Horus+ Scope

EZ-Horus OTO Blue
User Manual

DOC. No. 2014.02-A

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1. Category

Product Name	Digital Otoscope
Model Name	EZ-Horus OTO Blue
Accessory	1. Battery
	2. Disposable Specula
	a.) adult x 8
	b.) pediatric x 8
	3. Power Adapter
	4. USB Cable
	5. AV Cable

2. Symbols



Caution must be taken. Read user's manual before use



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



The operator is advised to read the instructions in the user's manual



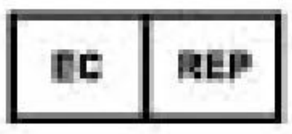
Manufacturer



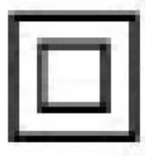
Date of Manufacturing



CE mark



European Authorized Representative



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

3. Warnings and Cautions

NOTE

Prior to installation and start-up of the device, carefully read the instructions provided herein! As with all technical devices, the proper function and safe operation of this device depend on the user's compliance with the safety recommendations presented in these operating instructions. Do not attempt to open the cover of the product to prevent the product from malfunctioning.

CAUTION



Always use the device in accordance with the directions and recommendations contained in this User's Manual.



When operating the device, please take note that the optical lens does not touch the eyes or nose of the patient. Avoid harming the patient.



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



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



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



Avoid using the device in a dusty environment, and keep the power cord away from any heat sources.



Prior to operation, please make sure the device does not appear to be damaged or broken. If there are cracks in the device's cover or other visual defects, please contact the manufacturer or a manufacturer-certified service facility.



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



Only use the Li-ion Battery 3.7V @ 2500mAh that is provided by the manufacturer or distributors. The battery has been designed to protect the circuit. To ensure safe product operation, if the battery reaches its lifetime or fails, please contact the manufacturer or distributor to buy a spare battery.

If you purchase a Micro SD Card with a different memory capacity, it must first be formatted to FAT32.

The eye must not be exposed to the illumination light of the product during operation.

Replace the disposable specula of EZ-Horus OTO Blue, Digital Otoscope, before each use for a new patient.

Gently insert the specula of EZ-Horus OTO Blue into the ear canal. Keep a safe distance between the specula and tympanic membrane. Do not contact the ear's tympanic membrane with the specula.

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

CLASS 1 LED PRODUCT

This device has been tested and found to comply with the regulations for medical devices of 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 device on and off, the user is encouraged to try to correct the interference with one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the space between the device and other devices.
- Connect the device to an outlet on a different circuit from that to which the other device(s) are connected.
- Consult the manufacturer or a 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.
This device complies with these requirements as shown in the tables in "15. (1) EMC (Electromagnetic Compatibility)" (Page 20-26). Follow the guidelines in the tables for use of the device in an electromagnetic environment.



During installation and operation of the device, observe the following instructions regarding 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 a small electric current.
- Do not use the device with portable and mobile radio frequency communication systems, as they can have an adverse effect on the operation of the device.
- Do not use cables or accessories that are not specified for the device because doing so may increase the emission of electromagnetic waves from the device and decrease the immunity of the device to electromagnetic disturbance.
- Do not touch the lens connecting pins of the control unit or the signal pad of lenses without special precautions.

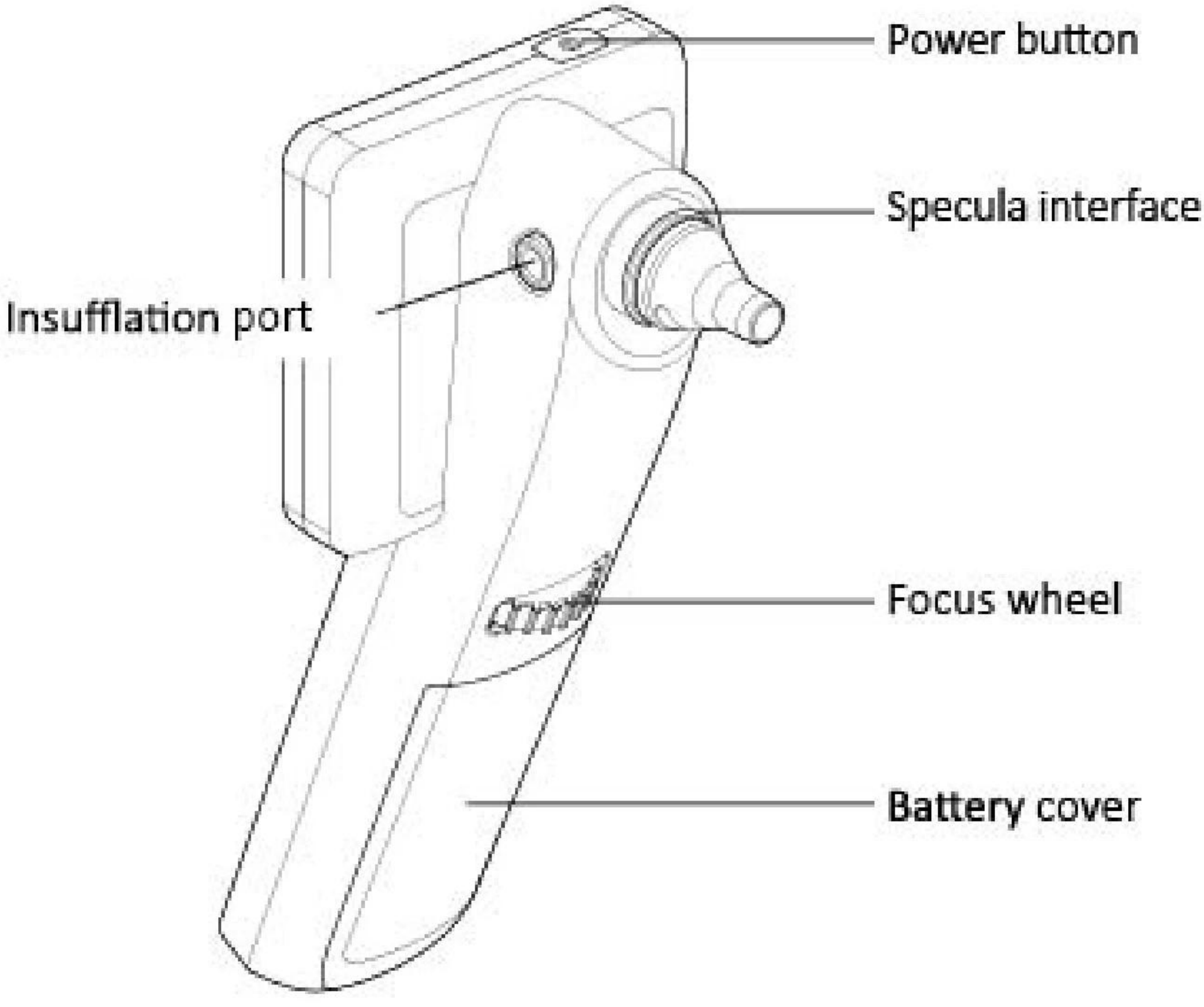


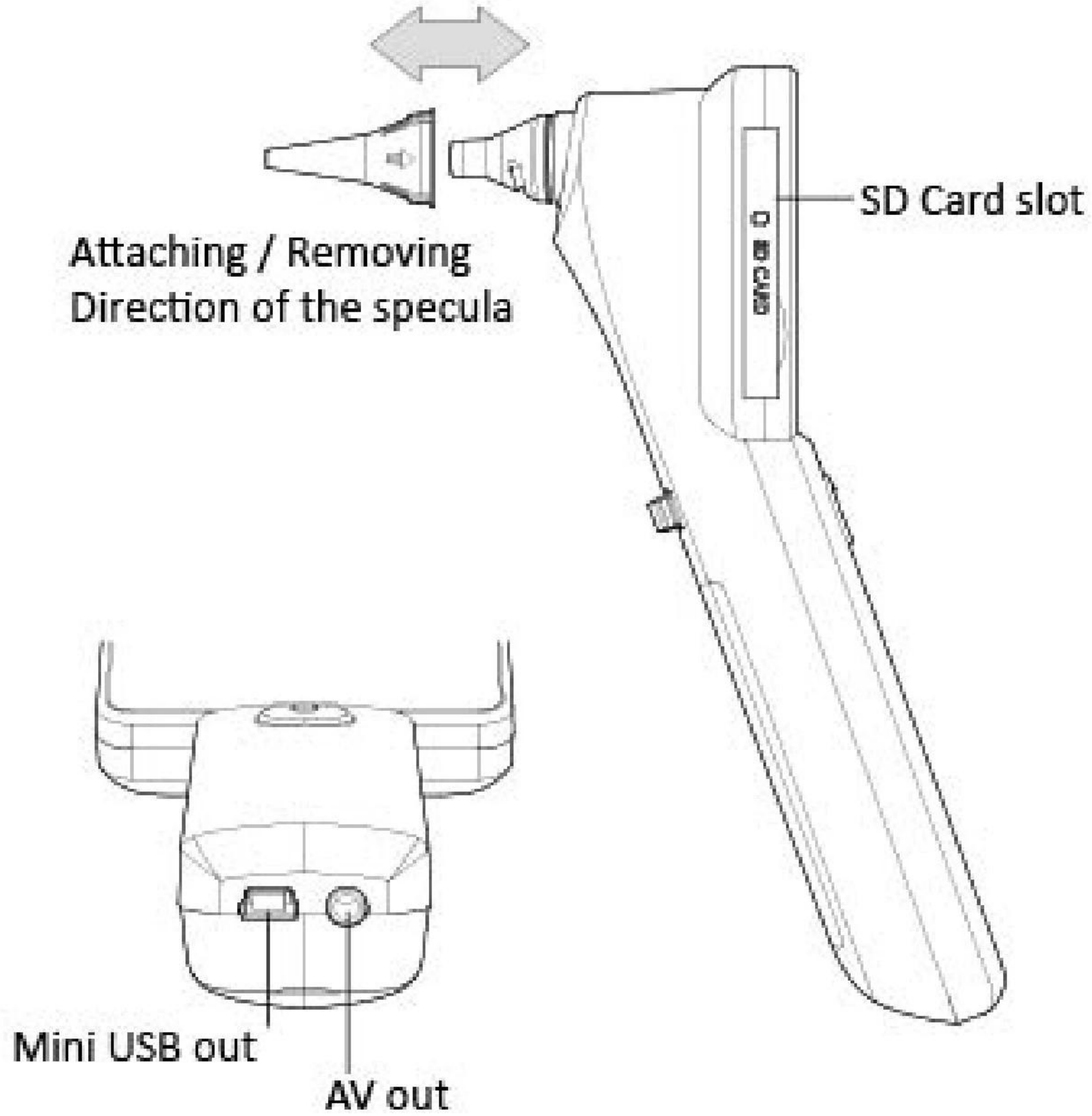
Users are responsible for managing the captured image data. The manufacturer will not assume any responsibility for the loss of data.

4. Intended Uses

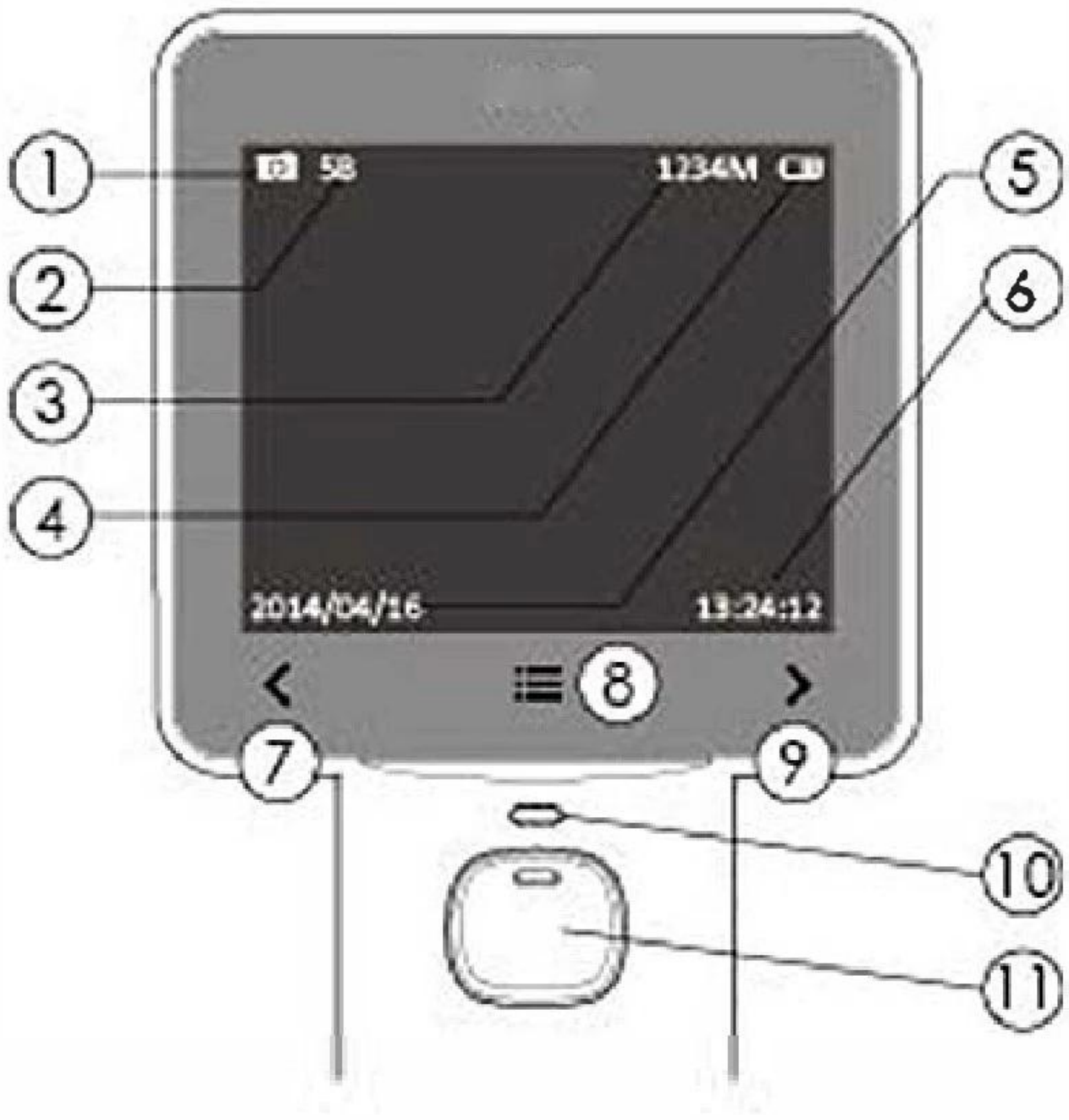
The EZ-Horus OTO Blue is a digital hand-held otoscope used to record digital photographs and video of the human ear canal and tympanic membrane. The EZ-Horus OTO Blue can also be used for the general inspection of the throat and nasal cavity and capture photographs and video of those areas.

5. User Interface



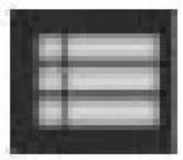
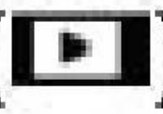

Attaching / Removing
Direction of the specula
SD Card slot
Mini USB out
AV out

6. Operating Instructions



1.Operation Mode:
Photo( )/ Video( ) /
Display( )
2.Brightness indicator: 1B ~ 10B
3.Free memory of SD card
4.Power indicator
5.Date indicator
6.Time indicator
7.Brightness decreasing / Function selection
8.MENU
9.Brightness increasing / Function selection
10.Status indicator
Blue Light – Normal Operation
Orange Light – In charging
11.Capture Button

Operation Mode V.S. Function of Buttons

Button / Mode				
Photo ()	Decrease brightness	Increase brightness	Enter menu selection	Capture Photo
Video ()	Decrease brightness	Increase brightness	Enter menu selection	Start/Stop Video recording
Display Photo file ()	Previous file	Next file	Delete file	*Return to Photo/Video Mode
Display Video file ()	Previous file ; Rewind	Next file ; Fast-forward	Delete file ; Stop displaying video file	Start/Pause displaying video file ; **Return to Photo/Video Mode

* : Press the button to return to the photo/video mode.

**: Hold on the capture button "1 second" to return to the photo/video mode.

NOTE

Without touching any buttons, the device automatically enters standby mode after 2 minutes, and turn off the device after 30 minutes.

Press the "shutter" button to wake up the device if device is in the "standby mode'.

7. Charging the Battery and Transferring Photos

- **Charging the Battery:**

Step 1. Connect the EZ-Horus OTO Blue and power adapter via a USB cable.

Step 2. Insert the power adapter into the wall plug to charge the device.

- **Transferring Photos:**

Connect the EZ-Horus OTO Blue to the computer via USB cable. In normal situations, the EZ-Horus OTO Blue becomes a standard storage device, and the user can review or copy the photos from this device to the computer.

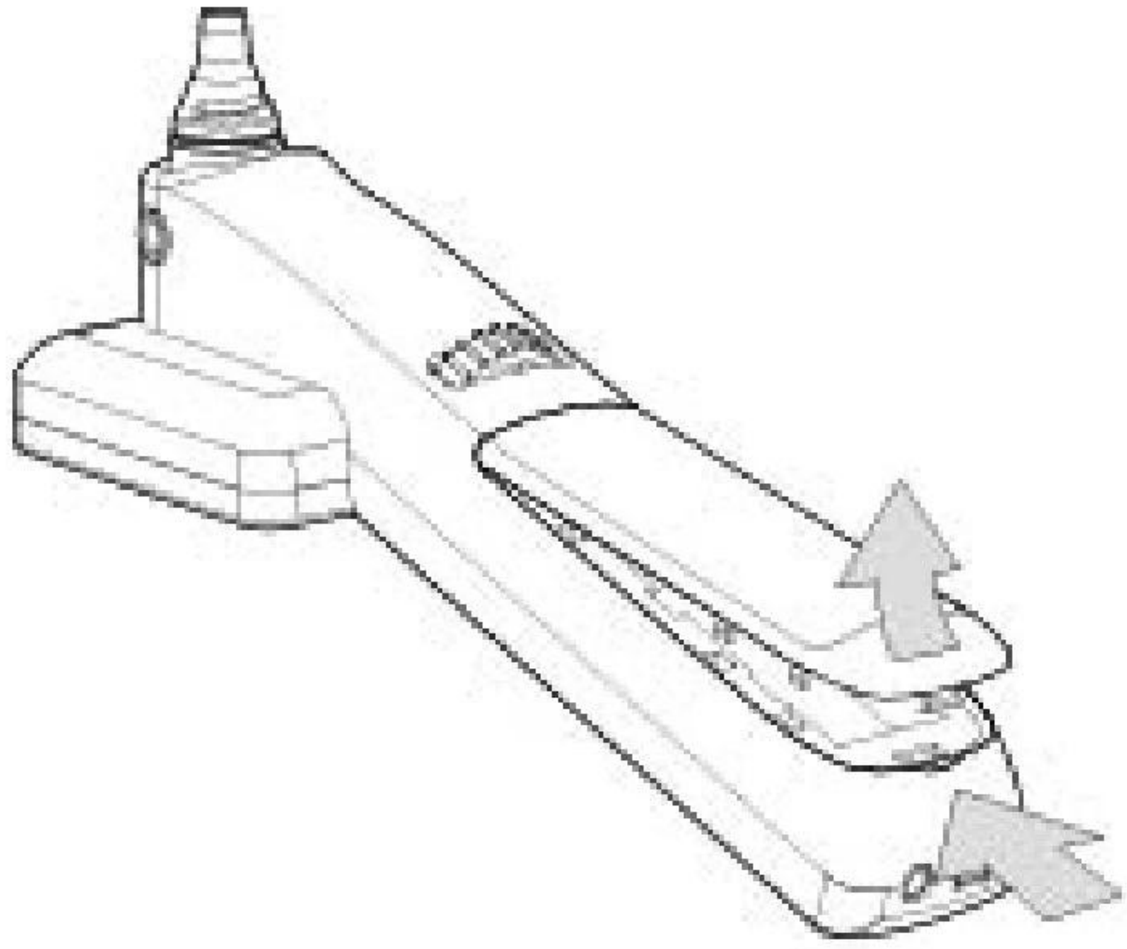
NOTE

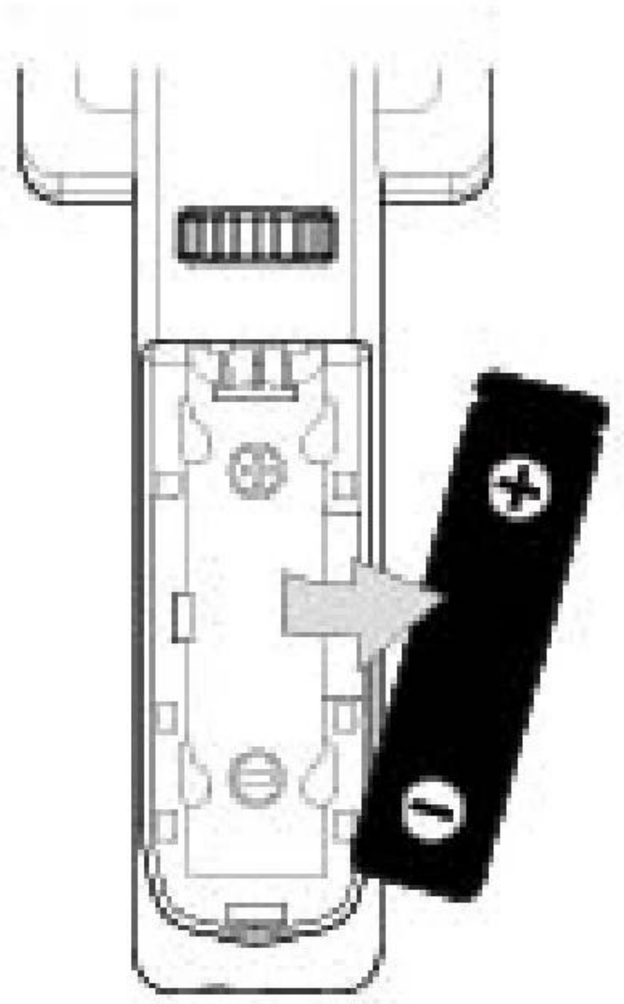
The EZ-Horus OTO Blue can also operate in "UVC" mode, in which the pictures can be shown on the LCD panel of the EZ-Horus OTO Blue and the screen of a computer if the EZ-Horus OTO Blue is connected to the computer via a USB cable.

If the user wants to operate in "UVC" mode, please enter the menu to enable this function.

8. Battery Replacement

Battery Replacement





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

- Tilt the battery cover and remove by lifting it up.
- Remove the original battery and replace it with a new battery, placed in the correct direction.
- Return the battery cover and secure it in place.

9. Cleaning and Disinfection

This device is a precision photoelectronic instrument that shall be handled with special care. Please note the following cleaning instructions:

- Power off the device before cleaning it.
- Disinfect the product with a soft cloth with alcohol (70% ethyl alcohol).
- It is recommended to clean the optical lens with a cleaning cloth or lens cleaning tissue such as the Lens Cleaning Tissue by THORLAB Inc. (www.thorlabs. com).

If new disposable specula are required, please contact the manufacturer or your own retailer.

NOTE

This device is not intended to be sterilized.

10. Operating Environment

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

11. Environment for Storage and Transportation

- Ambient temperature: -10°C to +40°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 700hPa ~ 1060hPa

NOTE

It is recommended to remove the battery if the device will be stored for more than two weeks.

12. Technical Description

- Focus Range 25~100 mm (Typical)
- Dimension 181 x 69 x 66 mm³ (Typical)
- Weight 206 Grams (Typical)
- Illumination Natural White LED

Focus:	**Manual Focus**
Image Resolution :	1440 x 1080 pixels
Screen:	**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:	8GB SD Card Supports 2G to 32GB in FAT32 Format

Power Source:	Rechargeable Lithium Battery 3.7V/2500mAh
External Power:	Source: 100~240 VAC , 50/60 Hz
Power adapter output spec:	5V DC, 1.2A
Operating time:	4 hours
Charging time:	4.5 hours
Expected service life: (defined by manufacturer)	5 years from the date of initial operation *Proper maintenance is necessary

13. 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 the requirements.
- The equipment is used in accordance with these instructions for use.

14. Environment

- Follow the local governing ordinances and recycling policies 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 policies 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 of this device and its parts may contaminate the environment.
- When disposing of the specula, 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.

15. 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)

• Equipment connected to 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 device 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 that system complying with the requirements of the device standard IEC 60601-1. When in doubt, consult the technical service department of your local representative.

EMC (Electromagnetic Compatibility)

This device complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2007) for electromagnetic compatibility as listed in the tables below. Follow the guidelines in the tables for use of the device in an electromagnetic environment.

EMC (IEC 60601-1-2: 2007)

Guidelines and manufacturer's declaration for electromagnetic missions		
This 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 guideline
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	*1	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	*2	

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

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

Guidelines and manufacturer's declaration for electromagnetic immunity			
This 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 guideline
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors 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	The 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	The 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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	<5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	The mains power quality should be that of a typical commercial or hospital environment. If the user of this 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 commercial or hospital environment
NOTE: UT 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	3Vrms 150 kHz to 80 MHz	3Vrms (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 distances $d=1.2\sqrt{P}$ 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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E1=3)	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[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 a frequency range of 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			
This 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 the frequency of the 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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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Please visit www.usophthalmic.com tor more Information.