

# INSTRUCTIONS FOR USE

## Ambu® SureSight™ Blade

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For use by individuals who have been trained and authorized to use video laryngoscopes.

For use in hospital environments.

For use with Ambu® SureSight™ Connect.

**Ambu SureSight Blade MAC #3**

**Ambu SureSight Blade MAC #4**

**Ambu SureSight Blade HYPER #3**

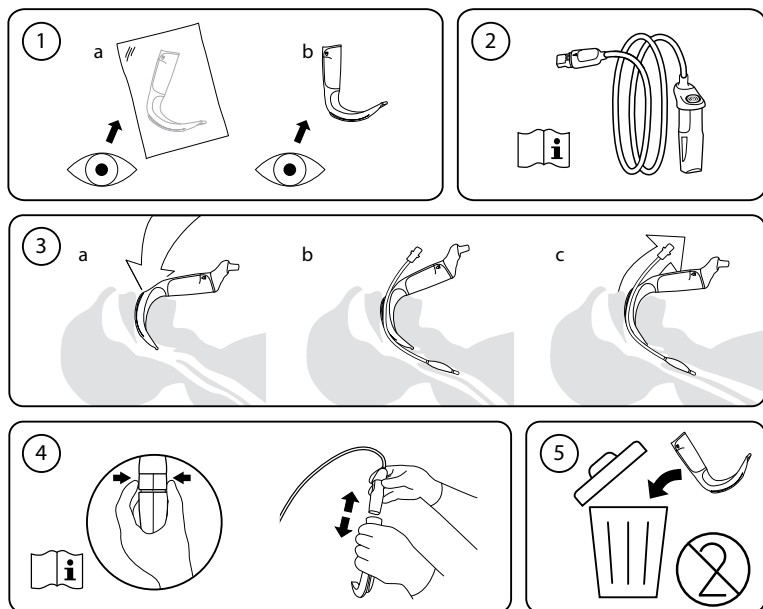
**Ambu SureSight Blade HYPER #3C**

**Ambu SureSight Blade HYPER #4**

# Ambu



## QUICK GUIDE



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## 1. Important information – Read before use

In this document the term *Blade* refers to Ambu® SureSight™ Blade, and *Video Laryngoscope* refers to the Ambu® SureSight™ Video Laryngoscope.

Read these instructions for use carefully before using Blade. These instructions describe the function, setup and precautions related to operating Blade. These instructions do not explain or discuss clinical procedures.

The operator must be trained in the use of clinical video laryngoscopy techniques before using Blade. The operator must also be familiar with the intended use, indications for use, warnings and cautions mentioned in these instructions for use.

There is no warranty on Blade.

Blade is a part of the Video Laryngoscope and cannot be used alone. These Instructions for use only cover Blade. The Video Laryngoscope refers to Blade used in combination with a compatible Ambu® SureSight™ device. If you need information on how to use other parts of the Video Laryngoscope, see the instructions for use for the device in question. Unless otherwise specified, Blade refers to all Blade variants.

These Instructions for use can be updated without further notice. Copies of the current version are available on request.

### 1.1. Intended use

Blade is a single-use blade intended for oral insertion and for guidance of endotracheal tubes. Blade is a part of the Video Laryngoscope which is intended to visualize and aid tracheal intubation procedures and visual examination of the upper airway.

#### 1.1.1. Intended patient population

Adults and pediatrics from 6 years of age due to the Blade sizes available.

#### 1.1.2. Intended use environment

Hospital settings.

### 1.2. Indications for use

The use of the SureSight Video Laryngoscope is indicated for:

- Patients with or without difficult airway anatomy who need tracheal intubation.
- Conditions where visual examination of the upper airway is needed.

### 1.3. Intended user

The Video Laryngoscope is intended to be used by individuals who have been trained in use of video laryngoscopes and who are authorized according to local medical regulations.

### 1.4. Contraindications

None known.

### 1.5. Clinical benefits

An indirect clinical benefit is derived from visualization and aid in endotracheal intubation procedures.

The endotracheal tube provides a secure airway for the patient.

## 1.6. Warnings and cautions

### WARNINGS

1. Prior to use, inspect that the light on Blade is activated, live image on the displaying unit is clear, and if applicable, that the battery level is sufficient. Do not use the device if any part of the inspection fails, as it may delay intubation or cause patient harm.
2. Do not reuse Blade as it is a single-use device. Reuse of Blade may cause infection.
3. The Video laryngoscope is intended to be used by individuals trained in use of Video Laryngoscopes and authorized according to local medical regulations. Incorrect use of the device could lead to potential adverse events.
4. Do not use Blade if the packaging is damaged, as the device may be contaminated.
5. Do not look directly at the light on Blade or shine it at the patients' eyes, as this may cause temporary flash blindness.
6. Do not use Blade if it is damaged. Using a damaged device may cause patient harm.
7. Only use Blade with compatible Ambu devices, as described in section 2.2. Failure may result in damage to the device or in patient/user injury.
8. Always check compatibility of endotracheal tube and a channeled Blade. Failure to do so could lead to damage of the endotracheal tube.
9. Avoid prolonged contact between the Blade and the mucosal membrane, as the surface of the device may get warm due to the heating caused by the light. Prolonged contact may cause mucosal injury.

### CAUTIONS

1. An extra Blade should be available for immediate use in case of device malfunction.
2. Do not expose the product to modifications, extreme temperatures or rough handling as this may cause malfunction of the device.

## 1.7. Undesirable side effects

Undesirable side effects in relation to the use of video laryngoscopes (not exhaustive): Mucosal injuries, edema, sore mouth/throat, inadvertent nerve stimulation or injury, dental trauma, dysphagia, esophageal intubation, emesis with concurrent aspiration.

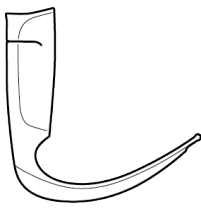
## 1.8. General notes

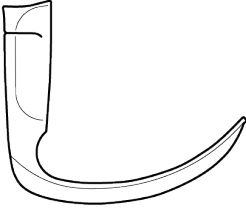


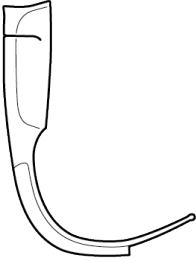
If, during the use of this device or as a result of its use, a serious incident occurs, report it to the manufacturer and to your national authority.

## 2. Device description

Blade is to be connected to a compatible SureSight device. Blade alone has no power source, and therefore no functioning electronics. For information about the compatible device, see the applicable Instructions for use.

### 2.1. Product variants

Ambu® SureSight™ Blade	Part numbers
MAC #3: 	390330000

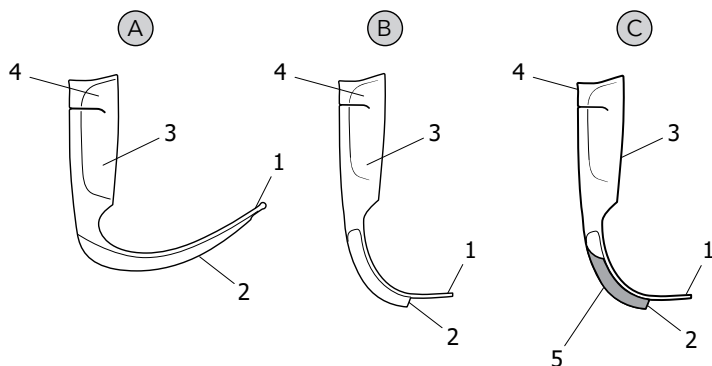
Ambu® SureSight™ Blade	Part numbers
<p>MAC #4:</p> 	<p>390340000</p>
<p>HYPHER #3:</p> 	<p>390230000</p>
<p>HYPHER #3C:</p> 	<p>390530000</p>
<p>HYPHER #4:</p> 	<p>390240000</p>

## 2.2. Product compatibility

SureSight devices
Ambu® SureSight™ Connect
Agents and lubricants
Water-based lubricants
Isotonic saline solution
Water
70 % ethanol
70 % isopropyl alcohol
Anti-fog agent
Gels and solutions
2 % lidocaine solution
2 % lidocaine gel
10 % lidocaine aerosol spray
Sevoflurane
Endotracheal tubes (ETT)
Blade HYPER C has been evaluated to be compatible with the following ETT inner diameter sizes:
<ul style="list-style-type: none"> <li>Blade HYPER #3C: ETT sizes 6.0 – 8.0 mm</li> </ul>
There is no guarantee that ETTs selected solely using this inner diameter size will be compatible. Compatibility of selected ETTs should be tested before the procedure.

## 2.3. Blade parts

Blade has been designed with the following functional components:



**Figure 1:** Blade comes in three different types: (A) MAC, (B) HYPER, and (C) HYPER C

No.	Part	Function
1	Blade	Tongue / Tip that is introduced in the airway. Different types and sizes are available
2	Camera and light	Camera and light for visualization
3	Handle	Functions as a handle and connecting interface to the compatible SureSight device
4	Release marks	Use these marks to release of Blade from the compatible SureSight device
5	Channel	Channel to help guide the endotracheal tube into place (only applicable for HYPER C)

### 3. Use of Blade

#### 3.1. Prepare and inspect Blade

1. Choose the size and type of Blade based on an individual patient evaluation.
2. Check the expiration date on the packaging label.
3. Inspect the Blade packaging for any damage. Do not use Blade if the packaging is damaged.
4. Unpack Blade.
5. Inspect Blade for any damage. A new Blade should be readily available so the procedure can continue in case a malfunction occurs.
6. Prepare and inspect the compatible SureSight device. To ensure safe and correct use of the device, read the compatible SureSight device's Instructions for use.
7. Attach Blade to the compatible SureSight device. An audible "click" indicates that it is correctly attached.
8. Point the end of the blade towards an object, e.g. the palm of your hand to verify that the light and live image are functioning as expected on the displaying unit. If there is no image, or if the image is blurred, see section 5 for the Troubleshooting section.
9. Perform the procedure.

#### 3.2. After use

1. Detach Blade from the compatible SureSight device by pinching the release marks.
2. Blade is contaminated after use. Dispose of it according to your local guidelines for disposal or collection of infected medical devices with electronic components.



## 4. Technical product specifications







	<b>Product specification</b> Applicable to all Blade variants
<b>Optical system</b>	
Field of view [°]	68 (±15 %)
Direction of view	Forward viewing
Depth of field [mm]	12 – 115
Illumination method	LED
Anti-fog technology	YES
Biocompatible	YES
<b>Storage and transportation condition</b>	
Transportation temperature [°C, (°F)]	-10 – 55 (14 – 131)
Storage temperature [°C, (°F)]	10 – 25 (50 – 77)
Transportation relative humidity [%]	10 – 95
Storage relative humidity [%]	10 – 85
Atmospheric pressure [kPa (psi)]	50 – 106 (7 – 15)
<b>Operating environment</b>	
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa (psi)]	80 – 106 (11 – 15)
Altitude [m]	≤ 2000
<b>Primary packaging material</b>	
Back (white)	High Density Polyethylene (HDPE)
Front (transparent)	Low Density Polyethylene (LDPE)
Label	Low Density Polyethylene (LDPE)

## 5. Troubleshooting

If you experience any problems with the system or product, use this troubleshooting guide to identify the cause and correct the error.

Problem	Possible cause	Recommended action
No live image on the compatible Ambu displaying unit or the image shown is frozen.	Compatible Ambu displaying unit is turned off.	Turn on compatible Ambu displaying unit.
	No blade is connected.	Connect Blade to the SureSight Connect.
	Failure in the connection between Blade and SureSight Connect.	Dismount and re-attach Blade.
	Blade is damaged.	Replace Blade with a new one.
	Failure in the connection between SureSight Connect and the compatible Ambu displaying unit.	Unplug and reconnect SureSight Connect. Make sure SureSight Connect is plugged into the grey connector of the compatible Ambu displaying unit.
	The compatible Ambu displaying unit and SureSight Connect have communication problems.	Restart the compatible Ambu displaying unit. See the Instructions for use for the compatible Ambu displaying unit.
	A recorded image is shown or a menu box is blocking the live image.	Return to live image by pressing the Live View tab. See the Instructions for use for the compatible Ambu displaying unit.
Low quality of the live image.	The image cannot be seen clearly upon inspection prior to the procedure.	Wipe the camera at the tip of Blade.
	Blood, saliva etc. on the camera.	Remove Blade from the patient and wipe the camera at the tip of the blade.
	Blade is damaged.	Replace with a new Blade.
	Image settings on the compatible Ambu displaying unit are not correct.	Adjust the image settings (colors, contrast, sharpness, brightness) on the compatible Ambu displaying unit to achieve desired result. See the Instructions for use for the compatible Ambu displaying unit.

## 6. Symbol description

Symbols for the SureSight Blade	Description	Symbols for the SureSight Blade	Description
	Global Trade Item number		This device is for single use only
	Electrical Safety Type BF Applied part		Do not use the device after the date stated on the packaging
	UL Recognized Component Mark for Canada and the United States		UK Conformity Assessed. Indicates that the product is in compliance with UK legislation for medical devices

A full list of symbol explanations can also be found on [ambu.com/symbol-explanation](https://www.ambu.com/symbol-explanation).

# Ambu



Ambu A/S  
Baltorpbakken 13  
2750 Ballerup  
Denmark  
T +45 72 25 20 00  
[ambu.com](http://ambu.com)



Ambu Ltd  
First Floor, Incubator 2  
Alconbury Weald Enterprise Campus  
Alconbury Weald  
Huntingdon PE28 4XA  
United Kingdom  
[www.ambu.co.uk](http://www.ambu.co.uk)

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