

INSTRUCTIONS FOR USE

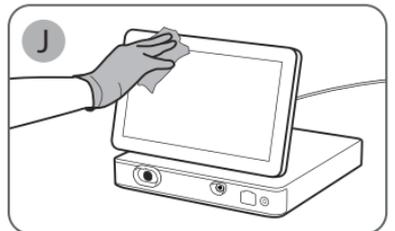
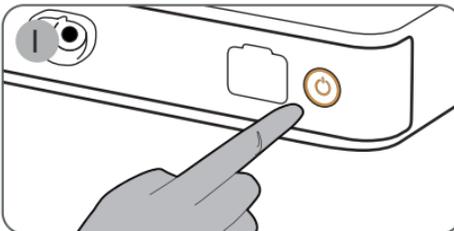
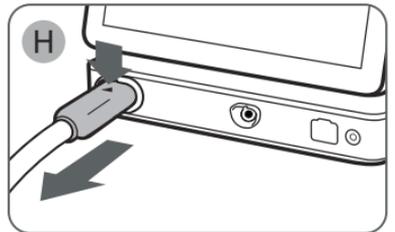
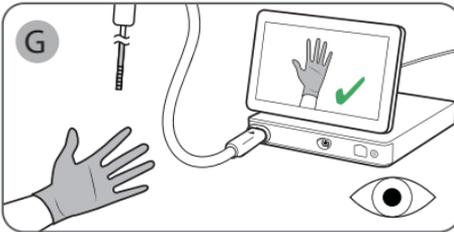
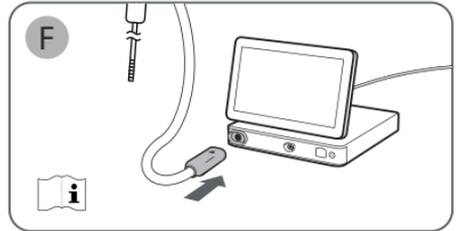
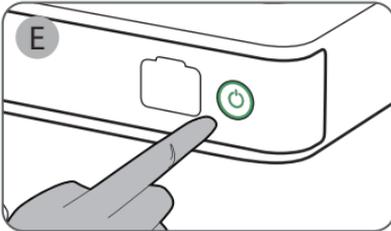
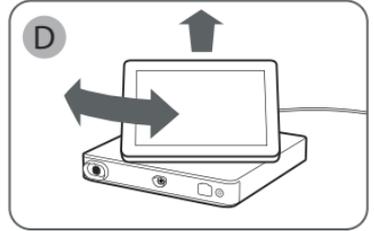
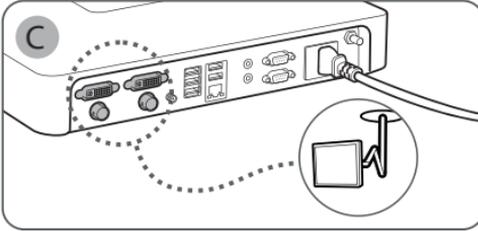
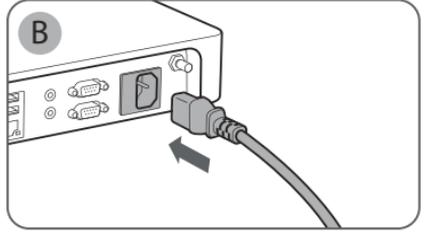
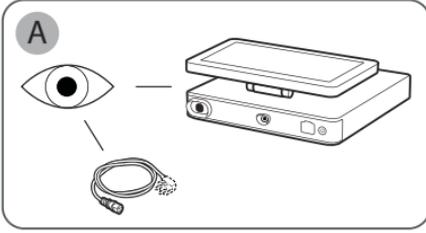


Ambu

Ambu® aBox™ 2

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

QUICK GUIDE



1. Important Information – Read Before Use	5
1.1. Intended use/Indications for use.....	5
1.2. Intended patient population.....	5
1.3. Intended user profile.....	5
1.4. Clinical benefits.....	5
1.5. Potential adverse events.....	5
1.6. General notes.....	5
1.7. Contraindications.....	5
1.8. Warnings and cautions.....	5
2. Device Description	7
2.1. Displaying unit parts.....	7
2.2. Product compatibility.....	7
2.3. Endoscope activation.....	8
2.4. Description of components.....	9
2.5. Spare parts.....	10
2.6. System overview.....	10
3. Explanation of Symbols Used	11
4. Getting Started	12
4.1. First-time setup.....	12
4.2. User profiles.....	14
5. General Settings	15
6. Network Setup	16
6.1. Wi-Fi setup.....	16
6.1.1. Wi-Fi network with WPA/WPA2 authentication.....	16
6.1.2. Hidden Wi-Fi network (Wi-Fi not showing on the list of available Wi-Fi connections).....	16
6.1.3. Wi-Fi network with WPA2 Enterprise authentication (username and password required).....	17
6.1.4. Import network certificate for WPA2 (TLS -transport security layer).....	17
6.2. LAN connection via Ethernet cable.....	18
6.3. Set up static IP address and/or DNS server for a Wi-Fi or LAN network.....	18
6.4. Disconnect from Wi-Fi network.....	18
6.5. Clear all network data from the displaying unit.....	18
7. Setup Connection to PACS and Worklist	18
7.1. Set up the displaying unit for server connection.....	18
7.2. Set up connection to PACS server.....	18
7.3. Set up connection to Worklist server.....	19
8. Output Setup	21
9. Endoscope Buttons Configuration	22
9.1. Configure the endoscope buttons.....	22
10. Operating the Displaying Unit	22
10.1. Preparation and inspection of the displaying unit before use.....	22
10.2. Starting and stopping a procedure.....	23
10.2.1. Starting a procedure.....	23
10.2.2. Stopping a procedure.....	23
10.3. Procedure workflow using the worklist.....	23
10.4. Overview of Live View functions.....	24
10.5. Using image adjustments.....	24
10.5.1. Adjust colour, contrast, sharpness and brightness.....	25
10.5.2. Rotate the live image.....	25
10.5.3. Use the zoom function.....	25
10.5.4. Light on/off.....	25
10.5.5. Adjust ARC (Advanced Red Contrast) setting.....	25

10.6. Using the stopwatch	26
10.7. Using dual view	26
10.8. Taking photos and recording videos	27
10.9. Current procedure folder	27
10.10. After use of the displaying unit	28
11. File Handling in The Archive	28
11.1. Accessing files in the Archive	28
11.2. Exporting files to PACS server or USB flash drive.....	29
11.3. Deleting files from the Archive	31
12. Connect External Equipment	31
12.1. Connecting to an External Monitor	32
12.2. Connecting USB Flash Drives.....	32
12.3. Connecting to an External Medical Imaging Recorder	32
12.4. Printing images via external medical printer	32
12.5. Connect external audio devices.....	33
12.5.1. Record sound during the procedure	33
12.5.2. Play sound recorded during a procedure	33
13. System Information and Software Updates/Upgrades.....	33
13.1. Device information page	33
13.2. Software updates/upgrades.....	34
13.3. Reporting a problem.....	34
13.4. Data reset.....	35
14. Cleaning and Disinfection of the Displaying Unit	35
15. Maintenance	37
16. Disposal	37
17. Technical Product Specifications	37
17.1. Standards applied	37
17.2. Specifications for the displaying unit.....	37
18. Troubleshooting.....	39
19. Warranty and Replacement	42
Appendix 1. Electromagnetic Compatibility	42
Appendix 2. Radio Frequency Compliance.....	46
Appendix 3. Cybersecurity.....	49
Appendix 3.1. Network Setup	49
Appendix 3.2. Data at Rest and In Transit	50
Appendix 3.3. Software Bill Of Materials (SBOM).....	50

1. Important Information – Read Before Use

Read these *Instructions for Use* carefully before using the Ambu® aBox™ 2. These *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® aBox™ 2.

In these *Instructions for Use*, the term *displaying unit* refers to Ambu® aBox™ 2. 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*.

1.1. Intended use/Indications for use

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

1.2. 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 devices.

1.3. 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.

1.4. Clinical benefits

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

1.5. Potential adverse events

None known for the displaying unit.

1.6. General notes

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

1.7. Contraindications

None known for the displaying unit.

1.8. 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 14.
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 loss of the live image during procedure, ensure to correctly connect the power cord to an appropriate power source that will ensure continuous power supply.
8. 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 bottom of the displaying unit.
9. 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.
10. 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

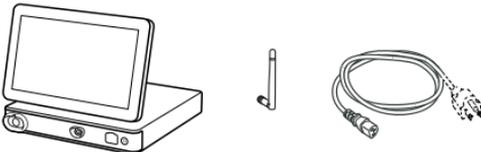
1. To prevent damaging the displaying unit, always place the displaying unit on a hard flat surface during use to avoid covering the ventilation holes at the bottom of the displaying unit. Be aware that covering the ventilation holes can also lead to a high surface temperature.
2. Using high frequency 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. Do not place any heavy objects on the top of the displaying unit when it is folded flat, as this could damage the equipment and lead to malfunction or exposure of electrical parts.
4. 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.
5. 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 10.1 fails.

6. To avoid malfunction of the equipment only use spare parts supplied by Ambu. Do not modify the spare parts.
7. Cleaning and disinfection wipes shall be moist, but not dripping to ensure no damage to internal electronics of the displaying unit.
8. 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 can be connected to compatible Ambu visualization devices to display video images. The following sections describe the components of the displaying unit and list compatible devices.

2.1. Displaying unit parts

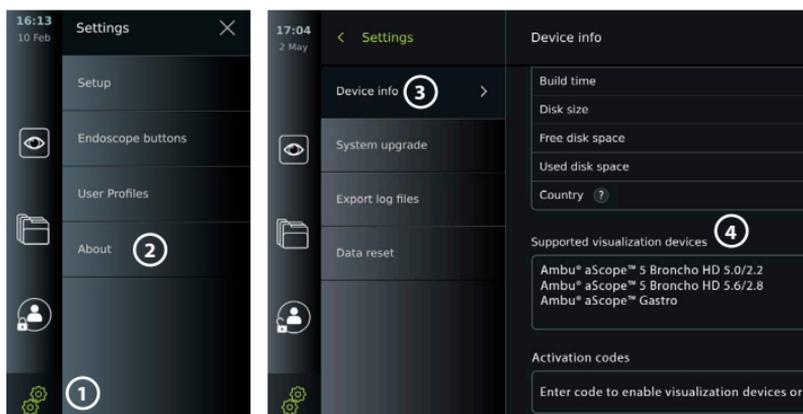
Ambu® aBox™ 2	Item number
	505001000

2.2. Product compatibility

aBox 2 includes two connector ports on the front marked in colours. Ambu visualization devices are compatible with aBox 2 at the colour-coded connection mechanism and connector geometry.

A full list of compatible visualization devices is displayed in the user interface of the displaying unit. To see compatible Ambu visualization devices:

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



Compatible external equipment

- External medical grade monitors (video output)
- External medical imaging recorders (video output and trigger output)
- USB flash drives
- 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 12.

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.

2.3. Endoscope activation

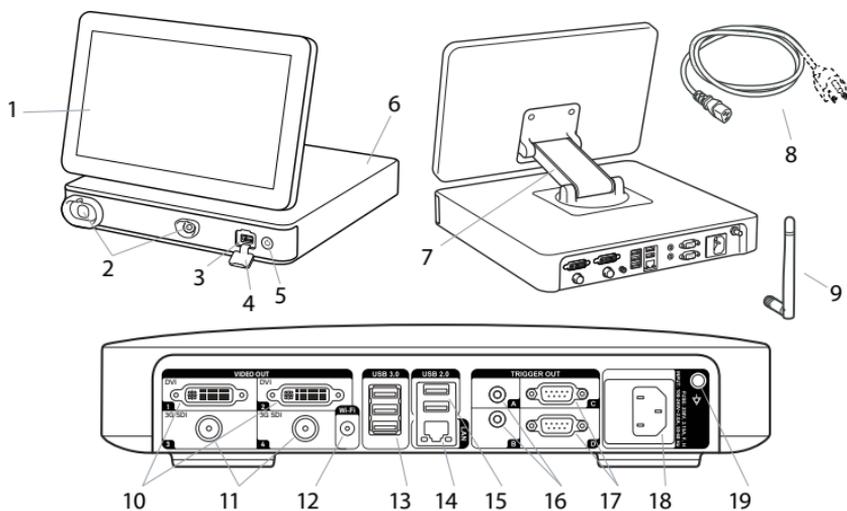
New endoscope types that are not found on the displaying unit's list of supported endoscopes (see section 2.2) must be activated with an activation code before they can be used with the displaying unit. The activation code is entered only once for each endoscope type, and once an endoscope type has been activated, it can be found on the list of supported visualization devices. The activation codes are found on Ambu's website via the URL shown on the displaying unit's screen 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.



2.4. Description of components

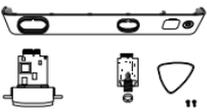


No.	Component	Function
1	Touch screen	Displays the graphical user interface and shows the live image from the Ambu visualization device.
2	VDI port (connector port for specific Ambu visualization devices)	Connector port geometry and colour ensures correct connection with compatible visualization devices.
3	USB 3.0 port (front)	Enables connection of external USB flash drives.
4	USB port cover (front)	Protects the front USB port.
5	Power button	Turns the power ON or switches to STANDBY mode.
6	Base	Contains the main unit.
7	Positioning arm	Enables manual positioning of the touch screen. The screen can be adjusted horizontally and vertically as well as rotated.
8	Power cable	Connects the displaying unit to a power outlet.
9	Wi-Fi antenna	Connect Wi-Fi antenna to the displaying unit for improved Wi-Fi signal.
10	Video output ports (2x DVI-D)	Enable connection to external monitor or external medical imaging recorder. See section 7.1. for details on the difference between using DVI-D and 3G-SDI on the displaying unit.
11	Video output ports (2x 3G-SDI)	
12	Wi-Fi antenna connector	Enables connection of Wi-Fi antenna.
13	USB 3.0 ports	Enables connection of external USB flash drives.
14	LAN port	Enables connection to ethernet.

No.	Component	Function
15	USB 2.0 ports	Enables connection of external USB flash drives.
16	Trigger output ports (2 x 3.5 mm jack)	Enable connection to an external medical imaging recorder to transfer trigger signals.
17	Trigger output ports (2 x D-SUB9)	
18	Power inlet	Enables connection to power cable.
19	Connector for potential equalization cable	Enables bonding of electrical products to eliminate potential differences between conductive parts.

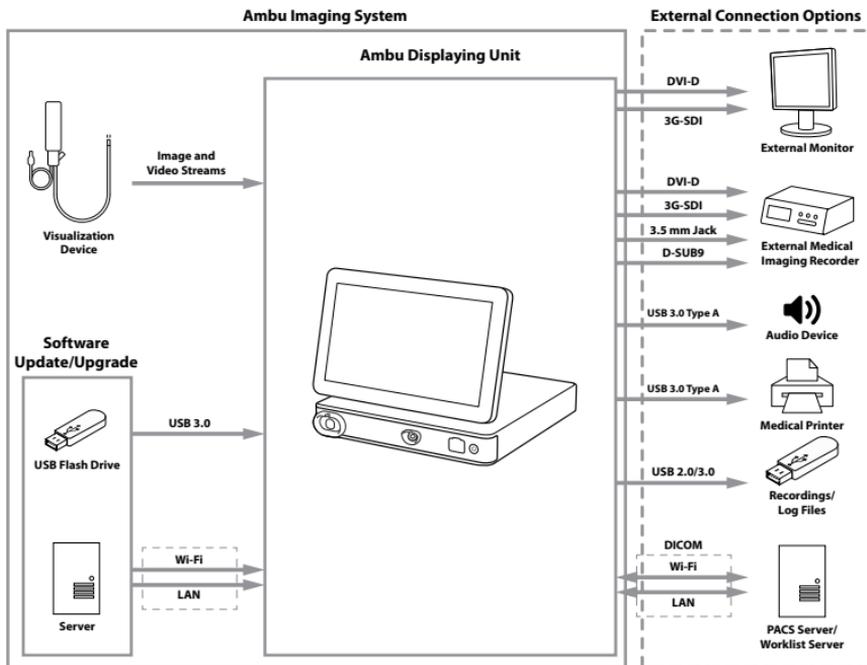
2.5. Spare parts

Spare parts are intended as replacements for components that are exposed to wear and tear during the lifetime of the device. Consult the troubleshooting guide in chapter 13 for issues that might require replacement of spare parts.

Spare parts	Name	Item number
	Ambu aBox™ 2 -Visualization device interface kit - Grey-Empty-Green Contains: One grey and one green visualization device interface board (VDI), a front cover with a color ring (grey and green), a plextum tool, and two screws for the VDI.	505000530
	Power cable – B (US, JP)	505000521
	Power cables – J (CH), K (DK), I (AUS)	505000520
	Power cable – G (UK), E/F (EU, not DK, CH)	505000522

2.6. System overview

A complete Ambu Imaging System is configured as illustrated in the figure below. The various connections are described in more detail in chapter 12.

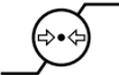


Please note that your organization is responsible for the following areas, which should be implemented according to your local policy:

- 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

Symbols for the displaying unit	Description	Symbols for the displaying unit	Description
	Warning		Caution
	Medical Device		Made in Taiwan
	Type BF applied part		Follow <i>Instructions for Use</i>
	Batch Code		Consult <i>Instructions for Use</i>
	CE marking		Japan Radio Law TELEC RF certification
	Australia and New Zealand's Regulatory Compliance Mark		Taiwan Radio Requirement NCC certification

Symbols for the displaying unit	Description	Symbols for the displaying unit	Description
	Medical – general medical equipment as to electrical 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		Waste Bin symbol, indicating that waste must be collected according to local regulation and collection schemes for disposal of electronic and electrical waste (WEEE)
	Universal Serial Bus (USB 2.0, USB 3.0)	DVI-D	Digital Visual Interface
3G-SDI	Serial Digital Interface	LAN	Local Area Network
Rx Only	US Federal Law restricts this device to sale by or on the order of a physician	IP31	Protection against solid particles and liquid ingress
	Humidity Limitation		Atmospheric Pressure Limitation
REF	Catalogue Number	UK CA	UK Conformity Assessed

A full list of symbol explanations can be found on ambu.com/symbol-explanation.

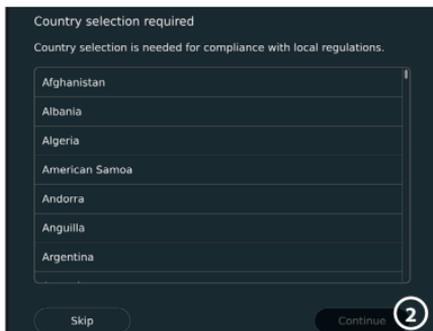
4. Getting Started

4.1. First-time setup

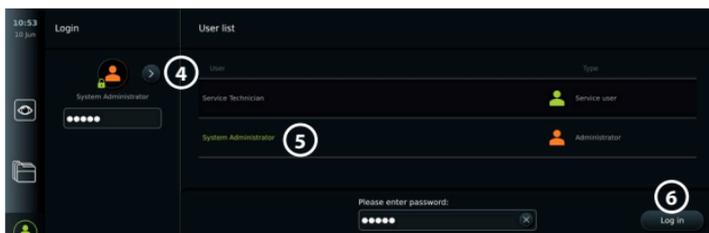
Follow the steps below before using the displaying unit for the first time. Letters in grey circles refer to the illustrations in the Quick Guide on page 2.

1. Unpack the displaying unit and verify that no parts are missing. Refer to the parts described in section 2.4.
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. Place the displaying unit on a hard and leveled surface. Be aware to place the displaying unit in a position where the power cord is accessible. The displaying unit can be placed on a medical cart to make it moveable. Make sure to proper position of the displaying unit to avoid falling down during transportation.
4. If necessary, connect the supplied Wi-Fi antenna to the back of the displaying unit.
5. Connect the power cable to a power outlet and insert the power plug into the power inlet on the back of the displaying unit **B**.
6. If needed, connect an external monitor **C** and/or medical imaging recorder to the back of the displaying unit.
7. If necessary, manually adjust the orientation of the touch screen of the displaying unit **D**.
8. 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) **E**, but 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.
9. Select the preferred language, then press **1**.
10. Select and confirm your country, then press Continue **2**. Press confirm **3**.

11. 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.
12. 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
 - Navigate to User profiles to change the Password. For security reasons you should change the factory default password as soon as possible.



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.



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.

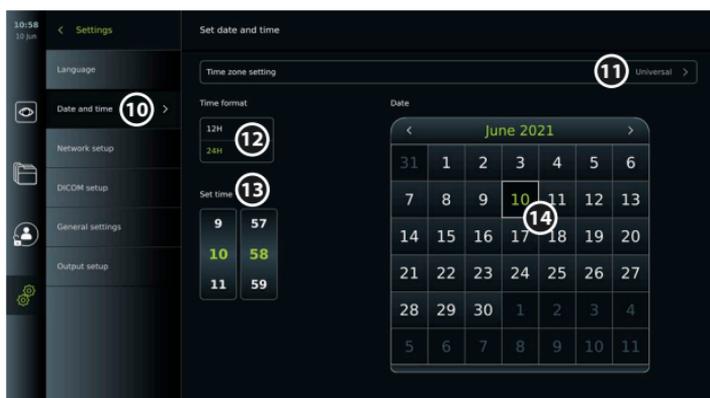
Note: If the Administrator password is lost, please contact your local Ambu representative.



13. 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** ⑩ 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** 14 in the calendar.



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 Technician
		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.

*** User profiles access to the Bin is described in section 11.3.

**** 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** **5**.
- Enter username, password, and repeated password in the respective input fields **6**, and press the **Save icon** **7**.

To delete a user profile, press the user name, then press the **delete icon**. Press **OK** to confirm.

Log in as any user profile:

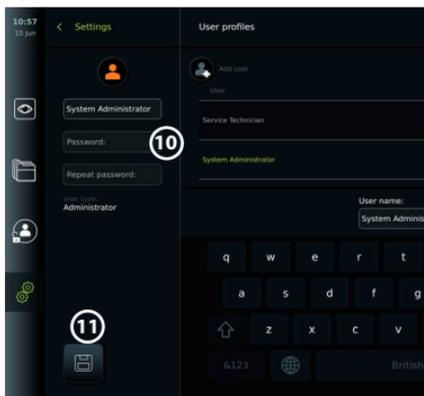
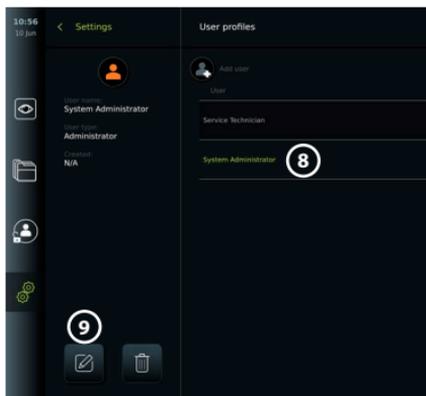
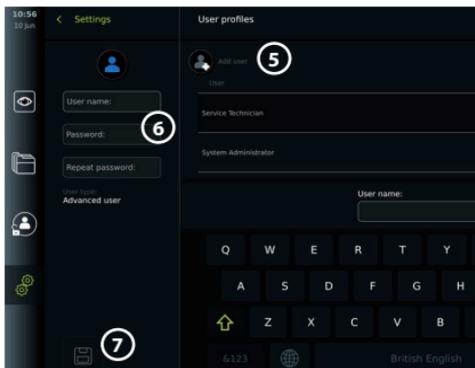
- Press the **Login tab**.
- Press **arrow right**, then press your user name.
- Enter your password and press **Login**.

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.

Change username or password:

- Press the **Settings tab**, then press **User Profiles**.
- Press the **username** **8**, then press the **edit icon** **9**.
- Enter the new username, password, and repeated password in the respective input fields **10** and press the **save icon** **11**.

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



5. 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.
- **Communication Settings** – Enabling allows the possibility to upgrade software online if connected to the internet.
- **Archive Settings** – Decide when a procedure is moved to the bin and when it is deleted from the bin.
- **Zoom, Stopwatch, ARC** – functions available during a procedure can be disabled for all types of scopes and users.
- **Login Settings** – determine if a user that is not logged in can still access the archive and see the worklist.
- **User inactivity settings** – choose if the displaying unit will logout the user due to inactivity.

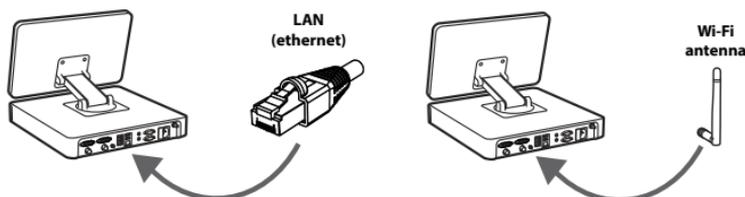
Be aware that if a function is disabled (not green), the symbol is not visible in the menu where it is normally located.

6. Network Setup

Importing a worklist or transferring imagery requires that the displaying unit is connected to the network via Wi-Fi or LAN/Ethernet cable.

6.1. Wi-Fi setup

The displaying unit supports WPA, WPA2 and WPA2 Enterprise authentication. Wi-Fi networks that redirect to a login webpage are not supported.



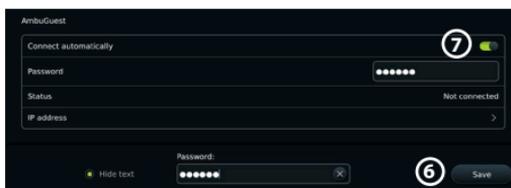
Enable Wi-Fi:

- 1) Press the **Settings** tab, then press **Setup** ①.
- 2) Press **Network setup** ②.
- 3) Press the **ON/OFF** slider to turn on Wi-Fi ③ (switch to green).
- 4) 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.
- 5) Press **Configure** ⑤ and wait while the displaying unit searches for available networks.



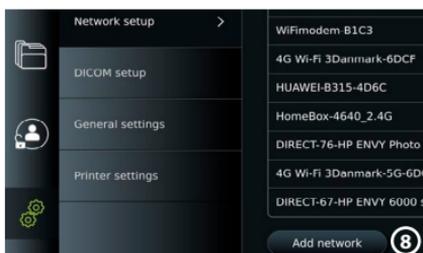
6.1.1. Wi-Fi network with WPA/WPA2 authentication

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



6.1.2. Hidden Wi-Fi network (Wi-Fi not showing on the list of available Wi-Fi connections)

- 1) Press **Add network** ⑧.
- 2) Press the input field next to **SSID** and enter the name of the hidden Wi-Fi network, then press **OK**.
- 3) Enter the remaining information in the input fields depending on the type of Wi-Fi network.



6.1.3. Wi-Fi network with WPA2 Enterprise authentication (username and password required)

- 1) Enter username in the **Identity** ⑨ field.
- 2) Enter password in the **Password** ⑩ field.
- 3) Select the required certificate ⑪.
- 4) Press **Connect** ⑫.
- 5) When the connection has been established, a Wi-Fi symbol appears in the Toolbar.
- 6) To enable automatic connection to this Wi-Fi, press the **Connect automatically** ⑬ ON/OFF slider (switch to green).



6.1.4. Import network certificate for WPA2 (TLS -transport security layer)

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



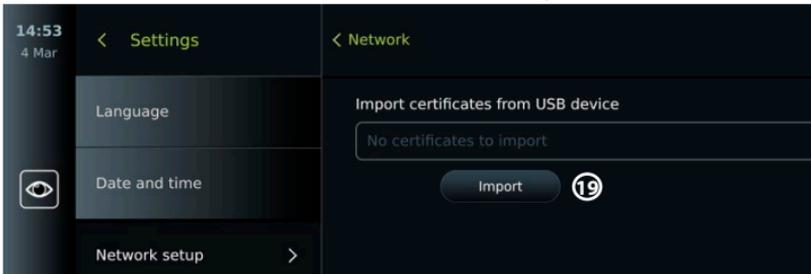
6.1.4.1. Import TLS certificates from a server

- 1) Ensure that the displaying unit is connected to a temporary Wi-Fi or LAN network (see section 5.1.1 or 5.2.).
- 2) Press **Server import**.
- 3) Enter **Certificate file name** ⑮, **Host name** ⑯, and **Port number** ⑰.
- 4) Press **Import** ⑱.



6.1.4.2. Import network certificates from a USB flash drive

- 1) Ensure that USB connection has been enabled for certificate import (see section 2.5). Insert USB containing network certificate. (see section 6.1.4).
- 2) Press **USB import** and wait while the displaying unit searches for network certificates on the USB flash drive.
- 3) 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.

6.2. LAN connection via Ethernet cable

- 1) Connect a LAN cable to the Ethernet connection port on the back of the displaying unit and to a router or LAN wall socket.
- 2) In the **Network** menu, check the LAN connection status shown below **Ethernet**.

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

- 1) In the **Network** menu, press the currently selected Wi-Fi network.
- 2) 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.



6.4. Disconnect from Wi-Fi network

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

6.5. Clear all network data from the displaying unit

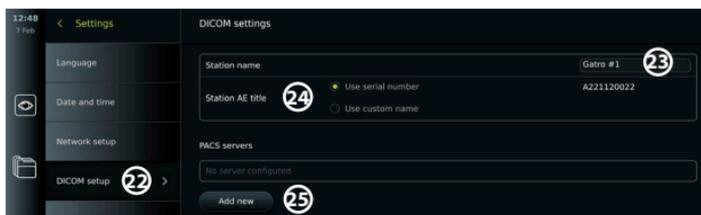
In the **Network** menu, press **Clear all data**. Press **OK**.

7. Setup Connection to PACS and Worklist

Importing a worklist and exporting of imagery requires that the worklist server/PACS (Picture Archiving and Communication System) server can send and receive data in DICOM (Digital Imaging and Communications in Medicine) format. Setting up server connections require that the displaying unit is connected to a Wi-Fi or LAN network (see section 6.1 and 6.2).

7.1. Set up the displaying unit for server connection

- Press the **Settings tab**, then press **Setup**.
- Press **DICOM setup** (22).
- It is optional to change the **Station name** (23). The Station name is used to recognize the unit if a special worklist needs to be pushed to a specific unit or if it is important to track from which unit data has been sent from. The default name is *AmbuMon* and 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.



7.2. 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 further below).
- 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.

19:59
2 May

Settings

Device Info

Network

Ethernet status

```
2: eth0: <NO_CARRIER,BROADCAST,MULTICAST,UP> mtu 1500 qlen 1000 state DOWN
link/ether 08:f3:8c:79:4a:55 brd ff:ff:ff:ff:ff:ff
RX: bytes packets errors dropped overrun mcast
0 0 0 0 0
TX: bytes packets errors dropped carrier collsns
0 0 0 0 0
```

Ethernet lease

Unavailable

Ethernet MAC

08:f3:8c:79:4a:55

Wi-Fi status

```
4: wlan0: <BROADCAST,MULTICAST,UP,LOWER_UP> mtu 1500 qlen 1000 state UP group default qlen 1000
link/ether 08:f3:8c:79:4a:55 brd ff:ff:ff:ff:ff:ff
inet 192.168.0.112/24 brd 192.168.0.255 scope global dynamic nopresence wlan0
valid lft 755490cc preferred lft 667490cc
inet6 fe80::13c2:f681:500b:3677:da scope link
valid lft forever preferred lft forever
RX: bytes packets errors dropped overrun mcast
2480166 8038 0 0 0
TX: bytes packets errors dropped carrier collsns
18888 0 0 0 0
```

Wi-Fi lease

```
broadcast address:192.168.0.255
dhcp_lease_time=86400
dhcp_message_type=9
dhcp_rebinding_time=72000
dhcp_renewal_time=12000
dhcp_server_identifier=192.168.0.1
dhcp_max_lease_time=1440.0.1.192.168.0.1
ip address=192.168.0.112
network_name=192.168.0.0
router=192.168.0.1
subnet_cidr=24
subnet_mask=255.255.255.0
dhcp_client_ip=00000000000000000000000000000000
dhcp_name_server=fe80::13c2:f681:500b:3677:da
dhcp_server_id=00010001179061320e5e5e5e5e5e5e5e
```

Wi-Fi MAC

08:f3:8c:79:4a:55

Destination	Gateway	Genmask	Flags	Metric	Ref	Use	iface
0.0.0.0	192.168.0.1	0.0.0.0	UG	304	0	0	wlan0
192.168.0.0	0.0.0.0	255.255.255.0	U	304	0	0	wlan0

7.3. Set up connection to Worklist server

- **Enable Worklist** (31) with the **ON/OFF** switched to green.
- Enter the required information in **Worklist server AE title**, **Worklist server hostname** and **Worklist server port number** (32).
- Press the required **TLS** (33) settings.
Note: If you enable TLS, you need to import the required TLS certificate from a server or USB flash drive.
- Choose the modality (ES=endoscopy, US=ultrasound) or enter a specific modality in the **Other** (34) field deciding which worklist you choose to retrieve.
- Enter the timeframe, that the retrieved worklist will show, in the **Display upcoming procedures (hours)** (35) field.
- **Hide past procedures older than (hours)** (36) allows you to limit the amount of procedures in the worklist.
- Press **Test worklist connection** (37) to verify that the information has been entered correctly and the server connection is 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.

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.

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**.



Information needed	Explanation
PACS name	This is the name of the PACS. Used in the export menu to select the PACS when transferring photos and videos.
PACS AE Title	PACS Application Entity Title. The maximum length of the AE Title is 16 characters.
Host name	IP-address, MAC address or full web address for the PACS.
Port number	Network port no. for the PACS.

8. Output Setup

The Administrator can view and reconfigure what **Trigger Outputs** (photo or video functions) (1) are sent via the output ports to a connected external medical imaging recorder.

To access the Trigger output menu:

- Press the **Settings**  tab in the toolbar on the left.
- Press **Setup** and press **Output setup**.

You can configure the trigger output channels A, B, C and D. By default, trigger output A sends a signal to take a photo and trigger output D sends a signal to start or stop a video recording on the medical imaging recorder. Trigger B and C does not have any trigger signals assigned by default.

Reconfigure the trigger outputs as an administrator:

- Select the trigger output channel you wish to reconfigure (A, B, C or D) and select an output signal in the selection menu that appears on the right side of the screen (2).
- It is important that the assigned function on the trigger output port of the displaying unit matches the function assigned to the connected input port of the medical imaging recorder.
- Test if the system behaves as expected.

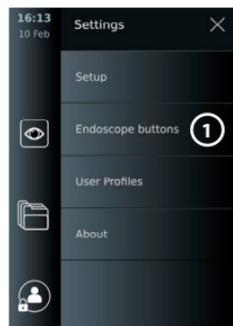
When set up correctly, the medical imaging recorder will capture a photo or start/stop a video sequence, if the corresponding function is activated via the buttons on a connected endoscope or directly on the buttons in the **Live view** tab.

In the menu Trigger duration the pulse length for can be set to align with your medical imaging recorder.



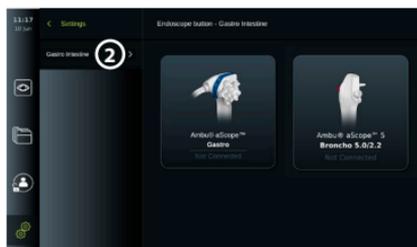
9. Endoscope Buttons Configuration

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. To view the current configuration of a compatible endoscope or to reconfigure the buttons, press the **Settings** tab in the **tool bar**, press **Endoscope buttons** and select an endoscope type ①. An overview will appear.



9.1. Configure the endoscope buttons

- Press the **Settings** tab, then press **Endoscope buttons**.
- Press the required endoscope category ② and select an endoscope.
- The screen shows an overview of the endoscope buttons with the available functions.
- Press the required endoscope button ③, then select long or short button press ④.
- Press the action to be performed when the selected button is pressed ⑤.
- Repeat for each button. The overview shows the selected functions next to the buttons.



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

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

Note: For some visualization devices e.g. ARC can only be assigned to be activated by a "long press".

10. Operating the Displaying Unit

10.1. 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.

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.
2. Clean and disinfect the displaying unit (see chapter 14).
3. Connect the displaying unit to a suitable power outlet using the included power cable and turn on the power outlet. The orange indicator light in the power button turns on to indicate that the displaying unit is in STANDBY mode.
4. Adjust position and orientation of the touch screen to your preference.
5. Turn ON the displaying unit by pressing the power button. The indicator light in the power button switches from orange (STANDBY mode) to green (ON). If an Ambu visualization device is connected, a live image is available while the user interface is loading.
6. If necessary, connect the displaying unit to the Wi-Fi network.
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.

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.
9. If required, an external monitor can be connected to the DVI or SDI port on the back of the displaying unit.

10.2. Starting and stopping a procedure

10.2.1. 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.

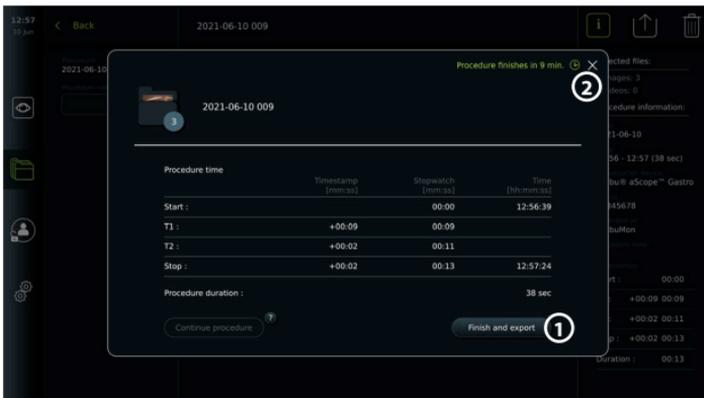
If a visualization device is connected, the live image is available soon after the displaying unit is turned ON. Even if a network error or other problems in the system occur, the Live view will still be available making it possible to use the displaying unit for clinical purposes.

10.2.2. Stopping a procedure

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

- Press **Finish and export** (1) to end the current procedure and export the recorded files.
- Press **X** (2) 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.



10.3. 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** (3) to open the patient list on the Worklist server.
- Press the **update icon** (4) to retrieve current patient information from the Worklist server.
- Press the **search field** (5) and enter the search term, e.g. patient name, procedure type, or the HCP's name.
- Press the **pin icon** (6) 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**.

10.4. 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 10.8.).
	Photo icon	Taking photos during a procedure, also during video recording (see section 10.8.).
	Current procedure folder icon	Saving photos and videos recorded during the current procedure (see section 10.8.).
	Worklist menu	Selecting a patient for the current procedure (see section 10.3.).
	Stopwatch	Recording the time and making time stamps during a procedure (see section 10.6.).
	Image adjustment	Adjusting colour, contrast, sharpness, brightness, zoom, and rotation (see section 10.5.1.).
	Image adjustment*	Adjusting colour, contrast, sharpness, brightness, zoom, rotation, and ARC (Advanced Red Contrast) (see section 10.5.1.).

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

10.5. Using image adjustments

- Press the **image adjustment icon** 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.
	Light off	Turns off the LED light on the distal end of the connected visualization device. When Light off is active, the icon  will show on the top right corner of the live image. Applicable for Ambu Gastroenterology aScope™ portfolio
	ZOOM	Zooms in on the live image. A  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  icon in the top right corner of the live image indicates that ARC is active (see section 10.5.5. for details).

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.

10.5.1. Adjust colour, contrast, sharpness and brightness

- Adjust the image settings by pressing the **icons** (7) at either end of the slider bars or by dragging the **sliders** (8) left or right.

10.5.2. Rotate the live image

- Press the **rotate icon** (9) 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.

Note: If Rotate is available the rotate icon will be replacing the 'Light' icon.



10.5.3. Use the zoom function

- Press the **Zoom icon** (10) to zoom in.
- Press the **Zoom icon** again to zoom out.
- When the zoom function is active, the zoom symbol is shown in the Live View screen.

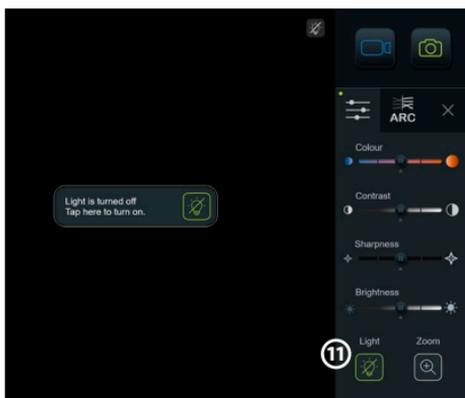
Note: It is also possible to zoom in and out by double tapping the screen. In zoom mode the image is cropped and the top and bottom of the image will not be shown.

10.5.4. Light on/off

The LED light on the distal end of the visualization device is powered on as soon as the visualization device is connected to the displaying unit and stays on until the visualization device is disconnected. Turning the light on and off is only applicable for some visualization devices.

- To activate Light off, open the **Image adjustment** (ARC) menu and press the **Light off** button (11).

When **Light off** is active, the icon will show on the top right corner of the live image (☒) and a notification will pop up at the center of the live image with an additional **Light off** button for deactivation).



Notes:

- Light on/off function applies for Ambu Gastroenterology aScope™ portfolio.
- The live image will continue to show the camera stream.
- The Light off function does not interfere with other functions (Zoom, ARC, photo or video and other functions can run at the same time).
- The Light off function will reset to default (the light will be on when a visualization device is connected), after a scope has been removed, after a procedure is finished and after reboot.

10.5.5. 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** **12**.
- Press the **ARC button** **13** to enable ARC adjustment (the button switches 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.

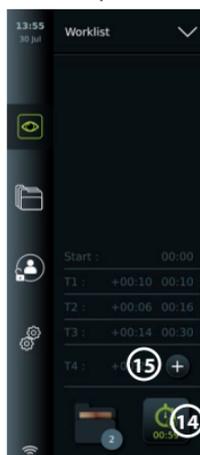
10.6. Using the stopwatch

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.

- Press the **stopwatch icon** **14** to start the stopwatch.
- Press the **plus sign** **15** 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.

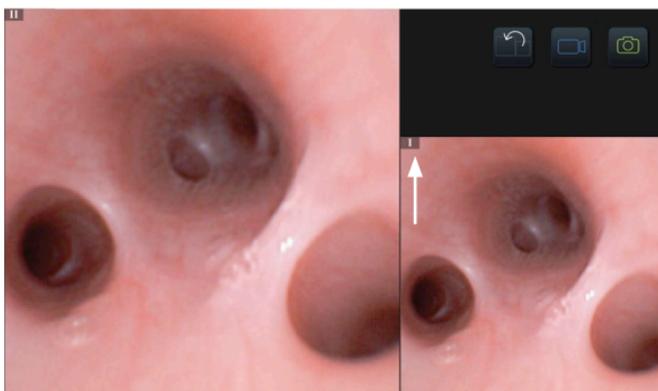


10.7. Using dual view

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.



10.8. Taking photos and recording videos

Take a photo:

- Press the **photo icon**  to take a photo and save it in the current procedure folder.

Record a video:

- Press the **video icon**  to start a video recording.
- Press the **video icon** again to stop the video recording and save the video in the current procedure folder.

Note: Zoom view will not be shown in recorded material.

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

Note: Maximum video recording time is 30 minutes per video. After a short warning on the screen, the recording will be stopped automatically, and a new recording can be started.

There is no limitation on the number of recordings made during one procedure.

10.9. Current procedure folder

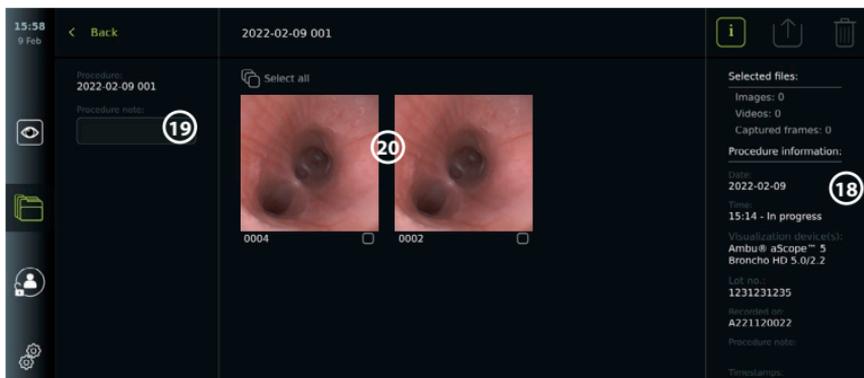
When a new procedure is started the current procedure folder is created automatically and named with the date of the procedure followed by the procedure number of the day (format: YYYY-MM-DD_XXX).

The image and video files created during the procedure are saved in the current procedure folder. During the procedure, the files in the current procedure folder are accessible from the Live View screen via the current procedure folder icon. After the procedure has ended, the current procedure folder moves to the Recent folder, which is accessible via the Archive tab in the Toolbar.

View the files in the current procedure folder:

The current procedure folder icon shows the total number of photos and videos saved during the current procedure.

- Press the **current procedure folder icon** .
- Press **arrow right** .
- The current procedure overview shows the files in the folder and information about the current procedure, such as date, time, connected endoscope and timestamps .
- To add a note to the folder, press the **Procedure note field**  and enter a short description to a specific procedure or file (max. 40 characters).
- Scroll through the thumbnails  and press the required image or video to see a larger view.
- To use video playback functions, see section 11.1.



10.10. 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 **H**. For disposal of the visualization device, please refer to the Instructions for Use for the specific visualization device.
2. Press the power button to turn the displaying unit OFF **I**. Press OK.
3. Clean and disinfect the displaying unit **J** (see chapter 14).

11. File Handling in The Archive

11.1. Accessing files in the Archive

Photos and videos created during previous procedures are saved in the Archive in the folder created when the procedure was started. 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**.
- 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.



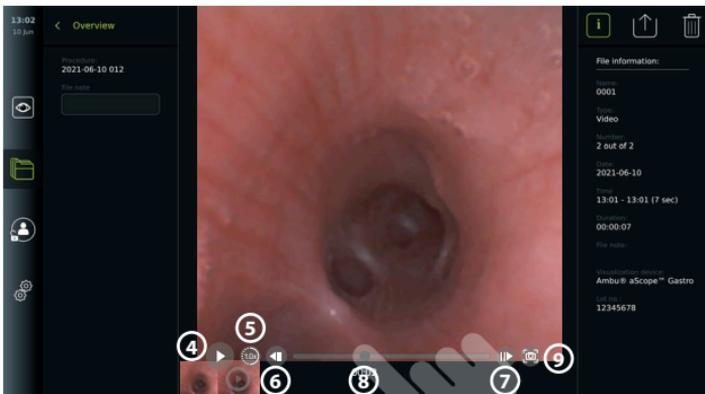
Use video playback functions:

- Press the **playback icon** **4**.
- To play the video in slow-motion, press the **slow-motion 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.



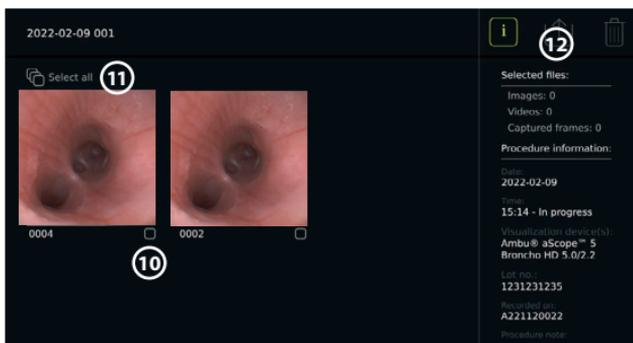
Photos and videos from the procedure are shown in descending order with the most recent on the left. Scroll sideways on the thumbnails to see all photos and videos from the procedure. On the right side of the screen, File information is available.

11.2. Exporting files to PACS server or USB flash drive

Before you export files, ensure that connection to the PACS server has been set up or USB connection has been enabled for file export and a USB flash drive connected to the displaying unit.

Select files for export:

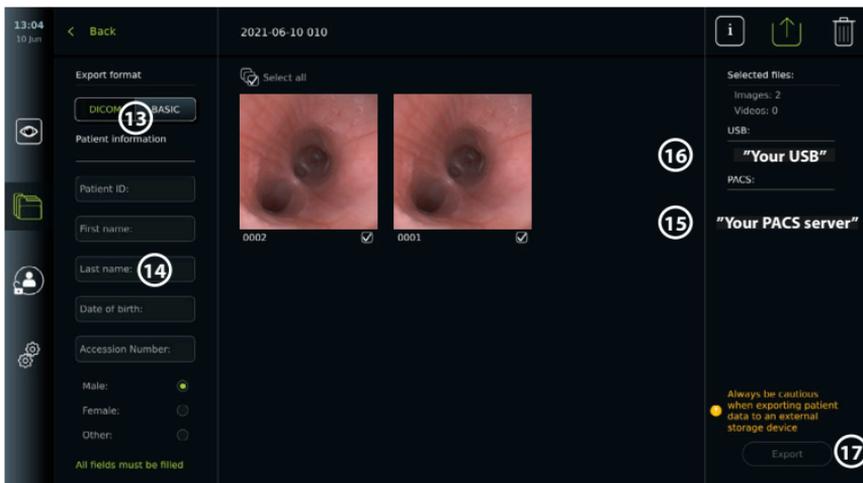
- Press the **Archive** tab, then press **Procedures**.
- Press the required procedure folder.
- Select the required files by ticking the boxes below the thumbnails **10**, or press Select all **11**.



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 Worklist before or during the procedure.

Note: Only DICOM format can be used for export to PACS server. See table below for more information about file formats.



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.

Export files:

- Press the name of the PACS server **15** or USB flash drive **16** shown below the export icon to select it as the file export destination (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.

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.



2020-02-04 001 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.

Storage settings	
Image (photo) using grey connector	PNG (800 x 800 pixels) – no compression
Image (photo) using green connector	PNG (400 x 400 pixels) – no compression
Video	MP4 – compressed when exported

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	BASIC file format (PNG and MP4). Photos and videos can be exported via a USB port in BASIC.
-	Patient information	Patient data can be retrieved automatically by selecting a patient in the Worklist (refer to section 7.3.) 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 chapter 5.).
-	USB	Select a connected USB flash drive to export photo(s) or video(s) to the USB flash drive in BASIC or DICOM format.
-	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 7.2.
	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.

Explanations of functions in export menu

Icon	Name	Function
	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

11.3. 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.

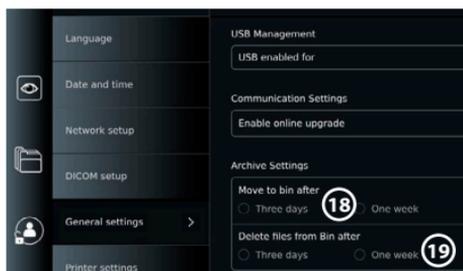
All users can move files to the Bin, but you need to be an Advanced or Admin user to permanently delete files.

Set time for automatic deletion of files:

- Press the **Settings tab**, then press **Setup**.
- Press **General Settings**.
- Press the required time period below, **Move to bin after** **18** and **Delete files from Bin after** **19**.

Move files from procedure folders 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 **20**, or press **Select all** **21**.
- Press the **delete icon** **22**, 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 **23**, then press OK.



12. Connect External Equipment

See the overview of input and output connections in section 2.4. 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.

12.1. Connecting to an External Monitor

If needed, connect an **external monitor** to one of the video out ports (3G-SDI or DVI-D) located on the back of the displaying unit (see section 2.4. for video out port locations). 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 DVI and/or 3G-SDI input(s). The recommended color space is sRGB.

If connection is established via **3G-SDI** the external monitor will mirror the complete user interface shown on the screen of the displaying unit.

If connection is established via **DVI-D**, the image shown on the external monitor will always show the Live View image and the following information:

- Stopwatch **00:00** (If enabled in General settings, see chapter 5.).
- Current procedure folder with a number to indicate the number of photos and videos made in the current procedure.
- Zoom icon Z in the top right corner of the live image indicates if the zoom function is active (must be enabled in **General settings** (see chapter 5.).
- ARC icon A in the top right corner of the live view image indicates if ARC is active.
- Live view image.
- Date and time.
- When ending a procedure, the Timestamp table will appear.
- When recording a video, the elapsed recording time next to a recording icon will show in the upper right corner.

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

12.2. Connecting USB Flash Drives

If needed, connect an **external USB** flash drive to the USB ports on the front or back of the displaying unit (see section 2.4. for USB port locations).

12.3. Connecting to an External Medical Imaging Recorder

If needed, connect an **external medical imaging recorder** to one of the video out ports (3G-SDI or DVI-D) located on the back of the displaying unit.

It is also possible to transfer trigger signals to the imaging recorder via the Trigger out ports A, B (3.5 mm jack), C or D (D-SUB9) located on the back of the displaying unit. See chapter 8 for instructions on how to view and reconfigure which functions are transmitted via the Trigger out ports.

Connecting video output to a medical imaging recorder:

- Connect a DVI-D or 3G-SDI cable to video output group 2 on the back of the displaying unit. See section 2.4. for Video out port locations.
- Connect the other end of the DVI-D or 3G-SDI cable to the corresponding video-in port on the medical imaging recorder.

Connecting trigger output to a medical imaging recorder:

- Connect a 3.5 mm jack or D-SUB9 cable to the trigger output channel you wish to use (A, B, C or D). See section 2.4. for Trigger out port locations.
- Connect the other end of the cable to the corresponding trigger input port on the medical imaging recorder.

Note: It is important that the assigned function on the trigger output port of the displaying unit matches the function assigned to the connected input port of the medical imaging recorder.

12.4. 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 5.3.).

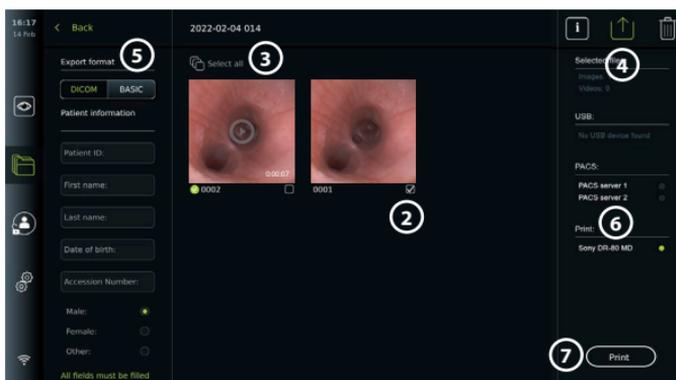
Select settings for printing:

- 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 **Recent**.
- 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.

12.5. Connect external audio devices

12.5.1. Record sound during the procedure

- Connect the displaying unit to an audio device via USB connection.
- A microphone icon in the Toolbar indicates if the microphone is compatible or not.

12.5.2. Play sound recorded during a procedure

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

13. System Information and Software Updates/Upgrades

13.1. Device information page

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

View device information:

- Press the **Settings tab**, then press **About**.
- The **Device info** ① page is shown on the screen.
- Scroll down to see all the information.

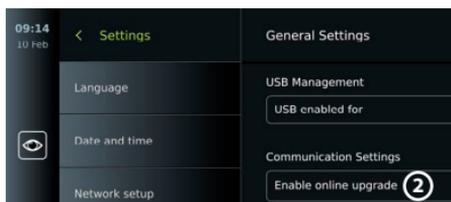


13.2. Software updates/upgrades

Software updates/upgrades can be performed online or installed from a USB flash drive.

Enable online updates/upgrades:

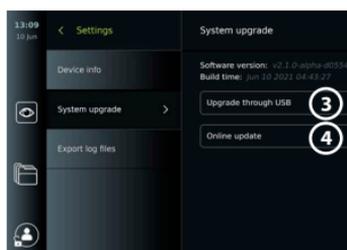
- Press the **Settings** tab, then press **Setup**.
- Press **General settings**.
- Press the **ON/OFF** slider next to **Enable online upgrade** (2) to enable the function (switch to green).



Install update/upgrade from USB flash drive:

Before you install software updates/upgrades via USB, ensure that USB connection has been enabled for system upgrade and a USB flash drive connected to the displaying unit.

- Press the **Settings** tab, then press **About**.
- Press **System upgrade**, then press **Upgrade through USB** (3).
- 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 6.1). 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** (4).
- Wait while the displaying unit is checking for available updates/upgrades.
- If a new software version is available, press **Upgrade software** (5).
- 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.

13.3. Reporting a problem

If you are experiencing problems with the displaying unit, please follow the Troubleshooting guide in chapter 13 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** ⑥.
- Wait while the log files are exported, then press **OK**.

**13.4. Data reset**

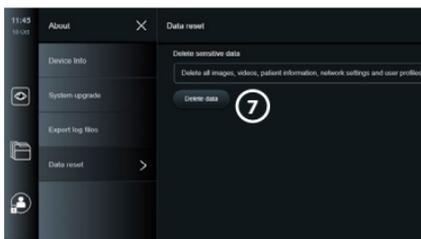
If a displaying unit is to be handled by a third party or needs to be disposed, it is advised to delete all sensitive data. Please follow your local guidelines for data protection. Only the Administrator can reset the data.

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** ⑦. 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.

**14. 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 chapter 10. The specified cleaning and disinfection procedures show compliance with the AAMI TIR12 and AAMI TIR30 guidelines.

15. Maintenance

The displaying unit shall be subject to preventive inspection prior to use according to chapter 10 and shall be cleaned and disinfected according to chapter 14.

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

16. Disposal

At the end of product life, clean and disinfect the displaying unit (see chapter 14).

Before disposing of the displaying unit, it is advised to follow these steps to erase all data:

- Log in as Administrator.
- Delete all files stored in the displaying unit from the **Archive** - Select all folders and press the bin .
- Delete Wi-Fi network and password though the **Settings– Setup – Network** setup menu.
- Delete DICOM network via the **Settings– Setup – DICOM setup** menu.
- Delete all Advanced Users from the **Settings– User profiles** menu.
- Then, dispose of the displaying unit in accordance with local guidelines for electrical and electronic waste.

17. Technical Product Specifications

17.1. Standards applied

The displaying unit function conforms with the following standards:

- 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.

17.2. Specifications for the displaying unit

Display	
Resolution	1920 x 1080 pixels
Orientation	Landscape
Display type	12.8" colour TFT LCD
Startup time	Live image available within 8 seconds

Connections		
USB connections	Front: 1 x USB 3.0 type A Back: 3 x USB 3.0 type A and 2 x USB 2.0 type A	
Video output	DVI-D (1920 x 1080 p, 60 fps) and 3G-SDI (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	
Trigger output	2 x D-SUB9 and 2 x 3.5 mm Jack	
Connection to potential equalization cable	DIN 42801 standard	
Memory		
Storage capacity	128 GB	
Electrical power		
Power requirement	100 – 240 VAC ; 2 A	
Protection against electrical shock	Class I	
Operating environment		
Operating temperature	10 – 40 °C (50 – 104 °F)	
Operating relative humidity	30 – 85 %	
Operating atmospheric pressure	80 – 106 kPa	
Operating altitude	≤ 2000 m	
Storage environment		
Storage temperature	0 – 40 °C (32 – 104 °F)	
Storage relative humidity	10 – 85 %	
Storage atmospheric pressure	50 – 106 kPa	
IP Protection Classification		
IP Protection Classification	IP31 – Protection against solid particles (3: < 2.5 mm) and liquid ingress (1: dripping water):	
Dimensions		
Height – touch screen in 90° angle (a)	278 mm (10.9")	
Height – touch screen folded flat (b)	121 mm (4.76")	
Width (c)	330 mm (13.0")	
Depth (d)	337 mm (13.3")	
Weight	8 kg (17.6 lbs)	

Power cables	
Power cables – 6 interchangeable types	<ol style="list-style-type: none"> 1. USA and Japan: Type B, Model NEMA, 5 AC grounded power plug 2. Australian: Type I, AS3112, AC grounded power plug 3. UK: Type G, BS1363, AC grounded power plug 4. European: Type E/F, CEE 7, AC grounded power plug 5. Danish: Type K, 2-5a, AC grounded power plug 6. Swiss: Type J, AC grounded power plug
Not all types of power cables can be shipped to all markets	
Length of power cables – US, AUS, DK	1800 mm (71") including connector

Contact your local Ambu representative for further information.

18. Troubleshooting

If a problem occurs with the displaying unit, please use this troubleshooting guide to identify the cause and correct the error. If the problem cannot be resolved by the actions in the troubleshooting guide, contact your local Ambu representative.

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 put the displaying unit in STANDBY mode (power button turns orange). 2. When the displaying unit is in STANDBY mode, press the power button again to turn it back ON (power button turns green). <p>If the displaying unit does not enter STANDBY mode, force it to completely turn OFF (no light in power button)</p> <ol style="list-style-type: none"> 3. Press the power button for 10 seconds to force it to completely turn OFF. 4. Press the power button again to turn the displaying unit back ON. <p>If restart and complete turn OFF does not work, reset displaying unit hardware</p> <ol style="list-style-type: none"> 5. Disconnect the power cable from the displaying unit. 6. Wait at least 10 seconds before reconnecting the power cable. 7. Press the power button to turn ON the displaying unit.

Problem	Possible cause	Recommended action
The displaying unit does not turn ON when the power button is pressed.	The displaying unit is not connected to power.	Connect the power cable to the displaying unit and to a power outlet. Make sure the power outlet is turned on.
	Ensure that the light indicator in the power button lights up when the displaying unit is connected to power.	
	The displaying unit does not turn ON even though the power is connected.	Perform a Power OFF Cycle (follow the procedure above this table).

Problem	Possible cause	Recommended action
<p>No live image from the visualization device on the displaying unit screen</p> <p>OR</p> <p>No LED light in the distal end of the visualization device.</p>	<p>A recorded image in the current procedure folder is blocking the live image</p> <p>OR</p> <p>A menu box is blocking the live image.</p>	<p>Return to live image by pressing the Live View tab .</p> <p>If this does not work perform a Power OFF Cycle (follow the procedure above this table).</p>
	<p>LED light switched off by activation of the Light off function.</p>	<p>Deactivate the Light off function (see section 7.3.8.).</p>
	<p>Failure on visualization device connection.</p>	<p>Connect/reconnect visualization device.</p>
	<p>The displaying unit and the Ambu visualization device have communication problems.</p>	<p>Perform a Power OFF Cycle (follow the procedure above this table).</p>
	<p>Failure on visualization device or VDI-port on the displaying unit.</p>	<p>Connect a new visualization device.</p> <p>If this does not work, the VDI-port on the displaying unit may be damaged.</p>
<p>Live image on the displaying unit is ONLY working while booting.</p>	<p>Processing failure.</p>	<p>Perform a Power OFF Cycle (follow the procedure above this table).</p>
<p>No image or User Interface on the external monitor.</p>	<p>External monitor is turned OFF.</p>	<p>Turn ON external monitor.</p>
	<p>Issue with SDI or VDI cable or cable connection.</p>	<p>Check if the cable is connected properly.</p> <p>If possible, try a new cable.</p> <p>Note: Cable may be damaged, or cabling quality or length may be insufficient. An RG6 grade cable with shielding is recommended.</p>
	<p>SDI – External monitor does not support 3G-SDI.</p>	<p>Make sure that your external monitor supports 3G-SDI (1920 x 1080 p 60 fps.).</p>
	<p>Wrong input channel is selected on the external monitor.</p>	<p>Make sure the correct input channel is selected on the external monitor.</p>
	<p>Wrong video output is chosen on the displaying unit.</p>	<p>Make sure to connect the video cable to one of the connector ports in the video output group, that is configured for external monitors. Default on a new device is Video Output group 1.</p>

Problem	Possible cause	Recommended action
Touch interface does not respond.	The displaying unit has internal communication problems.	Perform a Power OFF Cycle (follow the procedure above this table).
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.
Wi-Fi signal cannot be obtained.	Wi-Fi antenna cannot reach the Wi-Fi signal in the room.	Choose a new placement of the displaying unit OR make sure that the external Wi-Fi antenna is connected and oriented optimally.
Displaying unit cannot identify a connected USB device.	USB input may be disabled.	Log in as Administrator, go to Settings - Setup - General settings - to enable USB input.
	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).
	USB connector port is damaged.	Move the USB device to another USB connector port.
Buttons on endoscope is not registered by the displaying unit.	The endoscope buttons have not been configured.	View current configuration of endoscope buttons in section 5.10.
	None of the buttons activate any function on the displaying unit.	Unplug and reconnect the endoscope OR Connect a new endoscope.
	Issue with connection between endoscope and displaying unit.	If this does not work, the VDI-port in the displaying unit may be damaged.
	The displaying unit has internal communication problems.	Perform a Power OFF Cycle (follow the procedure above this table).
Activation of endoscope buttons is not registered by the displaying unit or any connected medical recorder	The trigger outputs have not been configured correctly.	For reconfiguration of trigger outputs refer to section 5.9.
	Communication problems between the endoscope and the displaying unit.	See problem "Buttons on endoscope is not registered by the displaying unit".
	The displaying unit has internal communication problems.	Perform a Power OFF Cycle (follow the procedure above this table).

19. Warranty and Replacement

Ambu warrants that the displaying unit 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:

- a) 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
- b) 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 14). 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.

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	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	+/- 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.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles	Mains power quality shall be that of 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
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.
Conducted Radio Frequency IEC 61000-4-6	3 V RMS 0,15 MHz – 80 MHz 6 V RMS in ISM bands 80 % AM at 1 kHz	3 V RMS 0,15 MHz – 80 MHz 6 V RMS in ISM bands 80 % AM at 1 kHz	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. 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.
Radiated Radio Frequency IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 – 2700 MHz 80 % AM at 1 kHz	



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
Immunity to Proximity Magnetic Fields, IEC 61000-4-39:2017	134,2 kHz Pulse Modulation 2,1 kHz 65 A/m* 13,56 MHz Pulse Modulation 50 kHz 7,5 A/m* *r.m.s before modulation is applied.	134,2 kHz Pulse Modulation 2,1 kHz 65 A/m* 13,56 MHz Pulse Modulation 50 kHz 7,5 A/m* *r.m.s before modulation is applied.	Proximity magnetic fields should be at levels characteristic of a typical location in a hospital environment.

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).

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 model(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

Wi-Fi	
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
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 mschavp2.
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 Static IP	Static IP address (IPv4) is configurable in the GUI.
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
Photo	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.

Title	Version	Used for
Linux	Linux Kernel version 4.19.217	The embedded Linux kernel is built custom by Ambu.
GStreamer	1.18.6	<p>The following plugins are used:</p> <ul style="list-style-type: none"> • v4l2src • glupload • gcolorconvert • vaapipostproc • vaapih264enc • matroskamux • tcpserversink • tcpclientsrc • filesink • qmlglsink
OpenSSL	1.1.1i	Used to generate the private key and authenticate the public key used to sign the upgrade package.
dcmtdk	3.6.6	Used for the DICOM protocol communicating to the PACS server.
DICOMConnect	3.3.3	Used for the DICOM protocol communicating to the PACS server.
RAUC	1.5.1	Used for system upgrades.
yocto	dunfell	Used to build the embedded Linux system.
Barebox	2021.03.0	Used for bootloading the Embedded system.

Ambu



Ambu A/S

Baltorpbakken 13

2750 Ballerup

Denmark

T +45 72 25 20 00

ambu.com

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