

INSTRUCTIONS FOR USE

Ambu® aScope™ 5 Broncho Sampler Set (part 2 of 2)

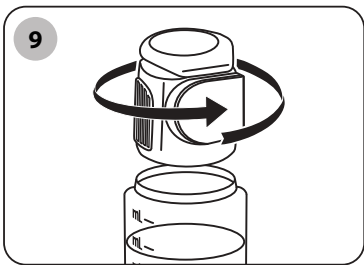
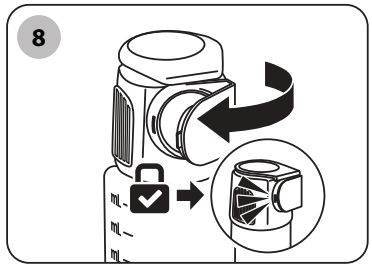
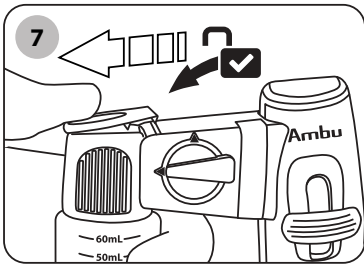
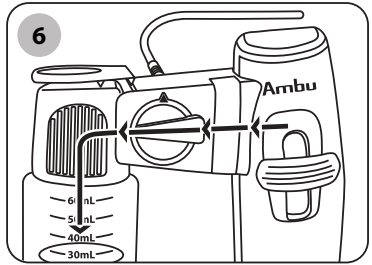
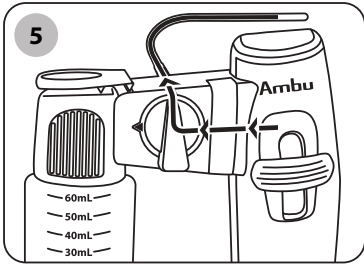
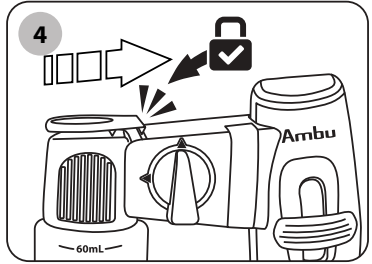
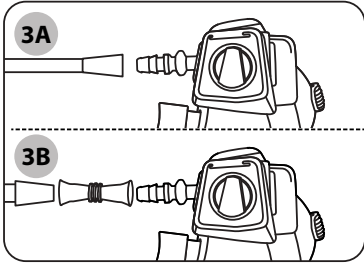
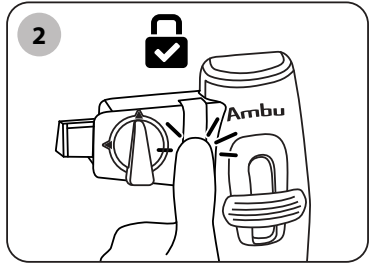
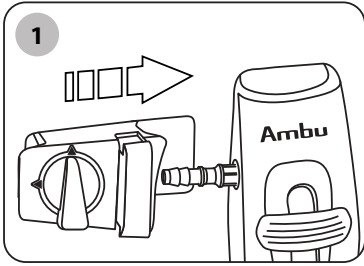
For use by trained healthcare professionals only.

For use in hospital environments.

For use with Ambu® displaying units.

Ambu





Contents

Page

English (Instruction for use) 4-9

1. Important information – Read before use

Read these *Instructions for Use* carefully before using the aScope™ 5 Broncho Sampler Set. These instructions contain part 2 of 2 of the instructions for the use of the aScope™ 5 Broncho Sampler Set:

- **Part 1 of 2:** Basic procedures using the aScope™ 5 Broncho.
- **Part 2 of 2:** Fluid sampling using the BronchoSampler 60 with the aScope™ 5 Broncho.

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

There is no warranty on the aScope™ 5 Broncho Sampler Set.

In these *Instructions for Use*, the term *BronchoSampler 60* refers to the closed loop fluid sampling system to be used with the aScope™ 5 Broncho as part of the aScope™ 5 Broncho Sampler Set. The term *aScope BronchoSampler™ 60 SC* refers to the sample container alone. See section 2.1. for more information.

1.1. Intended use

aScope 5 Broncho Sampler Set enables aspiration and collection of fluid samples.

1.2. Indication for use

Bronchoscopic fluid sampling via techniques such as Broncho Alveolar Lavage (BAL) and Bronchial Wash (BW). The collected specimens undergo microbiological and cytological laboratory analyses for diagnosis and/or surveillance of suspected respiratory infections, interstitial lung diseases or lung cancer.

1.3. Contraindications

None known for fluid sampling using the BronchoSampler 60. For basic procedures using the aScope™ 5 Broncho, please refer to the *Instructions for Use* part 1 of 2.

1.4. Warnings and cautions

For warnings and cautions related to the use of aScope™ 5 Broncho, please refer to the *Instructions for Use* part 1 of 2.

WARNINGS



1. For single-use only. The sample container is not intended to be reprocessed or reused, even when used on the same patient or procedure. Failure to ensure this may cause contamination of the sample and lead to misdiagnosis.

CAUTIONS

1. Do not use the aScope BronchoSampler 60 SC in a centrifuge, as this may cause the container to break or leak.
2. Do not transport the aScope BronchoSampler 60 SC in a pneumatic tube system, as this may cause the container to leak.

1.5. Potential adverse events

None known for fluid sampling using the BronchoSampler 60. For basic procedures using the aScope™ 5 Broncho, please refer to the *Instructions for Use* part 1 of 2.

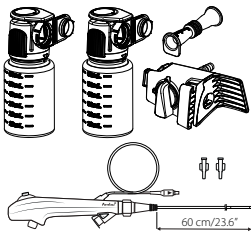

1.6. General notes

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

2. System description

The BronchoSampler 60 is designed for use in conjunction with the aScope™ 5 Broncho. For information about the use of the aScope™ 5 Broncho, please refer to the *Instructions for Use* part 1 of 2.

2.1. System parts

Item	Part name	Part number
	<p>aScope™ 5 Broncho HD 5.6/2.8 Sampler Set</p> <p>aScope™ 5 Broncho HD 5.0/2.2 Sampler Set</p> <p>aScope™ 5 Broncho 4.2/2.2 Sampler Set</p> <p>Contains two single sample containers, a suction adapter, a sampler bridge and an aScope™ 5 Broncho with two Introducers.</p>	<p>622002000</p> <p>621002000</p> <p>620002000</p>
	<p>aScope BronchoSampler™ 60 SC</p> <p>Contains a single sample container for collecting additional samples during the same procedure.</p>	<p>480500000</p>

NOTE: The BronchoSampler 60 is only available as part of a set packaged with a compatible aScope™ 5 Broncho. The aScope™ 5 Broncho Sampler Set is not available in all countries. Please contact your local Ambu representative for more information.

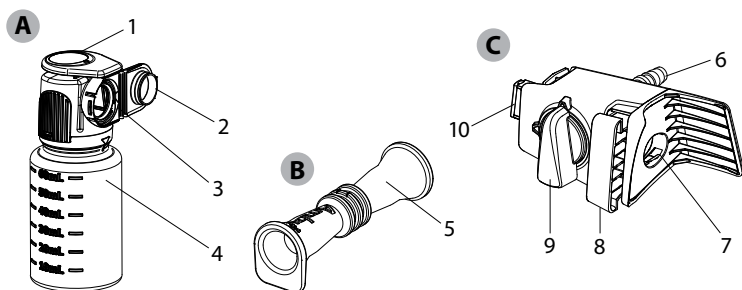
2.2. Product compatibility

Compatible Ambu devices for BronchoSampler 60
<ul style="list-style-type: none"> • Ambu® aScope™ 5 Broncho HD 5.6/2.8 • Ambu® aScope™ 5 Broncho HD 5.0/2.2 • Ambu® aScope™ 5 Broncho 4.2/2.2 • Ambu® aScope BronchoSampler™ 60 SC

Suctioning equipment

For suction tube compatibility, see section 5.2.

2.3. BronchoSampler 60 parts



		Function	
A	Sample container	Connects to the sampler bridge and holds the retrieved sample.	
B	Suction adapter	For connection between the suction connector and a suction tube with male interface.	
C	Sampler bridge	Connects to the aScope™ 5 Broncho and creates a closed loop for sampling.	
No.	Item A	Functions	Material
1	Flip top	A click-on locking mechanism for the sample container. Press down to disengage the locking mechanism.	PP
2	Sample container lid	For closing and protecting the sample.	PP
3	Connection interface	For connecting the sampler bridge and sample container.	Silicone PP
4	Sample container vial	For storage of the sample.	SBC
No.	Item B	Functions	Material
5	Suction adapter	For connection between the suction connector and a suction tube with male interface.	TPE
No.	Item C	Functions	Material
6	Suction connector	For connection of suction tubing.	PP
7	aScope™ 5 Broncho connection interface	For introduction of the aScope™ 5 Broncho suction connector to establish connection.	MABS TPE
8	Attachment lock	Locks the sampler bridge to the aScope™ 5 Broncho.	POM
9	Flow switch	Determines suction flow direction. Switch between sampling and suction mode.	POM
10	Connection interface	For connecting the sampler bridge and sample container.	MABS Silicone

3. Explanation of symbols used

Please refer to the *Instructions for Use* part 1 of 2 for an explanation of the symbols used for the aScope™ 5 Broncho Sampler Sets.

4. Use of BronchoSampler 60

Before using the **BronchoSampler 60** for the first time, follow the steps described below. Characters in grey circles refer to the illustrations in the Quick Guide on page 2.

4.1. Preparation and inspection

Refer to the *Instructions for Use part 1 of 2 for inspection, preparation and for the use of the aScope™ 5 Broncho*.

Preparation for use of the BronchoSampler 60 with aScope™ 5 Broncho.

1. Carefully connect the sampler bridge with the aScope™ 5 Broncho, by mounting the sampler bridge on the aScope™ 5 Broncho suction connector **1**. Ensure a tight fit.
2. Push in the attachment lock to secure connection **2**.
3. Carefully connect the vacuum suction tubing to the suction connector according to the supplier's manual **3A**. If the vacuum suction tubing has a male connector, use the suction adapter to ensure fit **3B**.
4. Attach the sample container to the sampler bridge by joining the connection interfaces and pressing the sample container towards the sampler bridge. Ensure the sample container is clicked on **4**. Do not use preservatives in the sample container.
5. To guard against potentially infectious materials during the procedure, wear personal protective equipment.

4.2. Operating the BronchoSampler 60

1. If suction is deemed relevant before sampling, ensure that the flow switch is aligned vertically and pointing upwards **5**. Perform suction by pressing the suction button on the aScope™ 5 Broncho in accordance with *Instructions for Use part 1 of 2*.
2. To prepare for sampling of specimen, turn the flow switch counterclockwise towards the sample container, and align it horizontally **6**.
3. Instillation of fluids should be performed in accordance with *Instructions for Use part 1 of 2 for aScope™ 5 Broncho*.
4. Perform sampling by pressing the suction button on the aScope™ 5 Broncho. Ensure that the endoscope is held upright and level while sampling. Do not fill the sample container above the maximum of the volume indicator scale.
5. If suction is deemed relevant, turn the flow switch clockwise to align it vertically and pointing upwards, and press the suction button on the aScope™ 5 Broncho. When suction is complete, turn the flow switch counterclockwise towards the sample container, and align it horizontally.
6. Remove the sample container by pressing the flip top and pulling the sample container from the sampler bridge **7**. Ensure that the endoscope is held level and that the flip top is depressed during the removal of a sample container which holds fluid.
7. Close the sample container by pressing the sample container lid towards the sample container interface and engage the lid until it closes. Once the click-lock is engaged, do not re-open the lid **8**.

4.3. After use

1. If deemed relevant, detach the sampler bridge from the aScope™ 5 Broncho by disengaging the attachment lock and pulling the sampler bridge off the aScope™ 5 Broncho. Disengage suction by pulling the suction tube off the sampler bridge.
2. If deemed relevant, access the sample container by turning the sample container vial clockwise **9**. It is recommended to handle contaminated substances in accordance with local guidelines.
3. Transportation and handling of a used sample container must be performed in accordance with local guidelines for transportation and handling of hazardous material.

Duration of use

- The BronchoSampler 60 is suitable for up to 60 minutes of use during a procedure.

NOTE: Always follow local guidelines for transportation/storage conditions of a filled sample container.

Disposal

The BronchoSampler 60 is a single-use device. BronchoSampler 60 is considered infected after use and must be disposed of in accordance with local guidelines for the collection of infected medical devices.

5. Technical product specifications

5.1. Standards applied

The BronchoSampler 60 function conforms with:

- ISO 8600-1: Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements.
- EN 14254: In Vitro Diagnostic medical devices – Single-use receptacles for the collection of specimens, other than blood, from humans.

5.2. Specifications for BronchoSampler 60

Suction connector¹	
Suction tube with female interface	Ø 5.5 – 9.0 mm
Suction tube with male interface Applicable when suction adapter is used	Ø 6.0 – 8.0 mm
Sample container	
Sample container volume	60 ml
Storage	
Recommended storage temperature ²	10 – 25 °C (50 – 77 °F)
Relative humidity	10 – 85 %
Atmospheric pressure	50 – 106 kPa
Operating environment	
Temperature	10 – 40 °C (50 – 104 °F)
Relative humidity	30 – 85 %
Atmospheric pressure	80 – 106 kPa
Altitude	≤ 2000 m
Sterilisation	
Method of sterilisation	ETO

1. Please check for compatibility with suction tubing before use.
2. Storage under higher temperatures may impact shelf life.

6. Troubleshooting

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

Problem	Possible cause	Recommended action
Absent or reduced suction or sampling capability.	The sample container is not attached, or poor connection of the sample container.	Connect or re-connect the sample container to the sampler bridge.
	Sampler bridge may not be connected properly to the aScope™ 5 Broncho.	Re-connect the sampler bridge to aScope™ 5 Broncho and push in the attachment lock to secure the connection.
	The suction pump is not turned on or not connected.	Turn the pump on and check the suction line connection.
	Vacuum suction tubing is not connected properly to the suction connector or the suction adapter.	Ensure that the parts are properly connected. If suction is still absent or reduced change to another vacuum suction tubing.
	The rubber seal may have come off the connection interface.	Re-insert the rubber seal manually. However, if it is believed that the rubber seal may be in contact with an unclean surface, it may be necessary to replace the sampler bridge.
Unable to connect sample container, sampler bridge, and/or endoscope.	The attachment lock may be closed before attaching the sampler bridge to an endoscope.	Pull out the attachment lock before attaching sampler bridge to endoscope.
	The sample container lid may be closed before insertion.	Replace the sample container with the spare provided. Do not attempt to open the sample container lid once closed.
Tubing cannot be attached to Sampler bridge.	Incorrect configuration of tubing (male to the male suction connector).	The suction adapter can be used to allow male-to-male connections.

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



**UK
CA**
0086

Ambu Ltd

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

Ambu® and other trademarks are trademarks of Ambu A/S