

Instructions for use

Rhino Laryngoscopes

Video models:

RS1-PAL / RS1-NTSC / RX1 / RSX-USB / RSX-P / RSX-HD

FS2 Fibre Endoscope

RS1-PAL / RS1-NTSC



FS2



RSX-USB / RSX-P / RSX-HD



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1 Risks and safety warnings

1. Please first check the packaging, the Rhino laryngoscope and the accessories to ensure they are complete and undamaged during transit. In the event of any damage, note down the details and notify your dealer or the manufacturer.
2. Before each procedure, take a test image of a familiar object to you can verify that the image quality and orientation are correct (even when the angle adjustment unit) and that the Rhino Laryngoscope is functioning correctly. In particular, you should also check the colour accuracy.
3. Use the Rhino Laryngoscope only for its intended purpose, in accordance with the provisions of the MPDG or MDR, generally accepted technical standards, and the applicable health and safety and accident prevention regulations.
4. Before using the rhino laryngoscope, carry out a visual inspection to ensure it is in good working order and in a satisfactory condition. The rhino laryngoscope is a high-quality, precision-engineered optical and electronic instrument; handle it with care.



Warning:

Do not use the Rhino Laryngoscope if it has any defects that could endanger patients, users or third parties, such as sharp edges caused by damage.



Warning:

Do not use the Rhino Laryngoscope if it is leaking. (See the section on leak testing.) Otherwise, serious infections may occur.



Warning:

When using a Rhino laryngoscope of the RSX-USB / RSX-P / RSX-HD types in conjunction with a video system, only use devices (PC, tablet, laptop) that have been tested in accordance with DIN EN 60601-1 or IEC 60601-1. Failure to do so could, in certain circumstances, pose a risk to the patient or the user.



Warning:

Handle pointed or sharp objects such as scalpels or needles with care when near the Rhino Laryngoscope to ensure that no mechanical damage is caused to the laryngoscope and, in particular, to the flexible insertion tube. This applies in particular when placing the device in a disinfection bath.



Warning:

Do not look directly into the light outlet at the distal end. The energy from 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.



Warning:

When using the FS2 Rhino Laryngoscope: Under no circumstances look into the connected light guide!



Warning:

The Rhino Laryngoscope must only be used by persons who, by virtue of their training, knowledge and practical experience, can ensure its correct handling.



Warning:

The distal end may heat up to 9°C above room temperature.



Warning:

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



Warning:

The operational safety and serviceability of this medical device depend not only on your skill but also on the care taken with the device. Regular cleaning and maintenance are therefore required (see the section on Cleaning, Maintenance and Disinfection).



Warning:

Qualified servicing and the use of genuine spare parts ensure that the operational safety, serviceability and value of your medical device are maintained.



Warning:

Prolonged or improper use (sharp kinking of the flexible insertion tube) may result in reduced illumination in the viewing area due to damage to the light guides (breakage). The illumination function should therefore be checked from time to time outside of examinations (illuminating a white sheet of paper).

Note: The Orlview image display programme supplied with the **video rhinolaryngoscopes** has been tested on the optionally available panel PC. Installing different software versions or other programmes on this PC may cause disruptions to the image display.

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

Ensure that no stored image is being viewed whilst current examinations are to be carried out.

2 Intended use

- The RS1 / RX1 / RSX-USB / RSX-P / RSX-HD / FS2 rhino-laryngoscopes are intended for endoscopic examinations in human ear, nose and throat medicine. The flexible rhino-laryngoscopes can be used to examine the nose, pharynx and larynx, as well as the nasal cavities and naso-pharynx. With the video models, the areas being examined can be displayed on high-resolution screens via a (panel) PC. With the FS2 fibre-optic model, the image is visible directly through the eyepiece.
- The rhino-laryngoscope is **not** intended for the examination of the paranasal sinuses or the lower laryngeal region.
- The rhino-laryngoscope is to be used exclusively in doctors' surgeries and clinics by staff who have received specific training in the use of laryngoscopes.



Warning:

The Rhino Laryngoscope must only be used on individuals who have a body orifice large enough to allow insertion of the insertion tube. This is particularly important to bear in mind when examining children's noses.

3 Symbols used

	On the type plate: Caution: follow the instructions for use
	Symbol for the separate collection of electrical and electronic equipment
	Type BF application part
	In the instructions for use: Caution, general hazard
IP 68	The device is dust-tight and protected against continuous submersion
	The device complies with Protection Class II
	The device is a medical device
	Swiss representative
	UK Authorised Representative
	Reference to Unified Device Identification

4 Functionality and use

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 area being examined can be displayed via the built-in data interface on a PC or monitor fitted with a high-resolution screen.

The rhino-laryngoscopes are intended for use in hospitals and doctors' surgeries and must only be used by staff who have received specific training in the use of laryngoscopes!

Follow the cleaning and disinfection procedures as described in these instructions for use.

4.1.2. Image processing

4.1.2.1. RS1 / RX1

For the RS1-PAL, RS1-NTSC and RX1 models, the image signal is transmitted in video format. This image format can be displayed directly on a monitor equipped with a suitable 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 software is suitable for displaying and saving the images on the optionally available panel PC.

4.1.3. How the RS1 works

At the distal end of the Video Rhino Laryngoscope is the outlet of a light guide which illuminates the area under observation. 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 transmitted via an electronic interface to a monitor or a PC.

The light used to illuminate the observation area is supplied either via a fibre-optic cable from an external light source (models RS1 / RX1) or from an LED integrated into the handpiece (all other models). 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 a mains adaptor supplied with the unit (models RS1 / RX1) or via the PC through the USB interface (RSX / RSX-P / RSX-HD).

4.2 Fibre-optic endoscope

The Rhino Laryngoscope FS2 is a fibre-optic laryngoscope and features 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 brought into focus using the focusing mechanism. At the distal end of the Rhino Laryngoscope is the outlet of a light guide, which illuminates the observation area.

The light used to illuminate the observation area is supplied via this light guide from an external light source through the light guide connector.

The distal end of the insertion tube can be angled within a range of $\pm 130^\circ$ by operating the adjustment lever.

4.3 Instructions for use

The instructions for use explain how to operate the medical device safely, correctly and effectively. Please read the instructions for use before use, starting with the chapter on risks and safety warnings. Keep the instructions close to the device. Observe the environmental conditions specified in the technical data.

The user manual does not replace the relevant basic medical and technical knowledge. Where necessary, the user must acquire such knowledge through specialist further training.

Orlvision accepts no liability for diagnoses or interpretations of findings made with the aid of medical devices purchased from Orlvision. The acquisition of specialist medical knowledge and its diagnostic and therapeutic implications are the sole responsibility of the user of the medical device.

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

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

4.4 – Contents of the package

The scope of delivery for the various types includes:

4.4.1. RS1 / RX1

Item No.	Description
Various	RS1 or RX1
M-830-00001-0010	USB stick 2 GN, USB 2.0 (+ ORLView software)
M-900-04003-0012	AC adapter 12V DC / 3A
900-04003-0006	AC adapter cable (EU)
M-860-00003-0057	Leak Tester (Naso)
930-00500-0004	Video Cable Type III
M-930-00500-0024	S-Video cable, 2 m (Naso)
900-06000-0076	Case for Video Rhino Laryngoscope
900-01006-0003	Light Guide Adapter Plug – Storz
Or alternatively	
900-01006-0004	Light Guide Adapter Plug – Wolf
Or alternatively	
900-01006-0002	Light Guide Adapter Plug – Olympus
850-10001-0042HA	BNC/RCA Adapter
M-860-00004-0035	Naso plug cap (D cap)
M-820-02001-0038	Cable with jack plug
M-860-00003-0086-P	Valve cover cap
M-820-02001-0036	Power cable_Naso

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

Item No.	Description
Various	RSX-USB, RSX-P or RSX-HD
M-860-00003-0057	Leak tester (Naso)
M-820-02001-0046	RSX USB connection cable
M-860-00003-0086-P	Valve cover cap
M-860-00004-0035	Naso plug cap (Cap D)
900-06000-0076	Case for laryngoscope
M-830-00001-0010	USB stick 2 GN, USB 2.0 (+ ORLView software)

4.4.3. **FS2**

Number	Description
M-105-22030-0700	FS2 Fibre Rhino-Laryngoscope
900-06000-0076	Case for Video Rhino-Laryngoscope
M-860-00003-0057	Leak Tester Orlvision (Naso)
900-01006-0023	Wolf Light-Port connector (FS2)
Or alternatively	
900-01006-0024	Storz connector Light-Port (FS2)
M-860-00003-0086-P	Valve cover cap

4.5 **Recommended accessories:**

4.5.1. **FS2 and RS1 / RX1**

Use only a medically approved cold light source.



Warning:

The light source must comply with the requirements of the DIN EN ISO 60601-1 standard!
The connection on the Rhino laryngoscope is compatible with fibre-optic cables featuring ACMI / Storz / Wolf endoscope connectors.

Options:

- Firefly ES201 light handle, 5W LED
- orlLED 180 light source, ILO



Warning:

When using a high-power cold light source and if there is dirt at the exit of the light guide or the light input connector on the laryngoscope, excessive heat build-up may occur due to light absorption. There is a risk of burns.

On request, we are also happy to offer a wide range of adapters for light sources and endoscopes from other manufacturers, as well as for LED handheld light sources.

4.5.2. **RSX**

Panel PC (available from orlvision)

5 Technical specifications

5.1 RS1, RX1

Parameter	RX1	RS1-PAL	RS1-NTSC
Focus range	10–55 mm	10–55 mm	10–55 mm
Angle of view	90°	90°	90°
Diameter of distal end	3.9 mm	3.9 mm	3.9 mm
Diameter of insertion tube	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
Overall length	540 mm	540 mm	540 mm
Video format	NTSC	PAL	NTSC
Resolution in pixels	320x240	500x582	510x492
White balance	Manual	Manual	Manual
Illumination: External cold light source and	fibre-optic light guide	fibre-optic light guide	fibre-optic light guide
Power supply	100–240 V / 50–60 Hz	100–240 V / 50–60 Hz	100–240 V / 50–60 Hz
Power	max. 1.5 W	max. 1.5 W	max. 1.5 W
Interface	RCA video	Y-C video	RCA
Weight in g	approx. 540g Handpiece	approx. 540g Handpiece	approx. 540g Handpiece
Risk class according to the MDR	1	1	1
Transport and storage temperature in °C	- 10°C to +60°C	- 10°C to +60°C	- 10°C to +60°C
Operating temperature in °C The distal end may 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%
Atmospheric 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 range	10–55 mm	10–55 mm	10–55 mm
Angle of view	90°	90°	90°
Diameter of distal end	3.9 mm	2.9 mm	3.9 mm
Diameter of insertion tube	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
Overall length	540 mm	540 mm	540 mm
Resolution in pixels	400x400	400x400	800x800
White balance	Factory setting set	Factory setting set	Factory setting set
Lighting: Internal LED	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
Power	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 +60°C	- 10°C to +60°C
Operating temperature in °C The distal end may 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%
Atmospheric 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

Parameter	FS2
Focus range	3 mm $\pm$ 1 to 50 mm -5 / +10
Field of view (FOV)	90° $\pm$ 5°
Diameter of distal end	2.9 mm + 0 / -0.1
Diameter of insertion tube	2.9 mm $\pm$ 0.1
Distal angle up / down	130° $\pm$ 5
Working length	300 mm
Total length	540 mm
Weight in g	Approx. 310 g
Risk class according to the MDR	1
Transport and storage temperature in °C	- 10°C to +60°C
Operating temperature in °C The distal end can be heated up to 9°C above room temperature.	0° to +35°
Relative humidity	0 to 100 per cent
Atmospheric 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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7 Swiss representative



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9 Use of Rhino laryngoscopes

9.1 RX1, RS1-PAL, RS1-NTSC

9.1.1. Connecting the laryngoscope

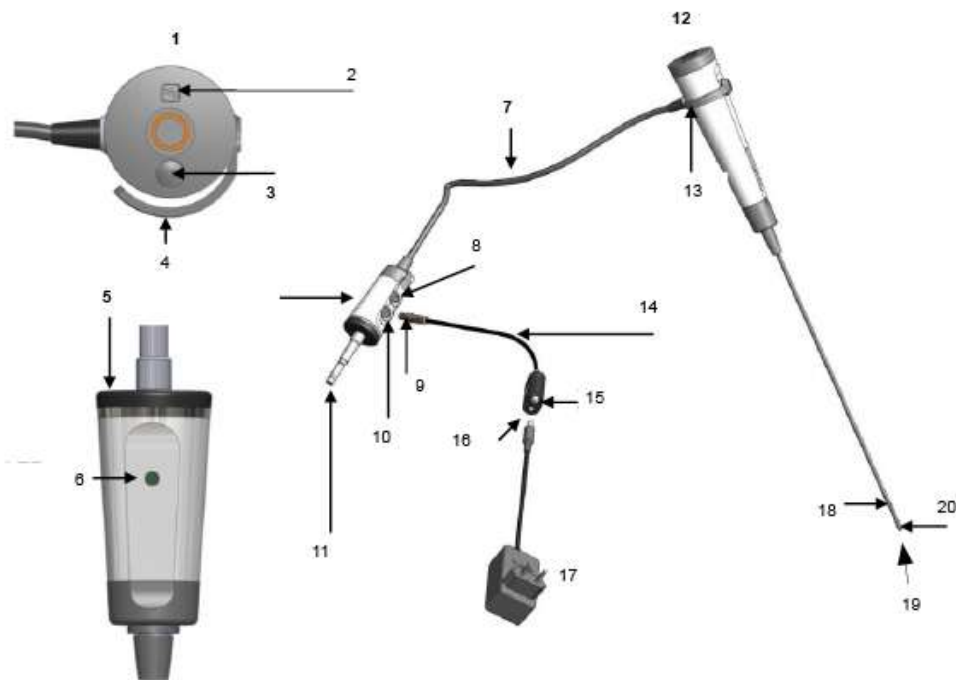


Figure 1: Connecting the RX1 / RS1

1 Handpiece	2 White balance	3 Capture button
4 Tilt lever	5 Fibre-optic connectors	6 LED indicator
7 Connecting hose	8 Valve for pressure test	9 Multipoint connector
10 Multipoint socket	11 Connection for cold light source	12 Handpiece
13 Adjustment lever (as 4)	14 Connection cable for power supply and video	15 Composite video out / S-video out
16 12V input	17 60601-1 certified 12V power supply unit	18 Angle adjustment unit
19 Distal end	20 Camera head	

The Video Rhino Laryngoscope should 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 secondary connector of the power supply unit is plugged into the connector.

Next, plug the connection cable into the fibre-optic connector, which is then connected to the cold light source.

An external monitor for displaying the video signal is connected to the Video Out socket; the image captured by the camera is then displayed on the screen.

The Rhino laryngoscope can now be used as intended; the green LED on the fibre-optic connector is lit.



Warning:

The monitor and light source must comply with the requirements of the DIN EN 60601 standard!

9.1.2. White balance

Caution: A white balance should be performed before each examination to ensure that the camera reproduces natural colours.

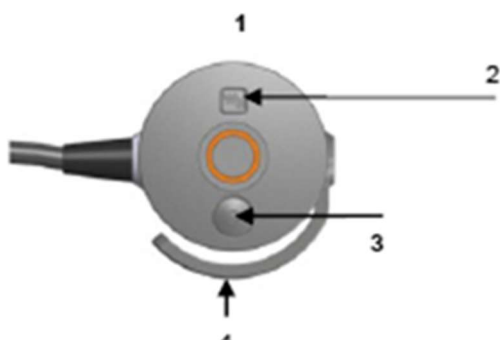


Figure 2: White balance RX1 / RS1

- 1: Handpiece
- 2: White balance
- 3: Capture button
- 4: Adjustment lever

To perform white balance, point the distal end directly at a white sheet of paper, position it within the working range (10–55 mm) and briefly press the white balance button on the handpiece.

9.1.3. Switching off

After use, switch off the laryngoscope by disconnecting it from the power supply and switch off the cold light source.

The necessary cleaning and disinfection procedures must then be carried out.

Please refer to the relevant section in these instructions for use.

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

9.2.1. Switching on

The Video Rhino Laryngoscope is switched on or off using the on/off switch (see Figure 3), or put into operation by connecting the cable to a PC, laptop or tablet.

Due to a design change, the on/off switch (2) has been rendered non-functional on all devices manufactured from 06/2024 onwards. Since then, the device has been switched on or off via the connection cable.

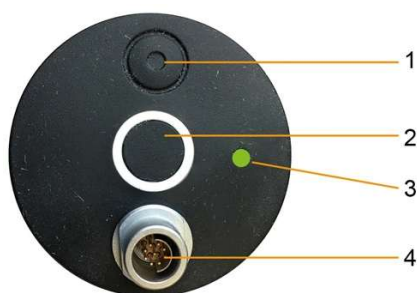


Figure 3: Controls on the RSX-USB / RSX-P / RSX-HD handpiece

- 1 Save button
- 2 On/off switch; not functional on units manufactured from June 2024 onwards
- 3 Status LED
- 4 Connection plug,

Caution: plug in only; do not twist

The Save button can be used to save an image. For further details on saving images, please refer to the description of the Orlview image processing software.

9.2.2. Switching off

After use, the laryngoscope must be taken out of service by switching it off to 06/2024 (see Figure 3) or by disconnecting the cable (remove the connector).

The necessary cleaning and disinfection procedures must then be carried out.

Please refer to the relevant section in these instructions for use.

9.3 FS2

The fibre-optic cable or light from an external cold light source must be connected to socket (4)

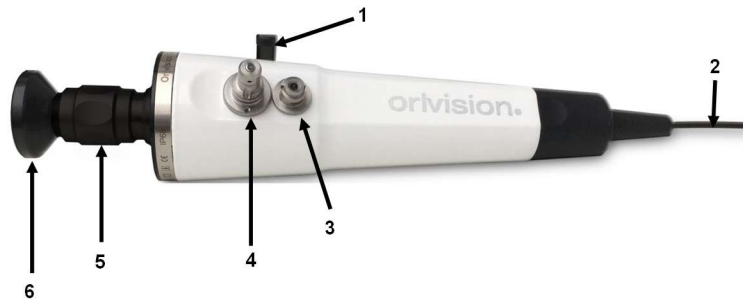


Figure 6: Components of the FS2

- 1: Adjustment lever
- 2: Flexible insertion tube
- 3: Connection for pressure test
- 4: Connection for optical fibre
- 5: Focusing mechanism
- 6: Eyepiece

Use the focusing mechanism (5) to bring the image into focus.

9.4 Insertion, angulation and withdrawal of the insertion tube (all types).

The insertion tube must be carefully inserted into the relevant areas to be examined (nasal and pharyngeal cavities). If necessary, the distal end can be adjusted by +/- 130° using the adjustment lever. The angle of deflection should be checked during a trial run. The examining doctor holds the laryngoscope in their hand to control the adjustment of the deflection unit and observes the image through the eyepiece.

After the examination, the adjustment lever must be returned to the zero position and the insertion tube carefully withdrawn.

10 Cleaning, maintenance and disinfection (all types)

When reprocessing, the machine-based method is always to be preferred in accordance with the KRINKO/BfArM recommendation.

10.1 Manual methods



Warning:

A leak test (see Chapter 10.3) must be carried out before each disinfection or use. If a leak is detected, the rhino-laryngoscope must be taken out of service immediately and sent to the manufacturer for repair. Immersion disinfection is ineffective if there are leaks!

We recommend the following disinfection method: immersion disinfection with 2% Sekusept® aktiv (manufactured by Ecolab). Soaking time: 5 minutes.



Warning:

During reprocessing, to protect the 9-pin connector, we recommend using the enclosed 'Plug Cap Naso' cover cap and the M-860-0003-0086-P cover cap to protect the valve connection; see also section 10.2.4.



Image: 7

Plug Cap Naso cover cap
Item No. 000-00000-2000

10.1.1. **Cleaning**

The Video Rhino Laryngoscope must be cleaned thoroughly after each use. To do this, wipe down all accessible external parts with a clean, disposable cloth soaked in a suitable disinfectant.

We recommend the following for cleaning: 2% Sekusept® aktiv (manufactured by Ecolab). Leave to act for 5 minutes. Ensure that the surfaces remain damp throughout. Wipe down with a dry disposable cloth afterwards.



Warning:

Please do not apply excessive mechanical force to the flexible end of the laryngoscope whilst wiping, as this could damage the optical fibres inside (breakage).

10.1.2. **Disinfection**

Disinfection must only be carried out by trained staff in accordance with the guidelines of the Robert Koch Institute.



Warning:

Leaving the laryngoscope immersed in concentrated alcohol for any length of time will cause irreversible damage. If necessary, carry out a brief wipe-down disinfection. However, ensure that the alcohol can evaporate immediately after the wipe-down disinfection.



Warning:

Under no circumstances should the USB cable be placed in the immersion disinfectant. The cable must only be cleaned and disinfected by wiping or surface disinfection.

10.1.3. **Final rinse**

Remove the Rhino laryngoscope and accessories from the disinfectant solution using fresh, single-use gloves. Place the disinfected laryngoscope in a basin or tub containing microbiologically safe water (drinking water quality). Use fresh water for each device. Rinse the external surfaces of the Rhino laryngoscope thoroughly with microbiologically safe water.

10.2 **Reprocessing with Tristel Trio Wipes**

Reprocessing with Tristel Trio Wipes must be carried out strictly in accordance with the manufacturer's instructions.

Extract from the instructions for use of the Tristel Trio Wipes system:

- Disinfect your hands and wear gloves when handling medical devices.
- Wear personal protective equipment (PPE).
- Please do not use the wipes if the packaging is damaged or if the wipe is discoloured, damaged or dry.
- Do not use the activator foam if the bottle is damaged.
- If you are using the logbook, keep the empty wipe packets and the activator foam until the reprocessing procedure is complete.
- Continuous wiping of the surface is not necessary and should be avoided to prevent the wipe from tearing.
- For professional use only.
- For use by healthcare professionals only.

- Do not use with soft metals such as copper or brass.



Warning:

Do not use after the expiry date. The expiry date and batch number are printed on the outside of the box.

STEP 1: CLEANING

The first step in the reprocessing of medical devices is to clean the surface to remove visible contaminants and organic material prior to subsequent disinfection.

9. Disinfect your hands and wear gloves when handling disinfectants and medical devices.
10. Take a pack of Pre-Clean Wipes.
11. Remove the cleaning wipe and spread it out in the palm of your hand.
12. Wipe the surface of the medical device until visible contaminants and organic material have been removed. If the device is heavily soiled, you may need to use several wipes.
13. Dispose of the used cleaning wipe and gloves in accordance with the applicable regulations. Do not reuse. If you are using the logbook, keep the empty wipe pack for documentation purposes.

STEP 2: ACTIVATION AND HIGH-LEVEL DISINFECTION

The second step in the reprocessing process is the high-level disinfection of the medical device.

14. Disinfect your hands and put on a fresh pair of gloves.
15. Take a pack of Sporicidal Wipes.
16. Remove the wipe and spread it out on the palm of your hand.



Warning:

Note: Activate the Sporicidal Wipe immediately after removing it from the packaging and use it straight away.



Warning:

PLEASE DO NOT SHAKE THE ACTIVATOR FOAM!

17. Remove the cap from the bottle containing the **activator foam**.
Apply two pumps **of activator foam** to the disinfectant wipe.
18. Fold the corners of the wipe towards the centre and press it together for 15 seconds. The wipe must be evenly covered with foam all over. A chlorine-like odour confirms that the wipe is ready for use. Use the activated wipe immediately.
19. Wipe the medical device in a single motion so that it is completely covered with foam. All surface areas must come into contact with the active wiping surface. Pay particular attention to corners, edges, recesses and areas where different materials are joined together.
20. Allow the wipe to act for at least 30 seconds.
21. Dispose of the used wipe in accordance with the applicable regulations. Do not reuse. If you are using the logbook, keep the empty wipe packaging for documentation purposes.

STEP 3: RINSING

The third step in the reprocessing process is to rinse the medical device. The **Rinse Wipe** is saturated with deionised water and a small amount of an antioxidant, which removes chemical residues from surfaces.

22. Take a pack of **Rinse Wipes**.
23. Remove the wipe and spread it out on the palm of your hand.
24. Wipe the surface of the disinfected medical device to remove any foam residue.
25. Dispose of the used wipe and gloves in accordance with the applicable regulations. Do not reuse. If you are using the logbook, keep the empty wipe packet for documentation purposes.



Warning:

Note: Once the reprocessing process is complete, the disinfected medical device should be left to dry. Store the medical device in a clean and dry place to prevent damage or recontamination.

10.3 Machine-based procedures

We recommend the following procedures using the BHT INNOVA® E3 CMS DC cleaning and disinfection machine from CANTEL GmbH or an equivalent machine capable of operating at the settings specified below.



Warning:

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

It is also recommended to use this protective cap during manual cleaning.

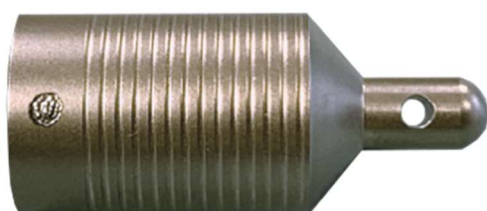


Image:8
Naso Bouchon protective cap
Item number 860-00003-0086



Image: 9
Naso Bouchon cover cap fitted

10.3.1. Preliminary cleaning:

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

10.3.2. **Cleaning**

Cleaning agent: 0.5% Dr. Weigert neodisher Mediclean forte®.

Automatic cleaning cycle using programme no. 24 with the following settings:

- Pre-cleaning stage for 4 minutes
- Drain step
- Cleaning stage: 0.5% at 37°C for 6 minutes
- Cleaning stage: 0.5% at 43°C for 6 minutes
- Drain stage
- Step: Intermediate rinse for 2 minutes



Warning:

A leak test (see Section 10.3) must be carried out before each cleaning, disinfection or insertion. If a leak is detected, the Rhino Laryngoscope must be taken out of service immediately and sent to the manufacturer for repair. Disinfection is ineffective if there are leaks!



Warning:

Please do not apply excessive mechanical force to the flexible end of the laryngoscope when wiping it, as this could damage the light guides inside (breakage).

10.3.3. **Disinfection**

Disinfectant: 1.0% Dr. Weigert neodisher endo SEPT PAC

10.3.4. **Automatic cleaning and disinfection programme**

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

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

10.4 **Leak test**



Warning:

The leak test must be carried out before **every reprocessing cycle!**



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



Figure: 10 Leak Tester connection

1. Firmly place the tester connection cap onto the tester connection and turn it a quarter turn clockwise. The tester is now securely connected to the laryngoscope and cannot be detached.
2. Connect the valve to the leak tester.
3. By pumping the leak tester, generate a test pressure of 160 (± 10) mmHg.



Warning:

If the pressure gauge reading drops by more than 10 mmHg within one minute, the laryngoscope must not be immersed in liquid.

In this case, wipe the outer casing with instrument disinfectant or 70% isopropanol, wrap the laryngoscope in a protective plastic sleeve, pack it in its original packaging and label it 'leaking, not disinfected'. Then hand it over to the service centre or the manufacturer.



Warning:

Never connect or disconnect the tester whilst submerged in water, as this may allow moisture to enter the device and necessitate repairs.

Once the leak test is complete, open the valve on the leak tester to release the excess pressure. Then turn the tester's connection cap anti-clockwise and remove it.

10.5 Care

Laryngoscopes must always be thoroughly cleaned; see the relevant instructions in this chapter. They must also be checked regularly for damage.

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 users. Repairs and maintenance work may only be carried out by **orlvision** or by specialist companies authorised by it. **orlvision** provides authorised companies with all necessary product documentation.



Warning:

Opening, repairing or modifying the laryngoscope without authorisation releases **orlvision** from any liability for operational safety. During the warranty period, this will invalidate any warranty claims.

11.1 Returns

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

When shipping and transporting the item, always connect the pressure tester to the tester connection with the valve open!

12 Disposal

Applies to models RX1, RS1, RSX-USB, RSX-P and RSX-HD.



Environmentally sound disposal in accordance with EU Directive 2012/19/EU. The laryngoscopes contain electronic components. To prevent environmental risks or hazards arising from improper disposal, the product, including its accessories, must be disposed of in accordance with the applicable EU Directive 2012/19/EU. Disposal can be arranged through the manufacturer.

To this end, please send the product to the manufacturer at:

Orlvision GmbH

Gewerbestraße 17

D-35633 Lahnau.

Disposal in household waste is prohibited.

The FS2 laryngoscope may be disposed of in household waste.

13 Electromagnetic compatibility

13.1 Operating environment specifications:

The Video Rhino Laryngoscopes are intended for use in low-interference RF environments such as doctors' surgeries. A shielded location is not required.

The FS2 laryngoscope is immune to electromagnetic interference.

13.2 Performance specifications

- **Key performance features** of the video rhino-laryngoscope include: display of images of the examination area (the nose, pharynx and larynx, the nasal cavities and nasopharynx). In the event of severe electromagnetic interference, the image quality of the video laryngoscope may be impaired.
- **Warning:** The use of this device in the immediate vicinity of other devices or when stacked with other devices should be avoided, as this may cause interference. The FS2 is an exception to this.
- Cables, transducers and accessories that can be replaced without affecting EMC performance: None
- **Warning:** The use of other accessories (in particular PCs) may result in malfunction
- **Warning:** Portable communication devices (radio transmitters) operated in the immediate vicinity may cause the device to malfunction. The FS2 is an exception.

14 Reporting of serious incidents

All serious incidents occurring in connection with any of the products described here must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is based.

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