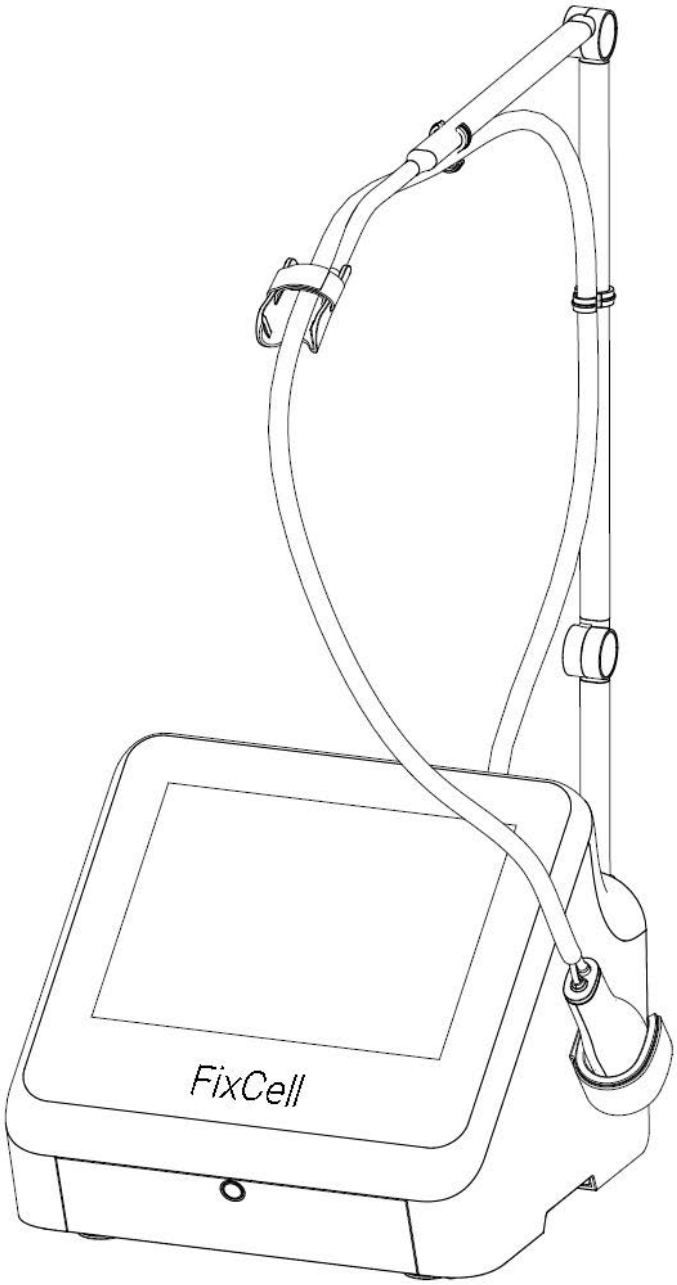
FixCell®

Medical Non-ablative Fractional Laser Systems

User Manual



Any user must carefully read this manual first. It tells the user the safe operation steps and the risks & hazards by abnormal operation. In case of any abnormal hazard and injury to person and device caused by the avoided operations in this manual， Evo Tecgnology shall not undertake the responsibility of the safety, reliability and performance .Evo Tecgnology will not give free maintenance for this kind of failure!

CE 0123

Contents

Safety and Regulatory

1.1 General Safety

The FixCell® Medical Non-ablative Fractional Laser Systems is a precise laser medical device that can only be used for medical applications. The system undergoes strict safety inspections before launch to the market, and regular operations will not cause safety accidents. Therefore, to protect the operators and patients to the hazard from laser exposure, please read this manual carefully. In addition, the operator of this device must have been trained in laser medical technology.

The FixCell® complies with 21 CFR, Chapter I, Subchapter J， as administrated by the Center for Devices and Radiological Health (CDRH) of the US Food and Drug Administration (FDA); CE-labeled devices comply with all appropriate performance standards as specified in Annex II of the Medical Device Directive MDD 93/42/EEC as amended by 2007/47/EC.

The FixCell® is classified as a Class IV laser by the CDRH and as Class 4 laser by the European standard EN 60825-1.

⚠ ***Warning:***

Do not use this laser device on the site with flammable and explosive materials. Do not place or store flammable and explosive materials around the device. Flammable and explosive materials include gasoline, alcohol, narcotics, solvents, desiccants, ointments, synthetic resins, etc.

⚠ ***Warning:***

Only professionals can enter the treatment room; make sure that all the staff in the treatment room are familiar with the operation of the instrument and know the way of shutting down the machine directly; Do not use the machine in places of flammable, explosive or other unsafe places.

1.2 Ocular hazard

The FixCell® is to be operated only in an enclosed room with protective eyewear

for all persons. Direct eye exposure is not safe at any distance within the room. All windows in the laser room must be covered with opaque material, and measures should be taken to prevent unauthorized access to the room. A remote interlock is provided, which can be connected to the treatment room doors disabling laser output if the door is opened during a procedure. In addition, compliance with ANSI Z136.3 and EN 60825-1 requires that laser safety signs be posted at all entrances whenever the laser is in use. An approved sign is provided with each system along with protective eyewear speciated for 1550-1560nm. Additional eyewear or safety signs may be obtained from Evo Tecgnology Service or sales department.

Warning:

The FixCell® emits a strong light energy, even cause serious eye damage or blindness.

Warning:

Whenever the main power and button switch are turned on, all persons in the treatment room, including the patient, must wear appropriate protection. Protective glasses must have an optical density (OD) of 5 or greater at a wavelength of 1550-1560nm. For users in the European Union or outside US, the standard EN 207 may be applied, and the protection level of eyewear must be L5.

Warning:

Regardless of whether you wear laser goggles, it is forbidden to look directly into the laser output window at any time, and it is forbidden to directly observe the laser beam or the reflected or scattered beam, otherwise, it will cause serious damage to the retina.

Warning:

Do not use it for the treatment of eyebrows, eyelashes, or other areas around the eyes.

The laser energy emitted by the FixCell® can cause serious eye damage or even blindness; For maximum safety, the patient must wear the metal protective eye goggles for all facial treatment.

Nominal ocular hazard distance

NOHD represents the distance at which the irradiance is lower than the corresponding MPE (maximum allowable exposure) under ideal conditions. If it is not intentionally observed, the NOHD of this device is 5 kilometers.

In the laser rooms, there should be eye-catching marks where protective eyewear is placed to ensure that all persons, including patients, wear protective eyewear before laser devices working to prevent any damage to the eyes.

The safety glasses and goggles are providing with the system in the corresponding wavelength range for eye protection.

To enhance the safety of patients, please follow the steps below:

- The patient wears the metal protective goggles before starting treatment.
- Unless the tissue is treated, always avoid laser shooting on the patient, even the red aiming light.
- All persons in the laser room must wear the laser glasses.

1.3 Fire hazard

***Warning*:**

Avoid lasers and laser beams near flammable materials, anesthetics, oxidizing gases such as nitrous oxide and oxygen, and other flammable solvents. No paper or plastic products are allowed in the laser working area. Within a certain distance, these materials will burn due to the absorption of considerable energy.

Some materials, such as cotton wool, can be ignited by working laser beam when the environment is rich in oxygen. Pay attention to the solvents and flammable solutions used for cleaning the device to avoid the risk of ignition of volatile gas.

Switch the system to "standby" in the operation intervals, and the footswitch is disabled at this time.

1.4 Laser plume precautions

There is a potential risk of laser plumes during the operation of the FixCell®. It is necessary to avoid exposure of the operator and patient to the smoke or vapor of the laser plume.

Caution:

During the laser treatment, the user should wear surgical masks to filter particles as small as 0.3μsurgical gloves should also be worn.

1.5 Burn hazard

The wavelength of the FixCell® is 1550nm, and the spectral belongs to the infrared range, which is invisible to the human eye. The maximum laser power output by this device can reach 15W, which can cause 3 degree burns even without focusing.

1.6 Laser reflection and direct hazard

***Caution*:**

Must wear surgical gloves during the laser treatment; long-sleeve gloves are recommended.

The device outputs visible 650nm laser and invisible 1550nm laser, both of which are harmful to the human body. Do not look directly at laser at any time, even if it does not cause burns to the human eyes, it may cause a certain damage.

It's necessary to ensure that there are no high reflective materials, such as mirrors, glass, etc.in the laser room to prevent the laser beam from reflecting through these materials and causing laser radiation hazards. Since most of the materials used for manufacturing medical surgical instruments are glass, chrome-plated, or nickel-plated metal, their light reflectivity is very high, during operating the laser device, be careful not to let the beam shoot on them, otherwise, the reflected laser beam will also cause harm to the human body.

1.7 Alarms

The device is in "standby" after startup, and the laser system is in “off “state. Only when it is switched to "ready”, the footswitch can trigger the laser, the system works normally.

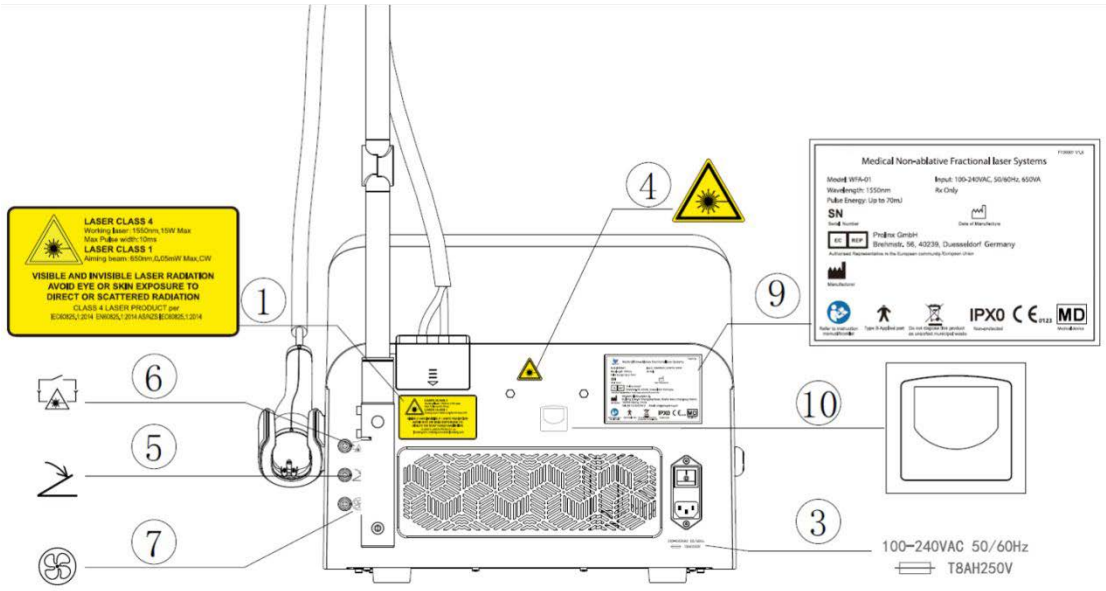
***Warning*:**

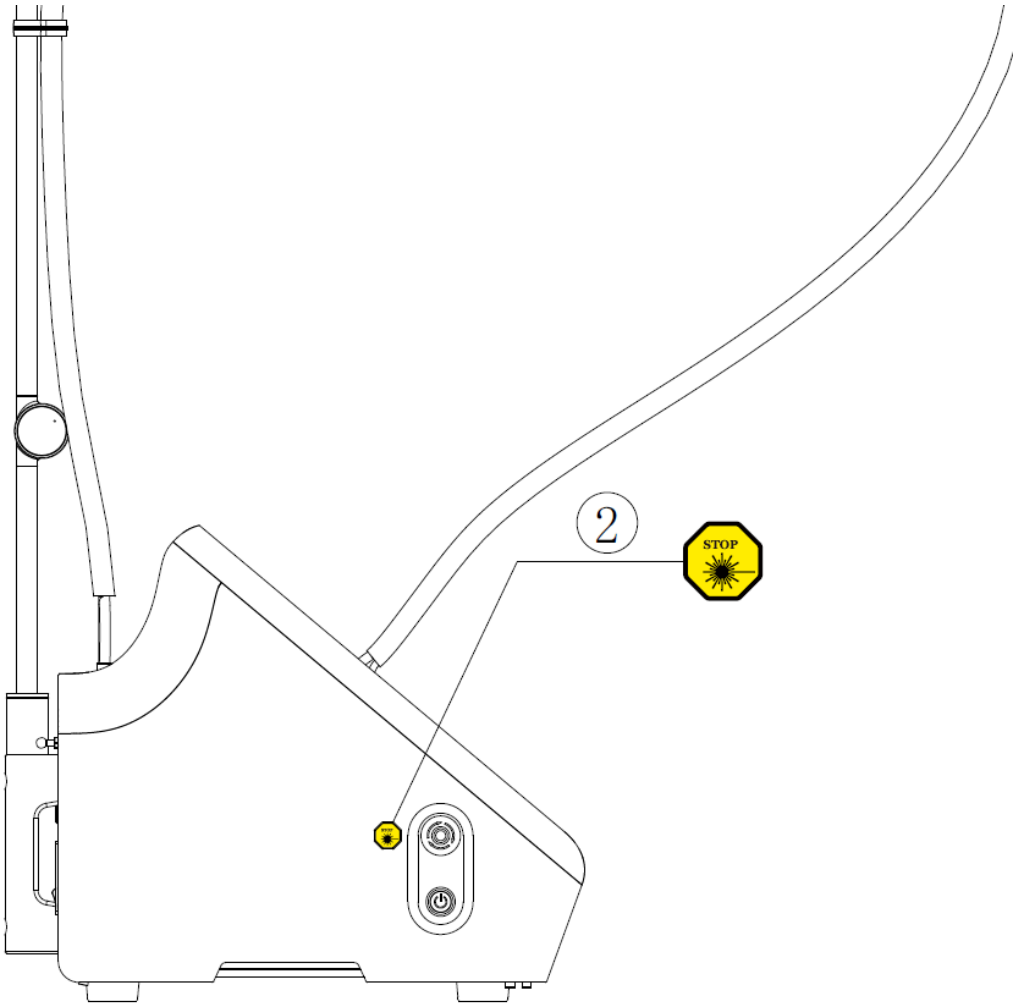
If the system fails and displays an error code, please stop using it immediately and contact the manufacturer or service provider as soon as possible.

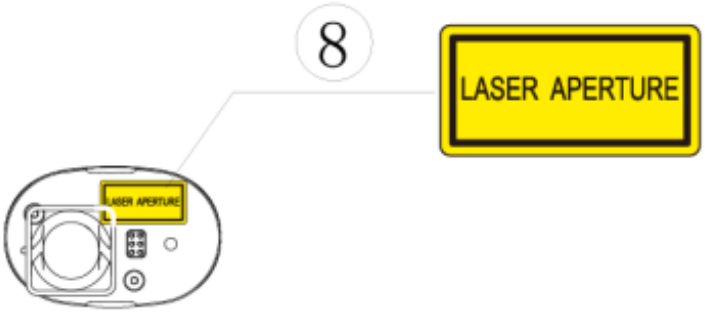
After the device is started, the laser monitoring systems will start immediately. If there is an operating error, the system alarm procedure will be triggered, the alarm interface will pop up on the screen, a warning alarm sounds, and the laser system switches to the “off” state, at this time even if the footswitch is pressed down, there is no laser output.

1.8 Regulatory and System Labels

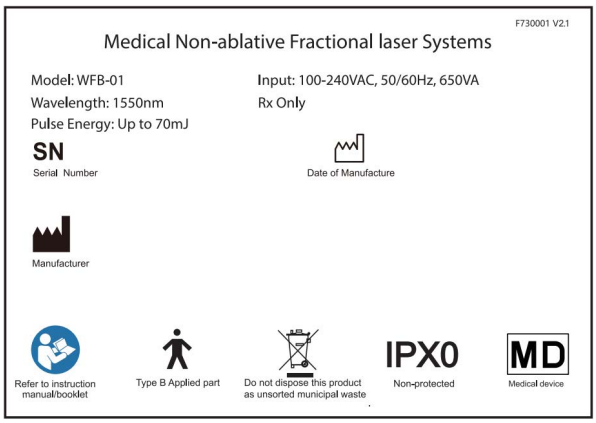
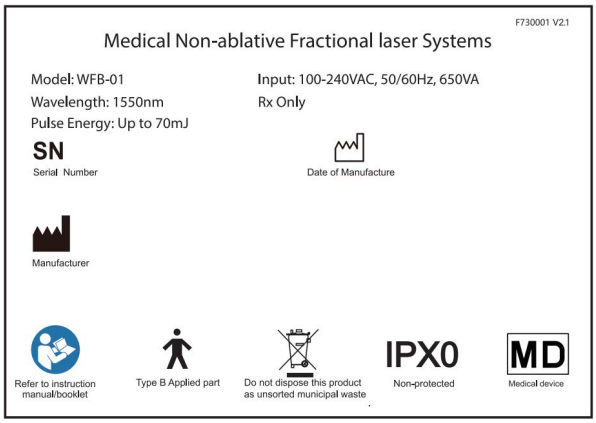
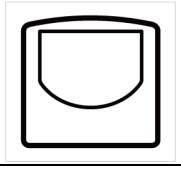
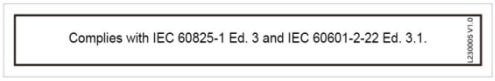
According to the relevant standards and regulations, the appropriate warning labels have been affixed in the following locations.

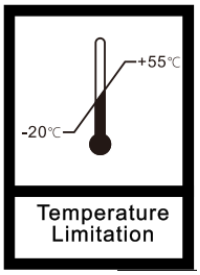
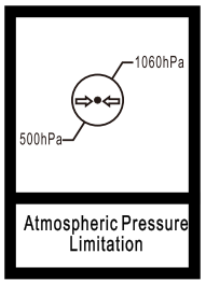
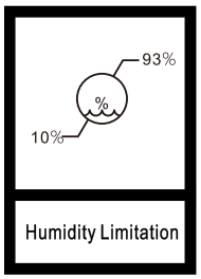
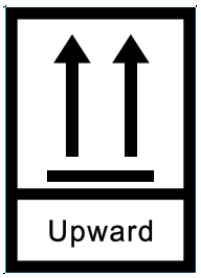



2
STOP


8
LASER APERTURE

NO.	Label	Description
1		Class 4 Laser description
2		Emergency Stop Switch
3		Electrical specification
4		Laser Emission
5		Foot switch Connector
6		External interlock receptacle
7		Cryoshot® Connector
8		Laser Aperture

9		Nameplate (CE)
		Nameplate (FDA)
10		Footswitch
11		FDA Standards
12		Earth Connection
13		Degree of Protection against harmful ingress of water (suitable for foot switch)
Labels on shipping box		

14		Temperature Limitation
15		Atmospheric Pressure Limitation
16		Humidity limitation
17		Upward
18		Handle with care
19		Keep Dry

Systems

2.1 Overview

This manual is specially prepared for medical staff and technicians to better use the FixCell®. In this manual you will find detailed content and other important information

on how to install, debug, operate and maintain the FixCell®.

***Warning*:**

In order to ensure the safety of operators and patients, please read this manual carefully before using the device, and fully understand all the contents of this manual.

More questions about safety, operation, and use, please contact Evo Tecgnology service or sales department directly.

The FixCell® adopts a portable design, the whole machine is compact and small, and the laser cavity uses an industrial-grade long-life erbium fiber laser, with stable output power and excellent beam quality; with a high-speed intelligent pattern generator, it can scan multiple patterns and provide scrambled scanning. A variety of scanning methods; humanized human-computer interaction design; power, spots density, scanning parameters can be freely set; 15-inch capacitive touch screen with Android operating system, excellent human-computer interaction, preset facial and scalp treatment parameters meet a variety of treatment requirements. It also provides fast treatment parameters recording functions for doctors,professionals or specialists.

The FixCell® can be used in conjunction with Cryoshot® cooling system (epidermal cooler).

2.2 Storage and transportation

The FixCell® is a precision optical instrument, and the users should not move it frequently with long distances. The shock-absorbing packaging provided by the original manufacturer must be used in the process of long-distance relocation, and try to keep it as stable as possible, otherwise it may cause the optical system to be out of adjustment and affect the energy output.

The FixCell® is a precision photoelectric device, which has the following requirements for the environment during transportation and storage:

- Storage temperature: -20°C to +55°C
- Relative humidity: 10% to 93%
- Atmospheric pressure: 500hPa ~ 1060hPa

During the transportation of the device, in addition to the environment to meet the requirements of storage conditions, good packaging is also required:

- The accessories and documents of the FixCell® should be packed in the packaging of neutral materials.
- The packaging must have good shock-absorbing performance, and it must be placed upright during transportation without falling or violent impact.
- Prevent rain and moisture during transportation.

2.3 Assembling requirements.

2.3.1 Assembling personnel requirements

The unpacking and assembling of this device should be completed by engineers of Evo Tecgnology, or designated distributors and responsible for on-site testing and inspection.

2.3.2 Unpacking and Inspection

Devices in the factory have been passed a rigorous inspection of packaging. Please according to the **Fast Operation Guide** with the device to unpack it. Check carefully with packing list (Annex **II)** whether the accessories are complete and save all the packaging materials. You need the original packing materials when storing it.

There is any question, please contact Evo Tecgnology Service or authorized representative

immediately.

2.3.3 Precaution of the operation room

The entrance of the treatment room should post laser warning signs with the wavelength of 1550nm.

Each entrance must be installed a laser warning light, whenever the laser is on, the warning light is on, to prevent others from entering the laser room during the laser working.

2.3.4 Precaution of the windows in operation room

When the device at work, prevent the dangerous of laser beam radiation through the windows of operation room.

2.3.5 Precaution of the laser reflection

In laser operation room, there should be ensured not highly reflective materials, such as mirrors, glass, prevent the laser beam reflected on them causing dangerous. As the manufacture of medical surgical instruments, mostly glass, chrome, or nickel-plated surface of the metal, as its high light reflectance, do not shoot the laser beam on it when operating the laser, otherwise, laser beams reflected from these instruments can harm the human body.

2.4 FixCell® Components

The FixCell® is comprised of :

- Host with touch screen
- Handpiece and Scanning Tips
- Power cable
- Foot switch

The FixCell® mainly including:

① 15’ touch screen：High-definition capacitive touch screen, with user-friendly UI design, can realize multi-parameter adjustment and storage

② handpiece cable bracket：Support handpiece cable, and can be rotated according to operation needs

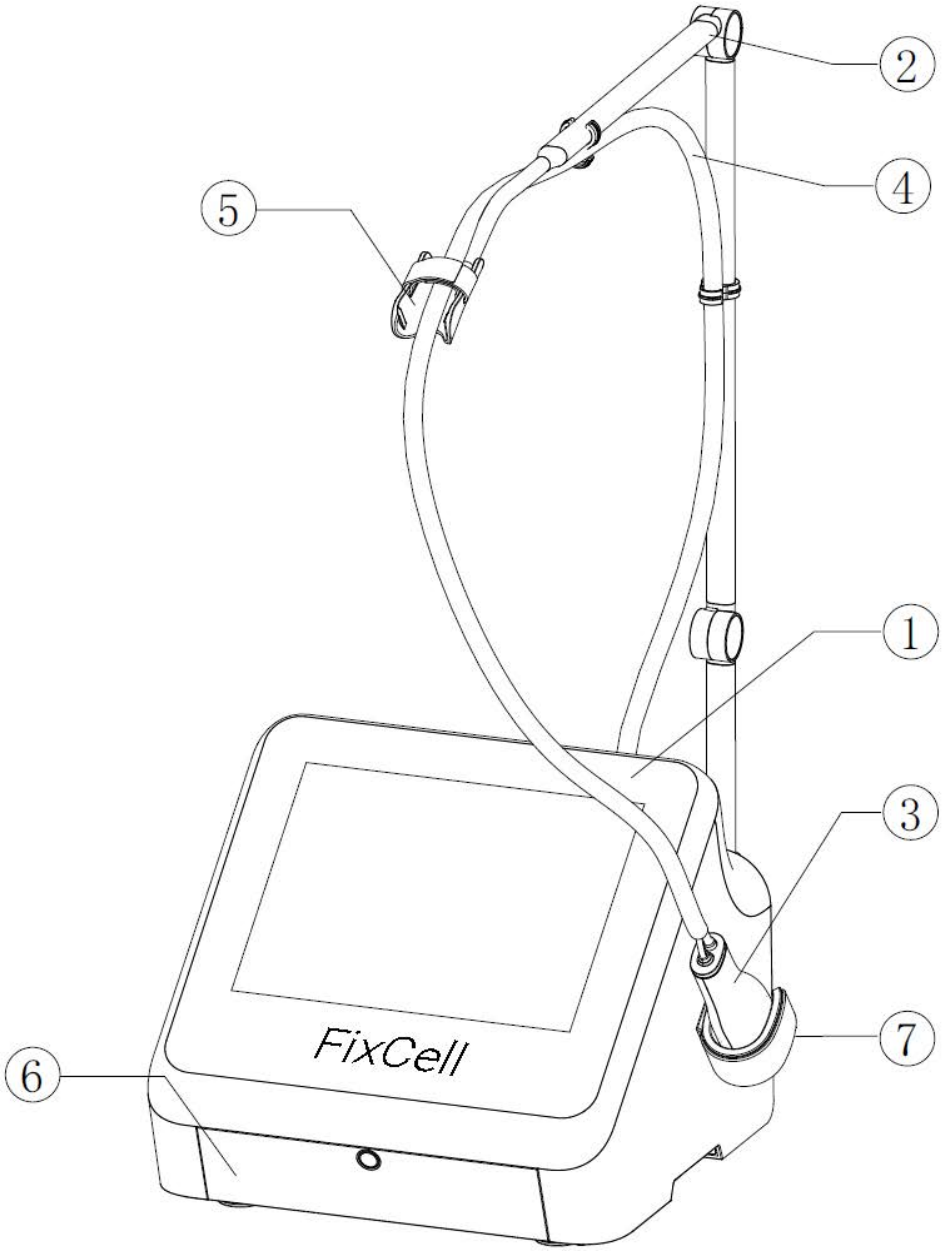
③ handpiece：There is a high-speed pattern generator inside, and the applicator tips are changeable according to the applications

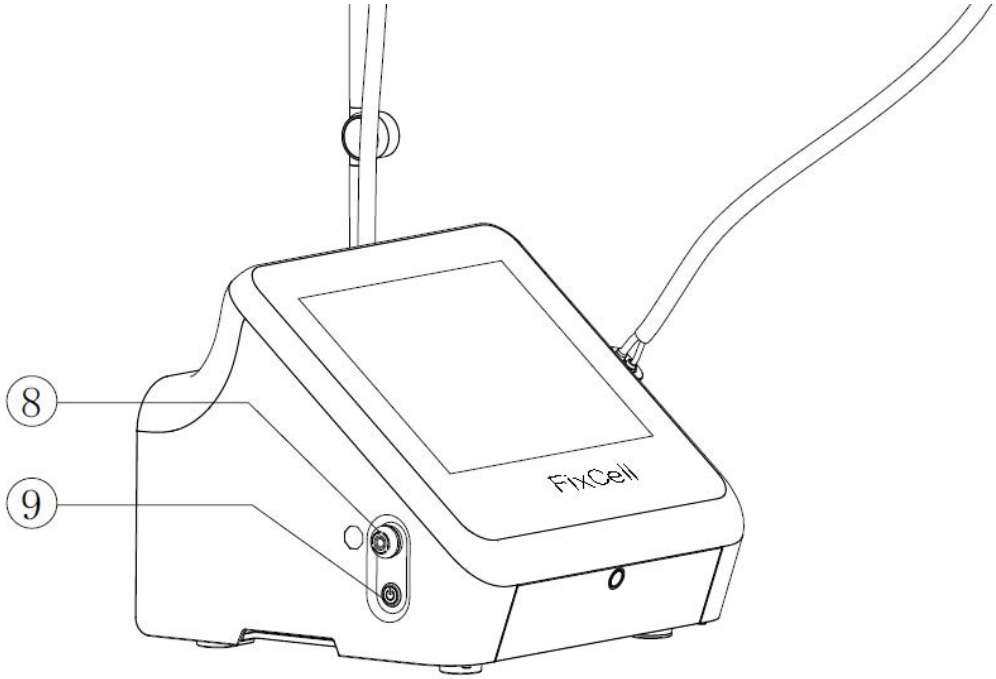
④ handpiece cable

⑤ front end bracket : For hanging of handpiece cable

⑥ container：Press to open or close, store various types of applicator tips

⑦ handpiece holder： Hold the handpiece



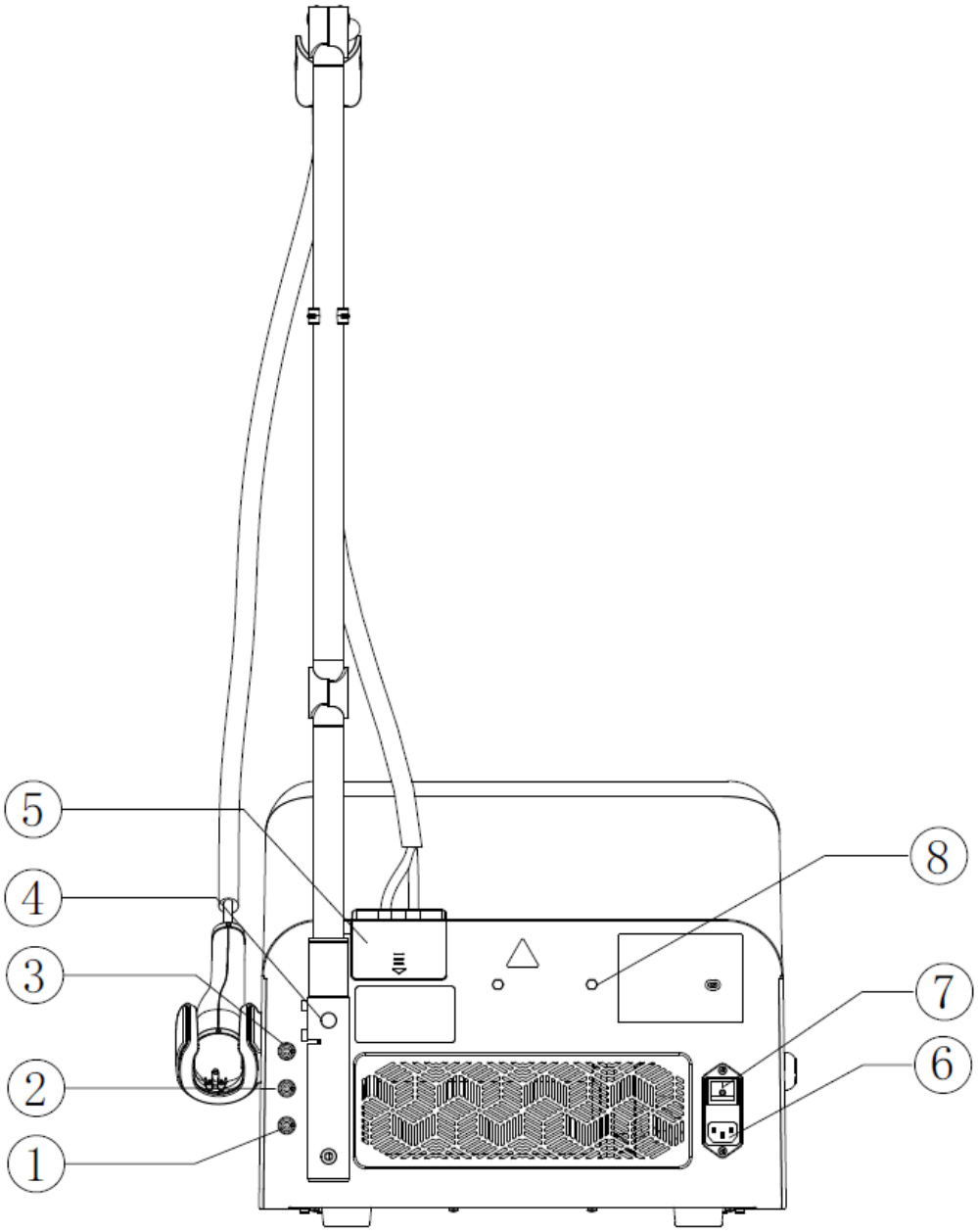


⑧ emergency button：Under emergency, press this key to stop the laser output and cut off the power supply.

⑨ power switch button： Control device power on or off

2.5 Host interface distribution

Device backside interfaces distribution as shown in the picture:



Including:

① Cryoshot® Connector: Connect Cryoshot®, which can be controlled automatically by FixCell® through this interface.

② Foot switch Connector: Connect the foot switch.

③ Interlock interface: Connect the interlock switch of the laser room.

④ handpiece umbilical bracket socket: Used to install handpiece umbilical bracket.

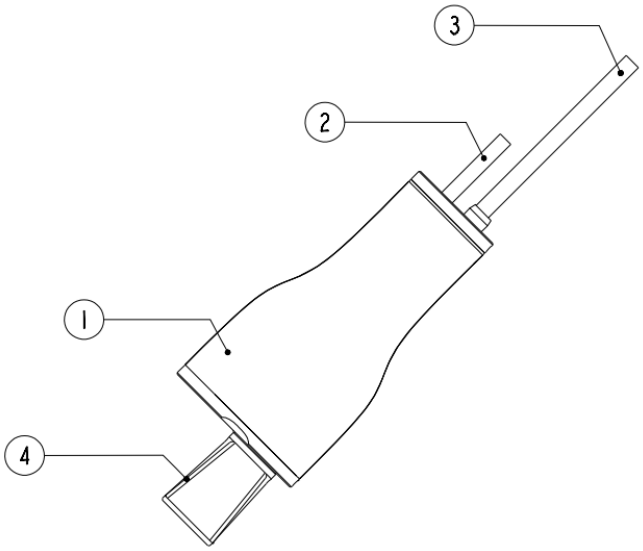
⑤ handpiece umbilical bracket locking hole: Use the hexagon wrench to lock the handpiece umbilical bracket.

⑥ Power Inlet: Device power supply interface

⑦ Power switch: "I" Power on, "O" Power off

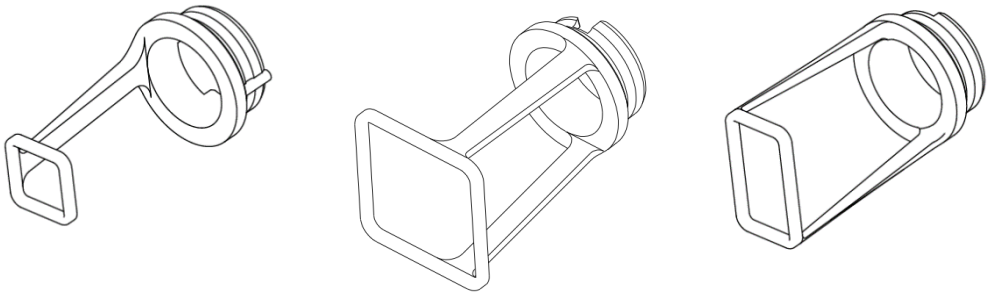
⑧ Foot switch hook：used to hang up the foot switch.

2.6 Hand piece

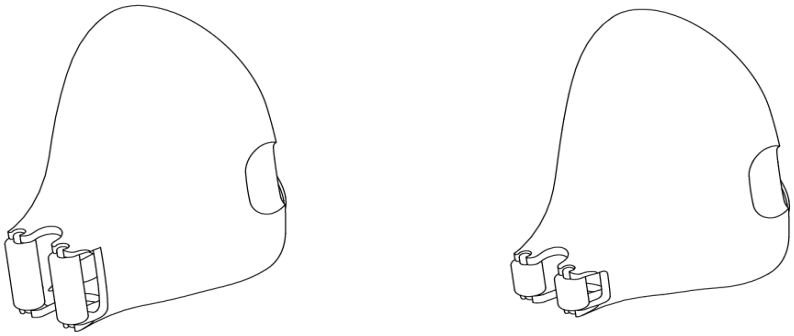


Including：

① Hand pieces：Provide laser emission and graphic scanning functions.
② Optical Fiber: Optical guiding fiber
③ Signal cable: Signal transmission cable
④ Applicator tips: AccuTip、EffiTip、GrowTip and OST-7 and OST-15



AccuTi　　EffiTip　　GrowTi



OST-15　　OST-7

- AccuTip: Scanning area 10mm×10mm.used for orbital, nasal alar and other small areas.
- EffiTip: Scanning area 20mm×20mm，.used for cheek, body and other large areas.
- GrowTip: Scanning area 10mm×20mm.used for hair line treatment.
- OST-15:Scanning width 15mm.rolling to track and output fractional laser.
- OST-7:Scanning width 7mm.rolling to track and output fractional laser.

2.7 Assembling Instructions

2.7.1 Unpacking

Firstly, remove the package of the device, take out the handpiece umbilical bracket and the host, put it in a steady place. The handpiece relates to the host through optical fiber, it cannot be split. During the unpacking process, please pay attention to place the handpiece well to prevent accidental falling.

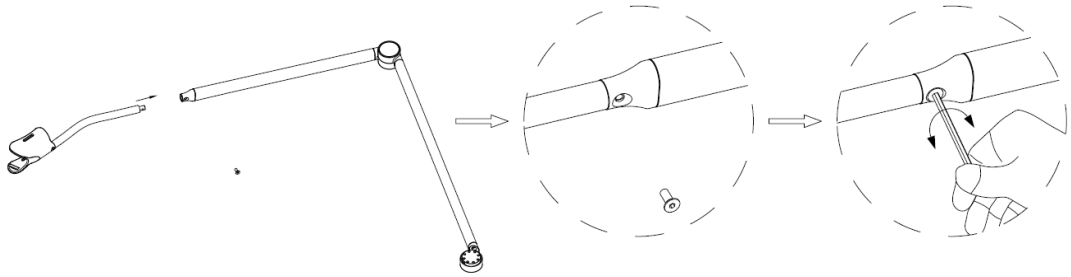
Warning：

All parts or materials of the device are specially provided by Evo Tecgnology, users cannot replace them by themselves.

2.7.2 Handpiece umbilical bracket assembling

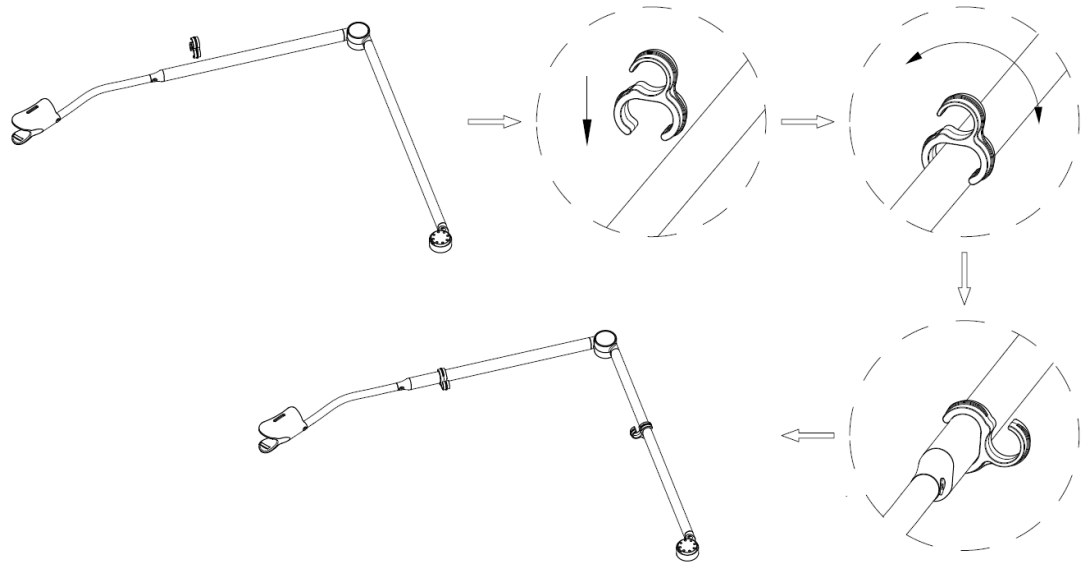
Step 1

Remove the trestle assembly and the hexagon wrench tool, insert the front-end bracket into the fixed position of the trestle assembly, and tighten the socket counter sunk head screws(M4*10) clockwise with the randomly delivered hexagonal wrench tool (2.5mm). As shown in the figure below.:



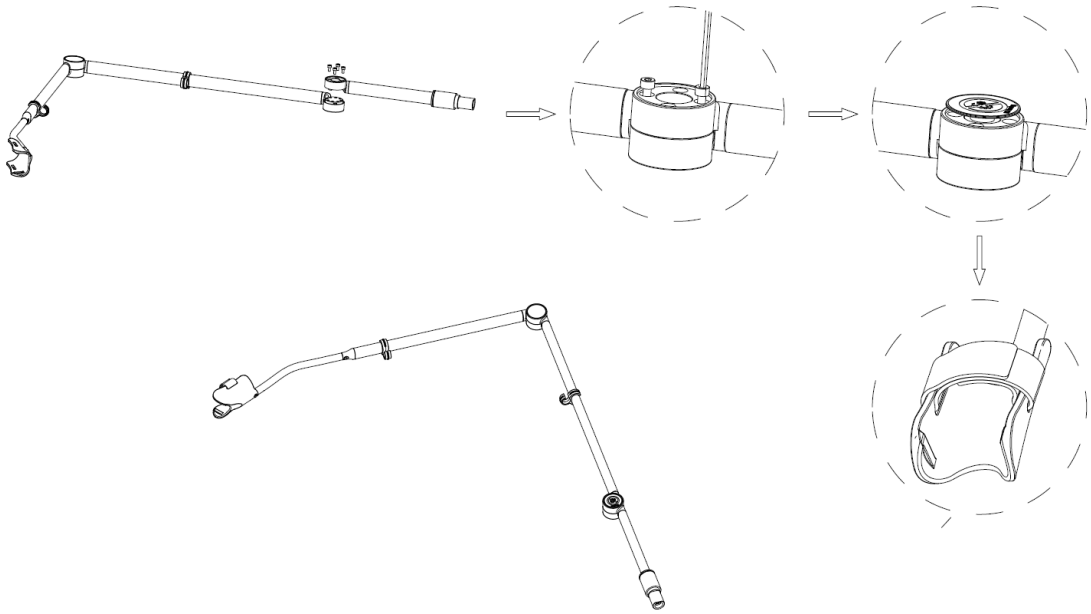
Step 2

After clamping the opening of the air pipe clamp clip into the side of the aluminum rod, rotate 90° to install in, as shown in the figure below:



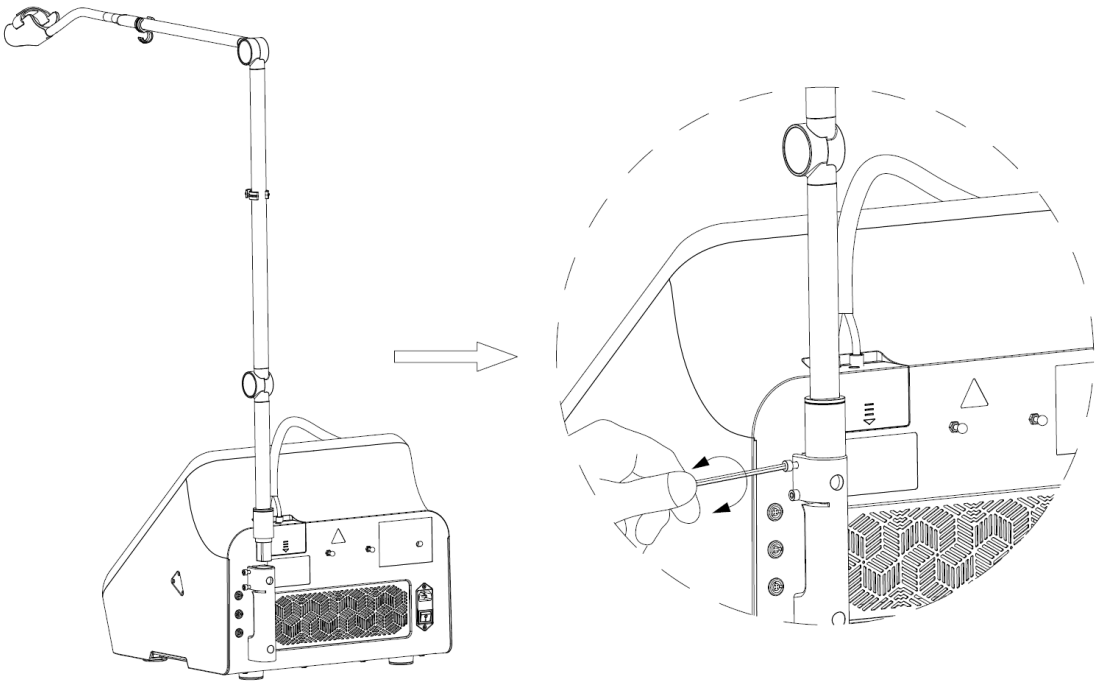
Step 3

Align the small upright assembly with the fixed position of the trestle assembly, lock the four-hexagon socket round head screws (M4*8) with the random delivered of hex wrench(3.0mm), and put the prohibit turning cover plate into the circular groove, and tie the bandage, as shown in the figure below:



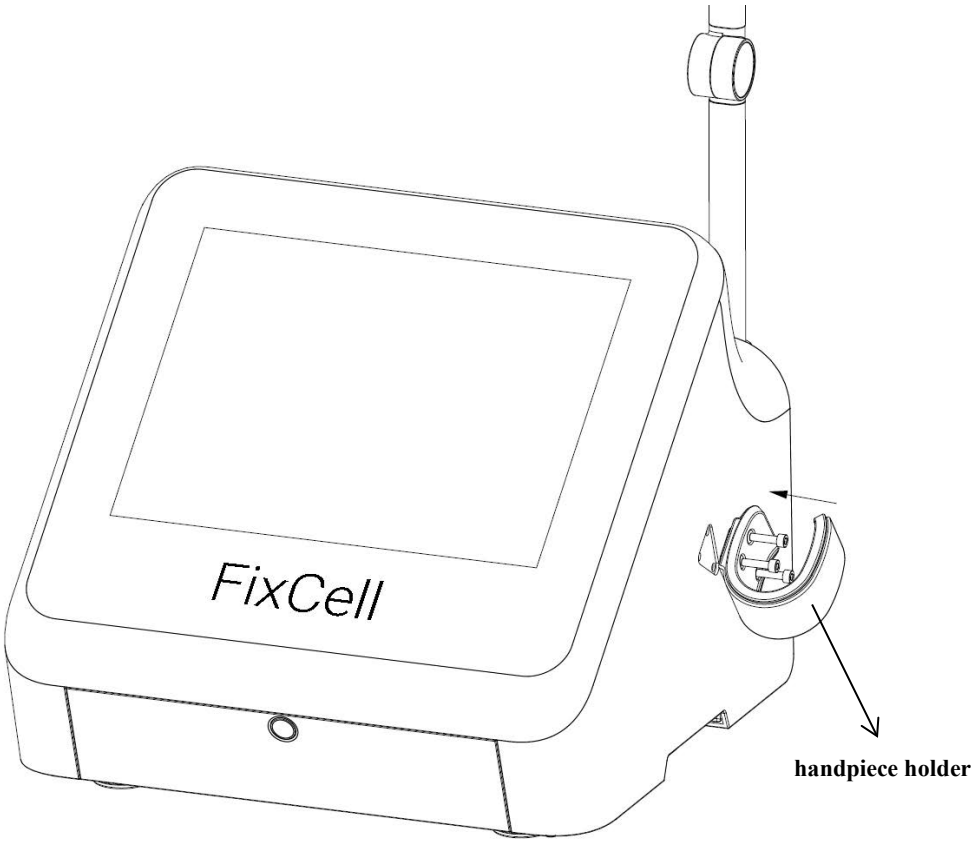
Step 4

Plug handpiece umbilical bracket into the socket as shown in the picture, use the hexagon wrench to tighten the umbilical bracket.



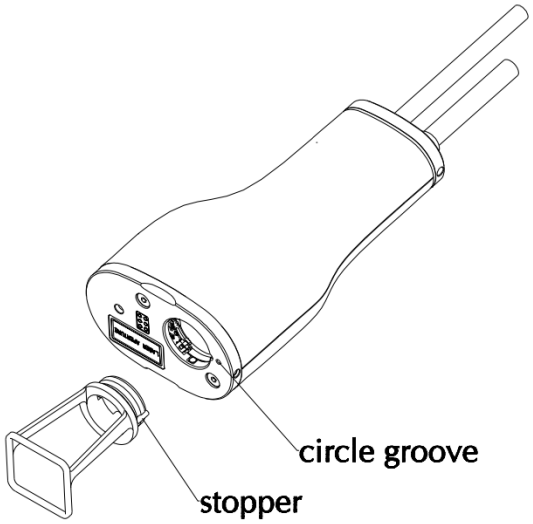
2.7.3 Handpiece holder assembling

Take out handpiece holder, install it on the right side of the host as shown in below picture; three screws are provided to fasten the handpiece holder.



2.7.4 Applicators assembling

When removing the Applicator tip from the handpiece, just pull out it with a little force. When installing the applicator tip, please point the stopper to the circular groove mark at the bottom of the handpiece, apply a little force and hear "Ka Ta", indicating that the applicator is installed in place. The system will identify the new applicator tip automatically on the screen.



2.7.5 Electrical connection

1) First, confirm the voltage of the power supply is the same as that of the device
2) Plug the power cord into the power inlet on the back of the host
3) Connect the laser room interlock or connect the interlock key in the accessories
4) Connect the foot switch
5) Tighten the handpiece umbilical brackets and insert the handpiece into the handpiece holder.

2.8 Specifications

Parameters	
Laser Wavelength	1550nm
Laser Type	Er: Fiber laser
Pulse Energy	Up to 70mJ*
Operating Mode	CW

Scan width	OST-7:7mm OST-15:15mm
Scan Area	AccuTip:10mmX10mm EffiTip:20mmX20mm GrowTip:10mmX20mm
Scan graphics	Rectangle, hexagon, oval, triangle, circle
Scan Mode	Transverse scan, longitudinal scan, random scan, Scramble scan
Aiming light power	< 5mW
Aiming light wavelength	650nm
input power	650W
power supply	100-240VAC，50/60Hz
Fuse	250V 8A
Classify	
IEC/EN60601-1	Class I Type B
IEC/EN60825-1	Class IV
MDD	Class IIB
FDA	Class II
CDRH	Class IV
（NOHD）	5km
Packing parameters	
Device Volume（L*W*H）	492mm*400mm*353mm
Packaging Volume	576mm*516mm*647mm
Net W	17kg
Operating ambient	
Temperature	+10℃ ～ +30℃
Humidity	30% ～ 70%
Atmospheric pressure	700hPa ～ 1060hPa
Storage environment	
Temperature	-20℃ ～ +55℃
Humidity	10% ～ 93%
Atmospheric pressure	500hPa ～ 1060hPa

*The pulse energy of the FDA cleared device is 70mJ.

Operation

3.1 Preparation

First, make sure that the device is placed stably on the Cryoshot® (optional). All the cables between them are connected correctly. Make sure that the foot switch, interlock and power cord are connected. Assemble an appropriate applicator tip according to the treatment.

All persons in the laser room are wearing protective eyewear.

The emergency stop button is not pressed.

***Caution*:**

FixCell® can only be operated by trained doctors, professionals or specialists..

***Caution*:**

The device must be shut down during non-operation to avoid the laser hazards.

3.2 System start

After the preparation, press the power switch button on the left side of the device to start it. Enter the **Welcome** interface and input the power password (the default password is "123456"). Enter the operation interface of the device and set appropriate parameters

'ing to the patient's condition for treatment. See the FixCell® clinical guidance for details.

3.3 Alignment inspection

***Warning*:**

Whenever any abnormal or emergency situation, please press the emergency stop button immediately to cut off the power supply of the device for safety.

Checking the alignment of the aiming beam and the laser beam every one month. Black photographic paper (as the target of laser) is necessary.

Steps to check the alignment :(keep the black paper at the end of the tip as still as possible).

- Wear protective glasses.
- Assemble **EffiTip** on the handpiece.
- Power on and enter the operation interface.
- At this time, the red aiming beam can be seen on the photo paper (if there is nothing or not clear, adjusting the aiming beam brightness in the setting interface.).
- Adjust to the maximum scanning area (20mm*20mm), the energy to 10mj, Spots density to 100(the minimum shots); Ready the device.
- Trigger the footswitch and the laser will shoot on the photo paper and leave burn marks on it.
- Release the footswitch and inspect all the marks in the aiming beams scanning area or not.

Figure 3-1 is a schematic diagram of acceptable and unacceptable situations.

If the two spots deviate seriously, please contact the Evo Tecgnology service or local agent.

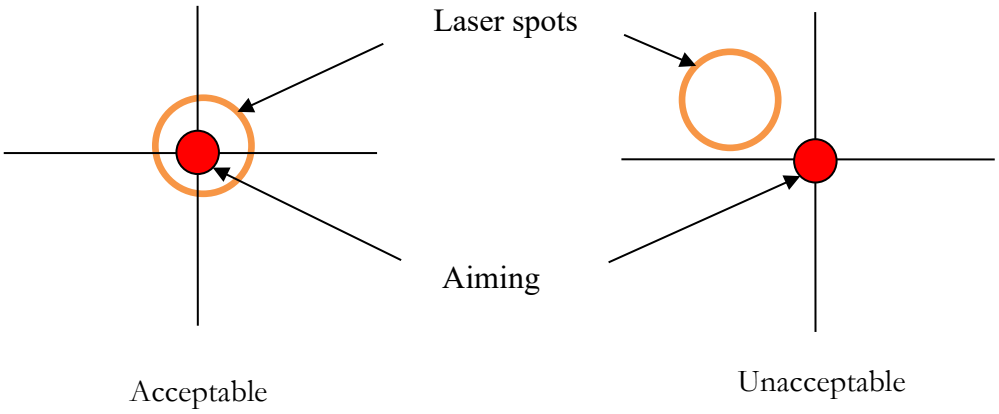


Figure 3-1 Alignment Inspection

3.4 Treatment process

After booting, the touch screen will first enter the **Welcome** interface (Figure 3-2).

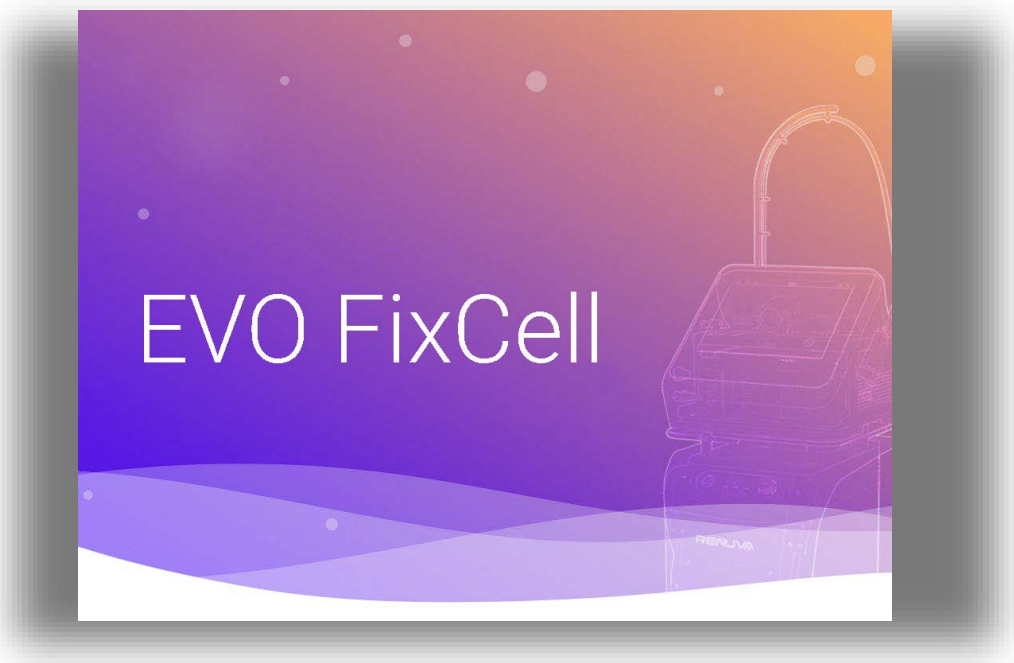
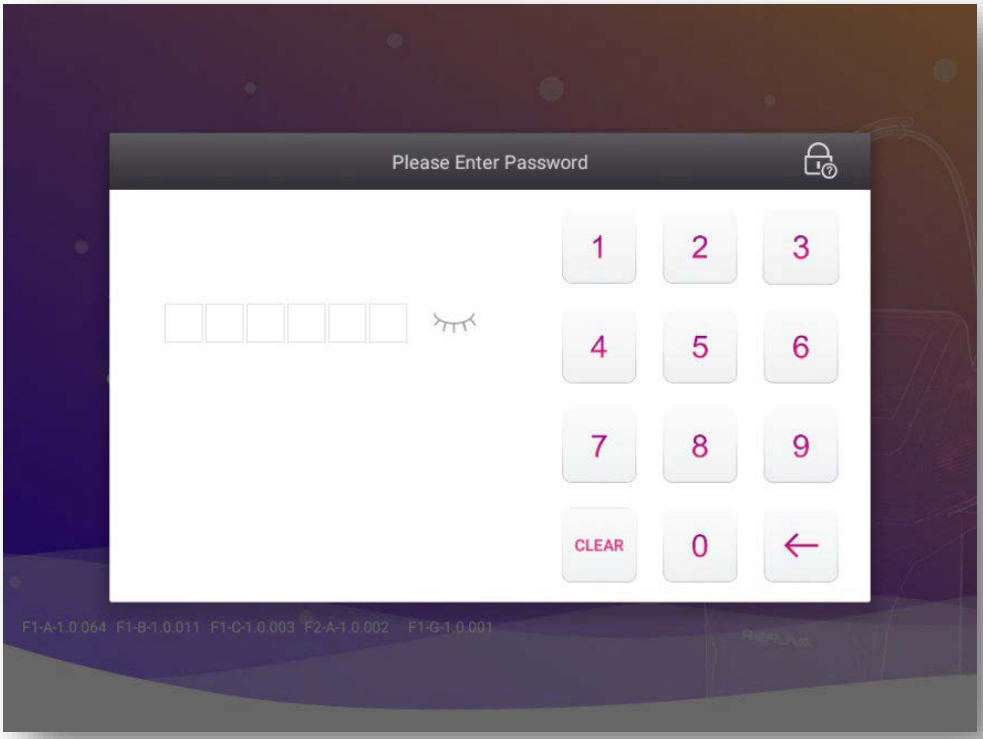


Figure 3-2 Welcome interface

The version number of the machine is displayed at the bottom of the screen, a password input window will pop up (Figure 3-3)

Figure 3-3 Password input interface



The default password is 123456 and the operation interface is showed as below (Figure 3-4).

Figure 3-4 Operation interface

①**Menu:** Clicking on the menu, which has buttons for screen lock, settings, fast parameters setting and calling, as shown in Figure 3-5-1.

②③**Cryoshot® and footswitch:** display the status of the Cryoshot® and footswitch; highlighted Icon means connected.

④**Single pulse laser energy：** the maximum is 70mJ

⑤**Shots density:** 100-500 shots/cm^2

⑥**Treatment shape：** circle, triangle, rectangle, hexagon, ellipse.

⑦**Scan mode:** horizontal, vertical, outward, inward, random, disorder.

⑯**Shoot Mode:** Single mode or Repeat mode.

"Single" and "Repeat" refer to the number of times the graphics scanning.

In the single mode, the laser output will stop automatically after scanning the set graphics once. In the repeat mode, the laser output will automatically stop after scanning the set graphics N times. (N is the number of repetitions set on the setting page, ranging from 2 to 10).

After the graphic is scanned and the laser is automatically stopped, if you still need to emit laser, you need to lift the footswitch and step on it again to continue emitting laser and the instrument will start a new round of laser emission.

If you lift the footswitch before finishing the graphic scanning, the instrument will stop emitting laser and maintain the current graphic progress. Stepping on the footswitch again, the instrument will emit laser and scan unfinished graphics(instead of scanning the new graphics) and the laser will automatically stop after scanning.

⑪**Part energy:** record the accumulated energy and shots of the selected part.

⑫**Total energy:** record the total energy of all treatments during the power is on.

⑧⑨**Face, scalp:** switch to face or scalp treatment

⑩**Applicators:** the type of treatment tip is using

⑬**Clear:** Clear the total energy manually.

⑭⑮**Standby /Ready:** In ready, trigger the footswitch, laser shots; In standby, no laser shots. When clicking Standby, a reminder box will pop up if the device is in repeat mode. As shown in Figure 3-5-2

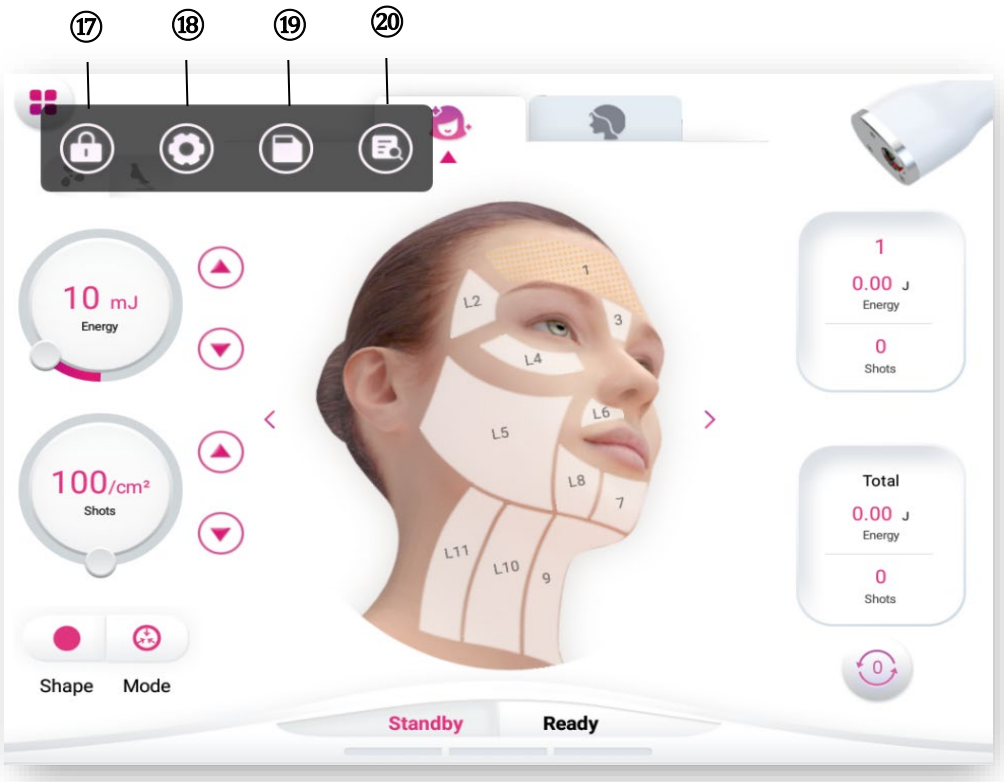


Figure 3-5-1

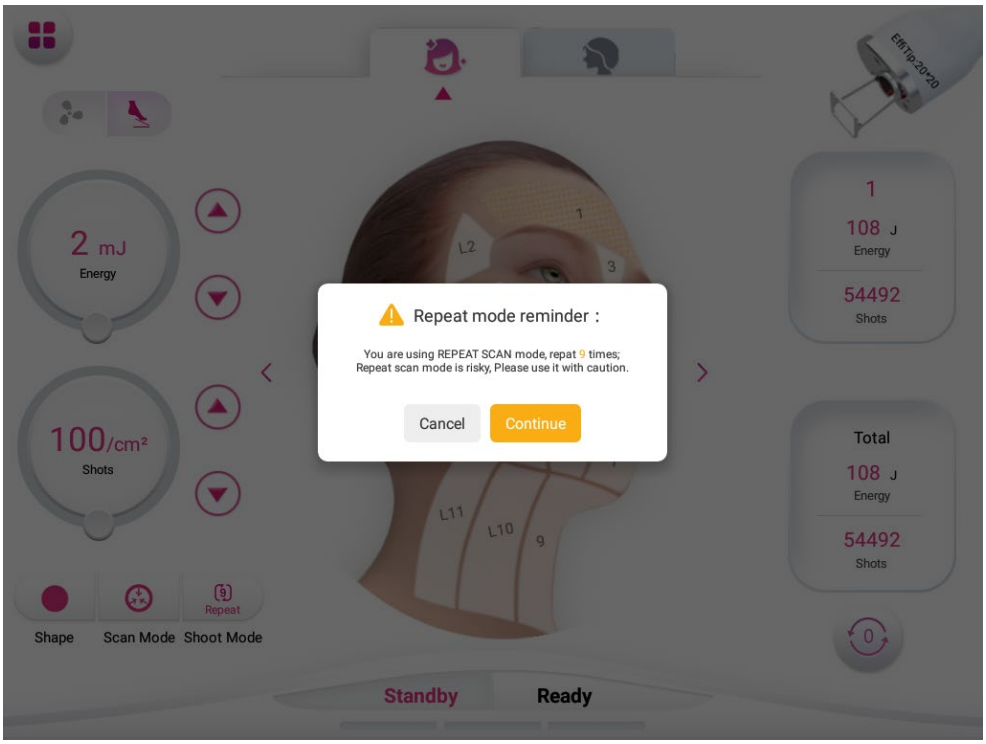


Figure 3-5-2

⑰**Locked:** click locked and the screen will be locked, swipe right and put password to continue. (Figure 3-6)

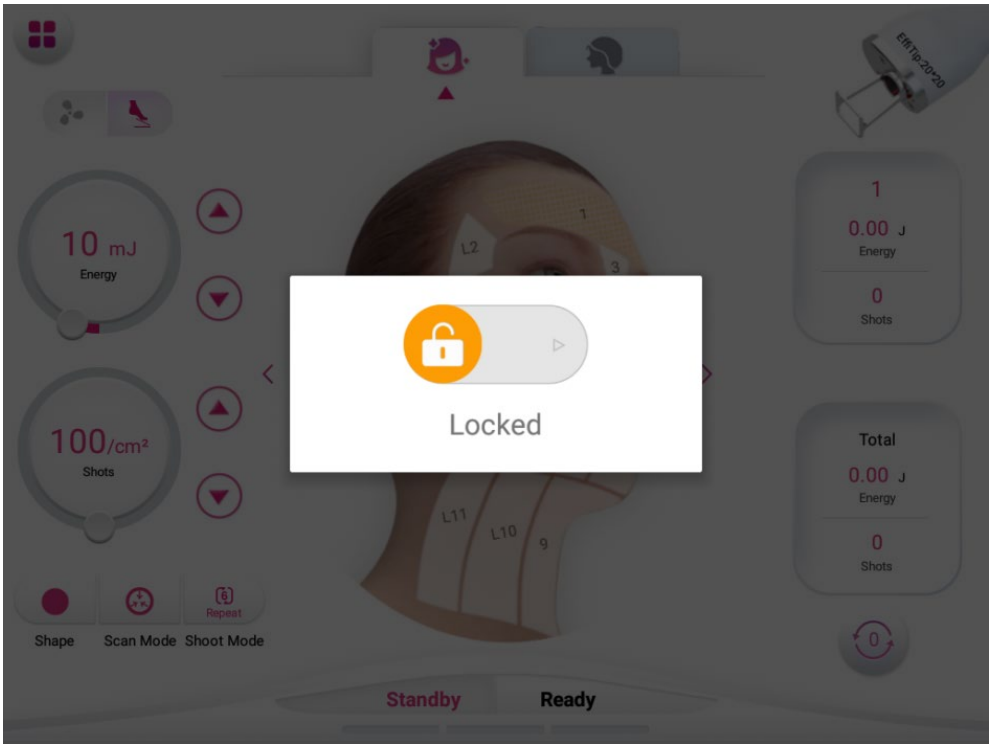


Figure 3-6

⑱**Save shortcut parameter:** Save the parameters at this time for direct recall later (Figure 3-7)

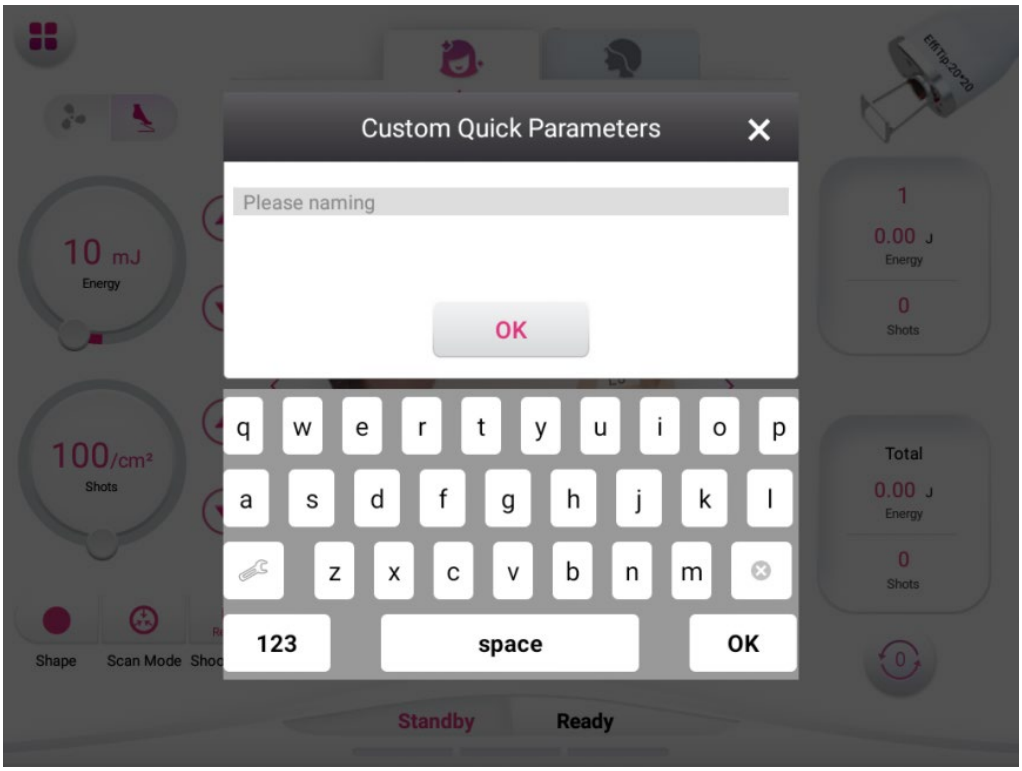


Figure 3-7

⑲**Inquire shortcut parameter:** Jump to the parameter list (Figure3-8)

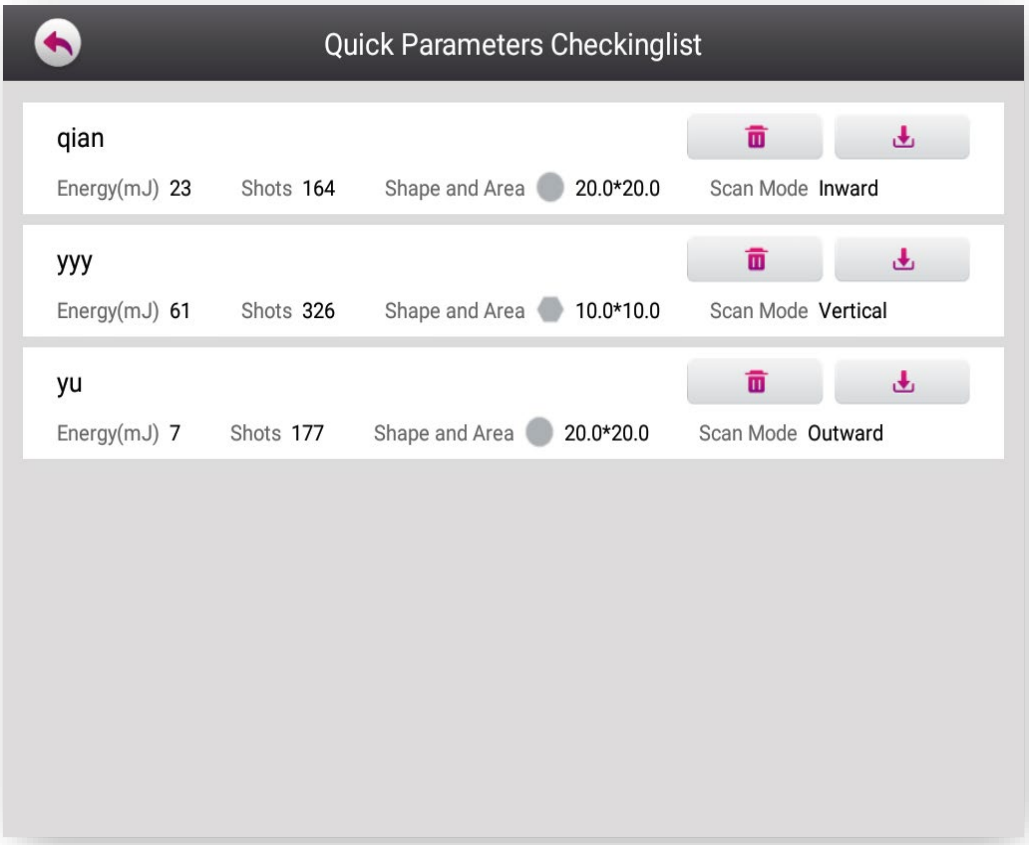


Figure 3-8

⑳**Setting:** Jump to the setting interface

When all the necessary items above are set, press the "Ready" button to enter the working state. After finishing the treatment, press the "Standby" button, the device enters the standby state.

3.5 Setting

The setting interface is shown in Figure 3-9-1

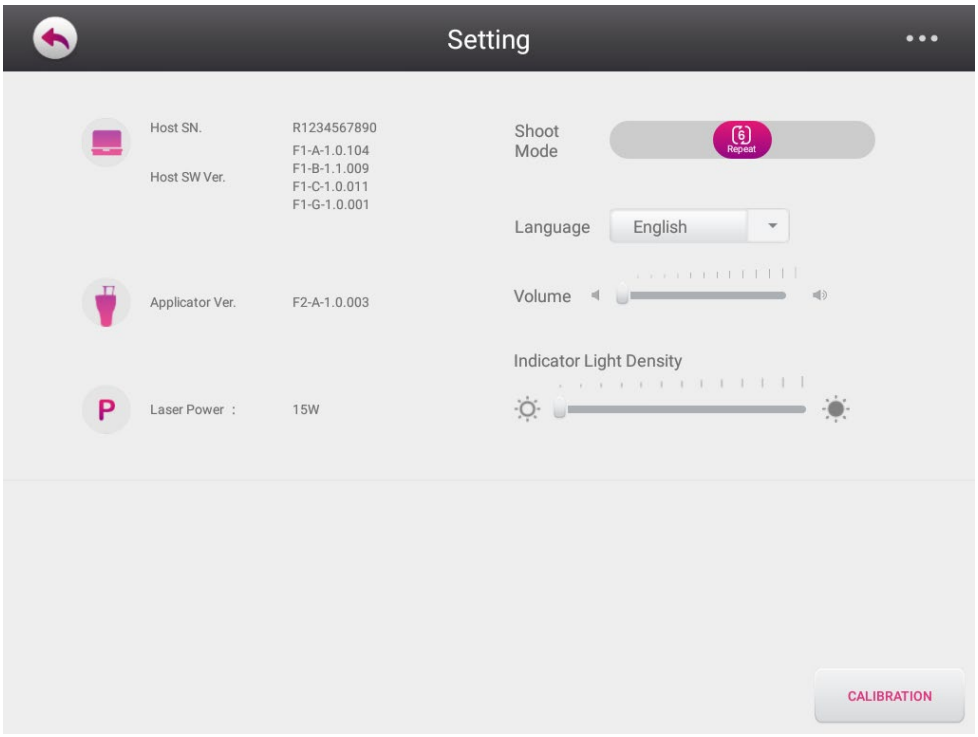


Figure 3-9-1

: return to the operation interface;

display the SN and software version of the device;

: Laser power of the device

Shoot Mode: laser output passes repeat times. This setting will be hidden if the device is in Single Pass mode.(Figure3-9-2)

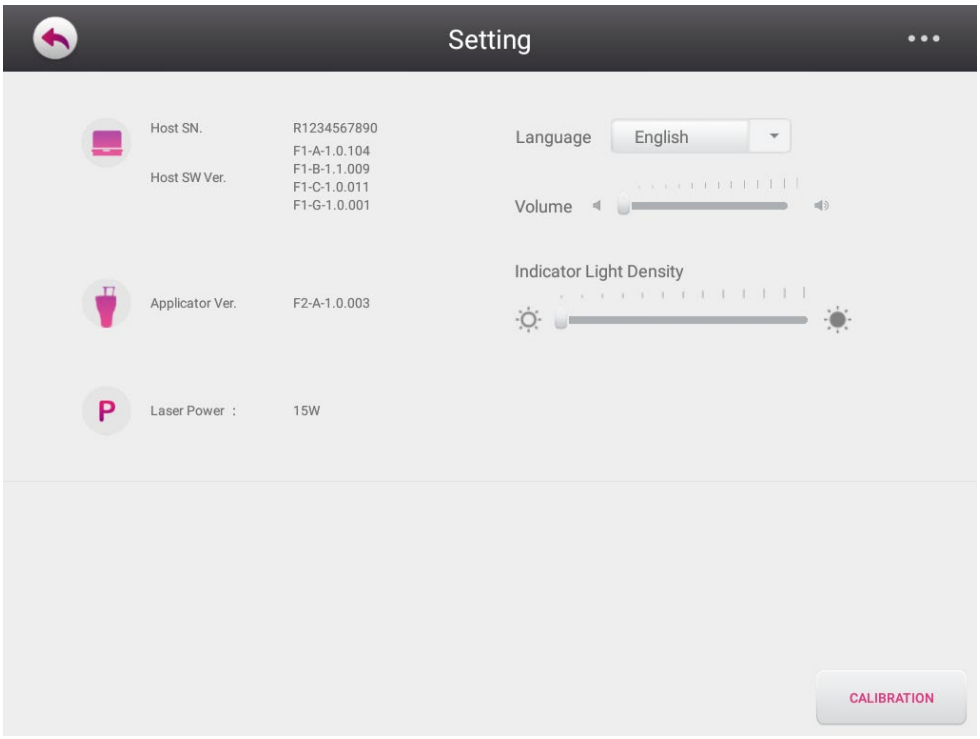


Figure 3-9-2

Language: select the device language.

Volume: adjust the volume of the device's prompt sound.

Indicator light density: adjust the brightness of the indicator light.

Calibration: click into the calibration interface.

3.6 Calibration

The calibration interface is shown in Figure 3-10

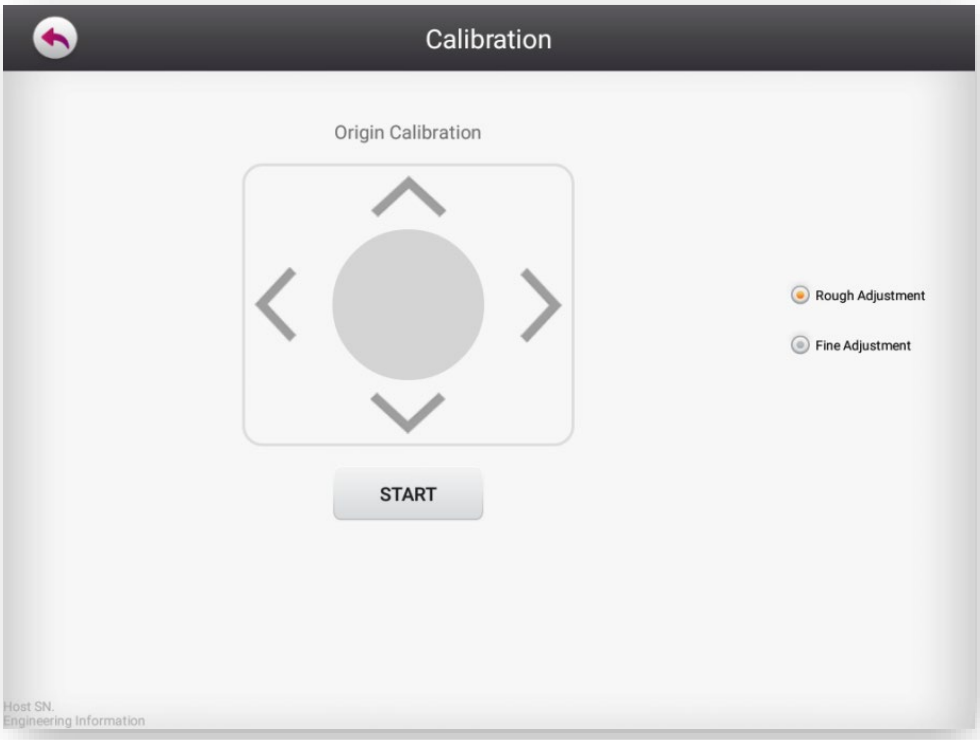


Figure 3-10

Rough adjustment: rough adjustment the scan area to the center of the tip.

Fine Adjustment: fine adjustment the scan area to the center of the tip.

Start: Start calibration.

3.7 Shut down

- It is better to return to the **Standby** state before shutting down. Make sure the main power switch on the back of the device should be in "O" position.
- Place the handpiece into the handpiece holder carefully to keep from slipping off.

Maintenance and instruction

4.1 Regular maintenance and inspection

It is very important to check the performance of the device on a regular basis to keep the device in the best working condition. The main inspection items are shown in Table 4-1

Checking list	Frequency	Items
Power cord and power inlet	every week	No damage or connection problem
Footswitch and connection socket	every week	No damage or connection problem
Front control panel and LCD touch screen	All times	No breakage, unnormal display or uncontrolled touch screen
Alignment	Once a Month	Reference to 3.3

Table 4-1

Warning:

Any unauthorized maintenance，including spare parts replacement is prohibited.

Note:

If there is any problem inside the device, please contact Evo Tecgnology service department or authorized agent.

4.2 Cleaning the applicators

The part of the machine in contact with the patient body is the treatment tips. After each treatment, need to use absorbent cotton dipped in 75% medical alcohol to wipe clean.

The focusing lens should be kept clean to ensure high transmittance of the laser beam to prevent being burnt from poor transmission. The focusing lens can be wiped gently with lens paper or cotton swab dipped in a little alcohol or water. Don't use excessive force or

scratch it with fingers to avoid damage to the surface film of the focusing lens.

4.3 Warnings and errors

If the machine fails, refer to the following table to find the cause of the failure, and take appropriate measures to eliminate the failure. More information, please contact Evo Tecgnology service department.

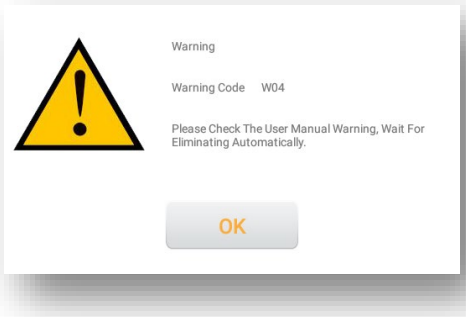
***Warning*:**

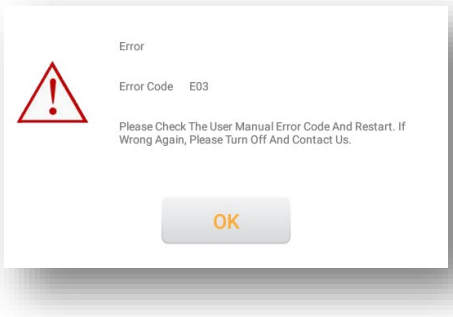
FixCell® can only be operated by doctors , professionals or specialists who have received relevant training.

***Warning*:**

Be sure to turn off the machine after treatment. Any unnormal operation may cause radiation exposure hazard.

When the machine detects an abnormality, it will sound an alarm and display a pop-up window like the following:





There are some abnormal situations (Table 4-2).

Table 4-2 the abnormal list

level	No.	Reason	Solution
Warning	W04	The door interlock is not connected	Check if the door interlock switch is connected

Warning	W05	Door interlock status	Check if the door interlock switch is connected
Error	E00	Mainboard communication is abnormal	Turn system off. Wait 30 seconds and then turn system on. If problem persists after system restart – call Evo Tecgnology service.
Error	E01	The galvanometer power supply is abnormal	
Error	E02	Laser power supply is abnormal	
Error	E03	Laser power is abnormal	
Error	E04	Red light is abnormal	
Error	E05	Laser PWM is abnormal	
Error	E06	Stop is abnormal	
Error	E07	Galvanometer abnormal	
Error	E08	Monitor communication abnormal	
Error	E09	Handpiece communication is abnormal	
Error	E10	Chiller communication is abnormal	

There are solutions about failure phenomenon. (Table 4-3)

4-3 General Trouble shooting

Failure phenomenon	Causes and troubleshooting
Nothing is displayed when the machine is powered on	Please check if the machine is not connected to the correct power source? Check whether the power cord is plugged into the power outlet and whether the power switch is in the "I" position? Is the emergency stop switch is pressed on?
Foot switch failure	The foot switch is not connected
The laser does not fall on the aiming light spot	The laser optical path offset, please check the laser optical path according to the method provided in 3.3
When the foot switch is pressed on, there is no laser emission	The foot switch connection is not good. The machine is not in the ready state (please check whether the "Ready" button is pressed)

4.4 Lifetime

The lifetime of the device is 5 years.
To ensure the safe and effective treatment, the machine needs to be checked and calibrated every 12 months.

4.5 Disposal

Dispose of the end-of-life machines and packaging materials in accordance with the corresponding national laws and regulations. Generally, the end-of-life products, packaging cardboard and protective plastics should be sent to a recycling agency, which should be able to dispose of plastic and metal parts, Scanned circuit boards, cables, wires, motors and other materials.

Clinical Guide

5.1Treatment principles

According to Fractional photo thermolysis, 1550nm non-ablative fractional laser, at a certain energy density, the laser beam with a diameter of 15～150μm penetrates the epidermis and enters the dermis, acting on the target base in the dermis—water, resulting in tissues with high water content in the skin. Such as: collagen, blood vessels, etc. absorb heat to produce cylindrical three-dimensional structure of Microscopic Thermal Zones, MTZ, the laser beam arranged in a lattice will divide the normal tissue evenly through the MTZs, the normal tissue cells around the MTZs are stimulated by heat to start the repair process, and promote the collagen The synthesis increases, to achieve the purpose of repairing and remodeling the skin tissue. The 1550nm non-ablative fractional laser produces thousands of MTZs. While the stratum corneum is relatively intact, it acts on a small area of the skin in a fractional arrangement. The total treatment area is less than 10% of the treatment area, which retains a large area. Part of the normal skin, to ensure rapid tissue repair.

5.2 Indications

1550nm non-ablative fractional laser can be used to treat skin diseases such as pigmentation (such as chloasma), acne, depressed scars left by acne, surgical scars, or scars after burns.

5.3 Contraindications

- Scarring hyperplasia or suspected scarring hyperplasia.
- Skin pigmentation changes after previous surgical operations.
- There will be skin atrophy or cortical changes after previous surgical operations.
- Patients are being treated with similar drugs such as isotretinoin.
- Patients with skin diseases such as skin lupus erythematosus and psoriasis.
- Are or have received immunosuppressive therapy with gold preparations such as Auranofin.
- Those who are pregnant or lactating.
- Severe diabetes, hypertension, and heart disease patients.
- People with mental disorders.

Before treatment, patients with the following conditions and not limited to the following conditions should make medical judgments:
1) There is a tendency to PIH after inflammation: 4-6 weeks before the first treatment, throughout the treatment regimen, and recommended that 4-6 weeks after the last treatment， preventive bleaching programs can be implemented for skin types IV to VI.

2) Suspicious malignant cancer.
3) Active infections: bacteria, viruses, fungi (active acne, hair follicle infection, etc.).
4) Active sunbathing, UV exposure, and sun exposure within half a month.
5) Take drugs (heparin, etc.) that can affect blood coagulation and easily cause ecchymosis in patients.
6) The healing ability is impaired or the use of drugs that change the wound healing response (glucocorticoids, non-steroidal anti-inflammatory drugs, etc.).
7) Topical retinol or retinol.
8) For a history of herpes simplex virus, antiviral drugs such as valacyclovir should be taken preventively.
9) Those who have an allergic reaction to lidocaine. Doctors, professionals or specialists should be familiar with the nature, symptoms, and treatment of epi anaesthesia, and consult and evaluate patients.

Annex 1: EMC

NOTE: EMC DECLARATION

The Medical Non-Ablative Fractional Laser Systems needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable and mobile RF communications equipment can affect the Medical Non-ablative Fractional Laser Systems.

All cables and maximum length of cables, Transducers, and other accessories with which the manufacturer of the Medical Non-ablative Fractional Laser Systems claims compliance with the requirements, Accessories that do not affect compliance with the requirements of these sub clauses need not be listed. Accessories, transducers, and cables may be specified either generically or specifically.

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.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this the Medical Non-ablative Fractional Laser Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 Medical Non-ablative Fractional Laser Systems, 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 re-orienting the equipment.

Table 4-1: Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Medical Non-Ablative Fractional Laser Systems is intended for use in the electromagnetic environment specified below. The customer or the user of Medical Non-ablative Fractional Laser Systems should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Medical Non-Ablative Fractional Laser Systems uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Medical Non-Ablative Fractional Laser Systems is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This Medical Non-Ablative Fractional Laser Systems is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Medical Non-ablative Fractional Laser Systems or shielding the location
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Table 4-2: Guidance and manufacturer´s declaration – electromagnetic immunity

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Medical Non-Ablative Fractional Laser Systems is intended for use in the electromagnetic environment specified below. The customer or the user of the Medical Non-ablative Fractional Laser Systems should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Medical Non-ablative Fractional Laser Systems requires continued operation during power mains interruptions, it is recommended that the Medical Non-ablative Fractional Laser Systems be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U_T is the a. c. mains voltage prior to application of the test level.		

Table 4-3: Guidance and manufacturer´s declaration – electromagnetic immunity

Guidance and manufacturer´s declaration – electromagnetic immunity
The Medical Non-Ablative Fractional Laser Systems is intended for use in the electromagnetic environment specified below. The customer or the user of the Medical Non-ablative Fractional Laser Systems should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Medical Non-ablative Fractional Laser Systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.
a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Medical Non-ablative Fractional Laser Systems is used exceeds the applicable RF compliance level above, the Medical Non-ablative Fractional Laser Systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Medical Non-ablative Fractional Laser Systems. c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4-4: Recommended separation distances between
portable and mobile RF communications equipment and the Medical Non-ablative Fractional Laser Systems

Recommended separation distances between portable and mobile RF communications equipment and the Medical Non-ablative Fractional Laser Systems				
The Medical Non-Ablative Fractional Laser Systems is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical Non-ablative Fractional Laser Systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Medical Non-ablative Fractional Laser Systems as recommended below, according to the maximum output power of the communications equipment				
Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

***Warning*:**

To avoid the risk of electric shock, the device must be connected to the power supply of an existing safety ground wire.

***Warning*:**

In addition to the accessories and cables provided by the manufacturer of this product, the use of accessories and cables other than those specified may result in increased emission or reduced immunity of the product.

This product should not be used near or stacked with other devices. If it must be used close to or stacked up, it should be observed to verify normal operation in its configuration.

Annex 2: Packing List

NO	Parts	PN	Count	Picture
1	FixCell(main console with handpiece)	F100001	1	
2	AccuTip	F211003	1	
3	EffiTip	F211001	1	
4	GrowTip	F211002	1	
5	OST-7	F213007	1	
6	OST-15	F213006	1	
7	Foot Switch	F113012	1	
8	Interlock	L013008	1	
9	Power cord （Choose one of them）	L143014	1	 Europe
		L143015		 Britain
		L143016		 China/Australia
		L143017		 U.S.A
10	Protection Goggle	F130011	1	

11	Eye Mask	L040008	1	
12	Trestle Assembly	F111002	1	
13	Front End Bracket	F112002	1	
14	Small Upright Assembly	F111003	1	
15	Cable Pipe Clamp	F132023	2	
16	Air Pipe Clamp	F132033	2	
17	Bandage	NF30014	1	
18	Prohibit Turning Cover plate	F112003	1	
19	Socket Countersunk Head Screws (M4mm*10mm)	1121119	1	
20	Hexagon Socket Round Head Screws (M4mm*8mm)	1121064	4	
21	Hexagon Socket Headset Screws (M5mm*18mm)	1121199	2	
22	Hexagonal Wrench Tool(2.5mm)	1121127	1	
23	Hexagonal Wrench Tool(3.0mm)	1121126	1	
24	Hexagonal Wrench Tool(4.0mm)	1121170	1	
25	Quicky Start Guide	F130409	1	