This is a guidance book on how to use and handle Nd: YAG laser ophthalmic therapy apparatus.

Even if you've had adequate training conducted by our company or any other authorized dealer, you are required to read this guidance book carefully, especially when you use this product for the first time. Please be sure to read it carefully, especially the part on safety precautions and warnings.

This guidance book applies to both Type LS-100 and Type LS-100A laser ophthalmic therapy apparatuses produced by our company.

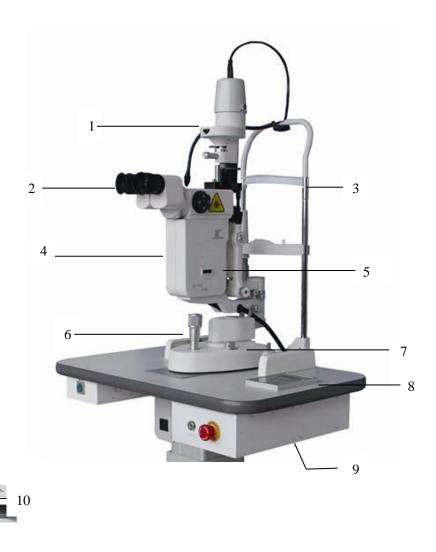
Introduction

Nd:YAG laser ophthalmic therapy apparatus of LS-100 series is a non-contact microsurgery instrument of high accuracy. It ensures surgery veracity by making YAG laser, aimed laser and slit-lamp microscope strictly coaxial and confocal.

It applies a saturated-absorption type of dye film to laser Q-switch, which compresses the energy of the YAG laser into narrow pulses to increase pick power until it "explodes" in target tissues. Ionization generated in this way quickly dissociates eye tissues and thus complicated ophthalmic microsurgery can be performed without cutting into the eyeball.

Main structure

This apparatus is mainly made up of Nd:YAG laser Q-switch, security protection system, slit-lamp microscope, power source and control system. As to the structure, operation and precautions of the slit-lamp microscope, please refer to its instructions.



Type LS-100A

- 1. slit lamp
- 2. microscope
- 3. frontal frame
- 4. laser and optical system
- 5. laser energy weakening dial
- 6. operating handle
- 7. slit lamp brightness control switch
- 8. control display panel
- 9. laser power source
- 10. foot switch

Performance Parameter

1. YAG laser parameters

a) wavelength 1064nm

b) mode multi-mode

c) operating mode Q-switch

d) pulse width 6ns

e) pulse energy 0~40mj

g) multi-pulse operation 1~4 pulses(optional)

h) pulse energy output instability $\leq \pm 10\%$

i) focus aperture angle 16°

j) focus beam diameter ≤30µm;

k) absorption-type weakening film transmittance(%) 100, 70, 50,

35, 25, 12, 6, 0;

2. Aimed Laser

a) wavelength 632~680nm

b) power $Pc \leq 1 \text{mW}_{\circ}$

Safety

1. Safety classification and warnings

This apparatus is a laser product of Category 3B and application part of Type B, Category I. common apparatus, non-AP or APG-kind apparatus.

2. Protective glasses warning

Check the integrity of optical filters and lens coating regularly. If any imperfection of its surface coating is to be found, please don't use it and get in touch with our company or any other dealer in service.

3. Explosion warnings

Flammable anesthetics or oxidizing gases like N_2O and O_2 must be avoided before laser treatment. Pay attention to ignition ability of solvents for cleaning and disinfection, flammable liquor as well as internal gases.

Some substances, such as cotton and woolen stuff, can be ignited by hyperthermia caused by focused beam in abundant oxygen. Solvents for cleaning and disinfection and flammable liquor should be volatilized before the use of the laser apparatus.

4. Electromagnetic disturbance warnings

When in use, this apparatus may be disturbed by exterior wireless power nearby (like mobile phone). Thus when using the laser system, please make sure all mobile phones are powered-off or alternatively taken outside the treatment room.

5. Security labels

See Appendix A

6. Main reference standards

This product is in accordance with:

Electrical Equipments for Medical Use, Part 1: General Requirements for Safety, GB 9706.1-2007

Electrical Equipments for Medical Use, Part 2: Special Safety Requirements for Diagnosis and Treatment of Laser Apparatus, GB 9706.20-2000

Security of Laser Products, Part 1: Classification, Requirements and Guidance, GB 7247.1-2001

General Specification for Continuous Wave Neodymium-doped Yttrium Aluminum Garnet laser therapy apparatus, YY 0307-2004

7. Production standard:

Registration Standards of Nd: Laser Ophthalmic Therapy Apparatus

8. Nominal Ocular Hazard Distance

Nominal ocular hazard distance (NOHD) means in regular operations, therapeutic laser beam has a barrier-free access to the patient's eyes with radiation exposure kept within its maximum permissible error (MPE). A distance beyond NOHD is thought to be safe. Otherwise, you are required to wear protective glasses to reduce the energy accessible to eyes and make it below MPE.

9. Protective lenses

Protective lenses are installed at the back of the binoculars.

Installation

1. Unpacking

This product is to be transported to the designated installation site. Please unpack it and check the packing list (see Appendix B).

2. Inspection before installation

Please conduct the following inspections before installation:

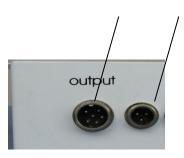
- a) Make sure that all spare parts have been received.
- b) Check if any part, cable, etc. is tarnished, deformed or damaged. Ensure no abrasion or fissure in the cables.
- c) Check if there is any detachment or damage of the optical lenses and weakening film.
- d) In the case of loss or damage of any part, please get in touch with our company or any other dealer in service immediately.

Network power requirement:

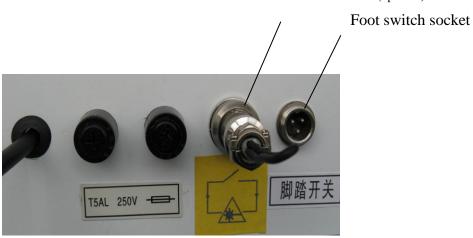
AC 220 V 50 Hz, reliable ground connection accessible

3. Device connection

Slit lamp Spotlight



Remote-control interlock connector(optional)



4 Installation of slit-lamp microscope

Please refer to instructions for slit lamp.

Clinical Application

- 1. This therapy apparatus is applied to posterior capsulotomy and peripheral iridectomy for angle-closure glaucoma.
- 2. Possible complications of laser therapy:
 - a) rise in intraocular pressure: A YAG laser iridectomy may lead to rise in intraocular pressure to varying degrees, which lasts a day or two. So please pay attention to the change of intraocular pressure after treatment and take hypertensive drugs when necessary.
 - b) inflammation: Inflammation may occur after laser therapy. In such case, hormone drops can be applied to get it under control. You may also get a sub-conjunctival injection of dexamethasone or alternatively take hormone orally.
 - c) haemorrhage: Iris haemorrhage may be caused during iris tresis. Usually, this can be stopped by pressing eyes with contact lens or hand.
 - d) damage of crystalline lens: Crystalline lens may be damaged.

Work condition

- 1. ambient temperature: $10^{\circ}\text{C} \sim 30^{\circ}\text{C}$;
- 2. relative humility: $\leq 70 \%$;
- 3. power supply: AC 220 V 50 Hz;
- 4. power: 500 VA
- 5. no strong electromagnetic field disturbance around

Operation and Use

Before starting the laser please make sure that the electricity cable are properly connected and the electrical power connecting with the cable are turned on.

- 1. Turn on the switch
- 2. Turn on the slit light and adjust it to $20^{\circ} 25^{\circ}$
- 3. Adjust the diopter
- a. Plug the plate
- b. Adjust the brightness of the slit light
- c. Hold the handle of the microscope and adjust the focal length to concentrate the aiming light, then adjust the right eyepiece to get a clear view of the plate and the red light. Then do the same adjustment with the left eyepiece.
- 4. Fix the patient's head on the frontal frame and adjust the handle of the microscope so that the aiming light and the slit light can fall on the operating spot of the patient's eye. Adjust the brightness and the breadth of the slip light if necessary, then adjust the handle slightly to make the aiming light concentrate and fix on the operating spot of the eye.
- 5. Choose appropriate energy in accordance with the requirement of the operation. Press pulse button to choose pulse 1 4 (loop), and the number and energy of the pulse (with the unit of mJ) will be showed on the display. Turn the transmittance dial to choose appropriate transmittance. The energy on the display times the transmittance equals the energy transmitted to the eye.

- 6. Press "ready" button and the standby/ready indicator flickers, which means the laser is working and ready for operation. After using, press the "standby" button, and the standby/ready indicator goes out, which means the laser is sleeping. (see diagram 3)
- 7. Press the handle switch or press the foot switch to send out YAG laser and do the operation.
 - 8. After the operation, turn off the slit light and power.

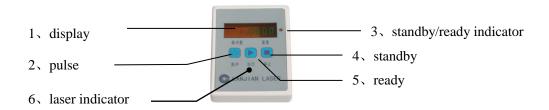


Diagram 3 control panel

Attention:

- 1. As for the use and operation of the laser, it is very important to adjust the diopter. Please strictly obey the operation procedures. Before the operation one's diopter must be correctly adjusted. Otherwise the laser will not be properly used and it may do harm to patients.
- 2. Everyone has different diopter and please correctly adjust the diopter for every patient.
- 3. Each time the aiming light should be aligned on the plate. The laser and aiming light are co-axial, confocal and invisible. Should there be any deviation

with the laser and aiming light, please contact our company or our authorized dealers.

- 4. Protecting lens are fitted on the microscope to protect the operators. During the operation other people present are prohibited to look directed at the laser and the patient's eye.
- 5. The laser is high precision optical, mechanical and electrical equipment, and should be put in a place free from dust, dampness and shake. When not in use, it should be fixed with casters.
- 6. When operating the laser, please choose appropriate energy and avoid sending out high level energy.
- 7. In operation please make sure the slit light handwheel, filter handwheel and dial switch are in the right position.
 - 9. The laser can only be operated by trained ophthalmologists.
 - 10. Please do not change warning signs of the laser.
- 11. Non professionals should not disassemble the optical part to avoid exposure of laser.
- 12. After operation please shut off the power, take off the key and lay the dust cover.
- 13. In emergency please press the red stop button and shut off the power to stop laser emission. When reusing, please turn the red button clockwise.

Attention: Operating, adjusting and performing the laser without obeying these stipulations may cause harmful radioactive exposure.

Maintenance

- 1. Wipe the surface of the laser with soft cloth wetted with noncorrosive detergents (soap powder, for example) or chemical sterilants, and then dry it with clean soft cloth or wind
- 2. Wipe the throat mold with throw-away paper mat attached with the laser or sterile it with medical alcohol.
- 3. The optical part and the lens should be clean, no fingerprint or other stain.

 Otherwise the performance of the laser will be affected. Please check and clean the optical part regularly.

Don't touch the lens with hand. Clean it with rubber suction bulb or lens tissue. If there is grease or fingerprint on the lens, please wipe it with cotton wool wetted with the mixture of alcohol and ether (the proportion: 7:3). It should be cleaned in this way: wipe the lens with cotton wool wetted with the mixture in a straight line, then throw the cotton wool away and change another.

- 4. To keep the laser in good performance, please maintain it once a year. The maintenance include general checkup, cleaning, adjusting and calibrating. Please contact our company or our authorized dealers. The calibrating procedure is demonstrated in Appendix C.
- 5. The laser has a service life of at least 8 years starting from production time. The laser is structural, so the service life can be extended when some parts are changed.
 - 6. The waste produced by the laser should be sent to environmental protection

department and thus disposed of.

Storage and Transportation

- 1. The lift table, slip light, power box, and optical part should be packed in cases with soft padding respectively. The optical part should be sealed with plastic bags and the case containing it should be filled full.
 - 2. The laser should be placed in dry and clean rooms with no corrosives.
- 3. The laser should be transported with caution. Violent shakes and collisions are prohibited.
- 4. The laser can not be drenched by rain, placed upside-down or tossed in transpiration, loading and unloading.
 - 5. Storage and transportation conditions:
 - a) temperature range: $-40~^{\circ}\text{C} \sim +55~^{\circ}\text{C}$;
 - b) relative humidity range: ≤93 %;

Common problems and troubleshooting: See Appendix D

Safety Signs Sign position Description
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T5AL 250V T2AL 250V	Rear panel of power box	Fuse	
	Name plate	Application part B	
IPX1	Foot switch cover	Shell protection level	
**	Laser output window	Laser output warning	
透过率	Attenuator handwheel	Laser attenuation sign	
	Rear panel of power box	Remote control interlock connector	
luminance min max	Power panel of slit light	Luminance adjustment sign	
激光 窗口 避免受到从本窗口射出的 激光辐射的照射	Laser output window	Laser window warning	
可见及不可见激光辐射 避免光束照射 3B类激光产品 6B7247.1-2001 Md: YAG激光: 1084nm 最大能量: 40mJ 指示光: 632nm-680nm 最大功率: ≤1mm	Optical part cover	Laser safety warning	
Nd: YAG激光眼科治疗机 国食药监械(准)字 标准编号: 额定电压 AC220V 额定频率 50HZ 最大输入功率 500VA	Side face of the power box	Name plate	

Appendix B

Number	Name	Model/Specification	Unit	Quantity	Remarks
1	Slit light microscope	Meiwo S350	a	1	
2	Laser adapter	LS-100A	set	1	
3	Laser protection lens	Inside	pair	1	
4	Electrical lift table		a	1	
5	Foot switch		a	1	
6	Fastening rope		a	1	
7	Elbow lift		a	2	
6	Bulb	OSRAM 6V-20W	a	1	
8	Target frame		a	1	
9	throat mold tissue		sheet	1	
10	specification		copy	1	
11	Conformity certificate		copy	1	
12	rubber suction bulb		a	1	
13	Cover cloth		piece	1	
14	fuse	Φ5×20 5A	piece	2	
15	cruciform screw driver	5×75	a	1	

Appendix C

The calibrating of laser energy should be done at least once a year, which is

also a part of annual routine checkup. For calibrating please contact our company

or our authorized dealers.

Equipment: 145D laser calorimeter

Calibrating:

Start the laser and output maximum energy. After 5 minutes, put the laser

calorimeter probe on the output window of the laser, and measure the energy 5

times. Then average the 5 figures and compare the average figure with the figure

shown on control panel. If the error exceeds $\pm 20\%$, please calibrate. For every

measurement the calorimeter should be returned to zero.

Appendix D

Failure	Possible reason	Solution	
Switch on but the laser	The power line is not connected	Check the connection between the power cable of the rear pane and the power socket	
cannot work	Emergency button is off	Turn the emergency button clockwise	
	The fuse is blown	Change the fuse of the rear panel	
	Attenuator handwheel is in	Check the position of	
YAG laser energy	wrong position	the attenuator handwheel	
attenuates	Q plate is damaged	Change a new Q plate	
	YAG laser ages	Change YAG laser	
	Foot switch or hand switch is in poor contact	Check foot switch or hand switch	
No YAG laser output	Power is not working properly	Check power output voltage	
	The slit light is blocked	Put the slit light $20^{\circ} \sim 25^{\circ}$	
	Attenuator handwheel is not	Adjust the Attenuator	
	in proper position	handwheel in proper position	

	xenon lamp is not working	Change the xenon lamp		
	The connecting line is in poor	Check the connecting		
No aiming light	contact	line		
	Semiconductor laser is	Change semiconductor		
	blown			
No slit light	Luminance button is on 0	Turn the button		
	Slit light handwheel can not	Adjust the handwheel		
	be properly adjusted			
	The slit light bulb is burned	Change the bulb		
	out			
Lift table cannot	Belt slips	Adjust the fastening screw of		
work	Den sups	the belt		