Instructions for use

Rhino laryngoscopes

Video types:
RS1-PAL / RS1-NTSC / RX1 / RSX-USB / RSX-P / RSX-HD

Fibre endoscope **FS2**

RS1-PAL / RS1-NTSC

FS2

RSX-USB / RSX-P / RSX-HD

Document is translated electronically!

Contents

1 Risks and hazard warnings

1. Please first check the packaging, the Rhino laryngoscope and the accessories for completeness and shipping damage. In the event of damage, make a note of the damage and inform your dealer or the manufacturer.

2. Before each treatment, take a test image of a known object so that you can
   the correct image quality, the correct image orientation (even when moving the bending unit) and the correct function of the Rhino
   (even when moving the bending unit) and that the Rhino laryngoscope is functioning correctly. Particular attention should also be paid to colour fidelity.

3. Only use the Rhino laryngoscope as intended, in accordance with the regulations of the MPDG and MDR, the generally recognised rules of technology and the applicable occupational health and safety and accident prevention regulations.

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

Caution:
Do not use the Rhino laryngoscope if it has defects that could endanger patients, users or third parties, e.g. sharp edges due to damage.

Caution:
Do not use the Rhino laryngoscope if it is leaking. (See section Leak test). Otherwise serious infections may occur.

Caution:
Only use devices (PC, tablet, laptop) tested in accordance with DIN EN 60601-1 or IEC 60601-1 together with a Video Rhino laryngoscope type RSX-USB / RSX-P / RSX-HD. Otherwise, the patient or user could be endangered in unfavourable cases.

Caution:
Handle pointed or sharp objects such as scalpels or needles with care in the vicinity of the Rhino laryngoscope so that no mechanical damage is caused to the laryngoscope and especially not to the flexible insertion tube. This also applies in particular to insertion into a disinfectant bath.

Caution:
Do not look directly into the light emission at the distal end. The energy of the internal light sources can cause eye damage. In particular, the Rhino laryngoscope must not be used for eye examinations contrary to its intended use.

Caution:
When using the FS2 Rhino laryngoscope: Never look into the connected fibre optic cable!

Caution:
The Rhino laryngoscope may only be used by persons whose training or knowledge and practical experience guarantee proper handling.

Caution:
The distal end can heat up to 9°C above room temperature during prolonged use of the Rhino Laryngoscope.
room temperature.

Caution:
Avoid direct sunlight, X-rays, sudden large temperature fluctuations or heating above 60°C and mechanical stress such as hard knocks and kinking of the insertion tube.

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 work is therefore necessary (see chapter Cleaning, care and disinfection).

Caution:
Qualified service and the use of original spare parts give you the guarantee that the operational safety, usability and value of your medical device will be maintained.

Caution:
Prolonged or improper use (sharp kinking of the flexible insertion tube) may result in reduced illumination in the observation room due to damage to the fibre optics (breakage). The illumination capability should therefore be checked from time to time outside of examinations (Illumination of a white sheet of paper).

Note: The Orlview image display programme supplied with the **Rhino laryngoscopes** has been tested on the optional panel PC. Installing different software versions or other programmes on this PC may result in malfunctions in the image display.

orlvision accepts no liability for such faults. We recommend that you do not modify the Panel PC.

Make sure that no saved image is being viewed when current examinations
are to be carried out.

2 Intended use

- The Rhino laryngoscopes RS1 / RX1 / RSX-USB / RSX-P / RSX-HD / FS2 are used for endoscopic examinations in human ear, nose and throat medicine. The flexible rhino laryngoscopes can be used to examine the nose, pharynx and larynx, nasal cavities and nasopharynx. With the video types, the examination regions can be displayed on high-resolution screens via a (panel) PC. With the fibre type FS2, the image is visible directly on the eyepiece.

- The Rhino Laryngoscope **is not** intended for the examination of the paranasal sinuses and the lower larynx.

- The Rhino Laryngoscope is used exclusively in medical practices and clinics by personnel specially trained in the use of laryngoscopes.

Caution:
The Rhino Laryngoscope may only be used on persons who have a sufficiently large body opening for the insertion of the insertion tube. This is particularly important for nasal examinations in children.

3 Symbols used

	On the rating plate: Attention, follow the instructions for use
	Symbol for separate collection of electrical and electronic equipment
	Applied part type BF
	In the instructions for use: Attention, general danger zone
IP 68	Device is dust-tight and protected against permanent submersion
	Device complies with protection class II
MD	Device is a medical device
	Swiss representative
UK REP UK Responsible Person	UK Authorised Representative
UDI	Reference to Unified Device Identification

4 Functionality and application

4.1 Video Rhino laryngoscopes

4.1.1. Application

The flexible video rhino laryngoscopes from orlvision GmbH (hereinafter referred to as orlvision) are high-quality medical devices. 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 PC or monitor equipped with a high-resolution screen via the available data interface.

Rhino laryngoscopes are intended for use in clinics and medical practices and may only be used by personnel specially trained in handling laryngoscopes!

Proceed as described in these instructions for use when cleaning and disinfecting.

4.1.2. Image processing

4.1.2.1. RS1 / RX1

With the RS1-PAL, RS1-NTSC and RX1 types, the image signal is transmitted in video format. This image format can be displayed directly on a monitor that has a corresponding video input (PAL; NTSC; HDMI).

4.1.2.2. RSX-USB / RSX-P / RSX-HD

Image processing software is required to display and analyse the images. The OrlView software is included in the scope of delivery. This is suitable for displaying and saving the images on the optionally available panel PC.

4.1.3. Functionality RS1

At the distal end of the Video Rhino laryngoscope is the exit of a light guide that illuminates the observation region. The lens enables imaging at a viewing angle of 90°. The image captured in this way is recorded by a video camera, converted into an electrical signal and made available to a monitor or PC via an electronic interface.

The light for illuminating the observation region is obtained either via an optical fibre from an external light source (types RS1 / RX1) or from an LED integrated in the handpiece (all other types). The distal end of the insertion tube can be angled within a range of +/- 130° by operating the adjustment lever.

4.1.4. Power supply

Power is supplied via the power supply unit supplied (types RS1 / RX1) or via the PC through the USB interface (RSX / RSX-P / RSX-HD).

4.2 Fibre endoscope

The Rhino Laryngoscope FS2 is a fibre-optic laryngoscope and has an optical focusing and imaging unit as well as an image guide. The image is captured at the distal end, guided via the image guide into the optical unit (multiple lens system) and can be viewed through the eyepiece. The image is focussed at the focussing point. At the distal end of the Rhino laryngoscope is the exit of an optical fibre that illuminates the observation region.

The light for illuminating the observation region is supplied through this light guide via the light guide plug from an external light source.

The distal end of the insertion tube can be angled within a range of± 130° by operating the adjustment lever.

4.3 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 commissioning and start 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 need to acquire such knowledge in specialised training courses.

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

Before each use, test the direction of movement of the bending unit by operating the adjustment lever to avoid incorrect bending direction.

We recommend using a lubricating gel on the shaft before inserting the shaft into the nasal cavity to be examined.

4.4 Scope of delivery

The respective scope of delivery for the different types includes

4.4.1. RS1 / RX1

- Handpiece with insertion tube and the connection plug for the cold light source (connected to the handpiece)
- Connection cable for connecting a monitor and the power supply unit
- Medically approved power supply unit for power supply
- Leak tester (article no. M-820-02001-0046)
- Cinch cable and an S video cable
- ACMI type adapter for connection to the light source (STORZ, WOLF and OLYMPUS type adapters are not included in the scope of delivery)
- Cover cap "Plug Cap Naso" for 9-pin plug connection (article no. 000-00000-2000)
- Cover cap for pressure test connection, article no. M-860-00003-0086
- Hard-shell case (article number 900-06000-0076)

4.4.2. **RSX-USB / RSX-P / RSX-HD**

- Video Rhino laryngoscope handpiece with insertion tube and the connector plug for the USB connection and the
- Connection Cable (article no. M-820-02001-0046)
- Leak tester (article no. M-860-00003-0057) for carrying out the leak test.
- Software OrlView
- Cover cap " Plug Cap Naso " for 9-pin plug connection, article no.000-00000-2000
- Cover cap for pressure test connection, article no. 860-00003-0086
- Hard-shell case (article number 900-06000-0076)

4.4.3. **FS2**

- Handpiece with insertion tube and connection sockets for the fibre optic cable to the cold light source and for connection to the pressure tester.
- Leak tester (article no. M-860-00003-0057)
- Hard case for the laryngoscope

4.5 Recommended accessories:

4.5.1. **FS2 and RS1 / RX1**

Only use a medically approved cold light source.

Attention:
The light source must fulfil the requirements of the DIN EN ISO 60601-1 standard!
The connection on the Rhino laryngoscope is compatible for light guides with ACMI / Storz / Wolf endoscope connection.

Possibilities:

- Lighthandle Firefly ES201, 5W LED
- Light source orlLED 180, ILO

Caution:
If a high-power cold light source is used and the outlet of the light guide or the light inlet plug on the laryngoscope is soiled, this can lead to excessive heat development due to light absorption. There is a risk of burns.

On request, we are also happy to offer you a wide range of adaptation options for light sources and endoscopes from other manufacturers and also for LED hand-held light sources.

4.5.2. **RSX**

Panel PC (available from orlvision)

5 Technical data

5.1 RS1, RX1

Parameters	RX1	RS1-PAL	RS1-NTSC
Focus area	10 - 55 mm	10 - 55 mm	10 - 55 mm
Picture angle	90°	90°	90°
Diameter distal end	3.9 mm	3.9 mm	3.9 mm
Insertion tube diameter	3.9 mm	3.9 mm	3.9 mm
Distal angulation up / down	130° / 130°	130° / 130°	130° / 130°
Working length	300 mm	300 mm	300 mm
Total length	540 mm	540 mm	540 mm
Video format	NTSC	PAL	NTSC
Resolution in pixels	320x240	500x582	510x492
White balance	manually	manually	manually
Lighting: External cold light source and	Fibre optic cable	Fibre optic cable	Fibre optic cable
Power supply	100-240V / 50-60Hz	100-240V / 50-60Hz	100-240V / 50-60Hz
Performance	max. 1.5 W	max. 1.5 W	max. 1.5 W
Interface	Cinch video	Y-C Video	Cinch
Weight in g	approx. 540g handpiece	approx. 540g handpiece	approx. 540g handpiece
Risk class according to MDR	1	1	1
Transport and storage temperature in ° Celsius	- 10°C to + 60°C	- 10°C to + 60C	- 10°C to + 60C
Operating temperature in ° Celsius The distal end can heat up to 9°C above room temperature.	0° to + 35°	0° to + 35°	0° to + 35°
Relative humidity	0 to 100%	0 to 100%	0 to 100%
Air pressure	950 to 1050 hPa	950 to 1050 hPa	950 to 1050 hPa
Protection class against environmental influences	IP 68	IP 68	IP 68
Protection class against electric shock	Class II	Class II	Class II
Operating mode	Continuous operation	Continuous operation	Continuous operation

5.2 RSX-USB, RSX-P, RSX-HD

Parameters	RSX-USB	RSX-P	RSX-HD
Focus area	10 - 55 mm	10 - 55 mm	10 - 55 mm
Picture angle	90°	90°	90°
Diameter distal end	3.9 mm	2.9 mm	3.9 mm
Insertion tube diameter	3.9 mm	2.9 mm	3.9 mm
Distal angulation up / down	130° / 130°	130° / 130°	130° / 130°
Working length	300 mm	300 mm	300 mm
Total length	540 mm	540 mm	540 mm
Resolution in pixels	400x400	400x400	800x800
White balance	Factory set	Factory set	Factory set
Lighting: LED internal	Fibre optic cable	Fibre optic cable	Fibre optic cable
Power supply	5V DC / 0.3 A via USB	5V DC / 0.3 A via USB	5V DC / 0.3 A via USB
Performance	max. 2.2 W	max. 2.2 W	max. 2.2 W
Interface	USB 2.0 "A"	USB 2.0 "A"	USB 2.0 "A"
Weight in g	approx. 320g handpiece	approx. 320g handpiece	approx. 320g handpiece
Risk class according to MDR	1	1	1
Transport and storage temperature in ° Celsius	- 10°C to + 60°C	- 10°C to + 60C	- 10°C to + 60C
Operating temperature in ° Celsius The distal end can heat up to 9°C above room temperature.	0° to + 35°	0° to + 35°	0° to + 35°
Relative humidity	0 to 100%	0 to 100%	0 to 100%
Air pressure	950 to 1050 hPa	950 to 1050 hPa	950 to 1050 hPa
Protection class against environmental influences	IP 68	IP 68	IP 68
Operating mode	Continuous operation	Continuous operation	Continuous operation

5.3 FS2

Parameters	data
Focus area	3 mm ± 1 to 50mm -5 / +10
Field of view (FOV)	90° ± 5°
Diameter distal end	2.9 mm + 0 / -0.1
Insertion tube diameter	2.9 mm ± 0.1
Distal angulation up / down	130° ± 5
Working length	300 mm
Total length	540 mm
Weight in g	Approx. 310g
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 heat up to 9°C above room temperature.	0° to + 35°
Relative humidity	0 to 100 %
Air pressure	950 to 1050 hPa
Protection class against environmental influences	IP 68
Operating mode	Continuous operation

6 Manufacturer

The manufacturer of the Rhino laryngoscopes is

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info@pfenniger-medizintechnik.ch

8 UK Authorised Representative

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Office: +44 1978 254569
Mobile: +44 7947 143383
michael@neuxmed.com

9 Use of the Rhino laryngoscopes

9.1 RX1, RS1-PAL, RS1-NTSC

9.1.1. Connection of the laryngoscope

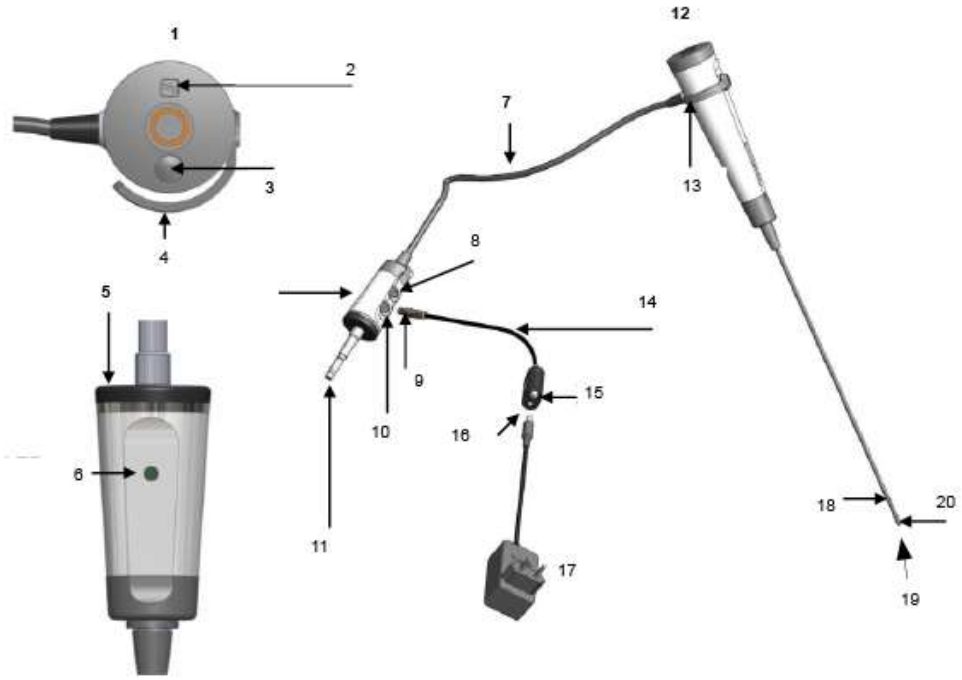


Figure 1: RX1 / RS1 connection

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 plug
10	Multipoint socket	11	Connection for cold light source	12	Handpiece
13	Adjustment lever (like 4)	14	Connection cable for power supply and video	15	Composite video out
16	12V input	17	60601-1 certified power supply unit 12V	18	Bending unit
19	Distal end	20	Camera head		

The Video Rhino laryngoscope must be connected as shown in Figure 1.
The power supply unit is connected to a mains socket (100 - 240 V AC, 50 - 60 Hz) and the power supply unit secondary connection must be plugged into the connecting plug.

The connection cable must then be plugged into the light guide plug, which in turn is connected to the cold light source.

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

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

Attention:
The monitor and light source must fulfil the requirements of the DIN EN 60601 standard!

9.1.2. White balance

Caution: A white balance should be carried out before each examination so that the camera reproduces the natural colours.

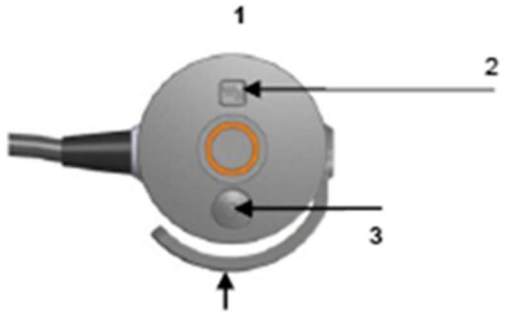


Figure 2: White balance RX1 / RS1
1: Handpiece
2: White balance
3: Capture button
4: Adjustment lever

For white balance, point the distal end straight at a white sheet of paper, assume the working range (10 - 55 mm distance) and briefly press the white balance button on the handpiece.

9.1.3. Switch off

After use, the laryngoscope must be switched off by disconnecting it from the power supply and the cold light source must be switched off.
Then carry out the necessary cleaning and disinfection work.
See the corresponding chapter in these instructions for use.

9.2 RSX-USB / RSX-P / RSX-HD

9.2.1. Switch on

The Video Rhino laryngoscope is switched on and off using the on/off switch (see Fig. 2) or switched on by connecting the connection cable to a PC, laptop or tablet.
The on/off switch (2) has been disabled on all appliances since 06/2024 due to the design. Since then, the appliance has been switched on or off via the connection cable.

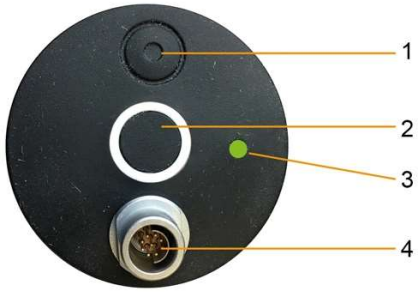


Figure 3: Operating elements on the RSX-USB / RSX - P / RSX - HD handpiece

1Save button
2 On/off switch, without function for appliances from 06/2024
3Status LED
4 Connection plug,
Attention: only plug in, do not turn

An image can be saved using the Save button. Further details on saving images can be found in the description of the Orlview image processing software.

9.2.2. Switch off

After use, the laryngoscope must be switched off by 06/2024 (see Fig. 3) or by disconnecting the cable connection (remove the connector plug).
The necessary cleaning and disinfection work must then be carried out.
See the relevant chapter in these instructions for use.

9.3 FS2

Light guide cable or light from an external cold light source must be connected to connection (4)

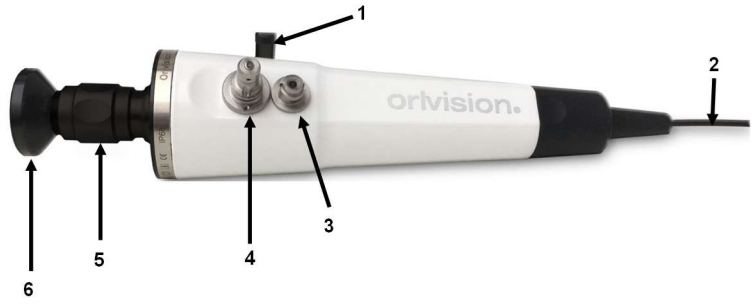


Figure 6: Elements on FS2
1: Adjustment lever
2: Flexible insertion tube
3: Connection for pressure test
4: Connection for fibre optic cable
5: Focussing device
6: Eyepiece

Use the focussing device (5) to focus the image.

9.4 Inserting, bending and retracting the insertion tube (all types).

The insertion tube must be carefully inserted into the regions to be examined (nose and throat). If necessary, the distal end can be adjusted by +/- 130° using the adjustment lever. The plane of the angulation should be checked in a free test. The examining doctor holds the laryngoscope in his hand to check the adjustment of the bending unit and observes the image in the eyepiece.

After the examination, return the adjustment lever to the zero position and carefully withdraw the insertion tube.

10 Cleaning, care and disinfection (all types)

According to KRINKO/BfArM recommendations, the automated process is always the preferred method for reprocessing.

10.1 Manual procedures

Caution:
A leak test (see chapter 10.3) must be carried out before each disinfection / insertion. If there is a leak, the Rhino laryngoscope must be discarded immediately and sent to the manufacturer for repair. If there are leaks, immersion disinfection will be ineffective!

We recommend the following disinfection: Immersion disinfection with 2% Sekusept® aktiv (manufacturer Ecolab). Immersion time 5 minutes.

Caution:
During reconditioning, we recommend using the enclosed "Plug Cap Naso" cover cap to protect the 9-pin plug connection and the M-860-0003-0086-P cover cap to protect the valve connection, see also section 10.2.4.

Picture: 7
Cover cap Plug Cap Naso
Art. No. 000-00000-2000

10.1.1. **Cleaning**

The Video Rhino laryngoscope must be carefully cleaned after each use. To do this, wipe all accessible external parts with a clean disposable cloth soaked in an appropriate disinfectant.

We recommend for cleaning: 2% Sekusept® aktiv (manufacturer Ecolab). Contact time 5 minutes. Make sure that the surfaces remain moist. Then wipe with a dry disposable cloth.

Caution:
Please do not exert any great mechanical force on the flexible end of the laryngoscope when wiping, as the fibre optics inside could be damaged (breakage).

10.1.2. **Disinfection**

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

Caution:
Permanent immersion of the laryngoscope in concentrated alcohol leads to irreversible damage. If necessary, carry out a brief wipe disinfection. However, make absolutely sure that the alcohol can evaporate immediately after wipe disinfection.

Caution:
Under no circumstances should the USB cable be immersed in the disinfectant. The cable may only be cleaned and disinfected using wipe disinfection / surface disinfection.

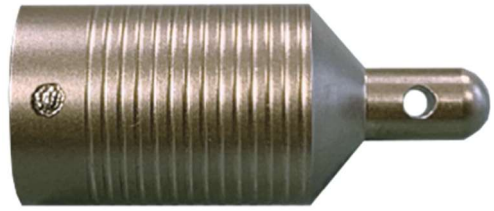
10.1.3. **Final rinse**

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

10.2 Mechanical 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 specified below.

Caution:
The laryngoscope is usually connected to the automatic pressure monitoring system during automated 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.



Picture:8
Cover cap article number 860-00003-0086

Picture: 9
Valve cover cap fitted

10.2.1. **Pre-cleaning:**

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

10.2.2. **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
- Emptying step
- Cleaning step 0.5% at 37°C for 6 minutes
- Cleaning step 0.5% at 43°C for 6 minutes
- Emptying step
- Intermediate rinse step for 2 minutes

Caution:
A leak test (see chapter 10.3) must be carried out before each cleaning or disinfection / insertion. If there is a leak, the Rhino laryngoscope must be discarded immediately and sent to the manufacturer for repair. Leaks will render disinfection ineffective!

Caution:
Please do not exert any great mechanical force on the flexible end of the laryngoscope when wiping, as the fibre optics inside could be damaged (breakage).

10.2.3. **Disinfection**

Disinfectant: 1.0 % Dr Weigert neodisher endo SEPT PAC

10.2.4. **Automatic cleaning and disinfection programme**

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

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

10.3 Leak test

Caution:
The leakage test must be carried out before **each reprocessing**!

Caution: The connection hose of the leak tester and the tester connection on the laryngoscope must be dry!

Image: 10 Leak Tester connection

1. Place the tester connection cap firmly on the tester connection and turn it a quarter turn clockwise. The tester is now firmly connected to the laryngoscope and can no longer be removed.
2. Close the valve on the leak tester.
3. Generate a test pressure of 160 (±10) mmHg by pumping on the leak tester.

Caution:
If the manometer display drops by more than 10 mmHg within one minute, the laryngoscope must not be placed in liquid.

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

Caution:
Never connect or disconnect the tester under water, otherwise moisture may penetrate the device and repairs 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 pull it off.

10.4 Care

The laryngoscopes must always be cleaned thoroughly, see the corresponding description in this chapter. Regular checks for damage are also necessary.

No further special care is required.

The laryngoscope must be stored in a dry place, protected from dust and damage.

11 Maintenance and repairs

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

Caution:
Unauthorised opening, repairs and modifications to the laryngoscope release **orlvision** from any liability for operational safety. During the warranty period, this will invalidate all warranty claims.

11.1 Return shipment

To avoid damage during transport and despatch in the event of a return, please only use the original shipping packaging.

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

12 Waste disposal

Valid for the types RX1, RS1, RSX-USB, RSX-P, RSX-HD.

Environmentally friendly disposal in accordance with EU Directive 2012/19/EU. The laryngoscopes contain 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.

Please send to the manufacturer for this purpose:
Orlvision GmbH, Gewerbestraße 17, D-35633 Lahnau.
Disposal in household waste is prohibited.

The laryngoscope FS2 can be disposed of with household waste.

13 Electromagnetic compatibility

13.1 Information on the operating environment:

The Video Rhino laryngoscopes are intended for less disturbed HF environments such as doctors' surgeries. No shielded location is required.

The FS2 laryngoscope is insensitive to electromagnetic interference.

13.2 Information on the performance characteristics

- **The main features** of the Video Rhino Laryngoscope are Display of images of the examination region (the nose, pharynx and larynx, nasal cavities and nasopharynx). The image quality of the Viedeo laryngoscope may be impaired by strong electromagnetic interference.
- **Warning:** The use of this device directly next to other devices or stacked with other devices should be avoided as this can lead to interference. The FS2 is an exception to this rule.
- Cables, converters and accessories that can be replaced without affecting the EMC: None
- **Warning:** The use of other accessories (especially PC) can lead to incorrect operation
- **Warning**: Portable communication (radio) devices that are operated in close proximity can lead to faulty operation. The FS2 is an exception.

14 Reporting of serious incidents

Any serious incident that has occurred in relation to any of these devices should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Notes

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