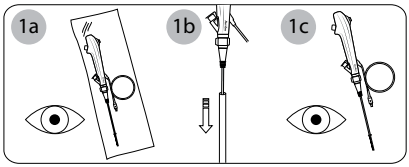
INSTRUCTIONS FOR USE

Ambu® aScope™ 5 Broncho HD

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

aScope 5 Broncho HD 5.0/2.2
aScope 5 Broncho HD 5.6/2.8

Ambu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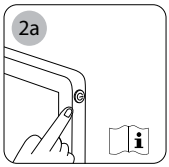
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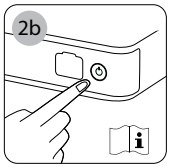
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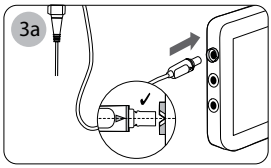
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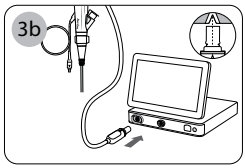
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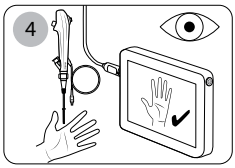
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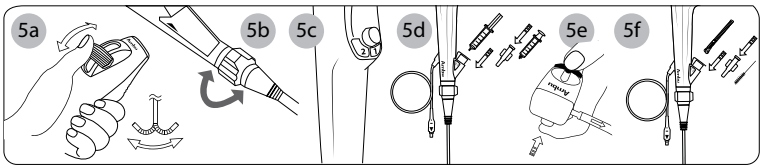
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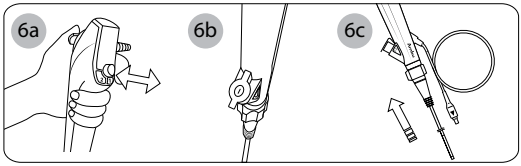
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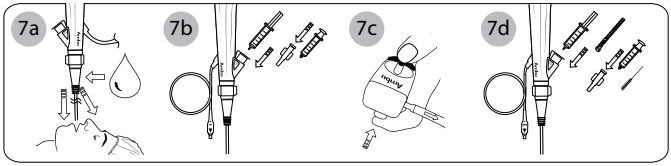
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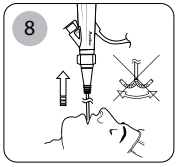
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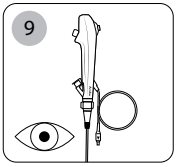
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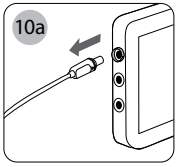
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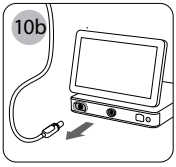
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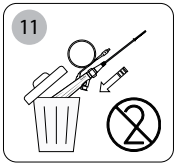
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Content Page

1. Important information – Read before use

Read these Instructions for Use carefully before using the aScope 5 Broncho HD. The *Instructions for Use* may be updated without further notice. Copies of the current version are available upon request. Note that these instructions do not explain or discuss clinical procedures. They only describe the basic operation and precautions related to 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 indicated in these instructions.
There is no warranty on the endoscope.
In this document, *endoscope* refers to instructions that apply to the endoscope only and *system* refers to information relevant for the aScope 5 Broncho HD and the compatible Ambu display unit and accessories. Unless otherwise specified, endoscope refers to all aScope 5 Broncho HD variants.

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

1.1. Intended use/Indications for use

aScope 5 Broncho HD is intended for endoscopic procedures and examination within the airways and tracheobronchial tree.
aScope 5 Broncho HD 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
Adults.

Intended use environment
For use in hospital environments.

1.2. Contraindications

None known.

1.3. Clinical benefits

Single-use application minimizes 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 could 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. To avoid contamination, do not use the endoscope if the product sterilization 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 could cause contamination, leading to infection.
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.). Failure to comply with this could 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 and withdraw the endoscope to avoid patient injury.
8. The device should not be used if adequate supplemental oxygenation cannot be provided to the patient during the procedure. Failure to comply could 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 applying suction. Failure to do so could 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 could cause patient injury.
11. Always check compatibility of the scope with both airway management accessories and endotherapy instruments. Failure to do so could 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 their 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, as this could result in patient injury.
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 could result in damage to mucosa or tissue.
15. Always watch the live endoscopic image on the Ambu display unit or external monitor when advancing or withdrawing the endoscope, operating the bending section or during suctioning. Failure to do so could result in damage to mucosa or tissue.
16. Make sure that the biopsy valve and its cap are properly attached prior to suction. During manual suction, make sure that the syringe tip is fully inserted into the working channel port/biopsy valve before applying 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 based on the patient's clinical characteristics. Failure to do so could 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 could result in injury to the patient and/or damage to the endoscope.
19. Do not damage the insertion portion during use. This could expose sharp surfaces that may cause damage to the mucosa or this could 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 must 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 (especially laser or electrosurgical equipment) in the endoscope before the instrument's distal end can be seen in the image on the display unit, as this could lead to patient injury or damage the endoscope.
22. The endoscope and active endotherapy instruments, e.g. HF and laser instruments, are not to be used when highly flammable gases, e.g. anesthetic aerosols, are present in the patient's airways. This could potentially cause patient injury.
23. The distal end of the endoscope may get warm due to heating from the light emissiontpart. Avoid long periods of contact between the distal tip and the mucosal membrane, as this could cause injury to mucosa.
24. When inserting or withdrawing the endoscope, the distal tip must be in a non-deflected position. Do not operate the control lever, as this could result in injury to the patient and/or damage to the endoscope.
25. Always perform a visual check as specified in these *Instructions for Use* before placing the endoscope in a waste container to minimize the risk of post-procedure complications.

26. The user must exercise professional judgment when deciding whether a bronchoscopy procedure will be appropriate for patients with severe heart disease (e.g. life-threatening arrhythmia and recent myocardial infarction) or acute respiratory failure with hypercapnia. Uncorrected coagulopathy is relevant if transbronchial biopsy is planned. There is a higher rate of serious complications in the mentioned categories of patients.
27. Use of endotherapy instruments, including Argon Plasma Coagulation (APC) probe and nd-YAG laser, may, in rare cases, cause gas embolism. Monitor the patient appropriately during and after treatment.
28. 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 could lead to patient leakage current that is too high and patient injury.
29. Endotherapy instruments must always be operated according to the respective manufacturer's *Instructions for Use*. Users must always be familiar with safety precautions and guidelines on the proper use of endotherapy instruments, including use of adequate personal protective equipment, e.g. wearing suitable protective filtering glasses when using laser equipment together with the endoscope. Failure to do so could result in patient or user injury.
30. Always operate the endoscope and display unit as described in the *Instructions for Use* for each product. Failure to do so could result in patient or user injurty.

CAUTIONS

1. Have a suitable backup system readily available for immediate use so the procedure can be continued if a malfunction were to occur.
2. Be careful not to damage the endoscope when used 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 could 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 could 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, use and storage.
6. Do not use a knife or other sharp instrument to open the pouch or cardboard box.
7. Using electrosurgical equipment with aScope 5 Broncho HD may disturb the image on the display unit and/or external monitor.
8. Do not remove the suction button for any reason, as this could result in damage to the endoscope and loss of suction.
9. US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
10. 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 could result in equipment damage.

1.5. Potential adverse events

Potential adverse events in relation to flexible bronchoscopy (not exhaustive): Tachycardia, bradycardia, hypotension, bleeding, bronchospasm/laryngospasm, cough, dyspnea, sore throat, apnea, seizure, desaturation/hypoxemia, epistaxis, hemoptysis, pneumothorax, aspiration pneumonia, pulmonary edema, airway obstruction, fever/infection, and respiratory/cardiac arrest.

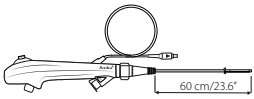
1.6. General notes

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

2. System description

The aScope 5 Broncho HD must be connected to an Ambu display unit. For information about Ambu display units, please refer to the *Instructions for Use* of the respective display unit.

2.1. System parts

Ambu® aScope™ 5 Broncho HD – Single-use device	**Part numbers**
	621001000US aScope 5 Broncho HD 5.0/2.2 622001000US aScope 5 Broncho HD 5.6/2.8

Product name	**Outer diameter [mm] "**	**Inner diameter [mm] "**
aScope 5 Broncho HD 5.0/2.2	5.0 mm/0.20" max 5.7 mm/0.22"	2.2 mm/0.09" min 2.05 mm/0.08"
aScope 5 Broncho HD 5.6/2.8	5.6 mm/0.22" max 6.3 mm/0.25"	2.8 mm/0.11" min 2.65 mm/0.10"

2.2. Product compatibility

The aScope 5 Broncho HD has been designed for use in conjunction with:

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

Note: The connector port color and geometry on the display unit must match the connector color and geometry on the visualization device.

Endoscopic accessories
– Endotherapy instruments compatible with the working channel ID (such as biopsy forceps, cytology brushes, endoscopic needles and electrosurgical probes).
– Accessories with standard Luer Slip and/or Luer Lock (using the enclosed introducer).
– High frequency electrosurgical equipment fulfilling EN 60601-2-2.

Lubricants and solutions
– Sterile water
– Isotonic saline solution
– Local anesthetic gel and solutions, e.g:
• 1 % lidocaine solution
• 2 % lidocaine gel
• Lidocaine 10 % aerosol spray
• Noradrenaline 0.5 mg
– Water based lubricants

Airway management accessories in compliance with EN ISO 5361
– Endotracheal tubes
– Laryngeal masks
– Tracheostomy tubes
– Laryngectomy tubes
– Double-swivel catheter mounts

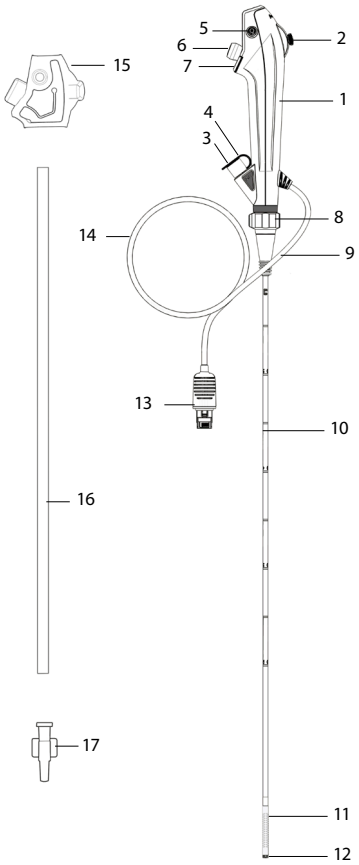
The aScope 5 Broncho HD has been assessed as compatible with the following endotracheal tube (ETT) and endotherapy instrument (EI) sizes:

	Minimum ETT inner diameter	EI compatible with a working channel of
aScope 5 Broncho HD 5.0/2.2 aScope 5 Broncho HD 5.6/2.8	6.0 mm 7.0 mm	2.2 mm 2.8 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 with inner diameter between 5.5 mm and 9.0 mm.

2.3. aScope 5 Broncho HD parts



No.	Part	Function
1	Handle	Designed for left or right hand.
2	Control lever	Moves the distal tip up or down in a single plane.

No.	Part	Function
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	Activates suction when pressed.
7	Endoscope buttons 1 & 2	Depending on settings in the display unit, the two remote switches enable direct activation of four different functions on the handle, such as image and video capturing, ARC and 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	Maneuverable part.
12	Distal tip	Contains the camera, light source (two LEDs), as well as the working channel exit.
13	Display unit connector	Connects to the connector port on the Ambu display unit.
14	Cable	Transmits the image signal to the Ambu display 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	Facilitates introduction of Luer Lock syringes.

3. Use of aScope 5 Broncho HD

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

3.1. Preparation and inspection of aScope 5 Broncho HD

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 that may harm the patient. **1c**
4. Turn on the Ambu display unit. **2a** **2b**

Refer to the Ambu display unit's *Instructions for Use* for preparation and inspection of the Ambu display unit. **2a** **2b**

Inspection of the image

1. Plug the display unit connector into the corresponding connector on the compatible display unit. Please ensure the colors 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 toward an object, e.g. the palm of your hand. **4**
3. Adjust the image preferences on the display unit if necessary (please refer to the display unit's *Instructions for Use*).
4. If the object cannot be seen clearly, wipe the lens at the distal tip with a sterile cloth.

The aScope 5 Broncho HD System consists of the aScope 5 Broncho HD and Ambu's Full-HD display unit. Compared to previous generations, the aScope 5 Broncho HD System provides a higher resolution, resulting in a clearer and improved image to the user.

Preparation of aScope 5 Broncho HD

1. Carefully slide the control lever upward and downward to bend the bending section as much as possible. Then slide the control lever slowly to its neutral position. Confirm that the bending section operates 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 operates smoothly and correctly. **5b**
3. Press the endoscope buttons one after the other. Short press < 1 second and long press > 1 second. For the default setting, please see the display unit's 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 as specified in 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.

3.2. Operating the aScope 5 Broncho HD

Holding the aScope 5 Broncho HD and manipulating the tip

The handle of the endoscope can be held with either hand.
Use your thumb to move the control lever up and down and your 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 to ensure an optimal bending angle at the distal tip. After bending, the control lever should be moved back to the neutral position. This will increase/ease maneuverability.

Rotation of the insertion cord **5b**

The rotation control ring enables the user to rotate the 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 in the neutral position (i.e. turned 0°) when the indicators are aligned. This will allow a maximal rotation of 120° to either side. A tactile click indicates when the rotation control ring has 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 display unit (see the Ambu display unit's *Instructions for Use*) and current settings can be found in the user interface of the display unit.

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

Biopsy valve 6b
The biopsy valve is attached to the working channel port to enable 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 inserting the endoscope into the patient. If the endoscopic image becomes unclear, clean the distal tip by gently rubbing it against the mucosal wall, or remove the endoscope and clean the tip. When inserting the endoscope orally, use of a mouthpiece is recommended to protect the patient from injury and the endoscope from damage.

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 doing 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 your index finger. Note that suction capability will be reduced if the introducer and/or an endoscopic accessory is positioned inside the working channel. For optimal suction capability, removing the introducer or syringe entirely during suctioning is recommended.

Insertion of endotherapy instruments or accessories 7d
Always make sure to select the correct size endotherapy instrument for the endoscope (see section 2.2). The 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 prevent the endotherapy instrument from bending or breaking. 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 could damage both the endotherapy instrument and the endoscope.

Insertion of active endotherapy instruments 7d
Active endotherapy instruments should always be operated as specified in the respective manufacturer's Instructions for Use. Users must 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 active endotherapy instrument (e.g. laser equipment or electrosurgical equipment) in the working channel until the instrument's distal end can be seen in the image.

Note that the use of active endotherapy instruments may interfere with the normal endoscopic image. This interference does not indicate that there is a malfunction in 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 affect 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.

3.3. After use

Visual check 9

1. Are there any missing parts on the bending section, lens, or insertion cord? If yes, 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, examine the integrity of the product and determine whether 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, examine the product to determine whether there are any missing parts.

If corrective actions are needed (step 1 to 3), follow local hospital procedures.

Disconnection
Disconnect the endoscope from the display unit 10. The aScope 5 Broncho HD is a single-use device. Do not soak, rinse, or sterilize this device, as such actions could leave harmful residues or cause the device to malfunction. The design and materials used are not compatible with conventional cleaning and sterilization procedures.

Disposal 11
The used aScope 5 Broncho HD is considered contaminated after use and must be disposed of in accordance with local guidelines for the collection of infected medical devices with electronic components.

4. Technical product specifications

4.1. Standards applied

The endoscope complies 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.

4.2. aScope 5 Broncho HD specifications

Insertion cord	**aScope 5 Broncho HD 5.0/2.2**	**aScope 5 Broncho HD 5.6/2.8**
Bending section[1] [°]	195 ↑, 195 ↓	195 ↑, 195 ↓
Insertion cord diameter [mm, (")]	5.0 (0.20) Ø 5.0 ± 0.2 (0.008)	5.6 (0.22) Ø 5.6 ± 0.2 (0.008)
Maximum diameter of insertion portion [mm, (")]	max. Ø 5.7 (0.22)	max. Ø 6.3 (0.25)
Distal tip diameter [mm, (")]	5.4 (0.21) Ø 5.4 ± 0.08 (0.003)	6.0 (0.24) Ø 6.0 ± 0.08 (0.003)
Minimum endotracheal tube size (ID) [mm]	6.0	7.0
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 HD 5.0/2.2**	**aScope 5 Broncho HD 5.6/2.8**
Instrument channel width[2] [mm, (")] Minimum instrument channel width[2] [mm, (")]	2.2 (0.09) min. Ø 2.05 (0.08)	2.8 (0.11) min. Ø 2.65 (0.10)
Storage	**aScope 5 Broncho HD 5.0/2.2 and HD 5.6/2.8**	
Recommended storage temperature[3] [°C, (°F)]	10 – 25 (50 – 77)	
Relative humidity [%]	10 – 85	
Atmospheric pressure [kPa]	50 – 106	
Optical system	**aScope 5 Broncho HD 5.0/2.2 and HD 5.6/2.8**	
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	
Sterilization	**aScope 5 Broncho HD 5.0/2.2 and HD 5.6/2.8**	
Method of sterilization	ETO	
Operating environment	**aScope 5 Broncho HD 5.0/2.2 and HD 5.6/2.8**	
Temperature [°C, (°F)]	10 – 40 (50 – 104)	
Relative humidity [%]	30 – 85	
Atmospheric pressure [kPa]	80 – 106	
Altitude [m]	≤ 2000	
Biocompatibility	**aScope 5 Broncho HD 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.

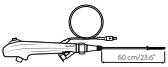
5. Troubleshooting

If problems occur with the system, please use this troubleshooting 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 display unit.	Connect an endoscope to the gray port on the display unit.
	There are communication problems between the display unit and the endoscope.	1. Reconnect aScope 5 Broncho HD by unplugging and reconnecting the endoscope. 2. Turn off the display unit and turn it on again (Power off/Power on). If there is still no image: 3. Refer to the display unit's Instructions for Use for a detailed troubleshooting guide, or use take a different 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 the live image by pressing the blue live image tab or restart the display unit by pressing the power button for at least 2 seconds. When the display unit is off, restart by pressing the power button again.
Low image 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 inserting the endotherapy instrument through the working channel.	Working channel is 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.	Make sure that the suction tube is properly connected to the endoscope and to the suction system. Make sure that the suction system is turned on.
	Endotherapy instrument/ introducer/syringe is inserted in the working channel port/biopsy valve (applicable if suction is absent or reduced).	Remove the 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 is detached from the biopsy valve.	Make sure that the cap is attached to the biopsy valve to avoid reduction of suction capability.

Problem	Possible cause	Recommended action
Biopsy valve.	Difficulty inserting an endotherapy instrument through the working channel.	Make sure that the endotherapy instrument and working channel size are compatible. When the cap of the biopsy valve is detached, it may be easier to insert any endotherapy instrument into the instrument channel port.
Endoscope buttons.	The setting of the endoscope buttons differs from the preferred setting.	Set the endoscope button function as preferred as described in the Ambu display unit's *Instructions for Use*.
Suction button.	The suction button is detached from the endoscope.	Remount the suction button and test the suction function as described in preparation step 5e. If that does not work, use a new endoscope.

6. Explanation of symbols used

Symbols for aScope 5 Broncho HD devices	Description	Symbols for aScope 5 Broncho HD 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).		Rated power output symbol.
	Field of view.		IFU symbol.
	Humidity limitation.	GTIN	Global Trade Item Number.
	Atmospheric pressure limitation.	MY	Country of manufacturer.
	Electrical Safety Type BF Applied Part.	MD	Medical Device.
	Do not use if the product sterilization barrier or its packaging is damaged.	c US	UL Recognized Component Mark for Canada and the United States.

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

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