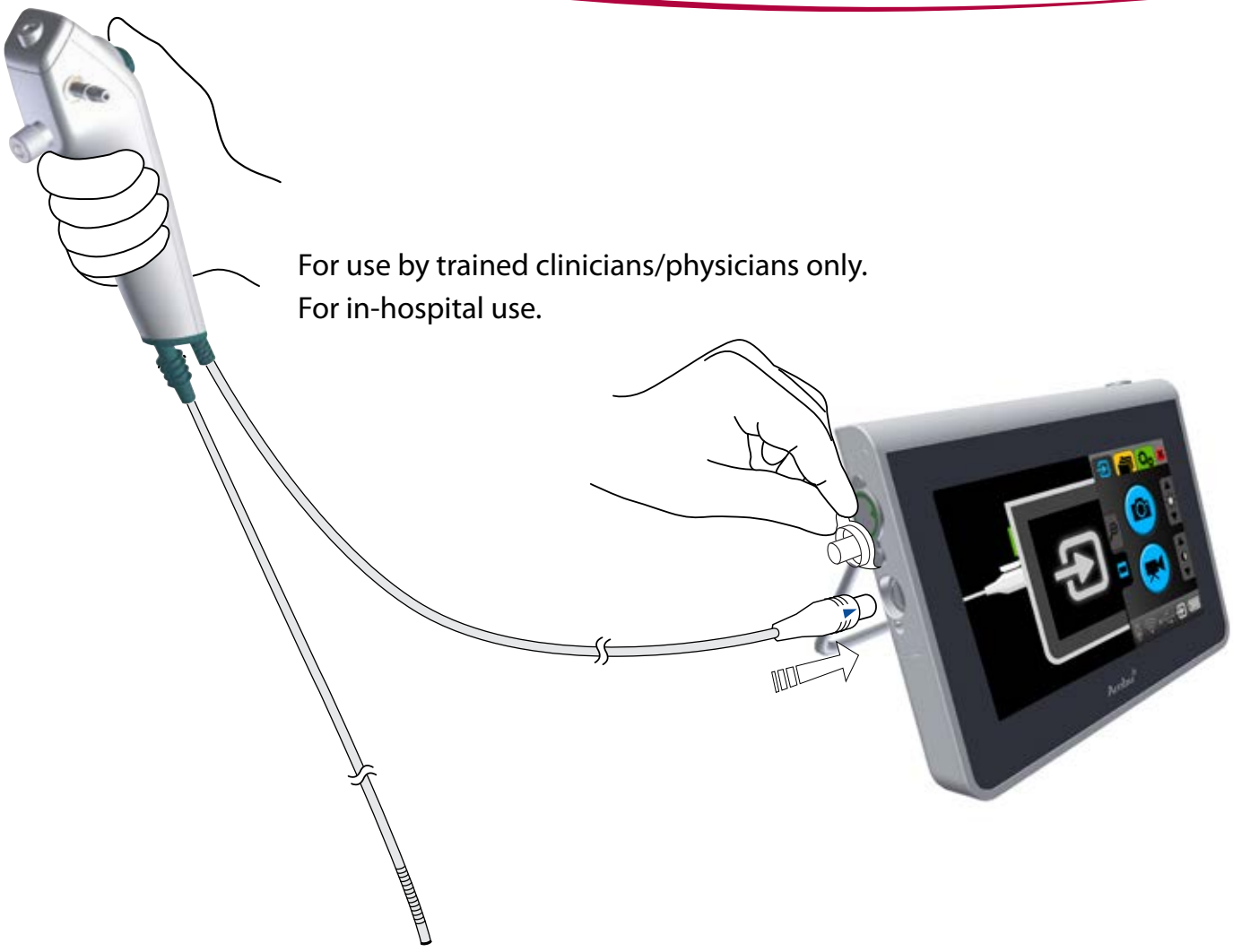
Instructions for use

Ambu® aScope™ 3 5.0/2.2 & aScope™ 3 Slim 3.8/1.2

Ambu® aView™



For use by trained clinicians/physicians only.
For in-hospital use.

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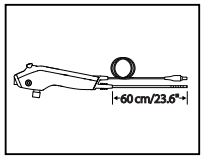
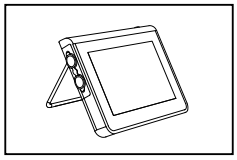
Ambu® aScope™ 3



Pat. Pending

Ambu® aView™



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1. Important information – read before use

NOTE

Read these safety instructions carefully before using the aScope 3 system. The Instructions for use may be updated without further notice. Copies of the current version are available upon request.

WARNING ⚠

- aScope 3 is a single-use device and must be handled in a manner consistent with accepted medical practice for such devices in order to avoid contamination of the aScope 3 prior to insertion.
- aScope 3 images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics.

1.1. Instructions

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 aScope 3 system. Before initial use of the aScope 3 system, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings, cautions, notes, indications and contraindications mentioned in these instructions.

1.2. Intended use

The aScope 3 endoscopes have been designed to be used with the aView monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

1.3. Indications for use

The aScope 3 system is for use in a hospital environment.

The aScope 3 is a single-use device designed for use in adults and children. It has been clinically evaluated for the following minimum endotracheal tubes (ETT) and double lumen tubes (DLT) sizes:

	Minimum ETT inner diameter	Minimum DLT size
aScope 3 Slim 3.8/1.2	5.0mm	37Fr
aScope 3 5.0/2.2	6.0mm	41Fr

Endoscopic accessories designed for a minimum working channel width up to 1,2 mm can be used with the aScope 3 Slim 3.8/1.2 .Endoscopic accessories designed for a minimum working channel width1 up to 2.0 mm can be used with the aScope 3 5.0/2.2.

There is no guarantee that instruments selected solely using this minimum instrument channel width will be compatible in combination.

WARNING ⚠

Do not use active endoscopic accessories such as laser probes and electrosurgical equipment in conjunction with the aScope 3 system, as this may result in patient injury or damage to aScope 3 system.

1.4. Warnings, Cautions and Notes

Throughout these instructions, appropriate warnings, cautions and notes are given describing potential safety hazards associated with the use of the aScope 3 system. The information given in these instructions serves only to instruct in the correct handling of the system.

Throughout these instructions, the following definitions are used:

WARNING ⚠

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the aScope 3 system.

CAUTION

Alerts the user to the possibility of a problem with the aScope 3 system associated with its use or misuse. Such problems include aScope 3 system malfunction, aScope 3 system failure, damage to the aScope 3 system or damage to other property.

NOTE

Advises owner/operator about important information on the use of this equipment.

GENERAL WARNINGS ⚠

- Do not use the aScope 3 system if it is damaged in any way.
- Perform a functional check before using the aScope 3 system (see section 4). Do not use the aScope 3 system if any part of the functional check fails.
- Do not attempt to clean and reuse the aScope 3 on another patient as it is a single-use device.
- The aScope 3 system is not to be used when delivering highly flammable anaesthetic gases to the patient. This could potentially cause patient injury.
- The aScope 3 system is neither MRI safe nor MRI compatible.
- Do not use the aScope 3 system during defibrillation.
- When handling the patient do not simultaneously touch the aView power socket or docking connector.
- Only to be used by skilled physicians trained in clinical endoscopic techniques and procedures.
- Excessive force should never be used when operating aScope 3.
- Patients should be adequately monitored at all times during use.
- Always watch the live endoscopic image on the aView when advancing or withdrawing the scope 3, operating the bending section or suctioning. Failure to do so may harm the patient.
- The aScope 3 system may cause interference or disrupt equipment operations nearby. It may be necessary to adopt procedures for mitigation, such as reorientation or relocation of the equipment or shielding of the room in which it is used.

GENERAL CAUTION

- Be careful not to damage the insertion cord or distal tip when using sharp devices such as needles in combination with the aScope 3.
- Be careful when handling the distal tip of the insertion cord and do not allow it to strike other objects, as this may result in damage to the equipment. The lens surface of the distal tip is fragile and visual distortion may occur.
- Do not exert excessive force on the bending section as this may result in damage to the equipment. Examples of inappropriate handling of the bending section include:
    - Manual twisting.
    - Operating it inside an ETT or in any other case where resistance is felt.
    - Inserting it into a preshaped tube or a tracheostomy tube with the bending direction not aligned with the curve of the tube.
- US federal law restricts these devices for sale only by, or on the order of, a physician.
- Keep the aScope 3 handle and the aView dry during preparation, use and storage.
- The batteries in aView are not changeable and must only be removed upon disposal.
- Portable electronic equipment may affect the normal function of the aScope 3 system

GENERAL NOTES

Have a suitable backup system readily available for immediate use so the procedure can be continued if a malfunction should occur.

Ambu is not responsible for any damage to the system or patient resulting from incorrect use.

2. System Parts

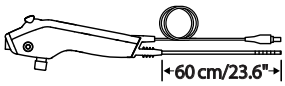
CAUTION

The aScope 3 system consists of the parts described in section 2. They may only be replaced by Ambu authorized parts. Failure to comply with this may reduce safety and efficiency.

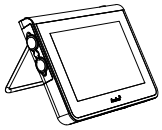
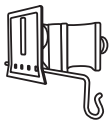
2.1. System Parts

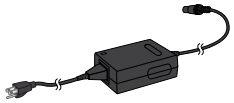
Before you install and use the system please ensure that the following items are available:

Ambu® aScope™ 3 – Single use device:

Ambu® aScope™ 3	Part numbers:	Instructions for use	Part numbers:
	403001000 aScope 3 5.0/2.2 402001000 aScope 3 Slim 3.8/1.2		492403000

Ambu® aView™ – Reusable device:

Ambu® aView™	Part numbers:	Bracket (e.g. for attaching the aView to an I.V. pole)	Part numbers:
	405001000		401000711

Power supplies		Part numbers:
	aView power supply manufacturer: FSP Group Inc. aView power supply part number: FSP030-REAM	 405000700

2.2. Description of the aScope 3 system

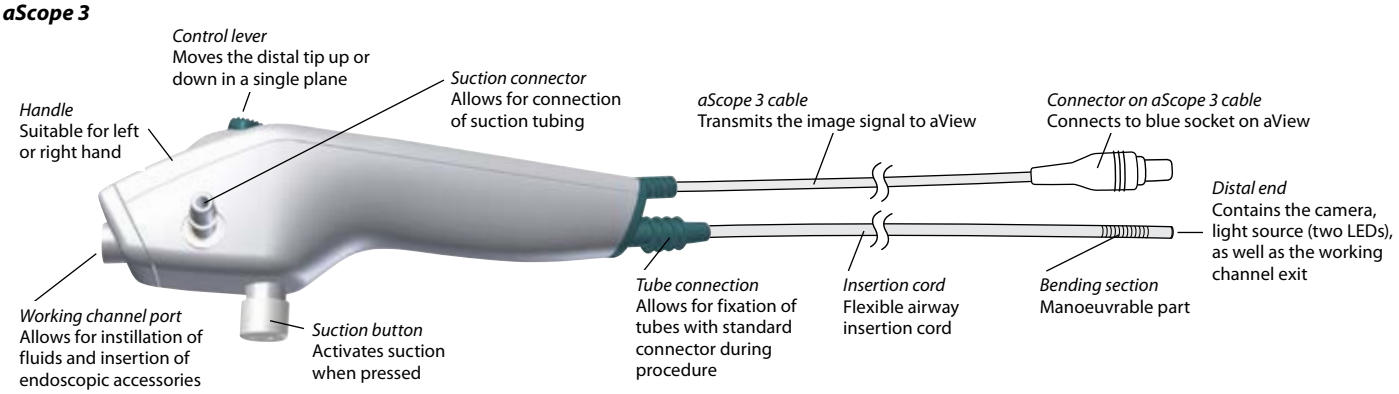
The aScope 3 system consists of the aScope 3 and the aView. To avoid risk of cross-contamination the aScope 3 is a sterile single use device.
The aView is reusable.

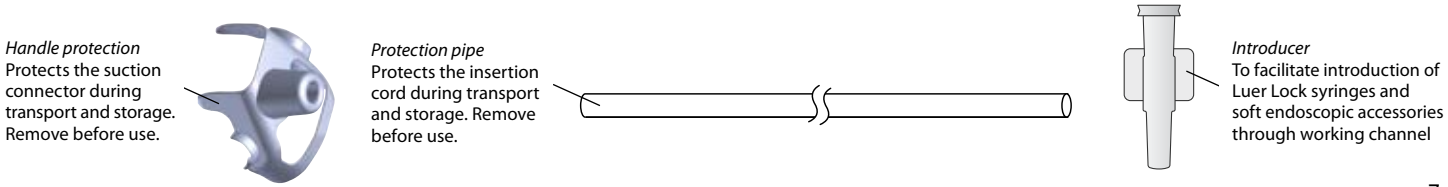
There are 2 different variants of the aScope 3: aScope 3 5.0/2.2 and aScope 3 Slim 3.8/1.2

Product Name		Differentiation
aScope 3 5.0/2.2		OD min 5.0 mm max 5.4 mm ID min 2.0 mm max 2.2 mm Green control lever and tube connection
aScope 3 Slim 3.8/1.2		OD min 3.8 mm max 4.2 mm ID min 1.2 mm max 1.2 mm Grey control lever and tube connection

Unless specified otherwise, the text relates to both products. In this document the term "aScope 3" always refers to both variants. If one of the variants is referred to specifically, the terms "aScope 3 5.0/2.2" or aScope 3 Slim 3.8/1.2" is used respectively.

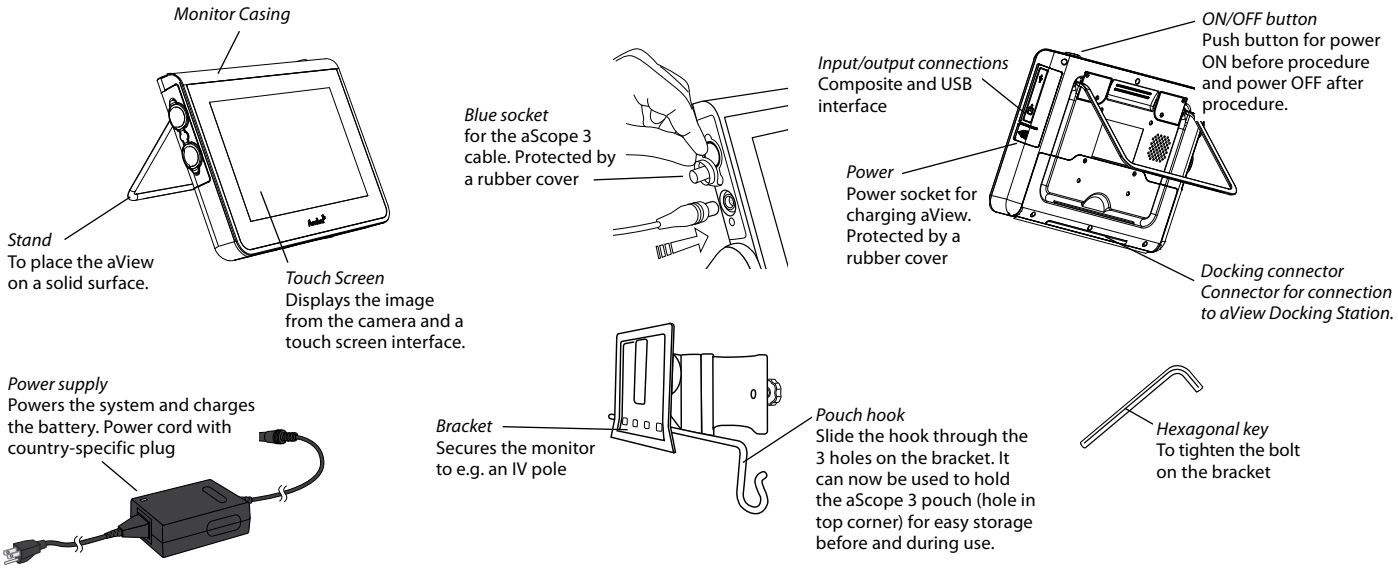
aScope 3



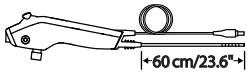
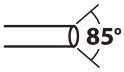
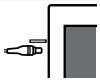


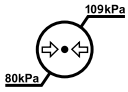
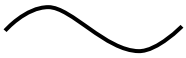
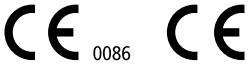
aView

The aView displays the video image from the aScope 3. During start up, aView powers up and configures the aScope 3. If the aView battery icon on the screen changes from fully charged to low battery (red battery) within 30 minutes, aView must be replaced.



2.3 Explanation of symbols used

Symbols for the aScope 3 devices	Indication
	Working length of the aScope 3 insertion cord
 Max OD	Maximum insertion portion width (Maximum outer diameter)
 Min ID	Minimum working channel width (Minimum inner diameter)
	Field of view
	Do not use if the product sterilisation barrier or its packaging is damaged
	The product does not contain natural rubber latex
	Connection for the aScope 3 devices
	Electrical Safety Type BF Applied Part.
	Use By, followed by YYYY-MM
STERILE EO	Sterile Product, Sterilisation by ETO.
	Single use product, do not reuse

Symbols for the aView	Indication
	Lights up when visualization device is connected. The icon colour will match the colour of the interface used.
 Max. battery status of the aView  Min. battery status of the aView  Fully charged battery still connected to charger	The icon remains white until one block is left, after which it turns red. When remaining battery capacity is 10% the red battery icon starts flashing
 Battery is charging  Battery current capacity  Battery damaged	Charging is shown with blocks flashing Current capacity is shown with non-flashing blocks
	On/Off button for aView. The button will light up green when on and not charging and orange when charging
	Humidity limitation: relative humidity between 30 and 85% in operating environment
	Atmospheric pressure limitation: between 80 and 109 kPa in operating environment
	Connection to external monitor
	Direct current
	Alternating current
	Symbol of Class II equipment.
IP30	Protection against solid objects
	Waste Bin symbol, indicating that waste must be collected according to local regulation and collection schemes for disposal of batteries. Only applicable for the battery inside the aView
	Waste Bin symbol, indicating that waste must be collected according to local regulation and collection schemes for disposal of electronic and electrical waste (WEEE). Only applicable for the aView
Li-ion	Battery type Lithium ion. Only applicable for the battery inside the aView
	Re-chargeable battery. Only applicable for the battery inside the aView
	Tested to comply with FCC Standards - Medical Equipment
Symbols covering both aScope 3 and aView	**Indication**
	Company Address
	Only for indoor use
	CE mark. The product complies with the EU Council directive concerning Medical Devices 93/42/EEC
	Reference Number

	Lot Number, Batch Code
	Serial Number
	Warning
	Consult Instruction for use
	Year of Manufacture, followed by YYYY

3. aScope 3 System Usage

NOTE

Have a suitable backup system readily available for immediate use so the procedure can be continued if a malfunction should occur.

3.1. Preparation and Inspection

WARNING ⚠

Do not use the aScope 3 system if it is damaged in any way or if any part of the functional check described below fails.

CAUTION

The aScope 3 system consists of the parts described in section 2. They may only be replaced by Ambu authorised parts. Failure to comply with this may reduce safety and efficiency.

Visual inspection of the aScope 3

1. Check that the pouch seal is intact.

WARNING ⚠

- Do not use aScope 3 if the product sterilisation barrier or its packaging is damaged.
- Do not use a knife or other sharp instrument to open the pouch or cardboard box.

2. Make sure to remove the protective elements from the handle and from the insertion cord.
3. Check that there are no impurities on the product.
4. Check that there is no evidence of shipping damage or other damage such as rough surfaces, sharp edges or protrusions which may harm the patient.

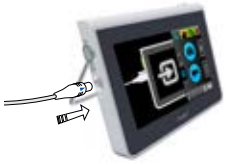
Visual inspection and preparation of the aView

CAUTION

- Pay attention to the battery symbol indicator on the aView monitor. Recharge aView when the battery level is low (see section 7.1).
- It is recommended that aView is recharged before every procedure and that a charger be readily available during use.
- Place or hang the aView display on a stable support while in use. Dropping aView could damage it.
- Position the power cord where it is unlikely to be stepped on. Do not place any objects on the power cord.
- If the aScope 3 system is used adjacent to or stacked with other equipment, observe and verify normal operation of the aScope 3 system prior to using it. Consult the tables in Appendix 1 for guidance in placing the aScope 3 system.

1. Check for any damage to the aView cable and power supply (free from wear and tear).
2. Closely examine the aView for any damage.
3. Switch the aView on by pressing the on/off button.
4. Check the battery indicator on the aView. If the time remaining is not sufficient for the procedure – charge the aView.
5. Be sure the power supply is present and working at any time.
6. It is recommended to locate the nearest wall socket before start of the procedure.
7. For instructions on how to use the aView with the mounting bracket, please refer to chapter 7.

Inspection of the Image



1. Connect aScope 3 to the aView by plugging the white aScope™ 3 connector with blue arrow into the corresponding blue female connector on the aView.

2. Verify that a live video image appears on the screen.
3. Point the distal end of aScope 3 towards an object, e.g. the palm of your hand.
4. Adjust the image preferences on the aView if necessary – please refer to chapter 7 for details.
5. If the object cannot be seen clearly, wipe the lens at the distal end using a clean cloth.

Preparation of aScope 3

1. Carefully slide the bending control lever forwards and backwards in each direction until it stops. Confirm that the bending section functions smoothly and correctly.
2. Slide the bending lever slowly to its neutral position. Confirm that the bending section returns smoothly to a neutral position.
3. Using a syringe insert 2ml of sterile water into the working channel port (if Luer Lock syringe use the enclosed introducer). Depress the plunger, ensure there are no leaks, and that water is emitted from the distal end.
4. If it is anticipated that suction will be required during the procedure, prepare the suction equipment according to the supplier's manual. Connect the suctioning tube to the suction connector and press the suction button to check that suction is applied.
5. If applicable, verify that endoscopic accessory of appropriate size can be passed through the working channel without resistance. The enclosed introducer can be used to facilitate the insertion of soft accessories such as microbiology brushes.

3.2. Operating the aScope 3

WARNING ⚠

- Excessive force should never be used when operating aScope 3.
- If any malfunction should occur during the endoscopic procedure, stop the procedure immediately, put the distal tip in its neutral and non-angled position and slowly withdraw the aScope 3 without touching the bending lever.
- Always observe the live endoscopic image while withdrawing the aScope 3.
- If needed remove secretion or blood from the airway before and during the procedure. The suction function of any appropriate suction device can be used for this purpose.
- The temperature of the distal end of the endoscope may reach up to 45C (113F) due to heating of the LEDs. Long, sustained contact with the mucosal membrane may cause mucosal injury. Avoid long periods of contact between the tip of the device and the mucosal membrane.

Holding the aScope 3

The handle of the aScope 3 can be held in either hand. Use the thumb to move the control lever and the index finger to operate the suction button. The hand that is not holding the aScope 3 can be used to advance the insertion cord into the patient's mouth or nose.

Manipulating the tip of the aScope 3

The control lever is used to flex and extend the tip of the aScope 3 in the vertical plan. Moving the control lever downward will make the tip bend anteriorly (flexion). Moving it upward will make the tip bend posteriorly (extension).

The insertion cord should be held as straight as possible at all times in order to secure an optimal tip bending angle.

CAUTION

Do not exert excessive force on the bending section as this may result in damage to the equipment. Examples of inappropriate handling of the bending section include:
- Manual twisting
- Operating it inside an ETT or in any other case where resistance is felt
- Inserting it into a preshaped tube or a tracheostomy tube with the bending direction not aligned with the curve of the tube

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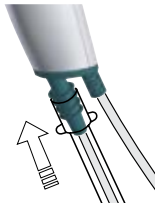


Tube connection

The tube connection can be used to mount ETT and DLT with an ISO connector during intubation.

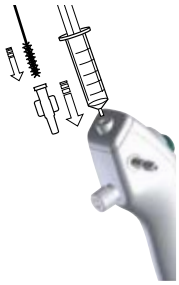
Insertion of the aScope 3

CAUTION

When inserting the aScope 3 orally, it is recommended to use a mouthpiece to protect the aScope 3 from being damaged.

Lubricate the insertion cord with a medical grade lubricant to ensure the lowest possible friction when the aScope 3 is inserted into the patient.

If the camera image of the aScope 3 becomes unclear the tip can be cleaned by gently rubbing the tip against the mucosal wall or remove the aScope 3 and clean the tip with a piece of sterile gauze or a hospital disinfection wipe. Continue the procedure until a satisfactory image is obtained.



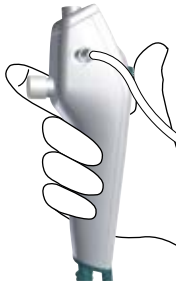
Instillation of fluids

Fluids can be instilled through the working channel by inserting a syringe into the working channel port at the top of the aScope 3. When using a Luer Lock syringe, use the included introducer.

Insert the syringe completely into the working channel port or the introducer before instilling fluid. Failure to do so may result in the fluid spilling from the working channel port.

Press the plunger to instill fluid.
Make sure you do not apply suction during this process, as this will direct the instilled fluids into the suction collection system.

To ensure that all fluid has left the channel, flush the channel with 2ml of air.



Aspiration

When a suction system is connected to the suction connector, suction can be applied by pressing the suction button with the index finger.

WARNING ⚠

- Always make sure that any tube connected to the suction connector is connected to a suction device.
- Apply a vacuum of 85 kPa (638 mmHg) or less when suctioning. Applying too large a vacuum may make it difficult to terminate suctioning.

CAUTION

Secure the tubing properly on the suction connector before suction is applied.

If the introducer and/or an endoscopic accessory is placed inside the working channel note that the suction capability will be reduced.

Insertion of endoscopic accessories

WARNING ⚠

- Do not use active endoscopic accessories such as laser probes and electrosurgical equipment in conjunction with the aScope 3 system, as this may result in patient injury or damage to aScope 3.
- Do not advance or withdraw aScope 3, or operate the bending section, while endoscopic accessories are protruding from the distal end of the working channel, as this may result in injury to the patient.

CAUTION

- Always make sure that the bending section is in a straight position when inserting or withdrawing an endoscopic accessory in the working channel. Never use excessive force when advancing or withdrawing an endoscopic accessory inside the working channel. Failure to observe the above may result in damage to the working channel.

Always make sure to select the correct size endoscopic accessory for the aScope 3 (See section 1.3).

Inspect the endoscopic accessory before using it. If there is any irregularity in its operation or external appearance, replace it.

Insert the endoscopic accessory into the working channel port and advance it carefully through the working channel until it can be seen on the aView. The enclosed introducer can be used to facilitate the insertion of soft accessories such as microbiology brushes.

Withdrawal of the aScope 3

WARNING ⚠

While withdrawing the aScope 3, the distal tip must be in a neutral and non-deflected position. Do not operate the bending lever, as this may result in injury to the patient and/or damage to the aScope 3.

When withdrawing the aScope 3, make sure that the control lever is in the neutral position. Slowly withdraw the aScope 3 while watching the live image on aView.

If the aScope 3 is used more than once on the same patient during the same procedure, place it on a sterile surface in between sessions.

3.3. After Use

WARNING ⚠

- Do not attempt to clean and reuse the aScope 3 on another patient as it is a single use device.
- Always perform a visual check according to the instructions in this section before placing the aScope 3 in a waste container.

Visual check

1. Are there any missing parts on the bending section, lens, or insertion cord? If yes, then take corrective action to locate the missing part.
2. Is there any evidence of damage on the bending section, lens, or insertion cord? If yes, then examine the integrity of the product and conclude if there are any missing parts.
3. Are there cuts, holes, sagging, swelling or other irregularities on the bending section, lens, or insertion cord? If yes, then examine the product to conclude if there are any missing parts.

In case of corrective actions needed (step 1 to 3) act according to local hospital procedures. The elements of the insertion cord are radio opaque.

Final steps

Disconnect the aScope 3 from the aView and dispose of the aScope 3 in accordance with local guidelines for collection of infected medical devices with electronic components.
Switch off aView by pressing the ON/OFF button for at least 2 seconds.

The aScope 3 is a single use device. The aScope 3 is considered infected after use and must be disposed of in accordance with local guidelines for collection of infected medical devices with electronic components. Do not soak rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. The design and material used are not compatible with conventional cleaning and sterilization procedures

At the end of product life open up the aView and remove the batteries. Dispose of the batteries and aView separately in accordance with local guidelines.

WARNING ⚠

Clean and disinfect the aView monitor after each use according to the instructions in section 4.

4. Cleaning and Disinfection of aView

Before initial use aView must be cleaned and disinfected according to the cleaning instructions. Immediately after and before each use clean and disinfect the aView.

WARNING ⚠

Disconnect aView from any mains power supply, remove any accessories and make sure the aView is completely turned off before cleaning and disinfection.

4.1. Cleaning

Clean the aView according to good medical practice using the below procedure:

1. Prepare a cleaning solution using a standard enzymatic detergent prepared per manufacturers recommendations. Recommended detergent: enzymatic, mild pH: 7-9, low foaming (Enzol or equivalent).
2. Soak a sterile gauze in the enzymatic solution and make sure that the gauze is moist and not dripping.
3. Thoroughly clean the button, rubber covers, screen, external casing of the monitor and stand with the moist gauze. Avoid getting the device wet to prevent damaging internal electronic components.
4. Using a sterile soft bristled brush that has been dipped in the enzymatic solution, brush the button until all evidence of soil is removed.
5. Wait for 10 minutes (or the time recommended by the manufacturer of the detergent) to allow the enzymes to activate.
6. Wipe the aView clean using sterile gauze that has been moistened with RO/DI water. Ensure all traces of the detergent are removed.
7. Repeat steps 1 to 6.

4.2. Disinfection

1. Wipe the surfaces of aView for approximately 15 minutes using a piece of sterile gauze moistened with the alcohol mixture indicated below (approximately once every 2 minutes). Follow safety procedures for the handling of isopropyl. The gauze should be moist and not dripping since liquid can affect the electronics inside the aView. Pay close attention to the button, rubber covers, screen, external casing and stand, slots and gaps on the aView. Use a sterile cotton swab for these areas.

Solution	Concentration	Preparation
Isopropyl (alcohol) 95%	70-80%	80cc of 95% Isopropyl (alcohol) added to 20cc of purified water (PURW)*

*Alternatively, use EPA-registered hospital disinfection wipes containing at least 70% isopropyl. Safety precautions and directions of use of the manufacturer must be followed.

After cleaning and disinfection, the aView must be submitted to the pre-check procedure in section 5.1.
Between procedures, aView must be stored in accordance with local guidelines.

5. Technical Product Specifications

5.1. aScope 3 Specifications

	aScope 3 Slim	aScope 3
Optical System		
Field of View	85°	85°
Depth of Field	8-19 mm	8-19 mm
Illumination method	LED	LED
Insertion portion		
Bending section[3]	130° up, 130° down°	150° up, 130° down°
Insertion cord diameter	3.8 mm (0.15″)	5.0 mm (0.20″)
Distal end diameter	4.2 mm (0.16″)	5.4 mm (0.20″)
Maximum diameter of insertion portion	4.3 mm (0.17″)	5.5 mm (0.21″)
Minimum endotracheal tube size (inner diameter)	5.0 mm	6.0 mm
Minimum double lumen tube size (inner diameter)	37 Fr	41 Fr
Working length	600 mm (23.6″)	600 mm (23.6″)
Channel		
Average inner diameter	1.2 mm (0.047″)	2.2 mm (0.087″)
Minimum instrument channel width[4]	1.2 mm (0.047″)	2.0 mm (0.079″)
Suction connector		
Connecting tube inner diameter	Ø7mm +/- 1mm	Ø7mm +/- 1mm
Operating environment		
Temperature	10 ~ 40°C (50 ~ 104°F)	10 ~ 40°C (50 ~ 104°F)
Relative humidity	30 ~ 85%	30 ~ 85%
Atmospheric pressure	80 ~ 109 kPa	80 ~ 109 kPa
Altitude	≤ 2000m	≤ 2000m

Storage and transportation

Temperature	10 ~ 40°C (50 ~ 104°F)	10 ~ 40°C (50 ~ 104°F)
Relative humidity	30 ~ 85%	30 ~ 85%
Atmospheric pressure	80 ~ 109 kPa	80 ~ 109 kPa

Sterilisation

Method of sterilisation	EtO	EtO

3 Please be aware that the bending angle can be affected if the insertion cord is not kept straight

4 There is no guarantee that accessories selected solely using this minimum instrument channel width will be compatible in combination.

5.2. aView Specifications

Display

Max. resolution	800 * 480
Orientation	Landscape
Display type	8.5" colour TFT LCD
Brightness control	Yes, ("+" / "-")
Contrast control	Yes, ("+" / "-")
Start up time	About 1 second

Memory

Storage capacity	8GB

Electrical power

Power requirement	18V 1,67A DC input
Battery type	11,1V 3760mAh

Operating environment

Temperature	10 ~ 40° C (50 ~ 104° F)
Relative humidity	30 ~ 85%
IP Protection Classification System	The aView is classified IP30.
Atmospheric pressure	80-109 kPa
Altitude	≤ 2000m

Dimensions

Width	241mm (9.49")
Height	175mm (6.89")
Thickness	33,5mm (1,32")
Weight	1500g (331lbs)

Connections

USB connection	Type A

Storage and transportation

Temperature	10 ~ 40°C (50 ~ 104°F)
Relative humidity	30 ~ 85%
Atmospheric pressure	80-109 kPa

Mounting interface

Mounting interface standard	VESA MIS-D, 75 C, VESA FDMI compliant display, Part D, with centre located mounting interface

Fixture	
Mounting interface	75mm (2.96”)
Fits poles with thicknesses	10mm ~ 45mm (0.4 ~ 1.8”)
aView power supply	
Weight	360g (0.79 lbs)
Electrical power	
Power requirement	100 - 240V AC; 50-60Hz; 0.6A
Power out	18V DC; 1.67A
Operating environment	
Temperature	10 ~ 40° C (50 ~ 104° F)
Storage	
Temperature	10 ~ 40°C (50 ~ 104°F)
Relative humidity	10 ~ 90%
Plugs	
Between the power supply and aView	Ø5.5mm DC jack connector
5 interchangeable types	1) Model NEMA 5 AC grounded power plug 2) Australian configuration: AS3112, AC grounded power plug 3) UK configuration: BS1363, AC grounded power plug 4) European configuration: CEE 7, AC grounded power plug 5) Danish configuration: 2-5a, AC grounded power plug

6. Connecting accessories

CAUTION

The aScope 3 system consists of the parts described in section 2. They may only be replaced by Ambu authorized parts. Failure to comply with this may reduce safety and efficiency.
The aView is not intended to be repaired. If defect the aView shall be discarded.

aView can be placed on a solid flat surface by using the stand on the back of aView. If needed, aView can be placed by using the supplied bracket.

6.1. Charging aView

Connect the aView power supply to the wall socket and insert the power plug into the power inlet of the aView.

If the aView is turned on during charging the ON/OFF button will light orange. The battery icon will change as shown here:


Max. battery status of the aView


Min. battery status of the aView

The icon remains white until one block is left, after which it turns red.
When remaining battery capacity is 10% the red battery icon starts flashing


Battery is charging

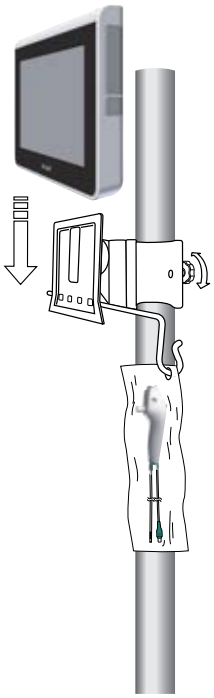

Battery current capacity

Charging is shown with blocks flashing
Current capacity is shown with non-flashing blocks

If the battery is fully charged and still connected to a charger the battery icon changes to: 

6.2 Maintenance of battery

To prolong battery life it is recommended to fully charge the monitor at least every third month and store it in a cool place. If the battery is flat the procedure takes approximately 3-4 hours. The battery should be charged at temperatures between 10 - 40°C.

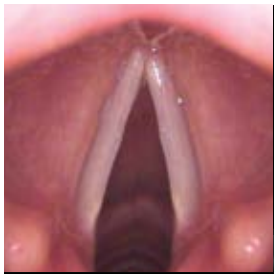


6.3. Mounting of the bracket to the aView

It is recommended to use the bracket supplied. The bracket is mounted on a pole by tightening the wing nut and the aView can then be placed on the bracket. To adjust the position of the aView horizontally, loosen the wing nut and the bracket can be repositioned. To adjust the position of the aView vertically, it can be moved up and down and will stay in the position chosen. Occasionally it may be necessary to tighten the screw on the side of the bracket. This is done with the hexagonal key supplied with the aView.
The maximum allowed weight on the bracket must not exceed the weight of one aView and one aScope 3.

7. How to Operate aView

7.1. MODES in aView



aView has 3 modes of operation:

STARTUP IMAGE MODE - Live image available while aView is loading.

When the User Interface is loaded aView automatically initiates SIMPLE MODE.

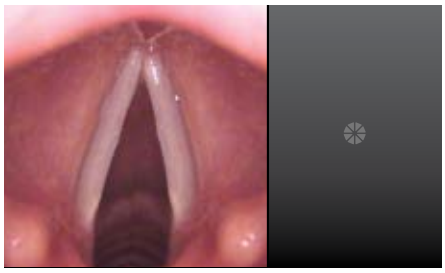
SIMPLE MODE - Live image available and the User Interface displays basic user functions.

Advanced functions can be initiated from SIMPLE MODE by pressing ADVANCED MODE button  . aView loads the User Interface for ADVANCED MODE.

ADVANCED MODE - Live image available and the User Interface displays advanced user functions.

- aView starts up in the **Blue tab** for *Live Image*  - Viewing and recording live image

---

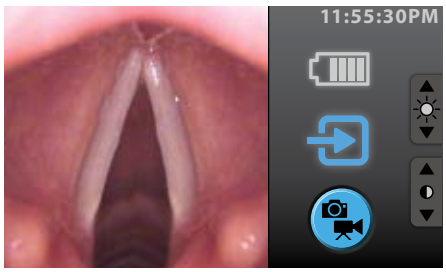


Startup Image Mode

STARTUP IMAGE MODE starts one second after the ON/OFF button is pressed and continues until the User Interface is loaded.

- Live image from a plugged in Ambu Visualization Device is available.

NOTE: The moving icon to the right of the live image indicates that the aView is loading the User Interface.



Simple Mode

SIMPLE MODE starts automatically once the aView User Interface is loaded.

- Live image from a plugged in Ambu Visualization Devices is available. Further functions available are battery status, brightness/contrast control and possibility of displaying device usage time for the connected device.

NOTE: Press  to enter ADVANCED MODE

Advanced Mode

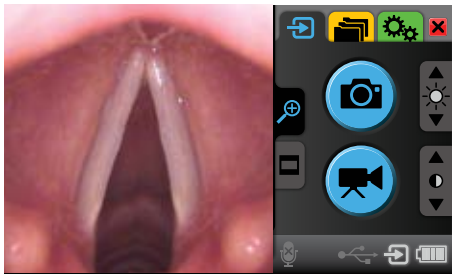
In SIMPLE MODE press to enter ADVANCED MODE

ADVANCED MODE has 3 tabs with different functions

Blue tab for Live Image - Viewing and recording live image
Yellow tab for File Management - Managing saved files
Green tab for Settings - System settings and User Accounts

- To change between the tabs press the tab.

NOTE: Press the RETURN SIMPLE MODE to enter SIMPLE MODE.



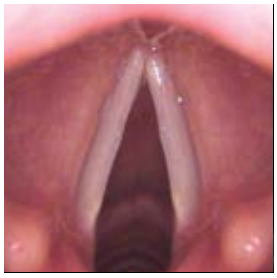
Blue tab for Live Image :

ADVANCED MODE starts in the blue *Live Image* tab .

- Live image from a plugged in Ambu Visualization Devices is available. Further functions available are recording, zooming in live image, battery status, status of microphone, brightness/contrast control and possibility of displaying device usage time for the connected device.

CAUTION: Be careful to check whether the image on the screen is a live image or a recorded image.

NOTE: When de-selecting a live image by leaving the blue *Live Image* tab to go to an other tab in ADVANCED MODE, aView asks for confirmation.



Live image vs. recorded image in ADVANCED MODE

When de-selecting a live image by leaving the blue *Live Image* tab to go to another tab in ADVANCED MODE, aView asks for confirmation before removing the live image.

To distinguish between a live image and a recorded image the button´s shape and colour changes when leaving the blue Live Image tab .

Round BLUE buttons are shown in the blue *Live Image tab* and indicates a live image.

Square YELLOW or GREEN buttons are shown the yellow *File Management tab* and the green Settings tab and indicates a recorded image.

Yellow tab for File Management :

Press the yellow *File Management* tab to view, delete, rename or transfer recorded files:

NOTE: Press the blue *Live Image* tab or RETURN SIMPLE MODE to view a live image from a connected Ambu Visualization Device with just one click.

Green tab for Settings :

Press the green *Settings* tab to setup system settings, to administer user accounts and to upgrade firmware.

NOTE: Press the blue *Live Image* tab or RETURN SIMPLE MODE to view a live image from a connected Ambu Visualization Device with just one click.

7.2. How to operate aView

aView only has one physical button located on the top for power ON and OFF.
All other functions are operated using the User Interface controlled from the front touch screen panel.

How to turn ON aView

(Assumption: aView is powered down)

Press power button on top of the aView for at least one second.

- The power button will light up orange for 2 seconds
- The power button will stay lit and orange if aView is charging or change to green and stay lit green if not charging.
- aView is now in STARTUP IMAGE MODE.
- A live image will appear within 1-2 seconds if a Ambu Visualization Device is connected or a blue screen will appear. - After about one minute, aView will be ready in Simple Mode.

NOTE: During startup the screen may flicker for about a second.

How to turn OFF aView

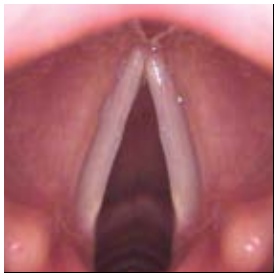
(Assumption: aView is powered ON)

Press the power button on top of the aView for at least two seconds.
The light of power button goes off if not charging or stays lit orange if charging.

A blue hourglass indicating that aView is powering down will appear on the screen and aView will power down.

How to view a live image

(Assumption: aView is powered off and the Ambu Visualization Device is connected)



Press the power button on top of the aView for at least one second.

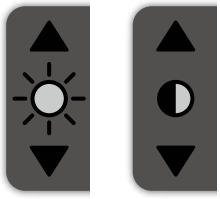
STARTUP IMAGE MODE is initiated showing the live image within 1-2 seconds. The moving icon is shown to the right to indicate that User Interface is loading.

SIMPLE MODE is automatically entered when the User Interface is loaded and the User Interface is shown to the right of the live image.

Press to enter ADVANCED MODE and the blue *Live Image* tab will be entered and the live image shown.

NOTE: Press or from anywhere in ADVANCED MODE to see the live image.

How to adjust brightness and contrast



(Accessible from SIMPLE MODE and ADVANCED MODE)

Press  the up arrow to increase brightness and the down arrow to decrease brightness.
- The arrow will light up red when pressed and the level attained will be shown for a few seconds instead of the brightness icon.

Press  the up arrow to increase contrast and the down arrow to decrease contrast.
- The arrow will light up red when pressed and the level attained will be shown for a few seconds instead of the contrast icon.

How to view Device Usage Time

(Accessible from SIMPLE MODE and ADVANCED MODE indicator bar)

Press to view the total time theAmbu Visualization Device connected has been turned on.
- Usage time is displayed for 2 seconds and then disappears automatically or will disappear when the touch screen is pressed.

NOTE: The device icon  will be in the colour of the device interface where the Ambu Visualization Device is connected.

How to take a SNAPSHOT

(Accessible in ADVANCED MODE – blue *Live Image* tab )

Keep the Ambu Visualization device as still as possible when taking a snapshot to prevent blurring of the picture.

Press  to take snapshot.
- The button turns red while the file is saved and then returns to blue.

NOTE: The snapshot is saved automatically in the folder for the device. See section 'Placement of files' for file placement.

How to record a VIDEO

(Accessible in ADVANCED MODE – Blue *Live Image* tab )

Press  to start recording video.
- The button turns red while recording.
- If audio recording is turned ON the microphone icon turns red  .

Press  to stop recording video.
- The button turns back to blue.
- If audio recording is turned ON the microphone icon turns back to white.

NOTE: The video is saved automatically in the folder for the device. See section 'Placement of files' for file placement.

To record audio together with the video the microphone must be turned on. See section 'How to mute and unmute microphone'.

How to locate recorded files and folders

(Accessible from ADVANCED MODE – *File Management* tab)

Press the yellow *File Management* tab to access the file structure.
(For file placement see section 'Placement of files')

Press a folder once to select.
- The folder icon will appear open when selected

Press to view the contents of the folder
- Files are shown as thumbnails: Video Snapshot
- Press to go up in the file structure.
- Press to see more content in current folder
- Repeat until the desired file or folder is located

NOTE: The location in the folder structure is shown in the top bar.

How to view snapshot

(Assumption: Snapshot has already been located.)

Press the snapshot to select

Press to view the snapshot
- Press or to toggle between snapshots in the folder

NOTE: Double click to Select and View.

How to view a video

(Assumption: Video has already been located.)

Press the video file to select

Press to view the file
- Press or to jump 10 seconds backward or forward in the video
- Press to pause video
- Press to decrease volume and to increase volume
- Volume is muted when is pressed to minimum

NOTE: Double click to Select and View.

How to delete a recorded file or folder

(Assumption: The file or folder have been located)

Press the file or folder to select
- The folder icon will appear open when selected
- File is highlighted when selected

Press to delete the file or folder
- Confirm delete by pressing
- Cancel delete by pressing

How to rename a file or folder

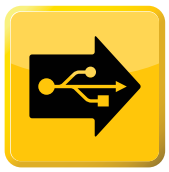
(Assumption: The folder, snapshot or video file has been located)

Press the file or folder to select
- The folder icon will appear open when selected
- File is highlighted when selected

Press to rename the folder or file.
- Foldername/filename and keyboard appears
- Use the backspace to delete old foldername/filename and enter the new one
- Confirm name by pressing
- Cancel rename by pressing

NOTE: Renaming is also possible when a selected file is being viewed.

How to transfer a file or folder to a USB stick



(Assumption: The folder or file has been located and a USB stick has been plugged in)

Press the file or folder to select
- The folder icon will appear open when selected
- File is highlighted when selected

Press to copy the file or folder to the USB stick
- The button will turn red while copying
- The button will turn back to yellow when the copy process is ended.

NOTE: Files are not deleted from aView in the copy process.

How to set the time and date

Accessible in ADVANCED MODE
– Green *Settings* tab

Press to access system time and date

Press 12H to toggle between 12 and 24 hour clock

Press ▲ to increase value and ▼ to decrease value
- Year, month, day, hour and minute can be set.
- Changes are saved automatically

Press to enable or disable clock in SIMPLE MODE

Press to return to main settings menu

NOTE: Time and date are only displayed in SIMPLE MODE.

How to MUTE and UNMUTE the microphone

Accessible in ADVANCED MODE
– Green *Settings* tab

NOTE: This button may be inactive (grey), depending on the software version installed on your aView..

Press to unmute the microphone when recording video
- Press to confirm unmute or press to cancel
- The button will turn red in the Green *Settings* tab when unmuted
- The microphone indicator will change from grey to white to indicate the microphone is on.
- The microphone indicator will turn red when recording audio together with the video recording.

Press to mute the microphone again.

NOTE: The microphone is by default muted when the aView is powered ON.

How to change the volume

Accessible in ADVANCED MODE

Green TAB 'Settings'

Press  the up arrow to increase the volume and the down arrow to decrease the volume.

- The arrow will turn red when pressed

NOTE: The volume can also be adjusted during video playback

How to login/logout of the ADMIN account

(Accessible in ADVANCED MODE

– Green *Settings* tab

Press ADMIN to show the account.

- ADMIN acount is displayed ADMIN.

Press ADMIN to select the ADMIN account.

Type PIN 0000.

- ADMIN is now logged in
- ADMIN is displayed in the file management tab and on the LOGIN button.

Press NAME in settings main menu to logout of the ADMIN account.

- ADMIN Account is now logged out
- ADMIN is no longer displayed in the file management tab and on the LOGIN button.

How to UPDATE the software

Accessible in ADVANCED MODE

– Green *Settings* tab

(Assumption: The ADMIN account is logged in)

Connect the power adapter before commencing a software update.

Press to enter software settings

Insert USB stick containing the upgrade file in its root directory

Press to initiate software upgrade.

- Do not unplug power or power down during update
- aView will restart when update has finished.
- If no USB stick is inserted or no file is found no update will initiate

NOTE: User files and accounts will remain after update.
Only use software upgrade files supplied by Ambu.

If the ADMIN is not logged in the is not accessible.

How to RESET to factory defaults

Accessible in ADVANCED MODE

– Green Settings tab

(Assumption: The ADMIN account is logged in)

Connect the power adapter before running the command to do a reset to defaults.

Press to enter software settings

Press to initiate reset to factory defaults.

- Press to confirm reset
- Press to cancel reset

NOTE: The user files and User Accounts will be deleted and software settings will be reset to defaults.

If the ADMIN is not logged in the is not accessible.

How to DELETE all user data

Accessible in ADVANCED MODE

– Green *Settings* tab 

(Assumption: The ADMIN account is logged in)

Connect the power adapter before running the command to delete all user data.

Press  to enter software settings

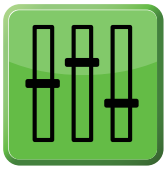
Press  to delete all user data

- Press  to confirm deletion of all data
- Press  to cancel deletion

NOTE: All settings will remain, but user data and user accounts will be deleted.

If the ADMIN is not logged in the  is not accessible.

How to setup Display settings



(Accessible in ADVANCED MODE

– Green *Settings* tab )

Press  to enter Display settings.

Press  the up or down arrow to adjust the colour for the Red, Green and blue.

- The arrow will light up red when pressed and the achieved level will be shown for a few seconds.
- The value for each colour is set to maximum as default, why more of one specific colour is obtained by decreasing the two others.

Press  the up arrow to increase brightness and the down arrow to decrease brightness.

- The arrow will light up red when pressed and the achieved level will be shown for a few seconds instead of the brightness icon.

Press  the up arrow to increase contrast and the down arrow to decrease contrast.

Press  to return all values to defaults.

Press  to return to main menu.

8. Trouble Shooting

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

WARNING ⚠

Do not use the aScope 3 system if it is damaged in any way.

No live image on the left side of the screen but User Interface is present on the display

Cause	Action
aScope 3 not connected to aView	Connect an aScope 3 to the blue port on aView.
aView is operated in yellow file management tab or green settings tab	Return to live image by pressing the blue Live image tab or the red button with a black X in the top right corner.
aView and aScope 3 have communication problems.	Restart aView by pressing the ON/OFF button for at least 2 seconds. When aView is OFF restart by pressing ON/OFF button once more.
aScope 3 is damaged.	Replace the aScope 3 with a new one.

The image shown to the left is frozen.

Cause	Action
A communication error has occurred between aScope 3 and aView.	Restart the system by pressing the ON/OFF button on aView for at least 2 seconds. When aView is OFF restart by pressing ON/OFF button once more.
A recorded image is shown in the yellow file management tab.	Return to live image by pressing the blue Live image tab or the red button with a black X in the top right corner.
	Restart aView by pressing the ON/OFF button for at least 2 seconds. When aView is OFF restart by pressing ON/OFF button once more.
The aScope 3 is damaged.	Replace the aScope 3 with a new one.

Low picture quality.

Cause	Action
Light reflecting on the aView screen	Move aView to a position where no direct light influences the screen.
Dirty/damp screen	Wipe the screen with a clean cloth.
Brightness and contrast settings not optimal	Adjust the contrast and brightness using the designated menu on aView.
Blood, saliva etc. on the lens (distal tip)	Gently rub the distal tip against the mucosa. If the lens cannot be cleaned this way remove the aScope 3 and wipe the lens with sterile gauze.

Absent or reduced suction capability.

Cause	Action
Channel blocked	Clean the working channel using a cleaning brush or flush the working channel with sterile saline using a syringe. Do not operate the suction valve when instilling fluids.
Suction pump is not turned on or not connected	Turn the pump on and check the suction line connection.
Suction valve is damaged	Prepare a new aScope 3.
Endoscopic accessory inserted in working channel	Remove endoscopic accessory.

Difficult to insert endoscopic accessory through the channel.

Cause	Action
Channel blocked	Clean the working channel using a cleaning brush or flush the working channel with sterile saline using a syringe. If it is impossible to clear the working channel, prepare a new endoscope.
Endoscopic accessory too big	Check that the accessory used is of the recommended size.
Suction valve is damaged	Prepare a new aScope 3.
Bending section not in neutral position	Move bending section into neutral position.
Soft endoscopic accessory difficult to pass through working channel seal	Use the enclosed introducer

Appendix 1: Electromagnetic Compatibility

Like other electrical medical equipment the aScope 3 system requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC) the aScope 3 system must be installed and operated according to the EMC information provided in this manual.

The aScope 3 system has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

WARNING ⚠

Electronic equipment may affect the normal function of the aScope 3 system.

WARNING ⚠

The aScope 3 system consists of the parts described in section 2. They may only be replaced by Ambu authorised parts. Failure to comply with this may reduce safety and efficiency.

WARNING ⚠

If the aScope 3 system is used adjacent to or stacked with other equipment, observe and verify normal operation of the aScope 3 system prior to using it. Consult the tables below for guidance in placing the aScope 3 system.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The aScope 3 system is intended for use in the electromagnetic environment specified below. The customer or the user of aScope 3 system shall ensure that it is used in such environment

Emissions Test	Compliance	Result	Electromagnetic Environment - Guidance
RF emissions CISPR 11 EN 55011	Group 1, Class B	Pass	The aScope 3 system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	N/A	N/A	
Voltage Fluctuations/Flicker emissions IEC/EN 61000-3-3	Complies		

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The aScope 3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the aScope 3 system shall ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC/EN 61000-4-2	+/-6kV contact +/-8kV air	2; 4; 6kV contact 2; 4; 8kV air	If floors are covered with synthetic material the relative humidity shall be at least 30%
Electrical Fast Transient/Burst – EFT IEC/EN 61000-4-4	AC Power port: +/-2kV Signal cable greater than 3 metres +/- 1kV	+/- 2kV Power line No signal cable greater than 3 metres.	Mains power quality shall be that of a typical commercial or hospital environment
Surge Immunity Test IEC/EN 61000-4-5	+/- 1kV differential mode +/- 2kV common mode	Open circuit Voltage: 1.2/50µs Short circuit current: 8/20µs AC power Port line to line: 1kV Line to earth (ground) 2kV	Mains power quality shall be that of a typical commercial or hospital environment
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5% Ut (95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (95% dip in Ut) for 5 sec.	100% reduction 0.5 period 40% reduction for 5 periods 30% reduction for 25 periods 100% reduction for 5 sec.	Mains power quality shall be that of a typical commercial or hospital environment If the use of aScope 3 system requires continued operation during power mains interruptions the aScope 3 system can be powered by the built in rechargeable battery.
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	

Conducted Radio Frequency Disturbance Test – CS. IEC/EN 61000-4-6	3Vrms 150kHz to 80MHz	0.15 – 80MHz, 3Vrms, 80% AM, 2Hz	Portable and mobile RF communications equipment shall be used no closer to any part of the aScope 3 system, including its cables, than the recommended separation distance calculated from the equipment of the frequency of the transmitter. Recommended Seperation Distance D = 1.17√P
Radio Frequency Electromagnetic Field Susceptibility Test – RS IEC/EN 61000-4-3	3V/m; 80Hz to 2.5GHz	80-2500 MHz, 3V/m, 80% AM(2Hz)	

Note 1: The guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (celluar/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey shall be considered. If the measured field strength in the location in which the aScope 3 system is used exceeds the applicable RF compliance level above, the aScope 3 system shall be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the aScope 3 system unit.

b) Over the frequency range 150kHz to 80MHz, field strengths shall be less than 3V/m

Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and aScope 3 system.

The aScope 3 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the aScope 3 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters and the aScope 3 system as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power (W) of transmitter	**Separation distance (m) according to frequency of transmitter**		
	150kHZ to 80MHz D = 1.17√P	**80MHz to 800MHZ D = 1.17√P**	**800MHz to 2.5GHz D = 2.33√P**
0.01	0.12m	0.12m	0.23m
0.1	0.37m	0.37m	0.74m
1	1.17m	1.17m	2.33m
10	3.70m	3.70m	7.37m
100	11.70m	11.70m	23.30m

For transmitters rated at a maximum output power not listed above, the recommended separation distance (D) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix 2. Standards Applied

The Ambu aScope 3 function conforms with:
- Council Directive 93/42/EEC concerning Medical Devices.
- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety.
- IEC 60601-2-18 Medical electrical equipment – Part 2-18: Particular requirements for the safety of endoscopic equipment.
- ISO 8600-1: Optics and photonics - Medical endoscopes and endotherapy devices - Part 1: General requirements.
- IEC 60601-1-2: Medical electrical equipment – Part 1-2 General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements for test.

- ISO 594-1: Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements.
- ISO 10993-1: Biological Evaluation of Medical Devices - Part 1: Evaluation and testing

The Ambu aView function conforms with:
- Council Directive 93/42/EEC concerning Medical Devices.
- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety.
- EN 60601-1-1 Medical electrical equipment – Part 1: General requirements for safety– Collateral standard: Electromagnetic compatibility - Requirements for test.

The Ambu aView power supply conforms with:
- Council Directive 93/42/EEC concerning Medical Devices.
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety.
- EN 60601-1-1 Medical electrical equipment - Part 1: General requirements for safety– Collateral standard: Electromagnetic compatibility - Requirements for test.

Appendix 3. Warranty and Replacement Program

The warranty period for the Ambu aView is one year from delivery to the customer. We agree to replace an aView free of charge if proof can be provided of faulty materials or faulty workmanship. In doing so we cannot accept the cost of transportation or risk of shipment. There is no warranty on the Ambu aScope 3.

A defective aView must be handled exclusively by persons authorised by Ambu A/S. During our inspection of the aView you will receive an identical replacement of the aView.
To prevent infection, it is strictly forbidden to ship contaminated medical devices. The medical device (aView or aScope 3) must be decontaminated on site before shipment to Ambu. The cleaning and disinfection procedures explained in 4.1 and 4.2 shall be followed. Ambu reserve the right to return contaminated medical devices to the sender.