

Otoscope

User Manual

[Product Name] Otoscope

[Model Number] OS801

[Manufacturer] Ningbo Albert Novosino Co.,Ltd.

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[Manufacturer Address] No.1 Xinheng 3 Road Cicheng Town, Jiangbei District, 315036 Ningbo China

[Intended Use]

An otoscope is a device intended to allow inspection of external ear canal under camera system. The device allows the user to view the ear canal and take photos and videos all with smart phone or tablet .The product is intended for a single user.

[Contraindications]

A proper patient history **MUST** be taken before using the otoscope. The device should not be used when:

- The patient has undergone ANY form of ear surgery.
- The patients has or has had a perforation in their ear drum.
- The patient has a grommet in their ear drum.
- The patient has had a middle ear infection within the past six weeks.
- The patient has acute otitis externa or tenderness of the pinna.

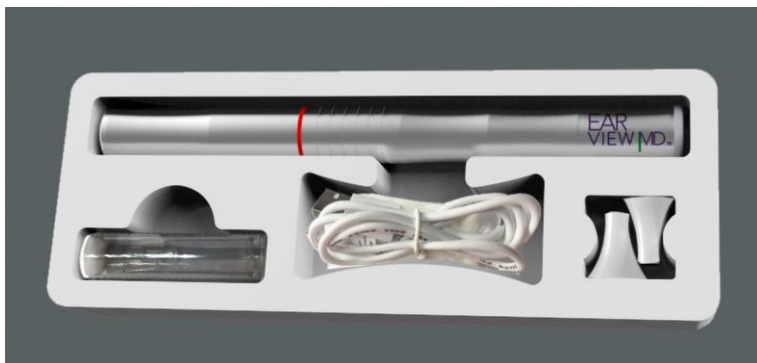


Read the user manual carefully before using this device. As you read the manual, pay special attention to the warning, caution, and note messages.

[Application]

The product is only suitable for inspection of external ear canal under camera system.

[Structure]



[Device Description]

The otoscope is a personal use electric device for inspection of external ear canal under camera system. The device is electrically powered from internal batteries.

The device consists of ear camera system, micro-USB power cord, safety cone tip, Microfiber cleaning cloth and other related accessories. The device is powered by rechargeable Li-ion batteries.



The electrodes are considered as one type BF applied part.

The device contains a rechargeable Li-ion battery(3.7V) which can be charged by external battery charger, the device is not able operate during charging.

The IP classification of the stimulator is IP22.

[Technical Specifications]

Power Supply: Rechargeable Li-ion batteries 3.7V DC, 350mAh,1.85Wh ; Input: 5V ---1.0A

Supply Connection :Internally powered equipment with separate AC adaptor for charging.

Battery lifetime: approx. 200 operation hours

Charging hours per time: 1-1.5 hours, running hours per time: 1-1.5 hours

Dimensions: 135*14mm (L*Dia)

Accessories:High-definition ear camera x1, Safety cone tip x2, Scoop attachments x2, Micro-USB power cord x1, Microfiber cleaning cloth x1, User manual x1

Operation condition: +5 ~ +40 °C, 35 - 70 % relative maximum humidity

Storage conditions: -5 ~ +50 °C, 30 - 80 % relative maximum humidity

Atmospheric Pressure (kPa): 700hPa - 1060hPa

IP Class: IP22 , Mode of operation: Continuous

Reference to standards:

IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11

Expected service life: 5 years or 200 operation hours.

This device complies with the requirements of the Medical Device Directive EU 2017/745 regulation.

Technical alterations reserved.

According to the Medical Product User Act a biennial technical inspection is recommended for professional users. Please observe the applicable disposal regulations.

[Operation Instructions]

1. Charge your oscotce by plugging in the micro-USB power cord to the device and a charging socket.
2. Download the app from the linkage below:
App for Android : <http://d.firim.pro/4rc9> App for iOS: <http://d.firim.pro/nbpt>
3. To power on the device, remove the cap. A purple light will appear to let you know your device is on.
4. Connect to the device's Wi-Fi by entering into the app. Go to your Wi-Fi settings and select EOSERA Wi-Fi.
5. Return to the Eosera app and press start to begin viewing live footage. Select "left ear" to switch between your right and left ear.
6. Press the photo button to take a picture. Press the video button to start recording a video. Press the video button again to stop recording.
7. Select the album button on the bottom of your screen to view photos and videos. Photos and videos will be saved to your phone or tablet automatically.
8. Place the cap back onto the device to turn off.

[Important Safety Instructions]

1. Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.
2. This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application
3. Never immerse this device in water or other liquids. For cleaning please follow the instructions in the «Cleaning and Disinfecting» section.
4. Do not use this device if you think it is damaged or notice anything unusual.
5. Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed.
6. Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installations. Keep a minimum distance of 3.3 m from such devices when using this device.
7. While some discomfort may be felt when first using the device, but not cause pain.

Protect it from:

- extreme temperatures
- impact and dropping
- contamination and dust
- direct sunlight
- heat and cold

8. 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.

[Cleaning and Disinfecting]

Clean with warm soapy water and rinse thoroughly after each use. Shake out excess water and let air-dry thoroughly.

Use an alcohol swab or cotton tissue moistened with alcohol (70% Isopropyl) to clean the device. Ensure that no liquid enters the interior of the device.



[Caution]

- Please read through these instructions carefully in order for you to understand all functions and safety information.
- Always switch off the device after use.
- Do not use while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place or drop into water or other liquid.
- Only use the power adaptor recommend in the manual.
- This is a single user product. Use by more than one person may present a health risk.
- Strictly for use in the outer ear canal (from the eardrum outward).



[Warning]

- If you are experiencing discomfort after use, discontinue use and contact your healthcare professional. The device is not replacing the need for the consultation of a physician, especially if not matching the patients' symptoms.

- Danger of electrocution! Keep the device dry! Never immerse in water or other liquids! Do not run water over the USB charge port.
- The device and accessories are not heat-resistant: keep away from radiators, open flame and sunlight
- Keep the device out of reach of children.
- No modification of this equipment is allowed.
- Do not aggressively shove or stick the camera into the ear canal or scrape the skin of the canal as it may cause bleeding, discomfort, or damage to the eardrum.
- Not for use in mouth or throat
- **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.

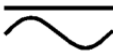
Warning: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC RF exposure Statement

The exposure standard for wireless devices employs a unit of measurement known as the Specific Absorption Rate(SAR). The SAR limit set by the FCC is 1.6 W/kg. The highest SAR level measured for this device is less than SAR limit, so this device meets the FCC Requirement.

[Explanation of marking note]

No.	Symbol	Note	No.	Symbol	Note
1		Manufacturer	2		Keep away from sunlight
3		Date of manufacture	4		Authorized representative in the European Community
5		Batch code	6		Use-by date
7		CE Marking	8		Keep dry

9		Warning	10		Operating instructions
11		Type BF applied part	12		Caution
13		Dispose with the locally regulation	14		Direct current
15	IP22	IP classification, the first number 2: Protected against solid foreign objects of 12.5 mm $\varnothing$ and greater; The second number 2: Protection against vertically falling water drops when ENCLOSURE tilted up to 15 °	16		Serial Number
17		Catalogue number			

[Storage Conditions And Methods]

The Products shall be stored in a cool and dry place away from water source and heating. Keep away from sunlight, and there shall be no acid corrosive gas or other harmful gas in the surrounding air. The storage time should not exceed five years from the production date. Recommended storage temperature is -5 ~ +50 °C, relative humidity is between 30%~80%.

[Dispose]



Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

[Guarantee]

This device is covered by a 1 year guarantee from the date of purchase. During this guarantee period, at our discretion, we will repair or replace the defective product free of charge. Opening or altering the device invalidates the guarantee. The following items are excluded from the guarantee:

Transport costs and risks of transport.

Damage caused by incorrect application or non-compliance with the instructions for use.

Damage caused by accident or misuse.

Packaging/storage material and instructions for use.

Regular checks and maintenance .

Should guarantee service be required, please contact the dealer from where the product was purchased, or your local service . You may contact your local service through our website:

www.albertnovosino.com/support

Compensation is limited to the value of the product. The guarantee will be granted if the complete product is returned with the original invoice. Repair or replacement within guarantee does not prolong or renew the guarantee period. The legal claims and rights of consumers are not limited by this guarantee.

[Term Of Validity] Five years

[Production Date / Batch No.] Refer to label on the package.



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