

# **ICE-XEL**

## **C02 Fractional Laser System**

### ***User's Manual***



**Version: 101009 V1.0**

**Dear customer,**

Thank you and welcome to choose our products of VIVA Concept Technology Co.,Ltd. To ensure proper use our products, we recommend that you read this manual carefully prior to operate. We believe that we can offer you satisfied service.

We can offer technical support for you at all times.

**Please note:**

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If there are any questions, please contact us!

**Pay Attention to Warnings, Cautions and Notes**

**WARNING** Warning means that not following instructions properly or ignoring them completely can endanger patients and/or operators.

**CAUTION** Attention means that not following instructions properly or ignoring them completely can damage the unit



**Warning**

**Read the user's manual prior to operation!**

**NOTE** Notes provide additional information.

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## Using this user's manual

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

Section	Contents
Preface	Brief technical overview and Medical use
Safety	General safety precautions when operating the device
Description	Description of the components and controls
Installation	Introduction of the installation and transport procedure
Operation	Operation of the device
Maintenance	Maintenance information
Clinical Application	Including application range, treatment process and side effect
Parameters selection	Basis of parameter selection and treatment evaluation
Specifications	Brief overview of the specification

## Pay Attention to Warnings, Cautions and Notes

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<b>NOTE</b>	Notes provide additional information



### NOTE

Read the user's manual prior to operation!

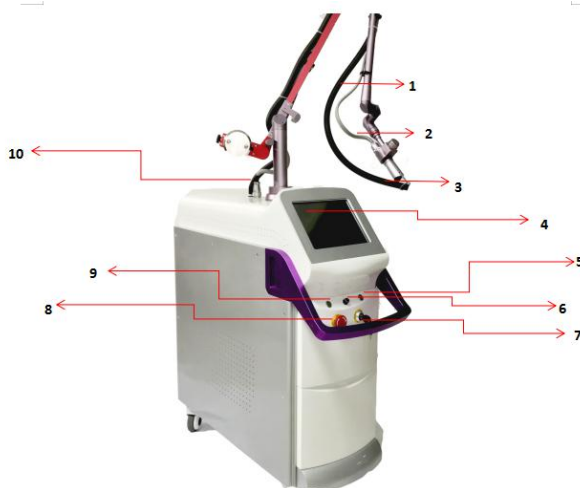
# Chapter 1 Preface

## 1.1 Overview

1. CO2 Fractional Laser System fires a laser beam through CO2 Fractional Laser tube, which split into numbers of microscopic beam producing tinier dot than general CO2 Fractional Laser System.
2. Comparing to conventional CO2 laser, CO2 Fractional Laser System source can emit steadier and more even laser. The treatment tip can vaporize the outmost layer of skin across a large surface by creating thousands of tiny, microscopic laser wounds, spaced in an even pattern across the skin, but leaving areas of healthy, untreated skin between them, the CO2 Fractional Laser System will generate heat effect on skin. The Photochemical reaction will improve collagen regeneration, which will accelerate skin self recovery, after the recovery of target skin, more whitening and smooth skin can be achieved.

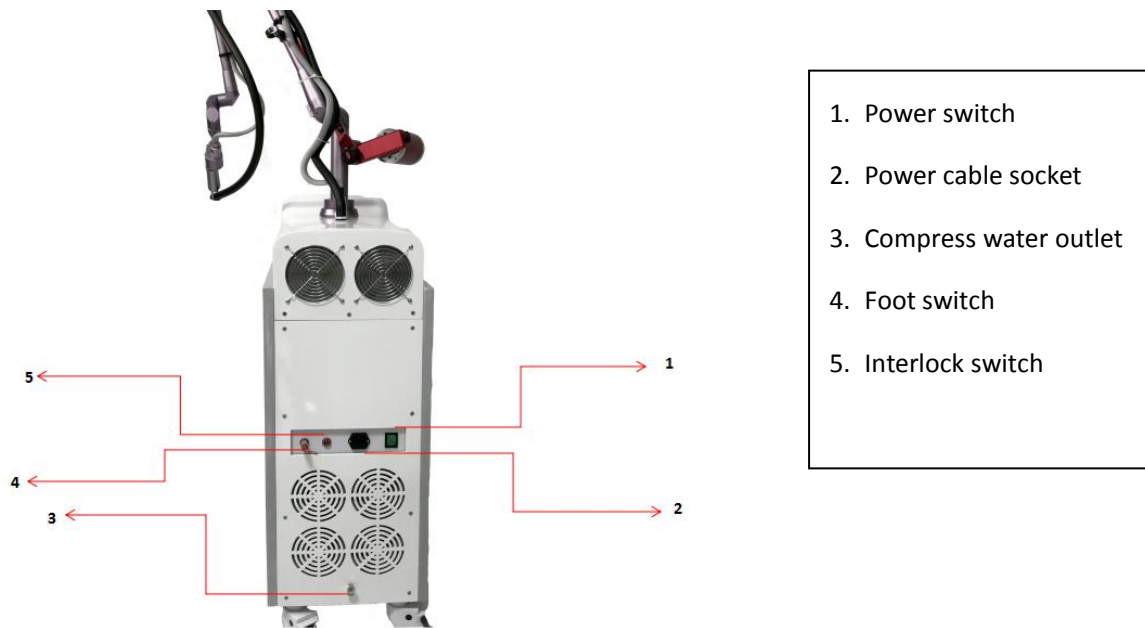
## 1.2 Parts introduction

### 1) Front view of the machine



1. Windpipe (black)
2. Data line ( gray)
3. Probe Fractional CO2 laser
4. Display
5. Compressor ON/OFF switch
6. Air speed adjustment button
7. Key switch
8. Emergency switch
9. Compressor frost removal
10. Air pipe connectors (white)

### 2) Back view of the machine



Name	Remark
Power switch	power on and off
Power cable socket	Inert power cable
Compress water outlet	Press the compressor defrost button, the compressor will automatically defrost and drain
Foot switch	Foot switch to control the light flash
Interlock switch	For clinic connect safety interlock switch



## Notice

**It is recommended that only the engineer who is authorized by the manufacturer may tear the seal of the back case for inspection and after maintenance. The customer is**

**not allowed to take apart of system by himself.**

### 1.3 Technology parameters

Name	Specification
Rated power consumption	800W
Pulse energy	1-30W (max 40w)
Laser wavelength	10600nm
Scanning graphic	Square, rectangle, round, oval, line graphics
Beam transmission	7-joint arm
Output type	Sequence mode, Random mode
Cooling	Wind cooling, Compressor cooling
Aiming beam	650nm
Aiming beam power	≤ 5mW
Scanning area	0.1*0.1mm - 20*20mm
Electrical requirements	220V±10%,50/60Hz or 110 V±10%,50/60Hz。
Display	10"True color touch screen
Net weight	100KG
Dimension( L*W*H)	52*117*117(cm)

### 1.4 Medical use-application areas

1. Skin renewing and resurfacing
2. Wrinkle removal. skin tightening
3. Acne and scar removal , melasma removal
4. Smooth burnt scars and surgery scars. traumatic scars ,etc.
5. Remove intractable chloasmas and pigmentation
6. Sun damage recovery
7. Collagen stimulation

8. Ablation and coagulation for the treatment of skin furrows and other textural irregularities

## 1.5 Environment requirements

Working temperature scope : +15~+30℃

Relative humidity scope: 30%-80%

Atmospheric pressure barometric : 86kpa – 106kpa

The store environment temperature: +5℃ - +55℃

Power supply: 220V±10%,50/60Hz or 110 V±10%,50/60Hz

Air quality: No caustic particle (such as acid) in the air, which can damage the electric wire, the electric component and optical component surfaces. The dust in the air should be as little as possible, or it can absorb the energy of light and be heated up. When the dust falls on the surface of the filter, it may damage the filter. Metal particles also could damage the electric component.

## Chapter 2 Safety

This chapter describes the proper use of the CO2 Fractional Laser System. Each operator must read and understand the User's Manual completely prior to starting the Device.

### 2.1 Responsibilities of the user



**WARNING**

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

Before each treatment, the user must check the functional performance of the device in order to avoid any risk of harm to patients or other persons. If the device is used together with peripheral units, the User's Manuals for the peripheral units must also be read thoroughly and understood.



### 2.1.1 Safety Measures

The laser is designed to prioritize the safety of the patient and medical personnel. The following are its parts of safety measures:

A. Upon switching on the system, the processor first undergoes a self-diagnostic test. The processor will then examine the system automatically and continuously during the entire treatment process.

B. Use the Turn on/off Switch to turn the power off in case of an emergency.

### 2.1.2 Safety Warning

Only personnel trained by the distributor are authorized to maintain the inner workings of this device. Any manipulation to the system may cause damage to the device and will void its warranty.

## 2.2 User Training



### WARNING

**The intense light delivered by this device may cause serious injury if handled improperly. All personnel using this device must remain vigilant and utilize safety protocols.**

The laser treatment systems require special expertise and care in its handling and use. Only persons who have received the required training, taking into consideration operating instructions, and who are familiar with its therapeutic effect and possible risks are permitted to use the laser unit.

Untrained or unqualified operating persons are not permitted to operate the laser treatment systems under any circumstances whatsoever. VIVA Concept CO.,LTD. offers comprehensive training courses for the Laser treatment systems.

Each user must have read and understood the User's Manual completely prior to starting the Laser treatment systems.

Patient's safety mainly depends upon a well-trained operators and a suitable treatment

room. The attending operators must inform the patient all the risks with the use of this device. The success of the treatment depends largely on the user's experience and knowledge of the biophysical connections.

## 2.3 Explanation to patients

The treatment process must be explained to the patient. The patient must give written-consent to the treatment.

## 2.4 Treatment Room








The treatment room should be clearly marked to prevent others from entering the room at the time of operation of the equipment. Do not allow the light to rays to fall on other locations of the skin than where the treatment is required. The entrance of laser treatment room should be labeled with warning signal of laser radiation, to prevent the entry in and exit out of the treatment room during treatment time.

Suggestion: Provide special-purpose laser operation room with air-conditioning, dehumidifier and so on. The operator and patient have their separate regions. The caution label should be pasted in the room before the surgical operation.

## 2.5 Transport Safety

Although the system is robust, you have to handle with care if you need to move it. This machine laser hull inside has nice optical system. The packing should be provided by the original factory in order to reduce the quiver in transportation, otherwise excessive shaking may cause the maladjustment of the laser system and influence output of the energy.



NO.	Mark	Specification
Label 1		Production information
Label 2		Sequence Number
Label 3		Product Date
Label 4		Product Address
Label 5		BF-type
Label 6		Conformity European
Label 7		Warning and Notice. Please read user's manual in detail

## 2.6 Safety Marking

The laser treatment machine uses the marking as follows. The marking sticks to the upper part of the machine box and the laser hull, Please keep in mind.

**Position: Back side**

## Chapter 3 Installation

The process of installation includes: (Performed by an authorized technician only)

1. Unpacking the device.
2. Staying the device for 24 hours, in order to avoid destruction by high humidity during long distant transportation.
3. Assembly of its components and ensure that all connections are firmly in place.
4. Installation treatment hand piece and connect the power supply.

5. Switch on the device and test all functions / parameters of the system.

After unpacking the parcel, before installing the device, **ensure that the device keeps the cool and dry place for 24 hours, in order to avoid destruction by high humidity during long distant transportation.**

### 3.1 Accessories

Name	Quantity	Model/Code
Eye-protection glasses	1	400nm-1200nm
Goggles	1	10600nm
Power cable	1	-----
Foot pedal	1	Big foot pedal
Bandage	10	-----
Galvanometer head	1	-----
Articulated arm	1	-----
User's manual	1	-----

### 3.2 Installation requirements

Before unpacking the Laser treatment systems, ensure that working environment conforms to the requirements of this section.

Before assembly of the device's components, ensure that high humidity is cleared away by opening the packing and staying the device for one day.

#### 3.2.1 Location Requirements

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

#### 3.2.2 Electrical Requirements

Before the Laser leaves the factory, it has already been marked the local rated voltage according to the customers' request. It corresponds to the electricity requirement as follows:

AC230V $\pm$ 10%, 10A, 50/60Hz. or AC115V $\pm$ 10%, 20A, 50/60Hz

Input electric current can't have momentary change, electric voltage or electric current

peak, sink. It is recommended that this device use a dedicated power supply with its own circuit breaker.



**CAUTION**

*Ensure that the electric voltage rating of this instrument (AC230V or AC115V refer to system labeling) matches the electric voltage of the outlet.*

### 3.3 Installation

#### 1) Disassemble the Package

After you Open the box, you will find the Unit machine pictures 1, the handle and spare parts like pictures 2



#### 2) Install the laser arm

##### 2-1) Install the laser arm main unit

The laser arm is 7 joint laser conductive passage, be careful not to take care and avoid heavy hits





Pay attention to this point mark,after you install laser arm right position,

Tighten the screws\*4 by screw drivers

### **2-2)Install Rubber cushion**



### **2-3)Install Counterweight**

Like the pictures, install the Counterweight and fix this with screws.



### 3) Install the black air pipe.

Connector one side to the machine with white connectors.the others side leave there.



### 4) Install the fractional heads and black pipe adaptor

One side connect the data cable to the machine, find the black spare parts pipe adapt like the pictures,install it with fractional together to laser arm end.others side install to laser arm like pictures.





5) **Install the pipe and cable fixed frame and bandage**



### 3.4 Move

If the device is to be moved within the general area,

1. Turn the equipment off
2. Put the treatment head on the support
3. Pull out the power cable
4. Relocate the unit (Avoid tilting the device)



**CAUTION**



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

## Chapter 4 Operation

This section describes the operational steps of the laser treatment system.



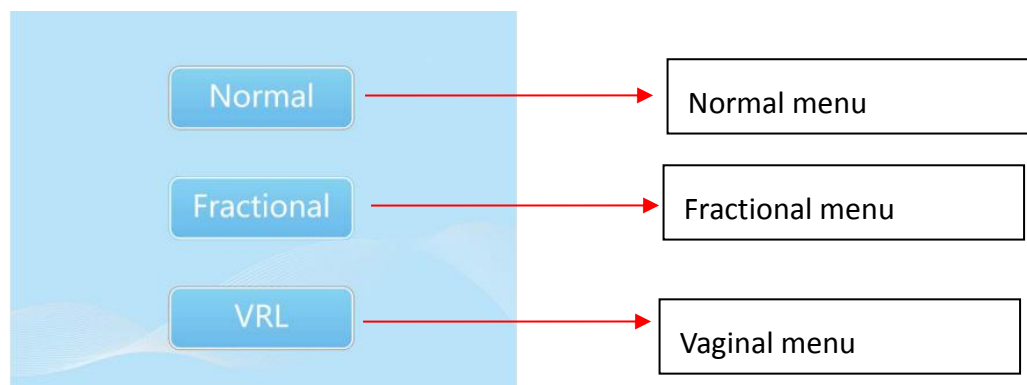
### Warning

1. There is high electric voltage in the laser treatment system, please must ensure that all front panels have been covered properly
2. When the laser treatment system starts, please keep the laser treatment head under control.
3. All personnel should be wearing the protection glasses in the treatment room.
4. Do not face the laser emission directly even with protective glasses on.
5. The laser treatment head must point directly at the target district.

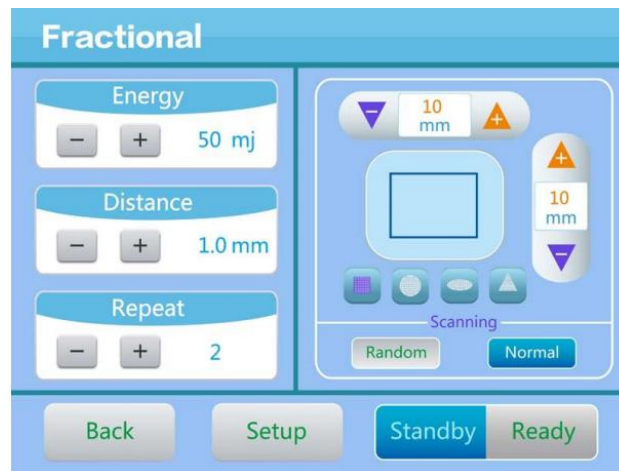
### 4.1 Laser treatment system software operation instruction

#### 1. Main interface

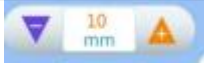

Connect power cable and the equipment, then turn on the machine; the treatment items will appear on the screen.



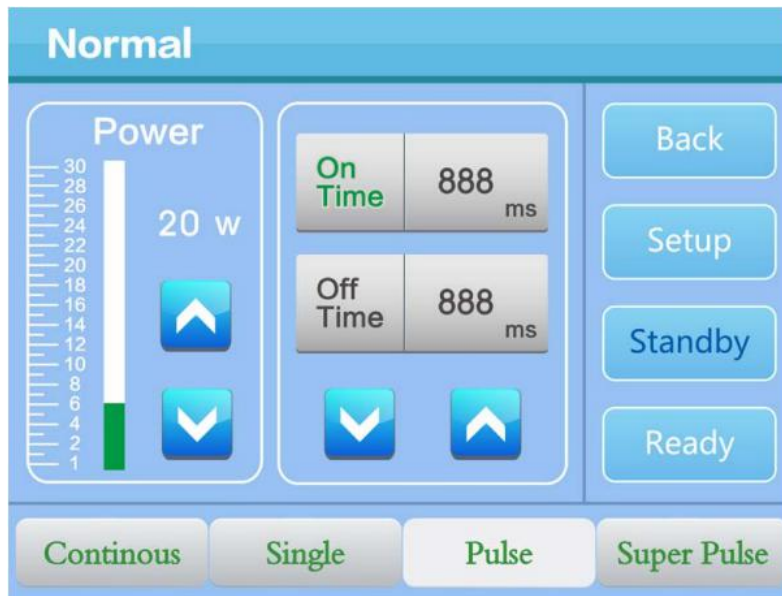
## 2. Fractional laser Menu:



	Press +,increase energy Press -,decrease energy	
	Press +,increase distance of points Press -,decrease distance of points	
	Press + increase scan times Press - decrease scan times	1-10 times
	Go back main interface	
	Set up mode	Do not change unless with engineer
	Press standby,	Laser is not ready for shooting
	Press Ready,laser is ready to shooting	
	Scan modes	scan points are not in order, randomly
	Scan modes	Scan points are performed sequentially from side to side
	Touch to choose different	

	scan shape	
	Graphic size change	you can change the shape size when press “+”, “-”
	Graphic size change	you can change the shape size when press “+”, “-”

### 3. Ultra-pulse Menu



The parameters of various items setting are the same as to CO2 Fractional Laser.

#### Explanation:









**Single mode:** Stepping the foot switch, it only emits a laser beam;

**Continuous mode :** Stepping foot switch, it emits laser continuously, emitting will stop when lifting foot switch;

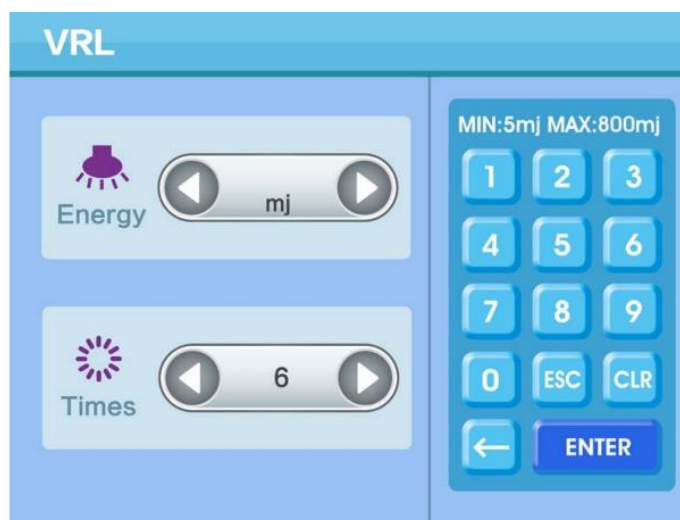
**Pulse mode:** Stepping foot switch, it will emits pulse continuously, emitting will stop when lifting foot switch.



**Super Pulse mode:** Stepping foot switch, it will emits super pulse continuously, emitting will stop when lifting foot switch.

Icon	Name	Function	Remark
------	------	----------	--------

	Power setting	Set power output	The range of power output is 1~30W
	Mode setting	Set working mode	There are three working modes: Single, loop and impulse.
	Laser output time setting	Set every laser output time	Interval used to the mode of Single, the range of its time setting is 1 ~ 100ms.
	Pulse width setting	Set pulse width	It can operate under the mode of pulse.
	Interval setting	Set pulse interval	It can operate under the mode of pulse.
	Standby/read y setting	Set working mode	— —
	Return	Switch to main interface	— —
	Up	Increase parameters	-----
	Down	Decrease parameters	-----

#### 4. Vaginal interface






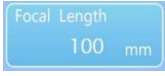

Icon	Name	Function	Remark
	Energy	Set laser energy	Adjust laser energy big and small or touch NO. directly input energy value on NO. Keyboard
	Times	Set laser scan times	1-10 times adjustable

## 5. Set up interface



Icon	Name	Function	Remark
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	Device ID	One machine one ID	ID can not change just display,show ID and SN for service.
	Red beam intensity adjust	Increase or decrease red light	Red brightness adjustable
	Factory mode	Engineer only	Engineer only
	Focal length	Tip 100 and 50 um use different	Standard setting by factory
	Back	Back to main interface	Back to main interface

### Danger

- 1.While entering the work mode, the laser head must not point at person; the laser head must aim at the target for treatment, and then press the pedal controller.
- 2.In spite of having the laser exportation or not, the laser treatment head cannot aim at operator and other non- sufferer.
- 3.The laser treatment head must not point at the eye.



## 4.2 Treatment

### 1. The procedure of treatment

- 1.Prior to treatment, operator must first get a detailed history, rule out any disorders that may contraindicate this treatment and finally physically inspect the treatment area.
- 2.Turn on the equipment, enter into treatment mode.
- 3.According to patients'situation , set treatment parameters.( At this time, treatment head don't aim at any person) Press working condition setting button and step foot

switch, begin to treatment.

4. When the treatment, observe the situation of patient, according to actual situation, adjust the parameters
5. During the treatment, avoid causing hurt, operator do the safeguard.
6. After treatment, close the power, smear cold gel on the treatment area.
7. Use damp and hot towel to clean treatment head, and then use the cotton ball with disinfection to disinfect treatment head.
8. Finally, treatment head put into the shipping container and plug power supply of equipment.

## **2. Nursing and announcement**

- 1) During the treatment, treatment head don't stay too long on the treatment area.
- 2) For treatment area, don't touch water for 24 hours, avoid cool water cleaning for 3-7 days.
- 3) Avoid hot and humid environment.
- 4) forbidden to eat spicy, seafood and stimulated food; eat less photosensitive vegetables (such as celery, turnip, spinach and caraway).
- 5) Pay attention to sun-care.
- 6) Forbidden to use efficiency cosmetics within 3 months.

## **Chapter 5 maintenance and support**

This section describes daily maintenance work of the Laser treatment system. It includes cleaning the equipment and leads the laser treatment head, replacing the laser treatment head etc. It also describes some familiar malfunctioning and solution.

The customer can carry out the listed maintenance measure in the chapter. Others are only can be maintained by authorized technical personnel of the dealer.



**Warning**

1. Before supporting this machine, the power supply must be cut off to avoid causing harm.

2.The customer is responsible for the damage caused by the following reasons:

①The customer dismantles the outer shell and accessories of the system without authorization.

②The contrived breakage, operation failure and the damage by maintenance for exceeding one's authority.

3.The damage of system caused by fire, the electric power system breaking down, lightning, flood disaster, blast.

## 5.1 Cleaning the equipment

Clean the outer part of the equipment weekly with soft wet tissue. You may also use a neutral detergent, but do not let the liquid sip into the machine.

## 5.2 Clean explanation lens of laser treatment head

After a period of using, check the cleanness of lens surface periodically. During the treatment pigment grains splash into the lens and affects output of light, causing blurriness of light. Use lens paper or cotton with absolute alcohols to wipe the lens lightly.

## 5.3 Obviate equipment malfunction

This section enumerated some malfunction phenomenon and obviating method:

phenomenon	Method
No display	Check power cable whether the connection is good
	Check whether the urgent switch is down, loosen the urgent switch clockwise.



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	If the air switch drops down, push up the switch, re-switch on. If the air switch drops down again, please contact the dealer.
	If the problem cannot be solved, please contact the maintain engineer.
While pressing the pedal controller , the system has no laser exportation	<p>Try to increase the work voltage to check whether the laser is emits or not.</p> <p>Check whether the system enters preparation mode or not.</p> <p>Check whether foot switch is normal or not, if it is damaged, replace it immediately.</p> <p>Check whether the “work” key is pressed or not.</p> <p>Please contact the dealer.</p>
The system cannot start	Rotate the key to proper position.
The laser outputs to becomes obviously weak or have" empty gun", not a laser	<p>The voltage might be too low and the equipment cannot work normally.</p> <p>The laser exportation lens is not clean; please wipe the lens.</p> <p>The laser light inside the machine is destroyed by fire, replace the laser gun;</p> <p>The instrument is too hot, shut down the laser for 30 minutes.</p> <p>Screw the treatment head down, check the front mirror, if it is damaged, replace immediately.</p>
The laser treatment head is leaks	If the laser treatment head is damaged, please change the laser treatment head or contact the dealer.
There is a ‘cheep’ sound in	The instrument does not be used over a long period,

the instrument operation process when pressing ready	<p>ready difficulty.</p> <p>The indoor temperature is too low, adjust to rise the indoor temperature properly, we suggest installing the air condition.</p> <p>Check the circuit immediately.</p> <p>The indoor humidity is too high, keep the room dry.</p> <p>The light is damaged, replace the light.</p>
The temperature of cooling system is higher	<p>Close the system; cool the system slightly, Re- start.</p> <p>Contact the dealer.</p>
The energy lowers gradually when using	<p>Check whether there are impurities on the mirror surface or not. If there is dust clean it.</p> <p>Whether the temperature of the handle is too hot or not, Leave the machine to cool for 30 minutes.</p> <p>Check if the front mirror is intact or not, if the mirror is broken, please contact the seller.</p>
The power of The laser treatment head goes down	<p>The life of laser treatment head is not long.</p>
The laser breaks down	<p>The light in the laser machine must be replaced. The treatment head probably is damaged, please contact the dealer.</p>

## Chapter 6 Other Contents

### 6.1 Operation skill of cosmetology

#### Attention

Please find out whether the customer has scar constitution, peeling skin or allergic skin first. Ask customers if they have artificial eyebrow, or purified of embroider, eyebrow and tattooed with other methods before. Observe if the scar had existed already. Explain to the patient that the pigmentation trace will remain for a period. The treatment must be repeated after 45 days. The beautician should build up the **Treatment File** for the customer.

## 6.2 Daily maintenance

A. maintenance:

a. machine insulation prohibited

b. take hope-pocket cover lens against dust, including whole machine. It's important.

c. take care of probe (important).

B. Maintains: unprofessional operator prohibited

## 6.3 Compare pictures

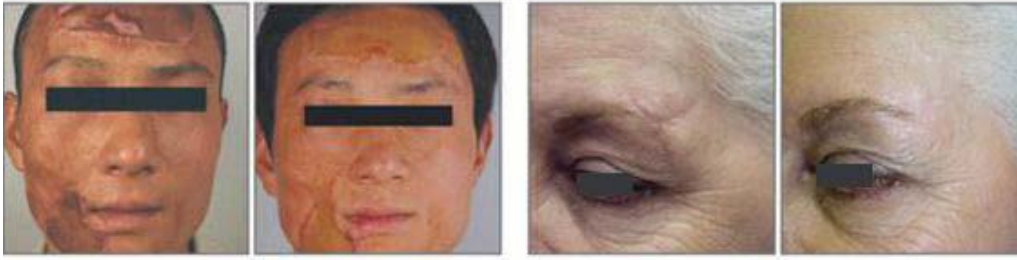
Acne removal



Wrinkle removal



Scar removal



Coffee spot removal



keratosis seborrheica



**Appendix:**

- 1.The technique items in the manual may be improved, please contact our company as request.
2. Electric principle diagram and part list will be provided as request.