HORUS SCOPE

USER MANUAL



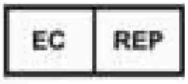
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1. Category

Product Name	Model Name	Accessory
Digital Eye-Fundus Camera Digital Ophthalmoscope	Horus Scope EZ-Horus 40 Horus Scope EZ-Horus 40	Eye Cup Foot-Switch (Optional Part) Slit-Lamp Jig (Optional Part)
Digital Otoscope	Horus Scope OTO Lens	Specula Horus Scope Adapter (Optional Part) Foot-Switch (Optional Part)
Digital Dermatoscope	Horus Scope Derma Lens	Contact plate Foot-Switch (Optional Part)
Digital Speculum	Horus Scope Imaging Lens	Foot-Switch (Optional Part)
Digital Anterior Scope	Horus Scope Anterior Lens	Foot-Switch (Optional Part)

2. Symbols

	Caution must be taken. Read user's 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's manual.
	Manufacturer.
	Date of Manufacture.
	CE mark.
	European Authorized Representative.
	This product has an internal rechargeable battery with a Class II power supply.

3. Warnings and Cautions

PLEASE NOTE:

Prior to installation and start-up of the device, carefully read the instructions provided here in! As with all technical devices, the proper function and safety operation of this device depend on the user's compliance with the safety recommendations which are presented in these operating instructions. Do not attempt to open the cover of the product, so as to avoid malfunction of product.



CAUTION:

U.S. Federal law restricts this device EZ-Horus 40 or EZ-Horus 25 to sale, distribute, and use by or on the order of a physician.



CAUTION:

For EZ-Horus 40 or EZ-Horus 25, while no acute optical radiation hazards have been identified for Eye-Fundus Camera or ophthalmoscope. However, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes, and persons with diseased eyes are at a greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using 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 on the order of typically less than 60 seconds per eye. Although there is benefit versus risk factor in any medical procedure, these more complicated exams should not exceed a three minute exam time in 24 hours. Significant use of this device beyond its intended use is not recommended, as it may cause harm to the eyes.



CAUTION:

Always use the device or foot-switch in accordance with the directions and recommendations contained in this User Manual.



CAUTION:

Operate the device, please take note that optical lens do not touch the eyes or nose of patient. Avoid harm to patient.



CAUTION:

To prevent fire or electrical shock, do not expose these appliances to rain or moisture.

CAUTION:

This device and foot-switch are not waterproof. If the optical lens and control unit get wet; do not attempt to dry with a heater, microwave, autoclave or UV light.

CAUTION:

Avoid subjecting the device or foot-switch to vibration or shock. When the product is not in use, please disconnect the power plug and keep it in a safe place.

CAUTION:

Avoid using the device or foot-switch in a dusty environment, and keep the power cord away from any heat source.

CAUTION:

Before operation, please make sure the appearance is not damaged or broken. If there are breaks in the device cover or other visual defects, please contact manufacturer or manufacturer certified service facility.

CAUTION:

Please do not charge the battery when the device is operated by the user.

CAUTION:

Only use Li-ion Battery 3.7V @ 2500mAh 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 lifetime or failure, please contact the manufacturer or distributor to buy the spare battery.

CAUTION:

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

CAUTION:

When use EZ-Horus 40, EZ-Horus 25 or Anterior Lens, do not increase the amount of illumination light more than required. Otherwise, the eye may be painful or injured.

CAUTION:

For illumination and photography by EZ-Horus 40, EZ-Horus 25 or Anterior Lens, do not select any higher exposure than it is required. Do not illuminate light on the eye over time during examination. Otherwise, the examined eye may be painful or injured.



CAUTION:

When pluging or unpluging the AV cable of foot-switch to control unit, the examineer might be triggering photo-taking. The foot-switch is only suitable for EZ-Horus control unit.



CAUTION:

The eye can't be exposed to the illumination light of Oto Lens, Derma Lens and Imaging Lens at operation.



CAUTION:

Attach Slit-Lamp jig to Slit-Lamp Equipment that Ezer qualified. Make sure the jig is completely locked by a downward push. The Slit-Lamp jig is only suitable for EZ-Horus 40/EZ-Horus 25. It can't be use for other models such as OTO Lens, Derma Lens, Imaging Lens or Anterior Lens.



CAUTION:

Replace the disposable specula of Horus Scope OTO Lens, Digital Otoscope, before each use for a new patient.



CAUTION:

Gently insert the specula of Horus Scope OTO Lens into ear canal. To keep a safety distance between the specula and tympanic membrane. Do not make the specula contact with ear's tympanic membrane.



CAUTION:

Clean the contact plate of Horus Scope Derma Lens, Digital Dermatoscope, before each use for a new patient. Disinfect the contact plate with soft cloth moistened with alcohol (70% ethyl alcohol). Replace the disposable contact plate if necessary.



CAUTION:

The Horus Scope adapter is only suitable for EZ-Horus control unit. It is compatible to assemble to endoscope and light source that EZ-Horus qualified. Disinfect the adapter with soft cloth moistened with alcohol (70% ethyl alcohol).



CAUTION:

No modification of this device is allowed. The performance would be changed if modify this device by user. Modification to this device may cause hazardous radiation exposure.



CAUTION:

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 by 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 "16. (1) EMC (Electromagnetic Compatibility)" (Page 43-46). Follow the guidance in the tables for use of the device in an electromagnetic environment.

CAUTION:

During installation and operation of the device, observe the following instructions about EMC (electromagnetic compatibility):

-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, 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 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 lens connecting pins of control unit, or signal pad of lenses without special precautions.

CAUTION:



Users are responsible for managing captured image data.

Manufacturer will not assume any responsibility for loss of data.

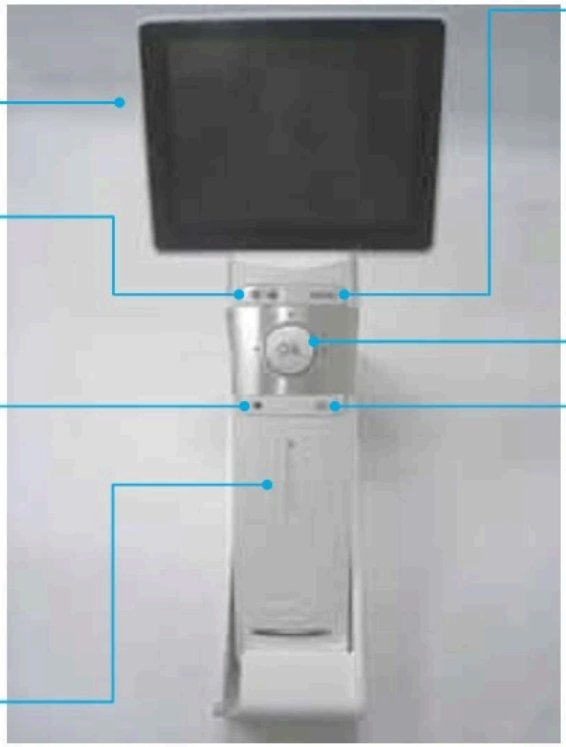
4. Intended for Use

Horus Scope EZ-Horus 40/EZ-Horus 25 is a digital hand-held eye-fundus camera/Ophthalmoscope used to record digital photographs and video of fundus (including retina, macula and optic disc) of the human eye and surrounding area. Horus Scope OTO Lens is a digital hand-held otoscope used to record digital photographs and video of the human ear's canal and tympanic membrane. Horus Scope Derma Lens is a digital hand-held dermatoscope used to record digital photographs and video of the human skin. Horus Scope Imaging Lens is a digital hand-held camera used to record digital photographs and video of the human body. Horus Scope Adapter is designed to connect the control unit of Horus Scope and the existing endoscope in the market. The assembly system (control unit & Horus Scope Adapter & existing endoscope in the market) can be used to record digital photographs and video of the body. Anterior Lens is a digital hand-held anterior scope used to record digital photographs and video of anterior area of the human eye and surrounding area.

5. User Interface

Control Unit (Horus Scope)

Front View



LCD Monitor

• Photo/Video Mode Switcher (Switching time is about 1 seconds)

•Brightness Decreasing at the Photo/Video mode

•Back to Normal Picture Size at "Display" mode.

Power Indicator

MENU

OK button:

•Capture image at the Photo/Video Mode

•Enter key function at "menu" mode

•Brightness Increasing at the Photo/Video mode

•Zoom In Picture at "Display mode". (Move the picture by moving the arrow button.)

Top View



Power Button

Rear View



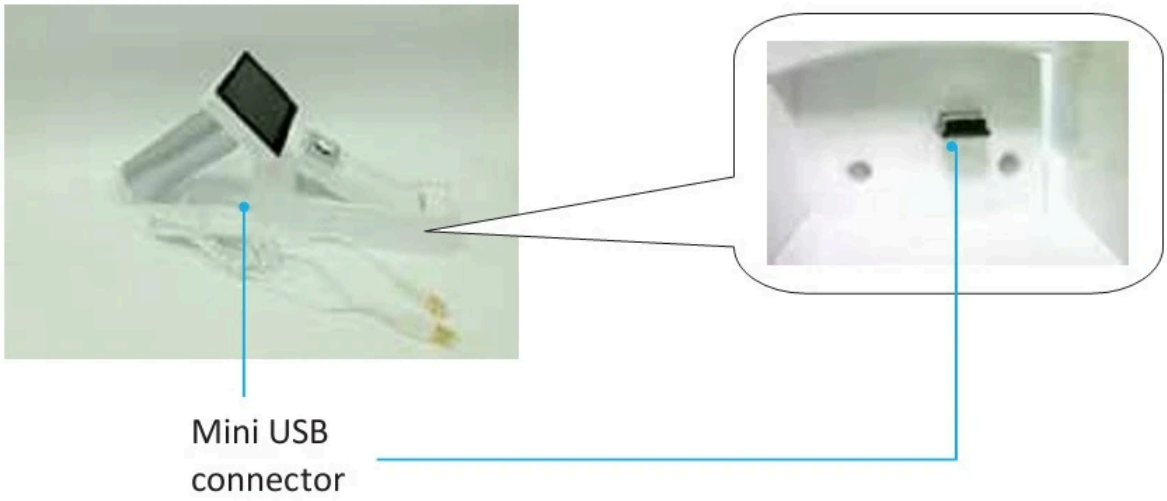
Bottom and Right Views





AV Out / Foot Switch Mini USB Strap Hook Micro SD Slot

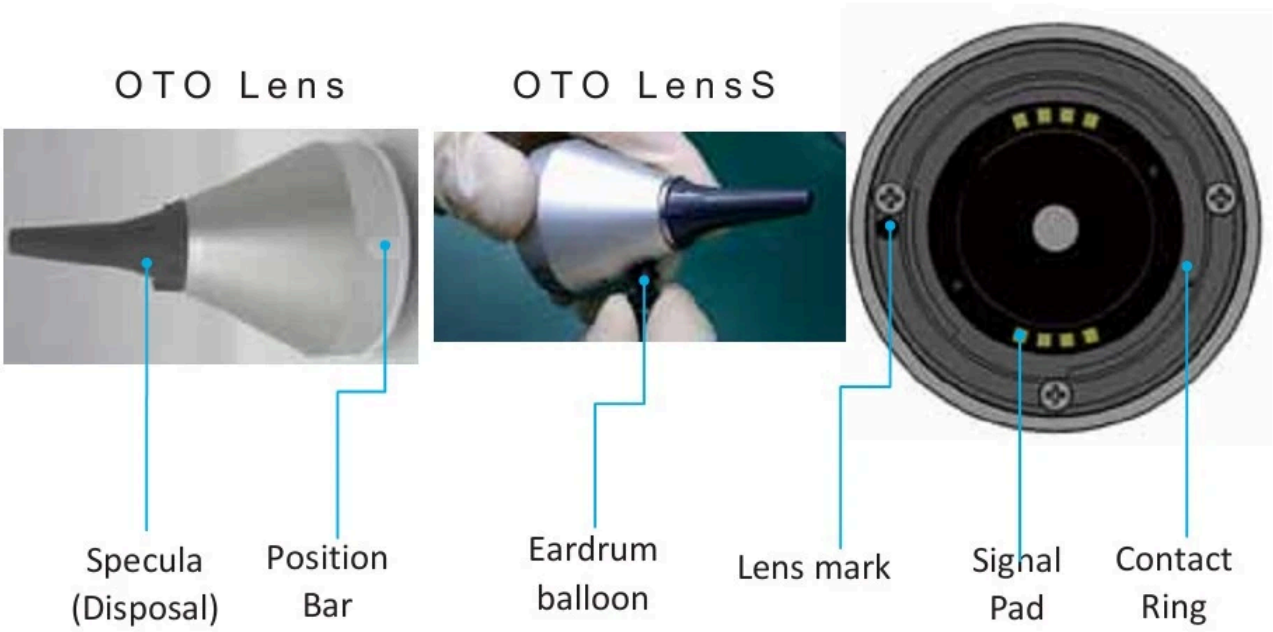
Charger Station



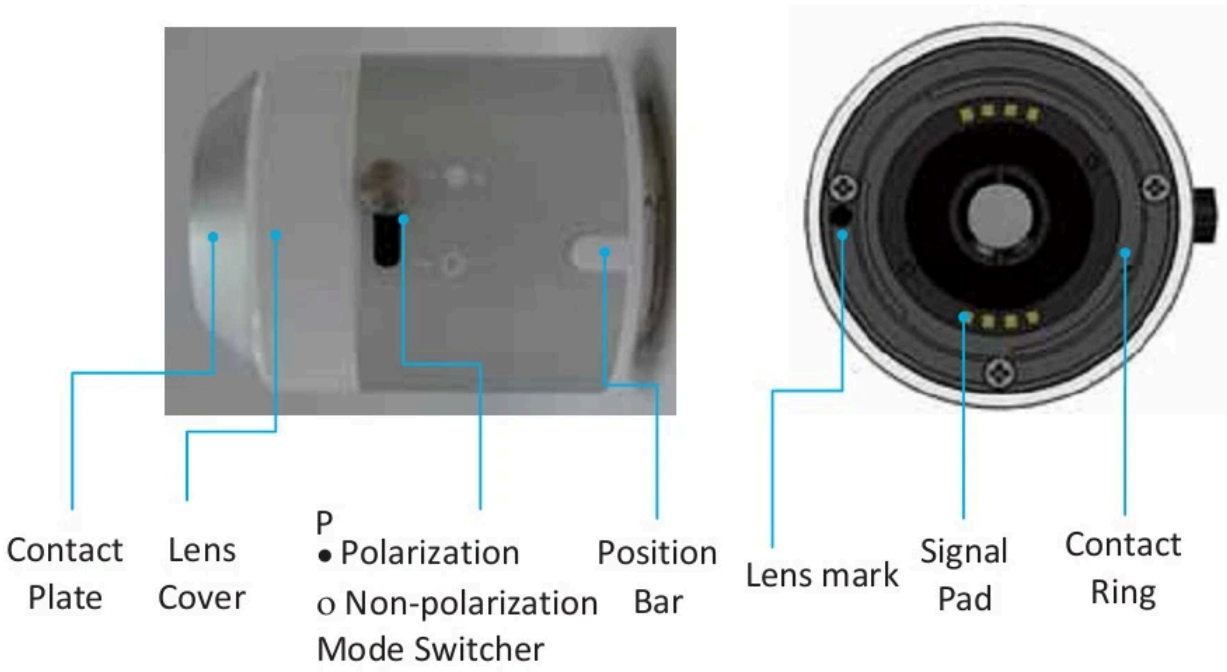
Optical Lens of Horus Scope EZ-Horus 40/EZ-Horus 25 (Digital Eye-Fundus Camera/Ophthalmoscope)



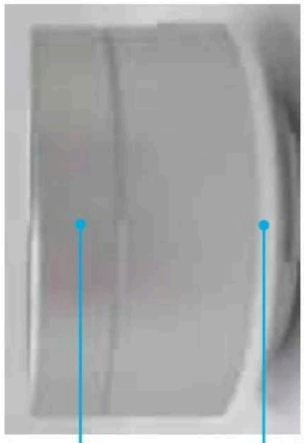
Optical Lens of Horus Scope OTO Lens/OTO LensS (Digital Otoscope)

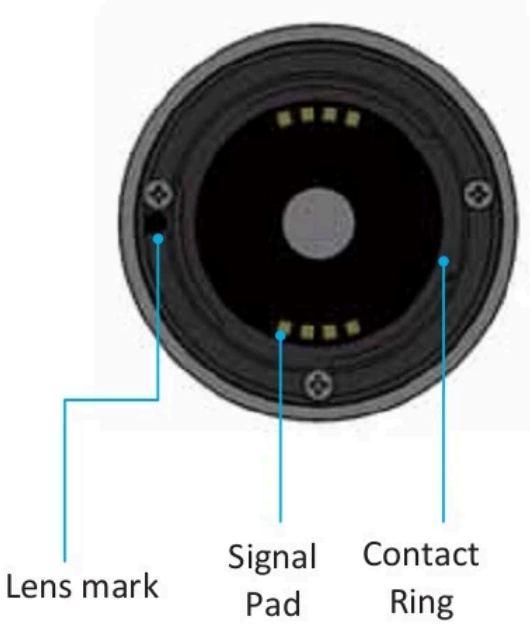


Optical Lens of Horus Scope Derma Lens (Digital Dermatoscope)

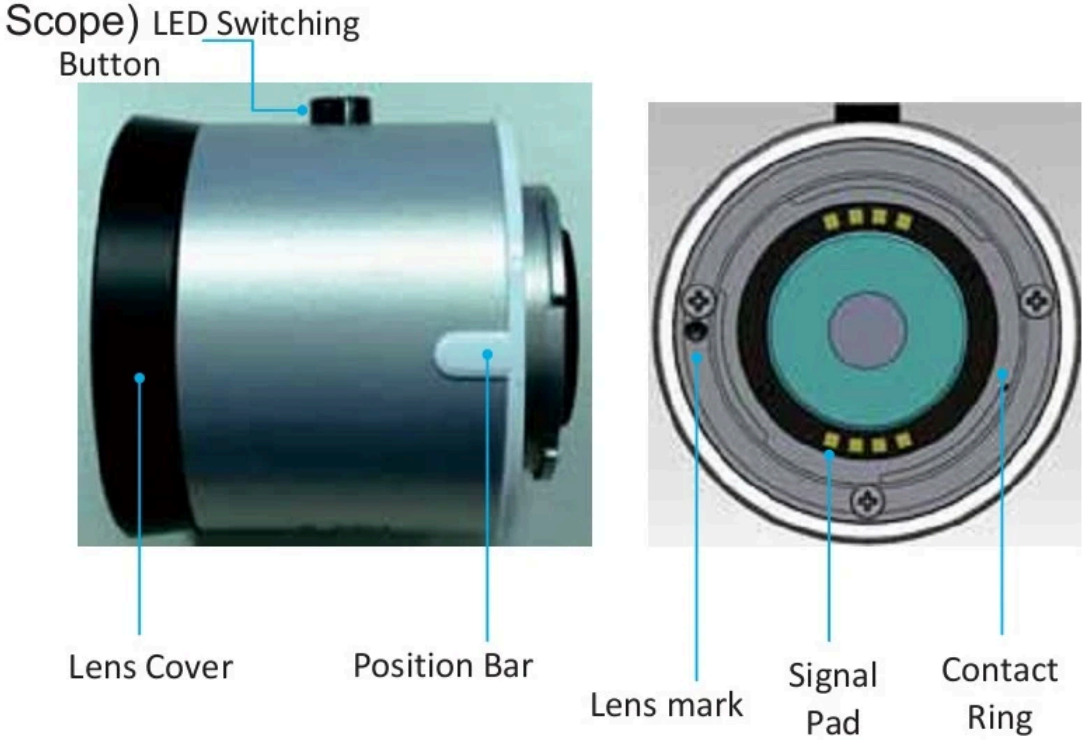


Optical Lens of Horus Scope Imaging Lens (Digital Speculum)





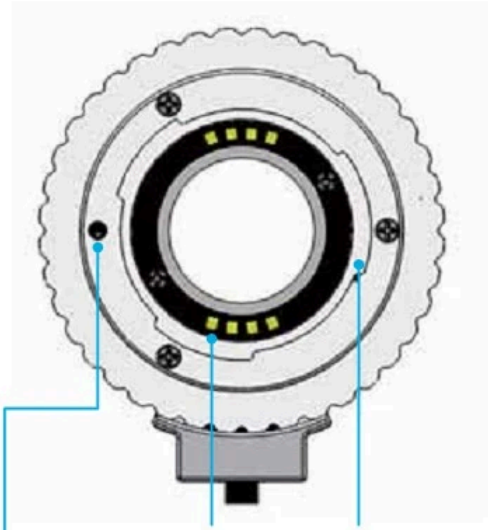
Optical Lens of Anterior Lens (Digital Anterior Scope)



Horus Scope Adapter



Switch for light source



Foot Switch



Eye Cup



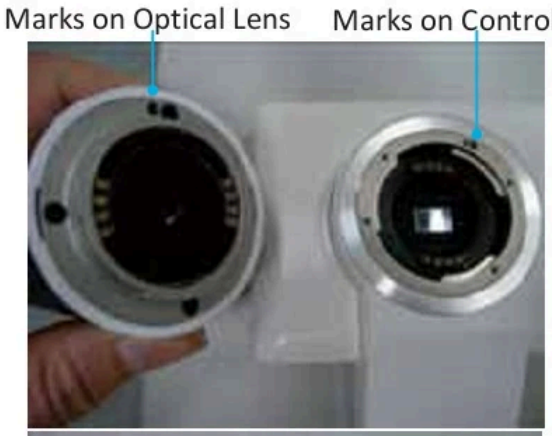
Slit-Lamp Jig



6. Operating Instructions

(1) Assembly of EZ-Horus 40/OTO Lens/Derma Lens/Imaging Lens/ Anterior Lens

Step 1: Align the Marks of Optical Lens and Control Unit.

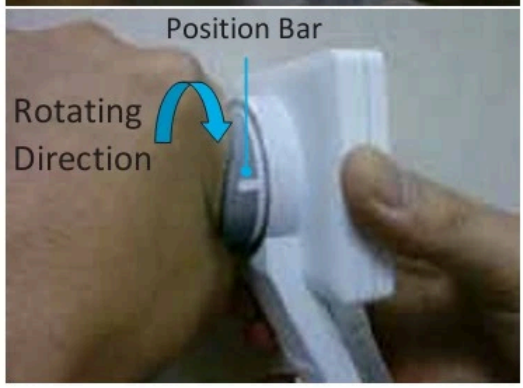


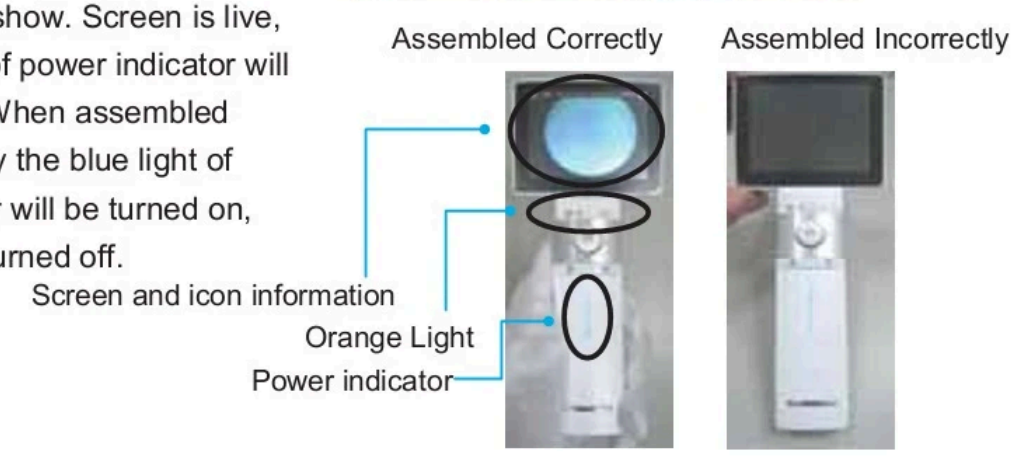
Step 2: Hold Optical Lens and attach it on Control Unit.



Step 3: Rotate and fasten Optical Lens in a counter-clockwise direction, where as the “Position Bar” is at the “Horizontal” direction.

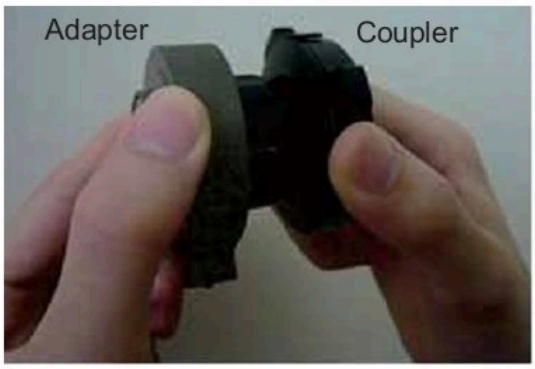
Note: When Optical Lens and Control Unit are assembled correctly, the orange light on / and **MENU** will be turned on. Icon information on the top will be show. Screen is live, and blue light of power indicator will be turned on. When assembled incorrectly, only the blue light of power indicator will be turned on, others will be turned off.

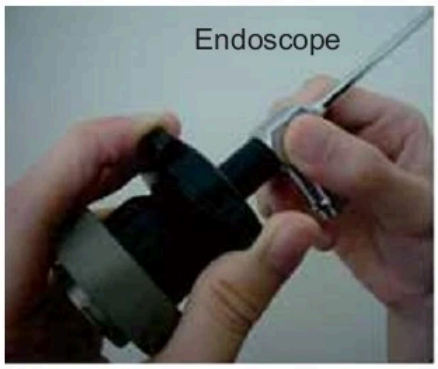




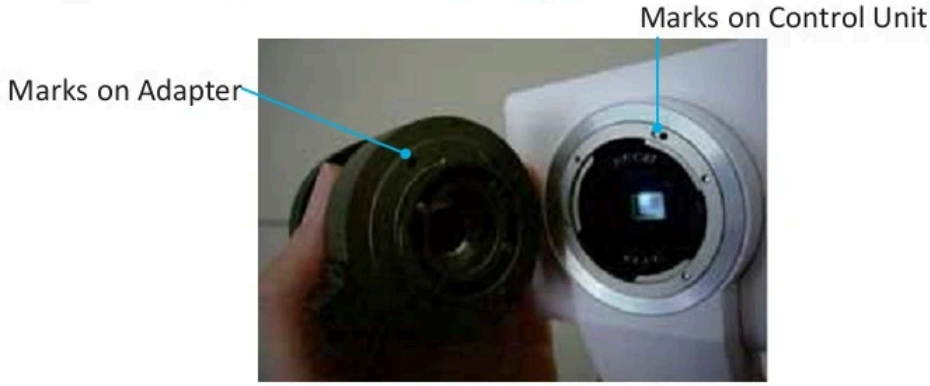
(2) Assembly of Horus Scope Adapter

Step 1: Connect “Horus Scope Adapter”, “Coupler” and “Endoscope”.





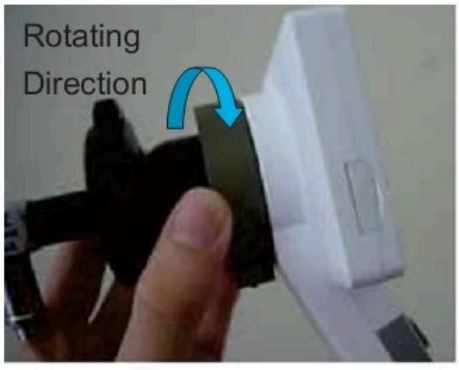
Step 2: Align the Marks of Horus Scope Adapter and Control Unit.

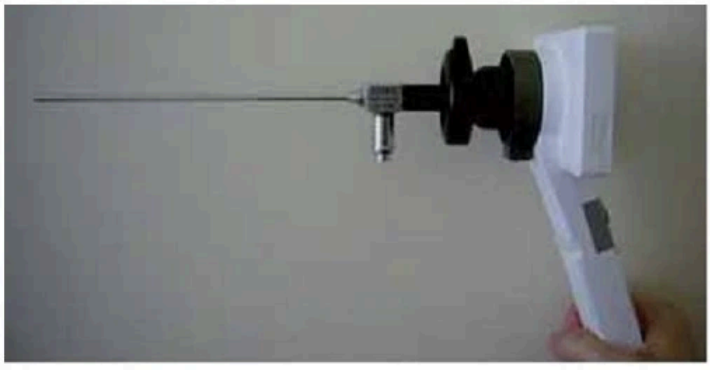


Step 3: Hold Horus Scope Adapter and attach it on Control Unit.

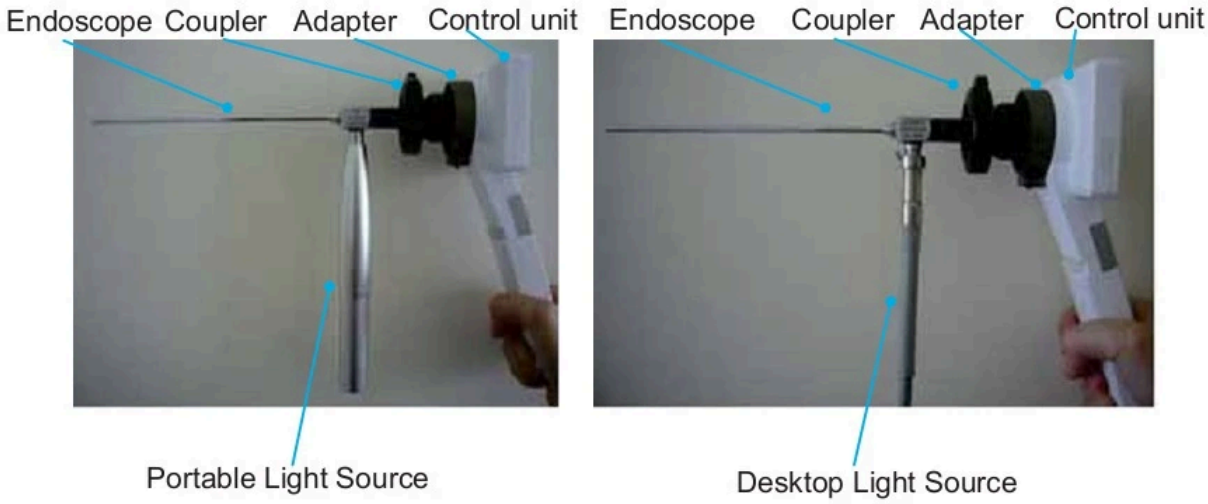


Step 4: Rotate and fasten Horus Scope Adapter in a counter-clockwise direction, where as the “switch” is at the bottom.



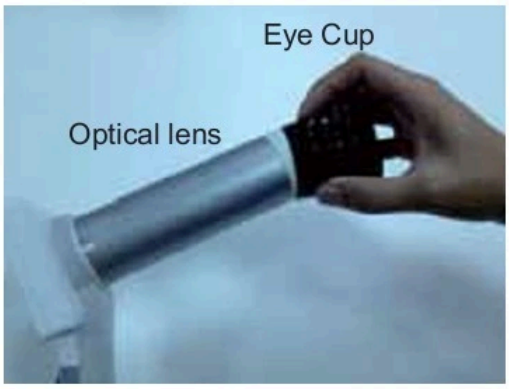


Step 5: Connect light source with endoscope. Horus Scope Control unit & Adapter & Existing endoscope, coupler and light source in the market.



(3) Eye Cup Installation (EZ-Horus 40 or EZ-Horus 25)

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 to fit the eye socket.



(4) OTO Lens Specula Installation and Removal

Step 1: Put the specula on the tip of otoscope lens.



Step 2: Rotate the specula tightly to otoscope lens in clockwise direction.

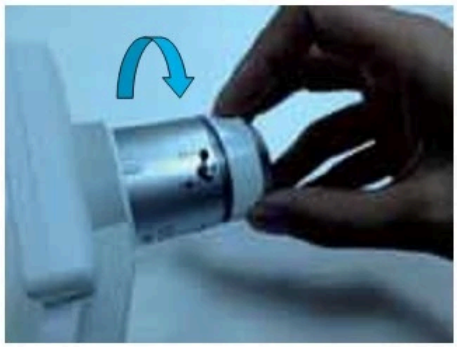


Step 3: To remove the specula, rotate in counter-clockwise direction.



(5) Derma Lens Contact Plate Replacement

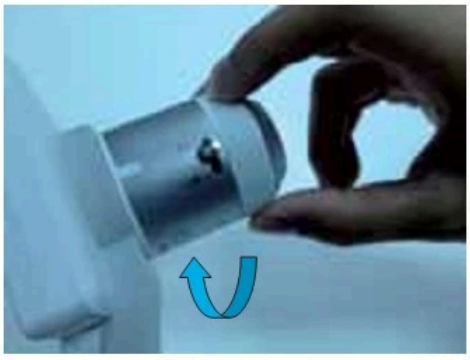
Step 1: Hold the white portion of Derma Lens, and rotate to loosen the contact plate module in counter-clockwise direction.



Step 2: Separate the white plastic parts, and use new one for replacement.

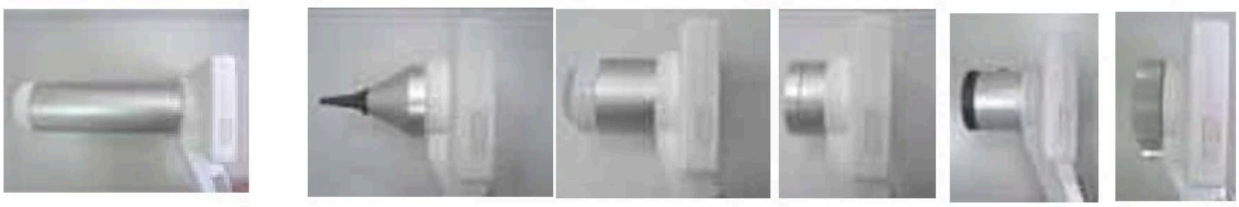


Step 3: Put contact plate module in front of Derma Lens, rotate tightly in clockwise direction.



(6) Operating procedure

Horus 40-25 | OTO Lens | Derma Lens | Imaging | Anterior | Adapter



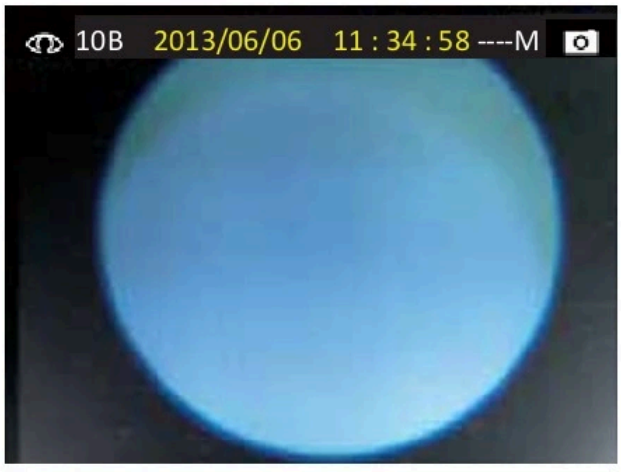
Step 1: Before the first use, insert the battery to the Control Unit and close the battery cover referring to Section 9. Place the Control Unit on Charger Station or connect to adapter via USB cable. Connect USB connector to the power plug. Let the battery charged for five hours. Battery charging refers to Section 7.



Step 2: The Control Unit is powered on by pressing the power button. Approximately 1~2 seconds later, the starting picture indicates on the LCD display.



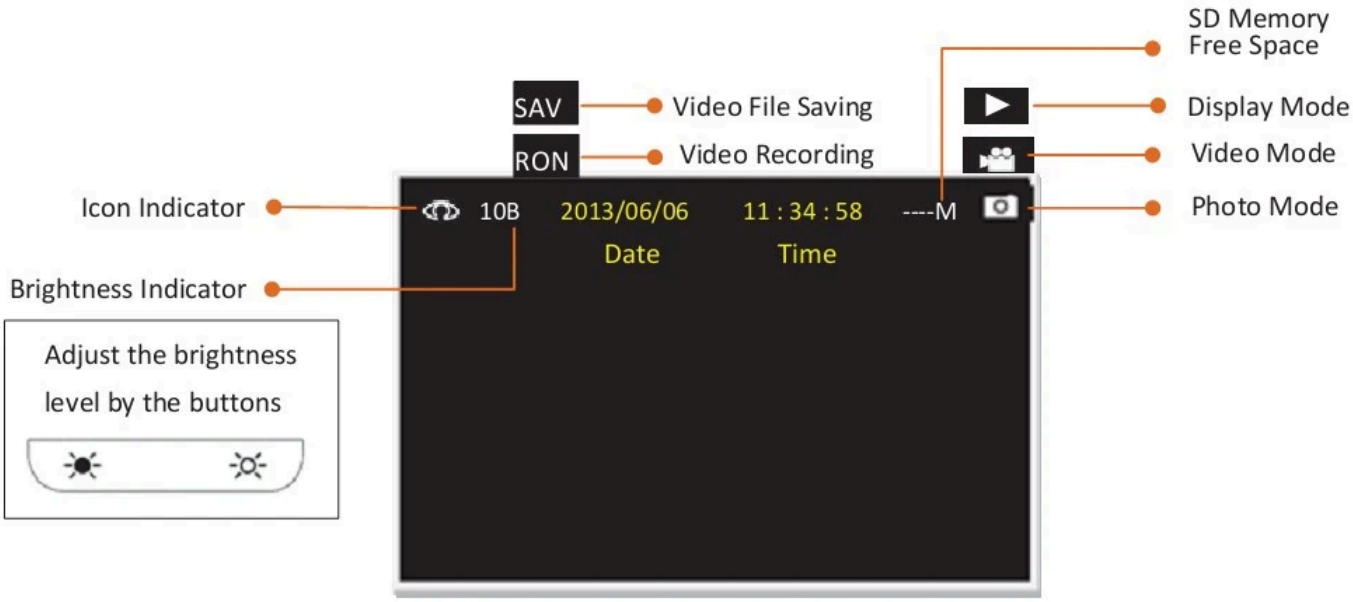
Step 3: Approximately for 20 seconds, the graphical indicators display on the top row of the LCD display. The user can start to capture the photograph in the photo mode. If the system did not have micro SD card inside, the system is not workable.



Step 4: Operation Screen

Icon Indicator

EZ-Horus 40 / 25	OTO Lens	Derma Lens	Imaging Lens	Anterior Lens	Horus Scope Adapter
Eye-Fundus Camera/Ophthalmoscope	Otoscope	Dermatoscope	Speculum	Anterior Scope	Adapter only White/Yellow light
					



Brightness Adjust Range:

	Model Name	Default Value	Min. Value	Max. Value
Eye-Fundus Camera	EZ-Horus 40 / 25	10	0	15
Otoscope	OTO Lens	5	0	10
Dermatoscope	Derma Lens	5	0	10
Speculum	Imaging Lens	0	0	10
Anterior Scope	Anterior Lens	3	0	5
Endoscope Adapter	Horus Scope Adapter	5	0	5

Picture Naming Rule:

	Model Name	Picture Name without ID	Picture Name with ID
Eye-Fundus Camera	EZ-Horus 40 / 25	EYHHMMSS.jpg	EYXXXXXHHMMSS.jpg
Otoscope	OTO Lens	OTHHMMSS.jpg	OTXXXXXHHMMSS.jpg
Dermatoscope	Derma Lens	DDHHMMSS.jpg	DDXXXXXHHMMSS.jpg
Speculum	Imaging Lens	GIHHMMSS.jpg	GIXXXXXHHMMSS.jpg
Anterior Scope	Anterior Lens	DAHHMMSS.jpg	DAXXXXXHHMMSS.jpg
Endoscope Adapter	Horus Scope Adapter	DRHHMMSS.jpg	DRXXXXXHHMMSS.jpg

Symbol	Refer to
EY	Eye-Fundus Camera
OT	Otoscope
DD	Dermatoscope
GI	Speculum: GI (General Imaging Lens)
DA	Anterior Scope
DR	Endoscope Adapter
HH	Hour
MM	Minute
SS	Second
XXXXX	Patient ID

Example:
DA161431.jpg
It means
DA: anterior scope picture; hour:16; minute:14; second:31
If set serial number 23458, the picture name shows DA23458161431.jpg

Step 5: Menu Screen

- Press “Menu” button and enter to “Menu” mode. It is recommended to set the operation condition according to the user’s requirement for the first time use.
- The user can press △ / ▽ to switch the pages as shown the table below.
- The user can press ◁ / ▷ to select “YES” or “NO”. And press “OK” button to confirm your choice.
- Press “Menu” button again. The user can return to the Operation Screen, and then start to capture the photograph or record the video in the selected mode.
- The functional setting is described and shown in the table below.
- The “Menu” screen will return to Operation Screen in 30 sec without pressing any button or the user can press “Menu” button and return to Operation Screen.

Step 6: Photo mode and Video mode

- The default setting is “photo mode”. User can take picture or video separately at “photo mode” or “video mode”. The “photo mode” was introduced at section 6 (7)~(9).
- Take video at “video mode”:

(1) Press “ / ” button，user can switch from “photo mode” to “video mode” in 1 second and vise versa. The “ ” will show on the right top of the LCD screen.



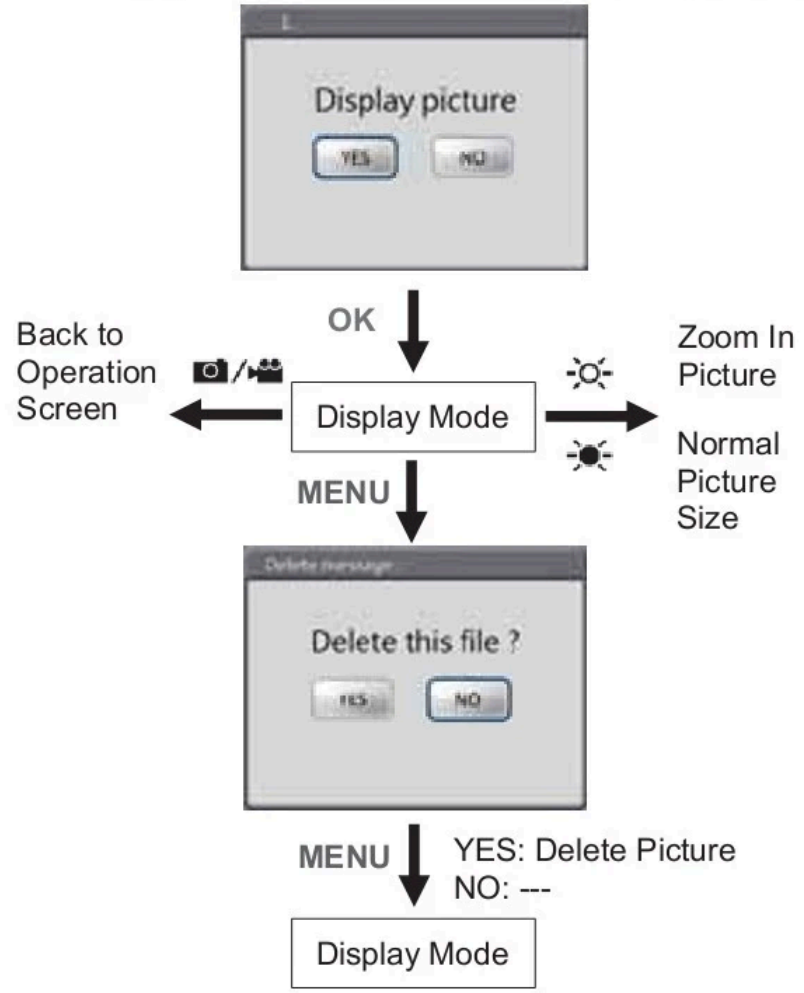
(2) Press “OK” button one time to take video. The “Brightness Indicator” will change to “RON”. The device takes video now. Press “OK” button one time to stop video-taking, the device will save file to SD card. The “Brightness Indicator” will change from “RON” to “SAV”.

(3) The device doesn’t support the video file display on the control unit. Please download the video file (.avi) to computer to display.

- Take picture during video-taking at “video mode”:

(1) The user press “△ / ▽ / ◁ / ▷” to take picture during video-taking. And press “OK” button to stop video-taking. The function is suitable for other lenses, but is not suitable for eye-fundus camera EZ-Horus 40 or 25.

(2) In order to get better video image, the user can press “+” button to turn on flash light aruond 1~2 second during video-taking. User can flash 1~2 second after another 3 seconds to start to flash again. The function is suitable for eye-fundus camera EZ-Horus 40 or 25, but is not suitable for other lenses. Please be careful when using this function. Please do not turn on flash several times in a short time, in order to avoid injury patient's eyes.

Page	Legend	Description	Setting
1			1. Product doesn't support the video file display. Please download the video file (.avi) to computer to display. 2. At "Display Mode", the file name is displayed at the upside of the viewing picture. Press △▽ to change the different folder of date, press ◁ ▷ to change the picture of different time. 3. At "Zoom In" mode, press △▽◁ ▷ to see the different area of the picture.
2		Icon display or not YES: Show icon, date, time. NO: Hide icon, date, time.	Default Value : YES
3		Date Setting YES: Date setting NO: Skip	Default value: (year-month-day) △▽: Adjust the value ◁ ▷:Select year/month/day Press "OK" button once the user confirms the setting.

4		Time Setting YES: Time setting NO: Skip	Default value : (hour : minute) △▽: Adjust the value ◁▷:Select hour /minute Press “OK” button once the user confirms the setting.
5		Standby Function Disable YES: Disable NO: Enable	Default value: Enable Press “OK” button once the user confirms the setting. Default standby time is 3 min.
6		SD card format YES: Make SD card format NO: Skip Note: All information will be deleted after SD card is formatted. The time required for formatting differs depending on the data volume in the micro SD card.	Default value : NO 1. Select “YES” and press “OK” button if the user wants to format SD card. The LCD display screen shows turned off while the SD card is formatting. About 5 seconds, the formatting is complete. The display screen shows "Complete" or "Unsuccess. 2. Appear "Unsuccess, reboot the device and format again.
7		Version of software Press “OK” to check the version of software.	Default value :

8		Searching mode selection YES: IR Search / VIS Photo NO: VIS Search / VIS Photo Note: This function is only suitable for Horus Scope EZ-Horus 40 or 25. It is not suitable for Horus Scope Derma Lens, OTO Lens, Imaging Lens, Anterior Lens and Adapter.	Default value : IR Search/VIS Photo Press “OK” button once the user confirms the setting.
9		Serial Number Setting YES: Set serial number NO: Not to set serial number	Default value : NO Select “Yes” △▽: Adjust the value ◁▷: Select XXXXX position to set the value. Press “OK” button once the user confirms the setting. If not to set serial number, the picture name shows EY161431.jpg It means EY: eye-fundus picture; hr:16;minute:14;second:31 If set serial number, the picture name shows EYXXXXX161431.jpg

10		USB live video enable YES: Enable the USB live video for PC, and disable the removable storage device (cannot check the data of micro SD card through PC) NO: Disable the USB live video for PC, and enable the removable storage device (can check the data of micro SD card through PC)	Default value : NO USB live video disable Press “OK” button once the user confirms the setting. Note: UVC means USB video device class. If you want to enable UVC function, please don’t connect the mini-USB cable to PC. Because of the mini-USB port of EZ-Horus ENT is set as the “Removable Storage Device” in the default. If connect the mini-USB cable to PC before enable UVC, the device will turn off the screen. To use this function, install webcam application corresponding to USB Video Class (UVC) in PC.
11		Auto white balance YES: Enable the auto white balance NO: Disable the auto white balance Note: This function is only suitable for endoscope lens. It is not suitable for other lenses. Because color temperature is different for an external light source of endoscope, so user need to do “auto white balance” to correct the color.	Default value : NO Auto white balance disable When connect endoscope lens to Horus Scope Adapter and control unit, and connect the external light source to endoscope lens. Aim the endoscope lens to a white paper, and then press “OK” button once the user confirms the setting. The auto white balance is complete around 2 seconds.

(7) Image-capturing by the Horus Scope EZ-Horus 40 or 25

Step 1: Modes Selection: (VIS means Visible Light Radiation; IR means infrared Light Radiation)

There are two modes for eye-fundus camera/Ophthalmoscope:

- VIS search/VIS photo mode: search eye-fundus by visible LED light, take photo or video by visible LED light.
- IR search/VIS photo mode: search eye-fundus by infrared LED light, take photo by visible LED light, and take video by infrared LED light.

  The default mode is IR search/VIS photo mode

  Note: When the device turns on, if device connected to the Charger Station or charger, or use a USB connector connected to the computer, the control unit will automatically enter “Sleep Mode”. When cable or charging device is removed, and then press the "OK" button once to awake it.
- Mode switching between VIS/VIS mode and IR/VIS mode

  (1) Press ”MENU” button，enter the selection page.



(2) User can press △ / ▽ to page 8 ”IR searching mode”.



(3) User can press ◁ / ▷ to select “YES” and press “OK” button. And then change to IR search mode.

(4) Follow the above procedure (1) to (3). Go to page 8，select ”NO” button. And then change to VIS search mode.

(5) While the search mode is IR mode，the photo is visible light but the video is infrared light.

(6) While the search mode is VIS mode，both photo and video are visible light as well.

Step 2: Capture eye-fundus image by EZ-Horus 40 or 25 directly

After Optical Lens is attached to the Control Unit, and “Menu” setting is completed. The user can start to capture the images. Approaches for capturing the image of human eye-fundus are as follows:

- Let examinee stays in <5 lux dark room; (The ambient is nearly impossible to see newspaper). Remove glasses or contact lenses. To make sure the eye's pupil is larger than 4 mm diameter, or sufficiently dilate
- Adjust focus to infinite by rotating “Focus Wheel”.
- Ask the examinee to look straight and keep the lenses at the same height of examined eye. Hold the control unit by one hand, and use another hand to hold the front side of lenses. To stabilize the lenses, you may put lenses on the part of hand between thumb and index finger and put your middle and index fingers on the examinee’s forehead, as showed below.





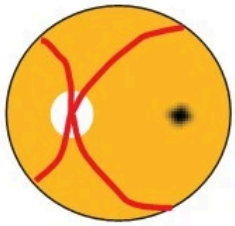
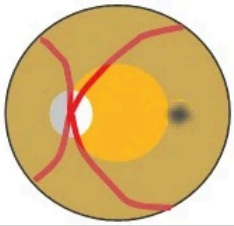
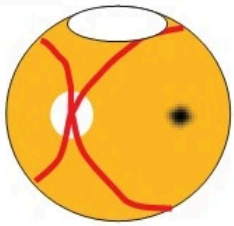
- View the examined eye and keep the lenses horizontal to the examined eye. Then move forward slowly, until you can see optic disk in controller screen. (For sanitary reason, make sure controller lens doesn’t touch patients’ eyes or nose)
- Adjust the brightness of the illumination by pressing

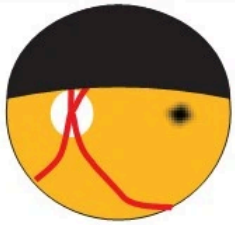
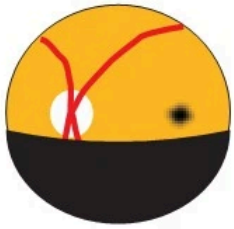
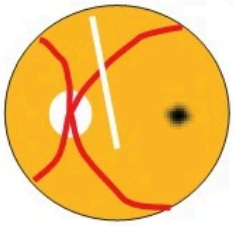
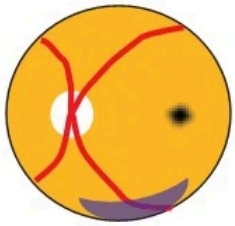
 buttons.

Reference Table:

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

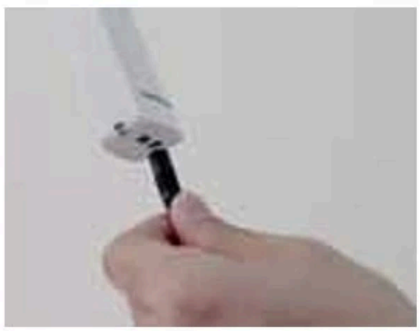
- Find optic disk in controller screen then optimize the image by rotating the "Focus Wheel".
- Fill the screen (circle area) with the image without any shining spot. The correct working distance is 24 mm (from lens tip to cornea)
- Press "OK" button to capture photographs or record videos.
- The display would be frozen and the image would be saved in the SD card. Press "OK" button if the user want to return to operation screen and take another images.
- The brightness is not adjustable in "Video mode".
- According to this table, you may get better image quality

Items	Possible Causes	Schematic Diagram
1. Normal image		
2. Small fundus image	The lens is too far away of eye of examinee	
3. White hot spot in the top of image	The lens is too close to the eye of examinee	

4. Dark shadow in the top of image	The lens is much lower than the visual axis	
5. Dark shadow in the bottom of image	The lens is much higher than the visual axis	
6. Circle or Line spot inside the view	The eyelashes are in the light path	
7. Blue or white shadow at the bottom of image	Cornea reflection	

Step 3: Capture eye-fundus image by foot-switch (Optional part)

(1) Hold the control unit by one hand. Connect the foot-switch to control unit by phone jack connector.



(2) Adjust focus by focus wheel.



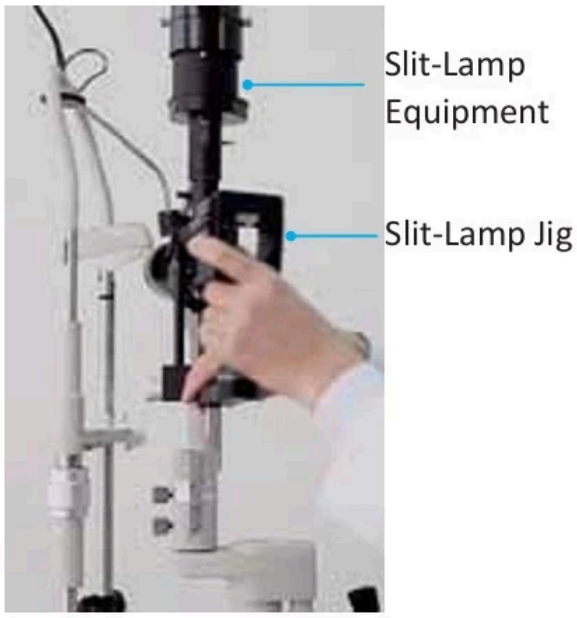
(3) Use foot-switch to take picture when image is clear, as showed below.



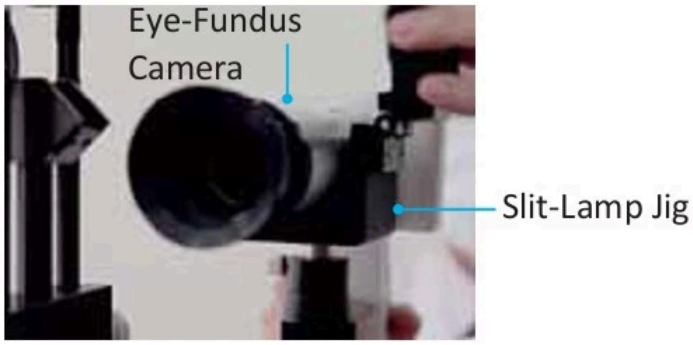


Step 4: Capture eye-fundus image with slit-lamp jig by foot-switch (Optional part)

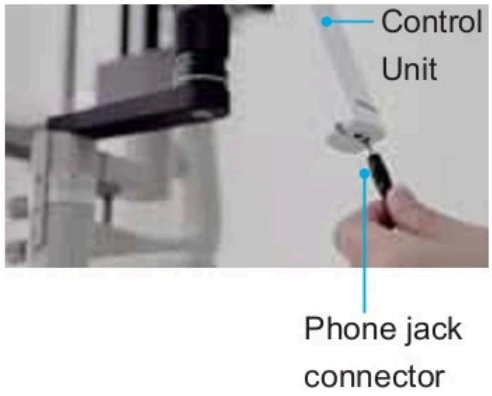
(1) Put the Slit-Lamp Jig into the Slit-Lamp Equipment.



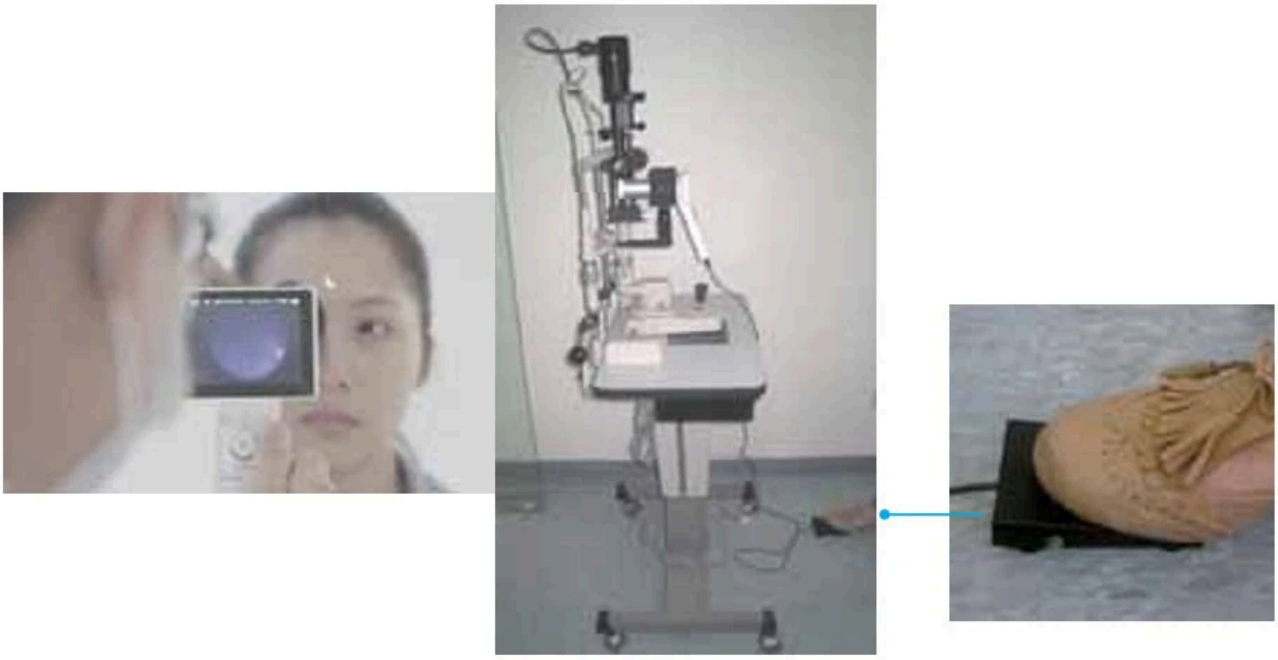
(2) Fixed the eye-fundus camera in the Slit-Lamp Jig.



(3) Connecting the phone jack connector to control unit.



(4) Use foot-switch to take picture when image is clear, as showed below.



(8) Image-capturing by the Horus Scope OTO Lens/Derma Lens/Imaging Lens

After Optical Lens is attached on the Control Unit and “Menu” setting is completed. The user can start to capture the images. Approaches for capturing the images as follows:

1. For Horus Scope OTO Lens, Digital Otoscope, let the Specula to gently insert into the ear canal and have to keep a safety distance between the specula and tympanic membrane. Do not make the specula contact with ear’s tympanic membrane.



2. For Horus Scope Derma Lens, Digital Dermatoscope, let the Contact Plate to gently contact with the skin.



3. For Horus Scope Imaging Lens, Digital Speculum, move Optical Lens to the object at the distance as the image shown on LCD display is that the user wants to capture and adjust.



4. Adjust the brightness of the illumination by pressing buttons.



5. Adjust and optimize the image in focus by rotating the Focus Wheel.
6. Press “OK” button to capture the photograph or record the video.
7. The display will be frozen without any action. The image file is saved in the SD card. Press “OK” button if the user wants to return to operation screen and take another images.
8. Replace the disposable specula before each use for a new patient.

Note: When the device turns on, if device connected to the Charger Station or charger, or use a USB connector connected to the computer, the control unit will automatically enter “Sleep Mode”. When cable or

charging device is removed, and then press the "OK" button once to awake it.

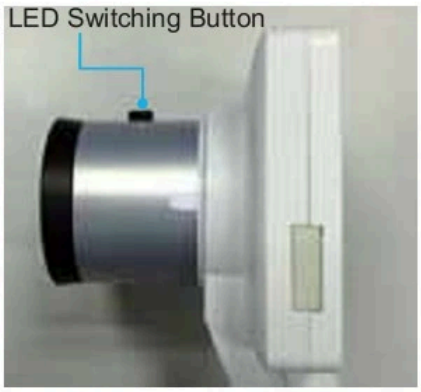
(9) Image-capturing by the Anterior Lens

After Optical Lens is attached on the Control Unit and “Menu” setting is completed. The user can start to capture the images. Approaches for capturing the images as follows:

1. For Anterior Lens, Digital Anterior Scope, keep the distance from cornea to lens about 30mm and fine tune the Focus Wheel to make image be clear.



2. If you want to take fluorescence image of cornea, you can switch to blue LED by the button on lens body. You have to push “menu” key twice to verify LED status. If you want to switch back to white LED, the same procedure as above.



White LED (Default)



Blue LED



3. Adjust the brightness of the illumination by pressing buttons.



4. Adjust and optimize the image in focus by rotating the Focus Wheel.
5. Press “OK” button to capture the photograph or record the video.
6. The display will be frozen without any action. The image file is saved in the SD card. Press “OK” button if the user wants to return to operation screen and take another images.

(10) Transfer Images to the electronic device

Step 1: Transfer images to the electronic device, for example, personal computer, laptop or mobile phone, via the USB cable connecting to Control Unit and Charger Station, or Micro SD card.



Mini USB connector

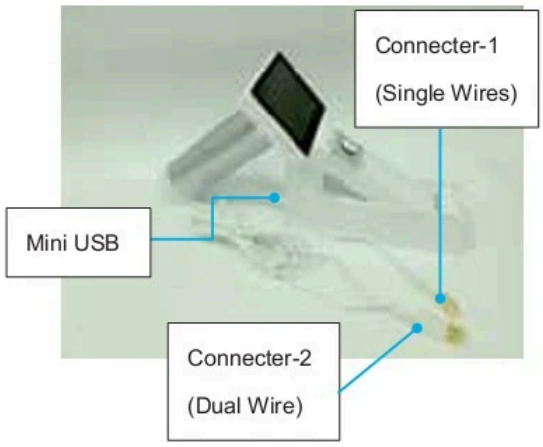




7. Battery Charging and Data Transferring：

Place the device and USB cable to the Charger Station, as right picture showed.

- Link connecter-2 to computer for battery charging and data transferring.
- Link connecter-1 to computer for battery charging only.
- Link connecter-1 or Connector-2 to Power Adapter for battery charging only.



Note: Suggest charging the battery after turning off the device. If charging the battery when device is on, over charge protection design will be activated automatically after 5 hours. And then the battery will discharge until no power.

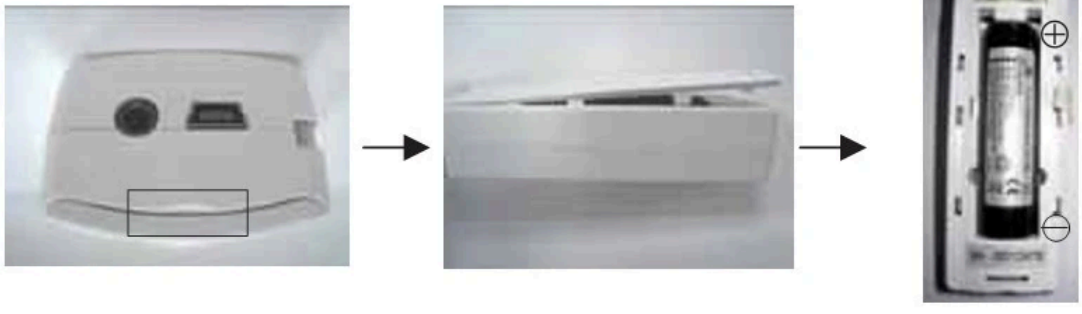
8. Instruction of Power Indicator：



State of Power Indicator		Status
Blue light		Normal operation
Orange light		In charge.
Sparkling blue light		Power less than 25%.
Mix blue and orange		Connect to PC by USB, Or USB live video enable
No light		System off

9. Battery Replacement

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.

10. Cleaning and Disinfection

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

- Power off device before cleaning it.
- Disinfect the control unit and charger station with the soft cloth with alcohol. Wait for cleaning liquid to dissolve before power on and connecting the charger station and USB cable to the control unit.
- It is recommended to clean the optical lens with cleaning cloth or lens cleaning tissue such as THORLAB Inc., (www.thorlabs.com) Lens Cleaning Tissue.

If the replacement for new eye-cup, disposable specula or new contact plate is needed, please contact with manufacturer or your own retailer.

Clean the contact plate before each use for a new patient:

- Disinfect the contact plate with soft cloth moistened with alcohol (70% ethyl alcohol).

Note: The device is not intended to be sterilized.

11. Operation Environment

- Ambient temperature: 0℃ to +35℃
- Relative humidity: 10% to 80%
- Atmospheric pressure: 700hPa ~ 1060hPa

12. Environment for Storage and Transportation

- Ambient temperature: -10℃ to +40℃
- Relative humidity range: 10% to 95%

Note: It is recommended to remove the battery if the device is stored over 2 weeks.

13. Technical Description

Horus Scope EZ-Horus 40, Digital Eye-Fundus Camera:

- View Angle 40 Degree (Typical)
- Diopter -20 ~ +20D (Typical)
- Dimension 16 × 9 × 20.5 cm (Typical)
- Weight 395 Grams (Typical)
- Search Fundus Lighting Two modes, natural white Light Emitting Diode (LED) or infrared LED.
- Camera / video flash light Natural White Light Emitting Diode (LED)

Horus Scope EZ-Horus 25, Digital Ophthalmoscope:

- View Angle 25 Degree (Typical)
- Diopter -20 ~ +20D (Typical)
- Dimension 12.5 × 9 × 20.5 cm (Typical)
- Weight 360 Grams (Typical)
- Search Fundus Lighting Two modes, natural white Light Emitting Diode (LED) or infrared LED.
- Camera / video flash light Natural White Light Emitting Diode (LED)

Horus Scope OTO Lens, Digital Otoscope:

- Focus Range 5~50 mm (Typical)
- Dimension 9 × 9 × 20.5 cm (Typical)
- Weight 325 Grams (Typical)
- Camera / video Natural White Light Emitting Diode (LED)

Horus Scope Derma Lens, Digital Dermatoscope:

- View Area 10 mm diameters (Diagonal) (Typical)
- Dimension 8 × 9 × 20.5 cm (Typical)
- Weight 370 Grams (Typical)
- Camera / video Natural White Light Emitting Diode (LED)

Horus Scope Imaging Lens, Digital Speculum:

- View Angle 88 Degree (Diagonal) (Typical)
- Dimension 5 × 9 × 20.5 cm (Typical)
- Weight 300 Grams (Typical)
- Camera / video Natural White Light Emitting Diode (LED)

Horus Scope Anterior Lens, Digital Anterior Scope:

- View Area 11mm(V)*19.6mm(H)*22.47mm(Diagonal) @ Working Distance 30mm (Typical)
- Dimension 6.5 × 9 × 20.5 cm (Typical)
- Weight 340 Grams (Typical)
- Camera / video Natural White/Blue Light Emitting Diode (LED)

Focus：	Manual Focus
Camera Resolution：	1920 × 1080 pixels
LCD Monitor：	3.5” Full Color TFT-LCD
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：	Micro SD Card, default 8GB. Supports 2G to 32GB 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, 0.3A; Output Spec. : 5V DC, 2A
Charger Station Input Spec.：	5V DC, 1.2A
Operating Time：	3 hours at 2.5 Watt condition
Charging Time：	5 hours by EZ-Horus ENT
Expected service life (defined by manufacturer)	5 years from the date of initial operation *Proper maintenance is necessary.

14. Liability

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

- Assembly operations, extensions, re-adjustments, 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.

15. Environment

- 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, be sure to follow the local governing ordinances.
- 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 specula, eye cup or contact plate, follow the disposal procedures for medical waste such as needles, infusion tubes, metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution.

16. 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 (Only for EZ-Horus 40 or 25)

- 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 that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

(1) 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)

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>*1</td></tr>
<tr><td>Voltage fluctuations/
Flicker emissions
IEC 61000-3-3</td><td>*2</td></tr>
</table>

*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 (V_1=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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E_1=3)	$d=1.2\sqrt{P}$ 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 metres (m). 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.