pcs



Fuse *2pcs

1.1.3 Main machine



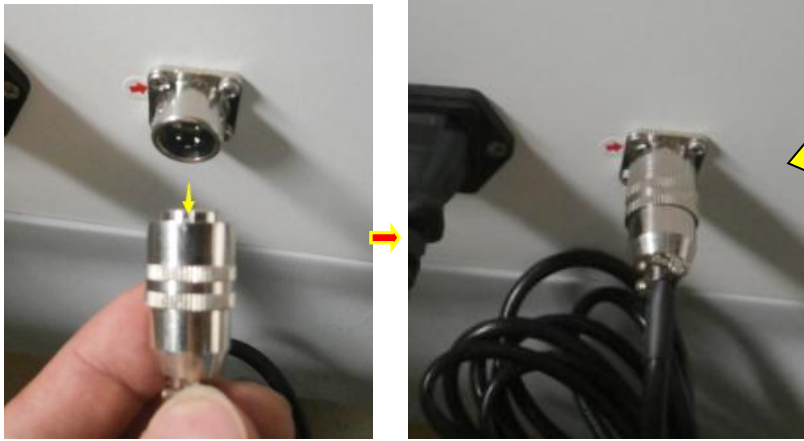
- ① **Emergency switch**
- ② **Button switch**
- ③ **LCD screen**
- ④ **Handpiece**
- ⑤ **Probe**
- ⑥ **Pedal socket**
- ⑦ **Power socket**
- ⑧ **Water drain**
- ⑨ **Water inlet**
- ⑩ **Water level indicator**
- ⑪ **Air switch**
- ⑫ **Water spilt**
- ⑬ **Filter cover**

1.2 Installation

1.2.1 Place the machine: Please place the machine in a clean surgery room or treatment room, the temperature of which is 22-28°C, and the moisture is less than 20%.

1.2.2 Connect the power line: one end is connected with machine power socket, the other end should be connected the well grounding single phase three wire socket

1.2.3 Connect the pedal



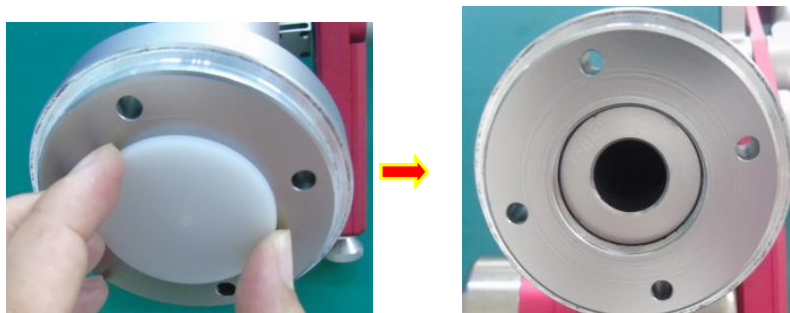
Notice: on the left picture, there is a breach at the end of pedal which is indicated in yellow arrow, when we install the pedal, we just keep the breach upward and then plug into the machine end.

1.2.4 Install the handpiece

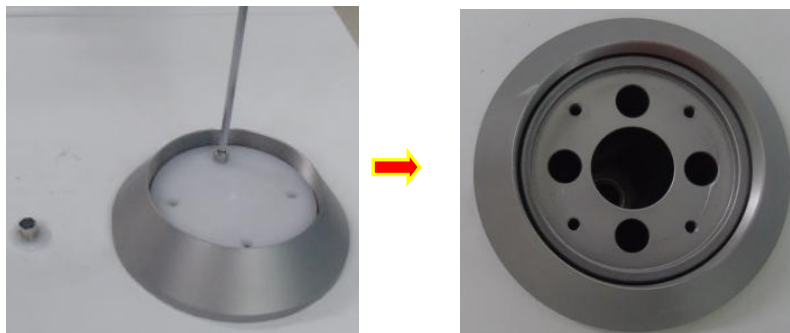
1.2.4.1 Take out the handpiece



1.2.4.2 Screw off the handpiece anti-dust cover in anticlockwise direction

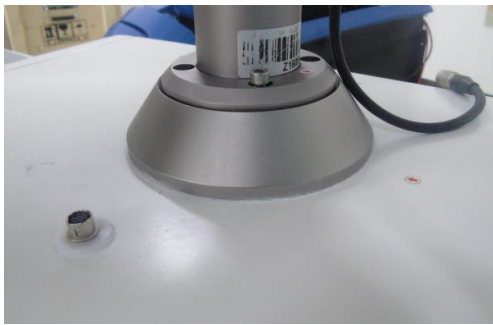
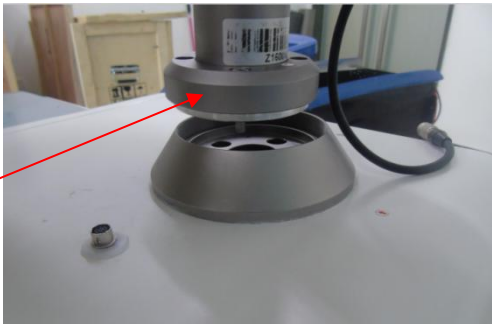


1.2.4.3 Screw off the dust-proof cover bolts on the main machine, with a 3mm spanner, then take off the dust-proof cover



1.2.4.4 Aiming the handpiece at the installation holes on the main machine and then plug inside vertically, please be noticed, the sticker must be toward the machine back, as shown as below:

Make it vertical



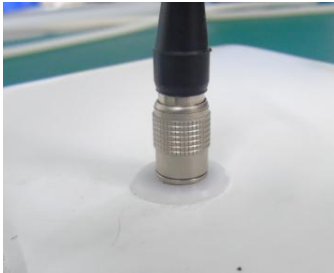
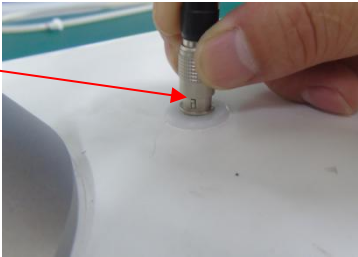
1.2.4.5 Tighten the screw

Tighten this screw



1.2.4.6 Plug into the wire connector

Aiming at the connector hole



Then we complete installation of the handpiece



1.2.5 Input the water

Put one end of the pipe inside the water inlet, and insert the funnel into the other end, then we start to input the distilled water, as the picture below:

Notice: the nozzle has been taken off during transportation, when input water, please insert the nozzle first

Notice: check the water level, don't over the red area indicated



1.2.6 Draw the water

Insert one end of the pipe inside the water outlet, and insert the funnel inside the other end, then we start to draw off the water. Shown as the picture below:

We only take off the water outlet nozzle during shipping, it should be inserted to water outlet when we input and draw off the water

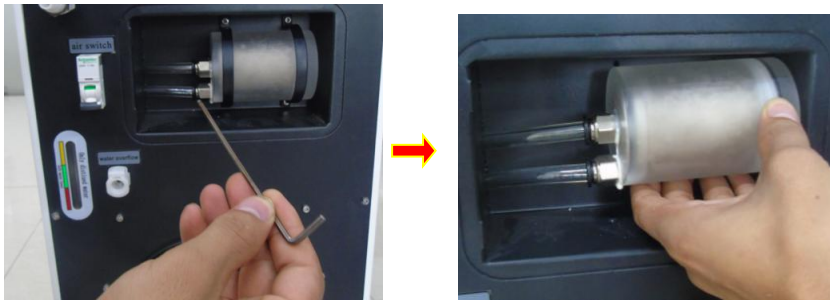


1.2.7 Replace the filter

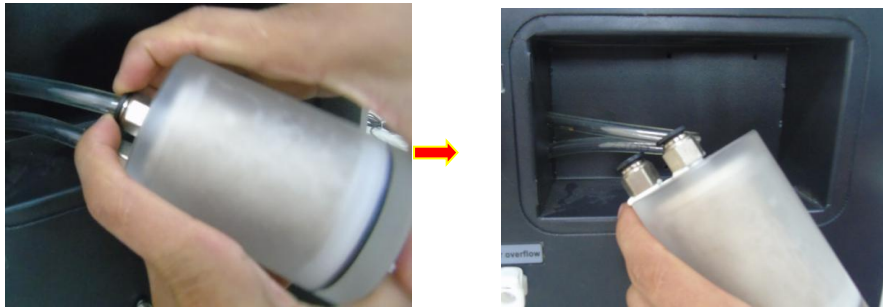
1.2.7.1 Take off the filter cover, as the picture below:



1.2.7.2 Screw off the 4 bolts which fix the filter bandage, with a 3mm spanner



1.2.7.3 Press the end of the two air tube locks downwards with the two index fingers, the air tube will bound automatically.



1.2.7.4 After take out the filter, we insert the air tube inside the new filter, and fix the 4 bolts, then the replacemnt is completed.

2. Clinical application

2.1 Principle of treatment

ND: YAD Q switch laser equipment adopt ND: YAD Q switch model, pulse width is only 5ns, Single pulse energy for 1064nm laser can reach Max1200mj, Emitting instantly laser energy smash diseased tissue chromophores, which mean burst by light: high-energy accumulated by laser emit instantly, 1064&532nm laser acts on the target tissue in a very short time (5ns) , Corresponding chromophore absorbs light energy to heat the rapid to expand and burst instantly. Some part (skin) chromophore after fragmentation excreted from the epidermis, other part (tissue below the skin) chromophore fragmented into small particles that can be engulfed by macrophages, after digested by macrophages eventually excreted through the lymphatic circulation, Chromophores in diseased tissue will be gradually reduced or even disappear, But the surrounding normal tissues absorb very little or do not absorb 1064 & 532nm wavelength laser so that they almost have no damage (almost no clinical side effects), You needn't rest after treatment, Because single-pulse energy of ND: YAD Q switch laser is continuously adjustable so the doctor really can obtain energy density (spot area of the same case) for clinical use.

2.2 Indications, contraindications and possible complications

ND: YAD Q switch laser equipment (equipment for short), is mainly used for the treatment of exogenous pigmented skin problems

2.2.1 Contraindication

- a. Light allergies crowd
- b. People who has a history of sunburn or will accept exposure, accept treatment carefully
- c. people using effective cosmetics (whitening product) within 3 months
- d. pregnant woman;
- e. people with severe hypertension, heart disease and diabetes, epilepsy, etc.
- f. Skin with herpes infections and damaged in a large area

2.2.2 Possible complications and treatment

2.2.2.1 Possible complications

- a. Improper treatment usually come about I , II degree burns (blisters)
- b. Pigment changes (post-inflammatory hyperpigmentation or hypopigmentation);

2.2.2.2 treatment for complications

- a. If burns reaction appears, please use burn ointment to cool topically. and you also can cool by ice bag or Water&Oxygen Jet Beauty Equipment
- b. chromatosis: use removing color drugs such as hydroquinone cream
- c. hypopigmentation: General treatment is not necessary, Patients usually have a history of sun exposure to lead to dark pigment is removed after partial sun.

2.3 therapeutic method

(The following treatment procedures and methods for reference only, actual parameters and operating procedures follow by use in clinical)

2.3.1 Before treatment

Ask→Watch→set up treatment file→Sign Treatment Consent→Photograph→prepare before treatment→Skin preparation→Parameter adjustment→Device Test→Wear Glasses and goggles→test

Ask:

Have an adequate communication with patients. Ask patient's skin lesion, current situation, tolerance to pain and its expectations on effect of the treatment, and so on. Know the patients' skin mental state, initial estimate the desired effect of treatment and communicate it with patient. According to asking, judge if the patient is contraindicated crowd.

Watch:

The device will have different treatment parameters for different patients, different parts, different disease, so we should know clear of the patient treatment area, skin tone of treatment area and the

condition of lesions. And to inquire whether the patient has medical history, sunburn history, and is about to get sun exposure and expectations of treatment. According to the patient's answer to the above question, know their expectations for effect of the treatment to ensure client's satisfaction According to asking, judge if the patient is contraindicated crowd.

Complete preoperative evaluation is an important part of the treatment process, Operator should understand the patient's medical history and make sure if the patient has physical scars, and the patient's work environment, age, etc. Take Real photo of the treatment area.

Establishment treatment file:

Fill the patient's relevant information into file table to ensure each page of the file is completed; Make a treatment plan according to the customer's skin type, lesion type (indications), the degree of skin aging. Let the customer confirm personally and signed the files, then photo and save, to facilitate comparison of patients later.

Photograph:

Take photographs of treatment area for save and comparison.

prepare before treatment:

Prepare the equipment, depilation device, essential oils, medical gloves, masks, goggles, protective eyewear, sterile gauze (or clean tissue) and so on.

Skin preparation: (Epilation)

Depilate before operation. Shave unwanted hair, then deep clean the treatment area. Gently wipe the residual moisture on skin with sterile gauze (or clean tissue) using sterile gauze (or clean tissue) after cleaning to avoid skin absorbing excessive water to affect the treatment effect.

Parameter adjustment:

According to the status of treatment area (skin type, skin lesion, location, age, etc.), treatment effect, operator adjust the treatment parameters.

Device Test:

After the booting into the user interface, test on test paper (or colored paper)to ensure that the equipment is working properly, stable performance.

Wear Glasses and goggles:

Patients wear special laser protection goggles, and the operators wear special protective glasses, masks and medical gloves.

Test:

Try on typical small lesions skin. Put the spot regulator affixed to the skin, and choose the appropriate spot size. Try on lesions skin with low energy and adjust the frequency and energy, until the color of lesion skin grow lighter or albinism (decide clinical endpoints according to the actual condition of patients).

2.3.2 During operations

During treatment, treatment handpiece keep perpendicular to the lesion area. one spot cover one spot.

During treatment, operator need adjust spot size, frequency and energy according to the treatment area and the lesion, and always pay attention to changes in the skin condition and observe clinical endpoints.

Clinical endpoints: It is ok if patients have an instant tingling, or skin pigmentation lighter albinism, bleeding point during the treatment(for post-inflammatory hyper, pigmentation and chloasma treatment it's time to stop as long as the skin grow red slightly to be hot).

Parameters:

Pigment type	Wavelength	Energy	Spot size	Clinical endpoints
Epidermis pigment	532	50-300	2-5	Epidermis gets white, inflamed, and sometimes bleeding a little
Epidermis-dermis pigment	1064	100-600		The pigment color gets light, with equal bleeding points, the skin gets red and warm
Dermis pigment	1064	300-600		Skin gets white, with equal bleeding points
Tattoos (dark, blue)	1064	200-600		Gets white, and the color fades away somehow
Tattoos (red, brown)	532	50-300	6-8	Gets white, and the color fades away somehow
eyebrow pigment	as per the color			
skin toning	1064	100-150		carbon is removed, skin get a little red and warm

2.3.3 After operation:

- a. Cooling with ice after operation
- b. Fill customer treatment files, record parameters and the energy of treatment, skin reactions and feelings of customers, sum up and accumulate experience
- c. Return to the standby state, rotate the key counter-clockwise to the closed state, cut off the power, clean the therapeutic window, put the instrument in situ (the keys is kept by specially-assigned person);

d. Tell the patient postoperative care, date the next treatment, and regular return visits and tracking

2.3.4 Postoperative care

- a. Fasting spicy food; ban alcohol and tobacco, seafood fat objects (beef, mutton, etc.)
- b. Avoid light sun after treatment
- c. Ensure that the treatment area dry, no makeup, disabled Cream, avoid thermal stimulation and mechanical stimulation;
- d. Do not massage, exfoliate within seven days

3. Specification

3.1 Specification

Laser wavelength (nm)		1064nm/532nm
Laser wavelength for aiming light		650nm (red color)
output energy for Laser terminal (mJ)	Single pulse	1064nm: 100mJ-1000m; 532nm: 50mJ-500mJ
	Double pulse	1064nm: 200mJ-2000m; 532nm: 100mJ-1000mJ
laser mode		Single / double pulse
pulse repetition rate (Hz)		1 Hz -10Hz
pulse width (ns)		6ns
Spot diameter (mm)		2mm-10mm adjustable
Power supply		2000W
rated operational current (A)		10A
Water tank capacity		8L
Number of articular optical arm		7articular optical arm
Dimension of machine (mm)		92×34×114.5cm
N.W. (Kg)		98kg

3.2 Working conditions

3.2.1 Working conditions

a environment temperature 10°C~35°C;

- b relative humidity $\leq 80\%$;
- c Atmospheric pressure range 760hpa~1060hpa;
- d Power supply ~220V 50Hz, ~110V 60Hz
- e Max power 2500W
- f No strong electromagnetic interference

3.2.2 Transportation and storage conditions

- a the requirement for transportation and storage condition are: environment temperature $10^{\circ}\text{C}\sim 35^{\circ}\text{C}$, relative humidity $\leq 80\%$, good air quality;
- b before the transportation , handpiece and other accessories must be removed and placed in crates save to prevent damage;
- c This instrument is a precision instrument, moving and shipping should avoid strong vibration and shock, non-inverted, to avoid damage to the instrument systems and electronic devices inside;
- d In the absence of dust outside the packaging, do not move or transport the instrument in dusty environments;
- e during the transportation, do not pull, hang, clip and hold, should transport with hands on the bottom.

4. Principle of treatment

4.1 Principle of the machine

ND: YAD Q switch laser equipment adopt ND: YAD Q switch model, pulse width is only 5ns, Single pulse energy for 1064nm laser can reach Max. 1200mj, Emitting instantly laser energy smash diseased tissue chromophores, which mean burst by light: high-energy accumulated by laser emit instantly, 1064&532nm laser acts on the target tissue in a very short time (5ns) , Corresponding chromophore absorbs light energy to heat the rapid to expand and burst instantly. Some part (skin) chromophore after fragmentation excreted from the epidermis, other part (tissue below the skin) chromophore fragmented into small particles that can be engulfed by macrophages, after digested by macrophages eventually excreted through the lymphatic circulation, Chromophores in diseased tissue will be gradually reduced or even disappear

The desired treatment parameters such as laser energy density is set by the user according to actual situation.

4.2 Machine composition

ND: YAD Q switch laser equipment consist by the host, treatment handpiece, light guide system, foot switch, power cord and accessories

4.2.1 Power system

Power system includes network power supply, laser power supply system, refrigeration power supply

system and auxiliary power supply system.

The power lines and rocker switch are used to control the on-off of hair removal instrument with the outside power supply. The key switch, emergency stop switch are used to control the on-off of network power, and then through the auxiliary power supply, provide the work current for the microprocessor control system, touch screen operation display system and other functional components, meanwhile, the on-off of power system for refrigeration and laser are realized by the pick-up and switching off of the relay that controlled by micro - processor. The power-on , energizing and the light emission process of main unit are subject to microprocessor control, in order to achieve controlling the hardware with software through microprocessor, so that the appliance operation are more stable and reliable.

Laser power system adopt the power devices to constitute current regulation loop, thus can change the volume of output current through system regulation power devices of microprocessor, thereby controlling the volume of output laser energy and work pulse width, through the feedback loop, export the current sampling signal and send to the micro - processor for real-time monitoring.

Various power supply components from the power system of laser hair removal instrument mostly adopt the safe and reliable switching power supply to achieve AC-DC conversion, these components passed through CE- certification, so that the safe effectiveness of the system get adequately guarantee, not only ensure the personal safety of users, but also ensures the long-term and reliable work of the devices itself.

The power system has the perfect self-protection function, it can continuously feed a number of important signal back to the microprocessor, once the important signal has an error, the microprocessor will promptly notify the users through the friendly man-appliance interface (Touch Screen) and take automatic protection treatment .After the error signal is released, the power system can automatically return to normal state.

4.2.2 Microprocessor control system

Instrument adopt the microprocessor control system. The microprocessor control system is composed of microprocessor, control loop and detection circuit.

Control module of hair removal instrument is highly automated, the user just needs to turn on rocker switch and key switch and eject emergency stop switch, after power-on, the system will automatically perform the self-check for the control system (include all the preset checks against some possible damages to the appliance and the user) and the calling of treatment parameters and other a series of actions.

If error occurs for self-check, the fault information will be displayed on the touch screen after system initialization, system self-check and parameter call-up are finished. This helps the user and the service personnel to get to know the running state of the appliance. If no error alarm arises, the user can turn on/off laser power supply, adjust output laser parameters and adjust laser operation mode through the touch screen. And through the touch screen, the user can also control whether to ignite lamp and whether to yield laser.

4.2.3 Operation Display System

Touch screen directly connected to the host microprocessor, the operator can work by operating its touch screen control, and learn the host state and other parameters through the information displayed on the screen; therapy device takes safe and reliable touch screen through CE certification .and designs very simple interface, easy man-machine dialogue.

The buzzer is used as the indication for laser output and fault alarm

4.2.4 Cooling System

Cooling system consists of cooling fan, cooling water recirculation system and water temperature and flow regulation system

After the laser hair removal instrument starting, the cooling system begins to work, water pump draw distilled water in the cooling water tank and then sent water into a xenon lamp laser, after cooling by air-cooled heat sink, the water go back into the tank

If the temperature exceeds the early warning value that pre-set, the system will automatically disable laser output and give alarm so as to avoid damage to the laser.

6. Operation instruction

6.1 Switch on the machine

Connect the machine with power, and switch on it. First switch on the main controlling switch and emergency switch, then insert the key into the key switch and turn it to “ON” , then the machine will start to work.

Attention



Whenever any abnormal emergency occurs, please press the emergency switch at once, and cut the power, to make sure the safety.

Please check the light path, before every treatment, please check the path is good between the aiming beam and the Yag laser

Attention

If we find the light is not focused on the path, please consult our technical department ASAP.

“Same path” means if aiming beam and the laser are on the same line, or if the laser spot falls on the place the aiming beam indicates. If the laser is deflected, the laser will not fall on the place the aiming beam indicates, then the treatment is not precise. The deflection problem is usually caused by intensive vibration.

6.1.1 Deflection problem may be caused by the following cases:

- a. Light guide articular arm
- b. Aiming beam
- c. Aiming beam path and laser path is not set properly.

6.1.2 how to check the deflection problem.

Tools needed: one piece of photo paper (as the laser target)

Put one piece of photo paper 10cm away from the laser probe, and keep it there, don't move.

1. Wear the laser protection glasses
2. Switch on the machine
3. Switch on the aiming beam, and shot it along with the central axis of the light guide arm.
4. Set the parameter to 100mJ
5. Make sure the red aiming beam fall on the photo paper.
6. press the pedal
7. check the laser burning falls at the center of aiming beam.
8. If the two lights is far from each other, then the yag laser will fall on the inner part of the light guide arm, to make the energy lose or reduce, and damage the guide beam and lens.

6.2 operation on the screen

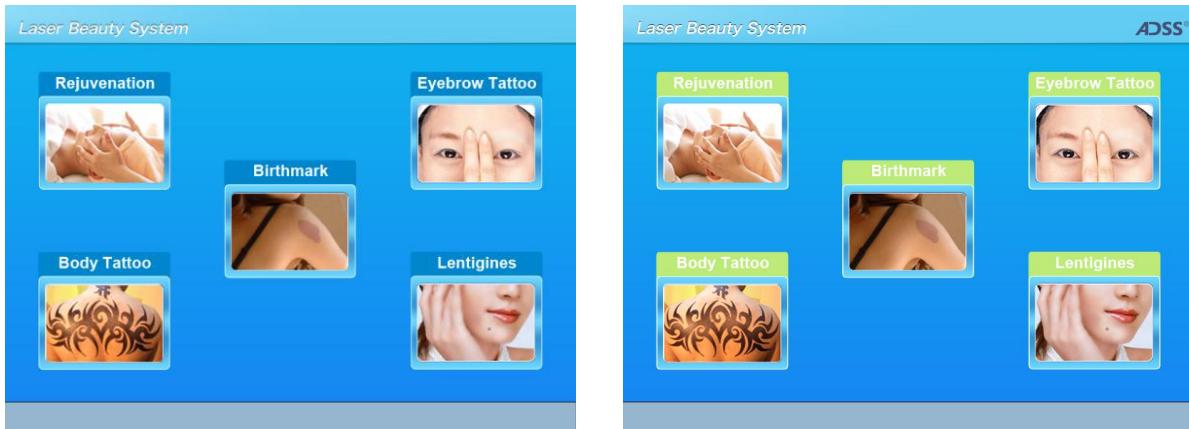
6.2.1 Self-checking screen after switch on the machine

After we switch on the key switch, the machine will show the self-check screen. (as the photo below)

When the customers press the “setting” menu, it will go to the pin input screen, and it will go to the setting screen after input the correct pins, this is the factory setting menu, not open to the customers.

6.2.2 Functions selection menu

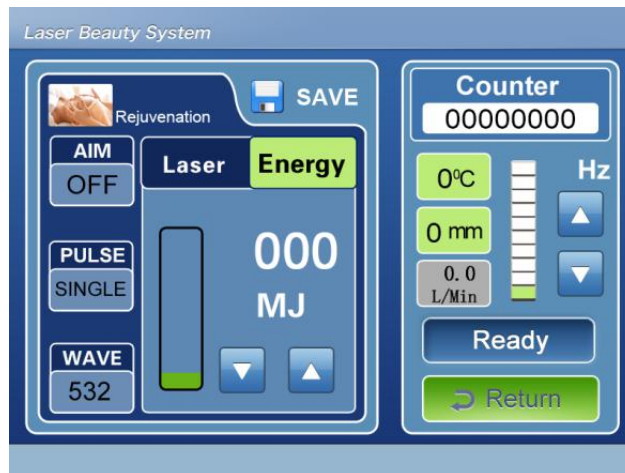
After the self-checking finished, it will enter into the functions selecting menu, as below, when customer press any function menu, it will go to the relative treatment menu.



Functions selection menu

6.2.3 Treatment menu

When select any function, it will go to the relative function treatment menu, as below.



Treatment menu

6.2.3.1 aiming beam switch

Under the standby condition, press the aiming beam switch “AIM” to switch on the beam, to facility the treatment.

6.2.3.2 Switch between single and double pulses

Enter into the screen, press the “PULSE” menu to switch the single and double pulses. Under 532nm mode, the single pulse energy is from 50MJ-500MJ, 50MJ as one step. The double pulse energy is from 100mj-1000mj, 100mj as one step. Under 1064nm mode, the single pulse energy is 100mj-1000mj, 100mj as one step; double pulse energy from 200mj-2000mj, 200mj as one step.

6.2.3.3 Switch between wavelengths

Under standby condition, press the “WAVE” menu to switch the laser wavelengths (1064nm&532nm) as per

treatment demands.

6.2.3.4 Energy set

Under standby condition, we set the laser energy as per treatment demands to press the energy adjusting menu **【▼】【▲】** (under 532nm wavelength, the energy scope is 50mj-500mj, 50mj as one step; under 1064nm wavelength, the energy scope is 100mj-1000mj, 100mj as per step).

6.2.3.5 Setting the frequency

Under standby condition, we set the laser frequency as per the treatment demand to press the energy adjusting **【▼】【▲】** (frequency scope 1HZ-10HZ, 1HZ as one step)

6.2.3.6. Standby/ready

Under Standby condition, press READY menu, then the READY menu will switch to STANDBY menu, the system will go to ready condition, at this time we press pedal, and hear the “bip bip bip” alarming sound, then the laser will shot, and stop once we release the pedal.

6.2.3.7 Return

Under Standby condition, press the “Return” menu to return to the function selection menu.

6.2.3.8 Temperature

Under the treatment menu, the screen shows the water temperature, when the temperature is over 55°C, the system will goes to water temperature alarm surface, and alarm, please shut off the power and fix the malfunction, then restart the machine.

6.2.3.9 Water flow

In the treatment surface, it shows the water flow influence, when the water influence is less than 2L/min, the system will turn to the water flow alarm surface and make alarm sound, please shut off the power and fix the malfunction, then restart the machine.

6.3 Instruction after using the machine

- a. After using the machine, we suggest return to the pause surface before switch off the machine.
- b. Turn the key switch to “off” position, to switch off the machine
- c. Put the light guide arm to a safe place, in case to cause laser deflection.
- d. Disconnect the probe and other tools, to clean and disinfect.

7. Maintenance and repair

7.1 Daily Maintenance

- a. After each operation, the treatment hand is placed on the bracket or the safety position to prevent falling damage;
- b. Do not use the box surface with a gasoline, alcohol, thinner, or chemical preparation, because it will cause the surface coating of the box to be peeled off;
- c. Clean the surface of the instrument and therapeutic room, please note that do not raise the dust, so as not to enter the instrument inside, affect the normal operation of the optical system;
- d. When the instrument is not in use, please remove the instrument key, close the emergency switch, and keep the key by hand to prevent the accident;
- e. The internal structure of the instrument is complex, do not disassemble, please be sure to contact the company's after-sales service department when it happen malfunction.
- f. in order to ensure the normal use of the instrument, the purchase or replacement of spare parts, please contact the manufacturer or agent;

Notice

①The customer only needs to carry on the daily cleaning maintenance to the instrument or under the guidance of the professional personnel of our company to carry out the simple trouble shooting, other maintenance work should be handed over to the technical personnel authorized by the company to complete;

②Before the maintenance of the machine must be take down and set aside the power cord, and with electrical maintenance is harmful for body and electrical equipment

7.2 main problems and maintenance

Breakdown information	Reasons and Elimination method
There is no display when machine Connect the power.	1,The machine is not connected to the AC power: check the power cord is plugged into the power outlet, the main control switch, emergency stop switch is open or not, the connection of the socket is connected or not. 2,Low voltage switching power supply fault: check the low-voltage switch power input, output socket, input, output voltage or not. 3.Control panel failure: contact the company's technical department.
Water flow switch fault	1, water flow switch sensor position offset 2, the connection line is not connected well.

Normal operation, liquid crystal don't have display	5V power supply damage or bad connection plug connection
high-voltage power supply	There is no high-voltage power supply: check the AB connector on the high voltage power supply

Breakdown information	Reasons and Elimination method
"POWER" to "ON" position, the machine does not have any action	1, did not "work" 2, poor access to insurance
Control key failure	1. Control panel's T5S35 isn't connect well. 2. The machine works in the computer preset "working" state, and hold the foot switch without laser output. Disassemble the foot switch
Aiming light is too weak	1, reflecting the lens is too much dust, wipe off the dust 2, helium neon light damage or damage to the power indicator light, should contact the company's technical department
YAG does not fall on the indicator light spot.	Light path problem: adjusting the optical path
When the foot switch is pressed, no laser output	Poor connection of foot switch
The adjustment of Frequency is out of control	CPU was damaged.
When the working state, the output laser energy is low	1. Water temperature rise or lack of water 2. Q crystal plate or pre board damage 3. Light path problem
Computer out of control	Turn off the power, then open the machine again, troubleshooting.
When the working state, the output laser energy suddenly increased	1. trigger board damage 2. bad connection 3. Q crystal plate damage

Matters needing attention:

- a. cannot be observed in the naked eye, in addition to skin treatment can not be used.
 - b. when the machine is running, in order to avoid eyes accidentally exposed to laser, all personnel involved in the operation should wear protective goggles.
 - c. laser should not be used in the environment with flammable anesthetics or volatile organic compounds.
 - d. special attention should be paid to the operation of the high voltage components of the laser device.
 - e. the heat dissipation part of the machine should be far away from the wall above 20cm.
 - f. use the cream of the operation when using the anaesthetic cream.
 - g. do not use wet hand contact with the machine.
- If you suspect that there is a problem, please immediately entrust the company's after-sales service, please do not repair.

8. Safety Protection

8.1 Laser safety

FG2015 regulating Q laser therapeutic instrument in a high intensity laser and infrared radiation will lead to eye tissue damage to the organization, especially; therefore, in order to avoid accidental observation of laser beam on the human body harm, all the treatment room doors and windows to block the laser with a high density of shading material spread. There must be warning signs in the treatment room.

This machine focuses on two aspects of functional and safety. The system designed a comprehensive security testing procedures. In view of the operation of laser high intensity, high energy output, all the relevant personnel must follow the following prevention and measures. Before use, check whether the parts are installed correctly and the insulation of the power cord is intact, and to determine the good eye protection device. Avoid direct or scattered radiation from the eyes or skin.

Do not look directly at the laser or reflected light, the output of the direct and reflected laser light contains sufficient energy to cause serious damage to the eye.

Anyone who does not wear proper protective glasses should not be close to the laser when the laser is working.

Please do not make the maintenance work outside the system drawing in the manual, and the maintenance should be done by the manufacturer or the manufacturer authorized by the manufacturer.

Do not let the system in a flammable environment such as narcotics, oxygen, etc..

In addition to the treatment area, do not point the laser fiber to it, in the output of the laser, please confirm the optical fiber output in a safe direction.



Alarm: before and during using the laser,if the operator don't use the screen controller, adjust instrument or operate the machine in a correct way, the operator and patient may be under dangerous laser irradiation

8.2 Characteristics of laser safety system

Each component of the therapeutic apparatus has a different electronic and mechanical safety design, and the following is a safety device designed to prevent inadvertent or improper operation.

1, "Key switch" it is an essential tool, control the open and close of this machine.

Note: when the system is not in use, the key is taken down and stored safely in order to prevent the irregular operation of the laser system.

2, "Emergency switch", it's set a function of the convenient emergency switch for user. Unless the power switch and the main switch is connected properly, the laser system can not be used, so the clinical use is very safe. After the emergency stop switch is pressed, all the operations will be suspended, and the device will be closed. In order to prevent the wrong setting and operation of the system to change the operating parameters of the instrument, the host design "standby / ready" switching function, only in the standby state, the system is allowed to set parameters.

3. In order to prevent the error setting and operation process of changing the operating parameters of the treatment instrument, the host design "standby / ready" switching function, only in the standby state, the system is allowed to set parameters.

4. Pedal switch is a switch control treatment instrument for work, switch external protective cover to prevent misoperation, its shell protection grade IPX1 (anti device drops), do not to the spilled liquid or used in a humid environment.

5. The "remote control interlock switch" is used to prevent the non - expected personnel entering the laser working area when the instrument is working. When the door is opened, the hair removal device will stop the laser output.

6. Therapeutic instrument is equipped with a pair of protective glasses, safety performance of the optical fully meet the all requirements of the European standard EN207:1998+A12002 and through the EU CE certification, before he output laser, please confirm has been supporting protective glasses.

7, **Only the following conditions are available with the laser system to work properly:**

- ※the power is connected with the instrument
- ※A key switch controller
- ※The control switch is in the state of emergency release
- ※The instrument is in the ready state and self without exception

The user must be qualified and have practical experience, otherwise, it is not necessary to operate.

8.3 (NOHD)

The therapeutic instrument is four kinds of laser products, in the process of output laser, is prohibited by the eye directly under the laser or reflective laser, to prevent damage to the eyes. The safe distance (NOHD) is 30.1m.

8.4 Laser safety mark

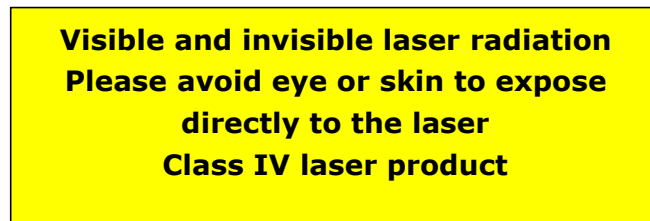
At the front and rear of the device panel, the two sides and the laser light window and so on, there are the following warning signs:

Class IV Laser product
GB7247.1-2012
Wavelength: 1064nm, 532nm
Max Energy: 2000mj, 1000mj
Pulse width: 6ns
Aiming beam wavelength: 650nm

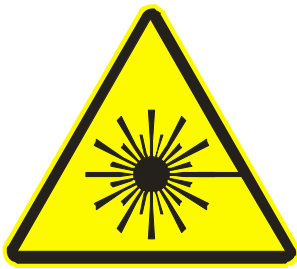
Pictures 8.1 Laser marking instructions



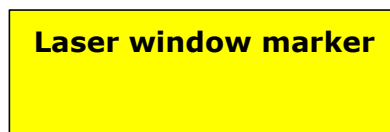
Pictures 8.3: Safety interlock mark



Pictures 8.2: Classification of laser marker



8.4: General laser



8.5: laser window marker



8.6: B type application part mark

Pictures 8.1

Laser marking instructions, at the bottom of the equipment behind the product nameplate. The results show that the maximum output, wavelength, and classified on the basis of the standard equipment of laser radiation, the marking shall be in line with the requirements of 5.8 GB7247.1-2012.

Pictures 8.2:

Classification of laser marker, on the top of the device, that such devices for class 4 laser products, have a certain degree of radiation, to avoid direct or diffuse radiation exposure of eye or skin, marking shall be in accordance with GB7247.1-2012 5.6 requirements.

Pictures 8.3:

Safety interlock marker, on both sides of the equipment, that once the side cover has been removed or demolished in the cancellation may allow the personnel contact laser radiation, marking shall comply with GB7247.1-2012 5.9.2 requirements.

Pictures 8.4:

General laser warning signs (see GB7247.1-2012 in Figure 14), under the equipment front transmission system output, that such equipment for laser products.

Pictures 8.5:

Laser marking laser window window marker, right in the transmission system equipment output, which indicates that the laser emitted, marking shall comply with GB7247.1-2012 5.7 requirements.

Pictures 8.6 type application part markers:

Application part anti electric shock type marker. To the left of the equipment transmission system output port, show equipment application part anti electric shock type for type B, marking shall be in accordance with the requirements related to GB9706.1-2007.

The laser light path adopts the fully closed design, which can effectively prevent the leakage of the laser radiation, and prohibit the use of the instrument in the open state of the seal cover.

8.5 Security measures

i.setting a dedicated work area is recommended, posting "Laser warning"、"dangerous" special laser safety warning signs in a conspicuous place.

ii.Workspace door should have"non-staff not allowed" warning mark.

iii.Avoid reflective material around the work area, in order to avoid accidental laser beam reflection, injuring personnel.

iv.Laser equipment should be kept and used by special person.

v.The key of equipment should be took off when user leaving.

vi.Users should wear the protected goggle that adaptive with the hair removal laser wavelength and power.

vii.Avoid shooting to eye directly or reflecting laser.

8.6 Electrical Safety

- i. Product Protection ground terminal has been marked in accordance with relevant standards, before the end of commissioning, maintenance personnel should check the protective grounding wire whether has been connected well as the required before the end of commissioning. When the device does not work, do not turn on the power.
- ii. Internal device and the light guide arm have high pressure, should not be opened by non-trained and qualified service personnel; repair maintenance personnel should pay attention to the related marks during process, avoiding electric shock.
- iii. Device working will release properly large electric current, never touch the electrode after the device has electric.
- iv. The device uses single-phase 220V AC alternating current, power supply 2000VA, hospitals should provide the appropriate power supply conditions for the related department .
- v. Staff should master the basic knowledge of electricity safety, and master laser treatment performance and operations.

- vi. Laser equipment should be operated under the allowable working conditions and environment
- vii. Treatment instrument electrical safety classification: Protection against electric shock type: Class I; the degree of anti-shock application part of Type BF application part

b) Fire Safety

- a. This device is prohibited to put other things around. Installation of equipment should ensure the power supply system have sufficient capacity.
- b. Should not place flammable and explosive material into the optical path of the laser or the place laser beam can shine. If the laser beam shine onto flammable, explosive materials and may cause a fire or explosion.
- c. Must avoid the use of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen. Some material like cotton-rich material will be fired at High temperatures generated by laser equipment normally used. Solvents and flammable solutions used for cleaning and disinfection should be evaporate before using laser device.
- d. Working room should be equipped with fire fighting equipment.

9. Technical documents

FG 2015ND: YAG Q-switched laser treatment based on YY 0505-2012 Medical electrical equipment - Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility requirements and testing standards, belong to Group 1 Class A equipment. Please installed and used in accordance with the following electromagnetic compatibility information.

- a) For this device, need to take on electromagnetic compatibility (EMC) special precautions, and must be installed and used according to EMC information provided in this manual. Portable and mobile RF communications equipment have effect on this equipment.
- b) The device should not be close to or stacked with other equipment, if have to, should observe and verify the device can be normal operation under using configuration.
- c) This device is suitable for hospitals, large clinics, small clinics, you can use these places public grid to provide power supply equipment, operated by professional person directly . FG 2015 ND: YAG Q-switched laser treatment may cause radio interference or disrupt the operation of nearby equipment, it may be necessary to take mitigation measures, such as re-adjust the direction, location or block sites of FG 2015 ND: YAG Q-switched laser machine.

i. Basic performance

Name	Specific Description
Laser Power	Laser power output values shall not exceed $\pm 20\%$ of the set value

ii. You must use cables and accessories provided by this equipment, cable information as below

Cable Name	Length
power cable (10A)	1.8m
Foot switch Cable	2.3m

Data Cable	1.5m
Warning: Excepts the internal components as spare parts sold cables, using other accessories and cables provisions may lead to the system or equipment emission increase or immunity reduction.	

iii. Table 201 Guidance and manufacturer's declaration---Electromagnetic emissions

Guidance and manufacturer's declaration---Electromagnetic emissions		
FG 2015ND : YAG Q-switched laser device intends to use in the specified electromagnetic environment as below, the purchasers and users should ensure that it is used in such an environment:		
Emission tests	Conformance	Electromagnetic environment - Guidelines
RF Transmitter GB 4824	Group 1	FG 2015ND: YAG Q-switched laser device only uses RF energy for its internal function. Therefore, it's RF emissions is very low, and the possibility of interference in nearby electronic equipment is small.
RF Transmitter GB 4824	Class A	FG 2015ND: YAG Q-switched laser device is suitable for use in all non-residential and residential facilities that public low-voltage power supplied network is not directly connected
Harmonic emissions GB 17625.1		
Voltage fluctuations/Flashing launch GB 17625.2		
Warning: The device should not be close to or stacked with other equipment, or if you must be close to or stacked to use, should observe and verify whether can be normally operated can be under its configure.		

iv. Table 202 Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
FG 2015ND : YAG Q-switched laser device intends to use in the specified electromagnetic environment as below, the purchasers and users should ensure that it is used in such an electromagnetic environment:			
Immunity Test	IEC 60601 Test level	Conformance level	Electromagnetic environment - Guidelines
Electrostatic discharge GB/T 17626.2	±6kV Contact discharge ±8kV Air discharge	±6kV Contact discharge ±8kV Air discharge	Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the corresponding humidity should be at least 30%
Electrical Fast Transient GB/T 17626.4	±2kV Power cord ±1kV Input / output lines	±2kV Power cord ±1kV Input / output lines	Mains power quality should have a typical commercial or hospital environment use
Surge GB/T 17626.5	±1kV Wire to Wire ±2kV Wire to Earth	±1kV Wire to Wire ±2kV Wire to Earth	Mains power quality should have a typical commercial or hospital environment use

Power input line voltage dips, short interruptions and voltage variationsGB/T 17626.11	<5%Ut , continued0.5 cycles (On Ut , >95% sag) 40%Ut , continued 5 cycles (on Ut , 60% sag) 70%Ut , continued 25 cycles (On Ut, 30% sag <5%Ut, continued 5s(On Ut 上, >95% sag)	<5%Ut , continued0.5 cycles (On Ut 上, >95% sag) 40%Ut, continued5 cycles (on Ut , 60% sag) continued 25 cycles (On Ut, 30% sag <5%Ut, continued 5s(On Ut 上, >95% sag)	Mains power quality should have a typical commercial or hospital environment use
Power frequency magnetic field (50Hz/60 Hz) GB/T 17626.8	3A/m	3A/m	Power frequency magnetic field should have a typical place in a typical commercial or hospital environment characteristic of the level of power frequency magnetic field

v. Table 204 Guidelines and manufacturer's declaration - electromagnetic immunity - for non-life-support equipment and systems

Guidelines and manufacturer's declaration—Electromagnetic Immunity			
FG 2015ND : YAG Q-switched laser device intends to use in the specifiedelectromagnetic environment as below, the purchasers and users should ensure that it is used in such an electromagnetic environment:			
Immunity Test	IEC 60601Test Level	Conformance level	Electromagnetic environment - Guidelines
Conducted RF GB/T 17626.6 RF radiation GB/T 17626.3	3V (Valid Values) 150kHz~80 kHz 3V/m 80MHz~2.5GHz	3V (Valid Values) 3V/m	Portable or mobile RF communications equipment should not be used closer than the recommended separation distance of any part of the FG 2015ND: Q-YAG laser device, including cable. The distance should have formula to count that with the corresponding transmitter frequency.

vi. Table 206 Recommended separation distance between Portable and mobile RF communications equipment and present devices - for non-life-support equipment and systems

Recommended separation distance between Portable and mobile RF communications equipment and the present device
FG 2015ND: YAG Q-switched laser device intends to use in radio frequency electromagnetic radiation harassment controlled environment. Based on the maximum rated output power of the communication device, purchasers and users can recommend theminimum distancebetweenportable and mobile RF communications equipment (transmitters) and FG

2015ND: Q-YAG laser device to prevent electromagnetic interference as below:

The maximum rated output power of the transmitter W	Corresponding to a different frequency transmitter isolation distance/m		
	150kHz~80MHz $d=[3.5/\sqrt{V1}]\sqrt{P}$	80MHz~800MHz $d=[3.5/\sqrt{E1}]\sqrt{P}$	800MHz~2.5GHz $d=[7/\sqrt{E1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23