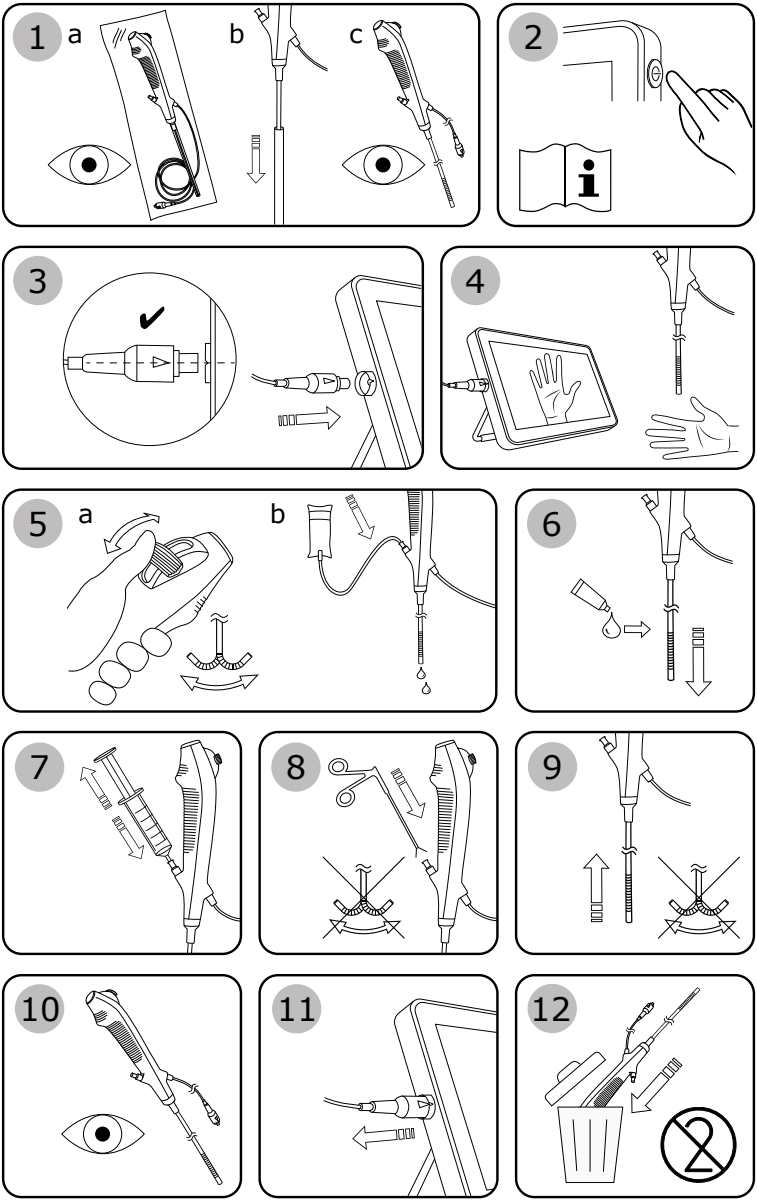
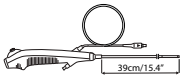
Ambu
Ideas that work for life

Instruction for Use

Ambu® aScope™ 4 Cysto

For use by trained clinicians/physicians only.
For use with Ambu® Displaying Units.





Pat. Pending

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1. Important Information – Read Before Use

Read these safety instructions carefully before using the aScope 4 Cysto. The Instruction 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 use of the aScope 4 Cysto. Before initial use of the aScope 4 Cysto, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings and cautions described in these instructions.

There is no warranty on the aScope 4 Cysto.

In this document "aScope 4 Cysto" refers to instructions which applies to the cystoscope only and "aScope 4 Cysto system" refers to information relevant for the aScope 4 Cysto, Ambu displaying units, and accessories.

1.1. Intended Use / Indication for Use

The aScope 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The aScope 4 Cysto is intended to provide visualisation via Ambu displaying units and can be used with endoscopic accessories.

The aScope 4 Cysto is intended for use in a hospital environment or medical office environment. The aScope 4 Cysto is designed for use in adults.

1.2. Contra-indications

- Febrile patients with urinary tract infections (UTIs) or severe coagulopathy
- Patients with acute infection (acute urethritis, acute prostatitis, acute epididymitis)
- Patients with known unpassable urethral stricture

1.3. Warnings and Cautions

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

WARNINGS ⚠

1. Do not soak, rinse, or sterilise the aScope 4 Cysto as these procedures may leave harmful residues or cause malfunction of the cystoscope. Reuse of the aScope 4 Cysto can cause contamination.
2. Do not use the aScope 4 Cysto if it is damaged in any way or if the inspection fails (see section 4.1.).
3. The distal end of the aScope 4 Cysto may get warm due to heating from the light emission part. Avoid long periods of contact between the distal end of the aScope 4 Cysto and the mucosal membrane as sustained contact with the mucosal membrane may cause mucosal injury.
4. The images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics.
5. Do not advance or withdraw the aScope 4 Cysto if endoscopic accessories are protruding from the distal end of the working channel as this may result in injury to the patient.
6. Do not activate energised endoscopic accessories before the distal end of the endoscopic accessory can be seen on the Ambu displaying unit and is protruding at a sufficient distance from the distal end of the aScope 4 Cysto as this may result in injury to the patient.
7. Be careful not to damage the insertion cord or distal end when using sharp or energised endoscopic accessories as this may result in injury to the patient.
8. Always watch the live cystoscopic image on the Ambu displaying unit when inserting or withdrawing the aScope 4 Cysto or operating the bending section. Failure to do so may result in injury to the patient.
9. Using energised electrosurgical equipment in conjunction with the aScope 4 Cysto may disturb the endoscopic image.
10. Use of the aScope 4 Cysto system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the aScope 4 Cysto system and the other equipment should be observed to verify that they are operating normally.
11. Do not perform laser surgical procedures or procedures with high frequency endoscopic accessories if flammable or explosive gases are present in the patients lower urinary tract as this may result in injury to the patient.
12. Patient leakage currents may be additive and too high, when using energised endoscopic accessories. Only energised endoscopic accessories classified as "type CF" or "type BF" applied part shall be used with the aScope 4 Cysto to minimise total patient leakage current.
13. Inflow of gas e.g. supplied by endoscopic accessories or due to over-insufflation of gas may cause gas embolism, leading to stroke or ischaemia in tissue.
14. Do not use the aScope 4 Cysto during defibrillation as this may result in injury to the user.
15. When using compatible laser devices, user shall be familiar with safety precautions, guidelines, and proper use of the laser devices, including, but not limited to, proper eye and skin protection.
16. Do not use unnecessary force when advancing, operating, or withdrawing the aScope 4 Cysto as this may result in patient injury.
17. Do not withdraw the aScope 4 Cysto fully deflected. Do not operate the bending lever and never use unnecessary force whilst withdrawing the cystoscope, as this may result in injury to the patient.

CAUTIONS

1. Have a suitable backup system readily available in case a malfunction should occur.
2. Be careful not to damage the aScope 4 Cysto when using endoscopic accessories in combination with the cystoscope.
3. US federal law restricts these devices for sale only by, or on the order of, a physician.

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.

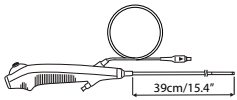
1.4. Adverse Events

Potential adverse events in relation to flexible cystoscopy (not exhaustive):
Intra-procedural pain or discomfort, haematuria, abdominal pain, dysuria - pain and discomfort on voiding, increased voiding frequency, urethral narrowing (strictures) due to scar tissue formation, and urinary tract infections (UTI).

2. System Description

The aScope 4 Cysto can be connected to the Ambu displaying units. For information about the Ambu displaying units, please refer to the Ambu displaying units Instruction for Use.

2.1. System Parts

Ambu® aScope™ 4 Cysto	**Item Number**
	601001000 aScope 4 Cysto (US deflection)

601001000 aScope 4 Cysto is not available in all countries.
Please contact your local sales office.

Product Name	**Colour**	**Outer Diameter [mm]**	**Inner Diameter [mm]**
601001000 aScope 4 Cysto	Green	max 6.0	min 2.2

Ambu® displaying unit	**Item Number**
	405011000 Ambu® aView™ 2 Advance

For Ambu displaying unit item number, please check the backside label on the Ambu displaying unit.

2.2. Product Compatibility

The aScope 4 Cysto have been designed to be used with:

Endoscopic Accessories

- Irrigation set (line and sterile water or saline bag) with Luer connection
- Syringe and other Luer connecting accessories
- Endoscopic accessories labelled for use in a minimum working channel size of (ID) 2.0 mm / 6.0 Fr or less*
- Holmium YAG laser (2.1 microns wavelength)
- High frequency surgical equipment fulfilling EN 60601-2-2. To keep high frequency leakage currents within allowed limits, the maximum sinus peak voltage level of the electrosurgical unit shall not exceed 2.2 kV_p

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

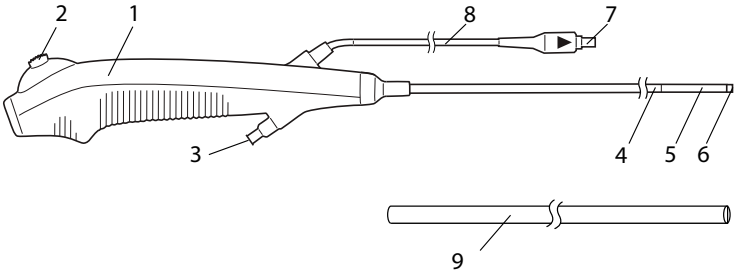
Chemicals and Substances

- Iodine based (30 g) contrast agent suitable for cystoscopy
- Water based soluble lubricants suitable for cystoscopy

Other Equipment

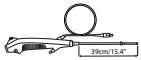
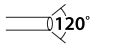
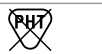
- X-ray

2.3. aScope 4 Cysto Parts



No.	Part	Function
1	Handle	Suitable for left and right hand
2	Bending lever	Moves the distal end up or down in a single plane
3	Working channel entry	Allows for instillation of fluids and insertion of endoscopic accessories
-	Working channel	Can be used for instillation of fluids and insertion of endoscopic accessories
4	Insertion cord	Flexible insertion cord
5	Bending section	Manoeuvrable part
6	Distal end	Contains the camera, light source (two LEDs), as well as the working channel exit
4-5-6	Insertion portion	The ensemble of insertion cord, bending section, and distal end
7	Connector on the aScope 4 Cysto cable	Connects to blue socket on Ambu displaying units
8	aScope 4 Cysto cable	Transmits the image signal to Ambu displaying units
9	Protection pipe	Protects the insertion cord during transport and storage. Remove before use.

3. Explanation of Symbols Used

Symbols	Indication
	Working length of the aScope 4 Cysto insertion cord
	Maximum insertion portion width (maximum outer diameter)
	Minimum working channel width (minimum inner diameter)
	Field of view
	Rated power input, d.c.
	The aScope 4 Cysto is not made with natural rubber latex
	Electrical Safety Type BF Applied Part
	Packaging level ensuring sterility
	The aScope 4 Cysto is not made with phthalates
	Global trade identification number
	Country of manufacturer

4. Use of the aScope 4 Cysto

The numbers in gray circles below refer to illustrations on page 2.

4.1. Inspection and Preparation of the aScope 4 Cysto

Visual inspection of the aScope 4 Cysto **1**

1. Check that the pouch seal is intact and discard the aScope 4 Cysto if the sterile seal has been damaged, as the cystoscope could be contaminated leading to infections **1a**.
2. Make sure to remove the protection pipe from the insertion cord **1b**.
3. Check that there are no impurities or damage on the aScope 4 Cysto such as rough surfaces, sharp edges or protrusions which may harm the patient **1c**. Do not use the aScope 4 Cysto if it is damaged in any way or if the inspection fails.

Refer to the Ambu displaying units Instruction for Use for preparing and turning on the Ambu displaying units **2**

Inspection of the Image

1. Connect the aScope 4 Cysto to the Ambu displaying unit by plugging the connector on the aScope 4 Cysto cable with blue arrow into the corresponding blue female connector on the Ambu displaying unit. Carefully align the arrows on the connector on the aScope 4 Cysto cable with the port on the Ambu displaying unit to prevent damage to the connectors **3**.
2. Verify that a live video image appears on the Ambu displaying unit by pointing the distal end of the aScope 4 Cysto towards an object, e.g. the palm of your hand **4**.
3. Adjust the image preferences on the Ambu displaying unit if necessary (please refer to the Ambu displaying unit Instruction for Use).
4. If the object cannot be seen clearly, wipe the distal end of the aScope 4 Cysto using a sterile cloth.

Preparation of the aScope 4 Cysto

1. Carefully slide the bending lever forwards and backwards to bend the bending section as much as possible. Then slide the bending lever slowly to its neutral position. Confirm that the bending section functions smoothly and correctly and returns to a neutral position **5a**.
2. Test fluid instillation by connecting an infusion set or syringe with sterile water or saline solution with Luer connection directly to the working channel entry or via a stopcock. Ensure that there are no leaks, and that water is emitted from the distal end **5b**.

4.2. Operating the aScope 4 Cysto

If any malfunction should occur during the cystoscopic procedure, stop the procedure immediately, put the distal end of the aScope 4 Cysto in its neutral and non-angled position and slowly withdraw the cystoscope.

Holding the aScope 4 Cysto and manipulating the distal end

The handle of the aScope 4 Cysto can be held in either hand. The hand that is not holding the cystoscope can be used to advance the insertion cord into the patient's lower urinary tract.

Use the thumb to move the bending lever. The bending lever is used to flex and extend the distal end of the cystoscope in the vertical plane. The distal end will bend in the following way for 601001000 aScope 4 Cysto:

- Moving the bending lever downward will make the distal end bend anteriorly (flexion). Moving it upward will make the distal end bend posteriorly (extension).
- The insertion cord should be held as straight as possible at all times in order to secure an optimal distal end bending angle.

Insertion of the aScope 4 Cysto 6

Lubricate the insertion cord with a soluble lubricant suitable for cystoscopy before the aScope 4 Cysto is inserted into urethra. If the camera image of the aScope 4 Cysto becomes unclear the distal end can be cleaned by gently rubbing the distal end against the mucosal wall or withdraw the cystoscope and clean the distal end.

Aspiration and instillation of fluids 7

Aspiration might be required during the procedure. Prepare a syringe for this. When required, attach the syringe to the aScope 4 Cysto and apply an aspiration force according to the wanted effect. For larger quantity of fluid, disconnect the syringe from the cystoscope, empty the syringe, and then reattach it to aspirate the remaining fluids.

Fluids e.g. sterile water or saline solution can be instilled through the working channel entry at the bottom of the aScope 4 Cysto handle by connecting a syringe or infusion set with Luer connection directly to the working channel entry or via a stopcock. If using a sterile water or saline bag, make sure to place it so that potential spillage will not affect other equipment.

Insertion of endoscopic accessories 8

Always make sure to select the correct size endoscopic accessory for the aScope 4 Cysto (see section 1.2). Insert the endoscopic accessory into the working channel entry and advance it carefully through the working channel until it can be seen on the live image on the Ambu displaying unit.

Withdrawal of the aScope 4 Cysto 9

When withdrawing the aScope 4 Cysto, make sure that the bending lever is in the neutral position. Slowly withdraw the cystoscope while watching the live image on the Ambu displaying unit.

4.3. After Use

Visual check 10

Check if there are any missing parts, evidence of damage, cuts, holes, sagging, or orther irregularities on the bending section, distal end, or insertion cord of the aScope 4 Cysto. If yes, then take corrective action to determine if any parts are missing and locate the missing part(s).

In case of corrective actions needed act according to local hospital procedures. The elements of the insertion cord are visible in x-ray (radio opaque).

Final steps

1. Disconnect the aScope 4 Cysto from the Ambu displaying unit **11**.
2. Dispose of the aScope 4 Cysto, which is a single-use device **12** . The aScope 4 Cysto is considered contaminated 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 sterilise the aScope 4 Cysto as these procedures may leave harmful residues or cause malfunction of the cystoscope. The product design and materials used are not designed for reuse and cannot withstand the reprocessing procedures used for reprocessing of endoscopes without the risk of degrading and being contaminated.

5. Technical Product Specifications

5.1. Standards Applied

The aScope 4 Cysto 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 Cysto Specifications

Insertion Portion	**aScope 4 Cysto**	**Optical System**	**aScope 4 Cysto**
Bending angle[1]	210° ± 15° ↑↓, min. 120 °	Field of view	120° ± 10°
Insertion cord diameter	16.2 Fr ± 0.3 Fr / 5.4 mm ± 0.1 mm (0.21" ± 0.004")	Depth of field	3 - 100 mm
Distal end diameter	16.2 Fr ± 0.3 Fr / 5.4 mm ± 0.1 mm (0.21" ± 0.004")	Illumination method	LED
Maximum diameter of insertion portion	Max 18 Fr / 6.0 mm (0.24")		
Working length	390 mm ± 10 mm (15.4" ± 0.4")		
Working Channel		**Sterilisation**	
Minimum working channel width[2]	Min. 6.6 Fr / 2.2 mm (0.086")	Method of sterilisation	ETO
Storage and Transportation		**Operating Environment**	
Transportation temperature	10 ~ 40 °C (50 ~ 104 °F)	Temperature	10 ~ 40 °C (50 ~ 104 °F)
Storage temperature[3]	10 ~ 25 °C (50 ~ 77 °F)	Relative humidity	30 ~ 85 %
Relative humidity	30 ~ 85 %	Atmospheric pressure	80 ~ 109 kPa
Atmospheric pressure	80 ~ 109 kPa	Altitude	≤ 2000 m
Electrical Power			
Power requirement	5 VDC 0.1 A input (from Ambu displaying unit)		
LED power requirement	18 mA (6.5 VDC) input (from Ambu displaying unit)		

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

6. Trouble Shooting

If problems occur with the aScope 4 Cysto 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 Ambu displaying unit but User Interface is present on the Ambu displaying unit or the image shown is frozen	The aScope 4 Cysto is not connected to the Ambu displaying unit	Connect the aScope 4 Cysto to the blue port on the Ambu displaying unit
	The Ambu displaying unit and the aScope 4 Cysto have communication problems	Restart the Ambu displaying unit (please refer to the Ambu displaying unit Instruction for Use)
	The Scope 4 Cysto is damaged	Replace the aScope 4 Cysto with a new one
	A recorded image is shown	Return to live image (please refer to the Ambu displaying unit Instruction for Use)
Low picture quality	Unwanted fluids etc. on the distal end	Gently rub the distal end against the mucosa. If the distal end cannot be cleaned this way remove the aScope 4 Cysto and wipe the distal end with sterile gauze
Absent or reduced flow of fluid e.g sterile water or saline solution or difficulty in inserting endoscopic accessory through the working channel	The working channel is blocked.	Clean the working channel using a cleaning brush or flush the working channel with sterile water or saline using a syringe
	The bending section is not in neutral position	Move the bending section into neutral position

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