

Instructions for use

Video Rhino Laryngoscope

RX1, RS1-PAL, RS1-NTSC



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1 Risks and hazard warnings

1.1 Notes

1. The Video Rhino Laryngoscopes **RS1 and RX1** are only designed for use in hospitals and clinics without direct connection to the public supply network.
2. Please first check the packaging, the Video Rhino Laryngoscope and the accessories for completeness and shipping damage. In case of damage, make a note of the damage and notify your dealer or the manufacturer.
3. Before each treatment, take a test image of a known object so that you can be sure of the correct image quality, the correct image orientation (even when the angulation unit is moving) and the proper functioning of the Video Rhino Laryngoscope. Pay particular attention to the colour fidelity and the correct transmission of the images without too many imperfections.
4. Only use the Video Rhino Laryngoscope for its intended purpose in accordance with the regulations of the MPG, in accordance with the generally recognised rules of technology, and in accordance with the valid occupational safety and accident prevention regulations.
5. Before using the Video Rhino Laryngoscope, visually inspect it to ensure that it is in good working order and in proper condition, including the power supply. The Video Rhino Laryngoscope is a high-quality precision mechanical-optical instrument; treat it with care.



Attention:

Do not use the Video Rhino Laryngoscope if it has any defects that may endanger patients, users or third parties, e.g. sharp edges due to damage.



Attention:

Avoid direct sunlight, X-rays, sudden sharp temperature changes or heating above 60°C and mechanical stresses such as hard impacts and kinking of the insertion tube.



Attention:

Only use the enclosed accessories or accessories approved by the manufacturer to connect the Video Rhino Laryngoscope to the mains and to other devices.



Attention:

Only use medically approved devices (PC, tablet, laptop) together with the Video Rhino Laryngoscope. Approved according to DIN EN 60601-1 or IEC 60601-1. Otherwise, the patient or user could be endangered in unfavourable cases.



Attention:

Handle pointed or sharp objects such as scalpels or needles carefully near the Video Rhino Laryngoscope so that no mechanical damage could be caused to the endoscope.



Attention:

When used with high-power light sources, light with high energy can escape from a light guide cable or laryngoscope. Deposits at the light exit area, insufficient working distances or direct tissue contact can thus lead to strong heating above 41C° and even tissue damage due to absorption. Therefore, avoid direct contact of tissue with the light emission area.



Attention:

Use the automatic control of the light source, if available, or manually adjust the light source to the - minimum light output required for the application to minimise burn risks.



Attention:

The high light energy emitted at the distal end can lead to high heating or even ignition when the laryngoscope is placed on heat-sensitive or combustible surfaces. Therefore, always store the laryngoscope in a suitable holder.

Remove dirt from the optical surfaces of the laryngoscope to prevent accidental heat build-up.

Reduce the intensity at the light source or switch it off when the laryngoscope is not in use.

Switch off the light source if the laryngoscope will not be used for a long time!



Attention:

Do not look directly into the light emission of the light source or a connected light guide! The energy of powerful light sources can cause serious and permanent eye damage.



Attention:

The Video Rhino Laryngoscope may only be used by persons who, on the basis of their training or knowledge and practical experience, can guarantee proper handling.

- 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).
- Qualified service and the use of original spare parts give you the guarantee that the operational safety, the operational capability and the value of your medical device are maintained.

2 Intended use

- The Video Rhino Laryngoscope RX1, RS1-PAL, RS1-NTSC is used for endoscopic examinations in human ear, nose and throat medicine. The flexible Video Rhino Laryngoscopes can be used to examine the nose, pharynx and larynx, nasal cavities and nasopharynx. The examination regions can be displayed on high-resolution screens via a (panel) PC.
- The Video Rhino Laryngoscope is not intended for examination of the paranasal sinuses and lower larynx.
- It is used exclusively in medical practices and clinics by staff specially trained in handling endoscopes.








Attention:

The Video Rhino Laryngoscope RX1, RS1-PAL, RS1-NTSC may only be used on persons who have a sufficiently large body opening for the insertion of the insertion tube. This is especially important for nasal examinations in children.

3 Symbols used

The symbols used have the following meaning

	On the type plate: Attention, follow instructions for use
	Symbol for separate collection of electrical and electronic equipment
	Applied part type BF
	In the instructions for use: Caution, general danger area
IP 68	Unit is dust-tight and protected against permanent submersion
MD	Device is a medical device
	Unit complies with protection class II

4 Functionality and application

4.1 General

It is an electronic system that must be protected from penetrating moisture. The type designations stand for the following variants:

RS1-PAL	Unit with CCD chip; video interface PAL format
RS1-NTSC	Unit with CCD chip; video interface NTSC format
RX1	Unit with CMOS chip; video interface NTSC format

4.2 Notes on use

The instructions for use explain how to operate the medical device safely, properly and effectively. Please read the instructions for use before putting the device into operation, starting with the chapter on risks and hazard warnings. Keep the instructions close to the device. Observe the ambient conditions specified in the technical data.

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

orlvision accepts no liability for diagnoses and interpretations of findings made with the aid of medical products acquired from **orlvision**. The acquisition of medical expertise and its diagnostic and therapeutic consequences are solely the responsibility of the user of the medical product.

Before each use, test the direction of movement of the bounce unit by operating the adjustment lever to avoid incorrect bounce direction. Check a test image to verify colour fidelity.

We recommend the use of a lubricant on the shaft before inserting the shaft into the nasal cavity to be examined.

4.3 Application

The flexible Video Rhino Laryngoscopes from **orlvision** GmbH (hereinafter referred to as orlvision) are high-quality medical products. They are used for endoscopic examinations in human ear, nose and throat medicine. The flexible Video Rhino Laryngoscopes can be used to examine the nasopharynx. The image of the examination region can be displayed on a high-resolution screen and saved.

The RS1/RX1 laryngoscope is intended exclusively for use in clinics and may only be used by personnel specially trained in handling endoscopes!

Perform a white balance before each use (see section 7.1). Proceed with cleaning and disinfection as described in these operating instructions.

4.4 How it works

At the distal end of the Video Rhino Laryngoscope is the exit of a light guide that illuminates the observation region. An attached lens enables imaging at a viewing angle of 90 °. The image thus captured is recorded by a video camera, converted into an electrical signal and made available at the output of the Video Rhino Laryngoscope as an analogue video signal for display on a monitor.

The light for illuminating the observation region is obtained from a cold light source. The distal end of the insertion tube can be angled within a range of $\pm 130^\circ$ by operating the adjustment lever.

The supply of electrical energy is ensured by a medical power supply unit included in the delivery.

4.5 Scope of delivery

The scope of delivery for the flexible Video Rhino Laryngoscope includes

- the Video Rhino Laryngoscope with insertion tube and the connector plug for the cold light source (connected to the handpiece)
- a connection cable for connecting a monitor and the power supply unit
- a medically approved power supply unit for power supply
- a leak tester
- one cinch cable and one S-video cable
- an adapter of the ACMI type for connection to the light source (adapters of the STORZ, WOLF and OLYMPUS types are not included in the scope of delivery)
- Plug Cap Naso
- Hard shell case (item number 900-06000-0076)
- this operating manual

5 Technical data

5.1 Data Video Rhino Laryngoscope

Parameter	RX1 / RS1
Focus area	10 - 55 mm
Angle of view	90°
Diameter distal end	3.9 mm
Diameter insertion tube	3.9 mm
Distal angulation up / down	130°/130°
Working length	310 mm
Total length	540 mm
Video format	NTSC/ PAL and NTSC
Resolution in pixels	320x240 / 500x582 and 510x492
White balance	manual
Illumination: Cold light source	Fibre optic cable
Power supply	100-240V / 50-60Hz
Power	max. 1.5 W
Interface	Cinch Video / Y_C Video, Cinch
Weight in g	approx. 540g handpiece
Risk class according to mdr	1
Transport and storage temperature in ° Celsius	- 10°C to + 60°C
Operating temperature in ° Celsius The distal end can warm up to 9°C above room temperature.	0° to + 40°
Relative humidity	0 to 100%
Air pressure	950 to 1050 hPa
Protection class against environmental influences	IP 68
Protection class against electric shock	Class II
Operating mode	Continuous operation

Table1

5.2 Electromagnetic radiation

With regard to radiation and interference immunity, the RS1 laryngoscope fulfils the conditions of the EN 60601-1-2:2007 (IEC 60601-1-2:2007, modified), Emission class A

Intended for use in hospitals without direct connection to the public supply network!

The RX1 / RS1 laryngoscope meets the conditions of EN 60601-1-2:2007 (IEC 60601-1-2:2007, modified) with regard to radiation and immunity:

6 Manufacturer

The manufacturer of the Video Rhino Laryngoscope is

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D-35633 Lahnau

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Fax.: +49(0) 64 41 67 92 98-99

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7 Swiss Representative



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Parkstrasse 25, CH-6410 Goldau

Tel.: +41 41 530 51 15
info@pfenniger-medizintechnik.ch

8 UK Authorised Representative



Jeremy Taylor, LiteOptics Ltd,
The Nucleus, Chesterford Research Park,
Little Chesterford, Essex CB10 1XL

Tel +44 (0) 1799 542716
enquiries@liteoptics.com

9 Recommended accessories

9.1 Cold light source

Only use a medically approved cold light source!

For example:

- Light source orILED 180, ILO



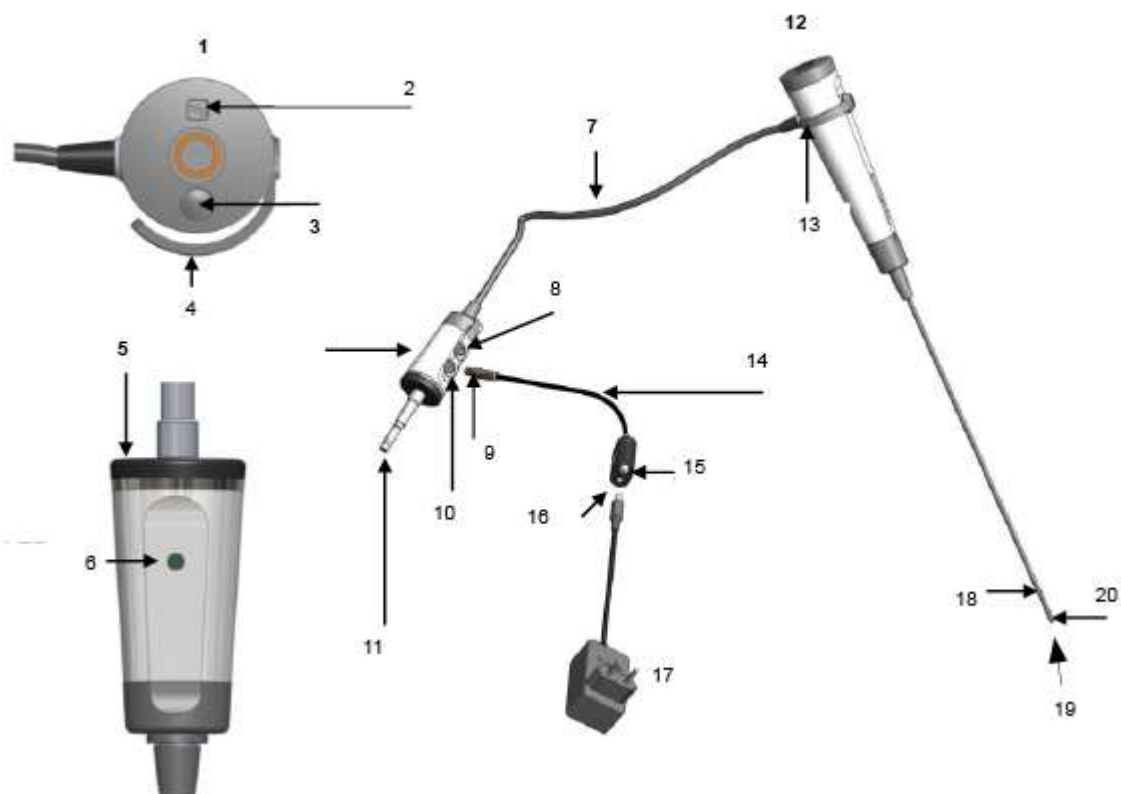
Attention:

Only use light sources that generate a maximum temperature of 320°C at the light inlet. Higher temperatures can damage the light guides and thus the unit.

9.2 Monitor

Only use a medically approved monitor!

10 Connection of the Video Rhino Laryngoscope



- | | | | | | |
|----|-------------------|----|---|----|----------------------|
| 1 | Handpiece | 2 | White balance | 3 | Capture Button |
| 4 | Adjustment lever | 5 | Light guide plug | 6 | LED display |
| 7 | Supply hose | 8 | Valve for pressure test | 9 | Multipoint connector |
| 10 | Multipoint socket | 11 | Connection for cold light source | 12 | Handpiece |
| 13 | Adjustment lever | 14 | Connection cable for power supply and video | 15 | Composite video out |

- | | | | | | |
|----|------------|----|--------------------------|----|------------|
| 16 | 12V input | 17 | Medical power supply 12V | 18 | Angle unit |
| 19 | Distal end | 20 | Camera head | | |

Figure 1: Connection laryngoscope

The Video Rhino Laryngoscope should be connected as follows. See also figure 1. Plug the power supply unit into a mains socket (100 - 240 V AC, 50 - 60 Hz). The secondary connection of the power supply unit must be plugged into the connector into which the video cable for the monitor is also plugged.

Then the connection cable must be plugged into the light guide plug and this in turn must be inserted into the cold light source.

An external monitor for displaying the video signal is connected to the Video Out connector, then the image captured by the camera appears on the screen.

Now the Video Rhino Laryngoscope can be used for its intended purpose, the green LED on the light guide plug is lit.



Attention:

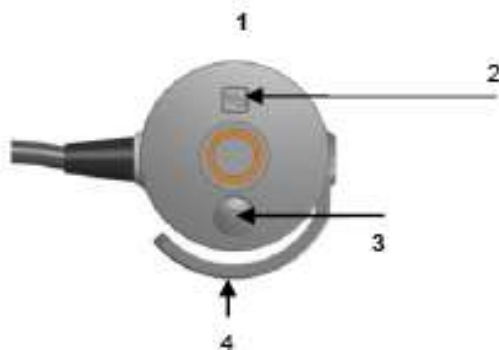
Monitor and light source must meet the requirements of the DIN EN 60601 standard!

11 Use of the Video Rhino Laryngoscope

11.1 White balance

Attention: Before each examination, a white balance should be carried out so that the camera reproduces the natural colours.

Handpiece



- | | | | | | |
|---|------------------|---|----------------------|---|----------------|
| 1 | Handpiece | 2 | White balance | 3 | Capture Button |
| 4 | Adjustment lever | | | | |

Figure 2: White balance

To do this, point the distal end straight at a white sheet of paper, take up the working range (10 - 55 mm distance) and briefly press the white balance button on the handpiece. See also figure 2.

11.2 Insert, angle and retract the insertion tube.

Carefully insert the insertion tube into the corresponding regions to be examined (nasal and pharyngeal cavities). If necessary, the distal end can be adjusted by 130° with the adjustment lever (see figure 3)± . The level of adjustment should be tested in a free trial. The examining doctor holds the laryngoscope in his hand to check the adjustment of the distal end and observes the image on the screen.

After the examination, return the control lever to the rest position and carefully withdraw the insertion tube.

11.3 Switch off

After use, the laryngoscope must be taken out of service by disconnecting it from the supply, the cold light source must be switched off and then the necessary cleaning and disinfection work must be carried out. See chapter 12.

12 Cleaning, care and disinfection

In accordance with KRINKO/BfArM recommendations, the machine method is always the preferred method for reprocessing.

12.1 Manual procedures

12.1.1. Cleaning

After each use, the Video Rhino Laryngoscope must be carefully cleaned. To do this, wipe it with a clean disposable cloth soaked in an appropriate disinfectant on all accessible external parts.

We recommend for cleaning: 2% Sekusept® active (manufacturer Ecolab). Leave on for 5 minutes. Make sure that the surfaces remain moist. Wipe with a dry disposable cloth afterwards.



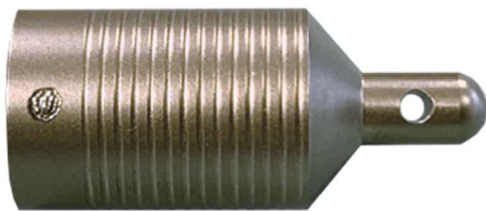
Attention:

Please do not exert any great mechanical forces on the flexible end of the endoscope when wiping it. endoscope, the light guides inside could be damaged (breakage).



Attention:

The cover cap M-860-0003-0086-P must be used to protect the valve connection.



Picture 5:
Cover cap Article number M-860-0003-0086-P



Picture 6:
Valve cover cap fitted

Disinfection

Disinfection may only be carried out by trained personnel and in accordance with the specifications of the Robert Koch Institute.



Attention:

Before each disinfection / insertion, a leak test (see chapter 9.3) must be carried out. In case of leakage, the Rhino laryngoscope must be discarded immediately and sent to the manufacturer for repair. In case of leakage, the immersion disinfection becomes ineffective!

We recommend the following disinfection: Immersion disinfection with 2% Sekusept® active. (manufacturer Ecolab). Immersion time 30 minutes.



Attention:

The enclosed "Plug Cap Naso" must be used to protect the 9-pole plug connection.



Picture 7:
Cover cap Plug Cap Naso

Attention:

Permanent immersion of the laryngoscope in concentrated alcohol will cause irreversible damage. If necessary, perform a short wipe disinfection. However, make absolutely sure that the alcohol can evaporate immediately after the wipe disinfection.



Attention:

Under no circumstances should the connection cable be immersed in the disinfectant. The cable may only be cleaned and disinfected by wipe disinfection / surface disinfection.

12.1.2. Final rinse

Remove the Rhino Laryngoscope and accessories from the disinfectant solution with fresh disposable gloves. Place the disinfected laryngoscope in a basin / tub with microbiologically safe water (drinking water quality). Use fresh water for each instrument. Rinse the Rhino laryngoscope outer surfaces thoroughly with microbiologically safe water.

12.2 Machine processes

We recommend the following procedures using the BHT INNOVA® E3 CMS DC washer-disinfector from CANTEL GmbH or an equivalent machine with the settings given below.

Cleaning

Cleaning agent: 0.5 % Dr. Weigert neodisher Mediclean forte®
Automatic cleaning process with programme no. 24 with the following settings:

- Step Pre-cleaning for 4 minutes
- Step Emptying
- Step Cleaning 0.5% at 37°C for 6 minutes
- Step Cleaning 0.5% at 43°C for 6 minutes
- Step Emptying
- Step Intermediate rinse for 2 minutes



Attention:

Before each cleaning or disinfection / insertion, a leak test (see chapter 9.3) must be carried out. In case of leakage, the Rhino laryngoscope must be discarded immediately and sent to the manufacturer for repair. In case of leakage, the disinfection will be ineffective!

Pre-cleaning:

Pre-cleaning with pre-soaked cloths with 0.5 % Dr. Weigert neodisher Mediclean forte® until the instrument is visually clean.



Attention:

Please do not exert large mechanical forces on the flexible end of the endoscope when wiping it, the light guides inside could be damaged (breakage).

Cleaning

Detergent: 0.5 % Dr. Weigert neodisher Mediclean forte®

Disinfection Disinfectant : 1.0 % Dr. Weigert neodisher endo SEPT PAC

Automatic cleaning and disinfection process with programme no. 22 NORMAL-PAA with the following settings:

- Step Pre-cleaning for 4 minutes
- Step Emptying
- Step Cleaning 0.5% at 37°C for 6 minutes
- Step Cleaning 0.5% at 43°C for 6 minutes
- Step Emptying
- Step Intermediate rinse for 2 minutes
- Step chemical disinfection with 1% disinfectant at 25°C for 10 minutes.
- Step Emptying
- Step Final cleaning at 20°C for 4 minutes



Attention:

Usually the laryngoscope is connected to the automatic pressure monitoring system during machine cleaning. If this is not done, we recommend using the optionally available cover cap M-860-0003-0086-P to protect the valve connection.

It is also recommended to use this cover cap for manual cleaning.

12.3 Leak test



Attention:

The leak test must be carried out before **each reprocessing!**



Attention:

The connection tube of the leak tester and the tester connection on the laryngoscope must be dry!

Place the tester connector cap firmly on the tester connector and turn it clockwise a quarter turn (see figure 3). The tester is now firmly connected to the laryngoscope and cannot be pulled off.

Close the valve on the leak tester.

Create a test pressure of 160 (±10) mmHg by pumping the leak tester.

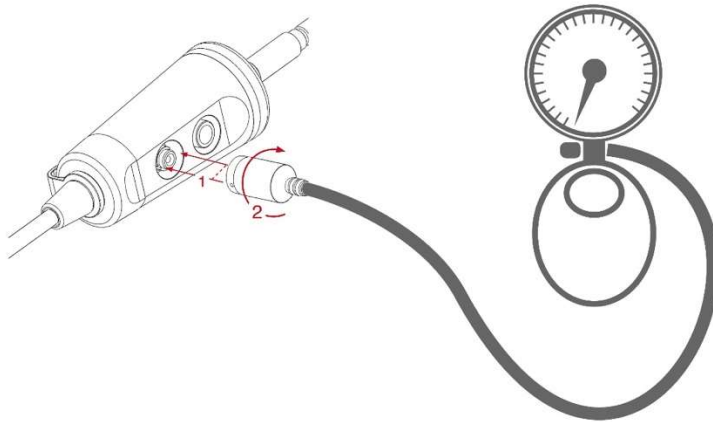


Figure 7: Connection pressure tester



Attention:

If the manometer reading drops by more than 10 mmHg within one minute, do not place the laryngoscope in liquid.

In this case, wipe the outer sheath with instrument disinfectant or isopropanol 70 %, wrap the laryngoscope in a protective foil cover, pack it in the original packaging and label it "leaking, not disinfected". Then hand it over to the service workshop or the manufacturer.



Attention:

Never connect or disconnect the tester under water, otherwise moisture may enter the unit and repair may be necessary.

After completing the leak test, open the valve on the leak tester to release the excess pressure. Then turn the tester connection cap to the left and then pull off the tester connection. To protect the 9-pin connector, we recommend using the optionally available cover cap.

After completing the leak test, open the valve on the leak tester to release the excess pressure. Then turn the tester connection cap to the left and pull off the tester connection.

12.4 Care

The Video Rhino Laryngoscope is easy to care for. Apart from thorough cleaning and regular inspection for damage, no special care is required. The laryngoscope should be stored in a dry place, safe from dust.

13 Maintenance and repairs

The components of the Video Rhino Laryngoscope 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.



Attention:

Unauthorised opening, repairs and modifications to the laryngoscope release **orlvision** from any liability for operational safety. This will void any warranty claims during the warranty period.

13.1 Return

In order to avoid damage due to transport and shipping in the event of a return, please use only the original shipping packaging.



Attention:

For shipping and transport, always connect the pressure tester to the light connection with the valve open!

14 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 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.

15 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.

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