GIMA
PROFESSIONAL MEDICAL PRODUCTS

OTOSCOPIO CON FOTOCAMERA
OTOSCOPE WITH CAMERA
OTOSCOPE AVEC CAMÉRA
OTOSCOPIO CON CÁMARA
OTOSCÓPIO COM CÂMAR
OTOSKOP MIT KAMERA
OTOSCOOP MET CAMERA
OTOSKOP MED KAMERA
OTOSKOP MED KAMERA
OTOSKOP MED KAMERA
OTOSKOOPPI, JOSSA KAMERA
OTOSKOPAS SU KAMERA
OTOSKOPS AR KAMERU
KAAMERAGA OTOSKOOP
OTOSKOP Z KAMERĄ
OTOSKOP S KAMEROU
OTOSKOP S KAMEROU
OTOSZKÓP KAMERÁVAL
OTOSKOP S KAMERO
OTOSKOP S KAMEROM
OTOSCOP CU CAMERĂ
ОТОСКОП С КАМЕРА
ΩΤΟΣΚΟΠΙΟ ΜΕ ΚΑΜΕΡΑ
منظار الأذن المزود بكاميرا

- Manuale d'uso e manutenzione
- Use and maintenance book
- Instructions de fonctionnement et entretien
- Manual de uso y mantenimiento
- Manual de uso e manutenção
- Betriebs und wartungs anweisungen
- Εγχειριδιο χρησης και συντηρησης
- Instrukcje użytkowania i konserwacji
- Návod k použití a údržbě
- Instruktioner för användning och underhåll
- Manual de utilizare şi întreţinere
- Návod na použitie a údržbu
- Instructies voor gebruik en onderhoud
- Brugs- og vedligeholdelsesvejledning
- Käyttö- ja huolto-ohjeet
- Kasutus- ja hooldusjuhend
- Priručnik za uporabu i održavanje
- Kezelési és karbantartási útmutató
- audojimo ir priežiūros instrukcijos
- Lietošanas un apkopes instrukcijas
- Instruksjoner for bruk og vedlikehold
- Navodila za uporabo in vzdrževanje
- Инструкции за употреба и поддръжка
- تعليمات الاستخدام والصيانة

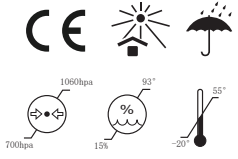
GIMA 31410

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PEOPLE'S REPUBLIC OF CHINA
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M31410-Rev.0-03-25

Otoscope Instruction Manual

Model: OT-501
Manual Version: A0
Date of issue: 2023.11

Intended use

The otoscope is a handheld device equipped with lighting and a camera, intended to be used to observe the external ear, ear canal, and eardrum on a smartphone screen. Its secondary use is to provide general illumination of the throat and nasal passages by means of additional attachments.

Target group

The otoscope can be used for children over the age of 1 under adult supervision or for independent use by anyone over the age of 12.

Contraindication

No contraindication

Explanation of symbols

	Caution: read instructions (warnings) carefully		Fragile, handle with care
	Manufacturer		Keep away from sunlight
	Date of manufacture	IP22	Covering Protection rate
	Follow instructions for use		Non-ionizing electromagnetic radiation
SN	Serial number		Parte applicata tipo BF
LOT	Lot number	EU REP	Authorized representative in the European community
	WEEE disposal		Imported by
MD	Medical device	CE	Medical Device compliant with Regulation (EU) 2017/745
UDI	Unique device identifier	REF	Product code
	Keep in a cool, dry place		Humidity limit
	Atmospheric pressure limit		Temperature limit

Safety instructions

Please read the instruction manual carefully before using this device, and keep the instruction manual for future use.
Should you give this device to another person, it is vital that you also pass on these instructions for use.
The Company will make available on request circuit diagrams, component part lists, descriptions, or other information necessary to assist the User's qualified technicians in repairing parts of the equipment specified by the manufacturer as repairable.
The materials which the user can come into contact with have no toxicity and no action on tissues comply with ISO10993-5, ISO10993-10 and ISO10993-23.

General warnings

- This product cannot be used for the diagnosis and treatment of any patient unless specified by a physician.
- This product is unsuitable for children under the age of 12 months.
- Do not use the product while charging.
- Children should be supervised by parents when using the otoscope.
- When using this product, please make sure that the product has an intact appearance and does not have any missing accessories.
- Please put the silicone speculum or tongue depressor tightly on the otoscope before use.
- If the ear canal is not perfectly straight, gently adjust the position of the otoscope to view your ear drum dearly.
- The camera's focal length is fixed at 18±5mm. Please adjust the distance between the camera lens and your ear if you can not clearly see the image.
- Do not drop or submerge the device in water or liquid.
- Do not break the otoscope with your hands.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.
- If the device does not work properly, or if you feel unwell or experience pain, stop using it immediately.
- It is not recommended for pets on the move.
- Do not leave the small parts where children can reach them. Children may swallow them. If a child accidentally swallows them, please contact a doctor immediately.
- For first-time users, please approach the ear canal, nasal or oral gently and slowly.
- Please follow the user manual for your first use.
- Do not modify this equipment without authorization of the manufacturer.
- Dispose of the equipment when its service life is reached. Follow local ordinances and recycling instructions regarding disposal or recycling of the equipment.
- No maintenance or servicing the when using.
- Do not use the product if it shows are signs of damage to itself. If damaged, do not attempt to repair the instrument! Please contact the dealer.
- The otoscope should not be repaired or serviced during use.
- When the performance changes (such as: abnormal display), please stop using it immediately and contact the after-sales service personnel in time.

Notice

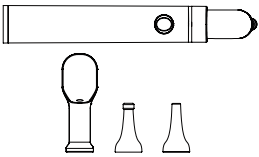
If users or patients have occurred any serious incident that relation to the device, please report to manufacturer and the competent authority of the Member State in which you are established.

Power Safety

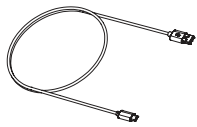
- Check the voltage rating before you connect this equipment to an electrical outlet. Please use a regular 5V1A charging plug to charge the product.
- If the device will not be used for an extended period, please charge the device at least once every 2 months to avoid the battery discharging completely and risking permanent damage.
- Do not leave the device in direct sunlight for extended periods. Place the AC adapter and the equipment in a ventilated area, such as on a desktop or floor, when you use it to charge the battery.
- Do not put heavy objects on the product.
- The AC adapter and the equipment may become hot while charging.

- Please do not put the product near the fire source under any circumstances.
- If the device begins to emit an unusual odor, heat up excessively, or show signs of swelling or deformation, stop using it immediately and contact the manufacturer for assistance.

Intended use

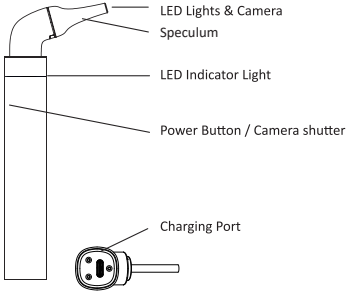


- 1 Otoscope
- 2 Silicone nose speculum
- 1 Charging cable



- 1 Tongue depressor
- 2 Silicone ear speculum
- 1 Operation manual

Product structure



Preparation

Charging the battery

Before use, charge the device by connecting the charging cable. Please use a USB-A power adapter or computer port to charge the device. The adapter should comply with the requirement of IEC 60601-1 standard, and the specifications must meet the requirements: input: AC 100~240V 50/60 Hz, output: DC 5V 1.0A.

LED Indicator Light. The device needs to be charged when the app indicates that the battery is low.



LED Flashing Blue:The device needs to be charged.



LED Solid Blue: Device is being charged.



LED Flashing White: The LED indicator will flash in white continuously if device is on but not paired with the app.

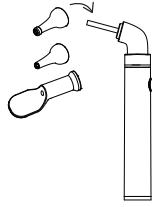


LED Solid White: Connection established.

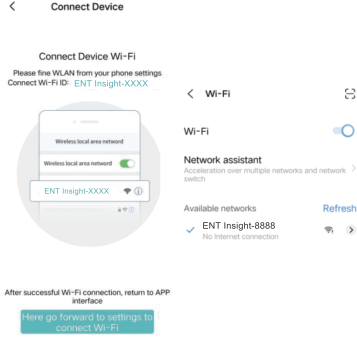
Usage

Note: Before using this device,you must download ENT INSIGHT.
You can use this app to inspect and take video/images of the ear and throat to submit via telehealth or keep track of changes.

- Search for “ENT INSIGHT ”in phone’s app store, download and install it.
- Take your device out of the box.
  Note: Clean the surface of the device with 75% alcohol solution before contacting the skin.



- One of the three accessories can be selected and slowly installed on the device.
- Press and hold the power button to turn on the device. The indicator light will flash white, indicating that the device is on and ready to be paired to the app.
- Connect to “ENT INSIGHT-XXXX” WIFI with a mobile phone, and the device will synchronize the APP screen.(XXXX is a random number)



Note: Wi-Fi products connect to a 2.4 GHz Wi-Fi signal only.
Signal strength may vary based on location, bandwidth, and network strength.

- After the device is paired to the app,the indicator light will be solid white.



● Return to the ENT INSIGHT App, press the centre button to turn on the camera and view the screen in real time.

Use of ear speculum	
Use of tongue depressor	
Use of nose speculum	

Note: Avoid excessive insertion into the ear canal and if the user experiences pain, discontinue use and consult a physician.

- A Short press of the device's button captures the current image like a shutter and saves it to an album.
- Turn off the device. When you are finished using the device, press and hold the power button to turn it off. If the device is left on, it will automatically turn off after 5minutes of inactivity

Troubleshooting

Problem	Solution
APP display is not functioning correctly.	Restart both the device and the app,then reconnect to your device's network and return to the app.
Upon returning to the app after connecting to the device's network, user is still directed to pair via Wi-Fi.	
Device does not respond on Startup.	Use the enclosed USB charging cable to charge device.
When the app shows low battery	
Indicator light flashes.	
App shuts down randomly.	Uninstall and reinstall the app.

Cleaning and Maintenance

- Turn off and unplug the device before cleaning.
- Clean the camera lens before and after each use with a soft, dry microfiber cloth or a cotton swab dipped in a small amount of 70%-80% alcohol. Don't use too much rubbing alcohol and don't use pure isopropyl alcohol.
- If you are having trouble seeing a clear image, make sure to check that the camera lens is clean. Use a small cotton swab to clean off any ear wax or dirt that may have accumulated on it.
- Wait about 5 minutes after cleaning to ensure the alcohol has completely evaporated before using the device.
- Never use abrasive cleaners, chemicals, or solvents as they can damage the device's surface or internal components.
- Avoid getting moisture in any openings or ports of the device. Allow the device to fully dry before plugging it in or using it.
- DO NOT wipe or press the lens of the otoscope excessively, it may da-

mage the lens.

- DO NOT attempt to disinfect the otoscope using glutaralde- hyde products, ethylene oxide gas, steam, or any other liquid or gas disinfectant.

Specifications

Product Name	Otoscope
Model	OT-501
Network Standard	IEEE 802.11 b/g/n
Antenna	Built-in antenna
Operating Frequency	2.4 GHz
Image Transmission Rate	30fps
Camera Diameter	4.0mm
Camera Light Source	6LEDs
Optimum Focal Length	18±5mm
Pixel	0.3M
Gyroscope	3 axis
Power Input	DC 5V 1A
Battery Type	800mAh lithium battery
Battery life	4 hours
Protection degree	IP22
Anti Electronic Shock Degree	Type BF
Anti Electronic Shock Type	Internal Power Supply
Weight	60g
Dimension	23x55x155mm
Service lifetime	Three years
Operating Environment	10°C to 40°C, relative humidity 15% to 93%, pressure 700hPa to 1060hPa
Transportation and Storage Environment	-20°C to 55°C, relative humidity 15% to 93%, pressure 700hPa to1060hPa

Essential Performance

- Operating Frequency: 2.4 GHz
- Optimum Focal Length: 18±5mm
- Pixel: 0.3M

FCC WARNING STATEMENT

CAUTION:

- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified

by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions

Guidance and manufacturer's statement - Electromagnetic emission	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Electromagnetic Immunity

Guidance and manufacturer's declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	Not applicable	Not applicable
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mians voltage prior to application of the test level.		

Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiat ed RF IEC61 000-4- 3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equip ment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601 -1-2 Test Level (V/m)	Compliance level (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28

	1720 1845	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1970					
	2450	2400 – 2570	Bluetoot, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC6100 0-4-39 (Test specifica tions for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies

AOJ HEALTH Technology Co., Ltd.

EU Declaration of Conformity

We, the undersigned (☑ Manufacturer, or ☐ The manufacturers authorized representative)

Manufacturer: AOJ HEALTH Technology Co., Ltd.
Address: Room 202, Building 5, Shuhe Industrial Park, Sanwei Community, Hangcheng Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certify and declare under our responsibility that the following product:

Product name	:	Otoscope
Model No.	:	OT-501
Brand name	:	-
Hardware version	:	V1.0
Software version	:	V1.0.0

Conformity with the relevant Union harmonisation legislation:

☑ Radio Equipment Directive (2014/53/EU)

Conformity with the following relevant harmonised standards, which are in force within the EEA:

Essential requirement		Applied standard	Refer to report
Article 3.1(a)	Health	EN 62479:2010 EN 50663:2017	2402Z102690E
	Safety	EN 62368-1:2014+A11:2017	2402Z102690E-SF
Article 3.1(b)	EMC	ETSI EN 301 489-1 V2.2.3: 2019-11 ETSI EN 301 489-17 V3.2.4: 2020-09	2402Z102690E-02
Article 3.2	Radio	ETSI EN 300 328 V2.2.2: 2019-07	2402Z102690E-22

Where applicable, all essential radio test suites have been carried out

Type	Model No.	Manufacturer
AC Adapter	-	-
Battery	14500	Shenzhen Honghaosheng Electronics Co., Ltd

Notified body involved

None

Additional information

None

Signed for and on behalf of manufacturer

CE

Name : Jack Wang
Title : VP
Email : sales@aojmedical.com
Signature : Jack Wang
Date : 05/02/2025