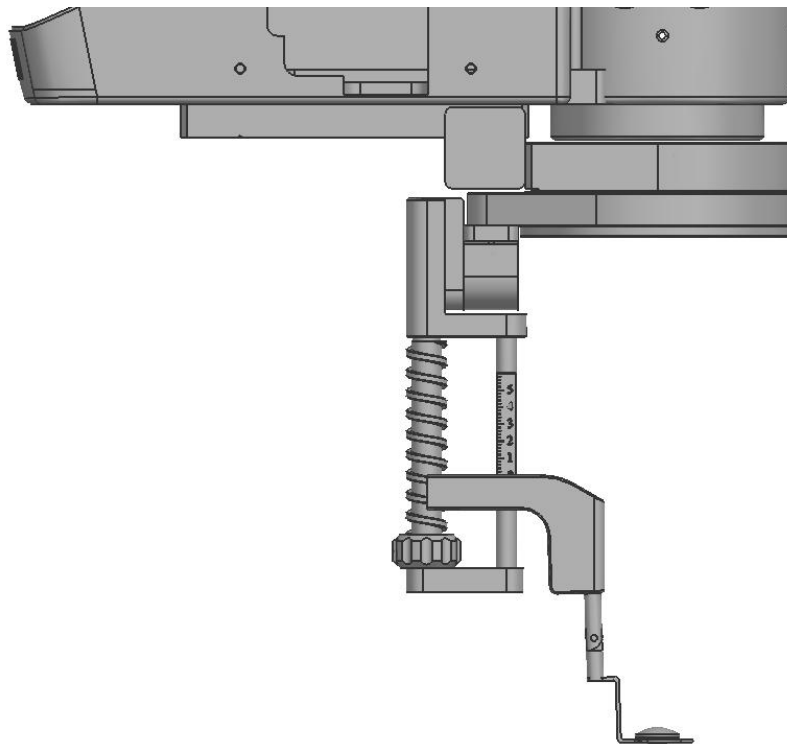


Fundus Viewing System

User Manual

(Model: 600B)



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Introduction











Thank you for choosing the non-contact wide-angle fundus viewing system of MediWorks. In order to use the device correctly, please read this manual carefully before use.

General requirements for safety

Before installing and using your device, please read and observe the precautions and instructions in this manual to ensure safe and dependable service.











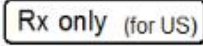








Precautions

Please carefully read the following safety precautions to prevent personal injury, property damage, and any other potential hazards or accidents.

-  Do not disassemble the device or attempt to perform operations that are not described in this manual. Improper operation with excessive mechanical force may cause product damage or personal injury. In case of device failure, please read the troubleshooting guide carefully and follow the troubleshooting methods and steps to solve problems; if the problems remain unsolved, please contact MediWorks Service and professional service personnel will be arranged to solve your problems.
-  This device shall be operated by qualified healthcare professionals.
-  Do not store or use the device in flammable, explosive, high-temperature, high-humidity, or dusty environments; use it in a clean room, and keep it clean and dry.
-  Users are requested to keep focused when using the device and to be careful when moving parts so that the non-contact lens and other parts do not injure the patient.
-  Do not touch the lens and prism surfaces with your hands or hard objects.
-  Before starting use, please carefully check that the condenser lens (part of the suspension unit), non-contact lens and other lenses are not damaged, cracked or broken.
-  Before starting use, ensure that the focusing unit and non-contact lens assembly have been sterilized as instructed in this manual.
-  Please dispose of waste generated by the device in accordance with relevant laws and regulations.
-  Follow the detailed cleaning and sterilization instructions in this manual.
-  Please familiarize yourself with the safety symbols and other graphic indicators used on the device for safe and proper use.

Description of symbols

The table below lists the graphics, symbols and marks used on the device and provides their descriptions.

Graphics/Symbols/Marks	Description
	Date of manufacture
	Refer to instruction manual
	Type B applied part
	WEEE logo.
	CE marking
	Serial number
	Manufacturer
	Medical device
	Unique device identifier
	Authorized representative in the European Community / European Union
	USA Federal law restricts this device to sale by or order of a physician.
	This way up
	Fragile, handle with care
	Keep dry
	Stacking limit by number
	Stacking limit by mass
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

Safety instructions

- Before installing or using the device, familiarize yourself with the operating instructions and all safety features of the device.
- Upon unpacking and before use, please carefully check its components according to the requirements in Chapter 3 of this manual, and install the device according to the installation requirements. Check and ensure that the installation meets the requirements according to the inspection procedure before putting the device into use.
- Follow all instructions for installation, use, sterilization, and disassembly. If you cannot understand these instructions, including warnings and cautions, contact MediWorks personnel before installation or use.
- Check all parts for damage and test before use, do not use if there is any damage or if any component is in need of repair.
- The device shall be used only with original accessories and parts supplied or specified by MediWorks, otherwise the warranty is void.
- The device shall be used only by qualified healthcare professionals.
- MediWorks is not responsible for any damage caused by improper use, cleaning, sterilization or maintenance.
- Do not operate the device outside of the stated environmental operating conditions.
- The device has no known hazardous chemicals or components. Please dispose of waste generated by the device in accordance with relevant laws and regulations.

Attention!

This product is covered by a limited warranty granted by your seller.

1. Device information and specifications

1.1. Scope of application

The 600B non-contact wide-angle fundus viewing system assists the surgical microscope in ophthalmic surgery.

1.2. Structural composition

The device consists of three components: a suspension unit, a focusing unit and non-contact magnifying lens assemblies (three types).

1.3. Intended use

- Intended purpose

The device is intended for use with the surgical microscope to observe the patient's fundus. It can be used throughout the entire posterior segment surgery procedure.

- Indications

The device assists the surgical microscope in fundus surgery.

- Intended population

The device is suitable for people with ocular diseases that require microscopic ophthalmic surgery.

- Intended users

The device is intended to be used by qualified healthcare professionals.

- Contraindications

There are no known contraindications to the device.

1.4. Specifications

1.4.1. Performance parameters of fundus viewing system

Table 1 Magnification of the non-contact lenses

Model	Wide-angle	Small-diameter wide-angle	Mid-field
Magnification	0.4X	0.43X	1X

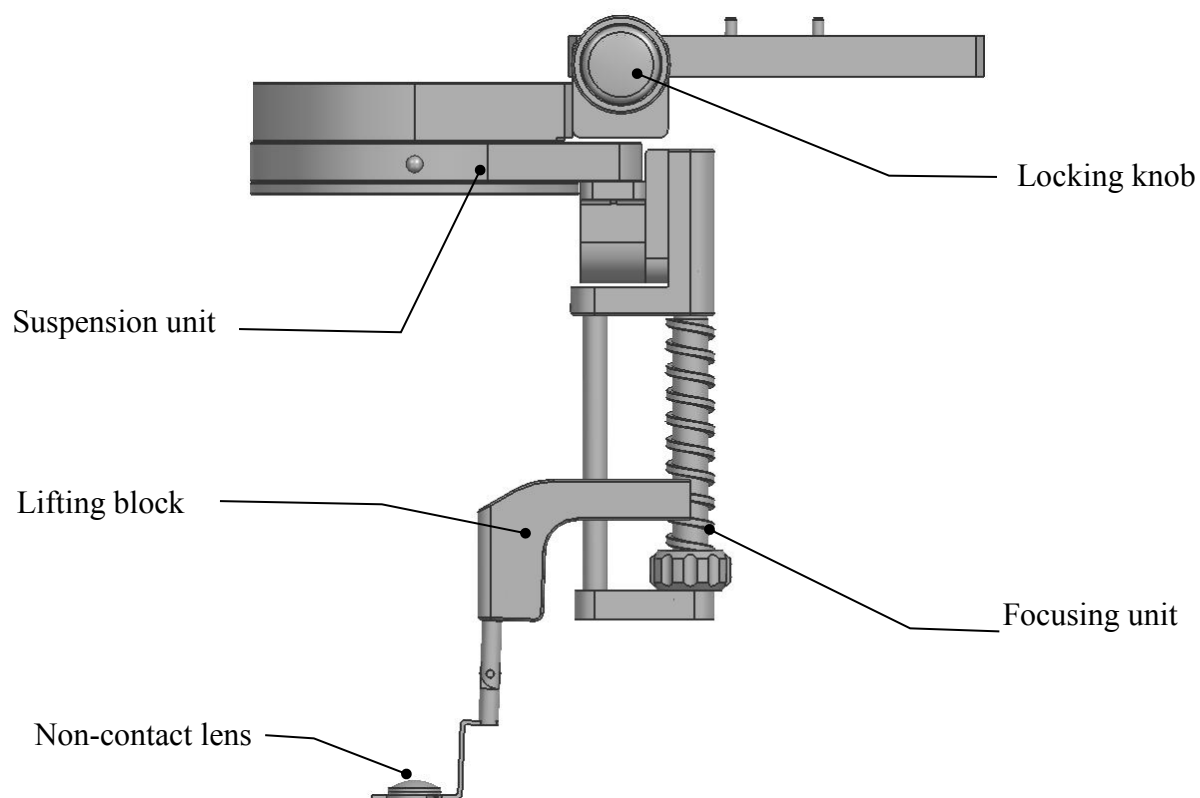
Table 2 Field of view and working distance of the non-contact lenses

Model	Wide-angle	Small-diameter wide-angle	Mid-field
Field of view	100°-130°	95°-115°	45°-55°
Working distance	4.5 mm-2.1 mm	3.2 mm-1.9 mm	5 mm-2 mm

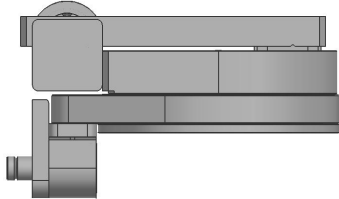
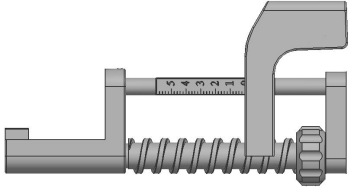



1.4.2. Technical specifications

Interfaces		Hard mounts to common surgical microscopes.
Sterility		Sterilizable components of this system are shipped in a non-sterile condition. Please sterilize them before use.
Materials		All metal components are surgical grade materials.
Weight and dimensions	Package dimensions	380 mm x 320 mm x 180 mm
	Gross weight	4.5 Kg
	Net weight	1.3 Kg
Operating environment	Temperature	+ 5°C ~ + 40°C
	Relative humidity	≤ 90%
	Atmospheric pressure	860 hPa ~ 1060 hPa
Storage environment	Temperature	- 40°C ~ + 55°C
	Relative humidity	≤ 90%
	Atmospheric pressure	860 hPa ~ 1060 hPa
Transport environment	Temperature	- 40°C ~ + 55°C
	Relative humidity	≤ 90%
	Atmospheric pressure	860 hPa ~ 1060 hPa

2. Device illustration



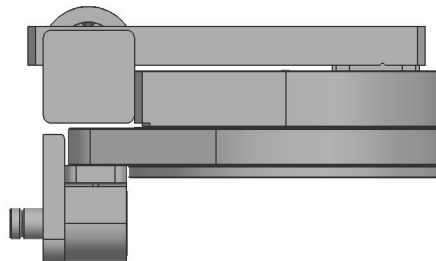
3. Unpacking checklist

No.	Item	Quantity	Illustration
1	Suspension unit	1	
2	Focusing unit	1	
3	Non-contact lens case	3	
4	Sterilizable cap	3	
5	Sterilization case	1	
6	M3 countersunk head screw	3	/
7	Allen wrench 2mm	1	/
8	User manual (installation guide included)	1	/
9	Packing list	1	/

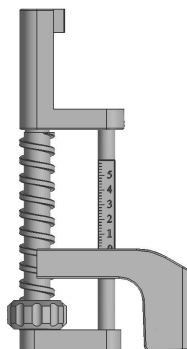
1. Non-contact lens cases: Open the lens cases, remove the non-contact lens assemblies and inspect all lenses for shipping damage. Check lens elements (quantity and type will vary depending on your order), and make sure the lenses are not cracked, loose or dislodged from their housings.



2. Suspension unit: Remove it from the foam box and check for looseness, rotational obstructions, etc.



3. Focusing unit: Remove it from the foam box and check for damage. Use only the focusing knob to adjust the height of the lens, but do not push or pull directly on the lifting block.



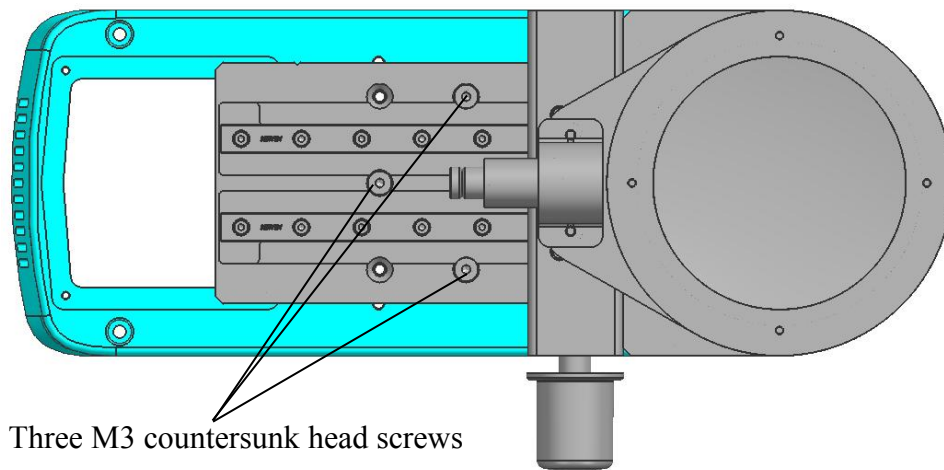
Note: It is recommended that you retain all original shipping materials and containers for future storage or transportation.

Carefully remove and place all components and parts and check that all of them are free from any shipping damage.

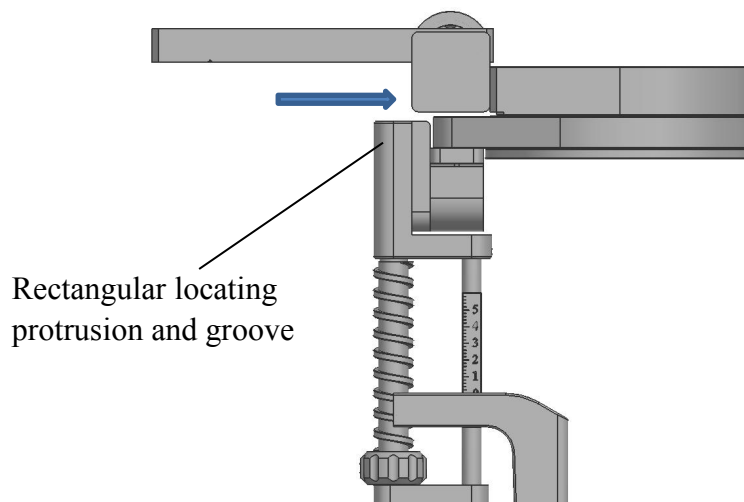
4. Installation

Before installation, carefully remove all components from the shipping containers and turn off the power to the microscope and microscope accessories.

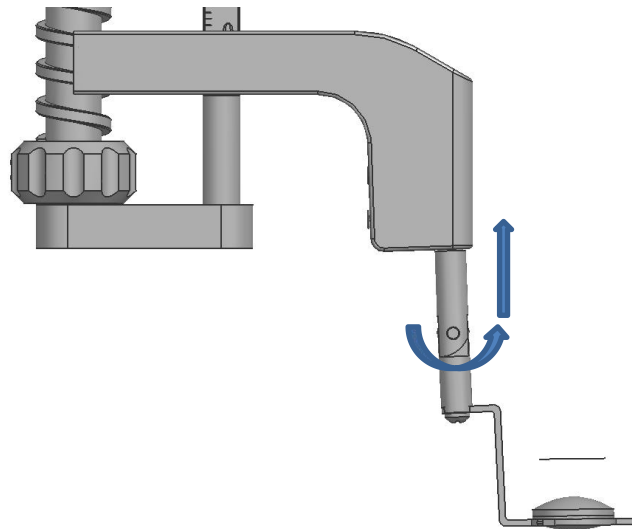
1. Open the packing box and remove the Allen wrench, three M3 countersunk head screws and sterilizable cap.
2. Slide the sterilizable cap onto the locking knob on the suspension unit, loosen the locking knob, pull the handle on the locking knob of the suspension unit forward so that the condenser lens is in the working position and tighten the locking knob. Secure the suspension unit to the lower housing of the microscope by installing the three screws enclosed to the locations shown in the figure below using the Allen wrench provided. By this time, the condenser lens is under the objective lens, and their optical axis should also be aligned.



3. Connect the focusing unit to the suspension unit by mating the rectangular positioning protrusion to the matching positioning groove. Gently push the rectangular positioning protrusion of the focusing unit inwards and ensure that it is vertically positioned in place and securely engaged with the suspension unit. When installing it, use the focusing knob to adjust the lifting block to a position above the “0” mark on the scale.



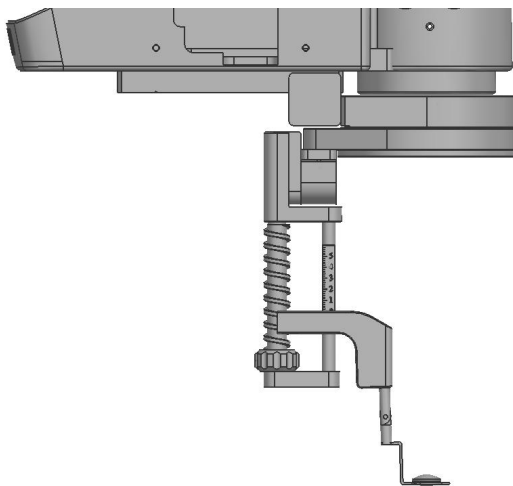
4. After the focusing unit is in place, hold the non-contact lens assembly and push it into the focus unit until the lens shaft is securely in place. You will feel that the lens is located in place and hear a light "click" when the lens is fully seated.
5. After inserting the non-contact lens, rotate the lens to its centered position if necessary. You will hear the locating detent "click" when the lens is correctly centered.



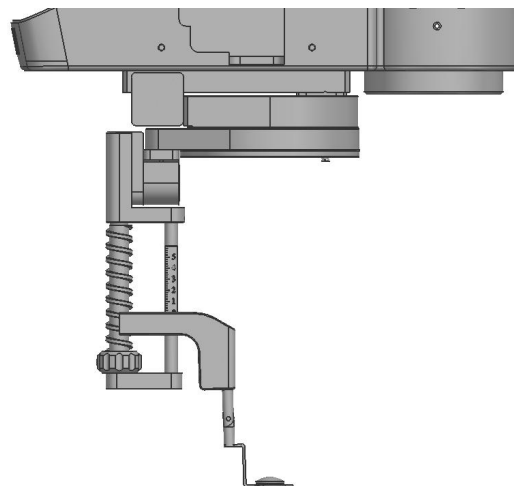
6. Lastly, use the focusing knob on the focusing unit to achieve a focused image. 360° rotate the focusing unit and non-contact lens assembly. At this time, the optical axes of the objective lens, the condenser lens and the non-contact lens should be aligned. If not, loosen the three screws used to secure the suspension unit, adjust the position of the suspension unit to achieve aligned optical axes, and then re-tighten the screws.

5. Operation

1. When using the fundus viewing system, the focusing unit and the non-contact lens must be cleaned and sterilized prior to use in any surgical procedure (see cleaning and sterilization section in this manual).
2. Attach the non-contact lens assembly to the microscope according to the installation instructions.
3. The fundus viewing system can be manually switched between the working position and the parked position by using the handle on the locking knob on the side of the suspension unit and be secured by tightening the locking knob. Pull the handle forward to deploy the fundus viewing system under the objective lens (in the working position) and then secure the system by tightening the locking knob. Push the handle backward to retract the fundus viewing system under the microscope housing (in the parked position) and then secure the system by tightening the locking knob.

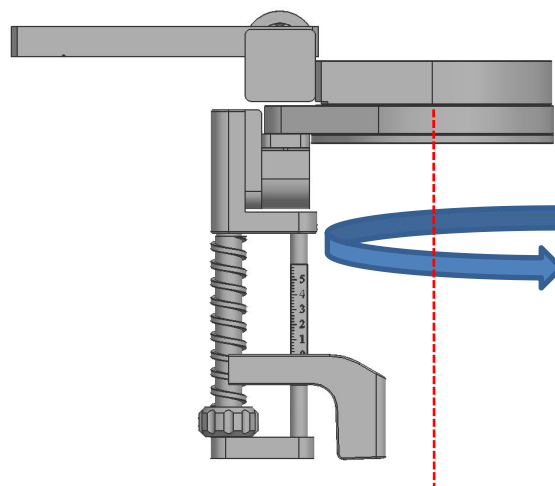


System in the working position

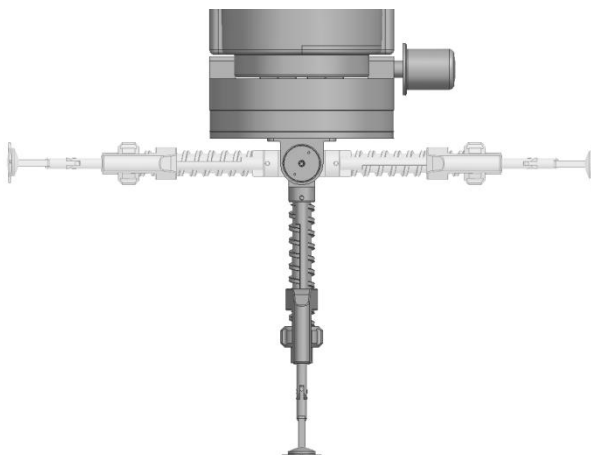


System in the parked position

4. The design of the fundus viewing system allows the focusing unit and the non-contact lens assembly to rotate 360° around the optical axis.

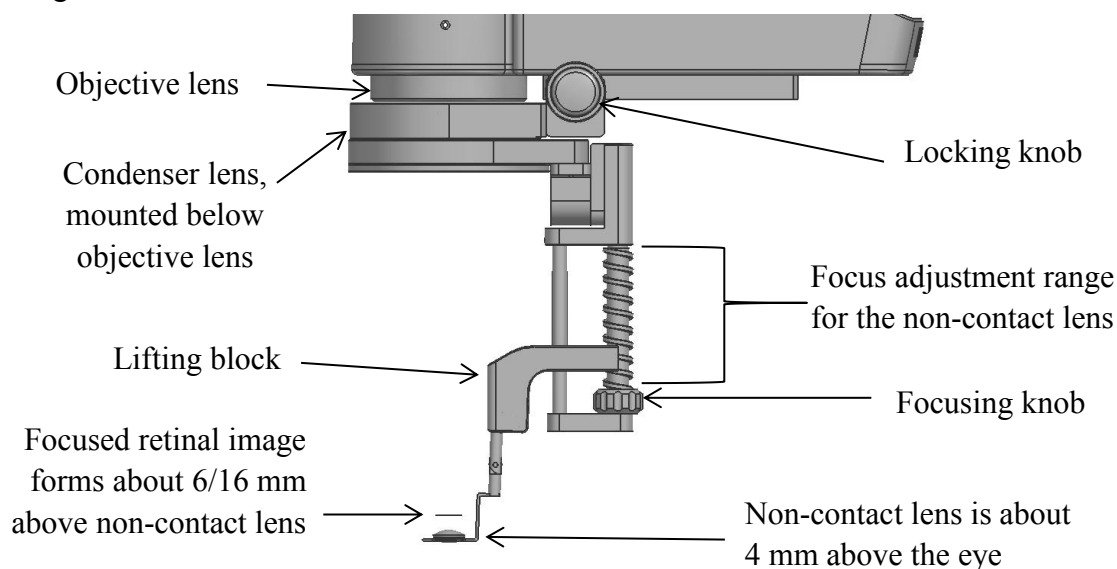


5. The design of the fundus viewing system allows the focusing unit and non-contact lens assembly to be rotated 90° "up" from either side of its vertically deployed position to its horizontally retracted position.



6. Acquiring retinal images

1. Use the handle on the locking knob of the suspension unit to push the fundus viewing system backward under the lower housing of the microscope so that the system is completely out of the field of view of the objective lens. Adjust the microscope up and down to achieve the clearest field of view, then pull the fundus viewing system to the working position and tighten the locking knob.
2. Look into the eyepiece of the microscope and use the focusing knob on the focusing unit to achieve a focused image. (Adjust the focusing knob, so that the non-contact lens moves up and down with the lifting block in the optical axis direction. In the initial adjustment, move the lifting block to a position above the “0” mark on the scale to allow sufficient space in the optical axis direction for the non-contact lens to move up and down to achieve the focus).
3. After a clear fundus image is achieved, if the image field of view is relatively small, you can use the foot control panel to lower the microscope lens properly to reduce the distance between the non-contact lens and the eye (the minimum distance: 5 - 3 mm). The image field of view will be increased accordingly. If the image focus changes at this moment (such as in patients with high myopia or complete retinal detachment), fine tune the focusing knob (no major adjustment is required) to focus clearly again;
4. In the process of obtaining the optimal retinal image, the working distance is mainly controlled by the foot control panel of the surgical microscope, and the image focus is mainly adjusted by the focusing knob.



Caution

In the process of obtaining retinal images and increasing the fundus image field of view, ensure that the vertical distance between the non-contact lens and the eyeball is at least 2 mm.

7. Dismantling

1. Remove the non-contact lens assembly from the focusing unit by grasping the lifting block on the focusing unit and the part of the shaft above the hinge of the lens assembly and pulling them apart until the lens is released. Then, follow the cleaning and sterilization instructions in this manual.
2. Disconnect the focusing unit from the suspension unit and follow the cleaning and sterilization instructions in this manual.
3. If required, reverse the installation instructions to dismantle and remove the remaining components.
4. The external surfaces of the housing and the condenser lens may be cleaned as described in the cleaning and sterilization section.
5. The removable sterilizable cap may be cleaned and sterilized according to the instructions in this manual.
6. The fundus viewing system is not designed for sterilization. Exposure to any sterilization process not specified in this manual may render the device non-usable and void the warranty.

8. Cleaning, sterilization and storage

1. Cleaning.

- a) Remove the focusing unit, the non-contact lens assembly and the sterilizable cap on the locking knob of the suspension unit;
- b) Use soft cotton balls dampened with distilled water to remove the deposits from each component. Pay special attention to any uneven surface, crevices, joints, corners and other hard-to-reach areas, such as surfaces around the periphery of the lenses, lens edges, knobs, non-contact lens insert hole, screw heads and grooves;
- c) Soak and rinse with distilled water over 40°C;
- d) Dry the components.

2. Sterilization.

- a) If applicable, wrap the non-contact lens with standard medical grade steam sterilization gauze. Note that each lens needs to be wrapped separately to avoid scratches;
- b) Use autoclaves to steam sterilize the focusing unit, the non-contact lens assembly and the sterilizable cap on the locking knob;
- c) Steam sterilize for at least 3 minutes at a minimum temperature of 132°C, and leave to dry for at least 10 minutes;
- d) Leave to cool for at least 30 minutes. The components can be moved and used only when their temperature drops to room temperature.

*Carefully check to ensure that all visible blood and contamination have been removed. Check for any signs of damage or wear. If damage or wear is apparent, contact MediWorks or your dealer.

3. Storage.

It is recommended to store the components in a clean, tidy and dust-free environment with an ambient temperature of 5°C ~ 40°C. Protect the lenses with care. It is recommended the components be wrapped in soft materials (not gauze) for storage.

Caution:

- Disassemble the device prior to cleaning and sterilization.
- Protect optical components (non-contact lenses) with care.
- Do not use tap water, organic solvents or corrosive cleaning agents (e.g. chloride, saline, etc.) for cleaning.
- Do not use ultrasonic cleaning equipment to avoid damage to the surface coating.
- Do not use protective oils containing silicone oil for maintenance.
- Avoid contamination of the lenses by oily substances.
- New, used or contaminated parts must be cleaned.
- Remove excess body fluids and tissue prior to cleaning. Body fluids and tissue should not be

allowed to dry on the device.

- Universal precautions for handling contaminated materials should be observed.
- The device should be cleaned as soon as possible after use to minimize drying of any body fluids and tissue.

9. Troubleshooting

If the desired retinal image is not obtained:

- Check that the condenser lens is in place and that the knob is tightened when it is in place.
- Verify that the optical axes of the objective lens, the condenser lens, and the non-contact lens are correctly aligned.
- Confirm that the focusing unit is in the vertical working position and that the non-contact lens assembly is in its locating position in the lifting block.
- When focusing, start with the focusing unit in the middle of the focusing adjustment range.
- Deploy the fundus viewing system under the objective lens so that the non-contact lens is 10-15 mm above the eye.
- Adjust the focusing knob to focus the retinal image.
- Refer to "Acquiring retinal images" section in this manual for steps above.
- If the problem is still not solved, please contact MediWorks Service or an authorized dealer.

10. Storage and transport

- Please retain all original shipping containers and packing materials.
- The shipping containers are customized to the components and should be used to prevent any damage that may occur during shipping.
- If you do not have the original packaging, you can order it from MediWorks. The fundus viewing system must be shipped in the packaging materials provided by MediWorks. Failure to do so will void the warranty for the device.
- Ensure the lenses are placed in specific lens cases to prevent any movement.
- Ensure that the suspension unit, focusing unit and lens cases are placed in the correct foam cutouts in the storage case.
- Place packing foam on top of all components and close the case.
- If shipping, it is recommended placing all cases within cardboard boxes to minimize any shipping damage.

11. Disposal



Dispose of the device in accordance with local laws and regulations.

If you have any questions, please contact Shanghai MediWorks Precision Instruments Co., Ltd..

Production date: see label

Service life: 8 years

Version: 1.1

20240726



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