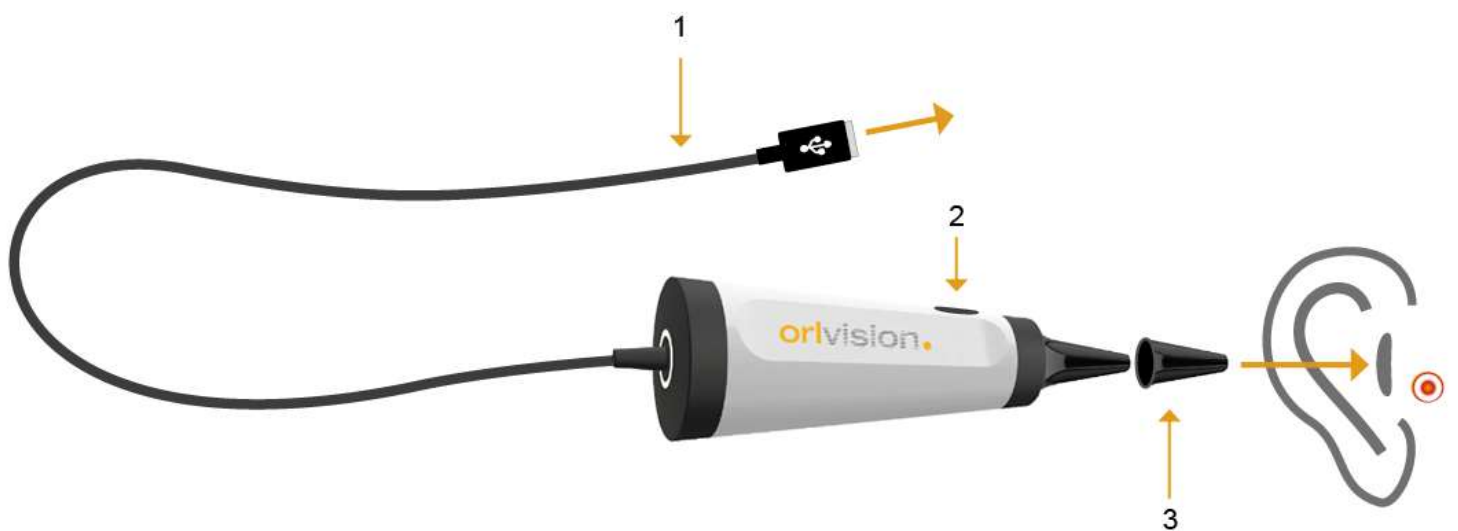


INSTRUCTIONS FOR USE

OX2

Video otoscope



1. Connection cable with USB interface: data output and 5V supply
2. capture button
3. Disposable ear funnel

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1 Risks and hazard warnings, symbols used

1.1 Notes



Caution:

Only use the otoscope for its intended purpose, in accordance with medical regulations, in accordance with the generally recognised rules of technology and in accordance with the applicable occupational health and safety and accident prevention regulations.



Caution:

Before using the otoscope, visually inspect it to ensure that it is in proper working order and condition. The otoscope is a high-quality precision-mechanical optical instrument; treat it with care.



Caution:

Do not use the otoscope if it has defects that may endanger patients, users or third parties, such as sharp edges due to damage.



Caution:

Before each use of the otoscope, make sure that the image is reproduced correctly by looking at a sample object.



Caution:

Make sure that no stored images are played back on the screen when an examination is performed.



Caution:

Avoid direct sunlight, X-rays, sudden sharp temperature changes or heating above 60 °C and mechanical stress such as hard impacts.



Caution:

Do not look directly into the light emission of the light source. The energy of the light sources can cause eye damage.



Caution:

During operation, the light emission tip can heat up to 10°C above ambient temperature.



Caution:

For hygienic reasons, it is strongly recommended to use the otoscope only with the specified disposable ear funnels and to dispose of them after single use.



Caution:

Only use medically approved accessories, such as a medically approved PC (test mark 60601-1). Otherwise, the patient or user could be endangered in unfavourable patient or user in unfavourable cases. Follow the instructions in chapter 9.



Caution:





The operational safety and usability of the medical device depend not only on your skills but also on the care of the device. Regular cleaning and care are therefore necessary (see chapter Cleaning, care and disinfection).



Caution:

Qualified service and the use of original spare parts guarantee that the operational safety, usability and value of your medical device are maintained.

2 Symbols used

	On the type plate: Attention, follow instructions for use
	Symbol for separate collection of electrical and electronic equipment
	In the instructions for use: Caution, general danger area
IP 65	Unit is dust-tight and protected against water jets from any angle
	Device is a medical device

3 Description

3.1 General

Otosopes from **orlvision** GmbH (hereinafter referred to as orlvision) are high-quality medical products. They are used for examinations in human ear medicine. The otoscopes can be used to examine the external auditory canal. The examination regions can be displayed on high-resolution screens and the images can be stored. The otoscope is used exclusively in medical practices and clinics as well as in practices of audiologists and hearing aid acousticians.

At the distal end of the otoscope is the exit of a light guide that illuminates the observation region. An attached lens enables imaging at a viewing angle of 60°. The image captured in this way is recorded by a video camera, converted into an electrical signal and made available at the output of the otoscope as a digital USB signal. The light for illuminating the observation region is generated by an LED integrated in the otoscope. The end of the otoscope is formed by a detachable sleeve, which will be referred to as the disposable tip in the following.

Electrical power is supplied by connecting to a medical PC via the USB interface.

The supplied image display software orlView must be installed in advance, with which images and videos can be displayed and saved.



Caution:

This is an electronic system that must be protected from penetrating moisture.

3.2 Scope of delivery

Included in the scope of delivery are:

- Handpiece with disposable tip
- Bracket (can be used as table or wall bracket)
- Instructions for use
- Software / Viewer "orlView" on USB stick



Otoscope in the holder

3.3 Recommended accessories

Disposable tip:

We recommend: Manufacturer Kirchner & Wilhelm GmbH + Co KG; type ear funnel grey. (optional Ø 2.5 mm order no.: 01.71212.002) or Ø 4.0 mm order no.: 01.71222.002).

3.4 Notes on use

These instructions for use explain how to operate the medical device safely, properly and effectively. operated. Please read the instructions for use carefully before putting the device into operation, starting with the chapter on risks and hazard warnings. Keep the instructions close to the device.

The instructions for use do not replace the corresponding basic medical and technical knowledge. The user may have to acquire such knowledge in special further training courses.

orlvision accepts no liability for diagnoses and interpretations of findings made using the medical devices you have purchased. The acquisition of medical expertise and its and their diagnostic and therapeutic consequences are the sole responsibility of the user of the medical device.

The otoscope may only be used by trained personnel who have been instructed in the handling of the device.

In particular, orlvision does not provide any guarantees should the otoscope be connected to another computer for image display.

4 Technical data

Parameter	Data
Focus area	5 - 25mm
Viewpoint	90°
Diameter distal end	4.0 mm disposable ear funnel
Total length	130 mm
Resolution in pixels	400 x 400
Lighting: LED	Light guide
Power supply	5 V DC via USB
Power consumption without USB	max. 0.1 A
Interface	USB 2.0
Weight in g	approx. 130 g
Risk class according to MPG	1
Transport and storage temperature in ° Celsius	- 10° to + 70°
Operating temperature in ° Celsius The distal end can warm up to 9°C above room temperature.	0° to + 40°
Relative humidity	0 to 95%
Air pressure	950 to 1050 hPa
Protection class against electric shock	Class II
Operating mode	Continuous operation
Protection class	IP65

5 Manufacturer

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6 Commissioning and use

6.1 Installation orlView

Use the supplied USB stick with a medical PC. Select the setup.exe file and follow the installation instructions on the screen. Select the otoscope for installation.
For operation of the software, see separate instructions.

6.2 Insertion of the disposable ear funnel



Caution:

Carefully insert the disposable ear funnel into the outer ear. For hygienic reasons, never use the otoscope never use the otoscope without a disposable ear funnel attached.

After the examination, carefully withdraw the otoscope.

6.3 Switch off

After use, the otoscope must be disconnected from the medical PC.
Afterwards the necessary cleaning and disinfection work must then be carried out.
See chapter 7.

7 Cleaning, care and disinfection (reprocessing)



Caution:

Permanent immersion of the otoscope in concentrated alcohol leads to irreversible deformations. If necessary, perform a short wipe disinfection. However, make absolutely sure that the alcohol can evaporate after the wipe disinfection.

7.1 Care

The otoscope is easy to care for. Apart from thorough cleaning and regular inspection for damage, no special care is required. The otoscope should be stored in a dry place and safely protected from dust.

8 Maintenance and repairs

The components of the otoscope are maintenance-free for their users. Repairs and maintenance work may only be carried out by the company **orlvision** or by specialist companies authorised by it. The company orlvision provides the authorised companies with all necessary product documentation.

Caution:

Unauthorised opening, repairing and alterations to the otoscope release the company **orlvision** from any liability for operational safety. During the warranty period, this will void any warranty claims.

9 Disposal



Environmentally friendly disposal according to EU Directive 2012/19/EU. The appliance contains electronic components. To prevent environmental risks or hazards due to improper disposal, the product, including the accessories, must be disposed of in accordance with the applicable EU directives 2012/19/EU. Disposal can be carried out by the manufacturer.

For this purpose, please send to the manufacturer at:

Orlvision GmbH, Gewerbestraße 17, D-35633 Lahnau.

Disposal in household waste is prohibited.

10 Electromagnetic compatibility

10.1 Details of the operating environment:

The otoscope is intended for low-interference RF environments such as doctors' offices. No shielded location is required.

10.2 Information on the performance characteristics

- **Essential features** of the otoscope are: Display of images of the examination region (middle ear). The image quality may be impaired if there is strong electromagnetic interference.
- **Warning:** Use of this unit immediately adjacent to other units or with other units stacked together should be avoided as this may cause interference.
- Cables, transformers and accessories that can be replaced without affecting the EMC: None
- **Warning:** The use of other accessories (especially PC) may lead to incorrect operation
- **Warning:** Portable communication (radio) equipment operating in close proximity may result in incorrect operation

10.3 Electrical immunity (immunity)

Static electricity discharge (ESD) according to EN 61000-4-2, level according to EN 60601-1-2	+/- 8 kV Contact discharge +/- 15 kV Air discharge
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10.4 Immunity test

Immunity to electromagnetic radiation according to EN 61000-4-3, level according to EN 60601-1-2 f = 80 MHz to 2.7 GHz	10V/M; 3 V/m
According to EN 60601-1-2 chapter 8.10; / PM, 18 Hz or 217 Hz 380 MHz - 5.8 GHz	9 - 28 V/m
Conducted RF according to EN 61000-4-6, level according to EN 60601-1-2, 150 kHz - 80 MHz	3 V/m ISM frequencies 6 V/m

10.5 Electromagnetic emission

HF interference emission (Radiated Emission) according to CISPR 11; (level according to EN 55011; 30 MHz to 1 GHz)	Class B
Conducted emission according to CISPR 11 (level according to EN 55011 with 150 kHz - 30 MHz)	Class B

11 Reporting of serious incidents

All serious incidents related to this product shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

These instructions for use have been machine translated.

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