INSTRUCTIONS FOR USE

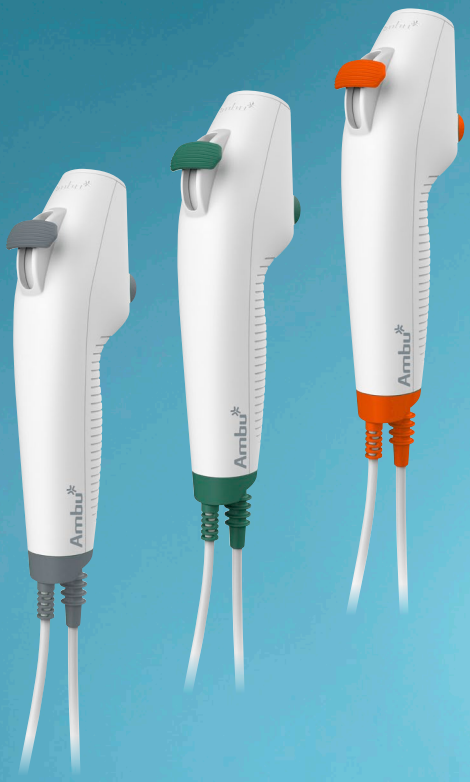
Ambu® aScope™ 4 Broncho Family

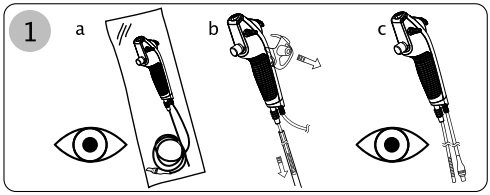
For use by trained clinicians/physicians only.
For in-hospital use.
For use with Ambu® displaying units.

Ambu® aScope™ 4 Broncho Slim
Ambu® aScope™ 4 Broncho Regular
Ambu® aScope™ 4 Broncho Large

Abridged version

Ambu

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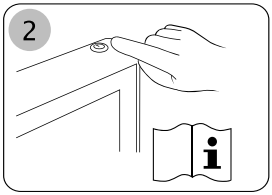
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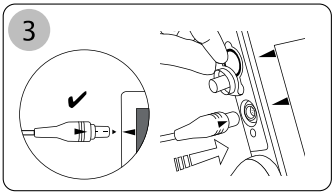
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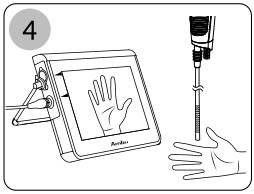
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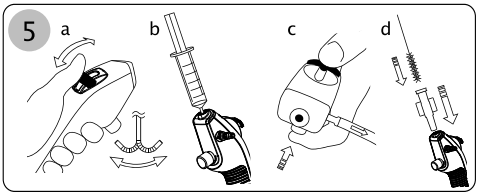
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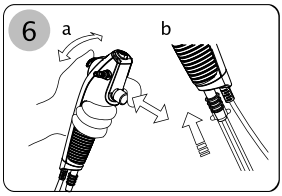
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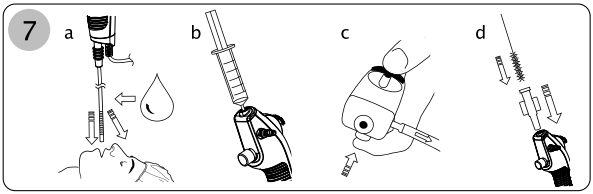
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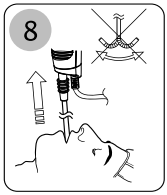
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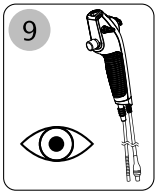
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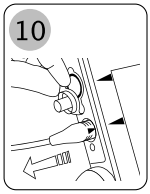
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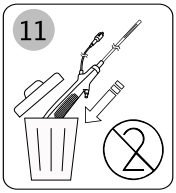
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1. Important information – Read before use

Read these safety instructions carefully before using the aScope 4 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, warnings, cautions and indications mentioned in these instructions.
There is no warranty on the endoscope.
In this document *endoscope* refers to instructions which applies to the endoscope only and *system* refers to information relevant for the aScope 4 Broncho and the compatible Ambu displaying unit and accessories. Unless specified otherwise, endoscope refers to all aScope 4 Broncho variants.

1.1. Intended use

The aScope 4 Broncho is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the airways and tracheobronchial tree.
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 indications

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. 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.
2. The endoscope 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.
3. 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 the endoscope.
4. The device should not be used if adequate supplemental oxygenation cannot be provided to the patient during the procedure.
5. The user must exercise professional judgement when deciding whether a bronchoscopy procedure will be appropriate for patients with the following conditions, since they have a higher rate of serious complications; malignant arrhythmia, unstable cardiac status, acute myocardial infraction within 4-6 weeks, refractory hypoxemia, bleeding diathesis or severe thrombocytopenia if biopsy is indicated.
6. Do not use the endoscope if it is damaged in any way or if any part of the functional check (see section 4.1) fails.
7. 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.
8. The endoscope is not to be used when delivering oxygen or highly flammable anaesthetic gases to the patient. This could potentially cause patient injury.
9. The endoscope is not to be used in a MRI environment.
10. Do not use the endoscope during defibrillation.
11. Only to be used by skilled physicians trained in clinical endoscopic techniques and procedures.
12. Do not use excessive force when advancing, operating or withdrawing the endoscope.
13. Patients should be adequately monitored at all times during use.
14. Always watch the live endoscopic image on the displaying unit when advancing or withdrawing the endoscope, operating the bending section or suctioning. Failure to do so may harm the patient.

15. Do not use the endoscope if the product sterilisation barrier or its packaging is damaged.
16. The distal tip 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 long, sustained contact with the mucosal membrane may cause mucosal injury.
17. Always make sure that any tube connected to the suction connector is connected to a suction device.
18. When withdrawing the endoscope, the distal tip must be in neutral and non-deflected position. Do not operate the control lever, as this may result in injury to the patient and/or damage to the endoscope.
19. Do not advance or withdraw the endoscope, or operate the bending section, while endoscopic accessories are protruding from the distal tip of the working channel, as this may result in injury to the patient.
20. Always make sure that the bending section is in a straight position when inserting or withdrawing an endoscopic accessory in 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.
21. Always perform a visual check according to the instructions in this *Instructions for use* before placing the endoscope in a waste container.
22. Electronic equipment and the endoscope system may affect the normal function of each other. If the system is used adjacent to or stacked with other equipment, observe and verify normal operation of both the system and the other electronic equipment prior to using it. It may be necessary to adopt procedures for mitigation, such as reorientation or relocation of the equipment or shielding of the room in which it is used.
23. The endoscope consists of parts supplied by Ambu. These parts must only be replaced by Ambu authorised parts. Failure to comply with this may result in patient injury.
24. Be careful to check whether the image on the screen is a live image or a recorded image and verify that the orientation of the image is as expected.
25. To avoid risk of electric shock, the system must only be connected to a supply mains with protective earth. To disconnect the system from mains remove the mains plug from the wall outlet.
26. Always check compatibility with endotracheal tubes and double lumen tubes.
27. If any malfunction should occur during the endoscopic procedure, stop the procedure immediately and withdraw the endoscope.
28. Insert the syringe completely into the working channel port before instilling fluid. Failure to do so may result in the fluid spilling from the working channel port.

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 insertion cord or distal tip when using sharp devices such as needles in combination with the endoscope.
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 equipment. 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 equipment. Examples of inappropriate handling of the bending section include:
   – Manual twisting.
   – Operating it inside an ETT 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. US federal law restricts these devices for sale only by, or on the order of, a physician.
6. Keep the endoscope handle dry during preparation, use and storage.
7. Do not use a knife or other sharp instrument to open the pouch or cardboard box.
8. Secure the tubing properly on the suction connector before suction is applied.
9. If needed remove secretion or blood from the airway before and during the procedure. The suction function of any appropriate suction device can be used for this purpose.
10. Apply a vacuum of 85 kPa (638 mmHg) or less when suctioning. Applying too large a vacuum may make it difficult to terminate suctioning.

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, reaction to drug or topical anaesthesia, fever/infection, and respiratory/cardiac arrest.

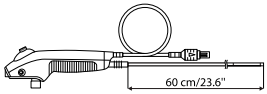
1.6. General notes

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 4 Broncho can be connected to the Ambu displaying unit. For information about the Ambu displaying unit, please refer to the displaying unit Instructions for use.

2.1. System parts

Ambu® aScope™ 4 Broncho – Single use device	**Part numbers**
	476001000 aScope 4 Broncho Slim 3.8/1.2 477001000 aScope 4 Broncho Regular 5.0/2.2 478001000 aScope 4 Broncho Large 5.8/2.8

aScope 4 Broncho Slim, aScope 4 Broncho Regular and aScope 4 Broncho Large are not available in all countries. Please contact your local sales office.

Product Name	**Colour**	**Outer diameter [mm]**	**Inner diameter [mm]**
aScope 4 Broncho Slim 3.8/1.2	Gray	min 3.8; max 4.3	min 1.2
aScope 4 Broncho Regular 5.0/2.2	Green	min 5.0; max 5.5	min 2.0
aScope 4 Broncho Large 5.8/2.8	Orange	min 5.8; max 6.3	min 2.6

2.2. Product compatibility

The aScope 4 Broncho Slim, Regular & Large have been designed to be used in conjunction with:

Displaying units
– Ambu aView
– Ambu aView 2 Advance

Endoscopic accessories
– Accessories with standard 6 % Introducer (Luer slip) and/or Luer Lock.

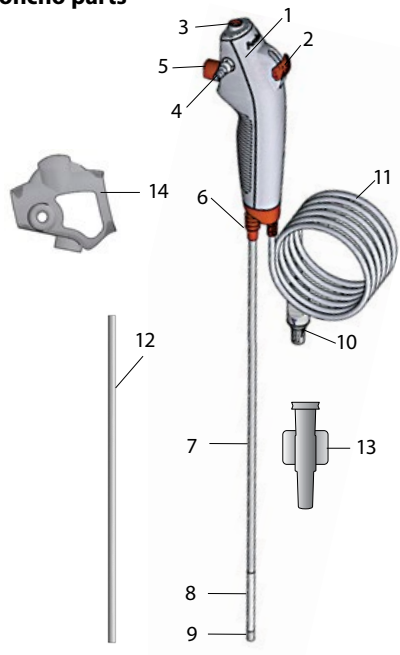
Endotracheal tubes (ETT) & Double lumen tubes (DLT)
– Tracheal tubes for use in anaesthetic and respiratory equipment in compliance with EN ISO 5361.

The aScope 4 family has been evaluated to be compatible wit the following endotracheal tubes (ETT), double lumen tubes (DLT) and Endoscopic accessories (EA) sizes.

	Minimum ETT Inner diameter	**Minimum DLT size**	**EA minimum working channel width**
aScope 4 Broncho Slim	5.0 mm	35 Fr	Up to 1.2 mm
aScope 4 Broncho Regular	6.0 mm	41 Fr	Up to 2.0 mm
aScope 4 Broncho Large	7.0 mm		Up to 2.6 mm

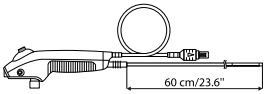
Suctioning equipment
– Suction tube of diameters between 6.5 mm & 9.5 mm.

2.3. aScope 4 Broncho 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	Working channel port	Allows for instillation of fluids and insertion of endoscopic accessories.
-	Working channel	Can be used for instillation of fluids, suction and insertion of endoscopic accessories.
4	Suction connector	Allows for connection of suction tubing.
5	Suction button	Activates suction when pressed down.
6	Tube connection	Allows for fixation of tubes with standard connector during procedure.
7	Insertion cord	Flexible airway insertion cord.
	Insertion portion	Same as insertion cord.
8	Bending section	Manoeuvrable part.
9	Distal tip	Contains the camera, light source (two LEDs), as well as the working channel exit.
10	Connector on endoscope cable	Connects to blue socket on displaying unit.
11	Endoscope cable	Transmits the image signal to the displaying unit.
12	Protection pipe	Protects the insertion cord during transport and storage. Remove before use.
13	Introducer	To facilitate introduction of Luer Lock syringes and soft endoscopic accessories through the working channel.
14	Handle protection	Protects the suction connector during transport and storage. Remove before use.

3. Explanation of symbols used

Symbols for the aScope 4 Broncho devices	Description
	Working length of the insertion cord.
Max OD	Maximum insertion portion width (Maximum outer diameter).
Min ID	Minimum working channel width (Minimum inner diameter).
	Field of view.
	Relative humidity limitation.
	Atmospheric pressure limitation.
	Temperature limitation.
	Electrical Safety Type BF Applied Part.
	Packaging level ensuring sterility.
	UL Recognized Component Mark for Canada and the United States.
	Medical Device.
	Global Trade Item Number.
	Country of manufacturer.
	INMETRO Certificate Medical Electrical Equipment
	Do not use if the product sterilisation barrier or its packaging is damaged.
	UK Conformity Assessed.
	UK Responsible Person.
	Importer (For products imported into Great Britain only).

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

4. Use of aScope 4 Broncho

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

4.1. Preparation and inspection of aScope 4 Broncho

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

Refer to the Ambu displaying unit *Instructions for use* for preparation and inspection of the Ambu displaying unit 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 displaying unit if necessary (please refer to the displaying unit *Instructions for use*).
4. If the object cannot be seen clearly, wipe the lens at the distal tip using a sterile cloth.

Preparation of aScope 4 Broncho

1. 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. 5a
2. Using a syringe insert 2 ml 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 tip. 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. 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 such as microbiology brushes. 5d
5. If applicable, verify that endotracheal tubes and double lumen tubes are compatible with endoscope before starting the procedure.

4.2. Operating the aScope 4 Broncho

Holding the aScope 4 Broncho and manipulating the tip 6a

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 mouth or nose.

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 distal 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 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.

Tube connection 6b

The tube connection can be used to mount ETT and DLT with an ISO connector during intubation.

Insertion of the aScope 4 Broncho 7a

Lubricate the insertion cord with a medical grade lubricant when the endoscope is inserted into the patient. If the camera image of the endoscope 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 endoscope from being damaged.

Instillation of fluids 7b
Fluids can be instilled through the working channel by inserting a syringe into the working channel port at the top of the endoscope. 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 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. It is recommended to remove introducer from the working channel port when it is not in use.

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 2.2). 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 displaying unit. The enclosed introducer can be used to facilitate the insertion of soft accessories such as microbiology brushes.

Withdrawal of the aScope 4 Broncho 8
When withdrawing the aScope 4 Broncho, make sure that the control lever is in the neutral position. Slowly withdraw the endoscope while watching the live image on the displaying unit.

4.3. 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. The elements of the insertion cord are radio opaque.

Disconnect
Disconnect the endoscope from the displaying unit **10**. The aScope 4 Broncho is a single use device. The aScope 4 Broncho is considered infected after use and must be disposed of in accordance with local guidelines for collection of infected medical devices with electronic components. Do not soak rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. The design and material used are not compatible with conventional cleaning and sterilization procedures.

Disposal
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. aScope 4 Broncho specifications

Insertion cord	**aScope 4 Broncho Slim**	**aScope 4 Broncho Regular**	**aScope 4 Broncho Large**
Bending section[1] [°]	180 ↑,180 ↓	180 ↑,180 ↓	180 ↑,160 ↓
Insertion cord diameter [mm, (")]	3.8 (0.15)	5.0 (0.20)	5.8 (0.23)
Distal tip diameter [mm, (")]	4.2 (0.16)	5.4 (0.21)	6.3 (0.25)
Maximum diameter of insertion portion [mm, (")]	4.3 (0.17)	5.5 (0.22)	6.3 (0.25)
Minimum endotracheal tube size (ID) [mm]	5.0	6.0	7.0
Minimum double lumen tube size (ID) [Fr]	35	41	-
Working length [mm, (")]	600 (23.6)	600 (23.6)	600 (23.6)
Working channel	**aScope 4 Broncho Slim**	**aScope 4 Broncho Regular**	**aScope 4 Broncho Large**
Minimum instrument channel width[2] [mm, (")]	1.2 (0.047)	2.0 (0.079)	2.6 (0.102)
Storage	**aScope 4 Broncho Slim/Regular/Large**		
Temperature[3] [°C, (°F)]	10 – 25 (50 – 77)		
Relative humidity [%]	10 – 85		
Atmospheric pressure [kPa]	50 – 106		
Transportation	**aScope 4 Broncho Slim/Regular/Large**		
Temperature[3] [°C, (°F)]	-10 – 55 (14 – 131)		
Relative humidity [%]	10 – 95		
Atmospheric pressure [kPa]	50 – 106		
Optical system	**aScope 4 Broncho Slim/Regular/Large**		
Field of view [°]	85		
Direction of view [°]	0 (forward pointing)		
Depth of field [mm]	6 – 50		
Illumination method	LED		

Suction connector	
Connecting tube ID [mm]	Ø 6.5 – 9.5
Sterilisation	**aScope 4 Broncho Slim/Regular/Large**
Method of sterilisation	ETO
Operating environment	**aScope 4 Broncho Slim/Regular/Large**
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. 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 left side of the screen but User Interface is present on the display or the image shown to the left is frozen.	The endoscope not connected to the displaying unit.	Connect an endoscope to the blue port on the displaying unit.
	The displaying unit and the endoscope have communication problems.	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.
	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.
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.

Problem	Possible cause	Recommended action
Absent or reduced suction capability or difficulty in inserting endoscopic accessory 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 pump is not turned on or not connected.	Turn the pump on and check the suction line connection.
	Suction button 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 port.	Use one of the enclosed introducers.

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