

nuCORE

Multi-Functional Laser & IPL Platform

User Manual

Version 2.1

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Jacksonville, FL
(904) 664-5759 · WORLDAESTHETIX.COM

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This User's Manual is divided into the following sections:

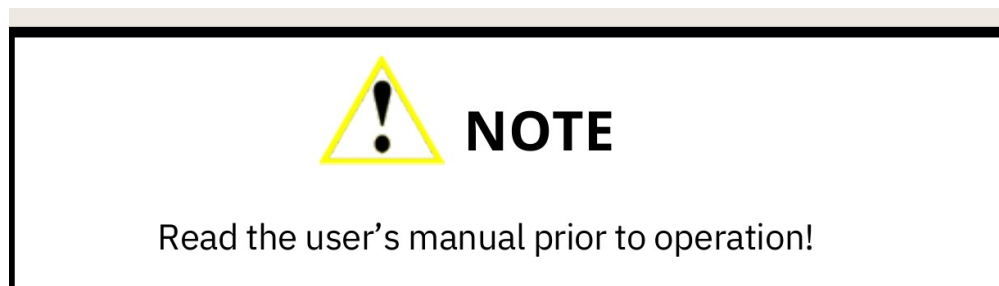
- **Preface** — brief technical overview and medical usage.
- **Safety** — general safety precautions when operating the device.
- **Description** — description of the components and controls.
- **Installation** — introduction to the installation and transport procedures.
- **Operation** — device operation.
- **Maintenance** — maintenance information.
- **Clinical Application** — application range, treatment, process, and side effects.
- **Parameters Selection** — basis of parameter selection and treatment evaluation.
- **Specifications** — brief overview of the specifications.

Pay attention to the Warnings, Cautions, and Notes throughout this manual:

- **WARNING:** alerts the operator to observe the following instructions. Ignoring them can endanger patients and/or operators.
- **CAUTION:** instructs the operator on the proper use of the system and its accessories. Not following the protocol, or ignoring it, can irreversibly damage the unit.
- **NOTE:** provides additional information in each section as a highlight.

NOTE

Read the user's manual prior to operation!



Chapter 1 Preface

1.1 Overview

The nuCORE 8:1 is a new platform treatment system with a 12.1" display screen that combines IPL, diode laser, triple diode laser, Q-switched Nd:YAG laser, Er:YAG fractional laser, 1064 nm long-pulse Nd:YAG, Er:Glass fractional laser, and picosecond Nd:YAG laser functions. This 8-in-1 platform allows you to select a function by attaching different handpieces. The system uses standard AC power and is equipped with wheels for in-office mobility.

This device uses multiple therapeutic modalities, in combination or in isolation, for ablative and non-ablative treatment of the skin's surface. The system includes a lamp, additional energy sources, and dedicated handpieces intended to apply the different energies to the skin.

1.2 Device brief introduction

Model name: nuCORE 8:1. Product name: Multi-functional Laser System.



Figure 1.1

1.3 Device structure

This device (Figure 1.1) is composed of three parts: (1) the main unit, (2) the control panel, and (3) the treatment handpiece. The control panel includes the color 12.1" TFT LCD touchscreen. The LCD screen shows the working mode, with settings included in the display. Medical Use — Application Areas

1. IPL: The IPL therapy is intended for medical use in the treatment of the following dermatologic conditions:

- a. Permanent hair reduction — long-term stable reduction in the number of hairs regrowing after a treatment regimen;
- b. Moderate inflammatory acne vulgaris;
- c. Benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles);
- d. Cutaneous lesions, including scars;
- e. Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal, and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas, and venous malformations; permanent hair removal in patients with exuberant and hirsutism; reduction of pigmented lesions; reduction of vascular lesions; and treatment of acne.

2. Diode laser — 808 nm:

a. Hair removal is intended for permanent reduction of hair regrowth.

3. Triple diode laser — 755 + 808 + 1064 nm: Hair removal is intended for permanent reduction of hair regrowth. Multiple wavelengths for different skin colors (Fitzpatrick I–VI).

Chapter 2: Operating Safety

Precautions

2.1 Introduction

This chapter describes the proper use of the platform treatment system. Each operator must have read and understood the User's Manual completely prior to operating the device.

2.2 Responsibilities of the User

Before each treatment, the user must check the functional performance of the device in order to rule out any risk to patients or third parties. If the device is used in conjunction with peripheral units, the User's Manuals for the peripheral units must also have been thoroughly read and understood.

WARNING

This device may cause thermal injury if used improperly. Medical personnel must familiarize themselves with the machine's safety instructions and operational procedures prior to use.

2.3 Burn Hazard

This platform emits a wavelength that is invisible to the human eye but can cause serious burns to the eyes.

2.4 Reflected and Direct Eye Exposure Hazards

The laser beam emitted by the platform system is in the invisible range of the spectrum and presents an eye hazard. As a precaution against accidental exposure to the output laser beam or its reflections, all personnel must use appropriate safety eyewear.

WARNING

Do not look directly into the laser beam or allow it to be reflected from any reflective surfaces. Maintain a minimum distance of 200 mm between the laser exposure aperture and the operator's eyes. The device must be managed so as not to direct the laser near the eyes, and protective eyewear must be worn at all times, even when the device is in standby mode.

2.5 Fire prevention

The Multi-function Platform system is not suitable for use in the presence of flammable mixtures with air or oxygen. Do not operate the system in the presence of volatile solvents such as alcohol or gasoline. If alcohol-based products are used to disinfect the platform treatment system, ensure that the alcohol has completely evaporated prior to operation.

2.6 Safety Features 2.6.1 Electrical and machine safety

The unit uses a 110–240 V, 50/60 Hz, single-phase power supply. Its power consumption should be less than 1600 W. Use a 16 A (110–240 V, 50/60 Hz), single-phase, three-wire outlet that meets international standards. This device connects to ground through three lines; connecting the ground wire is important to operational safety. Do not open the control or rear panel even if the unit is switched off. Only authorized personnel may repair or maintain the platform treatment system. Tampering with the unit will void its warranty. The key switch is used to turn the unit on and off. Remove the key when the unit is not in use to prevent unauthorized access. The emergency cut-off switch is used to

shut down the device in case of any emergency. After engaging the emergency shut-off button, turn the device off by rotating the key counterclockwise. Rotating the emergency cut-off switch in the direction indicated by the white arrows will release the button.

WARNING

To avoid risk of electric shock, this equipment must only be connected to a supply main with a protected grounded wire.

2.6.2 Optical safety

All personnel (including the patient) should wear protective glasses. Do not substitute treatment/safety glasses with other types of tinted eyewear, which may not meet the specific safety requirements of the unit. Note: gauze, eye-shields, and tarsi are all effective in protecting the eyes. Clearly identify the room in which the laser system is located, and place the warning sign (supplied with the system) in a visible location. Allow access to the treatment room only to personnel essential to the procedure and well trained in the required safety procedures. Make sure that all treatment room personnel are familiar with the system controls and know how to shut down the system instantly. Never look directly into the laser beam emitted from the handpiece tip, even when wearing protective eyewear. Never direct the laser beam at anything other than the target area.

2.6.3 Operating Safety Precautions

Never leave the system in READY mode unattended. Never activate STANDBY mode if you are not going to administer treatment. Always turn off the system when not in use. Never allow untrained personnel to operate the system. Never activate the footswitch or the handpiece trigger without first verifying that the handpiece is safe for treatment. Mind the cables on the floor during operation.

2.6.4 Corrosion Precautions

Never allow the power supply cable, footswitch cable and handpiece cable to contact corrosive liquids in case of potentially fatal electrical shock.

2.7 System Safety Features

The platform treatment system is equipped with a number of safety features. All treatment room personnel should be familiar with the location and operation of these safety features. The treatment room should be maintained at an indoor temperature of 5–30°C.

2.7.1 Operational Mode Access

The system will enter operational mode only after the circuit breaker is turned to the ON position and the inserted switch key is turned to the ON position.

2.7.2 Software Protections

Upon switching on the system, the processor first undergoes a self-diagnostic program. The processor then examines the system automatically and continuously throughout the entire treatment procedure. The intelligent system continuously monitors the system during operation. If a malfunction occurs, the system displays an error message to the operator. In case of a serious error, the software aborts system operation.

2.7.3 Emergency Shut-Off Knob

The red Emergency Shut-off Knob is designed for emergency shutdown. When pressed, it immediately shuts off power supply to the entire system. To resume normal operation, release the knob by turning it clockwise to restart the system.

2.7.4 Semi-Automatic Circuit Breaker

A 16-ampere circuit breaker is installed behind the device adjacent to the power cord. Loads in excess of 16 amperes will trip this switch. Simply moving the switch upward will restore power to the system.

2.7.5 Laser Beam Emission Indicators

There are two visual indicators:

- (1) When the system is powered on, the aiming beam will indicate power with a red LED light.
- (2) When the system is in READY mode and during laser emission (when the handpiece trigger or footswitch is activated), the "Warning" mark will appear on the treatment screen.

2.7.6 Remote Interlock Connector

The system incorporates a Safety Remote Interlock Connector for connecting an external interlock to the entrance door of the treatment room. When the external remote interlock is connected to the interlock connector, it disables system operation when the entrance door is open.

2.7.7 Ventilation System

The main unit, where the water cooling system is located, contains two fans to ensure proper cooling of the water. Additional fans cool the driver.

2.7.8 Cooling System

Both the flow rate and the water temperature are monitored by the control system in order to eliminate the risk of overheating the YAG rod. Lasing is disabled if the water flow value reaches or falls below 20, or if the water temperature reaches or exceeds 55°C. In addition, the temperature of the water is monitored directly.

2.7.9 Tissue Cooling System

The handpiece tip is cooled by a TEC method via a cold sapphire to reduce patient discomfort during treatment and to reduce post-procedure side effects, such as local skin redness and swelling. The tip temperature is reduced to -4°C during system operation.

2.8.2 Safety Recommendations

The following are general safety recommendations for the procedure room.

Ensure that all personnel and patients wear protective eyewear.

Never look directly into the aiming beam or its reflection. Permanent eye damage can occur.

Remove all shiny or reflective objects, such as rings, watches, or jewelry, and any metallic objects from the treatment area.

Do not depress the footswitch without first verifying the location of the articulated arm and the attached handpiece, to prevent unintended exposure.

- Do not leave the device unattended while in the Ready or Emission mode.

When the device is not in use, rotate the key switch to Off, turn the circuit breaker switch off, remove the laser key, and store the key in a secure location.

- Do not allow untrained personnel to operate the device.

Do not attempt to remove the protective covers from the device cabinet. Only factory-authorized service technicians or representatives should remove the protective covers.

Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide and oxygen, which may ignite during normal use of the platform. Allow cleaning and disinfecting solvents to evaporate before using the device.

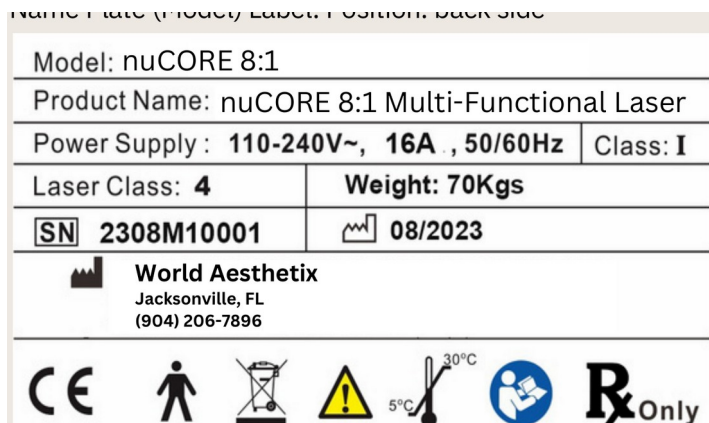
The electromagnetic radiation intensity of this product conforms to Class A standard requirements. To enable the instrument to work normally and stably, the equipment should be used in an environment without strong electromagnetic interference. If auxiliary electrical equipment is used, it should not produce strong electromagnetic interference and should be able to resist a corresponding level of EMC interference (please see Section 8.2).

NOTE

Please read the safety recommendations above carefully until you are familiar with them. Refer to these precautions before operating, as needed.

2.8.3 System Labels

Identification labels are attached to the system device: Name Plate (Model) Label: Position: back side nuCORE 8:1 nuCORE 8:1 Multi-Functional Laser World Aesthetix Jacksonville, FL



(904) 664-5759. Explanation: serial number; production date; manufacturer; European Authorized Representative information; a security certification mark; type B; environmental protection; general warning; use of ambient temperature. Always read the User's Manual before operating.

Explanation:			
SN	serial number	08/2023	production date
World Aesthetix	manufacturer information	EC REP	European Authorized Representation
CE	A security certification mark		
Person icon	typeB	Environmental protection icon	Environmental protection
Warning triangle	General warning	Thermometer icon	use of ambient temperature
Person reading book icon	Always read the User's Manual before operating		

- Electrical Requirements Label — located next to the power cable connection port.



- Safety Laser Radiation Symbol — located on the rear of the system.



- (4) Laser Emission Danger — warns against possible exposure to laser beam radiation and specifies the type and classification of laser beams present.



- (5) Laser Class 4 Label — located on the rear panel of the system. Identification labels are attached to the handpiece:

Label is located on the rear panel of the system.



- (6) Laser Aperture Label — located near the handpiece tip.



Chapter 3 Description

This chapter introduces the main parts of the system, the accessories, and the process of installation and debugging.

3.1 Parts and control

The multi-function laser platform system is composed of the following parts. Figure 3.1 Main parts of the laser system



Figure 1.1

1. Treatment handpiece

2. Display screen

3. Main unit

3.1.1 Main unit

The main unit is an integral part of this system; it consists of the following parts.

1. Power supply module: regulates electrical supply to the entire system.
2. Control panel: regulates and coordinates the various components of the system for optimum performance.
3. Display module: displays the settings and information of the system and accepts user instructions.
4. Radio frequency generator: provides a 1 MHz radio frequency signal to the treatment electrodes to ensure adequate RF energy penetrates the epidermis and dermis during operation.
5. High-current capacitors: deliver adequate electrical energy to ensure sufficient power during operation.
6. Cooling system: maintains a stable thermal environment for optimum performance.

3.1.2 Control panel

Operation of this machine is done through the control panel. It includes the following parts: 1) Key switch: used to turn the power supply on and off (clockwise to turn on, counterclockwise to turn off). 2) Emergency turn-off switch: the red button on the front panel of the machine is used to immediately shut off the machine's power supply in case of any

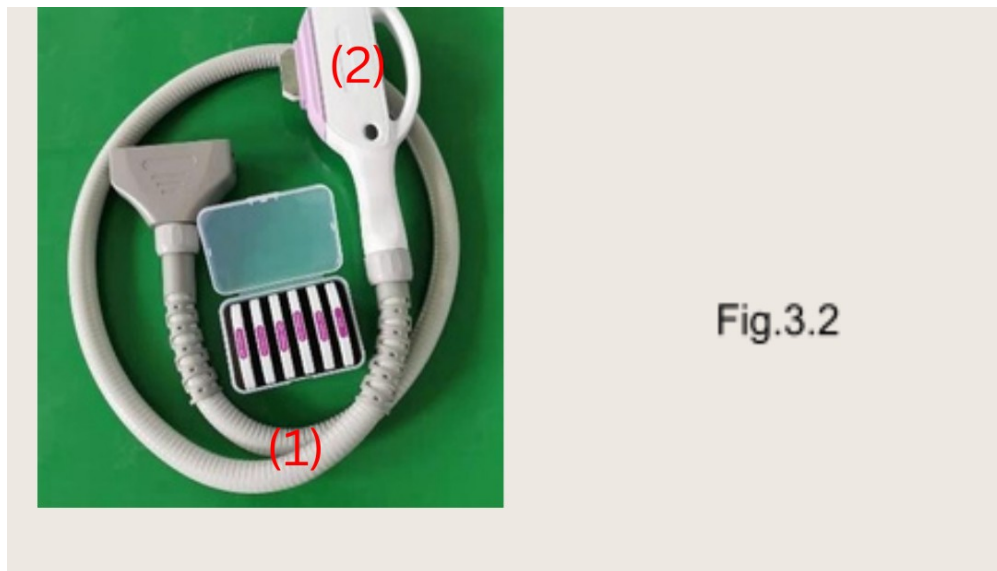
emergency. Depressing this button will cut off the power supply to the whole system. Rotating the button in the direction of the arrow printed on its surface will disengage the button and reengage the power supply. When this button is engaged, remember to turn the key switch to the off position afterward. 3) Touch screen display: the LCD (liquid crystal display) shows the operational settings and adjustments, as well as system status, all displayed on the screen.

3.1.3 Treatment handpieces

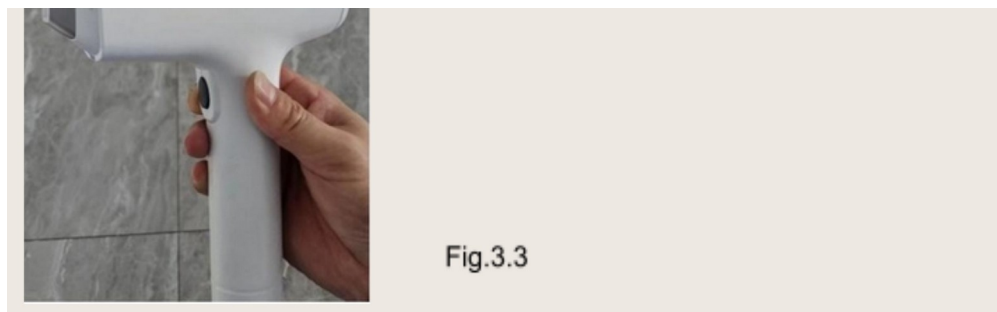
There are a total of 8 treatment handpieces for this system (IPL, diode laser, triple diode laser, Q-switched Nd:YAG laser, Er:YAG fractional laser, 1064 nm long-pulse Nd:YAG, Er:Glass fractional laser, and picosecond Nd:YAG laser). When you attach a different treatment handpiece, the system recognizes which of the 8 handpieces is connected and enters the proper treatment software automatically.

3.1.3.1 The IPL treatment handpiece

The IPL handpiece consists of: (1) Cable housing: this contains the power cable, liquid coolant tubing, and control data cable; (2) IPL head: this houses the control switch, flash lamp, sapphire crystal, filter piece, and electronic semiconductor cooling system. Depressing the trigger on the laser treatment head discharges the flash lamp at the settings displayed on the control panel. Depressing the footswitch likewise discharges the device (on selected models only). The supplied sapphire crystal measures 15 mm x 50 mm (IPL) and is superior in both clarity and longevity, thereby increasing both the efficiency of the flash lamp and the lifespan of the treatment head. It is very important to keep the sapphire crystal clean. Be sure to clean it with a soft cloth after each treatment. A disinfectant such as alcohol can be used between treatments. Dried gel on the sapphire crystal will reduce the efficiency of the flash lamp. Replace the plastic guard over the crystal to prevent damage. In the event that the sapphire crystal is damaged (i.e., nicked or cracked), contact your dealer immediately.



3.1.3.2 Diode laser treatment handpiece — 808 nm

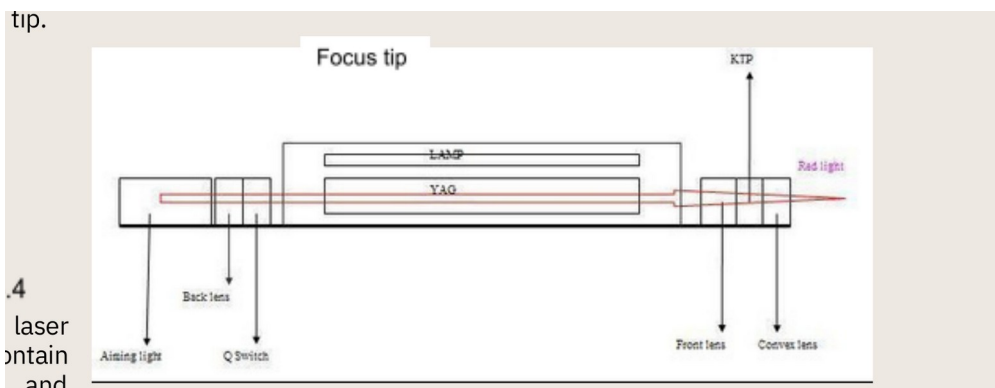


3.1.3.3 Diode laser treatment handpiece — 755 + 808 + 1064 nm



3.1.3.4 Picosecond Nd:YAG treatment handpiece

The picosecond Nd:YAG laser handpiece consists of: (1) Cable housing: this contains the power cable, liquid coolant tubing, and control data cable; (2) Laser head: this contains the control switch, flash lamp, YAG bar, KTP, and focus tip. The laser handpiece contains 532 nm and 1064 nm tips, a Ø7 beam expander, and an array lens. The 1064 nm is for the treatment of blue or black pigment; the 532 nm is for the treatment of red and brown pigment; the Ø7 beam expander is for soft peeling. Please select the treatment tip according to your treatment procedure. When you begin treatment, check the treatment area and select the treatment tip (1064 nm or 532 nm). After installing the selected treatment tip, note that the operator must select the correct wavelength (532 nm or 1064 nm) on the screen. Using the wrong wavelength can damage the machine and crack or break the handpieces.





Warning: The 8:1 platform system has specific operating requirements. The operator must not establish contact between the handpiece and the surface of the treatment region. It is the practitioner's responsibility to fulfill these requirements. Failure to do so can create the potential risk of cross-contamination or biological incompatibility from one patient to another, which may increase the risk of injury to the patient. Do not allow the tip to make physical contact with the skin during treatment.

3.1.3.5 2940 nm Er:YAG laser treatment handpiece

The Er:YAG laser handpiece consists of: 1) A cable and housing: this contains the power cable, liquid coolant tubing, control data cable, and treatment handle housing, sheath, and handpiece connector (Ref. Fig. 3.6). 2) Laser head: A. Beam expander: Ø6 mm, Ø9 mm (optional); B. Microbeam 9×9 (81) dots (pixels), 7×7 (49) dots (pixels); C. Focusing lens: Ø1–3.5 mm (optional); D. Vaginal care handle (optional). Warning: The platform system has specific operating requirements. The operator must not establish contact between the handpiece and the surface of the treatment region. It is the physician's responsibility to fulfill these requirements. Failure to do so can create the potential risk of cross-contamination or biological incompatibility from one patient to another, which may increase the risk of injury to the patient.



3.1.3.6 1064 nm long-pulse Nd:YAG laser treatment handpiece

The long-pulse laser handpiece consists of the following. Do not allow the tip to make physical contact with the skin during treatment.

1) A cable and housing: this contains the power cable, liquid coolant tubing, control data cable, and treatment handle housing, sheath, and handpiece connector (Ref. Fig. 3.7). 2) Laser head: 2.2 × 5 mm, Ø6 mm, and Ø9 mm sapphire tip set (Ref. Fig. 3.7).



Fig.3.7

3.1.3.7 1540 nm Er:Glass laser treatment handpiece

The Er:Glass laser handpiece consists of: 1) A cable and housing: this contains the power cable, liquid coolant tubing, control data cable, and treatment handle housing, sheath, and handpiece connector. 2) Laser head (two types of microbeam lenses): 1×100 dots and 1×324 dots (Ref. Fig. 3.8). Warning: The platform system has specific

operating requirements. The operator must not establish contact between the handpiece and the surface of the treatment region. It is the physician's responsibility to fulfill these requirements. Failure to do so can create the potential risk of cross-contamination or biological incompatibility from one patient to another, which may increase the risk of injury to the patient.



3.1.3.8 Q-switched Nd:YAG 1064/532 nm treatment handpiece

The Q-switched Nd:YAG laser handpiece consists of: (1) Cable housing: this contains the power cable, liquid coolant tubing, and control data cable (Ref. Figure 3.9). Do not allow the tip to make physical contact with the skin during treatment.

Figure 3.9. The laser handpiece contains 3 tips: 532 nm and 1064 nm (Ref. Figure 3.9) and a beam expander. The 1064 nm is for the treatment of blue or black pigment; the 532 nm is for the treatment of red and brown pigment; the beam expander is for soft peeling. Please select the treatment tip according to the color of the target treatment area. When you begin treatment, first check the treatment area and select the treatment tip (1064 nm or 532 nm). After installing the selected treatment tip, be sure to select the chosen wavelength (532 nm or 1064 nm) on the screen, because the energy shown on the screen corresponds to the wavelength; selecting the wrong wavelength will cause the wrong energy to be shown on the screen. Figure 3.9 shows the 1064 nm and 532 nm tips and the beam expander tip.



figure 3.9

CAUTION

Only engineers certified by World Aesthetix are authorized to service and maintain this machine.



3.2 Equipment detail list:

The following is the detailed list of equipment for this device: 1) Main host; 2) Handpieces; 3) Protective glasses (operator); 4) Protective goggles (patient); 5) Power cable; 6) Footswitch; 7) Remote interlock connector; 8) Water filling kit (drainage hose + funnel); 9) Key; 10) RFIC cards; 11) Water filter; 12) User's manual.

3.3 System software

The software of the platform has four functions:

1. Applications that allow the practitioner to choose the best parameters for each patient according to their condition.
2. Controlling the working process of the system to prevent unexpected issues.
3. Examining the system energy.
4. Choosing the treatment ranges.

3.4 Environmental requirements

Air Quality:

The system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components, and the surfaces of optical components. Airborne dust particles should be kept to a minimum. Dust particles absorb light and heat up; hot particles located on optical components can damage them. Metallic dust is destructive to electrical equipment.

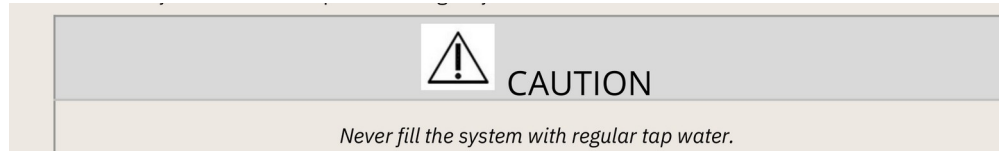
CAUTION

Laser fume and/or plume may contain viable tissue particulates. Water quality: the system should be operated using only distilled water.



CAUTION

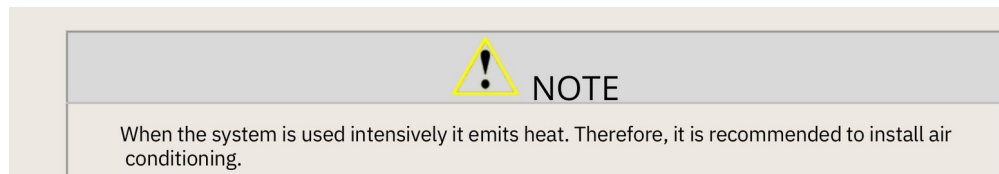
Never fill the system with regular tap water. Temperature and humidity:



- Operating temperature: 5°C–30°C
- Storage temperature: -40°C–55°C
- Operating relative humidity: 70%
- Storage relative humidity: 93%
- Atmospheric pressure: 86 kPa – 106 kPa

NOTE

When the system is used intensively, it emits heat; therefore, it is recommended to install air conditioning.



Chapter 4 Installation

The installation process includes the following (to be performed by an authorized technician only):

1. Unpacking the device and ensuring all systems and parts are present.
2. Resting the device for one day in order to avoid damage from high humidity during long-distance transportation. Simply unboxing and assembling it on day one is sufficient.
3. Assembling its components and ensuring that all connections are firmly in place.
4. Filling the water tank with distilled water only.
5. Installing a treatment handpiece and connecting the power supply.
6. Switching on the device and testing all functions and parameters of the system.

4.1 Equipment detailed list

The following is the detailed list of equipment for this device: main host; the IPL treatment handpiece with 6 filters (optional); the diode laser treatment handpiece (optional); the picosecond Nd:YAG laser handpiece with 1064 nm and 532 nm tips (optional); the Q-switched Nd:YAG laser handpiece with 1064 nm and 532 nm tips (optional); Er:YAG fractional laser handpiece with 49 and 81 ablative microbeams (optional); 1064 nm long-pulse Nd:YAG laser handpiece with 3 mm, 6 mm, and 9 mm sapphire tips (optional); Er:Glass fractional laser handpiece with 100 and 324

non-ablative microbeams (optional); protective glasses; protective goggles; power cable; footswitch; funnel; drainage hose; key; RFIC card; 3-piece O-ring for faucet; user's manual; tap connector.

4.2 Installation requirements

Before unpacking the platform, ensure that the working environment conforms to the requirements of this section. Before assembling the device's components, ensure that high humidity is cleared away by opening the packaging and resting the device for one day.

4.2.1 Location requirements

The device should be positioned in an area with adequate ventilation, away from devices that produce heat (e.g., a refrigerator).

4.2.2 Electrical Requirements

Before the device leaves the factory, it is set to the local rated voltage according to the customer's request. It corresponds to the following electrical requirement: AC 110–240 V $\pm 10\%$, ≤ 16 A. The input current must not have momentary surges, or voltage or current peaks, sinks, or spikes. It is recommended that this device use a dedicated power supply with its own circuit breaker.

CAUTION

Ensure that the voltage rating of this instrument (AC 110–240 V, or refer to the system labeling) matches the voltage of the outlet. Equipotentiality: the device is provided with a terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR. Its purpose is to provide a direct connection between the device and the potential equalization busbar of the electrical installation, which reduces the impedance between the enclosures of different devices and, ultimately, reduces the effect of power fluctuations on the device.

4.2.3 Environment Requirements

Air quality: there should be no caustic particles (such as acid) in the air, as these can damage the electrical wiring, electrical components, and optical component surfaces. Dust in the air should be kept to a minimum, as it can absorb the energy of light and heat up. When dust falls on the surface of the filter, it may damage the filter. Metal particles can also damage electrical components. Temperature: the platform treatment system has an optimal working temperature between 5°C and 30°C. Relative humidity should not exceed 70%. It is best that the unit be installed in an air-conditioned room where the relative humidity and temperature can be maintained at optimal levels.

4.2.4 EMC Environment Requirements

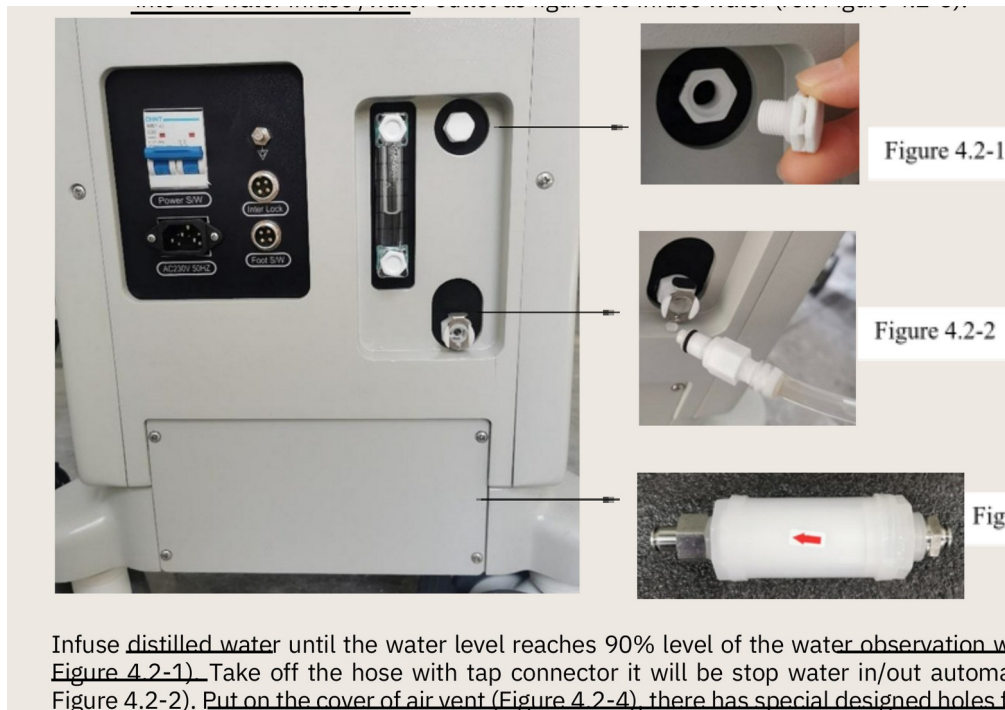
In order to maintain a stable working environment, this device should be operated in an environment without strong EMI. If auxiliary electrical equipment is used, it should be free of strong EMI and able to withstand Class A EMC (please see Section 8.2).

4.3 Installation

- 1) The device should be placed in a room with an indoor temperature of 5–30°C; the humidity should not be higher than 70%. Operating and treatment rooms must be kept clean at all times.
- 2) Install the handpiece support and handpiece hanger with screws (Ref. Figure 4.1).



3) Take off the cover of the air vent (Figures 4.2-1 and 4.2-2). Insert the hose with the tap connector into the water inlet/water outlet as shown to infuse water (Ref. Figure 4.2-3). Infuse distilled water until the water level reaches 90% of the water observation window (see Figure 4.2-1). Remove the hose with the tap connector; the water flow will stop automatically (see Figure 4.2-2). Put the cover back on the air vent (Figure 4.2-4); there are specially designed holes to let the air out (see Figure 4.2-1).



Infuse distilled water until the water level reaches 90% level of the water observation window (Figure 4.2-1). Take off the hose with tap connector it will be stop water in/out automatically (Figure 4.2-2). Put on the cover of air vent (Figure 4.2-4), there are specially designed holes for

- 4) Ensure that the key is in the off position and that the emergency cut-off button is not engaged. If it is engaged, release it by rotating the button in the direction of the arrow indicator.
- 5) Attach the power cord, the footswitch cord, and the interlock cord (Ref. Figure 4.3).
- 6) Switch the circuit breaker to the "On" position.

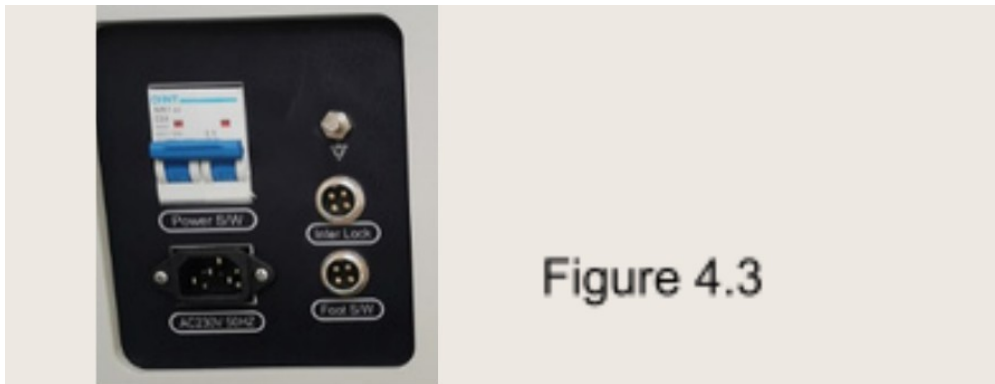


Figure 4.3

6) Switch the circuit breaker to the “On” position.

7) Insert one treatment handpiece into the socket of the system firmly and properly (Ref. Figure 4.3A, B).

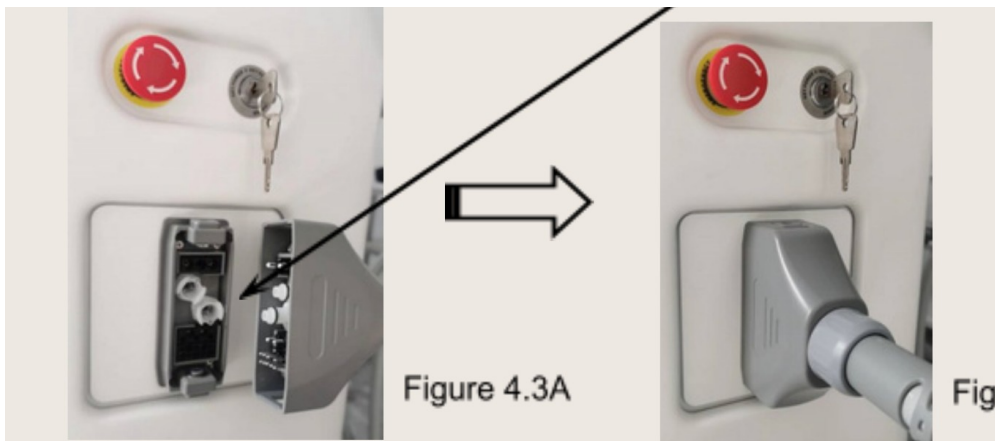


Figure 4.3A

Figure 4.3B

8) Switch the unit on by inserting the key and turning it clockwise. At this point, water circulation and the cooling system start automatically.

9) Observe whether water circulation is running well. If the system beeps and shows the status in Figure 4.4 (the second icon, a red cross), you need to disperse any bubbles or air in the unit (please contact the distributor for service). Figure 4.4.



10) After the cooling system runs well for at least 5 minutes, you can proceed to the next stage of assembling the system.

11) Then switch off the system. Screw on the infusion/ventilation vent; there are specially designed holes to let the air out.

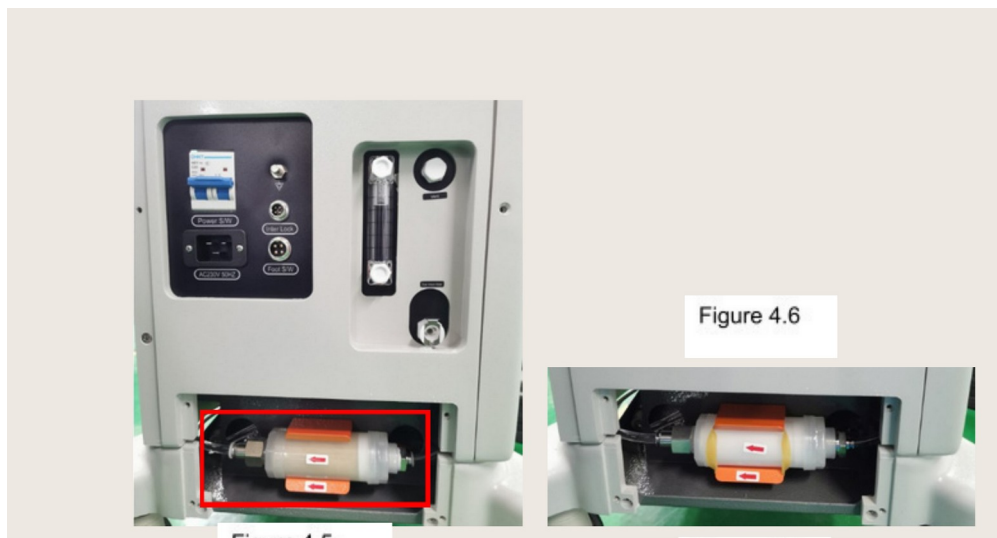
12) When you need to replace the water:

1. Drain the remaining water contained in the handpiece. Take particular care not to spill any water on the electronic terminals. Wipe off any spilled water with a soft, absorbent cloth.

2. Replace the water and water filter every 2–3 months; please follow the steps below carefully. Disconnect the handpiece. Using the infusion/drain tap with hose (as in Figure 4.2-2), unscrew the ventilation screw caps (as in Figure 4.2-1) to drain excess water from the cooling tank. Insert the drainage hose and tap into the outlet; the water will come out. Pull out the hose and tap, and fasten the air vent cap firmly. Unscrew and open the rear cover of the bottom part (Ref. 4.5), and discard the used water filter by pressing the two sides of the quick-connector button to disconnect it from the water tube (Ref. 4.6).

13) Replace the treatment handpieces.

1. IPL handpiece, 12 × 35 mm or 15 × 50 mm. According to the following figure, the various wavelengths are changeable using 420/510/560/610/640–1200 nm and SHR filters as standard specification. Be careful not to overexert while inserting it into the slot. Pull the filter out by the two ends of the light handpiece slowly and straight. You need to clean the surface of the filter before each use. Any dirt or debris will easily damage the filter when the xenon light passes through during operation. Figure 4.8.





2. Diode Laser Handpiece 12x23mm- 808nm

2. Diode laser handpiece, 12 × 23 mm — 808 nm. After the cooling system runs for at least 5 minutes, you can use the diode laser handpiece for hair removal treatment. Figure 4.9.

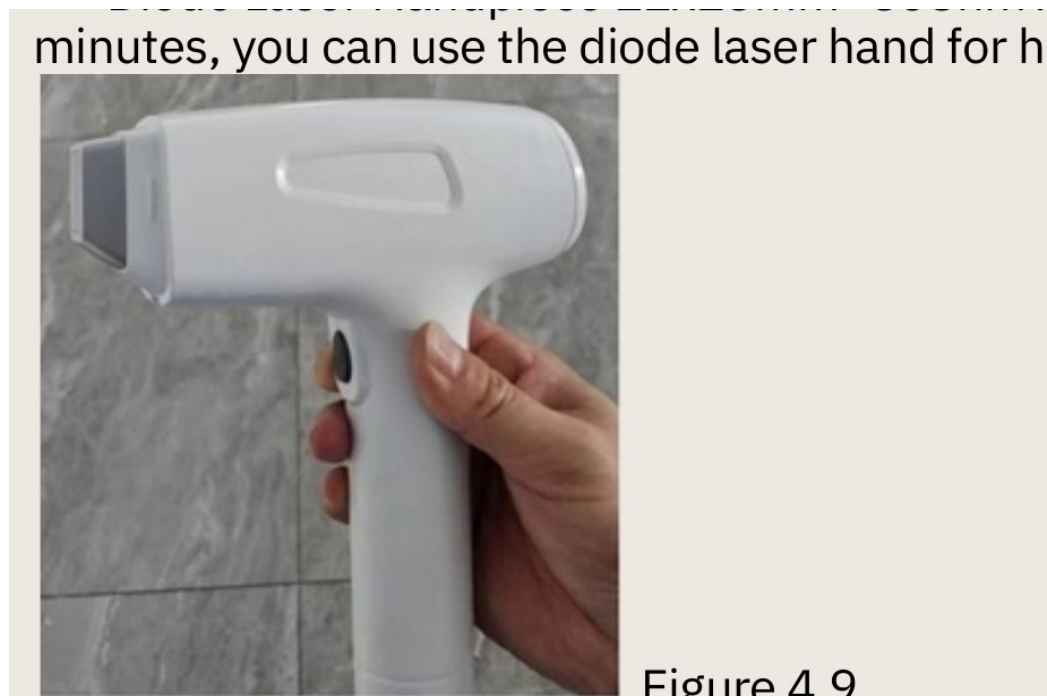
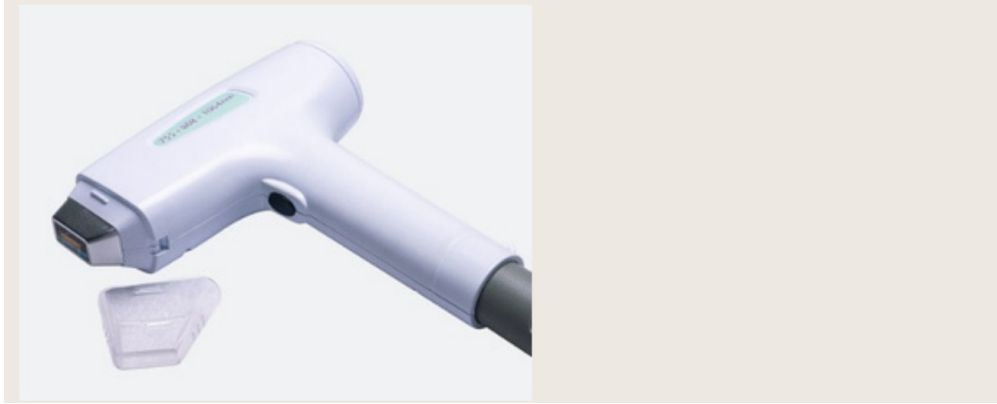


Figure 4 9

3. Diode laser handpiece, 12 × 23 mm — 755 & 808 & 1064 nm. After the cooling system runs for at least 5 minutes, you can use the diode laser handpiece for hair removal treatment.

4. Picosecond Nd:YAG laser handpiece. After the cooling system runs for at least 5 minutes, screw on the treatment tip according to the patient's treatment and Fitzpatrick type. Figure 4.10.



5. Er:YAG fractional laser handpiece. Screw on the treatment tip (49/81 microbeams; focusing lens: Ø1–3.5 mm, optional; beam expander: Ø6 mm, Ø9 mm, optional) according to the treatment. Figure 4.11.



Figure 4.12

6. 1064 nm long-pulse Nd:YAG laser handpiece. Plug in the appropriate sapphire tip (2.2 × 5 mm, 6 mm, or 9 mm) according to the treatment. Figure 4.12.

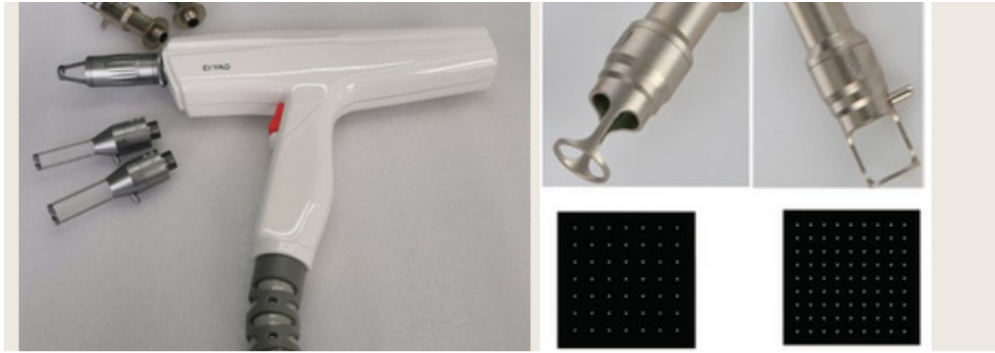


Figure 4.12

7. Er:Glass fractional laser handpiece. Screw on the treatment tip (100/324 microbeams) according to the treatment.



Fig

Figure 4.13

8. Q-switched Nd:YAG laser handpiece. After the cooling system runs for at least 5 minutes, screw on the treatment tip according to the pigment type and proceed with the treatment. Figure 4.14.



Fig

4.4 Moving the equipment

If the unit is to be moved within the general area:

1. Turn the unit off.
2. Place the treatment head on the support.
3. Unplug the power cable.
4. Release the wheel brakes.
5. Relocate the unit (avoid tilting the unit).

WARNING

Do not move the system by pulling the handpiece.

CAUTION

If the instrument is to be moved outside the practice, please contact your dealer.

4.5 Transport and Storage Procedure

4.5.1 Procedure

1. Drain the water from the device before storage and transportation.
2. The device should be installed vertically in the outer packing box during transport.

The instrument is fixed on the base (>670 mm × 660 mm × 1420 mm) so that the wheels of the instrument will not glide.

3. There are waterproof and soft gasket materials in the outer packing box to protect the instrument from damage; handle with care. Markings such as "Handle with care," "Keep dry," and "This side up" should be on the box.

4.5.2 Environment

1. Environmental temperature range: -40°C to +55°C;
2. Relative humidity range: 93%;
3. Atmospheric pressure range: 86 kPa – 106 kPa.

Chapter 5 Operation

This chapter describes the operating procedure of the platform treatment system.

WARNING

1. WARNING — HIGH VOLTAGE: ensure that all panels are secured prior to operation.
2. Do not place the equipment where it is difficult to disconnect the appliance coupler.
3. To avoid the risk of electric shock, this equipment must only be connected to a supply main that is grounded.
4. To avoid the risk of electric shock, this equipment must only be connected to a supply that is grounded.
5. All personnel in the treatment room must wear the protective filtered glasses supplied.
6. Make sure the patient is wearing the opaque protective goggles prior to treatment.
7. Avoid looking directly into the intense light during treatment, even if you are wearing the protective glasses.
8. Do not point the treatment head outside the treatment field.
9. Modifications are not permitted for safety reasons.

5.1 Software operation

5.1.1 With selection of IPL:

Turn the unit on by turning the key switch clockwise. The screen will show the working menu and will run a system check diagnostic program (see Figure 5.1). When you attach a treatment handpiece, the software will recognize its function and select the treatment automatically. The interface will jump to the main screen, as in Figure 5.2. If you want to change to another treatment handpiece, you must turn off the machine first, attach the handpiece you need, and restart the machine. The screen will show the main menu (see Figure 5.1). Press “Enter” to select the therapy program.

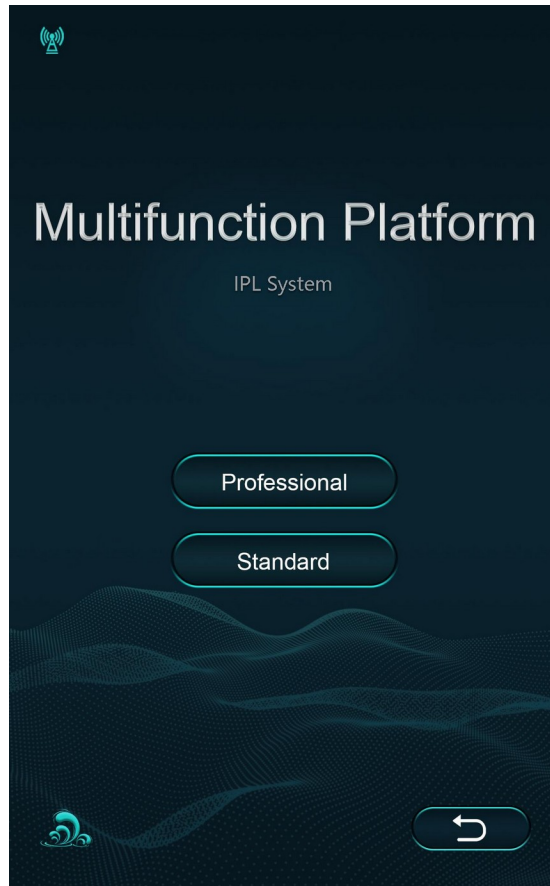


Figure 5.1

1. Main menu. Note: the device recognizes the type of handpiece automatically; the other handpiece type buttons are inactive (Figure 5.1).

2. Skin type, gender, mode selection, and treatment head. For the two handpieces, A (12 × 35 mm) and B (15 × 50 mm), there are five preset treatment modalities: Hair Removal (HR), Skin Rejuvenation (SR), Pigmentation Therapy (PT), Acne Therapy (AT), and Vascular Therapy (VT) (see Figure 5.2).

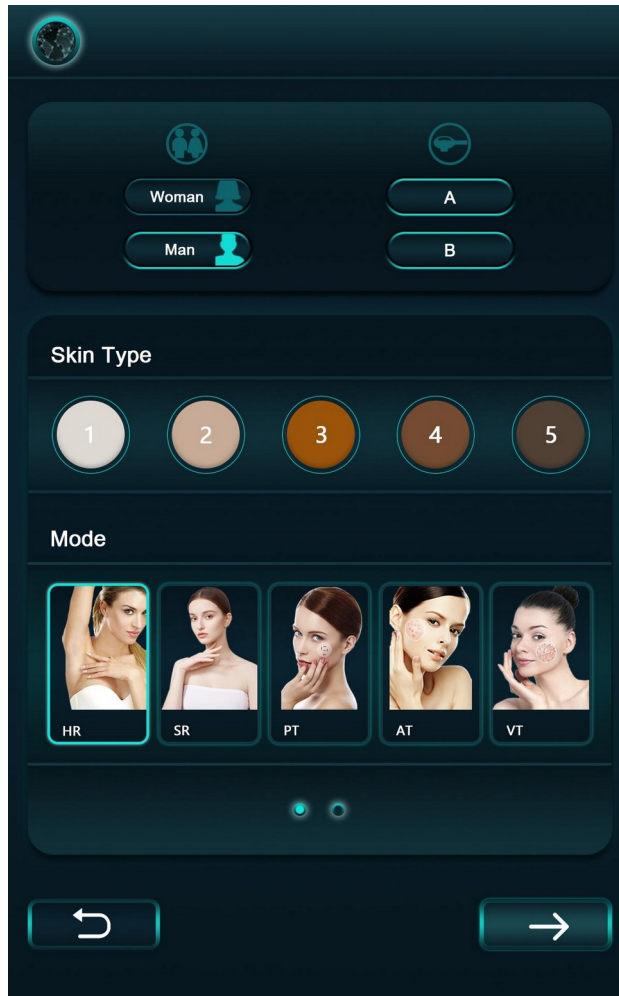


Figure 5.2

3. Once you select HR mode, press the “Enter” key to go to the next step. There are 4 working modes to select from when you choose Handpiece A or B: SHR Mode, Standard Mode, Professional Mode (optional filter), and Stack Mode (see Figure 5.20).

SHR Mode:

1. SHR Mode is for fast and painless hair removal treatment. The pulse repetition rate can be selected from 2 Hz to 6 Hz, and the working time can be set with the “Timer” button from 5 seconds to 60 seconds (we recommend a setting of 20 or 30 seconds). The preset treatment protocol makes the hair removal procedure easy. You only need to adjust the energy and cooling levels, then start (see Figure A-5.21)

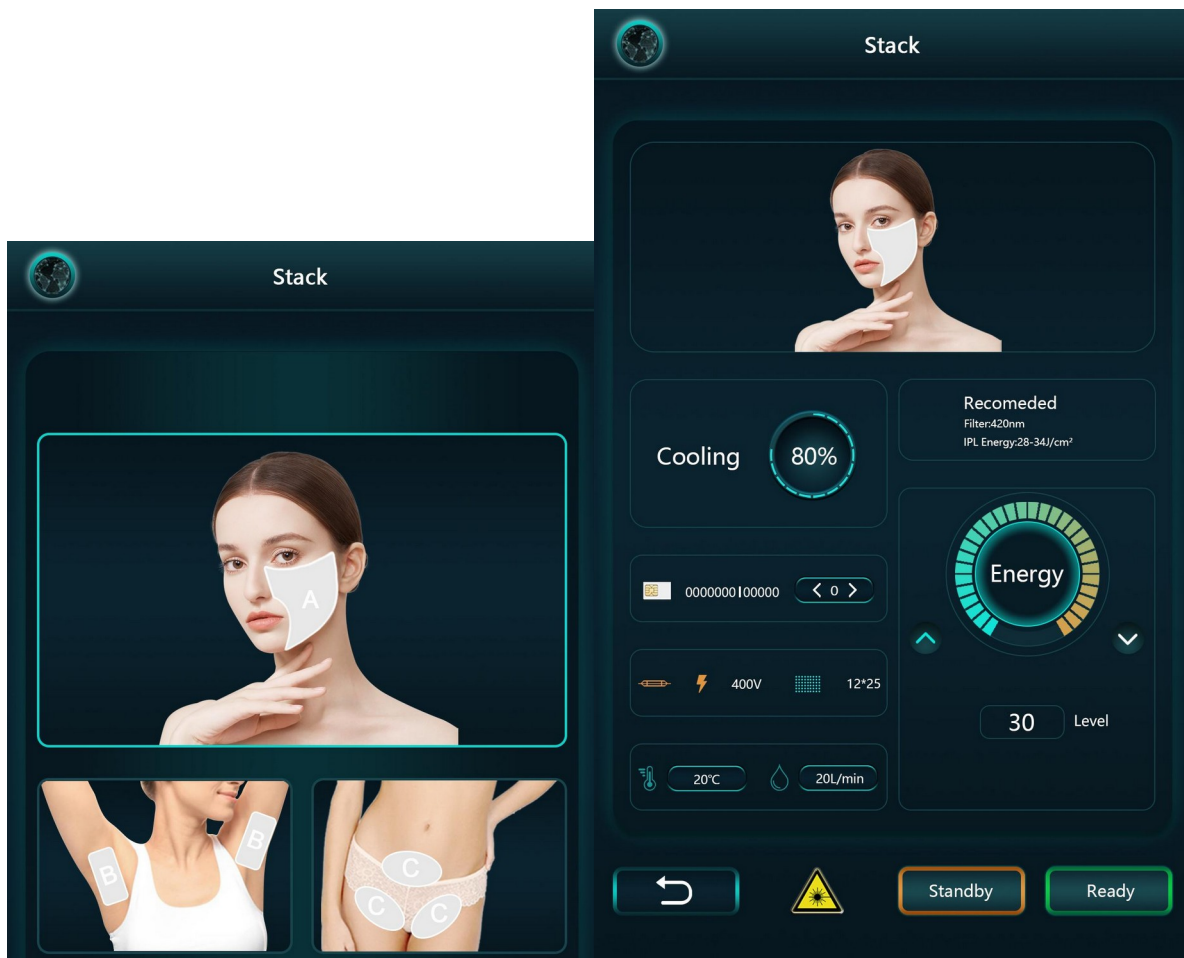


Figure 5.0



Figure 5.21 (SHR)

Figure 5.19

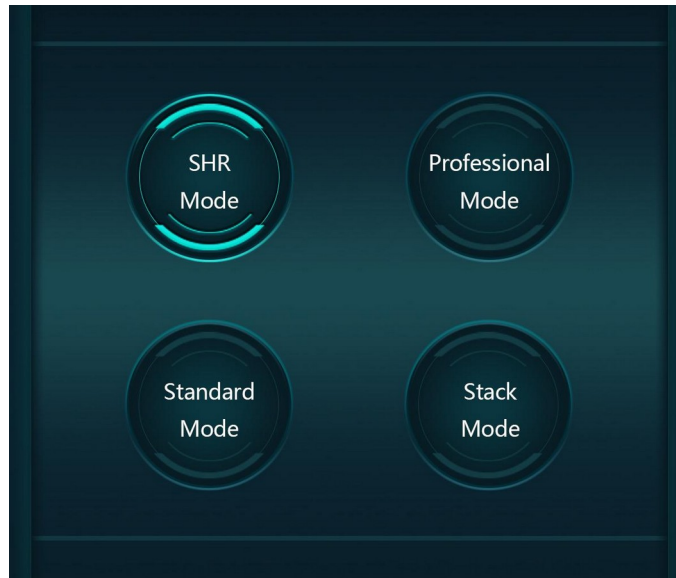


Figure 5.3

2) In Standard Mode, choose the hair density, hair color, and hair thickness, then go to Standard Mode (HR) (see Figure 5.19); the system will recommend all parameter settings, as well as the filter and energy level settings. The filter type in use and the treatment spot size are also displayed on the screen. You are only allowed to adjust the energy and cooling levels. Once you press "Ready," the system will stop blinking the "Recommended" icon (see Figure 5.6).

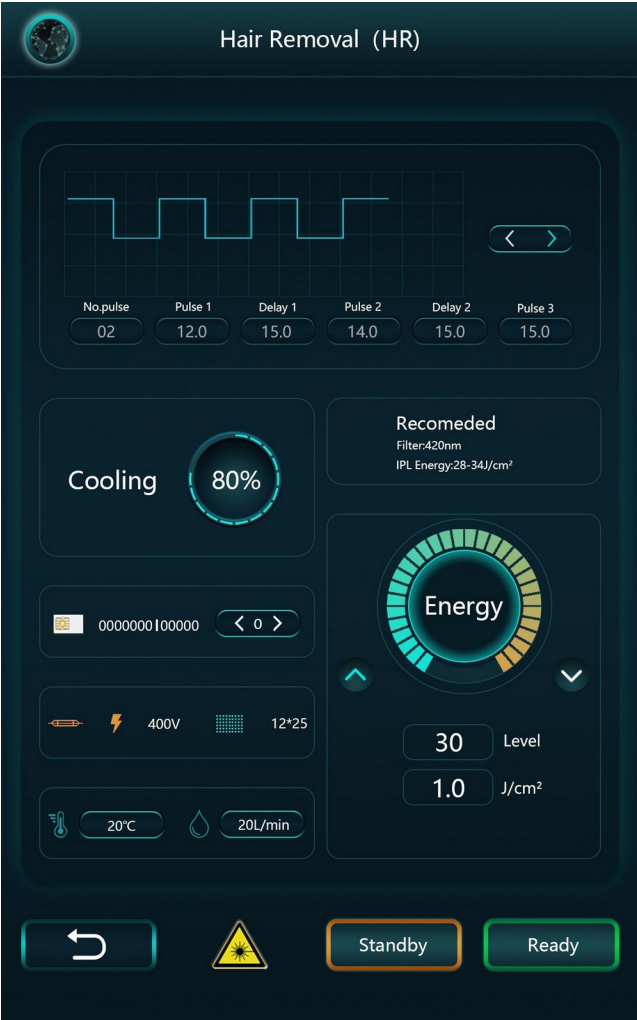


Figure 5.6

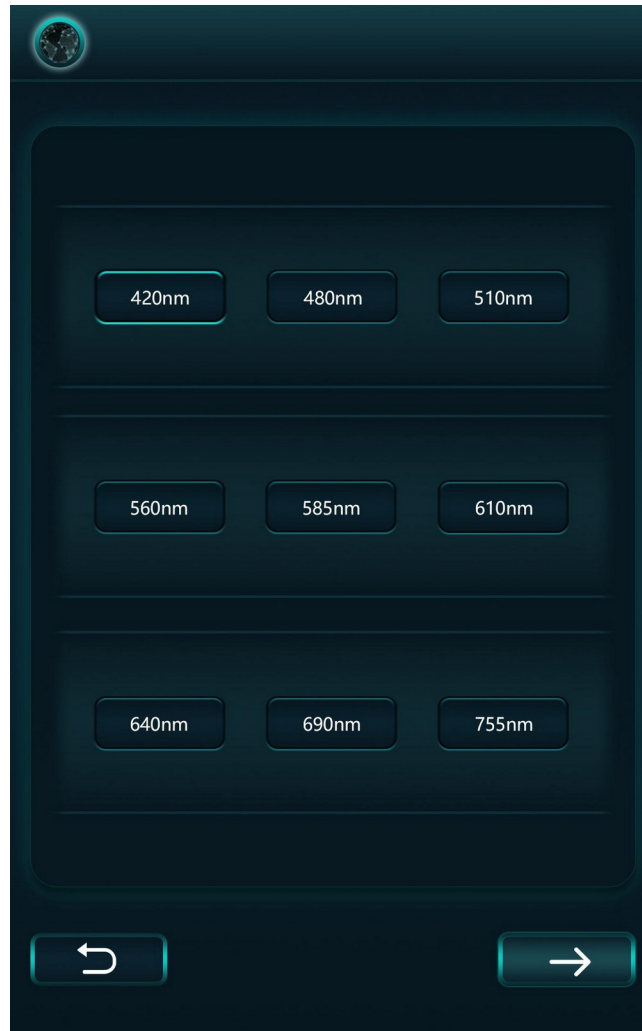


Figure 5.7

3) In Professional Mode, you need to enter the filter type requested by the system (Figure 5.7). Professional Mode allows you to manually adjust each parameter (see Figure 5.8).

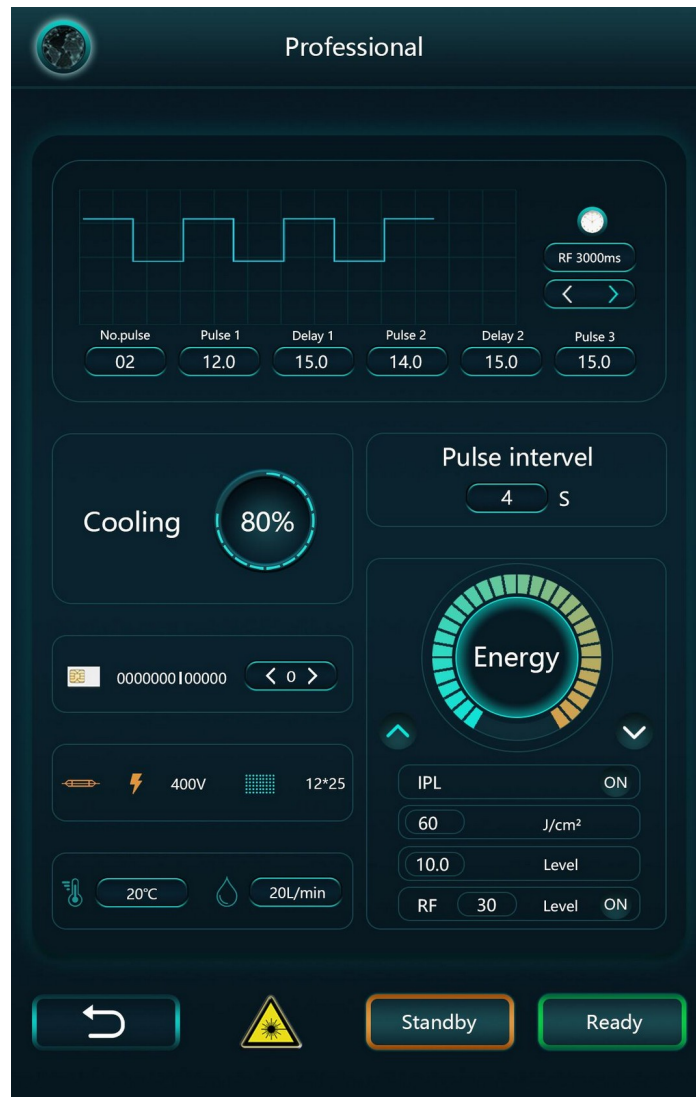


Figure 5.8

4. In Stack Mode, you can choose the treatment area as A, B, or C (Figure 5.0). You are only allowed to adjust the energy and cooling levels. Once you press “Ready,” the system will stop blinking the “Recommended” icon (see Figure 5.0).

5. Once you select SR mode, press the “Enter” key to go to the next parameters. There are 3 working modes to select from: SSR/BBL Mode, Standard Mode, and Professional Mode (optional filter) (see Figure 5.11).

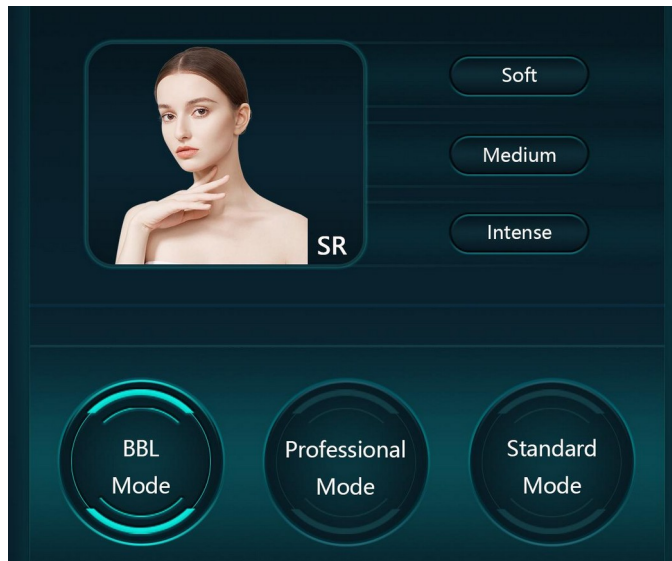


Figure 5.11

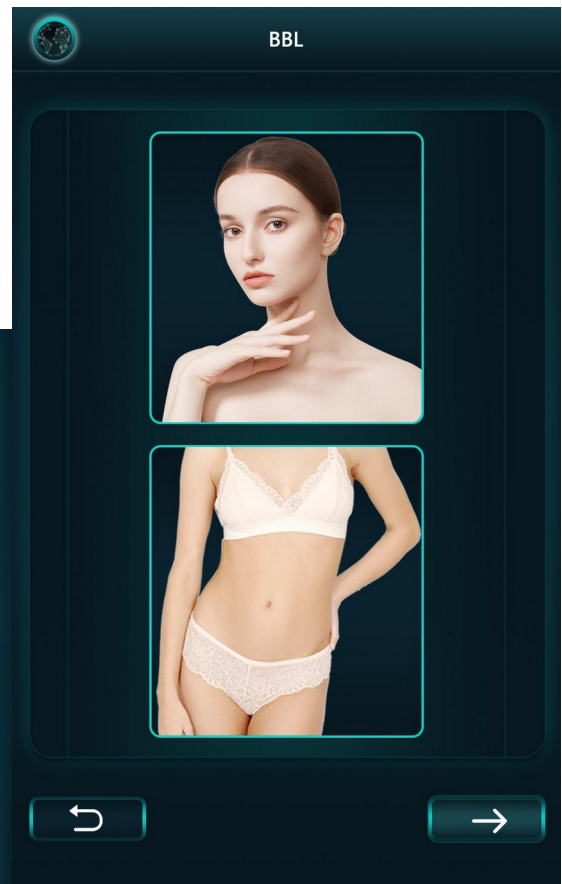


Figure 5.12

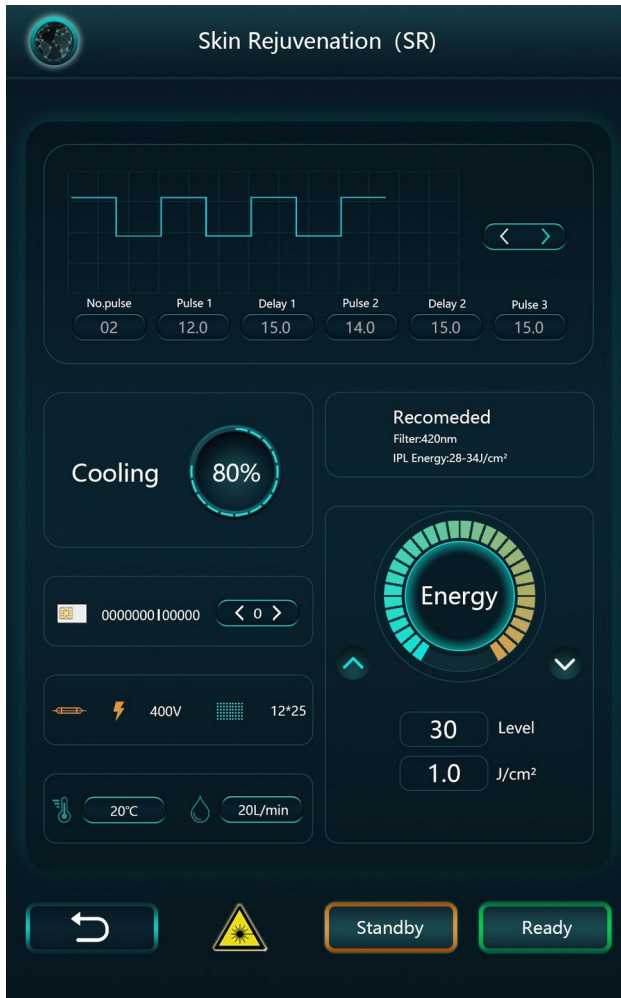


Figure 5.13



Figure 5.15

5. Treatment mode and parameter setting windows (see Figure 5.13).

A. Power output window: displays the IPL output energy setting. There are two indications of the output measurement on the screen. The “J/cm²” shows the real energy output in J/cm², and the “Level” lists the energy output as a level grade. The output power can be increased or decreased in the Treatment Menu by pressing the “Up” or “Down” button, respectively. The IPL power of this system can be adjusted from level 10 to level 60.

B. Pulse width: the length of time, from 10 to 400 ms, that the skin is exposed to the pulse of light. To increase or decrease the parameter settings, use the arrow buttons.

C. Recommended: this option is given when you select Standard, SHR, BBL, or Stack mode.

- Filter: the device suggests a filter according to each treatment's needs.
- Energy: the energy density output, measured in J/cm².

D. Temperature adjustment window: allows the user to modify the temperature of the handpiece sapphire window (tip). The cooling level setting can be increased or decreased from 20% to 100% by touching the buttons. The sapphire of the handpiece will start cooling 2–3 minutes after pressing the “Standby” key. The TEC coolers stabilize the temperature of the handpiece applicator tip at the desired level of 5°C.

E. Treatment counters: when the IC card function is off, the treatment counter displays the total shot count / current shot count; when the IC card function is on, it displays the current shot count / IC card shot count (the IC card function is optional).

F. System Information window:

- a. Water temperature status: the number shows the temperature of the water tank. If it is overheating (over 55°C), the number will turn from blue to red.
- b. Water flow speed status: the number shows the speed of the water circulation flow. If the flow speed is too low, the number will be shown in red.
- c. Handpiece simmer status: after touching "Standby," this indicates that the flash lamp is in "simmer" status.
- d. Capacitor charge status: the blue sign will turn red after the charge is full and the capacitor is ready. e. Voltage value: when the capacitor charges, the voltage value will change from 150 to 400 V.

G. Spot size: shows the spot size.

H. Standby and Ready button. Standby: touch "Standby" after setting the operating parameters. The handpiece compressor cooling function is activated and will cool after 2–3 minutes. Note: if the doctor pauses the procedure for more than 3 minutes during treatment, the Standby function must be turned off. Ready: accesses the ready mode before active laser emission. Once the system enters "Ready" mode, laser emission can start upon activation of the footswitch or the handpiece trigger. If you want to change operating parameters during the treatment, you must turn off the "Ready" function, because operating parameters cannot be changed in Ready mode. H. General warning: when the IPL has output energy, the general warning sign is displayed.

I. Back: press the back button to return to the previous page. You may switch off the power system now. This will terminate the active treatment phase and disengage the lamp; the service lifetime of the treatment handpiece is maximized.

5.1.2 Diode Laser Treatment Menu — 808 nm

1. Main menu

2. Once you enter the handpiece icon, follow the next pages to select basic data: gender and skin type (see Figure 5.17), then press Enter for the operation mode.

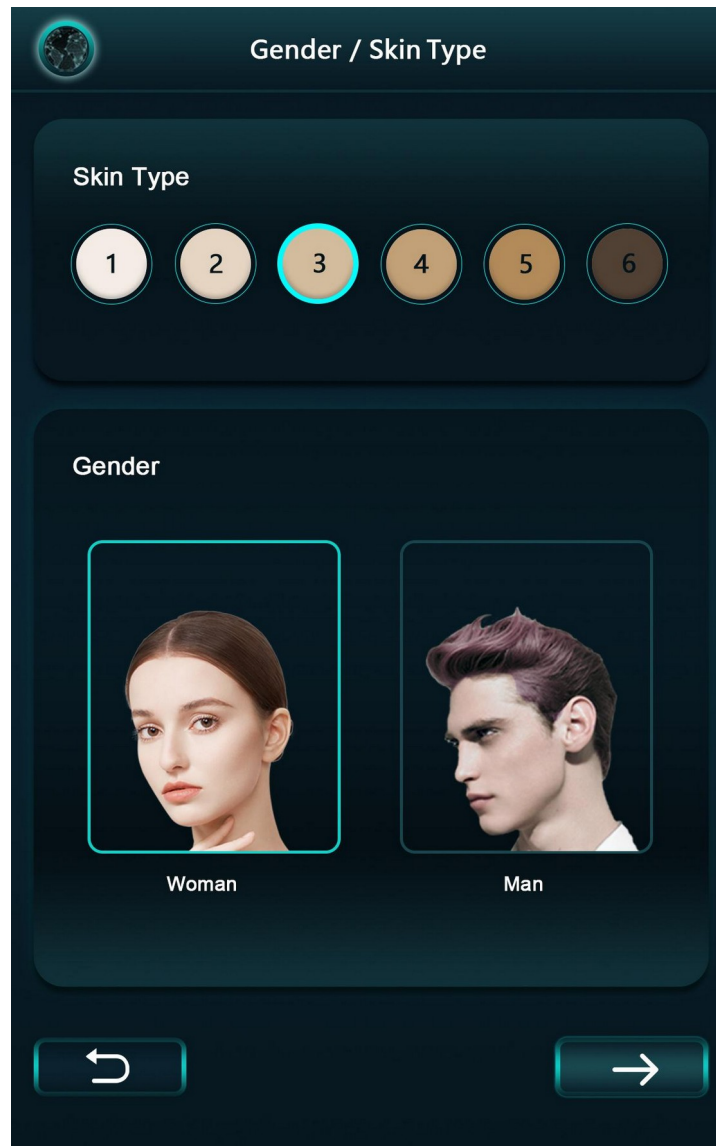


Figure 5.17

3. There are 4 working modes to select from: SHR Mode, Professional Mode, SSR Mode, and Stack Mode (see Figure 5.22).

1) SHR Mode is for fast and painless hair removal treatment. The pulse repetition rate can be selected from 2 Hz to 15 Hz. The preset treatment protocol makes the hair removal procedure easy. You only need to adjust the energy and cooling levels to meet the exact requirement (see Figures 5.22 and 5.23).



Figure 5.22

Figure 5.23

- 2) In Professional Mode, you are free to adjust the setting of any item (see Figure 5.24). You may adjust the Hz, joules, etc., as you like.
- 3) In SSR Mode, the system will recommend all parameter settings, as well as the filter and energy level settings. You are only allowed to adjust the energy and cooling levels. Once you press "Ready," the system will stop blinking the "Recommended" icon (see Figure 5.23). For women, you select face or body SSR (see Figures 5.24 and 5.25).
- 4) In Stack Mode, you can choose the treatment area: A, B, C, D, E, or F (Figure 5.27). You are only allowed to adjust the energy and cooling levels. Once you press "Ready," the system will stop blinking the "Recommended" icon (see Figure 5.28).

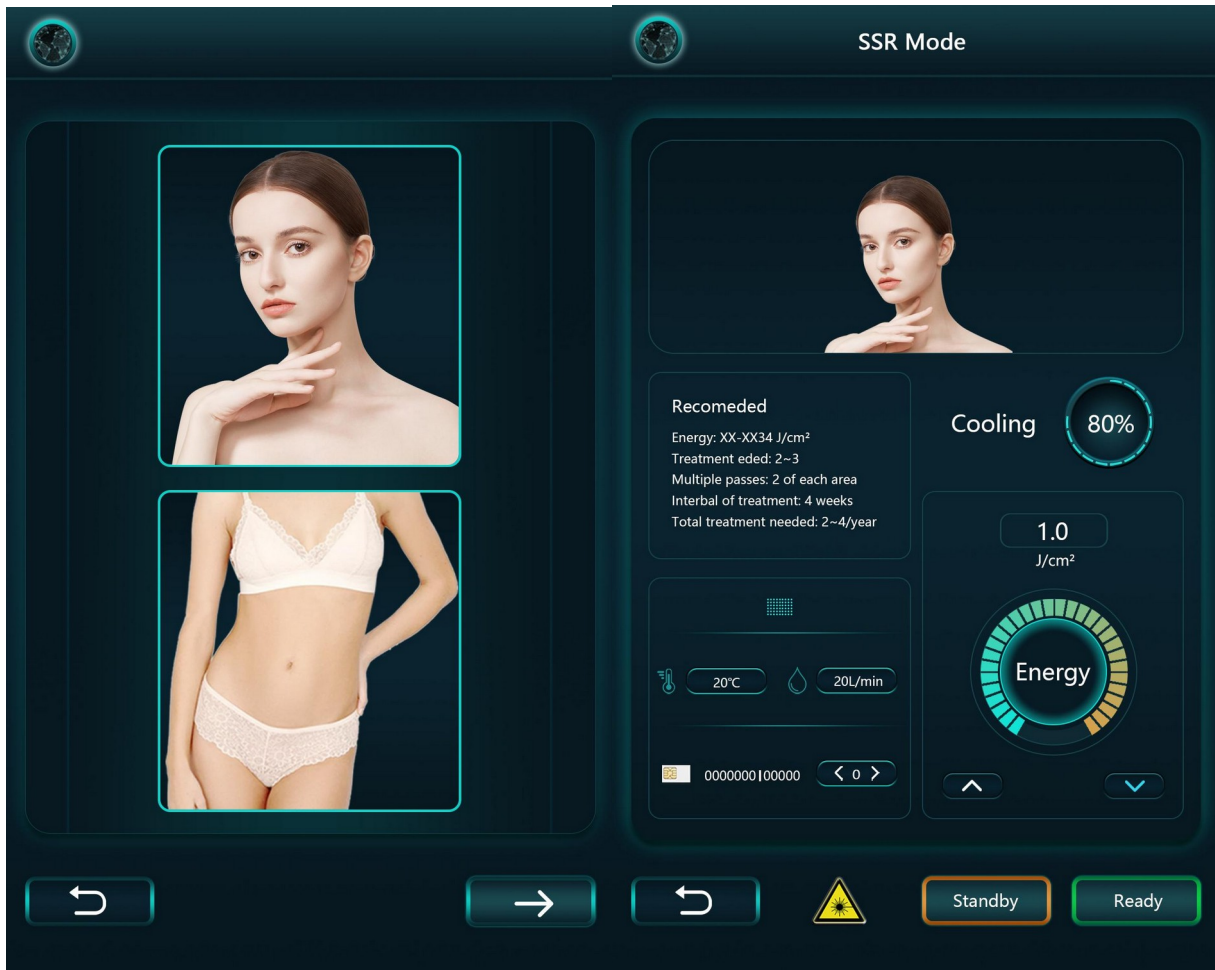


Figure 5.24

Figure 5.25

4. The parameter setting windows include the following (Figure 5.24-5.25).

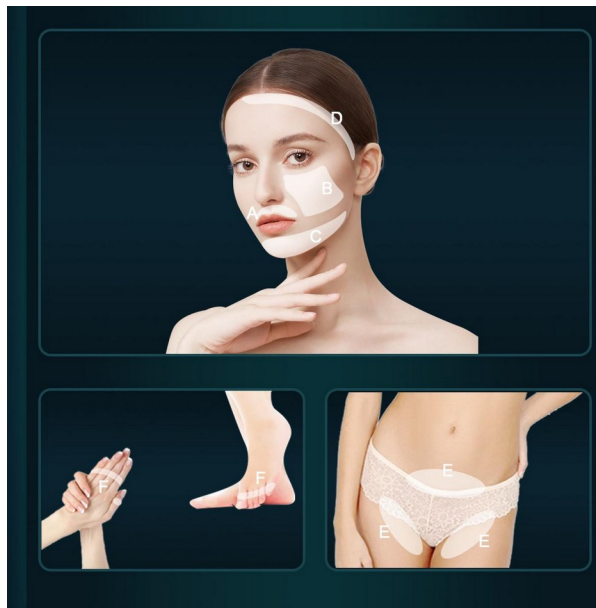


Figure 5.27

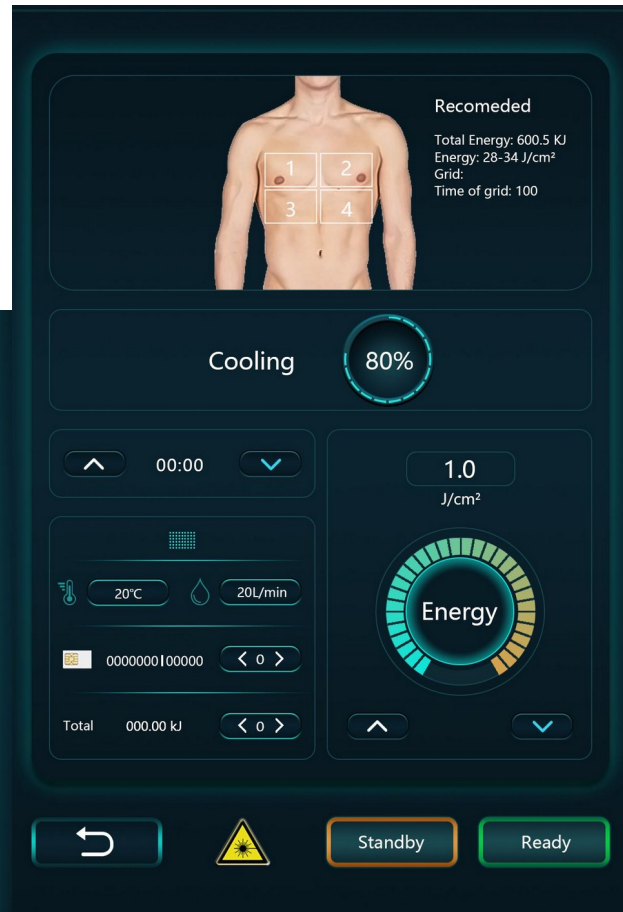


Figure 5.28

A. Power output window: displays IPL output energy setting. There are two indications of the output measurement on the screen. The “J/cm²” is measured with real energy output in J/cm², the “Level” is listed as energy output on Level grade. The output power can be increased or decreased at the Treatment Menu by depressing the: “Up or down” button respectively. The power of this system can be adjusted from 10 to 60 levels.

B. Pulse width: It is the length of time from 10 to 400ms that the skin is exposed to the pulse of light. To increase or decrease the parameter settings, use the up or down arrow buttons.

C. Recommended: This item will be given when you select Standard/SHR/BBL/STACK mode. Total Energy: Device will give suggested filters according to each treatment needs. Energy: The energy density output, measured in Joules/cm². Grid: small units to union of a treatment area; for example, there are 12 grids for back. The square measure of a grid is 10(W)x 20cm (L). Time of grid: The system will recommend the treatment time of grid on the screen. The time will decrease progressive to zero during the treatment. You may increase the treatment time if the client needs more passes or treatments of stubborn areas of concern.

D. Temperature adjustment window: It allows the user to modify the temperature of the Handpiece sapphire window (tip). To increase or decrease the cooling level setting is from 20% to 100% by touching the buttons. The sapphire of the handpiece will start cooling after pressing the “Standby” key which takes 2–3 minutes. The TEC coolers ensure stabilization of the handpiece applicator tips temperature at a desired level of -15°C.

E. Treatment counters: The Treatment counter displays when IC card function is off: the total counter of shots / current counter of shots; when IC card function on: current count of shots/IC card shots number; (IC card function for optional)

F. System Information window: shows the available control options. Any warnings or system errors are displayed here.

a. Water temperature status: The number is shown as the temperature of the water tank. If it is overheating (over 55°C) the numeric will turn from blue to red color.

b. Water flow speed status: the number is shown as the speed of the water circulation flow. If the flow speed is too low the numeric will be shown as red.

G. Standby & Ready Button: Standby: Touch the “Standby” after you select the optimal parameter setting. The handpiece compressor cooling function is activated and it will cool after 2-3 minutes. Please be sure if the practitioner pauses the procedure during the treatment over 3 minutes, the Standby function must be turned off. Ready: To access the ready mode before active laser emission. Once the system enters “Ready” mode, laser emission can start upon activation of the footswitch or the handpiece trigger. If you want to change operating parameters during the treatment you need to turn off the “Ready” function. Because in Ready mode the operating parameters cannot be changed.

H. Frequency (Repetition Rate): Professional mode-6 modes(1Hz/ 2Hz/ 3Hz/ 5Hz/ 8Hz/ 10Hz) for selection means shots number per second. It is recommended that the operator start at a low Frequency with 1Hz. Once experience is gained, the higher repetition rates (up to 10Hz) may be utilized.

I. Total energy (Kj): To accumulate all grid energy in 1000J of a unit (measurement) on the screen. The energy will increase progressively.

J. Time of treatment: To accumulate the time during the treatment.

K. Back: Press the button to go back a page. You may switch off the power system now. This will terminate the active treatment phase and disengage the lamp; the service lifetime of the treatment handle is maximized.

5.1.3 Diode Laser Treatment Menu — 755 & 808 & 1064 nm

2. Main menu

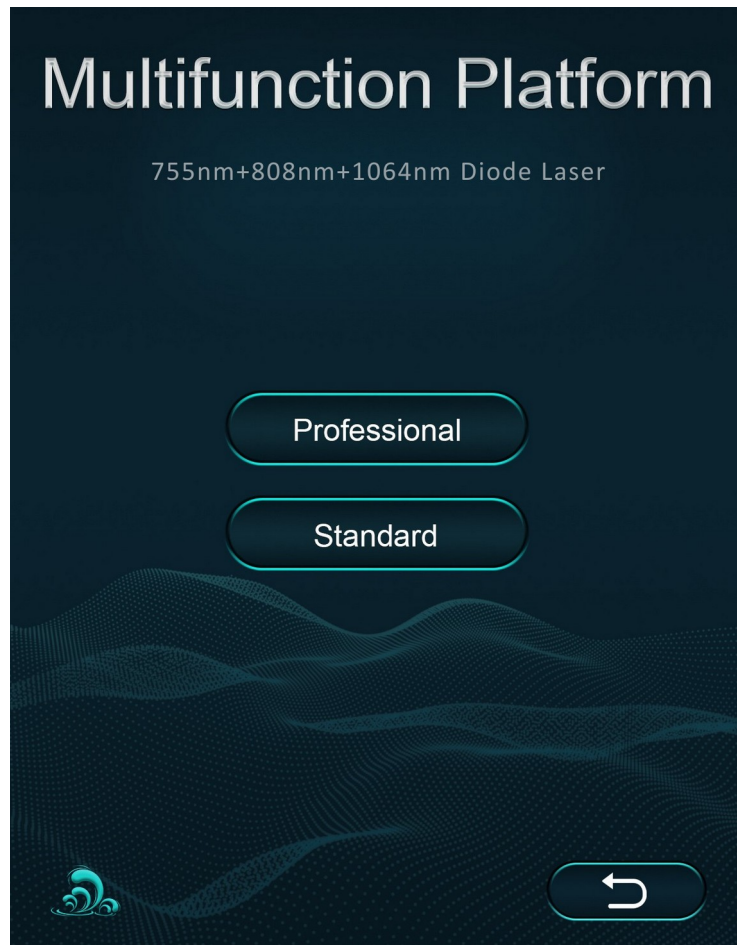


Figure 5.29

2. Once you enter the handpiece icon, follow the next pages to select basic data: gender and skin type (see Figure 5.30), then press Enter for the operation mode.

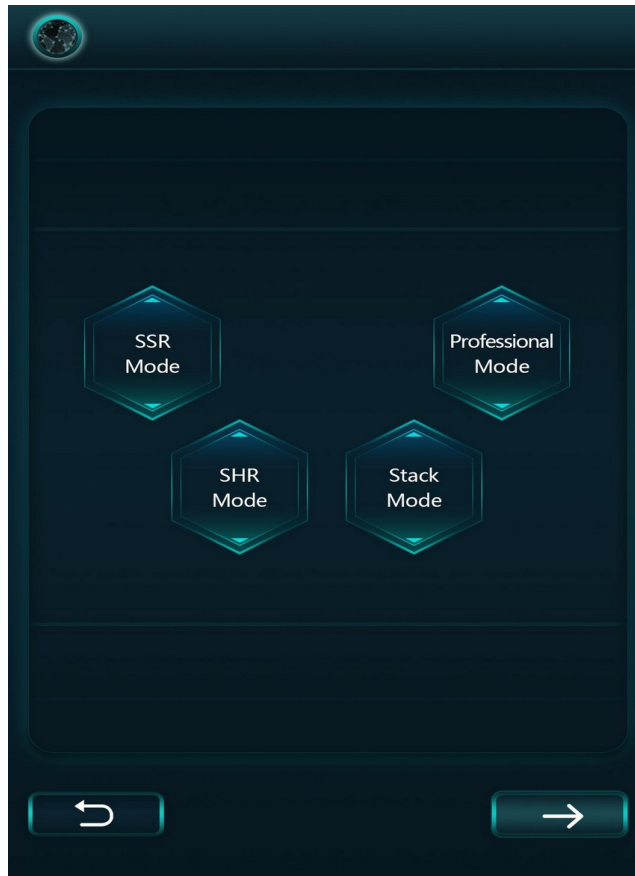


Figure 5.30

3. There are 4 working modes to select from: SHR Mode, Professional Mode, SSR Mode, and Stack Mode (see Figure 5.31).

5) SHR Mode is for fast and painless hair removal treatment. The pulse repetition rate can be selected from 2 Hz to 15 Hz. The preset treatment protocol makes the hair removal procedure easy. You only need to adjust the energy and cooling levels to meet the exact requirement (see Figures 5.32 and 5.33).

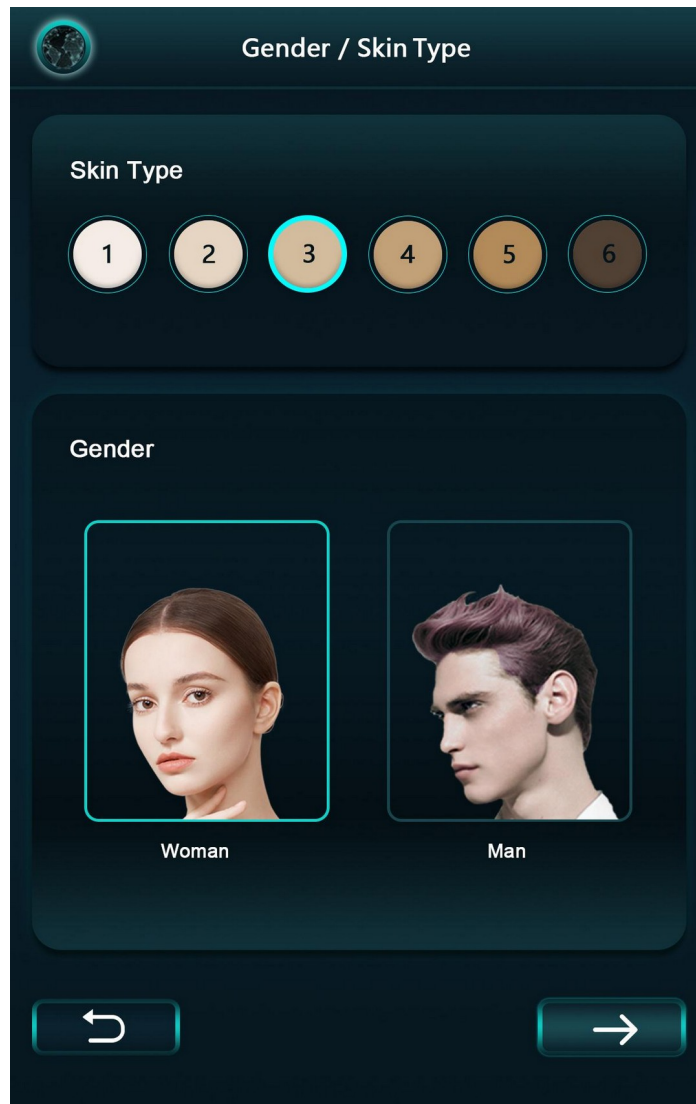


Figure 5.31

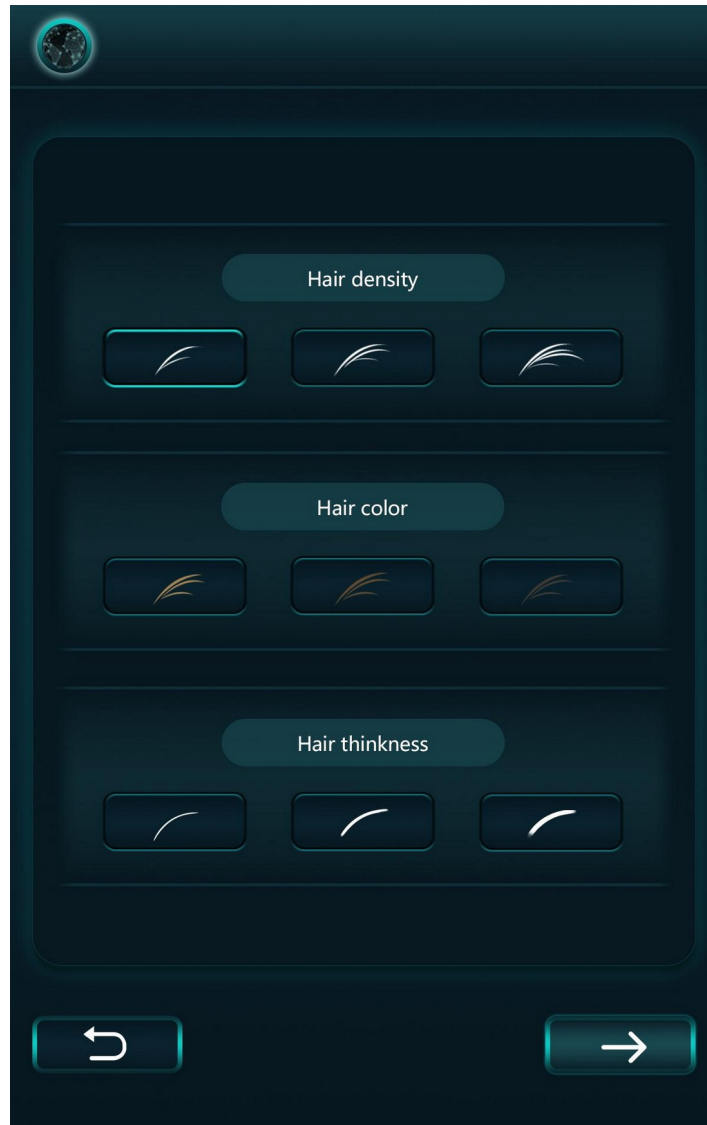


Figure 5.32

6) In Professional Mode, you are free to set your parameters (see Figures 5.33 and 5.34).

7) In SSR Mode, the system will recommend all parameter settings, as well as the filter and energy level settings. You are only allowed to adjust the energy and cooling levels. Once you press "Ready," the system will stop blinking the "Recommended" icon (see Figure 5.35).

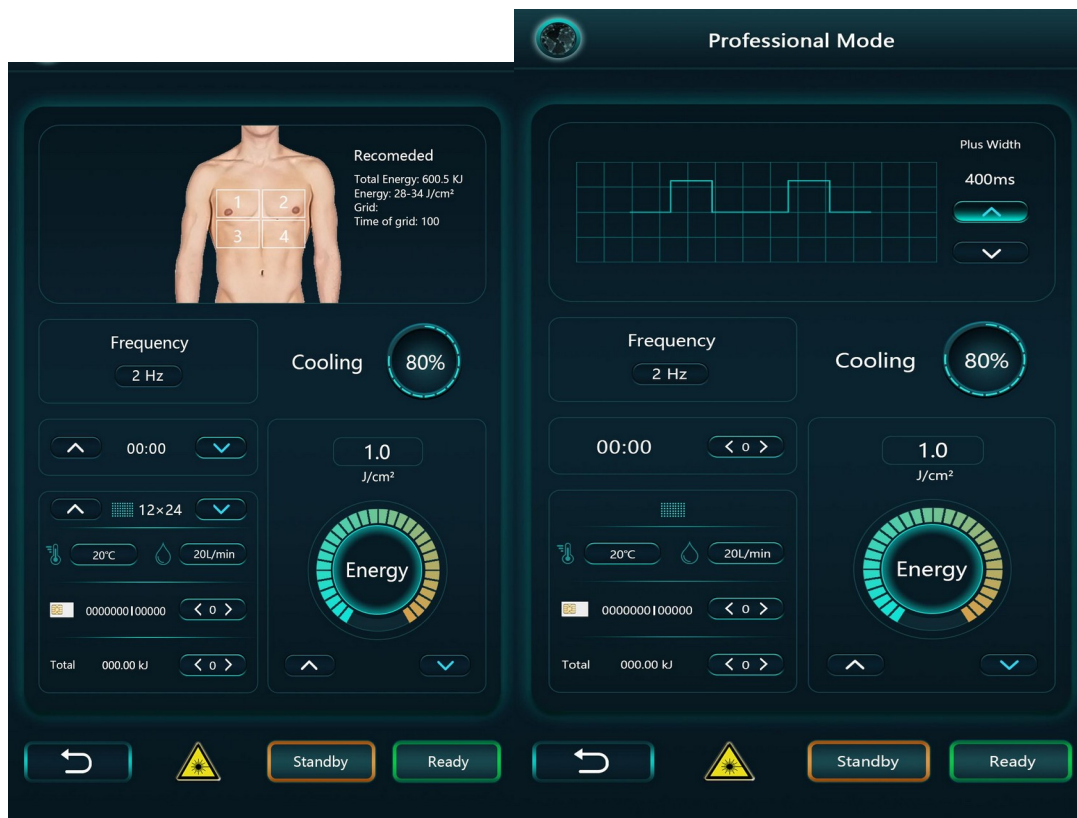


Figure 5.33

Figure 5.34

For women, there are face and body SSR options to select from (see Figures 5.35 and 5.36).

8) In Stack Mode, you can choose the treatment area as A, B, C, D, E, or F (Figure 5.37). You are only allowed to adjust the energy and cooling levels. Once you press “Ready,” the system will stop blinking the “Recommended” icon (see Figure 5.38).

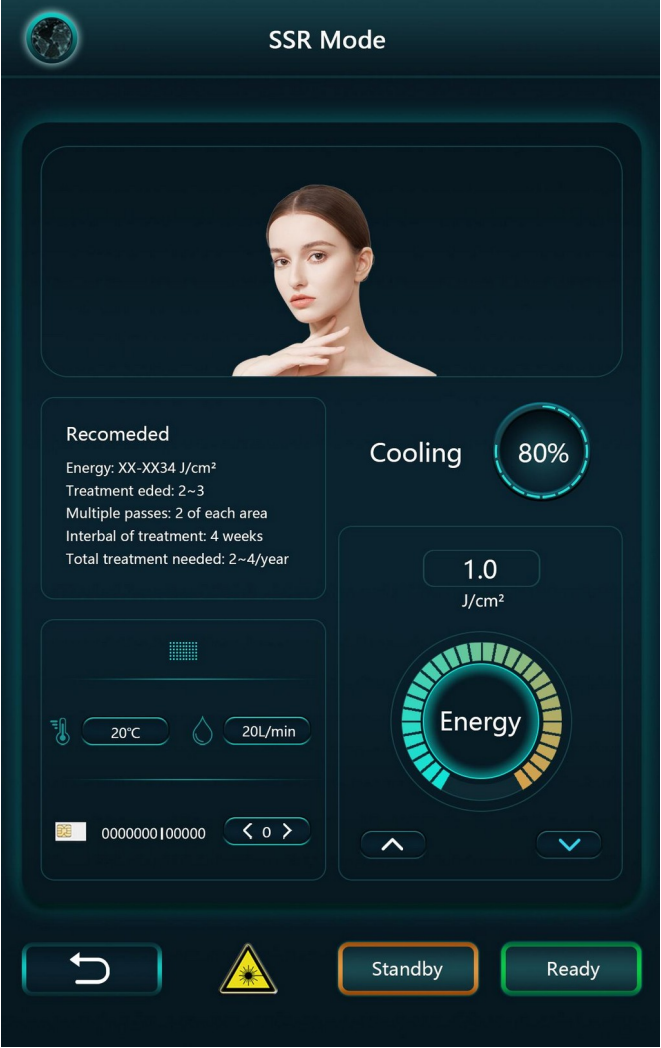


Figure 5.35

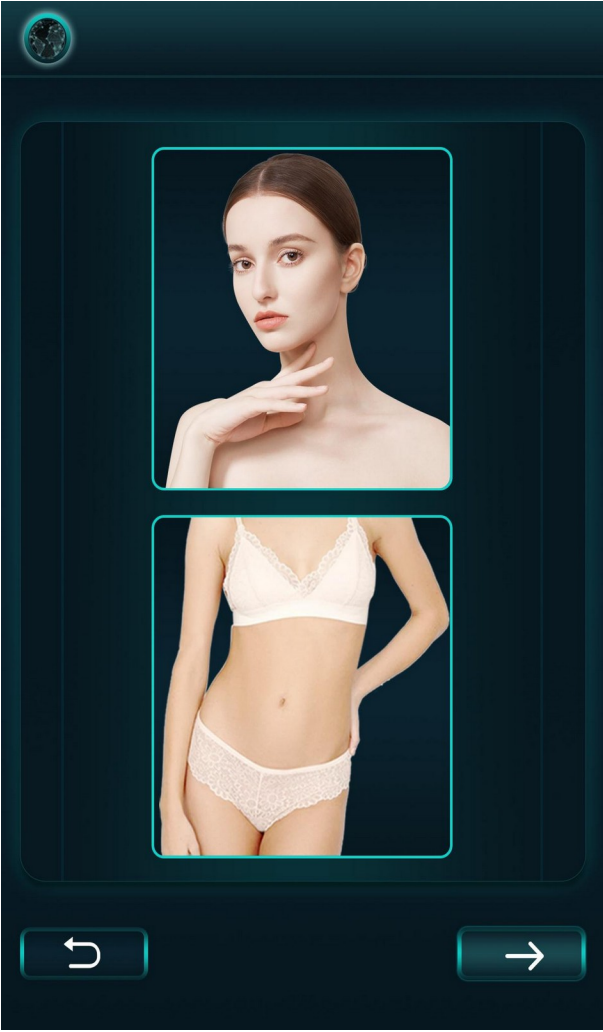


Figure 5.36



Figure 5.37

Figure 5.37

5. The parameter setting windows include the following items (Figure 5.38).



Figure 5.38

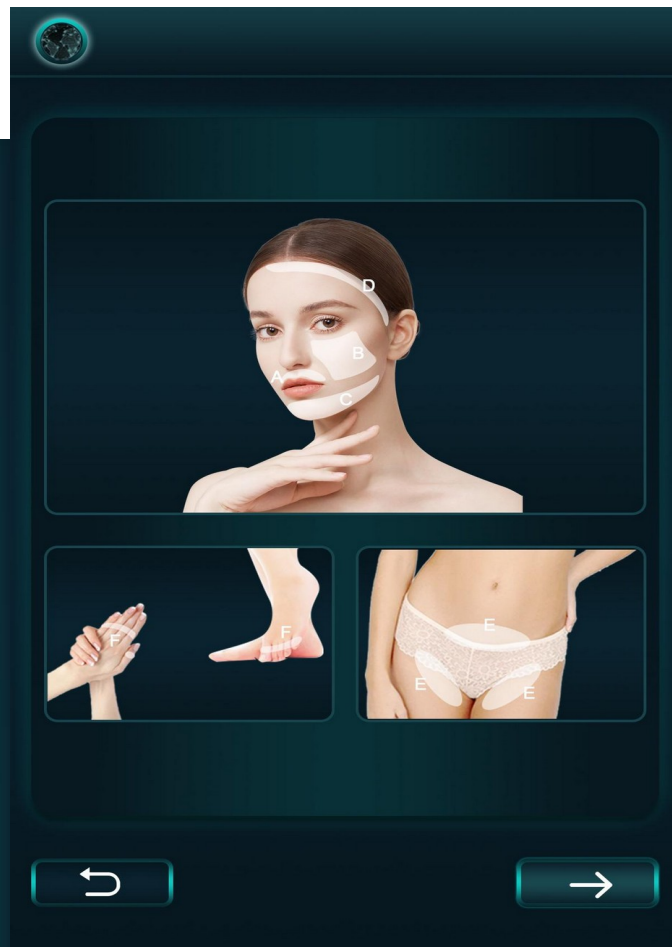


Figure 5.39

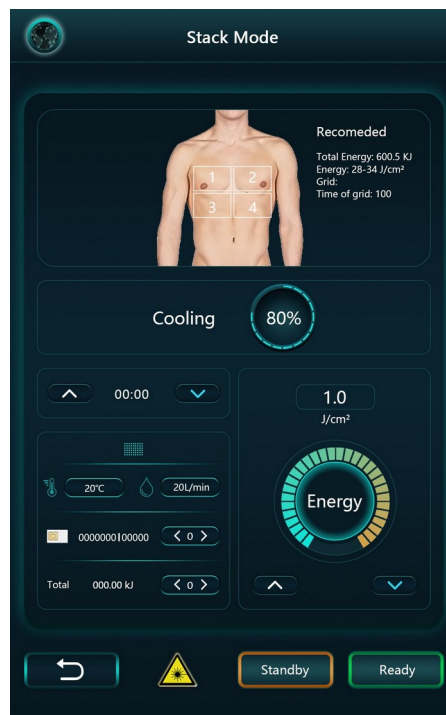


Figure 5.40

A. Power output window: displays IPL output energy setting. There are two indications of the output measurement on the screen. The “J/cm²” is measured with real energy output in J/cm², the “Level” is listed as energy output on Level grade. The output power can be increased or decreased at the Treatment Menu by pressing the: “Up or down” button respectively. The power of this system can be adjusted from 10 to 60 levels.

B. Pulse width: It is the length of time from 10 to 400ms that the skin is exposed to the pulse of light. To increase or decrease the parameter settings, use the up or down arrow buttons.

C. Recommended: This item will be given when you select Standard/SHR/BBL/STACK mode. Total Energy: Device will give the suggested filter according to each treatment needs. Energy: The energy density output, measured in Joules/cm².

Grid: small units to union of a treatment area; for example, there are 12 grids for back. The square measure of a grid is 10(W)x 20cm (L). Time of grid: The system will recommend the treatment time of grid on the screen. The time will decrease progressively to zero during the treatment. You are allowed to increase time and prolong the treatment procedure if the total energy is not enough for special client.

D. Temperature adjustment window: It allows user to modify temperature of Handpiece sapphire window (tip). To increase or decrease the cooling level setting is from 20% to 100% by touching the “ ” buttons. The sapphire of handpiece will start cooling after pressing the “Standby” key. Cooling takes 2–3 minutes. The TEC coolers to ensure stabilization of the handpiece applicator tips temperature at a desired level of -15°C.

E. Treatment counters: The Treatment counter displays when IC card function off: the total counter of shots / current counter of shots; when IC card function on: current counter of shots/IC card shots number; (IC card function for optional)

F. System Information window: shows the available control options. Any warnings or system errors are displayed here.

a. Water temperature status: The number is shown as the temperature of the water tank. If it is overheating (over 55°C) the numeric will turn from blue to red color.

b. Water flow speed status: the number is shown as the speed of the water circulation flow. If the flow speed is too low the numeric will be shown as red color.

G. Standby & Ready Button: Standby: Touch the “Standby” after choosing the parameter setting. The handpiece compressor cooling function is activated and it will be cooled after 2-3 minutes. Please be sure if the doctor pauses the practice during the treatment over 3 minutes, the Standby function must be turned off. Ready: To access the ready mode before active laser emission. Once the system enters “Ready” mode, laser emission can start upon activation of the footswitch or the handpiece trigger. If you want to change operating parameters during the treatment you need to turn off the “Ready” function. Because in Ready mode the operating parameters cannot be changed.

H. Frequency (Repetition Rate): Professional mode-6 modes(1Hz/ 2Hz/ 3Hz/ 5Hz/ 8Hz/ 10Hz) for selection means shots number per second. It is recommended that the operator start at a low Frequency with 1Hz. Once experience is gained, the higher repetition rates (up to 10Hz) may be utilized.

I. Total energy (Kj): To accumulate all grid energy in 1000J of a unit (measurement) on the screen. The energy will be increased progressive.

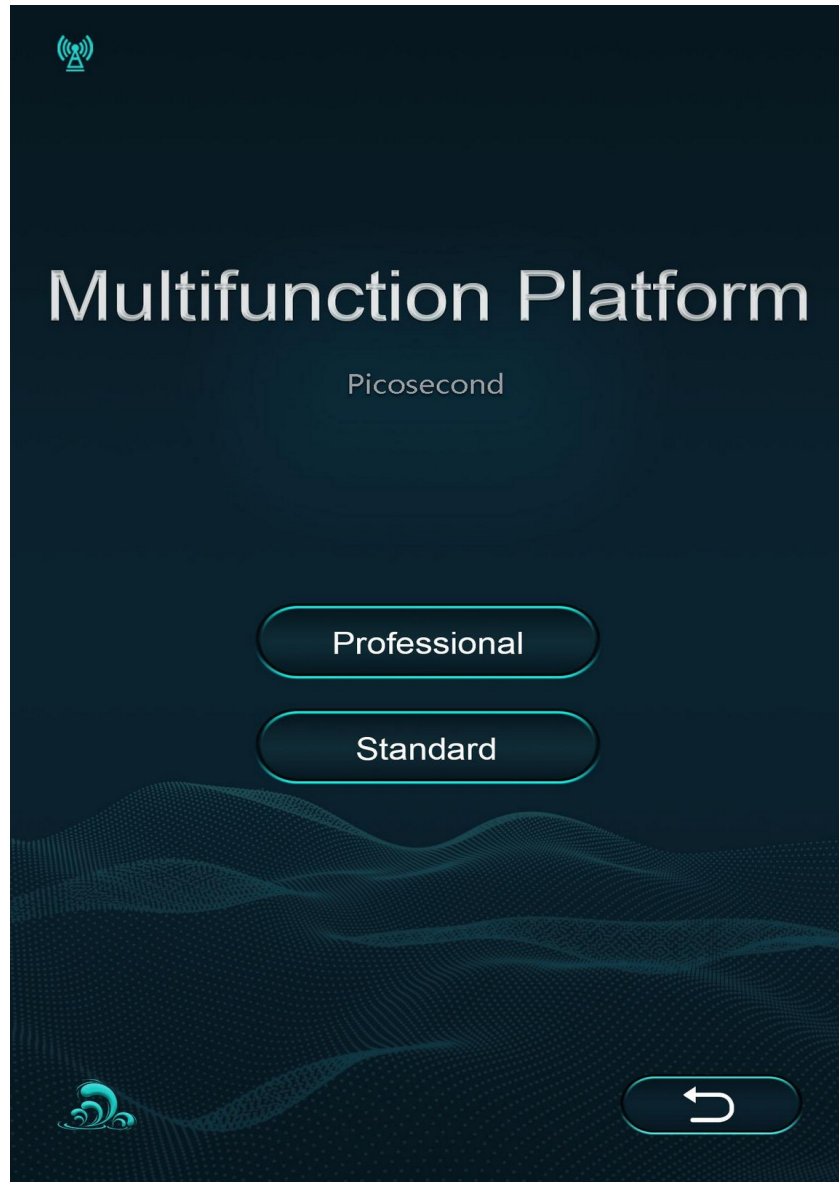
J. Time of treatment: To accumulate the time during the treatment.

K. Back: Press the “ ” button to go back to a page. You may switch off the power system now. This will terminate the active treatment phase and disengage the lamp; the service lifetime of the treatment handle is maximized.

5.1.4 Picosecond Nd:YAG laser treatment menu

1) When choosing Professional Mode, select the desired wavelength handpiece from the storage case.

2) When choosing Standard Mode, select the desired treatment; there are 16 treatments in total to select from: Tattoo (black, blue, brown), Tattoo (red, purple, orange), Skin Resurfacing, Skin Resurfacing with array lens, Carbon Peeling, Speckled Nevus (small size), Nail Fungus, Age Spot, Café-au-lait Spot, Sun Spot, Lentigo, Melasma, Seborrheic Keratosis, Hyperpigmentation, Nevus of Ota, and Speckled Nevus (large size).



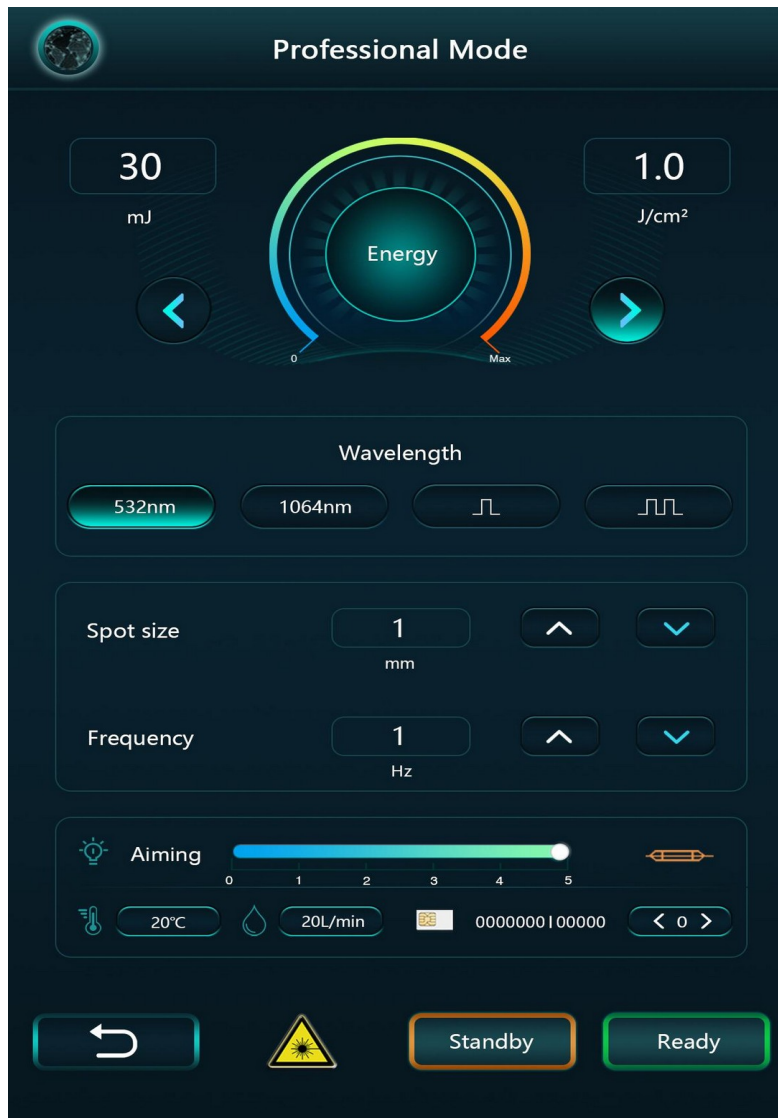
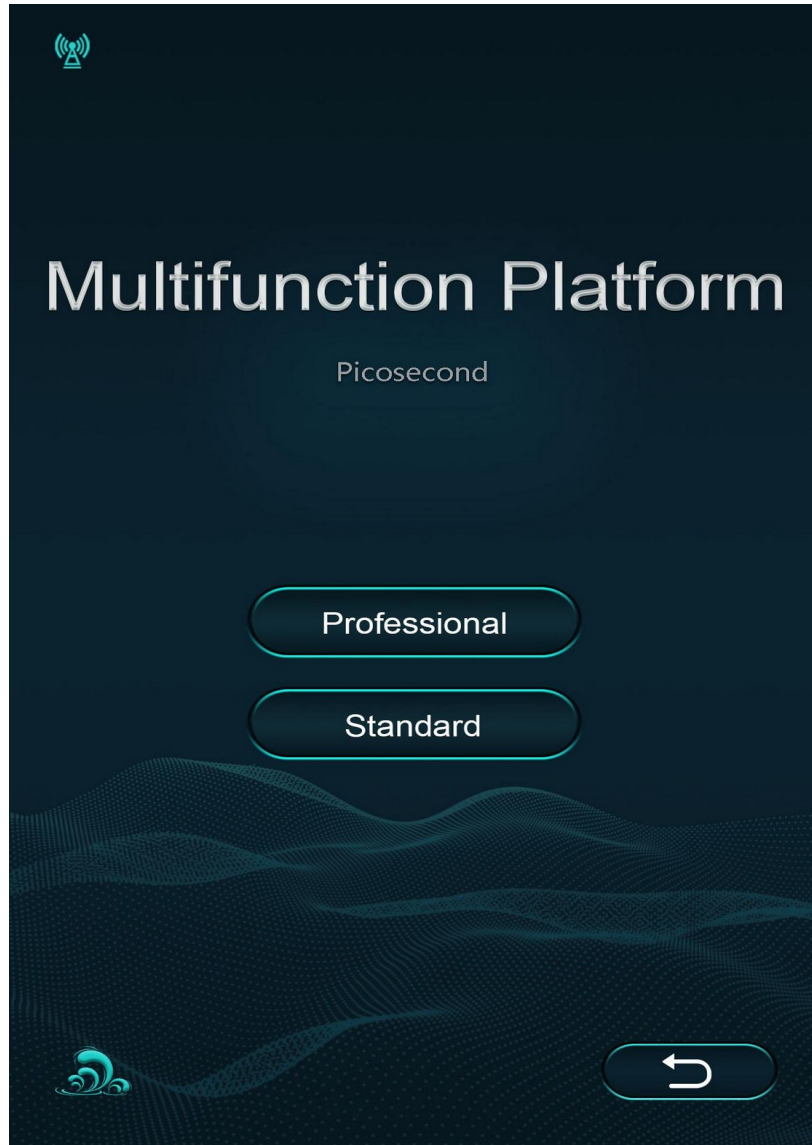


Figure 5.42

- 3) Attach the handpiece tip (1064 nm or 1064+532 nm) to the handle.
- 4) Press the wavelength window until it becomes highlighted.
- 5) Adjust the spot size, energy, and repetition rate to the desired settings.
- 6) Touch “Standby” and “Ready” to prepare for treatment after the user inserts the IC card correctly; the IC CARD ONLINE icon will be shown in the system information window.
- 7) Movements should be gentle and rhythmical, but not irritating or uncomfortable.
- 8) Evaluate the treatment area for any untoward side effects, such as pain. During treatment, the spot size can be adjusted to your requirements.
- 9) After treatment, copy the treatment parameters to the customer’s record sheet and place the device in Standby Mode by depressing the “Standby” button.
- 10) Press “Back” to return to the main menu.

11) Turn off the device by turning the key switch counterclockwise and switching off the power breaker. Clean the lens of the treatment tip and sanitize the treatment head with alcohol-soaked cotton balls.

12) Replace the treatment handpiece on its support.



CAUTION

1. Improper repetition rate operation will result in damage to the product, which will not be covered under the normal-use warranty.
2. Improper wavelength selection will result in damage to the product, which will not be covered under the normal-use warranty. Definition of operation interface items:

1. Wavelength setting:

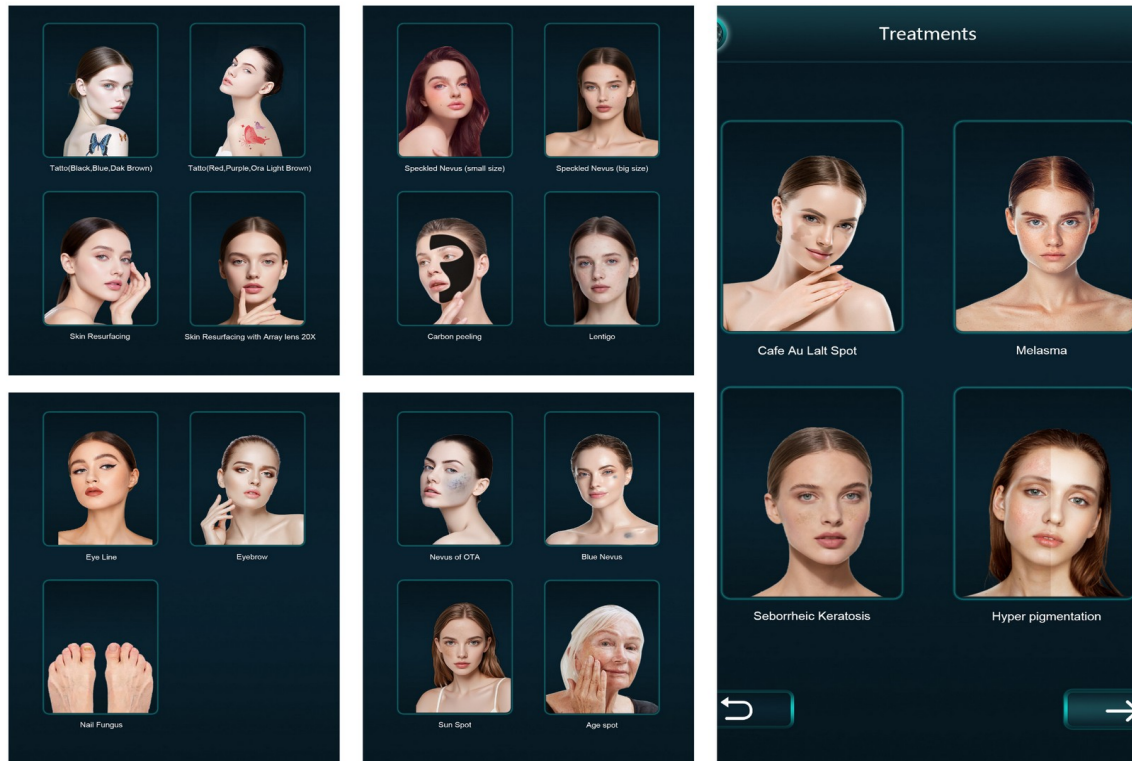


Figure 5.44

For Q-switched Nd:YAG laser systems, there are two kinds of wavelengths and treatment tips. The 1064 nm tip is for the treatment of blue or black pigment; the 532 nm tip is for the treatment of red and brown pigment. Please select the treatment tip according to the color of the target treatment area and press the 1064 nm or 532 nm button on the treatment menu (Ref. picture 5.2).

2. Energy setting:



Figure 5.45

Figure 5.46

Please select the energy using the ▲ or ▼ buttons. The 1064 nm energy can be changed from 50 mJ to 900 mJ; the 532 nm energy can be changed from 50 mJ to 400 mJ. Please note:

When you operate the device for the first time, please use the energy preset on the screen. The factory has calibrated the energy and software to ensure the best energy starts at this level. After some time of use, as the lamp and bar age, the temperature of the handpiece increases, which changes the characteristics of the YAG bar. The same energy level setting used previously may not produce as strong an energy output as before. In this case, please increase the energy level by one or two steps. When you increase the energy level and find the output energy is as strong and stable as before, please use this energy level. If the energy output weakens again, please repeat the previous procedure. Please note: do not increase the energy level too much, as it may cause overheating or burns on the treatment area. The smaller the handpiece spot size, the stronger the energy. Please refer to the following table for the scale of the adjustable focusing tip, and follow the suggested guidance when performing treatment:

Scale (mm)	Spot Size Ø (mm)
1	1
1.5	1.5
2	2
2.5	2.5
3	3

3.5	3.5
4	4
4.5	4.5
5	5

Warning: The laser system has specific operating requirements. The operator must not establish contact between the handpiece and the surface of the treatment region. It is the practitioner's responsibility to fulfill these requirements. Failure to do so can create the potential risk of cross-contamination or biological incompatibility from one customer to another, which may increase the risk of injury to the customer. Do not allow the tip to make physical contact with the skin during treatment.

3. Frequency setting:

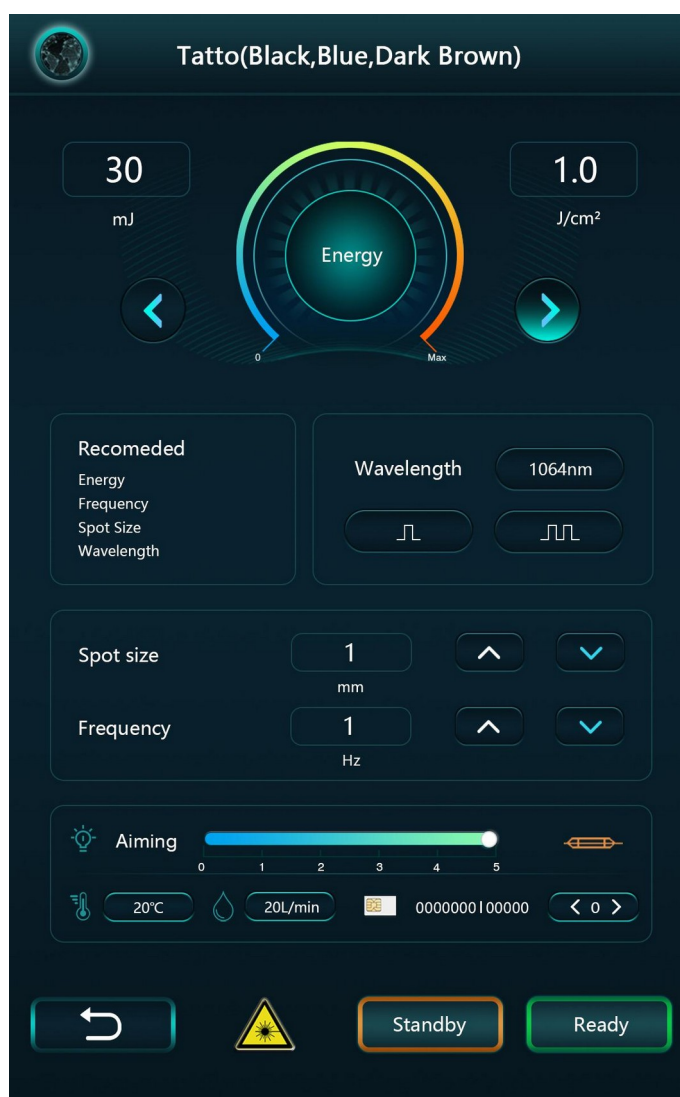


Figure 5.47

Frequency refers to the number of pulses emitted in one second; the frequency range is 1 Hz to 10 Hz. Please select the frequency using the ▲ or ▼ buttons. In general, we recommend using below 5 Hz.

4. System information window:

Shows the available control options. Any warnings or system errors are displayed here.

- a. Water temperature status: the number shows the temperature of the water tank. If it is overheating (over 55°C), the screen will show an error message accompanied by a beep from the system. The system will not be allowed to operate if the water temperature is in an error state.
- b. Water current status: indicates whether water circulation is normal or abnormal; if the number is ≤ 20 , the screen will show an error message accompanied by a beep from the system. The system will not be allowed to operate if the water circulation is in an error state.
- c. IC card status: when the system has the IC card function, the IC card status online icon will be shown on the screen after the IC card is inserted correctly. A warning may appear when the IC card has a bad connection, is damaged, is inserted incorrectly, or its shot count has run out. The IC card icon will indicate an error accompanied by a beep from the system, and its shot count will be 0. The error message code descriptions are listed in the following Maintenance section, 6.5.2.

5. Spot size:

Spot size scale selection from 1 mm to 5 mm.

6. Treatment counters:

When the IC card function is off, the treatment counter displays the total shot count / current shot count; when the IC card function is on, it displays the current shot count / IC card shot count (the IC card function is optional).

7. Reset counter:

Press this button and the counter will be reset to zero.

8. Standby/ Ready/Back:

Press "Standby" to simmer the lamp on, and press "Ready" for treatment. Press "Ready" and "Standby" after treatment to disconnect the simmer function. Press the "Back" button to return to the treatment menu. You may switch off the power system now. This will terminate the active treatment phase and disengage the lamp; the service lifetime of the treatment handpiece is maximized.

9. Recommended parameter setting:



Figure 5.49

Standard Mode provides the recommended parameter setting (including the energy, frequency, and spot size). Please choose the largest spot size and lowest energy in the recommended parameter range to start the treatment. For example, if the recommended energy range is 300–500 mJ and the recommended spot size range is 4–5 mm, choose the 5 mm spot size with 300 mJ energy to perform the treatment. This is very important to provide a safe treatment.

5.1.5 2940 nm Er:YAG Fractional laser treatment menu

After entering the main screen, it is necessary to choose the proper treatment tip for the next page of the treatment interface (see Figure 5.50).

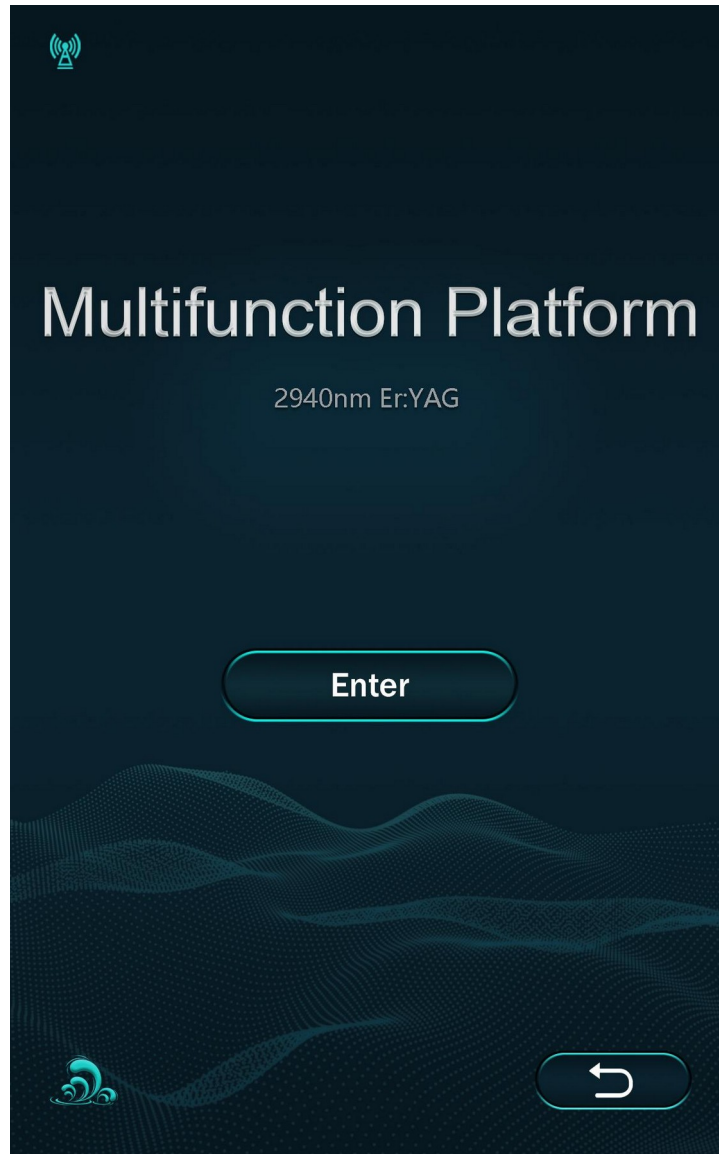


Figure 5.50

3. Treatment mode & Parameter setting windows include the following parameter adjustments: (See Figure 5.51).

A. MTZs Density Selection display: shows the current accepted treatment MTZs Density, there are two modes for selection. One is 49dots another is 81 dots.

B. Frequency Selection display: there are two modes 1Hz and 2Hz. 1Hz (1shot per second) and 2Hz (2 shots per second).

C. Pulse Selection display: It is pulse duration, there are three pulse width selected- Short (1.5ms), Medium(2.0ms), Long(2.5ms).

D. Multifunction Laser Platform power output window: displays energy output energy setting It is the output measured in mJ/MTZ. The output power can be increased or decreased at the Treatment Menu by depressing the: "Up or down" button respectively. The power of this system can be adjusted from 12 up to 28mJ/TMZ when choose 49dots and from 4 up to 20mJ/TMZ when choose 81dots. The beam expander(Ø6 mm, Ø9 mm) can be adjustable from 500 to 2000mJ, the zoom lens(Ø1-3.5mm) can be adjustable from 500 to 2000mJ.

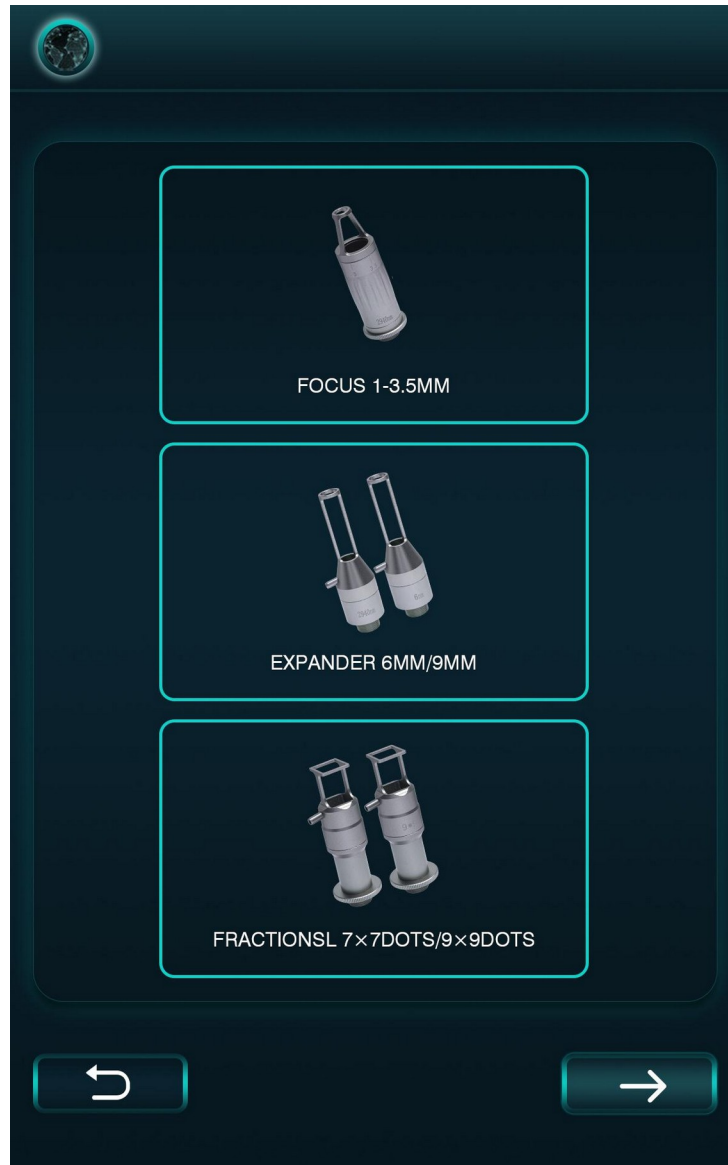


Figure 5.51

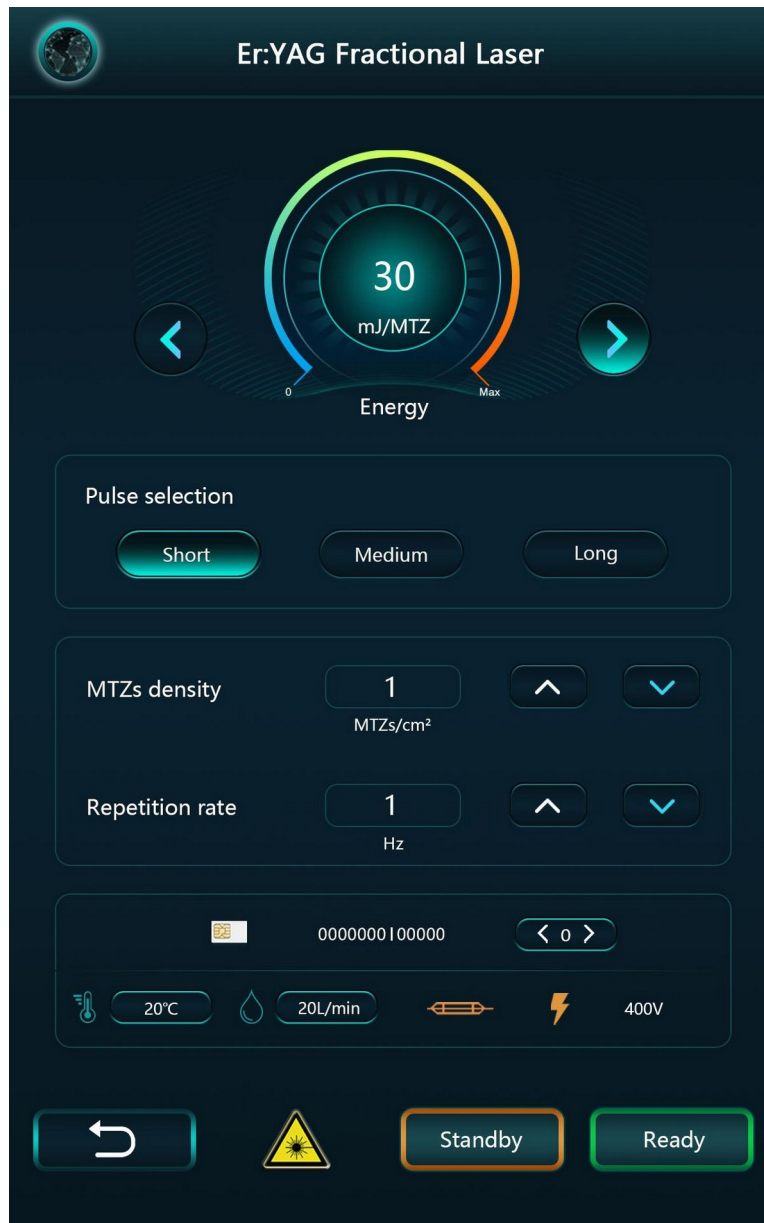


Figure 5.52

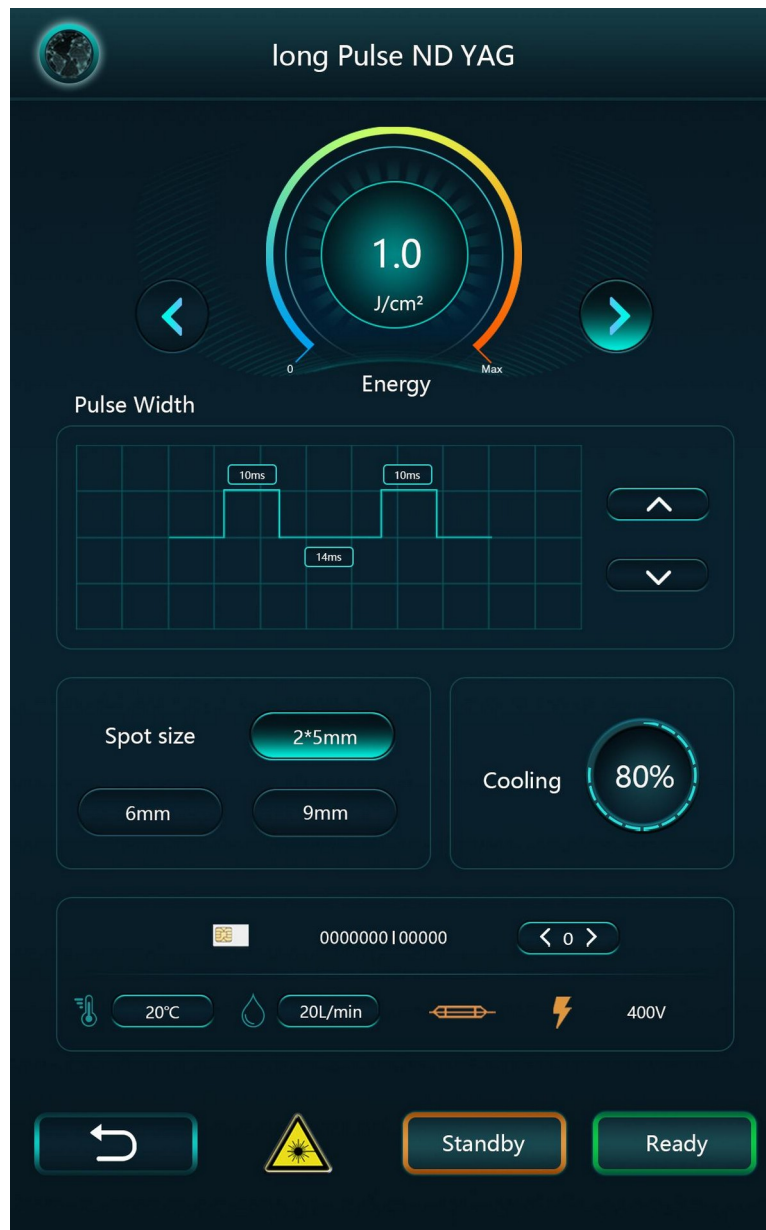
5.1.6 1064 nm long-pulse Nd:YAG laser treatment menu

Brief description of the major items for treatment mode:

A: Spot size: three tips can be selected: 2.2 x 5 mm, Ø6 mm and Ø9 mm. The 2.2 x 5 mm sapphire tip is mainly for vascular treatment; Ø6 mm and Ø9 mm sapphire tip is mainly for hair removal.

B: Pulse width: It is the length of time from 10 to 40ms that the skin is exposed to the pulse of light. Press the pulse width "10.0" button to activate its function and by using the ▲ or ▼ arrow buttons to increase pulse width. It is recommended that vascular treatment use the pulse width 30ms; hair removal ≥ 20 ms.

C: Energy density (J/cm²): The energy density output, measured in Joules/cm², is set by the user for every treatment. The energy range: 2.2 x 5 mm sapphire tip: 150–500J/cm²; Ø6 mm sapphire tip: 60–260J/cm²; Ø9 mm sapphire tip: 10–110J/cm². To increase or decrease the energy setting, use the ▲ or ▼ arrow buttons.



A: Spot size B: Pulse width C: Energy density

Figure 5.53

NOTE

A list of suggested parameters is provided by World Aesthetix. Always refer to this set of parameters prior to treatment. Please remember that this manual is used mainly as a guide and the parameters are not absolute.

5.1.7 1540 nm Er:Glass Fractional laser treatment menu

Brief description of the major items for treatment mode:

A. MTZs Density: There are two Microbeam lenses for your selection. (a) 100MTZs/cm², (b) 324MTZs/cm². Select 100MTZs/cm² for deep skin tissue, select 324MTZs/cm² for superficial area.

B. Pulse width: It is the length of time from 10ms and 15ms that the skin is exposed to the pulse of light. Touch the number to change the pulse width.

C. Repetition Rate: To set the Pulse Repetition rate parameter for 1Hz mode and single mode. 1Hz (1shot per second) and single mode (1 shot per push button).

D. Energy density (mJ/MTZ): The energy density output, measured in mJ/MTZ, is set by the user for every treatment. The fluence is the total energy delivered in the selected pulse type (measured in mj), divided by the microbeams (measured in MTZ). It is adjustable from 10–70 mJ/Microbeam for 10*10 Pixel, adjustable from 5–25 mJ/Microbeam for 18*18 Pixel. To increase or decrease the energy setting, use the ▲ or ▼ arrow buttons.

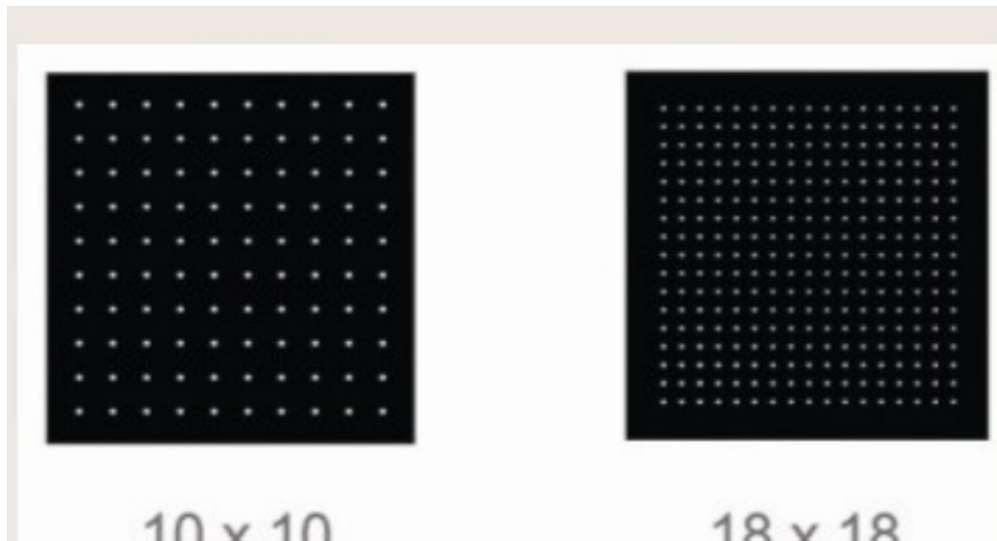


Figure 5.56

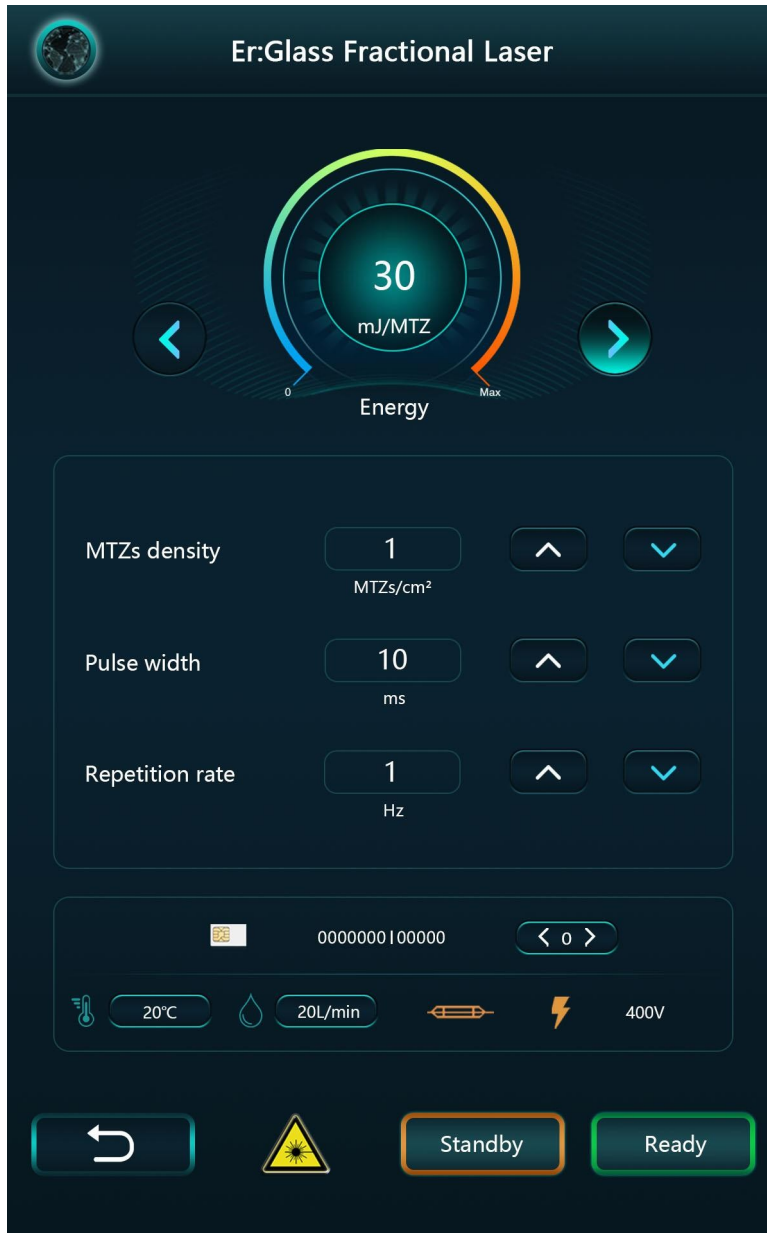


Figure 5.55

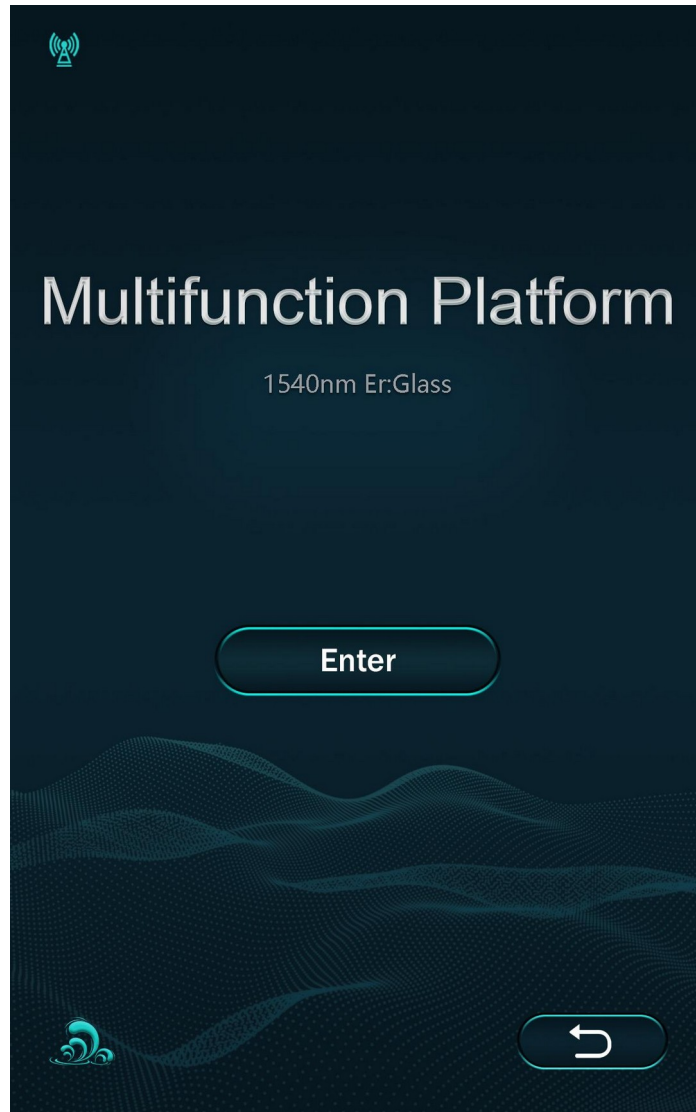


Figure 5.54

5.1.8 Q-Switched Nd:YAG laser treatment menu

- 1) When choosing Professional Mode, select the desired wavelength handpiece from the storage case.
- 2) When choosing the Standard Mode, select desired treatment, there are total 16 treatments for your selection: Tattoo (black, blue, brown), Tattoo (Red, Purple, Orange), Skin resurfacing, Skin resurfacing with array lens, Carbon peeling, Speckled Nevus (small size), Nail Fungus, Age spot, Cafe Au Lait Spot, Sun Spot, Lentigo, Melasma, Seborrheic Keratosis, Hyper Pigmentation, Nevus of OTA, Speckled Nevus (big size).
- 3) Attach the handpiece tip (1064 or 1064+532nm) to the handle
- 4) Press the wavelength window until it becomes highlighted.
- 5) Adjust spot size, energy and repetition rates to desired settings.
- 6) Touch the "Standby" and "READY" to ready for treatment after the user inserts an IC card and the IC CARD ONLINE icon will be shown on the system information window.

- 7) Movements should be gentle and rhythmical, but not irritating or uncomfortable.
- 8) Evaluate the treatment area for any unwanted side effect such as pain. During treatment, the spot size can be adjusted as to your requirements.
- 9) After treatment, copy the treatment parameters to the customer's record sheet and place the device on Standby Mode by depressing the "STANDBY" button.
- 10) Press "BACK" mode to the main menu
- 11) Turn off the device by turning the key switch, reverse clockwise and turn off the power breaker.

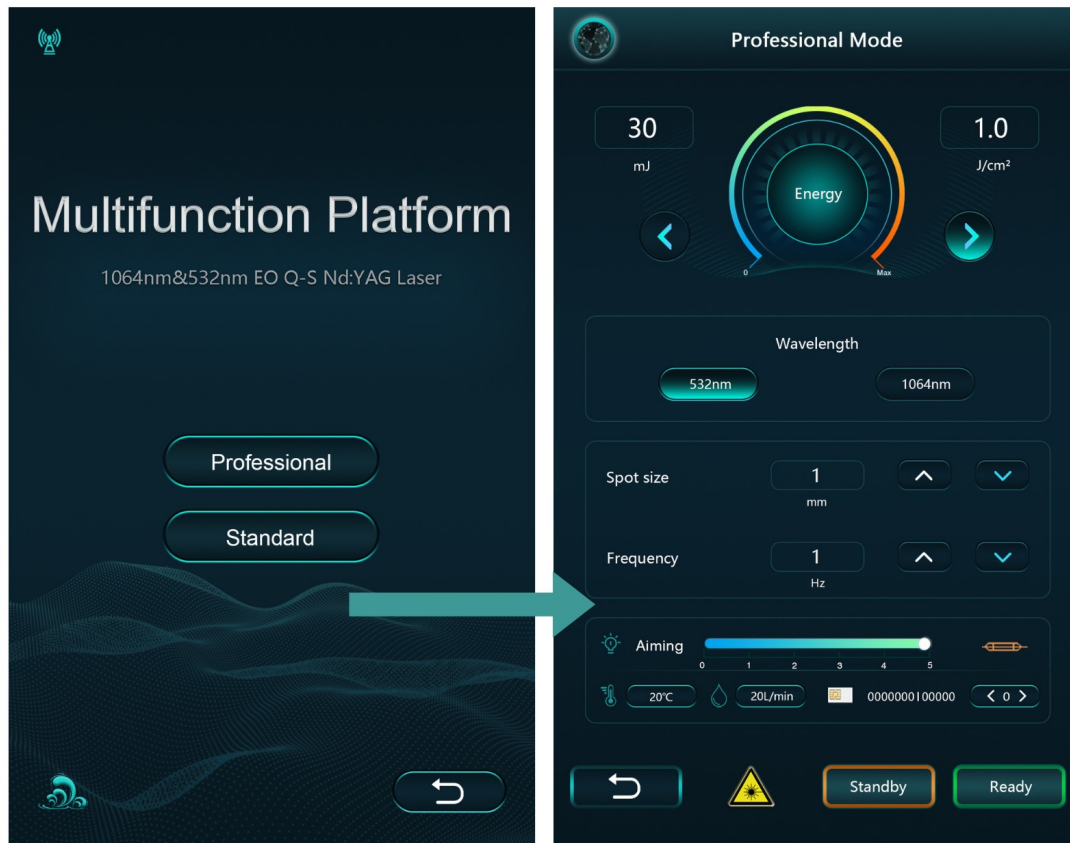


Figure 5.57

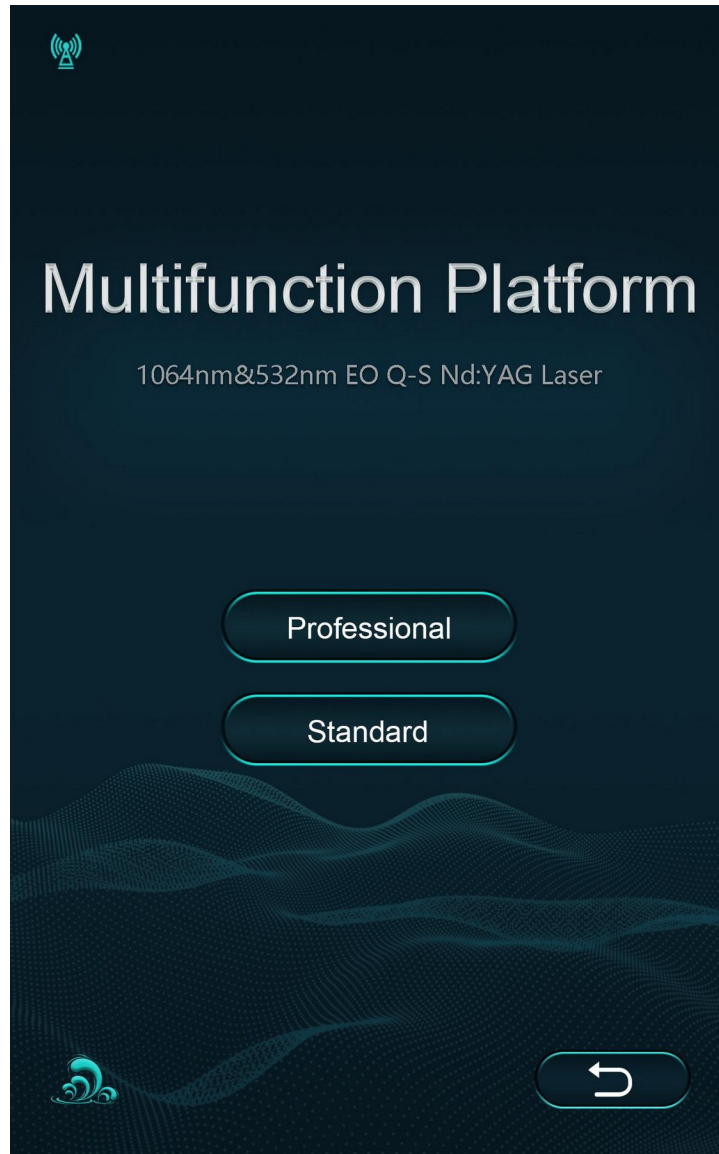


Figure 5.58

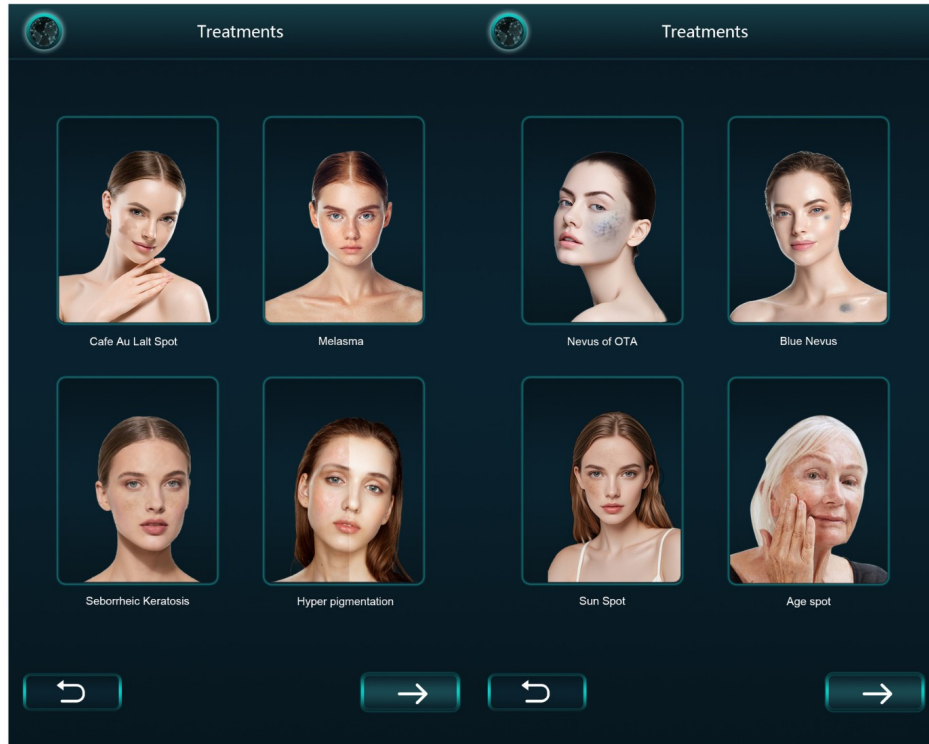


Figure 5.59

Clean the lens of the treatment tip and sanitize the treatment head with alcohol-soaked cotton balls.

12) Replace the treatment handpiece on its support.

CAUTION

Improper repetition rate operation will result in damage to the product, which will not be covered under the normal-use warranty. Improper wavelength selection will result in damage to the product, which will not be covered under the normal-use warranty. Definition of operation interface items:

1. Wavelength setting:

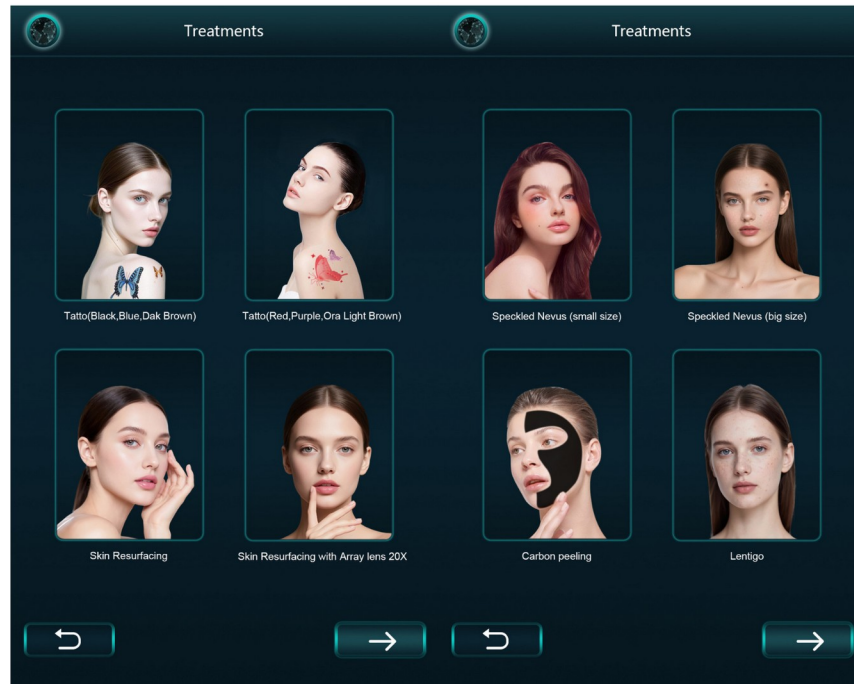


Figure 5.60

For Q-switched Nd:YAG laser systems, there are two kinds of wavelengths and treatment tips. The 1064 nm tip is for the treatment of blue or black pigment; the 532 nm tip is for the treatment of red and brown pigment. Please select the treatment tip according to the color of the target treatment area and press the 1064 nm or 532 nm button on the treatment menu.

2. Energy setting:

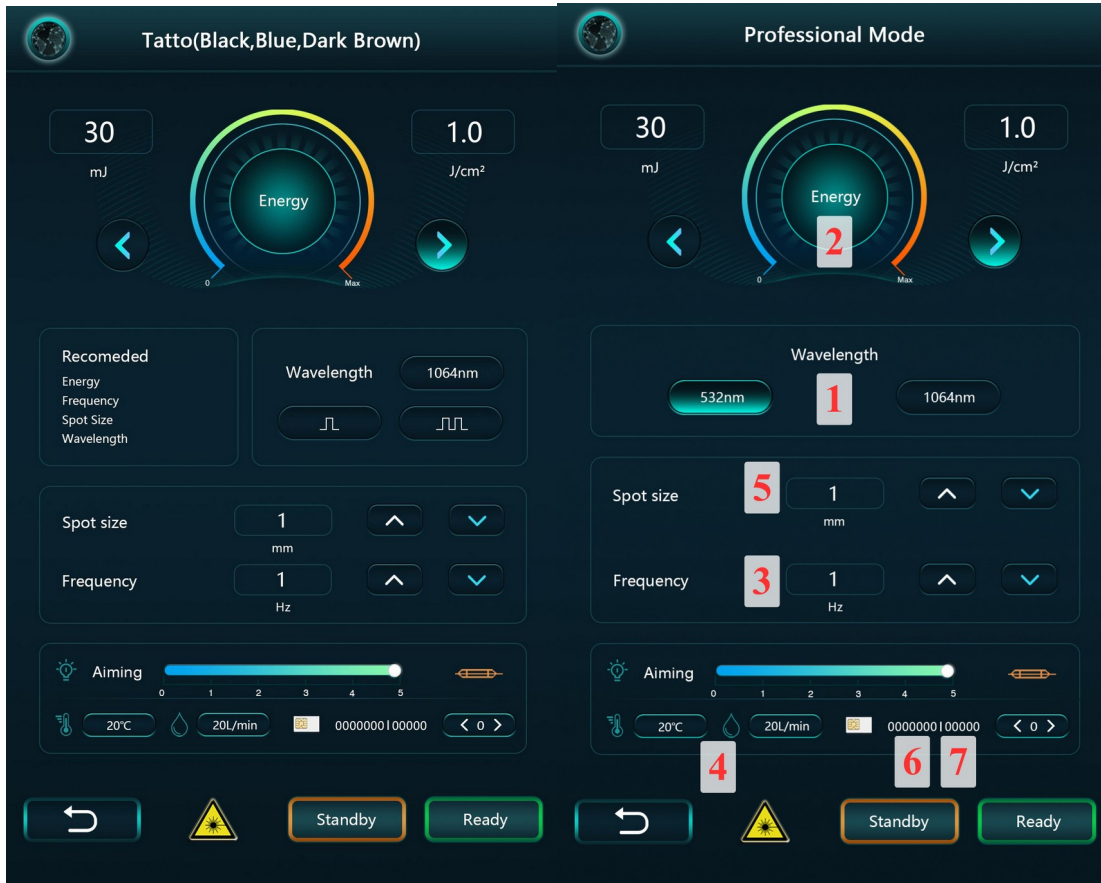


Figure 5.61

Figure 5.62

Scale (mm)	Spot Size Ø (mm)
1	1
1.5	1.5
2	2
2.5	2.5
3	3
3.5	3.5
4	4
4.5	4.5
5	5

Warning: The laser systems have specific operating requirements. The operator must not establish contact between the handpiece and the surface of the treatment region. It is the practitioners responsibility to fulfill these requirements. Failure to do so can create the potential risk of cross contamination of biological incompatibility from one customer to another , it may increase the risk of injury to the customer. Do not allow the tip to establish physical contact with the skin during treatment.

3. Frequency setting: frequency refers to the number of pulses emitted in one second; the frequency range is 1 Hz to 10 Hz. Please select the frequency using the ▲ or ▼ buttons. In general, we recommend using below 5 Hz.

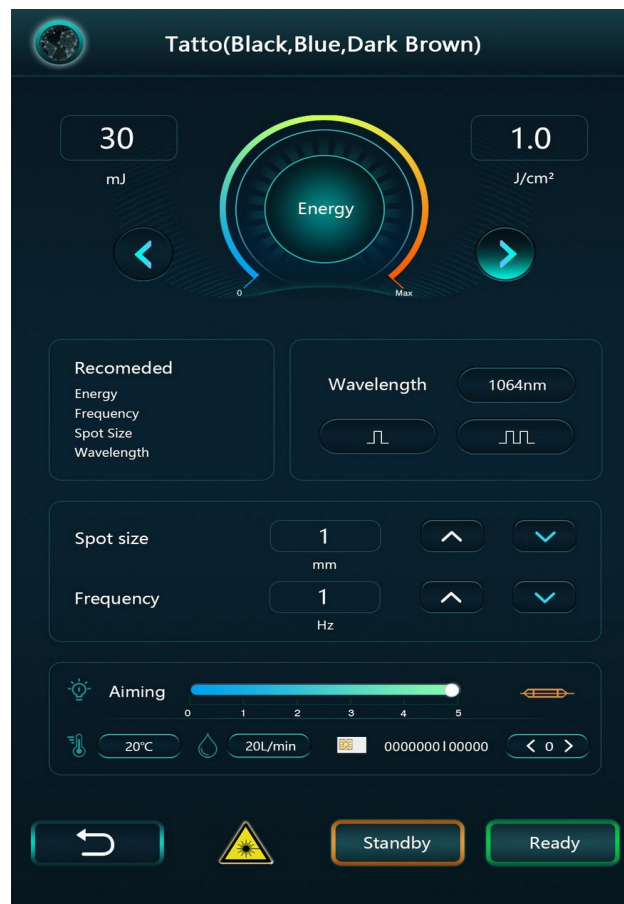


Figure 5.63

4. System information window: shows the available control options. Any warnings or system errors are displayed here.

d. Water temperature status: the number shows the temperature of the water tank. If it is overheating (over 55°C), the screen will show an error message accompanied by a beep from the system. The system will not be allowed to operate if the water temperature is in an error state.

e. Water current status: indicates whether water circulation is normal or abnormal; if the number is ≤ 20 , the screen will show an error message and will beep until resolved. The system will not be allowed to operate if the water circulation is in an error state.

f. RFIC card status: when the system has the RFIC card function, the IC card status online icon will be shown on the screen after the RFIC card is inserted correctly. If the RFIC card has a bad connection, is

damaged, is inserted incorrectly, or its shot count has run out, the RFIC card icon will indicate an error accompanied by a beep from the system, and its shot count will count down to 0. The error message code descriptions are listed in the following Maintenance section, 6.5.2.

5. Spot size:

Spot size scale selection from 1 mm to 5 mm.

6. Treatment counters:

When the RFIC card function is off, the treatment counter displays the total shot count / current shot count; when the RFIC card function is on, it displays the current shot count / RFIC card shot count (the RFIC card function is optional).

7. Reset counter:

Press this button and the counter will be reset to zero.

8. Standby/ Ready/Back:

Press “Standby” to simmer the lamp on, and press “Ready” for treatment. Press “Ready” and “Standby” after treatment to disconnect the simmer function. Press the “Back” button to return to the treatment menu. You may switch off the power system now. This will terminate the active treatment phase and disengage the lamp; the service lifetime of the treatment handpiece is maximized.

9. Recommended parameter setting:



Figure 5.65

Standard Mode provides the recommended parameter setting (including the energy, frequency, and spot size). Please choose the largest spot size and lowest energy in the recommended parameter range to start the treatment. For example, if the recommended energy range is 360–500 mJ and the recommended spot size range is 4–5 mm, choose the 5 mm spot size with 360 mJ energy to perform the treatment. This is very important to provide the safest treatment.

Chapter 6 Maintenance

This chapter describes how to use and maintain the 8-in-1 platform system, including cleaning the equipment and filter, changing the laser tip/IPL/EPL/RF head, and infusing distilled water; it also describes some malfunctions and solutions. The customer can carry out the maintenance through the measures listed in this chapter. Maintenance and any other work may only be performed by authorized professionals.

WARNING

Before any maintenance work, turn the power off and unplug the device. Failure to turn off the power may cause electric shock, damage to the device, and bodily injury. Never attempt to remove the back panel or device casing. Unauthorized tampering with the device's internal system will automatically void the warranty.

6.1 Cleaning the Main unit

The main unit casing or body must be cleaned with a soft, damp cloth once a week. A neutral detergent may be used, but be careful not to let any liquid enter the unit's internal mechanism.

6.2 Cleaning the handpiece

The laser tips, IPL sapphire crystal, and RF head of the handpiece must be kept clean at all times. The laser treatment tip must be cleaned once per week. Any dust or dirt on the lens of the treatment tip may reduce its lifespan. The gel must be cleaned off the IPL sapphire tip after treatment, or the cooling effect may be reduced. Always use a soft, damp cloth or wet cotton balls. Sanitize the treatment head with alcohol-soaked cotton balls.

6.3 Replacing the laser tip/IPL/EPL/RF treatment handpiece

A preventive inspection of the handpiece should be done daily. The inspection consists of checking the integrity and appearance of the tip. To prevent dust from entering the tips, every time you finish a treatment you must place the tips in a sealed bag and then in the box. When you feel the handpiece energy is getting low, please contact your local distributor for service or a replacement.

6.4 Refilling the water supply

Observe the water level through the water observation window at the rear of the unit. The water level is best maintained at the midpoint of this window. Distilled water can be added by following the instructions in Section 4.3, Installation.

6.5 System Troubleshooting

This section lists some malfunction symptoms and solutions.

Symptom	Solutions
No power	1. Check the power cable. 2. Check the circuit breaker / fuse. 3. Check the key switch. 4. Disengage the emergency cut-off switch by rotating it in the direction of the arrows indicated. 5. Notify your distributor.
When a button on the screen is touched, the system does not respond	1. Restart the machine. 2. Please contact World Aesthetix.
System failed to initialize	1. Not enough power; please check the main power supply.

Symptom	Solutions
	2. Please contact the dealer.
No energy output	1. Try to increase the energy to check whether the laser is emitted or not. 2. Check whether the system enters ready mode or not. 3. Check whether the footswitch is connected firmly and working well; if it is damaged, replace it immediately. 4. Check whether the "Work" key is pressed or not. 5. Please contact World Aesthetix.
Malfunction of flash lamp on the IPL treatment head	1. The treatment head / flash lamp has reached its maximum life span (100,000 shots). Replace the treatment head. 2. The IPL treatment head is damaged; please change the IPL treatment head or contact World Aesthetix.
IC card icon shows blue	Please check the IC card to ensure it is inserted correctly, or whether the total counter is zero. Check the power supply and cord.
The IPL treatment head is leaking	1. The O-ring for the faucet is likely damaged. Pull out the treatment handpiece, then take the O-ring from the accessories and push it into the water conduit on the handpiece side. 2. The IPL treatment head is potentially damaged; please contact the dealer.
The treatment handle is warm	1. The system is designed for continued use for up to six hours in optimal environmental temperature and humidity. 2. Always place the system in standby mode while awaiting treatment. The system might have been left on for an extended period. Turn the unit off, let it cool down for half an hour, then restart. 3. Contact the dealer.
The power of the IPL treatment head has weakened	The treatment head has nearly reached its maximum life span (100,000 shots); the fluence can be adjusted by a few joules to compensate.

1. Check power cable No power

2. Check circuit breaker / fuse

3. Check key switch

4. Disengage the emergency cut off switch by rotating towards the direction of the arrows indicated

5. Notify your distributor While touching the button on

1. Restart machine the screen, the system has no reaction

2. Please contact the World Aesthetix.

1. Not enough power, please check main power supply.

System failed to initialize

2. Please contact the dealer.

1. Try to increase the energy to check whether the laser is emitted or not.

2. Check whether the system enters ready mode or not.

3. Check whether the foot switch is connected firmly or not. If the energy output is not working well, if it is damaged, replace it immediately.

4. Check whether pressing the "work" key or not.

5. Please contact the World Aesthetix. Malfunction of flash 1. The treatment head / flash lamp has reached its maximum life span (100,000) shots. Replace the treatment head lamp on the IPL.

2. The IPL treatment head is damaged, please change the treatment head. IPL treatment head or contact the World Aesthetix. Please check the IC card to ensure it is inserted correctly or if the IC CARD icon with blue color total counter is zero. Check power supply and cord.

1. O-Ring for faucet is likely damaged. Pull out the treatment handpiece, then take out O-Ring from accessories and push into water conduit on handpiece side. The IPL treatment head is

2. The IPL treatment head is potentially damaged, please leaking contact the dealer.

1. The system is designed for continued use for up to six hours in optimal environmental temperature and humidity. The treatment handle is 2. Always place the system on standby mode while awaiting warm treatment. The system might have been left on for an extended period. Turn the unit off, let it cool down for half an hour then re-start

3. Contact the dealer.

The treatment head has nearly reached its maximum life. The power of the IPL treatment head has weakened span (100,000 shots) the fluence can be adjusted by a few joules to compensate.

6.6 Maintenance by the Operator

Trained and authorized personnel may carry out routine maintenance work. Authorized persons are exclusively those who have been trained by World Aesthetix. The following routine maintenance work must be carried out:

Maintenance work	Interval
Check and clean the outside surface	Daily
Disinfect and sterilize accessories	Before/after use
Electric cable	Daily
Handpiece plug	Weekly
Energy breaker handle	Daily
Footswitch	Daily

Routine Maintenance Work Maintenance work interval Check and clean outside surface Check Daily disinfect and sterilize accessories before/after use electric cable daily the handpiece plug weekly the energy breaker handle daily the footswitch daily User's Manual

Chapter 7 Clinical Application

7.1 Training

Only professional personnel with appropriate training may operate this device. Unauthorized use may cause thermal injury to oneself or others and may cause irreparable damage to the unit.

7.2 Intended Use and Indications

7.2.1 IPL application 7.2.1.1 Selective Thermolysis

The Intense Pulsed Light system works on the basis of selective thermolysis. The technology is similar to that of lasers. Intense pulsed light, as the name implies, is a concentrated amount of light energy produced by a xenon flash lamp across the broad spectrum of 400 to 1200 nm. Different types of filters can be attached to the unit to limit the wavelength/spectrum of the intense pulsed light. The Hair Reduction (HR) treatment uses a 610/640 nm filter that is best suited to target dark pigments such as melanin. The Skin Rejuvenation (SR) treatment encompasses a broader spectrum of 510/560 nm. The Skin Rejuvenation parameters are best suited to target collagen fibers, which stimulates collagen regeneration. This stimulation of collagen regeneration is best suited for the treatment of fine, superficial, static lines and wrinkles, and for the treatment of enlarged pores and superficial acne scars. The Vascular (VL) and Pigmented (PL) parameters are selective for red blood cells and dark pigments, respectively, which makes them suited for the treatment of superficial vascular and pigmented lesions. Although this device does not generate significant thermal energy compared to lasers, it does produce sufficient thermal energy when coupled with proper filtering and proper practitioner technique. This is a very powerful tool for the practitioner in his or her practice. This IPL treatment causes no downtime and allows the patient to resume work immediately after treatment.

7.2.1.2 Treatment Range

1. VL (420–1200 nm): Acne and telangiectasia
2. VL (510–1200 nm): Telangiectasia and fine superficial veins
3. PL (510–1200 nm): Freckles, superficial melasma, café-au-lait
4. SR (560–1200 nm): Fine static wrinkles, hair pores, scars
5. HR (610–1200 nm): Permanent hair removal
6. HR (640–1200 nm): Permanent hair removal
7. HR (690–1200 nm): Permanent hair removal
8. VL (480–1200 nm): Acne and telangiectasia
9. SR (585–1200 nm): Vascular lesions (telangiectasia), alleviation by photothermic activity.
10. HR (755–1200 nm): Permanent hair removal * Item 7–10 are optional items.

7.2.1.3 Overview of Areas Sensitive to Pain

Face: (Figure 7.1 Pain zones of the face). Body: (Figure 7.2 Pain-sensitive zones of the body).

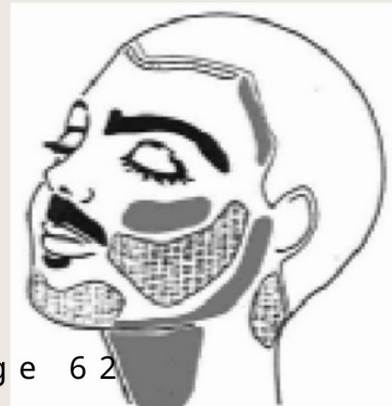
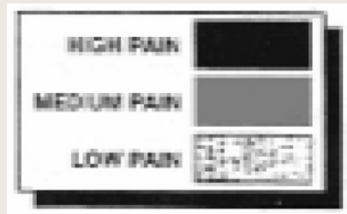
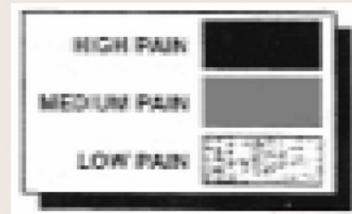
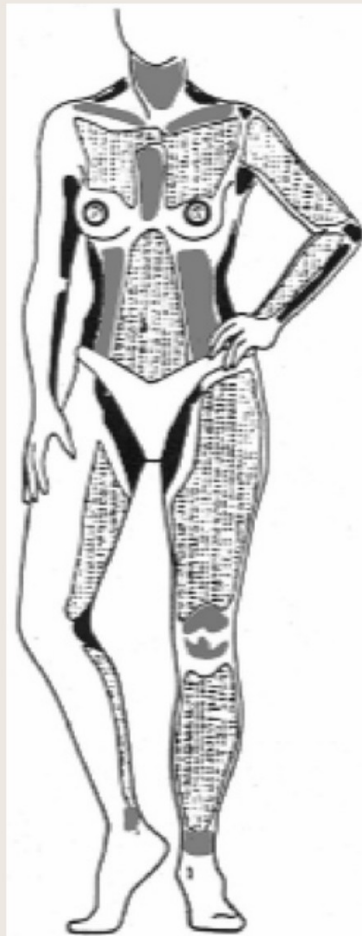


Figure 7.1 — Pain zones of the face



(Figure 7.2 Pain-sensitive zones of bo

Figure 7.2 — Pain-sensitive zones of the body

7.2.1.4 Hair Growth Table

Region	Terminal anagen follicle depth	Duration of TELOGEN	Duration of ANAGEN	Number of follicles/cm ²	Daily growth rate
HEAD					

Upper Lip	1–2.5 mm	6 weeks	4 months	500	0.38 mm
Beard-Chin	2–4 mm	10 weeks	1 year	500	0.32 mm
Cheeks	2–4 mm	3 months	4–8 weeks	880	0.16 mm
Eyebrows	2–2.5 mm	3 months	4–8 weeks	350	0.35 mm
Ear Scalp	3–5 mm	3–4 months	2–6 years	65	0.3 mm
BODY					
Axillae	3.5–4.5 mm	3 months	4 months	60	0.21 mm
Legs	2.5–4 mm	5 months	4 months	70	0.3 mm
Thighs/Pubic	3.5–5 mm	3 months	4 months	80	0.35 mm
Area/Arms	3–4.5 mm	4 months	3 months	65	0.3 mm
Breast/Trunk	2–4.5 mm	—	—	70	—

7.2.1.5 Contraindications

1. Inflammatory dermatosis.
2. Cutaneous infections.
3. Immune system defects.
4. History of keloid formation.
5. Psychologically ill patients.
6. Pregnancy.
7. Skin cancer.
8. Bleeding disorders.
9. Photodermatoses.
10. Active herpes simplex.
11. Taking of drugs that increase sensitivity to light.
13. Patients with sun-tanned skin should postpone IPL hair removal until the tan subsides.
14. A certain delay is also recommended where waxing or plucking has been used.

7.2.2 Diode laser application Treatment Parameters Definitions & Suggestion

Settings

7.2.2.1 Skin type parameter selection

The ratios of light absorption for different skin types vary. Darker skin absorbs light energy more easily, and lighter skin absorbs less light energy.

7.2.2.2 Cooling level selection

The cooling system is used to cool the handpiece tip and protect it from skin burns caused by overheating. The cooling system starts working after the system power is switched on, cooling the probe to a certain temperature before operation. It takes around 2–3 minutes after activating the cooling function before operation. There are five cooling levels to select from.

7.2.2.3 Pulse type (pulse width & frequency)

Choosing the correct pulse type (pulse width and frequency) is essential for an optimized treatment. When treating darker skin types, longer pulses must be used to ensure that the surrounding tissue is not damaged. If the operator uses Professional Mode, it is recommended to start at a low frequency. Once experience is gained, higher repetition rates (up to 10 Hz) may be utilized.

7.2.2.4 Fluence

Fluence measures the light energy delivered to the skin, in units of energy per unit area (J/cm^2). With a large spot size ($15 \times 50 \text{ mm}$), the scattering effect is minimized, resulting in a constant fluence and deeper penetration. The greater the fluence, the higher the temperature of the target hair, the surrounding tissue, and the epidermis. Dense hair (approximately 30–40 hairs per cm^2) produces higher temperatures due to the higher melanin concentration per cm^2 . Cooling of the follicles by heat conductivity produces excess heat in the surrounding tissues, which can result in tissue damage. Therefore, as hair density increases, fluence should be reduced.

7.2.2.5 Suggestion parameter setting table

Please follow the pre-programmed suggested parameters (protocol) by selecting SHR mode and Stack mode, step by step. SHR mode is applied to treatment areas such as the arms, legs, chest, and back (Ref. Figure 7.3). After selecting treatment area “B,” the recommended data will be shown on the screen (Ref. Figure 7.4). The total grid area for “B-Chest” is 8 grids. The recommended energy starts from $5.2 \text{ J}/\text{cm}^2$; 7 kJ of energy is needed for each grid over an area of $10 \text{ (W)} \times 20 \text{ (L)} \text{ cm}$ (200 cm^2) within a 1-minute-10-second period to follow the treatment procedure. The total energy should reach 56 kJ as the recommended treatment dose for area “A.” Stack mode is applied to treatment areas such as the chin, cheek, upper lip, sideburns, bikini line, and fingers and toes (Ref. Figure 7.5). After selecting treatment area “B,” the recommended data will be shown on the screen (Ref. Figure 7.6). The total grid area for “B-Cheek” is 1 grid. The device needs 8 kJ of energy for each grid over an area of $10 \text{ (W)} \times 20 \text{ (L)} \text{ cm}$ (200 cm^2) within a 75-second period to follow the treatment procedure. The total energy should reach 8 kJ as the recommended treatment dose for area “B.” Evaluate the treatment area for any side effects. The treated area may become pink and a little puffy; this is normal. The reaction subsides quickly, and within a day or so the areas return to normal. During treatment, the parameters can be adjusted to meet your requirements. The number of treatments needed is 4–6 sessions, and the treatment interval is 4–6 weeks.

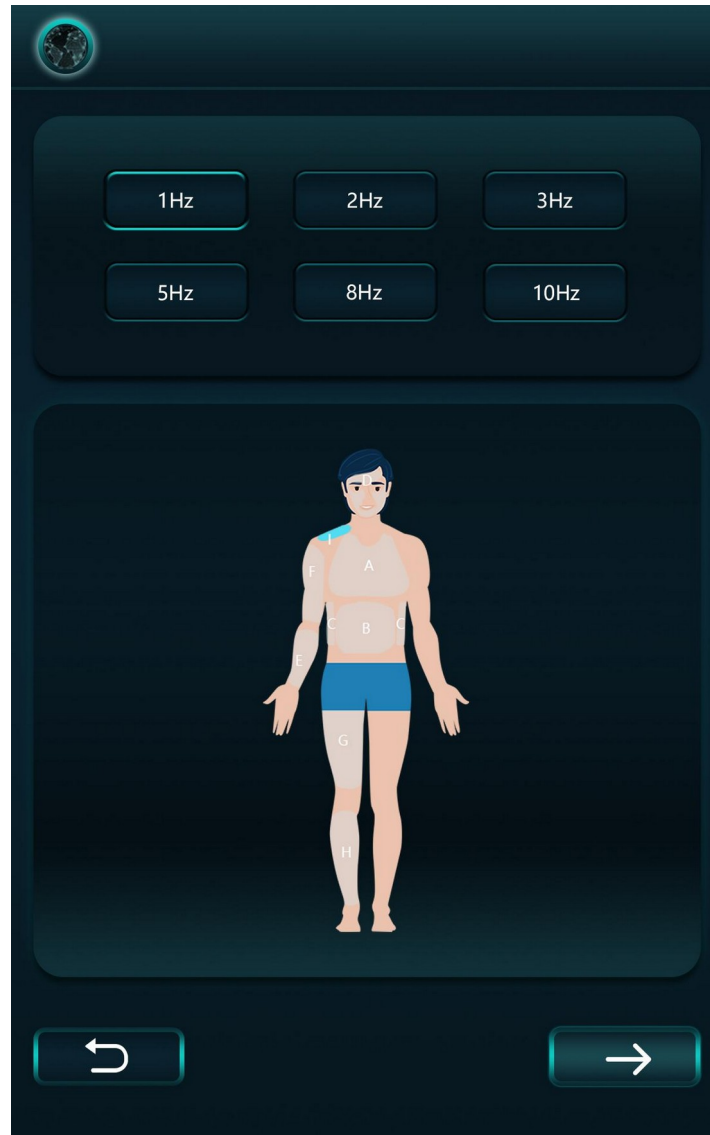


Figure 7.3 SHR mode — treatment-area and skin-type selection.

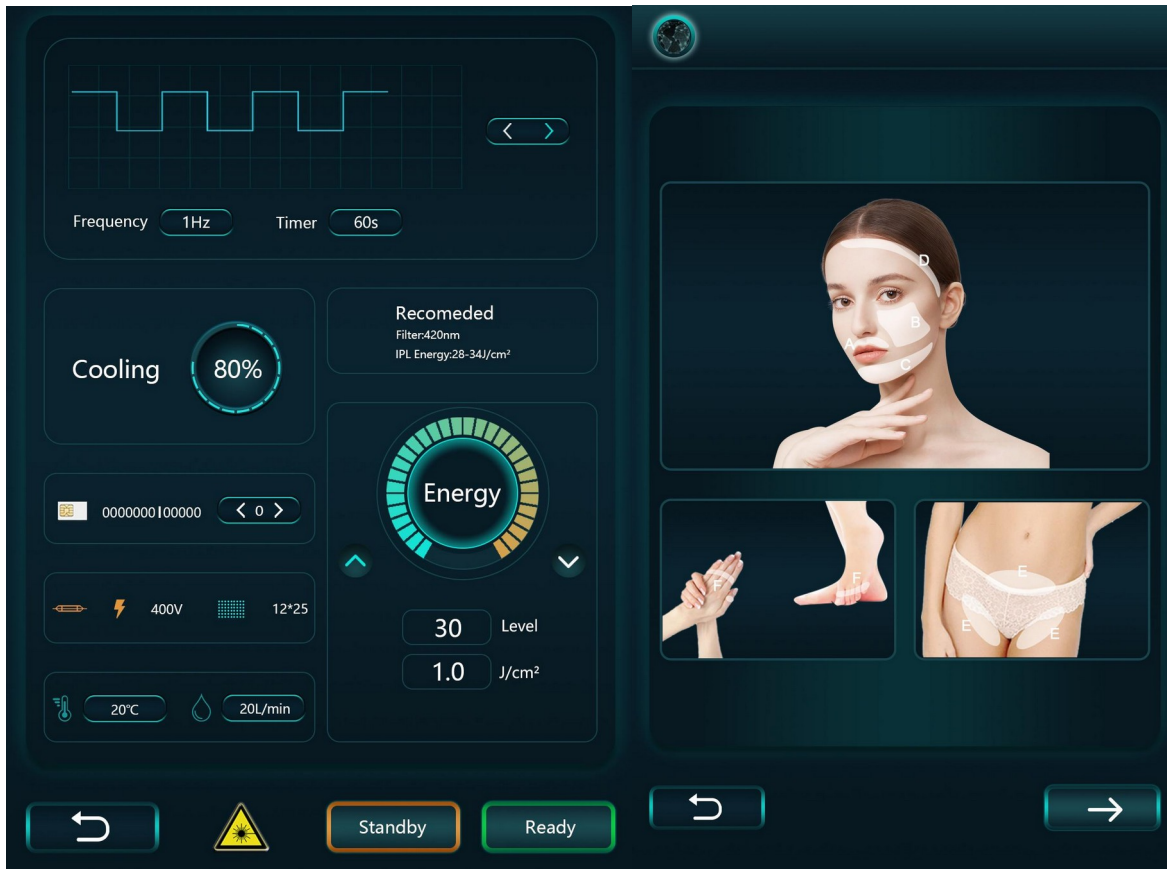


Figure 7.4 SHR mode — recommended parameter screen.

Figure 7.5 Stack mode — treatment-area selection.

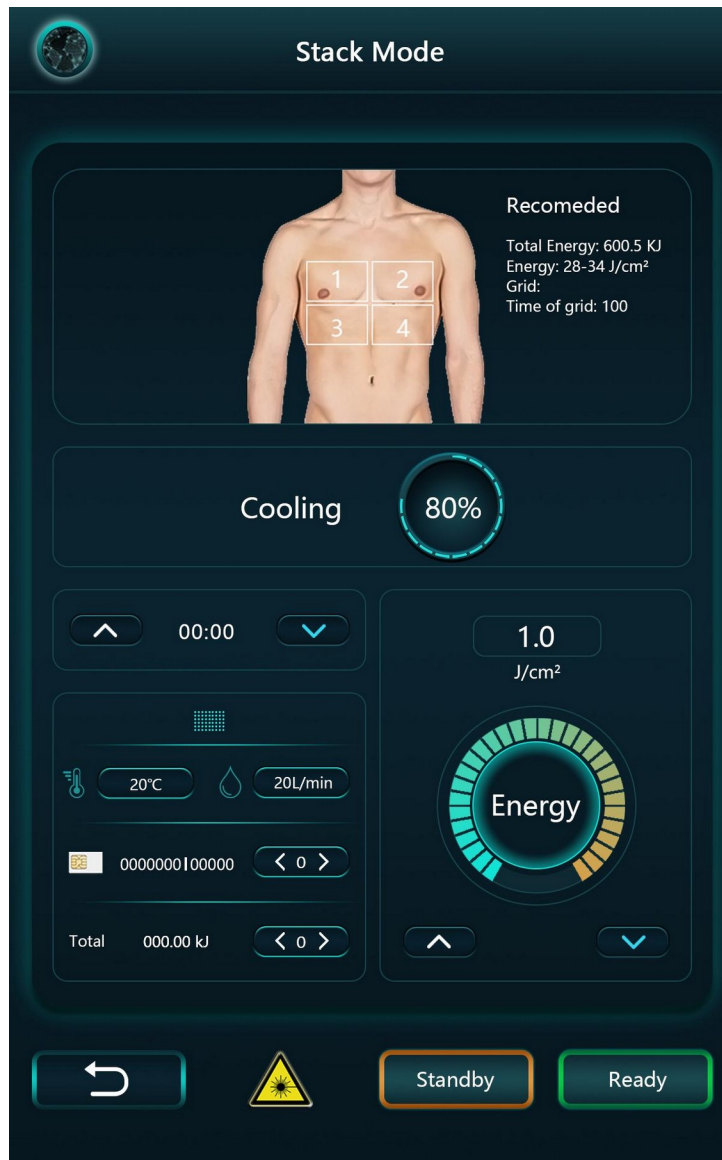


Figure 7.6 Stack mode — recommended parameter screen.

7.2.2.6 Pre-Treatment

The treatment parameters for hair removal depend on the skin type and the color, type, density, and depth of the hair to be treated. Once the treatment parameters are selected, shave and clean the treatment site to eliminate any surface hair and debris that could interfere with the treatment.

7.2.2.7 Patch Skin Testing

Fluence is critical to optimize treatment efficacy and minimize any expected side effects. In order to select the appropriate fluence for a new treatment, the operator should perform two skin tests before treatment, in the following sequence:

1. Select two representative areas of healthy skin adjacent to the treatment area.
2. Select the appropriate pulse type (pulse width and frequency) in correlation with the skin type.
3. Select two different levels of fluence, varying by one level, to adjust the initial parameter values.

4. Trigger a pulse.
5. Evaluate the skin test results after 30 minutes. For Skin Types IV–VI, evaluate again 24 to 48 hours later.
48 hours later.
6. The desired result is mild erythema (for Skin Types I–IV only; erythema is much more difficult to observe in Skin Types V and VI). If erythema did not occur using the recommended parameters, increase the fluence by one level and repeat steps 3 to 5 above.

7.2.3 1064/532 nm Q-Switched Nd:YAG laser

The Q-switched Nd:YAG laser system works on the basis of selective photothermolysis. During phototherapy of such lesions, the tattoo particles are targeted to absorb the emitted light, where it is rapidly converted into heat, damaging the targeted lesion. Moreover, the nanosecond shock of the Q-switched laser causes an acoustic shock in the targeted area, leading to fragmentation of the particles (this especially affects the more particle-dense targets). Due to the rapid and selective nature of this process, the adjacent normal tissue is spared from these effects, thus avoiding collateral damage. The Q-switched Nd:YAG module provides the flexibility to adjust the treatment parameters according to patient and lesion characteristics in order to achieve optimal clinical results. The treatment parameters that appear in the user interface consist of: energy density, derived from spot size; and frequency, to match the user's experience.

7.2.3.1 Treatment Range

1. Removal of embroidered eyebrow
2. Removal of eyeliner
3. Removal of lip and lip-line tattoo
4. Removal of tattoos and traumatic tattoos
5. Removal of pigmented nevus
6. Removal of seborrheic keratosis
7. Removal of café-au-lait spots, freckles, and chloasma. The tattoo or pigmented lesion color must be darker than the skin in the designated treatment area. Note that this is especially important to ascertain in darker skin types.

7.2.3.2 Contraindications

WARNING

The following are relative contraindications for treatment with the Q-switched Nd:YAG laser.

1. Pregnant or nursing.
2. Current or history of cancer, especially malignant melanoma or recurrent non-melanoma skin cancer, or pre-cancerous lesions such as multiple dysplastic nevi.
3. Any active local or systemic infection.
4. Diseases that may be stimulated by light at 1064 nm, such as a history of recurrent herpes simplex or systemic lupus, etc.
5. Use of photosensitizing medications and/or herbs that may cause sensitivity to 1064 nm light exposure, such as isotretinoin, tetracycline, or St. John's wort.
6. Photosensitivity in general, or any sensitivity to the sun that causes a rash or an allergic reaction.
7. Immunosuppressive diseases, including AIDS and HIV infection, or use of immunosuppressive medications.
8. History of immune system hyperactivity, such as allergic response, especially in relation to tattoo particles.

9. Significant concurrent illness, such as diabetes, epilepsy, or congestive heart disease.
10. History of bleeding coagulopathies, or use of anticoagulants.
11. History of keloid scarring.
12. Damage to natural skin texture and/or dry skin.
13. Exposure to sun or artificial tanning during the 3–4 weeks prior to treatment.
14. Highly vascularized area in the lesion's immediate proximity.
15. Skin type that is darker than the tattoo or the pigmented lesion, especially in skin types five and six.
16. Tattoo younger than 6 months.
17. Tattoo with iron or titanium oxide (if the patient knows the pigment composition).

7.2.4 1540 nm Er:Glass fractional laser

The 1540 nm Er:Glass fractional laser is intended for skin resurfacing and the removal of surgical scars, acne scars, and wrinkles. It is intended for use on all skin types (Fitzpatrick Skin Types I–VI), including tanned skin.

7.2.4.1 Contraindications

1. Cancer; in particular, skin cancer.
2. Pregnancy (including IVF: in vitro fertilization).
3. Use of photosensitive medications and herbs.
4. Diseases that may be stimulated by light at 810 nm.
5. Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and post-treatment.
6. Use of other hair removal methods, such as waxing, within 6 weeks before treatment.
7. Active infection of herpes simplex in the treatment area.
8. Diabetes (insulin-dependent).
9. History of keloid scarring.
10. Fragile and dry skin.
11. Hormonal disorders (that are stimulated under intense light).
12. Use of anticoagulants.
13. Epilepsy.
14. History of coagulopathies.

7.2.4.2 Adverse Effects

The use of the system is similar to the use of other platform-based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

1. Severe or prolonged erythema (redness) and edema (swelling) within 2–24 hours of treatment, which could last for several weeks.
2. Irritation, itching, a mild burning sensation, or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.

48 hours of treatment at the applications site.

3. Blisters, epidermal erosions, or peri-lesional hyperpigmentation may develop and remain evident for several days to several weeks following treatment.

4. Eye damage from reflected or prolonged unprotected exposure to intense light or laser light. Protective goggles (appropriate to the application) must be worn during all phototherapy treatments to prevent eye injury.

7.2.5 2940 nm Er:YAG fractional laser

The 2940 nm laser is intended for the removal of wrinkles and scars, treatment of pigmentation disorders, and shrinking of skin pores. It is intended for use on all skin types (Fitzpatrick Skin Types I–VI), including tanned skin. The laser system (wavelength 2940 nm) is a solid-state laser. The effect is due to the high absorption peak of water at this wavelength: the skin is quickly heated by this laser, instantly peeling off the pathological tissue. The treatment features a shallow exposure depth only; therefore, the affected part can heal with nearly no recovery time. It smooths fine lines and wrinkles on the face, including around the eyes. It reduces sun damage, improves the texture and tone of the skin, and fades brown spots, sun spots, and pigmentation on the face, neck, chest, back, forearms, and hands.

7.2.5.1 Contraindications

1. Cancer; in particular, skin cancer.
2. Pregnancy (including IVF: in vitro fertilization).
3. Use of photosensitive medications and herbs.
4. Diseases that may be stimulated by light at 2940 nm.
5. Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and post-treatment.
6. Use of other hair removal methods, such as waxing, within 6 weeks before treatment.
7. Active infection of herpes simplex in the treatment area.
8. Diabetes (insulin-dependent).
9. History of keloid scarring.
10. Fragile and dry skin.
11. Hormonal disorders (that are stimulated under intense light).
12. Use of anticoagulants.
13. Epilepsy.
14. History of coagulopathies.

7.2.5.2 Adverse Effects

The use of the 2940 nm Er:YAG is similar to the use of other laser-based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

1. Severe or prolonged erythema (redness) and edema (swelling) within 2–24 hours of treatment, which could last for several weeks.
2. Irritation, itching, a mild burning sensation, or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.

48 hours of treatment at the applications site.

3. Blisters, epidermal erosions, or peri-lesional hyperpigmentation may develop and remain evident for several days to several weeks following treatment.
4. Eye damage from reflected or prolonged unprotected exposure to intense light or laser light.

Protective goggles (appropriate to the application) must be worn during all phototherapy treatments to prevent eye injury.

7.2.6 1064 nm long-pulse Nd:YAG laser

The long-pulse Nd:YAG laser system is intended for hair removal and permanent hair reduction. It is intended for use on all skin types (Fitzpatrick Skin Types I–VI), including tanned skin. The hair removal procedure is based on the principle of selective photothermolysis. This method involves disabling hair regrowth mechanisms by raising the temperature of the hair follicle high enough to damage the germinative cells without damaging the epidermis and the surrounding tissues. The germinative cells are those that divide and differentiate to become the cells comprising the hair follicle.

7.2.6.1 Contraindications

1. Cancer; in particular, skin cancer.
2. Pregnancy (including IVF: in vitro fertilization).
3. Use of photosensitive medications and herbs.
4. Diseases that may be stimulated by light at 1064 nm.
5. Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and post-treatment.
6. Use of other hair removal methods, such as waxing, within 6 weeks before treatment.
7. Active infection of herpes simplex in the treatment area.
8. Diabetes (insulin-dependent).
9. History of keloid scarring.
10. Fragile and dry skin.
11. Hormonal disorders (that are stimulated under intense light).
12. Use of anticoagulants.
13. Epilepsy.
14. History of coagulopathies.

7.2.6.2 Adverse Effects

The use of the long-pulse laser is similar to the use of other laser-based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

1. Severe or prolonged erythema (redness) and edema (swelling) within 2–24 hours of treatment, which could last for several weeks.
2. Irritation, itching, a mild burning sensation, or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.
3. Blisters, epidermal erosions, or peri-lesional hyperpigmentation may develop and remain evident for several days to several weeks following treatment.

4. Eye damage from reflected or prolonged unprotected exposure to intense light or laser light. Protective goggles (appropriate to the application) must be worn during all phototherapy treatments to prevent eye injury.

7.2.7 Picosecond laser

The picosecond Nd:YAG laser system works on the basis of selective photothermolysis. During phototherapy of such lesions, the tattoo particles are targeted to absorb the emitted light, where it is rapidly converted into heat, damaging the targeted lesion. Moreover, the picosecond shock of the laser causes an acoustic shock in the targeted area, leading to fragmentation of the particles (this especially affects the more particle-dense targets). Due to the rapid and selective nature of this process, the adjacent normal tissue is spared from these effects, thus avoiding collateral damage. The picosecond Nd:YAG module provides the flexibility to adjust the treatment parameters according to patient and lesion characteristics in order to achieve optimal clinical results. The treatment parameters that appear in the user interface consist of: energy density, derived from spot size; and frequency, to match the user's experience.

7.2.7.1 Treatment Range

1. Removal of embroidered eyebrow
2. Removal of eyeliner
3. Removal of lip and lip-line tattoo
4. Removal of tattoos and traumatic tattoos
5. Removal of pigmented nevus
6. Removal of seborrheic keratosis
7. Removal of café-au-lait spots, freckles, and chloasma. The tattoo or pigmented lesion color must be darker than the skin in the designated treatment area. Note that this is especially important to ascertain in darker skin types.

7.2.7.2 Contraindications

WARNING

The following are relative contraindications for treatment with the Q-switched Nd:YAG laser.

18. Pregnant or nursing.
19. Current or history of cancer, especially malignant melanoma or recurrent non-melanoma skin cancer, or pre-cancerous lesions such as multiple dysplastic nevi.
20. Any active local or systemic infection.
21. Diseases that may be stimulated by light at 1064 nm, such as a history of recurrent herpes simplex or systemic lupus, etc.
22. Use of photosensitizing medications and/or herbs that may cause sensitivity to 1064 nm light exposure, such as isotretinoin, tetracycline, or St. John's wort.
23. Photosensitivity in general, or any sensitivity to the sun that causes a rash or an allergic reaction.
24. Immunosuppressive diseases, including AIDS and HIV infection, or use of immunosuppressive medications.
25. History of immune system hyperactivity, such as allergic response, especially in relation to tattoo particles.
26. Significant concurrent illness, such as diabetes, epilepsy, or congestive heart disease.
27. History of bleeding coagulopathies, or use of anticoagulants.
28. History of keloid scarring.
29. Damage to natural skin texture and/or dry skin.

30. Exposure to sun or artificial tanning during the 3–4 weeks prior to treatment.
31. Highly vascularized area in the lesion's immediate proximity.
32. Skin type that is darker than the tattoo or the pigmented lesion, especially in skin types five and six.
33. Tattoo younger than 6 months.
34. Tattoo with iron or titanium oxide (if the patient knows the pigment composition).

7.3 Essential Treatment Information

WARNING

To the practitioner: before carrying out the treatment, please read this section in detail.

1. Prior to treatment, the physician must first obtain a detailed history, rule out any disorders that may contraindicate this treatment, and finally physically inspect the treatment area.
2. Cosmetics should be removed with a non-alcohol, neutral cleansing agent such as Bactolin™, Cetaphil™ Gentle Skin Cleanser, or Celeteque Facial Wash.
3. Apply a generous amount of cooled, non-tinted gel to the treatment area (for IPL/EPL).
4. Slight erythema may appear after the procedure. This is normal and will fade gradually over a few minutes to hours.
5. Always record the parameters, fluence, number of shots, and the area treated after each treatment.
6. Apply a cold compress prior to proceeding to the next treatment area.
7. Avoid the use of cosmetics for 24 hours after each treatment.
8. Avoid sun exposure after each treatment.

7.4 Preoperative Preparation

7.4.1 Inquiry

1. Avoid sunlight and artificial UV light exposure for 3–4 weeks prior to treatment.
2. Discuss current treatment plan.
3. Clarify and confirm the patient's expectations.
4. Rule out any conditions contraindicating this treatment.

7.4.2 Explanation

1. Discuss the possible number of treatments required.
2. Inform the patient of the possibility of a stinging or warm sensation during treatment.
3. Inform the patient of the possibility of transient erythema.

7.4.3 Optical Protection

1. The patient should wear protective opaque goggles.
2. The physician should wear the protective filtered goggles.

7.4.4 Anesthesia

1. In general, anesthesia is not required during treatment.

2. There may be some discomfort or pain associated with treatment (RF: no pain). A local anesthetic may be used.

Discomfort is reduced by the built-in cooling semiconductor in the IPL/EPL/RF treatment head.

4. Discomfort is also reduced by using refrigerated coupling gel.

5. For patients with poor tolerance, 4% lidocaine cream is preferred over EMLA during treatment (EMLA causes some vascular constriction).

7.4.5 Counseling

During the first visit, the physician (or an authorized member of the staff) should inform the patient of the following:

1. The laser or IPL/RF therapy may consist of multiple treatments given over several months at 6–10 week intervals.
2. Transient whitening, erythema, edema, and skin elevation usually appear immediately following treatment. In very rare cases, some bleeding and oozing may occur.
3. Gradual clearing of the lesion may take a few months. Some professional tattoos may take more than a year to clear. There is a small risk of adverse reactions, such as changes in the texture and pigmentation of the skin, which are usually transient.

7.4.6 Photographic Documentation

1. Pre- and post-operative photographic documentation is desired, if possible.
2. Please make sure that the camera settings, lighting, and distance are kept uniform.

7.5 Possible Side Effects of Treatment

7.5.1 Discomfort

When a laser pulse is triggered, it may cause varying degrees of discomfort. Some patients feel a burning sensation on the skin, and some feel a dull pain. The burning and pain sensations may last for ten minutes or up to several hours after treatment. The IPL/EPL/RF generates heat and is precisely modulated by computers and filters. The use of the built-in cooling semiconductor, as well as the application of cool coupling gel, diminishes discomfort during treatment. The sensation of this heat is comparable to that of being flicked with a rubber band. Any residual sensation after treatment is kept to a minimum by applying cold packs, left on for 5 to 10 minutes.

7.5.2 Scab formation

Scab formation after treatment can occur, particularly if (1) a greater-than-recommended amount of power/fluence has been used; or (2) for the treatment of pigmented lesions, where sometimes the only way to treat the pigmentation is to physically destroy the pigment-containing structures. In doing so, vesicle formation and scab formation are expected. It is advised to apply cool packs after treatment and to apply an antibiotic ointment over the treated area until the scab has fallen off.

7.5.3 Pigmentation change

Post-treatment darkening of target lesions can occur. This is particularly expected for the treatment of pigmented lesions. In a few days to weeks, the scab will fall off.

7.5.4 Scar formation

Scar formation is not an expected side effect.

7.5.5 Swelling and Erythema

Some transient swelling and erythema can occur, especially during treatment. This is normally transient and can be treated with cool compresses (5 to 10 minutes); mid-potency topical steroids such as betamethasone valerate or mometasone furoate can be applied for 1 to 2 days.

7.6 Treatment Parameters

7.6.1 IPL treatment parameters 7.6.1.1 Brief introduction

The parameters are settings or sets of instructions given by the user to the computer in order to modulate the light produced by the xenon flash lamp. The therapeutic effect of this device depends on the proper selection and use of these parameters.

7.6.1.2 Parameters

1. Wavelength: refers to the spectrum of light emitted by the xenon flash lamp (between 400 and 1200 nm).

2. Fluence: the intensity or level of power emitted by the flash lamp, measured in J/cm².

Generally, the greater the fluence, the greater the amount of light and heat produced.

3. Number of pulses: the energy can be divided into 1–15 pulses. This method of treatment prevents epidermal burns by allowing the target chromophores to cool between pulses.

4. Pulse width: the duration of light exposure (T1, T2), measured in milliseconds (ms). T1, T2, and T3 are set from 1–20 ms; T4, T5...T15 are set the same as T3. The maximum is no longer than 40 ms. This is the duration of time that the target chromophores absorb filtered light energy from the xenon flash lamp.

5. Pulse delay: the duration (D1 and D2) between pulse widths, measured in ms. D1, D2, D3...D5 are set from 1–100 ms. This is the interval between pulse widths when the target chromophores are not exposed to the intense pulsed light. The pulse delay allows the target chromophores to remain heated and the surrounding epidermis to cool down before exposure to the next intense pulsed light.

7.6.1.3 Parameter Principles

Condition	Recommended Parameter Adjustment
The darker the skin	1. Decrease the fluence 2. Increase the pulse delay (allow more cooling) 3. Increase RF Power
The lighter the skin	1. Increase the fluence 2. Decrease the pulse delay 3. Lower temperature of treatment probe
The darker the hair / pigmented lesion	1. Decrease the fluence 2. Increase the pulse delay (allow more cooling)
The lighter the hair / pigmented lesion	1. Increase the fluence 2. Decrease the pulse delay
Fine blood vessels	1. Higher fluence 2. Decrease the pulse delay 3. Decrease the pulse width
Thicker blood vessels	1. Increase the pulse delay (allow more cooling) 2. Increase the pulse width
The smaller the target size / lesion	1. Decrease the pulse delay
The larger the target size / lesion	1. Increase the pulse delay (allow more cooling)
Bony prominences (forehead, malar area, shins)	1. Decrease the fluence by 10–20% 2. Decrease the RF Power by 30–50%

During the interval of active treatment (Pulse Width T1, T2) the target chromophores are exposed to the intense pulsed light, then absorb light energy and produce heat. This heat is dissipated during the passive treatment phase (Pulse Delay D1 & D2) to allow the surrounding epidermis to cool down and to prevent burns. Therefore, this method of selective photothermolysis makes use of time and light modulation to ensure that the target chromophores remain heated while the surrounding epidermis is cooler.

Start with a lower energy, around 2–3 levels below the initial parameter suggestion, after proper setting of the basic data requested by the system. Evaluate the patient response, then gradually increase the energy one level at a time. Note that treatment over bony areas such as the malar area, forehead, and shins produces more discomfort, so reduce the fluence by 2–3 levels. When treating very densely pigmented areas, reduce the fluence by 2–3 levels.

7.6.1.4 Parameter Selection

Hair / Skin Characteristic	Recommended Setting
Dark hair	Shorter pulse width
Light hair	Longer pulse width
Deep hair	Longer pulse width
Superficial hair	Shorter pulse width
Thick hair	Longer pulse delay & lower fluence
Thin hair	Shorter pulse delay & higher fluence
Dense hair growth	Lower fluence
Sparse hair growth	Higher fluence
Darker skin color	Longer pulse delay & lower fluence
Lighter skin color	Shorter pulse delay & higher fluence
More sensitive skin	Lower fluence
Less sensitive skin	Higher fluence

7.6.2 Diode laser treatment parameters

Table of pulse width vs. energy. Energy is given in J/cm² for the 12 × 23 mm spot at the stated pulse width per shot.

1 Hz (1 shot per second)

Pulse width	Energy (J/cm ² , 12 × 23 mm spot)
100 ms	2–26
200 ms	5–43
300 ms	10–62

2 Hz (2 shots per second)

Pulse width	Energy (J/cm ² , 12 × 23 mm spot)
50 ms	2–15
100 ms	2–26
150 ms	5–35

3 Hz (3 shots per second)

Pulse width	Energy (J/cm ² , 12 × 23 mm spot)
40 ms	1–13
80 ms	2–22
100 ms	2–26

5 Hz (5 shots per second)

Pulse width	Energy (J/cm ² , 12 × 23 mm spot)
20 ms	1–9
30 ms	1–11
40 ms	1–13
60 ms	2–17

7.6.3 Picosecond Nd:YAG Laser treatment parameter

7.6.3.1 Brief introduction

The picosecond Nd:YAG module provides the flexibility to adjust the treatment parameters according to patient and lesion characteristics in order to achieve optimal clinical results. The treatment parameters that appear in the user interface consist of: energy density, derived from spot size; frequency, to match the user's expertise; and wavelength, selected according to the color of the pigmentation.

7.6.3.2 Parameters

1. Wavelength: refers to the spectrum of light emitted by the xenon flash lamp and focus tip (532 nm or 1064 nm).
2. Energy density: the intensity or level of power emitted by the flash lamp and YAG bar, measured in J/cm². Generally, the greater the energy density, the greater the amount of light and heat produced. When the spot size is at the focus point, the energy density reaches its maximum. When the distance between the treatment tip and the

treatment surface is below 6 cm (when the distance is near), the energy is lower. When the distance between the treatment tip and the treatment surface is above 7 cm (when the distance is farther), the energy is lower.

3. Frequency: the number of pulses emitted per trigger or per second. The frequency range is 1 Hz to 10 Hz. The treatment tip with the focus adjustment function can adjust the spot size from Ø1 to Ø5 mm. The energy at a lower scale is higher; at a higher scale it is lower. The table is listed below. Warning: The laser system has specific operating requirements. The operator must not establish contact between the handpiece and the surface of the treatment region. It is the practitioner's responsibility to fulfill these requirements. Failure to do so can create the potential risk of cross-contamination or biological incompatibility from one customer to another, which may increase the risk of injury to the customer. Do not allow the tip to make physical contact with the skin during treatment.

7.6.3.4 Parameter setting table

Laser treatment parameter table							
Treatments	Wave length (nm)	Energy (mj)	Frequency (Hz)	Spot size (mm)	Total treatments (time)	Treatments interval (Month)	Pulse number
Tattoo Removal (Black, Blue, Brown)	1064	120~270	4~6	3~5	3~6	0.7~1.5	1
Nevus of Ota, Ito	1064	300~500	4~6	3~4	4~6	2~3	2
Eye Line	1064	140~290	4~6	3~5	1~3	1~2	1
Eye Brow	1064	150~300	4~6	4~5	1~3	1~2	1
Blue Nevus	1064	400~600	4~6	3~4	2~4	2~3	2
Speckled nevus (big size)	1064	300~400	4~6	3~4	4~5	2~3	1
Tattoo Removal (Red, Purple, Orange)	532	50~150	3~5	3~5	4~10	0.7~1.5	1
Speckled nevus (small size)	532	50~150	3~5	3~5	1~3	1~2	1
Coffee Au Lait spot	532	70~170	3~5	3~5	3~6	1~2	1
Age spot	532	50~150	3~5	3~5	1~3	1~2	1
Sun spots	532	50~150	3~5	3~5	1~3	1~2	1
Lentigo	532	70~170	3~5	3~5	3~6	1~2	1

Picosecond Nd:YAG laser treatment parameter setting table (532 / 1064 nm).

1. Use EMLA cream to lessen the discomfort from treatment procedures. It must be applied two hours before the procedure to the area that the doctor plans to treat.
2. For Skin Types I–III: 3 to 4 passes, with 2–3 overlapping passes.
3. For Skin Types IV–VI: 1 to 3 passes with lower energies, starting at 5 mJ/cm² and increasing the energy based on test spots.

7.6.7 Q-switched Nd:YAG laser treatment parameters 7.6.7.1 Brief introduction

The Q-switched Nd:YAG module provides the flexibility to adjust the treatment parameters according to patient and lesion characteristics in order to achieve optimal clinical results. The treatment parameters that appear in the user interface consist of: energy density, derived from spot size; frequency, to match the user's expertise; and wavelength, selected according to the color of the pigmentation.

7.6.7.2 Parameters

1. Wavelength: refers to the spectrum of light emitted by the xenon flash lamp and focus tip (532 nm or 1064 nm).

2. Energy density: the intensity or level of power emitted by the flash lamp and YAG bar, measured in J/cm². Generally, the greater the energy density, the greater the amount of light and heat produced. When the spot size is at the focus point, the energy density reaches its maximum. When the distance between the treatment tip and the treatment surface is below 6 cm (when the distance is near), the energy is lower. When the distance between the treatment tip and the treatment surface is above 7 cm (when the distance is farther), the energy is lower.

3. Frequency: the number of pulses emitted per trigger or per second. The frequency range is 1 Hz to 10 Hz. The treatment tip with the focus adjustment function can set the spot size from Ø1 to Ø5 mm. The energy at a lower scale is higher; at a higher scale it is lower. The table is listed below: Scale (mm) / Spot Size Ø (mm)

7.6.7.3 Parameter Principles	
Indication	Wavelength
Tattoo:	
• Black, blue tattoo	1064nm
• Dark Ink tattoo	
• Red, pink, purple, brown	532nm
• Light Ink tattoo	532nm
Vascular lesions	
• Port wine birthmarks	532nm
• Telangiectasis	
Epidermal Pigmented lesions	
• café-au- lait birthmarks	532nm
• solar lentiginos	
• senile lentiginos	
• Becker's nevi	
• Freckles	
• nevus spilus	
• Melasma (integument)	

Q-switched Nd:YAG laser — 7.6.7.3 Parameter Principles (indication vs. wavelength).

7.7.1 IPL treatment procedure

1. For IPL treatment, after selecting the treatment mode and skin type, attach the proper treatment filter and set the parameters as recommended on the screen.

2. Use the appropriate protective eyewear.

3. Apply a thin layer (2–3 mm) of coupling gel.

4. Set the treatment head parallel to the skin's surface, touch it lightly to the skin, and begin treatment.

Avoid excessive overlapping of treatment areas. Avoid doing double passes. For the first treatment, a test shot over an inconspicuous area can be performed.

5. After treating an area, carefully remove the gel and apply cool compresses (5–10 minutes).

6. Watch for side effects such as burns, pain, and erythema.

7. Proceed to the next treatment area.

8. Note down the treatment parameters before proceeding to the next treatment.

9. If a different treatment is desired:

10. Place the unit on standby by pressing the Ready key.

11. Insert the desired filter (420, 510, 560, 610, 640, 690 nm, or SHR).
12. Select the treatment mode and resume treatment.
13. Whenever the unit is not in use, set the device on standby by pressing the Standby key to extend the life of your flash lamp.
14. Turn off the unit and clean the treatment heads.

7.7.2 Diode laser treatment procedure

Treatment can begin after the treatment parameters are selected.

1. Ensure that the patient is lying comfortably with eye protection in place. All personnel in the treatment room should wear eye protection as well.
2. Clean the skin to remove perfumes, cosmetics, and sunscreens.
3. Press the single-treatment reset button to reset the pulse counter.
4. Verify that the handpiece tip is cold.
5. The ultrasound gel is best used chilled. Spread it thinly (2–3 mm) over the treatment area.

The gel is used to cool the treatment area before and during treatment. By pre-cooling the skin and absorbing heat from the epidermis, discomfort is kept minimal. The use of cool ultrasound gel is also helpful in identifying the areas that have just been treated, by observing the footprint left behind by the treatment head.

6. Place the handpiece perpendicular to the skin and establish contact with the skin. Press the tip against the skin with moderate pressure to make good contact.
7. Always perform a skin test to establish the cutaneous reaction when beginning treatment.
8. Carefully assess the skin test.
9. If the pulse has the desired effect, continue treatment with the same parameters.
10. Start treatment by activating the handpiece trigger or the footswitch.
11. Occasionally examine the treatment site for changes in skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although the absence of this phenomenon does not necessarily indicate that the current set of parameters is ineffective.
12. If adverse skin effects occur (such as excessive reddening) before a good follicular response is achieved, adjust the treatment parameters to reduce the aggressiveness of the treatment. Aggressiveness may be reduced by either decreasing the fluence by one level or by changing the pulse type (pulse width) to a less aggressive one.

1. If the skin shows no adverse effects and no morphological changes are observed, you may raise the energy by one level until the desired effect is reached.
2. If the practitioner pauses during treatment for more than 3 minutes, the Standby function must be turned off.
3. After treatment, it is recommended to cool the area immediately (see Section 7.8, Post-operative Nursing Care).

4. Press the “Ready” button and then the “Standby” button after treatment.
5. Turn off the device by turning the key counterclockwise. Clean the treatment sapphire with a soft cloth, then sanitize the treatment head with alcohol-soaked cotton balls. Note: number of treatments needed: 4–5 sessions; treatment interval: 4–6 weeks.

7.7.3 1064/532nm Q-switched laser treatment procedure

1. For Q-switched laser treatment, depending on the color of the pigmentation and the treatment area, you may choose to use the 532 nm or 1064 nm treatment tip.
2. Select the tip for the laser handpiece and screw it on (according to Figure 4.5) firmly and properly prior to turning the device on.
3. Touch the wavelength you are using for treatment on the screen, and set the spot size by changing the distance between the treatment tip and the treatment area (Ref. Fig. 5.2b) according to the treatment. Please note that you must set the actual spot size selected on the screen; in this way, the energy window will show the exact energy, combining wavelength and spot size.
4. Touch "Ready" to prepare for treatment after the user inserts the IC card correctly; the IC CARD ONLINE icon will be shown in the system information window.
5. Movements should be gentle and rhythmical, but not irritating or uncomfortable.
6. Evaluate the treatment area for any untoward side effects, such as pain. During treatment, the spot size can be adjusted to your requirements. If the patient feels the skin getting too hot, press the red button on the energy breaker handle immediately.
7. After treatment, copy the treatment parameters to the patient's record sheet and place the device in Standby Mode by depressing the "Standby" button.
8. Turn off the device by turning the key counterclockwise. Clean the lens of the treatment tip if there is dust on it, then sanitize the treatment head with alcohol-soaked cotton balls.
9. Replace the treatment handpiece on its support.

7.7.4 1540nm Er:Glass Fractional laser treatment procedure

1. Ensure that the patient is lying comfortably with eye protection in place. All personnel in the treatment room should wear eye protection as well.
2. Clean the skin to remove perfumes, cosmetics, and sunscreens.
3. Place the handpiece perpendicular to the skin and establish contact with the skin. Press the tip against the skin with moderate pressure to make good contact.
4. Always perform a skin test to establish the cutaneous reaction when beginning treatment.
5. Carefully assess the skin test.
6. If the pulse has the desired effect, continue treatment with the same parameters.
7. Start treatment by activating the handpiece trigger or the footswitch.
8. Occasionally examine the treatment site for changes in skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although the absence of this phenomenon does not necessarily indicate that the current set of parameters is ineffective.
9. If adverse skin effects occur (such as excessive reddening) before good follicular response is achieved, adjust the treatment parameters to reduce the aggressiveness of the treatment. Aggressiveness may be reduced by either decreasing the fluence by one level or by changing the pulse type (pulse width) to a less aggressive one.
10. If the skin shows no adverse effects and no morphological changes are observed, you may raise the energy by one level until the desired effect is reached.
11. If the doctor pauses the procedure for more than 3 minutes during treatment, the Standby function must be turned off.

12. After treatment, it is recommended to cool the area immediately (see Section 7.8, Post-operative Nursing Care).
13. Press the “Ready” button and then the “Standby” button after treatment.
14. Turn off the device by turning the key counterclockwise. Clean the treatment sapphire with a soft cloth, then sanitize the treatment head with alcohol-soaked cotton balls.

7.7.5 2940 nm Er:YAG Fractional laser treatment procedure

1. Remove all jewelry and any metal items from the client, then prepare the skin surface for treatment by first cleansing the area with the prescribed cleanser.
2. Observe proper optical safety by wearing the safety goggles provided with this device
(opaque for the patient and filtered for the operator).
3. Turn the device on by turning the key switch clockwise. The screen will show the main menu and will run a system check-up diagnostic program.
4. Select the MTZ density by touching “MTZs Density” and then “Frequency/Pulse.” After the desired parameters have been set, the energy output can be adjusted by touching the “Up” and “Down” buttons.
5. There is no need to apply gel or cream over the entire treatment area. Position the treatment head perpendicular to the treatment area and press the Trigger button on the treatment handle to begin treatment.
6. Depending on the treatment and skin condition, you may choose the proper treatment tip for the treatment. Screw the tip on firmly and properly prior to turning the device on.
7. Evaluate the treatment area for any untoward side effects, such as pain. During treatment, the parameters can be adjusted to your requirements.
8. Touch “Standby” and then “Work” to prepare for treatment, as shown in the system information window.
9. Movements should be gentle and rhythmical, but not irritating or uncomfortable.
10. When working on the face, be sure to use a “criss-cross” action, moving both horizontally and vertically toward the center of the face, as well as on the neck, chest, back, forearms, hands, and body. There should be 50% overlap.
11. After treatment, copy the treatment parameters to the patient’s record sheet and place the device in Standby Mode by depressing the “Work” button.
12. Turn off the device by turning the key counterclockwise. Clean the treatment tip with a soft cloth, then sanitize the treatment head with alcohol-soaked cotton balls.
13. Replace the treatment handpiece on its support and unplug the device.

7.7.6 1064 nm long-pulse Nd:YAG laser treatment procedure

1. Ensure that the patient is lying comfortably with eye protection in place. All personnel in the treatment room should wear eye protection as well.
2. Clean the skin to remove perfumes, cosmetics, and sunscreens.
3. Press the single-treatment reset button to reset the pulse counter.
4. Verify that the handpiece tip is cold.
5. Place the handpiece perpendicular to the skin and establish contact with the skin. Press the tip against the skin with moderate pressure to make good contact.
6. Always perform a skin test to establish the cutaneous reaction when beginning treatment.
7. Carefully assess the skin test.

8. If the pulse has the desired effect, continue treatment with the same parameters.
9. Start treatment by activating the handpiece trigger or the footswitch.
10. Occasionally examine the treatment site for changes in skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although the absence of this phenomenon does not necessarily indicate that the current set of parameters is ineffective.
11. If adverse skin effects occur (such as excessive reddening) before a good follicular response is achieved, adjust the treatment parameters to reduce the aggressiveness of the treatment. Aggressiveness may be reduced by either decreasing the fluence by one level or by changing the pulse type (pulse width) to a less aggressive one.
12. If the skin shows no adverse effects and no morphological changes are observed, you may raise the energy by one level until the desired effect is reached.

Chapter 8 Specifications

This chapter specifies the most important technical data and system classification for the laser platform system.

8.1 Specifications

Parameter	Data
Electrical connection data	
Line voltage	110–240 VAC (refer to system labeling)
Line frequency	50/60 Hz
Max. power consumption	1600 W
System classifications	
Type of protection against electrical shock	Class I equipment
Degree of protection against electrical shock	Type B equipment
Protection against ingress of water	IPX0 for main unit; IPX1 for footswitch
Classification under MDD 93/42/EEC	Class II equipment
Climate (during operation)	
Ambient temperature	+5 °C to +30 °C
Relative humidity	70%
Atmospheric pressure	86.0 kPa to 106.0 kPa
Climate (during transport and/or storage)	
Ambient temperature	–40 °C to +55 °C
Relative humidity	Up to 93%
Atmospheric pressure	86.0 kPa to 106.0 kPa
Dimensions and weights	
Height	650 mm
Width	480 mm
Depth	1150 mm
Weight	approx. 50 kg
Therapy — IPL	
IPL output power	1600 W
Light source	Intense pulsed light (xenon flash lamp)
Spectrum range	420–1200 nm
Energy density	10–50 J/cm ²
Pulse method	Intense pulsed light technology (adjustable)
Pulse sequence	1–15 pulses
Pulse delay	5–50 ms
Pulse width	2–20 ms
Total pulse width	Max. < 50 ms
Delivery system	Direct sapphire coupling
Spot size	15 mm × 50 mm
Therapy — Diode laser	
Laser type	CW, GaAlAs diode laser array
Wavelength	810 ± 10 nm
Energy density	1–62 J/cm ²
Pulse repetition rate	1–10 Hz
Pulse width	1–300 ms
Sapphire spot size	12 mm × 23 mm
Therapy — Triple Diode laser	
Laser type	CW, GaAlAs diode laser array
Wavelength	755 ± 10 nm, 810 ± 10 nm, 1064 ± 10 nm

Parameter	Data
Energy density	1–62 J/cm ²
Pulse repetition rate	1–10 Hz
Pulse width	1–300 ms
Sapphire spot size	12 mm × 23 mm
Therapy — Q-switched Nd:YAG laser	
Q-switched laser power	1000 W
Wavelength	Dual wavelength 1064 nm & 532 nm
Pulse width	980 ps
Pulse energy	360 mJ to 2000 mJ (1064 nm); 180 mJ to 1000 mJ (532 nm)
Light spot diameter	1–5 mm
Repetition frequency	1/2/3/4/5/6/7/8/9/10 Hz
Lead light method	Directly export laser
NOHD	1000 mm
Therapy — Picosecond Nd:YAG laser	
Laser power	1000 W
Wavelength	Dual wavelength 1064 nm & 532 nm
Pulse width	980 ps
Pulse energy	50 mJ to 800 mJ (1064 nm); 50 mJ to 400 mJ (532 nm)
Light spot diameter	1–5 mm
Repetition frequency	1/2/3/4/5/6/7/8/9/10 Hz
Therapy — Er:YAG fractional laser	
Wavelength	2940 nm
Energy	9×9 pixel: 4–20 mJ/microbeam; 7×7 pixel: 12–28 mJ/microbeam; beam expander (Ø6 mm, Ø9 mm): 500–5,000 mJ; zoom lens (Ø1–Ø5): 500–5,000 mJ
Pulse width	1.5 ms, 2.0 ms, 2.5 ms
Delivery system	Direct sapphire coupling
Pulse repetition rate	1 Hz
Laser output power	600 W
Therapy — 1064 nm Long-pulse Nd:YAG laser	
Wavelength	1064 nm
Sapphire spot size	2.2 × 5 mm, Ø6 mm, Ø9 mm
Pulse repetition rate	0.5–1 Hz
Pulse width	10–40 ms
Energy density	2.2 × 5 mm: 150–500 J/cm ² ; Ø6 mm: 60–260 J/cm ² ; Ø9 mm: 10–110 J/cm ²
Laser output power	1500 W
Therapy — Er:Glass fractional laser	
Wavelength	1540 ± 5 nm
Energy	10×10 pixel: 25–70 mJ/microbeam; 18×18 pixel: 6–24 mJ/microbeam
Pulse repetition rate	Single or 1 Hz
Pulse width	10 ms / 15 ms
Laser output power	500 W
Operation interface	12.1" touch True Color LCD
Cooling system	
Cooling system	Water cooling, forced-air cooling, and TEC water-tank cooling system with semiconductor chip
Cooling temperature	–4 °C to +10 °C

8.2 ELECTROMAGNETIC COMPATIBILITY(EMC)

8.2.1 Essential performance

The accurate output of the wavelength and pulse energy for each handpiece is defined as the essential performance of the device.

8.2.2 Classification and grouping

The nuCORE 8:1 Multi-function Platform System is classified as a Group 1, Class A apparatus according to CISPR 11:2015+A1:2016+A2:2019, Clauses 5.1 and 5.2. It is suitable for use in a professional healthcare facility environment, except near active HF surgical equipment and the RF-shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high. In addition, it is not suitable for use in environments that contain diathermy, electrocautery, RFID, near-field communications (NFC) systems, wireless power transfer (WPT), electronic article surveillance (EAS), or unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment.

The test requirements are below:

Phenomenon	or test method	Professional healthcare facility environment
RADIATED EMISSION	CISPR 11	3 m distance 30 – 230 MHz, 50 dB μ V/m 230 – 1000 MHz, 57 dB μ V/m
CONDUCTED DISTURBANCES	CISPR 11	Quasi-peak: 0.15 - 0.5 MHz, 79 dB μ V 0.5 – 30 MHz, 73 dB μ V Average: 0.15 - 0.5 MHz, 66 dB μ V; 0.5 – 30MHz, 60 dB μ V
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	$\pm$ 8 kV contact $\pm$ 2 kV, $\pm$ 4 kV, $\pm$ 8 kV, $\pm$ 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	380 to 390 MHz, 27 V/m 430 to 470 MHz, 28 V/m 704 to 787 MHz, 9 V/m 800 to 960 MHz, 28 V/m 1 700 to 1 990 MHz, 28 V/m 2 400 to 2 570 MHz, 28 V/m 5 100 to 5 800 MHz, 9 V/m
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	30 kHz, 8A/m 134,2 kHz, 65 A/m 13,56 MHz, 7,5 A/m
Electrical fast transients / Bursts	IEC 61000-4-4	$\pm$ 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	$\pm$ 0,5 kV, $\pm$ 1 kV
Surges Line-to-ground	IEC 61000-4-5	$\pm$ 0,5 kV, $\pm$ 1 kV, $\pm$ 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and
		80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycle
Results: Pass		

Electromagnetic immunity / emissions test levels (professional healthcare facility environment).

WARNING:

1. Use of this equipment adjacent to or stacked with other equipment should be avoided, because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2. Use of accessories, transducers, and cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer; otherwise, degradation of the performance of this equipment could result. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

APPENDIX

Overview of Areas Sensitive to Pain. Face and Body (see figures). Hair Growth Table. If you have any questions, please feel free to contact our company as follows: Jacksonville, FL

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