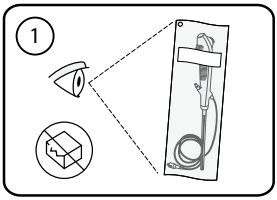
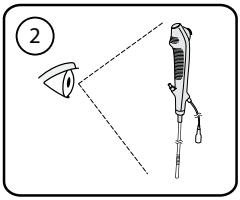
INSTRUCTIONS FOR USE

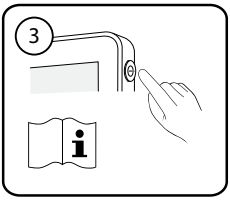
Ambu® aScope™ 5 Cysto HD

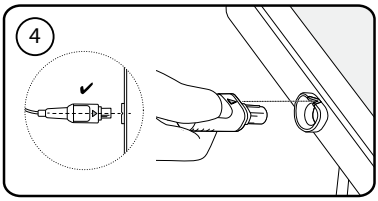
Ambu

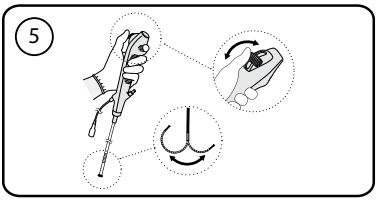
QUICK GUIDE

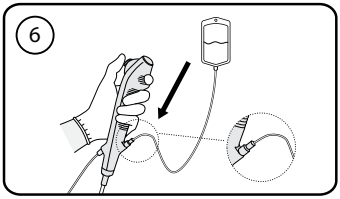


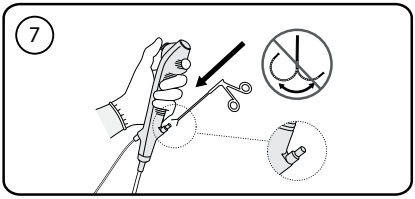


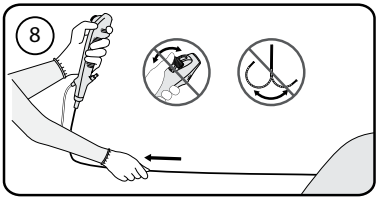


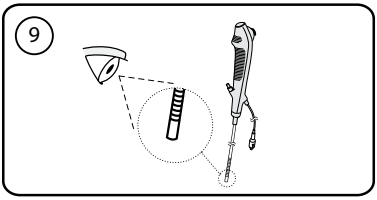


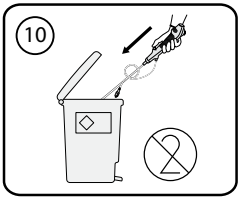












Content

Page

1. Important information – Read before use

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

Read these instructions for use carefully before using aScope 5 Cysto HD. The Instructions for Use may be updated without notice. Copies of the current version are available upon request. Please be aware that these instructions do not explain or discuss clinical procedures.

Before initial use of the endoscope, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, indications, warnings, cautions, and contraindications mentioned in these instructions.

aScope 5 Cysto HD is not covered by a warranty.

In this document "aScope 5 Cysto HD" refers to instructions which apply to the cystoscope only and "aScope 5 Cysto HD system" refers to information relevant to aScope 5 Cysto HD, compatible Ambu displaying units and accessories. Unless otherwise specified, endoscope refers to all aScope 5 Cysto HD variants.

1.1. Intended use

aScope 5 Cysto HD is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The cystoscope is intended to provide visualization via a compatible Ambu displaying unit and can be used with endoscopic accessories and instruments.

1.1.1. Intended patient population

aScope 5 Cysto HD is designed for use in adults requiring cystoscopy.

1.1.2. Intended use environment

aScope 5 Cysto HD is designed for use in a hospital environment or medical office environment.

1.2. Indications for use

aScope 5 Cysto HD is used in patients with disease in the lower urinary tract that requires visualization and examination with a flexible cystoscope and the use of endoscopic accessories and instruments.

1.3. Intended user

aScope 5 Cysto HD is for use by healthcare professionals: medical doctors, urologists, surgeons, or nurses under medical responsibility trained within cystoscopy procedures.

1.4. Contraindications

No contraindications are identified for aScope 5 Cysto HD.

1.5. Clinical benefits

Together with the compatible Ambu displaying unit, aScope 5 Cysto HD provides endoscopic access and visualization, enabling cystoscopic examination and procedures in the lower urinary tract.

1.6. Warnings and cautions ⚠

WARNINGS

1. To be used only by healthcare professionals trained in clinical endoscopic techniques and procedures specific to urinary tract endoscopy and in accordance with the intended use of the aScope 5 Cysto HD. Failure to comply with the above may cause patient injury.
2. The user must exercise professional judgement when deciding whether a cystoscopy procedure will be beneficial and necessary for high-risk patients.
3. Do not use the aScope 5 Cysto HD if it fails the inspection and preparation, as this can cause patient injury.
4. Do not attempt to clean and reuse the aScope 5 Cysto HD, as it is a single use device. Reuse of the product can cause contamination leading to infection.
5. The distal end of the aScope 5 Cysto HD may become hot from the heat from the light emission part. Avoid long periods of contact between the distal end of the aScope 5 Cysto HD and the mucosal membrane, as sustained contact with the mucosal membrane may cause mucosal injury.
6. aScope 5 Cysto HD camera images must not be used as an independent diagnostic of any pathology. Doing so may result in incorrect or missed diagnosis. Physicians must interpret and substantiate any findings by other means in light of the patient's clinical characteristics.
7. Do not withdraw the aScope 5 Cysto HD if an endoscopic instrument is protruding from the distal end of the working channel, as this can damage the urethral mucosa.
8. Do not activate an energized endoscopic instrument (e.g., laser equipment, electrosurgical equipment) in the aScope 5 Cysto HD 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 cause damage to the aScope 5 Cysto HD.
9. 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 the aScope 5 Cysto HD with endoscopic instruments.
10. Always watch the live image on the displaying unit when inserting or withdrawing the aScope 5 Cysto HD or operating the bending section. Looking at a recorded image may result in damage to mucosa or tissue.
11. Using electrosurgical equipment with the aScope 5 Cysto HD may disturb the image on the displaying unit.
12. Do not use the aScope 5 Cysto HD with laser equipment or electrosurgical equipment if flammable or explosive gases are present in the immediate area of the aScope 5 Cysto HD, as this can lead to patient injury, cause damage to the aScope 5 Cysto HD or disturb the image on the displaying unit.
13. Patient leakage currents may be additive and too high when using an energized endoscopic instrument in the aScope 5 Cysto HD. Only energized endoscopic instruments classified as "type CF" or "type BF" applied part may be used with the aScope 5 Cysto HD to minimise total patient leakage current.
14. Irrigation by insufflation of air, inert gas prior to electrosurgery or using laser assist gas may cause a gas embolism leading to stroke or ischemia.
15. Do not use the aScope 5 Cysto HD during defibrillation, as this could present an electrical shock hazard to the user.
16. When using compatible laser equipment, the user must 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 for immediate use so the procedure can be continued if a malfunction should occur.

1.7. Undesirable side effects

Undesirable side effects 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).

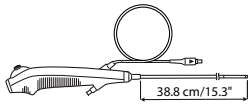
1.8. General notes

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

2. Device description

aScope 5 Cysto HD is to be connected to an Ambu displaying unit. For information about Ambu displaying units, please refer to the Ambu displaying units' Instructions for Use.

2.1. Device parts

Ambu® aScope™ 5 Cysto HD – Single-use device:	**Part numbers:**
	602001000 aScope 5 Cysto HD - Reverse Deflection 603001000 aScope 5 Cysto HD - Standard Deflection

aScope 5 Cysto HD variants (#602001000 and #603001000) are not available in all countries. Please contact your local sales office.

2.2. Product compatibility

aScope 5 Cysto HD has been designed to be used in conjunction 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).
– Thulium fiber laser (1.92 – 1.96 microns wavelength).
– High frequency electrosurgical 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 must not exceed 2.2 kVp.

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

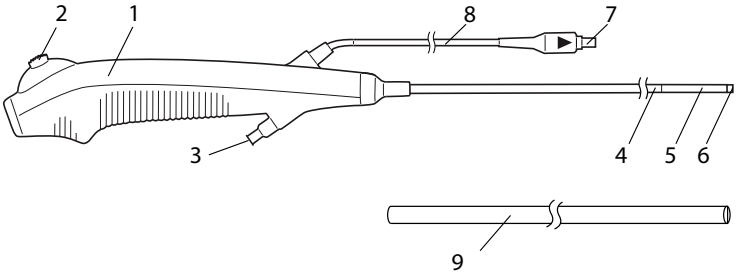
Contrast agents and lubricants

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

Other equipment

– X-ray

2.3. aScope 5 Cysto HD 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	Maneuverable part.
6	Distal end	Contains the camera, light source (two LEDs), as well as the working channel exit.
4-5-6	Insertion portion	The combination of the insertion cord, bending section, and distal end.
7	Connector on the aScope 5 Cysto HD cable	Connects to the grey socket on Ambu displaying units.
8	aScope 5 Cysto HD cable	Transmits the image signal to Ambu displaying units.
9	Protection pipe	Protects the insertion cord during transport and storage. Remove before use.

3. Use of aScope 5 Cysto HD

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

3.1. Preparation and inspection of aScope 5 Cysto HD

Visual Inspection of the aScope 5 Cysto HD (1)

1. Check that the pouch seal is intact before opening. Discard the aScope 5 Cysto HD if the pouch seal has been damaged, or the expiry date has been exceeded (1).
2. Make sure to remove the protection pipe from the insertion cord.
3. Check that there are no impurities on or damage to the aScope 5 Cysto HD such as rough surfaces, sharp edges or protrusions which may harm the patient (2).
4. Check the deflection of the controllable portion, by moving the control lever on the handle with your thumb 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 (5).

Discard the aScope 5 Cysto HD if it fails any of the check points mentioned above. Refer to the Ambu displaying units' Instructions for Use for preparing and turning the Ambu displaying units on (3).

Inspection of the image

1. Turn the displaying unit on. Connect the aScope 5 Cysto HD to the Ambu displaying unit by plugging the connector on the aScope 5 Cysto HD cable marked with a grey arrow into the corresponding grey female connector on the Ambu displaying unit. Carefully align the arrows on the connector on the aScope 5 Cysto HD cable with the port on the Ambu displaying unit to prevent damage to the connectors **3** **4**.
2. Verify that a clear and correctly oriented live video image appears on the Ambu displaying unit by pointing the distal end of the aScope 5 Cysto HD towards an object, e.g. the palm of your hand.
3. Adjust the image preferences on the Ambu displaying unit if necessary (please refer to the Ambu displaying unit's instruction for use).
4. If the object cannot be seen clearly, wipe the distal end of the aScope 5 Cysto HD using a sterile cloth.

Preparation of aScope 5 Cysto HD

1. 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 **6**.

Ensure that the check points above are successful before moving on to the procedure.

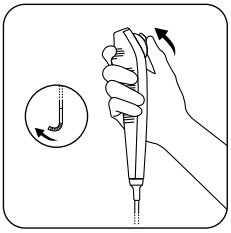
3.2. Operating the aScope 5 Cysto HD

In the event of a malfunction during the cystoscopic procedure, stop the procedure immediately, put the distal end of the aScope 5 Cysto HD in its neutral and non-angled position and slowly withdraw the cystoscope. Do not activate the control lever while withdrawing the cystoscope from the patient.

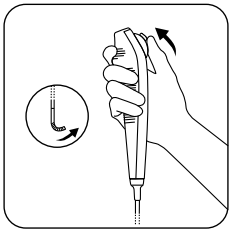
Holding the aScope 5 Cysto HD and manipulating the distal end

The handle of the aScope 5 Cysto HD 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 5 Cysto HD

Lubricate the insertion cord with a soluble lubricant suitable for cystoscopy before the aScope 5 Cysto HD is inserted into the urethra. Gently advance the insertion cord according to standard practice for the patient anatomy. If the camera image of the aScope 5 Cysto HD becomes unclear, the distal end can be cleaned by withdrawing the cystoscope and cleaning the distal end.

Aspiration and instillation of fluids 6
Aspiration may be required during the procedure. Prepare a syringe for this. When required, attach the syringe to the aScope 5 Cysto HD and apply an aspiration force to achieve the desired effect. For larger quantities 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 5 Cysto HD handle by connecting a syringe or infusion set with Luer Lock 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 7
If required, endoscopic instruments can be used with the aScope 5 Cysto HD.
Always make sure to select the correct size endoscopic instrument for the aScope 5 Cysto HD (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. Do not activate endoscopic instruments inside the working channel. The distal end of the instrument should be seen in the image during use.

Withdrawal of the aScope 5 Cysto HD 8
When withdrawing the aScope 5 Cysto HD, make sure that the control lever is in the neutral position. Slowly withdraw the cystoscope while watching the live image on the displaying unit.

3.3. After use

Visual check 9
Check for missing parts, evidence of damage, cuts, holes, sagging, or other irregularities on the bending section, distal end, or insertion cord of the aScope 5 Cysto HD. If required, take corrective action to determine whether any parts are missing and locate the missing part(s).

If corrective action is needed, follow the local hospital procedures. The elements of the insertion cord are visible in x-ray (radio opaque).

Final steps

1. Disconnect the aScope 5 Cysto HD from the Ambu displaying unit.
2. Dispose of the aScope 5 Cysto HD, which is a single-use device **10**. The aScope 5 Cysto HD 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 endoscopes without risking degrading and contamination. Reprocessing/reuse could damage the scope and cause injury to the patient.

4. Technical product specifications

4.1. aScope 5 Cysto HD specifications

Insertion portion	aScope 5 Cysto HD	Optical system	aScope 5 Cysto HD
Bending angle[1]	210° ± 15° ↑ min. 120° ↓	Direction of view	0°
Insertion cord diameter	16.2 Fr ± 0.3 Fr/ 5.4 mm ± 0.1 mm (0.21" ± 0.004")	Field of view	120° ± 18°
Distal end diameter	Max 16.8 Fr Max 5.6 mm (Max 0.22")	Depth of field	3 – 100 mm

Maximum diameter of insertion portion	Max 18 Fr/ 6.0 mm (0.24″)	Illumination method	LED
Working length	388 mm +12/-8 mm (15.3″ +0.5″/-0.3″)		
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 – 55 °C (14 – 131 °F)	Temperature	10 – 40 °C (50 – 104 °F)
Storage temperature[3]	10 – 25 °C (50 – 77 °F)	Relative humidity	30 – 85 %
Relative humidity	10 – 85 %	Atmospheric pressure	80 – 106 kPa
Atmospheric pressure	50 – 106 kPa	Altitude	≤ 2000 m

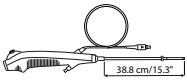
1. Please be aware that the bending angle can be affected if the insertion cord is not kept straight; or endoscopic instruments have been inserted.
2. There is no guarantee that accessories selected solely using this minimum working channel width will be compatible in combination.
3. Storage under higher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

5. Troubleshooting

If problems occur with the system or product, please use this troubleshooting guide to identify the cause and correct the error.

Problem	Possible cause	Recommended action
No live image on the Ambu displaying unit, but the user interface is present on the Ambu displaying unit or the image shown is frozen.	The aScope 5 Cysto HD is not connected to the Ambu displaying unit.	Connect the aScope 5 Cysto HD to the grey port on the Ambu displaying unit.
	The Ambu displaying unit and the aScope 5 Cysto HD are not communicating correctly.	Restart the Ambu displaying unit (please refer to the Ambu displaying unit's Instructions for Use).
	The aScope 5 Cysto HD is damaged.	Replace the aScope 5 Cysto HD with a new one.
	A recorded image is shown.	Return to the live image (please refer to the Ambu displaying unit's Instructions for Use).
Low picture quality.	Unwanted fluids etc. on the distal end.	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 flow of fluid, e.g. sterile water or saline solution, or difficulty inserting the 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.

6. Explanation of symbols used

Symbols for the aScope 5 Cysto HD devices	Description	Symbols for the aScope 5 Cysto HD devices	Description
	Working length of the aScope 5 Cysto HD insertion cord.	STERILE EO	Packaging level ensuring sterility.
Max OD	Maximum insertion portion width (maximum outer diameter).	GTIN	Global trade identification number.
Min ID	Minimum working channel width (minimum inner diameter).	MY	Country of manufacturer.
120°	Field of view.	c UL us	UL Recognised Component Mark for Canada and the United States.
	Rated power input, d.c.	UK RP	UK Responsible Person.
	Electrical Safety Type BF Applied Part.	UK CA 0086	UK Conformity Assessed.
MD	Medical device.		Importer (For products imported into Great Britain only).

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

Please Note: This is an abridged version of the IFU and all non-English languages have been removed.

Ambu

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

2797

UK RP

Ambu Ltd
First Floor, Incubator 2
Alconbury Weald Enterprise Campus
Alconbury Weald
Huntingdon PE28 4XA
United Kingdom
www.ambu.co.uk

0086

A492 6020 00 - V01 - 2023/06. TCC
11417