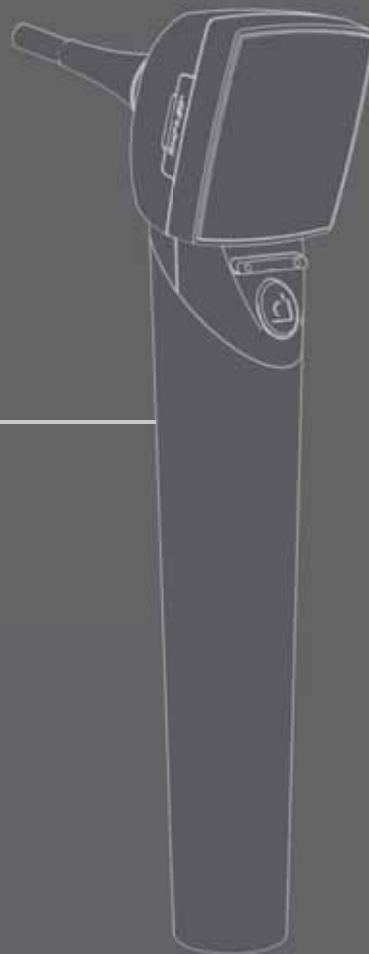


Sync  Vision
Digital otoscope

iO1 Elite

User Manual



iO1 Elite w/o-UM-01 Ver. A3

Sync  Vision

iO1 Elite

HD Digital Otoscope

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FDA



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ISO
CERTIFIED
13485

Preface

Intended use

The digital otoscope is intended to allow inspection of the external ear, ear canal, and tympanic membrane under magnification.

SyncVision iO1 Elite is a digital video Otoscope System camera alternative for medical specialists.

The operation and maintenance of SyncVision iO1 Elite guided in the manual must be followed precisely to assure the reliability of the product. Please read this manual cautiously before operating the device.

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If users experience difficulty or operational issues in the SyncVision iO1 Elite, kindly reach local dealer for product's technical support. Moreover, contact to the customer service either at +886-2-2278-2222 or info@sync-vision.com.

The SyncVision trademark and trade dress are used under license from SyncVision Technology Corp.

Any serious incident that has occurred in relation to the device should be reported to the manufacture and the competent authority of the Member State in which the user and/or patient is established.

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1 SyncVision iO1 Elite Overview

SyncVision iO1 Elite digital otoscope is a compliant with the requirements of the EEC and international medical standards. This product had an internal rechargeable battery with a Class II power supply.

SyncVision iO1 Elite makes medical treatment simple and easy, it has been designed to carry out the following functions:

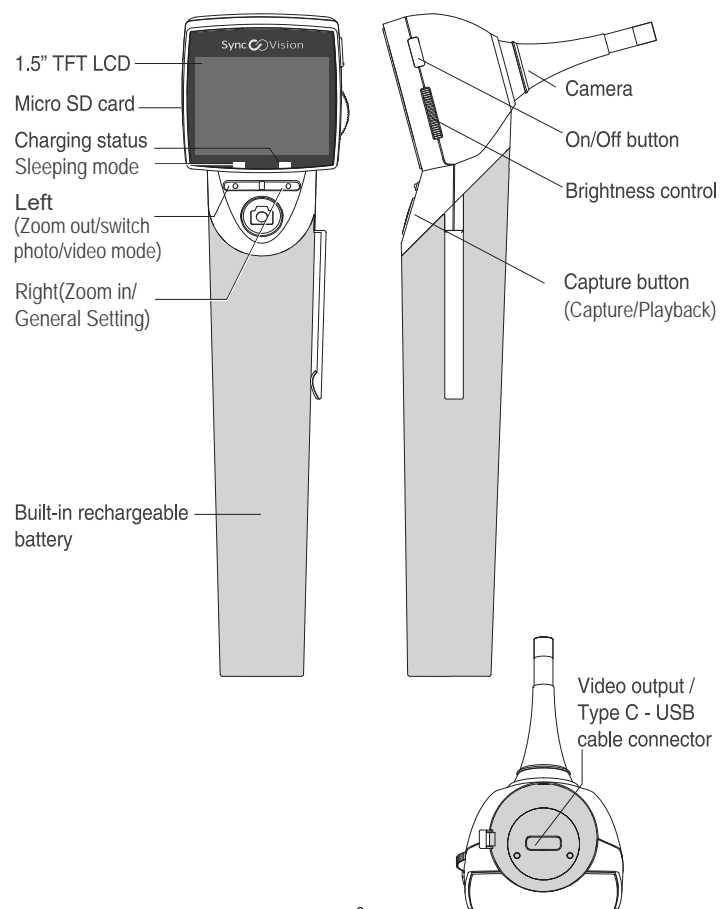
- Capture still images by one click, Built-in LCD provided instant image review
- Over 100,000 images/ 12 hours video can be stored in the Micro SD.
- Stored image can be transferred via Type C-USB cable to computer
- Cordless and no software installation provide User-friendly operation.
- Rechargeable Built-in battery can be operated with hours runtime.
- Brightness adjustment can adapt to different inspection condition to prevent blurriness problems.
- A Video outlet enables synchronized display on an external monitor.
- A USB Cable enables to transfer images & video from iO1 Elite to computer, or synchronizes images & videos on the computer.

Through using SyncVision iO1 Elite, it eliminates patient's worries about treatment by offering immediate and clear communication between the doctor and patient.















SyncVision iO1 Elite digital otoscope is designed as an assistive device for medical specialists to inspect ears.

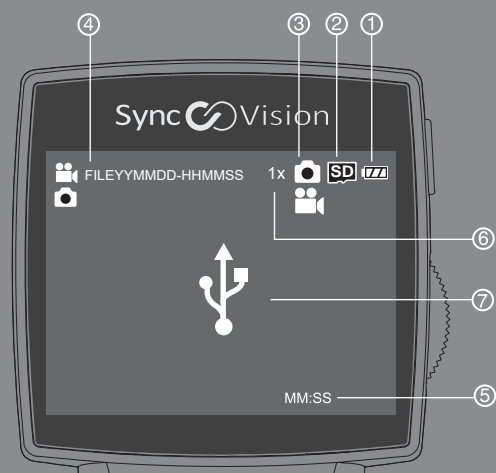
It should not be used for any other purposes.

Figures of SyncVision iO1 Elite



Markings and Symbols

	Manufacturer
	Date of manufacture
	Warning: Failure to heed this warning could result in damage to property or in bodily.
	Caution: Points out procedures that users must follow precisely to avoid damage to the system or any of its component.
	Warning electrical hazard
	Authorized representative in the European community
	Note: Provides additional information, such as expanded explanations, hints, or reminders.
	Type BF Applied Part, Classification in accordance with IEC 60601-1 (The top of camera)
	Operate only between 0 and 40°C
	Serial number
	CE mark
	Symbol of Class II
	Do not re-use
	See User manual before use, its' included Important information and Instructions for use. Therefore, it should be read carefully in order to avoid any problems.



Item	Description
① Battery status	Full 2/3 1/3 Low Charging
② MicroSD status	Success Empty
③ Mode indicator	Indicates the engaged mode(photo/video).
④ File name	File name of captured image. Y=year, M=month, D=day, H=hour, M=minute, S=second
⑤ Video record timer	MM:SS ; M=minute, S=second
⑥ Zoom in	Adjusting magnification of camera; from 1x to 2x
⑦ MSDC	Connecting to PC via the USB cable.

Standards

Electrical safety	IEC 60601-1:2005+AMD1:2012
EMC and regulatory compliance	IEC 60601-1-2:2014 E4.0

Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN60601-1 and IEC 60601-1). Furthermore, all configurations shall comply with 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. This device may not cause harmful interference, and this device must accept any interference received including interference that may cause undesired operation.

Safety Instruction

When operating the SyncVision iO1 Elite digital otoscope, obey the following warning and safety instructions:

1. Make sure the voltage of the power source is correct before connecting the equipment to the power outlet.
2. If the equipment is not used for a long time, disconnect it from the power source to avoid damage by transient over-voltage.
3. Unplug the AC adapter from MAINS socket to disconnect the device and MAINS.
4. For pluggable equipment, the power outlet must be installed near the equipment and must be easily accessible.



Danger of Electric Shock

- This is an electrical unit. DO NOT expose device to moisture. Such action may cause an electric shock or a malfunction.



Warning

- Preservation: Please put the digital otoscope in the shady place, and avoid sunray directly shining.
- DO NOT operate the device in the presence of inflammable anesthetics
- No modification of this equipment is allowed
- Operating environment in 40 °C or less.
- No reuse the disposable protective sheath.



Caution

- SyncVision iO1 Elite should be operated under supervision of a trained medical specialist or health professionals with learning to use the otoscope. Users are responsible for the operation and maintenance of this camera.
 - Please follow local rules and regulations regarding disposal or recycling of the device and its components.
 - Before each use, the outer surface of the ear specula, and the device which is intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may Cause a SAFETY HAZARD.
-
- The Video signal output connector is intended for connection to devices that comply with IEC 60601-1, or other IEC standards (for example, IEC 60950), as appropriate to the device.
 - Any desktop or laptop which is used with the camera shall be at least IEC 60950 or equivalent standards certified.
 - Power line operated equipment or accessories connected to this unit are comply with UL Listing Mark, and should not have been modified so as to defect the safety features.
 - Clean any parts of the unit that comes into contact with the patient and the operator after each image acquisition. Always use a new speculum for each patient.
 - When the camera is not in operation, ensure that the ON/OFF button is set to OFF.

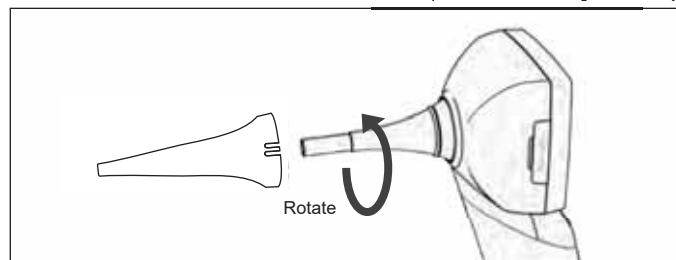
- The power adapter is certified by IEC 60601-1. Be sure use the provided AC Mains adapter only.
- Avoid damage of the USB cable. DO NOT tug the cable directly, gently push and pull the plug when disconnecting the cable.
- Fragile Device, handle with care. Take strict precautions against heavy throw or hit.
- This is not an user-replaceable device, any repair or service must be applied through the authorized SyncVision dealer services personal or the manufacturer.
- Keep the ear camera probe away from fluid or be moistening, if there is crack in the coating.

2 Setting Up / Power On/Off

Setting up the SyncVision iO1 Elite

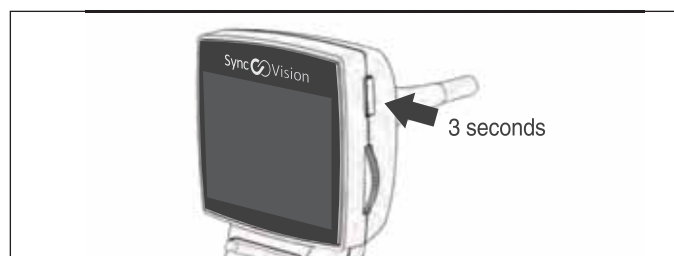
- 1.1 Please cover the ear specula to avoid scratching the ear canal .
- 1.1.1 Make sure the tip of probe is cleaned by wiping it with a moist lint-free cloth or lens tissue.
- 1.1.2 Insert the speculum into the ear camera probe directly.

NOTE: ⓧ Each ear speculum is for single use only.



Power On/Off

- Press and hold the power button for 3 seconds to switch the device on, and 3 seconds to turn off device.



General Settings

- Enter General Settings mode by long pressing Right button.
- Leave General Settings mode by long pressing Capture button.

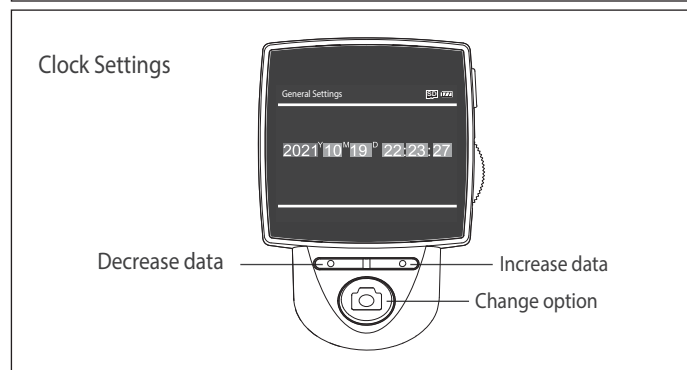
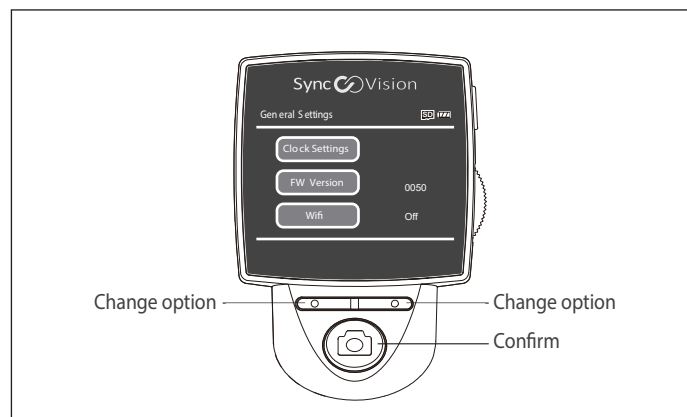
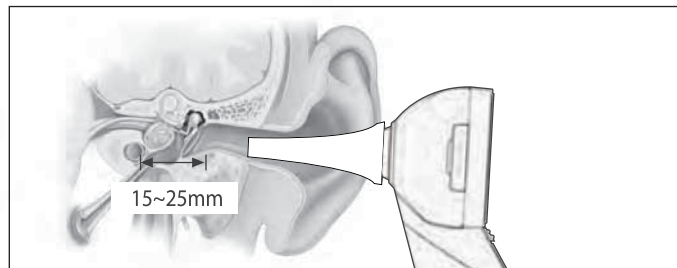



Image capture and review

- Hold the camera over the area you want to view.
Live video appears on the 1.5" TFT-LCD.
- Adjust the brightness as needed.
- You can press the Left and Right button to zoom out and in the image for review.

(The favorable focus range of ear camera is from 15mm~25mm.)

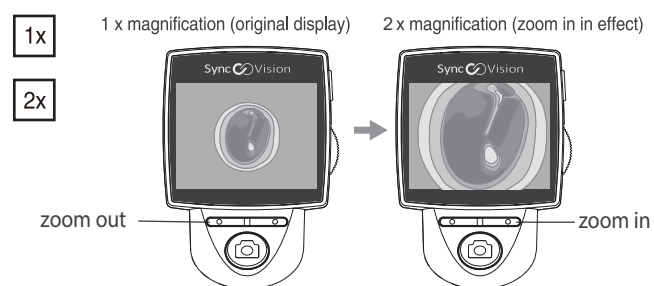


- The method to acquire an image:
(1) To press the capture button  on the camera less than one second. The still image appears on the 1.5" TFT-LCD.



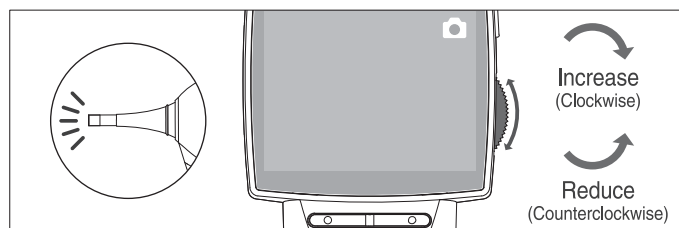
Zoom in

- In the real-time preview state of the photo/recording mode, press the left button to zoom out, press the right button to zoom in. There are two levels of magnification. The current magnification will be displayed in the screen.

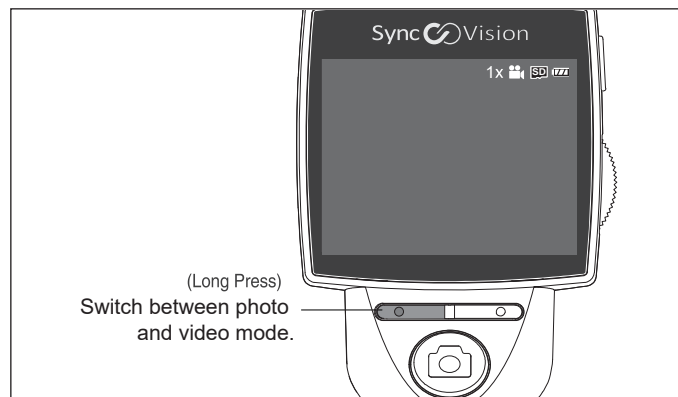




Brightness adjustment

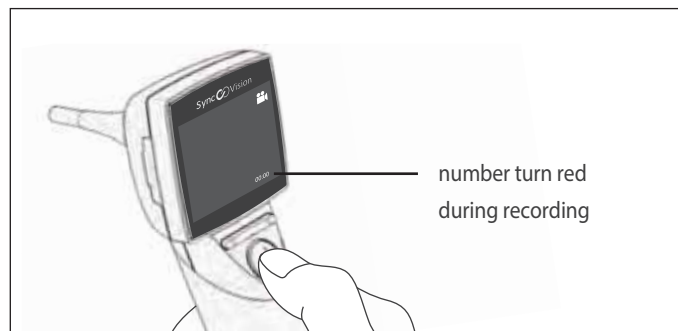
- Adjust the brightness to a appropriate level by turning the control dial .




Video mode

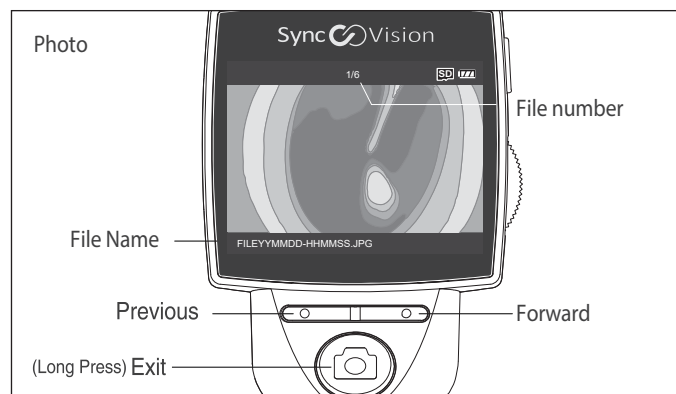
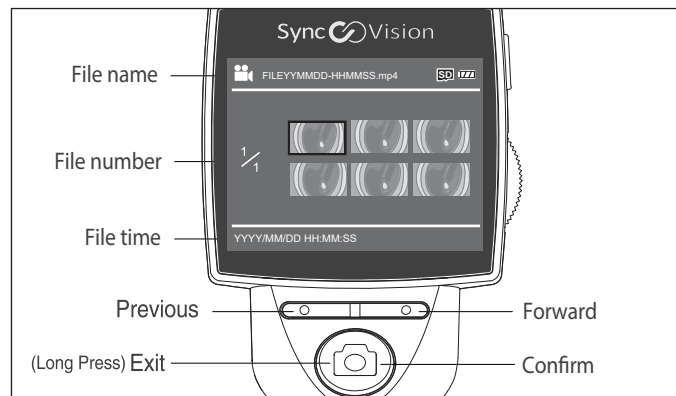


- Press “capture” button  to start video recording.
By pressing again “capture button”  to end the video record.

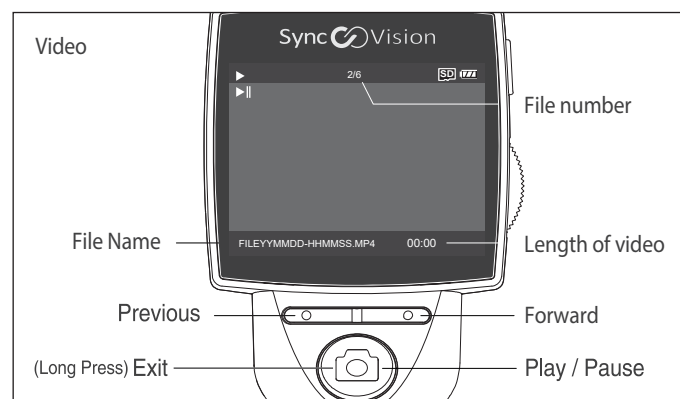


Play back mode

- Enter Play back mode by long pressing Capture button 

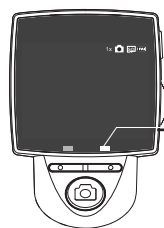


Play back mode



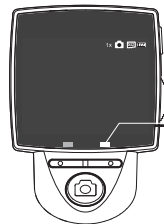
Status indicator

Low battery



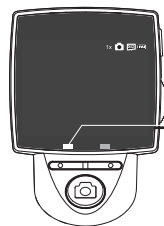
Flashing orange light indicates low battery, please apply charge ASAP.

Charging mode



When under the orange light will light up constantly when the device is under charging.
When the device is fully charged, the green light will light up.



Sleeping mode



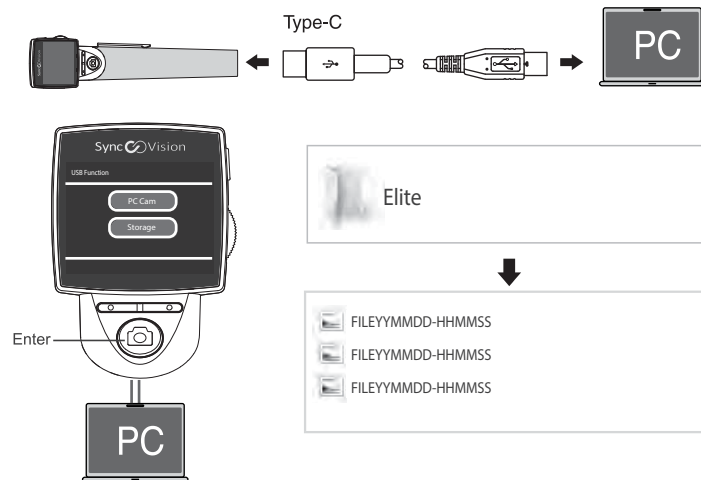
The blue flashing light indicates the device is under sleep mode and standing by.

File storage and transfer

- Portable Micro SD card enables the storage of over 100,000 images.

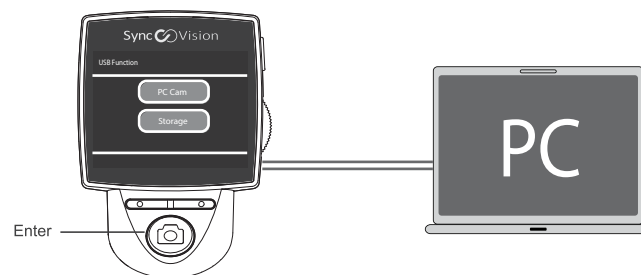
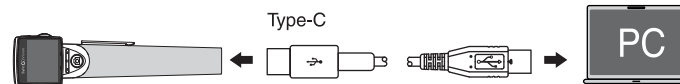
Micro SD card   Gently push and pull the MicroSD "click," when take-out memory card is necessary.

- Stored images or videos can be transferred via USB cable to the computer.
 1. Connect SyncVision iO1 Elite and PC by attached Type-C USB Cable.
 2. Select Storage
 3. Access "My computer" from the connected computer and find the "Elite" folder to review images & videos.
- Transfer purpose only, not operable.



Video output

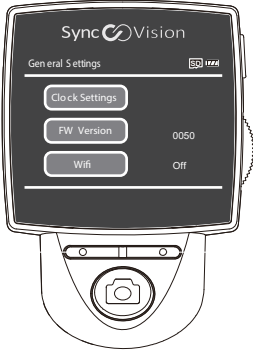
- Establish a connection to a PC or a Laptop to realize synchronized video output.
 1. Connecting iO1 Elite and PC by USB cable.
 2. Menu will be shown on camera, please select "PC Cam".
 3. Open the "media player software", then select the "USB Camera" to stream video on PC or Laptop.
 4. Ensure the media player supports streaming in HD (1280*720).



Wifi mode

Long press Right key into General Settings.

If you need to use WIFI to connect to the PC, please refer to the SyncView Wi-Fi User Manual.



The image shows the 'General Settings' screen of a SyncVision device. At the top, it says 'SyncVision' with a logo. Below that, 'General Settings' is written. There are three buttons: 'Clock Settings', 'FW Version' (showing '0050'), and 'Wifi' (showing 'Off').

Select the Wi mode by Right key and Left key.

Switch to Wi option and press Capture key into Wi mode.



The image shows the 'Wi' screen of a SyncVision device. At the top, it says 'Wi' with a logo. Below that, there are two buttons: 'Off' and 'AP'.

Please refer to the Wi manual for Wi connection methods.

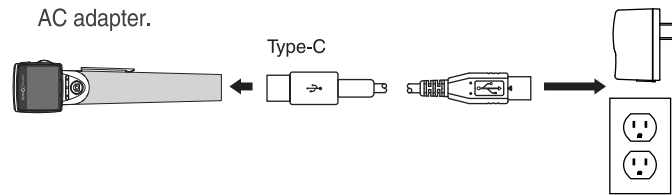
Select the Wi mode by Right key and Left key.

Switch to the preferred option.

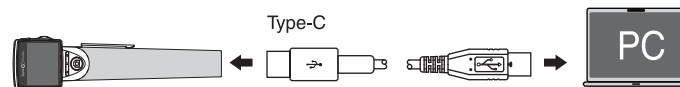
Confirm and exit by long press the capture key.

Charging

- Charging by connected both USB cable and AC adapter.

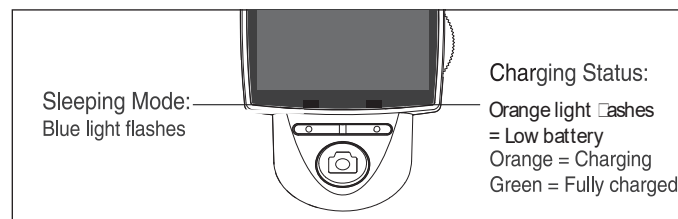


- Charging by connected SyncVision iO1 Elite and PC by attached Type-C USB Cable.
- Long press capture button to leave the USB Function list start charging.



Built-in rechargeable Battery and Sleeping Mode

- After 100% power recharged, the SyncVision iO1 Elite can continue to work for 6 hours.
- Battery condition shows on the upper right side of the screen.
- The device will initiate sleep mode if it stayed idle for 5 minutes. The blue flashing light indicates the device is under sleep mode and standing by. In sleep mode, you can push any of the buttons to wake and re-initiate the device instantly. If the device stayed idle for 30 minutes, it will be automatically shut-down for power saving purpose.



Warning: The battery is not a user-replaceable part, which must be ordered and replaced directly from the manufacturer.



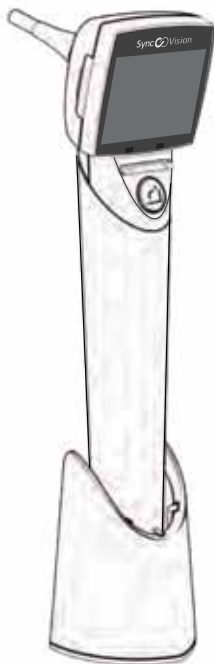
Note: When the “Low Battery” was indicated on the LCD screen, camera will be automatically shut-down within few seconds.

Dual-purpose pedestal

The dual purpose pedestal can be utilized in two ways.
It could be used as holding pedestal or charger pedestal.

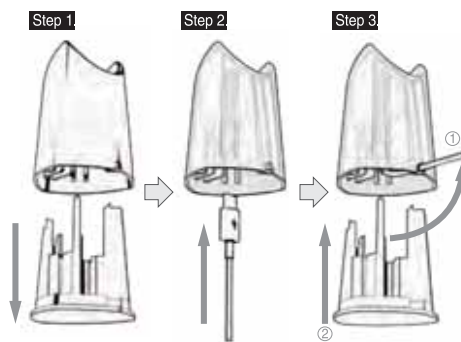
(A) Holding Pedestal:

You can either put the iO1 Elite perpendicularly or horizontally into the dual purpose pedestal.



(B) Charger Pedestal:

Open the rubber lid on the base and fix the type-C charging connector as illustrated below.
You would be able to utilize the base as charger pedestal since you can supply the power to the iO1 Elite when it is held perpendicularly in the pedestal.



3 Cleaning, Maintenance and Storage

The camera is delivered unsterilized. To ensure maximum hygienic safety for the patient, carefully follow the instructions in this user's manual to prepare the camera for use. After each patient, the camera must be thoroughly cleaned.



Caution:

Never put the camera in a sterilizing device or immerse it completely.

Cleaning of otoscope main device

The housing of the main device can be cleaned with a cloth moisten with water, alcohol, or a non-liquids should not be dripped or spilled over the surfaces of the LCD module or handle as they are not watertight.



Note:

If the camera is visibly soiled, it must be thoroughly cleaned.

Be careful not to use too much liquid to clean camera device.

Cleaning of changeable camera probe

1st Step: Take out the alcoholized pre-pad, or use a clean, lint-free cloth to thoroughly wipe the camera probe with a disinfecting solution,

2nd Step: Clean and wipe the outer sheath of the camera probe with the alcoholized pre-pad, or clean, lint-free cloth moisten with alcohol.

3rd Step: Gently clean the probe lens with the cotton swab.



Warning:

Care should be taken not to scratch the lens of the camera.

Maintenance

Daily: Perform above cleaning activities daily on iO1 Elite.

Monthly: Wipe the outer covers of the units with a soft, dry cloth.

Storage

- Place the camera in the dual-purpose pedestal when you are not using the otoscope.
- The digital otoscope should be placed in the storage compartment of the package.



Warning:

Unnecessary exposure to extremes in temperature and humidity should be avoided.

Disposing of the Battery



The Symbol indicates that the product is not to be discarded with normal household waste.

Before discards battery, please ensure the rechargeable battery be discharged completely.

It must be sent to the appropriate facility for recovery and recycling and follow all local regulations.

Troubleshooting

- When it's freeze or happens connection problem, long press on/ off button to turn off and reboot it again.
- Repair of this equipment can only be handled by authorized technicians of the manufacturer.

No image is displayed on the screen.

- Make sure the power is switched on.
- Make sure the power button can be pressed with ease.
- If you use an external monitor to synchronized display of the image; make sure the correct cable is used to connect the camera and the external monitor.
- If the system is NOT switched on by repeating above steps, please contact local dealers or manufacturer for technical support.


Camera cannot capture an image


- Make sure the portable MicroSD card is stored completely.
- Restored the MicroSD card to the camera .

Image is blurred.

- Make sure the lens of camera probe is not fogged, and clean the contact surface with cotton swab or alcoholized pre-pad.
- Make sure the protective sheath is flattened against the lens and properly inserted (transparent side facing the lens).
- If the image is still NOT displayed properly by above steps, please contact local dealers or manufacturer for technical support.

Cannot use General setting .

- Long press Right button  to enter General setting.

No MSDC icon  is showed on the LCD after device connected to PC via attached USB Cable.

No " Elite folder " is found from the "My Computer" of PC after the device was connected to the PC via attached USB Cable.

- Ensure the USB Cable is completed assembled to the camera.
- Restart the SyncVision iO1 Elite.
- Re-pull and plug-in the USB Cable to the USB slot of PC.
Or, re-pull and plug-in it to another USB slot of PC.



Note:

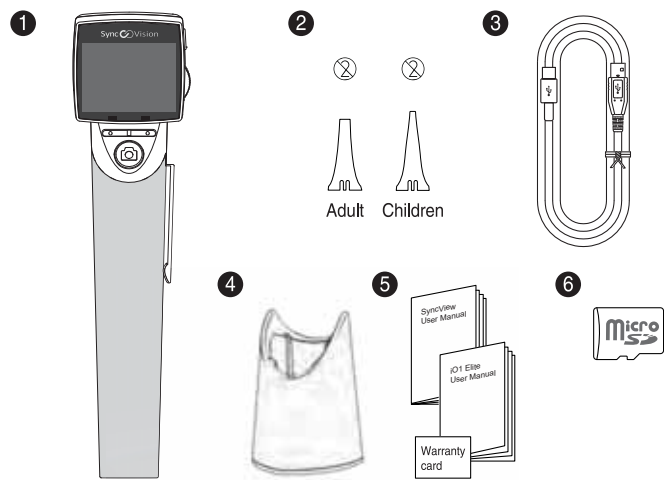
Suggested USB Slot to connect the SyncVision iO1 Elite Digital oscilloscope and PC or Laptop would be the USB 3.0 .

- If there's still No " Elite folder " could be found from the "My computer" of PC by above steps, kindly contact local dealers or manufacturer for technical support.

Technical features and Specifications

Dimensions	43x40x175mm
Weight	Approximate 140g
Display	1.5"full color TFT-LCD
Probe Size	Ø4.2mmx 43mm(L) (The specification may vary depending on the actual order and shipment.)
Resolution	Photo 1920*1080 (Full HD) Video 1080*720
Focus Type	Fixed
Light Source	High Luminance White LED
File Format	JPEG / MP4
Interface	USB / UVC / Type C
Memory	Micro SD card 32G MicroSD Class 10
WIFI standard	802.11
Power	Built-in rechargeable lithium battery (6 hours runtime, 3.7V/1620mAh) Unit input: 5V DC 1A
Power Adapter(option)	FranMar International Inc./ FRM06-S05 series I/P: 100-240 Vac, 50-60 Hz, 0.3-0.15 A O/P: 5 Vdc/ 1.2 A
Operation Environment	Temperature:0~+ 40°C Humidity:10~95%RH Atmospheric pressure:700hpa~1060hPa
Environment for Storage and Transportation	Temperature:-20~+60°C Humidity:10~90%RH Atmospheric pressure:700hpa~1060hPa

Components (Standard)



No.	Description	Q'ty
1	iO1 Elite Otoscope system	1
2	Disposable Specula (for adult)	5
	Disposable Specula (for children)	5
3	Type-C USB cable	1
4	Dual-purpose pedestal	1
5	User manual & Warranty card	3
6	Micro SD card	1

4 Warranty statement

SyncVision iO1 Elite digital otoscope system is warranted by the SyncVision Technology Corp. against defects in craftsmanship and materials for one year from the date the device was delivered. The camera is warranted for 1 year.

SyncVision Technology Corp., at its discretion, will repair or replace any parts of the products (other than users manuals and Micro SD card) that are defective in craftsmanship or materials if the product is proven faulty within the one year warranty, provided SyncVision Technology, is given notice in a timely manner. SyncVision Technology, will be responsible for shipping costs of any repair/replacement parts for the first 30 days after receipt of a system. The customer will be responsible for shipping costs for any replacement or repair of defective parts thereafter.

If products are returned to SyncVision, the original customer must obtain an RMA (Return Merchandise Authorization) number from SyncVision via e-mail. The customer must include the RMA number on the package and the customer must prepay all freight charges to return any product to a SyncVision designated location. SyncVision will ship replacements freight collect on an exchange basis to the customer. Products will become property of SyncVision that are returned to SyncVision under this warranty.

This warranty is non-transferable and limited, which excludes Micro SD card and does not cover damage is due to:

- 1) any defects in any product or part not supplied by SyncVision as part of the product;
- 2) fine tuning, relocation, modification or repair by other than SyncVision authorized personnel;
- 3) improper maintenance or installation, carelessness, or negligence or cause other than ordinary applications, industrial, commercial or personal;
- 4) any statements made about SyncVision products by regional offices, dealers, distributors, agents or salespeople unless confirmed in writing by a SyncVision Officer;
- 5) damage which occurs in shipment to or from Customer.

SyncVision's liability shall not exceed price of the individual piece whose loss or defect is the basis of the claim. SyncVision is not liable for loss of use of facility, loss of profits, loss of use of equipment or other incidental consequential damages. SyncVision is free of obligation beyond its standard warranty with regards to changes made in system component hardware by the manufacturer of that hardware. Without prior notice SyncVision reserves the right to make changes in its system hardware at any time. This limited warranty shall constitute the entire limited warranty and is granted by SyncVision instead of any or all other written, oral, implied or statutory warranties.

Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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 antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

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

FCC RF Radiation Exposure Statement

- 1) This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- 2) This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

This equipment should be installed.

RF Exposure Information (SAR)

This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels.

The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov after searching on FCC ID: 2ATTB-SV1511



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