



October 31, 2025

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Re: K252427

Trade/Device Name: Diode Laser Hair Removal Machine (GLD01)

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In  
Dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: August 1, 2025

Received: August 1, 2025

Dear Ray Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**TANISHA**  
**L. HITHE -S**

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Enclosure

# Diode Laser Hair Removal Machine

## GLD01 Model

### User Manual

File No.: MD01UM1.0

Version: UM1.1



**Caution: Federal law restricts this device to sale by or on the order of a physician!**

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## Preface

Welcome to use our Diode Laser Hair Removal machine. This manual applies to the standard Diode Laser Hair Removal machine.

### Attention:

If this is the first time for you to use this Diode Laser Hair Removal Machine, please read the User Manual carefully before the operation.

1. Please do not use the machine in the environments which exist the inter-face, and vibration of electromagnetic wave, and more over, in case operation of the Hair Removal Machine interfaces the other equipment.
2. Please do not use the Hair Removal Machine in the environments which contain flammable anaesthetic and Oxidizing gas, such as  $N_2O$  and  $O_2$ . Some material, such as cotton or wool textile, will be ignited in the environment which is rich in oxygen during the operation of Hair Removal machine. Make sure that the combustibile solution which used for clean and disinfection be evaporated before the operation of the Diode Laser Hair removal machine.
3. Please give the abandoned or replaced spare parts to the appointed administration or the manufacturer for the centralized management, in case the environment pollution.
4. All rights reserved. The content in this manual is copyrighted, without permission of SANHE MEDITECH CO., LTD, any organization or individual could not copy or save them in the database or retrieval system.

## Special Attention



### Caution

Diode Laser Hair Removal Machine could emit the high intensity infrared laser beam, in order to protect the eyes, according to the standard of NOHD, please wear the suitable protection glasses for operator and patient.

The following behaviors are forbidden:

- ✘ Please do not point the laser at the eyes and skin directly.
- ✘ Please do not power down the machine directly during the operation.
- ✘ Please make sure to be familiar with the structure and manual before operation.

**Note: Diode Laser Hair Removal Machine is only allowed to be used for the people who had got the enough safety and operation training.**

**Please turn off the cooling function, when the machine is under the condition of standby, otherwise the probe will be easily damaged.**

## 1. Package

Please open the package and check the spares parts,if there is any lack during the shipment, do not hesitate to contact us.

### 1.1 Accessories



**Handpiece**



**Protective glasses (1 pcs)**



**Goggles (1 pcs)**



**Foot Pedal (1 pcs)**



**Power line (1 pcs)**



**Water funnel (1 pcs)**

**Handpiece:** Treatment for permanent hair removal,to control the pulse light release.

**Protective glasses:** For operators,use to protect the eyes,prevent laser damage.

**Goggles:** For patients,use to protect the eyes,prevent laser damage.

**Foot Pedal:** Foot pedal with the same function of control button on handpiece, to control the pulse light release.

**Power line:** To transmit electrical energy from the power,make the machine to operate.

**Water funnel:** Input water.

## 2. Clinical Application

### 2.1 Application

The Diode Laser Hair Removal Machine (hereinafter referred to as Hair Removal Machine) is applied for the all skin types and hair types Hair Removal.

**Intended Use:** Diode Laser Hair Removal Machine (Model: GLD01) 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.

#### **Contraindication:**

1. A history of keloid scarring and photosensitivity;
2. Any inflammatory skin condition e.g. eczema, active Herpes Simplex, etc. at the treatment site;
3. Waxing, plucking, 'sugaring' or 'threading' depilation treatment of the area in the previous 6 weeks;
4. Who are allergic to hydroquinone or other bleaching cream;
5. Who is pregnant; until periods return and end of breast feeding, Skin cancer or any other cancer;
6. Who takes 13- Isotretinoin in the previous 6 months;
7. Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days.

**Note:** The Hair removal machine does not have obvious effect for the white color hair.

### 2.2 Clinical features

#### 2.2.1. Treatment features

The basic theory of Diode Laser Hair Removal Machine is the biological effect. The machine emits the laser which could be absorbed easily by the pigment located in hair follicle while won't damage the normal surrounding epidermis for all skin types and hair types. The light energy is absorbed by the pigment in the hair shaft and follicle then it is transformed into heat energy, thereby it rises the temperature of follicle, till the temperature is high enough, the follicle structure is destroyed irreversible, the destroyed follicle will be removed after a period of natural physical process, thus achieve the permanent hair removal purpose.

Modern Design, stable output, short time irradiation, permanent effect, easy to control, excellent clinical effect, high security.

### 2.2.2 Clinical effect

**Safety:** Diode Laser Hair Removal Machine has stable performance, long usage life: it is real time controlled by the intellectual CPU.

**Fast:** Fast coverage rate for hair removal with large 12x20 mm<sup>2</sup> spot, high efficiency.

**Efficacy:** Laser, which is in the spectrum of near infrared (0.75-1.50μm), could be absorbed by the melanin best, penetrates through the depth of dermis and adipose tissue and then act on the hairs with different positions and depths.

**Pain free:** Sapphire cooling tip, cools the epidermis down to 0 ~ 4 °C. Offers cooling all the way, comfort and without pain.

**Convenience:** Friendly use design, easy to operate man machine interface-- touch display, easy to operate.

**Permanence hair removal:** Applicable to all skin color, excellent result.

### 2.3 Possible Side Effect

1. Superficial damage may be found after the laser treatment.
2. Hyper pigmentation or depigmentation may occur. But this kind of complication is considered to be temporary and unusual; moreover, it could be recovered naturally after several months.
3. Mild pain may occur during operation, but it could be relieved by the local anesthesia ointment; while the anesthesia is not necessary.
4. Purpura (HSP) may occur on the treatment site within 1-3 days after treatment.
5. Minor swelling and redness will occur on the treated site, but normally it will disappear after several hours.

### 2.4 Clinical Application Attention.

1. Generally speaking, the treatment result and inflammation after the damage of skin relate to the energy density. The higher energy density will deliver the better effect and more inflammation, while the similar epidermis damage will be more serious. During the operation, please begin with the conservative treatment, to increase the energy density gradually, till achieve the satisfied effect.
2. The allowed peak energy is in inverse proportion to the pigment of skin. As usual, the darker the skin, the lower the energy density need to set, which is in order to reduce the epidermis's absorption of laser and heat. The contact cooling could reduce the epidermis's temperature, it is necessary for avoiding the heat damage, especially for patient who has darker skin.
3. Please shave off the hair cleanly and carefully pre treatment, because the visible hair could absorb the energy of laser and then produce intense heat, thus cause the heat damage in the local epidermis, as well as damage of laser treatment head.
4. The contact cooling system could diminish the increase of epidermis' temperature. The cooled laser treatment head will enhance the allowed energy density, while offer the local anesthetic action. We strongly recommend all the patients use the cooling mode during the operation. Especially for the people who has darker skin, because their absorption of the laser energy is much stronger than the light skin people's.

5. Please make sure to contact the hand-piece with the skin before the output of the laser, this is very important, only the experienced physician could use the repetition pulse function.
6. During the treatment, please must maintain the clean of the sapphire. Any martial on the treatment head will absorb the energy of laser and then increase the temperature, thus cause the damage of epidermis as well as pain.

## **2.5 Treatment method**

The following treatment procedure and methods are only for reference, the practica parameter and operation procedure are subject to the practical clinical usage.

### **2.5.1 Pre treatment preparation**

1. For the patient who has the darker skin, please protect the skin from sun exposure, with suitable clothing and use of sun block before first treatment for 4-6 weeks, people who has the tend of hyperpigmentation could use the hydroquinone medicine.
2. Keep the area to be treated clean and dry, give a close s have to the hair, lip in and dirt.

### **2.5.2 Anaesthesia**

The necessary for usage anaesthesia or not, depends on the treatment part (if it is in the sensitive site), area and patient's sensitivity to pain.

### **2.5.3 Treatment method**

1. Physician and patient need to wear the protection glasses, in case the eyes damage s by laser. Smear gel on the treatment site in order to reduce the local epidermis's temperature well and release the pain, while offer the lubrication action for the treatment head.
2. Set the treatment parameter according to the "Parameter setting" operation method in Chapter 6.3.1, do the test treatment first, then do the formal treatment after get the best effect by the test of energy density.  
The treatment parameter is designed individual according to different clinic situations and treatment problems. Generally speaking, 2-3 spot should be tested first, if every hair follicle feels injection pain, it means that the power density is right. The power is low if feels nothing. Reduce some laser power when some parts have a high density of the hair follicle.
3. Press the laser hand piece during the treatment, that makes a perfect connection with the skin surface, drives the part blood and reduces hematoglobulin which to absorb the power of laser. In order to get a good skin surface cooling effect, there must be a 0.25-0.5s stop between the skin and the hand piece before the operation, and the hand piece moves to next treatment spot immediately.
4. Actually, overlapping should be keep appropriate. Because overlapping will damage the skin, so the rate should be controlled under 10% . The over wide interval pulse will weaken the treatment result.
5. During the treatment, In order to keep the safety and effect, the sapphire treatment head should be cleaned often, to avoid the parts hair and others.

6. As hair from different parts has different growth cycle, so the treatment interval changed accordingly. Like the hair on the head, relative short rest period, (about 12-16 weeks). The interval of two treatments is 30 days, which makes the hair to the growth period. The hair on the body and limbs, the rest time is 12-24 weeks; the interval of two treatments is 60 days. Generally speaking, the best time is when the hair begins to re-grow.
7. Use some chlorotetracycline eye ointment, erythrocine and others kind of antimicrobial ointment on the treatment part after every treatment, or wash lightly on the treatment surface to avoid the local infection. Use the sunblock (SPF>15: PA+++ ) to avoid direct sunshine and prevent the pigmentation.

#### **2.5.4 Warnings after treatment**

The core after treatment is strict sun protection and gentle care to avoid skin irritation and pigmentation.

##### **1. Sun protection is the top priority**

- Avoid exposure to the sun within 24 hours after device-use. Within 1-2 weeks after going out, apply broad-spectrum sunscreen with SPF30+, PA+++ and above, and apply it every 2-3 hours.

- Priority should be given to physical sun protection, such as wearing hats, parasols, and long-sleeved clothing, to reduce direct contact with the treatment area.

##### **2. Skin cleansing and moisturizing**

- Within 6-12 hours after device-use, avoid touching water and bathing in the treatment area to prevent infection; after 24 hours, the treatment area can be gently rinsed with normal water, and hot water is prohibited.

- Apply alcohol-free and fragrance-free medical moisturizer/cream promptly after cleaning to relieve dry and redness of the skin and promote barrier repair.

##### **3. Avoid stimulating behavior**

- Within 1 week after device-use, do not use matte, exfoliating products, do not do sauna, hot spring, or strenuous exercise (avoid excessive sweating that stimulates the skin).

- It is forbidden to scratch or rub the treatment area. If slight itching occurs, it can be relieved by cold compress or applying moisturizing cream. Do not scratch and cause skin damage.

##### **4. Diet and rest assistance**

- Temporarily avoid spicy, irritating foods and light-sensitive foods (such as celery, coriander, mango, etc.) to reduce the risk of skin sensitivity.

- Maintain a regular schedule and drink plenty of water to help skin metabolism and accelerate recovery.

#### **2.6 Cleaning of the laser handpiece**

Before and after each treatment, use cotton swab dipped in 75% medical alcohol to wipe the laser head, especially for the sapphire place, and wipe it 1 or 2 times.

Note: Please enter the OFF state or turn off the power when disinfecting.

Allow to air dry.

Inspect for visible contaminants. Make sure no any spot or remnant.

If visible any contaminants remain, repeat steps above.

**2.7 Clean the device**

The device should be cleaned at least once a week. Shut off the machine, wipe the device surface (including the touch screen). Use a clean, dry cloth to wipe away dirt, oil, and dust.

Inspect for visible contaminants.

Do not use alcohol or other organic solvents to wipe the touch screen.

If visible any contaminants remain, repeat steps above.

### 3. Technique Parameter

#### 3.1 Technique parameter

Laser Type	diode laser
Language	English
Display	15 inch color touch LCD screen
Wavelength	808nm
Output power	800W
Laser bar	Coherent 12 laser bars
Spot Size	12×20mm <sup>2</sup>
Pulse width	33-400ms
Energy	10-120J/ cm <sup>2</sup>
Frequency	1-10Hz (continuous mode)
Cooling	water + air + semiconductor
Temperature of Probe	0~10℃
Hand piece Cooling System	Sapphire TEC cooling+water cooling+Real-time monitoring
Water System Cooling	High power condenser module+Fan cooling+Real-time monitoring
Water System Protection	Water pump, water flow, water temperature etc.
Continuous Operation time	24 hours
Voltage	AC110V, 50/60Hz,10A

#### 3.2 Working circumstance and condition:

##### Working circumstance:

- a) Ambient temperature: 5℃~40℃ ;
- b) Relative humidity: ≤80%
- c) Atmospheric pressure range: 860hPa~1060hPa;
- d) Power supply: 110V,50Hz/60Hz

##### Shipping and reserve condition:

- a) Temperature range: -20~60℃
- b) Relative density range: ≤100%;
- c) Atmospheric pressure range: 500hPa~1060hPa。

## 4. Working principle

### 4.1 Host machine principle

Diode laser hair removal machine, a kind of disease treatment device, through continuous high energy laser to achieve the transformation of power, light, thermal. It is also a laser treatment machine together with the laser, electronic, computer science and medicine techniques.

The working principle for the machine: The microprocessor control the laser power, which can provide the constant current for the laser module. The inner high energy diode, from the laser module, transform the electronic to light energy, which output the constant laser with wavelength .The laser light on the skin by leaded crystal, penetrate into the deep tissue of the skin. The light energy is absorbed and then turned into the thermal energy, which can destroy the hair follicle tissue, make it gone and never grow again.

The parameter of the laser density should be designed by the actual condition.

### 4.2 Host machine element

The diode laser machine consists with the power system, microprocessor controller system, operation and screen system, cooling system, laser module and security alarm system. Figure 4-1

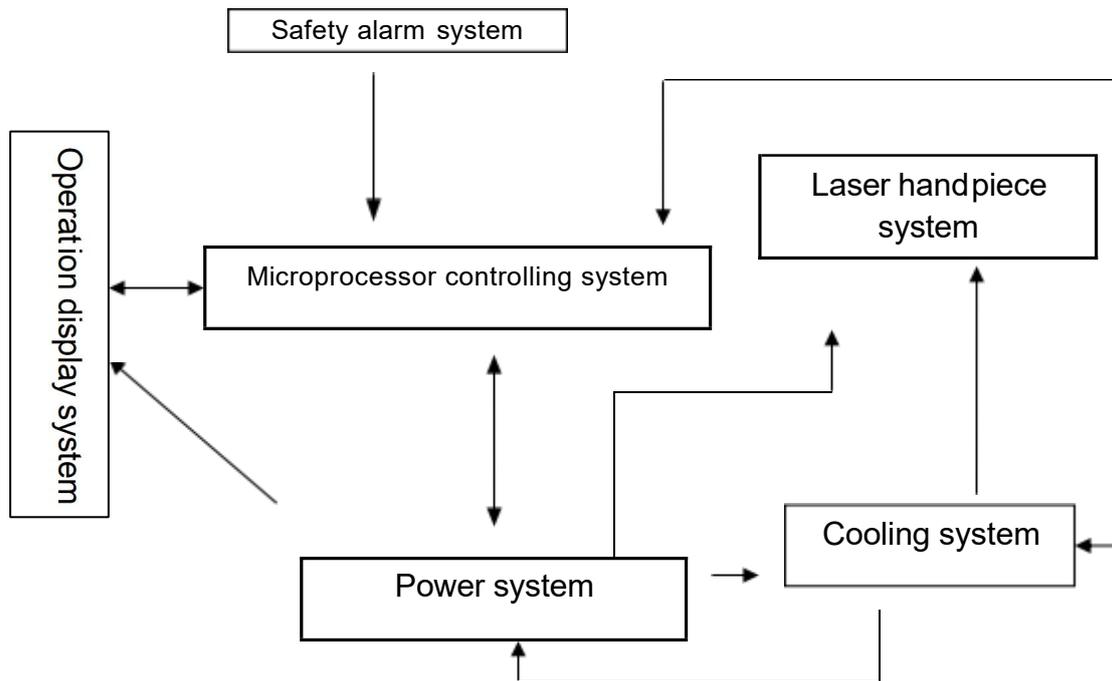


Figure 4.1 diode laser hair removal machine system diagram

#### 4.2.1 Power supply system

The power supply consists of net power, laser power, cooling power system and auxiliary power system. Figure 4.2

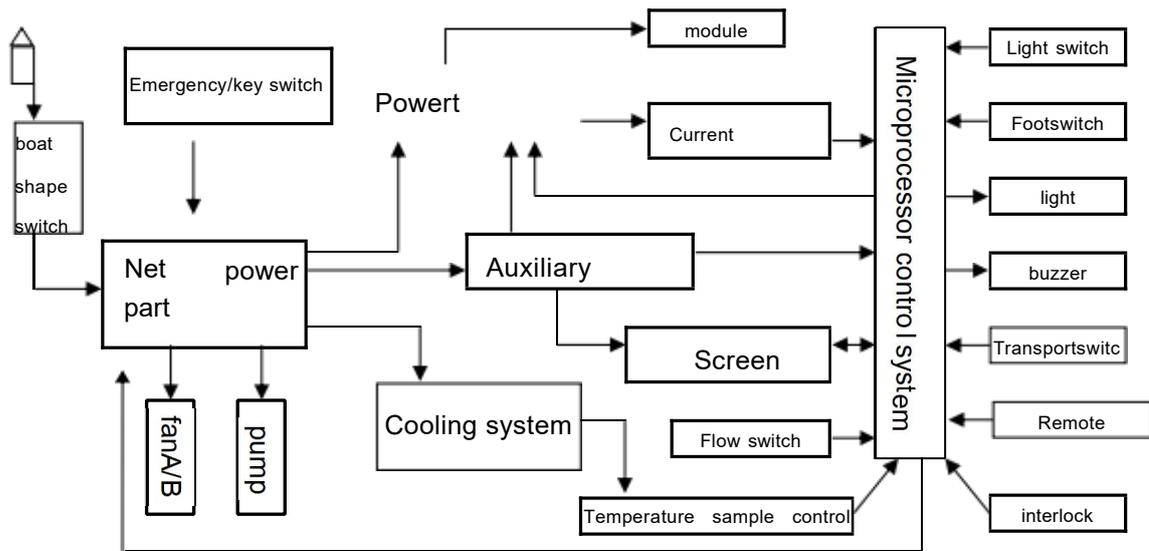


Figure 4.2 electric circuit diagram

Power wire and the boat shape switch is the stop-go control for the machine with outer power supply. The key and the emergency switch used for the cut of the controlling net power supply, then provide current for microprocessor system, screen and other parts through auxiliary power system. The power system for cooling and laser is achieved by the microprocessor. The microprocessor control the host, ready and light output, so it also means control the hardware and make the machine more stable and more reliable.

The power system uses the power parts to make a current regulation loop. Laser device changes the size of output current through the regulation of microprocessor. Which can achieve the real-time monitoring by the control of output laser power and pulse energy, also send the current sampled signal by the feedback.

Most power supply parts of the machine are all reliable and have the CE certification. All can transform between direct and alternate. This is not only very safe for the user, but also can make the machine more effective and steady.

The power system has a perfect self-preservation function. It can send information back to the microprocessor, which can show to the screen if there are something wrong with the data, and to then to protect automatically. The system begins to work when all the problems removed.

#### 4.2.2 Microprocessor system

The diode laser hair removal machine uses the microprocessor system, which consists of microprocessor, control feedback and test feedback. figure 4.2

The machine is highly module automation. So it is very easy to operate. Users only need to turn on the Air switch, Key switch, and Emergency switch. The machine can check and adjust the parameters automatically.(including all the test which may have some damage to the machine.)

The system first to initialize, self-check and adjust the parameter. If there is something wrong during the self-check step, it will show on the screen, the user and service man understands fully what happened. They control the laser power supply, output laser parameter, laser working module and other operations through screen if there is no caution alert .

#### **4.2.3 Operation display system**

The operation display system consists of touchable screen, indicator light and buzzer. The touchable screen directly linked with the host microprocessor. The user can control the microprocessor and get information about the host machine and relative parameter through it. The screen is reliable with the CE certification.

The direct lamp shows the working condition. Buzzer is a tip for the output of laser and fault alarm.

#### **4.2.4 Cooling system**

The cooling system consists of cooling fan, cooling water circle and temperature controlling system.

When the device turns on, the cooling system begins to work and the water get to the appointed temperature. The fan is cooling for the host electric parts and heat sink, remove the heat by the air flow. When the machine is working, the inner circle water will take away the heat replacer to the radiator which to scatter the heat. That makes the circle water and machine in a balance temperature condition. The control system, monitor the temperature, through the temperature sampling system. There is also an alarm degree, if the temperature is abnormal, the interface alarm display and sound to caught attention.

## 5. Electromagnetic compatibility statement

Caution: According to the FDA Guidance Electromagnetic Compatibility (EMC) of Medical Device the risks associated with exposure to specific common EM emitters such as radiofrequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment, that are not adequately addressed by IEC 60601-1-2.

Therefore, please stay away from the equipment listed above during the use of our products.

If the product is subjected to electromagnetic interference, the following situations may occur:

- 1) Device stops working and screen gets out of control;
- 2) The laser energy is unstable and the light output frequency is abnormal.

Solutions:

- 1) Cut off potential sources of interference. Immediately turn off interference appliances within 30 cm of the equipment or move the device outside the interference area.
- 2) Restart: Turn off the product and wait for 30 seconds before turning it on again. Select the low-energy gear and try to trigger in the non-skin area to observe whether the light returns to normal (such as the light is stable and the screen control is normal) to determine whether the interference has been eliminated.
- 3) If these methods are not resolved, please contact the manufacturer's after-sales department (please refer to section 10).

1	<b>Guidance and manufacturer's declaration – electromagnetic emission</b>		
2	The model GLD01 is intended for use in the electromagnetic environment specified below. The customer or the user of the model GLD01 should assure that it is used in such an environment.		
3	<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
4	RF emissions CISPR 11	Group 1	The model GLD01 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  The GLD01 is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
5	RF emissions CISPR 11	Class A	
6	Harmonic emissions IEC 61000-3-2	Not applicable	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	± 0.5 kV, ± 1 kV differential mode line-line	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 % UT (100 % dip in UT ) for 0.5 cycle at 0° , 45° , 90° , 135° ,180° , 225° , 270° , and 315°  0 % UT (100 % dip in UT ) for 1 cycle at 0°  70 % UT (30 % dip in UT ) for 25/30 cycles at 0°  0 % UT (100 % dip in UT ) for 250/300 cycle at 0°	0 % UT (100 % dip in UT ) for 0.5 cycle at 0° , 45° , 90° , 135° ,180° , 225° , 270° , and 315°  0 % UT (100 % dip in UT ) for 1 cycle at 0°  70 % UT (30 % dip in UT ) for 25/30 cycles at 0°  0 % UT (100 % dip in UT ) for 250/300 cycle at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model GLD01 product name requires continued operation during power mains interruptions, it is recommended that the model GLD01 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands <sup>a</sup>	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands	<p>Portable and mobile RF communications equipment should be used no closer to any part of the model GLD01, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800\text{MHz to } 2.7\text{GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>c</sup> should be less than the compliance level in each frequency range<sup>d</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m  80 MHz to 2.7 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the D01 is used exceeds the applicable RF compliance level above, the D01 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the D01.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

<b>Recommended separation distances between portable and mobile RF communications equipment and the model GLD01</b>			
The model GLD01 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model GLD01 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model GLD01 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter  W	<b>Separation distance according to frequency of transmitter m</b>		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

### Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency (MHz)	Maximum Power (W)	Distance (m)	IEC 60601 Test Level	Compliance Level (V/m)	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $E = \frac{6}{d} \sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<b>WARNING!</b>	<p>This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.</p> <p>The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.</p>
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<b>WARNING!</b>	Portable RF communications equipment (including peripherals such as Wireless power transfer, 5G cellular, antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Diode Laser Hair Removal Machine, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
<b>WARNING!</b>	Security Systems (such as electromagnetic anti-theft system and metal detectors) should not be used near to any part of the Diode Laser Hair Removal Machine, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
<b>WARNING!</b>	Please note some of these RF emitters (e.g, RFID Radio-frequency identification) or EAS (electronic article surveillance) in the intended environment of use might not be visible and the device can potentially be exposed to fields from these RF emitters without the user's awareness. So, please check the use environment of Diode Laser Hair Removal Machine before each use, to ensure there are no RF emitters around or nearby the Diode Laser Hair Removal Machine
<b>WARNING!</b>	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Diode Laser Hair Removal Machine, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## 6. Operation safety notice

- ⊗ Operator must wear the professional protective glasses before or during the operation.
- ⊗ Patients must wear the professional protective eyepatch before or during the operation.
- ⊗ Please do not see the visible intense pulse light directly.
- ⊗ The protection eyepatch cannot defend all the light and light reflected by glass, reflector, smooth surface of metal. So it is strict forbidden to directly watch the light.
- ⊗ Flammable and explosive things should be kept away from operating room, such as stupeficient, liquid and gas,.
- ⊗ Operator and patient are forbidden to wear watch and necklace etc. during the treatment.
- ⊗ It must supply strict protection to the customer's eyes. If not well protected, it may cause harm to the customer's eyes, such as keratitis, cornea brushing off, or even lose sight
- ⊗ Please do not optionally open the panel of the machine even power stopped, in case high voltage danger.
- ⊗ It is needed to tighten up the screw caps of machine when make movement.

### **Cautions:**

- ⊗ **Prepare before operation, or it's not allowed to do any operation:**
  1. **Connect handles on machine.**
  2. **Input enough water into machine. Water source: pure wate.**
  3. **Connect power supply, foot pedal, open air switch.**
  4. **Turn on machine, make sure good water circulation inside(water flow sound inside).**
  5. **Wait machine running 2 minutes, turn off machine and add some water into machine again.**
  6. **Turn on machine again and adjust the operating parameter and test the flash light.**

**Pls make sure do as above steps, or it's not allowed to do any operation. Badly, the handpiece or machine will be damaged.**
- ⊗ **Vertically shoot the light on skin, and keep the head no gap to skin.**
- ⊗ **Keep the machine have a rest every 2-3 hours continuously working.**
- ⊗ **The handle is fragile, pls keep special care when hanging to the holder or in handle .**

## 7. Operation Instruction

### 7.1 Machine diagram



**Front**



**Back**

## 7.2 Host Machine Operation

Host control section includes a touch screen, Key switch, Emergency switch.

Touch screen is the main operation and display part of the hair removal system. Through the touch screen, you can achieve the functions include shutdown, laser parameter settings and ready and use the laser. You could only do the parameter setting, mode switch, refrigerator opening and shutdown under standby mode.

The red light flashes on the handpiece shows now it is out putting laser which means it is under working condition.

Handpiece is the working part of the hair removal system, the laser comes from the handle according to the energy set by the host control screen.

The Red button is the emergency switch. Press the emergency button to disconnect the power supply of control system and laser, then turn right the button will back to normal status.

Foot switch or button switch (pick anyone of them) for the output operate under the ready status.

There is a air switch button at the back side of the host used to control the main power off and on. When you do not use the equipment, you should turn the key to "OFF" , then turn off the air switch button in case of inappropriate use.



**Warning: It will produce dangerous radiation exposure if you do not operate the control part, regulate part or operate the system in the required method before or during the treatment.**

### 7.3 Turn on procedure

1. Check and make sure the handpiece is plugged well in handpiece connector. (Note: the handpiece must connect the above place during the operating, otherwise the machine running the error.)
2. The foot switch is connected in the place marked "Foot Switch".
3. After the completion of the above step 1 and 2, plug the three core power cord into the corresponding currents in the AC110V power outlet;
4. Open the air switch button on the back of the machine, turn right of the emergency stop switch to keep it in the release state, then turn right the Key Switch to turn on the machine, the system start and the touch screen shows interface.
5. Wait a few minutes, after the machine finish the automatically detect procedure, the machine will enter the standby screen and it is now starting successfully. (If the cooling system has problem and cannot keep the temperature at a given number, then the machine is failure, the machine cannot enter standby mode, will always remain in the initial LOGO screen).

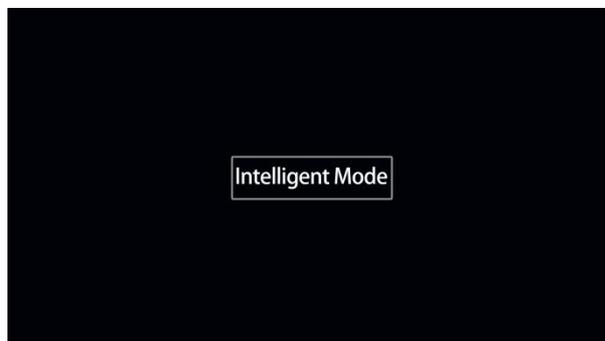
### 7.4 System Control

- Step 1. When turning on the device, the screen will show as the picture 1:  
Press the middle position on the screen, to go next page.



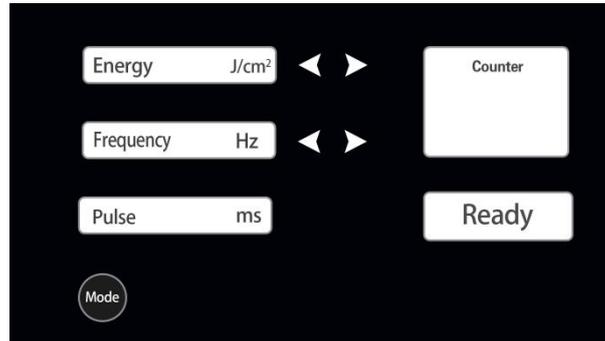
picture 1 start screen

- Step 2. To select the Intelligent Mode as the picture 2:



picture 2

Step 3. To set the treatment parameters in picture 3:



picture 3

#### 7.4.1 Parameter setting

**Energy:** Click the two triangle button to adjust the energy ,adjust the energy by 10J/cm2 numerical increase or reduce the size of energy density, the range is 10 ~ 120 J / cm2.

**Frequency:** Click the two triangle button to adjust the frequency by 1Hz every step, the range is 1~10Hz.

**Pulse:** The pulse width increase with energy,the range is 33-400ms.

#### 7.4.2 Ready

At the first, the machine under Stop status, when click on the “Ready” button, it will become operating mode, then press the hand piece button,or press foot pedel to shoot laser, now could start to do laser hair removal treatment on skin.

During the treatment, if need to change parameter, make sure the machine status at Stop mode first, then set the parameters again.

After treatment, make sure the machine Stop, and put the handpiece back to the handpiece holder well.

### 7.4.3 Counter

The system uses Intelligent Counter to record the amount of light pulse during this working. The pulse count will be cleared automatically when reboot the machine; the current pulse count can be cleared by clicking the button when the machine is running.

### 7.4.4 Mode

Return to the interface in picture 2.

### 7.5 Treatment parameters

Skin type	Treatment areas	Energy J/cm2	Frequency Hz	Treatment times /month	Interval treatment time	Treatment courses /times
I	Face	8-13	4	1	3-4 weeks	3~5
	Underarm	6-8	2	1	3-4 weeks	3~5
	Arm	8-13	4	1	3-4 weeks	3~5
	Back	8-13	4	1	3-4 weeks	3~5
	Bikini	2-5	1	1	3-4 weeks	3~5
	Leg	8-13	4	1	3-4 weeks	3~5
II	Face	8-13	4	1	3-4 weeks	3~5
	Underarm	6-8	2	1	3-4 weeks	3~5
	Arm	8-13	4	1	3-4 weeks	3~5
	Back	8-13	4	1	3-4 weeks	3~5
	Bikini	2-5	1	1	3-4 weeks	3~5
	Leg	8-13	4	1	3-4 weeks	3~5
III	Face	6-10	4	1	3-4 weeks	4~6
	Underarm	3-5	2	1	3-4 weeks	4~6
	Arm	6-10	4	1	3-4 weeks	4~6
	Back	6-10	4	1	3-4 weeks	4~6
	Bikini	2-4	1	1	3-4 weeks	4~6
	Leg	6-10	4	1	3-4 weeks	4~6
IV	Face	6-10	4	1	3-4 weeks	4~6
	Underarm	3-5	2	1	3-4 weeks	4~6
	Arm	6-10	4	1	3-4 weeks	4~6
	Back	6-10	4	1	3-4 weeks	4~6
	Bikini	2-4	1	1	3-4 weeks	4~6
	Leg	6-10	4	1	3-4 weeks	4~6
V	Face	5-8	4	1	3-4 weeks	5~7
	Underarm	3-5	2	1	3-4 weeks	5~7
	Arm	5-8	4	1	3-4 weeks	5~7
	Back	5-8	4	1	3-4 weeks	5~7
	Bikini	2-4	1	1	3-4 weeks	5~7
	Leg	5-8	4	1	3-4 weeks	5~7
VI	Face	5-8	4	1	3-4 weeks	5~7
	Underarm	3-5	2	1	3-4 weeks	5~7
	Arm	5-8	4	1	3-4 weeks	5~7
	Back	5-8	4	1	3-4 weeks	5~7
	Bikini	2-4	1	1	3-4 weeks	5~7
	Leg	5-8	4	1	3-4 weeks	5~7

Pulse: The pulse width increase with energy,the range is 33-400ms.



**Note: The above parameters are for reference only!**

**Allows the trained user to titrate upwards if needed.**

## 7.6 Malfunction Alarm

The hair removal apparatus with malfunction alarm system.

When the alarm sounds with buzzing , immediately turn off the machine, the buzzing will stop , then check the fault.

1. Measures for dealing with water flow switches alarm  
Checking whether the water tank is lack of water, or if there is leaking water pipes and radiators. Please contact with after-sales maintenance staff if the alarm is continuing after checking and confirmation.
2. Measures for dealing with water temperature alarm  
Turn down or stop the light shooting for a while, then restart. Please contact with after-sales maintenance staff if the alarm is continuing after checking and confirmation.
3. Measures for dealing with water level alarm  
Checking whether the water level in the tank is too low. Contact with after-sales maintenance staff if the alarm is continuing after checking and confirmation.

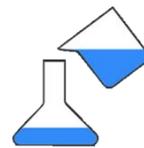
Notice : When the alarm sounds with buzzing , the following logos will flash in the upper left corner of screen.



Water flow



Water temperature



Water level

## 7.7 Shut down Procedure

1. Turn left the "Key Switch "to turn off the machine.
2. Close the "Air switch" back of the machine, disconnect the external power supply.
3. When encountering an emergency situation, press the "Emergency switch".(Notice: No forced shutdown without exceptional circumstances.)



Notice: In the course of treatment in cases of emergency need to quickly stop the lights shooting please press the Emergency switch on the machine.

## 8. Routine Maintenance

Routine maintenance on equipment must be needed to ensure the normal use. Laser machine is a kind of precision device; particularly careful maintenance must be mentioned.

### 1. Check or replace the power fuse tube.

If the current exceeds the allowable current 10A/150V, the fuse will quickly blow. Turn off all power switch, unplug the power cord; using a small flat screwdriver to open fuse light jacket with counterclockwise rotation, then take out the fuel tube from the jacket.

The fuse tube only can be replaced by the manufacturer authored standard type (10A/250VAC.).

Put the new fuel tube into jacket and screw back; reconnect the power cord into the back of the machine; turn on the power switch and key lock; to check the machine can run smoothly or not.

### 2. Maintenance of the mainframe.

Clean, dry, dust-free, ambient temperature as 4 ~ 40 °C are seriously desired for the equipment installation sites. The equipment must be shielded if quits from using for long time; dust, water vapor and other pollutants should attack the machine which maybe decrease laser output energy or even damaged the whole device.

Dry, ventilated, non-corrosive gas, no direct sunlight restoration is needed.

In the temperature regions which are below 0 °C, on the situation of quit from using for long time and transportation the cooling water must be drained from the mainframe (Suggestion: Professional operators marked as qualified from the training that offered by the manufacture or engineers from the manufacturer have the recommend to do the drain ).

### 3. Laser handles maintenance

Avoid falling, hitting, clashing and non-authorized opening of the laser handles which formed by precision optical components.

Optical crystal face should be checked and properly cleaned before using. Cleanliness impacts the output quality critically.

Avoid handle transmission system damage that caused by extreme bending when in use.

### 4. Cooling system maintenance

Regular checks of the cooling fan must be needed. Laser should not be working properly, or even the whole machine is damaged due to the cooling fan ruins which cause the accumulation of heat inside the device.

Regular inspections of water storage tank, the cooling capacity and water quality must be mentioned. Maintenance personnel should add or recharge the cooling water in time.

5. The point of load must be the rack when carrying the machine.

Handles play only the role of movement; External-force should not be pressured on the handles and the shell. The machine cannot be moved when in use ( when lights shooting.), and not too much inclination (Tilt angle  $\leq 5^\circ$ ).

6. Non-professional maintenance personnel shall not install or disassemble the instrument mainframe, laser handle, foot switch or other accessories. Please turn to local agent if anything wrong.

7. Check the on-off power supply situation about the "Power Switch", "key switch" and "emergency stop switch" once a week during restoration. Please contact with manufacturer if there is problem.

## 9. Safety Protection

### 9.1 Laser safety

Diode laser hair removal equipment could emit high-intensive infrared laser radiation, which will do harm to tissues, especially for ocular tissue. To avoid harm to people, all the doors and windows of the treatment room should be covered by high-density shading material. There must be warning sign outside of the treatment room.

Diode laser hair removal equipment emphasizes function and safety. This system has all-sided safety testing procedures. Because of its high intensity and high energy, all of the related people should abide by the following matters. Before the treatment, please check whether the spare parts are installed right, whether insulated part of the wire is complete. Please make sure you have worn something to protect your eyes.

Avoid eye or skin irradiated.

Laser Wavelength: 808nm

Fluence: 120 J/cm<sup>2</sup>

Class 4 laser product

The LASER OUTPUT emitted by the laser equipment shall not deviate from the pre-set level of output by more than  $\pm 20\%$ .

Please don't look directly at the laser or reflected laser. Both of them will do serious harm to your eyes.

People who do not wear protecting glasses are forbidden to be close to the laser when the machine works.

Do not repair anything which is not shown in the instruction book. Manufacturer or the distributor that is authorized by manufacturer should be responsible for the maintenance.

Do not put the machine under the flammable circumstance. Keep it away from anaesthetic and oxygen. By the way, please make sure the flammable liquid which is used to clean the diamond of the hand piece evaporates before usage.

Do not make the laser points at any areas that are not for treatment. Make sure the output end points at safe direction.



Attention: You need to follow our instructions to use the control component and accommodation component before or during the treatment. Or, you and your customers will be in danger.

## 9.2 System characteristics of laser safety

Diode laser hair removal equipment has different electron and mechanical safety design for different parts. The following instructions are safety devices designed for wrong operation:

1. Key switch: It control's the power supply of the machine. Very necessary. Blue light shows whether it is on or off.
2. Emergency switch: It is used to stop immediately. Only if the power switch connects with the main switch correctly, the machine could be used. Therefore, it is very safe. When you press emergency switch, the machine will be turned off. Of course, all of the operations will be stopped. Turn off the main power, turn emergency switch according to clockwise direction until it rises. Then press it again to restart the machine.
3. To prevent changing the parameter because of wrong operation, the machine has "standby/ready" function. Only when you press "ready", you could change the parameters.
4. Foot switch: It controls the output. There's a protective cover outside of the foot switch. It could prevent wrong operation. The protection grade is IPX1. Do not sprinkle any liquid on it or make it under moist environment.
5. Transmission system detector switch: It is used to test whether the handpiece is connected well with transmission system. If they are not connected well, the machine won't let laser output.
6. Remote interlock control: It is used to keep other people who enter the treatment room away from laser radiation. When the door of the treatment room is opened, machine will stop outputting laser.
7. There are four rollers beneath the machine. If it is not necessary for the machine move, you should press down the lock catch to prevent movement.
8. There are two pairs of protection glasses, type SD-4. Its protection wavelength is 800-1000nm. The glasses accord with European standard EN207: 1998+A12002. They have CE certificate. Please make sure the operator have worn the glasses before laser output.
8. Diode laser machine has many tips when it works. Including: flicker shows the laser output, red light flickers and buzzer repeats buzzing.

**Only if all of the following conditions are met, the machine could work normally:**

- ✘The machine is connected well with the power supply
- ✘Turn on key switch
- ✘Emergency switch is released
- ✘The machine is "ready" and no abnormal situation is found by itself

Operator must pass the training and have operating experience. Or, he is forbidden to do the treatment.

### 9.3 Nominal ocular hazard distance (NOHD)

This diode laser machine is class IV laser product. Do not look directly at the laser or reflected laser. Both of them will do serious harm to your eyes. The NOHD is 30.1m during normal use.

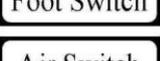
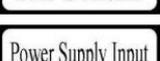
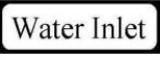
### 9.4 Mark for laser safety

There are some warning marks on the machine as followed:



### Signs Specifications

signs	Specifications	Position
	Caution	On the back of the machine
	Electric	On the back of the machine
	Laser	On the back of the machine
	Laser output	On the side of the handpiece
	The harm of laser	On the back of the machine

	Warning of laser	On the back of the machine
	Read instruction manual carefully before operation.	Warning mark
	Wear eye protective glasses before operation.	Warning mark
	Inspect and change the filter regularly.	Warning mark
	Change the water once a month. Must be pure water or distilled water.	Warning mark
	The degree of equipment protection against electric shock "B"	Nameplate
	CE certificate	Nameplate
	Forbid to discard at will.	Nameplate
	Serial Number	Nameplate
	Date of Manufacture	Nameplate
	Manufacturer	Nameplate
	Voltage	On the back of the machine
	Fuse	On the back of the machine
	Label	On the back of the machine
	Label	On the back of the machine
		
		
		
		
		
	Caution	On the Packaging box
	Caution	On the Packaging box
	Nameplate	On the back of the machine

### **9.5 Safety protection measures**

1. You'd better put up "laser warning" "danger" or other warning board specially for laser safety at the conspicuous place.
2. Please put up "Authorized Personnel Only" outside of the treatment room.
3. Move away any reflectors in the treatment room to avoid the reflection of laser. The reflection will hurt surrounding people.
4. You'd better ask certain person to take care of the laser machine.
5. After using the machine, the operator should pull the key.
6. The operator should wear protection glasses that are suitable for the laser wavelength and power.
7. Do not point the laser directly at eyes or reflect laser to eyes.

### **9.6 Electrical safety**

1. We have marked the ground connection end according to related standard. After the debugging, maintenance person should check whether the ground connection is well connected. When the machine doesn't work, please don't make it power on.
2. There's high voltage in the inner part of the machine and laser hand piece. Do not open them if you are not trained by us. Maintenance people should pay attention to all the marks to avoid electric shock.
3. There's strong electric current when the machine works. Do not touch electrode when it powers on.
4. This machine adopts 110V ac single-phase power. 2000VA. the treatment room should use corresponding power supply.
5. The operator should know basic knowledge about using electricity safely. They should also know how to operate the machine correctly.
6. This machine should be used under the right circumstance.
7. Diode laser machine is: shock proof class I. Application part's shock proof grade is BF type.

### **9.7 Fire safety**

1. Do not pile up sundries around the machine. Make sure there are enough capability for the power supply when you install the machine.
2. Do not put explosive and flammable materials in the laser option path or the place that the laser beam could irradiate. Or, it may catch fire or even explosion.
3. Do not use flammable anesthetic or oxidizing gas, like  $N_2O$  or  $O_2$ . Because some material will be light up by the high temperature caused by using the machine normally. Make sure the flammable liquid which is used to clean and sterilize the crystal evaporates before usage.
4. It is necessary to prepare fire extinction appliance.

### **9.8 Disposal of Waste Safety**

Waste generated during use of the product, the equipment and accessories at the end of the expected service life, users can dispose of it in accordance with the local waste management regulations

## 10. After-sales service

We offer good after-sales service, including installment, debugging, train and maintenance. The warranty is two years for the machine, 12 months for the handle. During the warranty, it is free to repair the machine and handle. Of course, two years later, we could also help you to repair. And technical advice is free to supply you all the time.

**Manufacture:** SANHE MEDITECH CO.,LTD

**Address:** #15 Building,Zhongnan High-tech Industrial Park,Liushan Street, Yanjiao, Sanhe, Hebei,065201,China

**Tel/Fax:**86-10-61594366

The assigned 510(k) Number:           K252427          

## **510(k) Summary**

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date Prepared: 10/18/2025
2. Sponsor Identification

### **SANHE MEDITECH CO.,LTD**

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4. Identification of Proposed Device

Trade Name: Diode Laser Hair Removal Machine

Common Name: Powered Laser Surgical Instrument

Model(s): GLD01

### **Regulatory Information**

Classification Name: Powered Laser Surgical Instrument

Classification: II

Product Code: GEX

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Review Panel: General & Plastic Surgery

## 5. Identification of Predicate Device(s)

510(k) Number: K211335

Product Name: Diode Laser Machine, Model: BM-100

Manufacturer: Zhengzhou Bestview St Co., Ltd.

## 6. Device Description:

The Diode Laser Hair Removal Machine (Model: GLD01) consists with the power system, microprocessor controller system, operation and screen system, cooling system, laser module and security alarm system.

The microprocessor control the laser power, which can provide the constant current for the laser module. The inner high energy diode, from the laser module, transform the electronic to light energy, which output the constant laser with wavelength. The laser light on the skin by leaded crystal, penetrate into the deep tissue of the skin. The light energy is absorbed and then turned into the thermal energy, which can destroy the hair follicle tissue, make it gone and never grow again.

## 7. Indication For Use Statement:

Diode Laser Hair Removal Machine (Model: GLD01) 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.

## 8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device Diode Laser Hair Removal Machine Model: GLD01	Predicate Device (K211335) Diode Laser Machine Model: BM-100	Remark
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	SAME
Class	II	II	SAME
Product Code	GEX	GEX	SAME
Indication for use	The Diode Laser Hair Removal Machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type	The Diode Laser Machine (Model: BM-100) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin	SAME

	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.	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.	
Prescription use or not	Prescription use	Prescription use	SAME

Table 2 Performance Comparison

ITEM	Proposed Device Diode Laser Hair Removal Machine Model: GLD01	Predicate Device (K211335) Diode Laser Machine Model: BM-100	Remark
Laser Type	Diode laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser Wavelength	808nm	808nm	SAME
Spot Size	2.4cm <sup>2</sup> (12×20mm)	2.25 cm <sup>2</sup> (15mm x 15mm)	Analysis 1
Fluence	10-120J/ cm <sup>2</sup>	0-120 J/cm <sup>2</sup>	Analysis 2
Frequency	1-10Hz	1-10 Hz	SAME
Pulse Duration	33-400ms	10-400 ms	Analysis 3
Power Supply	A110V, 50/60Hz, 10A	220/110 VAC/50Hz-60Hz	Analysis 4

**Analysis 1 - Spot size**

The difference on Spot size between the subject device and predicate device is minor and would not impact the safety and effectiveness, because the final safety and effectiveness about clinical indications will depends on the amount of energy output per unit area, which would produce thermal effects to the patient's skin area irradiated to achieve claimed indication for use. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety of the product can be ensured.

**Analysis 2 - Fluence**

The proposed device has different Fluence from the predicate device.

For the difference on fluence between the predicate and proposed device(s), we can see that the fluence range of proposed device is within the range of the predicate device. The fluence between the proposed device and the predicate device only with minor difference. And we think this minor difference will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

**Analysis 3 - Pulse Duration**

The proposed device has different pulse duration from the predicate device.

For the difference on pulse duration between the predicate and proposed device(s), we can see that the pulse duration range of proposed device is within the range of the predicate device. The pulse duration between the proposed device and the predicate device only with minor difference. And we think this minor difference will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

**Analysis 4 - Power Supply**

The power supply for the proposed device is different from the predicate device. However, electrical safety and EMC test has been conducted on the proposed device and the test result show that the device can work normally under this power supply. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Table 3 Safety Comparison

ITEM	Proposed Device Diode Laser Hair Removal Machine Model: GLD01	Predicate Device (K211335) Diode Laser Machine Model: BM-100	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22, IEC 60825-1	SAME
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SAME
Irritation	No evidence of irritation	No evidence of irritation	SAME
Sensitization	No evidence of sensitization	No evidence of sensitization	SAME

**9. Non-Clinical Test Conclusion**

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020 Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements

- IEC 60601-2-22: 2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

#### 10. Clinical Test Conclusion

No clinical study is included in this submission.

#### 11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device Diode Laser Machine, Model: BM-100 (K211335).