

# Horus<sup>+</sup> Scope

Eye Anterior Camera

User Manual



## **Contents**

### **Preparation**

<i>Before use</i>	1
<i>Names of components</i>	3
<i>Charging the battery</i>	6
<i>Power indicator</i>	6
<i>Assembling</i>	8
<i>Using the Setup mode</i>	9
<i>Entering the patient ID</i>	12

### **Taking pictures**

<i>Sequence of operations</i>	14
<i>Photo mode</i>	15

### **Playback**

<i>Display mode</i>	16
<i>Enlarged viewing</i>	17
<i>Deleting pictures</i>	17

### **Miscellaneous**

<i>Files transferring</i>	19
<i>Viewing on a computer / laptop screen</i>	19
<i>Viewing on a TV screen</i>	19
<i>Usage cautions and notes</i>	19
<i>Technical description</i>	24
<i>Liability</i>	24
<i>Disposition</i>	24
<i>Symbols and standards</i>	25



## Preparation

### Before use

Prior to installation and start-up of the eye anterior camera, 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.

#### Eye anterior camera handling



Keep the camera away from excessive vibration, force, or pressure.



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

- Drop or hit the eye anterior camera against a hard surface.
- Exert excessive forces on the lens or the monitor.



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



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

- Operate in extremely dusty or sandy places.
- Expose the eye anterior camera to rain or moisture.

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



Condensation may occur when the eye anterior 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 eye anterior camera.



If condensation does occur, turn off the eye anterior camera and wait for about two hours before using it. Once the eye anterior 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 eye anterior camera DEA 200, 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 eye anterior camera, please follow the below instructions.

- Always use the eye anterior camera or accessories in accordance with the directions and recommendations contained in this user manual.
- When operating the device, please make sure that does not touch the eyes or nose of the patient in order to avoid harm
- For illumination and photography with the DEA 200, do not select a brightness 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 eye anterior camera or card prevent recording.

### Also refer to “Usage cautions and notes”

Please also refer to “Usage cautions and notes” for more instructions of the battery, SD card, etc.

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

## Names of components

### Scope of Delivery

Product Name	Model Name	Accessories
Eye anterior Camera	MiiS Horus <sup>+</sup> Scope DEA 200	1. Forehead Stopper 2. Correction Plate 3. User manual 4. Calibration Instruction

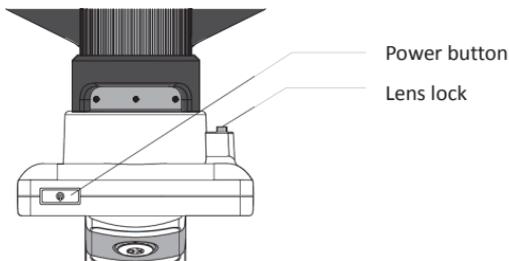
### Intended for use

MiiS Horus<sup>+</sup> 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.

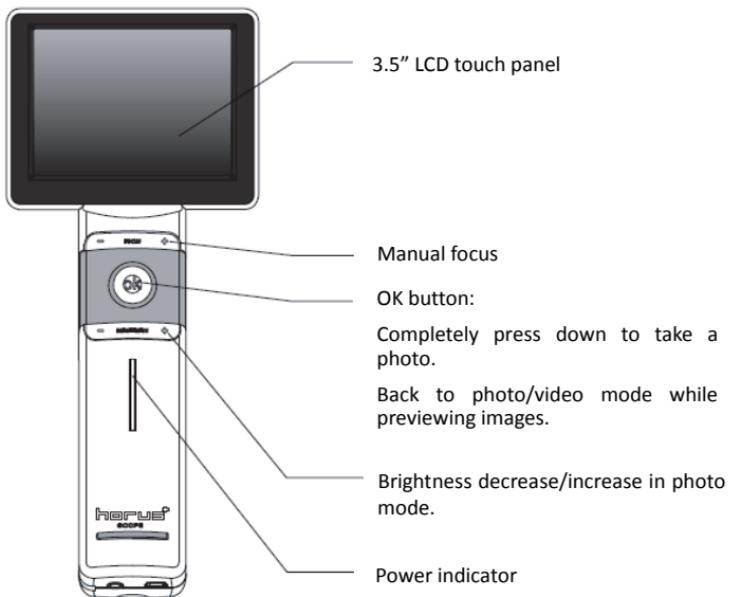
### User interface

#### *Control Unit (Horus<sup>+</sup> Scope DSC 200)*

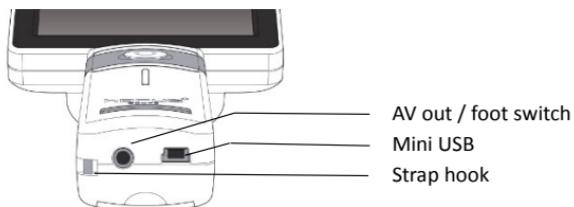
Top view »



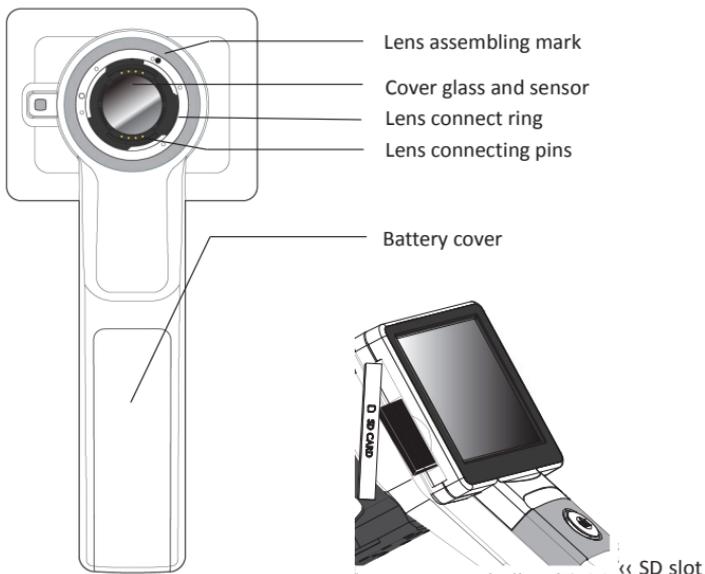
Front view >>



Bottom view >>



Rear view »



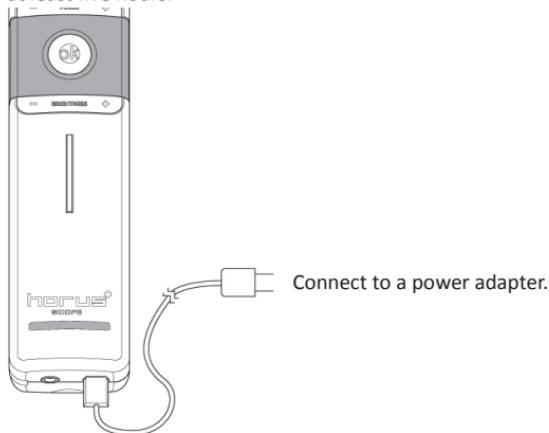
### Optical Lens of Horus+ Scope DEA 200 (Eye anterior camera)



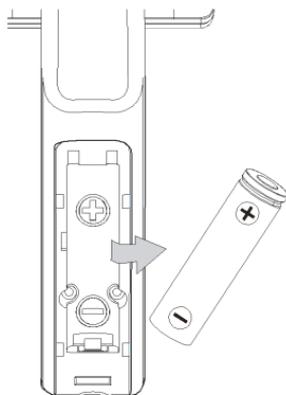
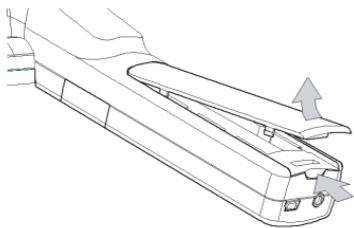
## Charging the battery

### 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.



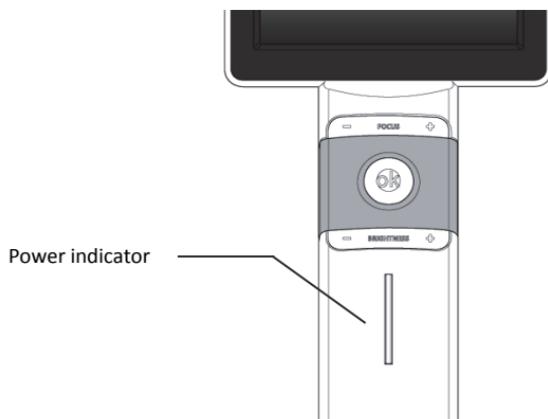
### Battery replacement



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

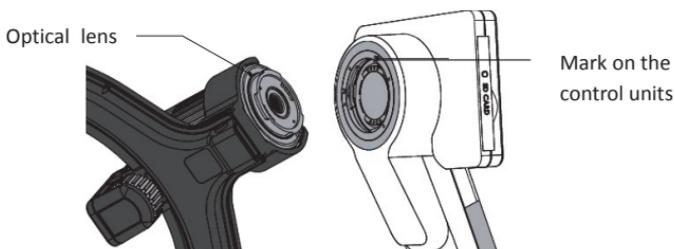


System Status	Power off			Power on		
Light color	NO Light	Blinking blue Light	Orange Light	Blue Light	Blinking blue Light	Mixed blue and orange Light
						
Information	System off	Power less than 25%	Charging	Normal operation	Power less than 25%	Connect to PC via USB cable or enable USB live video

## Assembling

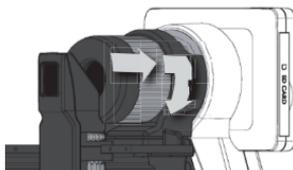
### Step 1. ↘

Align the marks of the optical lens and control unit.



### Step 2. →

Hold the optical lens and attach it to the control unit. Rotate and fasten the optical lens in a clockwise direction. You will hear a click when the lens locks into the control unit.

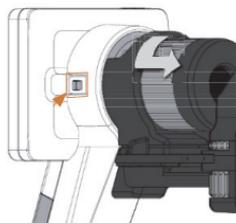


### Step 3. ←

Turn on the power. When optical lens and control unit are assembled correctly, the information icons will appear on the top of LCD touch panel. The screen will turn on, and then the blue light of the power indicator will also turn on.

### Step 4. →

To unlock the optical lens, press the lens lock and then rotate the optical lens in a counterclockwise direction. Then the optical lens will be unfastened.



## Using the Setup mode

### Turn on the power

To turn on the system, press the power button to turn on the control unit. Approximately one to two seconds later, the boot screen will appear on the LCD panel.



#### Note:

When below conditions occur, user needs to turn off the power and reassemble the optical lens and control unit.

1. Optical lens isn't correctly assembled to the control unit.  
→ When turning on the device, the device will stay at boot screen and can't enter to control interface.
2. The black screen appears on the LCD panel during operation.  
→ Please check the optical lens is well-assembled to the control unit.

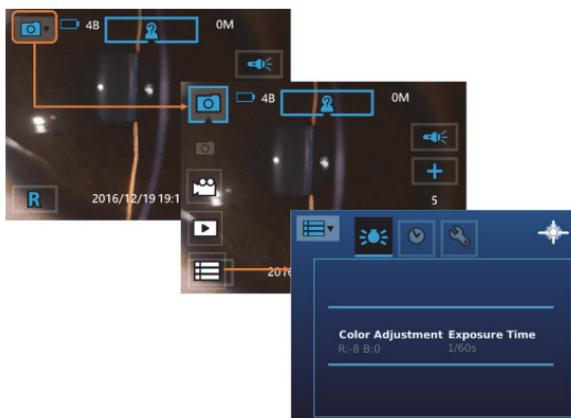
### Enter the Setup mode

Using the [Setup] menu

It is recommended that all setting items are set according to user's requirements for first-time use.

### Bring up the [Setup] menu

Touch the photo icon and then touch the setup icon.



## Exit the [Setup] menu

Once a setting adjustment is made, the new value affects the system immediately. Use the upper back button  or the OK button to exit the screen.

## Setting

### [Background Illumination]

User can turn on/off and adjust brightness of the background illumination by icon in live view mode. The brightness levels are between 0B to 5B.



### [Exposure time/Color]

User can adjust Exposure time/Color setting by touching the corresponding column

1. Exposure time from 1/30" to 120". (Default: 1/60")
2. Color adjusting range from 0 to 20. (Default: R:3, B:15)



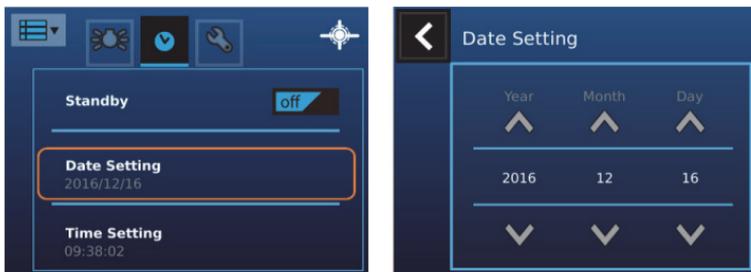
### [Standby]

User can set standby mode to be on or off. Once the mode is on, the LCD panel will be turned off if the system is idle for three minutes. Tap on the item to toggle the setting.



### [Date Setting]

User can change the current date setting from the screen.



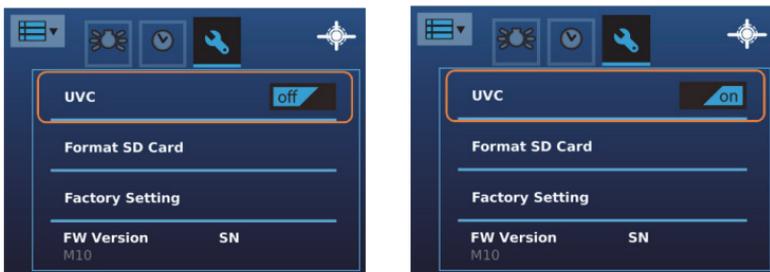
### [Time Setting]

User can change the current time setting from the screen.



### [UVC]

When you connect DEA 200 to a computer via USB cable, the product works as a USB storage device. If UVC mode is on, pictures can be shown both on the LCD panel of the product and the screen of the computer. To display image on the computer, please install webcam application prior to enabling UVC mode. A freeware webcam application (e.g., Horus UVC view, provide by MiiS) is a software that can receive UVC signal on the computer. User can search for relevant information over the Internet.



### [Format SD Card]

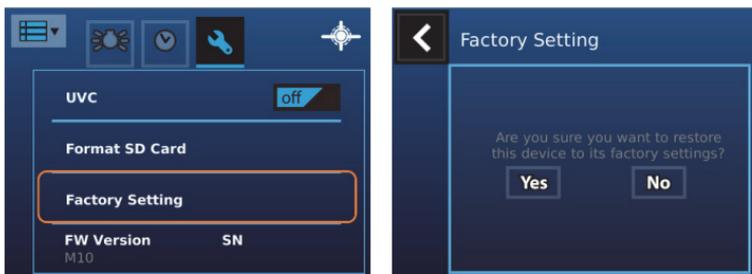
User can format the SD card.



NOTE: All information will be deleted after SD card is formatted.

### [Factory Setting]

User can recover the device to its factory settings.



## Entering the patient ID

Using patient ID as partial file name is supported in DEA 200.

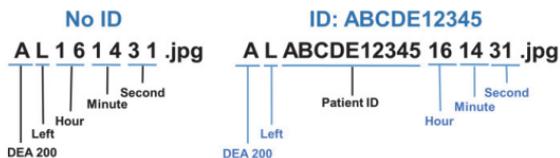
### File naming rule

	Model Name	Picture Name without ID	Picture Name with ID
Eye anterior camera	DEA 200	ALHHMMSS.jpg ARHHMMSS.jpg	ALXXXXXXXXXHHMMSS.jpg ARXXXXXXXXXHHMMSS.jpg

### Meaning of each symbol:

Symbol	Meaning
AL	Left eye photo taken by the eye anterior camera
AR	Right eye photo taken by the eye anterior camera
HH	Hour
MM	Minute
SS	Second
XXXXXXXXXX	Patient ID, up to 10 characters.

Example:



The image name is explained as follows:

AL: Left eye photo taken by the eye anterior camera at 16: 14 and 31 second.

If the given patient number is ABCD12345, the image name would be written as **ALABCD12345161431.jpg**.

### Create a new patient ID from scratch

By gently pressing the OK button, the user always goes back to a shooting mode, either photo or video mode; from the top information icons, tap  to start the process.



## Taking pictures

### Sequence of operations

#### Step 1: Turn on the power

Press the power button to turn on the control unit. Approximately one to two seconds later, the boot screen will appear on the LCD panel. After about 15 seconds, the information icons will appear on the top of the LCD panel.

#### Step 2: Make sure SD card is inserted

Once the SD card has been inserted, the user can start to take photographs in any shooting mode, either photo or video mode.

#### Step 3: Choose a shooting mode

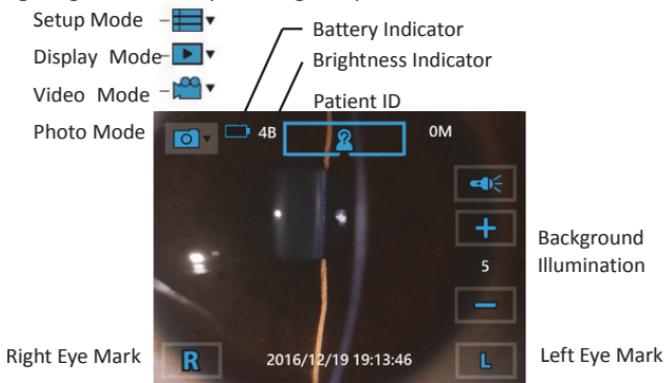
Tap the photo or the video mode icon to enter a shooting mode.

#### Step 4: Select slit shape and color filters

Select slit shape and color filters by rotating wheels on slit module.

#### Step 5: Aim and preview

Position the camera correctly and adjust to appropriate settings to get a clear preview. The image brightness can only be changed in photo mode.

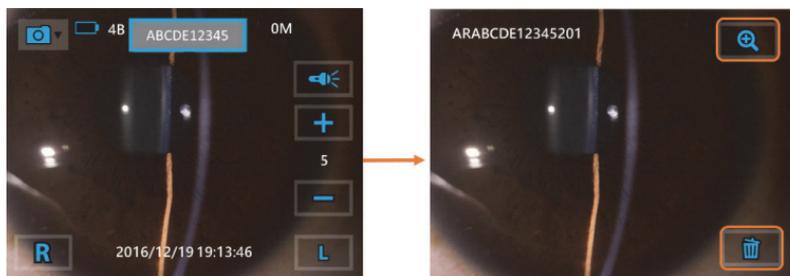


#### Step 6: Press the OK button to shoot

## Photo mode

The device's default setting is "photo mode." The user can take a picture or video in "photo mode" or "video mode," respectively.

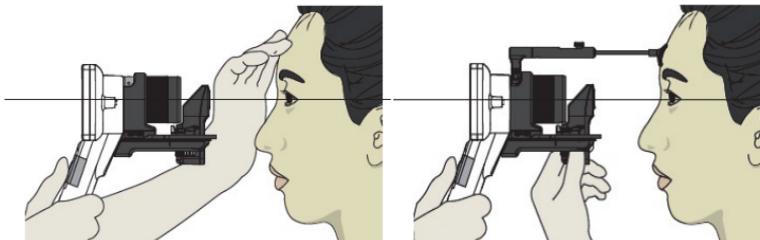
Photo mode: Press down the OK button halfway to do auto-focus or press "focus key" to do manual focus; press it all the way to take a still picture. The screen will show the image you just take, user can zoom in/out for detail check and also delete it, until press OK button to go back live view mode.



To adjust the brightness of the image, user can press the background illumination brightness adjustment icons. The higher value you set, the brighter image you get. Image brightness adjustment range:

### 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.



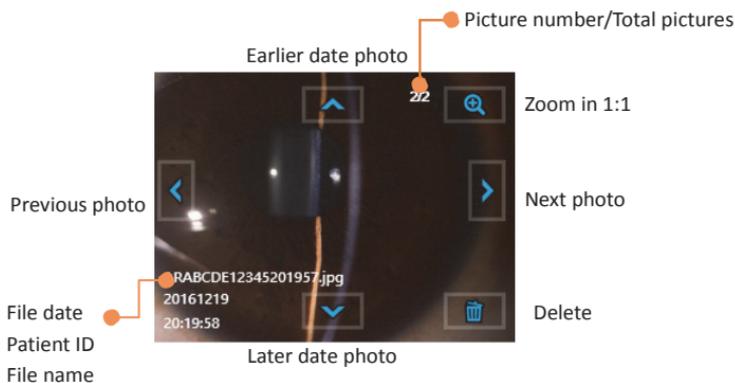
View the examined eye keeping the lens horizontal to the examined eye. Then move forward slowly until you can see the full exterior of eye in the controller screen. (For sanitary reasons, make sure the controller lens does not touch the patient's eyes or nose.)

## Playback

### Display mode

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

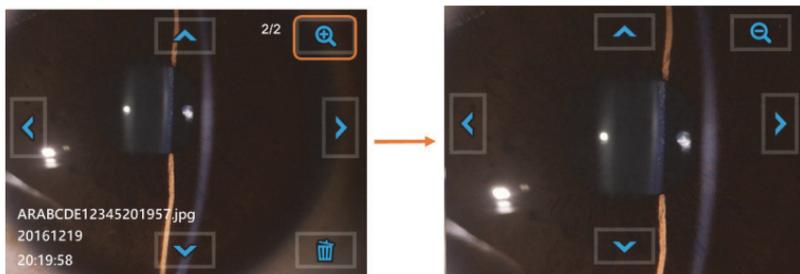
 **Display mode:**



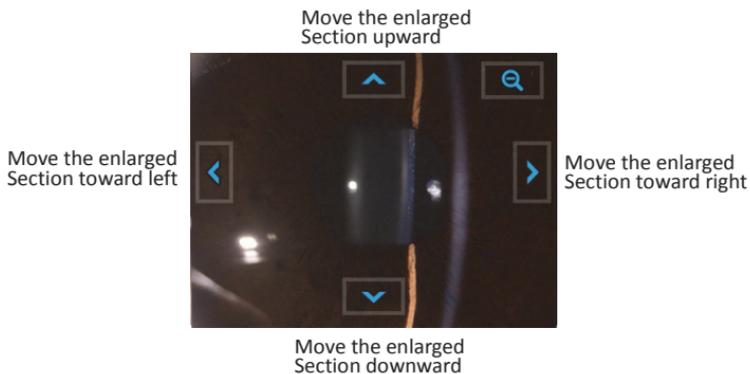
Click the left or right arrow symbols to go to the previous or next photo, respectively. Click the up or down arrow symbol to backward in days or forward in days. Zoom in and out on the photo while in display photo. The user can delete photos by touching the delete icon.

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

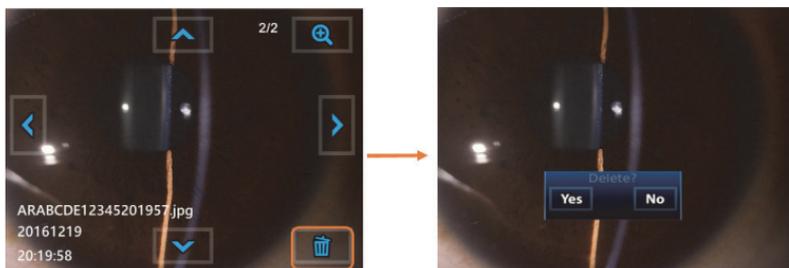
## Enlarged viewing



After the image is enlarged (1:1), the arrows would work as pan functions. 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

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 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.

### 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 an AV cable, you can simultaneously view images on both sides.

### Usage cautions and notes

#### 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 optical 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.

#### 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 time, 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 lifetime, please contact the manufacturer or distributor to buy the spare battery.

#### NOTE



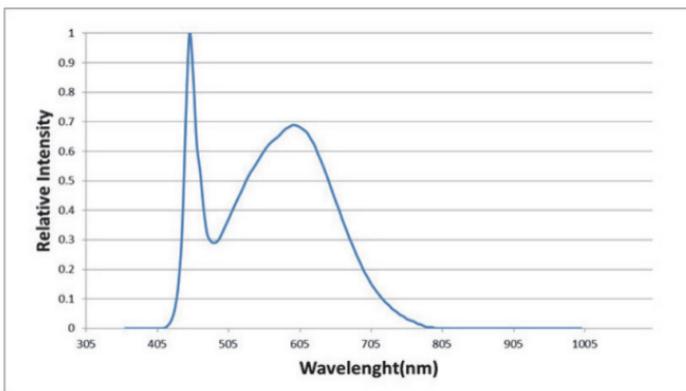
- The battery cannot be affected by external force impact. Its appearance cannot be damaged.
- If the battery is broken or damaged by external force, DO NOT USE to avoid dangerous.
- When installing the battery, DO NOT put the positive electrode into the battery first, then press the negative electrode into the battery groove. This may damage the battery and cause short circuit.
- Press the battery evenly to put it into the battery groove.
- Please DO NOT apply excessive force when installing the battery.

#### Optical Radiation hazard



“CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 60 seconds.”

#### RELATIVE SPECTRAL DISTRIBUTION OF ILLUMINATION LIGHT



#### Memory cards



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

## NOTE



Please do not draw out memory card when you capture images or record video.



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 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 software to completely delete the data from the card. Data on memory cards should be managed responsibly.

## Accessories

About the foot switch:



The foot switch is not waterproof.

Avoid subjecting the foot switch to vibration or shock.

- Avoid using the foot switch in a dusty environment.

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.

## Protection



- 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 operation 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 operation 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 the 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 soft 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 optical lens with a cleaning cloth or lens cleaning tissue, such as THORLABS Inc. ([www.thorlabs.com](http://www.thorlabs.com)) lens cleaning tissue.
- If a replacement for the eyecup is needed, please contact the manufacturer or retailer. Clean the eyecup before each use:
- Disinfect the eyecup 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).

### Operating Environment

- Ambient temperature: 10°C to +35°C
- Relative humidity: 30% to 90%
- Atmospheric pressure: 800hPa to 1060hPa
- 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 1060 hPa

### Environment for Transportation

- Ambient temperature: -40°C to +70°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 500 hPa to 1060 hPa
- 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, DEA 200, to be sold and distributed, and it should be used only by or on the order of a physician.
- 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.

## Technical description

<b>Image System Specification (Zoom Lens)</b>	
View Area	Wide End (H)23.88*(V)17.71mm(typ. $\pm 5\%$ )
	Tele End (H)11.88*(V)8.91mm(typ. $\pm 5\%$ )
Working distance	80mm
Focus Range	Typical working distance: 80mm
Resolution at Object space	50 lp/mm at Tele end
	20 lp/mm at Wide end
<b>Illumination System Specification (Slit Illumination)</b>	
Illumination Angle (degrees)	$\pm 45$ degree (+/- 5%)
Slit Length(mm)	10 mm (+/- 10%)
Min Slit Width (mm)	$\leq 0.2$ mm
Max Slit Width (mm)	Equal to slit length. (10mm)
Slit Width Selection	$\leq 0.2, 0.2, 0.5, 2.0, 5.0, \phi 10$ mm
Parallelism	$\leq 0.5$ degrees (at slit size $0.2 \times 10$ mm)
Filter	Transparent, Cobalt Blue, Red-free(Green)
Light	Conform to Group II of ISO 15004-2:2007
Weight	0.58kg (typ. $\pm 5\%$ , with Control Unit)

## 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.



Manufacturer



Date of Manufacture



CE mark



European Authorized Representative



This product has 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



- 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.

### 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 an electromagnetic environment.

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

<b>Guidance and manufacturer's declaration electromagnetic emissions</b>		
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 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC 61000-3-2	Class A	
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.

<b>Guidance and manufacturer's declaration electromagnetic immunity</b>			
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	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, 2kV Line to ground	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2kV 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% UT for 0.5 cycle (1 phase) 0% UT for 1 cycle 70% UT for 25/30 cycles (50/60 Hz) 0% UT for 250/300 cycles (50/60 Hz)	0% UT for 0.5 cycle (1 phase) 0% UT for 1 cycle 70% UT for 25/30 cycles (50/60 Hz) 0% UT for 250/300 cycles (50/60 Hz)	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 (50/60 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.			

<b>Guidance and manufacturer's declaration electromagnetic emissions</b>			
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.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment guidance</b>
Conducted RF IEC 61000-4-6	3Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	3Vrms (V1=3) at 0.15 – 80 MHz & 6V at ISM Frequency	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. Recommended separation distance $d=(3.5/V1) \sqrt{P}=1.2 \sqrt{P}$ (150 kHz to 80 MHz) $d=(3.5/E1) \sqrt{P}=1.2 \sqrt{P}$ (80 MHz to 800 MHz) $d=(7/E1) \sqrt{P}=2.3 \sqrt{P}$ (800 MHz to 2.7 GHz) 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m (E1=3) 80 MHz to 2.7 GHz 80% AM at 1 kHz	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above 3 V/m, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

### Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150KHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.







# horus

SCOPE