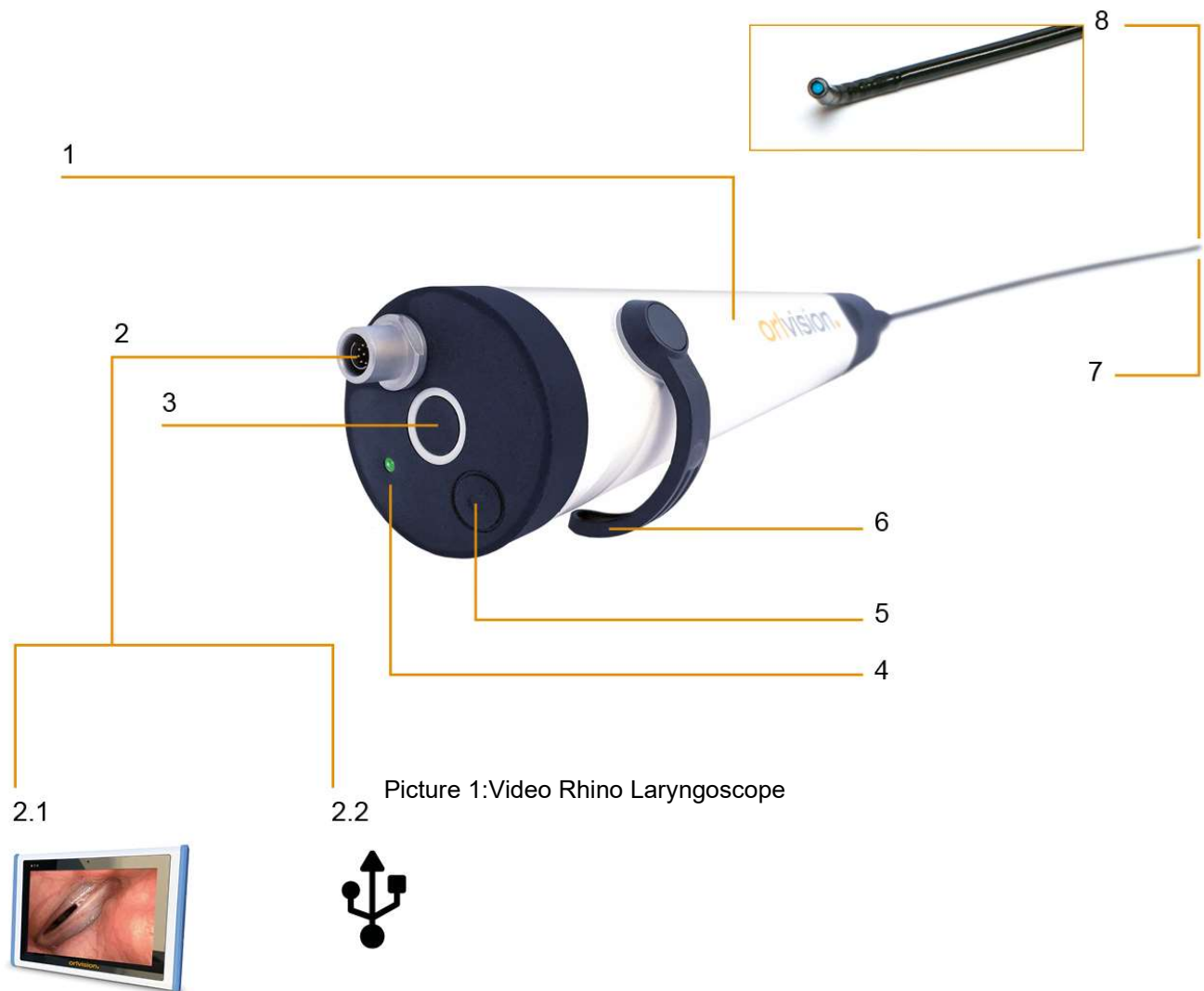


Instructions for use

Video Rhino Laryngoscope

Type RSX-USB / RSX-P



- 1 Integrated LED
- 2 USB interface
- 2.1 Tablet PC
- 2.2 USB
- 3 Power on/off

- 4 Status LED
- 5 Release button
- 6 Probe control
- 7 Distal end
- 8 Sensor with precise optics



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1 Risks and hazard warnings

1. 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.
2. Before each treatment, take a test image of a known object so that you can be sure of the the correct image quality, the correct image orientation (even if the angulation unit moves) and the orientation (even if the angulation unit is moved) and that the Video Rhino Laryngoscope is working laryngoscope. Particular attention should also be paid to colour fidelity.
3. Only use the Video Rhino Laryngoscope for its intended purpose, in accordance with the of the MPDG or MDR, in accordance with the generally recognised rules of technology, as well as in accordance with the valid occupational safety and accident prevention regulations.
4. Before using the Video Rhino Laryngoscope, visually inspect it to ensure that it is in good working order.
to ensure that it is in proper working order and condition. The Video Rhino Laryngoscope is a high-quality precision mechanical-optical instrument; handle it with care.



Caution:

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



Caution:

Do not use the Video Rhino Laryngoscope if it is leaking. (See chapter 9).
Serious infections may otherwise occur.



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.

The computer must have double insulation (2 MOPP).

Otherwise, the patient or user could be endangered in unfavourable cases. Observe the instructions in chapter 7.



Caution:

Handle pointed or sharp objects such as scalpels or needles carefully in the vicinity of the Video Rhino Laryngoscope carefully so that no mechanical damage could be caused to the endoscope and especially to the flexible insertion tube.

This also applies in particular to insertion into a disinfection bath.



Caution:

Do not look directly into the light exit at the distal end. The energy of the internal light sources can cause eye damage. In particular, do not use the laryngoscope for eye examinations contrary to its intended use.



Attention:

Do not look into the connected light guide!



Caution:

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 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.



Caution:

The distal end may heat up to 10°C above room temperature during prolonged use of the laryngoscope.

above room temperature.

Note: The supplied image display programme Orlview has been tested on the optionally available panel PC, which is available as an option. The installation of different software versions or other programmes on this PC may cause faults in the image display. Orlvision does not accept any guarantee for such faults. We recommend that you do not modify the Panel PC.

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

5. 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.
6. The operational safety and usability of the medical device depend not only on your skills but also on the care of the device.
but also on the care of the device. Regular cleaning and care are therefore necessary (see chapter Cleaning, care and disinfection).
7. 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.
8. Prolonged or improper use (sharp kinking of the flexible insertion tube) may result in reduced illumination in the observation room due to damage to light guides (breakage). The ability to illuminate should therefore be checked from time to time outside examinations (Illumination of a white sheet of paper).

2 Intended use






- The Video Rhino Laryngoscope RSX-USB / RSX-P 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 RSX-USB / RSX-P 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

	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
	Device is a medical device

4 Functionality and application

4.1 Application

The flexible Video Rhino Laryngoscopes RSX-USB / RSX-P 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 PC equipped with a high-resolution screen via the USB interface.

The RSX-USB laryngoscope is intended for use in clinics and doctors' surgeries and may only be used by personnel specially trained in handling endoscopes!

Proceed with cleaning and disinfection as described in these instructions for use.

4.2 Image processing

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

4.3 How it works

At the distal end of the Video Rhino Laryngoscope is the exit of a light guide that illuminates the observation region. The lens allows imaging at a 90° angle of view. The image thus captured is recorded by a video camera, converted into an electrical signal and made available to a PC via a USB interface.

The light for illuminating the observation region is obtained from an LED integrated in the handpiece. The distal end of the insertion tube can be angled in a range of +/- 120° by operating the angulation lever.

Power is supplied via the PC through the USB interface.

Using the optional software, pictures or videos can be displayed and also saved.

4.4 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 angulation unit by operating the adjustment lever to avoid an incorrect angulation direction.

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

4.5 Scope of delivery

The scope of delivery for the flexible Video Rhino Laryngoscope is as follows:

- the Video Rhino Laryngoscope handpiece with insertion tube and the connector for the USB connection and the
- Connection Cable RSX-USB / RSX-P (Article no. M-820-02001-0046)
- A hand air pump (Leak Tester; item no. M-860-00003-0057).
for carrying out the leak test.
- The OriView software
- These instructions for use or a note on downloading from the homepage
- Cover cap " Plug Cap Naso " for 9-pole plug connection
- Cover cap for connection pressure test, article no. M-860-0003-0086-P

5 Technical data

Parameter	Data RSX-USB	Data RSX-P
Focus area	10 - 55 mm	10 - 55 mm
Angle of view	90°	90°
Diameter distal end	3.9 mm	2.9 mm
Diameter insertion tube	3.9 mm	2.9 mm
Distal angulation up / down	120° / 120°	120° / 120°
Working length	310 mm	310 mm
Total length	540 mm	540 mm
Resolution in pixels	400x400	400x400
White balance	Factory set	Factory set
Lighting: LED internal	Fibre optic cable	Fibre optic cable
Power supply	5V DC / 0.3 A via USB	5V DC / 0.3 A via USB
Power	max. 2.2 W	max. 2.2 W
Interface	USB 2.0 "A	USB 2.0 "A
Weight in g	approx. 320g handpiece	approx. 320g handpiece
Risk class according to MDR	1	1
Transport and storage temperature in ° Celsius	- 10°C to + 60°C	- 10°C to + 60°C
Operating temperature in ° Celsius The distal end can warm up to 9°C above room temperature.	0° to + 40°	0° to + 40°
Relative humidity	0 to 100%	0 to 100%
Air pressure	950 to 1050 hPa	950 to 1050 hPa
Protection class against environmental influences	IP 68	IP 68
Operating mode	Continuous operation	Continuous operation

Table1

6 Manufacturer

The manufacturer of the Video Rhino Laryngoscope RSX-USB/RSX-P is
orlvision GmbH
Industrial Road 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

7 Use of the Video Rhino Laryngoscope

7.1 Switch on

The Video Rhino Laryngoscope is switched on and off using the on/off switch (see Fig. 2).

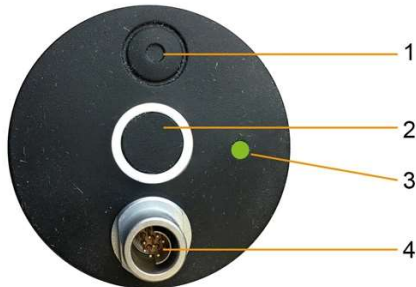


Figure 2: Operating elements on the handpiece

- 1 Save button
- 2 On-off switch
- 3 Status LED
- 4 Connector plug, attention: only plug in, do not turn

The save button can be used to save an image. For more details on saving images, see the description of the image processing software.

7.2 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 $\pm 120^\circ$ with the adjustment lever (see figure 3). The plane of the angulation should be checked 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.



Figure 3: Adjustment lever

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

7.3 Switch off

After use, the laryngoscope must be switched off (see Fig. 2) and then the necessary cleaning and disinfection work must be carried out. See chapter 8.

8 Cleaning, care and disinfection

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

8.1 Manual procedures

8.1.1. 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. Alternatively, we recommend using Triamin disinfectant wipes from Wet Wipe (available from Orlvision). Contact time depending on possible organisms 5-15 minutes, see separate data sheet, available at www.wetwipe.eu.



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).

8.1.2. 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 8.3) must be carried out. In case of the Rhino Laryngoscope must be discarded immediately and sent to the manufacturer for repair. In case of leaks, the immersion disinfection becomes ineffective!

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



Attention:

To protect the 9-pole plug connection, we recommend using the enclosed "Plug Cap Naso". cover cap "Plug Cap Naso".



Fig. 4: Cover cap Plug Cap Naso



Caution:

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 USB cable be immersed in the disinfectant. The cable may only be cleaned and disinfected by wipe disinfection / surface disinfection.

8.1.3. 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.

8.2 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 8.3) 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).

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

DisinfectionDisinfectant: 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 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.



Fig. 5, Cover cap Article number M-860-0003-0086-P



Figure 6: Valve cover cap fitted

8.3 Leak test



Attention:

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



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

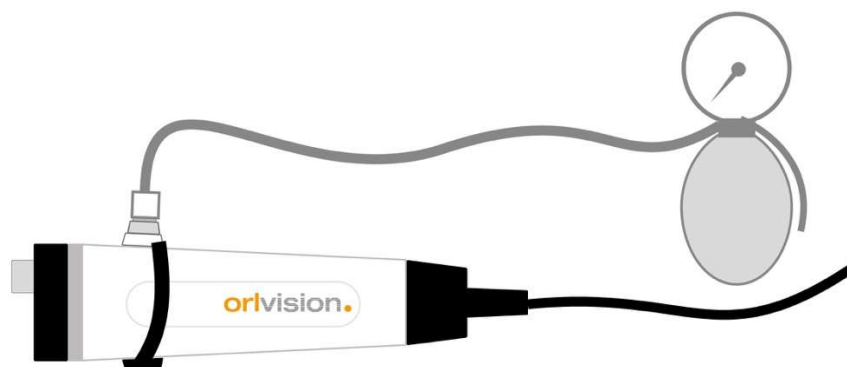


Figure 7: Leak tester connection

1. Place the tester connection cap firmly on the tester connection and turn it clockwise a quarter turn. The tester is now firmly connected to the laryngoscope and cannot be removed.
2. Close the valve on the leak tester.
3. Create a test pressure of 160 (± 10) mmHg by pumping the leak tester.



Caution:

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 pull it off.

8.4 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.

9 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.

9.1 Return

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

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

10 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.

11 Electromagnetic compatibility

11.1 Information on the operating environment:

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

11.2 Information on the performance characteristics

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

11.3 Electrical immunity (immunity)

Parameter	Data RSX-USB	Data RSX-P
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	

11.4 Immunity test

Parameter	Data RSX-USB	Data RSX-P
Immunity to electromagnetic radiation according to EN 61000-4-3, level according to EN 60601-1-2 f = 80 MHz to 2.7 GHz	10V/M; 3 V/m	
According to EN 60601-1-2 chapter 8.10; / PM, 18 Hz or 217 Hz 380 MHz - 5.8 GHz	9 - 28 V/m	

Parameter	Data RSX-USB	Data RSX-P
Conducted RF according to EN 61000-4-6, levels according to EN 60601-1-2, 150 kHz - 80 MHz	3 V/m ISM frequencies 6 V/m	

11.5 Electromagnetic emission

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

12 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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