USER MANUAL

Diode Laser Hair Removal Device

Version No.: A/0
File No.: CZM-WI-03
Issue Date: 22/08/2019

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Furthermore, all CHUANG ZAO MEI appliances are designed and manufactured following the strictest international safety standards. This is the guarantee you need to use our device, which will offer you high performance during its long useful life.

With the purchase of this device, you are already part of this huge family. Again, welcome！

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Chapter 1 Introduction

1.1 About this manual

This instruction manual details step by step the correct procedure to be followed to safely and efficiently use the Diode Laser Hair Removal Device EVOLUTION MEDICAL and M-I-X MEDICAL (Hereinafter referred to as "EVOLUTION" and "M-I-X", or “device”, respectively), indicated for use in aesthetic medicine, for hair removal treatments.

The EVOLUTION and M-I-X is designed to meet international safety and performance standards. Personnel operating the device must have a thorough understanding of the proper operation of the EVOLUTION and M-I-X.

This manual has been prepared to aid medical and technical personnel to understand and operate the device. Do not operate the device before reading this manual and gaining a clear understanding of device operation. If any part of this manual is not clear, please contact your CHUANG ZAO MEI representative for clarification.

The User manual will be updated with the continuous improvement and upgrade of the device.

1.2 Maintenance

The EVOLUTION and M-I-X is a precision, technical medical device that requires periodic routine maintenance, which must be performed by CHUANG ZAO MEI authorized technical personnel. Failure to obtain maintenance service voids all warranties expressed and implied. Please contact CHUANG ZAO MEI or your local representative for details.

1.3 Modification of the Device

Unauthorized modification of the hardware, software, or specifications of the EVOLUTION and M-I-X device voids all warranties, expressed and implied. CHUANG ZAO MEI takes no responsibility for the use or operation of such a modified device.

Chapter 2 Safety

2.1 Introduction

This chapter describes general safety issues regarding the use of the EVOLUTION and M-I-X device, with special emphasis on optical and electrical safety.

With proper operation and maintenance, trained and qualified medical practitioners can use the EVOLUTION and M-I-X device safely. The supervising physician and all other personnel operating or maintaining the EVOLUTION and M-I-X must be familiar with the

safety information provided in this chapter.

The primary consideration should be for the safety of the patient, the physician and other personnel. Patient safety is mainly assured with a well-trained staff and a well laid out treatment room. Patient education is also important, including information about the nature of the treatment.

2.2 Device Safety Measures

The EVOLUTION and M-I-X was designed to maximize safety for both patient and personnel. The following are some of the EVOLUTION and M-I-X preventive safety measures:

2.2.1 Electrical Safety

The following electrical safety features are incorporated in the EVOLUTION and M-I-X device.

1. A semi-automatic circuit breaker, located on the service panel, protects the system by tripping when power overload occurs. To resume normal operation, lift the circuit breaker handle and restart the device.

2. Software protection, includes:

    a) The software checks all safety related hardware after the device is switched on.

    b) If an error occurs, the device displays a warning message to the operator and disables further operation.

    c) When the device is started, the system will automatically detect whether the handle is plugged in.

    d) A self-test of the electrical circuitry takes place after the device is turned on. The test circuits continuously monitor system operation during treatment.

2.2.2 Laser Safety

The following Laser safety features are incorporated in the EVOLUTION and M-I-X.

1. Closed light guide geometry is used to transmit Laser energy to the treatment site. Laser energy is emitted only through the front plane of the light guide.

2. The device incorporates a safety remote interlock connector for connecting an external interlock on the entrance door to the treatment room. The external remote interlock is serially connected with the foot switch; when installed, it disables the device and prevents operation when the entrance door is opened.

3. An Emergency Stop Switch expedites shutdown when necessary. When pressed, it

immediately shuts down device operation.

4. Only enter the correct power-on password to turn on the device. When the operator leaves, the power should be turned off to prevent unauthorized use of the device.

5. The system features two emission indicators: a red emission indicator lamp located on the handle's tip and a buzzer.

6. As long as the laser has output, the red emission indicator lamp will light up and buzzer will emit sound, and the light and sound are completely synchronized with the laser output.

7. Laser emission is enabled only if both the foot switch and the handle's trigger are pressed at the same time, reducing the risk of unintentional Light/Laser emission.

8. Water is circulated through the module as soon as the system is turned on in order to cool the light source.

9. The flow and temperature of the water are monitored in order to eliminate the risk of module overheating. Laser emission is not permitted if the water flow stops or if the water temperature is equal to or higher than 40ºC (104ºF).

Warning:

- *Any Laser emitting device can cause injury if used improperly. High voltages are present inside the EVOLUTION and M-I-X device. Personnel who work with lasers must always be aware of the possible dangers and must take the proper safeguards as described in this manual.*
- *Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the EVOLUTION and M-I-X device by children or incapacitated persons may be dangerous.*

2.3 General Precautions , Cautions and FCC Caution

The following precautions, cautions and warnings must be observed for the safe use of the EVOLUTION and M-I-X.

2.3.1 Precautions

Observe the following precautions when using the EVOLUTION and M-I-X.

- Physicians and clinicians should read this manual thoroughly before attempting to operate the EVOLUTION and M-I-X.

- The handle's light guide must be kept clean at all times. Remember to clean the

cooling gel from the light guide after each patient use.

- The device weighs approximately 105 lbs. (48 kg.) and may cause injury if proper care is not used when moving it. The system is well balanced and is designed to be moved but should always be moved carefully and slowly. Never pull the system by the module or its umbilical cable.

2.3.2 Cautions

Observe the following cautions when using the EVOLUTION and M-I-X.

- Only CHUANG ZAO MEI authorized personnel may service the device. This includes making internal adjustments to the power supply, cooling system, optics, handles, etc.
- Verify that the EVOLUTION and M-I-X is wired for the appropriate electrical voltage of your country (AC 120 V).
- Maintenance performed by the operator must only take place when the device is shut down and disconnected from the electrical power source. Performing maintenance procedures with the device powered-up can be hazardous to the operator and/or destructive to the device.
- Always turn off the device when it is not in use.
- Never leave the device in Ready mode unattended.
- Never allow untrained personnel to operate the device.
- Never press the handle's trigger and/or foot switch unless the handle is safely oriented at a specific and intended target.
- The handle and tips must always be visually inspected before treating the patient. If any wear or damage is apparent, do not use the module or tip.
- Never leave the device turned on, open or unattended during device maintenance.

2.3.3 FCC Cautions

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

- This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

- This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
- This equipment should be installed and operated with minimum distance 20cm between the radiator& your body.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

2.4 Warnings Related to Laser Energy Emission

2.4.1 Burn Hazards

The EVOLUTION and M-I-X emits high-intensity light/laser radiation which is invisible to the human eye and can cause third degree burns.

2.4.2 Direct and Reflected Eye Exposure Hazards

- It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing CHUANG ZAO MEI recommended protective eye glasses.
- It is good practice to instruct the patient to close their eyes during treatment even when wearing Protective glasses.
- Fit the patient with opaque eye protection that completely blocks light from the eyes.
- The Ocular Hazard Distance (OHD) is 10 m.

2.4.3 Safety Eyewear

- All personnel must use safety eyewear and must ascertain that the eyewear provides adequate protection: for the diode laser module OD>7 at wavelength range of 808nm.
- The safety eyewear and Protective glasses supplied with the device offer adequate protection, and more can be ordered from your CHUANG ZAO MEI representative.

2.4.4 Explosion and Fire Hazards

- The absorption of optical energy raises the temperature of the absorbing material. Take precautions to reduce the risk of igniting combustible materials in and around

the treatment area.

- The system is not suitable for use in the presence of flammable MIXtures with air or oxygen.
- Do not operate in the presence of volatile solvents such as alcohol, gasoline or other solvents.
- Do not use any flammable substances such as alcohol or acetone in the preparation of the skin for treatment. If necessary, use soap and water to clean before treatment.
- If alcohol is used to clean and disinfect any part of the EVOLUTION and M-I-X device, allow it to dry thoroughly before operating the device.
- Flammable materials must be kept at a safe distance from the device.

2.4.5 High Voltage Hazards

The device utilizes AC 110V. To avoid personnel injury, do not operate the device before ensuring that the exterior panels are properly closed. Do not attempt to remove or disassemble the exterior panels.

The EVOLUTION and M-I-X device produces very high voltages in various components. Some components may retain a charge after the power supply has been turned off, so no part of the exterior housing should be removed, except by CHUANG ZAO MEI authorized personnel.

Whenever device maintenance is performed, never leave the EVOLUTION and M-I-X device turned on, open or unattended.

2.4.6 Grounding the System

The device is grounded through the grounding conductor in the power cable and internal grounding pin.

Warning:

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

2.5 System Safety Features

The EVOLUTION and M-I-X device is equipped with a number of safety features. All treatment room personnel should be familiar with the location and operation of these safety features.

2.5.1 Emergency stop switch

This switch is used for emergency shutdown. When pressed, it immediately shuts off power to the entire device.

To release the emergency switch button, turn clockwise until the switch pops out.

2.5.2 Switch

Power on, power off.

2.5.3 Main Circuit Breaker

A semi-automatic circuit breaker, located on the rear panel, protects the device against excessive current consumption. The circuit breaker disconnects power to the device in case of an electrical overload. To resume device operation, lift the circuit breaker handle.

2.5.4 Remote Interlock Connector

The device incorporates a safety remote interlock connector that should be connected to an external Microswitch on the entrance door to the treatment room. The external remote interlock is serially connected with the foot switch; therefore, when installed, it disables the device and prevents operation when the entrance door is opened.

2.5.5 Double-Tiered Security for Laser Emission

Diode laser beam emission is enabled only when the operator presses both the foot switch and handle's trigger; therefore, accidental lasing may only occur due to double error condition (minimum risk).

2.5.6 Tissue Cooling System

The handle light guide is cooled by a thermoelectric cooling method to reduce patient discomfort during treatment and to reduce post-procedure side effects, such as local skin redness and swelling. The tissue is cooled through a metallic ring and a Quartz glass window. The light guide's temperature is reduced to -7ºC (19ºF) during device operation.

Chapter 3 Installation

3.1 Introduction

The EVOLUTION and M-I-X is designed for installation in an office or a clinic and requires minimal site preparation. When the EVOLUTION and M-I-X device is purchased, complete on-site installation, including initial system testing and calibration, is included.

Device transportation and installation are carried out by CHUANG ZAO MEI authorized technical personnel, who will do the following:

- Unpack the device and position it in its pre-selected location.
- Verify the integrity of the device and its components.
- Connect device components (handle, foot switch, interlock connector).
- Plug the device into a designated electrical outlet.
- Fill the cooling system reservoir with deionized water.
- Test the device for proper calibration and functional operation of all components and software.
- Coordinate the performance of an on-site safety inspection, if required.

3.2 Unpacking and acceptance

The semiconductor laser hair removal machine is strictly packaged when shipped from the factory. Please carefully check the packing box for damage before receiving it. Check the packing list to check whether the ordered components are complete, and please save all the packing materials. You need to store the product in the original packaging when you send it back to Guangzhou CHUANG ZAO MEI Technology Co., Ltd. or store the equipment.

Please follow the packing list to check whether it is complete. If you have any questions, please call +86 020-86016362 immediately.

3.3 Device Components List

The EVOLUTION AND M-I-X platform includes the following components:

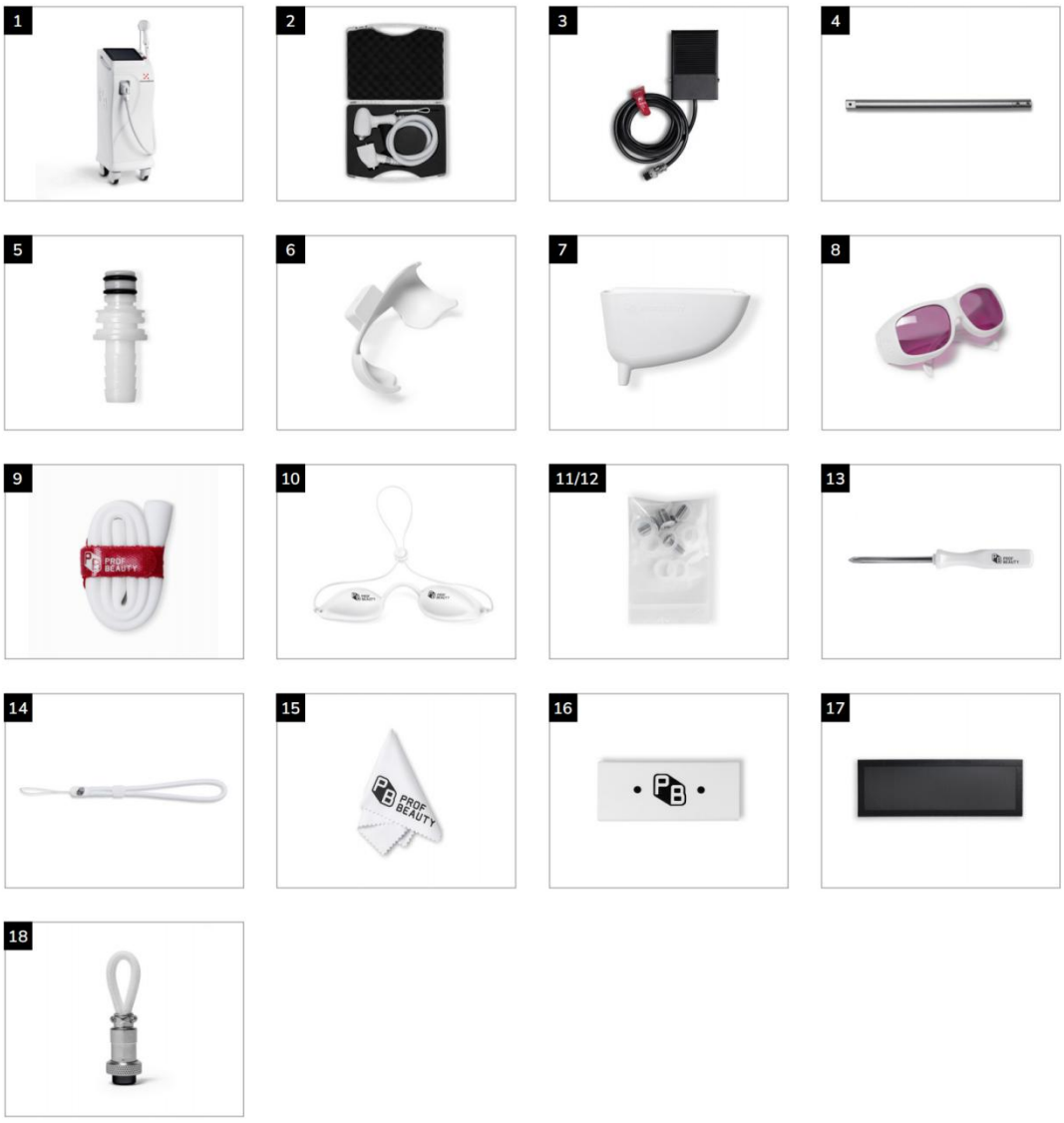


Figure 3.3-1

Table 3.3-1

No.	Component	Function Description
1	Main unit	The main part of the device, including the interface display and interactive functions of the display screen, and the laser drive power output.
2	Laser treatment handle	In the handle part of the device, the laser is output through the laser treatment handle to irradiate the patient for treatment.
3	Foot switch	To prevent the device from accidentally emitting light, the

No.	Component	Function Description
		device can only emit light when stepped on.
4	Support rod	Fix the plastic hanger on the device to place the handle
5	Connector	Connector between device and water pipe
6	Hanger	Place the handle
7	Funnel	Filling funnel
8	Protective glasses	Protect user eyes from laser radiation
9	Water pipe	Used to inject or discharge coolant into device
10	Silicone goggles	Protect patient eyes from laser radiation
11	Screws	Two sizes of "3*10" and "4*8" are included for fixing the hanger
12	Rubber rings	Prevent water leakage at the handle connection
13	Screwdriver	Designed for tightening and loosening threaded fasteners
14	Bracelet rope	Connect the handle to prevent the handle from slipping off the hand
15	Glasses cloth	Cleaning of glasses
16	Glasses case	For storing glasses
17	Dust-proof fan net	Can be magnetically attracted to the air inlet of the rear panel to prevent dust
18	Security lock	Prevent the device from being turned on/off without permission

3.4 Unpack the Device

3.4.1 Open the safety lock on the air box packaging

3.4.2 Take out the Main unit

3.4.3 Take out the accessory box

3.5 Device Installation

3.5.1 Install hangers and support rods

Take out the relevant accessories from the accessory box

No.	Name	Quantity	Picture

No.	Name	Quantity	Picture
1	Hanger	1	
2	Support rod	1	
3	Screwdriver	1	
4	Screws	"3*10" size: 2pcs; "4*8" size: 2pcs.	

3.5.2 Installation steps (refer to Figure 3.5-1 to Figure 3.5-4)

1. Connect the support rod to the hanger.

2. Fix the connection between the support rod and the hanger with “3*10” size screws.

3. When you observe the machine from the front, insert the fixed support rod and hanger into the card slot in the upper right corner of the Main unit.

4. Fix it with two “4*8” size screws.

Figure 3.5-1

Figure 3.5-2

Figure3.5-3

Figure 3.5-4

Warning:
During the assembly process, no effort is required. If it can't be assembled, it must be repaired.

3.5.3 Handle Connection

Warning:
It is forbidden to separate the handle interface from the machine during use!
Never use tools to tighten the Handle connector -- finger-tight pressure is sufficient.

Handle connection steps (see Figure 3.5-5):

1. Insert the Handle connector into the Main unit connection port, as shown in view A, as far as it will go in.

2. Turn the connector latch in a clockwise direction(B).

3. As you turn the latch, the connector will continue to go into the port until you can turn it no more - now the handle is properly connected to the system.

4. To disconnect the handle, reverse steps 1 through 3 above.

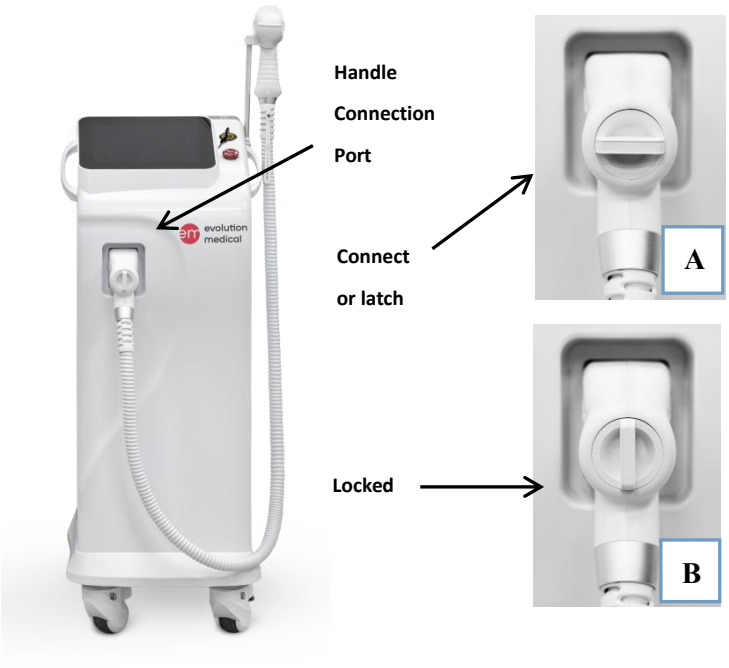


Figure 3.5-5

3.5.4 Remote Interlock Connection (see Figure 3.5-6)

Diode Laser Hair Removal Device is equipped with a remote interlock connector to provide maximum safety. The connector is situated on the service panel. An external switch should be connected to this connector to create a remote interlock system. This switch should be mounted on the entrance door, so that if the door opens the switch contacts also open and disable system operation.

To connect the remote interlock:

1. Ture the system off.
2. Remove the Security lock from the port on the system rear panel.
3. Link the external switch.
4. To make the machine operate normally, please reverse the above steps.

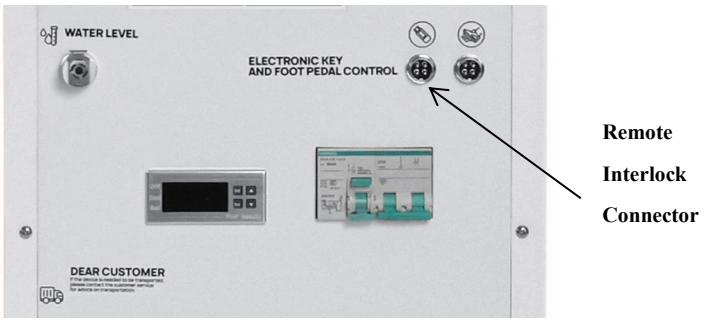


Figure 3.5-6

3.5.5 Foot switch connection

The foot switch supplied with the system is pneumatically operated for increased safety.

To connect the foot switch, connect the foot switch's black tube to the connection port on the system's service panel. (See Figure 3.5-7 and Figure 3.5-8)

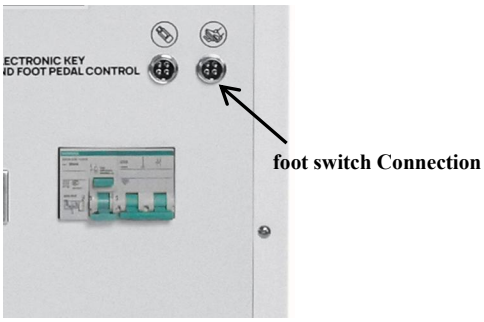


Figure 3.5-7

Figure 3.5-8

3.5.6 Filling the Coolant Reservoir

The cooling system's reservoir must be filled with deionized water. It is imperative that the level of the water in the reservoir be checked every three months and deionized water added if necessary.

Refer to Chapter 7: Maintenance for instructions of how to properly fill the water reservoir.

3.6 Cooling System Drainage

If the device is to be stored in a cold area where the temperature may fall below 0^{o} C (32^{o} F), the deionized water must be drained from the cooling system.

3.7 Moving the Device

To move the device within the clinic, do the following:

1. Place the handle in its cradle.
2. Disconnect the power cable.
3. Release the wheel breaks.
4. Slowly push or pull the system using the Side handle.

3.8 Working Environmental Requirements

Air Quality: the system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components.

Air-borne dust particles should be kept to a minimum. Dust particles absorb light/laser energy and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

Water Quality: the system should be operated using deionized water only. Regular tap water contains sediments that may damage the cooling system.

Temperature: to ensure that the system performs optimally, maintain room temperature between 20℃ and 30℃ (68 ℉- 86℉) and relative humidity of less than 80%.

3.9 Transportation Environment Requirements

Temperature limitations: In the storage and transportation environment, the temperature should be controlled between -50℃ and +50℃ (-58℉and +122℉).

Humidity limitations: In the storage and transportation environment, the humidity should be controlled below 80%.

Air pressure limitations: In the storage and transportation environment, the air pressure limit should be between the 90kPa and 110kPa.

Chapter 4 Device Description

4.1 Introduction

This chapter provides a detailed description of the EVOLUTION and M-I-X device. The description covers the device's intended use, environment conditions, Product characteristics and features, main components, controls, and functional, and device specifications.

4.2 Device name and model

Device name: Diode Laser Hair Removal Device

Model: EVOLUTION MEDICAL, M-I-X MEDICAL

4.3 Classification of the Device

4.3.1 According to IEC 60601-1

- According to the method of protection against electric shock:
  the device is Class I equipment.
- According to the degree of protection against electric shock:
  the device is type B applied part.
- device is not suitable for use in presence of a flammable anesthetic Mixture with air or with oxygen or nitrous oxide.

4.3.2 According to IEC 60825

- Class IV Laser

4.4 Intended Use and Contraindications and Cautions

4.4.1 Intended Use and Indications

The Diode laser (Hair removal device) (Model: EVOLUTION MEDICAL, M-I-X MEDICAL) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

4.4.2 Intended User

Nurses and doctors trained in the use of designated medical equipment.

4.4.3 General Contraindications

- Cancer; in particularly, skin cancer
- Pregnancy (including IVF)
- Use of photosensitive medication and herbs for which 808nm light exposure is contra-indicated
- Diseases which may be stimulated by light at 808nm
- Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and post treatment
- Active infection of herpes simplex in the treatment area
- History of keloid scarring
- Diabetes (insulin dependent)
- Fragile and dry skin
- Hormonal disorders (that are stimulated under intense light)
- Use of anticoagulants
- Epilepsy
- History of coagulopathies
- Use of oral Accutane (Isotretinoin) within the preceding 6 months
- Use of depilatories or other hair removal treatments such as waxing, plucking or electrolysis within the preceding 6 weeks
- Patients with tattoos, nevi, or malignant pathological changes in the treatment area

4.4.4 Adverse Effects of Treatment

The use of the EVOLUTION and M-I-X is similar to the use of other light-based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

- Severe or prolonged erythema (redness) and edema (swelling) within 2-24 hours of treatment that could last for several weeks.
- Irritation, itching, a mild burning sensation or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.
- Blisters, epidermal erosions, or peri-lesional hyperpigmentation may develop and remain evident for several days to several weeks following treatment.
- Eye damage from reflected or prolonged unprotected exposure to intense light. Protective goggles (appropriate to the wavelength) must be worn during all treatments to prevent eye injury.

It is important to observe tissue reaction during treatment. Poor patient screening and excessive optical energy may cause thermal damage and cause unwanted adverse effects.

4.4.5 Potential Side Effects of Treatment

- **Discomfort** - when a pulse is triggered, some patients experience various degrees of discomfort. Some patients describe the sensation as stinging, while others liken it to a

rubber band snap or a burning sensation that may last for up to one hour after treatment. Most patients tolerate the sensation during treatment.

- **Damage to Natural Skin Texture** - in some cases, a crust or blister may form. Normal wound care should be followed.
- **Change of Pigmentation** - there may be a change of pigmentation in the treated area. Most cases of hypopigmentation or hyperpigmentation occur in people with skin types IV to VI, or when the treated area has been exposed to sunlight within 3 weeks before or after treatment.

  In some patients, hyper-pigmentation occurs despite protection from the sun. This discoloration usually fades in three to six months, but in rare cases, (mainly hypo-pigmentation) the change of pigment may be permanent.
- **Scarring** - there is a chance of scarring; such as, enlarged hypertrophic or keloid scars. To reduce the chance of scarring, it is important to carefully follow all pre- and post-treatment instructions.
- **Excessive Swelling** - immediately after treatment, especially on the nose and cheeks, the skin may swell temporarily. Swelling usually subsides within hours but may continue for up to seven days.
- **Fragile Skin** - the skin at or near the treatment site may become fragile. If this happens makeup should be avoided, and the area should not be rubbed (as this might tear the skin).
- **Bruising** - purpura, or bruising, may appear on the treated area which may last from a few hours to several days.
- Hair removal by lasers can cause increased hair growth in some individuals. The highest risk groups for this response, are females of Mediterranean, Middle Eastern, and South Asian heritage, treated on the face or neck.

4.5 General Device Description

4.5.1 Working principle

Laser depilation is based on the theory of selective photo thermolysis. There is abundant melanin in the hair follicle and hair stem. The melanin is distributed amidst the cells between the hairball substrate and it can be transferred to the structure of hair stems (such as medulla, cortex, and hair cuticle). The laser can precisely target the melanin and apply the depilation treatment selectively. After the melanin absorbs the laser energy, the temperature rises, in this way, the surrounding hair follicle tissues are damaged, and the hairs are removed.

4.5.2 Working style

The complete system consists of its Main unit, the Laser treatment handle, and a foot switch. The handle is pressed against the patient's skin and a light pulse is delivered when the handle's trigger and the foot switch are activated. The handle's tip is cooled by the EVOLUTION and M-I-X cooling system.

Output parameters and other system features are controlled from the Touch-Screen Control Panel on the Main unit, which provides an interface to the system's microcontroller through an LCD touch-screen.

4.6 Image, symbols & abbreviations

Image or symbols	Meanings
	Type B Applied Part
	Refer to the User Manual
	Warning
	Laser
	Laser aperture
	REMOTE INTERLOCK CONNECTOR
	EMERGENCY LASER STOP
 	Laser warning sign, which declares the IEC standard and related laser parameters
	Prohibits dispensing without prescription
	Keep Dry
	Not recyclable

Image or symbols	Meanings
	Fragile Articles
	Upward
	Handle with Care

4.7 Main components

Main components of Diode Laser Hair Removal Device: Main unit, Laser treatment handle, and Foot switch.

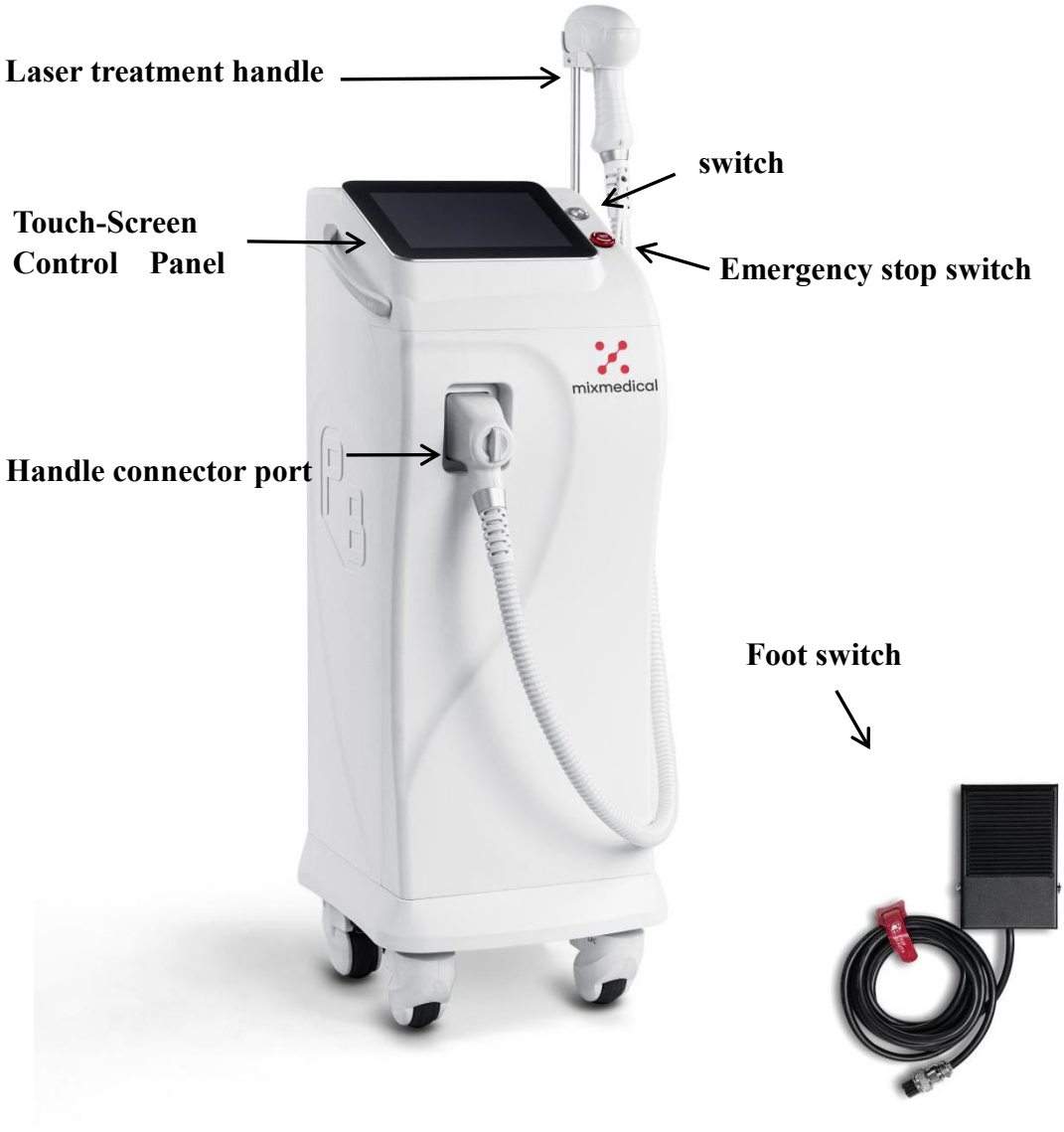


Figure 4.7-1

4.7.1 Main unit

The main unit includes the following components:

- Touch-Screen Control Panel
- Power system
- Microprocessor Control System
- Cooling system
- Circuit breaker

4.7.2 Device Controls

The EVOLUTION and M-I-X controls offer the following features (see Figure 4.7-1):

- **LCD Touch-Screen Panel** - this touch-controlled screen provides information on the status and settings of the device. The various screens of the display are described in detail in Chapter 5 - **Operating Instructions**.
- **Emergency Stop Switch** - this is a button designed for emergency shutdown of the system.

Warning:
Do not touch the surface of the LCD screen with sharp objects to prevent scratches.
Do not spill all kinds of liquids on the surface of the LCD screen to prevent damage.

4.7.3 Service Panel

The service panel (see Figure 4.7-2) is located on the system's back side. It incorporates all the required controls and connections for the system.

No.	Controls and Connections	Function Description
1	Vents	Transfer the heat generated by the machine in the working process in time to avoid affecting its normal operation.
2	Cooling system Filling ports	Add coolant to the water tank by connecting the water nozzle and the water pipe
3	Vent port	Circulates with the water filling port. After opening the mouth, the water filling port can be filled with water. When there is liquid out of the changing port, it is proved that the water tank has been filled with coolant.
4	Power cord port	Power the machine after plugging in
5	Remote Interlock Connector	Prevent the device from being turned on/off without permission
6	Foot switch Connection	Control the laser output of the machine by pedaling
7	Main circuit breaker	Leakage protection for the machine
8	Temperature control panel	Control the cooling effect of the refrigerator
9	Cooling system drain port	By connecting the water nozzle and the water pipe, the coolant inside the water tank is discharged

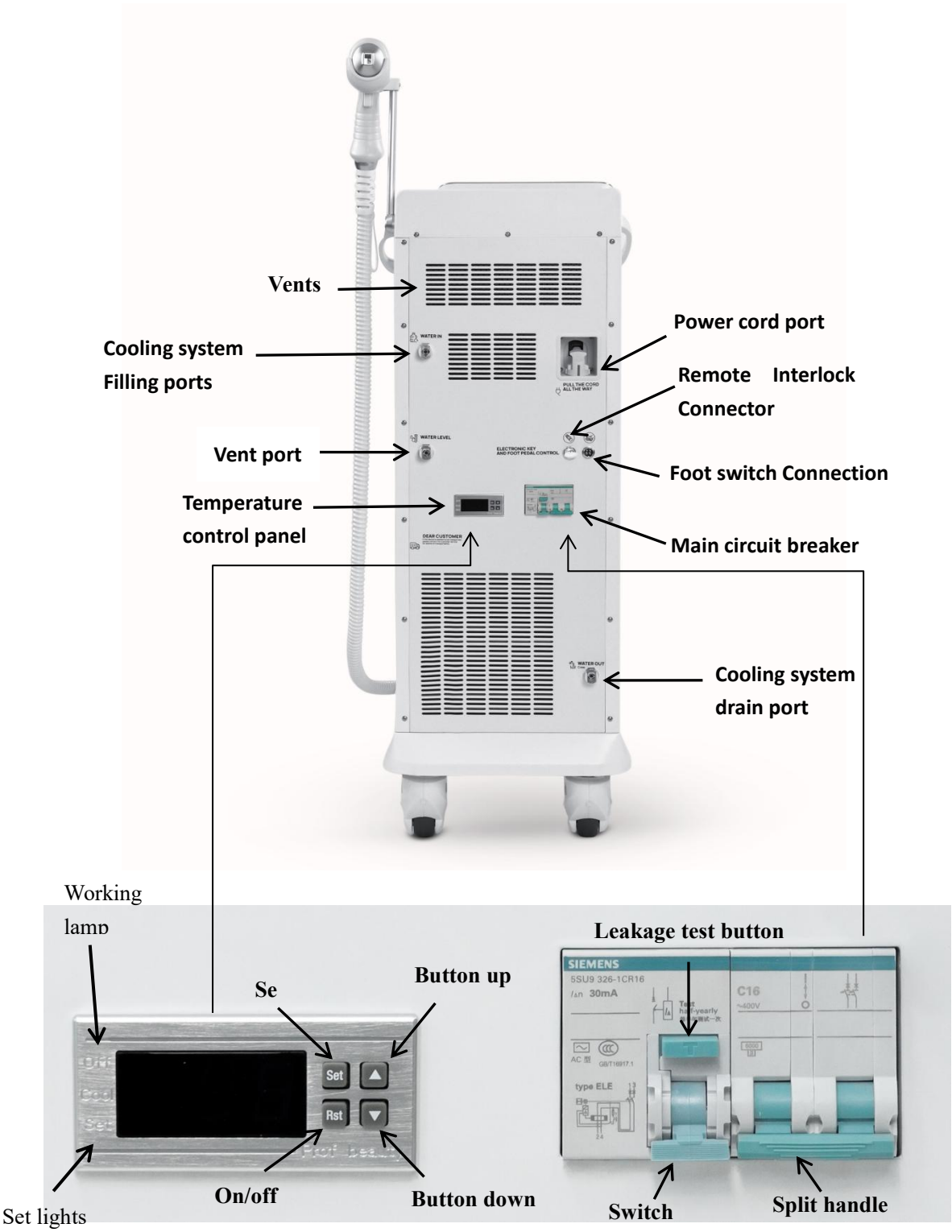

Vents
Cooling system
Filling ports
Power cord port
Remote Interlock
Connector
Vent port
Foot switch Connection
Temperature
control panel
Main circuit breaker
Cooling system
drain port
Working
lamp
Leakage test button
Se
Button up
Set
Rst
On/off
Button down
Set lights
SIEMENS
5SU9 326-1CR16
30mA
C16
type ELE
Switch
Split handle

Figure 4.7-2

4.8 Device Specifications

Item	EVOLUTION MEDICAL	M-I-X MEDICAL
Laser Wavelength	808nm±10nm	
Energy Density	1-77 J/cm^2	1-70 J/cm^2
Frequency	1Hz~10Hz	
Pulse Duration	3ms~320ms	
Spot Size	12.6mm*20.6mm	
Output Stability	±20%	
Laser Classification	Class IV	
WI-FI Specification	2.4GHz（IEEE 802.11b/g/n）: 2.400 GHz - 2.497 GH2 ; 5GHz（IEEE 802.11a/n/ac）: 4.900 GHz~5.845 GHz	
Power Supply	110V, 60Hz, single phase 1000VA	
Dimension	393×430×1130mm	
Weight	48Kg	

Chapter 5 Operating Instructions

Warning:
The use of semiconductor laser hair removal machine requires professional training by our company or an authorized agency before it can be used.

5.1 Preparation

5.1.1 The handle is the instrument that is in contact with the patient and disinfect with alcohol or tincture of iodine for more than 10 minutes before use.

5.1.2 Before you are ready to turn on the device, please make sure that the following things have been completed to avoid trouble during the treatment:

1) Is the voltage connected to the device 110V?
2) Is the main power cord of the equipment connected to the power socket?
3) Are laser safety glasses ready?

5.2 System startup

Confirm whether the leakage switch on the back panel protective shell is in the "ON" state and turn the emergency stop switch on the front panel clockwise to start the system.

After the device is started, the system initialization and other information appear on the screen, and then the system starts to self-check according to the program. If there is an error in the self-check, an error message will be displayed on the screen. Please refer to Chapter 7 "Troubleshooting" for troubleshooting.

After the system self-check is completed, enter the main interface (see Figure 5.2-1).

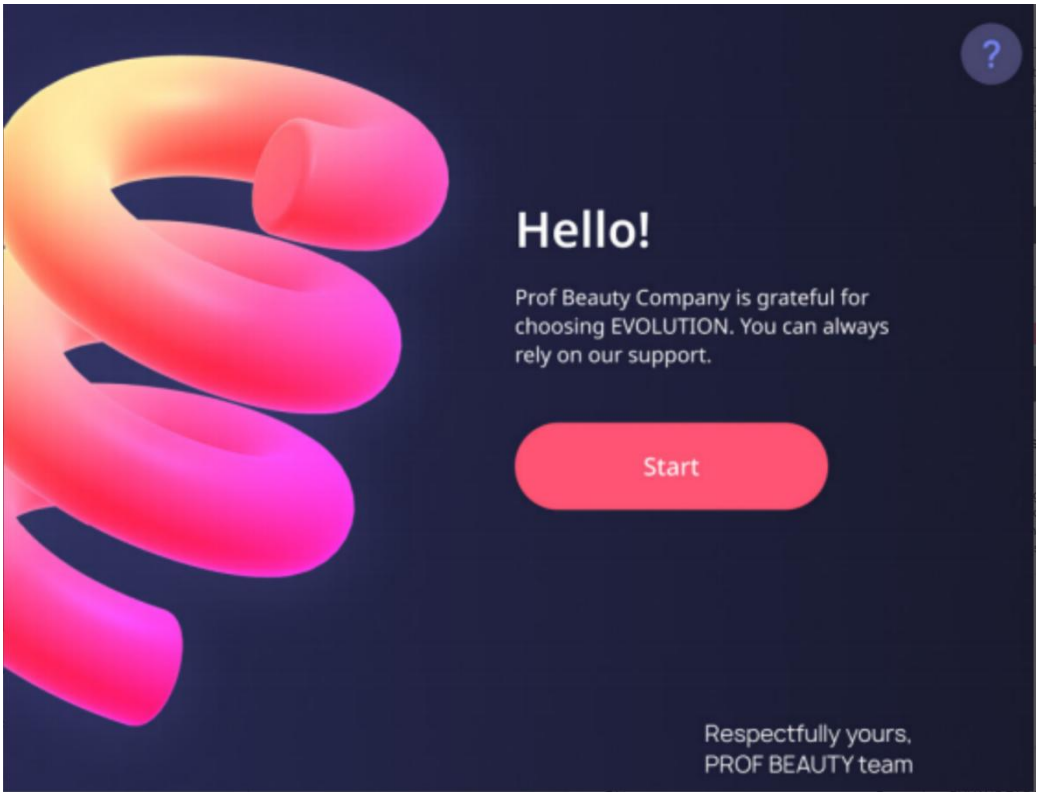


Figure 5.2-1

Note: The normal startup time of the system takes about 5 seconds.

Start: start operation

After clicking "Start", enter the password and click "Next" (Figure 5.2-2) to enter the operation page.

Warning:
When the operator leaves, he needs to click the small green house button to return to the password input interface to prevent the use of unexpected personnel.

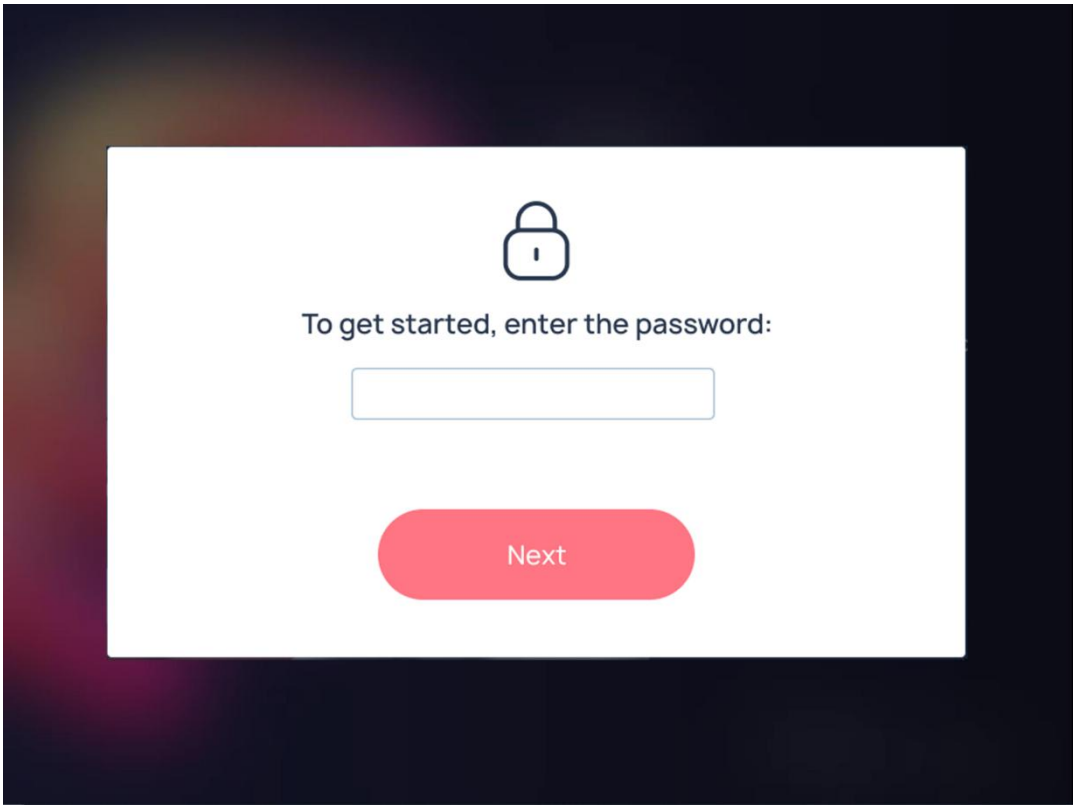


Figure 5.2-2

5.3 Touch LCD screen

This product uses a touch LCD screen with high sensitivity and good resolution as the operating window. You can directly click the software buttons on the screen with your finger to select and set various parameters, modes, and states.

5.4 Function interface

5.4.1 Customer Information (see Figure 5.4-1)

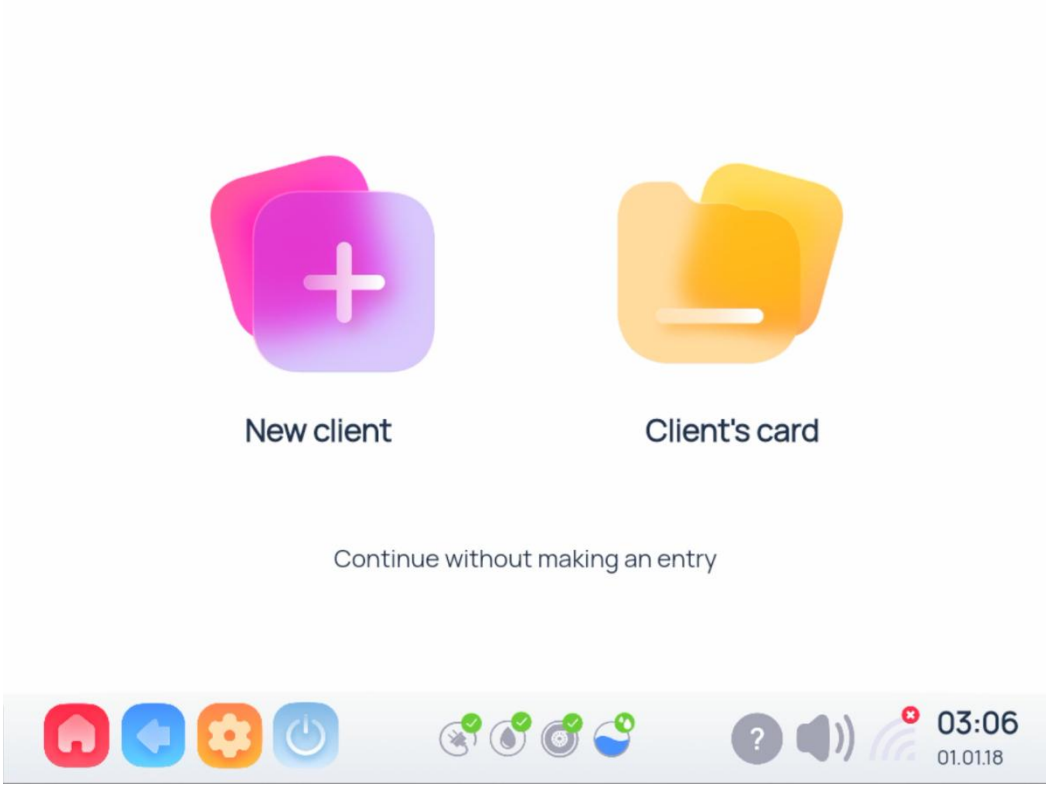


Figure 5.4-1

New client: Create new client information

Client card: existing customer information

Continue without an appointment: Continue without an appointment

Note: Click the corresponding icon to operate, new customers need to click "New client" and fill in the customer's personal information and then click "Save" to operate (see Figure 5.4-2); old customers need to click "Client card" to see the customer information for Editing and operating (see Figure 5.4-3); Click “Continue without an appointment” to directly enter the treatment interface (see Figure 5.4-6).

Note: To create new user information here, you need to obtain the patient’s informed consent, you can also fill in relevant information at will, and you need to fully inform the patient of the purpose of the information recorded here. In short, the final decision belongs to the patient. The ownership of the recorded information belongs to the patient, and the patient has the right to request deletion of the information at any time.

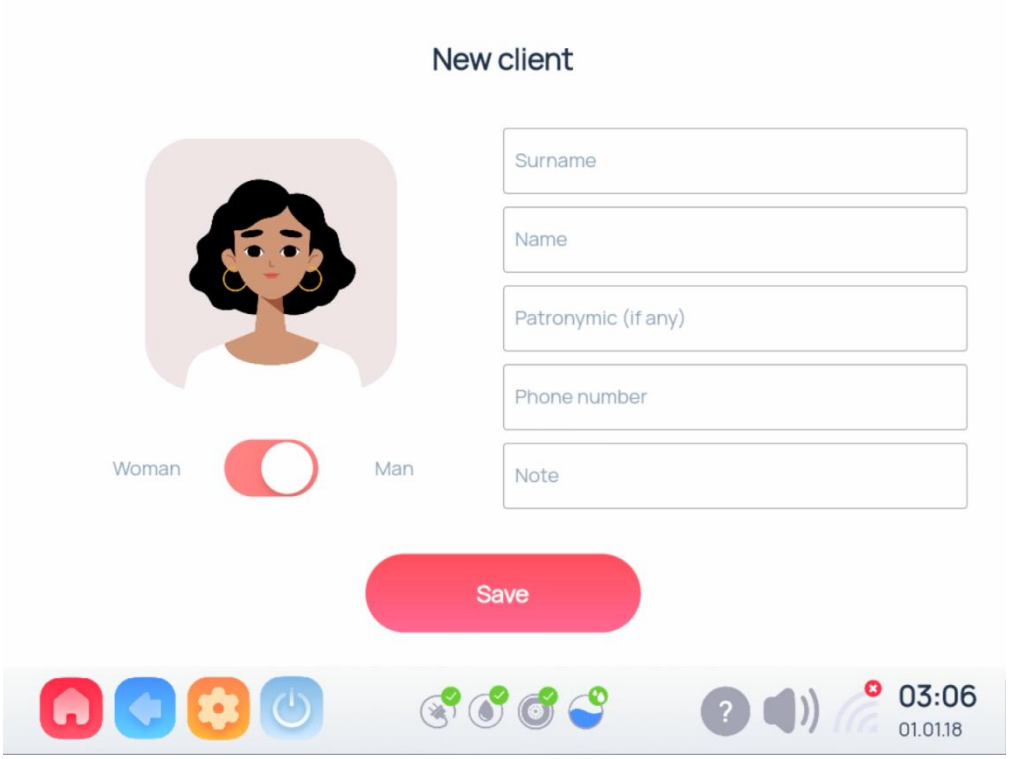


Figure 5.4-2

Button	**description**
Woman Man	choose gender
Save	Save data.

After clicking Save, you can enter the treatment interface (see Figure 5.4-6).

Note: For old customer information, please refer to the figure below. (See Figure 5.4-3)

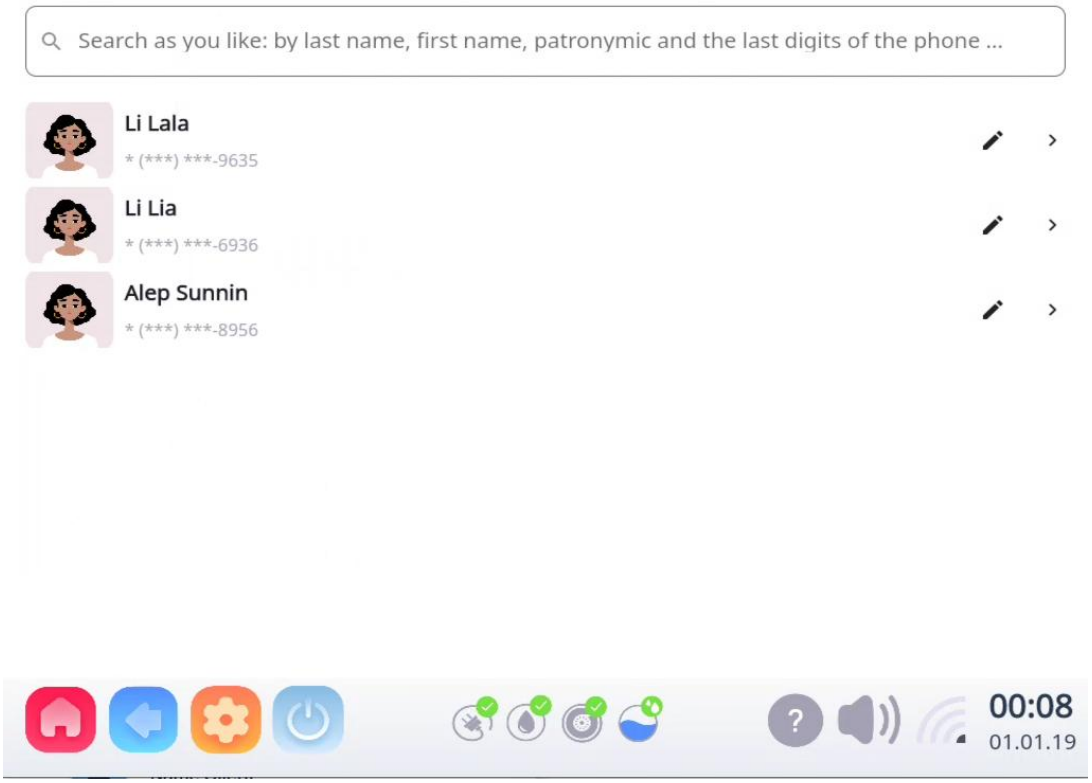


Figure 5.4-3

Note:After clicking on the patient information to be treated, please refer to the figure below. (See Figure 5.4-4)

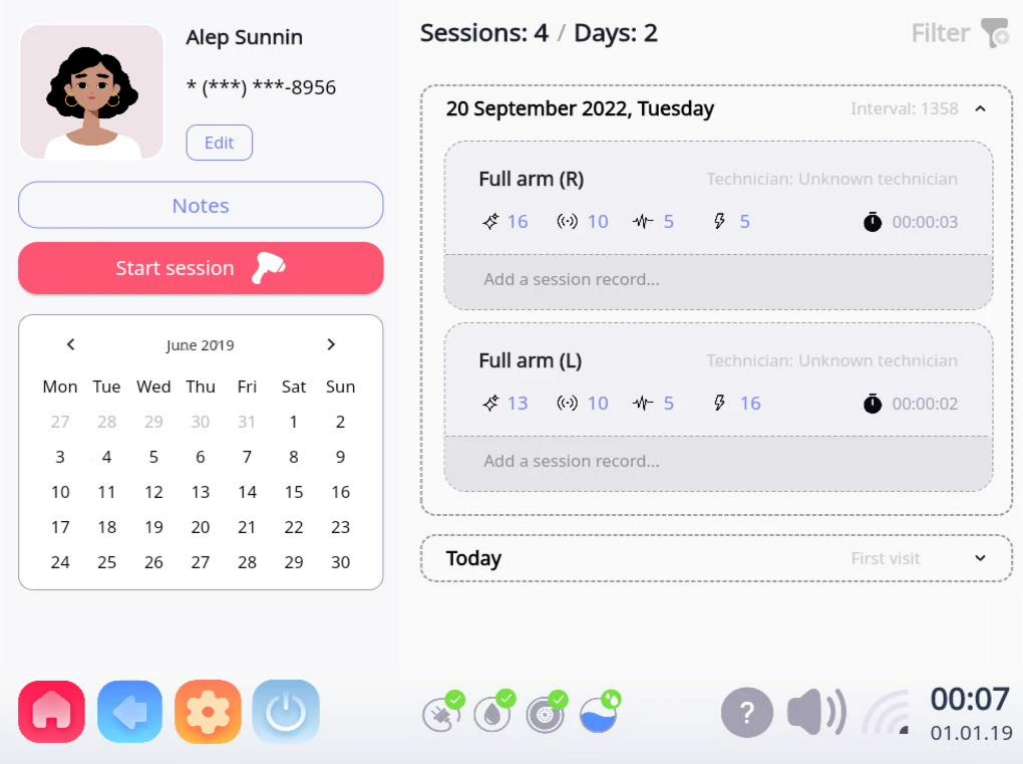


Figure 5.4-4

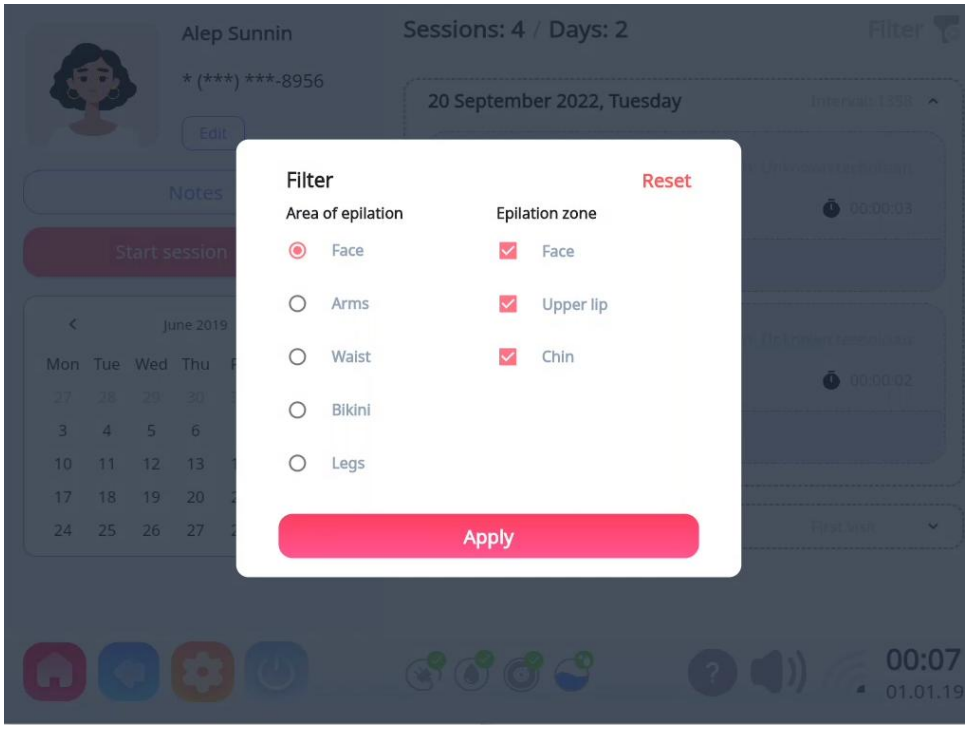
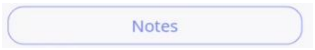
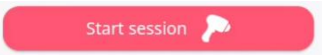
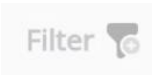
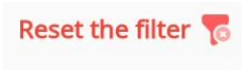


Figure 5.4-5

Button	description

	Edit customer information(see Figure 5.4-2)
	View the information of the note
	Start treatment interface (see Figure 5.4-8)
	Click the corresponding point to filter the treatment records of the corresponding part (see Figure 5.4-5)
	Parts can be reset

5.4.2 Select the treatment site (see Figure 5.4-6)

Figure 5.4-6

Note: Click on the white area corresponding to the above model to remove hair for that area, which will turn red when clicked. (Figure 5.4-7 and Table 5.4-1)

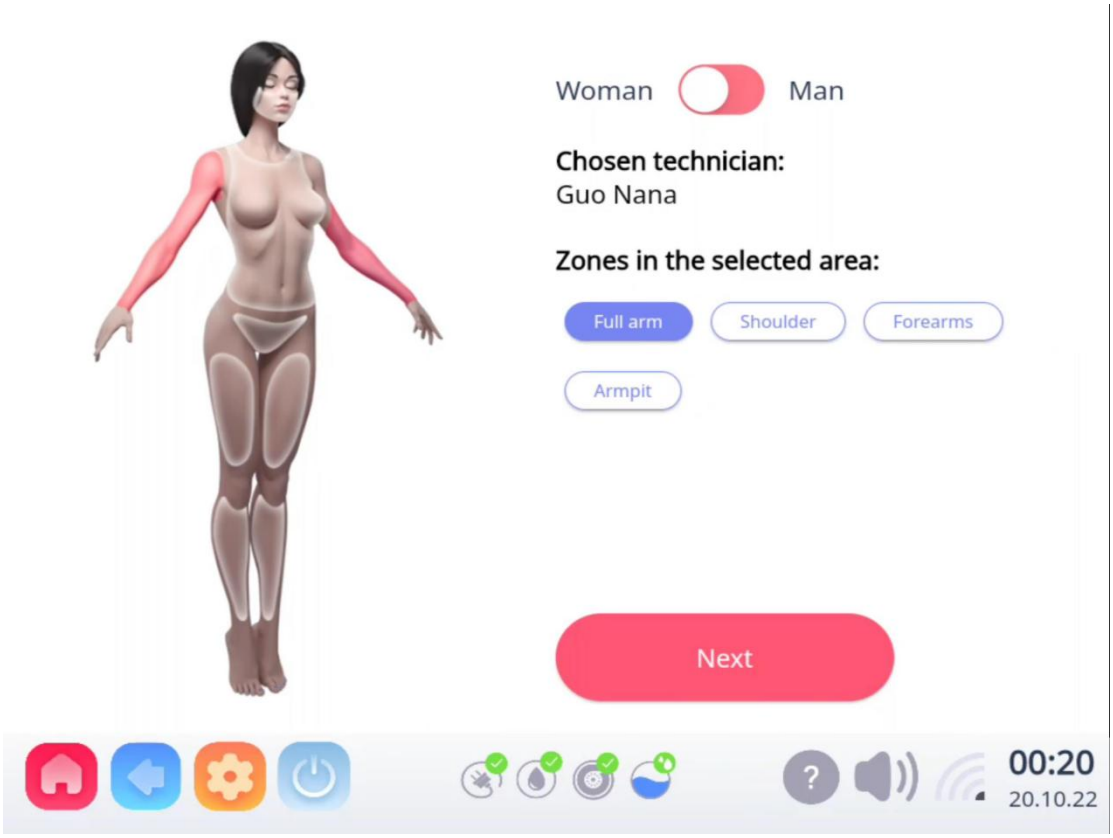
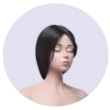
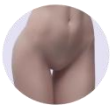


Figure 5.4-7

Note: Click the "Chosen technician": you can select the name of the corresponding operator (only as a record). How to add operator information, you can click "Technicians" in the "Administration" of the settings to add and modify the technician information or delete (see Figure 5.4-21).

Table 5.4-1

Hair removal area	Depilation area
	Face
	Upper lip
	Chin
	Full arm
	Shoulder
	Forearms
	Armpit
	Chest

Hair removal area	Depilation area
	Areoles
	Back
	Stomach
	Bikini
	Inner buttock area
	Pubic area
	Labia
	Full legs
	Upper leg
	Lower leg
	Buttocks
	Calves

Note: After selecting the area, you can enter the treatment interface to select treatment parameters. (See Figure 5.4-8)

5.4.3 Operation adjustment

The main interface displays (see Figure 5.4-8)

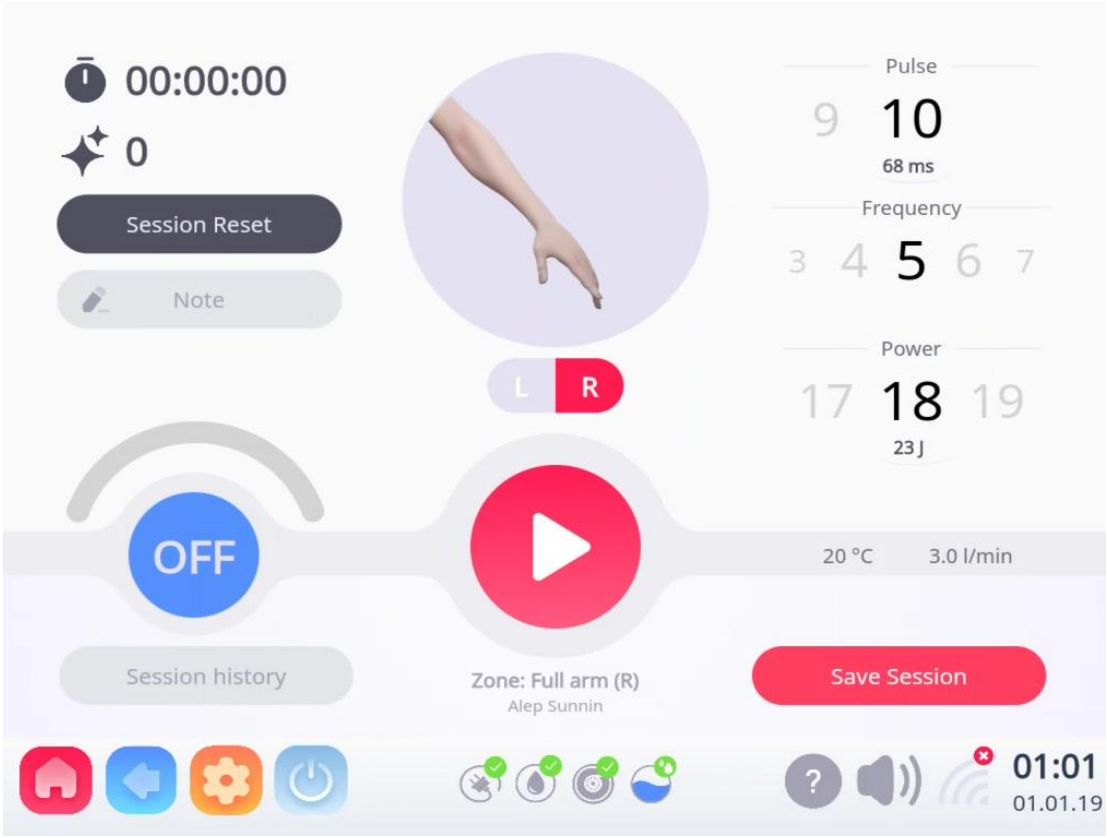
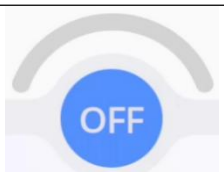


Figure 5.4-8

Table 5.4-2

Button	Description
Zone	Client's area
00:00:00	The duration of this project
0	The number of output pulses used in this project
Session Reset	Clear the pulse number and duration of this project
Note	Notes about customers
Session history	Click to view customer's hair removal record data
Save Session	Record keeping
Pulse	Pulse duration adjustment
Frequency	Frequency adjustment

Button	Description
Power	Power (Fluency) adjustment
	Cooling capacity adjustment（1~100）
	Standby/pause, cannot hair removal operation
	Start hair removal
	Setting operation interface
	Return last interface
	Main interface (Exit the login state and return to the password input interface (Figure 5.2-2)
	Shut down

5.4.4 Setting operation (see Figure 5.4-9)

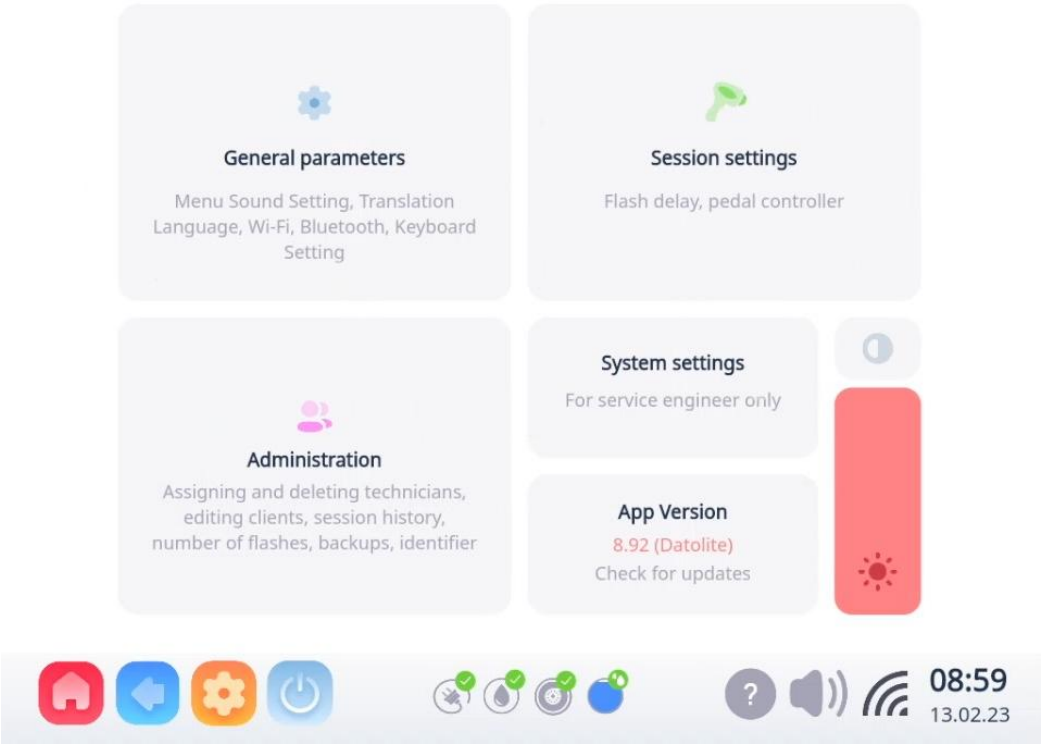


Figure 5.4-9

Button	Description
	Interface theme selection, toggle background color.
	Adjust screen brightness
	General parameters (see Figure 5.4-10)
	Session settings (see Figure 5.4-15)

Button	Description
	Administration (see Figure 5.4-16)
System settings	System settings (see Figure 5.4-24)
App version	Check for updates

5.4.4.1 General parameters (see Figure 5.4-10)

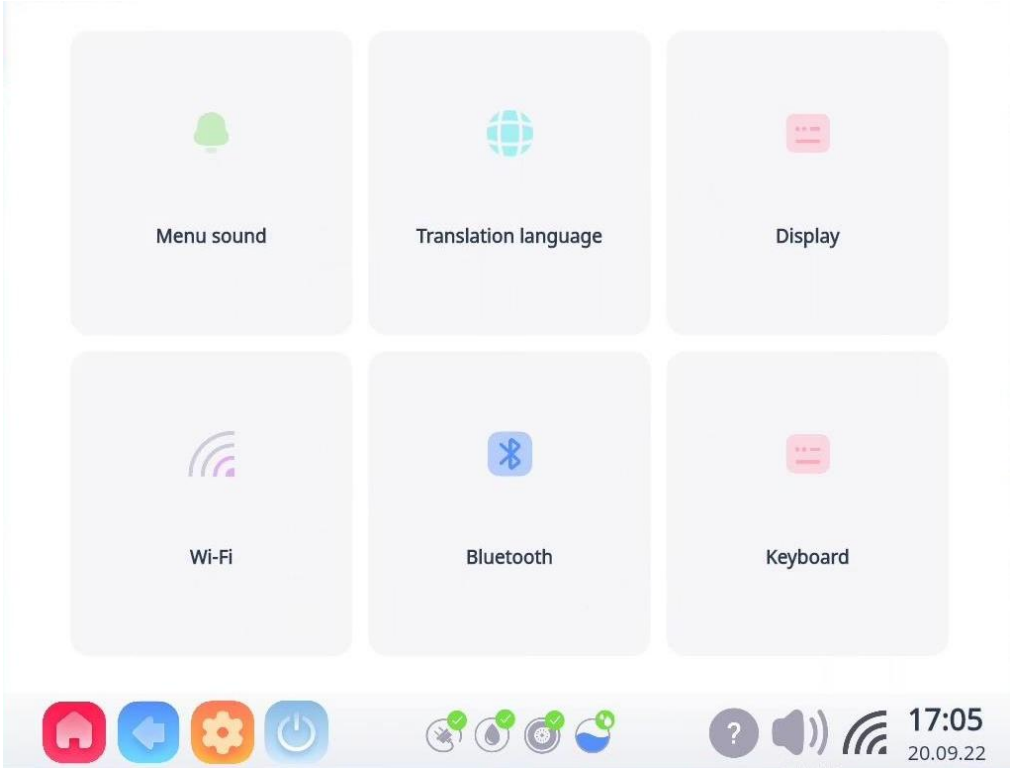


Figure 5.4-10

- Click “Menu sound” to adjust the volume of laser operation and choose different sounds ,push down to reduce sound, push up to reverse(see Figure 5.4-11).

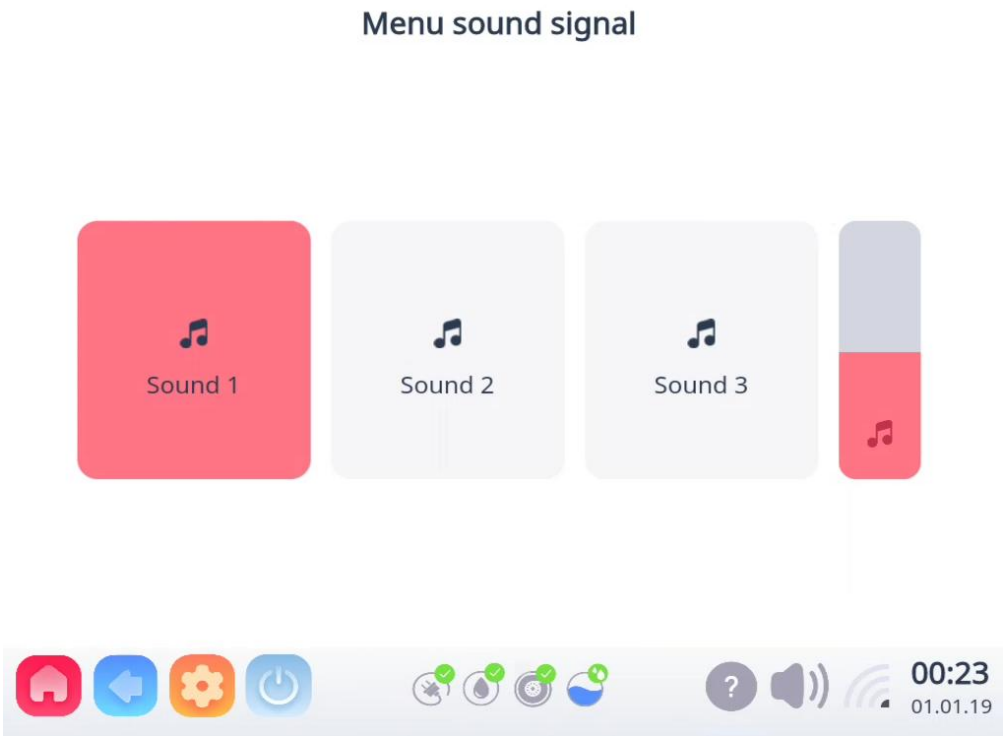


Figure 5.4-11

- Click “Translation language” to select the language.(see Figure 5.4-12)

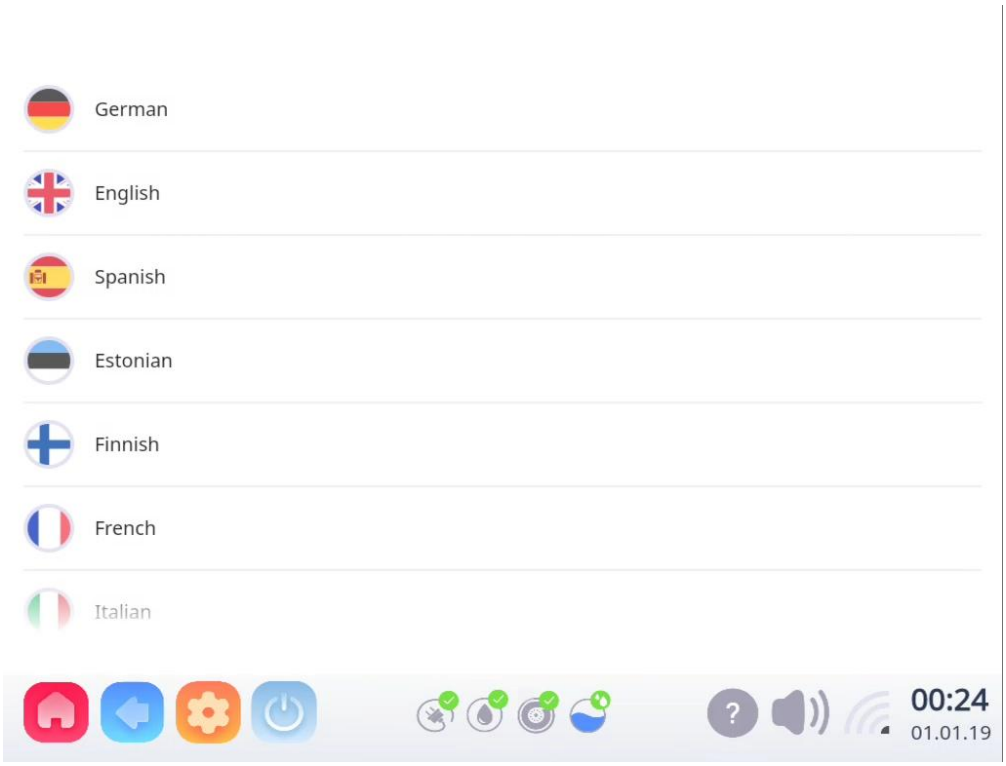


Figure 5.4-12

- Click "Display" to enable or disables page transition animation.When clicking this button to jump to each page, the speed will be slower, and when closing, it will be the opposite.(see Figure 5.4-13)

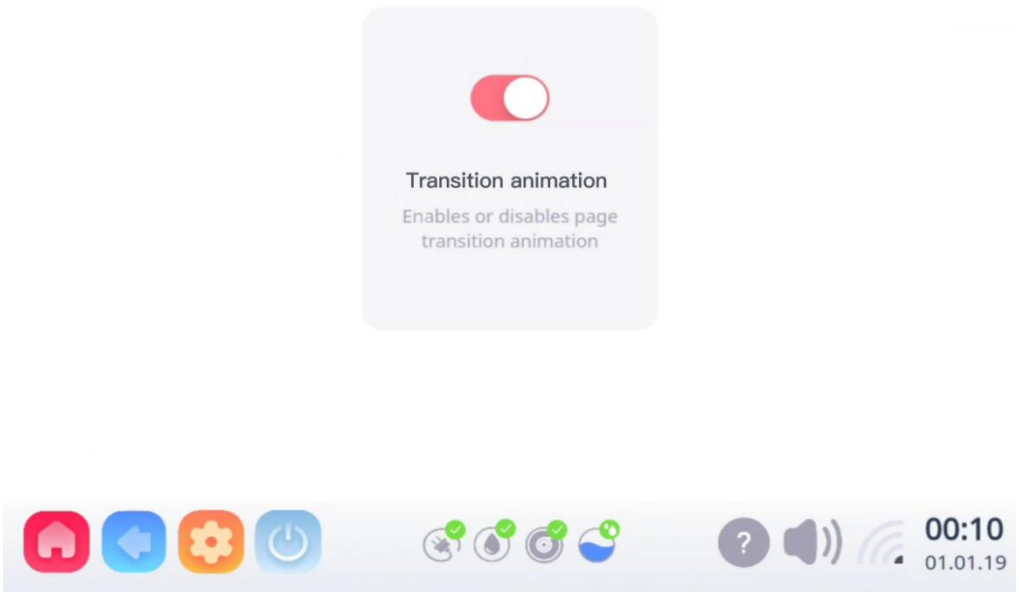


Figure 5.4-13

- Click “WIFI” to Select appropriate wifi for connection.
- Click "keyboard"to set the wifi control board language.(see Figure 5.4-14)

Do not modify it by yourself, this function is only operated under the guidance of relevant maintenance personnel.

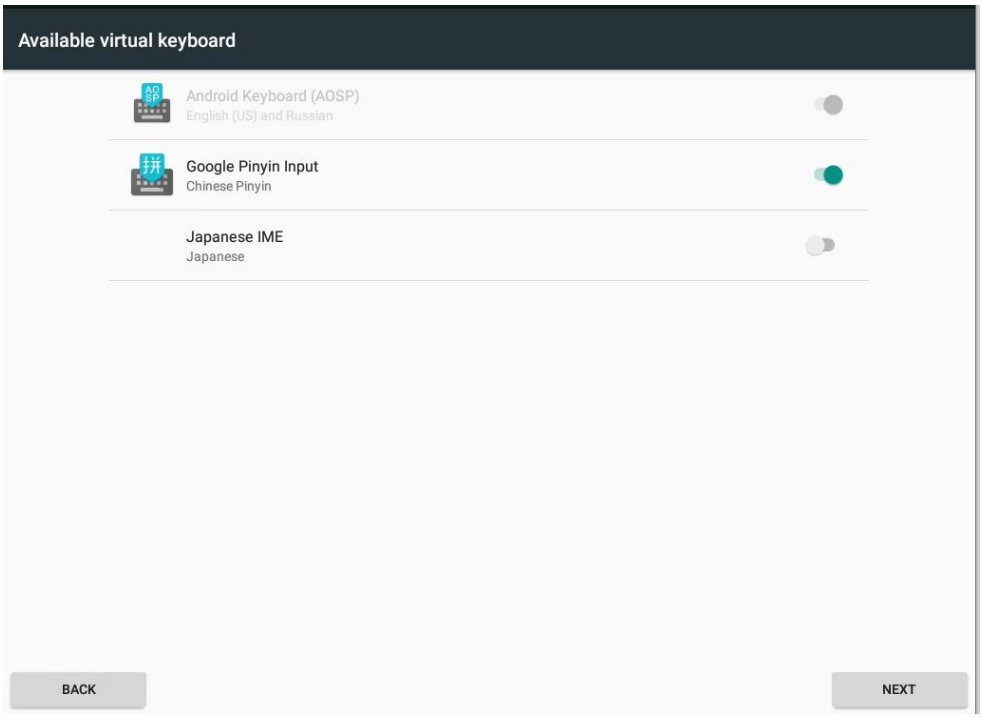


Figure 5.4-14

5.4.4.2 Session settings (see Figure 5.4-15)

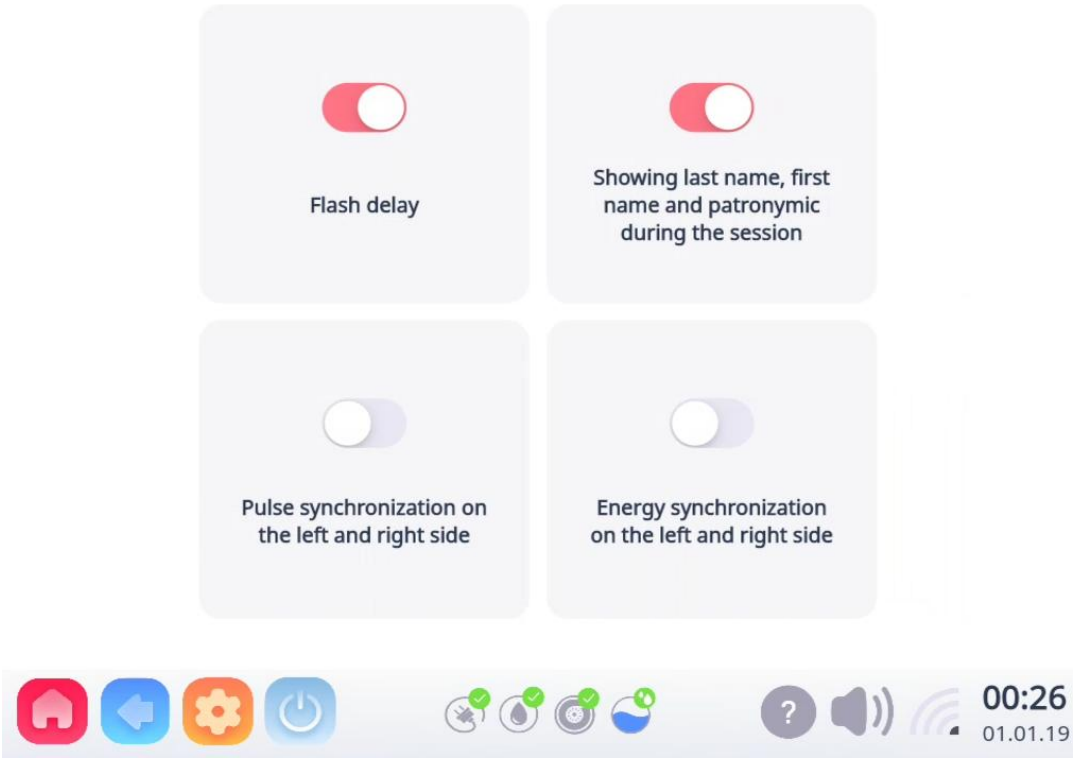
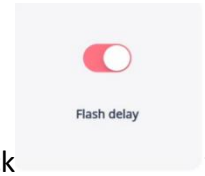


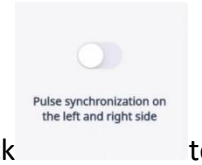
Figure 5.4-15

- Click 

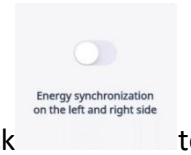
to delay the light output of the handle, with a delay of 300ms.

- Click 

to display the customer's last name in the treatment interface.

- Click 

to synchronize the pulses on the left and right side.

- Click 

to synchronize the energy on the left and right side.

5.4.4.3 Administration (see Figure 5.4-16)

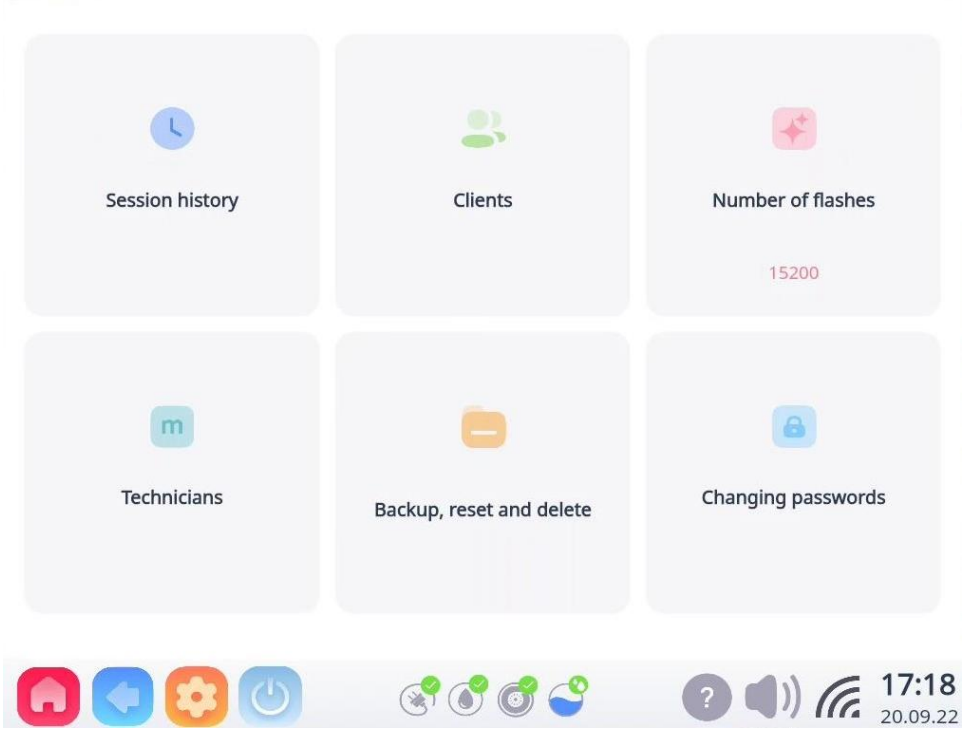


Figure 5.4-16

- Click “Session history” to view and manage the treatment history data (see Figure 5.4-17), the interface will display the information of all customers who have used the machine on the same day, including: customer name, contact information, treatment area, pulse, frequency, power data during treatment, total number of shots, time;Click any customer to view its detailed session history.(see Figure 5.4-18)

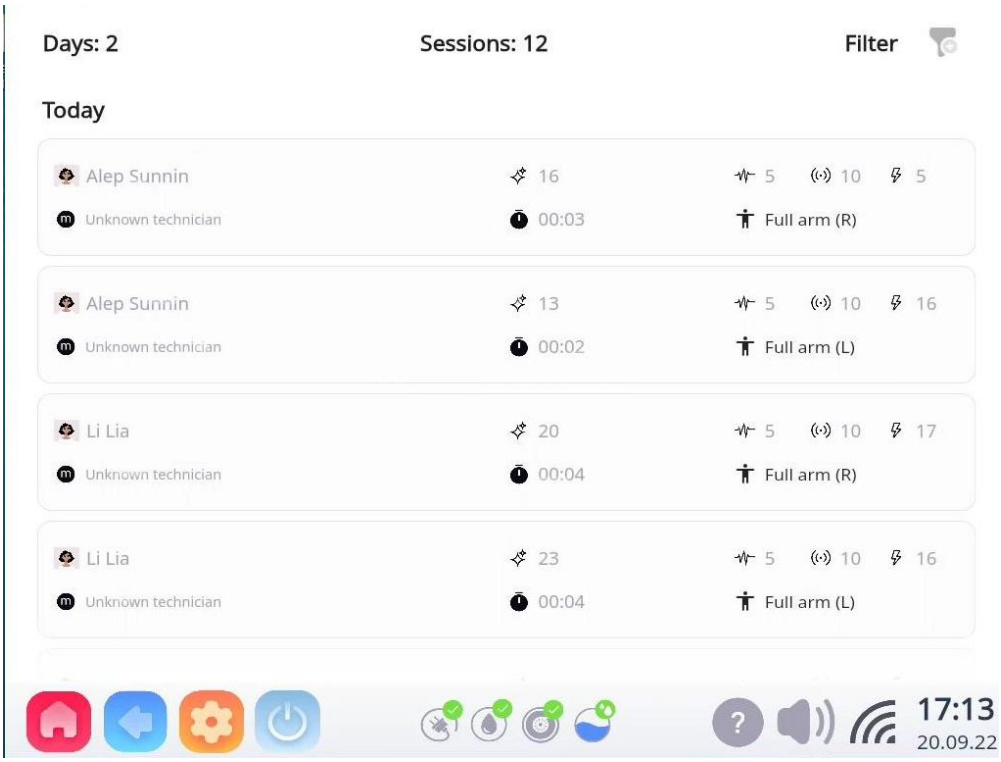


Figure 5.4-17

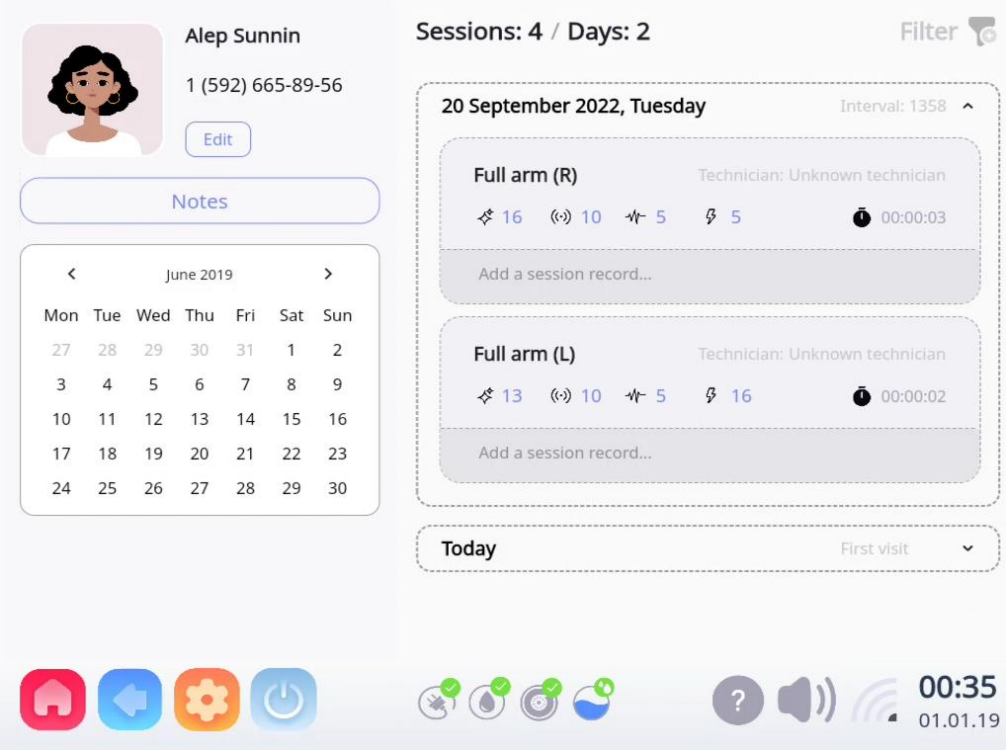


Figure 5.4-18

- Click “Clients” to view and manage client information (see Figure 5.4-19); Click " " to change the customer's personal information;Click to delete the client information; Click the customer name to edit and change the customer information(see Figure 5.4-20).

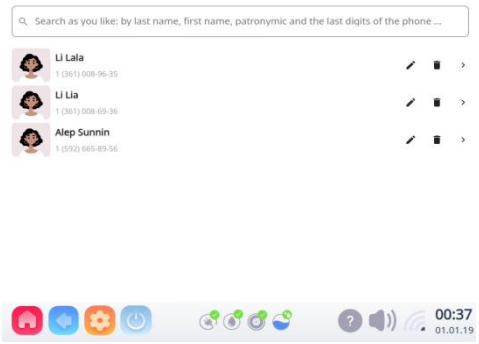


Figure 5.4-19

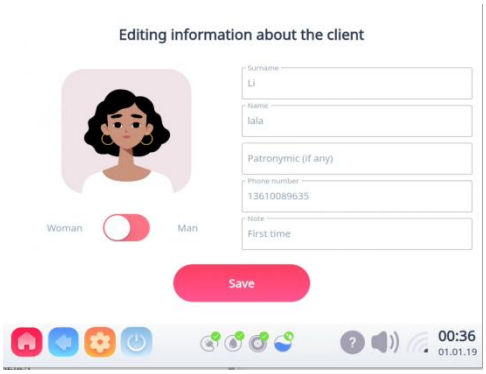


Figure 5.4-20

- Click “technicians” to view and manage operators (see Figure 5.4-21);

Click  to add operator information, after filling in relevant information, click “save” to add (see Figure 5.4-22);

Click  to edit and change the operator information;

Click  to delete the operator information.

Figure 5.4-21

Figure 5.4-22

- Click “backup， reset and delete” to restore the settings to factory settings (see Figure 5.4-23);

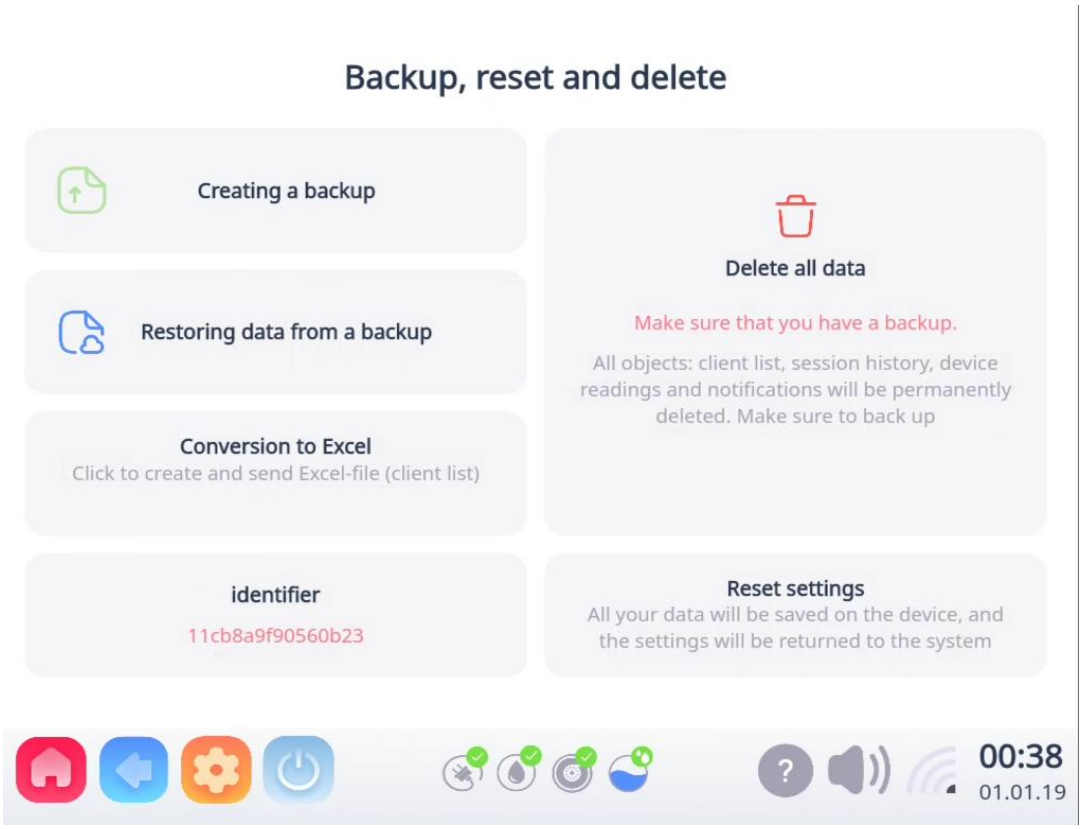
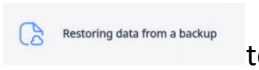


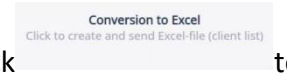
Figure 5.4-23

Click

to backup data to server;

Click 

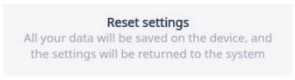
to restore deleted backup data;

Click 

to create and send excel-file (client list);

Click 

to clear all customer data;

Click 

to restore the device to factory settings.

- Click “changing passwords” to change the password;

5.4.4.4 System settings (see Figure 5.4-24)

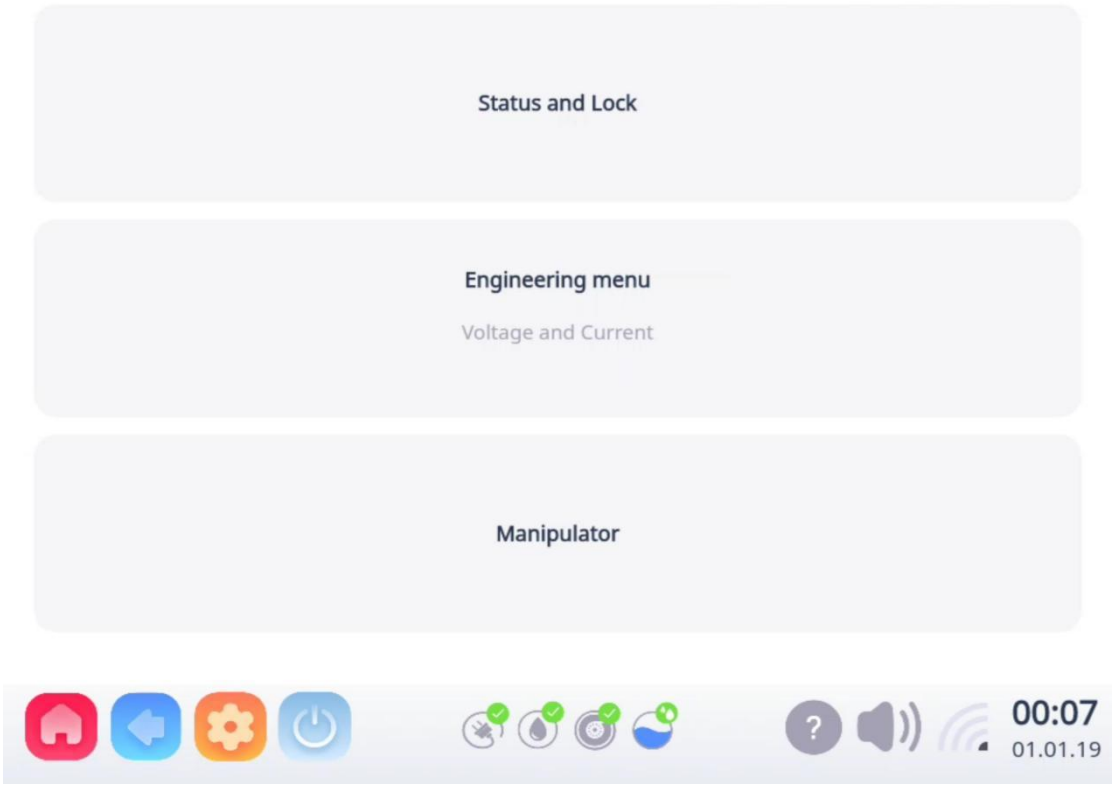


Figure 5.4-24

- Click “status and lock” to lock and detect liquid temperature、overheat protection、handpiece check、fluid movement and water lever(see Figure 5.4-25)

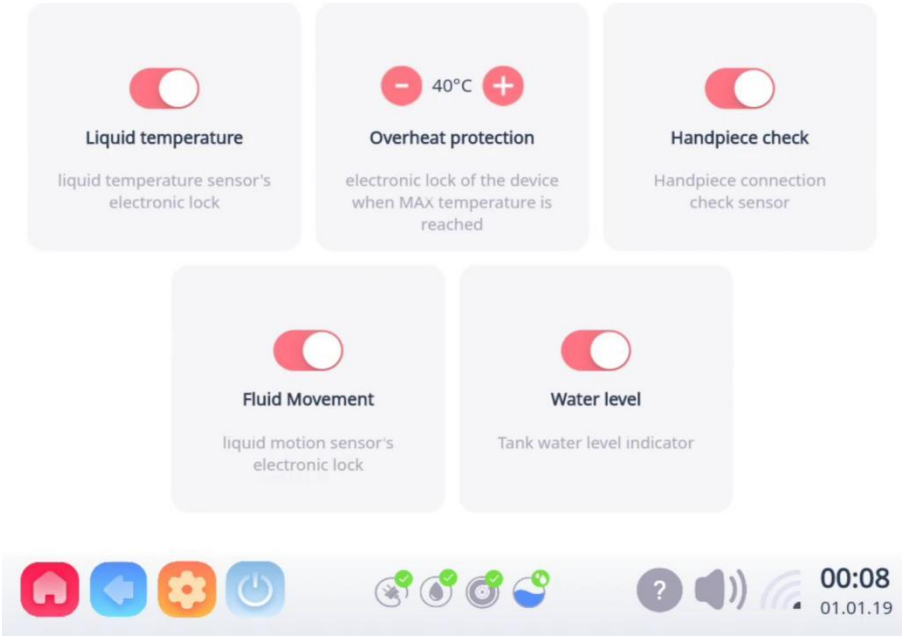


Figure 5.4-25

- Click "Liquid temperature" to turn on and off the monitoring function of the water temperature of the device, which is reflected in this position (see Figure 5.4-26). When the water temperature reaches the value set by "Device locking when reaching the maximum temperature" (the default setting is 40°C), it will automatically stop working and will not be able to emit light, but it will not be powered off. It can work again after the water temperature drops. The factory default is on.

After the function is turned off, the water temperature value will still be displayed in real time, but when the displayed value exceeds the set alarm value, the device will not take other measures.

Do not turn off this function by yourself, and only operate it under the guidance of relevant maintenance personnel. It is used for temporary measures after temperature sensor failure.

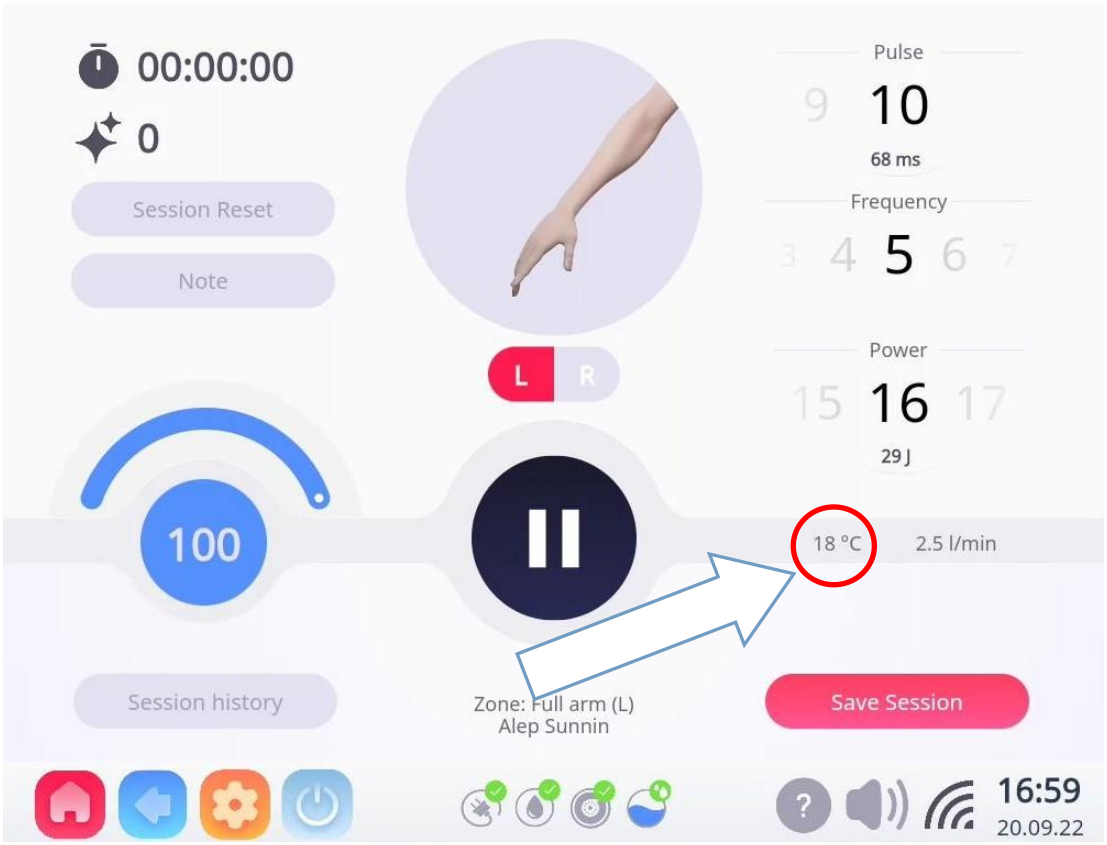


Figure 5.4-26

- "Overheat protection" displays the device alarm temperature threshold, click the plus and minus signs to adjust the temperature threshold. (The default setting temperature is 40°C).

- Click “Handpiece check” to turn on and off the monitoring of the connection status of the handle, and the monitoring results are reflected in this position (see Figure 5.4-27). The factory default is on.

Do not turn off this function by yourself, and only operate it under the guidance of relevant maintenance personnel. It is used as a temporary measure after the handle connection sensor fails.

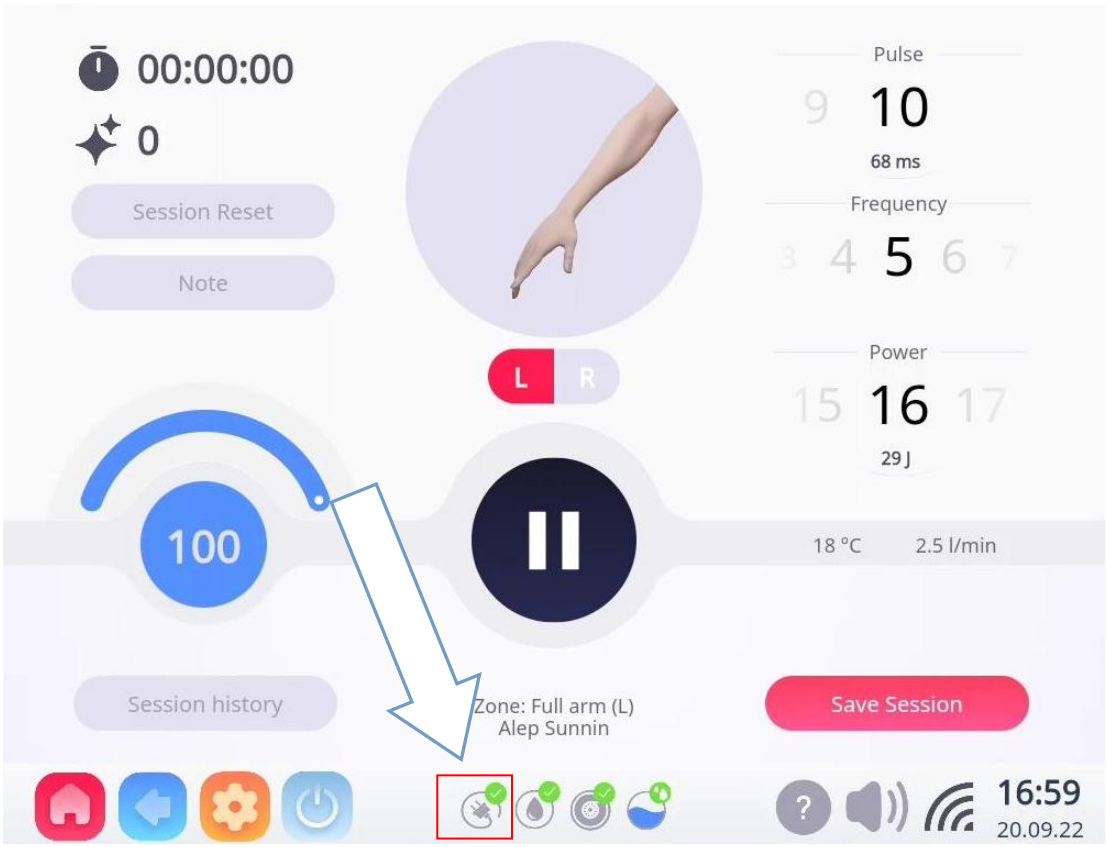


Figure 5.4-27

- Click "Fluid Movement" to turn on the water flow monitoring, which is reflected in this position (see Figure 5.4-28). (Normal value is 2.0 l/min or more). The factory default is on.

After this function is turned on, when the value is lower than 2.0 l/min, the device cannot work normally.

After this function is turned off, the water flow value will still be displayed in real time, but when the displayed value is lower than 2.0 L/min, the device will not take other measures.

Do not turn off this function by yourself, and only operate it under the guidance of relevant maintenance personnel. It is used for temporary measures after the water flow sensor fails.

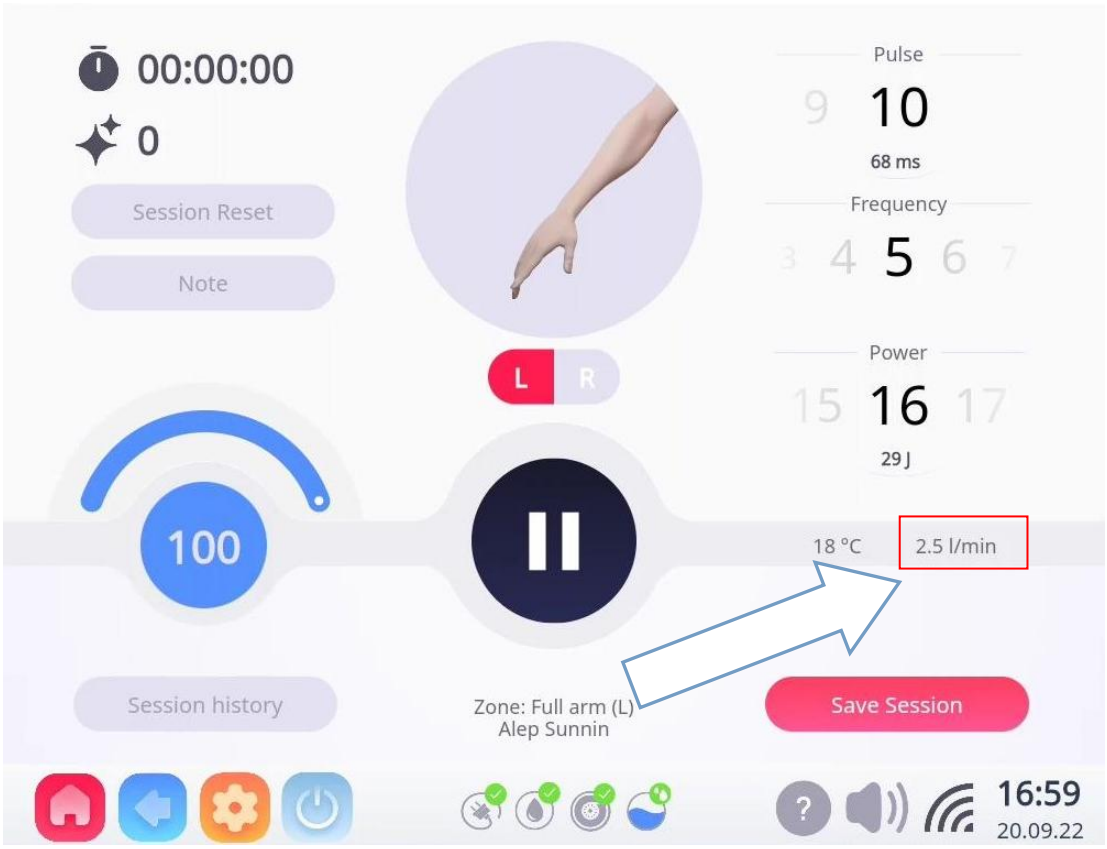


Figure 5.4-28

- Click “Water level” to turn on and off the monitoring of water level status, and the monitoring results are reflected in this position (see Figure 5.4-29). The factory default is on.

Do not turn off this function by yourself, and only operate it under the guidance of relevant maintenance personnel. It is used as a temporary measure after the Water level sensor fails.

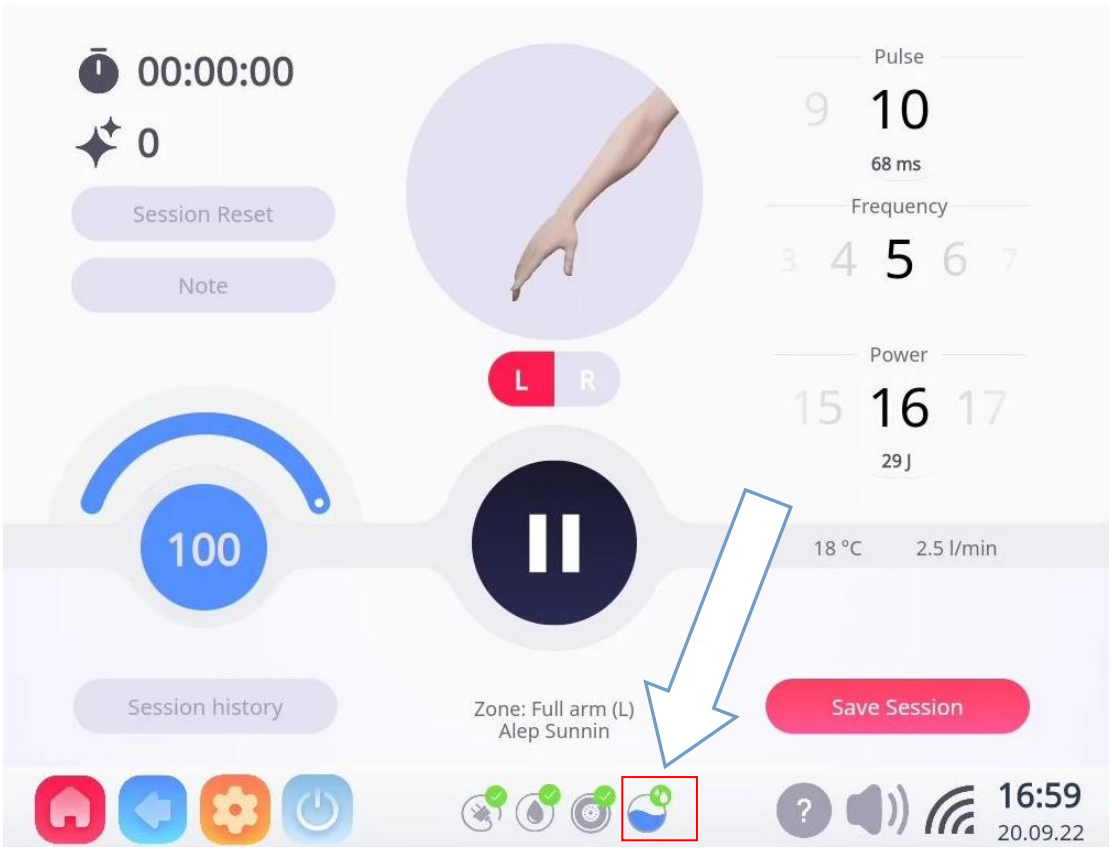


Figure 5.4-29

- Click"Controller version”to display current version information.

- Click "Engineering menu" to enter the service catalog interface, and you can view some electrical data of the device. (See Figure 5.4-30)

Figure 5.4-30

Icon	Description
Water pump (Voltage)	The working voltage value of the water pump
Water pump (Current strength)	The working current value of the water pump
Main’s voltage	the input mains voltage
Handlepiece cooling (voltage)	The working voltage value of laser handle cooling piece
Handlepiece cooling (Current strength)	The working current value of laser handle cooling piece
	Notification for low mains voltage

Icon	Description
	Adjust the voltage to prevent the unstable detection of the light output of the machine when the voltage is too low.

- Click "Manipulator"to monitor the handlepiece diodes.(See Figure 5.4-31)

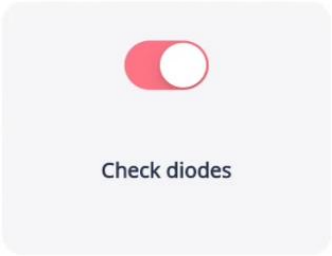


Figure 5.4-31

Do not modify it by yourself, this function is only operated under the guidance of relevant maintenance personnel.

Four icons are set at the bottom of the screen (see Fig. 5.4-32 and Table 5.4-4):

Figure 5.4-32

No.	Icon	Description
1		The handle is connected successfully
		The handle is connected failed
2		Normal water flow
		Abnormal water flow
3		The water pump is normal
		The water pump is abnormal
4		A lot of water, no need to add water.
		Moderate amount of water, need to add water
		lack of water, need to add water.

Table 5.4-4

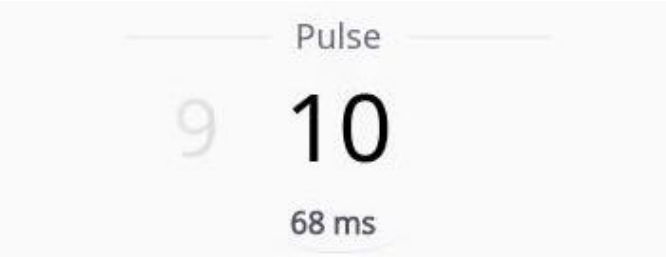
5.4.4.5 App Version

Click“App Version”to display the current version information and update the latest version.

5.5 Pulse/frequency/output method

5.5.1 Pulse

The pulse width is expressed as the output time of the working laser.



The pulse width setting range is 3-320ms. Adjust (decrease/increase) the value by clicking the "left and right" two arrow-shaped buttons.

The pulse width is limited by the frequency value, and the system will automatically determine the available pulse width range according to the adjusted frequency value.

5.5.2 Frequency

Frequency represents the laser pulse output period.

The frequency setting range is 1Hz-10Hz. Adjust (decrease/increase) the value by clicking the "left and right" two arrow-shaped buttons.

5.5.3 Output mode

When the handle button is pressed, the laser continuously outputs the pulse waveform with the set frequency and pulse width until the button is released to stop.

5.6 Power setting

5.6.1 Energy adjustable range

The energy setting range is 1-77J/cm^2(M-I-X: 1-70J/cm^2). Adjust (decrease/increase) the value by clicking the "left and right" two arrow-shaped buttons.

Start the test from low energy level when using the device and observe the treatment effect and patient acceptance to determine the final treatment parameters.

5.7 Treatment plan

5.7.1 Hair removal steps (take the arm as an example)

Step 1: cleaning

Before laser hair removal, it is necessary to pre-clean the part that needs to be removed and disinfect the part.

Step 2: Shave the hair

In order to make the laser better conduction during hair removal, the hair exposed on the body surface needs to be shaved.

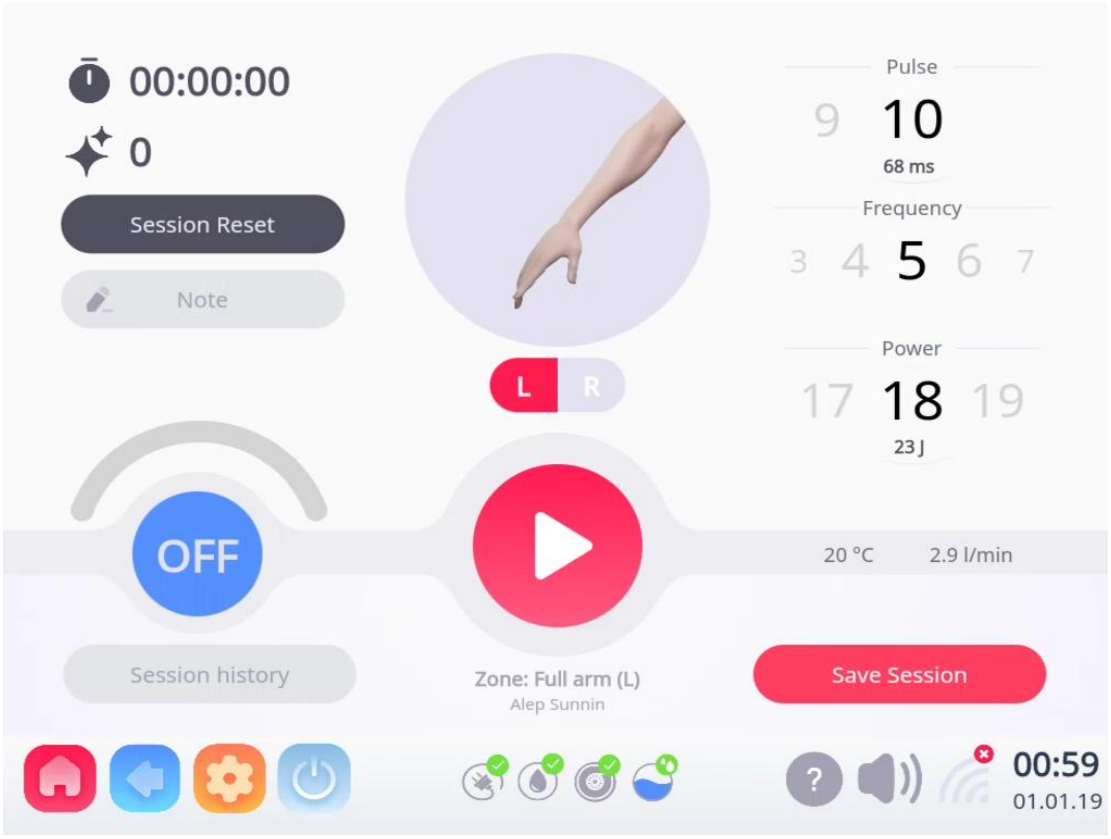
Step 3: Apply the gel

In order to protect the skin to the utmost extent and minimize the discomfort during the depilation process, apply the cold gel evenly to the areas that need to be depilated before depilation.

Note: Please purchase a transparent, colorless ultrasound gel that is legally-marketed, FDA-cleared from your local supplier.

Step 4: Set parameters

The output energy intensity, output frequency and laser output pulse duty cycle per unit area can be adjusted step by step to achieve the best user experience.

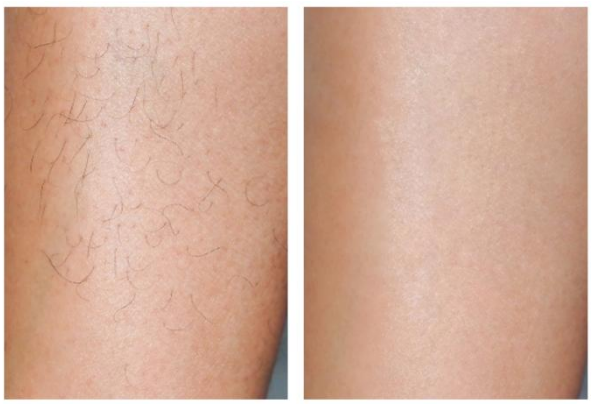


Step 5: Hair removal

Hair removal technique: The light spot is close to the skin, and the cross method is adopted to slide the hair removal place repeatedly 6-7 times with even strength.

Step 6: Clean

After washing, apply cold gel for 3-5 minutes and then wash.



Before treatment After treatment

Hair removal effect chart

Chapter 6 Maintenance

6.1 Introduction

This chapter contains maintenance instructions for the EVOLUTION and M-I-X.

Routine maintenance may be performed by clinic staff unless otherwise specified. Any maintenance procedure not mentioned in this chapter must be performed only by CHUANG ZAO MEI authorized technical personnel.

The system is designed to operate reliably with only periodic operator maintenance. The outer surfaces of the system should be kept clean for hygienic reasons and the light guides should be cleansed between sessions to maintain peak operating conditions.

6.2 Periodic Service

The system should be inspected and maintained periodically to keep it in peak operating condition.

The following routine service operations should be performed by clinic staff every 3 months:

- Cleaning and disinfecting
- Removing dust from filters
- Water filling (deionized water only)

The following routine service operations should be performed by CHUANG ZAO MEI authorized technical personnel:

- General system check
- Interior inspection, including cleaning accumulated layers of dust
- Software upgrade
- Laser emission output verification：

  The instrument needs to be calibrated for pulse laser energy once every 1 year from the date of delivery. The clinic staff or authorized personnel should contact a local department with metrology qualifications for calibration. If the measured output value error exceeds 20%, the manufacturer should be contacted in a timely manner. During the specified service life, calibration should be conducted at least once a year.

6.3 Routine Maintenance

The following routine maintenance procedures should be performed by the clinic staff on a regular basis.

6.3.1 Cleaning and Disinfecting the Device and Handles

The EVOLUTION and M-I-X and its handles, in particularly the applicator tips, are cooled intensively when the device is in Ready mode. Water may condense on the applicator tip's surface which could affect the treatment process. Following every treatment, take off the power, wipe the handle and the tip with a soft cotton swab dipped in 75% medical alcohol.

IMPORTANT NOTE: After cleaning with 75% medical alcohol, the surface of the treatment tip should be visually inspected to ensure that it is clean and free of spots and foreign objects. If the surface of the treatment tip is not clean, continue to clean the treatment tip with cotton sprayed with 75% medical alcohol until the surface of the treatment tip is thoroughly cleaned. Once the surface of the treatment tip has been cleaned, it should be allowed to dry naturally in the air to avoid the accumulation of fluid.

Do not wet the handle with water or immerse the handle in any liquid.

6.3.2 Cleaning the Filters

There are three filters on the device which must be cleaned of dust using a vacuum cleaner no less than once every three-month period (see Figure 6.3-1).

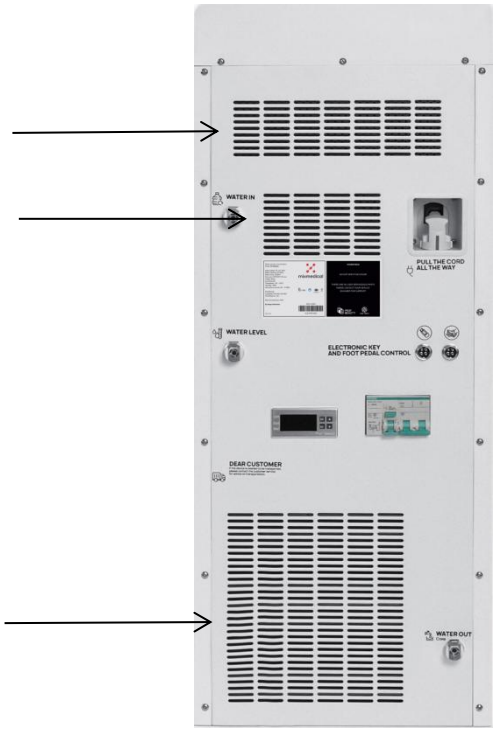


Figure 6.3-1

6.3.3 Filling/Draining the Cooling System's Water Reservoir

The EVOLUTION and M-I-X cooling system's water reservoir must be filled (or refilled) with deionized water in the following instances:

- Upon installation of a new device
- Every three months
- If the following error message appears on the LCD screen (Figure 6.3-2)

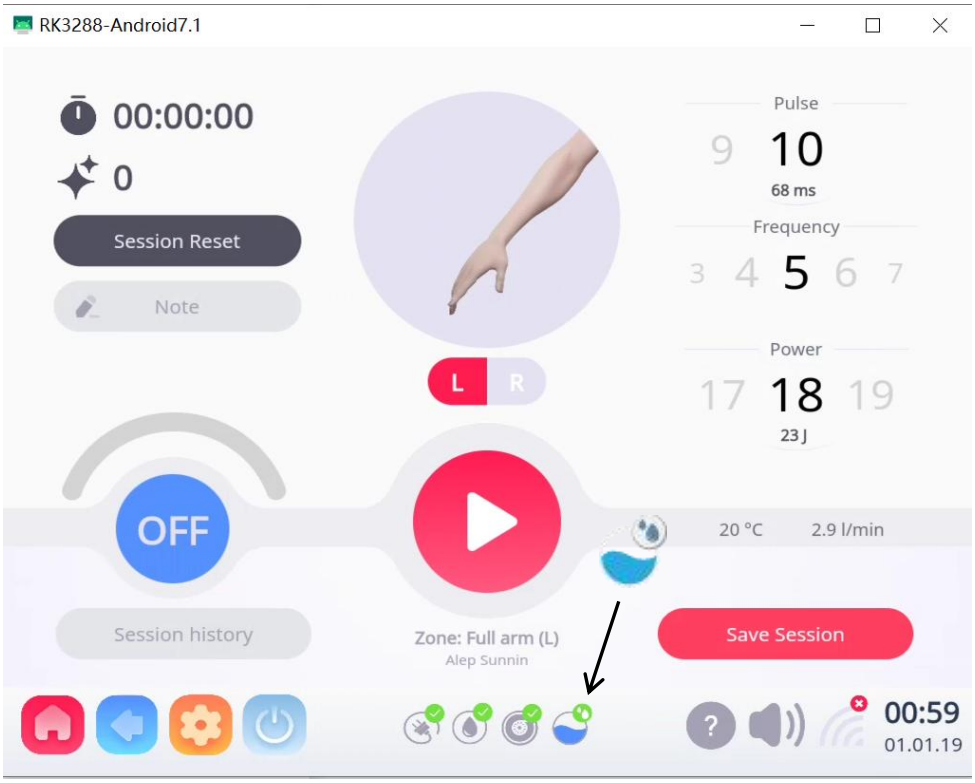


Figure 6.3-2

	High water level, no need to add water
	Medium water level
	No water, need to add water

Filling/refilling the water reservoir is done with the water filling kit that is supplied with the EVOLUTION and M-I-X, which includes (see Figure 6.3-3 to Figure 6.3-5):

Figure 6.3-3

Figure 6.3-4

Figure 6.3-5

Steps for assembling parts (see Figure 6.3-6 to Figure 6.3-8):

- Filling pipe: one side is connected to the funnel, and the other side is connected to the water nozzle.
- Connector: one side is connected to the water pipe; the other side is connected to the corresponding interface of the machine back panel.
- Funnel: connect the water pipe.

Figure 6.3-6

Figure 6.3-7

Figure 6.3-8

6.3.3.1 Water Filling Procedure (see Figure 6.3-9)

1. Take out two **water pipes**, two **connectors** and a **funnel** from the accessory box.

2. First connect one side of the connector to the water pipe, and the other side to the **Vent port**.

3. Connect one side of the other water pipe to the new connector, and the other side to the funnel.

4. Connect the connector of step 3 to **Cooling system filling port.**

5. Clip the funnel to the card slot on the top of the back of the machine (Figure 6.3-10).

6. Add coolant.

7. Once the water starts to overflow from the **Vent port**, stop filling.

8. Unplug the connectors of the **Vent port** and the **Cooling system Filling port**.

9. Plug in power.

10. Turn on the system, ready to run.

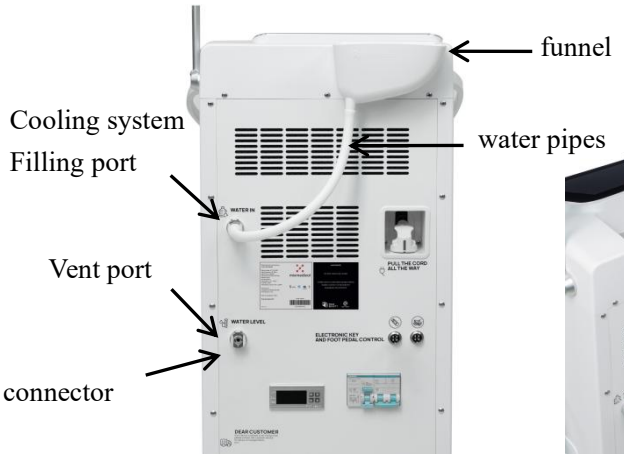


Figure 6.3-9

Figure 6.3-10

6.3.3.2 Water Draining Procedure (see Figure 6.3-11 and Figure 6.3-12)

If the system is to be stored in a cold environment where the ambient temperature may fall below 0℃(32℉), the deionized water must be drained from the cooling system to prevent it from freezing.

Draining is required when the system needs to be moved or shipped away, particularly in cold weather (to avoid freezing hazards).

1. Take out two water pipes and two connectors from the accessory box.

2. Connect the two water pipes to the two connectors respectively.

3. Insert the other ends of the two connected joints into the Cooling system drain port and Vent port.

4. After the water at the drain outlet dries, you can unplug the connection ports at both ends.

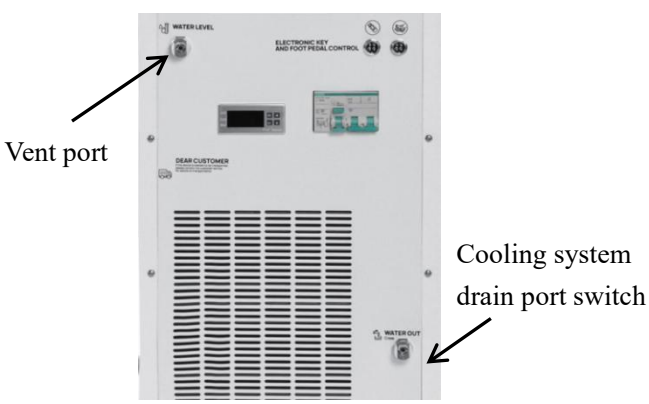


Figure 6.3-11

Figure 6.3-12

Chapter 7 Troubleshooting

7.1 Introduction

Fault phenomenon		Cause Analysis	Solution
Turn on the emergency switch, the system does not start.		a) The leakage switch is not turned on; b) Broken fuse.	a) Turn on the leakage switch; b) Unplug the power cord and check the fuse.
screen alarm	1) The handle is abnormal; 2) Abnormal water flow; 3) Abnormal water pump; 4) Abnormal water level; 5) Abnormal temperature;	1) The handle is not connected, and the handle is not tightened; 2) The water volume is low, and the pump works abnormally; 3) The water pump is burnt out; there is something stuck that prevents it from turning; 4) less water; 5) The cooling system is abnormal; the water flow is abnormal; the water level is abnormal.	1) Check the handle connection is correct, tighten the handle; 2) Check the water volume, check the pump work; 3) Turn off and check the water pump for damage; 4) add water; 5) Check whether the cooling system is abnormal; check whether the water flow is abnormal; Check for lack of water.

Note:
If the handle is abnormal, the customer can take corresponding measures to solve it;
If the water level is abnormal, please add water;
For other faults, please do not disassemble the machine for inspection by yourself. For relevant inspections, please contact the relevant after-sales maintenance personnel.

For any abnormal state that appears, the system will immediately display a fault error, and at the same time an alarm will be issued, the laser system power supply will be turned off, and any operation will be terminated. The operator can troubleshoot the fault through the alarm information prompted by the system; if the fault still cannot be handled, please contact the manufacturer or designated agent service provider immediately.

Chapter 8 Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission		
The Device is intended for use in the electromagnetic environment specified below. The customer or the user of Device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Device uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

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

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

No.	Essential Performance	The description of what the operator of the device can expect if the Essential Performance is lost or degraded due to electromagnetic disturbances
1	Laser wavelength: 808nm.	Please stop using the Device immediately and contact the device manufacturer or distributor for service as soon as possible.
2	Laser energy output: 1-77J/cm^2.	
3	Accuracy of laser energy output should be within 20%.	
4	Ability of the system to prevent any unintended laser emission.	
5	Ability of the system to stop laser emission as soon as foot switch is released.	

Chapter 9 Disposal

9.1 The Diode Laser Hair Removal Device has a service life of 5 years.

9.2 The device should be scrapped after the use period of 5 years is over. Please contact a professional recycling agency for the recycling of this product. Before recycling this product, all data of the device needs to be cleared before processing. This product contains electronic products. After the end of the life, the company will no longer provide any services and assume any responsibilities.