

Examination conditions of DEC 200

Examination conditions

After the optical lens, DEC 200 is attached to the control unit and setup is complete, the user can start taking images. Approaches for taking the image of human eye fundus are as follows:

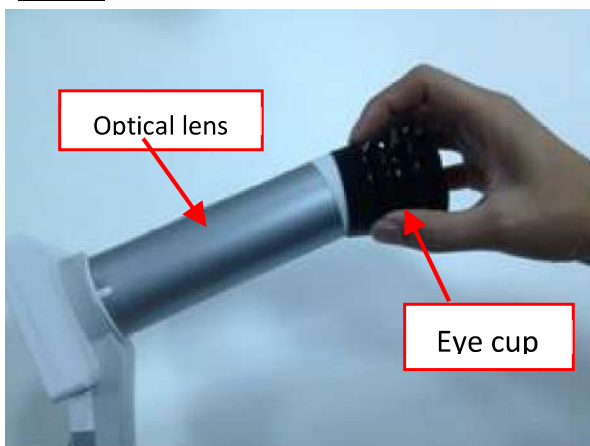
- Have the examinee stay in <5 lux dark room; in such an environment, a newspaper is nearly impossible to see. Remove the patient's glasses. Make sure that the eye's pupil has a diameter larger than 4mm, or be sure to sufficiently dilate in advance.

Eye Cup Installation

Step 1: Put the eye cup on the front of optical lens.

Step 2: If you want to change the direction of mask wing, one hand holds the lens, the other hand rotates mask to the direction you wanted. The idea is using the mask wing

Step.1

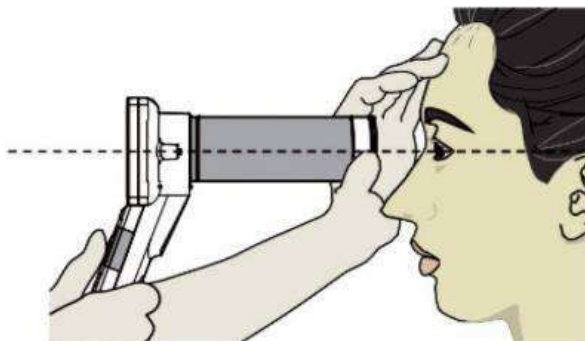


Step.2



Holding position

Holding the control unit with one hand and use the other hand to hold the front side of the lens. Maintain the lens at the same height of the eye being examined. To stabilize the lens, rest the lens 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 following image.

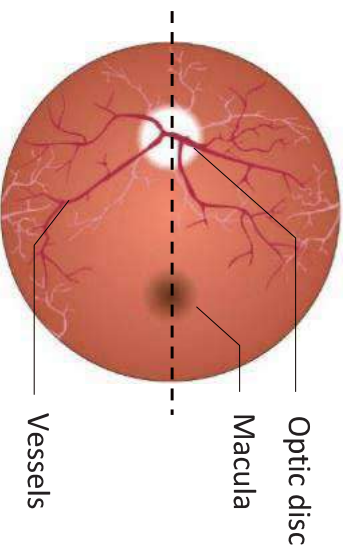


View the examined eye keeping the lens horizontal to the examined eye. Then move forward slowly until you can see the optic disk in the controller screen. (For sanitary reasons, make sure the controller lens does not touch the patient's eyes or nose.)

Q&A troubleshooting of DEC 200

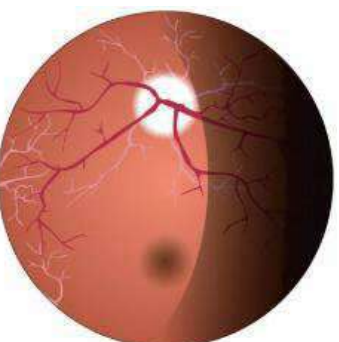
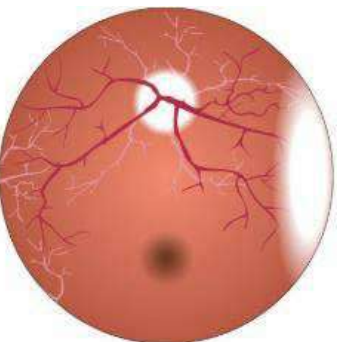
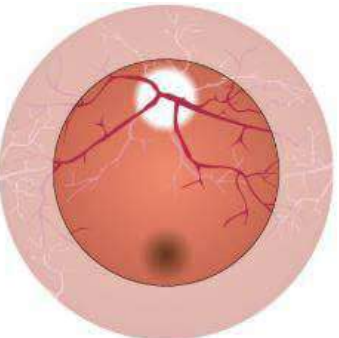
A good image should have two characteristics:

1. Positions
The macula and the optic disc are horizontally aligned in the middle.
2. High contrast
The macula, optic disc, and vessels are all clear.



If the above characteristics can't be found in the shot, possible failures might be the following:

- | | | |
|-----------------------|---|--|
| 1. Small fundus image | 2. White hot spot on the top of the image | 3. Dark shadow on the top of the image |
|-----------------------|---|--|

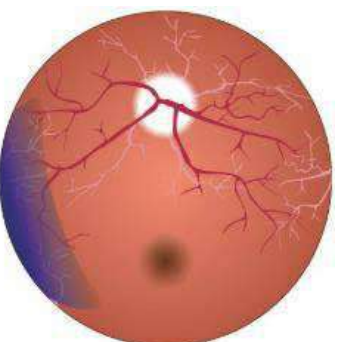
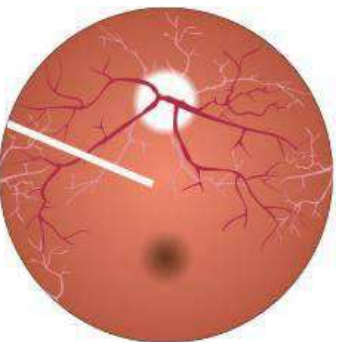
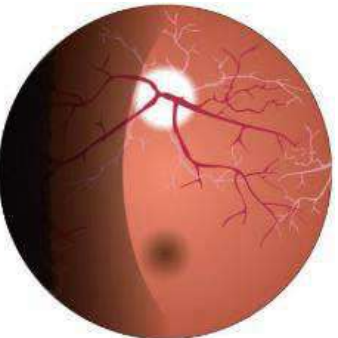


The lens is too far away from the examinee's eye.

The lens is too close to the examinee's eye.

The lens is much lower than the visual axis.

- | | | |
|---|---------------------------------|--|
| 4. Dark shadow on the bottom of the image | 5. Line or spot within the view | 6. Blue or white shadow on the bottom of image |
|---|---------------------------------|--|



The lens is much higher than the visual axis.

Eyelashes are in the light path.

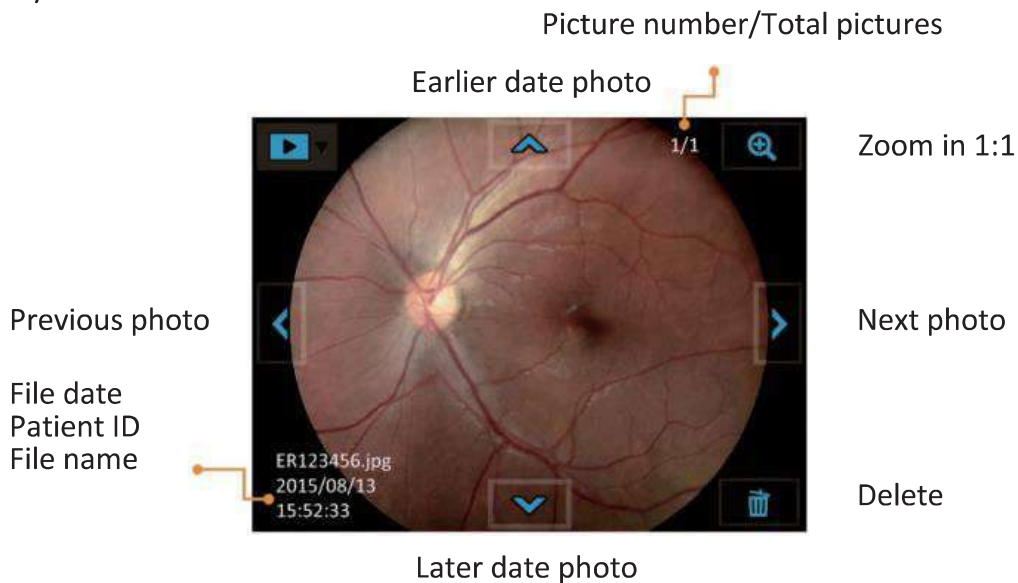
Cornea reflection

Playback

Display mode

Touch the photo icon and then the display icon to see the photos that have been taken.

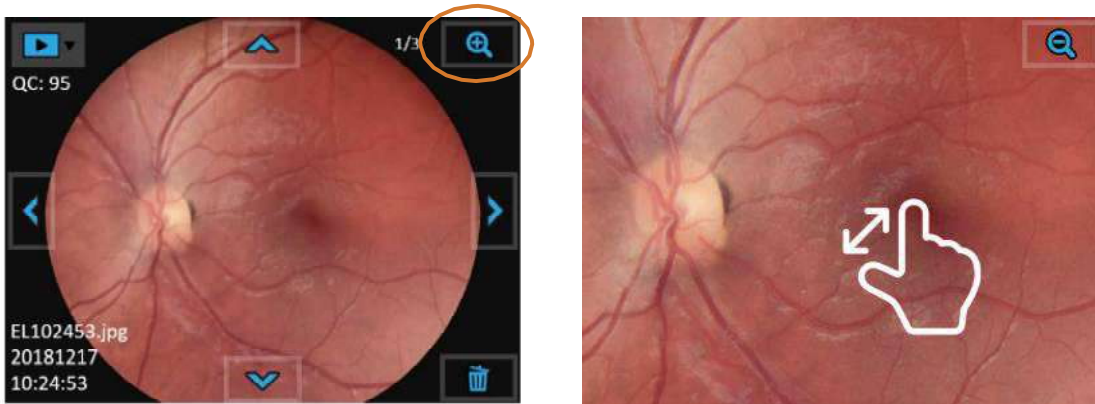
▶ Display mode:




Click the left or right arrow symbols to go to the previous or next photo, respectively. Click the up or down arrow symbol to backward in days or forward in days. Zoom in and out on the photo while in display photo. The user can delete photos by touching the delete icon.

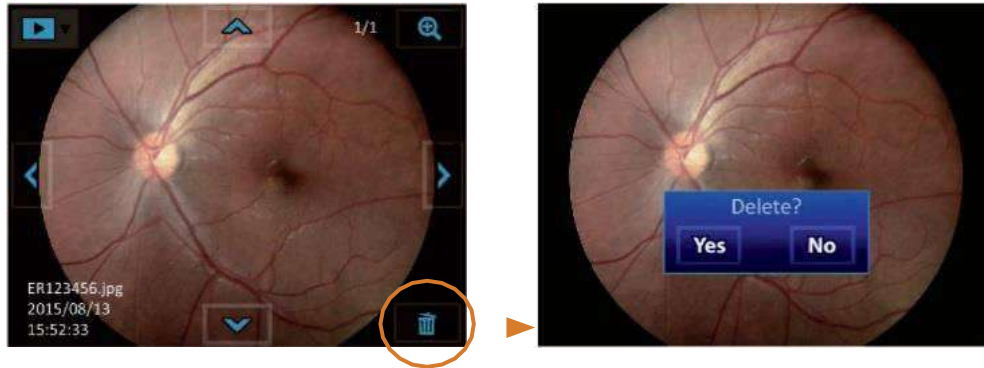
The device does not support the video file display on the control unit. Please download the video file (.avi) to the computer to watch.

Enlarged viewing



Click zoom in icon  and using two fingers to zoom in and out with pinching. Tap Zoom icon again to return the original scale.

Deleting pictures



Tap the delete icon to delete the image. By using the “delete” functions on your camera, this only changes the file management information and does not completely 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 software to completely delete the data from the card.

Miscellaneous

Files transferring

Transfer images to an electronic device (e.g., personal computer, laptop, or mobile phone) via the USB cable or SD card.

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.

Viewing on a computer/laptop screen

Turn on UVC mode to simultaneously view images both on LCD panel and the computer/laptop screen.

Viewing on a TV screen

Connect the camera and a TV through a Micro HDMI cable, you can simultaneously view live images on both sides.

UVC and HDMI

Photo mode:

When UVC was on and connected with the USB cable, HDMI will be turned off.

Video mode:

UVC and HDMI always be off.

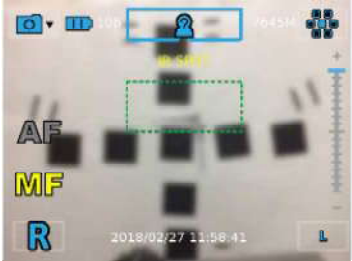
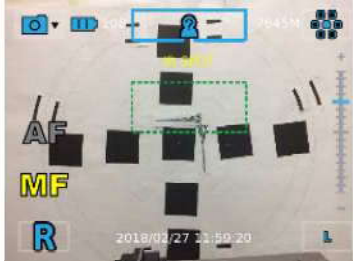
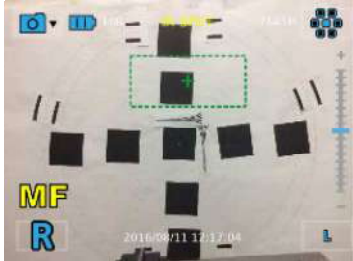

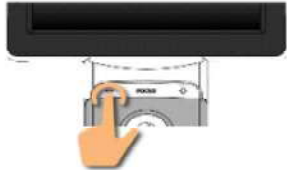

Preview and playback mode:

HDMI always be off. When UVC was on and connected with the USB cable, UVC will be on.

Focus calibration

A. DEC 200

Focus on an object at a distance of 5 meters or greater in MF mode. Please follow the steps to finish focus calibration of DEC 200.

Step 1	Step 2	Step 3
		
		
Adjust FOCUS[+] to max value.	Aim to a target 5M away. Decrease FOCUS value[-] till you have the clearest view of your target.	Long press the date and time till it changes to <u>"Save Motor Position"</u> to finish calibration.

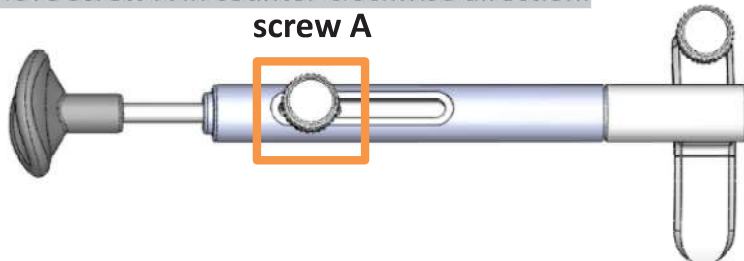
Caution: Please don't add [+] Focus value in step 2.

Please back to step 1 when you add Focus value accidentally.

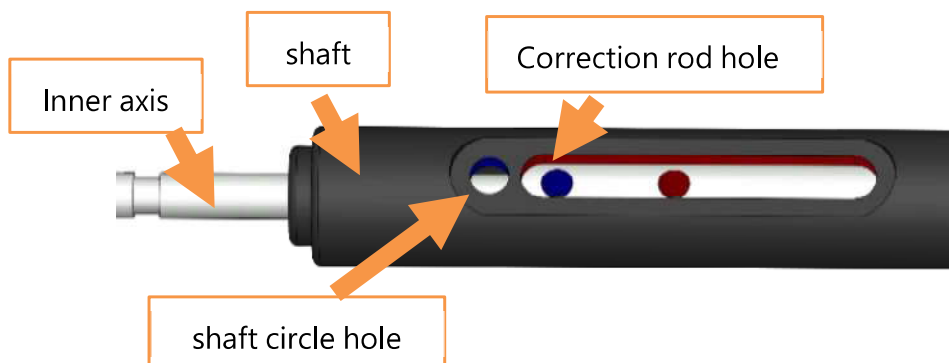
B. DEA 200

Assembling of Correction Rod

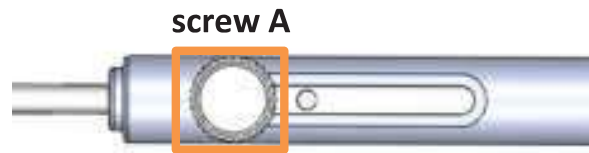
Step 1: Remove **screw A** in counter-clockwise direction.



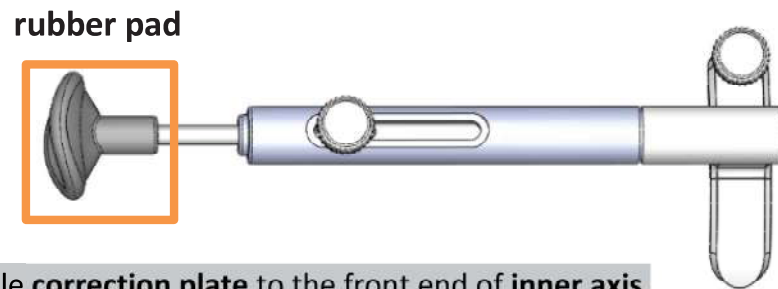
Step 2: Rolling the **inner axis** and the **shaft** to find out **correction rod hole**, then align the **shaft circle hole** with **correction rod hole**.



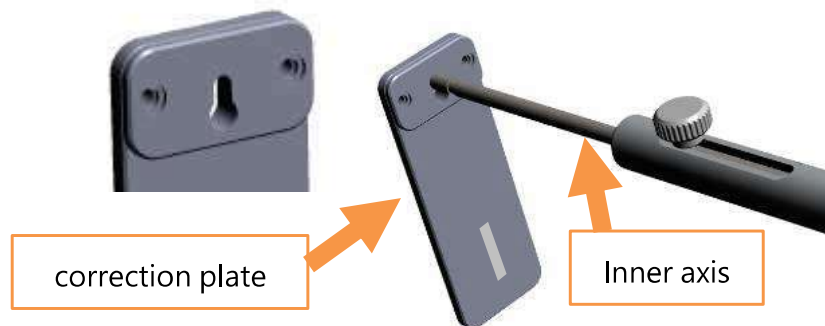
Step 3: Tighten **screw A** in clockwise direction to **correction rod hole** (under **shaft circle hole**).



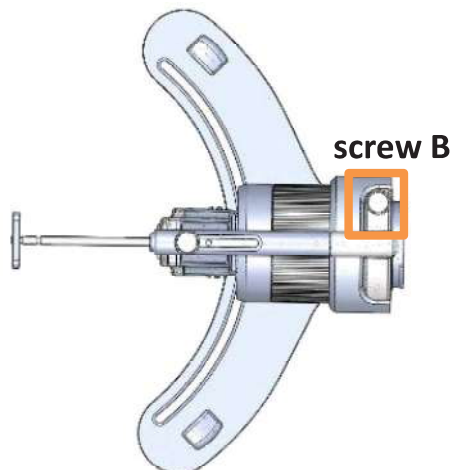
Step 4: Remove **rubber pad** of forehead stopper.



Step 5: Assemble **correction plate** to the front end of **inner axis**.



Step 6: Tighten screw B in clockwise direction to fix correction rod on DEA 200.



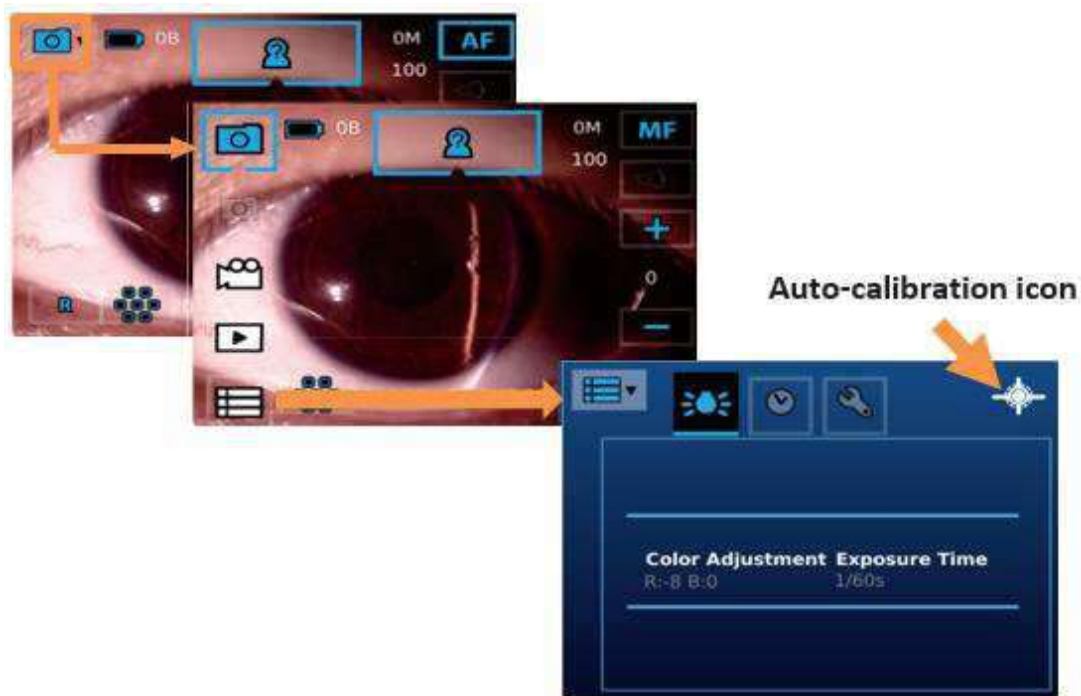
Sequence of Focus Calibration Operations

Step 1: Move Slit Module far away from Zoom lens. (more than 30 degrees)

Step 2: Rotate position of Zoom lens to Tele (16x) end.



Step 3: Enter to Auto-calibration mode by screen.



Step 4: Half press OK button to active auto focus function.

Check the image of correction rod on monitor.

If the image of correction rod is not clear, please loose your finger and half-press the button again



Miscellaneous

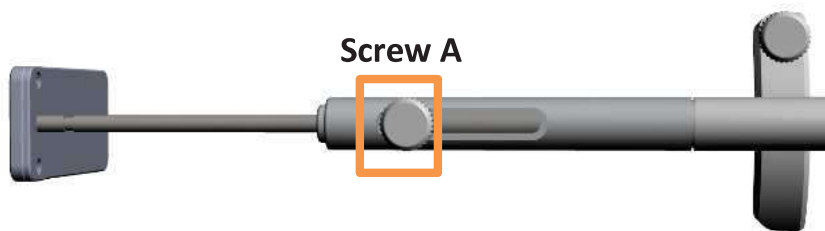
Step 5: Press date/time area on the screen for 3 seconds to save the working distance.



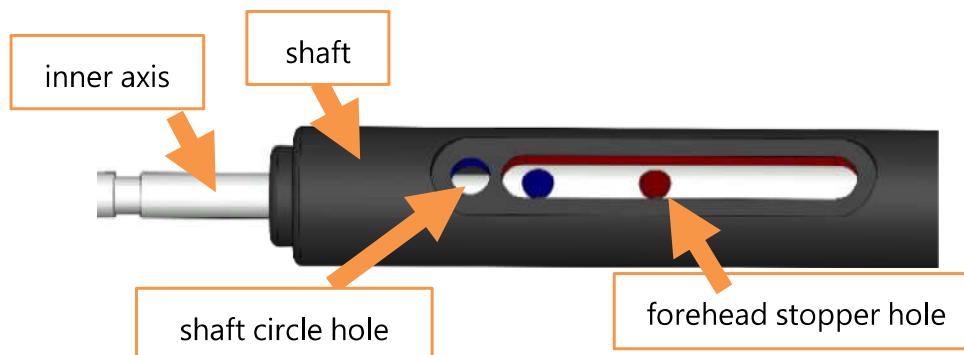
Step 6: Remove the Correction Rod and start to use the device with the best image quality.

Assembling of Forehead Stopper

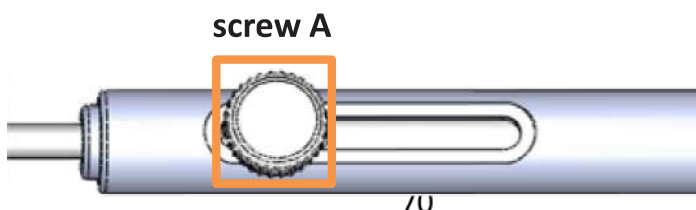
Step 1: Remove **screw A** in counter-clockwise direction



Step 2: Rolling the **inner axis** and the **shaft** to find out **forehead stopper hole**



Step 3: Tighten **screw A** in clockwise direction to **forehead stopper hole**.



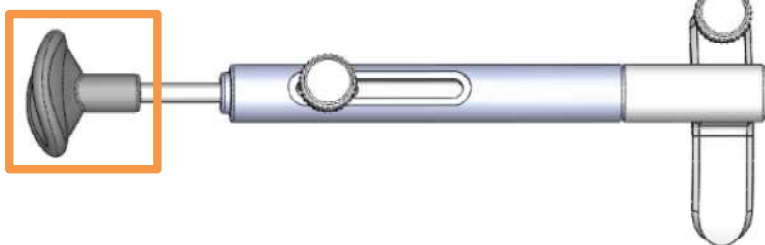
Step 4: Remove **correction plate** of correction rod.

correction plate



Step 5: Assemble **rubber pad** to the front end of **inner axis**.

rubber pad



Technical description

MiiS Horus+ Scope DEC 200, digital eye fundus camera:

- View Angle: 45 Degree (Typical)
- Diopter: -20 ~ +20D (Typical)
- Dimension: 20.1 x 9 x 20.3 cm (Typical)
- Weight: 450 Grams (Typical)
- Search Fundus Lighting: Two modes: natural white light-emitting diode (LED) or infrared LED.
Green LED for fixation.
- Camera/video flash light: Natural white LED

MiiS Horus+ Scope DEA 200, digital eye anterior camera:

- View Area: Wind End (H) 23.88*(V) 17.71 mm (typ.±5%)
Tele End (H) 11.88*(V) 8.91 mm (typ.±5%)
- Working Distance: 80mm (Typical)
- Illumination Angle: ±45 degree (typ.±5%)
- Slit Length: 10mm (typ.±10%)
- Slit Width: 0.2~10 mm
- Slit Width Selection: ≤0.2, 0.2, 0.5, 2.0, 5.0, Φ10 mm
- Filter: Transparent, cobalt blue, red-free (Green)
- Light: Conform to group II of ISO 15004-2:2007
- Weight: 580 Grams (Typical)

MiiS Horus+ Scope DGC 200, digital eye surface camera:

- View Angle: 21 Degree
- Dimension: 10.7 x 9 x 20.3 cm (Typical)
- Weight: 335 Grams (Typical)
- Camera/video light: Natural white LED or Blue LED

MiiS Horus Scope DAR 100, digital auto-refractometer:

- View Area: 122.88 mm x 92.16 mm
- Working Distance: 1000mm ± 5mm
- Dimension: 84 x 66 x 48 cm (Typical)
- Weight: 100 Grams (Typical)
- Camera light: Infrared LED
- Flash light: Natural Green LED

MiiS Horus Scope DSC 300, control unit :

Focus	Auto & manual focus
Picture Resolution	2560 x 1920 pixels
Video Resolution	2592x1944 pixels (5M) CMOS
LCD Monitor	3.5" TFT LCD, 230k pixels, 360 degree rotation
Image Format	JPEG (Photograph) and H.264 (Video)
Interface	Mini USB, HDMI, HDMI 2m
File Transfer	Mini USB Port to PC, USB 1.8m
Dynamic Video Output	Composite AV out, or USB live video enable from USB port
File Storage	Memory card, default 8GB. Supports 2 G to 32 GB by FAT32 Format.
Dimension	(L)202.5±5% x (W)89±5% x (H)88 ±5% mm
Weight	295±5% Grams
Power Source	Rechargeable Lithium Battery 3.6V / Capacity 3350 mAh
External Power	Source: 100~240 VAC, 50/60 Hz
Power Adapter Spec.	Input Spec.: 100-240Vac, 0.6-0.3A, 50-60Hz; Output Spec.: 5V DC, 1.2A
Charging station Input Spec.	5V DC, 1.2 A
Operating Time	Standby mode: 6 hours Operating mode: 2~4.5 hours (Depend on optical lens used)
Charging Time	6 hours by DSC 300
Expected service life (defined by manufacturer)	5 years from the date of initial operation *Proper maintenance is necessary.

Liability

Manufacturer considers itself responsible for the effects on safety, reliability, and performance of the device only if

- Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

Disposition



Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components, especially when disposing of the lithium ion battery, circuit board, plastic parts that contain brominated flame retardant, LCD, or power cord.



Follow the local governing ordinances and recycling plans when disposing of the circuit board with the lithium battery. Inappropriate disposal may contaminate the environment.



When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.



Inappropriate disposal may contaminate the environment.



When disposing of eyecup, follow the disposal procedures for medical waste such as needles, infusion tubes, and metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution.

Symbols and standards

Symbols



Caution must be taken. Read user manual before use.



Type BF indicates the device is classified as a device with a Type BF applied part.



The operator is advised to read the instructions of user manual.



Mandatory - Consult Directions for Use



Manufacturer



Date of Manufacture



Medical Prescription



CE mark



European Authorized Representative



Disposal of noncontaminated electrical and electronic equipment



This product had an internal rechargeable battery with a Class II power supply.

Standards

Electrical safety	IEC 60601-1:2005+A1:2012 (EN 60601-1:2006+A1:2013)
EMC and regulatory compliance	IEC 60601-1-2:2014 (EN 60601-1-2:2015)
Ophthalmic instruments-Fundamental requirements and test methods Part 2: Light hazard protection	ISO 15004-2:2007
Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	ISO 15004-1:2006
General radio compliance	Federal Communications Commission (FCC) Innovation, Science and Economic Development Canada's (ISED) National Communications Commission (NCC)

- Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible for the system complying with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

IC

Innovation, Science and Economic Development Canada

This device complies with Industry Canada licence-exempt RSS standard(s).

Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Innovation, Sciences et Développement économique Canada

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- (1) l'appareil ne doit pas produire de brouillage, et
- (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

NCC

第十二條

經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條

低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前項合法通信，指依電信法規定作業之無線電通信。

低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

FCC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

SAR

The device is designed and tested to meet the applicable limits for radio frequency (RF) exposure established by the Federal Communications Commission (U.S.A.) Specific Absorption Rate; (SAR) refers to the rate at which the body absorbs RF energy. The minimum allowable SAR distance is 5 mm, and the maximum allowable SAR limit is 4.0 W/kg, averaged over 10 gram of tissue for the device.

L'appareil est conçu et testé pour respecter les limites applicables aux fréquences radio (RF) exposition établie par la Federal Communications Commission (États-Unis).
Taux d'absorption; (SAR) fait référence à la vitesse à laquelle le corps absorbe de l'énergie RF.
La distance DAS minimale autorisée est de 5 mm et la limite DAS maximale admissible est de 4,0 W / kg, avec une moyenne de 10 grammes de tissu pour le périphérique.

EMC (Electromagnetic Compatibility)

The device complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2014) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in a Professional Healthcare Environment.


EMC (IEC 60601-1-2: 2014)

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A *1	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	*2	

*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A.
For the regions where the rated voltage is 127 V or less, this standard is not applicable.

*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard.
For the regions where the rated voltage is 127 V or less, this standard is not applicable.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles (50/60 Hz) 0% U_T for 250/300 cycles (50/60Hz)	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles (50/60 Hz) 0% U_T for 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m at 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	3 Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $E = \frac{6}{d} \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 


Test specifications for enclosure port immunity to RF wireless communications equipment						
Test frequency (MHz)	Band ^a MHz	Service ^a	Modulation ^b	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA400	Pulse modulation ^b 18 Hz	1.8	0.3	27
450	430-470	GMRS460, FRS460	FM ^c ±5kHz deviation 1 kHz sine	2	0.3	28
710	704 -787	LTE band 13,17	Pulse modulation ^b	0.2	0.3	9

Test specifications for enclosure port immunity to RF wireless communications equipment						
745			217 Hz			
780						
810	800-960	GSM 800/900, TETRA800, i DEN 820, CDMA 850, LTE Band 5	Pulse modulation ^b 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation ^b 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^b 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/ n	Pulse modulation ^b 217 Hz	0.2	0.3	9
5500						
5785						

^a For some services, only the uplink frequencies are included.

^b The carrier shall be modulated using a 50 percent duty cycle square wave signal.

^c As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.



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

The minimum separation distance for higher immunity test levels shall be calculated using the followin equation:

$$E = \frac{6}{d} \sqrt{P}$$

, where P is the maximum power in watts (W),d is the minimum separation distance in meters [m),and Fis the immunity test level in V/m.

Please visit www.miis.com.tw for more information.



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