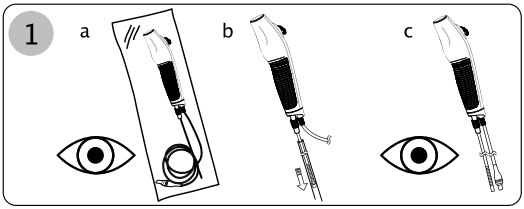
INSTRUCTIONS FOR USE

Ambu® aScope™ 4 RhinoLaryngo Slim

Abridged version

Ambu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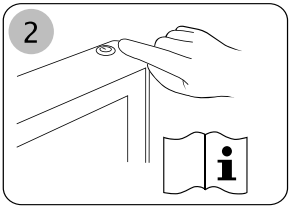
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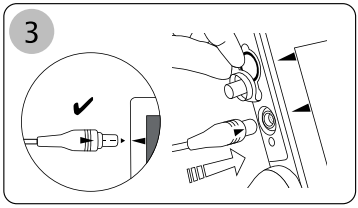
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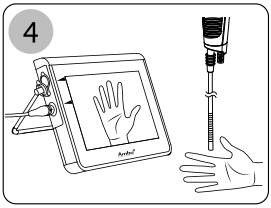
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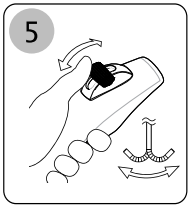
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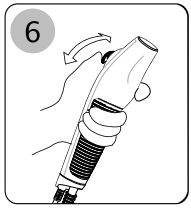
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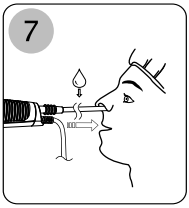
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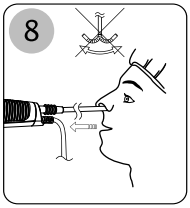
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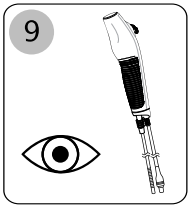
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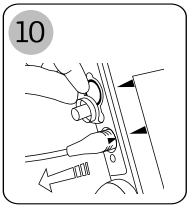
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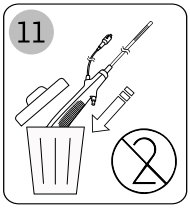
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1. Important information – Read before use

Read the safety instructions carefully before using the Ambu® aScope™ 4 RhinoLaryngo Slim. 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 Slim.

Before initial use of the aScope 4 RhinoLaryngo Slim 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 Instructions for use, the term endoscope refers to instructions for aScope 4 RhinoLaryngo Slim, and system refers to aScope 4 RhinoLaryngo Slim and the compatible Ambu displaying unit. This Instructions 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 Ambu displaying unit.
The endoscope is intended for use in a hospital environment. It is designed for use in adults.

1.2. Contra indication

None known.

1.3. Clinical benefit

Single use application minimises the risk of cross–contamination of the patient.

1.4. Warnings and cautions

WARNINGS ⚠

1. Only to be used by clinicians/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. Clinicians/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 the 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. Patients should be adequately monitored at all times. Failure to do so may harm the patient.

10. Always make sure that the bending section is in a straight position when inserting and withdrawing the endoscope. Do not operate the control lever and never use excessive force, as this may result in injury to the patient and/or damage to the endoscope.
11. Do not use excessive force when advancing, operating or withdrawing the endoscope as this may result in patient injury or damage to the endoscope.
12. The distal tip 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.
4. The color representation of blue dye might be impaired on the live endoscopic image only when used with the Ambu aView displaying unit. This caution does not apply when the endoscope is used with the Ambu aView 2 advance.
5. Operating the aScope 4 RhinoLaryngo Slim with reverse grip of the handle will cause an image on the display that is upside down.

1.5. Adverse events

Potential adverse events in relation to flexible rhinolaryngoscopy (not exhaustive):	Epistaxis, Laryngospasm, Damage to vocal cords, Damage to mucosa, Gag reflex, Pain/discomfort, Desaturation.

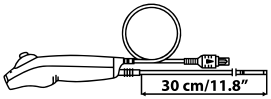
1.6. General notes

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

2. System description

The endoscope can be connected to the compatible displaying unit. For information about the compatible displaying unit, please refer to its Instructions for use.

2.1. System parts

Endoscopes	Part numbers
	510001000 aScope 4 RhinoLaryngo Slim

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

Product name	Colour	Outer diameter [mm]
aScope 4 RhinoLaryngo Slim	Purple	min 3.0; max 3.5

2.2. Product compatibility

The aScope 4 RhinoLaryngo has been designed to be used in conjunction with:

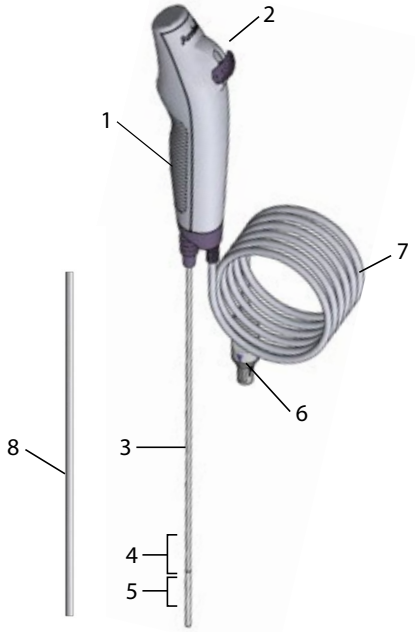
Displaying unit

– Ambu aView
– Ambu aView 2 Advance

Endoscopic accessories

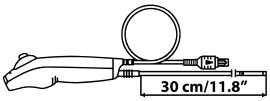
– Tracheostomy tubes size 6 or larger.

2.3. Endoscope parts



No.	Part	Function
1	Handle	Suitable for left and right hand.
2	Control lever	Moves the distal tip up or down in a single plane.
3	Insertion cord	Flexible airway insertion cord.
–	Insertion portion	Same as insertion cord.
4	Bending section	Manoeuvrable part.
5	Distal tip	Contains the camera and light source (two LEDs).
6	Endoscope cable connector	Connects to blue socket on the displaying unit.
7	Endoscope cable	Transmits the image signal to the displaying unit.
8	Protection pipe	Protects the insertion cord during transport and storage. Remove before use.

3. Explanation of symbols used

Symbols for the endoscope devices	Description
	Working length of the endoscope insertion cord.
	Maximum insertion portion width (Maximum outer diameter).
	Field of view.
	Electrical Safety Type BF Applied Part.
	Packaging level ensuring sterility.
	UL Recognized Component Mark for Canada and the United States.
	Medical device.
	Global trade identification number.
	Country of manufacturer.
	Do not use if the product sterilisation barrier orits packaging is damaged.
	Relative humidity limitation.
	Atmospheric pressure limitation.
	Temperature limitation.
	UK Conformity Assessed.
	UK Responsible Person.
	Importer (For products imported into Great Britain only).
	INMETRO Certificate Medical Electrical Equipment.

A full list of symbol explanations can be found on https://www.ambu.com/symbol-explanation.

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 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 *Instructions for use* for the compatible displaying unit for preparation and inspection of the displaying unit. **2**

4.2. Inspection of the image

1. Plug in the endoscope cable connector into the corresponding connector on the compatible displaying unit. 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 tip of the endoscope towards an object, e.g. the palm of your hand. **4**
3. Adjust the image preferences on the compatible displaying unit if necessary (please refer to the displaying unit *(Instructions for use*).
4. If the object cannot be seen clearly, clean the tip.

4.3. Preparation of the endoscope

Carefully slide the control lever forwards and backwards to bend the bending section as much as possible. Then slide the control lever slowly to its neutral position. Confirm that the bending section functions smoothly and correctly and returns to a neutral position. **5**

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. The control lever is used to flex and extend the distal tip of the endoscope in the vertical plan. Moving the control lever downward will make the distal tip bend anteriorly (flexion). Moving it upward will make the distal tip bend posteriorly (extension). The insertion cord should be held as straight as possible at all times in order to secure an optimal distal tip bending angle.

Insertion of the endoscope **7**

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 distal tip. When inserting the endoscope orally, it is recommended to use a mouthpiece to protect the scope from being damaged.

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 displaying unit.

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.

Disconnect 10
Disconnect the endoscope from the Ambu displaying unit.

Disposal 11
Dispose of the endoscope, which is a single–use device. The endoscope is considered contaminated after use and must be disposed of 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:
– EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
– EN 60601-2-18 Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

5.2. Endoscope specifications

Insertion cord	**aScope 4 RhinoLaryngo Slim**
Bending section[1] [°]	130 ↑ ,130 ↓
Insertion cord diameter [mm, (")]	3.0 (0.12)
Maximum diameter of insertion portion [mm, (")]	3.5 (0.14)
Minimum tracheostomy tube size (ID) [mm]	6.0
Working length [mm, (")]	300 (11.8)
Storage	**aScope 4 RhinoLaryngo Slim**
Temperature[2] [°C, (°F)]	10 – 25 (50 – 77)
Relative humidity [%]	10 – 85
Atmospheric pressure [kPa]	50 – 106
Transportation	**aScope 4 RhinoLaryngo Slim**
Temperature [°C, (°F)]	-10 – 55 (14 – 131)
Relative humidity [%]	10 – 95
Atmospheric pressure [kPa]	50 – 106
Optical system	**aScope 4 RhinoLaryngo Slim**
Field of View [°]	85
Direction of view [°]	0 (forward pointing)
Depth of Field [mm]	6 – 50
Illumination method	LED
Sterilisation	**aScope 4 RhinoLaryngo Slim**
Method of sterilisation	ETO

Operating environment	aScope 4 RhinoLaryngo Slim
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa]	80 – 106
Altitude [m]	≤ 2000

1. Please be aware that the bending angle can be affected if the insertion cord is not kept straight.
2. 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 displaying unit.	Connect an endoscope to the blue port on the displaying unit.
	The displaying unit and endoscope have communication problems.	Restart the displaying unit.
	The endoscope is damaged.	Replace the endoscope with a new one.
	A recorded image is shown on the displaying unit screen.	Return to live image on the displaying unit.
Low picture quality.	Blood, saliva etc. on the lens (distal tip).	If the object cannot be seen clearly, clean the distal tip.

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