SHR Treatment System User's Manual

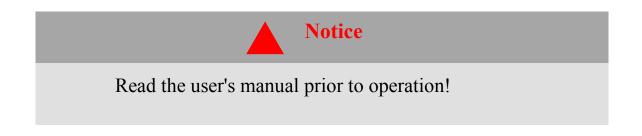


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Pay Attention to Warnings, Cautions and Notes

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	

NOTICE Notes provide additional information



Notes to users:

1 If it is the first time for you to use SHR 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.

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The differences between SHR and IPL,Laser Technology

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.

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Chapter 1 Description of the 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

Parameter	value
Power of power supply	2500 W
Capacitance	2
Filter	650-950nm
Energy	1 - 26 J/cm2 adjustable
Counter of pulse	Single
Pulse width	1-15 ms
Frequency	1-10 HZ
Working hours	1-30S
Spot size	18*50 mm
Display	8.4 color touch screen

Parameters of super hair removal

3 Therapeutic range

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	VIVA-100	1	
User manual		1	
Power cable		1	
Water pipe		1	
Eye shield		1	
Handpiece		1	
Кеу		1	
Funnel		1	
Support		1	

5 Parts introduction

1) Front view of the machine



1 Display	2.LED
3 SHR handle	4. Emergency Switch
5.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 $\times 490$ mm $\times 430$ mm 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 SHR Systems under any circumstances whatsoever. VIVA Technology Co.,Ltd offers comprehensive training courses for the SHR Systems.

Each user must have read and understood the User's Manual completely prior to starting the SHR 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 SHR system in the environment where the combustibility, anaesthetic and the air or carbon monoxides mixture exist.

Operating mode: Consecution.

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 SHR 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.

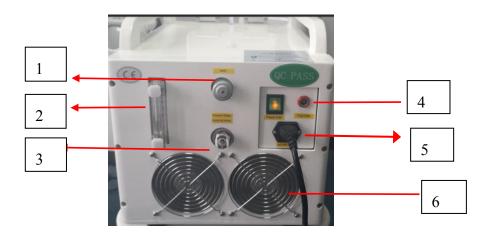
4. Fill the water tank with distilled water only.

5. Installation treatment handpiece and connect the power supply

Before assembly of the device's components, 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



low

2) Connection of handpiece with machine

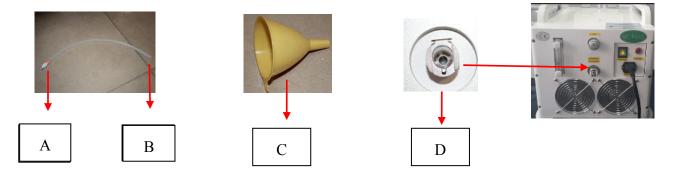






First: press the two gray buttons at the both sides of the handle.Second: make sure the contact pins are aiming at corresponding position.Third: plug the upper pin directly to the upper socket, then insert the lower one.

3) Fill Water



Installation:

1 Insert B into C

2 Insert A into D

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.



- 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 The main menu interface



The main function interface description

	Icon	name	Function
The main		Super hair	Switch to rapid hair removal treatment
power	-5,4	removal	interface
icon	OPT	function icon	
Date		The icon of the	Shows the time and set time and date
setting		time display	
Sound	T)	The icon of	Shows the situation of the tone of the
setting	N ²	tone instruction	device
Language	Α	The icon of	Select your local language.
setting		language	
		setting	
Update	((•))	No useful	Not open (OEM)

Setting	 Ø	Factory setting	Contact factory	
icon				

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

2 SHR therapy interface (Super Hair Removal)



Icon	Name	Function	Remark
I	Pre-store	Choose pre-store	Up to pre-store 5 groups parameters
	parameter select	therapy	
	button	parameter	
	Power	Display setting power	The range of power is 1-26J/cm ²
Hz	Pulse Width	Display setting width	The range of pulse width is 1-15(ms)
Hz	Frequency	Displays frequency	The range of frequency is 1-10(HZ)
(Lec	Working time	Shows working time	The range of time is 1-30(s)
+	Adjustment button	Setting parameter+	
_	Adjustment	Setting	
	button	parameter-	
業	Cooling intensity	Setting cooling	The range of cooling intensity is 1-5
	settings button	intensity	grade

	Save button	Save setting parameter	
5	Return button	Enter main function interface	
0	standby/Ready button	Standby/Ready situation	
3 41	The icon of the water flow alarm	Showsthecurrentwaterlevel	The icon of the water flow alarm
8 47	The icon of the temperature alarm	Shows the water temperature	The icon of the temperature alarm
9	The icon of charging	Shows the need to charge the device	The icon of charging
*	The icon of simmering instructions	Shows the current situation of simmering of the device	The icon of simmering instructions

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 corresponding

1) Time and Date



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

2) Sound setting



Press button to set system soundings,type in 0-20 value ,turn up and turn down sounding value.

3)Language setting



Α button, system enters language setting interface, as picture shows, Press

press language icon to set, finished it, press "Martin", system close language setting interface.

4)System update (no useful now)



button is for future update use, now is not available.

5)System setting



button go to factory mode, The Equipment only allow authorized Press engineer to set up the system.

Chapter 5. Clinical guidance

1 Treatment Parameters

Skin type	LJ/cm ² L	Hz	GEE
	Energy	Frequency	Timer
I	11-13J/cm2	5-7Hz	1-4S
П	10-12J/cm2	4-5Hz	1-4S
Ш	10-12J/cm2	3-4Hz	1-38
IV	7-9J/cm2	3Hz	1-38
V	7-8J/cm2	3Hz	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 BactolinTM, CetaphilTM 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.

5 Parameter Principles

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.

The darker the skin	1. Decrease the fluence
	2. Increase the pulse delay (allow more cooling)
The lighter the skin	Increase the fluence
	Decrease the pulse delay
The darker the hair / pigmented lesion	1. Decrease the fluence

	2. Increase the pulse delay (allow more cooling)
The lighter the hair / pigmented lesion	1. Increase the fluence
	2. Decrease the pulse delay
Fine blood vessels	1. higher fluence
	2. Decrease the pulse delay
	3. Decrease the pulse width
Thicker blood vessels	Increase pulse delay (allow more cooling)
	Increase the pulse width
The smaller the target size / lesion	1. Decrease pulse delay
The larger the target size / lesion	1. Increase pulse delay (allow more cooling)
Bony prominences (forehead, malar	1. Decrease the fluence by 10-20%
area, shins)	

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.

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.

2 System trouble shooting

Malfunction of flash lamp on the SHR treatment head	The SHR treatment head is probably damaged, please change the SHR 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 hours in optimal environmental temperature and humidity. 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 Contact the dealer.

Annotations:

- 1. The technical 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.

Manufacturer Name: VIVA concept Technology Co.,Ltd