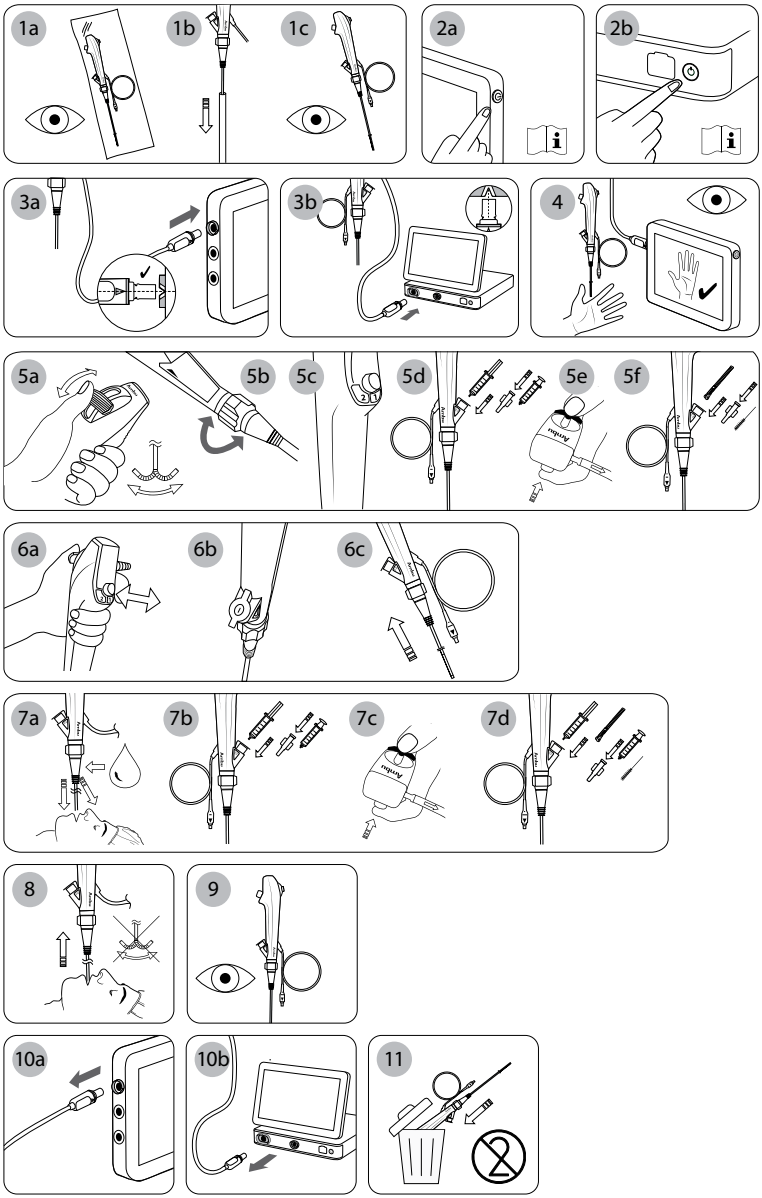
INSTRUCTIONS FOR USE

Ambu® aScope™ 5 Broncho

For use by trained healthcare professionals only.
For use in hospital environments.
For use with Ambu® displaying units.

aScope 5 Broncho 2.7/1.2
aScope 5 Broncho 4.2/2.2

Ambu



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Content Page

1. Important information – Read before use

Read these *instructions for use* carefully before using the aScope 5 Broncho. 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 operation of the endoscope. Before initial use of the endoscope, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, indications, warnings, cautions, and contraindications mentioned in these instructions. There is no warranty on the endoscope.
In this document *endoscope* refers to instructions which apply to the endoscope only and *system* refers to information relevant for the aScope 5 Broncho and the compatible Ambu displaying unit and accessories. Unless otherwise specified, endoscope refers to all aScope 5 Broncho variants.

In this document the term aScope 5 Broncho refers to the Ambu® aScope™ 5 Broncho.

1.1. Intended use/Indications for use

aScope 5 Broncho is intended for endoscopic procedures and examination within the airways and tracheobronchial tree.
aScope 5 Broncho is intended to provide visualization via a compatible Ambu displaying unit, and to allow passing of endotherapy instruments via its working channel.

Intended patient population
Adult.

Intended use enviroment
For use in hospital enviroments.

1.2. Contraindications

None known.

1.3. Clinical benefits

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

1.4. Warnings and cautions

WARNINGS ⚠

1. Only to be used by healthcare professionals trained in clinical endoscopic techniques and procedures. Failure to comply with this may result in patient injury.
2. The endoscope is a single-use device 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. In order to avoid contamination, do not use the endoscope if the product sterilisation barrier or its packaging is damaged.
4. Do not attempt to clean and reuse the endoscope as it is a single-use device. Reuse of the product can cause contamination, leading to infections.
5. Do not use the endoscope or an endotherapy instrument if it is damaged in any way or if any part of the functional check fails (see section 4.1.) as failure to comply may result in patient injury.
6. In order to promptly detect events of desaturation, patients should be monitored at all times during use.
7. If any malfunction occurs during the endoscopic procedure, stop the procedure immediately to avoid patient injury and withdraw the endoscope.

8. The device should not be used if adequate supplemental oxygenation cannot be provided to the patient during the procedure. Failure to comply may result in patient desaturation.
9. Always make sure that any tube connected to the suction connector on the scope is connected to a suction device. Secure the tubing properly on the suction connector before suction is applied. Failure to do so may result in patient or user injury.
10. Apply a maximum vacuum of 85 kPa (638 mmHg) when suctioning. Applying too large a vacuum may make it difficult to interrupt suctioning and may cause patient injury.
11. Always check compatibility of the scope with both airway management accessories and endotherapy instruments. Failure to do so may result in patient injury.
12. For non-intubated patients a mouthpiece should be used when inserting the endoscope orally to prevent the patient from biting the insertion cord and potentially damaging her/his teeth.
13. The shape and size of the nasal cavity and its suitability for transnasal insertion may vary from patient to patient. Individual differences in the shapes and sizes of the patients' nasal lumens, as well as their receptivity to transnasal insertion, must be considered prior to the procedure. Never use force during insertion or withdrawal of the endoscope transnasally because patient injury may occur.
14. Verify that the orientation of the image is as expected and be careful to check whether the image on the screen is a live image or a recorded image. Failure to do so will increase the difficulty of navigation and may result in damage to mucosa or tissue.
15. Always watch the live endoscopic image on the Ambu displaying unit or external monitor when advancing or withdrawing the endoscope, operating the bending section or during suctioning. Failure to do so may result in damage to mucosa or tissue.
16. Ensure the biopsy valve and its cap are properly attached prior to suction. During manual suction, ensure that the syringe tip is fully inserted into the working channel port/biopsy valve prior to suction. Failure to do so may expose unprotected users to the risk of infection.
17. The endoscope images must not be used as an independent means of diagnosis for any clinical finding. Healthcare professionals must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics. Failure to do so may result in delayed, incomplete, or inadequate diagnosis.
18. Always make sure that the bending section is in a straight position when inserting or withdrawing an endotherapy instrument into or out of the working channel. 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.
19. Do not damage the insertion portion during use. This may expose sharp surfaces that may cause damage to the mucosa or this may result in parts of the product being left inside the patient. Particular care should be taken to avoid damaging the insertion portion when using the endoscope with endotherapy instruments.
20. Bronchoscopists and assistants shall be familiar with the adequate personal protective equipment for bronchoscopy procedures in order to avoid contamination of staff.
21. Do not activate an endotherapy instrument in the endoscope before the instrument's distal end can be seen in the image on the displaying unit, as this can lead to patient injury or damage the endoscope.
22. The distal end of the endoscope may get warm due to heating from the light emission part. Avoid long periods of contact between the distal tip and the mucosal membrane as this may cause injury to mucosa.
23. When inserting or withdrawing the endoscope, the distal tip must be in a non-deflected position. Do not operate the control lever, as this may result in injury to the patient and/or damage to the endoscope.
24. Always perform a visual check according to the instructions in this *Instructions for use* before placing the endoscope in a waste container to minimize the risk of post procedure complications.

25. The user must exercise professional judgement when deciding whether a bronchoscopy procedure will be appropriate for patients with severe heart disease (e.g. life-threatening arrythmia and recent myocardial infarction) or acute respiratory failure with hypercapnia. Uncorrected coagulopathy is relevant if transbronchial biopsy is planned. Serious complications have a higher rate in the mentioned categories of patients.
26. Use of endotherapy instruments including cryo probe may in rare cases cause gas embolism. Monitor the patient appropriately during and after treatment.
27. Patient leakage currents may be additive when using active endotherapy instruments. Active endotherapy instruments must be classified as "type CF" or "type BF" according to IEC 60601. Failure to comply may lead to too high patient leakage current and patient injury.
28. Endotherapy instruments shall always be operated according to the respective manufacturer's *Instructions for use*. Users shall always be familiar with safety precautions and guidelines on the proper use of endotherapy instruments, including use of adequate personal protective equipment. Failure to do so may result in patient or user injury.
29. Always operate endoscope and displaying unit according to the *Instructions for use* for each product. Failure to do so may result in patient or user injury.
30. Do not use laser or high frequency endotherapy instruments (such as APC probe, hot snare, hot forceps, etc) with aScope 5 Broncho 2.7/1.2 and 4.2/2.2 as it is not compatible. Failure to comply may result in patient injury.

CAUTIONS

1. Have a suitable backup system readily available for immediate use so the procedure can be continued if a malfunction should occur.
2. Be careful not to damage the endoscope in combination with sharp endotherapy instruments such as needles.
3. Be careful when handling the distal tip and do not allow it to strike other objects, as this may result in damage to the endoscope. The lens surface of the distal tip is fragile and visual distortion may occur.
4. Do not exert excessive force on the bending section as this may result in damage to the endoscope. Examples of inappropriate handling of the bending section include:
   – Manual twisting.
   – Operating it inside an ET tube or in any other case where resistance is felt.
   – Inserting it into a preshaped tube or a tracheostomy tube with the bending direction not aligned with the curve of the tube.
5. Keep the endoscope handle dry during preparation and use, as liquids entering the endoscope handle may cause camera malfunction.
6. Do not use a knife or other sharp instrument to open the pouch or cardboard box, as this may lead to sharp edges on product or product malfunction.
7. Do not remove the suction button for any reason as this may result in damage to the endoscope and loss of suction.
8. Only use the endoscope with medical electrical equipment that complies with IEC 60601-1, any associated applicable collateral and particular standards, or equivalent safety standards. Failure to do so may lead to equipment damage.
9. US federal law restricts this device to sale by or on the order of a licensed health care practitioner.

1.5. Potential adverse events

Potential adverse events in relation to flexible bronchoscopy (not exhaustive): tachycardia, bradycardia, hypotension, bleeding, bronchospasm/laryngospasm, cough, dyspnoea, sore throat, apnoea, seizure, desaturation/hypoxemia, epistaxis, haemoptysis, pneumothorax,

aspiration pneumonia, pulmonary oedema, airway obstruction, fever/infection, and respiratory/cardiac arrest.

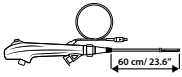
1.6. General notes

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 aScope 5 Broncho must be connected to an Ambu displaying unit. For information about Ambu displaying units, please refer to the respective displaying units' *Instructions for use*.

2.1. System parts

Ambu® aScope™ 5 Broncho – Single-use device:	**Part numbers**
	624001000US aScope 5 Broncho 2.7/1.2 620001000US aScope 5 Broncho 4.2/2.2

Product name	**Outer diameter [mm] "**	**Inner diameter [mm] "**
aScope 5 Broncho 2.7/1.2	2.7 mm/0.11" max 3.2 mm/0.13"	1.2 mm/0.05"
aScope 5 Broncho 4.2/2.2	4.2 mm/0.17" max 4.8 mm/0.19"	2.2 mm/0.09"

2.2. Product compatibility

The aScope 5 Broncho has been designed to be used in conjunction with:

Displaying units

– Ambu® aBox™ 2
– Ambu® aView™ 2 Advance

Note: Connector port colour and geometry on the displaying unit must match the connector colour and geometry on the visualization device.

Endoscopic accessories

– Passive endotherapy instruments compatible with the working channel ID (such as biopsy forceps, cytology brushes, endoscopic needles)
– Active endotherapy instruments compatible with the working channel ID (such as cryo probe)*
– Accessories with standard Luer slip and/or Luer Lock (using the enclosed introducer)

* aScope 5 Broncho 2.7/1.2 and 4.2/2.2 are not compatible with high frequency endotherapy instruments and laser.

Lubricants and solutions

– Sterile water
– Isotonic saline solution
– Waterbased lubricants
– Norepinephrine 0.5 mg
– Local anaesthetic gel and solutions e.g:
- 1 % lidocaine solution
- 2 % lidocaine gel
- Lidocaine 10 % aerosol spray

Airway management accessories in compliance with EN ISO 5361

– Endotracheal tubes
– Laryngeal masks
– Tracheostomy tubes

– Laryngectomy tubes
– Double-swivel catheter mounts

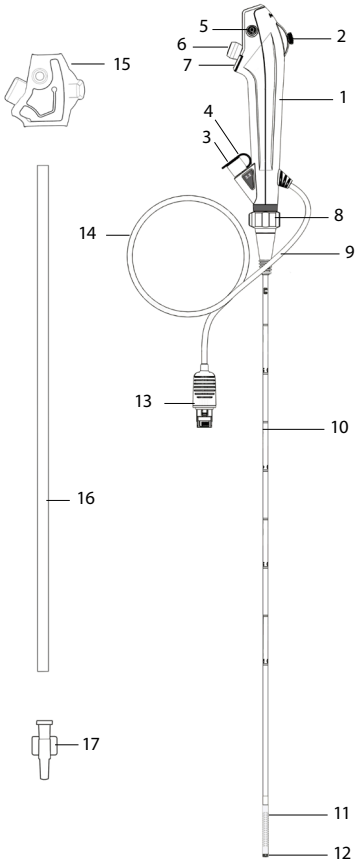
The aScope 5 Broncho has been evaluated to be compatible with the following endotracheal tubes (ETT) and endotherapy instruments (EI) sizes:

	Minimum ETT inner diameter	**EI compatible with a working channel of**
aScope 5 Broncho 2.7/1.2	3.5 mm	1.2 mm
aScope 5 Broncho 4.2/2.2	5.0 mm	2.2 mm

There is no guarantee that instruments selected solely using this working channel size will be compatible in combination. Compatibility of selected instruments should be tested before the procedure.

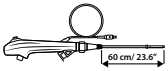
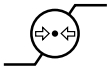
Suctioning equipment
– Suction tube of inner diameters between 5.5 mm and 9.0 mm.

2.3. aScope 5 Broncho parts



No.	Part	Function
1	Handle	Designed for left and right hand.
2	Control lever	Moves the distal tip up or down in a single plane.
3	Working channel port	Allows for instillation of fluids and insertion of endotherapy instruments.
	Working channel	Can be used for instillation/aspiration of fluids and insertion of endotherapy instruments.
4	Biopsy Valve	Attached to the working channel port. Endotherapy instruments can be inserted or a syringe can be attached.
5	Suction connector	Allows for connection of suction tubing.
6	Suction button	Suction when pressed.
7	Endoscope buttons 1 & 2	Depending on settings in Ambu displaying unit the two remote switches allow for direct activation on handle of four different functionalities such as image and video capturing, ARC, zoom.
8	Rotation control ring	Allows for rotation of the insertion cord during procedure.
9	Tube connection	Allows for fixation of tubes with standard connector during procedure.
10	Insertion cord	Flexible airway insertion cord.
	Insertion portion	Same as insertion cord.
11	Bending section	Manoeuvrable part.
12	Distal tip	Contains the camera, light source (two LEDs), as well as the working channel exit.
13	Displaying unit connector	Connects to the connector port on the Ambu displaying unit.
14	Cable	Transmits the image signal to the Ambu displaying unit.
15	Protective handle cover	Protects the control lever during transport and storage. Remove before use.
16	Protective pipe	Protects the insertion cord during transport and storage. Remove before use.
17	Introducer	To facilitate introduction of Luer Lock syringes.

3. Explanation of symbols used

Symbols for the aScope 5 Broncho devices	Description	Symbols for the aScope 5 Broncho devices	Description
	Working length of the insertion cord.		Temperature limit.
 Max OD	Maximum insertion portion width (Maximum outer diameter).		Warning.
 Min ID	Minimum working channel width (Minimum inner diameter).		IFU symbol.
	Field of view.		Global Trade Item Number.
	Humidity limitation.		Packaging level ensuring sterility.
	Atmospheric pressure limitation.		Do not use if the product sterilisation barrier or its packaging is damaged.
	Electrical Safety Type BF Applied Part.		UL Recognized Component Mark fof Canada and the United Staté.

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

4. Use of aScope 5 Broncho

Numbers in gray circles below refer to illustrations on page 2.

4.1. Preparation and inspection of aScope 5 Broncho

Lubricate the insertion cord with a water-based medical grade lubricant, to ensure the lowest possible friction when the endoscope is inserted into the patient.

Visual inspection of the endoscope 1

1. Check that the pouch seal is intact. 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
4. Turn on the Ambu displaying unit. 2a 2b

Refer to the Ambu displaying unit *Instructions for use* for preparation and inspection of the Ambu displaying unit. 2a 2b

Inspection of the image

1. Plug in the displaying unit connector into the corresponding connector on the compatible displaying unit. Please ensure the colours are identical and be careful to align the arrows. **3a** **3b**
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 displaying unit if necessary (please refer to the Ambu displaying unit *Instructions for use*).
4. If the object cannot be seen clearly, wipe the lens at the distal tip with a sterile cloth.

Preparation of aScope 5 Broncho

1. Carefully slide the control lever upwards and downwards 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. **5a**
2. Carefully turn the rotation control ring left and right to rotate the insertion cord as much as possible. Then turn the rotation control ring back to its neutral position. Confirm that the rotation control ring functions smoothly and correctly. **5b**
3. Press the endoscope buttons one after the other. Short press <1 second and long press >1 second. For default setting please see displaying unit *Instructions for use*. **5c**
4. Instill 2 ml of sterile water and 2 ml of air into the working channel using a syringe (if applying a Luer Lock syringe, use the enclosed introducer). Press the plunger to ensure that there are no leaks, and that water is emitted from the distal tip. **5d**
5. If applicable, prepare the suction equipment according to the manufacturer's Instructions for use. Connect the suctioning tube to the suction connector and press the suction button to check that suction is applied. **5e**
6. If applicable, verify that endotherapy instruments of appropriate size can be passed through the working channel without resistance. The enclosed introducer can be used for connection of Luer Lock syringes or to ease insertion of very soft instruments such as soft catheters and protected specimen brushes if necessary. **5f**
7. If applicable, verify that the accessories or endotherapy instruments are compatible with the endoscope before starting the procedure.
8. To guard against potentially infectious materials during the procedure, consider wearing personal protective equipment.

4.2. Operating the aScope 5 Broncho

Holding the aScope 5 Broncho and manipulating the tip

The handle of the endoscope can be held with either hand.
Use the thumb to move the control lever up and down and the index finger to operate the suction button. The control lever is used to flex and extend the distal tip of the endoscope in the vertical plane **5a** . Moving the control lever downward will make the 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 bending angle at the distal tip. After bending, the control lever should be moved back to neutral position. This will increase/ease maneuverability.

Rotation of the insertion cord **5b**

The rotation control ring enables the user to rotate insertion cord in relation to the handle, and vice-versa. This can be done either by holding the rotation control ring in place and then rotating the handle, or by holding the handle in place and then rotating the rotation control ring. In either case, make sure to check the rotation indicators on the rotation control ring and on the red ring above. The rotation is at neutral position (i.e. turned 0°) when the indicators are aligned, this will allow a maximal rotation of 120° to either side. There is a tactile click indicating when the rotation control ring is returned to the neutral position. Always view the live endoscopic image when operating the rotation control ring to avoid patient injury.

Endoscope buttons 5c 6a
The two endoscope buttons can activate up to four functions.
The endoscope buttons can be programmed via the Ambu displaying unit (see *Instructions for use* of the Ambu Displaying Unit) and current settings can be found in the user interface of the Ambu displaying unit.

During use of active endotherapy instruments the endoscope buttons cannot be activated on the handle but functions are still available using the Ambu displaying unit.

Biopsy valve 6b
The biopsy valve is attached to the working channel port allowing for insertion of endotherapy instruments or attachment of syringes.
The cap of the biopsy valve can be detached to ease insertion of an endotherapy instrument or accessory into the instrument channel port.
If not using an endotherapy instrument or accessory, always attach the cap to the biopsy valve to avoid leakage and spraying of fluids from the open biopsy valve or reduction of suction capability.

Tube connection 6c
The tube connection can be used to mount ETT with an ISO connector during intubation.

Insertion of the endoscope 7a
Lubricate the insertion cord with a water-based medical grade lubricant when the endoscope is inserted into the patient. If the endoscopic image becomes unclear, the distal tip can be cleaned by gently rubbing the distal tip against the mucosal wall or remove the endoscope and clean the tip. When inserting the endoscope orally, it is recommended to use a mouthpiece to protect the patient and the endoscope from being damaged.

Instillation of fluids 7b
Fluids can be instilled through the working channel by attaching a syringe to the biopsy valve. When using a Luer Lock syringe, use the included introducer. Insert the syringe tip or the introducer completely into the biopsy valve (with or without the valve's cap attached) and press the plunger to instill fluid. Make sure you do not apply suction during this process, as this will direct the instilled 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 endotherapy instruments or accessories 7d
Always make sure to select the correct size endotherapy instrument for the endoscope (see section 2.2). Maximum compatible instrument size is indicated at the working channel port. Inspect the endotherapy instrument before using it. If there is any irregularity in its operation or external appearance, replace it. Insert the instrument into the biopsy valve and advance it carefully through the working channel until it can be seen on the endoscopic image.

For insertion, hold the endotherapy instrument close to the opening of the biopsy valve and insert it straight into the opening using gentle short strokes to avoid the endotherapy instrument to bend or break. The enclosed introducer can be used to ease insertion of very soft instruments such as soft catheters and protected specimen brushes if necessary. Use of excessive force during insertion may damage the endotherapy instrument. When the bending section of the endoscope angulates significantly and insertion of the endotherapy instrument becomes difficult, straighten the bending section as much as possible.

Do not open the tip of the endotherapy instrument or extend the tip of the endotherapy instrument from its sheath while the instrument is in the working channel, as this may damage both the endotherapy instrument and the endoscope.

Insertion of active endotherapy instruments 7d

Use of active endotherapy instruments should always be operated according to the respective manufacturer's instructions for use. Users shall always be familiar with safety precautions and guidelines on the proper use of active endotherapy instruments, including use of adequate personal protective equipment.

Do not activate an endotherapy instrument in the working channel before the instrument distal end can be seen in the image.

It should be recognized that the use of active endotherapy instruments may interfere with the normal endoscopic image and this interference is not indicative of a malfunction of the endoscopic system. A variety of factors can affect the quality of the endoscopic image during use of active endotherapy instruments. Factors such as intensity, high power setting, close distance of the instrument probe to the endoscope tip and excessive tissue burning can each adversely influence image quality.

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 endoscopic image.

4.3. After use

Visual check 9

1. Are there any missing parts on the bending section, lens, or insertion cord? If yes, then take corrective action to locate the missing part(s).
2. Is there any evidence of damage on the bending section, lens, or insertion cord? If yes, then examine the integrity of the product and conclude if there are any missing parts.
3. Are there cuts, holes, sagging, swelling or other irregularities on the bending section, lens, or insertion cord? If yes, then examine the product to conclude if there are any missing parts.

In case of corrective actions needed (step 1 to 3) act according to local hospital procedures.

Disconnect

Disconnect the endoscope from the displaying unit 10. The aScope 5 Broncho is a single-use device. Do not soak rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. The design and materials used are not compatible with conventional cleaning and sterilization procedures.

Disposal 11

The used aScope 5 Broncho 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 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.
– IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and tests.

– ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
– ISO 8600-1 Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements.

5.2. aScope 5 Broncho specifications

Insertion cord	**aScope 5 Broncho 2.7/1.2**	**aScope 5 Broncho 4.2/2.2**
Bending section[1] [°]	210 ↑, 210 ↓	210 ↑, 210 ↓
Insertion cord diameter [mm, (")]	2.7 (0.11)	4.2 (0.17)
Maximum diameter of insertion portion [mm, (")]	3.2 (0.13)	4.8 (0.19)
Distal tip diameter [mm, (")]	3.0 (0.12)	4.4 (0.17)
Minimum endotracheal tube size (ID) [mm]	3.5	5.0
Working length [mm, (")]	600 (23.6) ± 10 (0.39)	600 (23.6) ± 10 (0.39)
Rotary function [°]	120	120
Depth marks [cm]	5	5
Working channel	**aScope 5 Broncho 2.7/1.2**	**aScope 5 Broncho 4.2/2.2**
Instrument channel width[2] [mm, (")]	1.2 (0.05)	2.2 (0.09)
Minimum instrument channel width[2] [mm, (")]	1.2 (0.05)	2.2 (0.09)
Storage	**aScope 5 Broncho 2.7/1.2 and 4.2/2.2**	
Recommended storage temperature[3] [°C, (°F)]	10 – 25 (50 – 77)	
Relative humidity [%]	10 – 85	
Atmospheric pressure [kPa]	50 – 106	
Optical system	**aScope 5 Broncho 2.7/1.2 and 4.2/2.2**	
Field of view [°]	120 (± 15 %)	
Direction of view [°]	0 (forward viewing)	
Depth of field [mm]	3 – 100	
Illumination method	LED	
Suction connector		
Connecting tube ID [mm]	Ø 5.5 – 9.0	

Sterilisation	**aScope 5 Broncho 2.7/1.2 and 4.2/2.2**
Method of sterilisation	ETO
Operating environment	**aScope 5 Broncho 2.7/1.2 and 4.2/2.2**
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa]	80 – 106
Altitude [m]	≤ 2000
Biocompatibility	**aScope 5 Broncho is biocompatible**

[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 endotherapy instruments selected solely using this minimum instrument channel width will be compatible in combination.
[3] Storage under higher temperatures may impact shelf life.

6. Troubleshooting

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 shown is frozen.	The endoscope is not connected to the displaying unit.	Connect the endoscope to the green port on the displaying unit.
	The displaying unit and the endoscope have communication problems.	1. Reconnect aScope 5 Broncho by unplugging and reconnecting the endoscope. 2. Turn off the displaying unit and turn it on again (Power off/Power on). Still no image: 3. Refer to the *Instructions for use* of the displaying unit for a detailed troubleshooting guide or alternatively take a new endoscope.
	The endoscope is damaged.	Replace the endoscope with a new one.
	A recorded image is shown in the yellow file management tab.	Return to live image by pressing the blue live image tab or restart the displaying unit by pressing the power button for at least 2 seconds. When the displaying unit is off, restart by pressing power button once more.

Problem	Possible cause	Recommended action
Low picture quality.	Blood, saliva etc. on the lens (distal tip).	Gently rub the distal tip against the mucosa. If the lens cannot be cleaned this way remove the endoscope and wipe the lens with sterile gauze.
Absent or reduced suction capability or difficulty in inserting endotherapy instrument through the working channel.	Working channel blocked.	Clean the working channel using a cleaning brush or flush the working channel with sterile saline using a syringe. Do not operate the suction button when instilling fluids.
	Suction is not active.	Ensure the suction tube is properly connected to the endoscope and to the suction system. Ensure suction system is turned on.
	Endotherapy instrument/introducer/ syringe inserted in working channel port/ biopsy valve (applicable if suction is absent or reduced).	Remove endotherapy instrument or introducer/syringe from the working channel port/biopsy valve. Check that the instrument used is compatible with the working channel's ID.
	Cap detached from biopsy valve.	Ensure that the cap is attached to the biopsy valve to avoid reduction of suction capability.
Biopsy valve.	Difficulty inserting an endotherapy instrument through the working channel.	Ensure compatibility of endotherapy instrument to working channel size. When the cap of the biopsy valve is detached, it may be easier to insert an endotherapy instrument into the instrument channel port.
Endoscope buttons.	The setting of the endoscope buttons differs from preferred setting.	Set the endoscope button function as preferred using the *Instructions for use* for the displaying unit.
Suction button.	Suction button detached from endoscope.	Remount suction button and test the suction function according to preparation step **5e**. If that does not work, then use new endoscope.

Ambu

Ambu A/S
Baltorpbakken 13
2750 Ballerup
Denmark
T +45 72 25 20 00
ambu.com

492 6300 31 – V03 – 2023/02. TCC 11445