Ambu
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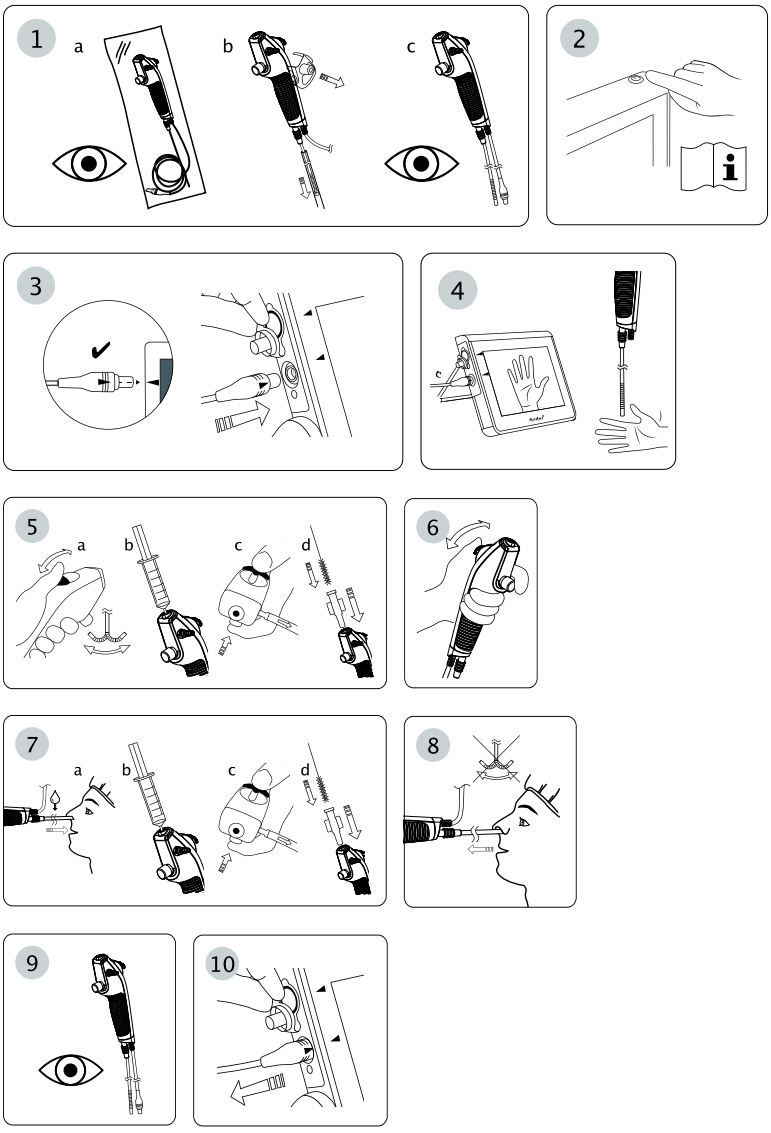
Instruction for Use

Ambu® aScope™ 4 RhinoLaryngo Intervention



CE 0086

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1. Important Information – Read Before Use

Read the safety instructions carefully before using the Ambu® aScope™ 4 RhinoLaryngo Intervention. The instructions for use may be updated without further notice. Copies of the current version are available upon request. Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operation and precautions related to the operations of aScope 4 RhinoLaryngo Intervention.

Before initial use of the aScope 4 RhinoLaryngo Intervention it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings and cautions mentioned in these instructions.

In this Instruction for Use, the term *endoscope* refers to instructions for aScope 4 RhinoLaryngo Intervention, and *system* refers to aScope 4 RhinoLaryngo Intervention and the compatible Ambu monitor. This Instruction for Use applies for the endoscope and information relevant for the system.

1.1. Intended Use

The endoscope is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is intended to provide visualization via a monitor.
The endoscope is intended for use in a hospital environment. It is designed for use in adults.

1.2. Warnings and Cautions

Failure to observe these warning and cautions may result in patient injury or damage to the equipment.
Ambu is not responsible for any damage to the system or patient resulting from incorrect use.

WARNINGS ⚠

1. Only to be used by physicians, trained in clinical endoscopic techniques and procedures.
2. The endoscope is a single-use product and must be handled in a manner consistent with accepted medical practice for such devices in order to avoid contamination of the endoscope prior to insertion.
3. Do not soak, rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. Reuse of the endoscope can cause contamination, leading to infections.
4. Do not use the endoscope if the sterilisation barrier or its packaging is damaged.
5. Do not use the endoscope if it is damaged in any way or if the preuse check fails (see section 4.1).
6. The images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics.
7. Do not use active endoscopic accessories such as laser probes and electrosurgical equipment in conjunction with the endoscope, as this may result in patient injury or damage to endoscope.
8. The endoscope is not to be used when delivering highly flammable anaesthetic gases to the patient. This could potentially cause patient injury.
9. Always watch the live endoscopic image on the compatible monitor during suctioning. Failure to do so may harm the patient.
10. Patients should be adequately monitored at all times. Failure to do so may harm the patient.
11. Always make sure that the bending section is in a straight position when inserting and withdrawing the endoscope. Do not operate the bending lever and never use excessive force, as this may result in injury to the patient and/or damage to the endoscope.

12. Do not use excessive force when advancing, operating or withdrawing the endoscope as this may result in patient injury or damage to the endoscope.
13. Do not advance or withdraw the endoscope or operate the bending section if endoscopic accessories are protruding from the distal end of the working channel as this may result in injury to the patient.
14. The distal end of the endoscope may get warm due to heating from the light emission part. Avoid long periods of contact between the tip of the device and the mucosal membrane as sustained contact with the mucosal membrane may cause mucosal injury.

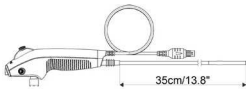
CAUTIONS

1. Have a suitable backup system readily available in case a malfunction should occur.
2. Be careful not to damage the insertion cord or distal tip. Do not allow other objects or sharp devices such as needles to strike the endoscope.
3. US federal law restricts these devices for sale only by, or on the order of, a physician.

2. System Description

The endoscope can be connected to the compatible monitor. For information about the compatible monitor, please refer to its Instruction for Use.

2.1. System Parts

Endoscopes	**Part numbers:**
	512001000 aScope 4 RhinoLaryngo Intervention

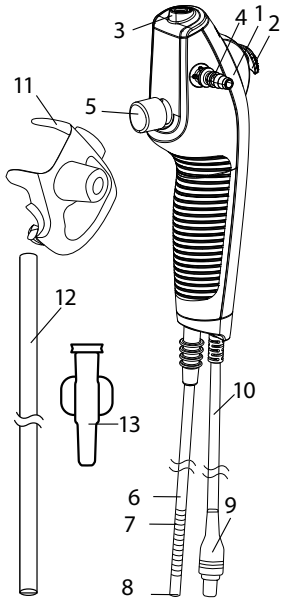
aScope 4 RhinoLaryngo Intervention is not available in all countries. Please contact your local sales office.

Product Name	**Colour**	**Outer Diameter [mm]**	**Inner Diameter [mm]**
aScope 4 RhinoLaryngo Intervention	Green	min 5.0; max 5.5	min 2.0

Compatible monitors	**Part numbers:**
 Ambu® aView™ (Reusable)	405002000 Model no. JANUS2-W08-R10 (SW versions v2.XX)

For aView model no., please check the backside label on aView.
aView is not available in all countries. Please contact your local sales office.

2.2. Endoscope Parts



No.	Part	Function	Material
1	Handle	Suitable for left and right hand	MABS
2	Control lever	Moves the distal tip up or down in a single plane	POM
3	Working channel port	Allows for instillation of fluids and insertion of endoscopic accessories	MABS + Silicone
-	Working channel	Can be used for instillation of fluids, suction and insertion of endoscopic accessories	PU
4	Suction connector	Allows for connection of suction tubing	MABS
5	Suction button	Activates suction when pressed down	MABS
6	Insertion cord	Flexible airway insertion cord	PU
7	Bending section	Manoeuvrable part	PU
8	Distal end	Contains the camera, light source (two LEDs), as well as the working channel exit	Epoxy
6-7-8	Insertion portion	The ensemble of insertion cord, bending section and distal end	See above
9	Connector on the endoscope cable	Connects to blue socket on the monitor	PVC
10	Endoscope cable	Transmits the image signal to the monitor	PVC
11	Handle protection	Protects the suction connector during transport and storage. Remove before use.	PP
12	Protection pipe	Protects the insertion cord during transport and storage. Remove before use.	PP

13	Introducer	To facilitate introduction of Luer Lock syringes and soft endoscopic accessories through the working channel	PC
-	Packaging	Sterile barrier	Cardboard, Tyvek

Abbreviations: MABS (Methyl Acrylonitrile Butadiene Styrene), PU (Polyurethane), TPE (Thermoplastic Elastomer), PP (polypropylene), PC (Polycarbonate), POM (Polyoxymethylen).

3. Explanation of Symbols Used

Symbols for the endoscope devices	Indication
	Working length of the endoscope insertion cord.
Max OD	Maximum insertion portion width (Maximum outer diameter).
Min ID	Minimum working channel width (Minimum inner diameter).
	Field of view.
	Do not use if the product sterilisation barrier or its packaging is damaged.
	This product is not made with natural rubber latex.
	Temperature limitation: between 10 °C (50 °F) and 40 °C (104 °F) in operating environment.
	Humidity limitation: relative humidity between 30 and 85% in operating environment.
	Atmospheric pressure limitation: between 80 and 109 kPa in operating environment.
	Manufacturer.
	Consult Instruction for Use.
CE 0086	CE mark. The product complies with the EU Council directive concerning Medical Devices 93/42/EEC.
	Electrical Safety Type BF Applied Part.
	Use By, followed by YYYY-MM-DD.
STERILE EO	Sterile Product, Sterilisation by ETO.
	Single use product, do not reuse.

REF	Reference Number.
LOT	Lot Number, Batch Code.
c UL us	UL Recognized Component Mark for Canada and the United States.
⚠	Warning.

4. Use of the endoscope

Optimize patient position and consider applying relevant anesthetics to minimize patient discomfort.
Numbers in gray circles below refer to illustrations on page 2.

4.1. Preuse check of the endoscope

1. Check that the pouch seal is intact before opening. **1a**
2. Make sure to remove the protective elements from the handle and from the insertion cord. **1b**
3. Check that there are no impurities or damage on the product such as rough surfaces, sharp edges or protrusions which may harm the patient. **1c**

Refer to the Instruction for Use for the compatible monitor for preparation and inspection of the monitor. **2**

4.2. Inspection of the Image

1. Plug in the endoscope into the corresponding connector on the compatible monitor. Please ensure the colours are identical and be careful to align the arrows. **3**
2. Verify that a live video image appears on the screen by pointing the distal end of the endoscope towards an object, e.g. the palm of your hand. **4**
3. Adjust the image preferences on the compatible monitor if necessary (please refer to the monitor Instruction for Use).
4. If the object cannot be seen clearly, clean the tip.

4.3. Preparation of the endoscope

1. Carefully slide the bending control lever forwards and backwards to bend the bending section as much as possible. Then slide the bending lever slowly to its neutral position. Confirm that the bending section functions smoothly and correctly and returns to a neutral position. **5a**
2. Using a syringe insert 2ml of sterile water into the working channel port (if applying a Luer Lock syringe use the enclosed introducer). Press the plunger, ensure that there are no leaks, and that water is emitted from the distal end. **5b**
3. If applicable, prepare the suction equipment according to the supplier's manual. **5c** Connect the suctioning tube to the suction connector and press the suction button to check that suction is applied.
4. A pre-check of compatibility of accessories is recommended. If applicable, verify that endoscopic accessory of appropriate size can be passed through the working channel without resistance. The enclosed introducer can be used to facilitate the insertion of soft accessories. **5d**

4.4. Operating the endoscope

Holding the endoscope and manipulating the tip **6**

The handle of the endoscope can be held in either hand. The hand that is not holding the endoscope can be used to advance the insertion cord into the patient's nose or mouth. Use the thumb to move the control lever and the index finger to operate the suction button. The control lever is used to flex and extend the tip of the endoscope in the vertical plan. Moving the control lever downward will make the tip bend anteriorly (flexion). Moving it upward will make the tip bend posteriorly (extension). The insertion cord should be held as straight as possible at all times in order to secure an optimal tip bending angle.

Insertion of the endoscope 7a
To ensure the lowest possible friction during insertion of the endoscope the insertion cord may be lubricated with a medical grade lubricant. If the images of the endoscope becomes unclear, clean the tip. When inserting the endoscope orally, it is recommended to use a mouthpiece to protect the scope from being damaged.

Instillation of fluids 7b
Insert a syringe into the working channel at the top of the endoscope to inject fluids. When using a Luer Lock syringe, use the included introducer. Insert the syringe completely into the working channel port or the introducer and press the plunger to inject fluid. Make sure suction is not applied during this process, as this will direct the injected fluids into the suction collection system. To ensure that all fluid has left the channel, flush the channel with 2 ml of air.

Aspiration 7c
When a suction system is connected to the suction connector, suction can be applied by pressing the suction button with the index finger. If the introducer and/or an endoscopic accessory is placed inside the working channel note that the suction capability will be reduced. For optimal suction capability it is recommended to remove the introducer or syringe entirely during suction.

Insertion of endoscopic accessories 7d
Always make sure to select the correct size endoscopic accessory for the endoscope (See section 5.2). Inspect the endoscopic accessory before using it. If there is any irregularity in its operation or external appearance, replace it. Insert the endoscopic accessory into the working channel port and advance it carefully through the working channel until it can be seen on the live image on the monitor. The enclosed introducer can be used to facilitate the insertion of soft accessories.

Withdrawal of the endoscope 8
When withdrawing the endoscope, make sure that the control lever is in the neutral position. Slowly withdraw the endoscope while watching the live image on the monitor.

4.5. After Use

Visual check 9
Inspect the endoscope for any evidence of damage on the bending section, lens, or insertion cord. In case of corrective actions needed based on the inspection act according to local hospital procedures.

Final steps 10
Disconnect the endoscope from the Ambu monitor and dispose the endoscope in accordance with local guidelines for collection of infected medical devices with electronic components.

5. Technical Product Specifications

5.1. Standards Applied

The endoscope function conforms with:
– IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
– IEC 60601-1-2: Medical electrical equipment – Part 1-2 General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements for test.
– IEC 60601-2-18: Medical electrical equipment – Part 2-18: Particular requirements for the safety of endoscopic equipment.
– ISO 8600-1: Optics and photonics - Medical endoscopes and endotherapy devices – Part 1: General requirements.
– ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
– ISO 594-1: Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements.

5.2. Endoscope specifications

Insertion portion	**aScope 4 RhinoLaryngo Intervention**
Bending section[1] [°]	130 ↑ ,130 ↓
Insertion cord diameter [mm, (")]	5.0 (0.20)
Distal end diameter [mm, (")]	5.4 (0.21)
Maximum diameter of insertion portion [mm, (")]	5.5 (0.22)
Minimum tracheostomy tube size (ID) [mm]	6.0
Working length [mm, (")]	350 (13.8)
Channel	**aScope 4 RhinoLaryngo Intervention**
Minimum instrument channel width[2] [mm, (")]	2.0 (0.079)
Storage and transportation	**aScope 4 RhinoLaryngo Intervention**
Transportation temperature [°C, (°F)]	10 ~ 40 (50 ~ 104)
Recommended storage temperature[3] [°C, (°F)]	10 ~ 25 (50 ~ 77)
Relative humidity [%]	30 ~ 85
Atmospheric pressure [kPa]	80 ~ 109
Optical System	**aScope 4 RhinoLaryngo Intervention**
Field of View [°]	85
Depth of Field [mm]	6 - 50
Illumination method	LED
Suction connector	**aScope 4 RhinoLaryngo Intervention**
Connecting tube ID [mm]	Ø7 +/- 1
Sterilisation	**aScope 4 RhinoLaryngo Intervention**
Method of sterilisation	ETO
Operating environment	**aScope 4 RhinoLaryngo Intervention**
Temperature [°C, (°F)]	10 ~ 40 (50 ~ 104)
Relative humidity [%]	30 ~ 85
Atmospheric pressure [kPa]	80 ~ 109
Altitude [m]	≤ 2000

1. Please be aware that the bending angle can be affected if the insertion cord is not kept straight.
2. There is no guarantee that accessories selected solely using this minimum instrument channel width will be compatible in combination.
3. Storage under higher temperatures may impact shelf life.

6. Trouble Shooting

If problems occur with the system, please use this trouble shooting guide to identify the cause and correct the error.

Problem	Possible cause	Recommended action
No live image on the screen but user interface is present on the display or the image is frozen	The endoscope is not connected to compatible monitor.	Connect an endoscope to the blue port on the monitor.
	The monitor and endoscope have communication problems.	Restart the monitor.
	The endoscope is damaged.	Replace the endoscope with a new one.
	A recorded image is shown on the monitor screen.	Return to live image on the monitor.
Low picture quality	Blood, saliva etc. on the lens (distal tip).	If the object cannot be seen clearly, clean the tip.
Absent or reduced suction capability or difficulty in inserting endoscopic accessory through the channel	Channel blocked.	Withdraw the endoscope and clean the working channel using a cleaning brush or flush the working channel with sterile saline using a syringe. Do not operate the suction valve when instilling fluids.
	Suction pump is not turned on or not connected.	Turn the pump on and check the suction line connection.
	Suction valve is damaged.	Prepare a new endoscope.
	Endoscopic accessory inserted in working channel (applicable if suction is absent or reduced).	Remove endoscopic accessory. Check that the accessory used is of the recommended size.
	Bending section not in neutral position.	Move bending section into neutral position.
	Soft endoscopic accessory difficult to pass through working channel seal.	Use the enclosed introducer.

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