

SHR + IPL/E-light 2 in 1 Treatment System User's Manual



Version: *150108 2.0*

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.
NOTICE	Notes provide additional information.



Notice

Read the user's manual prior to operation!

Notes to users:

1 If it is the first time for you to use OPT Instrument., be sure to carefully read this manual before powering on the appliance.

2 It is suggested that do not use the SHR Instrument. with the existence of electromagnetic interference, vibration and other environmental conditions with interference. During operation, the Radio frequency Instrument does not interfere other equipment /devices.

3 For safety purposes please pay special attention to the **Notes** and **Cautions** printed in red. These Notes and Cautions are indispensable for the correct and safe operation of this machine and the machine will provide a perfect and effective service for you.

4 The abandoned components from the scrapping or replacement of Radio frequency Instrument should be delivered to the designated agency or manufacturer for joint

treatment, so as to avoid environmental pollution.

5 All contents of this document are under the protection of copyright laws. This manual may not be reproduced or stored in database or retrieval system by any organization or individual without the express written permission of VIVA Concept technology Co., Ltd.

The differences between SHR and conventional IPL Laser

Traditional laser or IPL technologies employ short impulses of approximately 2-300 milliseconds, applying a vast amount of energy (12-120 J/cm²). Energy is transported to the hair root through melanin, where warmth of 65-72° Celsius is produced. Energy reaches the root of the hair follicle solely through melanin. Skin and red blood cells have a similar absorption coefficient as melanin and therefore also absorb the high levels of energy produced by the laser and IPL methods.

SHR technology, on the other hand, utilizes the melanin path only partially (50%), and combining In-Motion technology, gently warms the skin helping penetrate down to the follicles which produce hair growth.

Research has shown that a slower, but longer heating process is considerably more effective for permanent hair removal than high and short levels of energy. Therefore, when using SHR, the device is passed over the tissue multiple times (in motion) using low energy but a high rate of repetition (up to 10Hz, i.e. 10 times per second) instead of using the traditional method with single, high-energy impulses. Thus, the hair melanin, as well as the tissue of the stem cells, is heated with low energy at a slow pace and over a longer period of time to a comfortable temperature of 45° Celsius.

Contents

Chapter 1 Description of Machine	5
1 The principle of Super hair removal	5
2 Parameters of Super hair removal	5
3 Therapeutic range	6
4 Parts Contents.....	6
5 Parts introduction.....	7
6 Move	8
7 Transport and Storage procedure.....	8
Chapter 2 Safety	9
1 Safety measure.....	9
2 Safety Warning	9
3 User training	9
4 Explanation to Patients	10
5 Treatment Room	10
6 Safe Classification of Equipment	10
7	Fire Prevention
Error! Bookmark not defined.	
8	System Safety
Error! Bookmark not defined.	
9	Safe Classification of Equipment
Error! Bookmark not defined.	
10 Label of Equipment.....	10
Chapter 3 Installation	13
1 Installation Requirements	13
2 Installation.....	13
Chapter 4 Operation	18
1 The main menu interface.....	18
2 SHR therapy interface (Super Hair Removal).....	19
3 User Setting Menu	20
4 Recharge the IC card number	Error! Bookmark not defined.
Chapter 5 Clinical guidance	23
1 Treatment Parameters.....	23
2 Treatment must know.....	23
3 Treatment Procedures	24
4 Contraindications.....	25
5 Parameter Principles	25
Chapter 6 Maintenance	26
1 Refilling the water supply	26
2 System trouble shooting.....	26

Chapter 1 Description of Machine

1 The principle of Super hair removal

Based on the optimized pope technology on the basis of hair removal treatments and the filter with a wave band of 950-1200nm which is easily absorbed by water. This targets the specific area by a spectral range of 950nm, thus minimizing the accumulation of epidermal heat and burning. Since the spectrum is precise and optimized, the treatment will be able to penetrate deep into the skin with less energy and reach deep target tissues, improve the therapeutic effect and shorten the course of the treatment. The 650-950nm wide spectrum has an effect within the hair melanin of follicles without damaging the epidermal but targeting the hair follicles effectively, achieving excellent results for permanent hair reduction.

2 Parameters of Super Hair Removal

Parameters of super hair removal

Parameter	value
Power of power supply	3500 W
Capacitance	3
Wavelength (Spectrum)	<ul style="list-style-type: none">• 650-950nm(SHR)• 415/515/645-1200nm (E-light)
RF Power	Max. 100W
RF Energy	Up to 50W
Energy Density (Fluence)	10 - 60 J/cm2 adjustable
Spot size	<ul style="list-style-type: none">• 18x50mm2 (SHR);• 18*30mm2 (E-light-interchangeable)
Pulse Repetition Rate	0.2Hz; 2Hz
Pulse Duration	0.5-15ms
Pulse Delay	1-50ms

Pulses	1-15 pulses
Cooling	<ul style="list-style-type: none"> • Continuous Crystal contact cooling (-5°C~1°C) + • Air cooling + Closed water circulation cooling
Stand-by Working	Continuously for 20 hours
Display	10.4 color touch screen
Electrical Requirements	100-240VAC, 20A max., 50/60Hz
Dimensions (WxDxH)	65*45*115cm
Net Weight	60kgs

3 Therapeutic Range

- 1.Hair Removal;
- 2.Skin Rejuvenation;
- 3.Vascular and Pigmented Lesions;
- 4.Acne;
- 5.Skin Tightening and Face Lifting

Note: The treatment of hair removal such as the cheek, lip, beard area, neck, back, chest, armpit, arm, bikini, leg

4 Parts Contents

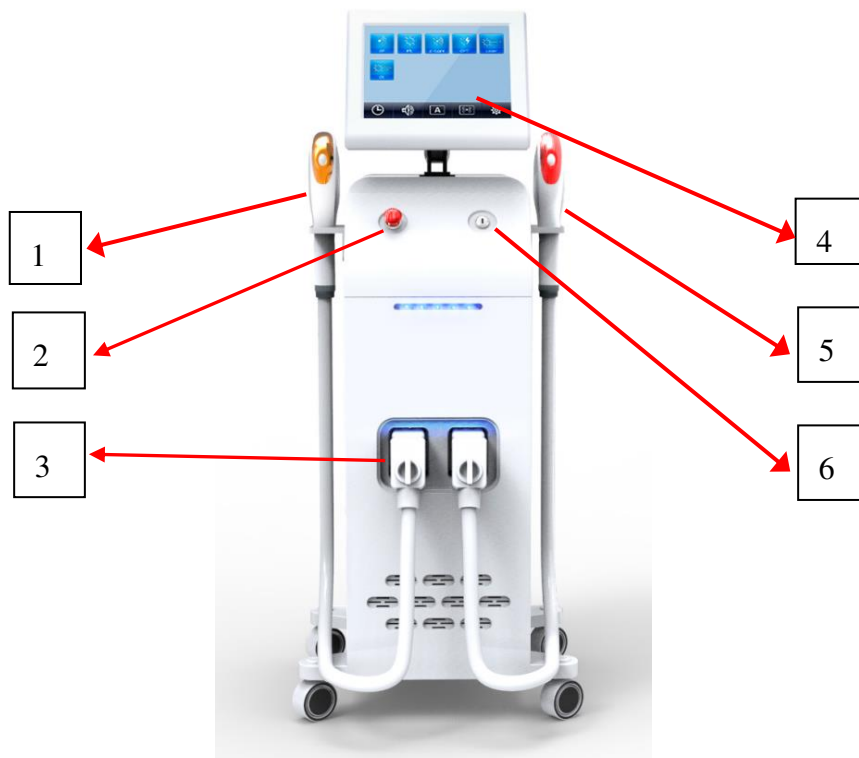
After you received the machine, please check all the parts of the machine according to the following Packing Contents List at first, and contact us immediately if you find any lost and damaged parts inside the packing.

Name	Specification	Quantity	Remarks
Main machine		1set	
Main machine		2 pc.	Amounted on the machine
User manual		1	
Power cable		1	

Water pipe		1	
Eye shield		1	
Hand piece		2	
Key		1	
Funnel		1	
Support		1	

5 Parts Introduction

1) Front view of the machine



1 IPL Treatment Hand piece

2 Emergency Switch

3 Hand piece Connector

4 Control Panel

5 SHR Treatment Hand piece

6 Key

6 Move

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

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

7 Transport and Storage procedure

1) Procedure

1. The cooling water in the instrument should be let out and cleaned during storage and transport.

2 .The device should vertically be installed in the outer packing box during transport. The instrument is fixed on the base >550mm×490mm×430mm so that the wheels of the instrument will not glide.

3. There are waterproof and soft gasket material in the outer packing box of the instrument and handle with care which the instrument should be supported by natural damage. The markings such as “Handle with care”, “No wetness”, “up” should be on the box.

2)Environment

1. Environment temperature range: +5 °C~ +55 °C ;
2. Relative humidity range: 30%~80%;
3. Atmospheric pressure Range: 86kpa -106kpa.

Chapter 2 Safety

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.

1 Safety measure

The IPL System 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 program. The processor will then examine the system automatically and continuously during the entire treatment procedure.

B. Use the Emergency Cut Off Switch (red button) to turn the power off in case of an emergency.

C. Remove the Key when not in use to prevent unauthorized access to the device.

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.

3 User training

The IPL Systems requires special expertise and care in its handling and use. Only persons who have received appropriate handling training on the device, 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 personnel are not permitted to operate the IPL Systems (with RF Function) under any circumstances whatsoever. VIVA Concept Technology Co., Ltd. offers comprehensive training courses for the IPL Systems.

Each user must have read and understood the User's Manual completely prior to starting the IPL Systems.

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

treatment room. The attending operators must inform the patient all inherent 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.

4 Explanation to Patients

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

5 Treatment Room

The treatment room should be clearly marked to prevent unnecessary access by other personal during the procedure.

6 Safe Classification of Equipment

The equipment safe classification: Electric shock protection — class I, type BF equipment;

Corrosion preventing liquid: commonness;

Can't use this IPL (with RF Function) system in the environment where the combustibility, anaesthetic and the air or carbon monoxides mixture exist.

Operating mode: Consecution.

7 Fire Prevention

The intense pulsed light device generates thermal energy. Avoid using combustible material such as acetone or alcohol in the operative field. If alcohol based products are used to disinfect the IPL device, ensure that the alcohol has completely evaporated prior to operation.

8 System Safety

The key switch is used to turn the unit on and off. Please 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 in a counterclockwise direction. Rotating the emergency cut off switch in the direction indicated by the white arrows will release the button.

A 10-ampere circuit breaker is installed behind the device adjacent to the power cord. Loads in excess of 10 amperes will trip this switch. Simply moving the switch upward

will restore power to the system. A self-diagnostic program then initializes the system and will continuously monitor the circuitry during operation.

9 Safe Classification of Equipment

The equipment safe classification: Electric shock protection — class I, type BF equipment;

Corrosion preventing liquid: commonness;

Can't use this IPL system in the environment where the combustibility, anaesthetic and the air or carbon monoxides mixture exist.

Operating mode: Consecution.

10 Label of Equipment

10.1 NAME PLATE (Model) LABEL :

Position: back side

Model Name: VA-307

Product Name: Intense pulsed light therapy system

Power Supply: 100V, 50/60Hz, 10A

SN VIVA Concept Technology Co., Ltd.



Floor 3, Building Rundu, Fengtai District, Beijing China.

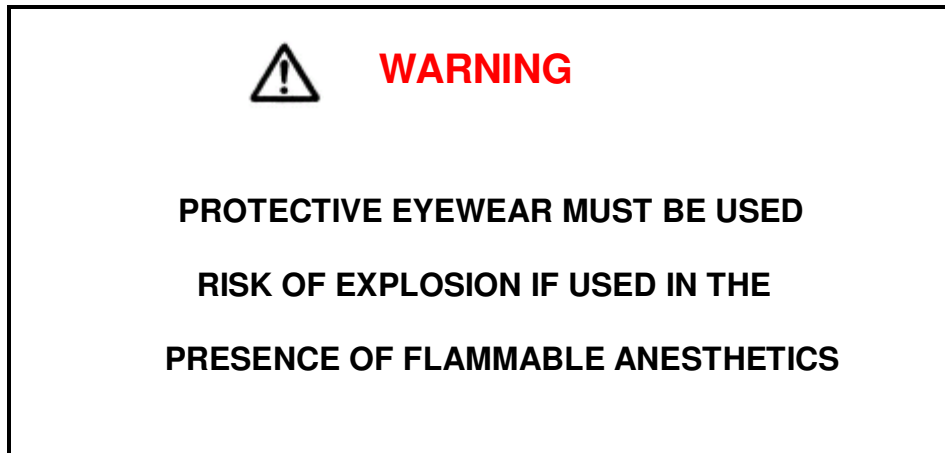
TEL: + (8610) -69257269

FAX: +(8610) -60252621



Before operating and maintaining the IPL Hair Removal , please read user's manual in detail

2. WARNING LABEL : Position: front side



3. CAUTION LABEL : Position: cover back side



2) DANGEROUS VOLTAGE WARNING LABEL : Position: inside



Chapter 3 Installation

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

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

1 Installation Requirements

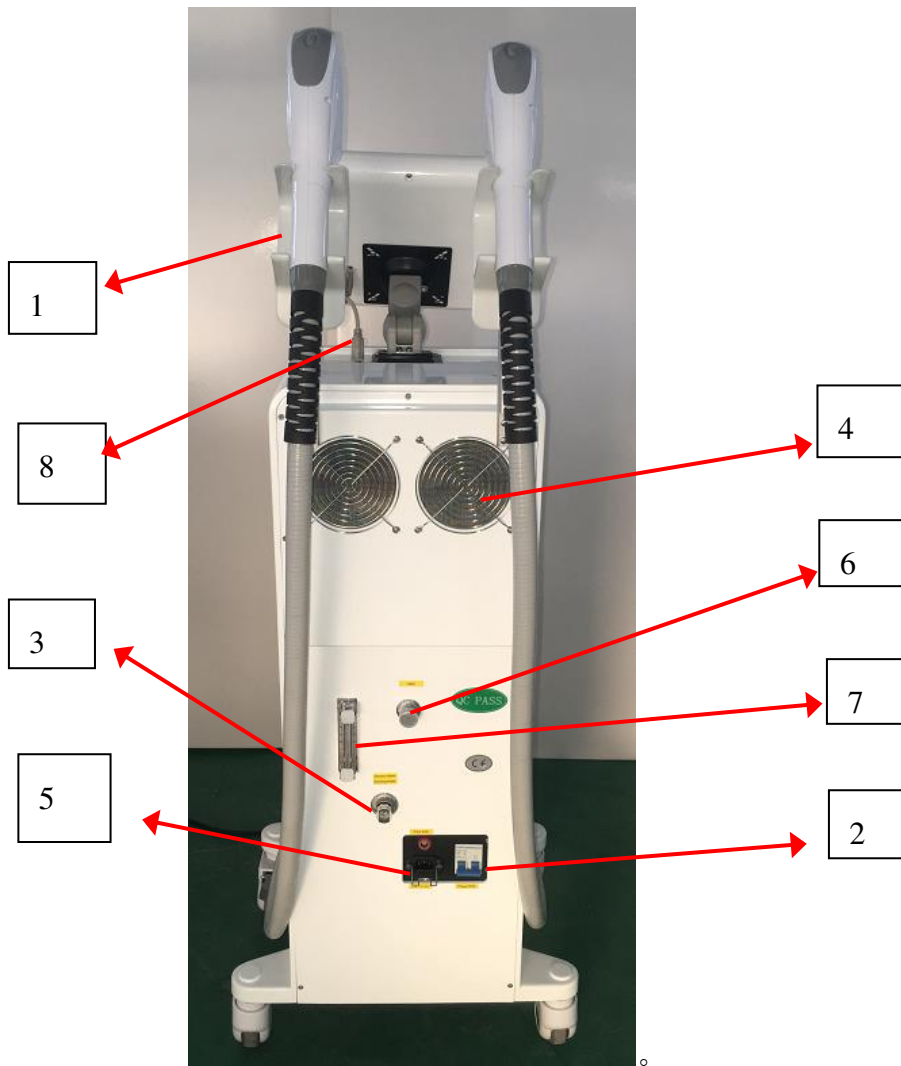
Before unpacking the IPL Systems, ensure that working environment conforms to the requirements of this section.

1. Unpacking the device.
2. Staying the device for 12 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. Fill the water tank with distilled water only.
5. Installation treatment handpiece and connect the power supply

Before assembly of the device's components, That is to say, after unpacking the parcel, before installing the device, ensure that the device keeps the cool and dry place for 12 hours, in order to avoid destruction by high humidity during long distant transportation.

2 Installation

1) Back view of the machine



- | | |
|-------------------------|------------------------|
| 1. Handpiece support | 2. Power supply switch |
| 3. Drain/Infusion Tap | 4. Ventilation |
| 5. Power Socket | 6. Vent |
| 7. Water viewing window | 8. Data cable |

2) Connection of hand piece with machine



Fig 1



Fig 2



Fig 3

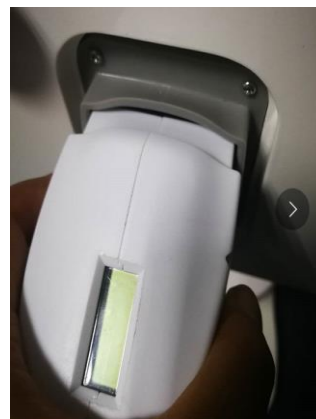


Fig 4



Fig 5

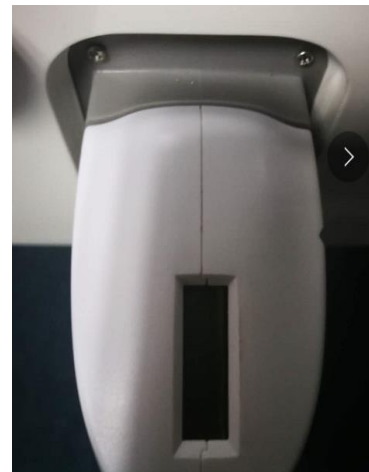


Fig 6



Fig 7

First: press the two gray buttons at the both sides of the handle.

Second: make sure the contact pins are aiming at corresponding position.

Third: plug the upper pin directly to the upper socket, then insert the lower one.

Attention: The installation of another handpiece are the same to the first handpiece



WARNING

This is essential to be sure to tighten the connectors, or high voltage is easy to poor contact, contact terminal will be burned off. In addition, easily caused leakage of water injection connector.

3) Fill Water



A

Fig6

B



Fig 7

C



D Fig7



Water Viewing Window

Installation:

- 1 Insert B into C
- 2 Insert A into D (D refers to 6 in Fig 3)
- 3 Fill water

At the same time, observe water gauge, when water reaches the water gauge of 80%--90% ,
Stop filling water.

Attention:

- 1 Use purified water or water without hydrogen, strictly prohibited mineral water
- 2 Replace water every 2-3 month.



CAUTION

- a) Only distilled water is to be used in the cooling system.
- b) When using the system for the first time, rinse the cooling system with distilled water.
- c) Ensure that the water level is adequate before treatment to prevent over heating.
- d) Distilled water is added periodically specially when working in warmer climates and when the treatment handpiece are changed often.
- e) Make sure that the treatment head is firmly secured and the screw caps are firmly screwed into place prior to operation.




Chapter 4 Operation






1 Main Menu Interface




Fig 9

The main function interface description

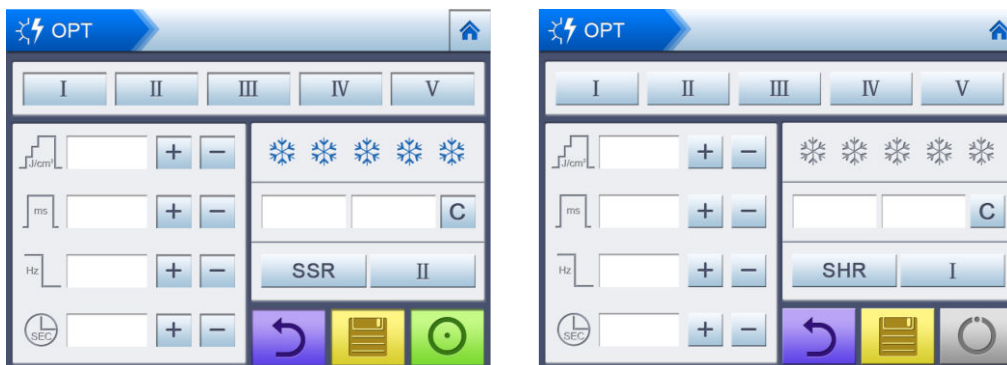
	Icon	name	Function
The main power icon		Rapid hair removal function icon	Switch to rapid hair removal treatment interface
Setting icon		The setting icon for the user	Pop-up user settings menu
The icon of system		The icon of the water flow	Shows the current water level



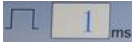








instructions		alarm	
		The icon of the temperature alarm	Shows the water temperature
		The icon of charging	Shows the need to charge the device
		The icon of simmering instructions	Shows the current situation of simmering of the device
		The icon of tone instruction	Shows the situation of the tone of the device
		The icon of the time display	Shows the time

Note: The device configuration is different, the main function shows different

	The icon of closing the interface	Close the interface of selecting the handpiece
---	-----------------------------------	--

2 SHR therapy interface (Super Hair Removal)



Icon	Name	Function	Remark
	Pre-store parameter select button	Choose pre-store therapy parameter	Up to pre-store 5 groups parameters
	Power	Display setting power	The range of power is 1-26J/cm ²
	Pulse Width	Display setting width	The range of pulse width is 1-15(ms)
	Frequency	Displays frequency	The range of frequency is 1-10(HZ)
	Working time	Shows working time	The range of time is 1-30(s)
	Adjustment button	Setting parameter+	——
	Adjustment button	Setting parameter-	——
	Cooling intensity settings button	Setting cooling intensity	The range of cooling intensity is 1-5 grade
	Save button	Save setting parameter	——
	Return button	Enter main function interface	——
	standby/Ready button	Standby/Ready situation	——

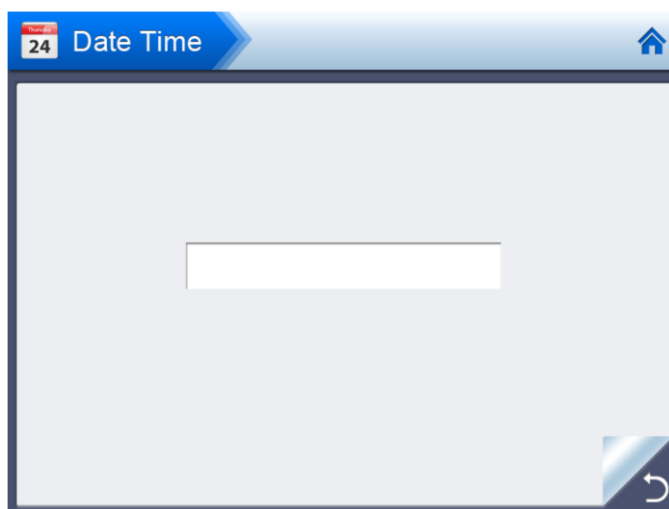
Enter SHR therapy interface, press parameter select button, click +/- to set, then press save button to save parameter. Press Ready button, system enters standby situation. At this time, press handpiece switch or foot switch, handpiece can output intense pulse light.

3 User Setting Menu

User press function button correspondingly, system enters function interface correspondingly.



1) Time and Date



Press "time and date" setting button, system enters time and date setting interface, as picture shows, first click "SET" button, and then click required numbers to set. Finally press "OK" button, save the setting and close setting interface.



2) Touch screen calibration



Press handpiece Trigger switch, Press touch screen calibration button, system enters touch screen interface.


3) Warning tone setting



Press Warning tone setting button, system enters warning tone interface, press the volume of tone, set tone. Press , open or close system warning tone, finished settings, press , system close warning tone interface.

4) Language setting







Press language button, system enters language setting interface, as picture shows, press language icon to set, finished it, press “”, system close language setting interface.

5) System Setting

The Equipment only allow authorized engineer to set up the system.

Chapter 5 . Clinical Guidance

1 Treatment Parameters

Skin type	 Energy	 Pulse	 Frequency	 Timer
I	9J/cm ²	10-15ms	11Hz	1-4S
II	9J/cm ²	10-15ms	11Hz	1-4S
III	8J/cm ²	15ms	10Hz	1-3S
IV	3-5J/cm ²	20-25ms	5-8Hz	1-3S
V	3-5J/cm ²	20-25ms	5-8Hz	1-2S

2 Treatment must know

1. Prior to treatment, the physician must first get 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 non-alcohol containing neutral cleansing agent such as Bactolin™, Cetaphil™ Gentle Skin Cleanser or Celeteque Facial Wash.
3. Apply a generous amount of cooled gel (non-tinted) on the treatment area.
4. A slight erythema may appear after the procedure. This is normal and will fade gradually in a few minutes to hours.
5. Always record the parameters, fluence, shots and the area treated after each treatment.
6. Apply a cold compress prior to proceeding to the next treatment area.
7. Avoid use of cosmetics for 24 hours after each treatment.
8. Avoid sun exposure after each treatment

3 Treatment Procedures

- 1 Open the machine, make the water circulation in a good condition.
- 2 Scrape the hair and leave about 1mm long.
- 3 Clear the treatment area.
- 4 Enter the main working interface, and adjust the treatment parameters according to skin type and hair color.
- 5 Smear cold gel to the skin, treatment head close to the skin surface of 1 to 2 mm. for sensitive parts, the gap is about 3mm, such as the lower eyelids, lips.
- 6 The operator wear protection eyeglasses and the client wear goggles.
- 7 Press the “Simmer”, and shot the handpiece 2-3 shoots on the floor. If a patient is the first time to have treatment, the operator need to test two to three spot behind the patient ear, and observe its response, adjust the scale and energy.
- 8 The treatment direction guide: from bottom to top, from outside to inside, first facial, perioral sequence of operations extended from the forehead to the nose. The degree of overlap of each spot is a spot size of 1/3. Around the eyes and forehead, first of all, adjust the energy, then operating.

when the treatment area has no obvious skin reaction, the operator can increase energy density, but not exceed 1 to 2 J/cm² energy.

9 Treatment is over, clean the handle head and treatment area.

4 Contraindications

Treatment area has inflammation, infections or dermatosis.

Patients with defective, hemorrhagic disease, or skin cancer.

Patients those have scar formation history or diseases such as

Gravida, Herpes or Simplex.

Actinic Dermatitis or taking photosensitive drugs.

The hair removal treatment is unavailable for sun burnt skin as treatment should be postponed for 2 - 3 months.

Patients with Botox injections, hyaluronic acid should do treatment after half a year.

Treatments are also forbidden for patients who have just had plastic surgery, have deep scars, wounds or the nevus area.

5 Parameter Principles

The darker the skin	<ol style="list-style-type: none"> 1. Decrease the fluence 2. Increase the pulse delay (allow more cooling)
The lighter the skin	<p>Increase the fluence</p> <p>Decrease the pulse delay</p>
The darker the hair / pigmented lesion	<ol style="list-style-type: none"> 1. Decrease the fluence 2. Increase the pulse delay (allow more cooling)
The lighter the hair / pigmented lesion	<ol style="list-style-type: none"> 1. Increase the fluence 2. Decrease the pulse delay
Fine blood vessels	<ol style="list-style-type: none"> 1. higher fluence 2. Decrease the pulse delay 3. Decrease the pulse width
Thicker blood vessels	<p>Increase pulse delay (allow more cooling)</p> <p>Increase the pulse width</p>
The smaller the target size / lesion	<ol style="list-style-type: none"> 1. Decrease pulse delay
The larger the target size / lesion	<ol style="list-style-type: none"> 1. Increase pulse delay (allow more cooling)
Bony prominences (forehead, malar area, shins)	<ol style="list-style-type: none"> 1. Decrease the fluence by 10-20%

5 Side effects

During the treatment it is normal to have mild sensation, erythema on the treatment area. Where necessary also apply cold compresses and aftercare creams.

Chapter 6 Maintenance

1 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 within the midpoint of this window. Distilled water can be added.

2 System trouble shooting

No power	Check power cable
	Check circuit breaker / fuse
	Check key switch
	Disengage the emergency cut off switch by rotating towards the direction of the arrows indicated
	Notify your distributor
Key pads are none responsive	Please contact the dealer.
System failed to initialize	Not enough power, please check main power supply. Please contact the dealer.
Malfunction of flash lamp on the IPL treatment head	The IPL treatment head is probably damaged, please change the IPL treatment head or contact the dealer.
The IPL treatment head is leaking	O-Ring for faucet is likely to lose, Pull out the treatment handpiece, then take out O-Ring from accessories and push into <u>water conduit</u> . The SHR treatment head is probably damaged, please change the SHR treatment head or contact the dealer.
The treatment handle is warm	The system is designed for continued used for up four

	<p>hours in optimal environmental temperature and humidity.</p> <p>Always place the system on 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 re- start</p> <p>Contact the dealer.</p>
--	--

Annotations:

- 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**