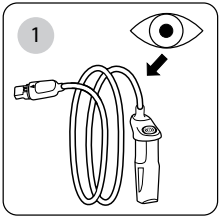
INSTRUCTIONS FOR USE

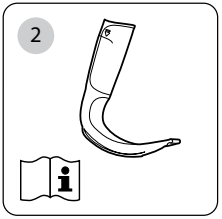
Ambu® SureSight™ Connect

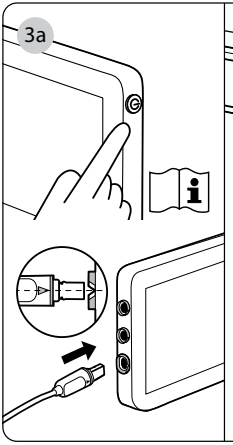
For use by individuals who have been trained and authorized to use video laryngoscopes.
For use in hospital environments.
For use with Ambu® displaying units.

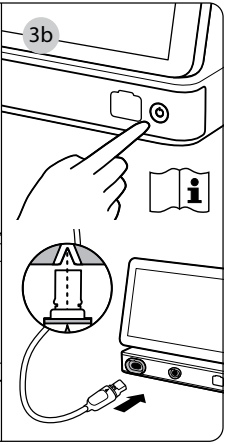
Ambu

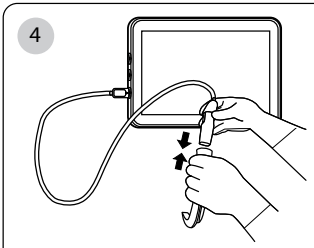
QUICK GUIDE

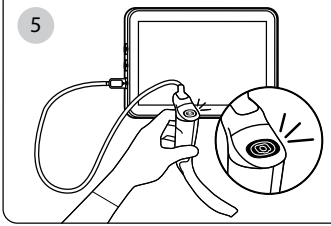


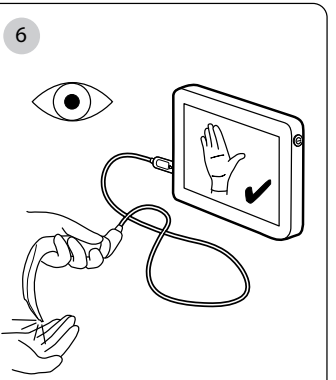


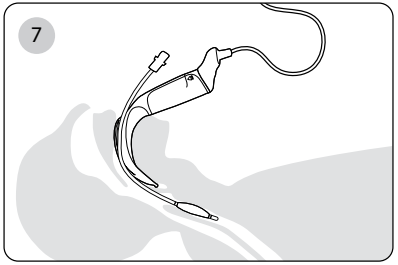








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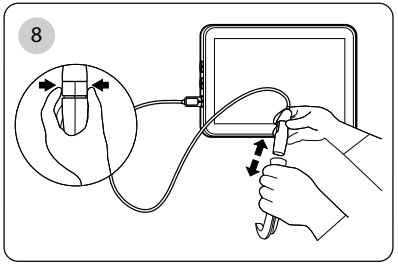
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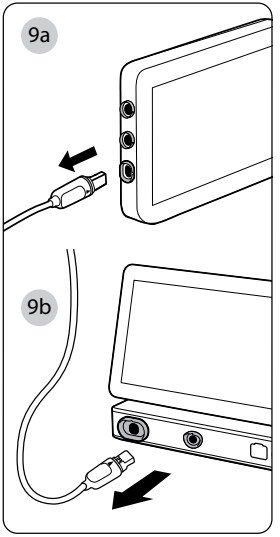
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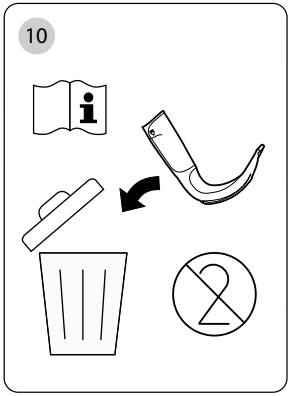
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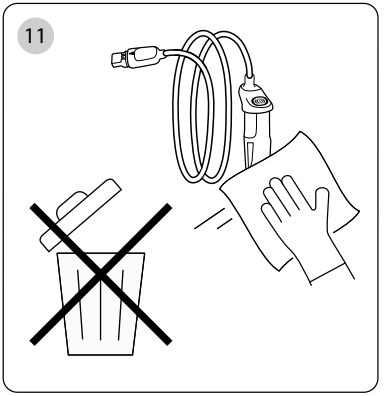
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1. Important information – Read before use

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

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

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

Connect is a part of the Video Laryngoscope and cannot be used alone. In this document *Connect* refers to instructions that apply to Connect only, and *Video Laryngoscope* refers to information relevant to the system. The Video Laryngoscope consists of Connect, a compatible Ambu displaying unit and a Blade. Instructions for use for the Ambu displaying unit and Blade are provided separately with the respective devices. These Instructions for use can be updated without further notice. Copies of the current version are available on request.

1.1. Intended use

Connect is a reusable adapter intended to convert and transmit the live video image from the Blade camera module to the compatible Ambu displaying unit, enabling the user to visualize the upper airway.

Connect 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

See the "Intended patient population" section in the SureSight Blade Instructions for use for more information.

1.1.2. Intended use environment

Hospital settings.

1.2. Indications for use

The use of the 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 the use of video laryngoscopes and who are authorized according to local medical regulations.

1.4. Contraindications

No contraindications identified.

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. Do not use Connect if the cleaning and disinfection is not performed as instructed in section 3.4. Insufficient cleaning and disinfection may cause risk of infection.
2. 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.
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. Prior to use, set up the Video Laryngoscope according to the instructions in section 3.
5. Only use Connect with compatible Ambu devices, as described in section 2.2. Failure may result in damage to the device or in patient/user injury.
6. Ensure the Blade connector on Connect is dry before using it. Failure may cause the device to malfunction or cause electric shock.
7. Ensure Connect is unplugged from the displaying unit before the cleaning and disinfection. Failure may cause the device to malfunction or cause electric shock.

CAUTIONS

1. Do not clean and disinfect Connect using other methods than instructed in section 3.4, as this may cause the device to malfunction.
2. An extra Blade should be available for immediate use in case of device malfunction.
3. Do not expose the product to modifications, extreme temperatures or rough handling e.g. excessive force or load, drop, shock, violent vibrations, 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.

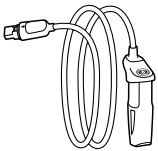
1.8. General notes

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

2. Device description

Connect is designed to be used in combination with Blade and a compatible Ambu displaying unit.

2.1. Device parts

Ambu® SureSight™ Connect	Part number
	390510000

2.2. Product compatibility

The Connect is designed to be used with:

Displaying units
Ambu® aView™ 2 Advance (Software version v.2.4.0 or newer)
Ambu® aBox™ 2 (Software version v.2.4.0 or newer)
Video laryngoscope blades
Ambu® SureSight™ Blade
Agents and lubricants
Water-based lubricants
Isotonic saline solution
70 % ethanol
70 % isopropyl alcohol
Gels and solutions
Disodium tetraborate
Subtilisin
Isopropyl alcohol
Quaternary ammonium compounds
n-Alkyl Dimethyl Benzyl Ammonium Chloride

2.3. Connect parts

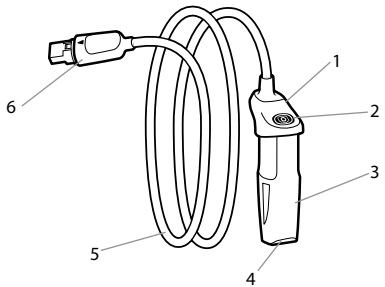


Figure 1: SureSight Connect

No.	Part	Function
1	Top	Top part of the handle, visible when connected to Blade and includes the image capture button.
2	Image capture button	Button with built-in light to capture image and record live video: – Short press (<1s) button to capture an image. – Long press (>1s) button to start/stop a video recording.
3	Blade interface	Functions as a handle and connecting interface to the Blade.
4	Blade connector	Connector interface for the Blade.
5	Cable	The cable and the displaying unit connector supply the Connect with power and transmit the image to a compatible Ambu displaying unit.
6	Displaying unit connector	Connects the Connect with a compatible Ambu displaying unit. Make sure to match the color (gray) and arrow with the gray connection port.

3. Use of Connect

3.1. Preparation and inspection of Connect

1. Before using Connect, inspect the device for any damage. Do not use the device if it is damaged.
2. Turn on the compatible Ambu displaying unit. See section 2.2 for compatible Ambu displaying units. To ensure correct and safe use of the device read the Ambu displaying unit's Instructions for use.
3. Plug in Connect to the compatible Ambu displaying unit.
4. The device is ready for use when:
   – The Ambu displaying unit shows an animation of Connect.
   – The image capture button on Connect shows a blinking light.
5. Prepare and inspect Blade. To ensure correct and safe use of the device read the Blade's Instructions for use.
6. Attach Blade to the device. Blade is attached to the device when you hear a "click", and the image capture button shows a permanent light.
7. Point the end of 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 Ambu displaying unit. If there is no image, or if the image is blurred, see the Troubleshooting section.
8. Perform the procedure.

Note: A live image is displayed on the compatible Ambu displaying unit within 5 seconds after connecting the Video Laryngoscope and turning on the Ambu displaying unit. Graphical user interface, image processing, and image capture and recording features are not available until the full startup of the Ambu displaying unit is complete.

3.2. Image and video capture

Capture images during the procedure:
Shortly press the image capture button on Connect (<1 second).

Record videos during the procedure:
Start a video recording by a long press on the image capture button (>1 second). Stop the video recording by another long press. You can capture an image while recording videos. See instructions for capturing images.

Images and videos are stored on the compatible Ambu displaying unit. If you need to transfer images and videos, see the instructions for use for the Ambu displaying unit you are using.

3.3. After use

1. Detach Blade by pressing the release marks on the sides of Blade.
2. Unplug Connect from the Ambu displaying unit.
3. Dispose of Blade. Read Blade's Instructions for use.
4. Clean and disinfect Connect according to the instructions and store the device.

3.4. Clean and disinfect Connect

Connect is a reusable medical device. According to the Spaulding classification, Connect is categorized as a non-critical device.
Connect should be cleaned and disinfected after each use, following one of the two procedures described below. Any deviation from these instructions and related potential consequences shall be properly evaluated for effectiveness by the person responsible for cleaning and disinfection to ensure that Connect continues to fulfill its intended purpose.
Cleaning/disinfection procedures are recommended to be carried out as soon as possible after each use.

Limitations: Cleaning and disinfection wipes shall be moist but not dripping. Refrain from using wipes containing chlorine as chlorine may damage the surface of Connect over time. Connect is not compatible with ultrasonic or automatic cleaning procedures. Connect shall not be immersed or submerged. Connect shall be unplugged before cleaning and disinfection.

Procedure 1 – Enzymatic detergent cleaning and Super Sani-Cloth® or diluted isopropyl alcohol disinfection

Cleaning

Use an enzymatic alkaline detergent, e.g., Cidezyme™ from ASP, prepared in accordance with the manufacturer's instructions. Clean according to the following instructions:

1. Soak clean lint-free gauze in the enzymatic alkaline detergent and make sure that the gauze is moist and not dripping.
2. Wipe all surfaces of Connect until all visible soil is removed. The gauze must remain moist.
3. Soak clean lint-free gauze in distilled water and make sure that the gauze is moist but not dripping.
4. Wipe all surfaces of Connect to remove any detergent residue.

Disinfection

Use Super Sani-Cloth® wipe from PDI or a 70 % Isopropyl Alcohol / 30 % water wipe according to the following instructions:

1. Wipe all surfaces of Connect for 2 minutes.
2. Take a new wipe and repeat step 1, and then proceed to step 3.
3. Soak sterile gauze in distilled water and make sure that the gauze is moist but not dripping.
4. Wipe all surfaces of Connect to remove any disinfectant residue.
5. Let Connect air dry.

Procedure 2 – Cleaning and disinfection using Clinell® Universal Range wipes

Cleaning and disinfection

Use Clinell® Universal Range wipe from GAMA Healthcare. Clean and disinfect according to the following instructions:

1. To clean, wipe all surfaces of Connect until all visible soil is removed. The wipe must remain moist.
2. To disinfect, take a new wipe and wipe all surfaces of Connect for 2 minutes. The wipe must remain moist.
3. Take a new wipe and repeat step 2, and then proceed to step 4.
4. Soak sterile gauze in distilled water and make sure that the gauze is moist but not dripping.
5. Wipe all surfaces of Connect to remove any residue.
6. Let Connect air dry.

Note: The specified cleaning and disinfection procedures show compliance with the AAMI TIR12:2020 and AANSI AAMI ST98:2022 guidelines. Other cleaning and disinfection solutions have not been verified to prove efficacy. If other cleaning and disinfection solutions are used, contact your local Ambu representative.

3.5. Maintenance and disposal

Maintenance

Connect must be cleaned and disinfected as indicated in section 3.4. No other maintenance or calibration activities are required.

Disposal

At the end of product life, clean and disinfect the device. Dispose of the device in accordance with your local guidelines.

4. Technical product specifications

Electrical system	
Power supply	Power is supplied via connection to a compatible Ambu displaying unit. See section 2.2.
User interface	1 image capture and video recording button
Storage and transportation conditions	
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)
Operating environment	
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa, (psi)]	80 – 106 (11 – 15)
Altitude [m]	≤ 2000

General	
Use (lifetime)	Reusable (3 years)
IP Classification (SureSight Video Laryngoscope)	IP34
Biocompatible	Yes

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 the compatible Ambu displaying unit.
	No Blade is connected.	Attach Blade to Connect.
	Failure in the connection between Blade and Connect.	Detach and reattach Blade.
	Blade is damaged.	Replace Blade with a new one.
	Failure in the connection between Connect and the compatible Ambu displaying unit.	Unplug and plug in Connect.
		Make sure Connect is plugged into the gray connection port of the compatible Ambu displaying unit.
	The compatible Ambu displaying unit and 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.

Problem	Possible cause	Recommended action
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 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. Warranty and replacement

6.1. Limited warranty

Ambu warrants that the device (as defined in section 2.1) will conform to the specifications described by Ambu and be free from defects in material and workmanship for a period of two (2) years from the date of invoice.

Under this limited warranty, Ambu will be responsible only for either supplying authorized spare parts or replacement of the device, as Ambu may decide in its sole discretion.

In case of replacement of spare parts, the customer is obliged to provide reasonable assistance to Ambu, including, where relevant, by customer's technicians pursuant to instruction from Ambu.

Unless otherwise expressly agreed in writing, this warranty is the only warranty which applies to the device, and Ambu expressly disclaims any other warranty, expressed or implied, including any warranty of merchantability or fitness for a particular purpose.

The warranty applies only if it can be established that:
a) The device has not been disassembled, repaired, tampered with, altered, changed, or modified by persons other than technical personnel and

b) The defects or damage to the device does not result from abuse, incorrect use, negligence, improper storage, inadequate maintenance or use of unauthorized accessories, spare parts, consumables, or supplies.

In no event shall Ambu be liable for any indirect, incidental, consequential or special damages of any kind (including without limitation loss of profits or loss of use), whether or not Ambu shall be or should be aware of the possibility of such potential loss or damage.

The warranty applies only to the original customer of Ambu and cannot be assigned or otherwise transferred.

In order to avail itself of this limited warranty, if requested by Ambu, the customer must return the device to Ambu (at its own expense and risk of shipment). In compliance with applicable regulations, any device that has come into contact with potentially infectious material must be decontaminated before being returned to Ambu under this limited warranty (pursuant to the cleaning and disinfection procedures as specified in these Instructions for use. Ambu is entitled to reject a device which has not been duly decontaminated.

7. Symbol description

Symbols	Description	Symbols	Description
c UL us	UL Recognized Component Mark for Canada and the United States	**IP34**	Ingress Protection classification
UK CA	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.

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