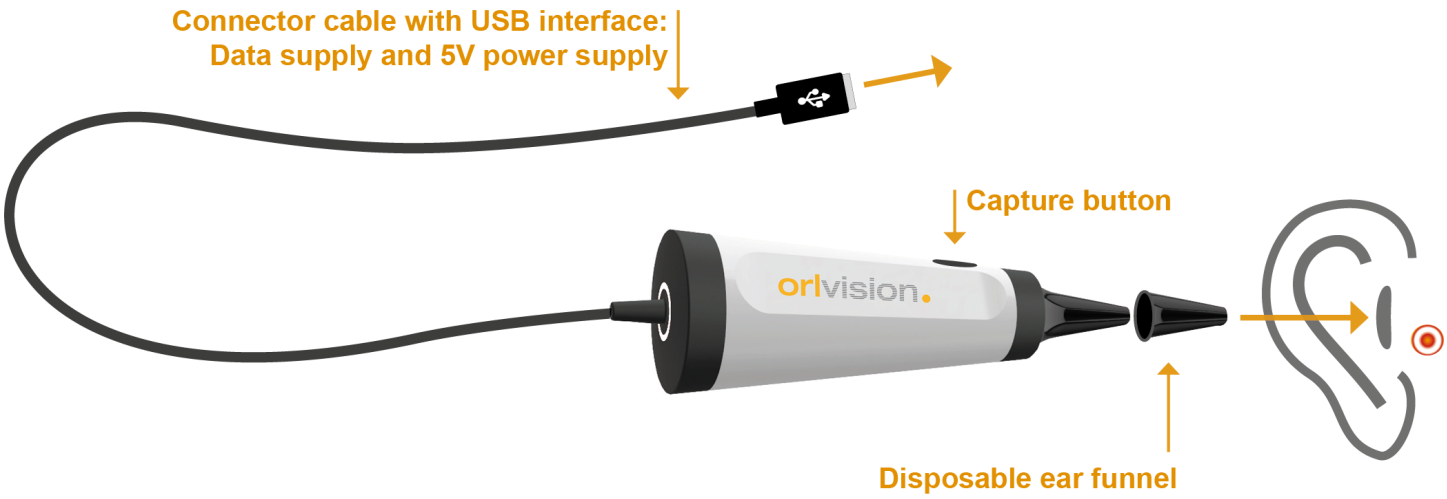
OX2

Video-Otoscope



Contents

1 Description ... 3
1.1 General ... 3
1.2 Scope of Delivery ... 3
1.3 orlView System Requirements ... 3
1.4 Recommended Accessories ... 3
1.5 Instructions for Use ... 4
2 Risk and Hazard Warnings, Symbols ... 4
2.1 Warnings ... 4
2.2 Symbols ... 5
3 Technical Data ... 5
4 Manufacturer ... 5
5 Commissioning and Use ... 6
5.1 Installation orlView ... 6
5.2 Switching On ... 6
5.3 Set-up and Operation ... 6
5.4 Overview of orlView User Interface ... 7
5.5 Inserting the Ear Funnel ... 7
5.6 Switching Off ... 7
6 Cleaning, Disinfection and Care ... 8
6.1 Cleaning ... 8
6.2 Disinfection ... 8
6.3 Care ... 8
7 Maintenance and Repair ... 9
8 Disposal ... 9
9 Electromagnetic Compatibility ... 10
9.1 Details about the Operating Environment: ... 10
9.2 Details to the Features ... 10
9.3 Electrical Immunity ... 10
9.4 Immunity Test ... 10
9.5 Electromagnetic Emission ... 10

1 Description

1.1 General

The otoscopes from **orlvision** GmbH (named orlvision hereafter) are high-quality medical devices. They are for examining the outer auditory canal of the human ear for medical purposes. The studied regions can be displayed on high-resolution screens and the images can be saved. The otoscope is used exclusively in medical practices and clinics, as well as in practices by audiologists and hearing care professionals.

There is a light conductor exit at the distal end of the otoscope, which illuminates the viewed area. The lens enables an image with a field of view of 60°. The captured image 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 illumination of the observation region is generated by an LED, which is integrated into the otoscope. The end of the otoscope is covered a removable sleeve, which is referred to below as a disposable tip.

Energy is supplied by connecting the device to a computer via the USB interface.

The supplied image presentation software orlView, for displaying and storing the images and videos, must be installed beforehand.

Attention: This is an electronic system and it is imperative that it be protected from penetrating moisture.

1.2 Scope of Delivery

The following is included in the delivery:

- Handpiece with disposable tip
- Holder (can be used as table or wall mount)
- Instructions
- Software / Viewer „orlView“ on a USB-Stick

Otoscope in the holder

1.3 orlView System Requirements

When installing the orlView software, you are advised to meet at least the following system requirements:

≥ Windows 10

For use on Mac systems, you need a suitable Windows environment that meets the above criteria.

1.4 Recommended Accessories

Disposable Point:
We recommend: manufacturer Kirchner & Wilhelm GmbH + Co KG; Typ Ohrtrichter grau (ear funnel gray) (Ø 2.5 mm
order.-no.: 01.71212.002) or Ø 4.0 mm order.-no.: 01.71222.002).

1.5 Instructions for Use

This manual explains how to operate the medical device safely, properly and effectively. Please read the instructions for use carefully before you start to use it. Begin with the chapter Risks and Hazard Warnings. Keep the instructions near the device.

These instructions do not replace the corresponding medical and technical knowledge. The user must have or acquire this knowledge in professional advanced training courses.

orlvision assumes no liability for diagnoses and result interpretations made with the help of the medical devices you have purchased. The acquisition of medical expertise 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 assume any warranties should the otoscope be connected to another non-medical) computer for image display.

2 Risk and Hazard Warnings, Symbols

2.1 Warnings

• Warning: use the otoscope only as intended, according to medical regulations and in accordance with the generally accepted rules of technology and the valid occupational safety and accident prevention regulations.

• Before using the otoscope, make sure - through visual inspection – that it is in proper and safe working condition. The otoscope is a high quality fine mechanical optical instrument, treat it with care.

• Attention: Do not use the otoscope if it has defects, such as sharp edges or other damage that could cause harm to the patient, the user or other persons.

• Attention: Before each use of the otoscope, make sure of its correct image reproduction by looking at a sample object.

• Attention: When an exam is performed, make sure that no saved images are displayed on the screen.

• Attention: Avoid exposure to direct sunlight, x-rays, sudden strong temperature fluctuations or temperatures over 60 °C as well as mechanical strain such as hard jolts or impacts.

• Attention: Never look directly at the light emission from the light source. The light can damage the eye.

• Attention: During use, the light exit tip can heat up to 10 ° C above ambient temperature. Therefore, never use the otoscope at room temperatures above 32 ° C without the ear funnel.

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

• Attention: Use only medically approved accessories, such as a medically approved computer (test mark 60601-1). It could possibly endanger the patient or user. Follow the instructions in chapter 9.

- Note: The operational safety and capability of the medical device depend not only on your ability, but also on the care of the device. Regular cleaning and maintenance is necessary (see chapter Cleaning, Disinfection and Care).
- Note: Qualified service and the use of original spare parts give you the assurance that the operational safety, capability and the value of your medical device are maintained.

2.2 Symbols

The used symbols have the following meanings

	Attention, general hazard area		Symbol for separate collection of electrical and electronic equipment
	Pay attention to the operating instructions!	IP65	The device is splash-proof

3 Technical Data

Parameters	Data
Depth of Focus	5 - 50mm
Field of View	60°
Distal Tip Diameter	4,0 mm disposable ear funnel
Length Overall	130 mm
Resolution in Pixels	400 x 400
Illumination: LED	Optical Fiber
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	0° to + 40°
Relative Humidity	0 to 95%
Air Pressure	950 to 1050 hPa
Protection Grade against Electrical Shock	Class II
Operating Mode	Continuous Operation
Protection Class	IP65

4 Manufacturer

orlsvision GmbH
Gewerbestraße 17
D-35633 Lahnau

Tel.: +49(0) 64 41 67 92 98 - 0
Fax.: +49(0) 64 41 67 92 98-99
info@orlvision.de
www.orlvision.de

5 Commissioning and Use

5.1 Installation orlView

Insert the supplied USB stick into a medical computer. Select the setup.exe file and follow the installation instructions.

5.2 Switching On

After successful installation, you can connect the otoscope to the medical computer via USB interface.

The otoscope turns on automatically when the USB is connected and off again when it is disconnected.
Open the image display program „orlView“. The live image will appear. By clicking on the picture it becomes full screen. Clicking again restores the original appearance.

On the right you can see the already taken and saved pictures. Picture settings can be made on the left.

5.3 Set-up and Operation

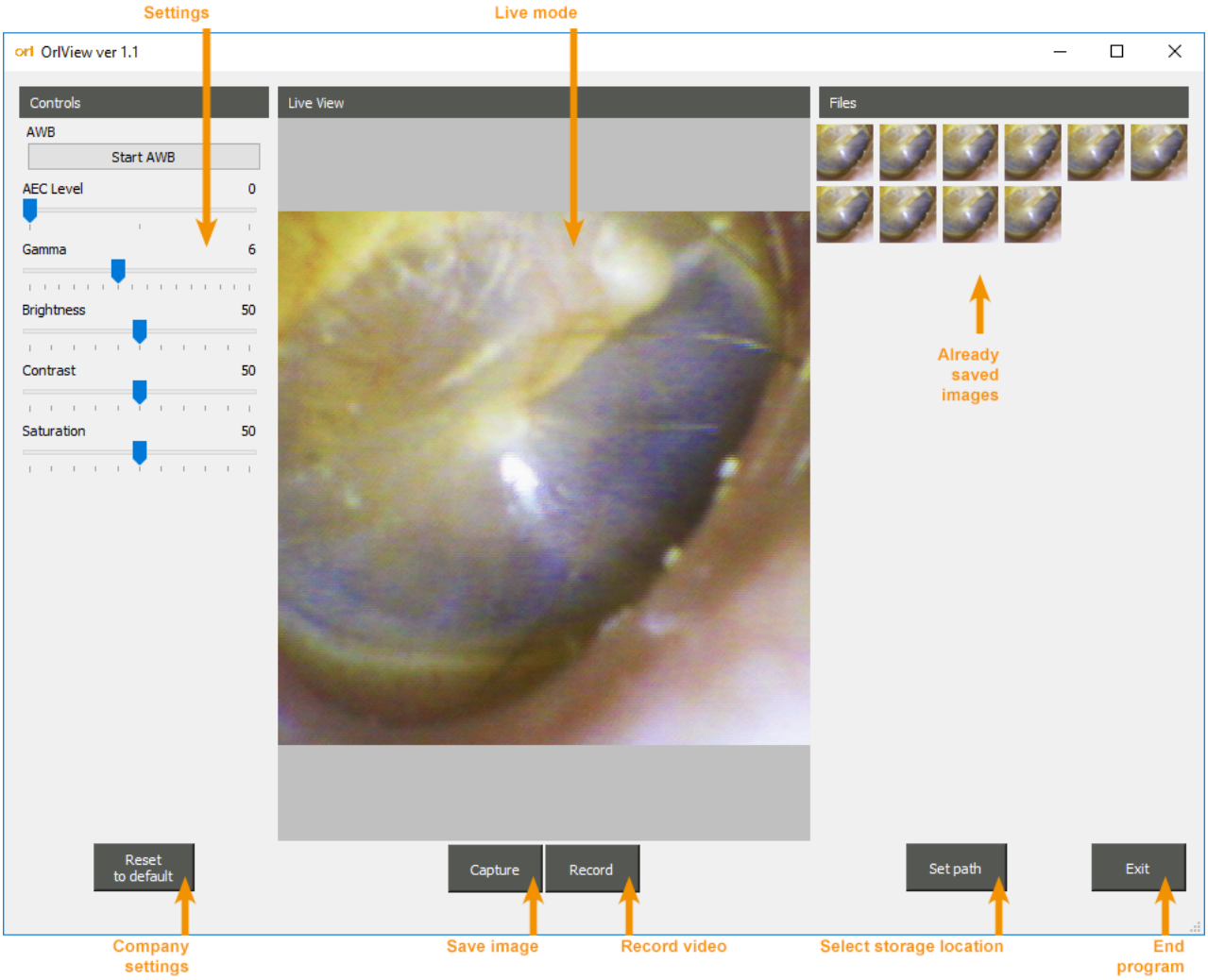
The different settings are shown under „Controls“. There are the following possibilities:

- AWB: Auto White Balance. To do this, aim the otoscope at a white area and then activate the AWB start button.
- AEC Level/ Auto Exposure Compensation
- Gamma/ Tonal Correction
- Brightness
- Contrast
- Saturation

The settings can be made by moving the slider.
Other operating options are (see screen display)

- save image
- record video
- select storage location
- end program
- reset to default

5.4 Overview of orlView User Interface



5.5 Inserting the Ear Funnel

The disposable ear funnel should be inserted carefully into the outer ear. For hygienic reasons, never use the otoscope without a disposable ear funnel.
After the examination, carefully withdraw the otoscope.

5.6 Switching Off

After use, the otoscope is to be disconnected from the medical computer. Then the otoscope must be cleaned and disinfected. See chapter 6.

6 Cleaning, Disinfection and Care

6.1 Cleaning

The disposable tip must be replaced after each use. Clean the otoscope as necessary. To do so, wipe it with a clean, disposable cloth. The distal end under the disposable tip needs to be cleaned especially carefully. Dirt can cause poor image quality.

6.2 Disinfection

Disinfection may only be carried out by trained personnel and following the instructions of the Robert Koch Institute. We recommend the following disinfectant for the otoscope:

- Schülke microzid AF wipes

Attention: Immersing the otoscope in concentrated alcohol leads to irreversible deformations. If necessary, carry out a short wipe disinfection. However, make absolutely sure that the alcohol can evaporate after wiping.

6.3 Care

The otoscope is easy to care for. Aside from thorough cleaning and regular checks for damage, no special care is required. The otoscope should be stored dry and protected from dust.

7 Maintenance and Repair

The components of the Otoscope are maintenance-free for their users. Repair and maintenance work must only be carried out by the company **orlvision** or by specialized professionals authorized by them. The authorized companies will be provided with all the necessary product documentation by **orlvision**.

Attention: Unauthorized opening, repairing and changes to the otoscope releases the company, **orlvision,** of any liability for operational safety. If done during the warranty period, all warranty claims are made invalid.

8 Disposal

Environmentally safe disposal is to occur according to EU guidelines 2002/96/EG. The device contains electronic components. To prevent environmental risks and hazards due to improper disposal, this product, including the accessories must be disposed of according to the applicable EU guidelines 2002/96/EG. It is forbidden to throw this product in the household garbage. It must be brought to the return and recycle center.

9 Electromagnetic Compatibility

9.1 Details about the Operating Environment:

The otoscope is intended for places with low RF-emissions, such as doctors' offices. There is no need for a shielded location.

9.2 Details to the Features

- **Essential feature** of the otoscope is the display of images of the examination region (middle ear). In case of strong electromagnetic interference, the picture quality can be affected.
- **Warning:** Using this unit directly beside other equipment or with other equipment in a stacked form should be avoided, as it may cause interference.
- Cables, transducers, and accessories that can be replaced without compromising EMC: None
- **Warning:** The use of other accessories (especially computer) can lead to incorrect operation
- **Warning**: Portable communication (radios) operating in the immediate vicinity may cause erroneous operation

9.3 Electrical 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	+/- 8 kV contact discharge +/- 15 kV air discharge

9.4 Immunity Test

Immunity to electromagnetic radiation after EN 61000-4-3, level after EN 60601-1-2 f = 80 MHz to 2.7 GHz	10V/M; 3 V/m	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	9 – 28 V/m
Conducted RF according to EN 61000-4-6, level after EN 60601-1-2, 150 kHz - 80 MHz	3 V/m ISM Frequencies 6 V/m	3 V/m ISM Frequencies 6 V/m

9.5 Electromagnetic 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

orlvision GmbH
Gewerbestrasse 17
D-35633 Lahnau

Tel. +49(0)6441679298-0
Fax +49(0)6441679298-99

info@orlvision.com
www.orlvision.com

CE