

INSTRUCTIONS FOR USE

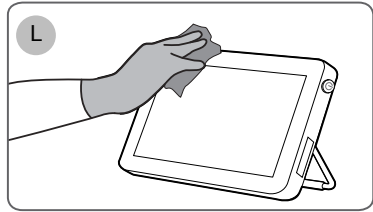
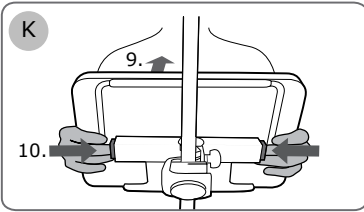
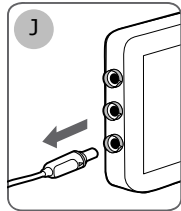
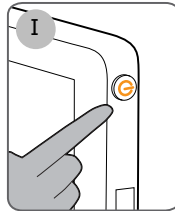
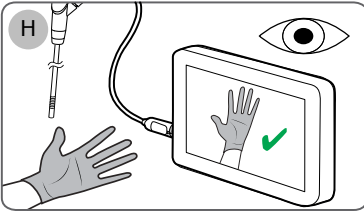
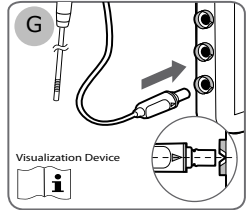
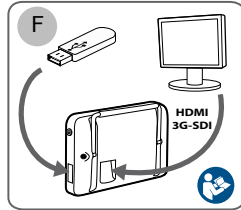
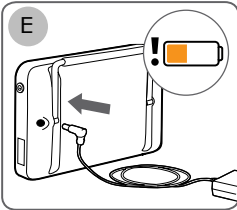
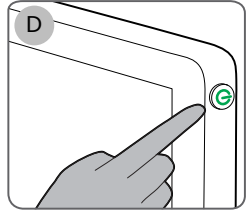
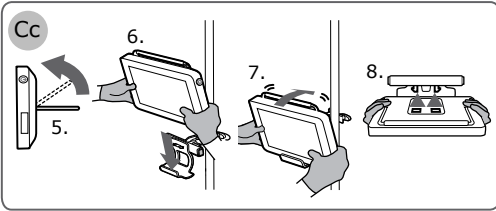
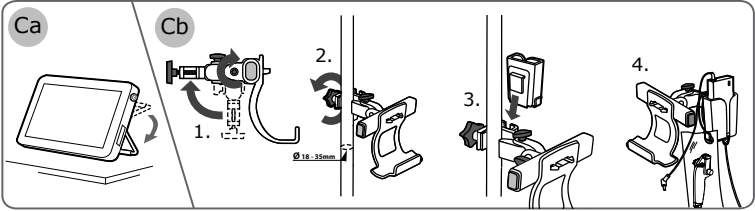
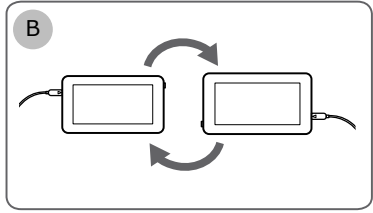
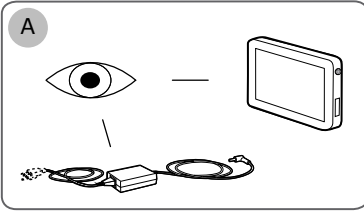
Abridged version



Ambu

Ambu® aView™ 2 Advance

For use by trained healthcare professionals only.
For use with compatible Ambu® visualization devices.



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Ambu is a registered trademark and aScope and aView are trademarks of Ambu A/S.

1. Important information – Read before use

Read these *Instructions for Use* carefully before using the Ambu® aView™ 2 Advance.

The *Instructions for Use* may be updated without further notice. Copies of the current version are available upon request. The latest version is available on ambu.com. Please be aware that the instructions do not explain or discuss clinical procedures. They describe only the basic operation and precautions related to the operation of the Ambu® aView™ 2 Advance.

In these *Instructions for Use*, the term *displaying unit* refers to Ambu® aView™ 2 Advance. The terms *visualization device* and *endoscope* are used interchangeably throughout the document and refer to compatible Ambu endoscopes and other visualization devices that can be connected to and used with the displaying unit.

These *Instructions for Use* apply only to the displaying unit. For information on a specific Ambu visualization device, refer to the relevant *Instructions for Use*.

According to the Spaulding's/CDC classification, the displaying unit including the mounting bracket is a non-critical device.

1.1. Intended use

The Ambu® aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices.

1.2. Indications for use

As the aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices, the intended medical indication will be defined by the connected visualization devices.

1.3. Intended patient population

As the displaying unit is intended to display live imaging data from specific Ambu visualization devices, the intended patient population will be defined by the connected Ambu visualization device.

1.4. Intended user profile

Healthcare professionals trained on procedures with compatible visualization devices typically assisted by other healthcare professionals and medical technicians with knowledge of setting up medical devices.

1.5. Clinical benefits

In conjunction with a compatible single-use visualization device, the Ambu® aView™ 2 Advance provides visualization and inspection of hollow organs and cavities in the body.

1.6. Contraindications

None known for the displaying unit.

1.7. Potential adverse events

None known for the displaying unit.

1.8. General notes

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

1.9. Warnings and cautions

Failure to observe these warnings and cautions may result in patient injury or damage to the equipment. **Ambu is not responsible for any damage to the equipment or patient injury resulting from incorrect use.**

WARNINGS

1. To avoid patient injury during procedure, be careful to check whether the image on the screen is a live image or a recorded image and verify that the orientation of the image is as expected.
2. To minimize risk of contamination, always wear gloves during handling of the displaying unit and ensure that the displaying unit is cleaned and disinfected before and after each use in accordance with the chapter 10.
3. Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the displaying unit and the attached visualization device, including cables specified by the manufacturer. Otherwise, this could result in degradation of the performance of this equipment.
4. To avoid risk of electric shock only connect mains or battery powered ancillary equipment, if it is approved as medical electrical equipment.
5. To avoid risk of electric shock, this equipment shall only be connected to a supply mains with protective earth.
6. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
7. To avoid patient injury due to overheating of the displaying unit causing it to suddenly shut down during procedure, do not cover the ventilation holes at the back of the displaying unit.
8. Do not touch any metal parts of the displaying unit while using high frequency tools (e.g. electrosurgical equipment), due to the risk of electric shock and burns.
9. To ensure that images and videos are correctly exported to external systems and to avoid potential misdiagnosis due to mixing-up of patient data, carefully check that the patient identifiers are correct before starting, saving and exporting the procedure.



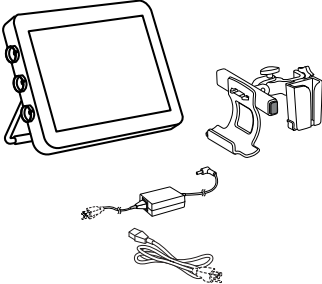
CAUTIONS

1. To prevent damaging the displaying unit, always place the displaying unit on a hard flat surface or mounted on the bracket or a suitable VESA mount during use to avoid covering the ventilation holes at the back of the displaying unit. Be aware that covering the ventilation holes can also lead to a high surface temperature.
2. Using high frequency tools (e.g. electrosurgical equipment) in proximity of a connected visualization device may affect the live image. This is not a malfunction. Wait a few seconds for the image to return to normal.
3. Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
4. To avoid malfunction during procedure, do not use the displaying unit if it is damaged in any way or if any part of the functional check described in section 6.1 fails.
5. To avoid malfunction of the equipment only use spare parts supplied by Ambu. Do not modify the spare parts.
6. Cleaning and disinfection wipes shall be moist, but not dripping to ensure no damage to internal electronics of the displaying unit.
7. If using wipes containing hypochlorite or citric acid during cleaning, ensure that all residue is completely removed. Wipes containing hypochlorite or citric acid may affect the screen's antireflective coating over time. You should limit the use of wipes containing hypochlorite or citric acid to required cases only.

2. Device description

The displaying unit is a reusable device that can be connected to compatible Ambu visualization devices to display live imaging data (see section 2.2). The following sections describe the components of the displaying unit and list compatible devices.

2.1. Displaying unit parts

Ambu® aView™ 2 Advance	Item number
	405011000

2.2. Product compatibility

aView 2 Advance includes up to three connector ports on the side of the displaying unit that are marked in colours. Ambu visualization devices are compatible with aView 2 Advance at the colour-coded connection mechanism and connector geometry.

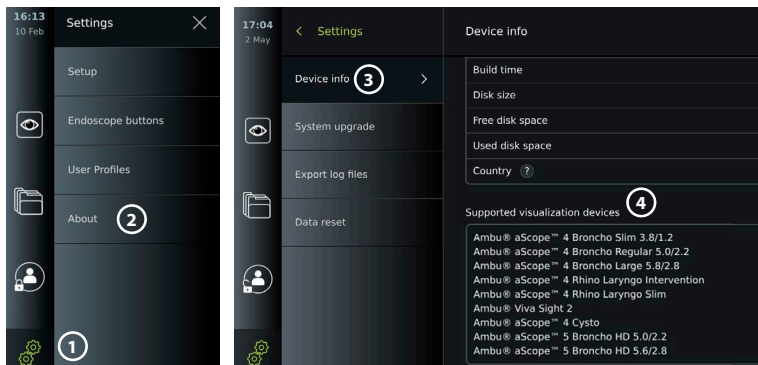
A full list of visualization devices supported in your country is displayed in the user interface of the displaying unit.

To see supported Ambu visualization devices:

- Press the **Settings tab** ①, then press **About** ②.
- Press **Device info** ③, then scroll to **Supported visualization devices** ④.

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

Note: aView 2 Advance is NOT compatible with any products in the Ambu Gastroenterology aScope™ portfolio or scope generations prior to the aScope™ 4 family, e.g. Ambu aScope™ 3 family.



Compatible external equipment

- | | |
|---|---|
| <ul style="list-style-type: none"> • External medical grade monitors (HDMI, 3G-SDI video outputs) • USB 3.0 Type A flash drives | <ul style="list-style-type: none"> • Medical USB printer • USB powered audio devices that comply with IEC 60601-1, IEC 60950-1 or IEC 62368-1 |
|---|---|

Note: Verified compatibility with Sony UP-DR80MD digital colour printer for medical applications. For specifications of connections to external equipment, refer to chapter 8.

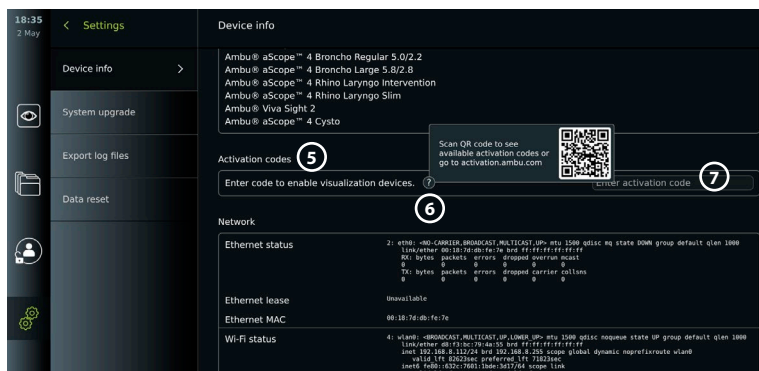
Note: IEC 60950-1 and IEC 62368-1 are consumer electronic standards and do not cover patient safety. Therefore do not touch the accessories while touching the patient and place the equipment out of reach of the patient.

2.2.1. Endoscope activation

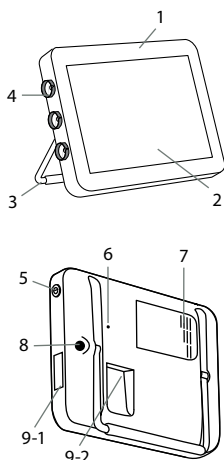
New endoscope types not found on the list of supported visualization devices (see section 2.2) must be activated with an activation code before they can be used. The activation code is entered only once per endoscope type. Hereafter, the endoscope type can be found on the list of supported visualization devices. The activation codes are found on Ambu's website via the URL, or QR code shown next to the input field where the activation code is to be entered.

Activate a new endoscope type:

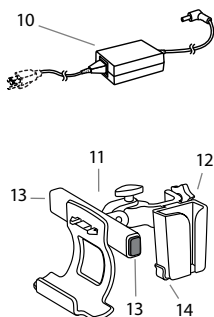
- Press the **Settings** tab, then press **About**.
- Scroll to **Activation codes** ⑤ and press the **question mark** ⑥ to find the URL or QR code for the activation codes.
- Enter the URL in the address field of the internet browser on your connected device, e.g. computer, tablet or mobile phone or scan the QR code with your mobile phone.
- Find the activation code for the endoscope to be activated and enter the code into the input field below **Activation codes** ⑦.



2.3. Description of components



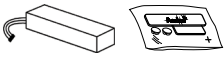
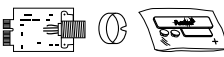

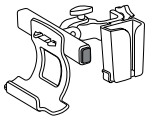
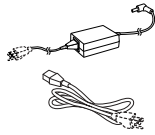
No.	Part	Function
1	Casing	-
2	Touch screen	Displays the image from the Ambu visualization device and the graphical user interface.
3	Stand	Use the stand to place the displaying unit on a solid surface and to carry the displaying unit while turned OFF.
4	Connector ports for Ambu® visualization devices	Match and align colours, arrows and geometry on visualization device plug and the connector port.
5	Power button	Push button for power ON and OFF.
6	Hardware reset button	Reset the displaying unit hardware without impacting stored data.
7	Ventilation holes	Cools hardware during use.



No.	Part	Function
8	Power inlet	Power inlet for charging the displaying unit.
9-1	USB connection	Two inputs/outputs for USB 3.0 Type A.
9-2	Input/output connection	HDMI, 3G-SDI, LAN (Ethernet)
10	Power supply	Powers the displaying unit. Power cord with country-specific plug.
11	Bracket	Secures the displaying unit to e.g. an IV pole.
12	Power supply bracket	Secures the placement of the power supply.
13	Release buttons	Releases displaying unit from the bracket.
14	Hook	Holder for pouches containing visualization devices.

2.4. Spare parts

Spare parts are intended as replacements for components exposed to wear and tear during the device's lifetime. Consult the troubleshooting guide in chapter 14 for issues that might require a change of spare parts. In addition to the list below, Ambu® aView™ 2 Advance - Power Supply and Ambu® aView™ 2 Advance – Bracket described in section 2.3. are available as spare parts.

Spare part		Item numbers
	Ambu® aView™ 2 Advance - Battery Kit. This kit contains a battery and a replacement part kit.	405012100
	Ambu® aView™ 2 Advance - Visualization device interface kit - Blue. Ambu® aView™ 2 Advance - Visualization device interface kit - Grey. Ambu® aView™ 2 Advance - Visualization device interface kit - Green. This kit contains a visualization device interface board, a colour ring, and a replacement part kit.	405014100 405000503 405000502
	Ambu® aView™ 2 Advance - Fan Kit. This kit contains a fan and a replacement part kit.	405016100
	Ambu® aView™ 2 Advance - Bracket. This kit contains a bracket and a Bracket Guide.	405013100
	Ambu® aView™ 2 Advance power supply manufacturer: FSP Group Inc. Ambu® aView™ 2 Advance power supply manufacturer: FSP065M-DBA.	E / F (EU) + J (CH) 405015300 G (UK) 405015400 B (US/JP) 405015200 I (AUS, ZH) 405015100 K (DK) 405015500

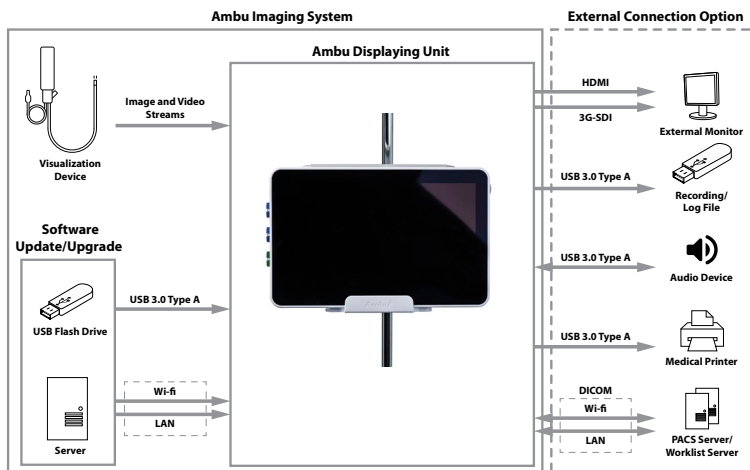
The spare parts are not available in all countries. Please contact your local Ambu representative.

2.5. System overview

A complete Ambu Imaging System is configured as illustrated below. The various connection options are described in chapter 5.









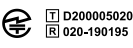


Please note that your organization is responsible for the following areas, which should be implemented according to your local policy:

- Network setup
- Ensuring availability and confidentiality of the network
- Ensuring confidentiality and integrity of physical devices
- Management of the displaying unit user profiles
- Maintenance of user passwords
- Monitoring and audit of the Ambu imaging system
- Complete data erasure before disposal of the displaying unit



3. Explanation of symbols used

Symbol	Description	Symbol	Description
	Warning		Caution
	Follow the <i>Instructions for Use</i>		Country of Manufacturer
	Consult <i>Instructions for Use</i>	IP30	Protection against solid objects
	Waste Bin symbol, indicating that waste must be collected according to local regulation and collection schemes for disposal of electronic and electrical waste (WEEE)		Medical – general medical equipment as to electric shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1:2005+ AMD 2012, CAN/CSA-C22.2 No. 60601-1:14+IEC 60601-2-18:2009

Symbol	Description	Symbol	Description
	Catalogue number		Waste Bin symbol, indicating that waste must be collected according to local regulation and collection schemes for disposal of batteries
	Universal Serial Bus (USB)	HDMI	High-Definition Multimedia Interface
3G-SDI	Serial Digital Interface	LAN	Local Area Network
	Batch Code		Medical Device
	Humidity limitation		Atmospheric pressure limitation
Rx only	US Federal Law restricts this device to use by or on the order of a physician		CE marking with identification number of the notified body
	Japan Radio Law TELEC RF certification		Australia and New Zealand's Regulatory Compliance Mark
	Taiwan Radio Requirement NCC certification		

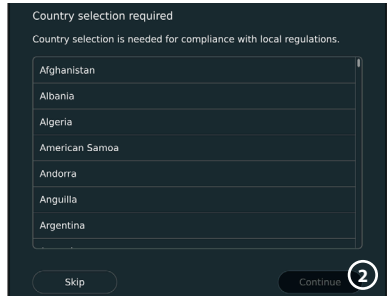
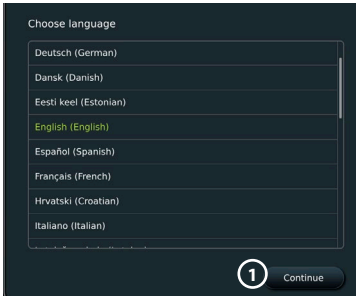
4. Getting started

4.1. First-time setup

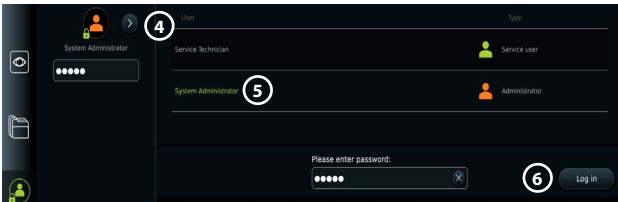
Follow the steps below before using the displaying unit for the first time. Letters in grey circles refer to the illustrations in the Quick Guide on page 2.

1. Unpack the displaying unit and verify that no parts are missing. Refer to the parts described in chapter 2.
2. Closely examine the displaying unit and other parts for any damage. Do not use the displaying unit if it is damaged in any way **A**.
3. Connect the power supply to a power outlet and insert the power plug into the power inlet on the back of the displaying unit **E**.
4. Turn ON the displaying unit by short pressing the power button. The indicator light in the power button switches from orange (STANDBY mode) to green (ON) **D**. A live image is available soon after the monitor is turned on if a visualization device is connected. If no visualization device is connected, the interface will illustrate how to correctly connect a visualization device to the displaying unit.
5. Go to *Appendix 3. Cybersecurity* and ensure that the use of the displaying unit's software and connectivity is aligned with your organization's policies.
6. Select the preferred language, then press **Continue** **1**.
7. Select your country, then press **Continue** **2**. Press **Confirm** **3**.

IMPORTANT: Selecting the **correct country from the first time** is a requirement for regulatory compliance, and the selected country cannot subsequently be changed by any users of the displaying unit. If selection of a new country is necessary, please contact your local Ambu representative. The displaying unit's language can be changed by the Administrator at any time.



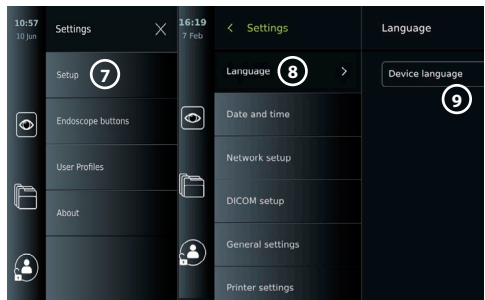
8. Log in as **Administrator** to get access to system settings:
- Press the **Login tab** in the Toolbar.
 - Press **arrow right** (4), then press **System Administrator** (5).
 - Enter the password and press **Log in** (6). The factory default password is *AmbuAdmin*
 - Follow the instructions on the screen to change the password (required on first use).



Note: If the Administrator password is lost, please contact your local Ambu representative.

9. Change system language:
- Press the **Settings tab**, then press **Setup** (7).
 - Press **Language** (8).
 - Press **Device language** (9), and select the required language. The system language changes immediately when selected.

10. Set date and time:
- Press **Date and time** (10).
 - Press **Time zone setting** (11), and select the required time zone.
 - Press **Set date and time** to return to the previous menu.
 - Select the required setting below **Time format** (12).
 - Scroll the hours and minutes below **Set time** (13) to set the time.



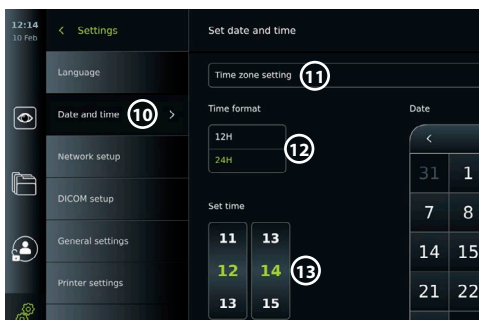
- Select the required date in the calendar.

Note: It is important to set time and date correctly to ensure that patient procedures are saved and exported in correct order.

4.2. User profiles

User profiles are created as different user types according to their purpose (see table below). Only the Administrator has full access to the displaying unit's settings and functions, including the creation of new users.

For daily operation it is recommended to create minimum one Advanced user profile, either as a shared department login or as individual profiles. It is not possible to create additional Administrator or Service Technician user profiles.



User profile types and system access					
User profile type		Default user	Advanced user	Administrator	Service user
		Access without login	Daily operation	Administrator with full access	Service related tasks
	Login required	-	x	x	x
	Live View	x	x	x	x
	Video recording	x	x	x	x
	Photo	x	x	x	x
	Current procedure	x	x	x	x
	Worklist	-*	x	x	-*
	Image adjustments	x**	x**	x	x
	Archive	-*	x	x	-*
	Settings	-	x****	x	x****

* The Administrator can enable or disable access without login.

** The Administrator and the Service Technician can enable or disable functions for other users.

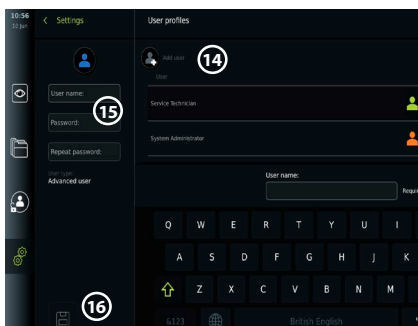
*** Some settings are not accessible for the Service Technician.

**** Some settings are not accessible for the Advance user and the Service Technician.

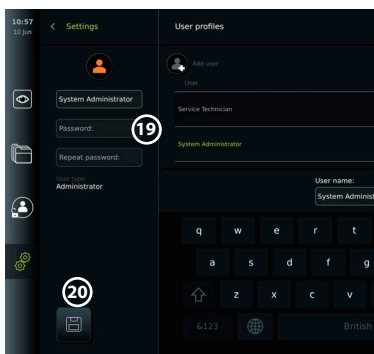
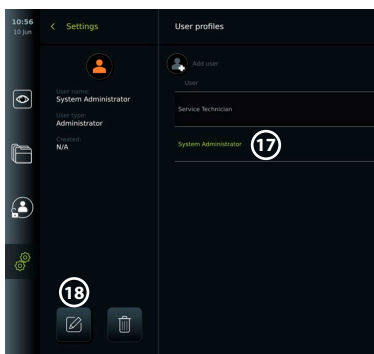
Create an Advanced user:

- Press the **Settings** tab.
- Press **User Profiles**, then press **Add user** **14**.
- Enter username, password, and repeated password in the respective input fields **15**, and press the **Save icon** **16**.

Note: Passwords must be minimum 8 characters. Any character is allowed, but it is recommended to use a combination of upper- and lower-case letters, numbers, and symbols to enhance password protection.



- To delete a user profile, press the user name, then press the **delete icon**.



- Press **OK** to confirm.

Log in as any user profile:

- Press the **Login tab**.
- Press **arrow right**, then press your user name.
- Enter your password and press **Login**.

Change username or password:

- Press the **Settings tab**, then press **User Profiles**.
- Press the **username** **17**, then press the **edit icon** **18**.
- Enter the new username, password, and repeated password in the respective input fields **20** and press the **save icon** **19**.

Note: The Administrator can change username and password for other user types.

4.3. General settings

The Administrator can enable and disable functionalities for all users.

In the **Setup** menu under the tab **General Settings** the following functionalities can be enabled or disabled using the **ON/OFF** sliders:

USB Management – possibility to enable file export, software upgrade, import of TLS certificate and ability to print using the USB port. Refer to sections 5.2.3, 7.2, 8.4, 9.2.

Communication Settings – enabling allows the possibility to upgrade software on-line if connected to the Internet. Refer to section 9.2.

Archive Settings – decide when a procedure is moved to the bin and when it is deleted from the bin. Refer to section 7.3.

180° Rotation, Zoom, Stopwatch, ARC – functions available during a procedure can be disabled for all types of scopes and users. Refer to sections 6.6, 6.7.

Login Settings – determine if a user that is not logged in can still access the archive and see the Worklist. Refer to sections 6.4, 7.1.

User inactivity settings – choose if the displaying unit will logout the user due to inactivity.

Note: Be aware that if a function is disabled (not green), the symbol is not visible in the menu where it is normally located.

4.4. Mounting the displaying unit on a pole

The displaying unit can be mounted on a pole with wheels for easy portability, e.g. an IV pole. Pole mounting brackets are supplied with the displaying unit. Letters in grey circles refer to the illustrations in the Quick Guide on page 2.

Attach the bracket to a pole: **cb**

- Fold out the bracket and tighten the nut in the centre.
- Attach the bracket to the pole, and ensure the knob is tightened sufficiently.
- Attach the power supply bracket to the main bracket and place the power supply in the power supply bracket.

- The hook on the power supply bracket can be used for storing visualization devices in pouches. In addition, the power adapter cable can be rolled up on the power supply bracket to improve cable management.

Place the displaying unit in the bracket: **Cc**






- Fold the stand upwards against the upper edge of the displaying unit.
- Place the lower edge of the displaying unit in the bracket. The stand must be oriented upwards.
- Push the displaying unit backward until the lock engages, and a click is heard. The hooks on the bracket must engage with the holes on the back of the displaying unit.
- Ensure that the displaying unit is securely placed in the bracket before letting go with your hands.

Remove the displaying unit from the bracket: **K**

- Use both hands to hold the displaying unit while pressing the two grey release buttons on the bracket behind the displaying unit.
- Pull the displaying unit towards yourself.

4.5. Battery and power

The displaying unit's remaining battery power is shown by the colour of the power button and the battery icon in the Toolbar. For information about power supply, see section 2.3.

Power button light indicator	Battery icon in Toolbar	Remaining battery power	Action required before use
Green	Green 	> 40 %	-
Orange	Orange 	< 40 %	Charge 
Blinking orange*	Red 	< 20 %	Charge 

* Also when powered OFF.

5. Network setup

Always use a secure network when handling images and patient data. See technical details about the configuration of LAN and Wi-Fi in Appendix 3. Cybersecurity.

5.1. Wi-Fi and LAN/Ethernet setup

Importing a Worklist or transferring imagery requires that the displaying unit is connected to the network via Wi-Fi or LAN/Ethernet cable. The displaying unit supports WPA, WPA2 and WPA2 Enterprise authentication. Wi-Fi networks that redirect to a login webpage are not supported.

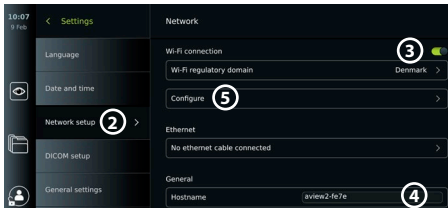
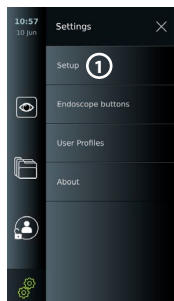
5.1.1. Set up the displaying unit for Wi-Fi connection:

- Press the **Settings** tab, then press **Setup** ①.
- Press **Network setup** ②.
- Press the **ON/OFF** slider to turn on Wi-Fi ③ (switch to green).
- If required by your organization's Wi-Fi network, press the input field next to **Hostname** ④ and enter the hostname.


Note: The hostname is provided by your organization's IT administrator and is used for identifying the displaying unit on the Wi-Fi network. The hostname can be 1-63 characters long excl. dots and can consist of numbers and upper- or lowercase letters (A-Z/a-z). Hyphens cannot be used as first or last character.

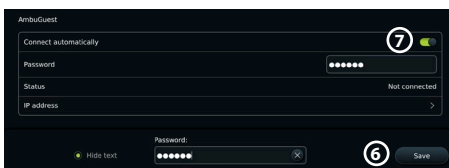
- Press **Configure** ⑤ and wait while the displaying unit searches for available networks.

Note: If a Wi-Fi network has been set up previously, press **Configure a new network**.




5.1.2. Set up Wi-Fi network with WPA/WPA2 authentication:

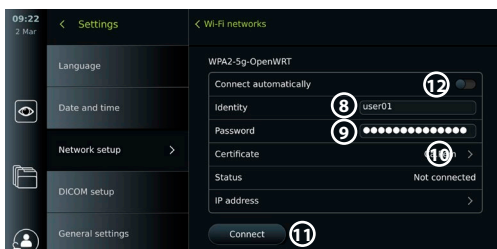
- Select the required Wi-Fi network from the list.
- Enter the password and press **Save** (6), then press **Connect**.
- When the connection has been established, a Wi-Fi symbol  appears in the Toolbar.
- To enable automatic connection to a previously used Wi-Fi network, press the **ON/OFF** slider next to **Connect automatically** (7) (switch to green).



5.1.2.1. Set up Wi-Fi network with WPA2 Enterprise authentication:

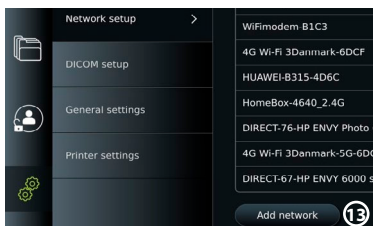
Note: When setting up Wi-Fi network with WPA2 Enterprise authentication the first time, a displaying unit will require to trust your network-provider service. Follow the instructions in section 5.1.4, instead contact either your IT administrator or the network-provider.

- Select the required Wi-Fi network from the list.
- Press the input field next to **Identity** (8) and enter the username.
- Press the input field next to **Password** (9) and enter the password.
- If the certificate name is not present, then press the arrow next to **Certificate** (10) and manually import it to the system (see section 5.1.4.).
- Press **Connect** (11).
- When the connection has been established, a Wi-Fi symbol  appears in the Toolbar.
- To enable automatic connection to a previously used Wi-Fi network, press the **ON/OFF** slider next to **Connect automatically** (12) (switch to green).



5.1.2.2. Set up hidden Wi-Fi network:

- Below the list of available networks, press **Add network** (13).
- Press the input field next to **SSID** and enter the name of the hidden Wi-Fi network, then press **OK**.
- Enter the remaining information in the input fields depending on the type of Wi-Fi network (see sections 5.1.2./5.1.2.1.).



5.1.3. Set up wired LAN connection via Ethernet cable:

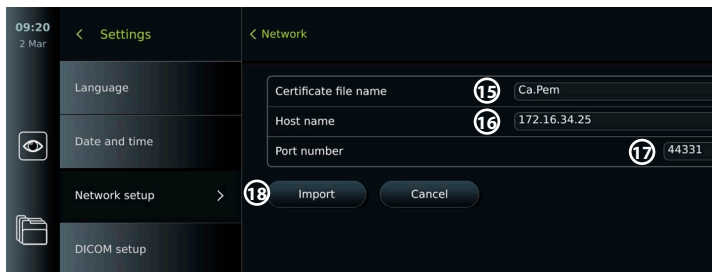
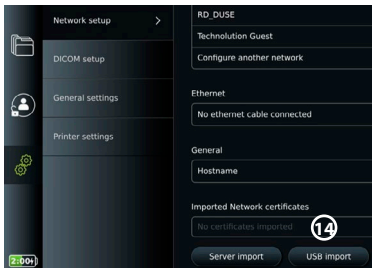
- Connect a LAN cable to the Ethernet connection port on the back of the displaying unit (see section 2.3.) and to a router or LAN wall connector.
- In the **Network** menu, check the LAN connection status shown below **Ethernet**.

5.1.4. Import network certificate for WPA2 Enterprise authentication:

- In the **Network** menu, scroll to **Imported Network certificates** **14**.

To import TLS certificates from a server:

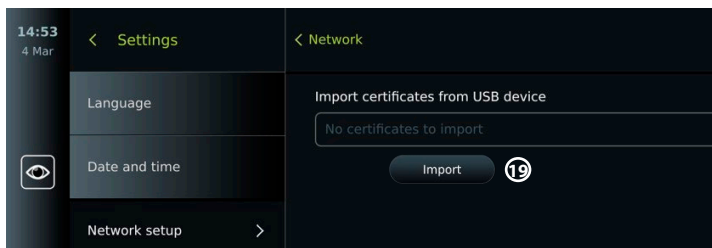
- Ensure that the displaying unit is connected to a temporary Wi-Fi or LAN network (see section 5.1.2. or 5.1.3.).
- Press **Server import**.
- Press the input field next to **Certificate file name** **15** and enter the file name.
- Press the input field next to **Host name** **16** and enter the hostname.
- Press the input field next to **Port number** **17** and enter the port number.



- Press **Import** **18**.

To import network certificates from a USB flash drive:

- Ensure that USB connection has been enabled for certificate import (see section 4.3.) and a USB flash drive connected to the displaying unit (see section 2.3.).



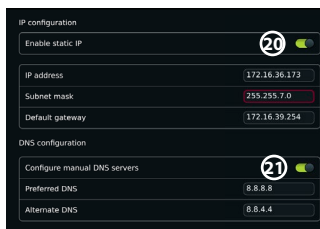
- Press **USB import** and wait while the displaying unit searches for network certificates on the USB flash drive.
- Select the required network certificate and press **Import** **19**.

Note: When the network certificate has been imported, the name of the certificate file is shown below **Imported Network certificates** in the **Network** menu.

5.1.5. Set up static IP address and/or DNS server for a Wi-Fi or LAN network:

- In the **Network** menu, press the currently selected Wi-Fi network.
- Below the name of the Wi-Fi network, press the **arrow** next to **IP address**.

Press the **ON/OFF** slider next to **Enable static IP** **20** or **Configure manual DNS servers** **21** (switch to green) and enter the required information.



5.1.6. Disconnect from Wi-Fi network:

- In the **Network** menu, press the currently selected Wi-Fi network, then press **Disconnect**.

5.1.7. Clear all network data from the displaying unit:

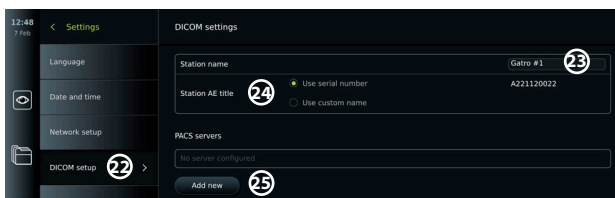
- In the **Network** menu, press **Clear all data**.
- Press **OK**.

5.2. PACS and Worklist setup

You can transfer patient data between the displaying unit and external servers. Before procedure you can retrieve patient data from the Worklist server, including information about an upcoming procedure. After procedure, the images and videos created during procedure can be exported in DICOM format from the Archive to a PACS server. Before setting up server connections, ensure that the displaying unit is connected to a Wi-Fi or LAN network (see section 5.1.).

5.2.1. Set up the displaying unit for server connection:

- Press the **Settings** tab, then press **Setup**.
- Press **DICOM setup** **22**.
- Press the input field next to **Station name** **23** and enter the device name. The default name is *AmbuMon*

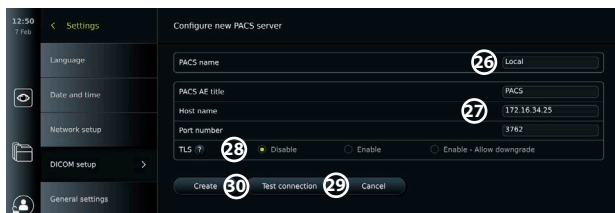


Note: The maximum length of the station name is 16 characters.

- Press **Use serial number** or **Use custom name** next to **Station AE title** **24**. If you selected **Use custom name**, press the input field and enter the name.

5.2.2. Set up connection to PACS server:

- Press **Add new** **25** below **PACS servers**.
- Press the input field next to **PACS name** **26** and enter the name you want to use for the PACS connection.
- Press the input fields next to **PACS AE title**, **Host name** and **Port number** **27** and enter the required information in each field.
- Press the required setting next to **TLS** **28**.



Note: If you enable TLS, you need to import the required TLS certificate from a server or USB flash drive (see instructions in section 5.2.3.).

- Press **Test connection** **29** to verify that the information has been entered correctly and the server connection can be established.
- Press **Create** **30** to save the server connection setup.

Some PACS systems may require the MAC address and the IP address of the displaying unit. The MAC address is unique for each displaying unit, while the IP address is assigned by the hospital network.

Retrieve the MAC address and IP address of the displaying unit:

- Login as **Administrator**, then go to **Settings - About - Device Info**.
- Depending on whether Wi-Fi or Ethernet is used, find the information tab **Network**.

The MAC address is a 48-BIT address grouped into 6 octets. In the example below, the MAC address is highlighted in red boxes depending on the network setup. The IP address assigned by your network can also be found. In the example below, the IP address is highlighted in a blue box.

The screenshot shows the 'Device info' screen with the 'Network' section expanded. Under 'Ethernet status', the MAC address '08:18:7d:db:fa:7a' is highlighted in red. Under 'Wi-Fi status', the MAC address '08:f3:3c:79:6a:55' is highlighted in red, and the IP address '192.168.0.112' is highlighted in blue. The 'Wi-Fi lease' section shows various DHCP and DNS settings.

5.2.3. Set up connection to Worklist server:

- Press the **ON/OFF** slider next to **Enable Worklist** **31** (switch to green).
- Press the input fields next to **Worklist server AE title**, **Worklist server hostname** and **Worklist server port number** **32** and enter the required information in each field.
- Press the required setting next to **TLS** **33**.

Note: If you enable TLS, you need to import the required TLS certificate from a server or USB flash drive (see instructions further below).

- Press the required modality or enter one in the input field **34**.

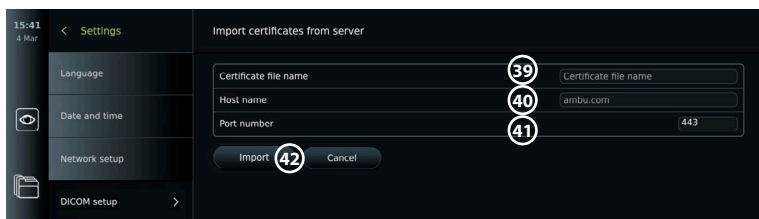
The screenshot shows the 'DICOM settings' screen. The 'Worklist settings' section is expanded. The 'Enable Worklist' slider is turned on (green) and circled 31. The 'Worklist server AE title', 'Worklist server hostname', and 'Worklist server port number' fields are circled 32. The 'TLS' setting is set to 'Disable' and circled 33. The 'Modality' dropdown is set to 'ES' and circled 34. The 'Display upcoming procedures (hours)' field is set to '24' and circled 35. The 'Hide past procedures older than (hours)' field is set to '12' and circled 36. The 'Test worklist connection' button is circled 37. The 'Server Import' and 'USB Import' buttons are circled 38.

- Press the input field next to **Display upcoming procedures (hours)** **35** and enter the required number of hours.
- Press arrow right to select **Hide past procedures older than (hours)** **36** and enter the required number of hours.

- Press **Test worklist connection** (37) to verify that the information has been entered correctly and the server connection can be established.

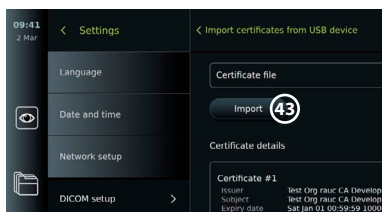
Import TLS certificate from server or USB flash drive:

You can use TLS for enhanced security when setting up PACS and Worklist server connections. Enabling TLS requires a TLS certificate to be imported to the displaying unit from a server or from a USB flash drive. If multiple TLS certificates are imported to the displaying unit, the PACS/Worklist server will select the required TLS certificate automatically. For import from server, ensure that the displaying unit is connected to a Wi-Fi or LAN network (see section 5.1.). For import from USB flash drive, ensure that USB connection has been enabled for certificate import and a USB flash drive connected to the displaying unit (see section 4.3.).



To import TLS certificates from a server:

- Press **Server import** (38).
- Press the input field next to **Certificate file name** (39) and enter the file name.
- Press the input field next to **Host name** (40), and enter the hostname.
- Press the input field next to **Port number** (41) and enter the port number.
- Press **Import** (42).



To import TLS certificates from a USB flash drive:

- Press **USB import** and wait while the displaying unit searches for TLS certificates on the USB flash drive.
- Select the required TLS certificate and press **Import** (43).

Note: When the TLS certificate has been imported, the name of the certificate file is shown below **Imported TLS certificates**.

Server information	Explanation
PACS name	The name entered here is the one shown on the list of available servers in the Export menu.
PACS AE Title/ Worklist server AE title	The title entered here is used by the server to identify the displaying unit's individual software application.
Host name/ Worklist server hostname	IP-address, MAC address or full web address for the server.
Port number/ Worklist server port number	Network port number for the server.

6. Operating the displaying unit

6.1. Preparation and inspection of the displaying unit before use

Before using the displaying unit for a patient procedure, follow the relevant steps below and any other necessary steps according to your organization's procedures and requirements for preparation and inspection of this type of device.

Letters in grey circles refer to the illustrations in the Quick Guide on page 2.

1. Closely examine the displaying unit and other parts for any damage. Do not use the displaying unit if it is damaged in any way **A**.
2. Clean and disinfect the displaying unit (see chapter 9) **L**.
3. Select a secure and convenient location for the displaying unit. Then place the displaying unit on a solid flat surface by folding out the stand located on the back side, or mount the displaying unit on a pole using the pole mount supplied with the displaying unit (see section 4.4) **Ca**.
4. Press the power button to turn the displaying unit ON and wait approximately 20 – 30 seconds while the displaying unit is starting up **I**.
5. If necessary, charge the displaying unit by connecting the power supply to a mains socket and inserting the power plug into the power inlet on the back of the displaying unit. The battery indicator shows a lightning icon ⚡ when the displaying unit is charging **E**.

Note: Make sure the power supply is always present and functional. It is recommended to locate the nearest power outlet before starting any procedure.

6. If necessary, connect the displaying unit to the Wi-Fi network (see section 5.1).
7. Connect the Ambu visualization device to the displaying unit by plugging its connector into the corresponding connector port on the displaying unit. Ensure that the arrows are aligned and the colour matches on the connector and its port **G**.

Note: For preparing and operating the Ambu visualization device, please refer to the Instructions for Use for the specific visualization device.

8. Verify that a live video image appears on the screen by pointing the distal end of the Ambu visualization device towards an object, e.g. the palm of your hand. Ensure that the live image has the correct orientation **H**.
9. If required, an external monitor can be connected to the HDMI or SDI port on the back of the displaying unit (see section 2.3) **F**.

6.2. Setting up endoscope button configuration

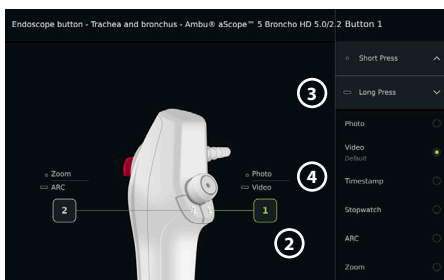
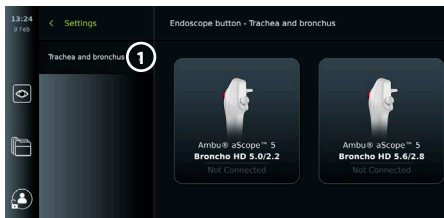
The Administrator and the Service Technician can set up the endoscope button configuration, also when the endoscope is not connected. All other users can view the current button configuration, but not change it. The available functions depend on the type of the selected endoscope.

Configure the endoscope buttons:

- Press the **Settings** tab, then press **Endoscope buttons**.
- Press the required endoscope category **1** and select an endoscope.
- The screen shows an overview of the endoscope buttons with the available functions.
- Press the required endoscope button **2**, then select long or short button press **3**.
- Press any action from the list to be performed when the selected button is pressed **4**.
- Repeat for each button.
The overview shows the selected functions next to the buttons.

Note: Each endoscope type come with a default button configuration.

Note: The changes made will be saved and apply for all visualization devices of the same type.



6.3. Starting and stopping a procedure

6.3.1. Starting a procedure

When an Ambu visualization device is connected to the displaying unit, a new procedure starts when one of the following actions is performed: 1) a patient is selected from Worklist, 2) a photo or video is captured, or 3) the stopwatch is activated.

If a visualization device is connected, the live image is available soon after the displaying unit is turned ON. Even if a network error or other problems in the system occur, the Live view will still be available making it possible to use the displaying unit for clinical purposes.

6.3.2. Stopping a procedure

Disconnect the Ambu visualization device from the displaying unit and select one of the following options:

- Press **Finish and export** (5) to end the current procedure and export the recorded files (see section 7.2.).
- Press **X** (6) to end the procedure without exporting files.
- Reconnect the visualization device (or a replacement visualization device) to return to the current procedure and continue the procedure.



6.4. Procedure workflow using the Worklist

The displaying unit can retrieve patient information from a Worklist server. When a patient is selected in the Worklist drop-down menu, the selected patient's information will be saved with the images and videos created during the current procedure.

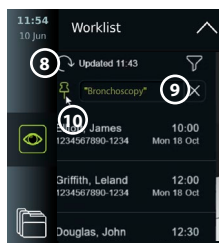
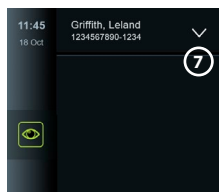
The patient's information can be retrieved before or during the procedure. If the procedure is ended with no patient selected, the patient's information must be entered manually.

Update Worklist and search for patient:

- Press **arrow down** (7) to open the patient list on the Worklist server.
- Press the **update icon** (8) to retrieve current patient information from the Worklist server.
- Press the **search field** (9) and enter the search term, e.g. patient name, procedure type, or the HCP's name.
- Press the **pin icon** (10) to keep the current search term active while scrolling through the search results.
- The search term will remain pinned until it is unpinned by pressing the **pin icon** again.









Select a patient from the Worklist:

- Press the patient's name, then press **Confirm**.
- To select a different patient, press the new patient's name and press **Change**.
- To deselect a patient, press the selected patient's name and press **Deselect**.





6.5. Overview of Live View functions









When an Ambu visualization device has been connected to the displaying unit, the Live View functions are available via the Live View tab.

Overview of Live View functions		
Icon	Name	Function
	Live View tab	Showing the live image when an Ambu visualization device is connected.
	Video recording icon	Starting and stopping video recording during a procedure (see section 6.3.).
	Photo icon	Taking photos during a procedure, also during video recording (see section 6.3.).
	Current procedure folder icon	Saving photos and videos recorded during the current procedure (see section 6.10.).
	Worklist menu	Selecting a patient for the current procedure (see section 6.4.).
	Stopwatch	Recording the time and making time stamps during a procedure (see section 6.7.).
	Image adjustment	Adjusting colour, contrast, sharpness, brightness, zoom, and rotation (see section 6.6.).
	Image adjustment*	Adjusting colour, contrast, sharpness, brightness, zoom, rotation, and ARC (Advanced Red Contrast) (see section 6.6.).

* This icon is shown only when ARC is enabled and the connected endoscope supports the function.

6.6. Using image adjustments

- Press the **image adjustment icon**  or  to open the menu.
- After adjusting the image settings, press **X** to save the settings.

Explanations of functions in Image adjustments 		
Icon	Name	Function
	Colour	Adjusts the image colour temperature from cold to warm.
	Contrast	Adjusts the image contrast. A higher value equals a larger difference between dark and bright areas.
	Sharpness	Enhances the image details. A higher value equals a more detailed image.
	Brightness	Adjusts the overall screen brightness. A higher value equals more brightness.
	ZOOM	Zooms in on the live image. A Z icon in the top right corner of the live image indicates that Zoom is active.
	ARC tab	Open the ARC tab to adjust advanced red colour contrast. An A icon in the top right corner of the live image indicates that ARC is active.
	Image rotation 180°	Rotate the live image in 180 degrees.

Note: Some image adjustments can be disabled by the Administrator.

Note: The changes made will be saved and apply for all visualization devices of the same type.

Adjust colour, contrast, sharpness and brightness:

- Adjust the image settings by pressing the **icons** (11) at either end of the slider bars or by dragging the **sliders** (12) left or right.

Rotate the live image:

- Press the **rotate icon** (13) to rotate the live image 180 degrees.
- Press the **rotate icon** again to rotate the live image back to normal.
- When image rotation is active, the rotation symbol (R) is shown in the Live View screen.

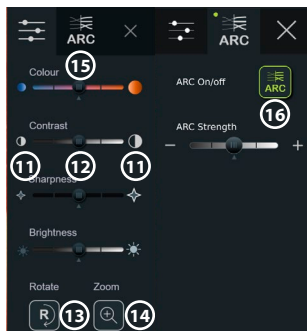
Note: Rotation is only available if the connected endoscope supports the rotation function.

Use the zoom function:

- Press the **Zoom icon** (14) to zoom in.
- Press the **Zoom icon** again to zoom out.
- When the zoom function is active, the zoom symbol (Z) is shown in the Live View screen.

Note:

- It is also possible to zoom in and out by double tapping the screen. The zoomed in picture is cropped.
- If photos or videos are recorded while using the zoom function, the original full-size image area is recorded as if the zoom function was not activated.
- The Stopwatch 00:00 button, the Current Procedure folder, and the Worklist dropdown menu are not visible when Zoom is activated, but it is still possible to use the stopwatch function if activated via the endoscope buttons (refer to section 6.2 for configuration of endoscope buttons).
- Zoom can be enabled/disabled in General settings by Administrator (see section 4.3).



Adjust ARC (Advanced Red Contrast) setting:

ARC is Ambu's proprietary red-colour contrast enhancement algorithm, which amplifies the red colour relative to other colour components at the same location. ARC is intended to improve the visibility of red colour tones in the image. An adjustment of the strength of ARC for each individual type of visualization device will be stored after the displaying unit has been turned off.

- The watermark (A) will not be visible on captured images or videos.
- Videos recorded with ARC active will look slightly desaturated, as some colour correction in the image processing system is disabled while ARC is active.
- Press the **ARC tab** (15).
- Press the **ARC button** (16) to enable ARC adjustment (the button switch to be green and a small green dot will appear on the ARC tab).
- Adjust the ARC setting by pressing the icons at either end of the slider bars or by dragging the slider left or right.
- When ARC is enabled, the ARC symbol (A) is shown in the Live View screen.

Note: ARC is only available if the connected endoscope supports the ARC function.

Note: Adjustment of the strength of ARC for each individual type of visualization device will be stored after the displaying unit has been turned off.

6.7. Using the stopwatch

You can use the displaying unit's stopwatch to record the duration of the procedure or parts of the procedure. While the stopwatch is running, you can make timestamps to mark specific points in time.

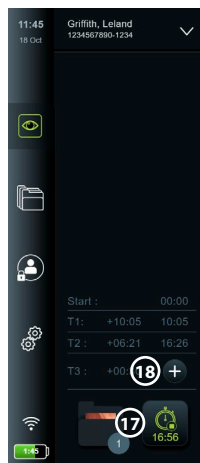
Use the stopwatch:

- Press the **stopwatch icon** (17) to start the stopwatch.
- Press the **plus sign** (18) to make a timestamp while the stopwatch is running.
- Press the **stopwatch icon** again to pause the stopwatch.
- When the stopwatch has been paused, you can start it again by pressing the **stopwatch icon**, or press the **plus sign** to start the stopwatch with a new time stamp.

Note: The stopwatch keeps running in the background even if it is covered by the Live View screen, e.g. while Dual View is active.

Note: The stopwatch will stop running when the visualization device is removed. If the same visualization device is reconnected within 60 seconds, the stopwatch will resume automatically. If more than 60 seconds pass, press

Continue procedure to resume the procedure and keep the stopwatch running.

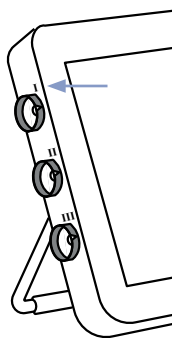
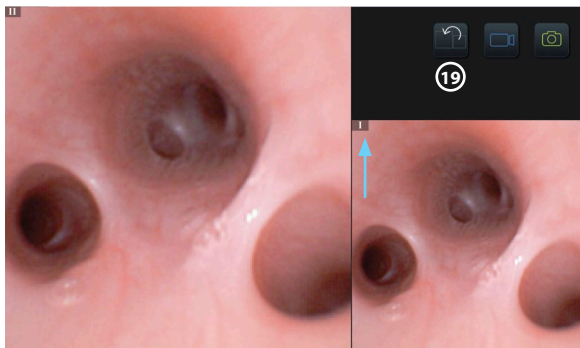


6.8. Using Dual View

With Dual View, the Live View screen can show live image from two visualization devices connected at the same time.

Use Dual View:

- Connect two Ambu visualization devices to connector ports on the displaying unit.
- The Live View screen shows two images, one larger and one smaller. The number shown in each image corresponds to the number on the connector port of the displaying unit.



- Press the **switch icon** (19) to switch image sizes.

6.9. Taking photos and recording videos

Take a photo:

- Press the **photo icon** (camera icon) to take a photo that is automatically saved in the current procedure folder.

Record a video:

- Press the **video icon** (video camera icon) to start a video recording.
- Press the **video icon** again to stop the video recording that is automatically saved in the current procedure folder.
- If needed, record a video with sound simultaneously (see section 8.3.).

Note: Image rotation is saved in the video recording, but zoom function is not.

Note: It is possible to take photos while recording a video.

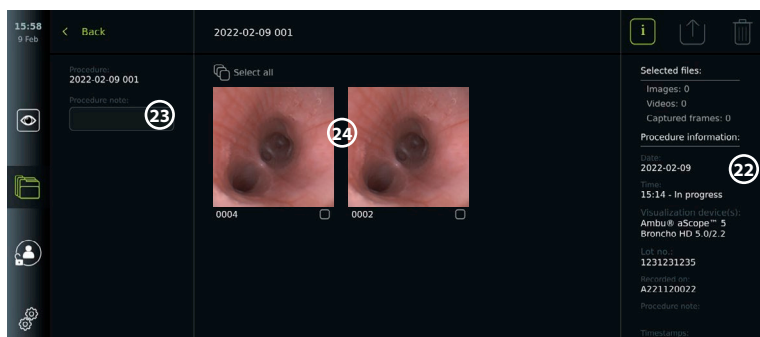
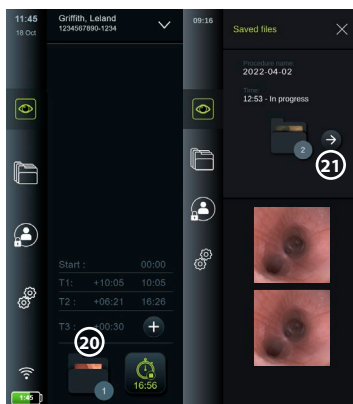
Note: A video can be maximum 30 min. You will be notified that the video recording is soon to stop. A new recording can be started immediately.

6.10. Current procedure folder

The current procedure folder is created automatically and named with the date of the procedure followed by the procedure number of the day (format: YYYY-MM-DD_XXX). The image and video files created during the procedure are saved in the current procedure folder. After the procedure has ended, the current procedure folder moves to the Procedures folder, which is accessible via the Archive tab in the Toolbar.

View the files in the current procedure folder:

- Press the **current procedure folder icon** 20. The current procedure folder icon shows the total number of photos and videos saved during the current procedure.
- Press **arrow right** 21.
- The current procedure overview shows the files in the folder and information about the current procedure, such as date, time, connected endoscope and timestamps 22.
- To add a note to the folder, press the **Procedure note field** 23 and enter the text (max. 40 characters). The notes field can be used for adding a short description to specific procedures or files.
- Scroll through the thumbnails 24 and press the required image or video to see a larger view.
- To add a note to the file after opening it, press the **File note field** and enter the text (max. 40 characters).
- To use video playback functions, see section 8.3.2.



6.11. After use of the displaying unit

Follow the steps below after use of the displaying unit. Letters in grey circles refer to the illustrations in the Quick Guide on page 2.

1. Disconnect the Ambu visualization device from the displaying unit J. For disposal of the visualization device, please refer to the Instructions for Use for the specific visualization device.
2. Press the power button 1 to turn the displaying unit OFF I. Press OK.
3. If necessary, remove the displaying unit from the bracket. Use both hands to hold the displaying unit while pressing the two grey release buttons on the bracket behind the displaying unit. Pull the displaying unit towards yourself K.
4. Clean and disinfect the displaying unit (see chapter 9) L.
5. If the power button 1 is flashing orange when the displaying unit is turned OFF, the battery level is below 20 %. In this case, charge the displaying unit.

7. File handling in the Archive

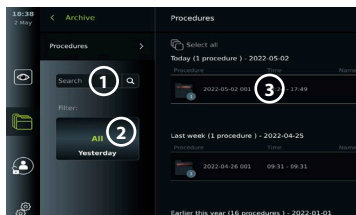
7.1. Accessing files in the Archive

In the Archive, files can be viewed, exported, printed, and deleted.

View photos and videos in the Archive:

- Press the **Archive tab**, then press **Procedures**.

- To search for a folder: Enter the date or note of the folder in the search field **1** and/or scroll the wheel to filter by time period **2**. The wheel list will filter procedures automatically when a range is selected. To get a full overview, move the range selector back to **All**.



- Press the required procedure folder **3** to view the files created during the patient procedure.
- Scroll through the thumbnails and press the required image or video to see a larger view.

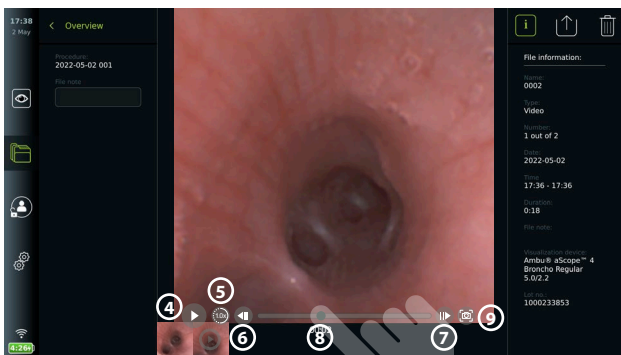
Use video playback functions:

- Press the **playback icon** **4**.
- To play the video in slowmotion, press the **slowmotion icon** **5** repeatedly to switch between playback speeds.
- During video playback, press the **pause icon** **4** to pause the video.
- To move forwards or backwards while the video is paused, press **arrow left** **6** or **arrow right** **7**, or drag the **slider** **8** left or right.

Capture a frame from a video:

- When playback has been paused, press the **capture frame icon** **9**. The captured frame is saved as a photo in the procedure folder.

Note: Images saved as captured frames have a lower image quality than regular photos. Captured frame images are saved with a capture frame icon shown in the image.



Photos and videos from the procedure are shown in descending order with the most recent at the top left. Below each photo or video thumbnail is the file name and a Selection box icon. The Select all icon is found above the photos and videos overview. The file name is: XXXX, indicating the image count, starting from 0001. Scroll sideways on the thumbnails to see all photos and videos from the procedure. On the right side of the screen, the Procedure file information is available.

7.2. Exporting files to PACS server or USB flash drive

Before you export files, ensure that connection to the PACS server has been set up (see section 5.2.) or USB flash drive is inserted and the USB file export option is enabled (see section 4.3.).

Select files for export:

- Press the **Archive tab**, then press **Procedures**.
- Press the required procedure folder.
- Select the required files by ticking the boxes below the thumbnails **10**, or press **Select all** **11**.

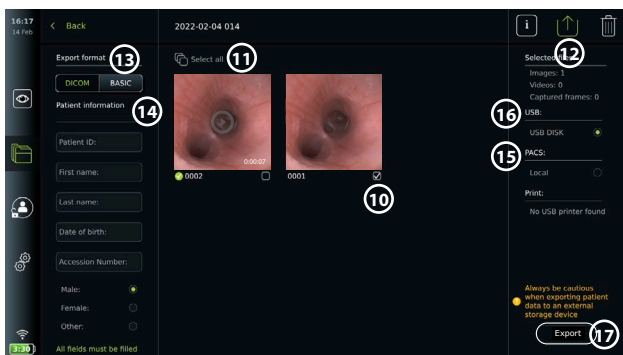
Select file format:

- Press the **export icon** (12).
- Select **DICOM** or **BASIC** file format (13).
- If you selected DICOM format, all patient information fields (14) must be filled out manually, unless the patient information has been retrieved from the Worklist before or during the procedure.

Note: Export to a PACS server requires that DICOM format is chosen. See table below for more information about file formats.

Export files:

- Press the name of the PACS server (15) or USB flash drive (16) you want to export to (green dot).
- Press **Export** (17).
- Wait until the file export has been confirmed by a pop-up on the screen before you disconnect the displaying unit from the Wi-Fi network or remove the USB flash drive.



Notes:

- Always check if the entered patient data is correct before exporting to PACS.
- Protected Health Information (PHI) will be saved on the local storage of the displaying unit until the files are deleted, either manually or with auto delete function. Notice access to PHI requires logging in.
- Always use a secure network when exporting files from the displaying unit.
- A stable network connection (Wi-Fi or LAN) is required when exporting photos and videos to a PACS server. If a network error occurs while exporting, the export will be cancelled. You can choose to export files to a USB flash drive instead or wait until the connection has reestablished before exporting to the PACS server.







When files are exported to a USB flash drive, they are placed in a folder with a name composed by the procedure name and the note (if any). Example below: The procedure name is 2020-02-04 001 and the note written is "For teaching". The exported files in the folder will be called; YYYY-MM-DD XXX ZZZZ, where XXX is the procedure count and ZZZZ is the photo count within the procedure.



2022-02-04 001 For teaching

Note: It is recommended to perform regular backup of the displaying unit by exporting files to a PACS server or USB flash drive. Protected Health Information (PHI) is stored with password protection in the displaying unit's memory and is **not** deleted from the displaying unit by exporting files. To delete PHI from the displaying unit, the files must be deleted from the displaying unit, either manually or using the auto-delete function (see section 7.3.).

File formats	Connector	BASIC file format
Image (Uncompressed)	Blue	400 x 400 pixels – PNG format
	Grey	800 x 800 pixels – PNG format
	Green	400 x 400 pixels – PNG format
Video (Compressed)		MP4 format

Explanations of functions in export menu 		
Icon	Name	Function
-	DICOM*	Photos and videos can be exported to a USB flash drive or a PACS server in DICOM format.
-	BASIC	Photos and videos can be exported to a USB flash drive in BASIC format. The BASIC format exports photos in PNG, videos in MP4.
-	Patient information	Patient data can be retrieved automatically by selecting a patient in the Worklist (refer to section 6.4) or it can be entered manually. Patient data will be saved on the local storage of the displaying unit until the files are deleted, either manually or with auto delete function (can be configured by Administrator in General settings, see section 4.3.).
-	USB	Select a connected USB flash drive to export photo(s) or video(s) to the USB flash drive in BASIC or DICOM formats.
-	PACS**	Select a connected PACS server to export photos and videos to the server in DICOM format. For setting up connection to the PACS server see section 5.2.
	Export button	Press the Export button, to export selected photos and videos when all necessary settings have been made.
	Info	Press Info to view the photo, video or procedure information in the procedure folder.
	Export menu	Press the Export menu button to open the Export menu.
	Bin	Press the Bin button to permanently delete photos and videos and any patient data from the displaying unit.
	Export indicators	To indicate if an export of a photo or video was successful, a green export indicator will appear next to the photo or video. A red indicator means the photo or video was not exported.




* Digital Imaging and Communications in Medicine

** Picture Archiving and Communication System

7.3. Deleting files from the Archive

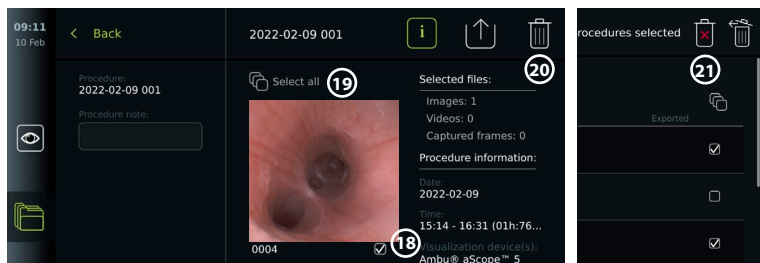
Deleted files are moved to the Bin until they are deleted permanently. The Administrator can set the files to be moved to the Bin or deleted permanently after a certain time. By default, files in the Bin are deleted permanently after three months. All type of users can move files to the Bin but the Advanced user or Admin user have rights to permanently delete files.

Move files from Procedures folder to the Bin:

- Press the **Archive tab**, then press **Procedures**.
- Press the required procedure folder.
- Select the required files by ticking the boxes below the thumbnails , or press **Select all** .
- Press the **delete icon** , then press **OK**.

Delete files permanently:

- Press the **Archive tab**, then press **Bin**.
- Press the required folder.
- Select the required files by ticking the boxes below the thumbnails, or press **Select all**.
- Press the **permanently delete icon** (21), then press **OK**.



8. Connect external equipment

See the overview of input and output connections in section 2.3. Please consult the *Instructions for Use* of the external equipment for further information. Ensure that the displaying unit is in STANDBY mode (orange light in power button), turned OFF or disconnected (no light in power button) when connecting the equipment.

8.1. Connecting to an external monitor

Live image or playback video shown on the displaying unit's screen can be shown simultaneously on an external monitor via cable connection (3G-SDI or HDMI). The image on the external monitor is the mirror image of the displaying unit's screen, including the software interface.

Use a medical grade monitor with resolution of at least 1920 x 1080, 60 frames per second (fps) and a monitor size of at least 27" with HDMI and/or 3G-SDI input. The recommended colour space is sRGB.

Connect the displaying unit to an external monitor:

- Connect the 3G-SDI or HDMI cable from the external monitor to the connector port on the back of the displaying unit (see section 2.3).
- Ensure that the correct input setting has been selected on the external monitor (please refer to the instructions for use supplied with the external monitor).

Note: It is advised to connect the external monitor while the displaying unit is turned off.

Note: Automatic image rotation is not supported with a HDMI connected external monitor. Please change orientation of the displaying unit to correct the HDMI monitor view.

8.2. Connecting USB flash drives

If needed, connect an external USB flash drive to the USB ports on the side of the displaying unit (see section 2.4. at 9-1 for USB port locations).

8.3. Connecting an audio device

8.3.1. Record sound during the procedure

- Connect the displaying unit to an audio device via USB connection (see section 2.4. at 9-1).
- A microphone icon in the Toolbar indicates if the audio device is compatible or not.

8.3.2. Play sound recorded during a procedure

- Connect an audio device to the displaying unit's USB connector port to listen to audio during video playback.

Note: Video files that contain audio recording are shown with an audio icon.

8.4. Printing images via external medical printer

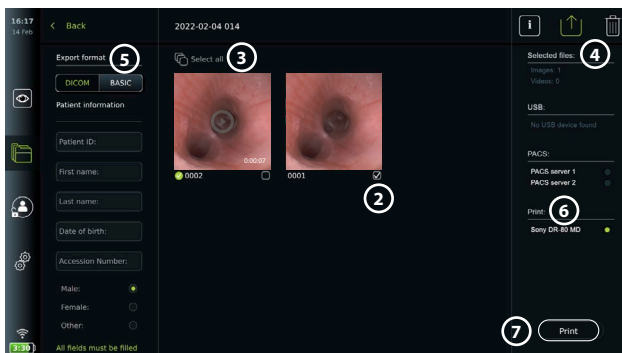
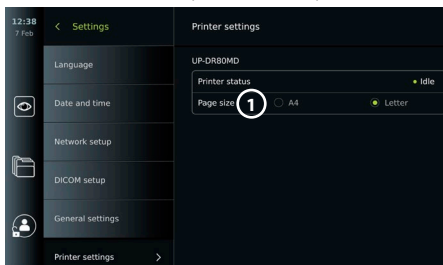
Before you print images via a medical printer, ensure that USB connection has been enabled for printing and a medical printer has been connected via USB (see section 4.3.).

Select settings for printing:

- Press the **Settings** tab, then press **Setup**.
- Press **Printer settings**.
- Press the required **page size** ①.

Print images via medical printer:

- Press the **Archive** tab, then press **Procedures**.
- Press the required procedure folder.
- Select the required images by ticking the boxes below the thumbnails ②, or press **Select all** ③.
- Press the **export icon** ④, then press **Basic** ⑤.
- Ensure that the printer name is shown below the export icon to verify that connection has been established ⑥.
- Press **Print** ⑦.



Note: Patient data is not included on the printed image.

Note: Verified compatibility with Sony UP-DR80MD digital colour printer for medical applications.

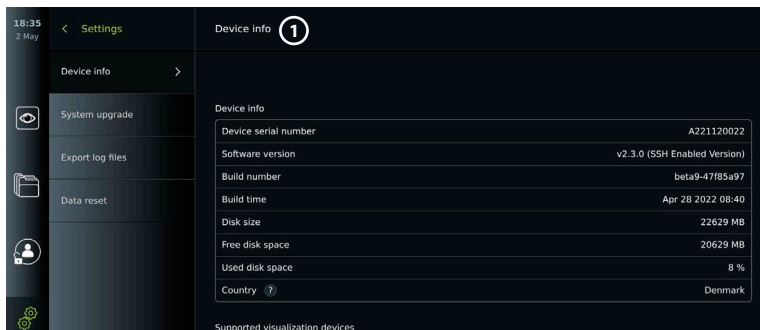
9. System information and software updates/upgrades

9.1. Device information page

You can view information about the displaying unit, e.g. software version, free disk space, etc.

- Press the **Settings** tab, then press **About**.
- The **Device info** ① page is shown on the screen.

Scroll down to see all the information.

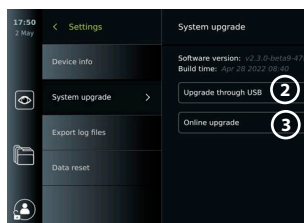


9.2. Software updates/upgrades

Software updates/upgrades can be performed online or installed from a USB flash drive. Before starting the update/upgrade, ensure that the battery level is more than 40 %, otherwise connect the power supply to the displaying unit (see section 2.3.).

Install update/upgrade from USB flash drive:

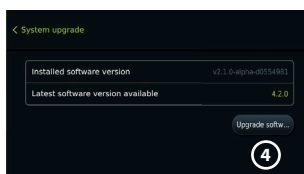
- Press the **Settings tab**, then press **About**.
- Press **System upgrade**, then press **Upgrade through USB** **(2)**.
- Press the USB flash drive name, then press **Next**.
- Follow the instruction on the screen to finish installing the update/upgrade.



Perform online update/upgrade:

Before you perform online update/upgrade, ensure that online updates/upgrades have been enabled (see below) and a Wi-Fi network connection has been set up (see section 5.1.). Check that the network you connect to can reach the address: <https://api.services.ambu.com> to ensure that the displaying unit can retrieve any available update/upgrade.

- Press the **Settings tab**, then press **About**.
- Press **System upgrade**, then press **Online upgrade** **(3)**.
- Wait while the displaying unit is checking for available updates/upgrades.
- If a new software version is available, press **Upgrade software** **(4)**.
- Follow the instructions on the screen to finish installing the update/upgrade.



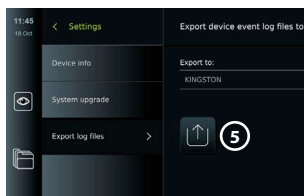
Note: Software updates/upgrades cannot be carried out when an endoscope is connected to the displaying unit or simultaneously with other functions or procedures.

9.3. Reporting a problem

If you are experiencing problems with the displaying unit, please follow the Troubleshooting guide in chapter 14 to find a solution. If this does not solve the problem, please contact your local Ambu representative. To solve the problem, Ambu may need a log file providing information about the displaying unit system.

Export a log file:

- Press the **Settings tab**, then press **About**.
- Press **Export log files**.
- Press the USB flash drive name, then press the **Export icon** **(5)**.
- Wait while the log files are exported, then press **Ok**.



9.4. Data reset

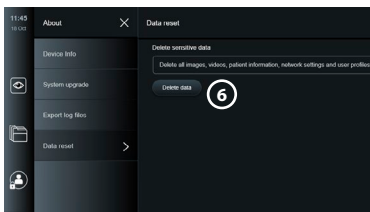
If a displaying unit is to be handled by a third party or needs to be disposed, it is advised to delete all sensitive data. Please follow your local guidelines for data protection. This function can only be accessed by an Administrator user profile.

The data reset function will delete:

- All procedure folders with saved images and videos including patient information retrieved from the Worklist.
- All created user profiles, the Administrator and Service user profiles will be reset to default password.
- Wireless network settings and certificates.
- DICOM, PACS and Worklist server settings and certificates.

Reset the data:

- Press the **Settings** tab, then press **About**.
- Press **Data reset**, then press **Delete** **6**. A dialog box appears informing of the consequences and asking to confirm.
- Press **Confirm**, then enter **Administrator password** and press **Continue**.
- A dialog box appears informing that this operation may take a while, the operation can succeed or fail. If failed, please try again.



10. Cleaning and disinfection of the displaying unit

The displaying unit is a reusable medical device. According to the Spaulding classification, the displaying unit is a non-critical device.

The displaying unit should be cleaned and disinfected before and after each use, following one of the procedures below. Any deviation from the instructions should be properly evaluated for effectiveness and potential adverse consequences by the person responsible for cleaning and disinfection to ensure that the device continues to fulfill its intended purpose. Cleaning procedures should begin as soon as possible following use. Excessive soil should be removed on accessible areas of the device, excluding electrical ports.

Cautions: Cleaning and disinfection wipes shall be moist but not dripping to ensure no damage to the internal electronics of the displaying unit. If using wipes containing hypochlorite or citric acid, ensure that all residue is completely removed. Wipes containing hypochlorite or citric acid may affect the screen's anti-reflective coatings over time. You should limit the use of wipes containing hypochlorite or citric acid to required cases only.

Limitations: The displaying unit is not compatible with ultrasonic or automatic cleaners and should not be immersed.

Procedure 1 – Cleaning and disinfection with hypochlorite

Hypochlorite-based wipes approved for disinfection of medical devices, e.g., Sani-Cloth® Bleach from PDI, should be used in accordance with the wipe manufacturer's instructions.

Cleaning: Use a wipe to remove heavy soil. All blood and other body fluids must be thoroughly cleaned from surfaces and objects. Inspect the displaying unit for cleanliness, function, and integrity before disinfection by germicidal wipe. If visible soil remains, reclean the displaying unit.

Disinfecting:

1. For heavily soiled surfaces, use a wipe to pre-clean the displaying unit prior to disinfecting.
2. Unfold a clean wipe and thoroughly wet the surface of the displaying unit.
3. The treated surfaces must remain visibly wet for a full four (4) minutes (or the time recommended by the manufacturer of the disinfectant, at least 4 minutes). Use additional wipes if needed to assure continuous 4 minutes wet contact time.
4. Let the displaying unit air dry.

Procedure 2 – Cleaning and disinfection with quaternary ammonium compounds

Wipes containing a mixture of quaternary ammonium compounds and isopropyl alcohol approved for disinfection of medical devices, e.g., Super Sani-Cloth® from PDI, should be used in accordance with the wipe manufacturer's instructions.

Cleaning: Use a wipe to remove heavy soil. All blood and other body fluids must be thoroughly cleaned from surfaces and objects. Inspect the displaying unit for cleanliness, function, and integrity before disinfection by germicidal wipe. If visible soil remains, reclean the displaying unit.

Disinfecting:

1. For heavily soiled surfaces, use a wipe to pre-clean the displaying unit prior to disinfecting.
2. Unfold a clean wipe and thoroughly wet the surface of the displaying unit.
3. The treated surfaces must remain visibly wet for a full two (2) minutes (or the time recommended by the manufacturer of the disinfectant, at least 2 minutes).
Use additional wipes if needed to assure continuous 2 minutes wet contact time.
4. Let the displaying unit air dry.

Procedure 3 – Enzymatic detergent cleaning and alcohol disinfection

Cleaning:

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, external side of rubber covers, screen, external casing of the monitor with the moist gauze. Avoid getting the displaying unit wet to prevent damaging internal electronic components.
4. Wait for 10 minutes (or the time recommended by the manufacturer of the detergent) to allow the enzymes to activate.
5. Wipe the displaying unit clean using sterile gauze that has been moistened with RO/DI water. Ensure all traces of the detergent are removed.
6. Repeat steps 1 to 5.

Disinfecting: Wipe the surfaces of the displaying unit 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 displaying unit. Pay close attention to the button, external side of rubber covers, screen, external casing and slots and gaps on the displaying unit. Use a sterile cotton swab for these areas.
Solution: Isopropyl (alcohol) 95 %; Concentration: 70 – 80 %; Preparation: 80 cc 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.

Note: After cleaning and disinfection, the displaying unit must be submitted to the pre-check procedure in section 6.1. The specified cleaning and disinfection procedures show compliance with the AAMI TIR12 and AAMI TIR30 guidelines.

11. Maintenance

The displaying unit shall be subject to preventive inspection prior to use according to section 6.1 and shall be cleaned and disinfected according to chapter 10.

No other preventive inspection, maintenance, or calibration activities are required for the displaying unit.

11.1. Maintenance of battery

To prolong battery life it is recommended to fully charge the displaying unit at least every third month. If the battery is discharged, the procedure can take up to 3 hours. The battery should be charged at temperatures between 10 – 35 °C.



CAUTION: To avoid malfunction of the equipment only use spare parts supplied by Ambu. Do not modify the spare parts.

Note: If the battery needs replacement, contact your local Ambu representative.

12. Disposal

At the end of product life, clean and disinfect the displaying unit (see chapter 10). Before disposing of the displaying unit, it is advised to delete all sensitive data (see section 9.4.). Then, dispose the displaying unit in accordance with local guidelines for electrical and electronic waste.

13. Technical product specifications

13.1. Standards applied

The displaying unit function conforms with:

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements for test.
- IEC 60601-2-18 Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

The power supply conforms with:

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

13.2. Specifications for aView 2 Advance

Display	
Resolution:	1920 x 1080 pixels
Orientation:	Landscape
Display type:	12.8" colour TFT LCD
Start up time:	5 seconds
Connections	
2 x USB connection:	USB 3.0 Type A
Digital video out:	HDMI and 3G-SDI (see note) Video format: 1920 x 1080 p, 60 fps
Wi-Fi:	Supports IEEE Standards 802.11ac/a/b/g/n
LAN:	Ethernet RJ45 connector, 10/100/1000 Mbps

Note: For 3G-SDI interface, it is recommended to use a quality cable with better shielding (e.g. RG6 grade).

Memory	
SSD hard drive capacity:	32 GB including Operating System
Mounting interface	
Mounting interface standard:	VESA MIS-D, 75 C, VESA FDMI compliant display, Part D, with centre located mounting interface
Electric power	
Power requirement:	19.0 VDC; 3.43 ADC
Battery type:	14.4 VDC 6500 mAh
Battery Operation:	Typical battery runtime of a new, fully charged battery (the displaying unit turned ON and scope connected) is 2.5 hours or more depending on the connected scope (see note)
Protection against electric shock:	Internally powered
Note: For more information about battery time with different scopes connected, please contact your local Ambu representative.	

Environment conditions	
Storage temperature:	0 – 40 °C (32 – 104 °F)
Operation temperature:	10 – 35 °C (50 – 95 °F)
Operation relative humidity:	30 – 85 %
Operation atmospheric pressure:	80 – 106 kPa
Operation altitude:	≤ 2000 m
IP Protection Classification System:	The aView 2 Advance is classified IP30: Protection against solid objects
Dimensions	
Width (a):	331 mm (13.03")
Height (b):	215 mm (8.46")
Thickness (c):	52 mm (2.05")
Weight:	2.7 kg (6.0 lbs)



13.3. Specifications for aView 2 Advance bracket

Bracket	
Fits poles with thicknesses	Ø 18 – 35 mm (0.7 – 1.5")

13.4. Specifications for aView 2 Advance power supply

Dimensions	
Weight:	360 g (0.79 lbs)
Electric power	
Power requirement:	100 – 240 V AC; 50 – 60 Hz; 1.0 – 2.0 A
Power out:	19.0 VDC 3.43 ADC
Protection against electric shock:	Class I
Operating and storage environment	
Temperature:	10 – 40 °C (50 – 104 °F)
Relative humidity:	30 – 85 %
Power cables	
Power supply connection:	Ø 6.5 mm DC jack connector
Country-specific plug types: Not all types of power cables can be shipped to all markets.	<ol style="list-style-type: none"> 1. USA and Japan: Model NEMA 5 AC grounded power plug 2. Australian: AS1312, AC grounded power plug 3. UK: BS1363, AC grounded power plug 4. European: CEE 7, AC grounded power plug 5. Danish: 2-5a, AC grounded power plug 6. Swiss: Type J, AC grounded power plug (only available as a spare part)

Contact Ambu for further information.

14. Troubleshooting

If problems occur with the displaying unit, please use this troubleshooting guide to identify the cause and correct the error. If the actions in the troubleshooting guide cannot resolve the problem, contact your local Ambu representative.


If replacement of spare parts is necessary, please refer to the Spare Part Replacement Manual included in the spare parts kit, or you can find it on ambu.com. Here you will also find information about the available Ambu authorized spare parts.

Many problems can be solved by restarting the displaying unit through a Power OFF Cycle. This can be done in 3 different ways and should be tried in the following order:

Power OFF Cycle
<p>Note: Do not power off the displaying unit during the software update/upgrade download and installation process.</p> <p>Restart the displaying unit</p> <ol style="list-style-type: none"> 1. Press the power button to turn OFF the displaying unit. 2. When the displaying unit is OFF, press the power button again to turn it back ON.
<p>If the displaying unit does not enter STANDBY mode, force it to completely turn OFF (no light in the power button)</p> <ol style="list-style-type: none"> 1. Press the power button for 10 seconds to force Turn OFF. 2. Press the power button again to turn the displaying unit back on. <p>If this does not work, reset displaying unit hardware</p> <ol style="list-style-type: none"> 1. Remove all connected items, including the power supply. 2. Press the hardware reset button on the back of the displaying unit*. 3. Reconnect the power supply. 4. Press the power button to turn ON the displaying unit.

* Access the hardware reset button using the pin tool with a diameter of 1.5 mm and length of 16 mm.

Problem	Possible cause	Recommended action
The displaying unit does not turn ON when the power button is pressed.	No power is left on the displaying unit battery.	Connect the power supply to the displaying unit.
	The displaying unit does not turn ON even though the power supply is connected.	Check that the light on the power supply is ON when it is plugged into a working wall socket. If there is no light, the power supply may need to be replaced. Perform a Power OFF Cycle (follow the procedure above this table).
The battery is not charging.	The internal temperature in the displaying unit is below 10 °C or above 45 °C.	If any of the following conditions apply, correct it to cool down the displaying unit: <ol style="list-style-type: none"> 1. Check if the back of the monitor has free access to airflow. 2. Check that the fan is running by looking through the ventilation holes, feeling for airflow at ventilation holes, and/or by listening for fan noise. If the fan is not running, it may need to be replaced. 3. Check if the displaying unit is placed in direct sunlight or is exposed to other heat sources.
Battery uptime is low.	The capacity of the internal battery has degraded due to wear and tear.	If you experience that the battery life of the displaying unit after a full charge is below 1 hour, consider replacing the battery.

Problem	Possible cause	Recommended action
No Live image from the visualization device on the displaying unit screen OR No LED light in the distal end of the visualization device.	Failure on visualization device or visualization device connection.	Connect/reconnect visualization device.
	The displaying unit and the Ambu visualization device have communication problems.	Perform a Power OFF Cycle (follow the procedure above this table).
	Failure on visualization device connector port.	Try one of the other visualization device connector ports. If an image is obtained from the other connector port, then the first connector port may need to be replaced. If none of the connector ports provide an image, try again using a new visualization device.
	A recorded image is shown in the Procedure Folder tab OR A menu box is blocking the live image.	Return to live image by pressing the Live View tab  OR If this does not work, perform a Power OFF Cycle (follow the procedure above this table).
The Live image on the displaying unit screen is only working while booting.	Processing failure.	Perform a Power OFF Cycle (follow the procedure above this table).
No image or User Interface on the external monitor.	The external monitor is turned OFF.	Turn ON the external monitor.
	An issue with cable or cable connection.	Check that the SDI or HDMI cable is connected correctly. If possible, try a new cable. It is recommended to use a high-quality cable with better shielding. (e.g. RG6 grade).
	Wrong input channel is selected on the external monitor.	Make sure the correct input channel is selected on the external monitor.
	SDI – External monitor does not support 3G-SDI.	Make sure that your external monitor supports 3G-SDI (1920 x 1080 p 60 fps.).
The colours, contrast, sharpness, and brightness look different on the external monitor than on the displaying unit screen.	Image settings on the external monitor are not correct.	Adjust the image settings on the external monitor to achieve the desired result. Refer to the <i>Instructions for Use</i> for the external monitor.
The touch interface does not respond.	The displaying unit has internal communication problems.	Perform a Power OFF Cycle (follow the procedure above this table).

Problem	Possible cause	Recommended action
Low picture quality.	Dirty/damp screen.	Wipe the screen with a clean cloth as described in chapter 9.
	Image Adjustment settings are not optimal.	Open the Image Adjustment menu to adjust colour, contrast, sharpness and brightness.
	The distal end in the visualization device is dirty/damp.	Refer to the <i>Instructions for Use</i> of the visualization device.
Displaying unit cannot identify a connected USB device.	USB connector port is damaged.	Move the USB device to another USB connector port.
	USB cable or external USB device is damaged.	Connect a new USB cable or a new USB device.
	The displaying unit has internal communication problems.	Perform a Power OFF Cycle (follow the procedure above this table).
	The USB connection may be disabled	Login as an Administrator, go to Settings – Setup – General settings – enable USB connection.
Failed data transfer from displaying unit to USB flash drive.	USB format is incorrect.	The displaying unit supports data transfer to USB flash drives formatted as exFAT, EXT4, NTFS, BTRFS and FAT32.

15. Warranty and replacement

Ambu warrants that the displaying unit (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 one (1) year from the date of invoice.

Under this limited warranty, Ambu will be responsible only for either supplying authorized spare parts or replacement of the displaying unit, as Ambu may decide in its sole discretion. In case of replacement of spare parts, the customer is obligated to provide reasonable assistance to Ambu, including, where relevant, by customer's biomedical technicians pursuant to instruction from Ambu.

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

The warranty applies only if it can be established that:

- The displaying unit has not been disassembled, repaired, tampered with, altered, changed, or modified by persons other than technical personnel (except with the prior written consent of Ambu or in accordance with the instructions in the Spare Part Replacement Manual); and
- The defects or damage to the displaying unit 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 loss or damages of any kind (including without limitation loss of profits or loss of use), whether or not Ambu is 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 displaying unit to Ambu (at its own expense and risk of shipment). In compliance with applicable regulations, any displaying unit 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 in chapter 9). Ambu is entitled to reject a displaying unit which has not been duly decontaminated, in which case this limited warranty shall not apply.

Appendix 1. Electromagnetic compatibility

Like other electrical medical equipment, the system requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC) the system must be installed and operated according to the EMC information provided in this *Instructions for Use*. The system has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.


Guidance and manufacturer's declaration – Electromagnetic emission		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment guidance
RF emission CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following NOTE 1 is heeded.
Harmonic emission IEC/EN 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

Note 1: The emissions Characteristics of this equipment makes it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to the radio-frequency communication service. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration – Electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2, 4, 8, 15 kV air	+/- 8 kV contact +/- 2, 4, 8, 15 kV air	If floors are covered with synthetic material the relative humidity shall be least 30 %.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	+/- 2 kV power supply lines N/A	Mains power quality shall be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth		Mains power quality shall be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – Electromagnetic immunity

The system is intended for use in the electromagnetic environment specified below.
The customer or the user of the system should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<p>< 5 % U_T (95 % dip in U_T) for 0.5 cycle</p> <p>40 % U_T (60 % dip in U_T) for 5 cycles</p> <p>70 % U_T (30 % dip in U_T) for 25 cycles</p> <p>< 5 % U_T (95 % dip in U_T) for 5 sec.</p>	<p>100 % reduction 0.5 period</p> <p>40 % reduction for 5 periods</p> <p>30 % reduction for 25 periods</p> <p>100 % reduction for 5 sec.</p>	Mains power quality shall be that of a typical commercial or hospital environment.
Conducted Radio Frequency IEC 61000-4-6	<p>3 V RMS 0,15 MHz – 80 MHz 6 V RMS in ISM bands 80 % AM at 1 kHz</p>	<p>3 V RMS 0,15 MHz – 80 MHz 6 V RMS in ISM bands 80 % AM at 1 kHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey: a) Should be less than the compliance level in each frequency range. b) Interference may occur in the vicinity of equipment marked with the following symbol.</p>
Radiated Radio Frequency IEC 61000-4-3	<p>3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz</p>	<p>3 V/m 80 – 2700 MHz 80 % AM at 1 kHz</p>	<p>Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey: a) Should be less than the compliance level in each frequency range. b) Interference may occur in the vicinity of equipment marked with the following symbol.</p> <p style="text-align: center;"></p>

Note 1: At 80 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/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 system is used exceeds the applicable RF compliance level above, the system shall be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. Over the frequency range 150 kHz to 80 MHz, field strengths shall be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and system.

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters and the 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		
	150 kHz to 80 MHz $D = 1.17\sqrt{P}$	80 MHz to 800 MHz $D = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $D = 2.33\sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.33 m
10	3.70 m	3.70 m	7.37 m
100	11.7 m	11.7 m	23.3 m

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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix 2. Radio frequency compliance

To ensure Radio Frequency Compliance (RF) the system must be installed and operated according to the RF information provided in this *Instructions for Use*.

Guidance and manufacturer's declaration – Radio frequencies

This device complies with Directive 2014/53/EU issued by the Commission of the European Community.

Operations in the 5.15 – 5.35 GHz band are restricted to indoor usage only:



Check RF regulations in the individual countries

Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE) and United Kingdom (UK).

The full text of the EU declaration of conformity is available at the following internet address: www.ambu.com.

Industry Canada statement (IC)

EN: This device complies with ISED's licence-exempt RSSs. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FR: Le présent appareil est conforme aux CNR d'ISED applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) le dispositif ne doit pas produire de brouillage préjudiciable, et (2) ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

Caution/Avertissement:

EN: (i) the device for operation in the band 5150 – 5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems; (ii) where applicable, antenna type(s), antenna models(s), and worst-case tilt angle(s) necessary to remain compliant with the e.i.r.p. elevation mask requirement set forth in section 6.2.2.3 shall be clearly indicated.

FR: Le guide d'utilisation des dispositifs pour réseaux locaux doit inclure des instructions précises sur les restrictions susmentionnées, notamment:

(i) les dispositifs fonctionnant dans la bande 5150 – 5250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage p
(ii) lorsqu'il y a lieu, les types d'antennes (s'il y en a plusieurs), les numéros de modèle de l'antenne et les pires angles d'inclinaison nécessaires pour rester conforme à l'exigence de la p.i.r.e. applicable au masque d'élévation, énoncée à la section 6.2.2.3., doivent être clairement indiqués.

Radiation Exposure Statement/ Déclaration d'exposition aux radiations:

EN: This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with greater than 20 cm between the radiator & your body.

FR: Cet équipement est conforme aux limites d'exposition aux rayonnements ISED établies pour un environnement non contrôlé. Cet équipement doit être installé et utilisé à plus de 20 cm entre le radiateur et votre corps.

Federal Communication Commission Interference Statement (FCC)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures: Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help.

FCC Caution:

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

This device meets all the other requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator & your body.

Wi-Fi:

Standard	IEEE802.11ac, IEEE802.11a ,	IEEE802.11b , IEEE 802.11g , IEEE 802.11n
ISM frequency Band	2.4/ 5 GHz	
Data Rate	802.11a: 54, 48, 36, 24, 18, 12, 9, 6 Mbps 802.11b: 11, 5.5, 2, 1 Mbps 802.11g: 54, 48, 36, 24, 18, 12, 9, 6 Mbps	802.11n: MCS 0 to 15 for HT20MHz MCS 0 to 15 for HT40MHz 802.11ac: MCS 0 to 8 for HT20MHz MCS 0 to 9 for HT40MHz MCS 0 to 9 for HT80MHz

Wi-Fi:		
Modulation Techniques	802.11ac: 256QAM, 64QAM, 16QAM, QPSK, BPSK 802.11a: 64QAM, 16QAM, QPSK, BPSK	802.11b: CCK, DQPSK, DBPSK 802.11g: 64QAM, 16QAM, QPSK, BPSK 802.11n: 64QAM, 16QAM, QPSK, BPSK
Transmit Output Power – 2x2 (Tolerance: ±1.5dBm@2.4GHz ±2dBm@5GHz)	802.11b / CCK : 18 dBm 802.11a : 13 dBm @6,24,36Mbps 12 dBm @48Mbps 10.5 dBm @54Mbps 802.11g / OFDM: 18 dBm@6,9,12,18,24Mbps 17 dBm@36Mbps 16 dBm@48Mbps 16 dBm@54Mbps 2.4G: 802.11n / HT20: 18 dBm@MCS0 16 dBm@MCS7 802.11n / HT40: 17 dBm@MCS0 16 dBm@MCS7	5G: 802.11n / HT20: 12.5 dBm@MCS0 10 dBm@MCS7 802.11n / HT40: 11.5 dBm@MCS0 10 dBm@MCS7 AC: HT20: 10 dBm@MCS7 9 dBm@MCS8 HT40: 8 dBm@MCS8 7 dBm@MCS9 HT80: 7 dBm@MCS8 6 dBm@MCS9

Appendix 3. Cybersecurity

This appendix is intended for the IT network responsible at the organization where the displaying unit is used. It contains technical information regarding the setup of the IT network and the devices connected to the displaying unit. It also contains information regarding the types of data contained in and transmitted from the displaying unit.

The displaying unit is of medium security risk (according to NIST) as:

- The displaying unit does not allow any input from external devices (except from Ambu visualization devices and secured software updates).
- Essential functionality is secured in case of network problems.

Appendix 3.1. Network setup

When preparing the network for connection to the displaying unit, the following should be considered:

Overview of the existing ports and their communication protocols		
Item	Standards used	Comments
Wireless communication	IEEE 802.11	The device uses a WPA_Supplicant to support WPA2 Wireless communication as TKIP and CCMP. The authentication and integrity of the communication is provided by the underlying FIPS 140-2 compliant chipset wireless driver. Wi-Fi option supports WPA2 Enterprise for mschapv2.

Overview of the existing ports and their communication protocols		
Item	Standards used	Comments
LAN communication	IEEE 802.3 IEEE 802.3ab IEEE 802.3az PICMG3.1	The device uses a standard Gigabit Ethernet controller supporting a 1000base-T interface.
Access test	ICMP/ping	Allowing ease-of-discovery for hospital IT infrastructure.
Network adaptor configuration	DHCP	Only configurable through DHCP. Special configurations for the network adapter such as static IP are currently not supported.
Re-routing		The device does not support re-routing traffic from Wi-Fi to LAN or vice versa, therefore the device cannot act as a NAT (Network Address Translation) gateway.
PACS servers	DICOM	To support a broad range of network infrastructures and PACS servers, the device supports DICOM without CMS (Cryptographic Message Syntax) encryption for transporting photo(s) and video(s) to the PACS server.
Ports		There are no open ports, the device firewall only accepts TCP responses for DICOM and replies to ICMP ping requests.

Note: There are no open ports, the device firewall only accepts TCP responses for DICOM and replies to ICMP ping requests.

Appendix 3.2. Data at rest and in transit

The displaying unit uses SQLite3 databases to secure information about the scopes, procedures and network configurations. The SQLite database is not accessible from the GUI, but photos, videos and a limited log can be exported to a PACS server and/or USB device. The following exportable data are stored:

Item	Format	Comments
Photos	DICOM object/PNG	
Video	DICOM object/MP4 (h.264)	
Ambu Application log	Clear-text format	The log files exported are mainly for troubleshooting purposes by Ambu staff, in case you encounter problems with the displaying unit. The files are compressed in a format more secure than Windows standard compression function. Unzipping the data requires a third-party tool (e.g., 7-zip).

Photos and videos can be transferred to a PACS server. The following formats and protocols are used during the transfer from the displaying unit to the PACS server:

Item	Format	Protocols	Comments
Photos	DICOM object/PNG	DICOM without CMS	Can use either Wi-Fi or LAN communication.
Video	DICOM object/MP4 (h.264)	DICOM without CMS	Can use either Wi-Fi or LAN communication.

Appendix 3.3. Software Bill Of Materials (SBOM)

The following main off-the-shelf software components are used in the displaying unit. Main known vulnerabilities of each component including explanations of why they are acceptable for this application are continuously updated by Ambu. Contact your local Ambu representative for an up-to-date list with this information. Vulnerabilities with a low CVSS score are omitted as a consequence of the medium security risk rating of the displaying unit.

Title	Version	Used for
Qt	5.14.2	Qt is used for the graphical user interface (GUI).
Boost	1.78.0	Boost is used for IO file interaction and asynchronous handling.
libyaml-c	0.2.2	Is used to parse YAML files on the device. YAML files are used for configuration, including keys and values.
libyaml	0.6.2	Is used to parse YAML files on the device. YAML files are used for configuration, including keys and values.
SQLite3	3.31.1	Main database.
Linux	Linux Kernel version 4.19.217	The embedded Linux kernel is built custom by Ambu.
GStreamer	1.18.6	The following plugins are used: <ul style="list-style-type: none"> • v4l2src • glupload • gcolorconvert • vaapipostproc • vaapih264enc • matroskamux • tcpserver sink • tcpclientsrc • filesink • qmlglsink
openssl	1.1.1i	Used to generate the private key and authenticate the public key used to sign the upgrade package.
dcmktk	3.6.6	Used for the DICOM protocol communicating to the PACS server.

Title	Version	Used for
DICOMConnect	3.3.3	Used for the DICOM protocol communicating to the PACS server.
Barebox	2021.03.0	Used for bootloading the Embedded system.
RAUC	1.5.1	Used for updating new software on the embedded system.
yocto	dunfell	Used to build the embedded Linux system.

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