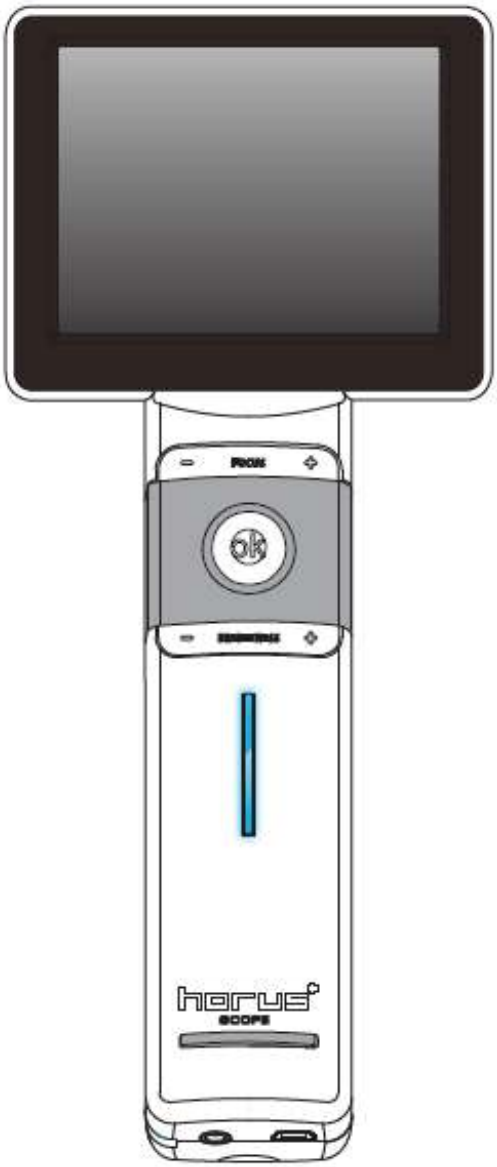

MiiS Horus Scope

DSC 300

User Manual

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Contents

Before use

Prior to installation and start-up of the Horus+ Scope, carefully read the user manual. As with all technical devices, the proper function and safety operation of this device depend on the user complying with the safety recommendations presented in these operating instructions. In addition, please make sure it does not appear damaged or broken. If there are breaks on the outer casing or other visual defects, please contact the manufacturer or a certified service facility.

⚠ This device to be sold and distributed, and it should be used only by or on the order of a physician in hospital or Clinic.

Camera handling

Protect the camera from excessive vibration, force, or pressure.

⚠ Avoid using the camera under the following conditions, which may damage the lens, the monitor, or the control unit and may also cause the camera to malfunction or prevent recording:

- Dropping or hitting the camera against a hard surface.
- Exerting excessive force on the lens or the monitor.

The camera is not dust resistant, splash resistant, or waterproof. Avoid using the camera in places with excessive dust or sand, or where water can come into contact with the camera.

⚠ Avoid using the camera under the following conditions, which present the risk that sand, water, or foreign material entering the camera through the lens or gaps around buttons. Be especially careful because these condition may dam- age the camera, and such damage may not be repairable:

- Operate in extremely dusty or sandy places
- Exposing the camera to rain or moisture

Focus calibration

A. Focus calibration of DEC 200

⚠ When using DEC 200 under the following conditions, focus calibration is necessary.

- The last four digits of the serial number of the control unit and optical lens do not match.
- The control unit or optical lens is used for the first time after it is returned from repair.

If focus calibration is not performed, the auto focus function may fail to work properly.

Condensation (when the lens or the monitor is fogged up)

⚠ Condensation may occur when the camera is exposed to sudden changes of temperature or humidity. Avoid these conditions because they may soil the lens or the monitor, cause mold, or damage the camera.

To ensure the quality and performance of image, calibrate the working distance of your DEA 200 **every month** is recommended.

⚠ If condensation does occur, turn off the camera and wait for about two hours before using it. Once the camera adjusts to the surrounding temperature, the fogging will clear naturally.

Safe eye screening

⚠ While no acute optical radiation hazards have been identified with the camera, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level necessary for diagnosis. Infants, aphakes, and persons with diseased eyes are at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument that uses a visible light source within the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography. The intended use of this device is for routine ophthalmic exams of typically less than 60 seconds per eye. While any medical procedure has its benefit versus risk factor, more complicated exams should not exceed three minutes of exam time within 24 hours. Significant use of this device beyond its intended use is not recommended as it may cause harm to the eyes.

⚠ During the operation of using the camera, please follow the below instructions.

- Always use the camera or accessories in accordance with the directions and recommendations contained in this user manual.
- When operating the device, please make sure that the optical lens does not touch the eyes or nose of the patient in order to avoid harm.
- For illumination and photography with the camera, do not select an exposure higher than required. Do not shine light on the eye beyond the recommended time during examination. Otherwise, the examined eye may experience pain or be injured.

No compensation for missed shots

⚠ We cannot compensate for missed shots if technical problems with the camera or card prevent recording.

Usage cautions and notes

Before use

⚠ The manufacturer specified performance criteria as below :
During the test, the EUT function will be abnormal and after test, the EUT's function can be resumed by operator was accepted. Unless basic safety and essential performance lost.

⚠ 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.

⚠ The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM may provide a description or list of equipment with which the ME EQUIPMENT or ME SYSTEM has been tested in a stacked or adjacent configuration and with which stacked or adjacent use resulted in normal operation.

⚠ All cables can only be used by the manufacturer or distributors. and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of IEC/ EN 60601-1-2 Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY).

⚠ 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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ In the above warning, "[ME EQUIPMENT or ME SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM.

When in use

⚠ The camera may become warm if used for long periods of time, but this is not its fault.

⚠ Keep the camera as far away as possible from electromagnetic equipment (such as

micro- wave ovens, TVs, video games, etc.).

⚠ Do not use the camera near radio transmitters or high-voltage lines.

⚠ Never leave the camera and the battery in a car or on a car hood in the summer. Doing so may cause leakage of the battery electrolyte, overheating, fire, or a battery explosion due to the high temperature.

⚠ If the fundus lens and control unit get wet, do not attempt to dry with a heater, microwave, autoclave, or UV light.

⚠ Do not extend the supplied cables. Do not keep the power cord near any heat source.

⚠ When the camera is not in use, please disconnect the power plug and keep it in a safe place.

⚠ In any operating conditions, the camera can be returned to the photo mode is regarded as the normal state.

Charging the battery

⚠ The time required for charging varies depending on the conditions of battery usage. Charging takes longer at high or low temperatures and when the battery has not been used for some time.

⚠ The battery will get warm during charging and for some time thereafter.

⚠ The battery will be drained completely if not used for long periods of me, even after being charged.

⚠ Only use Li-ion Battery 3.6V / Capacity 3350 mAh which shall be provided by the manufacturer or distributors. The battery has designed the protection circuit. To ensure the safety of the product operation, if the battery reaches its life time, please contact the manufacturer or distributor to buy the spare battery.

NOTE

The battery cannot be affected by external force impact. Its appearance cannot be damaged. If the battery is broken or damaged by external force, DO NOT USE to avoid dangerous.

Memory cards

⚠ If you purchase different memory capacity of SD card, must be preceded format to FAT32.

⚠ To prevent damage to cards and data:

- Avoid high temperatures, direct sunlight, electromagnetic fields, and static electricity.
- Do not bend, drop, or expose to strong impacts.
- Do not touch the terminals or allow them to become dirty or wet.
- When operating this device, please do not remove or insert the SD card.

When disposing of/transferring memory cards:

⚠ If using the “format” or “delete” functions on your camera or computer, this only changes the file management information and does not completely delete the data from the memory card. When disposing of or transferring your memory cards, we recommend physically destroying them or using commercially available computer data erasing so ware to completely delete the data from the card. Data on memory cards should be managed responsibly.

Accessories

About the Fundus Image Management System (L type), Model: SD 1:

⚠ The Fundus Image Management System is a software which can analyze op c nerve images shot by DEC 200.

⚠ It can estimate the relative amount of hemoglobin at different regions of the op c nerve, and other indexes such as Vertical Cup/Disc ratio, the Cup/Disc area ratio.

⚠ Please refer to the user manual of SD 1 for more details.

About the slit lamp jig:

⚠ Attach the slit lamp jig only to slit lamp equipment that has been qualified by MiiS. Make sure the jig is completely locked by pushing it downward.

⚠ The slit lamp jig is only suitable for DEC 200.

Protect i on

⚠ Do not attempt to remove the cover from the product to prevent the product from malfunctioning.

⚠ No modification of this device is allowed. The performance would be subject to any modification and may cause hazardous radiation exposure.

EMC (electromagnetic compatibility)

During installation and opera on of the device, observe the following instructions:

⚠ Do not use the device simultaneously with other electronic equipment to avoid electromagnetic interference with the operation of the device.

⚠ Do not use or stack the device near, on, or under other electronic equipment to avoid electromagnetic interference with the opera on of the device.

⚠ Do not use the device in the same room as other electronic equipment, such as life-support equipment that has major effects on the life of the patient and results of treatment, or any other measurement or treatment equipment that involves small electric current.

⚠ Do not use the system with portable and mobile radio frequency communication systems because that may have an adverse effect on the operation of the device.

⚠ Do not use cables or accessories that are not specified for the device because that may increase the emission of electromagnetic waves from the device and decrease the immunity of the device to electromagnetic disturbance.

⚠ Do not touch the lens connecting pins of the control unit or the signal pad of the lenses without special precautions.

Cleaning and Disinfection

The device is a precision photo electronic instrument that shall be handled with specific care. Please note the following cleaning instructions:

⚠ Turn off the device before cleaning it.

⚠ Disinfect the control unit and charging station with the so cloth with alcohol (75% ethyl alcohol). Wait for the cleaning liquid to dissolve before turning the power on and connecting the charging station and USB cable to the control unit.

⚠ It is recommended to clean the fundus lens with a cleaning cloth or lens cleaning tissue, such as THORLABS Inc. (www.thorlabs.com) lens cleaning tissue.

If a replacement for the eyecup or contact plate is needed, please contact the manufacturer or retailer. Clean the eyecup or contact plate before each use:

⚠ Disinfect the eyecup or contact plate with soft cloth moistened with alcohol (75% ethyl alcohol).

NOTE

The device is not intended to be sterilized. Disinfect the control unit and charging station with a soft cloth with alcohol (75% ethyl alcohol).

Maintenance

⚠ Please check control unit and optical lens once every 3 months.

It is the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on DSC 300 may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

Please note that the actual controls and components, menu items, and other information of your camera may differ from those in the illustrations provided in these instructions.

Operating Environment

- Ambient temperature: 10°C to +35°C
- Relative humidity: 30% to 90%
- Atmospheric pressure: 800hPa to 1013hPa
- Shock (without packing): 10 G, duration 6 ms

Environment for Storage

- Ambient temperature: -10°C to +55°C
- Relative humidity range: 10% to 95%

- Atmospheric pressure: 700 hPa to 1013 hPa

NOTE

It is recommended to remove the battery if the device is stored over two weeks.

Environment for Transportation

- Ambient temperature: -40°C to +70°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 500 hPa to 1013hPa
- Vibration, sinusoidal: 10 Hz to 500 Hz: 0.5G
- Shock: 30 G, duration 6 ms
- Bump: 10 G, duration 6 ms

NOTE

It is recommended to remove the battery if the device is stored over two weeks.

Regulations

- U.S. Federal law restricts this device to be sold and distributed, and it should be used only by or on the order of a physician in hospital.

- This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2: 2014. These limits are designed to provide reasonable protection against harmful interference in a standard medical installation. If this device does cause harmful interference to other devices, which can be determined by turning the system off and on, the user is encouraged to try to correct the interference through one or more of the following measures: Reorient or relocate the receiving device.
  - Increase the separation between the system and other devices.
  - Connect the device to an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer or field service technician for help.
- The International Electro technical Commission sets the essential requirements for electrical and electronic equipment that may disturb or be disturbed by other equipment. The device complies with these requirements as shown in the tables in “Symbols and standards: EMC”. Follow the guidance in the tables for use of the device in an electromagnetic environment.

Names of components

Scope of Delivery

Product Name	Model Name	Accessories
Control unit	MiiS Horus Scope DSC 300	1. Battery 2. Power adapter 3. Mini USB cable 4. Micro HDMI cable 5. Charging station 6. Micro SD card 7. Portable chin rest (Optional) 8. Image Management System, Model: SA 1 standalone (option) 9. Image Management System, Model: SB 1 (free download) 10. Image Management System, Model: SD 1 standalone (option)
Digital eye fundus camera	MiiS Horus+ Scope DEC 200	1. Eyecup 2. MiiS Horus Portable Chin Rest: CR 100 (Optional) 3. Slit lamp jig (Optional)
Digital eye anterior camera	MiiS Horus+ Scope DEA 200	1.Forehead
Digital eye surface camera	MiiS Horus+ Scope DGC 200	
Digital auto refractometer	MiiS Horus Scope DAR 100	

Intended for use

MiiS Horus+ Scope DEC 200 is a digital hand-held eye fundus camera used to record digital photographs and video of fundus (including retina, macula, and optic disc) of the human eye and surrounding area.

MiiS Horus+ Scope DEA 200 is a digital hand-held eye anterior camera used to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area

MiiS Horus+ Scope DGC 200 is the eye surface optical lens used to record digital photographs and video of anterior area of human eye and surrounding area.

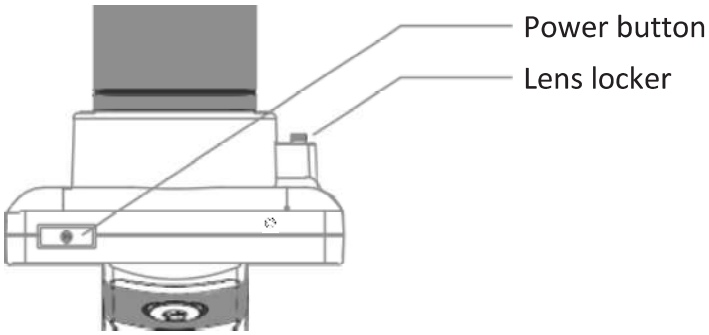
MiiS Horus Scope DAR 100 is the eye auto-refractometer used to measure and record the subject's refraction, pupil size and pupil distance.

It is the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on DSC 300 may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

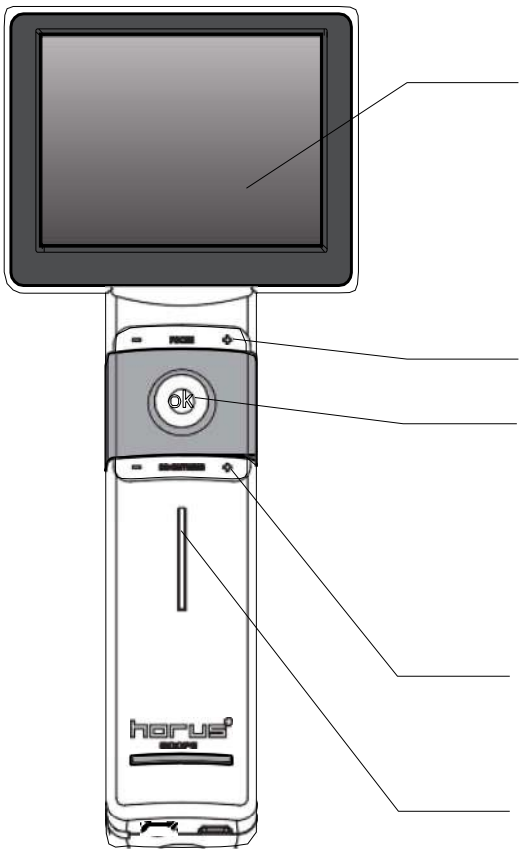
User interface

Control Unit (MiiS Horus Scope DSC 300)

Top view ››



Front view ››



3.5 ” LCD touch panel

Manual focus

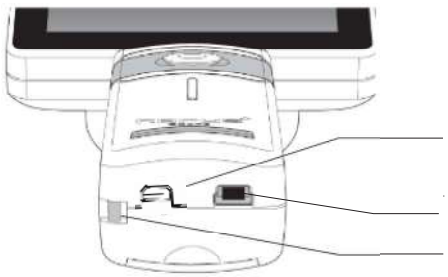
OK button:

- Completely press down to take a photo
- Back to photo/video mode while previewing photos

Brightness decrease/increase in photo mode

Power indicator

Bottom view ››

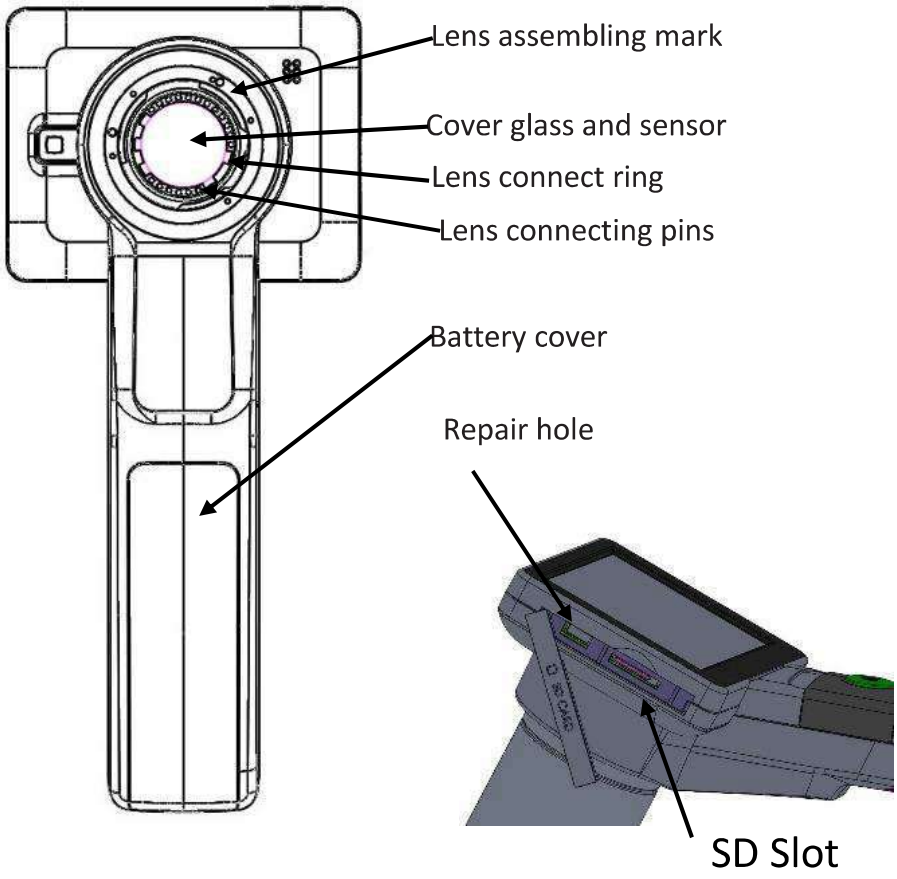


HDMI out

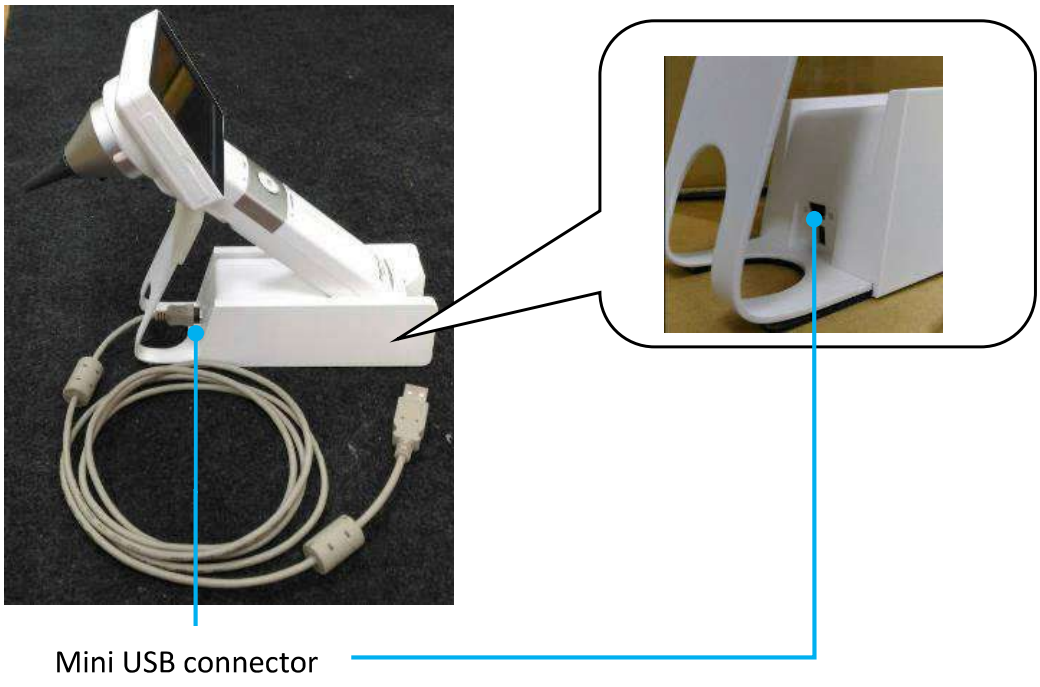
Mini USB

Strap hook

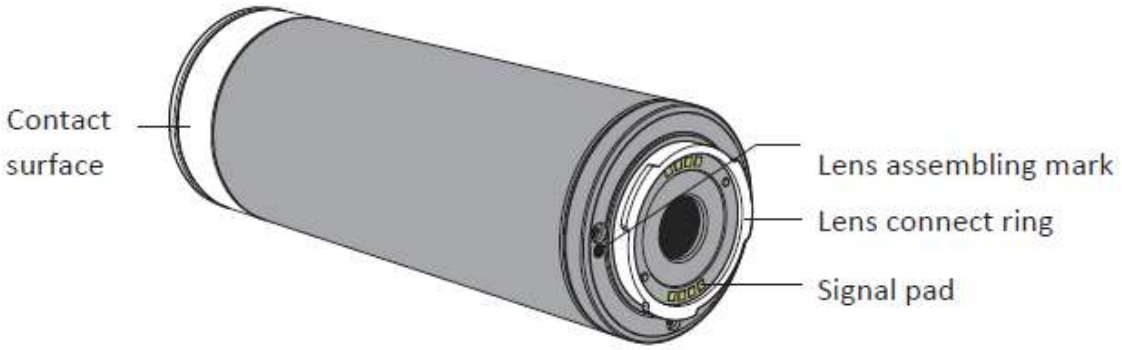
Rear view ››



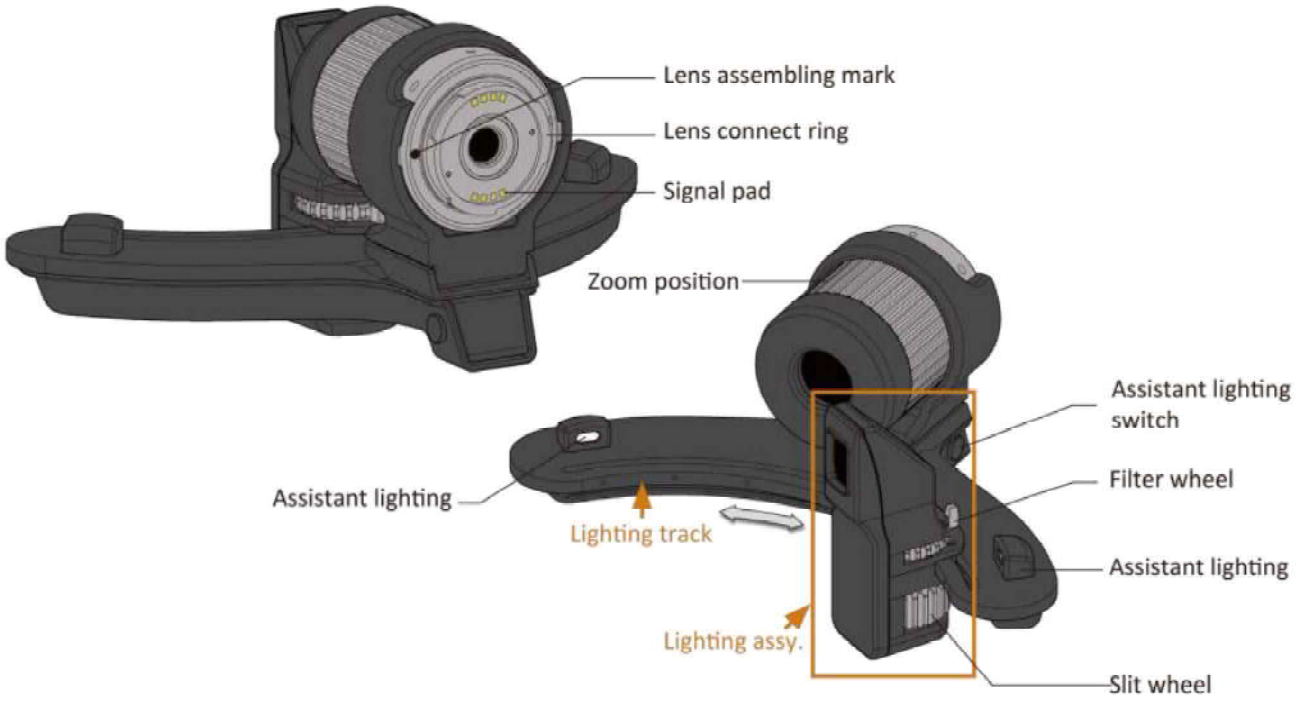
Charging Station



Optical Lens of MiiS Horus+ Scope DEC 200 (Digital Eye Fundus Camera)



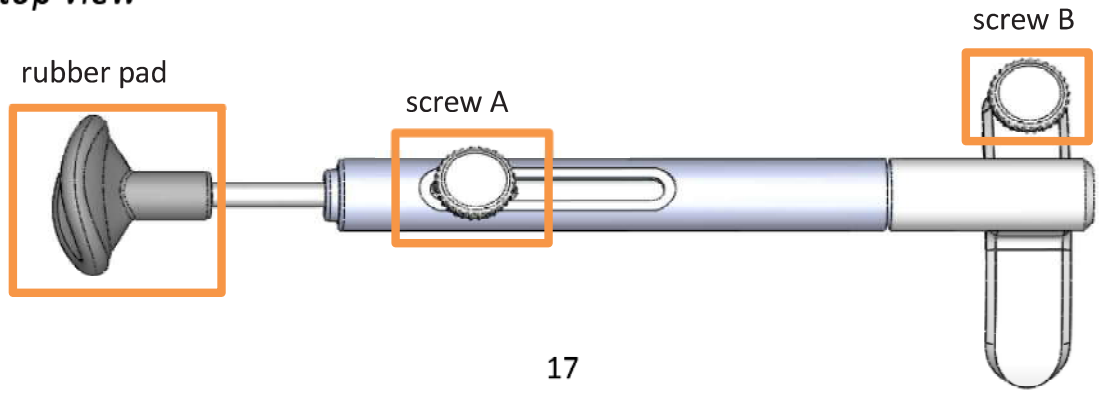
Optical Lens of MiiS Horus+ Scope DEA 200 (Eye anterior camera)



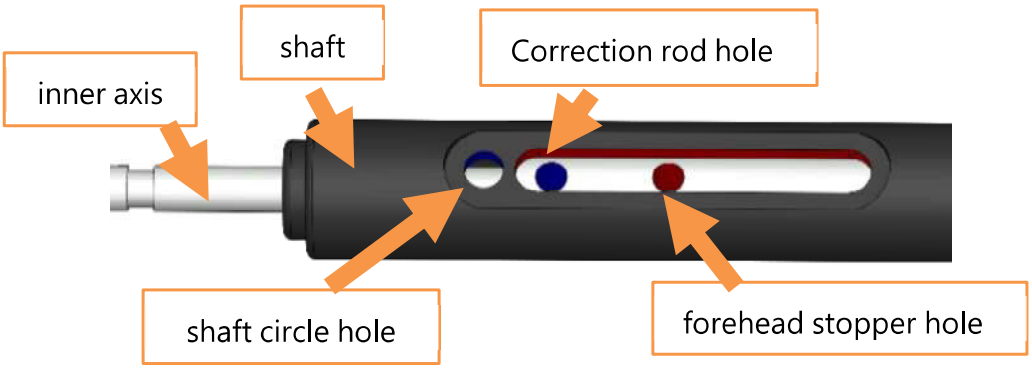
Calibration parts of MiiS Horus+ Scope DEA 200 (Eye anterior camera)

Forehead Stopper

top view



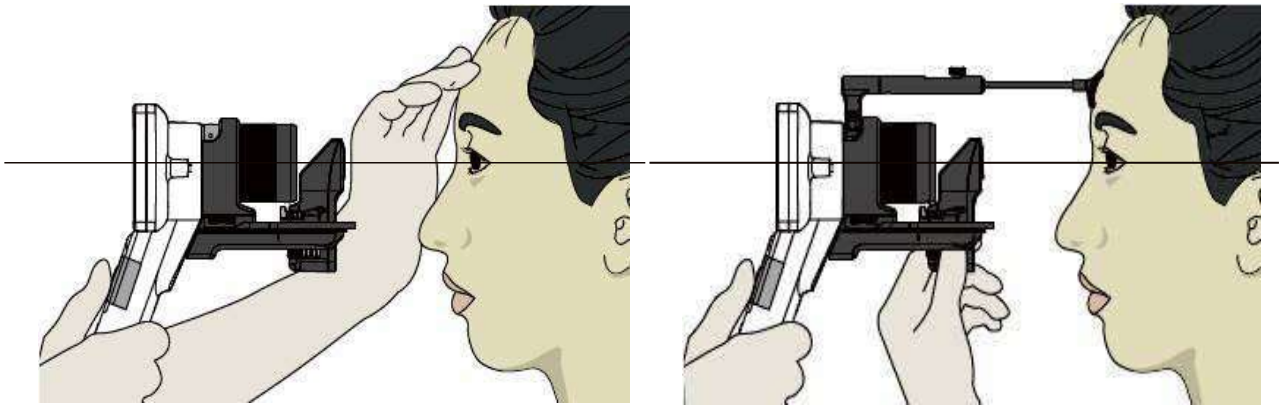
partial enlargement of stick



Correction Plate

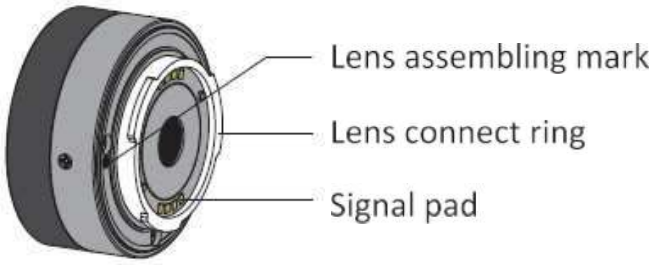
Holding position

Hold the control unit with one hand and use the other hand to hold the lighting track. Maintain the lens at the same height of the eye being examined. To stabilize the lens, rest the track on the part of the hand between the thumb and index finger and put your middle and index fingers on the examinee's forehead, as showed in the left image. Besides, using the accessory of forehead holder can replace the support on the examinee's forehead, as the below right image.

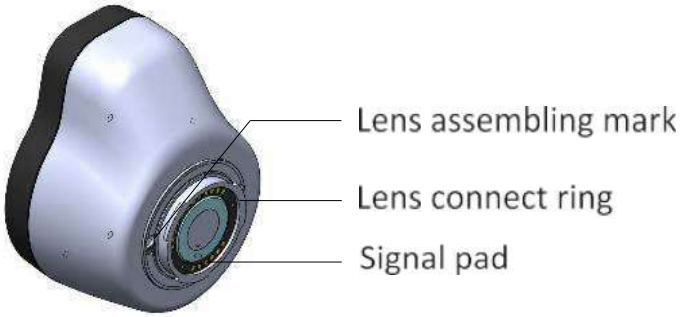


View the examined eye keeping the lens horizontal to the examined eye. Then move forward slowly until you can see the full exterior of eye in the controller screen. (For sanitary reasons, make sure the controller lens does not touch the patient's eyes or nose.)

Optical Lens of MiiS Horus+ Scope DGC 200 (Digital Eye Surface Camera)



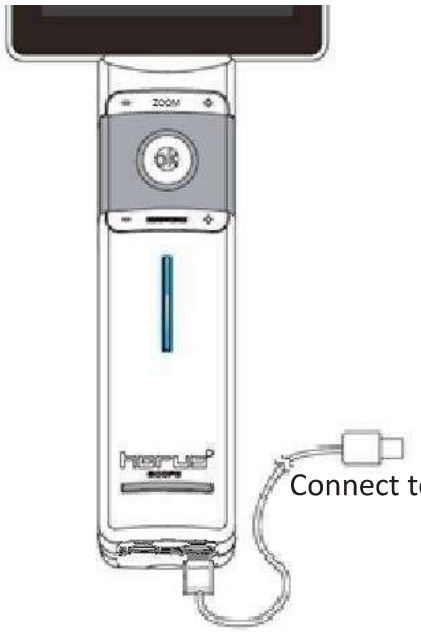
Optical Lens of MiiS Horus Scope DAR 100 (Digital Eye Auto-Refractometer)



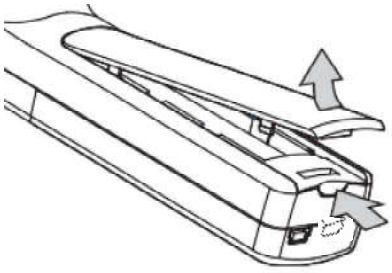
Charging the battery

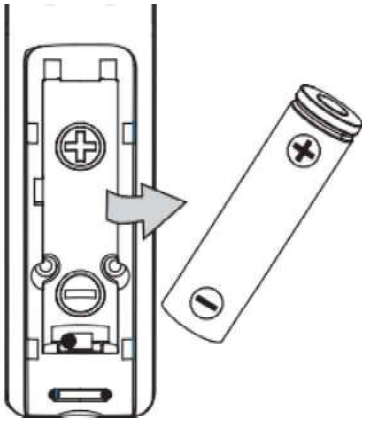
Always charge before first use

Prior to first use, insert the battery into the control unit and close the battery cover referred to the below section. Connect USB connector to the power adapter. Let the battery be charged for at least five hours.



Battery replacement

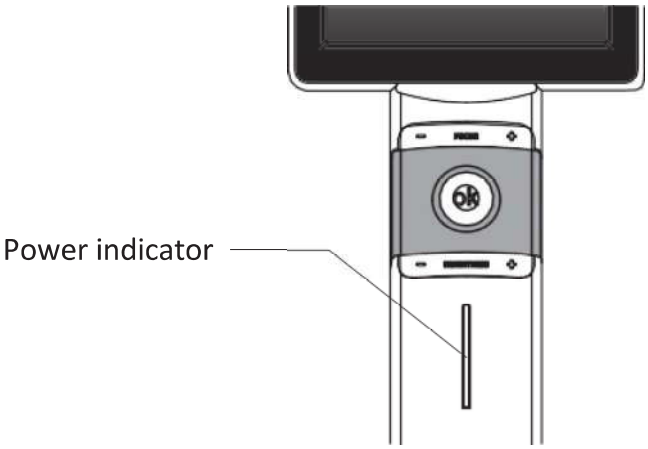




Open the battery cover by digging out the gap in the bottom of battery cover with a finger or something pointed.

- Tilt the battery cover and remove the battery cover by lifting it up.
- Remove the original battery and replace a new battery along the correct direction.
- Place the battery cover and secure it in place.

Power indicator



System Status	Power off			Power on		
Light color	No Light	Blinking blue Light	Orange Light	Blue Light	Blinking blue Light	Mixed blue and orange Light
						
Information	System off	Power less than 25%	Charging	Normal operation	Power less than 25%	Connect to PC via USB cable or enable USB live video