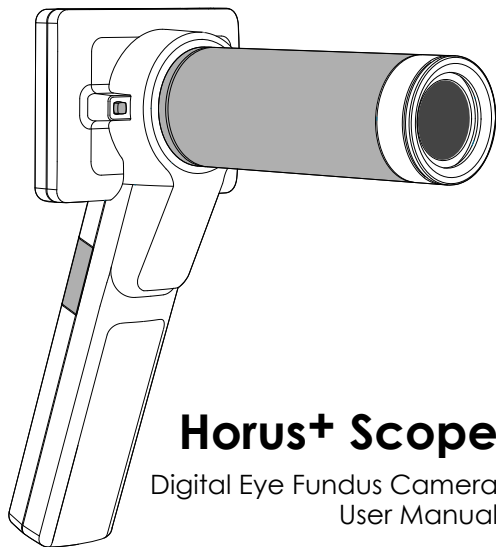




Horus+ Scope

Digital Eye Fundus Camera
User Manual

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Preparations

Before use

Prior to installation and start-up of the digital eye fundus 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.

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 conditions may damage the camera, and such damage may not be repairable:

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

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.

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 EZ-Horus 45, 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 EZ-Horus 45, 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.

Also refer to “Usage cautions and notes”

Please also refer to “Usage cautions and notes” (→ 29) for more instructions of the battery, SD card, etc.

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.

Names of components

Scope of Delivery

Product Name	Model Name	Accessories
Digital eye fundus camera	Horus+ Scope EZ-Horus 45	1. Eyecup 2. Battery 3. Power adapter 4. USB cable 5. AV cable 6. Charging station 7. SD card 8. Foot switch (Optional part) 9. Slit lamp Jig (Optional part)

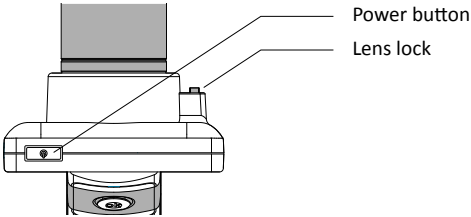
Intended for use

Horus+ Scope EZ-Horus 45 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.

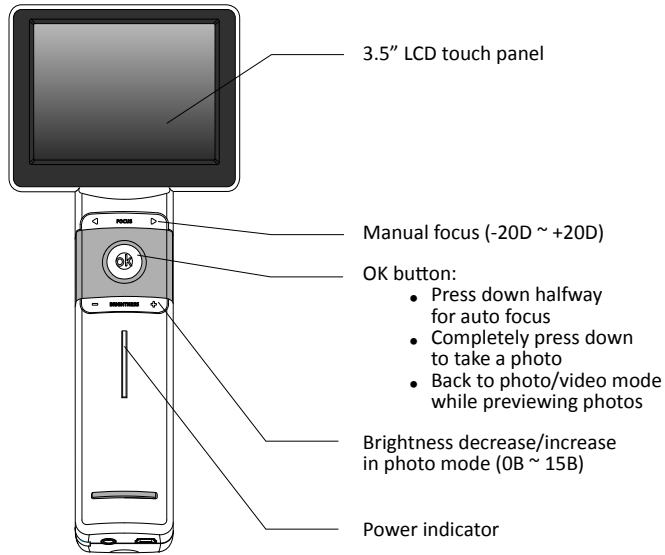
User interface

Control Unit (Horus+ Scope EZ-Horus 45)

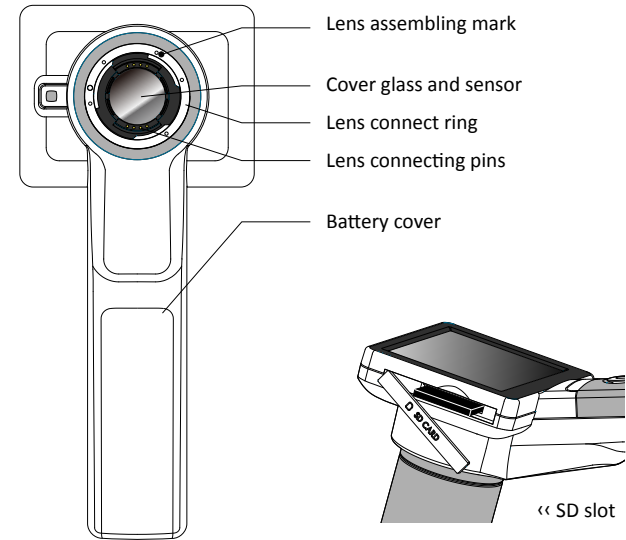
Top view >>



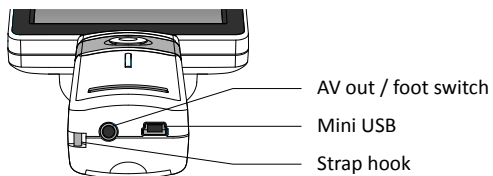
From view »



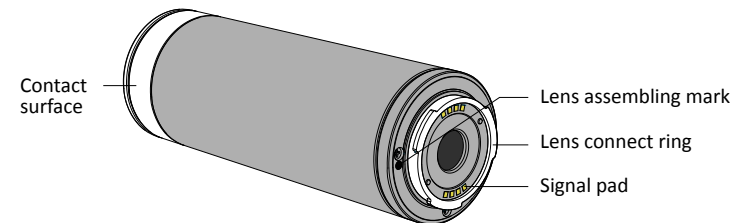
Rear view »



Bottom view »



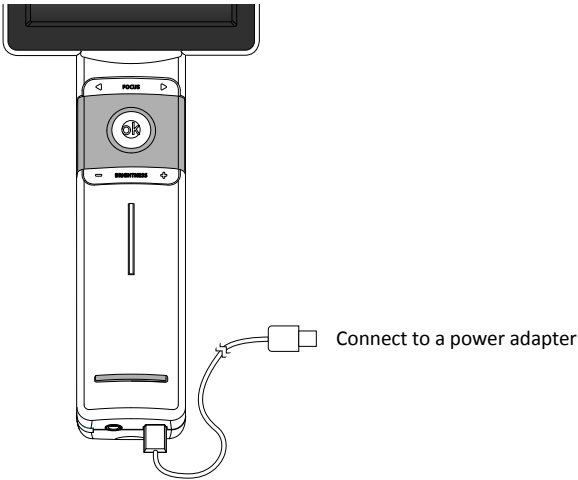
Optical Lens of Horus+ Scope EZ-Horus 45 (Digital Eye Fundus Camera)



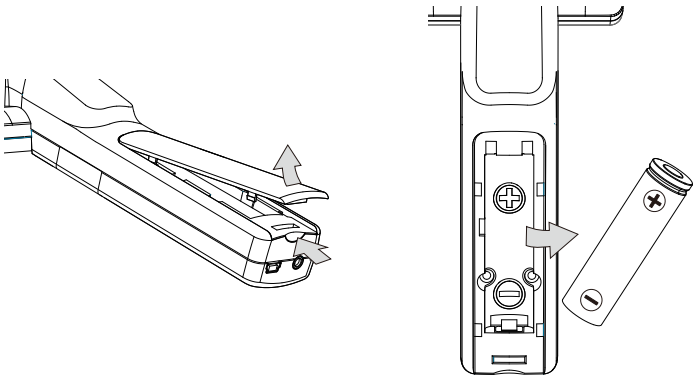
Charging the battery

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.



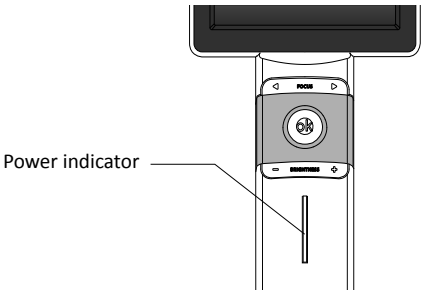
Battery replacement



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

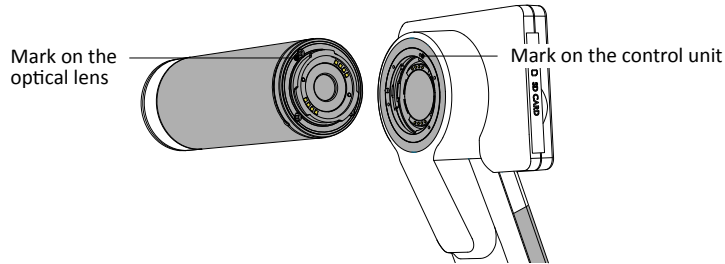


System status	Power off		Power on		
Light color	No light	Orange light	Blue light	Blinking blue light	Mixed blue and orange light
					
Information	System off	Charging	Normal operation	Power less than 25%	Connect to PC via USB cable or enable USB live video

Assembling

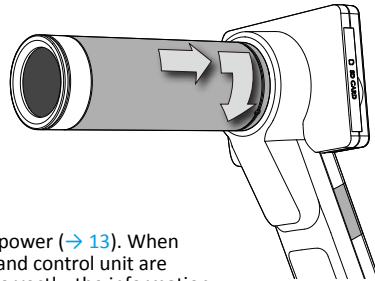
Step 1. ↘

Align the marks of the optical lens and control unit.



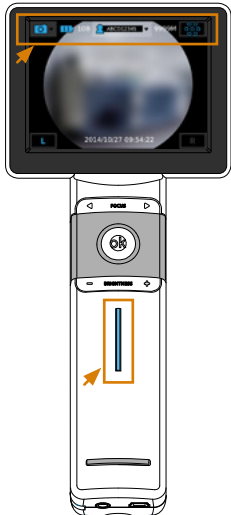
Step 2. →

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.



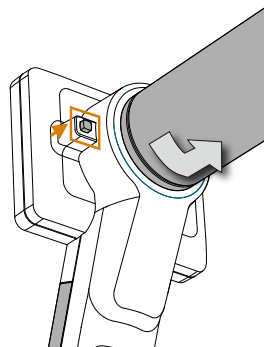
Step 3. ←

Turn on the power (→ 13). 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 (→ 11) 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.

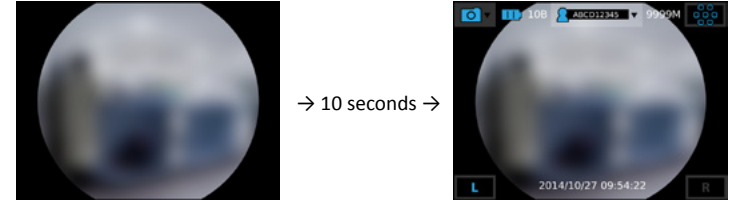


Using the Setup mode

Turn on the power

To turn on the system, press the power button (→ 7) to turn on the control unit. Approximately one to two seconds later, the boot screen will appear on the LCD panel.

Once the LCD panel shows the live image, it takes about 10 seconds for the on-screen display (OSD) to be superimposed.



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.



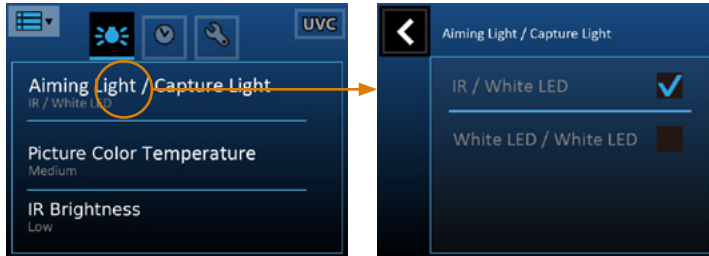
Exit the [Setup] menu

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.

Settings

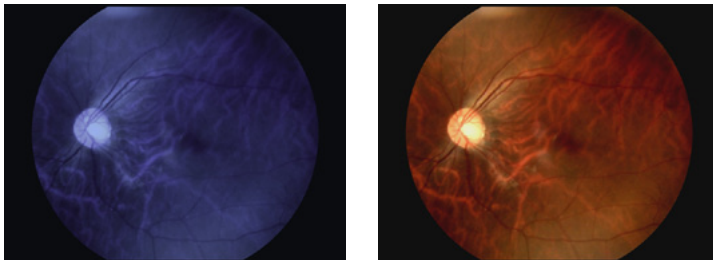
[Aiming Light/Capture Light]

The default setting of [Aiming Light/Capture Light] is [IR/White LED]. In the setting, EZ-Horus 45 employs IR illumination for alignment and focusing to assure patient comfort. With IR, the user observes fundus images monochromatically. At the moment of pressing the shutter button, the system will turn on the white LED instantly. Static images and motion pictures will be captured in full color.



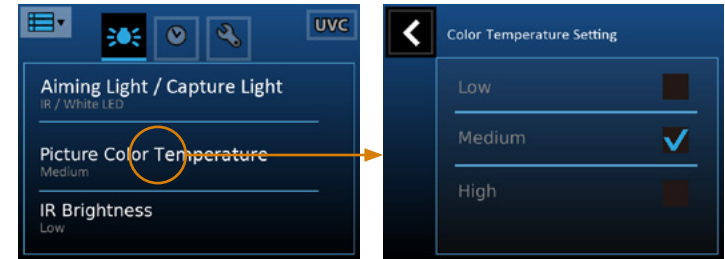
If the setting is [White LED/White LED], then the user observes images in full color and capture static images and motion pictures in full color.

Sample images of monochrome and full color.



[Picture Color Temperature]

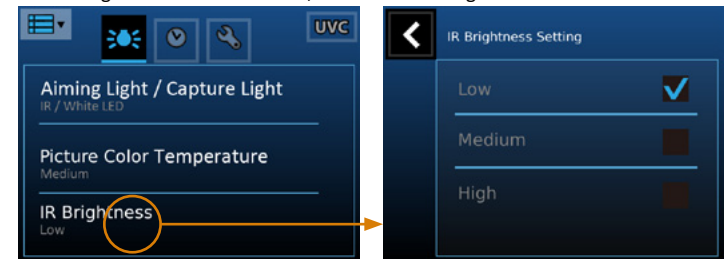
The picture color temperature has three levels; the default setting is medium.



[Low] sets the color temperature for a warmer color tone. [High] sets the color temperature for a cooler tone.

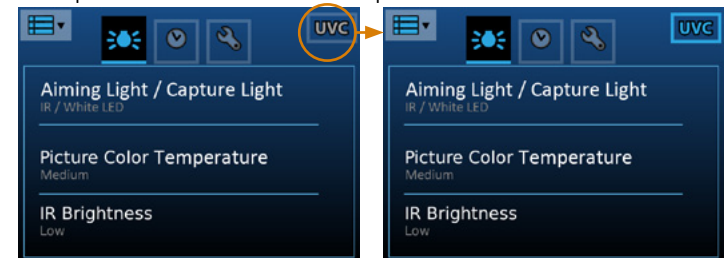
[IR brightness]

The IR brightness has three levels; the default setting is low.



[UVC]

When you connect EZ-Horus 45 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.

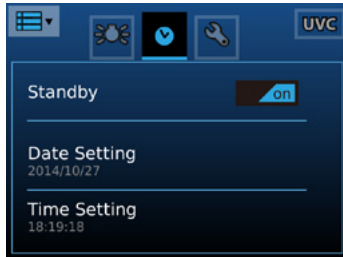


To display image on the computer, please install webcam application prior to enabling

UVC mode. A freeware webcam application (e.g., AMCap) is a software that can receive UVC signal on the computer. User can search for relevant information over the Internet.

[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.



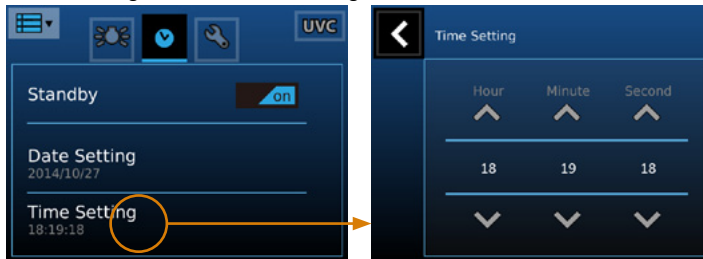
[Date Setting]

User can change the current date setting from the screen.



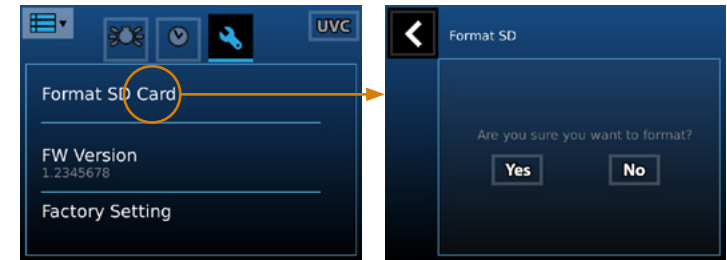
[Time Setting]

User can change the current time setting from the screen.



[Format SD Card]

User can format the SD card.

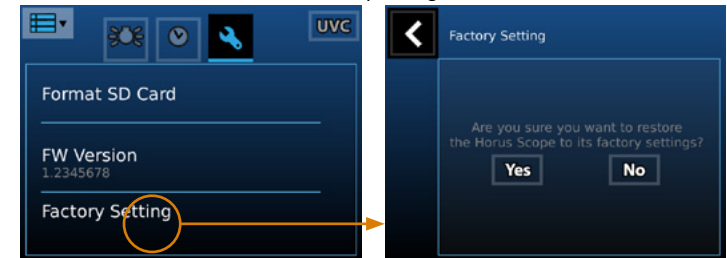


NOTE

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 EZ-Horus 45.

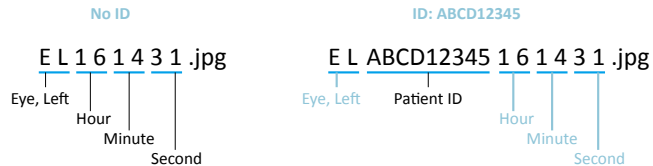
File naming rule

	Model Name	Picture Name without ID	Picture Name with ID
Eye fundus camera	EZ-Horus 45	ELHHMMSS.jpg ERHHMMSS.jpg	ELXXXXXXXXHHMMSS.jpg ERXXXXXXXXHHMMSS.jpg

Meaning of each symbol:

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

Example:



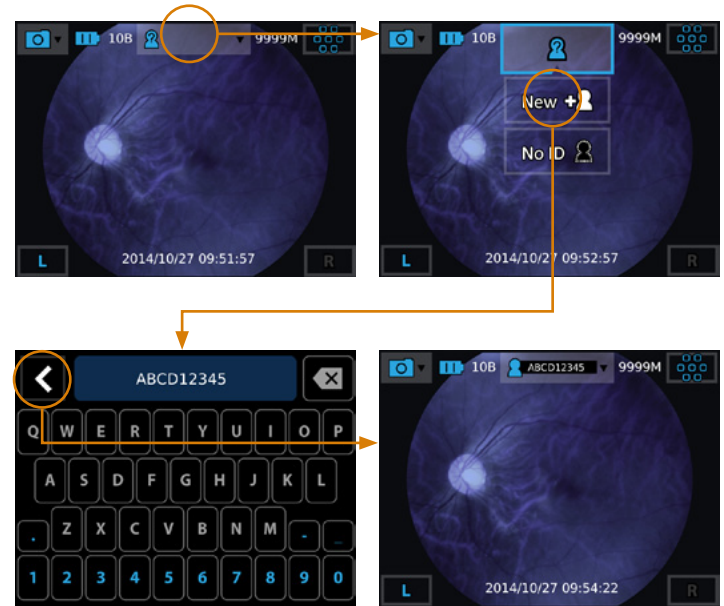
The image name is explained as follows:

EL: Left eye photo taken by the eye fundus camera; hour: 16; minute: 14; and second: 31.

If the given patient number is ABCD12345, the image name would be written as ELABCD12345161431.jpg.

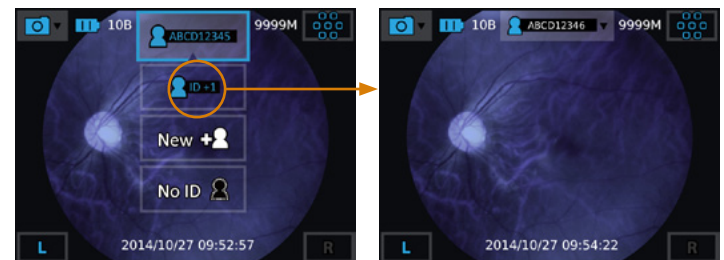
Create a new patient ID from scratch

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.



Create a new patient ID on an existing one

After a patient ID is set, the user can quickly create a new patient ID that is based on the existing ID plus 1 e.g., ABCD12345 → ABCD12346.



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 10 seconds, the information icons will appear on the top of the LCD panel. (Also refer to “turn on the power” → 13.)

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

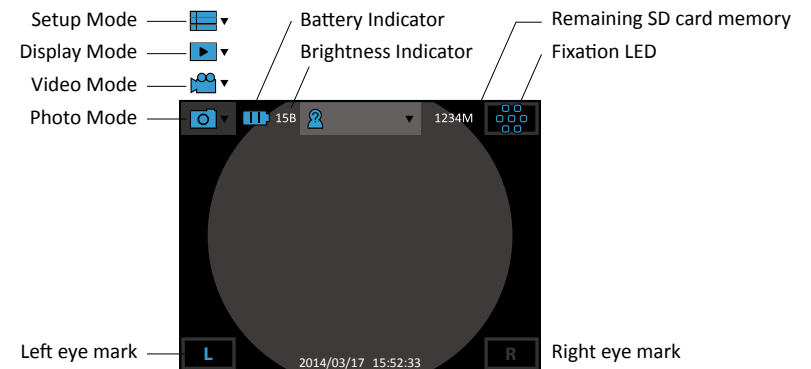
Tap the photo or the video mode icon to enter a shooting mode.

Step 4: Mark left/right eye

By doing so, the user can tell whether a photo/video is left eye or right eye record from its file name. (Default value is left eye.)

Step 5: Aim and preview

Position the camera correctly and adjust to appropriate settings to get a clear preview (→ 24). The image brightness can only be changed in photo mode, whereas the fixation lamp can be adjusted in both photo mode and video mode. You can rely on the auto focus of EZ-Horus 45 to improve clarity or adjust focus manually.

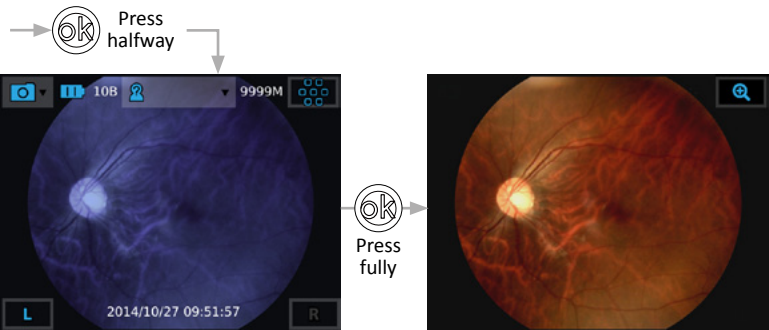


Step 6: Press the OK button to shoot.

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 focus; press it all the way to take a still picture.



The default setting of “Aiming Light/Capture Light” is “IR/White LED”. Therefore, the left image before pressing the OK button is monochrome color and the right one is full color (→ 14).

When a picture is just taken, the screen shows the result image in auto review mode. To leave auto review, gently press the OK button.

To adjust the brightness of the image, user can press the brightness adjustment keys (“User interface” → 8) of the control unit:  to change value.

The higher value you set, the brighter image you get. Image brightness adjustment range:

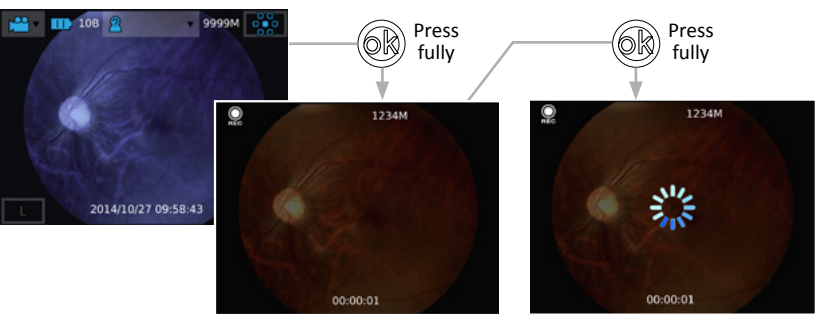
	Model Name	Default Value	Min. Value	Max. Value
Eye fundus camera	EZ-Horus 45	10	0	15

Reference Table:

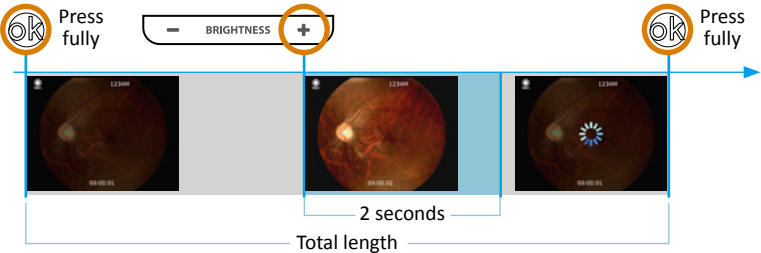
Brightness Indicator	Classification	Note
0-5B	Light Skin Blond	
5-10B	Light Skin Brunette	10B is default
10-15B	Dark Skin	

Video mode

 **Video mode:** Completely press the OK button to start recording. Press again to end recording. The default setting of “Aiming Light/Capture Light” is “IR/White LED.” See process below:



During the video shooting, user can press “the brightness adjustment key +” to enhance the white LED for two seconds. It helps capture brighter motion pictures within a video.



Fixation setting and holding position

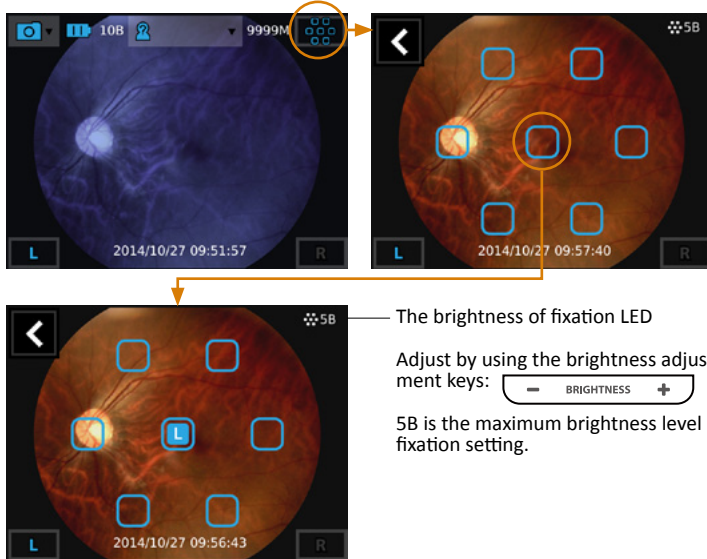
Examination conditions

After the optical lens 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 or contact lenses. Make sure that the eye's pupil has a diameter larger than 4 mm, or be sure to sufficiently dilate in advance.
- Auto focus to infinity by pressing the OK button halfway down. Once the preview image is clear, then the focus is right for eye screening.

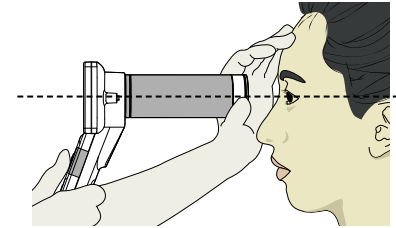
Fixation lamp

Choose fixation LED position and ask the examinee to look at the fixation LED. Adjust the brightness of fixation LEDs by using the brightness adjustment keys of the control unit.



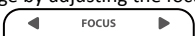
Holding position

Hold 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.)

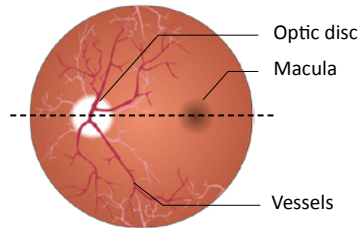
Adjust focus and fine tune

- Find the optic disk then optimize the image by adjusting the focus distance by using the focus adjustment keys of the control unit .
- Fill the screen (circle area) with the image without any shining spot. The correct working distance is 24 mm (from the lens tip to cornea).
- Completely press down the OK button to take photographs or record videos.
- The image that was taken will be showed on the screen and is saved on the SD card. Press the OK button to go back to the operation screen and take another image or record another video.

Q&A troubleshooting

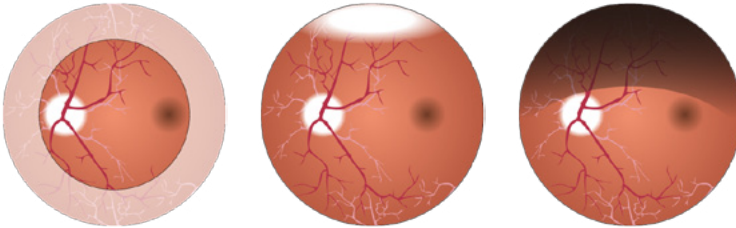
A good image should have two characteristics:

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.



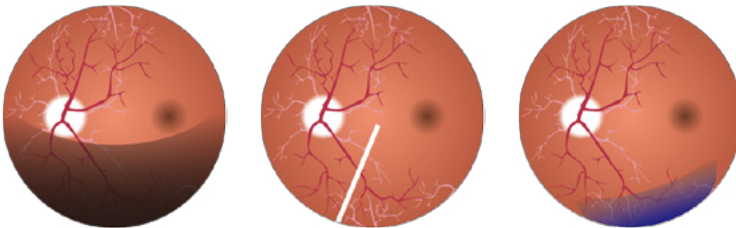
If the above characteristics can't be found in the shot, possible failures might be the following:

- | | | |
|-----------------------|---|--|
| 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 |
|---|---------------------------------|--|



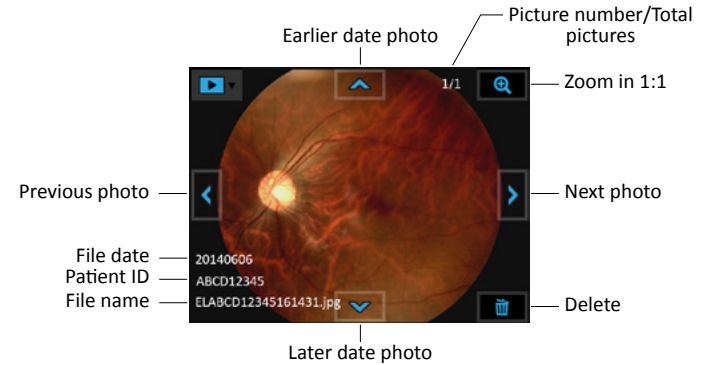
- | | | |
|---|----------------------------------|-------------------|
| The lens is much higher than the visual axis. | Eyelashes are in the light path. | Cornea reflection |
|---|----------------------------------|-------------------|

Playback

Display mode

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

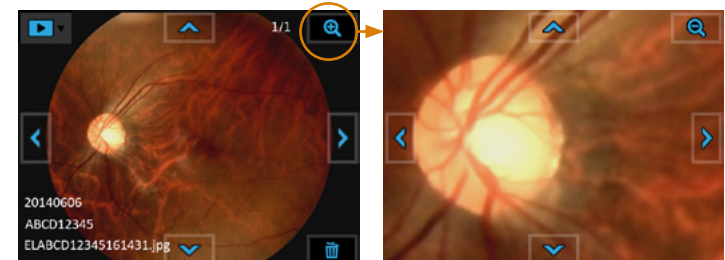
▶ Display mode:



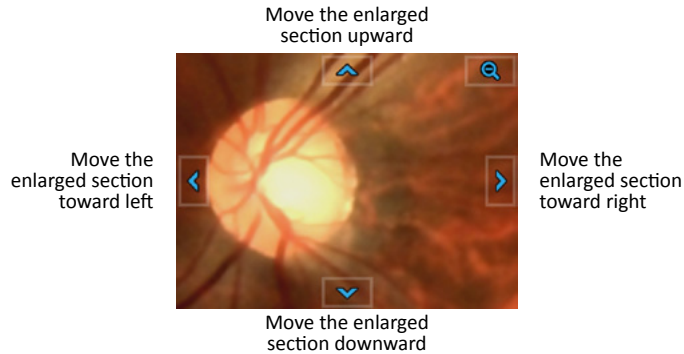
Click the left or right arrow symbols to go to the previous or next photo, respectively. Click the up or down arrow symbol to backward in days or forward in days. Zoom in and out on the photo while in display photo. The user can delete photos by touching the delete icon.

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

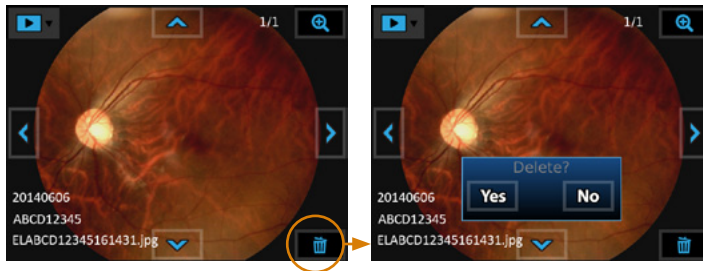
Enlarged viewing



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 (→ 15) 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 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 microwave 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 3.7V @ 2,500mAh 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.

Memory cards

If you purchase different memory capacity of micro 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 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. The slit lamp jig is only suitable for the EZ-Horus 25, EZ-Horus 40 and the EZ-Horus 45.

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.

CLASS 1 LED PRODUCT

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 photoelectronic 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 (70% 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) 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 (70% ethyl alcohol).

NOTE

The device is not intended to be sterilized. Disinfect the control unit and charging station with a soft cloth with alcohol (70% 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 |

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 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, EZ-Horus 45, 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: 2007. 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 Electrotechnical 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" (→ 34). Follow the guidance in the tables for use of the device in an electromagnetic environment.

Technical description

Horus+ Scope EZ-Horus 45, digital eye fundus camera:

- View Angle: 45 Degree (Typical)
- Diopter: -20 ~ +20D (Typical)
- Dimension: 20.9 x 9 x 20.3 cm (Typical)
- Weight: 500 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

Focus	Auto & manual focus
Camera Resolution	2592 x 1944 pixels
Picture Resolution	2560 x 1920 pixels
Video Resolution	1280 x 960 pixels
LCD Monitor	3.5" Full Color TFT-LCD Touch Panel
Image Format	JPEG (Photograph) and H.264 (Video)
Interface	Mini USB, AV out port
File Transfer	Mini USB Port to PC
Dynamic Video Output	Composite AV out, or USB live video enable from USB port
File Storage	SD Card, default 8GB. Supports 2 G to 32 GB by FAT32 Format.
Power Source	Rechargeable Lithium Battery 3.7V/2500mAh
External Power	Source: 100~240 VAC, 50/60 Hz
Power Adapter Spec.	Input Spec.: 100~240 VAC, 50/60 Hz, 0.3 A; Output Spec.: 5V DC, 2 A
Charging station Input Spec.	5V DC, 1.2 A
Operating Time	3 hours at 2.5 Watt condition
Charging Time	5 hours by DSC 200
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.
-  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 (EN 60601-1:2006)
EMC and regulatory compliance	IEC 60601-1-2:2007 (EN 60601-1-2:2007)
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: 2007) 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: 2007)

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 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	
Harmonic emissions IEC 61000-3-2	*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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles < 5% U _T (> 95% dip in U _T) for 5 sec	<5% U _T (> 95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles < 5% U _T (> 95% dip in U _T) for 5 sec	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	3 A/m	3 A/m	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 150 kHz to 80 MHz	3 Vrms (V1=3)	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 $d=1.2 \sqrt{P}$ 150 kHz to 80 MHz $d=1.2 \sqrt{P}$ 80 MHz to 800 MHz $d=2.3 \sqrt{P}$ 800 MHz to 2.5 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E1=3)	

		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 Interference may occur in the vicinity of equipment marked with the following symbol: 
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, 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		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2.5 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 metres (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.			

Please visit www.usophthalmic.com for more information.