# SDL-L

**Diode Laser Therapy Systems** 

**User Manual** 

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Beijing Sincoheren Science and Technology Development Co., Ltd.

# Contents

1. Overview	5
1.1 Copyright	5
1.2 Models Nomination	6
2. Storage and Transportation Requirements	6
3. Requirements to Equipment Installer and Workshop	6
3.1 Requirements to Equipment Installer	6
3.2 Unpacking and Inspection	6
3.3 Warning Signs	7
3.3.1 Entrance Sign	7
3.3.2 Laser Irradiation through the window	7
3.3.3 Prevention of Laser Reflection	7
3.3.4 Laser Safety Mark	7
4. Safety Protection and Technology Guarantee	7
4.1 Brief Introduction	7
4.2 Eye Protection	8
4.3 Electrical Protection	8
4.4 Fire Hazards	9
4.5 Protection from Risk of Laser Beam Scattering	9
4.5 Protection from Risk of Laser Beam Scattering	
с С	9
4.6 Setting of Safety Warning	9 10
4.6 Setting of Safety Warning 4.7 Safety Label and Position	9 10 15
<ul> <li>4.6 Setting of Safety Warning</li> <li>4.7 Safety Label and Position</li> <li>5. Technological Theory and Scope of Application</li> </ul>	9 10 15 16
<ul> <li>4.6 Setting of Safety Warning</li> <li>4.7 Safety Label and Position</li> <li>5. Technological Theory and Scope of Application</li></ul>	9 10 15 16 16
<ul> <li>4.6 Setting of Safety Warning</li> <li>4.7 Safety Label and Position</li></ul>	9 10 15 16 16 16

6.2 The Main Console (picture)	
6.2.1 Touch Screen	
6.2.2 Key Switch	
6.2.3 Emergency Switch	19
6.2.4 Handpiece Connector	19
6.3 Handpiece	20
6.3.1 Indicator Light of Laser Output	
6.3.2 Laser Aperture	20
7. Technical Parameters and Relevant Requirements	21
7.1 Technical Parameters	21
7.2 Relevant Requirements	21
8. Equipment Installation	22
8.1 Standard Accessories	
8.2 Installation	23
8.2.1 Installation Environment Requirements	
8.2.2 Installation Procedures	
8.2.3 Water Injection	24
8.2.3 Water Injection 9. Operation Instruction	
	24
9. Operation Instruction	
9. Operation Instruction 9.1 Preparations	
<ul> <li>9. Operation Instruction</li> <li>9.1 Preparations</li> <li>9.2 System Start-up</li> </ul>	
<ul> <li>9. Operation Instruction</li> <li>9.1 Preparations</li> <li>9.2 System Start-up</li> <li>9.3 Skin Test</li> </ul>	
<ul> <li>9. Operation Instruction</li> <li>9.1 Preparations</li> <li>9.2 System Start-up</li> <li>9.3 Skin Test</li> <li>9.4 Treatment Process</li> </ul>	
<ul> <li>9. Operation Instruction</li> <li>9.1 Preparations</li> <li>9.2 System Start-up</li> <li>9.3 Skin Test</li> <li>9.4 Treatment Process</li> <li>9.4.1 Welcome Interface</li> </ul>	
<ul> <li>9. Operation Instruction</li> <li>9.1 Preparations</li> <li>9.2 System Start-up</li> <li>9.3 Skin Test</li> <li>9.4 Treatment Process</li> <li>9.4.1 Welcome Interface</li></ul>	
<ul> <li>9. Operation Instruction</li></ul>	

#### Beijing Sincoheren Science and Technology Development Co., Ltd. SDL-L Diode Laser Therapy Systems File No.: XKYR-SM-A/0-1H13-02

10. Maintenance and Repair	40
10.1 Equipment Maintenance	40
10.2 Clean of Treatment Head	40
10.3 Equipment Repair	40
10.4 Usable Life, Periodical Inspection and Disposal Requirements of Equipment	41
11. Service and Contacts	41

# 1. Overview

Thank you for choosing SDL-L Diode Laser Therapy Systems produced by Beijing Sincoheren Science and Technology Development Co.,Ltd.

SDL-L Diode Laser Therapy Systems is produced according to the latest trend of the global epilation market. With a long pulse width and typical 808nm wavelength, this laser hair removal system penetrates epidermis to reach hair follicles. Based on the selective photo-thermal theory, laser energy is preferentially absorbed by melanin in hair, damaging the hair follicle which the loses nutrition losing its ability to regenerate, which can very on hair growth stage At the same time, the unique sapphire contact cooling technology in the handpiece cools down the epidermis to prevent a burning sensation. Therefore, SDL-L Diode Laser Therapy System can be a less painful treatment and have permanent hair removal after 8-10 sessions.

This device adopts a continuous pulse output mode. Once appropriate parameters are set, treatment can begin by sweeping over the area to be treated. During the treatment process, the laser with 808nm wavelength penetrates epidermis and reaches corneum layer and be absorbed by the melanin down to the hair follicle and surrounding tissues which is then turned from energy into heat. If hair is at desired hair growth follicle is then damaged and ceases to grow.

An Effective and quick slide treatment based on consecutive pulse output makes laser hair removal more safe, convenient and quicker.

As the Class 4 laser products,SDL-L Diode Laser Therapy Systems produces laser beam with a high power density. Please be very careful when using Diode Laser. This equipment must be operated by a professional to avoid danger or injury. Please read this operating manual carefully before using it. Please contact with Beijing Sincoheren if you have any questions about safety and operation.

# 

No modification of this equipment is allowed !

Please unplug the power if there is urgent condition in need of outage.

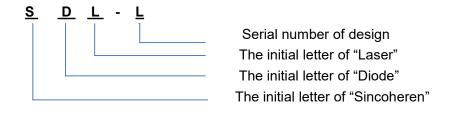
# 1.1 Copyright

The SDL-L Diode Laser Therapy Systems is one of many important intellectual properties belonging to Sincoheren. Its design, hardware and software are all patented. Counterfeiting is strictly prohibited.

Beijing Sincoheren reserves copyright to this User Manual. Its reproduction in parts or entirety can

only be approved by Sincoheren. The manual will be updated along with product update at our discretion.

#### **1.2 Models Nomination**



# 2. Storage and Transportation Requirements

This product can only be placed in the original package for transportation and storage recommended to avoid injury and damage.

This product should be stored in a well-ventilated and dry environment with the temperature of  $20 \degree C$  —55  $\degree C$  and relative humidity of 10%—93%. Pollution from acid, alkali as well as corrosive products should be avoided as well. Direct exposing to sunlight and sharp shaking during the transportation are forbidden.

Please use its original package if second transportation is needed.

# 3. Requirements to Equipment Installer and Workshop

#### 3.1 Requirements to Equipment Installer

The work of unpacking and installation of the product should be completed by engineers from Beijing Sincoheren or other appointed service agents, who will also be responsible for spot test and acceptance check.

#### 3.2 Unpacking and Inspection

All our products are carefully packed prior to delivery, please ensure you check packing list to ensure there is no accessories missing or damage to equipment. We recommend keeping all packing materials in case of sending device back for repair if needed or for storage purposes.

Please feel free to contact us or our authorized representatives for further questions.

#### 3.3 Warning Signs

Each operating room should display a warning sign. Its entrance should display an additional warning sign stating "Class 4 LaserProduct at work".

#### 3.3.1 Entrance Sign

Each laser operating room should have warning signs clearly displayed.

- > Each operating room should be prepared with laser safety warning sign with clearly stated;
- The laser warning light should be placed on each workshop entrance. When the laser device is at work, the warning light should also be turning on to prevent others coming into the operating room.

#### 3.3.2 Laser Irradiation through the window

Laser beam radiation through window should be avoided when device is in use.

#### 3.3.3 Prevention of Laser Reflection

Avoid any mirrors in treatment room; always check if there is any reflective equipment as well as jewelry on client which could also reflect.

#### 3.3.4 Laser Safety Mark

All entrances and exits of workshop as well as windows through which laser may leak radiation should be marked with safety sign and present warning that laser is dangerous.

# 4. Safety Protection and Technology Guarantee

#### **4.1Brief Introduction**

SDL-L Diode Laser Therapy System is precise medical laser equipment, which is developed for medical professionals. The systems of this Device have gone through strict safety test and standard operation will not bring about malfunctions. Therefore, the safety of operating personnel and patients from being injured by laser radiation, please carefully read this chapter and relevant connections in other chapters. Besides, operating personnel of Laser Device should have taken relevant training to operate device.

SDL-L Diode Laser Hair Therapy Systems belongs to Class 4 Laser Product, which has high energy, thus people should be very careful during process of operating the Device. Any inflammable goods should not be close to laser beams!

#### 4.2 Eye Protection



Avoid looking at direct, reflected or scattered laser beams. Avoid direct observation of laser beam from optical output or handpiece as it may damage retina.

#### **NOHD-Nominal Ocular Hazard Distance**

NOHD represents that irradiance or exposure dose are lower than the Maximum Permissible Exposure (MPE) distances. The NOHD value of this Diode Laser Therapy System is 4.57 meters, if it is not intended observation.

Safety goggles in the workshop should be marked with clear signs so as to guarantee all persons including patients wear safety goggles for eye protection.

Safety goggles with relevant wavelength are equipped with device.

#### 4.3 Electrical Protection

This Device quotes following electric safety standards:

EN60335-1:2012 Household and similar electrical appliances - Safety- Part1: General

requirements

EN55014-1:2006+A2:2011Electromagnetic compatibility —Requirements for household

appliances, electric tools and similar apparatus —Part 1: Emission

EN 55014-2:1997 Electromagnetic compatibility-Requirements for household appliances



To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

#### 4.4 Fire Hazards



Laser Device and laser beams should be avoided near inflammable good, such as anesthetics and other inflammable solvents. There should not be any papers or plastic products in laser working areas, within distances, those materials will cause burning if considerable energy is absorbed.

If Equipment is not in use during the process of changing patients, machine mode should always be set on standby.

#### 4.5 Protection from Risk of Laser Beam Scattering

Avoid laser beams' exposing on combustible materials, as it will cause burning.

Handpiece should be placed back on handpiece holder if there is no treatment.

In Treatment this device should only be operated by a medical professional, any other person is prohibited to operate device.



Take away keys if the laser device is not in use.

Dangerous radiant exposure may be caused if the device is not controlled or adjusted in accordance with this instruction.

#### 4.6 Setting of Safety Warning

After your turn device on, it will first be set on standby, allowing no power through device. Only by pressing on ready will allow device to perform service.

With complete optimization, SDL-L Diode Laser Therapy System will release an alarm and pop out warning interface if any link breaks down or run-time error appears. At the same time, the master control program will emit a warning sound, part of laser system will turn into the state of shut down and the handpiece could not control laser outlet, either.



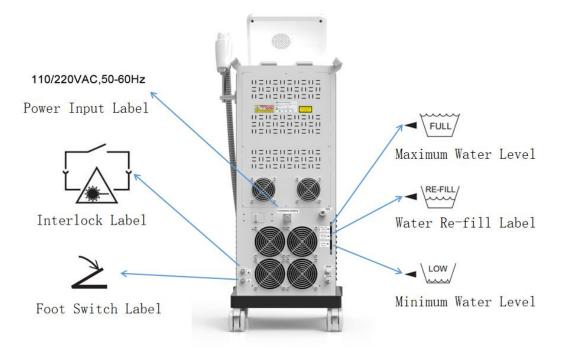
When the fault code is shown in the case of product malfunction, please stop using product and contact manufacturer or service agents as soon as possible.

#### 4.7 Safety Label and Position

According to relevant standards and regulations, appropriate warning marks are pasted on relevant positions, which are shown in the following picture.

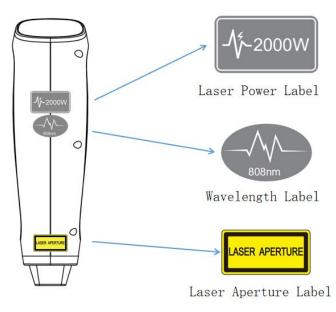


Emergency Shut-off, Attention Label Switch Label and Its Position



Power Input Label, Interlock Label, Foot Switch Label, Maximum Water Level,

Water Re-fill Label, Minimum Water Level and Its Position



Laser Power Label, Wavelength Label, Laser Aperture Label and Its Position

#### Beijing Sincoheren Science and Technology Development Co., Ltd. SDL-L Diode Laser Therapy Systems File No.: XKYR-SM-A/0-1H13-02

Serial Number	Description	Label
1	Laser Warning	AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION
2	Attention	Please make sure to turn off the machine before plug or unplug treatment handle.
3	Class 4 Laser Description	INVISIBLE LASER RADIATION AVOID EYE AND SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCTS per IEC60825.1:2014 EN60825.1:2014 AS/NZS IEC60825.1:2014
4	Emergency Shut-off	<b>STOP</b>
5	Key Switch	
6	Maximum Water Level	FULL
7	Minimum Water Level	

#### Beijing Sincoheren Science and Technology Development Co., Ltd. SDL-L Diode Laser Therapy Systems File No.: XKYR-SM-A/0-1H13-02

8	Water Re-fill Label	RE-FILL
9	SDL-L label	Diode Laser Therapy Systems Model: SDL-L Input: 110/220VAC, 50-60Hz, 3600VA Wavelength: 808/755/1064nm Fluence: 1-60J/cm <sup>2</sup> Pulse Width: 5-120ms SN M Beijing Sincoheren Science and Technology Development Co.,Ltd. Room 305, No.43 Xizhimen North Street, Haidian District, 100044 Beijing, China Pulse Middle Co.,Ltd.
10	Power Input and Fuse Protector	110/220VAC,50-60Hz
11	Interlock Connector	
12	Foot Switch	$\geq$
13	Water Inlet	Inlet
14	Vent	VENT
15	Drain	DRAIN
16	Laser Aperture	LASER APERTURE

17	Laser Power	_√ź~1600W
18	Wavelength	808nm
19	Prohibit Stacking	Prohibit Stacking
20	Keep Dry	Keep Dry
21	Temperature Limitation	-20°C TEMPERATURE LIMITATION
22	Atmospheric Pressure Limitation	500hPa 500hPa Atmospheric Pressure Limitation

23	Humidity Limitation	9/2 10% 93% Humidity Limitation
24	Upward	<b>D</b> pward
25	Handle with Care	Handle With Care
26	Earth Connection	
27	Degree of Protection against harmful ingress of water	IPX1

# 5. Technological Theory and Scope of Application



Only professional medical staff with specific trainings of laser products and clinical applications can operate this Device.

#### 5.1 Technological Theory

Laser Selective Photothermal effect plays a decisive role in hair removal. As the fundamental theory for Diode Laser's hair removal function, Laser Selective Photothermal makes the target tissues (melanin in follicle and hemoglobin in hair papilla nutrient vessels) shows perfect absorbency to specific wavelength. Treatment time for each pulse should be equal to or less than target issues' thermal relaxation time. Thus photothermal effects will be limited in target issues, and prevent thermal energy's damage to surrounding tissues. At the meantime, hair follicles will be effectively damaged and hair regeneration will be prevented. There is also no possibility for the formation of scars. This kind of effect is featured with degeneration of hair follicles, depigmentation of regenerated hair. While the hair follicles in the growing period have full pigmentation, it is easy for them to absorb laser beams in a certain wavelength so as to achieve the therapeutic objective. In consequence, Diode Laser Therapy System is safe and permanent for hair removal. With a wavelength of 808nm, Diode Laser Therapy System penetrates into the skin with a depth of 2.5mm. Its influences cover hair follicles in different positions with different depths. Scattered in hair follicles stromal cells, melanin will be transferred to hair shaft during the process of hair growth. Melanin is rich in hair follicle epithelium, hair papilla, and hair cortex. Melanin selectively absorbs laser energy and the produced energy immediately forms local high temperature, which damages hair follicles and hair shaft, hinders and terminates hair growth. Laser energy tends to be easily absorbed by melanin in hair follicle and hemoglobin in dermal papilla nutrient vessels, and then producing photothermal effects. When the temperature in hair follicles rises to some certain degree, thermal expansion happened in hair follicle fractures melanin cells and be pushed out of hair pores by steams. At the same time, dermal papilla nutrient vessels are damaged because of hemoglobin solidification. Under above dual functions, effective hair removal will be achieved.

#### 5.2 Scope of Application

Intended for the treatment of leg veins, other lenign vascular lesions, hair removal, and permanent hair reduction.

#### **5.3 Contraindications**

Patients with the following conditions are not allowed to proceed with treatment.

- Patienthad been treated with other ways (honey wax hair removal, electrolytic hair removal) in 6 weeks;
- 2) Patient with active infection lesionsor open wounds in area of treatment;

- 3) Patient having history of photosensitive disease or taking photosensitizer Within the last 3 months;
- 4) People having a history of using 13-cis retinoic acid in 6 months;
- 5) Patients with cicatrix;
- 6) Patients who have had sun exposure within the last 4 weeks;
- 7) Patients in pregnancy or breast feeding;
- 8) Existing tattoos in treatment area;
- 9) Hypertension or severe heart condition patient;
- 10) Diabetes, AIDS, SLE or epileptic patients, or patients have taken treatments with glucocorticoid.
- 11) Patients with mental disorder.

# 6. Product Descriptions

#### 6.1 Brief Introduction

Major components of SDL-L Diode Laser Therapy Systems:

-----Main Console

-----Treatment Handpiece

-----Foot Switch

# 6.2 The Main Console (picture)



Major components of the main console include:

- 1) 12.1 inch touch screen
- 2) Emergency switch
- 3) Key switch
- 4) Connector of treatment handpiece
- 5) Treatment handpiece
- 6) Holder of treatment handpiece
- 7) Power cord Inlet
- 8) Interlockconnector
- 9) Foot Switch
- 10) WaterInlet
- 11) Vent
- 12) Drain

#### 6.2.1 Touch Screen

Diode Laser Therapy System adopts 12.1 inch touch screen, which is the main interface for operation. All the parameters setting and system control and equipment status are to be realized through this screen.

Sharp objects are not allowed to touch the surface of screen to avoid scratching.

All liquids are not allowed to splash the touch screen to avoid damage.

#### 6.2.2 Key Switch

Key switch controls The ON and OFF system. When it is in the position of "O", the system is in the inactive state.

Two keys are randomly equipped with the Device. Only when the key switch is in the position of "O", can the key be pulled out. When the key switch is in the position of " | ", the system of the Device will be launched and touch screen will display the main interface.

Keys for the switch should be kept and managed by manager or professional trainings.

# 

Please take away keys from its switch if the equipment is not in use.

#### 6.2.3 Emergency Switch

Emergency switch is used for laser output shut down in emergency. Before reset of the Device, please turn the key switch to the position of "O" and then rotate emergency switch according to arrow directions to the normal state. After that, turn the key switch to the position of " | ". The system will be launched again.

#### 6.2.4 Handpiece Connector

The connector is used for connecting the main console and handpiece.

In the form of slot, this connector closely links control system, cooling system in the main console and corresponding lines in the handpiece. Therefore, the outlet control of laser stack in handpiece and cooling control of Sapphire contact refrigeration.

When connecting the host machine to the handle, pay attention to the direction of the interface. After adjusting the docking position, press the knob at the back of the handle interface, gently press the knob vertically inward and turn it clockwise, about 310°, until the handle knob cannot be turned, release the handle knob, and the handle is successfully connected.



Handpiece connector bears tight link between main console and diode laser stack's circuit, control and cooling systems. In order to guarantee perfect connection, it is not allowed to

pull out electrical plug. If necessary, please cut off the power of the main console, and carry out the operation of installation or disassembling.

#### 6.3 Handpiece

Warning

Treatment handpiece is commonly called a handpiece, which is the vital part and the main applied part for laser output, its inner structure is very precise and complex, private disassembly is forbidden.

#### 6.3.1 Indicator Light of Laser Output

A display on the handle displays energy density and frequency parameters and provides a laser output indicator.

When the system is in "standby" state, the screen shows green waveform;After the parameters are adjusted and the system is switched into the "ready" state, the yellow waveform is displayed on the screen, indicating the normal operation of each system and the laser can be fired for treatment.After pressing the button on the handle, the screen displays a red waveform.

As long as the laser has an output, the screen will display a red waveform, and the red waveform and the laser output will fully synchronize to indicate the laser output state.

In case of emergency and abnormal output of the system, the system will immediately turn off the laser output and display green waveform on the gamepilot screen. At the same time, the alarm interface of the host control screen will give a prompt of failure status.



During the treatment process, if the indicator light is out, please loosen laser output button on the handpiece immediately, at the same time switch the emergency shut-off, or conduct other trouble shooting operations.

#### 6.3.2 Laser Aperture



# In the working state, 808nm Diode Laser output through this aperture. Do not directly look at aperture or focus it on inflammable goods or anything reflective.

Laser aperture is mainly composed of sapphire crystal. In the meantime of guarantee the laser output, it will provide effective refrigeration for the epidermis and protect skin from injury.

In the process of operating, the laser aperture should be kept clean all the time, since dirt or hair residue may affect laser output and bring injury to skin.

The laser aperture in handpiece is a component that is directly in touch with patient skin, thus timely sterilizing before and after the operation of the Device is necessary.

# 7. Technical Parameters and Relevant Requirements

#### 7.1 Technical Parameters

Laser source	Diode stack	
Laser wavelength	808nm/755nm/1064nm	
Laser class	Class 4	
Electric Security Classification	Type B Class I	
Pulse width	5ms-120ms	
Frequency	1Hz-10Hz	
Spot size	12mm×16mm	
Fluence	1-60J/cm2	
Cooling methods	Air cooling, water cooling and semi-conductor cooling	
Input power	3600VA	
Power source	110VAC/220VAC,50-60Hz	
Dimensions (Length Width Height)	45cm×45cm×106cm	
Net weight	55Kg	

#### 7.2 Relevant Requirements

#### Working environment requirements:

Relative humidity: 30%-70%

#### Storage environment requirements:

Storage temperature in transportation: -20°C-+55°C

Relative humidity: 10%—93%

Atmospheric pressure: 500hPa—1060hPa

# 8. Equipment Installation

#### 8.1 Standard Accessories

index	Material code	Accessories	Quantity
1	1H13	Main Console	1
2	3H201	Treatment Handpiece	1
3	2DG0037	Кеу	2
4	3H16	Foot Switch	1
5	3H15	Interlock Plug	1
6	2AP0146	Fuse	2
7	2K*0065	Protective Goggle	1
8	2DH0008	Eyeshade	1
9	2DH0131	Instruction Manual	1
10	2F*0002	Power Cord	1
11	2DH0009	Funnel	1
12	2DH0013	Warranty Card	1
13	2DH0014	Certificate of Inspection	1
14	2DF0116/2DF0117	CPC Sockets	1
15	2DF0064	Silicon Tube	1
16	21*0069	Hex Wrench for M3	1
17	GM3*25Y3B	M3x25 Hex socket head cap screws	5
18	GM5*20P1B	M5X20 Cross recessed pan head screws	3
19	2DH0200	SDL-L Holder of treatment handpiece Installation Instructions	1

# 8.2 Installation

# 8.2.1 Installation Environment Requirements

Before dismantling external packing, it should be guaranteed that installation area, environment and equipment power supply meet requirements put forward in this chapter.

During installation, the equipment should be away from thermal ventilation and keep safe distance from other hazardous materials.

Before delivery, the input power is preinstalled in accordance with local nominal voltage or met with customer's demand.

The electrical requirements in the process of installation are in as followed:

- Power input: 110-240VAC 50-60Hz;
- The ground electrode in the power protection sheath should be connected with earth through wall Line; a well earthed circuit is very crucial to safe operation;
- ➢ In order to guarantee the Device is operating in an appropriate state, indoor temperature should be kept about 20 ℃, relative humidity should not be above 70%; Air-conditioner is needed when necessary.

# 8.2.2 Installation Procedures

- > Unfold the outer packing and put the Device in the primarily settled position;
- Unpack the accessories bag, follow the instruction to fix the Holder of treatment handpiece on the main console;
- Unpack the treatment handpiece packingand insert handpiece into the connector in the main console;
- Connecting the interlock plug;
- Connecting the Footswitch;
- Connect the power cord;
- > Insert the key into the switch and prepare to start the device.



It is necessary to assemble interlock switch properly for valid operation. There is a interlock plug which has been shorted Pin 1 and Pin 2 in accessories bag can disable the interlock detecting function.

#### 8.2.3 Water Injection

Prepare 3 liters of distilled water or pure water. Please plug the funnel with CPC water nozzle into the water inlet socket, which is located on the back of the equipment in an unpowered condition. Add distilled water or pure water into the box and observe water level indicator on the side of equipment. Make sure the water is not above the maximum water level. When the system begins operation, please keep observing water level indicator. If the water level is lowered, it is suggested to add more water, make sure the water is above the RE-FILL water level. Plug treatment handpiece, connect power wire and start the equipment and keep the water way operating for 1 minute. After the completing water injection, please unplug funnel with CPC water nozzle.

Attention: press down the aluminum flake of CPC water nozzle, then the funnel with CPC water nozzle can be unplugged easily.

The water block shall be installed into vent when equipment is in transporting with water in-filled. The water block can be unplugged by inward pressing.

It is advisable to change water once a month.

With the function of water flow testing, this equipment will continuously give an alarm if water in tank is insufficient or air is existing in water circulation. As a consequence, alarm releasing is a normal phenomenon if water flow test fails because a little air in the waterway may not be completely discharged for the first time of water adding or changing. All you need to do is to reset the device for 3 to 5 times till all air entirely emitted from waterway. The alarm will then be relieved.



Water used in the Device should only be Distilled water or purified water. Tap water or mineral water is forbidden.

# 9. Operation Instruction

#### 9.1 Preparations

Before treatment, please confirm the following information:

1) Make sure that water level is in the stipulated level;

- 2) Examine whether all accessories have been connected;
- 3) Make sure that all people in treatment area are wearing protective goggles oreyeshade;
- 4) Make sure that the emergency switch is releasing.

#### 9.2 System Start-up

After finishing preparatory work, turn the power inlet switch to the position of "—". Thenturn the key switch clockwise to the position of " |". The system will start-up and the display screen will show "Welcome".

After System Start-up, the system will load into a self-testingprocess. If there is any error, it will automatically release alarm and the error code will also be shown on the screen. Please take "malfunctions diagnosis and analysis" for reference, or call us or our agents for help immediately.

#### 9.3 Skin Test

Skin test is very important before treatment; relevant details are as followed:

- Choose appropriate area for a test patch. If the target treatment area is the whole face, try to choose a position that will not influence facial beauty, such as bottom of ear. If the target treatment area is chest, neck or other parts of the body, then the area that will not affect visual appearance should be chosen for experimental test. Meanwhile, injured or infected skin should not be treated.
- 2) Before skin test, the surface of skin should be cleaned. A thin layer about 2-3mm of conductive gel should be spread in the skin test area. Take out laser treatment head and closely touch skin vertically with appropriate pressure slide in the direction of hair growth for 2 to 3 times. Wait for 5 to 10 minutes and then remove the gel, observe the test effect.
  - If there appears erythema or edema around hair follicle without epidermis reactions, it achieves a perfect effect. The following treatment could be set with the same energy and pulse type.
  - If there is not any visible change on the skin, skin test should be continued with 1-2J/cm<sup>2</sup> energy increased.
  - If the patient feels severe pain or there appears blister in the skin test area, it is probably because the energy is too high or too much repetitive treatment is given. Then the energy should be lowered if the treatment continues.



- 1) Patients and operators should wear protective goggles during the process of treatment and patient should take a position of clinostatism;
- 2) The target area should be cleaned before treatment;
- 3) Closely touch the skin surface and press it appropriately;
- 4) The operation should be done in accordance with hair follicle's growth direction;
- 5) Whether the anesthesia is needed or not is based on whether the treatment area is sensitive;
- 6) Keep contact with patients while treating and pay attention to asking patients' feeling and adjust reasonable parameters for treatment;
- 7) Patients with darken complexion and thick hair should be treated with low energy density; while patients with light skin and thin hair should be treated with high energy density;
- 8) Clean the treatment head with wet gauze timely and keep the treatment head sanitized;
- 9) The Device must be turned off and keep it cool after the treatment is finished.

#### 9.4 Treatment Process

Make sure the emergency shut-off knob is released. Turn on the key switch, the water cooling and screen begin to work and the system will be launched. After 5 seconds, a colorful screenwill be shown. The system will enters the welcome interface.

# 9.4.1 Welcome Interface



Picture 1 Welcome Interface

The system will automatically transfer into start-up and self-test interface in 5 seconds.

# 9.4.2 Self-test Interface

Ŗ	azorlase®				
	The Interlock testir	Ig			✓
	Treatment handpie	ece temper	ature testing		✓
	Water temperature	e testing	A A		<b>√</b>
	Water flow testing				
	Calibration parame	ter testing		A	
		$\mathbb{N}$	60 %		
		>			XX
			Medical	Beau	ty
			$\gg$		

Picture 2 Start-up and Self-test interface

Self-tests include: status of interlock connection, treatment handpiece temperature, water temperature, water flow, and handpiece calibration parameter.

If the test is successful, this sign " " will be shown infollow grid, if not, " X" will be shown. If any of above tests is failed, the warning messagebox will pop out (warning display shown in picture 9). Relevant failure code will be shown to remind the customer referringto the User Manual. The system will be stopped until all the failure be solved.

After all parameters pass the self-test, the interface will stop waiting for the selection of treatment mode, including "Medical" mode and "Beauty" mode.

# RescueseImage: Second seco

#### 9.4.3 Medical Working Interface

Picture 3 Medical Working interface

Select the "Medical" mode on the self-test interface and switch to the Medical work interface (Figure 3).

Fluence, Pulse width, Frequency, Skin Options and body parts in this interface can be adjusted with relevant buttons.

# 9.4.3.1 Fluence

Fluence can be adjusted with buttons of "-" and "+". Different skin options have different values.

The default value of Fluence is 8J/cm<sup>2</sup>.

#### 9.4.3.2 Pulse width

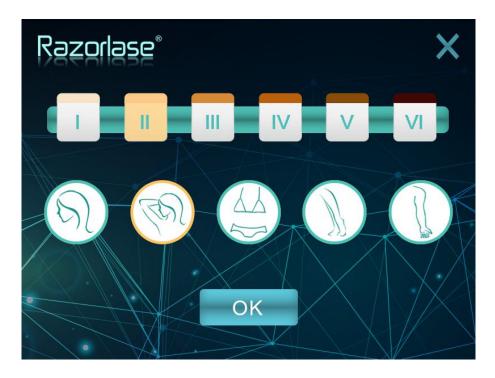
Pulsewidth can be adjusted with buttons of "-"and" + ". The pulse width could adjust from 5~120 ms, but it will be constraint by the fluence and frequency. Default value when Start-up is 20 ms.

#### 9.4.3.3Frequency

Frequency value can be adjusted by "—" and "+" for decreasing and increasing values. It could be adjust from 1 Hz to 10 Hz. The default value of Frequency is 4 Hz.

# 9.4.3.4 Skin Optionand body parts

Skin options and body parts adjusting window could be displayed bypressing.



Picture 4 skin type and treatment parts window

Skin types can be chosen based on real situations. There are 6 skin levels, "I, II, III, IV, V, VI", which can be chosen by pressing the number. The default level is "III";

"Body Parts" are the treatment parts. There are 5 body parts, "Facial area, Oxter area, Bikini area, Lower Limb, Upper Limb", which can be chosenby pressing the picture. The default body parts is "Facial Part".

# 9.4.3.5 Standby and Ready

The switch button could be changed between Standby and Ready. The default state is

"Standby" Standby". All parameters "standby" state can be adjusted with relevant buttons. In the state of Standby, the device can't emit light. Press "Ready", the system will switch to ready state Ready. Then all adjustment buttons turn grey and can't be adjusted in "ready" state. Light emitting could be realized according to the setting parameters.

#### 9.4.3.6 Treatment Temperature

 $^{2}$   $^{2}$   $^{2}$  displays the sapphire window temperature thatcontact with the skin . It could be adjust from -4°C to 10°C. The default is 4°C.

#### 9.4.3.7 Counter

123 displays the counter of laser light emitting. Counter can be cleared by pressing 3. Every time the system is turned off, the value will be zero.

#### 9.4.3.8 Wavelength shows

2:Automatically identify and display the wavelength of the Handpiece.

#### 9.4.3.9 Treatment Parameters

Surgeons could adjust the technical parameters, such as "Fluence", "Frequency" and "Pulse Width" in accordance with different skin types and treatment areas. It is advisable that skin-test shall be done before formal treatment so as to avoid discomfort or skin damage. For different skin types and treatment areas, the system have defaulted the maximum Fluence for safety. The following parameters, based on clinical practices for different skin types and treatment areas, can be taken for reference:

Skin Types	Body Parts	Fluence (J/cm <sup>2</sup> )	Frequency (Hz)	Pulse Width (ms)
	Facial Part	10	4	25
	Oxter Part	10	4	25
I	Bikini Area	9	5	20
	Lower Limb	6	7	15
	Upper Limb	6	7	15

#### Treatment Parameters Reference

#### Beijing Sincoheren Science and Technology Development Co., Ltd. SDL-L Diode Laser Therapy Systems File No.: XKYR-SM-A/0-1H13-02

Facial Part	9	4	20
Oxter Part	9	4	20
Bikini Area	8	5	20
Lower Limb	6	7	15
Upper Limb	6	7	15
Facial Part	8	4	20
Oxter Part	11	3	25
Bikini Area	8	4	20
Lower Limb	7	5	15
Upper Limb	7	5	15
Facial Part	8	3	20
Oxter Part	9	3	20
Bikini Area	7	4	20
Lower Limb	6	5	15
Upper Limb	6	5	15
Facial Part	5	3	25
Oxter Part	8	3	25
Bikini Area	8	3	25
Lower Limb	4	5	20
Upper Limb	5	5	20
Facial Part	3	3	20
Oxter Part	6	3	20
Bikini Area	5	3	20
Lower Limb	3	5	20
Upper Limb	3	5	20
	Oxter PartBikini AreaLower LimbUpper LimbFacial PartOxter PartBikini AreaLower LimbBikini AreaLower LimbFacial PartOxter PartBikini AreaLower LimbFacial PartOxter PartBikini AreaLower Limb	Oxter Part9Bikini Area8Lower Limb6Upper Limb6Facial Part8Oxter Part11Bikini Area8Lower Limb7Upper Limb7Facial Part8Oxter Part9Bikini Area7Lower Limb6Upper Limb6Upper Limb6Upper Limb6Sikini Area7Lower Limb6Upper Limb6Ster Part8Bikini Area8Lower Limb4Upper Limb5Facial Part3Oxter Part6Bikini Area8Lower Limb4Upper Limb5Facial Part3Oxter Part6Bikini Area3	Oxter Part         9         4           Bikini Area         8         5           Lower Limb         6         7           Upper Limb         6         7           Facial Part         8         4           Oxter Part         11         3           Bikini Area         8         4           Lower Limb         7         5           Upper Limb         7         5           Upper Limb         7         5           Upper Limb         7         5           Upper Limb         7         5           Facial Part         8         3           Oxter Part         9         3           Bikini Area         7         4           Lower Limb         6         5           Upper Limb         6         5           Upper Limb         4         5           Upper Limb         5         5           Facial Part         3         3           Oxter Part         8         3           Lower Limb         4         5           Upper Limb         5         5           Facial Part         3         3 </th

Note: It is suggested that skin test shall be done before treatment based on parameters set in the form, which can be personalized adjusted. (6 times for permanent hair removal, 4 times for permanent hair reducing)

Customer can also readjust parameters based on patients' skin reaction before treatment each time and guarantee no damage will be caused to patient skin and achieve a best treatment result.



Warning

Skin test is a must before treatment; the energy shall be increased from lower level; find out the most appropriate energy and then carry out treatment with large areas.

# 9.4.4 Beauty work interface



Picture 5 Beauty Working interface

Select the "Beauty" mode in the self-check interface and switch to the Beauty work interface (Figure 3).

This interface has Fluence, total energy, pulse frequency, skin type and treatment site, and the corresponding parameters can be selected or adjusted.

#### 9.4.4.1 Fluence

Fluence can be adjusted with buttons of "—" and "+". The range of regulation is influenced by the type of skin and the setting of the treatment site. In the case of class III skin where the treatment site is the forearm, the default value for fluence is 8 J/cm2.

#### 9.4.4.2 Total energy

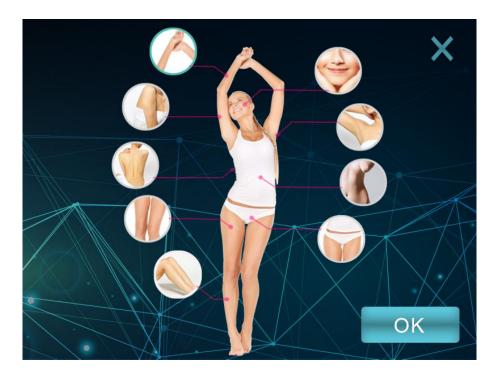
Total energy is the amount of energy needed to heal a particular site. The total energy value is determined by skin type and treatment site and cannot be adjusted manually. In the case of class III skin, where the treatment site was the forearm, the total energy value was 17.0KJ.

#### 9.4.4.3 Frequency

Frequency is determined by skin type and site of treatment and cannot be manually adjusted. In the case of class III skin where the treatment site is the forearm, the default light output frequency is 5 Hz.

#### 9.4.4.4 治疗部位

Select the treatment site. Click the button to switch to the interface for selecting the treatment site (Figure 6).



Picture 6 treatment site selection interface

treatment site selection: There are 9 parts to choose from: face, underarm, abdomen, bikini area, calf, thigh, back, upper arm and lower arm. The user can Click the corresponding treatment site to choose.The default position of the system boot is the forearm.

#### 9.4.4.5 Skin Option

Skin Option Skin types can be chosen based on real situations. There are 6 skin levels, "I, II, III, IV, V, VI", which can be chosen by pressing the number. The default level is "III".

#### 9.4.4.6 Progress

Progress After the user selects the skin type and treatment site, the system will automatically

give the recommended energy density, total energy and light frequency, and automatically calculate the total time required for treatment. When the user starts the treatment, the progress bar will be updated in real time, and the interface will display the remaining time in real time. When the progress bar reaches 100%, the treatment is completed and the system will automatically switch to the Standby state and stop laser output.

#### 9.4.4.7 Laser state control

The switch button could be changed between Standby and Ready. The default state is

"Standby" Standby". All parameters "standby" state can be adjusted with relevant buttons. In the state of Standby, the device can't emit light. Press "Ready", the system will switch to ready

state Ready. Then all adjustment buttons turn grey and can't be adjusted in "ready" state. Light emitting could be realized according to the setting parameters.

#### 9.4.4.8 Treatment Temperature

 $^{2}$   $^{2}$   $^{2}$  displays the sapphire window temperature thatcontact with the skin . It could be adjust from -4°C to 10°C. The default is 4°C.

#### 9.4.4.9 Wavelength shows

Automatically identify and display the wavelength of the Handpiece.

#### 9.4.4.10 Treatment Parameters

According to different skin types and treatment sites, physicians can adjust the "Fluence" parameter by themselves. It is suggested that skin test must be conducted before use to avoid discomfort or skin damage in patients. At the same time, the machine has its highest energy limit set according to different skin color and parts. The following table shows the relevant parameter Settings based on clinical practice for different skin types and treatment sites for reference:

Skin Types	Body Parts	Fluence (J/cm2)	Frequency (Hz)	Total Energy (KJ)
	Face	18	1	1.1
I	Chest&Abdomen	9	6	48
	Axilla	9	3	6
	Back	9	6	56
	Bikini	9	4	9

<b>Treatment Parameters I</b>	Reference
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#### Beijing Sincoheren Science and Technology Development Co., Ltd. SDL-L Diode Laser Therapy Systems File No.: XKYR-SM-A/0-1H13-02

	Upper Arm	9	5	24
	Lower Arm	9	5	18
	Upper Leg	9	5	42
	Lower Leg	9	5	32
	Face	16	1	1.1
	Chest&Abdomen	8	6	48
	Axilla	8	3	6
	Back	8	6	56
II	Bikini	8	4	9
	Upper Arm	8	5	24
	Lower Arm	8	5	18
	Upper Leg	8	5	42
	Lower Leg	8	5	32
	Face	14	1	1.1
	Chest&Abdomen	8	6	46
	Axilla	8	3	6
	Back	8	6	54
III	Bikini	8	4	9
	Upper Arm	8	5	23
	Lower Arm	8	5	17
	Upper Leg	8	5	41
	Lower Leg	8	5	31
	Face	12	1	1.1
	Chest&Abdomen	6	6	46
	Axilla	7	3	6
	Back	6	6	54
IV	Bikini	7	4	9
		6	5	23
	Upper Arm Lower Arm	6	5	17
		6	5	41
	Upper Leg	6	5	31
	Lower Leg Face	10	1	1.1
	Chest&Abdomen	5	6	44
	Axilla Back	6 5	3 6	6 52
V	Bikini	6	4	9
		5	5	22
	Upper Arm			
	Lower Arm	5	5	16
	Upper Leg	5	5	40
	Lower Leg	5	5	30
	Face	8	1	1.1
	Chest&Abdomen	4	6	44
	Axilla	5	3	6
VI	Back	4	6	52
	Bikini	5	4	9
	Upper Arm	4	5	22
	Lower Arm	4	5	16
	Upper Leg	4	5	40
	Lower Leg	4	5	30

# 9.4.5 Set-up Interface

Press the button interface, the system will switch to set-up interface.



Picture 7 set-up interface

# 9.4.5.1Equipment SN and Handpiece SN

Equipment SN and Handpiece SN are used for product traceability and cannot be modified by the user.

# 9.4.5.2 Prompt tone

6

Laser emitting prompt tone button is provided, and the volume can be

adjusted from0-5. Press for increasing volume to the maximum 5 while for decreasing volume to the minimum 0. 0 means no prompt tone while laser emitting. The default volume is 3.

#### 9.4.5.4 Language

Clicking the button will bring up the interface of language selection. The system can set five languages, Namely Chinese, English, German, Spanish and Russian. The

default language is English.See Figure 8.The user can click the icon corresponding to the national flag of the language and select the language when the font background becomes white.



Picture 8 Language selection interface

# 9.4.5.5 Modes of Laser Light Emitting

Three modes of laser emitting and two buttons are provided: handpiece and foot switch buttons. Three modes of laser emitting are:

1) Laser emitting by pressing the button on Handpiece: Choose handpiece button and

relevant grid will become chosen

gray while non-selected foot switch will be , the system emits laser only through pressing buttons on handpiece.

2) Laser emitting by operating the foot switch: Choose foot switch button and relevant grid

will become chosen 🖾 🗹, icon background will also turns green from gray while

non-selected handpiece button will be *main the system emits laser only through* stamping the foot switch.

3) Laser emitting by both pressing the button on handpiece and operating the foot switch together: When both handpiece and foot switch are chosen, two grids will be lighted

, and icon's background will also turns green. Laser emitting can

only be realized by firstly stamping foot switch and then press button on handpiece.

#### 9.4.5.6 Total Counter

1234 displays the total number of laser light emitting with the handpiece.

#### 9.4.5.7 Save setting

Press, the setting will be saved and the system will be switched to system working interface.

 $\wedge$ 

# Attention

If the energy is not appropriate after the system is launched, for readjusting energy, customer needs to touch "Standby" and set relevant parameters.

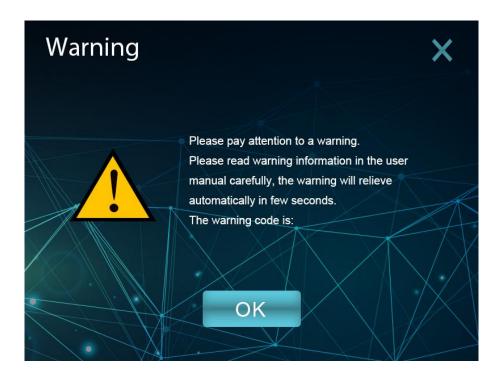
Please press emergency shut off knob if any emergency happens;

Treatment skin with any damage or infection is not allowed;

Keep contacting with patients during treatment process; asking patients' feelings and adjusting treatment parameters.

Pay attention to the cooling down of surface skin. For those patients who are sensitive to pain, having large skin areas for hair removal or larger energy needed, the treatment can be done together with cold compress.

# 9.4.6 Warning Alarm Interface



Picture 9 Warning Alarm Interface

If abnormities occur when system is in operation, the warning message will be popped out. The surgeon could ignore the warning information by clicking the button "OK", Once the "OK" is pressed, the system will be back to the screen before and can work normally. Wait the system back to normal and continue to work. Users can understand the alarm problems of the system according to alarm code. The warning code are shown in the following form:

Warning code	Implication	
W01	overheated water tank	
W03	overheated water pump	
W04	overheated diode stack	
W05	Interlock connecting error	
E01	oversize of output pulse width	
E02	Undersize of output pulse width	
E03	Oversize electric current of constant current driver board	
E04	undersize electric current of constant current driver board	

E05	undersize of water flow rate	
E06	handpiece linkage error	
E07	overheated treatment heads	
E08	Energy calibration parameter error	
E09	constant current driver board error	



# Warning

According to application regulations of laser equipment, the remote control interlock must be open if the laser device is in use, so as to avoid accidents. The interlock shall be correctly installed. If W05 occurs after system is launched, it means the interlock is unconnected. Please check relevant components.

If there is no way to use interlock because of force majeure, please contact with our professional engineers.

# 9.5 Equipment Turn Off

Click "Standby" and turn the key switch to "O". Meanwhile, turn the power inlet switch to "O".

# 10. Maintenance and Repair

# **10.1 Equipment Maintenance**

The surface of the Device should be sanitized with alcohol wipes at least once a week. Neutral detergent can be used but pay attention do not leak the liquid into the Device.

# 10.2 Clean of Treatment Head

Optical crystal should be cleaned all the time, and they must be cleaned after treatment every time. As to the cleaning, firstly, soft cloth should be used to scrub and then use another piece of cloth with anhydrous alcohol for cleanout and leave it naturally dry.

# 10.3 Equipment Repair

The following table lists some malfunctions and breakdowns that may happen to the Device and corresponding measures:

phenomenon Possible causes	Measures
----------------------------	----------

	Power unconnected	Check power source	
No display	Emergency switch is pressed	Loosenthe emergency switch and leave it the state of upspring	
	Other reasons	Please contact with maintenance department	
the system has no reactions when pressing buttons on the screen	Display screen malfunction or other reasons	Please contact with maintenance department and do not disassemble it by yourself.	
System won't be	Key is not turned on the right position	Swing the key clockwise to the right position	
started	Other reasons	Please contact with maintenance department and do not disassemble it by yourself.	

Note: Please contact with us timely if you have any doubt during device using process.

# 10.4 Usable Life, Periodical Inspection and Disposal Requirements of Equipment

The usable life of main console is 5 years. As the main applied part, the treatment handpiecehas a warranty period of 1 year since the date of contract signing. After using 1 year, the pulse energy of handpiece will be decreased and need to be replaced.

Since equipment contains following materials and components, such as iron, copper, aluminum, non-biodegradable plastics and printed circuit board, therefore at the end of device's life, the above materials and electric components must be recycled and processed at particular locations designated by local environment department.

# **11. Service and Contacts**

Beijing Sincoheren takes strong commitments:

The equipment has a warranty period of 1 year since the date of contract signing. But human caused damage and consumable items are not covered in warranty.

Beijing Sincoheren provides on-site maintenance service for malfunctions of equipment in warranty period.

The equipment enjoys lifetime maintenance; relevant costs will be charged for parts replacement. Manufacture: Beijing Sincoheren Science and Technology Development Co.,Ltd. Address: Room 305, No.43, Xizhimen North Street, Haidian District, Beijing, 100044, China FacilityAddress: E zone, 3rd floor, 12 plant, No. 2, Kechuang East 5 Street, TongZhou District, Beijing 101111,China

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BeijingSincoheren S&T Development Co.,Ltd. reserves the final explanation of this User Manual

#### Beijing Sincoheren Science and Technology Development Co., Ltd. SDL-L Diode Laser Therapy Systems File No.: XKYR-SM-A/0-1H13-02

#### Addendum:

Version	Description	Date
A/0	Initial publication	2021-11-24