

# INSTRUCTIONS FOR USE

## Ambu® aScope™ 4 Cysto

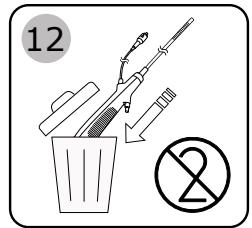
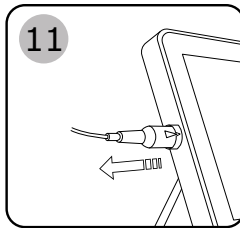
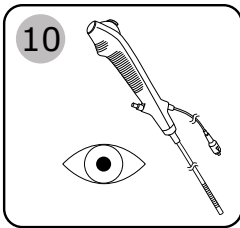
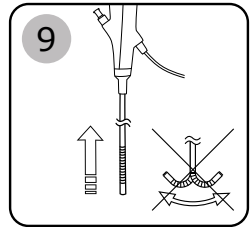
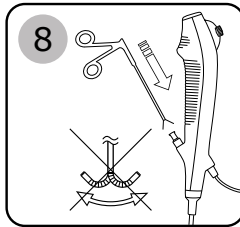
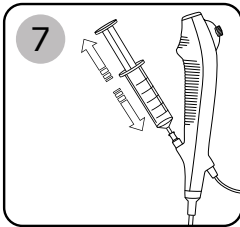
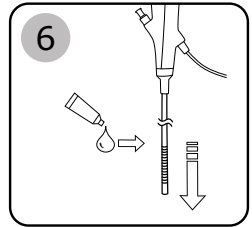
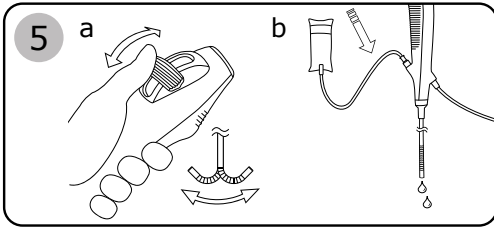
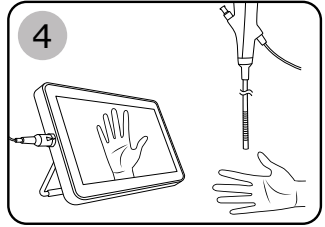
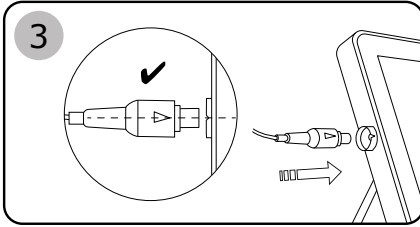
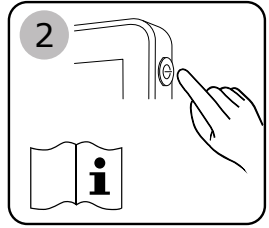
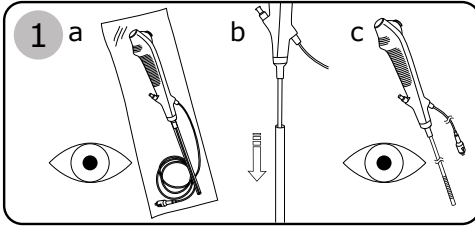
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For use by trained clinicians/physicians only.  
For use with Ambu® displaying units.

**Abridged version**

# Ambu





## Contents

## Page

English (Instructions for use) .....	4-11
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## 1. Important information – Read before use

Read these safety instructions carefully before using the aScope 4 Cysto. 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 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 visualization via the reusable Ambu Displaying Unit and can be used with endoscopic accessories and instruments.

The aScope 4 Cysto is intended for use in a hospital environment or medical office environment. The aScope 4 Cysto is designed for use for adult patients requiring cystoscopy.

### 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. Clinical Benefits

Together with the compatible Ambu displaying unit, the aScope 4 Cysto provides endoscopic access and visualisation, enabling cystoscopic examination and procedures in the lower urinary tract.

### 1.4. Warnings and cautions

#### **WARNINGS**

1. Do not use the aScope 4 Cysto if the Inspection and Preparation of the aScope 4 Cysto fails as it can cause patient injury.
2. Do not attempt to clean and reuse the aScope 4 Cysto as it is a single use device. Reuse of the product can cause contamination leading to infections.
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. aScope 4 Cysto camera images must not be used as an independent diagnostic of any pathology. Doing so may result in incorrect or missing diagnosis. Physicians must interpret and substantiate any findings by other means and in the light of the patient's clinical characteristics.
5. Do not withdraw aScope 4 Cysto if an endoscopic instrument is protruding from the distal end of the working channel as this can damage the urethral mucosa.
6. Do not activate an energised endoscopic instrument (e.g. laser equipment, electrosurgical equipment) in the aScope 4 Cysto before the distal end of the instrument can be seen in the image on the displaying unit as this can lead to patient injury or damage aScope 4 Cysto.
7. Do not damage the insertion portion during use as it may leave parts of the product inside the patient, or expose sharp surfaces that may cause damage to mucosa. Care should be taken to avoid damaging the insertion portion when using aScope 4 Cysto with endoscopic instruments.

8. Always watch the live image on the displaying unit when inserting or withdrawing the aScope 4 Cysto or operating the bending section. Looking at a recorded image may result in damage to mucosa or tissue.
9. Using electrosurgical equipment with aScope 4 Cysto may disturb image on displaying unit.
10. Do not use aScope 4 Cysto with laser equipment or electrosurgical equipment if flammable or explosive gases are present in the immediate area of aScope 4 Cysto as this can lead to patient injury, damage aScope 4 Cysto or disturb image on displaying unit.
11. Patient leakage currents may be additive and too high when using an energised endoscopic instrument in the aScope 4 Cysto. Only energised endoscopic instruments classified as "type CF" or "type BF" applied part shall be used with aScope 4 Cysto to minimise total patient leakage current.
12. Irrigation by insufflation of air, inert gas prior to electrosurgery or using laser assist gas may cause gas embolism leading to stroke or ischaemia.
13. Do not use aScope 4 Cysto during defibrillation as this may result in electrical shock to the user.
14. When using compatible laser equipment, user shall be familiar with safety precautions, guidelines, and proper use of the laser equipment, including, but not limited to, proper eye and skin protection to avoid laser injuries.

## CAUTIONS

1. Have a suitable backup system readily available in case a malfunction should occur.
2. US federal law restricts this device 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.

## 1.5. 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).

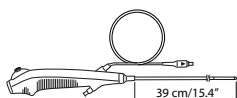
## 2. System description

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 *Instructions for use*.

### 2.1. System parts

Item number	Product name	Colour	Outer diameter [mm]	Inner diameter [mm]
600001000	Ambu® aScope 4™ Cysto, Reverse Deflection	Green	max 6.0	min 2.2
601001000	Ambu® aScope 4™ Cysto, Standard Deflection	Green	max 6.0	min 2.2

#### Ambu® aScope™ 4 Cysto



aScope 4 Cysto (#600001000 and #601001000) are not available in all countries. Please contact your local sales office.

### 2.2. Product compatibility

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

#### Displaying units

– Ambu aView 2 Advance

## Endoscopic accessories and instruments

- Irrigation set (line and sterile water or saline bag) with Luer connection.
- Syringe and other Luer connecting accessories.
- Endoscopic instruments 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 electro-surgical equipment fulfilling EN 60601-2-2. To keep high frequency leakage currents within allowed limits, the maximum sinus peak voltage level of the electro-surgical unit shall not exceed 2.2 kVp.

\* 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.

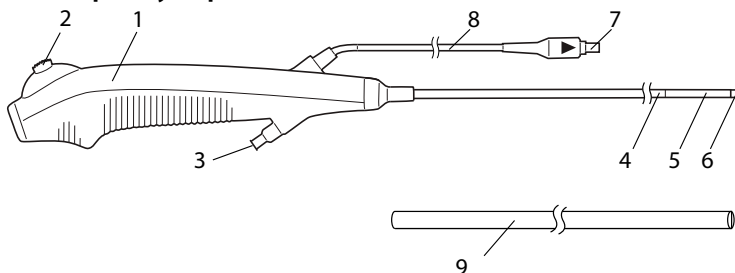
## Contrast agents and lubricants

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

## Other equipment

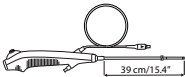
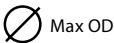
















- X-ray.

## 2.3. aScope 4 Cysto parts



No.	Part	Function
1	Handle	Suitable for left and right hand.
2	Control 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 instruments.
-	Working channel	Can be used for instillation of fluids and insertion of endoscopic instruments.
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	Description
	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.
	Electrical Safety Type BF Applied Part.
	Medical device.
	Packaging level ensuring sterility.
	Global trade identification number.
	Country of manufacturer.
	Do not use if the product sterilisation barrier or its packaging is damaged.
	Relative humidity limitation.
	Atmospheric pressure limitation.
	Temperature limitation.
	UL Recognized Component Mark for Canada and the United States.
	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 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 before opening and discard the aScope 4 Cysto if the pouch seal has been damaged. 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.

#### Refer to the Ambu displaying units *Instructions 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 correctly oriented 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 *Instructions 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 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. 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.

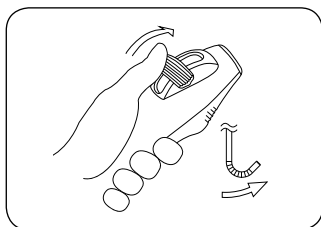
### 4.2. Operating the aScope 4 Cysto

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.

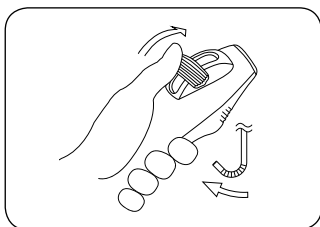
#### Holding the aScope 4 Cysto and manipulating the distal end

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.

- Depending on the bending lever, the model is called standard (lever up = tip up) or reverse (lever up = tip down).



Standard Deflection  
Lever Up = Tip Up  
Lever Down = Tip Down



Reverse Deflection  
Lever Up = Tip Down  
Lever Down = Tip Up



- 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 instruments 8**

Always make sure to select the correct size endoscopic instrument for the aScope 4 Cysto (see section 2.2.). Inspect the endoscopic instrument before using it. If there is any irregularity in its operation or external appearance, replace it. Insert the endoscopic instrument 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 control lever is in the neutral position. Slowly withdraw the cystoscope while watching the live image on the displaying unit.

### **4.3. After use**

#### **Visual check 10**

Check if there are any missing parts, evidence of damage, cuts, holes, sagging, or other 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. 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
Bending angle <sup>1</sup> [°]	210° ± 15° ↑, min. 120° ↓
Insertion cord diameter [mm, (")]	16.2 Fr ± 0.3 Fr / 5.4 mm ± 0.1 mm (0.21" ± 0.004")
Distal end diameter [mm, (")]	16.2 Fr ± 0.3 Fr / 5.4 mm ± 0.1 mm (0.21" ± 0.004")
Maximum diameter of insertion portion [mm, (")]	Max 18 Fr / 6.0 mm (0.24")
Working length [mm, (")]	390 mm ± 10 mm (15.4" ± 0.4")
Working channel	aScope 4 Cysto
Minimum working channel width <sup>2</sup>	Min. 6.6 Fr / 2.2 mm (0.086")
Storage	aScope 4 Cysto
Temperature <sup>3</sup> [°C, (°F)]	10 – 25 (50 – 77)
Relative humidity [%]	10 – 85
Atmospheric pressure [kPa]	50 – 106
Transportation	aScope 4 Cysto
Temperature [°C, (°F)]	-10 – 55 (14 – 131)
Relative humidity [%]	10 – 95
Atmospheric pressure [kPa]	50 – 106
Optical system	aScope 4 Cysto
Direction of view [°]	0 (forward pointing)
Field of view [°]	120 ± 10
Depth of field [mm]	3 – 100
Illumination method	LED
Sterilisation	aScope 4 Cysto
Method of sterilisation	ETO
Operating environment	aScope 4 Cysto
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa]	80 – 106
Altitude [m]	≤ 2000
Electrical power	aScope 4 Cysto
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 instruments.
2. There is no guarantee that endoscopic instruments 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.

Problém	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 <i>Instructions for use</i> ).
	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 <i>Instructions for use</i> ).
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 instrument 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.

# Ambu



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2797



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