



User Manual



OTOSCOPE

USER MANUAL

Otoscope instructions for ophthalmologist. It is an internally powered device. Please read through this brochure before use, and keep it handy for future reference.

SYMBOLS:

	Manufacturer
	Authorized Representative in the European Community
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.
	Type B Applied Part
	Attention, consult accompanying documents

SAFETY INFORMATION

To assure the correct use of the product, basic safety measures should always be followed including the warnings and cautions listed in this instruction manual.

WARNINGS & CAUTIONS:

- Do not use the device where it may be exposed to flammable gas.
- Protect this device from water, moisture, Impact, dropping, direct sunlight, heat and fire.
- Do not touch the lens directly by hand or something hard.
- Please use the bulb type specified in this instruction brochure.
- Keep the device out of the reach of unsupervised infants and children.
- Do not disassemble or attempt to repair the device or components.

GENERAL

DESCRIPTION:

The otoscope is a classic medical device in ENT. The devices adopt the total reflection of optical fiber, and make the light path and observation of light tend to be coaxial through the optimization design, which increase the visual field of view. It is used to view the tympanic membrane and external ear canal to diagnose outer and middle ear pathologies.

TECHNICAL SPECIFICATIONS:

- Enhanced XHL Xenon Halogen Technology.
- 3x magnification for the viewing window.
- 8107 bulb used.



- Fiber optic illumination.
- An insufflation bulb for pneumatic testing.

HOW TO USE THIS DEVICE

- Turn on (or off) the device by pushing downwards (or upwards) as fig.1;
- Select a reasonable tip for patient's ear canal and push it onto the head and screw the tip clockwise, refer to fig.2. Generally, the tip size of 4mm is for adults and 2.4mm is for children;
- Put the otoscope with a tip into the ear canal of patient (fig.3), and examine through the viewing window which is with 3x magnification;

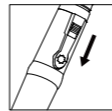


fig.1

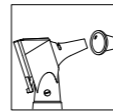


fig.2

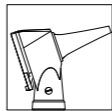


fig.3

ATTENTION:

The otoscope should only be used to examine ear when a tip is fitted. It is an intermittent operated device, 1 minute ON, 5 minutes OFF.

MAINTENANCE

CHANGING SPARE PARTS:

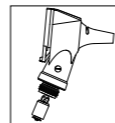


fig 4



fig 5

1. Changing the bulb (fig.4)

- Turn off the power and unscrew the head from the handle of device;
- Pull the old bulb downwards, and replace with new one;
- Screw the head back on to the handle.

Attention:

- Please use the specialized bulb (Model: 8107) for this device.
- After the bulb burns out, the temperature will remain high for approximately 5 minutes. Please wait for a moment to avoid injury.

2. Changing the batteries (fig.5)

- Unscrew the bottom cover from the handle
- Remove the old AA batteries, and replace with new ones. Ensure the anode of the batteries points to the head of the device
- Screw on the bottom cover of the handle.

Attention:

- AA alkaline batteries are recommended.
- Replace all batteries simultaneously and do not use alkali manganese batteries with lithium as bulb life will be reduced.
- Do not leave worn batteries in the handle.
- Please take out batteries from the device if not in use for a prolonged period.
- Batteries should be disposed of in accordance with local regulations.

Cleaning and Disinfection:

- Clean the surface of device with 75% alcohol solution at least once a week, avoiding the magnifying glass (viewing window) in the head. And corrosive or polishing detergent is prohibited.
- Disinfect the tips of otoscope with saturated steam for 20 minutes at 273.2°F

Attention:

Do not soak, autoclave or let water dip into the device

PERIODIC SAFETY CHECKS

Preventive inspection and maintenance to be performed including the frequency of such maintenance. The following safety check should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the equipment and accessories for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.
- Verify that the device functions properly as described in the instructions for use.

SPECIFICATION

Illumination	Fiber Optic Illumination / Direct Illumination	
Luminance	18.5 Lumen	
Magnification	3 x	
Tip Sizes	2.4mm, 3mm, 4mm, 5mm	
Bulb	Specified Model: 8107 2.5V, 0.7A, $\Phi = 4.8\text{mm}$	
Batteries	2 AA alkaline batteries	
Operation	Temperature	50°F ~ 95°F
	Humidity	30% ~ 75%
	Air pressure	700 hPa - 1060 hPa
Storage & Transport	Temperature	-68°F ~ 158°F
	Humidity	10% ~ 90% (without condensation)
	Air pressure	500 hPa - 1060 hPa
Standards	MDD 93/42/EEC Class I IEC 60601-1:1995, IEC 60601-1-2:2007	

ELECTRICAL CLASSIFICATION

Equipment Classification with respect to protection from electric shock: Internally powered equipment.
Degree of protection from electric shock: TYPE B.
Equipment not suitable for use in the presence of flammable mixture: Yes.

Mode of operation: intermittent operation.

The manufacturer reserves the right to make technical changes without notice in the interest of progress. Prior notices will not be given in case of any amendments within this manual.



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