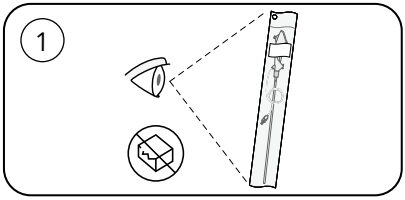
INSTRUCTIONS FOR USE

Ambu® aScope™ 5 Uretero

For use by trained healthcare professionals only.
For use in hospitals.
For use with Ambu® displaying units.

Abridged version ENG

Ambu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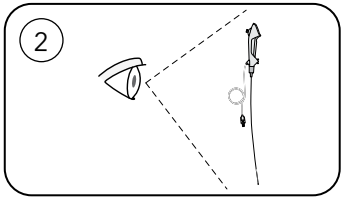
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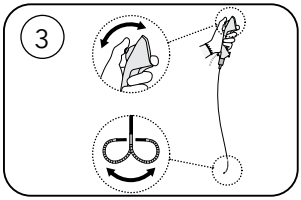
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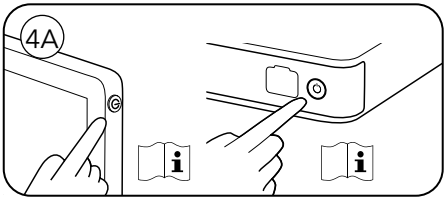
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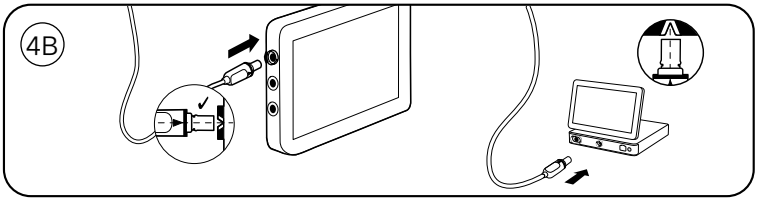
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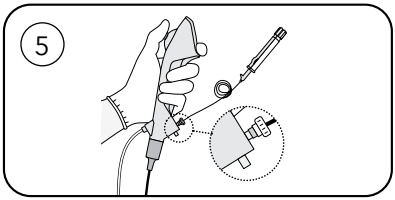
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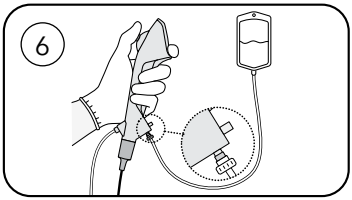
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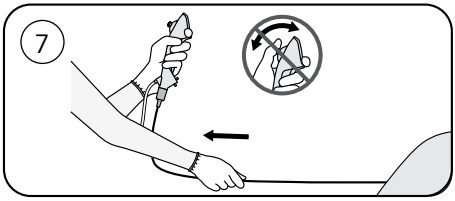
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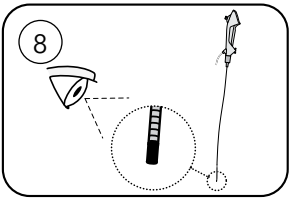
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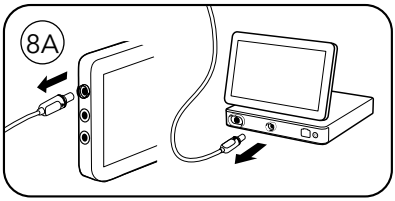
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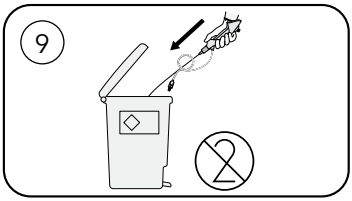
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CONTENTS **PAGE**

1. Important information – Read before use

Read these *Instructions for use* carefully before using the aScope 5 Uretero. 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 ureteroscope. Before initial use of the ureteroscope, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings, cautions, indications and contraindications mentioned in these instructions. There is no warranty on the ureteroscope.

In this document *ureteroscope* refers to instructions which apply to the aScope 5 Uretero only and system refers to information relevant for the aScope 5 Uretero and the compatible Ambu displaying unit.

1.1. Intended use

The aScope 5 Uretero is a sterile, single-use, flexible, digital video ureteroscope intended to be used for endoscopic access and visual guidance in the upper urinary tract.

aScope 5 Uretero is intended to be used with the compatible Ambu displaying unit and can be used in conjunction with endoscopic instruments via its working channel.

1.1.1. Intended patient population

aScope 5 Uretero will be used for adult patients requiring ureteroscopy.

1.1.2. Intended use environment

The aScope 5 Uretero is intended to be used in a hospital operation room environment, where aseptic techniques for handling of the product are in place.

1.2. Indications for use

aScope 5 Uretero is intended for patients requiring retrograde (transurethral) and/or antegrade (percutaneous) ureteroscopy procedures for visualization and examination with a flexible ureteroscope, and for removal of renal and ureter calculi.

1.3. Intended user

The aScope 5 Uretero (including sterile packaging) can be used by medical doctors, urologists, surgeons, or nurses under medical responsibility trained within ureteroscopic procedures. The product must be handled in accordance with recognized medical practice and guidelines for performing ureteroscopy. The user is wearing medical gloves.

1.4. Contraindications

No contraindications identified for the aScope 5 Uretero.

1.5. Clinical benefits

aScope 5 Uretero provides endoscopic access to the upper urinary tract. Together with the compatible Ambu displaying unit, aScope 5 Uretero also offers visualization of the upper urinary tract. The endoscopic access and live image enable stone removal procedures in the ureter and kidney.

1.6. Warnings and cautions ⚠

WARNINGS

1. Only to be used 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 Uretero. Failure to comply with this may cause patient injury.
2. Do not use the product if the inspection and preparation of the product (See section 3) fails as it may cause patient injury such as mucosal abrasion, bleeding, perforation, avulsion, infection or sepsis.

3. Do not attempt to reuse, reprocess or sterilize the aScope 5 Uretero as it is a single use device. Reuse, reprocessing or resterilization of the product may cause structural and functional damage which may cause patient injury including but not limited to mucosal abrasion or bleeding.
   Reuse, reprocessing or resterilization of the product may also cause contamination leading to infections or sepsis. Cleaning residues left on the product may cause allergic reactions.
4. Always watch the live image on the displaying unit when inserting or withdrawing the aScope 5 Uretero or operating the bending section. Navigation based on a recorded or impaired image may cause patient injury including but not limited to mucosal abrasion, bleeding or perforation.
5. Do not use excessive force during use as doing so may cause patient injury (including but not limited to mucosal abrasion, bleeding or perforation) to the patient and/or damage to the aScope 5 Uretero.
6. Advance endoscopic instrument with caution and ensure continuous visualization of the endoscopic instrument protruding from the distal end of the working channel as failure to do so may cause patient injury including but not limited to mucosal abrasion, bleeding or perforation.
7. Do not use excessive force during insertion and withdrawal of endoscopic instruments as doing so may cause injury to the patient (including but not limited to mucosal abrasion, bleeding or perforation) and/or damage to the aScope 5 Uretero.
8. Advance, withdraw or activate bending section of the aScope 5 Uretero with caution if an endoscopic instrument is protruding from the distal end of the working channel as this may cause mucosal injury.
9. Do not activate a laser unless the distal end of the instrument can be identified on the screen of the displaying unit, as failure to do so may cause patient injury and/or damage to the aScope 5 Uretero.
10. If any malfunction should occur during the ureteroscopic procedure, stop the procedure immediately, put the distal end of the aScope 5 Uretero in its neutral and non-angled position and slowly withdraw it from the patient. Failure to do so may cause patient injury including but not limited to mucosal abrasion, bleeding, perforation or avulsion.
11. The distal end of the aScope 5 Uretero may get warm due to heating from the light emission part. Avoid unnecessary prolonged periods of contact between the distal end of the aScope 5 Uretero and the mucosal membrane as this may cause thermal injury to the mucosa.
12. Endoscopic instruments shall always be operated according to the respective manufacturer's *Instructions for use*. Users shall always be familiar with safety precautions and guidelines on the proper use of endoscopic instruments, including use of adequate personal protective equipment e.g. wearing suitable protective filtering spectacles when using laser equipment together with the endoscope. Failure to do so may cause patient or user injury.
13. Patient leakage currents (flow of current through the patient connected to applied part) may be additive and too high when using an active endoscopic instrument in combination with the aScope 5 Uretero. Only active/energized endoscopic instruments classified as "type CF" or "type BF" applied part shall be used. Failure to do so may cause major cardiac conductivity impairment and hemodynamic instability.
14. Do not activate and/or operate the laser until the live image is satisfactory, or it may cause exposure of the laser to the mucosa and subsequently thermal injury and perforation of the mucosal tissue.
15. Do not use the aScope 5 Uretero during defibrillation as this may cause electrical shock to the user and/or patient or damage to the system.
16. Do not use the aScope 5 Uretero with laser equipment or electrosurgical equipment if flammable or explosive gases are present in the immediate area of the aScope 5 Uretero as this can lead to patient injury, damage the aScope 5 Uretero or disturb the image on the displaying unit.
17. Do not use high frequency endoscopic instruments (such as monopolar Bugbee electrodes) with the aScope 5 Uretero as it is not compatible. Failure to comply may result in patient injury.

CAUTIONS

1. Do not use the device without a suitable back-up system readily available as this may lead to an inability to complete the procedure in case of device failure.
2. Always progress with caution when inserting and advancing endoscopic instruments in a bent endoscope as this can cause damage to the working channel and introduce patient injury such as mucosal abrasion, bleeding and/or perforation.

1.7. Potential adverse events

Potential adverse events in relation to flexible ureteroscopy (not exhaustive): Mucosal abrasion, bleeding, perforation, infection, sepsis, avulsion, intussusception, hematuria, vesicoureteral reflux (VUR), stricture and renal damage.

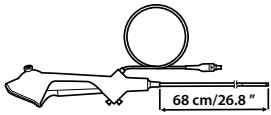
1.8. General notes

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. Device description

The aScope 5 Uretero is designed to be connected to the Ambu displaying unit.
For information about the Ambu displaying units, please refer to the Ambu displaying units *Instructions for use*.

2.1. Device parts

Ambu® aScope™ 5 Uretero	Part numbers
	604001000 aScope 5 Uretero - Standard Deflection 605001000 aScope 5 Uretero - Reverse Deflection

aScope 5 Uretero (#604001000 and #605001000) are not available in all countries.
Please contact your local sales office.

2.2. Product compatibility

The aScope 5 Uretero has been designed to be used with:

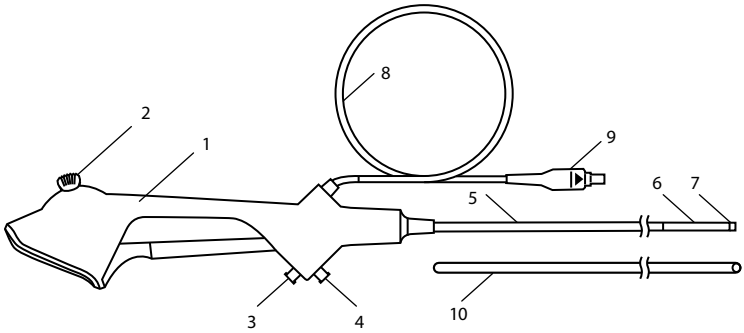
Displaying units
- Ambu® aBox™ 2
- Ambu® aView™ 2 Advance

Note: Connector port color and geometry on the displaying unit must match the connector color and geometry on the visualization device.

Endoscopic accessories
- Ureteral access sheaths compatible with the outer diameter of the ureteroscope
- Accessories with standard Luer slip and/or Lock e.g. stopcocks, valves and syringes
- Endoscopic instruments with a maximum diameter of the insertion portion of 1.1 mm/3.3 Fr. (baskets, guidewires, laser fibers and biopsy forceps).
  Different types and sizes of instrument affect the bending ability of the endoscope.
  The aScope 5 Uretero has been tested and is compatible with the following laser technologies:
  - Holmium laser technology
  - Thulium fiber laser technology

Lubricants
- Isotonic saline solution
- Water based soluble lubricants suitable for ureteroscopy
- Iodine based contrast agent diluted per normal practice
- Sterile water

2.3. aScope 5 Ureteroscope 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	Instrument inlet	Allows for insertion of endoscopic instruments into working channel.
4	Irrigation inlet	Allows for irrigation (instillation of fluid) and suctioning of fluids.
3, 4	Working channel system	Allows access to the working channel running to the distal end of the ureteroscope.
5	Insertion cord	Flexible insertion cord.
6	Controllable portion	Maneuverable part.
7	Distal end	Contains the camera, light source (two LEDs), as well as the working channel exit.
5, 6, 7	Insertion portion	Consists of flexible insertion cord, the controllable portion and the distal end.
8	Cable	Transmits the image signal to the Ambu displaying units.
9	Displaying unit connector	Connects to the green socket on the Ambu displaying units.
10	Protective pipe	Protects the insertion portion during transport and storage. Remove before use.

3. Use of the aScope 5 Uretero

The numbers in ( ) below refer to illustrations on page 2.

3.1. Preparation and inspection of the aScope 5 Uretero

Inspection of the aScope 5 Uretero (1)

1. Check that the pouch seal is intact before opening. Discard the aScope 5 Uretero, if the pouch seal has been damaged or the expiry date has been exceeded.
2. Remove the protection pipe from the insertion portion and check that there are no impurities or damages on the aScope 5 Uretero such as rough surfaces, sharp edges or protrusions which may harm the patient (2).
3. 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. Confirm that the deflection works correctly. (3)

Discard the aScope 5 Uretero if any of above checking points failed.

Inspection of the image

1. Turn on the Ambu displaying unit **4A**. Connect the aScope 5 Uretero to the Ambu displaying unit by plugging in the aScope 5 Uretero Displaying unit connector with the green arrow visible into the corresponding green female connector on the Ambu displaying unit. Carefully align the arrow on the aScope 5 Uretero connector with the port on the Ambu displaying unit to prevent damage to the connectors **4B**.
2. Verify that a clear live image appears on the screen by pointing the distal end of the ureteroscope towards an object, e.g. the palm of your hand. White balancing is not needed for the aScope 5 Uretero.
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 tip of the aScope 5 Uretero using a sterile cloth.

Preparation of the aScope 5 Uretero

1. Connect a compatible standard Luer Lock/slip sealing device to the instrument inlet to prevent fluid from leaking from the inlet during the procedure **5**. Instruments like baskets and laser fibers can be inserted in the instrument channel.
2. Connect the irrigation supply tubing (gravity-fed bag, or pump) with a compatible fitting (standard Luer Lock/Slip fitting) directly to the irrigation inlet or via a standard Luer Lock/Slip stopcock **6**. Let the fluid run to test the flow through the ureteroscope working channel system. Ensure that there are no leaks, and that water is emitted from the distal end of the ureteroscope. Standard Luer lock/Luer Slip syringes can also be connected to the inlet for supplying contrast fluid or to do suctioning.

3.2. Operating the aScope 5 Uretero

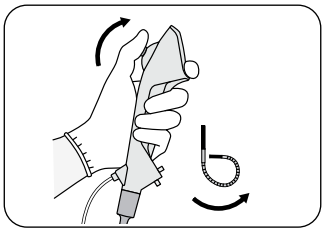
If any malfunction should occur during the ureteroscopic procedure, stop the procedure immediately, put the distal end of the aScope 5 Uretero in its neutral and non-angled position and slowly withdraw from patient **7**. Do not activate the control lever while withdrawing the ureteroscope from the patient.

Holding the aScope 5 Uretero and manipulating the distal end

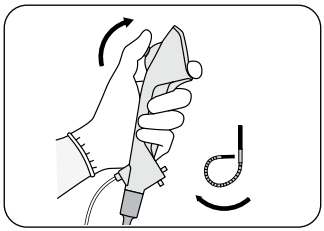
The handle of the aScope 5 Uretero can be held in either hand. The hand that is not holding the handle can be used to guide and advance the insertion cord into the patient's urinary tract. Use the thumb to move the control lever. The control lever is designed to deflect the distal end of the ureteroscope in the vertical plane.

For aScope 5 Uretero Standard Deflection, when moving the control lever forward (Lever up), the distal end bends up (Tip up). When moving the control lever backwards (lever down), the distal end bends down (Tip down).

For aScope 5 Uretero Reverse Deflection, when moving the control lever forward (Lever up), the distal end bends down (Tip down). When moving the control lever backwards (lever down), the distal end bends up (Tip up).



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



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

Insertion of the aScope 5 Uretero

The insertion cord should be held as straight as possible at all times in order to secure an optimal distal end bending angle. Gently advance the insertion cord per standard practice to

the patient anatomy. The insertion cord may be lubricated using a soluble lubricant suitable for ureteroscopy before insertion.

The aScope 5 Uretero may be inserted through a compatible access sheath. Advance gently to the desired treatment area and do not bend the controllable portion inside the access sheath.

Do not bend the insertion cord in a sharp angle close to the handle as shown in illustration ⚠, as this may cause a kink to the insertion cord, hence the maneuverability of the ureteroscope might be compromised.

Irrigation
Fluids e.g. saline solution can be instilled through the working channel via the irrigation inlet by connecting a syringe or irrigation supply with standard Luer Lock/Slip connection directly to the irrigation inlet via a stopcock. If using a saline bag, make sure to place it so that potential spillage will not affect the equipment.

Insertion of endoscopic instruments
Always make sure to select the correct size endoscopic instrument for the aScope 5 Uretero (see section 2.2.). Inspect the endoscopic instrument before using it. If there is any irregularity in its operation or external appearance, replace it. Connect a compatible standard Luer Lock/ slip sealing device to the instrument inlet to prevent fluid from leaking from the inlet while using endoscopic instruments during the procedure. It is recommended not to have a fully deflected bending section when inserting the endoscopic instrument. Insert the endoscopic instrument 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 laser in the working channel.
The distal end of the instrument should be seen in the image during use.

It should be recognized that the use of lasers may interfere with the normal endoscopic image and this interference is not necessarily indicative of a malfunction of the endoscopic system. A variety of factors can affect the quality of the endoscopic image during use of lasers. Factors such as intensity, high power setting, close distance of the instrument probe to the ureteroscope end and excessive stone treatment can each adversely influence image quality.

Withdrawal of the aScope 5 Uretero **7**
When withdrawing the aScope 5 Uretero, make sure that the controllable portion is not deflected by releasing the control lever **7**. Slowly withdraw the ureteroscope while watching the live image on the displaying unit.

3.3. After use

Visual check **8**
Check if there are any missing parts, evidence of damages, cuts, holes, sagging, or other irregularities on the bending section, distal end, or insertion cord of the aScope 5 Uretero.
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 on x-ray (radio opaque).

Final steps
1. Disconnect the aScope 5 Uretero from the Ambu displaying unit **8A**.
2. Dispose of the aScope 5 Uretero, which is a single-use device. **9** The aScope 5 Uretero 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 aScope 5 Uretero has not been designed to be re-processed or resterilized. Doing so might damage the endoscope and cause injury to the patient.

4. Technical product specifications

4.1. aScope 5 Uretero specifications

Insertion portion	aScope 5 Uretero	Optical system	aScope 5 Uretero
Bending angle	270° min. 255°	Direction of view	0° (forward viewing)
Distal tip	7.9 Fr	Field of view	90°

Insertion cord diameter	8.1 Fr/2.7 mm (0.11")	Depth of field	2 – 50 mm
Bending section diameter	9.0 Fr/3.0 mm (0.12")	Illumination method	LED
Maximum diameter of insertion portion	Max 9.0 Fr/ 3.0 mm (0.12")		
Working length	680 mm (26.8")		
Working channel		**Sterilisation**	
Working channel width	3.6 Fr/1.2 mm (0.047") min. 1.15 mm	Method of sterilization	ETO
Storage and transportation		**Operating environment**	
Transportation temperature	-10 – 55 °C (14 – 131 °F)	Temperature	10 – 40 °C (50 – 104 °F)
Storage temperature	10 – 25 °C (50 – 77 °F)	Relative humidity	30 – 85 %
Transportation humidity	10 – 95 %		
Storage humidity	10 – 85 %	Atmospheric pressure	80 – 106 kPa
Atmospheric pressure	50 – 106 kPa	Altitude	≤ 2000 m

Electrical power

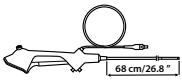
Power requirement 3.42 VDC 0.5 A input (from Ambu displaying unit) [8 mA consumption]
LED power requirement max. 10 mA 12 VDC input (from Ambu displaying unit)
[6 V consumption].

5. 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 Ambu displaying unit but User Interface is present on the Ambu displaying unit or the image shown is frozen.	The aScope 5 Uretero is not connected to the Ambu displaying unit.	Connect the aScope 5 Uretero to the green port on the Ambu displaying unit.
	The Ambu displaying unit and the aScope 5 Uretero have communication problems.	Restart the Ambu displaying unit (please refer to the Ambu displaying unit's Instructions for use).
	The aScope 5 Uretero is damaged.	Replace the aScope 5 Uretero with a new one.
	A recorded image is shown.	Return to live image (please refer to the Ambu displaying unit's Instructions for use).
Debris on the camera lens.	Unwanted fluids etc.on the distal end.	Rinse by flushing with saline using a syringe. If the distal end cannot be cleaned this way, remove the aScope 5 Uretero and wipe the distal end with sterile gauze.
Absent or reduced flow of fluid e.g saline solution.	The working channel is blocked.	Flush the working channel with saline using a syringe. This should not be done with the aScope 5 Uretero inside the patient to avoid potential flush debris or other foreign matter into the patient.

6. Explanation of symbols used

Symbols	Description	Symbols	Description
	Working length of the aScope 5 Uretero insertion cord		Country of manufacture. Date of manufacture.
 Max OD	Maximum insertion portion width (Maximum outer diameter)		Do not use if package is damaged
 Min ID	Minimum instrument channel width (Minimum inner diameter)		Humidity limitation
	Field of view		Atmospheric pressure limitation
	Electrical Safety Type BF Applied Part		Temperature limit
	Medical device		UL mark on electronic products (UL Recognized Component Mark for Canada and the United States)
	Single sterile barrier system		UK Conformity Assessed. Indicates that the product is in compliance with UK legislation for medical devices and has passed conformity assessment by UK Approved Body.
	Global trade item number		UK Responsible Person
	Importer		

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

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