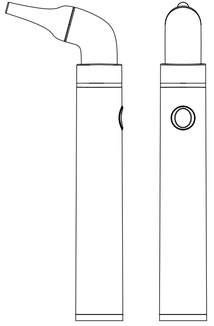
# Otoscope
# Instruction Manual

Model: OT-501



Manual Version: A0
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## 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.

## 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 |
| | Information Manufacturer |
| | Date of manufacture |
| | Refer to instruction manual |
| SN | Serial number |
| LOT | Batch code |
| MD | Medical device |
| UDI | Unique Device Identifier |
| | Keep dry |
| | Fragile, handle with care |
| | Keep away from sunlight |
| IP22 | 2 Protected against solid foreign objects of 12.5 mm Ø and greater;<br>2 Protected against vertically falling water drops when enclosure tilted up to 15° |
| | Non-ionizing electromagnetic radiation |
| | Type BF Applied part |
| | Importer |

## 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

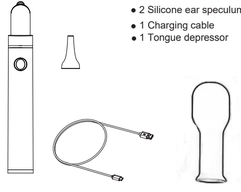
- This product cannot be used for the diagnosis and treatment of any patient unless specified by a physician.
- This product is unsuitable for children under the age of 12 months.
- Do not use the product while charging.
- Children should be supervised by parents when using the otoscope.
- When using this product, please make sure that the product has an intact appearance and does not have any missing accessories.
- Please put the silicone speculum 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, 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

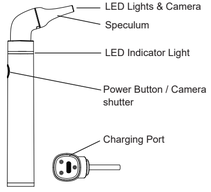
- Check the voltage rating before you connect this equipment to an electrical outlet. Please use a regular 5V1A charging plug to charge the product.
- If the device will not be used for an extended period, please charge the device at least once every 2 months to avoid the battery discharging completely 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 ear speculum
- 1 Charging cable
- 1 Tongue depressor

## 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.

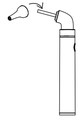
- LED Flashing Blue:The device needs to be charged.
- LED Solid Blue: Device is being charged.
- LED Flashing White: The LED indicator will flash in white continuously if device is on but not paired with the app.
- LED Solid White: Connection established.

## Usage

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

- Search for "**Digital Endoscope**" 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 "**Digital Endoscope**" 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 Digital Endoscope App,press the centre button to turn on the camera and view the screen in real time.

| | |
|---|---|
| **Use of ear 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 damage 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 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment) | 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<br>745<br>780 | 704 – 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 9 | 9 | |
| | 810<br>870<br>930 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 28 | 28 | |
| | 1720<br>1845<br>1970 | 1700 – 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 28 | 28 | |
| | 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 IEC61000-4-39 (Test specifications 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 |

FCC Warning

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.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

FCC Radiation Exposure Statement

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

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Made in China

# OTOSCOPE
# INSTRUCTION MANUAL

Model: OT-501

Manual Version: A0
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