

**Nd: YAG Laser System**  
**for Ophthalmology**  
USER'S MANUAL

**Version 1.0**







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## Labels and Indicators

### Power Input

~AC220V Mains Input Socket

### Fuse

Fuse Holder, 5S 2A/250V Slow Fuse×2, φ5×20

### Key Switch

Power Switch



Power On



Power Off

### Hand Trigger Switch

Laser Output Control Switch



Type B Applied Part



Note! Please refer to the User's Manual.



Emergency Stop Label



Remote Interlock Connector Label



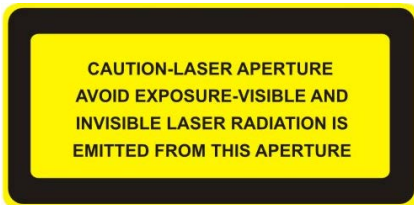
Manufacturer



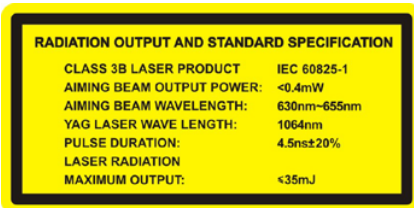
Product Series Number



Class 3B Laser Product Warning Label



Laser Aperture Label of Class 3B Laser Product



Radiation Output and Standard Specification



Safety Interlock Panel Label



## **WARNINGS**

- Please read the User's Manual carefully before installation and operation.
- Unplug the power supply before cleaning!
- Please refer to §6. Attentions for more attentions.

The User's Manual provides instructions for the operation of the Nd: YAG Laser System for Ophthalmology (hereinafter referred to as Device). The Device should be operated by qualified ophthalmologic doctors. Please read the User's Manual carefully before installation and operation to get a systematic and clear understanding of the Device for safe and correct operation.

The unit runs under a mode of intermittently loading and continuously running (therefore, the user should keep the unit in a standby mode for 5 minutes after the unit has been loading the working laser for 2 minutes), and the user should turn the unit off after the treatment.

### **YAG Laser Emission Warnings**

When the Device is in the state of READY, press the Emission button, there will be visible/invisible laser emitted from the aperture of objective lens of the microscope. Avoid exposure to laser beam; do not face laser beam and do not expose tissues to laser beam.

Observation under the slit-lamp microscope optical system is safe to eyes since the built-in filters provide protection.

### **Aiming Laser Emission Warnings**

When the Device is in the state of READY, there will be visible laser emitted from the aperture of objective lens of the slit-lamp for the purpose of aiming and positioning. Do not look directly at the beam unless it is so required for operation.

### **YAG Laser Reflection and Radiation Warnings**

All objects which reflect visible light can reflect YAG laser with a wavelength of 1064nm. Do not place such reflective materials for example glass, metal and other reflective objects in the laser beam path.

### **Explosion Risk Warnings**

Do not operate the Device under flammable anesthetic gas mixed with air or under flammable anesthetic gas mixed with oxygen or nitrous oxide, since focused beam is likely to be ignited. Some materials, such as cotton, gauze and others contained oxygen, will be ignited by the high-temperature of focused beam. Attentions should be given to the risks of ignition caused by solvent used for cleaning and disinfection as well as combustible solution and the internal gas. Cleaning and disinfection must be carried out before using and make sure the residuals completely evaporate before using.

### **Key Switch**

The device can only be started by the key and when the system starts, the indicator lights up. It is not able to pull out the key when the system is powered on. The device can be shut down by the key. To prevent unauthorized using, take the key away from the power switch when the Device is not used.

### **Emergency Stop**

The Emergency Stop is a red mushroom-shaped button. When the button is pressed, the laser emission can be cut off urgently and laser output terminated.

### **Nominal Ocular Hazard Distance (NOHD)**

NOHD >7m

## **Chapter 1. Introduction**

### **1.1 General Description**

The Nd: YAG Laser System for Ophthalmology produces 1064nm wavelength laser pulse. The laser pulse and dual-spot aiming beam can position precisely on the ocular tissue to be treated through slit-lamp microscope. The YAG laser energy is concentrated and focused on a spot of about 30 $\mu$ m, producing light-induced explosion effect in the action of such a high optical power density, to dissociate ocular tissue rapidly for a purpose of surgery.

The laser beam energy disperses rapidly in front of and behind the focal point so as to avoid injuries to tissues outside the focal point resulting from laser beam. When the dispersed beam reaches fundus oculi, its power density is below one ten thousandth of that at the focal point and the action time is only a few nanoseconds; so under normal circumstances it is not easy to cause injury to fundus oculi thus ensured the safety of surgery.

The device has a built-in laser security protective system to guarantee continuous, stable and safe operation of the device.

The YAG laser and aiming laser are coaxial and confocal with the focal plane of the microscope and meanwhile are confocal with the slit-lamp, which ensured the clarity of observation and the accuracy of surgery. The device utilizes micro-processor control technique, with digital display and is easy to operate; sophisticated ophthalmic micro-surgery can be implemented without cutting the eyeball, which is simpler and easier than the conventional surgery, thus enhances the security.

### **1.2 Intended Use**

Utilizing the light-induced explosion of 1064nm laser pulse to tissues, the Device is intended to be used for ophthalmologic lens capsulotomy, incision or excision of iris, vitreous surgery and other clinical surgeries for therapy of the non-pigmented tissue lesions of anterior segment for eyes.

### **1.3 Contraindications**

It is prohibited to use the Device on patients with severe corneal opacity or who are unable to cooperate with doctor.

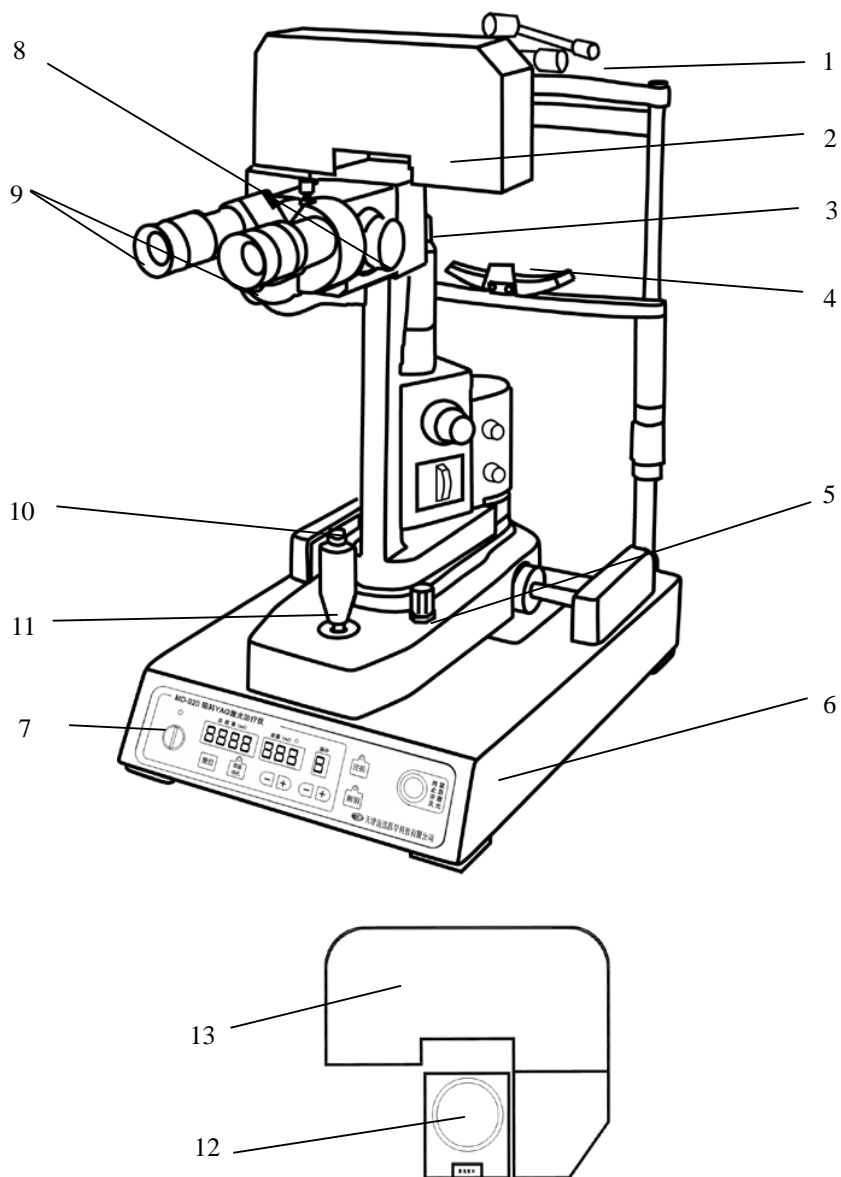
For patients of fundus oculi optic nerve disease: it is prohibited or prudently to use the other anterior segment laser surgeries of the Device to avoid causing blindness or getting sicker.

### **1.4 Software Version**

MD-920 V1.0

## Chapter 2. Principle of Work

### 2.1 Product Composition



**Figure 2.1 Structure of the Product**

- |  |  |
|--|--|
| 1. Fixation Lamp                           | 8. Microscope Zoom Hand-Wheel              |
| 2. Laser Box                               | 9. Microscope Eyepiece                     |
| 3. Slit-Lamp Microscope                    | 10. Laser Emission Button                  |
| 4. Jaw Holder                              | 11. Joystick                               |
| 5. Brightness Knob of Slit-Lamp Microscope | 12. Laser Output Aperture (Objective Lens) |
| 6. Power Control Case                      | 13. Laser Box (back)                       |
| 7. Control Case Panel                      |  |

The Device consists of the Q-switched neodymium-doped yttrium aluminum garnet (Nd: YAG) laser, aiming beam laser, beam delivery system, power supply, control system and slit-lamp microscope.

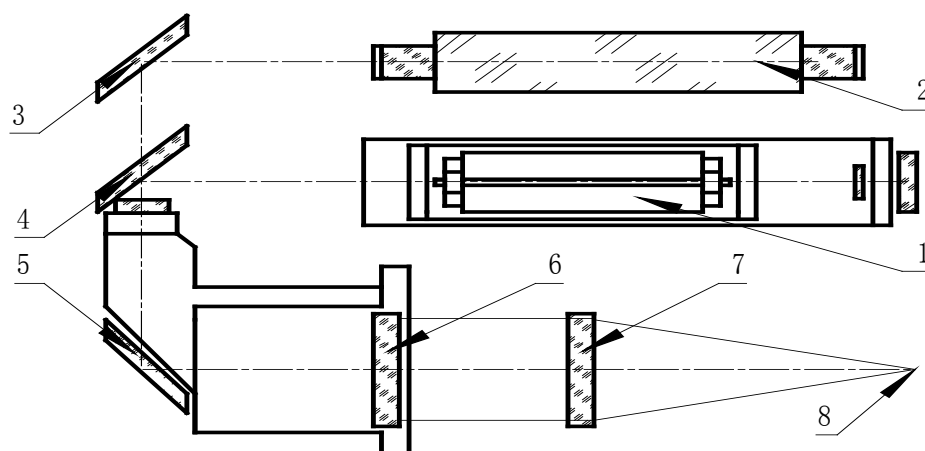
The YAG laser, aiming beam laser, beam delivery system are installed inside the laser box; and the laser box is placed above the slit-lamp microscope and is moving with the slit-lamp microscope. The power supply and its control system are installed inside the power control case and the power control case is located inside the pedestal of the slit-lamp microscope. The three parts are connected into one, thus makes the structure compact and easy to operate. The structure of the Device is shown in Figure 2.1.

The performance, structure, operation and attentions of slit-lamp microscope, which is used by the device, are specified in the User's Manual of Slit-Lamp Microscope.

Electric Lift Table (optional): The YAG Laser System for Ophthalmology is usually placed on Electric Lift Table or on other worktables. The height of the Electric Lift Table is adjustable with four wheels and brake at its bottom, which make it easy for movement and positioning. Users should select Electric Lift Tables that comply with the relevant standards and passed the approval of medical product registration.

## 2.2 Working Principle

### 2.2.1 Q-Switch YAG Laser Working Principle



**Figure 2.2 Schematic Diagram of Beam Path**

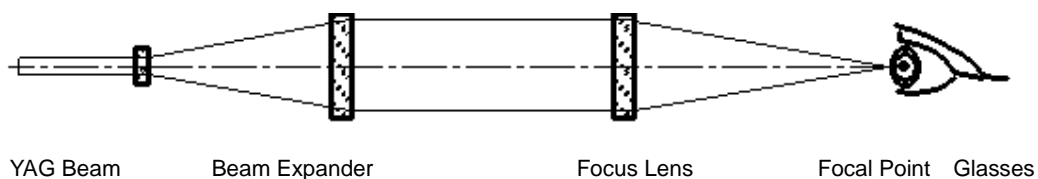
1 YAG Laser	3 Total Reflector	5 Dual-beam Reflector	7 Focus Lens (Laser Aperture)
2 Aiming Laser	4 Spectroscope	6 Beam Expander Lens	8 Laser Focal Point

The Q-switch YAG laser emits a narrow pulse with the width of about 4.5 ns, the laser pulse peak power is up to  $10^6$  W, in this way the strong laser beam will focus on a diameter of about  $30\mu\text{m}$  region through lens, and the power density at the focal point will be up to  $10^{11}\text{W} / \text{cm}^2$  or more. In the action of such a high optical power density, it produces light-induced explosion effect to dissociate ocular tissue rapidly for a purpose of surgery.

See Figure 2.2 for the beam path principle of the Device.

### 2.2.2 Working Principle of High-Magnification Beam Expander

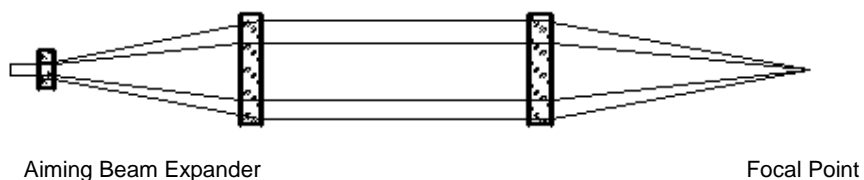
The working principle is shown in Figure 2.3. High magnification beam expander expands YAG laser beam and then focuses by the focus lens, so that the laser energy at the focal point is very concentrated, and then disperse rapidly in front of and behind the focal point for the purpose of surgery as well as avoiding injury to tissues outside the focal point resulting from laser beam. When the dispersed beam reaches fundus oculi, its power density is below one ten thousandth of that at the focal point and the action time is only a few nanoseconds; so under normal circumstances it is not easy to cause injury to fundus oculi thus ensured the safety of surgery.



**Figure 2.3 Schematic Diagram of YAG High-Magnification Beam Expander**

### 2.2.3 Working Principle of Dual-Beam Aiming Indicator

The working principle is shown in Figure 2.4. Two parallel beams focus strictly on the focal point through the focus lens, and the spot becomes oval or separate into two points after leaving the focal points. It is easy to determine through visual observation and the accuracy to determine the position of focal point with this method is very high.



**Figure 2.4 Schematic of Aiming Beam Indicator**

## Chapter 3. Main Specifications

### 3.1 Classification

1. As per the radiation safety of laser product according to IEC60825-1: Class 3B laser product
2. As per the type of protection against electric shock: Class I.
3. As per the degree of protection against electric shock: Type B applied part
4. As per the degree of protection against ingress of liquids: IPX0 for the equipment.
5. As per the mode of operation: Intermittent load continuous operation; the Device can emit laser after continuous load for 2 minutes under the state of "ready" and an interval of 3 minutes.
6. As per the safety degree under flammable anesthetic gas mixed with air or under flammable anesthetic gas mixed with oxygen or nitrous oxide: not belong to AP and APG equipment.

### 3.2 Working Conditions

1. Temperature: 10°C~30°C, Relative humidity $\leq$ 70%
2. Power supply:  $\sim$ 220V $\pm$ 10%, 50Hz $\pm$ 2%
3. Rating power: 150VA

### 3.3 YAG Laser Parameters

1. Laser wavelength: 1064 nm $\pm$ 5 nm
2. Laser mode: multi-mode
3. Laser pulse output: single-pulse, dual-pulse and three-pulse
4. Time characteristics of the laser pulse output
  - a) Laser pulse width: 4.5ns  $\pm$  10%
  - b) Duration of laser pulse sequence: dual-pulse $\leq$ 30 $\mu$ s; three-pulse $\leq$ 50 $\mu$ s
  - c) Maximum emission repetition rate of laser pulse sequence: 2.5Hz $\pm$ 20%
5. Laser output energy (in front of eyeball)
  - a) Maximum output energy of single-pulse: 11mJ $\pm$ 20%
  - b) Maximum output energy of dual-pulse: 19mJ $\pm$ 20%
  - c) Maximum output energy of three-pulse: 28mJ $\pm$ 20%
  - d) Output energy adjustment: 100%~6% 7-grade adjustable, the allowable tolerance between actual output and preset value is  $\pm$ 20%
6. Laser output energy reproducibility:  $R_p \leq \pm 10\%$
7. Laser beam convergence angle: 18 $^\circ$  $\pm$ 20%
8. Focal plane spot diameter: 30 $\mu$ m $\pm$ 20%

### 3.4 Aiming Laser Parameters

1. Aiming laser wavelength: 630 nm~680 nm
2. Aiming laser output power:  $P_C < 0.4$  mW
3. The aiming beam and working beam of laser should coincide with each other through visual observation in the focal plane under the slit-lamp microscope.

### 3.5 Slit-Lamp Microscope

The Slit-Lamp Microscope should have laser protective lens so as to ensure that all laser radiation exposed to operator will not exceed Class 1 limitations.

### 3.6 Safety

Be in conformity with the requirements of IEC 60601-2-22 and IEC 60825-1.

### 3.7 Storage and Transportation Conditions

#### 3.7.1 Transportation

Keep the Device stable during moving. Avoid severe vibration which will change the laser path structure and lead to the abnormal work of the Device.

For long-distance transportation, disconnect all parts including the slit-lamp microscope from the Device and pack them into the original packages before transport; reinstall the products according to Chapter 4 of the User's Manual after transport.

Severe impact and crash, rain and snow shall be avoided during transportation.

#### 3.7.2 Storage

The packed Device should be stored in a well-ventilated room with no corrosive gas. The temperature is -20°C~40°C and the relative humidity no more than 80%.



## Chapter 4. Installation

### 4.1 Environment Requirements

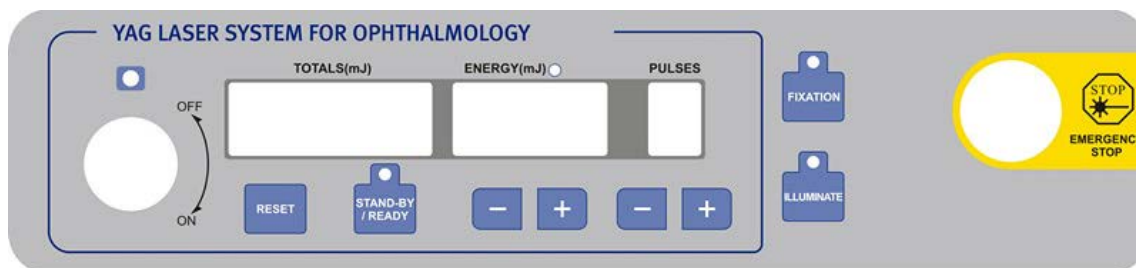
1. The Device is required to be working in an environment with temperature of 10°C-30°C, and relative humidity no more than 70%. To ensure the stable running of the Device, please use it in a clean room and air-conditioned environment is recommended.
2. Proper grounded single-phase three-pole power socket should be used. Improper connection of protective earth may cause not only interference, but also the risk of current leakage. The mains voltage should meet the requirements of §3.2 in the User's Manual.
3. Do not use the Device in locations subject to intense electric or magnetic fields. Avoid high electromagnetic devices (e.g. Microwave, RF generator) and direct sunlight.

### 4.2 Installation Methods

1. Take out the main unit of the Device from the package and place it in the center of the electric lift table or other worktables. The supporting feet of the main unit can't be suspended; keep them stable and horizontal.
2. Check if there is any abnormality for the appearance of main unit, such as surface damage, cracks, water stain and etc.
3. Open the cover of laser box (unscrew the two fastening screws and pull out the cover slightly along vertical direction), and check if the laser components, optic parts and cables are well fixed. Close the cover and fasten it after checking.
4. Install Remote Interlock Connector above the door of Therapeutic Room to ensure that the Device is able to emit laser normally only when the door of Therapeutic Room is closed; thus prevent bystanders from accidental radiation hazards of YAG laser emission.
5. It is able to start up the Device for examination when there is no abnormality. (See §5. Operation for starting up the Device)

## Chapter 5. Operation

### 5.1 Functions and Operations of Control Panel



**Figure 5.1 Control Panel**

#### 1. Control Panel

The control panel is covered by a durable polycarbonate film which is used to protect the surface and is convenient for cleaning. Pressing each key will make a sound so as to let users know that some settings are changed. The operating system contains microprocessor controller for monitoring and controlling the functions of the system. If there is an error, the microprocessor will prevent the working of Laser Emission switch and display error code on the monitor (see §8. Judgment and Treatment of Simple Problems). Intense electromagnetic interference will possibly lead to messy codes on the monitor; turn off the power lock switch and restart the Device, the problem will be corrected.

#### 2. Key Switch

The Key Switch is the power switch of the main unit. Rotate it 90 ° clockwise will turn on the power; and rotate 90 ° counterclockwise will turn off the power.

Note: It is not able to pull out the key when the system is powered on. Take the key away from the power switch when the Device is not used in order to prevent unauthorized using.

#### 3. READY/STAND-BY Key

Stand-by Mode: Turn on the power lock switch, the Device is in the state of Stand-by, and both therapeutic laser and aiming laser do not work, except that the slit-lamp microscope can work normally when pressing “ILLUMINATION”.

Ready Mode: Press “READY” key, there is a “beep” sound. The yellow indicator lights up in 2 seconds, which means the Device can work normally and is ready to emit laser.

#### 4. PULSES Key

The “+” “-” keys of “PULSES” are used to select the mode of single-pulse, dual-pulse or three-pulse each time pressing the EMISSION key.

Single-pulse mode is selected automatically when the Device is turned on. Press “+” once to

select dual-pulse and press again to select three-pulse mode; press “—” for reducing. The display window will show the number of pulses selected.

#### **5. ENERGY Selection**

The YAG therapeutic laser energy is controlled by “+” “—” keys of “ENERGY” on the panel. The keys are used to adjust the laser energy emitted each time. The monitor will display the value of selected energy.

#### **6. TOTAL ENERGY Display**

The TOTAL ENERGY display is the accumulative total energy used during the therapeutic process, the unit is mJ. The value increases accumulatively at each time of laser emission.

#### **7. RESET Key**

Press RESET key, the total energy display returns to zero. Press this key before each therapy to delete the total energy display of the previous course.

#### **8. EMERGENCY STOP**

In case of emergency, press the EMERGENCY STOP button will turn off the power of the Device immediately to terminate laser output. Rotate it along the arrow direction to release the key to working state. Normally, the EMERGENCY STOP key must be in the released state, in order to ensure its normal work.

#### **9. EMISSION Button**

When the Device is in “READY” mode, press EMISSION switch, laser beam emits from the objective lens of the microscope with “beep” sound of warning. Note: the EMISSION switch must be quickly released after each emission.

### **5.2 Start Up of the Device**

Close the door of the Therapeutic Room, insert the key into the Key Switch and rotate 90° clockwise to reach the position of ON, the green indicator above the Key Switch lights up. When the door of the Therapeutic Room is opened, the Remote Interlock Connector installed above the door will act to stop YAG laser emission, thus prevent bystanders from accidental hazards of laser radiation.

### **5.3 Pressing “ILLUMINATION” Key**

The brightness of slit-lamp can be adjusted through the Brightness Knob on the right of the slit-lamp pedestal. Rotate it clockwise to increase brightness and rotate counterclockwise to decrease brightness. If high brightness is not required, keep it in the minimum brightness to reduce heat produced so as to extend the lamp’s life. The duration of lamp at maximum brightness should be no more than 10 minutes.

## **5.4 Diopter Adjustment and Attentions**

### **5.4.1 Diopter Adjustment**

1. Press “ILLUMINATION” Key, the slit-lamp light up. Select proper slit width and brightness. The brightness of slit-lamp can be adjusted through the Brightness knob on the right of the slit-lamp pedestal.
2. First, observe the right eyepiece (eyepiece has rubber jacket, operators wearing glasses can fold the jacket) which has a built-in coordinate with your right eye. Rotate the diopter Adjustment Ring until the vision of the coordinates becomes clearest. Place the target plate well, and move the Slit-Lamp until the target plate is observed clearly through the eyepiece. And then observe the left eyepiece without coordinates; rotate the diopter Adjustment Ring until the same target can be clearly observed through the eyepiece. Move the target plate to the position that will not affect the normal work. Repeat the adjustment procedure once for the first operation to confirm its correctness.

### **5.4.2 Attentions**

1. Due to the specific characteristics of the Device’s working principle, it is important for the diopter adjustment. The operator should be sure to remember that: the operating procedures must be strictly followed; strictly adjust the diopter to the correct value before starting therapy, otherwise the laser therapy will not be precise and even lead to adverse effects to the safety of patients.
2. After adjustment, the operator should remember his/her diopter. For future operations, place the diopter to the right position or readjust the diopter.
3. The diopter of each operator is different, so it is not replaceable.

## **5.5 Pressing “READY” Key**

Press “READY” key, there will be a “beep” sound, and the YAG laser and aiming beam are turned on. The yellow indicator above the “READY” key lights up and it is able to select pulse number and energy value.

## **5.6 Energy Setup**

1. Press “READY” key, the automatic settings of the Device are: output energy: single-pulse, and energy value is about 3.5mj;
2. The operator can select pulse number through “+” “-” keys of “PULSE” and select energy through “+” “-” keys of “ENERGY” according to the energy required; Meanwhile the display window will show the selected values. As an experience, the therapeutic energy settings should possibly be the minimum value, thus ensure the security.

## 5.7 Slit-Lamp Microscope

### 5.7.1 Technical Parameters

#### 1. Microscope

Type	double-eyepiece Galileo magnification with crossing angle				
Type of Magnification	5-grade rotary drum				
Eyepiece	12.5×				
Total Magnification	6×	10×	16×	25×	40×
(Field of View)	( $\varnothing$ 33mm)	( $\varnothing$ 22.5mm)	( $\varnothing$ 14mm)	( $\varnothing$ 8.8mm)	( $\varnothing$ 5.5mm)
Diopter Adjustment	-5D~+3D				
Pupil Distance Adjustment Range	55mm~75mm				

#### 2. Illumination

Slit Projection Magnification: 1.16×

Slit Width: 0mm~14mm continuously adjustable (slit is circular at 14mm)

Slit length: 1mm~14mm continuously adjustable

Spot Diameter: 14mm, 9mm, 5.5mm, 0.3mm

Slit Angle: 0°~180° continuously adjustable in vertical and horizontal directions (Note: turn right 20°~25° when utilizing laser)

Filters: heat-reflecting filter, red-free filter, cobalt blue filter

Illuminating Lamp: 6V/20W Halogen Bulb

Brightness: >120000Lx

#### 3. Travel of Pedestal

Axial: 90mm

Lateral: 100mm

Micro (axial and lateral): 15mm

Vertical: 30mm

#### 4. Jaw Holder

Vertical Travel: 80mm

Fixation Lamp: red LED

## 5.7.2 Procedures of Operation

### 1. Use of Focus Bar



1. Sign of Diopter
2. Slit Width Control Knob
3. Spindle Hole

**Figure 5.2**

The Focus Bar is provided as standard accessory, used to determine the correct adjustment of the microscope. Insert the Focus Bar into the Spindle Hole, with the flat side facing the objective lens of the microscope, which is the operator side.



**Note: Take out the Focus Bar after adjustment.**

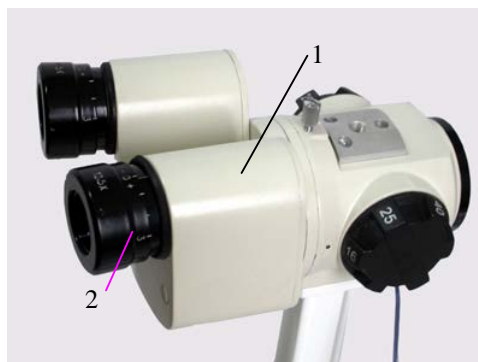
### 2. Brightness Adjustment

Turn on the power switch and set the Brightness Knob in the middle position. Adjust Slit Width Control Knob to get the slit width of 2~3mm.

### 3. Diopter Correction

The focal point of the microscope is adjusted according to emmetropia. If the operator is non-emmetropia, the diopter of eyepiece should be adjusted.

One eyepiece has four short dividing lines, normally placed in the right eye, which will be helpful to obtain accurately focused image after installing some accessories.



1. Prism Box
2. Adjustment Ring

**Figure 5.3**

It is suggested to correct the diopter as per the following sequences:

- ✧ First, rotate the Diopter Adjustment Ring counterclockwise to the end;
- ✧ Then, rotate the Diopter Adjustment Ring clockwise until the clearest slit image presented on the Focus Bar, at this moment the dividing lines in the eyepiece are clearest.;
- ✧ Adjust the other eyepiece with the same method;
- ✧ Write down the diopter value of each eyepiece for future reference.

#### 4. Adjustment of Pupil Distance

Separate the Prism Box of the microscope to two sides with both hands; adjust the pupil distance until the image on the Focus Bar can be observed simultaneously through the eyepiece with both eyes, thus obtain the ideal pupil distance.

#### 5.7.3 Patient Position and Fixation Lamp

Let the patient to put his/her jaw on the Jaw Holder and forehead against the Jaw Belt. Adjust the Jaw Holder Height Adjustment Handle under the Jaw Holder until the corner of patient's eye is aligning with the Horizontal Mark.

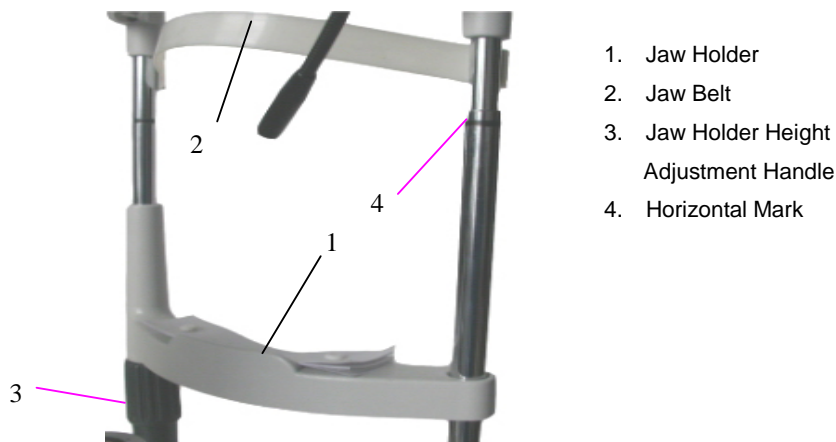


Figure 5.4

#### 5.7.4 Operation of Pedestal

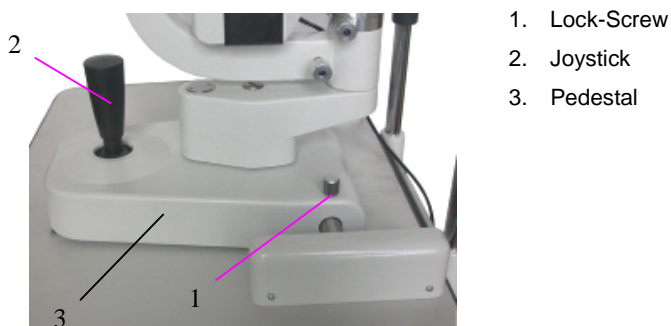


Figure 5.5

### 1. Coarse Adjustment along Horizontal Direction

As shown in Figure 5.5, keep the Joystick vertically and move the pedestal to let the microscope moving horizontally, so as to align with the target approximately.

### 2. Vertical Adjustment

Rotate the Joystick and adjust the height of the microscope to align it with the target. Rotate clockwise will raise the microscope and rotate counterclockwise will lower the microscope.

### 3. Fine Tuning along Horizontal Direction

Tilt the Joystick around so the microscope can be moved slightly in the horizontal plane. While observing through the eyepiece, make adjustment to aim the target accurately and obtain clear image.

### 4. Locking the Pedestal

After fine tuning to the microscope, tighten the Lock-Screw of the pedestal so as to fix the pedestal and keep it unmovable.

#### 5.7.5 Operation of Illuminating Parts



Figure 5.6

### 1. Changing Width of Slit Image

As shown in Figure 5.6, rotate the Slit Width Control Knob will change the slit width from 0mm to 14mm (when the width is 14mm, the slit becomes circular spot).

### 2. Changing Aperture and Slit Length

As shown in Figure 5.6, move the Aperture and Slit Length Selection Set will obtain four circular spots of different sizes with the diameters of 14mm, 9mm, 5.5mm and 0.3mm separately. When it is slit image, the slit length can be changed continuously from 1mm to 14mm.

### 3. Rotating Slit Image

As shown in Figure 5.7, swing the slit subject horizontally will rotate the slit image vertically and horizontally at any angle. The rotation angle can be shown by the Reading Dial, with a small scale as  $5^\circ$  and a big scale as  $10^\circ$ .



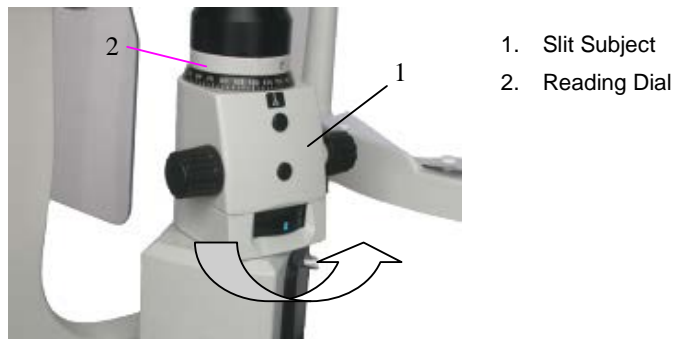


Figure 5.7

#### 4. Select Filter

As shown in Figure 5.6, move the filter selection set horizontally will transfer four different filters (including a through-hole) into the beam path respectively. Heat-reflecting filter is used normally. The blue groove represents cobalt blue filter, white represents heat-reflecting filter, red represent through-hole and green represents red-free filter.

#### 5. Dispersion Illumination

To use dispersion illumination, it is able to turn the Dispersion Piece to the front of the projection prism, as shown in Figure 5.8. Turn the Dispersion Piece down after using. When Dispersion Piece is used, the slit width should be set at the maximum aperture, otherwise the brightness will be reduced.

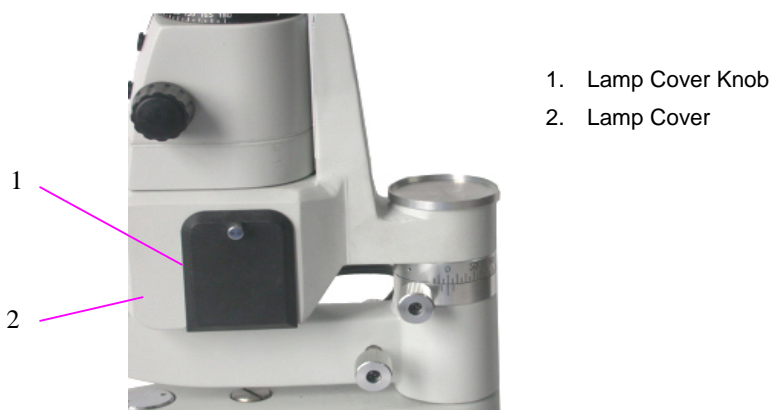


Figure 5.8

#### 5.7.6 Maintenance

##### 1. Replacing Illuminating Bulb

- a) Turn off the power switch;
- b) Rotate the Lamp Cover Knob counterclockwise to open the Lamp Cover;



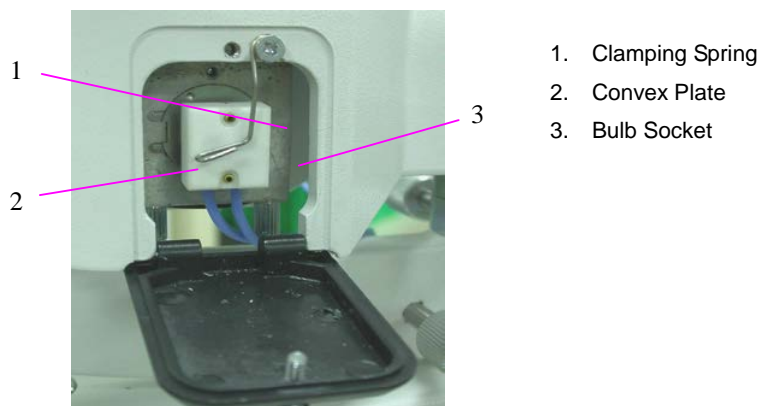
**Figure 5.9**

- c) Loosen the screw on the clamping spring with screwdriver (O), rotate downward to turn it away from the clamping spring. Take out the bulb socket, unplug the old bulb from the bulb socket, put the new bulb, and install the bulb socket following the procedures opposite to that of taking out the bulb. The groove of bulb fixation plate should align with the convex plate of the bulb socket, otherwise the illumination light will be uneven (see Figure 5.9);



**Note: Bulb Hot!**

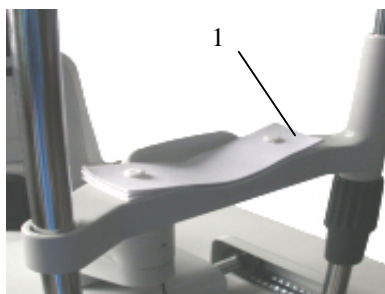
- d) Close the Lamp Cover, and tightening the Lamp Cover Knob;  
e) Turn on the power switch and check if the new bulb lights up.



**Figure 5.10**

## 2. Replacing Jaw Holder Pad Paper

When the pad papers are used up, pull out the two Fixing Pins on the Jaw Holder and place the new pad papers. Install the two Fixing Pins.



1. Fixing Pin

Figure 5.11

### 3. Cleaning

#### a) Cleaning of lens and projection prism

If there are dusts on the lens or projection prism, brush off with the brush (M) attached with the standard accessories. If there is still dirt, wipe gently with soft cotton moistened with absolute alcohol.



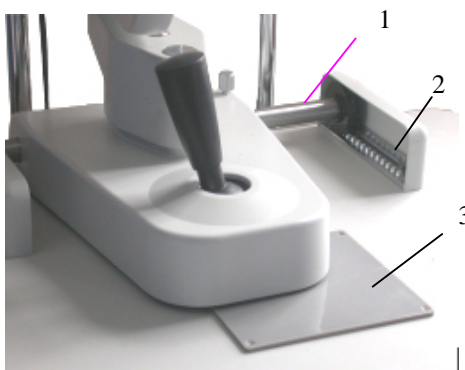
**Note: Do not wipe with fingers or other hard objects.**

#### b) Cleaning of Sliding Panel, Rail and Shaft

If the sliding plate, rail and shaft are not clean, movement along horizontal and vertical directions will not be smooth. Use clean and soft cloth to wipe them.

#### c) Cleaning and Disinfection of Plastic Parts

Clean the plastic parts such as Jaw Holder, Jaw Belt and others with soft cloth dipped in soluble detergent or clean water, then wipe off with alcohol for disinfection.



1. Shaft  
2. Rail  
3. Sliding Plate

Figure 5.12

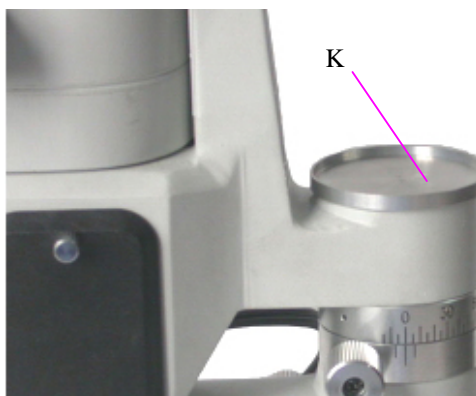


**Note: Do not use any corrosive detergent, to avoid damage to the surface.**

### 4. Protection

During the using of slit lamp, there are often dusts, physiological saline or other dirt falling into the hole

of the main spindle of the lighting arm, in order to protect the instrument from damage, place the Protective Cap (K) on the hole of the spindle, as shown in Figure 5.13.



**Figure 5.13**

### **5.7.7 Attentions to the Operation of Slit-Lamp**

1. Use the Jaw Belt to keep the position of patient's head fixed.
2. Adjust Jaw Holder: rotate the Jaw Holder Height Adjustment Handle to the height that is suitable for patient eyes.
3. Adjustment of slit-lamp microscope: slit-lamp microscope can move around to the position required for therapy; Joystick tilting provides a fine tuning to the positions in any direction; rotate Joystick can adjust its height.
4. The rotating angle of the lamp is  $20^{\circ} \sim 25^{\circ}$  to the right the angle of less than  $20^{\circ}$  will affect the energy output of the laser therapy.
5. Press down the "FIXATION" switch when required, then the Fixation Lamp lights up. Place the Fixation Lamp in front of the position where patient should stare.
6. Adjust the Joystick to let the aiming beam and slit-lamp light irradiate the surgical site of patient's eye (height and direction can be adjusted). Adjust the Joystick slightly so that the aiming dual-beam spot in the eye aims at the surgical site and converge to one point accurately.
7. To prevent cross-infection, put single-use sterile gauzes or face tissues on the Jaw Holder, Jaw Belt for padding, which should be replaced promptly after use.

### **5.8 Laser Emission**

Press the laser Emission button on the Joystick to emit YAG laser for surgery.

Release promptly after each pressing of the laser Emission button, the energy selected will be recorded for one time automatically. There is a "beep" sound accompanied with emission, and the indicator of laser output energy lights up one time, which mean that the Device has emitted laser

energy and is under the state of READY again.

### **5.9 Abnormity Treatment**

If the device is found abnormal during surgery, press the red “EMERGENCY STOP” button on the right side of the control panel, the Device will stop working immediately. Rotate the “EMERGENCY STOP” button clockwise after the problem has been resolved and making sure the Device can resume working normally.

### **5.10 Shut Down of the Device**

After surgery or when the therapy is stopped, rotate the Key Switch of power counterclockwise to turn off the power of the Device and take the Key away, in order to prevent unauthorized usage.

## Chapter 6. Attentions

Please obey the following attentions strictly. Failure to follow the instructions may cause injuries to people present and patients, or cause damage to the Device.

1. The unit runs under a mode of intermittently loading and continuously running (therefore, the user should keep the unit in a standby mode for 5 minutes after the unit has been loading the working laser for 2 minutes), and the user should turn the unit off after the treatment.
2. The Device should be operated by qualified and trained ophthalmologists.
3. Please read the manual carefully before installation and operation; Operations should be in strict accordance with the methods specified in the User's Manual.
4. The work environment of the Device should be clean, and to ensure the stable operation of the Device, air-conditioned environment is recommended.
5. Proper grounded single-phase three-pole power socket should be used. Improper connection of protective earth may cause not only interference, but also the risk of current leakage. The mains voltage should meet the requirements of §3.2 in the User's Manual.
6. Do not use the Device in locations subject to intense electric or magnetic fields. Avoid high electromagnetic devices (e.g. microwave, RF generator and etc.) and direct sunlight.
7. Install Remote Interlock Connector above the door of Therapeutic Room to ensure that the Device is able to emit laser normally only when the door of Therapeutic Room is closed; thus prevent bystanders from accidental radiation hazards of YAG laser emission
8. YAG Laser Emission Warnings: When the Device is in the state of READY, press the Emission button, there will be invisible laser emitted from the aperture of objective lens of the microscope. Avoid exposure to laser beam; do not face laser beam and do not expose tissues to laser beam
9. Aiming Laser Emission Warnings: When the Device is in the state of READY, there will be visible laser emitted from the aperture of objective lens of the slit-lamp for the purpose of aiming and positioning. Do not look directly at the beam unless it is so required for operation.
10. YAG Laser Reflection and Radiation Warnings: All objects which reflect visible light can reflect YAG laser with a wavelength of 1064nm. Do not place such reflective materials for example glass, metal and other reflective objects in the laser beam path.
11. Explosion Risk Warnings: Do not operate the Device under flammable anesthetic gas mixed with air or under flammable anesthetic gas mixed with oxygen or nitrous oxide, since focused beam is likely to be ignited. Some materials, such as cotton, gauze and others contained oxygen, will be ignited by the high-temperature of focused beam. Attentions should be given to the risks of ignition caused by solvent used for cleaning and disinfection as well as

- combustible solution and the internal gas. Cleaning and disinfection must be carried out before using and make sure the residuals completely evaporate before using.
12. Key Switch: The device can only be started by the key and when the system starts, the indicator lights up. It is not able to pull out the Key when the system is powered on. The device can be shut down by the Key. To prevent unauthorized using, take the Key away from the power switch when the device is not used.
  13. Emergency Stop: The Emergency Stop is a red mushroom-shaped button. When the button is pressed, the laser emission can be cut off urgently and laser output terminated.
  14. Laser Output Aperture: The Laser Output Aperture is located at the objective lens of the microscope, there will be visible/invisible laser emitted during therapy. Do not look directly at it.
  15. The Slit-Lamp Microscope should have protective lens inside the objective lens so as to ensure that all laser radiation exposed to operator will not exceed Class 1 limitations. The operator can not wear laser protective glasses.
  16. Service personnel are prohibited to look directly at laser beam when repairing beam path. Laser protective glasses (laser reflectivity $\geq$ 95% to helium-neon laser aiming beam with the wavelength of 1064nm and 635nm) should be worn.
  17. Appropriate energy should be selected according to patient's condition. On the premise that the requirements of therapy are satisfied, laser pulse with possibly smaller energy should be adopted
  18. It is suggested to set the rotating angle of slit-lamp at 30°~35° to the right, to ensure that the slit-lamp will not block laser energy output.
  19. Pay attention to place the slit hand-wheel, filter hand-wheel of slit-lamp as well as the magnification hand-wheel of the microscope in the correct position in order to avoid misoperation.
  20. Keep the Device stable during moving. Avoid severe vibration which will change the laser path structure and lead to the abnormal work of the Device.
  21. For long-distance transportation, disconnect all parts including the slit-lamp microscope from the Device and pack them into the original packages before transport; reinstall the products according to Chapter 4 of the User's Manual after transport.
  22. For the requirements of Therapeutic Room, please refer to §Appendix A Provisions for the Operating Room of YAG Laser Therapeutic Apparatus for Ophthalmology.

## **Chapter 7. Cleaning, Disinfection and Sterilization**

To prevent cross-infection, please pay attention to:

Check before use that the single-use sterile gauzes or face tissues should be put on the Jaw Holder, Jaw Belt for padding, which should be replaced promptly after use.

Use sterile gauzes with medical alcohol to make careful cleaning and disinfection every day to the Jaw Holder and Jaw Belt and surrounding areas that contacts patients.



## Chapter 8. Judgment and Treatment of Simple Problems

SN	Trouble Appearance	Trouble Cause	Treatment
1	No display on the monitor of the Control Case Panel	Power is not connected	Check mains and socket; Check the fuse
		EMERGENCY STOP button has been pressed	Release EMERGENCY STOP button (rotate the switch clockwise)
2	Messy code on the monitor	Electromagnetic interference.	Turn off the power and restart the Device
3	EAO 1 appears on the monitor	Failure of YAG laser and aiming laser circuit	Restart the Device
4	EAO 2 appears on the monitor	Failure of driving circuit	Restart the Device
5	Weak YAG laser output	YAG laser energy reduced	Check with the black photographic paper in the attachments to make laser spot at 3mm in front of the laser focal point. If it is not circular, the energy reduced, otherwise, it is normal.
		Slit-lamp blocked laser beam path	See item 17 of Attentions
6	No YAG laser output	Laser Emission button is broken.	Press Emission button again
		Laser is blocked by slit-lamp	See item 17 of Attentions
7	No aiming beam	Slit-lamp blocked laser beam path	See item 17 of Attentions
8	Slit-Lamp is not lit	Brightness knob is in the minimum position	Rotate the Brightness knob to the right to increase brightness
		Aperture position of the slit-lamp is incorrect	Adjust the position of Hand-Wheel correctly
		Slit-lamp bulb is broken	Replace the bulb

The specification of the fuse of the Device is 5S 2A/~250V slow fuse, always use the same product in case of replacement.

The specification of bulb of the slit-lamp is: halogen bulb, always use the same product in case of replacement.

Contact the Manufacturer to purchase the accessories. Don't use accessories with other specifications.

If above operations are not effective, please don't open the housing without authorization. Contact the supplier immediately. Explain the problems in detail for proper and in time support.

The Device is a high-tech product designed elaborately. Only qualified trained engineers are authorized to repair the Device.

The Manufacturer is not responsible for problems caused by any kind of unauthorized repair.

## **Chapter 9. Maintenance and Environment Protection**

1. Keep the Device clean. Do not use any corrosive detergent when cleaning the surface of the Device and avoid ingress of water or other liquids into the housing and keyboard. Clean the housing of the Device with soft cloth with neutral detergent. Disconnect the mains power plug before cleaning.
2. Check the Device completely before surgery. In case of any abnormality, do not use it until the reason has been found out, the problem has been resolved and making sure the Device can resume working normally.
3. Pay attention to the protection against moisture and avoid contamination and mildew of optical parts. Put on the dust cover and dust cloth.
4. The Device is a high-precision laser therapeutic product. In case of problem, check according to the requirements of Chapter 8. If not effective, contact the supplier/manufacturer immediately. Unauthorized personnel are not allowed to make repair or modification.
5. Environmental Protection: During the process of therapy, the Device will not produce hazardous waste, residuals and etc. By the end of the Device and accessories' service life, the disposal should conform to the local environment protection provision. (It is suggested to take the same measures with the disposal of computer and other electronic devices.)
6. Please refer to Annex C for Regular Calibration of Laser Pulse Output Energy.

## Chapter 10. Warranty

1. The product has a warranty of one year from the date of purchasing, on the premise of using in accordance with the User's Manual.
2. If the Device does not work properly, please contact your local distributor or the manufacturer immediately. Do not open and/or repair the Device without authorization
3. Following repairs will be charged within warranty period:
  - Problems caused by man-made damages;
  - Damages caused by unauthorized disassembly and/or repair;
  - Damages caused by inappropriate use and operation.
4. The Manufacturer provides continuous maintenance and repair after warranty period with certain charges.

If required, we can provide the complete maintenance and repair manual to the authorized and qualified engineers.

## **Appendix A Provisions for the Operating Room of YAG Laser Therapeutic Apparatus for Ophthalmology**

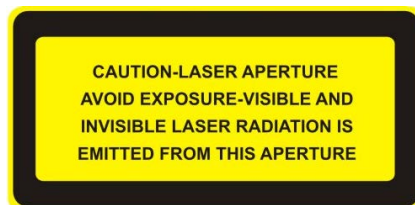
The YAG Laser Therapeutic Apparatus for Ophthalmology is a high precision optical instrument. Strict control of the work environment is an essential condition to the normal operation of the Device; therefore, following provisions are made for the operating room:

1. The Device should be installed in a dustproof and dampproof room. It should not share the same room with other common works.
2. The temperature of the operating room should be controlled at 15 °€30 °C.
3. There should be dampproof measures. For coastal, rainy and damp regions, dehumidifier should be installed indoor to keep the relative humidity less than 70%.
4. The floor should be made dustproof treatment: such as laying carpet, plastic, ceramic and wood floor or other dustproof measures.
5. Doors and windows should be sealed to prevent dust and moist air into the room. Air conditioner can be used, but it is not allowed to use electric fans and ceiling fans to prevent pollution to the optical path of the Device due to dust raised from ground.
6. Please replace special shoes when entering into the operating room, in order to reduce dust into the room.
7. The AC Power Supply of the Device should have reliable grounding line to ensure personal safety.
8. Install an interlock switch connecting to the device above the door of the operating room to ensure that laser will be emitted only when the door is closed.
9. The operating room should be kept away from corrosive gases and liquids, to prevent damage to the Device.
10. No smoking in the operating room.
11. The entrance of the working area should post standard laser radiation warning labels.
12. For the purpose of safety, non-working-staffs are not allowed to enter the operating room.

## Appendix B Duplicates of Laser and Warning Labels



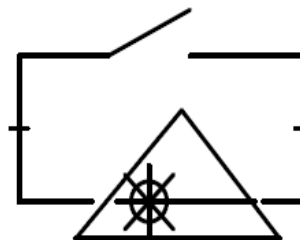
Class 3B Laser Product Warning Label



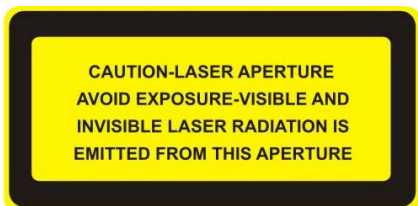
Laser Aperture Warning Label



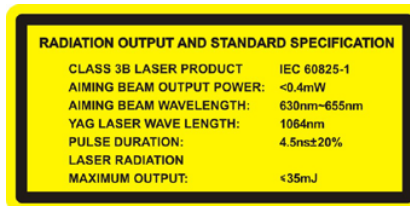
Emergency Laser Stop Label



Remote Interlock Connector Label



Safety Interlock Panel Label



Radiation Output and Standard Explanation Label

## Appendix C Regular Calibration of Laser Pulse Output Energy

This product shall, in accordance with local regulatory requirements, be regularly calibrated by qualified organizations or personnel. (When no specific requirement is stipulated by the regulations), it's suggested a user calibrate its product no less than once within two years. The recommended method is as follows:

### 1. Devices for Calibration

A laser energy meter for calibration shall meet the following requirements:

- 1) The device has a wavelength range that covers 1,064nm;
- 2) The device has a measuring range of up to 40mJ, and a resolution of up to 0.1mJ.

### 2. Method for Calibrating Laser Pulse Output Energy

#### 1) Calibration of Rated Output Energy at Single-Pulse

Warm up the laser system for 5 minutes; select "1" at "Pulse" column; put the measuring probe of the laser energy meter in front of the laser aperture, to be exactly, at about  $\Phi 6$ - $\Phi 8$  of spot diameter before the focus of the aiming beam; measure the laser pulse energy of the laser system with the standard values of its laser output energy being 3.85mJ, 5.5mJ and 11mJ, respectively; measure every 10 seconds, and for 10 times in total; calculate its average value as the calibrated value of the laser output energy.

#### 2) Calibration of Rated Output Energy at Multiple Pulse

Select 2 at "Pulse" column; use the above-mentioned method to measure the average value of the laser pulse energy of the laser system with the standard values of its laser output energy being 9.5mJ, 13.3mJ and 19mJ.

Select 3 at "Pulse" column; use the above-mentioned method to measure the average value of the laser pulse energy of the laser system with the standard values of its laser output energy being 14mJ, 19.6mJ and 28mJ.

3. Calibration personnel shall issue a calibration certificate with calibration results. A user of the laser system shall refer to this calibration certificate in order for proper correction on the laser output energy that is needed in a treatment.

Prepared on October 20, 2015