

# **Operating Microscope**

## **OPM500 User Manual**

*Shenzhen CERTAINN Technology Co., Ltd*

Please read the manual carefully before using the device

# INTRODUCTION

Thank you for purchasing the OPERATING MICROSCOPE OPM500.

## PURPOSE OF THIS MANUAL

This user manual is designed by CERTAINN TECHNOLOGY and only applies to OPM500 Operating microscope. It may cause damage or inaccurate inspection results if it is used in an inappropriate way. This manual is recommended to be used as reference material for operation and training. Please keep this Manual with the instrument for future reference.

## REVISION HISTORY

Part Number	Rev	Software ver	Description	Release Date
	V1.0			

- 
1. No part of this manual may be copied or reprinted, in whole or in part, without prior written permission.
  2. The contents of this manual are subject to change without prior notice and without legal obligation.
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## PREFACE

First of all, thank you for purchasing an Operating microscope from Shenzhen Certainn Technology Co., Ltd. The OPM500 is used for observation during microsurgery and diagnosis and treatment.

The Operating microscope refers to a compound micro-magnification instrument composed of cold light source, objective lens, eyepiece, optical zoom system and bracket. Surgical microscopes can generally be divided into three parts: mechanical systems, observation systems, and lighting systems. Vertical operating microscopes (floor-mounted) are generally used for ophthalmic surgery, the feature of this type of surgical microscope is that it can be placed arbitrarily, and is more flexible and easy to install. The Operating microscope is suitable for the development of ophthalmic microscopy in hospitals and ophthalmic research centers above the township level, and widely used in ophthalmic surgery and ophthalmic experiments in medical colleges and universities. It is a necessary medical equipment for ophthalmic microsurgery.

The purpose of this user manual compiled by CERTAINN is to provide training, use and reference guides. We require users to be professionally trained medical personnel or technical personnel.

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# 1. IMPORTANT NOTICE

- ✧ Please read this user manual carefully before using this instrument.
- ✧ This user manual only applies to OPM500.
- ✧ This user manual contains the information needed to operate the OPM500, and includes operating procedures, safety precautions and specifications.
- ✧ Before operating this instrument, you must fully understand the safety precautions and operating procedures. Please keep this user manual properly for future reference.
- ✧ This instrument can only be operated by professional medical personnel, and can only be used for the content specified in this user manual and operated in accordance with the instructions.
- ✧ The maintenance of this instrument can only be performed by qualified service personnel authorized by CERTAINN.
- ✧ Due to the continuous improvement of the product, CERTAINN reserves the right to change the technical specifications without the prior notice
- ✧ The final interpretation of the user manual is owned by CERTAINN.

## 2. INSTRUMENT INSTALLATION

This instrument should only be installed by an authorized service representative of CERTAINN, so detailed assembly and installation instructions are not provided here (some basic accessories that users may use, such as optical splitters, assistant binocular, etc. will be introduced in Installation manual.) CERTAINN will install it on-site for free at the same time as the delivery.

### **Installation Requirements**

The instrument must be installed in a well-ventilated room with a flat floor, and the ventilated instrument cover for the device's heat dissipation must not be blocked.



**Note: Failure to provide proper ventilation conditions may cause heat build-up effects, resulting in component failure and/or fire.**

## 3. SECURITY REQUIREMENTS

### Safety Notes

- This product complies with the requirements of EU medical device regulations
- According to IEC 60601-1 classification, this instrument is categorized as following:
  - Class I instruments - Type of protection against electric shock
  - No application parts
  - The mainframe is an ordinary equipment, Degree of protection against liquid immersion: IPX0.
  - The waterproof level of the foot controller is IPX8
  - Continuous operation - operation mode



**Note:** When transporting or moving, please place it in the direction indicated on the instrument, otherwise the instrument may lose its balance!



**Note:** When transporting the instrument, keep the instrument stable and in a movable state!



**Note :** The instrument cannot work in flammable, explosive, and strong electromagnetic interference places!



**Note :** To prevent electric shock, this equipment must be plugged into a grounded socket. Never remove or disable the grounding pin. The instrument can only be installed by an authorized service representative of CERTAINN.



**Note :** The working voltage of the instrument has been preset. Before connecting the main power supply of the instrument, it is necessary to confirm whether the power supply selected in the working room matches the instrument.

When the instrument is connected to the main power supply with a voltage selector, if the voltage is selected incorrectly, the instrument will be seriously damaged.



Note: This instrument is allowed to be transported by general transportation, but it must be protected from severe impact, vibration and rain and snow splashing during transportation. The transportation requirements are stipulated in the order contract.



Note: Do not use the instrument on uneven or inclined surfaces to avoid tipping.



Note: Do not use this instrument for other purposes other than those specified in this user manual.



Note: This instrument may cause combustible gas or steam to burn. Do not use in the presence of flammable anesthetics (such as nitrous oxide) or in the presence of pure oxygen.



Note: The software and hardware of this instrument have been carefully designed to protect clinicians, users and patients from potential damage from mechanical, diagnostic or therapeutic error. Unauthorized modification of the software or hardware (including peripherals) of this instrument may endanger the safety of the operator and the patient, the performance of the instrument, and the integrity of patient data. Unauthorized modification will also invalidate the instrument warranty.



Note: Please check under the guidance of professionals. Non-professionals are prohibited from using this instrument without authorization.



Note: Only technicians authorized by CERTAINN can disassemble or repair this instrument, and users are not allowed to disassemble or repair without authorization. (In the event of malfunctions, error messages or operating

problems, please call our customer service: in China, please call 4006-885-339, outside of China, please contact your local distributor.)



Note: The waterproof level of the foot controller is IPX8, and there are no special measures to prevent the intrusion and damage of water or other liquids in other parts. Do not place the container with liquid on or near the instrument, and do not use spray on or near the instrument.



Note: Unless you need to slide the casters to move the instrument, lock the casters under other conditions.



Note: In order to maintain patient safety, peripheral devices such as monitors must be placed at least 1.5 meters (4.9 feet) away from the patient to ensure that no part of the patient's body touches the peripheral device during the examination. In addition, the operator of the instrument must not attempt to touch the patient and peripheral equipment at same time while examining the patient.



Note: Do not place the device to a position that is difficult to execute the disconnection on the device.



Note: Do not disassemble the case of the instrument without authorization to prevent potential optical hazards.

IEC 60601-1-2: 2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class A product

### **Instructions for use**

The ME EQUIPMENT or ME SYSTEM is suitable for professional healthcare facility environment and so on.



Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

 Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

 Warning: Information pertaining to ESSENTIAL PERFORMANCE and necessary recurrent essential performance and basic safety testing including details of the means, methods and recommended frequency.

NOTE: This information is directly derived from the ESSENTIAL PERFORMANCE identified by the manufacturer in 4.3.

 Warning: Do not modify this equipment without authorization of the manufacturer.

 Warning: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment .

 Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 Warning : 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 Operating microscope (OPM500), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

 Warning: NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals

(CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

**EMC (IEC 60601-1-2: 2014)**

## Technical description

- 1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

<b>Guidance and manufacturer's declaration - electromagnetic emissions</b>	
<b>Emissions test</b>	<b>Compliance</b>
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	NA
Voltage fluctuations/ flicker emissions IEC 61000-3-3	NA

Table 2

<b>Guidance and manufacturer's declaration - electromagnetic Immunity</b>		
<b>Immunity Test</b>	<b>IEC 60601-1-2 Test level</b>	<b>Compliance level</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
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV	Power supply lines: ±2 kV input/output lines: ±1 kV
Surge IEC 61000-4-5	line(s) to line(s): ±0.5, ±1 kV line(s) to earth: ±0.5, ±1,	line(s) to line(s): ±0.5, ±1 kV line(s) to earth: ±0.5, ±1,

	±2 kV  100 kHz repetition frequency	±2 kV  100 kHz repetition frequency
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	0% 0.5 cycle  At 0°, 45°, 90°, 135°, 180 °, 225°, 270° and 315°  0% 1 cycle  And  70% 25/30 cycles  Single phase: at 0  0% 300 cycle	0% 0.5 cycle  At 0°, 45°, 90°, 135°, 180 °, 225°, 270° and 315°  0% 1 cycle  And  70% 25/30 cycles  Single phase: at 0  0% 300 cycle
Power frequency magnetic field  IEC 61000-4-8	30 A/m  50Hz/60Hz	30 A/m  50Hz/60Hz
Conducted RF  IEC61000-4-6	150KHz to 80MHz:  3Vrms  6Vrms (in ISM bands)  80% Am at 1kHz	150KHz to 80MHz:  3Vrms  6Vrms (in ISM bands)  80% Am at 1kHz
Radiated RF  IEC61000-4-3	3 V/m  80 MHz – 2,7 GHz  80 % AM at 1 kHz	3 V/m  80 MHz – 2,7 GHz  80 % AM at 1 kHz
NOTE U <sub>T</sub> is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for	Test Freque ncy (MHz)	Ba nd (M Hz)	Servic e	Modula tion	Modul ation (W)	Dist ance (m)	IM MUNITY TE ST

ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)							<b>LEVEL</b> (V/ m)
	385	38 0 – 390	TETR A 400	Pulse modulati on 18 Hz	1,8	0.3	27
	450	38 0 – 390	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	70 4 – 787	LTE Band 13, 17	Pulse modulati on 217 Hz	0,2	0.3	9
	745						
	780						
	810	80 0 – 960	GSM 800/900, TETR A 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulati on 18 Hz	2	0.3	28
	870						
	930						
	1720	1	GSM	Pulse	2	0.3	28
1845	700 –	1800;	modulati				
1970	1	CDMA	on				
	990	1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz				

	2450	2	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5	WLAN	Pulse modulation	0,2	0.3	9
	5500	100 –	802.11	modulation			
	5785	5	a/n	217 Hz			
		800					

**Recommended separation distances between portable and mobile RF communications equipment and the OPM500 Operating microscope**

The OPM500 Operating microscope is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OPM500 Operating microscope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OPM500 Operating microscope as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>Note 1: At 80 MHz and 800 MHz, the higher frequency applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

### Accessory Equipment



**WARNING:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment and IEC62368 or IEC 60601-1、IEC60601-1-2 or CISPR 32, CISPR 24 and CISPR 35

Furthermore, all configurations shall comply with the system standard IEC 60601-1-1 and IEC 6060-1-2. Any person who connects additional equipment to the signal input part or signal output part on Figures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1 and IEC 6060-1-2. If in doubt, consult the technical service department or your local representative.

## 4. SYMBOLS AND LABELS

 Medical device

 Please read the manual prior to any operation.

 Note: please refer to the attached documentation. Note: The user manual contains important operation and maintenance instructions

 Risk of electric shock. Note: Indicates that there is a risk of electric shock due to the presence of uninsulated high voltage in the instrument. Do not remove the instrument cover or parts.

 Fuse

 Manufacturer

 Date of manufacture

 Authorized representative in the European community

 Serial Number

 Batch Number

 Number/Part Number

 Model

 "ON" (power )

 "OFF" (power )

 Warning : hot surface

 Warning: Crushing of hands

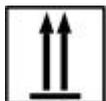
 Compliance with EU directives

### Protective Packing Symbols

The protective packing symbols specify the handling requirements and the transport and storage conditions.

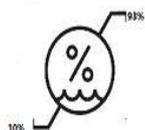
 Fragile, Handle with care

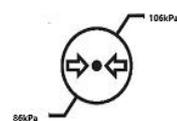
 Keep Dry

 This end up

 No Stacking

 Temperature limit ( -40 to 55 deg. C )

 Humidity limitation ( 10% to 93% )

 Atmospheric pressure limitation ( 86kPa to 106kPa )



No Roll over



1. The device will be put on the European market after September,2021.
2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union. It is very important that customers understand and follow all laws regarding the proper decontamination and safe disposal of electrical equipment.

disposal of electrical equipment.

### Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

When determined that the device is ready for disposal, it is to be recycled following the policies and procedures reflecting respective country’s requirements. Do not dispose of device as general waste.



Warning: Violations of operating procedures may result in malfunctions and personal injury. Violating the handler can damage the instrument or accessory device!



The part that identifies this symbol in the manual must be executed!

**Product label: The equipment is labeled with the product label**

<b>MOPTIM<sup>®</sup></b>		<b>CE</b>	
<b>Name : Operating microscope</b>			
<b>Model: OPM500</b>			
<b>Input : AC 100-240V 50/60Hz 1.5A</b>		<b>Made in China</b>	
<b>Shenzhen CERTAINN Technology Co., Ltd.</b>			
<b>Address: Bldg. 2-C, Zone 2, GOTO Digital Technology Park, No.137</b>			
<b>Bulan Rd., Longgang District,518112,Shenzhen,</b>			
<b>PEOPLE'S REPUBLIC OF CHINA</b>			
<b>ECIREP</b>	<b>Fausto Guzzetti</b>		<b>MD</b>
	<b>Address: Via Diaz 25 , 21057,Olgiate Olona(VA),Italy</b>		
<b>SN</b>	<b>CB0073501</b>	<b>LOT</b>	<b>SC21030115</b>
			<b>2021-03</b>

Figure 4.1 Product label

## 5. PRODUCT DESCRIPTION

The Operating microscope refers to a compound micro-magnification device composed of cold light source, objective lens, eyepiece, optical zoom system and bracket. Operating microscope can generally be divided into three parts: mechanical systems, observation systems, and lighting systems. Vertical operating microscopes (floor-mounted) are generally used for ophthalmic surgery. The feature of this type of operating microscope is that it can be placed arbitrarily, and is more flexible and easy to install.

### 5.1 Scope of Application

OPM500 Operating microscope is used to provide magnification and illumination to enhance the visual effect, which is convenient for doctors to observe and record the surgery process on the human body. It is only suitable for ophthalmology.

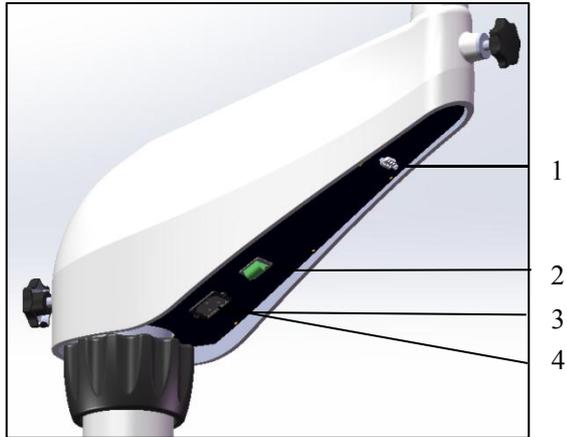
### 5.2 Structure Description

OPM500 Operating microscope is composed of optical system, bracket system and pedestal, lighting system, control system, camera system, and assistant binocular (optional).



1. Assistant Binocular tube
2. Eyepiece
3. Optics carrier
4. Objective lens
5. Focus module
6. Pitch adjustment module
7. Horizontal moving station
8. Crossbeam
9. Suspension arm
10. Floor stand
11. Foot pedal
12. Pedestal
13. Casters

Figure 5.1 Operating Microscope



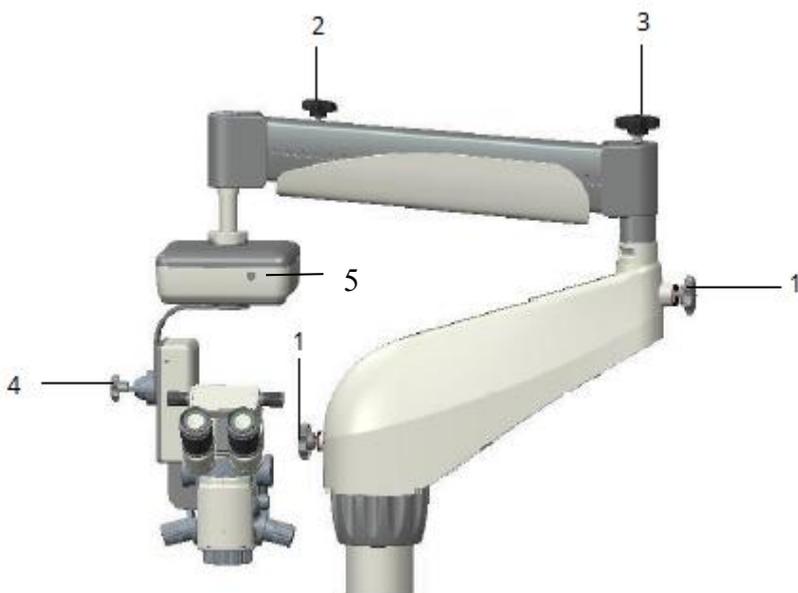
- 1. Foot pedal connection
- 2. Power switch
- 3. Power socket
- 4. Fuse

Figure 5.2 Suspension arm



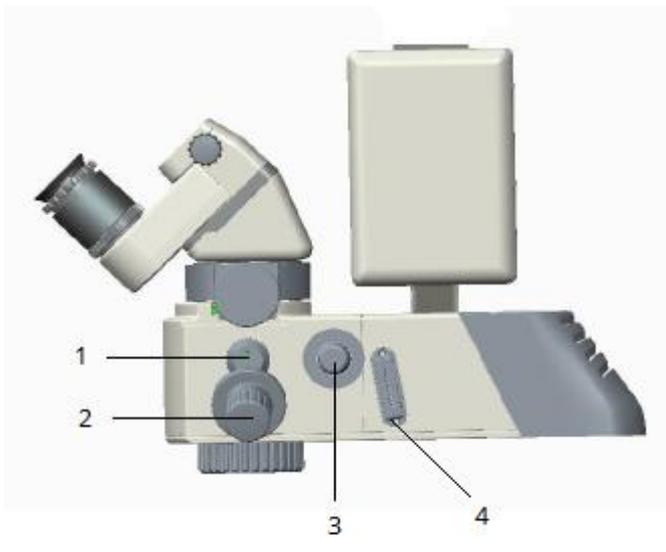
- 1. XY Horizontal movement adjustment joystick
- 2. Focus adjustment
- 3. Zoom adjustment

Figure 5.3 Foot pedal

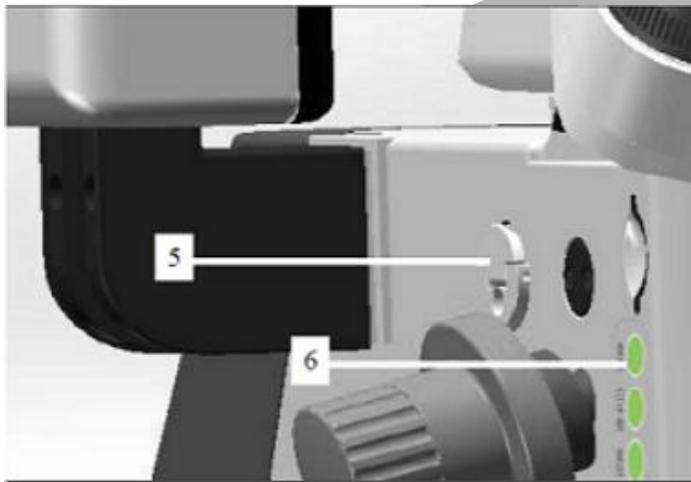


- 1. Brake knob
- 2. Cross beam locking knob
- 3. Balance adjustment knob
- 4. Pitch adjustment knob
- 5. Reset Button (Reset the horizontal moving station module and focus module)

Figure 5.4 Brake knob and adjustment knob



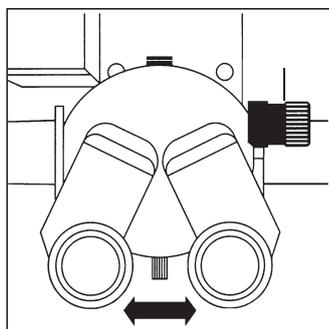
1. Magnification indicator panel
2. Handle
3. Illumination switch and brightness adjustment knob
4. Filter slot (UV protection filter GG475,5x protection filter)
5. Manual zoom knob, in case of emergency, directly turn this knob to adjust the magnification.



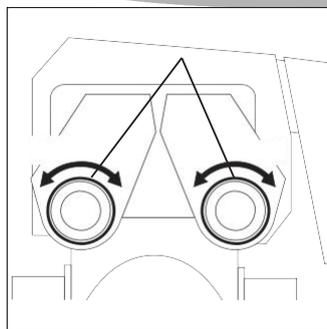
6. Video control panel, respectively control video/stop, white balance, camera reset.

b

Figure 5.5 Optics carrier



Interupillary distance adjustment



Refractive adjustment



Assistant binocular tube

Figure 5.6

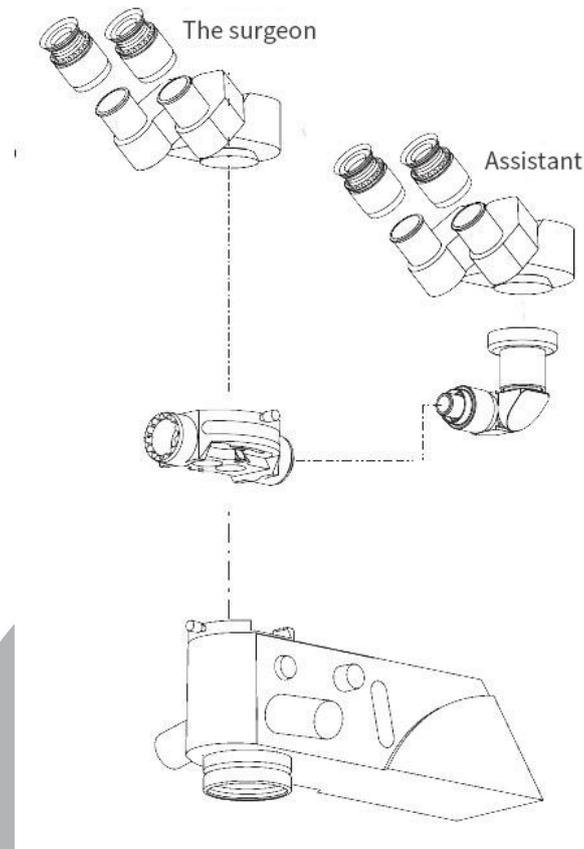
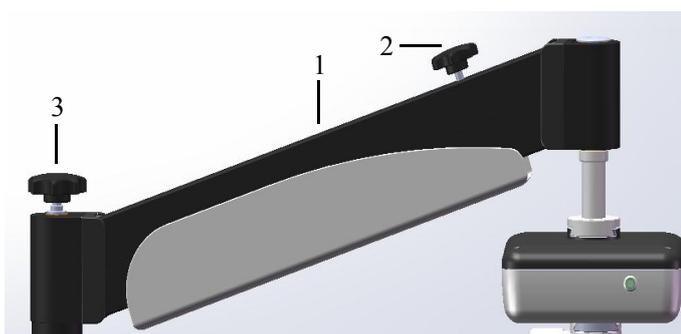


Figure 5.7 Assistant binocular connection diagram

**Replace the operating microscope accessories, balance crossbeam**



**Warning: There is a danger of injury when the operating microscope swings downwards!**

- ⇒ Locking Crossbeam(1)
- ⇒ Do not change accessories or try to rebalance the operating microscope when it is above the surgical area.
- ⇒ The crossbeam must be balanced and adjusted after replacement of accessories.

Figure 5.8

**Lock the Crossbeam**

- ⇒ Place the crossbeam as horizontally as possible. (1)
- ⇒ Tighten the cross beam locking knob(2) to lock the upper and lower positions of the cross beam.

### Clean optical accessories

- ⇒ Check the cleanliness of the eyepiece and objective lens.
- ⇒ Remove dust and dirt.

### Mounting accessories

- ⇒ Equip the operating microscope with all the necessary accessories.

### Balance beam

- ⇒ Hold the microscope tightly.
- ⇒ Loosen the brake knob(2) used to lock the vertical position, at this time, the beam can move up and down.
- ⇒ Manually move the beam to determine if it requires more force to move up or down.

If it needs more force to move up:

- ⇒ Rotate the balance adjustment knob (3) in the direction of weight increment (counterclockwise).

If it needs more force to move down:

- ⇒ Turn the balance adjustment knob (3) in the directions of weight reduction(clockwise)



The force required to adjust the beam to move downward is slightly greater than the force required to move upward.

## 5.3. Operating Instruction

### 5.3.1 Moving the Operating Microscope



When moving the operating microscope,make sure to keep it at transportation status.

#### Lock the crossbeam

- ⇒ Adjust the cross beam (1) to be close to horizontal.
- ⇒ Tighten the cross beam locking knob (2) to lock the upper and lower positions of the crossbeam.
- ⇒ Loosen the rotary brake knob (3) and fold up the crossbeam.
- ⇒ Adjust the operating microscope to the transport state and tighten the brake knob(3).



Figure 5.9

### **Move the operating microscope and fix it to a new position.**

- ⇒ Unplug the power from the instrument.
- ⇒ Place the foot controller in the foot rack.
- ⇒ Release the caster brake

#### **Transportation status**

- ⇒ Push the handle to transfer the operating microscope to the target position.
- ⇒ Step on the caster brake at the installation position.

## **5.3.2 Place the Operating Microscope above the Operating Table**

- ⇒ Push the handle to move the microscope carefully to the operating table and fix it in place to prepare for the upcoming surgery.
- ⇒ Step on the caster brake.
- ⇒ Plug the power cord into the socket.
- ⇒ Take the foot pedal out of the foot pedal bracket and place it in a suitable position on the ground.
- ⇒ Check all terminals and make sure all accessories are firmly installed in place.
- ⇒ Loosen the rotary brake knob and adjust the bracket to the balanced position.

Make the joints easier to rotate:

- ⇒ Loosen the rotary brake knob (3).

Make the joints not easy to rotate:

- ⇒ Tighten the rotary brake knob (3).
- ⇒ Loosen the locking knob(2) used to lock the upper and lower positions of the beam .
- ⇒ Unfold the beam.
- ⇒ Check the weight setting of the beam by lifting the microscope and correct it if necessary. For details, please refer to the method of balancing the beam.

## **5.3.3 Check the Function of Light**

- ⇒ The main light is on when turning on the operating microscope.

⇒ Rotate the brightness adjustment knob (figure 5.5a, 3) to the right to increase the brightness.



**Warning Lighting failure can be dangerous to the patient!**

⇒ Keep a spare LED lamp assembly.

### Replacement of the LED lamp assembly



1. LED lamp
2. Fixing screw of LED cover.

Figure 5.10



**Warning:** The LED lamp will heat up during the working process, please pay attention to check whether the LED lamp has cut off the electricity and cooled down when replacing the LED lamp

There is no spare LED lamp installed inside the operating microscope, and an LED lamp assembly needs to be prepared for replacement in case of damage and placed in a place where it is easy to access.

Replacement method: Power off the operating microscope, remove the black plastic protective shell, unplug the LED cable, and remove the 4 fixing screws of the LED lamp assembly. Replace with a new LED lamp assembly and lightly fix it with two screws.

Connect the plug of the LED cable, turn on the power and the LED switch, and light up the LED lamp. Place white paper under the lens and adjust the focus, adjust the up and down position of the LED lamp assembly, to ensure that the color of the illumination spot is uniform and the edges are clear. Then install the 4 screws of the LED lamp assembly, adjust the cable position, and finally install the protective shell and fix it with screws. As shown in figure 5.11)

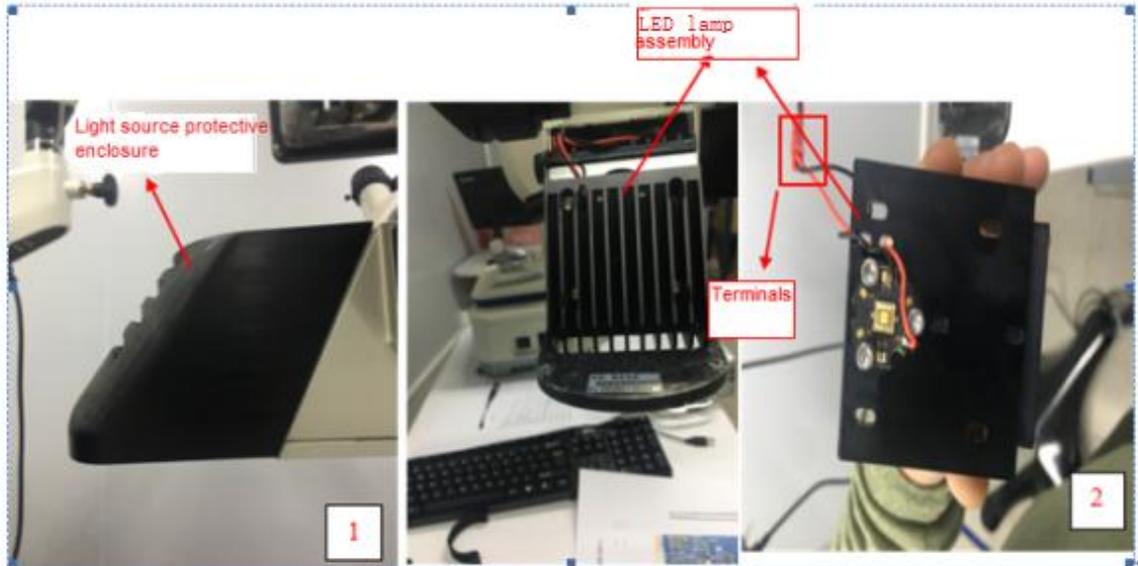


Figure 5.11

### 5.3.4 Turn on the Operating Microscope

⇒ Turn on the power switch

The lamp lights up, and the XY horizontal movement device and focusing device automatically move to the center position.

### 5.3.5 Video Record Function

⇒ The default setting is to record when the power is turned on, and the video is saved on the SD card.

Press the REC button on the left side of the body to stop and save the video, and press it again to start recording the video.

Short press the “WB” to switch the white balance mode, and long press the “WB” for manual white balance calibration (place the standard grey card in the focal position in advance).

## 6. LIGHT RADIATION HAZARDS

### **Warning**

The light from this instrument may be harmful to the eyes, and the risk of eye damage increases with exposure time. It is recommended to set the lighting intensity to the lowest level necessary for surgery. Infants, aphakic patients (not replaced with ultraviolet-protected intraocular lenses), children, and people with eye diseases are high-risk groups. The irradiation time cannot exceed the maximum time specified in the instructions. If in the previous 24 hours, the eyes of the patient who needs treatment have looked directly at a strong visible light source or irradiated the eyes with similar ophthalmic equipment, such as fundus photography, the risk will increase.

Protect patients through the following safety measures:

- Short lighting time
  - Low brightness setting
  - Use protection filters
  - Turn off the lighting during interruptions in operation
- ⇒ When exposed to the light, do not exceed the dangerous reference value. If the exposure exceeds 1.7 minutes at the maximum power output, the risk reference value is exceeded.

The following table can be used as a guideline to inform the surgeon of potential dangers.

The data is calculated based on the worst-case scenario:

- Aphakia
- No eye movement at all (the same area is always under exposure)
- Continuous exposure, such as when there is no surgical instrument in the eye
- The pupils are enlarged to 7 mm.

The calculation method is based on ISO standards 1, 2) and the recommended maximum daily radiation dose 3). A safety factor of 10 is used to determine these limits.

Light setting	Maximum allowable exposure time (min)		
	Without filter	With GG435 filter	With GG475 filter
25%	6.7	9.1	20.1
50%	3.3	4.6	16.5
75%	2.2	3.0	11.0
100%	1.7	2.3	5.1

The 5× retina protection filter can extend the maximum allowable exposure time to 5 times.



## 7. DAILY MAINTENANCE

The OPM500 product designed by CERTAINN requires only a small amount of maintenance by the user. Except for routine cleaning after use, most of the maintenance activities described here only need to be performed occasionally.

### 7.1 Troubleshooting

If the instrument does not work normally, please check according to the following table, and then contact CERTAINN, or the local authorized dealer for maintenance.

Phenomenon	Remedy
The device is not powered	<ul style="list-style-type: none"> <li>● Check the power cord plug;</li> <li>● Check the fuse, if it is blown, replace the fuse of the same specification.</li> </ul>
The light is not on	<ul style="list-style-type: none"> <li>● Check whether the LED lamp switch is turned on</li> <li>● If the device is powered on and the LED lamp switch is turned on, you need to replace the spare LED lamp. (Note: A spare LED lamp must be prepared).</li> </ul>
The image is not clear	<ul style="list-style-type: none"> <li>● Check whether there are stains on the surface of the eyepiece and objective lens. Clean it according to the method in section 7.3.</li> </ul>

## 7.2 Replace the Fuse

There are two fuses at the power socket. The instructions for checking and replacing the fuse are as follows:



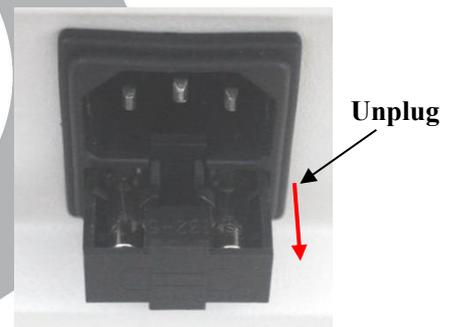
Note: In addition to replacing the fuse and LED lamp, other operations of disassembling the instrument and replacing parts can only be performed by authorized service engineers of CERTAINN.



Note: Please strictly follow the instructions below to ensure safe inspection and replacement of the fuse. Be sure to turn off the power of the instrument and unplug the power cord before continuing the following operations. As you complete each step, always use the minimum force necessary to avoid damage or injury.

### Check and replace fuses

1. Ensure the power switch.
2. Unplug the power cord from the power socket;
3. Pull out the fuse box;
4. Take out the fuse from the fuse box;
5. Check whether the fuse is damaged, and discard any defective fuse.
6. Insert a new fuse into the fuse box and slide back the fuse box.



The type and rating of the two fuses: T 5A H 250 V.



**Warning: Be sure to use a fuse of the same type and rating. Otherwise, it may cause a fire hazard.**

## 7.3 Cleaning

If the instrument case is stained, please wipe it with a soft cloth. For stubborn stains, please wipe with a soft cloth dampened with a neutral detergent diluted with water, wring it out, and then wipe with a soft cloth.

Protection against harmful ingress of water or particulate matter :



Note: Except for the foot pedal, this instrument has no special measures to prevent damage from water or other liquids. In order to avoid damage to the instrument and safety hazards, cleaning agents (including water) must be used carefully, and only dampened with non-linen cloth (not dripping water), and sprays cannot be used on or near the instrument. Please do not use organic solvents like paint thinner.

Foot switch waterproof grade: IPX8

Foot switch waterproof test: Leave the foot pedal in 1.1M water to soak for 30 minutes.

## Clean the Lens

If the lens is contaminated by tears or fingerprints, or touches the patient's eyelashes, please clean the lens.

The stains will affect the sharpness of the image. It is recommended to check whether the objective lens and eyepiece are stained before use. If there is, please clean it according to the following procedures.

From a certain angle, check the lens for dust or dirt with the naked eye.

If the dirt adheres to the lens, please use absorbent cotton dipped in absolute ethanol to wipe, and follow the circular motion from the center to the edges until it is clean.

During the operation, if the dirt such as blood is splashed on the microscope objective lens during the operation, pay attention to it and clean it in time. Otherwise, blood stains and other dirt will condense on the lens, which will be difficult to clean and easily wear the lens.

Clean the lens thoroughly in time after use.



Note: If there are foreign objects on the objective lens, please do not wipe it forcefully. Be sure to wipe gently. Otherwise, the objective lens may be scratched.

## 7.4 Disinfection and Sterilization



The rubber hood of the eyepiece may be in contact with the operator. Our company recommends using the most common alcohol disinfectant on the market, clean and disinfect before use.

During the operation, the gloved hand of the operator may hold the sterilizable handle cover to control the position of the lens, and then touch the surgical instrument, so the sterilizable handle cover needs to be sterilized before use.

Sterilization method: sterilizing steam (high pressure steam sterilizer), 134 °C , t > 10 min.

Our company has not conducted multiple tolerance verifications on the sterilizable handle cover, so it is recommended for one-time use.

## 7.5 Storage



When the instrument is not used for a long time, please place the device in the following environment:

Ambient temperature	-40°C to + 55°C
Relative humidity	10% to 93%
Atmospheric pressure	86 kPa to 106 kPa
No corrosive gas, well ventilated indoor	

# 8. SPECIFICATIONS AND CONFIGURATION

## 8.1 Specifications

Technical indicators

Operating Microscope	
Optical magnification	5-step electric adjustment (6.4×, 10×, 16×, 25×, 40×)
Focusing	40mm electric adjustment, adjustable speed With reset function
Objective lens	200mm focal length, apochromatic
Eyepiece	High eye point eyepiece
	Diopter adjustment ±5
LED lighting	LED lighting
	2 filter slots
	Pitch adjustment ±15 degrees
Foot pedal	8 function foot pedal, waterproof IPX8
XY mobile platform	Horizontal electric control (speed adjustable)
	40×40mm, with reset function
Annex	
Assistant binocular	Binocular Stereo Synchronous Observation Mirror
Binocular tube	Interpupillary distance 55~75mm adjustable
Video/photography	Built-in high-definition surgery panoramic recording system*, resolution 1920×1080, with white balance function.

\*Note 1: The built-in high-definition recording system does not split light from the observation light path and does not occupy the assistant binocular interface. When the assistant binocular is not installed, bright enough images can be observed under lower illumination intensity, providing longer operation time.

## ○ Environmental conditions

- Transport and storage

Temperature:  $-40^{\circ} \sim +55^{\circ} \text{C}$

Relative humidity: 10%  $\sim$  93%

Air pressure: 86Kpa $\sim$ 106Kpa

- work

Temperature:  $+5^{\circ} \sim +40^{\circ} \text{C}$

Relative humidity: 30%  $\sim$  80%

Air pressure: 86Kpa $\sim$ 106Kpa

## ○ Electrical requirements



Warning: Please be sure to use the same type and rating of the fuse. Otherwise, it may cause a fire hazard.

- Power supply: AC 100-240V, 50/60Hz, 1.5A
- Fuse rating: T5A H 250 V

## 8.2 Configuration

### Standard accessories

Name	Quantity
Bracket assembly	1
Foot pedal	1
XY Horizontal moving station	1
Focus module	1
Optics carrier	1
Objective lens	1
Eyepiece binocular tube	1
Eyepiece	2
Beam splitter	1
Power cable	1
Fuse	2
LED lamp assembly	1
SD card 32G	1
Disinfectable handle cover	4
Disinfectable knob cover	2
Knob cover	4
Dust cover	1
Retinal protection lens assembly	1
5×Protection lens assembly	1
Filter lens box	1
User Manual	1
Production Certification	1
Warranty card	1
Optional	
Assistant binocular	1
Assistant binocular tube	1
Assistant binocular 10×eyepiece	2

## 9. LEGAL NOTICES

### Limited Warranty

This guarantee provides you with specific legal rights, depending on where you are located, you may also have other rights. Within one year from the date of delivery (hereinafter referred to as the "guarantee period"), Shenzhen Certainn Technology Co., Ltd. (hereinafter referred to as "CERTAINN", "seller", "we" or "our") shall provide the original purchaser (Hereinafter referred to as "you", "your" or "purchaser") guarantee that its OPM500 Operating microscope is free from defects in materials or workmanship, except for the following components and software. In the event of a failure, the seller's responsibility is limited to repair or replacement on the basis of exchange, which will be reported as defective by the buyer immediately during the warranty period and confirmed by the seller during inspection. Unless otherwise stated in this article, this warranty covers all parts, labor, travel, and expenses during the warranty period. This guarantee applies only to the original purchaser and should not be transferred or distributed in any way.

The warranty claim process should proceed as follows: When you believe that the OPM500 instrument is defective, immediately report the defect to CERTAINN. Whenever possible, we will provide "at the customer's location" service to repair your OPM500 instrument. However, we will decide whether the repair can be carried out in our maintenance department. In this case, we will pay all transportation costs, unless we find that your OPM500 instrument is not qualified for repairs under this warranty, in which case you will be responsible for paying half of the transportation costs. If your OPM500 is not eligible for repairs under the warranty, we will notify you, and any repairs authorized by you will be charged at our standard price. All replacement parts belong to CERTAINN.

This warranty specifically covers OPM500, including instrument meters. This warranty does not cover: operating consumables, consumables such as paper or storage media, or any service for external printers. These items will be covered by the manufacturer's guarantee, and service arrangements must be made through the manufacturer. If due to accident, negligence, misuse, force majeure, transportation or other non-general use reasons, or

consumables or accessories do not meet CERTAINN 's correct operation specifications, and therefore need to be repaired or replaced parts, this warranty does not apply. This warranty does not apply to any items that have been repaired or modified not by CERTAINN.

All data stored on the memory card is the record of the purchaser, and you are responsible for maintaining the integrity of these files. CERTAINN is not responsible for the loss of patient files stored on the memory card.

For the quality and performance of the software, you will bear all risks. CERTAINN does not guarantee that the software will meet your requirements, that the operation of the software will be uninterrupted or error-free, and that all software errors will be corrected. You are responsible for the installation, use, and results obtained from the OPM500 instruments and programs.

This warranty does not extend to any removable medium damaged as a result of accident, misuse, abuse, or service or modification by a person other than CERTAINN. If such software proves to be defective after purchasing it, you (not CERTAINN) bear the full cost of all necessary services, repairs or corrections. CERTAINN has no responsibility or obligation for any person or entity related to any claim, loss, liability or damage directly or indirectly caused or alleged to be caused by any software provided with OPM500 or provided by CERTAINN.

We have made a lot of reasonable efforts to ensure that product manuals and promotional materials accurately describe OPM500 specifications and performance at the time of publication. However, due to continuous improvement and product updates, we cannot ensure that the printed materials remain accurate after the publication date, and we are not responsible for changes, errors or omissions. All instrument specifications are subject to change without notice.

#### Limitation of liability

The guarantee contained in this article replaces and does not include all other express or implied guarantees, unless required by law, including but not limited to implied guarantees of merchantability and applicability for specific purposes. CERTAINN and any other parties involved in the creation, production, or delivery of this equipment or software (collectively referred to as the "related parties") neither shall be liable for any damage, loss of use, or any

such loss, regardless of whether the damage or loss is caused by natural disasters, your purchase, possession, or failure to perform your responsibility for the proper installation, management, supervision or use of OPM500 or the software, and regardless of whether such liability is based on tort, contract or other aspects.

If the above restrictions are deemed unenforceable, the maximum liability of CERTAINN (and the " related parties ") to you should not exceed the cost you paid for the equipment. CERTAINN (and/or related parties) shall not be liable for direct, indirect, consequential or incidental damages (including damages caused by business and expected loss of profits, business interruption, loss of business information, etc.) under any circumstances, even if CERTAINN or related parties have been notified that such damage may be caused, it will not be liable. Some places do not allow the exclusion or limitation of limited warranty or consequential damages or incidental damages, so the above limitations or exclusions may not apply to you.

#### Acknowledgment

You acknowledge that you have read all the provisions in this Chapter, including this License and Limited Warranty, understand them, and agree to be bound by their terms and conditions.

## 10. SERVICE COMMITMENT

Thank you again for purchasing and using our OPM500 Operating microscope

CERTAINN has established a complete and strict quality control system, the products produced have undergone strict inspection and testing.

Please read this User Manual carefully before using, and operate in strict accordance with the operating procedures, to avoid any error or damage to the device.

Please feel free to contact us:

If you have any questions while using the device.

If there is any malfunction.

If you have any comments or suggestions on our work.

If you no longer use our instruments, please dispose of them in accordance with local laws and regulations.

All employees of our company will welcome your calls with the highest enthusiasm, answer your questions in the most cordial manner, solve your problems as quickly as possible, and sincerely accept your criticisms and suggestions.

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Website: <http://www.moptim.com>

(The contents of this manual are subject to update without notice)