USER MANUAL

Ophthalmic Surgical Microscope

Model: SM621

Shanghai MediWorks Precision Instruments Co., Ltd.

Preface

Thank you for purchasing the SM621 Ophthalmic Surgical Microscope produced by Shanghai MediWorks Precision Instruments Co., Ltd. In order to use this device properly, please read this manual carefully in advance.

General Requirements for Safety

Before installing and using this device, please read the following precautions carefully to avoid personal injury, product damage, and possible hazards.

(1) Do not use the device in flammable, explosive, high-heat and dusty environments; it should be used indoors, and keep the product clean and dry;

(2) Please check the correct connection of all wire plugs and sockets before use, and ensure that the device is well grounded;

(3) Please note the ratings of all electrical connection ports;

(4) Please use a fuse tube that meets the specified type and rating of this product;

(5) The special power cable for this device should be used;

(6) The device should be placed on a flat ground to prevent the device from tipping over;

(7) Do not touch the surface of each optical lens with hands or hard objects;

(8) To replace the bulb and fuse tube, first turn off the main power switch and unplug the power cable;

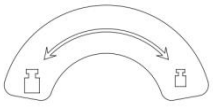
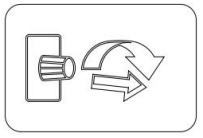
(9) Please pay attention to the high temperature of the bulb after use to avoid burns;

(10) When the device is out of use, the arm set should be folded and locked first, then the power supply should be cut off, and a dust cover should be covered;

(11) If there is a fault, please read the troubleshooting guide first; if the fault still cannot be eliminated, please contact the authorized dealer of the company or the maintenance department of the manufacturer.

Symbols Used

Symbol	Description
⚠	Read user instructions for Warnings, Cautions and additional information
	Date of manufacture
	WEEE logo, please dispose of the waste generated by the device in accordance with relevant laws and regulations
	Protective earth terminal
I	Located on the power switch, indicating that the main power is on.
O	Located on the power switch, indicating that the main power is off.
CE	CE mark.
	Refer to instruction manual/ booklet
	Manufacturer
SN	Serial Number
MD	Medical Device
UDI	Unique Device Identifier
EC REP	Authorized representative in the European Community/ European Union
Rx only (for US)	USA Federal law restricts this device to sale by or order of a physician.
	Warning label for safety limit position

	"Backup LED Button" label
	"MediWorks" logo
	"Suspension arm balance adjustment" label
	"Suspension arm horizontal limit" label
	Label for adjusting the friction of the axis of rotation of the surgical microscope
	Maximum load of the suspension arm is 15 kg
	"Warning Hot Surface" label
	"Suspension bracket balance adjustment" label

Contents

1 Features and Specifications of the Device

1.1 Scope of Application

SM621 Ophthalmic Surgical Microscope is suitable for providing magnification and illumination of the surgical field during ophthalmic surgery.

1.2 Structural Composition

The SM621 consists of a base, an equipment rack, microscope components (including assistant microscope), a foot control panel and embedded operating software (version R1.0). The equipment rack consists of a column, a support arm, a suspension arm and a suspension bracket. Microscope components consist of optical systems (including objective lenses, variable magnification optical systems, lens tubes and eyepieces), illumination systems, and electrical devices.

1.3 Features

The SM621 is a two-observer surgical microscope, the main microscope and the assistant one, with XY direction fine-tuning mechanism. The main microscope has the electric continuous zoom and the electric fine-tuning functions, which can be controlled by the foot control panel. The assistant microscope provides a five-step zoom function and can be manually fine-tuned. The eyepiece viewing angle can be adjusted arbitrarily between 0°~180°.

- The LED light source is used to prevent hurting the eye tissue. Backup LED can be switched in an electric one-click way. The lighting is sufficient and uniform. The LED brightness can be adjusted through the foot control panel.
- The operating modes consist of black dot filter (macular protection) mode, 25% gray filter mode, red-free mode, blue blocking (retinal protection) mode, and no-filter mode. It can be electrically switched through the foot control panel.
- The arm set applies spring balance design, so that the surgical microscope can move up and down, left and right, and can stay at the required height according to the operation needs. The locking has an electromagnetic brake, which can unlock or lock all the joints of the arm with one button, meanwhile, it provides the safe protection once the spring fails.

- When the suspension arm is moved up beyond the working range, the surgical microscope will be in the parking position. At this time, the LED light will automatically be switched off, and the position of XY or focus will be reset.
- Individual XY and focus reset functions: a short press of the "Reset" button on the XY coupling centers the XY position, while a long press of the "Reset" button for three seconds centers the focus position.
- Memory storage function: the parameters before shutdown (magnification, brightness, filter position, etc.) will be stored in memory, and the next startup will default to the parameters when the last shutdown.
- The fine tuning speed of XY and focus is optional. There are "high speed" and "low speed" gears for users to choose according to their needs.
- The interpupillary distance of the assistant microscope can be accurately adjusted, and the interpupillary distance of the assistant microscope can be adjusted through aseptic operation of the protective caps during use.
- The operating environment of the microscope is that the ambient temperature is 5℃～+40℃, the relative humidity is ≤80%, and the atmospheric pressure is 700 hPa～1060hPa .
- The power supply is ~100V-240V/50Hz-60Hz. It is equipped with a backup power supply, which automatically switches to the backup power supply when the power supply is lost.

1.4 Intended Use

- Intended Purpose

The purpose of the SM621 Ophthalmic Surgical Microscope is to support microsurgery in the field of ophthalmology by providing magnification and illumination of the ophthalmic surgical area and ensuring efficient, stable and precise movements.

- Indications for Use

The SM621 Ophthalmic Surgical Microscope is indicated for ophthalmic surgery. Such as retinal, corneal and cataract surgeries performed in hospitals, clinics or other medical institutions.

- Intended Population

The device is intended for people with eye diseases requiring microsurgery of the eye.

- Intended Users

The device is intended to be used by well-trained technicians.

- Contraindications

There are no known contraindications to this product.

Warning statement:

The installation, operation and use of the device shall only be for the intended purpose, which is defined in this manual. Please pay attention to the warning information described in this manual, related to safety. Any unauthorized personnel shall not conduct the activities on the device.

Instrument classification:

According to the IEC 60601-1 classification standard of medical electrical equipment, the Ophthalmic surgical microscope is a general equipment of Class I continuous operation instrument, which cannot be used under two circumstances: a flammable anesthetic gas and air mixture, oxygen or nitrous oxide gas and air mixture.

1.5 Specifications

(1) Microscope

Magnification	Assistant microscope:	4.2x, 6.5x, 10.4x, 16.7x, 26.3x
	Main microscope:	4.3x～25.5x
Field of view diameter	Assistant microscope:	ø 50.3, ø 32.1, ø 20.1, ø 12.7, ø 8
	Main microscope:	ø49.4 ～ ø8.2

(2) Working distance

Objective focal length	F=200 mm
Actual working distance	193.6 mm

(3) Eyepiece

Diopter adjustment range	±7D
Eyepiece magnification	12.5x

(4) Eyepiece tube

Angle of view	0° ～180°
Interpupillary distance adjustment range	52 mm~75 mm

(5) Illumination

Illumination technique	Stereo Coaxial Illumination 0° illumination: provides a brighter red reflex 6° illumination: provides a more stereoscopic visual field
Maximum illumination intensity	≥70 000 lx

(6) Filters

Built-in filter mode	Black dot filter (macular protection) 25% gray filter Red-free filter Blue blocking filter(retinal protection) No filter

(7) Position adjustment

Maximum extension radius	1270 mm
Vertical adjustment range (from ground to objective lens)	790 mm ~ 1310 mm

(8) Electrical data

Input voltage	AC 100V-240V / 50Hz-60Hz
Input power	110VA
Light source	12V LED (Close to the color temperature of halogen lamp)

(9) Product safety features

① Classification by type of protection against electric shock: Class I;

② Classification according to the degree of protection against electric shock: no classification, no application part;

③ Classification according to the waterproof grade: the waterproof grade of the shell is IPX0, and the one of the foot control panel is IPX 6 ;

④ Classification according to the degree of safety in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non-AP/APG type;

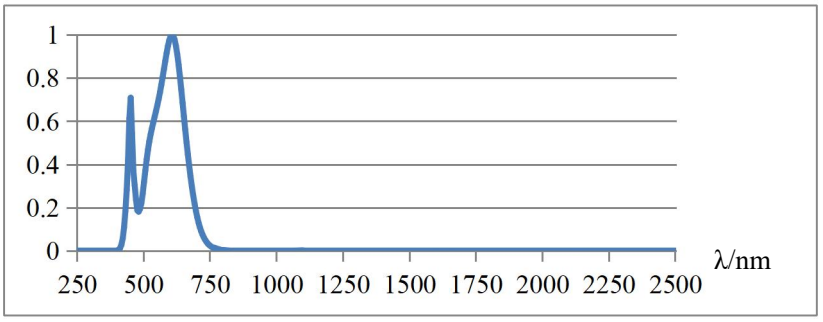
⑤ Classification by operation mode: continuous operation;

⑥ Whether the surgical microscope has the applied part of protection against the effect of defibrillation discharge: none;

⑦ Whether this device has a signal output or input part: no signal output or input part;

⑧ Permanently Installed Equipment or Non-Permanently Installed Equipment: Non-Permanently Installed Equipment.

(10) Normalized spectrogram



Maximum exposure guide value

Project	Maximum output	50% maximum output
Use a retinal protector	600s	1200s
Not using retinal protection	100s	200s

WARNING: The light emitted by this device is potentially dangerous, and the longer the exposure time, the greater the risk of eye injury. If the device is irradiated under the maximum light intensity for 100s , it will exceed the safety guide value.

（11）Weight parameters

The weight of the equipment is 200 Kg, and the total weight after packaging is 320kg.

（12）Size specifications

Size of device：130cm×66.4cm×176cm

Dimensions after packing：103.5cm×83.5cm×200.5cm

2 Graphical Description of Each Part

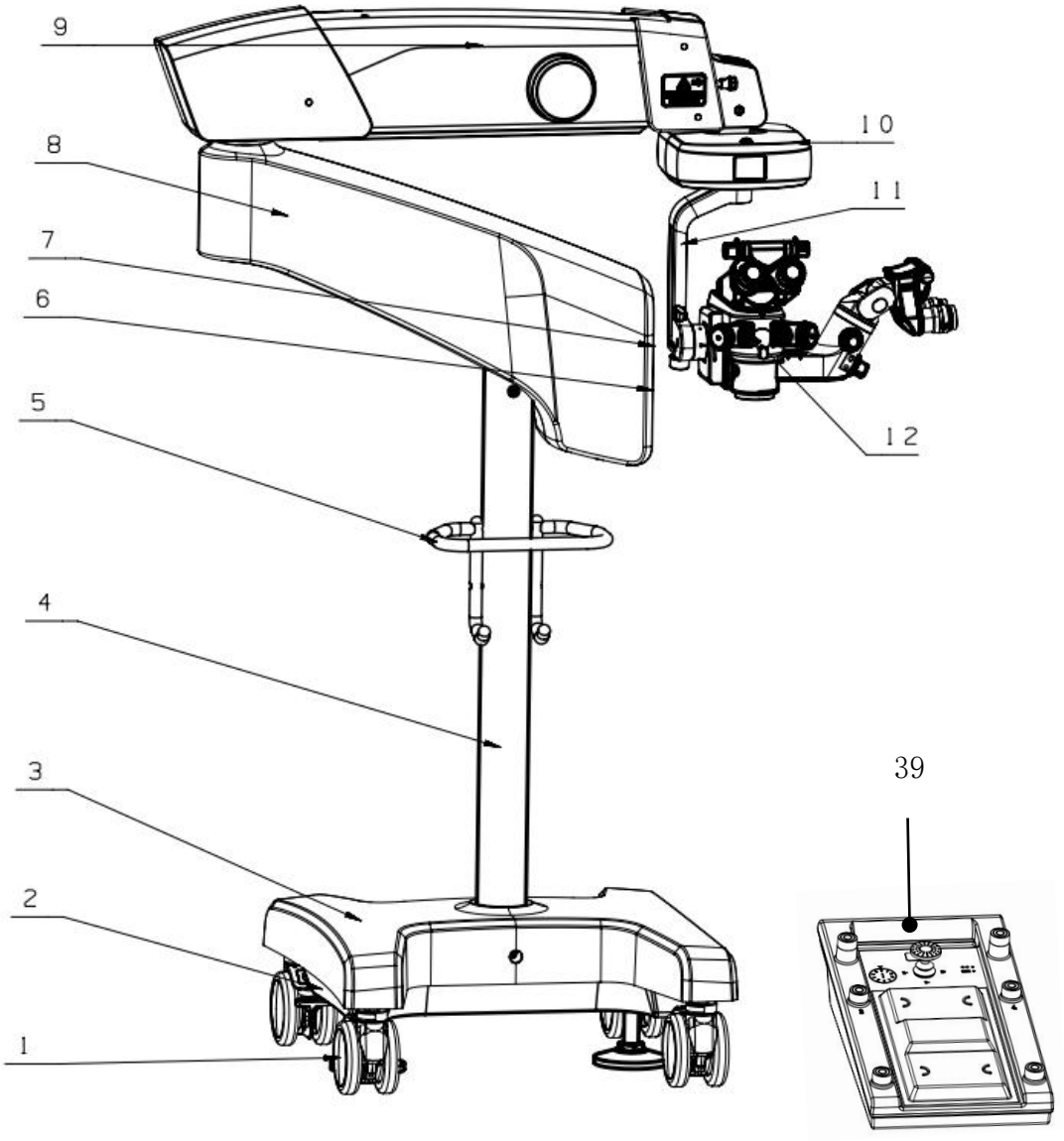


Figure 1

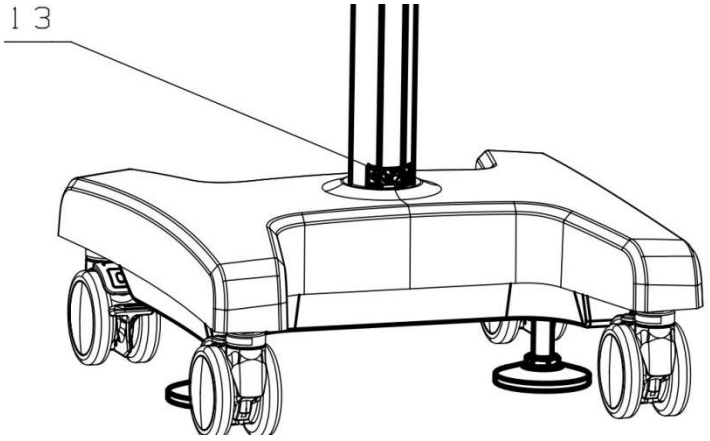


Figure 2

[01] Casters

It is used to support the device and facilitate transporting. There is a foot brake on the caster. Press the foot brake to lock the caster, and release the foot brake to unlock.

[02] Base

It is used to lower the center of gravity, keep the device stable and support and fix the column.

[03] Base cover

Used to decorate the base and protect the user and base from bumping.

[04] Column

For connecting the base and the arm set to form a height space.

[05] Hand rail

For pushing and pulling the device.

[06] Pairing indicator

For pairing the wireless foot control panel: Adjust the two coding dial arrows to the same number, which indicates that the pairing is completed.

[07] Power switch

By switching to I, the device is powered on, while switching to O is to cut off the power.

[08] Support arm

Together with the suspension arm, it forms the arm set of the device to form a working space.

[09] Suspension arm

Together with the support arm, it forms the arm set of the device to form a working space, which can be adjusted up and down.

[10] XY coupling

For fine-tuning the horizontal direction of microscope on X+, X-, Y+, Y-.

[11] Suspension bracket

Used to connect XY coupling and microscope

[12] Microscope part (Main microscope and assistant microscope)

[13] Power cable socket

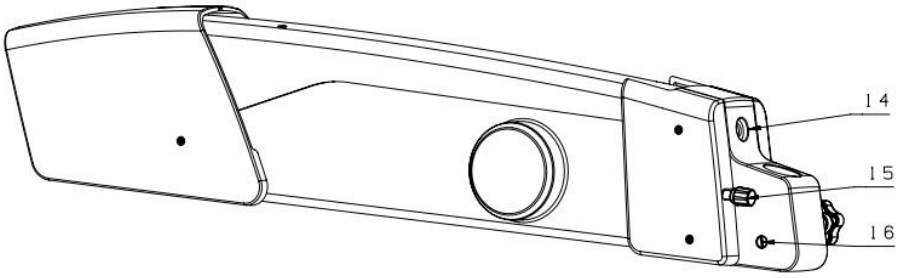


Figure 3

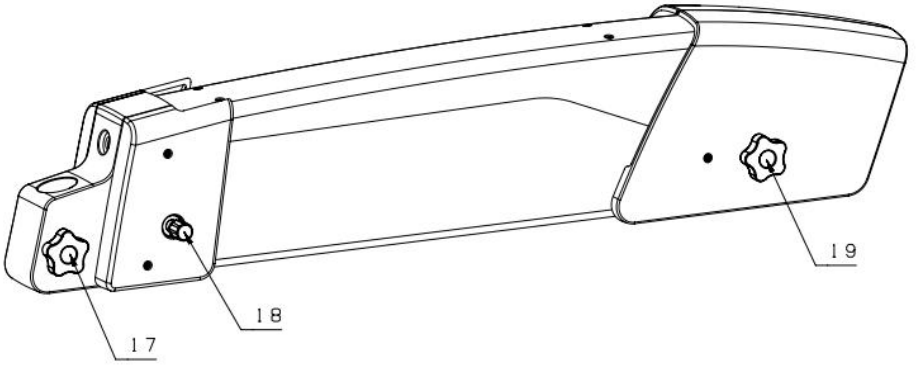


Figure 4

[14] Circular connector receptacle

Used to connect the suspension arm to the microscope part for power and communication.

[15] Suspension arm safety limit knob

This rotary knob is used to set the minimum working distance from the surgical field in the vertical direction. Press and hold the center button on the handle and make the

surgical microscope able to move vertically. Move the surgical microscope to the focus position above the patient's eye. Lock the position by turning the rotary knob clockwise until it stops. This sets the minimum working distance for the microscope.

[16] Limit screw

[17] Star knob for locking and adjusting

Used to lock the microscope part in any position by rotating it horizontally.

[18] Suspension arm horizontal limit knob

It is used to limit the suspension arm in horizontal position, which cannot swing up and down, pull this knob out and rotate 180° to cancel the limit, and pull it out and rotate 180° again to restore the limit.

[19] Star knob for balance adjustment

It is used to adjust the balance of the up and down swinging force of the suspension arm.

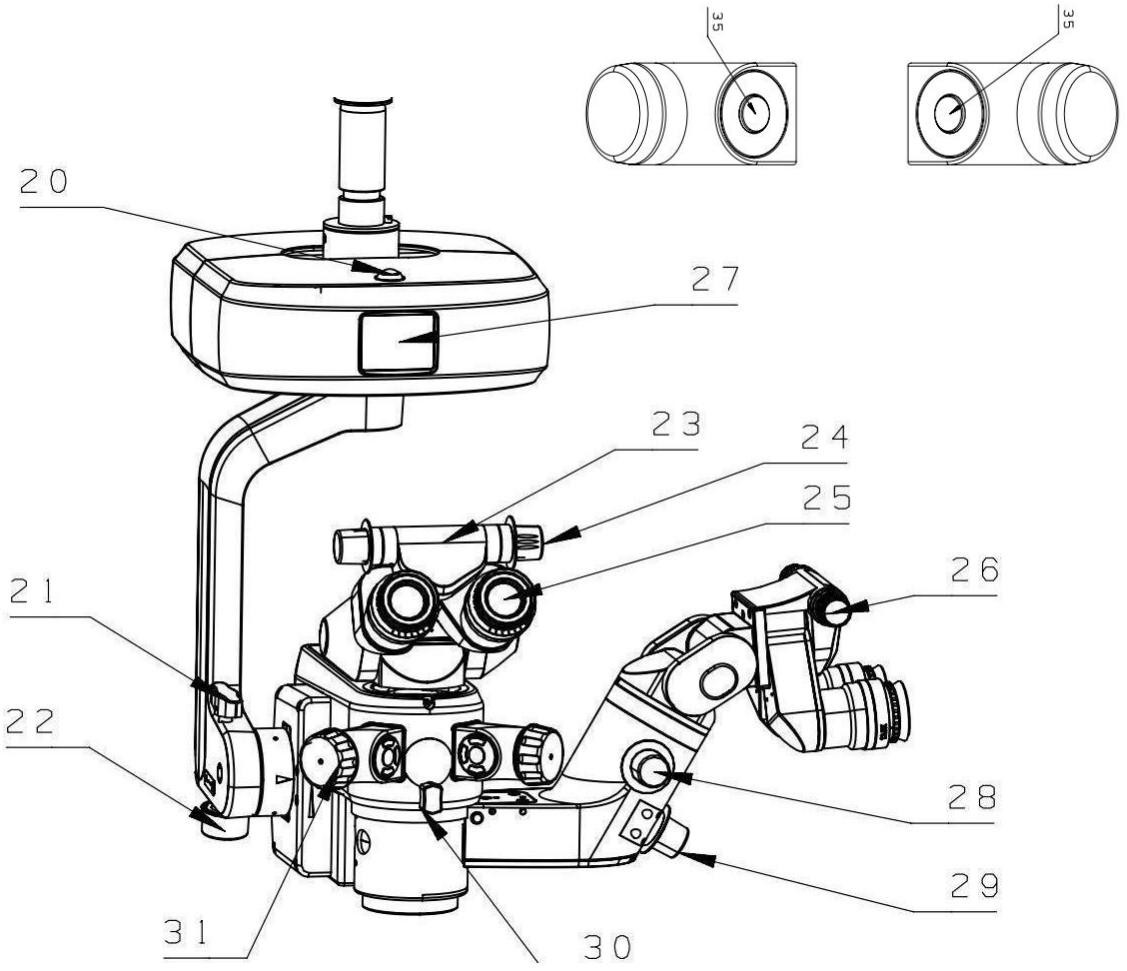


Figure 5

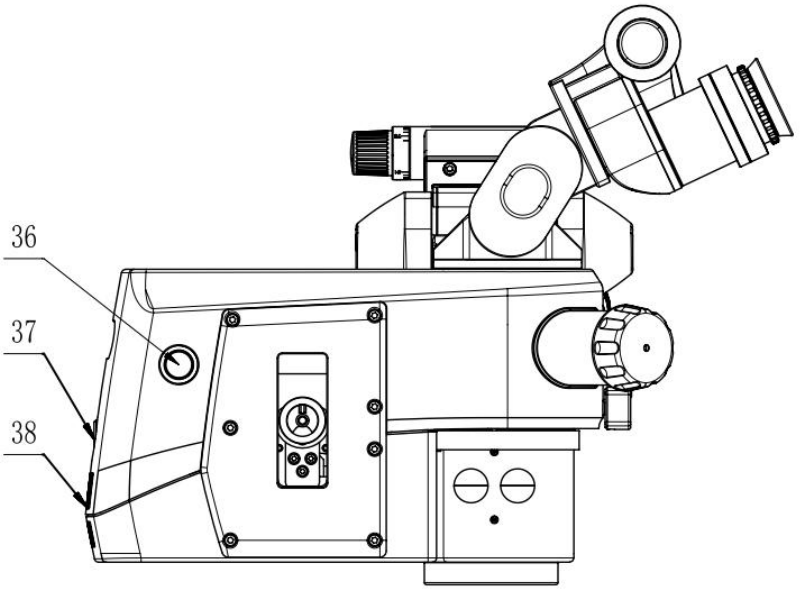


Figure 6

[20] Reset button on the XY coupling

A short press of the button centers the XY position, while a long press of the button for three seconds centers the focus position.

[21] Adjustment knob for tilting the microscope

[22] Adjustment knob for lens front and rear balance

[23] Binocular tube with viewing angle adjustable in 180°

The viewing angle can be changed according to the height and habits of the operator.

[24] Interpupillary distance adjustment knob

Used to adjust the interpupillary distance of the lens, with a scale for indication.

[25] 12.5X Eyepiece

There are diopter adjustment ring and eyecup height adjustment ring on the eyepiece.

[26] Assistant microscope binocular tube

The viewing angle can be changed according to the interpupillary distance, height and habits of the operator.

[27] Display

[28] Zoom (Magnification changing) knob

Use this knob to manually adjust the assistant microscope magnification.

[29] Focus knob

Used for fine-tuning the focal length of the assistant microscope.

[30] Assistant microscope locking knob

It is used to lock the assistant microscope after turning left and right.

[31] Handles

For grip when positioning the microscope.

[35] Center button on the handle

Used to unlock the electromagnetic brake.

[36] Backup LED switching button

For switching to backup LED with just one touch.

[37] Circular connector port

For power input and communication of microscope control board.

[38] Ventilation openings

Used for heat dissipation of the LED light source and must not be covered.

[39] Foot control panel

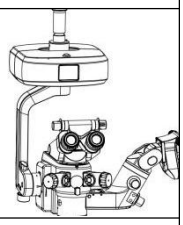
Used to control the operations of surgical microscope such as zooming, focusing, switching filters, XY plane movement, etc.

3 Installation of the Device

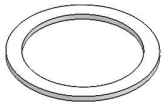
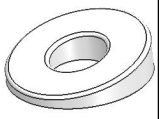
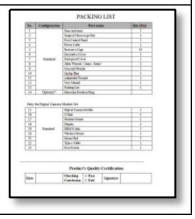
This device is generally installed by the user referring to this manual. If it is really difficult to install, you can contact the authorized dealer or manufacturer for installation.

The device is packaged in separate boxes. When unpacking, open the box cover according to the direction on the box, and take out all parts in sequence. Install in the following order after unpacking.

3.1 Unpacking Checklist

No.	Part Name	Quantity	Image
1	Stand (comprising the arms, the column, and the base)	1	
2	Microscope Part	1	
3	Foot Control Panel	1	
4	Allen Wrench 8mm	1	
5	Allen Wrench 2mm	1	
6	Power Cable	1	

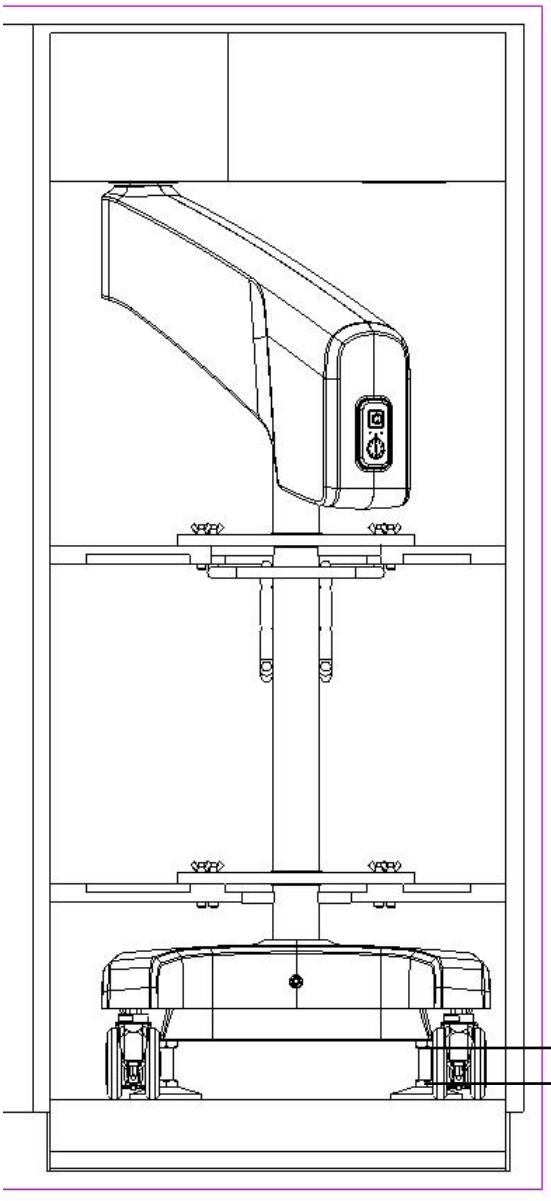
7	Dust Cover	1	
8	Circlip Pliers (for the lock nut)	1	
9	Crescent Wrench (for the limit screw)	1	
10	Adjustable Wrench	1	
11	Protective Caps for Zoom Knob	9	
12	Protective Caps for Locking Knob	3	
13	Protective Caps for Assistant Microscope Locking Knob	3	
14	Protective Caps for Interpupillary Distance Adjustment Knob	12	

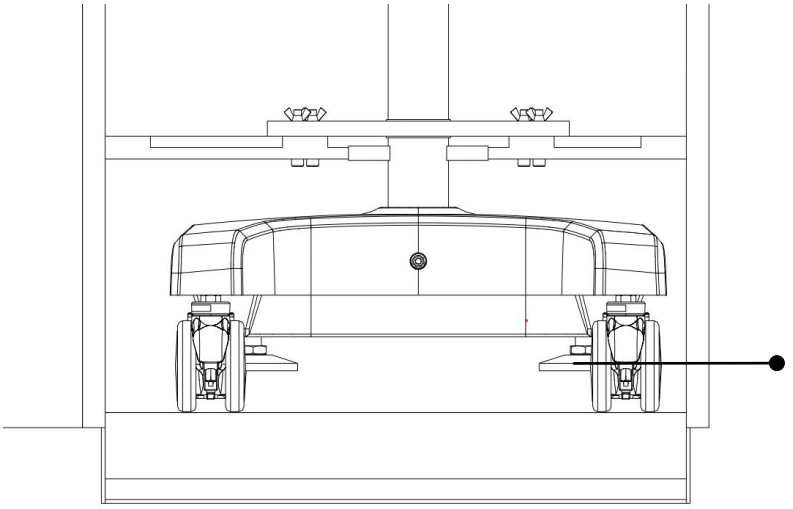
15	Protective Caps for Handles	6	
16	Gasket	1	
17	Decorative cover	1	
18	User Manual	1	
19	Packing List	1	

Please refer to the packing list for details and updates.

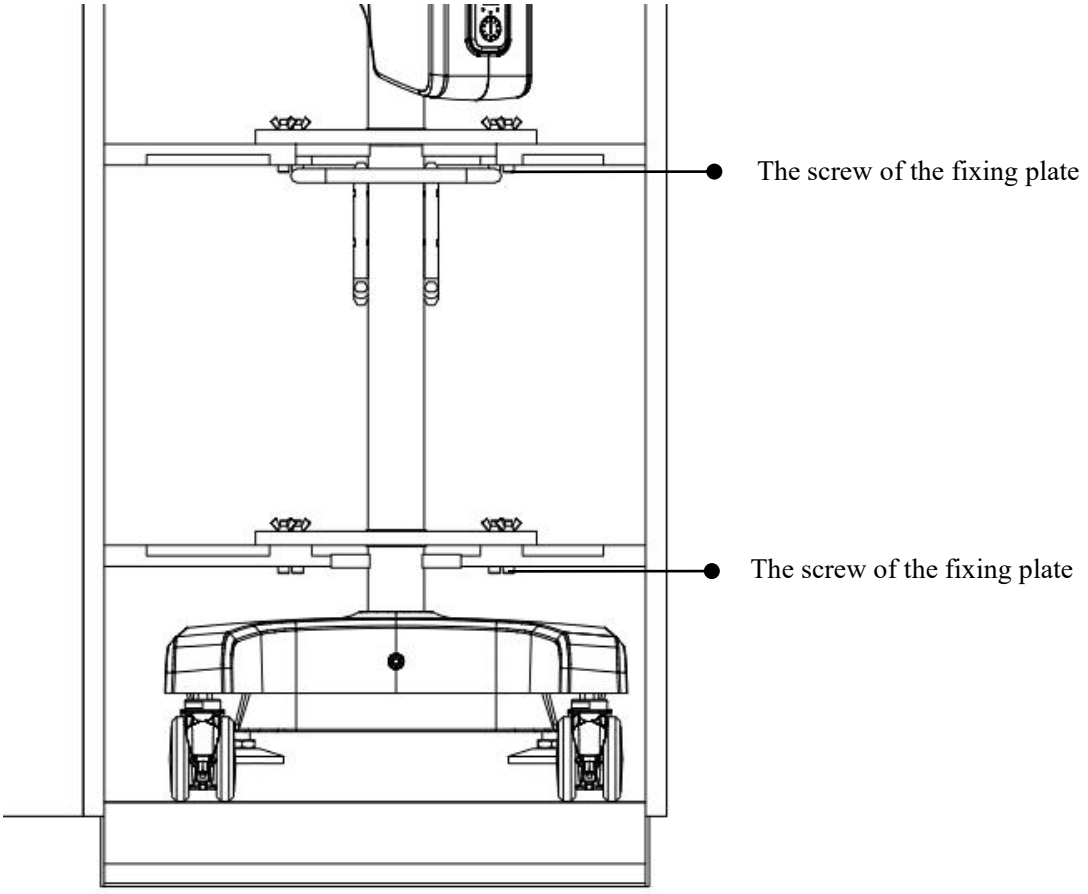
3.2 Remove the Fixtures of the Stand

1. Open the wooden box and remove the fixed foam.
2. Loosen the nut above the leveling mounts to the lowest position with an adjustable wrench, and then rotate the nut below the leveling mounts upward to raise it to the highest position using the same adjustable wrench.



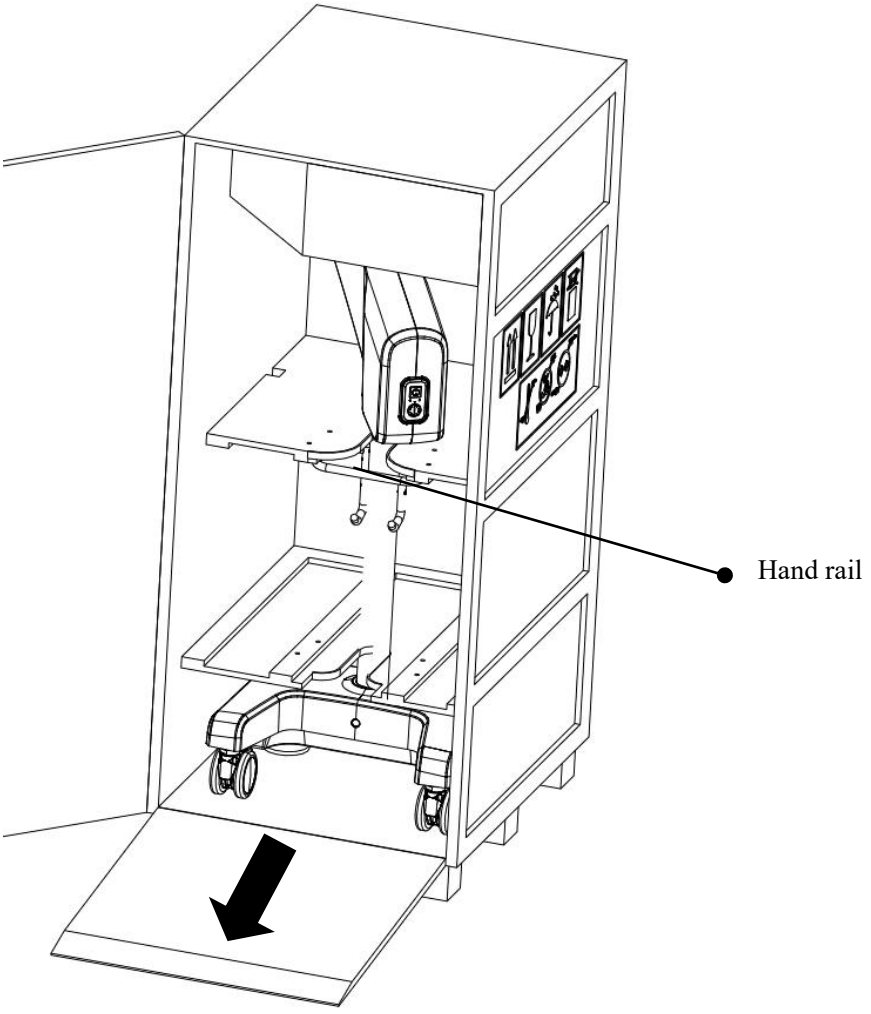


3. Use an 8-mm Allen wrench to loosen and remove the 8 screws from the fixing plate, then remove the fixing plate.



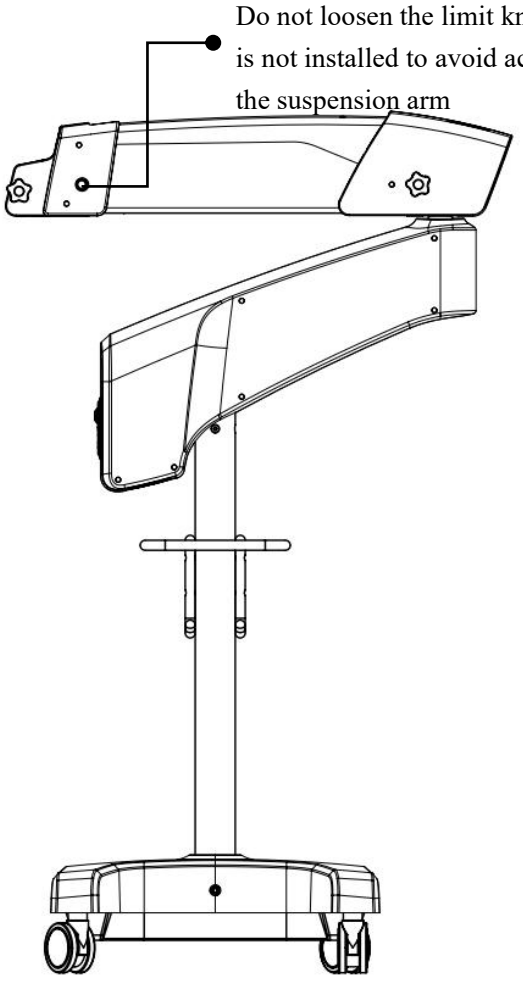
3.3 Move the stand out of the crate

Open the brakes on the casters and use the hand rail to move the stand. Carefully and slowly pull it out from the crate along the slope.



Caution:

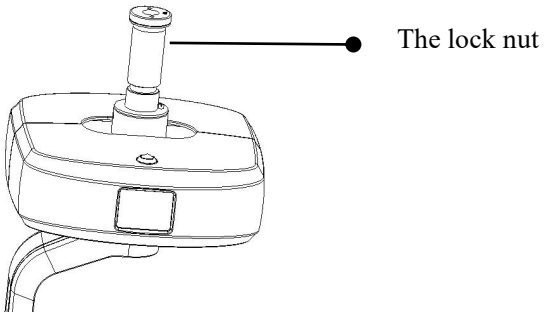
- **It is recommended to have two people handle the device due to its weight.**
- **Be extremely careful when moving on slopes and avoid collisions of any kind.**
- **After moving the device out, ensure it is placed steadily in an upright position.**



Caution: Before the suspension arm is installed with the microscope part, do not open the limit knob to avoid accidental injury by lifting the suspension arm. If you want to loosen the limit knob, you must pull down the suspension arm by hand to release it.

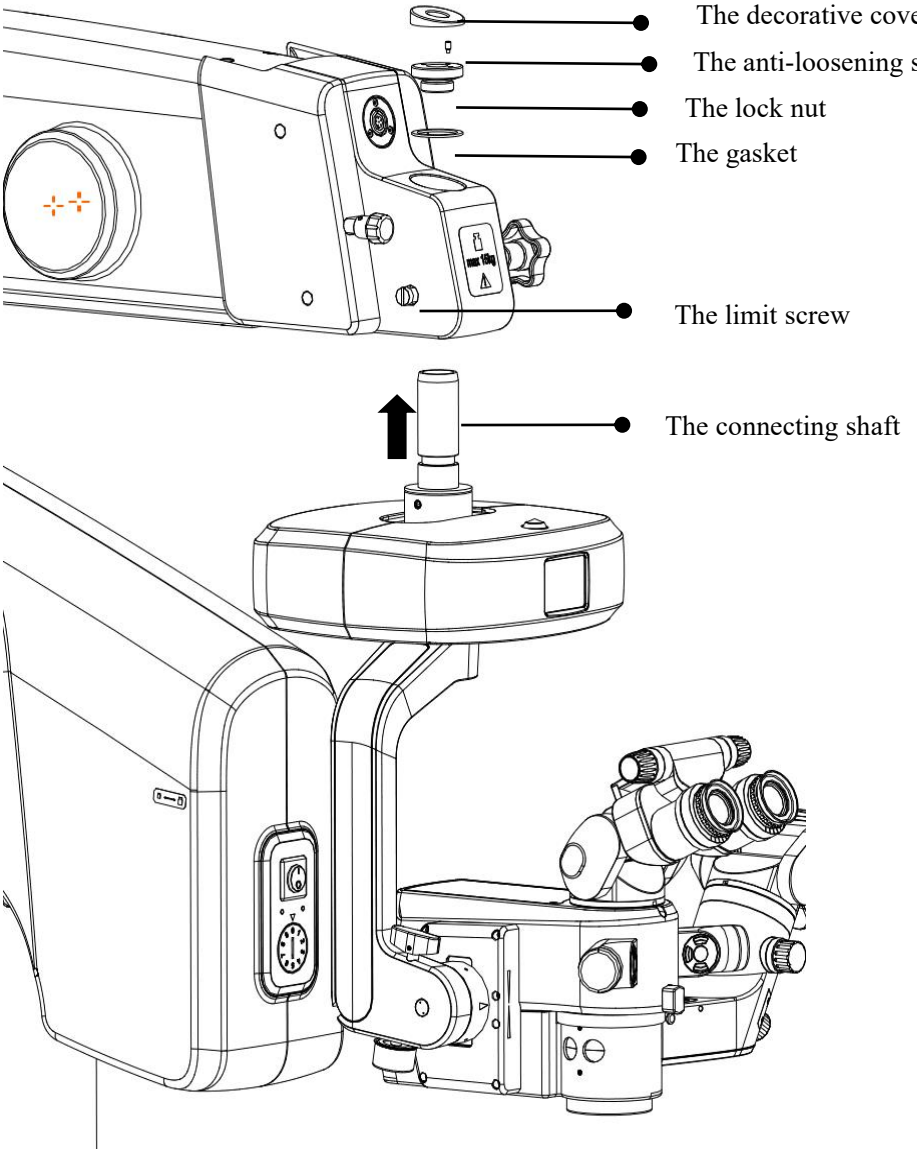
3.4 Installing the Microscope Part

1. Take out the microscope part, and remove the lock nut above the connecting shaft.

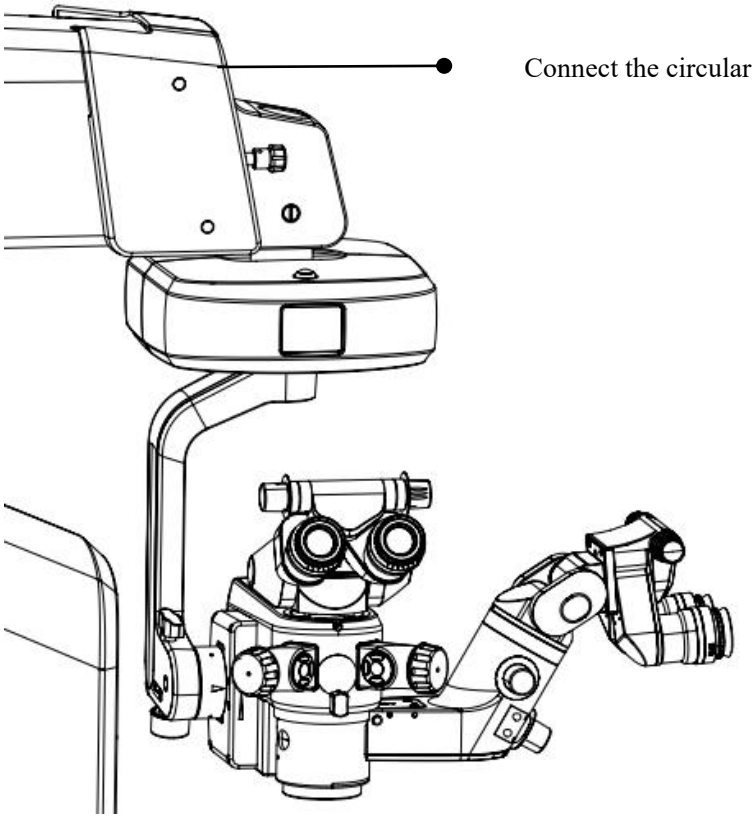


2. Follow the steps and the figure below:

- Rotate the limit screw out by 3 mm with the crescent wrench.
- Insert the connecting shaft of the microscope part into the mounting hole of the suspension arm, and tighten the limit screw with the crescent wrench.
- Install the gasket and tighten the lock nut with circlip pliers.
- Tighten the anti-loosening screw with a 2-mm Allen wrench.
- Finally, install the decorative cover, ensuring that the circular connector passes through the mounting hole, gasket, lock nut, and decorative cover.



3. Insert the circular connector to the circular connector receptacle on the suspension arm.



3.5 Connection of the Power Cable

Take out the power cable, insert one end of the power cable into the power input socket of the device (bottom of the column) and the other end into the local power socket.

3.6 Precautions for Operating the Device

Before starting the device, please confirm that the following terms have met the requirements:

1. Check whether the local power supply voltage and frequency are consistent with the device. If there is a discrepancy, do not start the device.

Caution : Please make sure that the input voltage / frequency of the device is consistent with the local grid voltage / frequency .

2. Check the grounding of the power supply to make sure the device is well grounded.

3. The device is equipped with a three-core power cable, please select a suitable power socket to match it.

Caution: Please use the special power cable for this device, or the power cable conforming to IEC227 standard, to ensure that the device is well grounded.

4. The power switch has two states. When the switch is set to "I", the power is turned on, and the switch glows green; when the switch is set to "O", the power is cut off, and the switch does not emit light. Before the device power cable is connected to the power socket, the power switch should be in the "O" state.

5. Insert the plug of the device's power cable into the local power outlet.

6. Remove the protective cover of the eyepiece and the dust cap of the objective lens .

6. Turn on the power switch, the light source indicator will light up. Observe the device lighting to confirm that the lighting is normal.

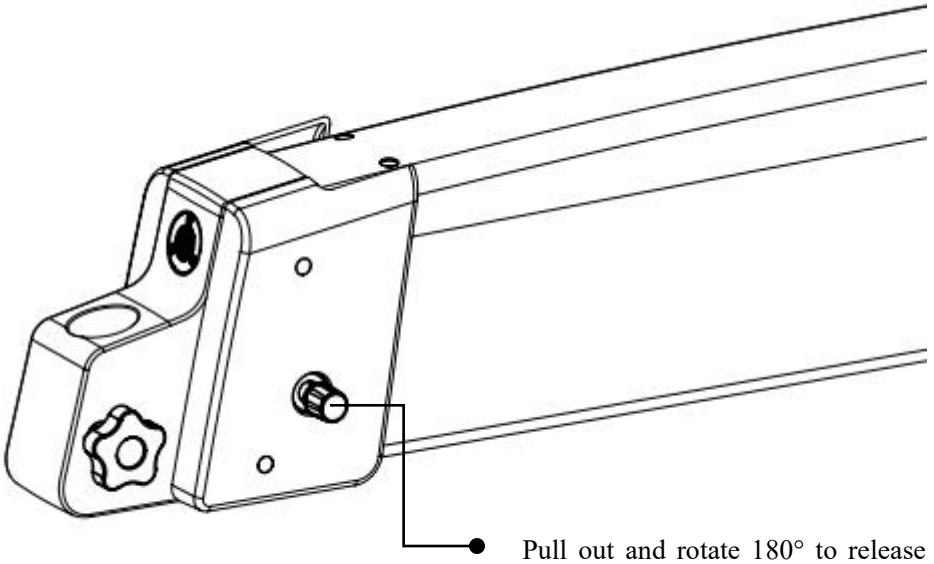
7. The working environment of the equipment should avoid electromagnetic interference as much as possible.

8. If the device will not be used for a long time, please remove the battery in the foot control panel.

3.7 Function Check

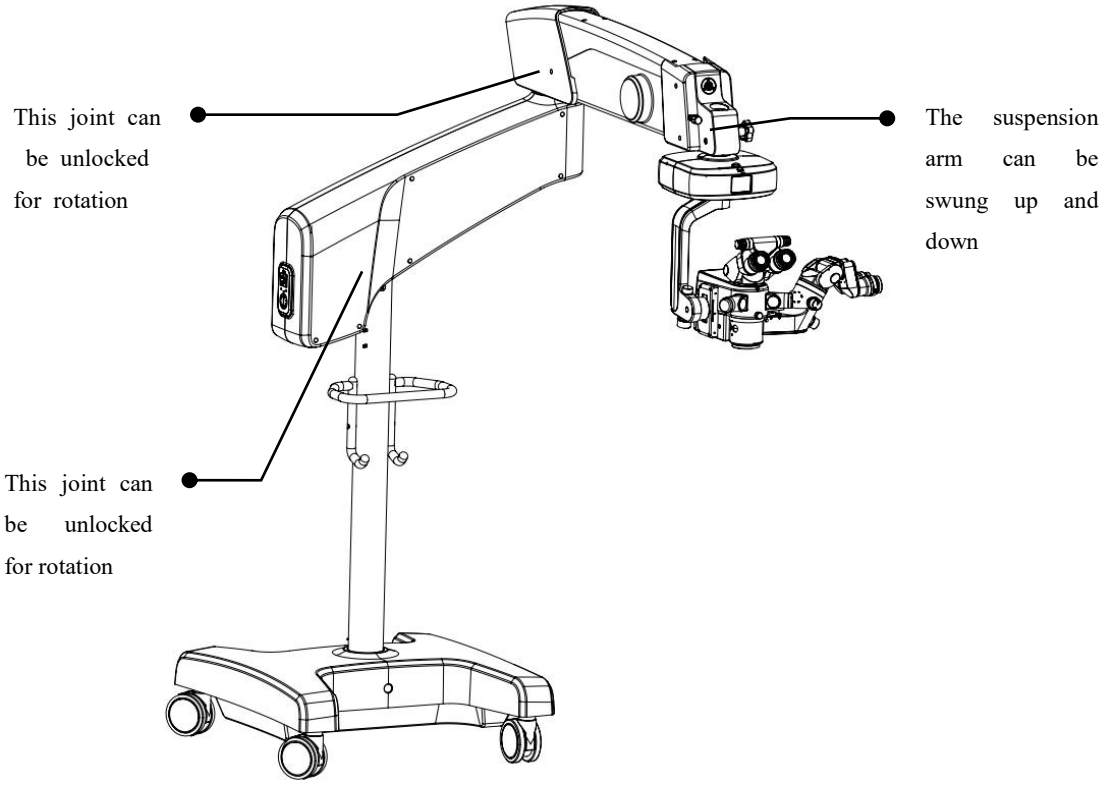
1. Release the suspension arm limit

Pull out the suspension arm horizontal limit knob [18] by hand, and rotate it 180° to release the suspension arm limit (when pulling out, pull down the suspension arm by hand, it will be easily pulled out).



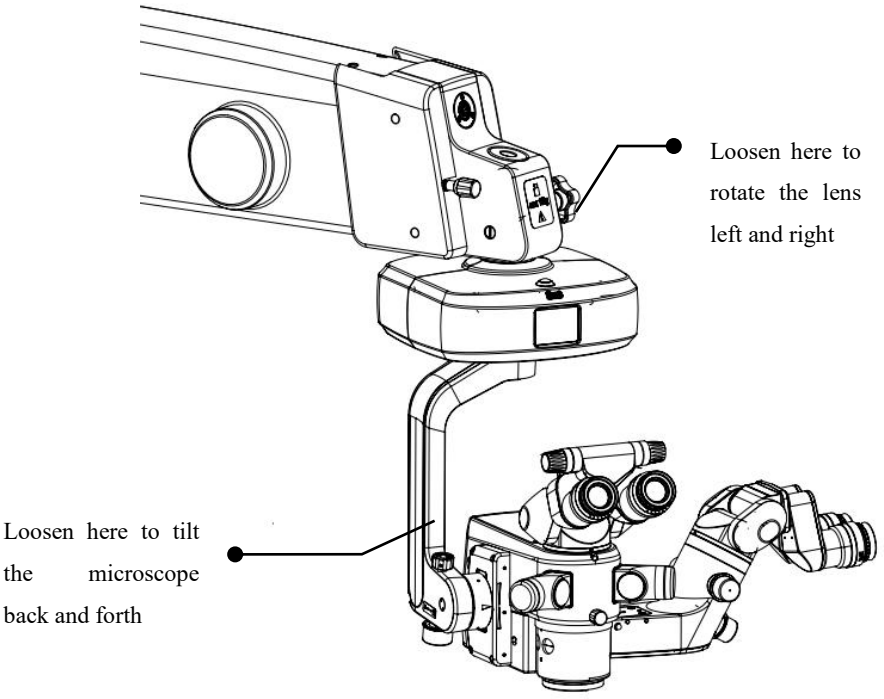
2. Check joint brakes of support arm and suspension arm

Turn on the power switch, press and hold the center button on the handle (unlock brake button) [35] , the support arm and suspension arm can move up, down, left, right, back and forth, and release the button to automatically lock. When the suspension arm moves up and down within the normal working range, the LED light source is turned on, and when the suspension arm moves upward beyond the normal working range, the LED light source will automatically turn off.



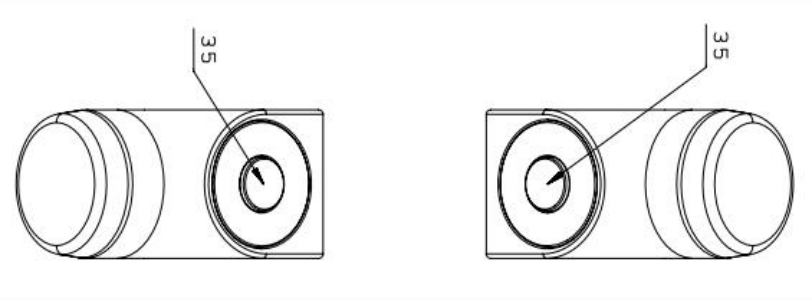
3．Adjust the microscope part to rotate and swing

Loosening the star knob [17] enables the microscope part to swing left and right. Loosening the lock knob for lens front and rear balance [21] enables the microscope part to swing back and forth.

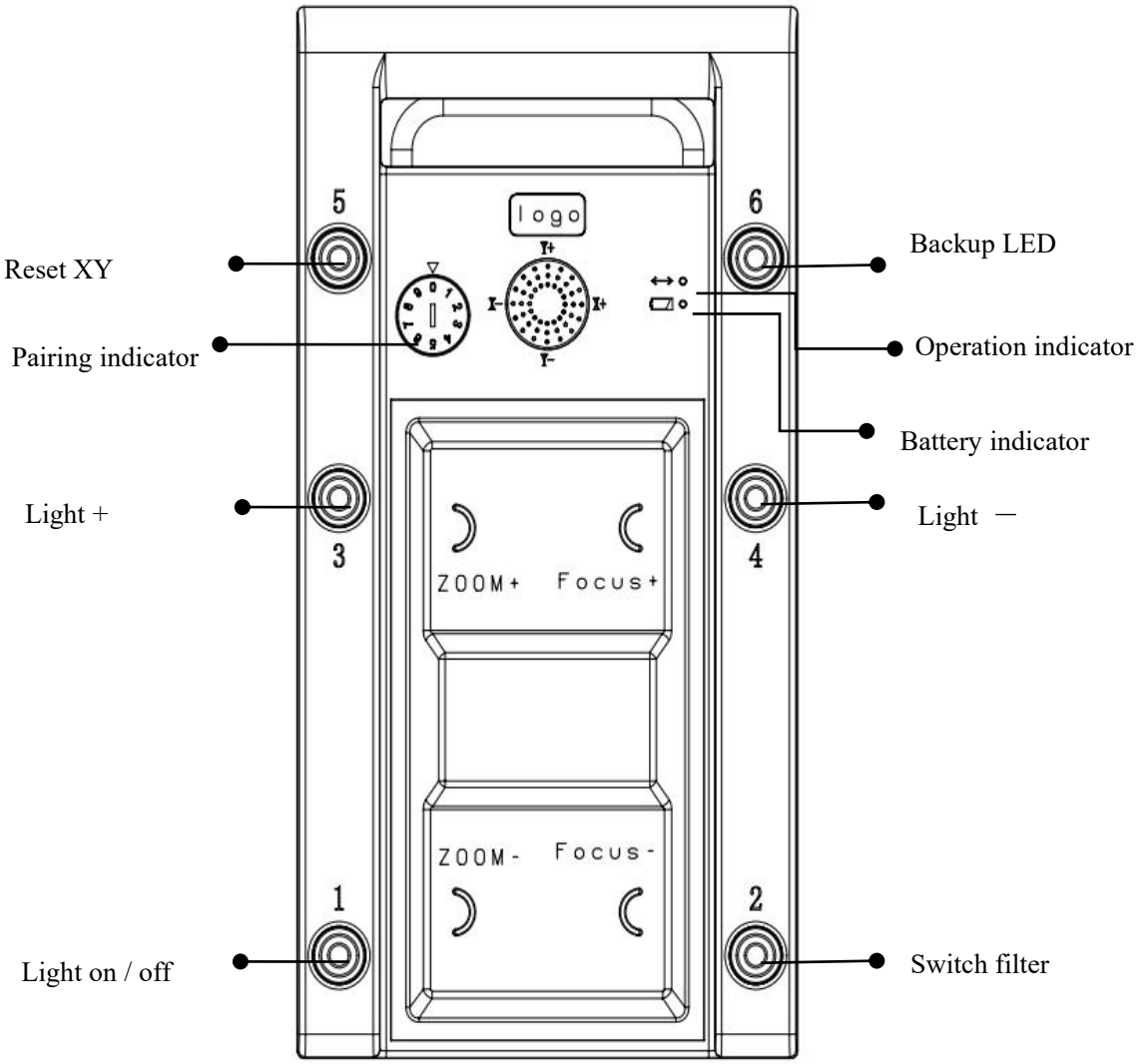


4. Test all functions on the handles and the foot control panel

Check whether the button function of the handle and foot control panel works properly according to the sign in the following figure. [35]: for unlocking the brake.



Function diagram of foot control panel



5. Adjust the microscope part

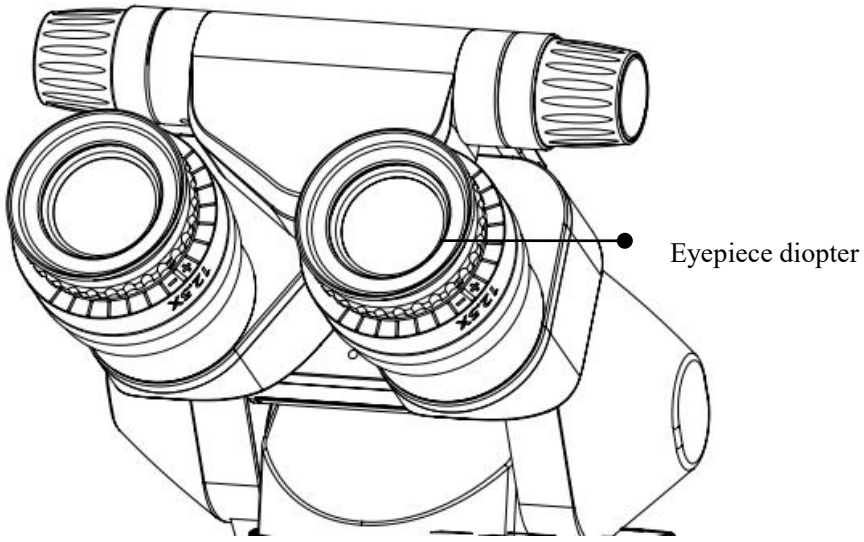
a) Unlock the brake and adjust the lens to the proper position

Turn on the power switch, find a surface to be observed, hold the handle and press the center button, the brakes of the support arm and suspension arm will be fully unlocked. Adjust the front and rear, left and right, and up and down positions, and adjust the light spot to the surface of the object to be observed (the light spot is in

focus on the focal plane, a circular light spot will be irradiated, and if it is not on the focal plane, there will be multiple circular light spots that are not concentric).

b) Adjust the diopter

In order to observe a clear image at the working distance of the objective lens, the eyepiece diopter must be adjusted. The scale value of the eyepiece diopter adjustment ring is 1D per grid, and the adjustment range is ±7D. Rotate the diopter adjustment ring to match the scale value corresponding to the white line on the ring with the diopter of the surgeon. If the surgeon wears glasses for surgery, since the glasses have corrected the surgeon's diopter, just align the white line on the diopter adjustment ring with the 0 position.



How to adjust the diopter if the non-emmetropic doctor's eye diopter is unknown? Set both eyepieces to +5D, remove the binocular tube along with the eyepiece from the surgical microscope body, and aim it at a distant object, just as you use binoculars, when the object looks different. Clearly, slowly turn the diopter adjustment ring on the eyepiece clockwise until the image of the object is clear, stop turning the adjustment ring, if necessary, repeat this process three times and

take the average of the diopter. Adjust the second eyepiece in the same way. Reinstall the binocular tube and eyepiece on the surgical microscope body, and tighten the set screws on the lens body to fix it.

c) Adjust the focus

Adjust the eyecup to see the full field of view, use the [ZOOM+] button of the foot control panel to adjust the magnification of the surgical microscope to the highest value. Use the [Focus+] and [Focus－] button of the foot control panel to fine-tune the height of the lens to make the image clearly focus on the object, and then adjust to the required working magnification, when the magnification is changed, the image surface can still be sharp, but the depth of field is different for each magnification.

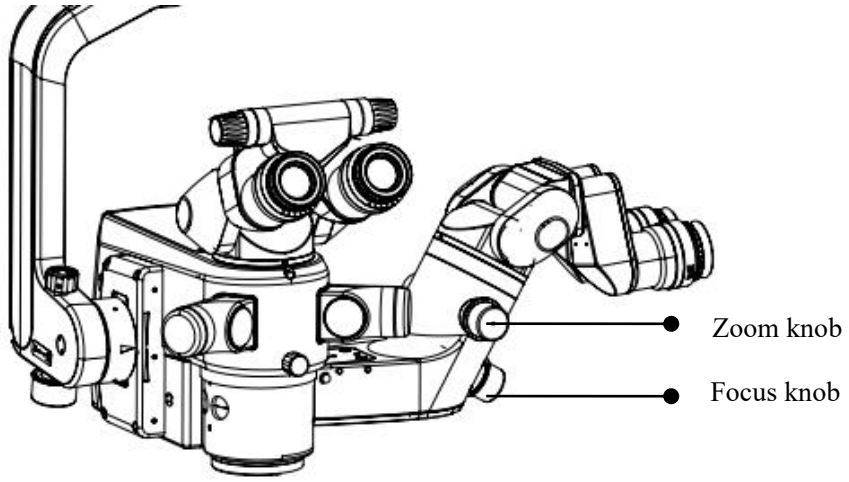
Caution: If multiple surgeons use a single surgical microscope, it is necessary to make a table with the diopter of each surgeon and place the table near the surgical microscope.

d) Adjust the assistant microscope

i. The diopter adjustment of the assistant microscope is the same as that of the main microscope

ii. Assistant microscope focus adjustment

Adjust the eyecup to see the full field of view, turn the zoom knob [28] to adjust the magnification of the assistant microscope to the highest magnification, then turn the focus knob [29] to focus the image clearly, and then adjust to the desired working magnification. When the magnification is changed, the image can still be kept clear, but the depth of field is different for each magnification.



4 How to Use the Device

4.1 Precautions for Use

(1) Do not look directly at the light source through optical components such as objective lenses.

(2) Do not cover the ventilation openings of the light source.

(3) Read the warning label on the device carefully.

(4) Cannot be installed in a location where it is not easy to disconnect the power.

4.2 Check Before Using the Device

(1) Turn on the power and the light source works normally.

(2) Press and hold the center button (unlock button) on the handle and the support arm and suspension arm can be freely moved forward, backward, left, right, up and down.

(3) The functions of the buttons on the foot control panel and handle work normally.

(4) Backup LED works well (**important**).

(5) Both power indicator lights are normal (green light is normal, red light is abnormal), and the indicator light is next to the power switch (**important**).

(6) The foot brakes of the casters on the base are locked, and the device is stable on the ground.

(7) Eyepieces and binocular tubes adjusted into place

1) The surgical microscope and binocular tube have been adjusted to a position that

is convenient for the surgical position.

2) The correct interpupillary distance has been set.

3) The eyecup has been adjusted to a position where the full field of view can be seen.

4) The eyepiece diopter has been adjusted to the correct scale.

(8) Users should put protective caps on the zoom knob, interpupillary distance adjustment knob, focus knob, lens handle and other parts.

4.3 Use Steps of the Device

(1) Confirm that the preparations before use have been completed.

(2) The device is checked in good condition as required (Set the safety limit height of the microscope before first use).

(3) Turn on the power.

(4) Move the surgical microscope up and down to the working position.

(5) Turn on the light source and adjust the brightness of the light source.

(6) Select the filter to use.

(7) Move the surgical microscope lens to the top of the surgical area, and adjust the surgical microscope to a posture suitable for the surgical position.

(8) Adjust the zoom knob to select the desired magnification.

(9) Hold the handle to move the surgical microscope, observe through the eyepiece to roughly adjust the focus of the operating area, and then perform fine-tuning to make the field of view clear.

(10) Move the suspension arm up to the non-working range and turn off the light source.

(11) When the surgical microscope is no longer in use, switch off the power supply.

(12) When using multiple devices in the same room, it is necessary to stagger the indication numbers of each support arm and the foot control pairing indicator, so as to avoid misoperation of one foot control panel to control multiple devices.

Caution: Make sure the ventilation openings are not covered.

4.4 Movement and Storage of the Device After Use

(1) Turn off the power switch and disconnect the power cable from the power source.

(2) Remove all used protective caps and shields for disinfection before next use.

(3) Close the arm set to the position closest to the column and lock it, and tighten all the tightening knobs so that the joints of the arm set and the microscope cannot rotate freely.

(4) Depress the upper part of the foot brake on the caster to release the lock.

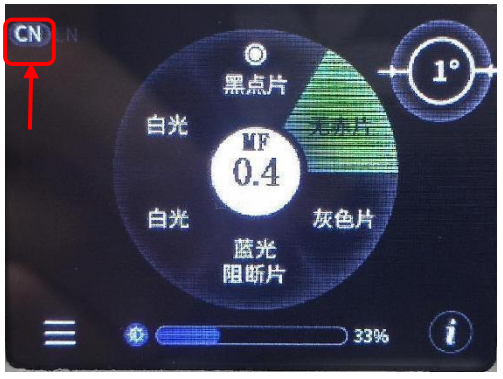
(5) Hold on to the upright while moving, and move slowly and carefully to avoid collisions.

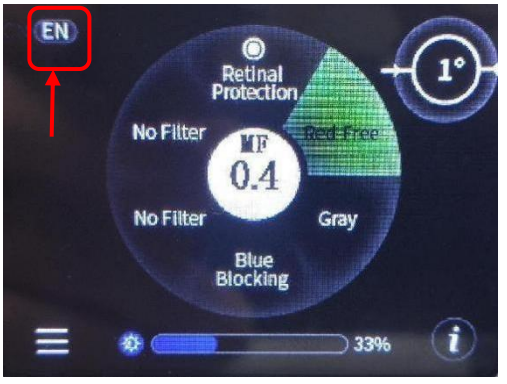
(6) After moving to the predetermined position, depress the foot brake of the caster to lock the caster.

(7) Cover the surgical microscope with a dust-proof cloth bag.

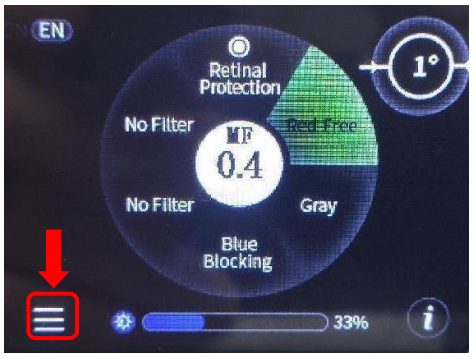
4.5 Operations on the Display

1. Switching between Chinese and English modes: Tap the CN/EN button in the upper left corner of the figure below to switch to the corresponding Chinese and English modes.

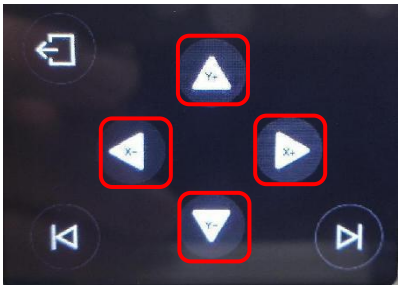




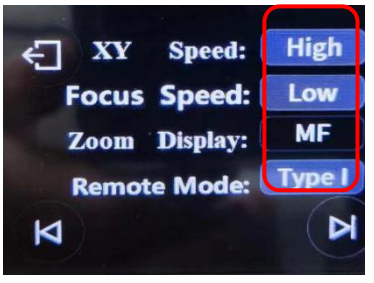
2. Adjusting the magnification (zoom) and the focus: Tap the icon shown in the left figure below to enter the interface shown in the right figure. Then, press “+” and “-” to adjust the magnification and the focus distance.



3. Adjusting the movement of the XY coupling: Tap the  icon shown in the left figure below to enter the interface shown in the right figure. Then, you can adjust the movement of the XY components by pressing the four movement buttons. These buttons are located in the red-lined area shown in the right figure below.

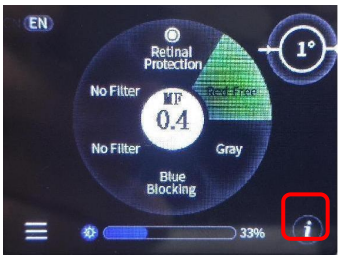


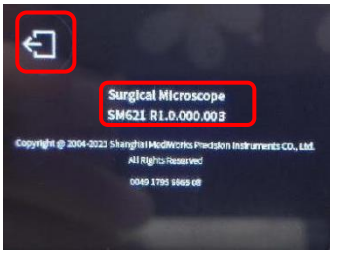
4. Setting speeds: Tap the  icon shown in the left figure below to enter the interface shown in the right figure. Press the "High / Low" buttons to set the XY Speed or the Focus Speed. Press the "MF / Magnification" button to set the ZOOM Display ('MF' refers to the magnification factor, which ranges from 0.4 to 2.4, and 'Magnification' refers to the total magnification of the main microscope, which ranges from 4.3x to 25.5x). Press the "Type I / Type II" button for the remote mode of the foot control panel.



5. Checking the system information: Tap the  icon to check the software currently

installed on your system. To return to the main interface, press the  button

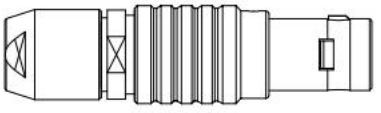




4.6 How to Use the Emergency Cable of the Foot Control Panel

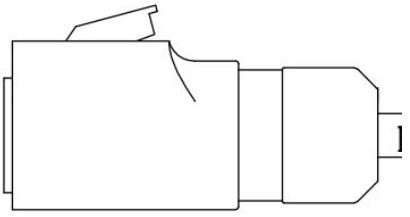
When the wireless foot control panel is unable to operate the device, do not turn off the device.

Connect the XY component and the foot control component with the 5-meter emergency cable of the foot control panel. This will enable operation in wired mode.



A

Plug the A-end of the emergency cable (as shown on the left) into the socket on the XY coupling.



B

Plug the B-end of the emergency cable (as shown on the left) into the socket on the foot control panel.

5 Routine Maintenance of the Device

5.1 Replacement of Consumables

Caution: The replaced waste should be disposed of as general industrial waste.

5.1.1 Replacing the LED Light Source

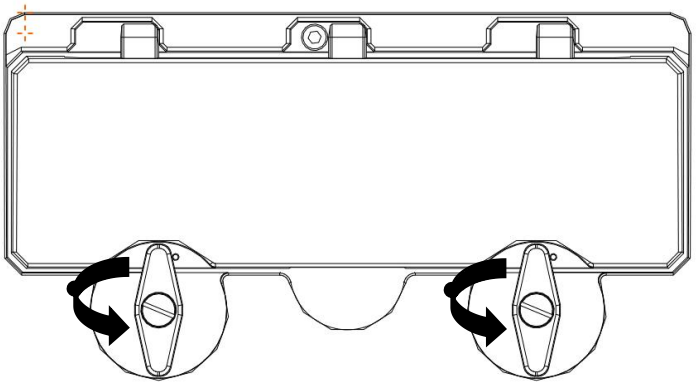
The device has two LED light sources, one is a backup to avoid damage to the light source during the operation and affects the operation. If any one of the LED light sources is

damaged, please contact the manufacturer or authorized dealer.

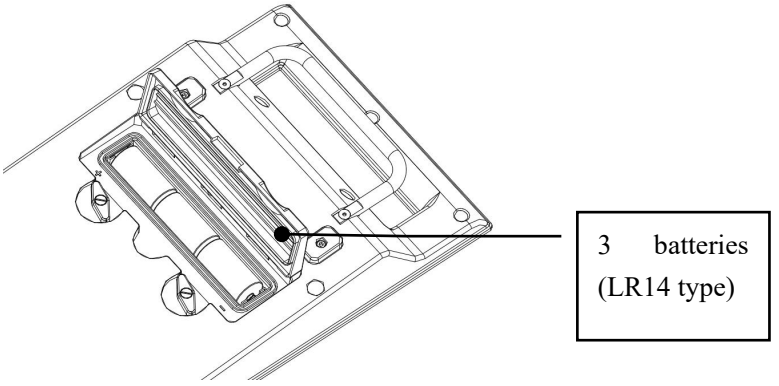
Caution: Not recommended for use without a backup light source.

5.1.2 Replacing the Foot Control Panel Battery

Rotate the battery compartment block to the left to open the battery cover.



Open the battery cover to remove the battery, replace with a new battery (pay attention to the positive and negative poles of the battery), then close the battery cover with the screws and lock it.



5.2 Cleaning and Disinfection of Device

The company recommends users to clean and maintain the device once every three months, or as needed.

1．This device is a precision device, please do not disassemble it without the maintenance personnel of our company or professionals with equivalent qualifications.

2．Power off the device before cleaning.

3. After the device has passed the inspection, it can guarantee normal use, but it must be properly maintained. When the user is not familiar with the structure and performance of the device, please do not disassemble it casually to prevent damage or reduce the performance of the device.

4. The device should not be placed in dusty, humid and corrosive gas environment to prevent damage to the device.

5. The surface of the device and the lens protective cover can be wiped with a clean damp cloth, and the dirt can be wiped off with a damp cloth dipped in a mixture of 50% ethanol and 50% distilled water. Do not use corrosive or abrasive cleaners.

6. In order to prevent dust, the optical lens and lens body should not be left open after removing the objective lens, binocular tube and eyepiece, and cover the objective lens and eyepiece with a protective cover when not in use. The blood stains, body fluids and other dirt on the surface of the optical lens should be wiped off with optical lens tissue or absorbent cotton, dipped in distilled water and a little household detergent. The remaining stains can be wiped off with lens tissue or absorbent cotton dipped in a small amount of solvent, such as absolute ethanol and ether mixture (1:1), gently wipe the lens (swirl from the center outwards), do not use corrosive or abrasive cleaners.

7. It is recommended to use 75% ethanol for disinfection, wipe twice for 3 minutes .

8. Accessories that are not in use should be removed and stored in an device case with desiccant.

Caution: After the device is used, the dirt on the lens should be cleaned in time. The dirt on the lens such as the objective lens will make cleaning and disinfection very difficult. Devices should be cleaned and disinfected frequently, if possible.

5.3 Disposal of Waste

The waste generated by this device is LED light source, lens tissue or absorbent cotton.

Please do not throw it away at will. If there is a special waste disposal facility near you, please use it as much as possible. Discarded devices shall be disposed of in accordance with the provisions of the relevant local environmental protection laws, please do not pollute the environment.

6 Troubleshooting Guide

If there is a malfunction, firstly please check the troubleshooting guide listed in Table 1. If the malfunction still cannot be solved, please explain the phenomenon of the device failure, and contact the dealer authorized by the Mediworks or the after-sales service department of the Mediworks.

Table 1 Trouble Shooting

Malfunction	Possible Cause	Solution
No electrical function in device	Power is not on	Turn on the power switch or plug in the power cable
	Mains power failure	Contact a local electrician
Lights are off	Power cable not plugged in	Plug in the power cable
	The power switch is not turned on	Turn on the power switch
	Power cable failure	Replace the power cable
	Electricity failure	Contact a local electrician
	Device electrical failure	Contact the repair service
	The surgical microscope is in the non-working area, and the micro switch of the suspension arm is disconnected	The suspension arm of the surgical microscope is moved down from the non-working area to the working area
	Damaged LED light source	Contact the repair service
Lighting spot brightness is too dim	The life of the LED light source has expired	Contact the service
	The ventilation openings of the LED light source is covered by objects, or the	Remove the cover, clean the ventilation openings. Contact the maintenance service

	ventilation openings fails due to blockage, resulting in the light decay of the LED light source	organization to confirm whether to replace the LED light source
Lights often go out during surgery Then it lights up	The ventilation openings of the LED light source cover are covered by objects, or the ventilation openings fail due to blockage	Remove covering. Clean the ventilation openings
	Fan damage	Contact the service
	Device electrical failure	Contact the service
The magnification change fails	/	Contact the manufacturer's maintenance service department
Defective or non-switchable filter	/	Contact the manufacturer's maintenance service department
Damaged bulb (spare lights available)	/	Contact the manufacturer's maintenance service department
Power failure one (Power indicator turns red)	/	Contact the manufacturer's maintenance service department

7 Responsibility

According to the user's maintenance needs, the company can provide the circuit diagram of the device and the list of electrical components and other information.

The service life of this device is 8 years.

If you need to consult relevant information, provide relevant services, or have any questions, please contact the authorized dealer or the manufacturer directly.

8 Transport and Storage

When transporting the device, it should be protected from moisture and inversion, and avoid violent vibration. Relative humidity 0%～ 90% , ambient temperature -40℃～+ 55℃, atmospheric pressure 860 hPa ～ 1060hPa , no corrosive gas.

The device should be stored in a well-ventilated room with an ambient temperature of -40℃ to 55℃ , a relative humidity of 0% to 90 % , and an atmospheric pressure of 860hPa to

1060hPa.

If the installed device needs to be transported and moved over a short distance, all movable parts in the device should be locked, and the device should not be tilted more than 10° . If the device needs to be transported over a long distance, it should be repackaged and then transported.

If the storage period of the device exceeds 8 years, please contact the manufacturer or authorized distributor for re-testing of the device.

Discarded devices shall be handled in accordance with the relevant local environmental protection laws, please do not pollute the environment.

9 Electromagnetic Compatibility Information

Below cables information are provided for EMC reference.

Table 2 cables information

Cable	**Max. cable length, Shielded/unshielded**		**Number**	**Cable classification**
AC Power Cable	3.0 m	Unshielded	1 Set	AC Power

Important information regarding Electro Magnetic Compatibility (EMC)

SURGICAL MICROSCOPE needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; SURGICAL MICROSCOPE conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

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 SURGICAL MICROSCOPE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The use of accessories, and cables other than those specified by MediWorks, with the exception of accessories and cables sold by MediWorks of SURGICAL MICROSCOPE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the SURGICAL MICROSCOPE.

WARNING: Use of this equipment SURGICAL MICROSCOPE adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

When the AC input voltage is interrupted, the SURGICAL MICROSCOPE will shut down and if the power supply restored, it will restore to previous condition automatically, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

EMI Compliance Table

Table 3 Emission

Phenomenon	**Compliance**	**Electromagnetic environment**
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment and
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

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.

EMS Compliance Table

Table 4 Enclosure Port

Phenomenon	**Basic EMC standard**	**Immunity test levels**
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 5
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 5 Proximity fields from RF wireless communications equipment

Test frequency (MHz)	**Band (MHz)**	**Immunity test levels**
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		

930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 6 Input a.c. power Port

Phenomenon	**Basic EMC standard**	**Immunity test levels**
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Production Date : Refer to label

Version: 1.3 20240510

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