INSTRUCTIONS FOR USE

Ambu

Ambu® aBox™ 2

For use by trained healthcare professionals only.
For use with Ambu® visualization devices.
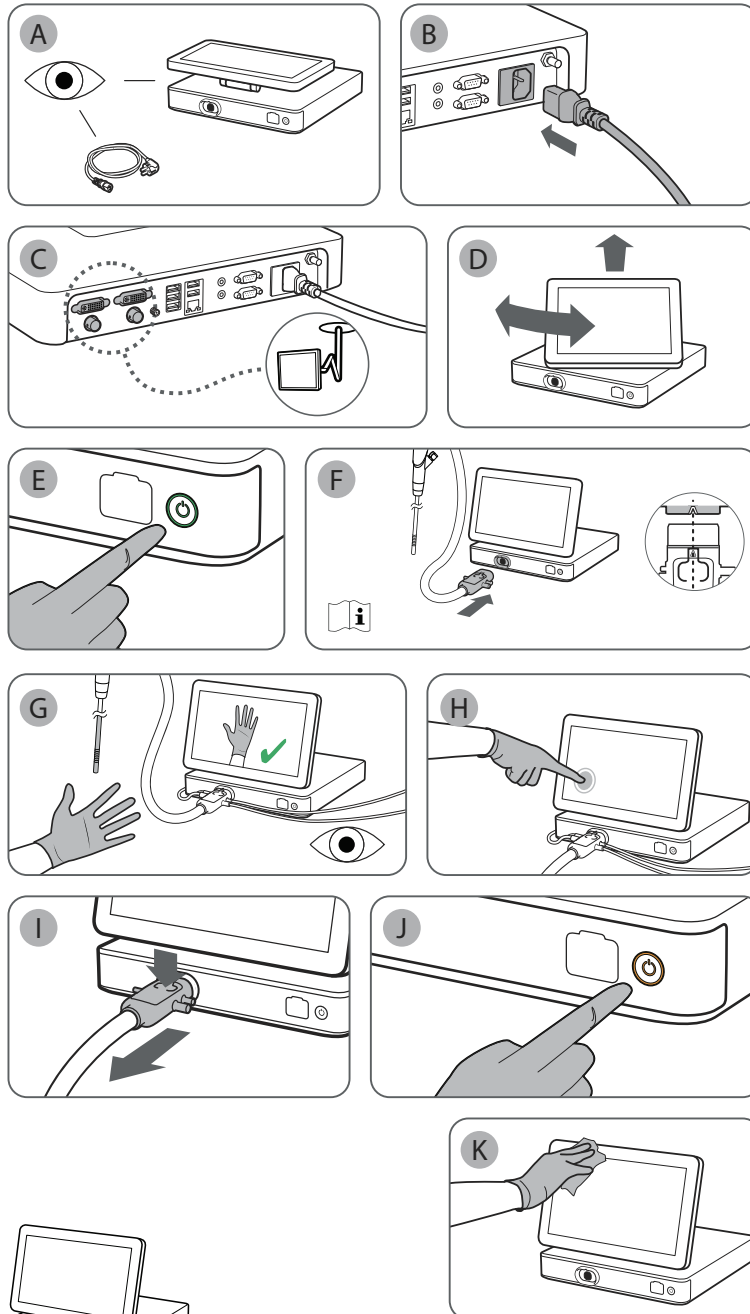
INSTRUCTIONS FOR USE

Ambu

Ambu® aBox™ 2

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

Quick Guide

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

Content   Page

1. Important Information – Read Before Use

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

In the *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. Contraindications
None known for the displaying unit.

1.6. 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 chapter 9.
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 ancillary equipment, which 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. To avoid electric shock and burns, do not touch any conductive metal parts of the displaying unit while using high frequency tools (e.g. electrosurgical equipment).

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 7.1 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.

1.7. Potential Adverse Events
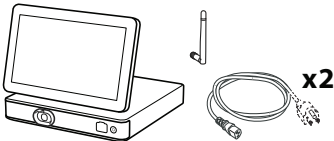None known for the displaying unit.

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

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:
x2	505001000

2.2. Product Compatibility

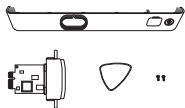| Compatible Ambu visualization devices |
|---|
| • Ambu® aScope™ Gastro |

The listed devices may not be available in all countries. Please contact your local Ambu representative. Please refer to the *Instructions for Use* of the relevant visualization device.

| Compatible external equipment |
|---|
| • External monitors (video output)
• External medical imaging recorders (video output and trigger output)
• USB flash drives |

For specifications of connections to external equipment, refer to chapter 6.

2.3. 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 (VDI) kit - Grey Contains: A visualization device interface (VDI) board, a front cover with a colour ring (grey), a plectrum tool, and two screws for the VDI	505000510
	Power cables - J (CH), K (DK), I (AUS)	505000520
	Power cable - B (US, JP)	505000521
	Power cables - G (UK), E/F (EU, not DK, CH)	505000522

2.4. Description of Components
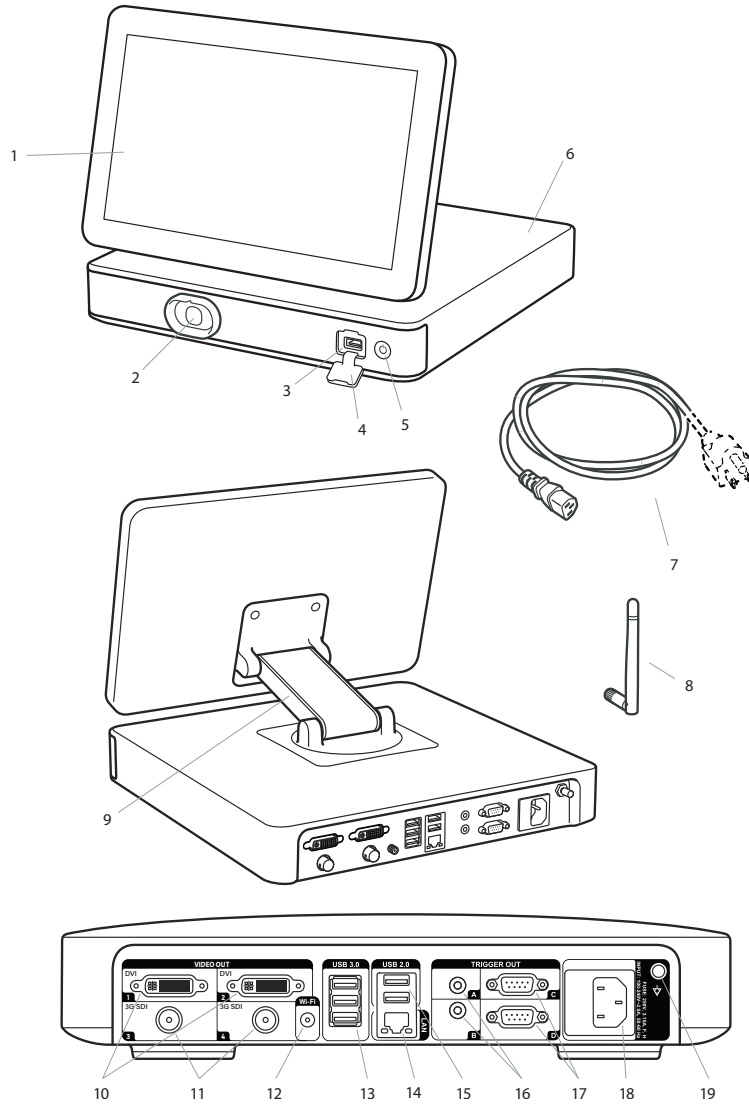

No.	Component	Function
1	Touch screen	Displays the image from the Ambu visualization device and the graphical user interface.
2	VDI port (connector port for Ambu visualization devices)	Connector port geometry and colour ensures correct connection with compatible visualization devices.
3	USB 3.0 port (front)	Enables connection of external USB flash drives.
4	USB port cover (front)	Protects the front USB port.

No.	Component	Function
5	Power button	Turns the power ON or switches to STANDBY mode.
6	Base	Contains the main unit.
7	Power cable	Connects the displaying unit to a power outlet.
8	Wi-Fi antenna	Connect Wi-Fi antenna to the displaying unit for improved Wi-Fi signal.
9	Positioning arm	Enables manual positioning of the touch screen. The screen can be adjusted horizontally and vertically as well as rotated.
10	Video output ports (2x DVI-D)	Enable connection to external monitor or external medical imaging recorder. See section 6.1 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.
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. 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 6.
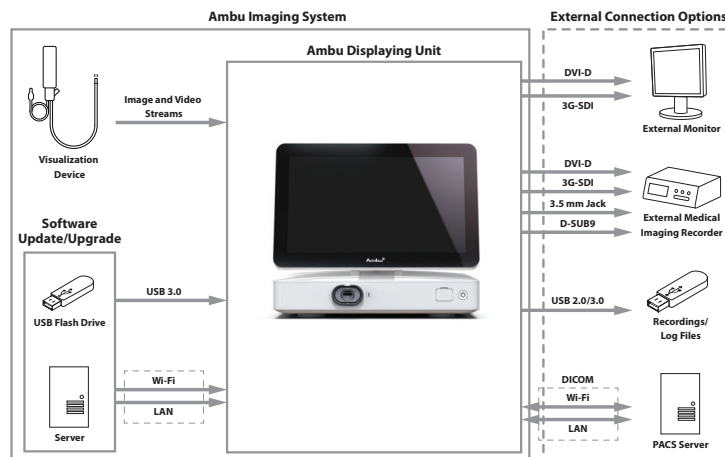
Please note that your organization is responsible for the following areas, which should be implemented according to your local policy and schedule:

- 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
MD	Medical Device	TW	Made in Taiwan
👤 Type BF	Type BF applied part	📖	Follow *Instructions for Use*
LOT	Batch Code	📖	Consult *Instructions for Use*
CLASSIFIED c(UL)us E354633	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	Humidity Limitation	Pressure	Atmospheric Pressure Limitation
REF	Catalogue Number		

4. First-Time Setup

Before using the displaying unit for the first time, follow the steps described here. Letters in grey circles ⬤ refer to the illustrations in the Quick Guide on page 2.

1. Unpack the displaying unit and verify that no parts are missing. Refer to the parts described in chapter 2.
2. Closely examine the displaying unit and other parts for any damage. Do not use the displaying unit if it is damaged in any way **A**.
3. 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 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 the power inlet on the back of the displaying unit using the supplied power cable (see section 2.3). Connect the other end to a suitable power outlet and switch on the power outlet **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**. The touch screen's position and orientation can be adjusted to a preferred position via the adjustable positioning arm connected to the base.
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**.

The user interface takes approximately 20 seconds to start up, 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.

5. Setting Up the Software

In this chapter, the numbers in circles ◯ refer to the described part on the images.
On the user interface of the displaying unit, the **tool bar** containing the main system menus, **Live View** 👁, **Archive** 🗁, **Login** 👤 and **Settings** ⚙, is always accessible on the left side of the screen and the active menu is emphasized with a green colour ①.
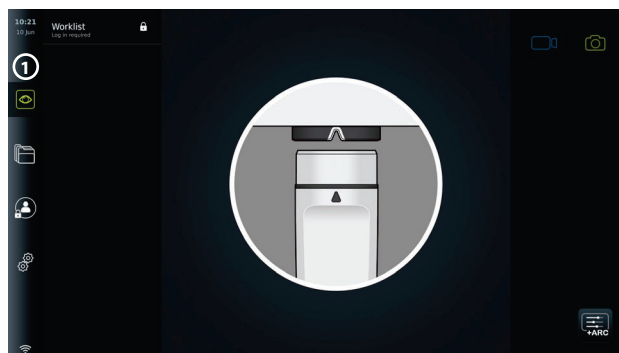
5.1. Software Installation

No installation is required for the software. For software updates/upgrades refer to chapter 8.2.

5.2. How to Log In

By default, login is required to gain full functionality of the displaying unit. Without logging in, the default user is active, and you only have access to the functions in Live view, the Current procedure folder and to view Device info in About under the Settings ⚙ tab.

To log in, press the **Login** (icon) tab in the **tool bar** on the left. The first level menu will appear and show the last user to log in to the displaying unit.
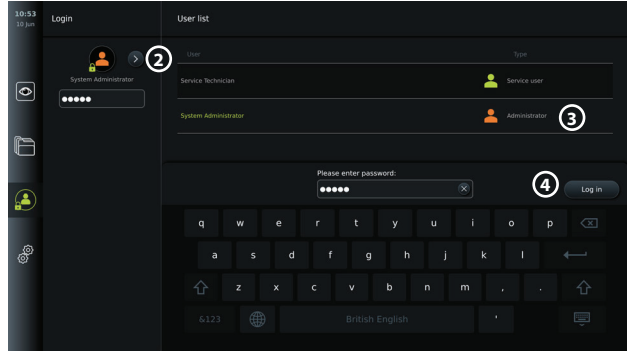
5.2.1. To log in as Administrator
- Press the **arrow** ② and select the **Administrator** ③ user profile from the User list.
- Enter the factory default password: *AmbuAdmin*.
- Press **Log in** ④.

The password must be changed during first-time setup. Find password requirements in section 5.3.4. If you lose the Administrator password, contact your local Ambu representative for assistance.

NOTE: Access to **Archive** without login can be enabled by an Administrator in **General settings** explained in section 5.8. By default, users are logged out of the device after 10 minutes of inactivity.

5.2.2. To log in as another user
- Press the **arrow** ② to open the **User profiles** menu.
- Select the desired user account and type the password in the **Enter password** field.
- Press the **Log in** button.

A confirmation dialog box will appear in the lower left corner if login was successful and the **Login** (icon) icon will change to (icon) indicating that the device functionality is unlocked.

5.2.3. Edit password for Administrator
Editing the Administrator password follows the same procedure as editing the Advanced user password (see section 5.3.3). Note that it is not possible to edit the Administrator user profile name or create new Administrator profiles.

5.3. User Profiles
In the **User profiles** menu under the **Settings** (icon) tab, you can create new or edit existing user profiles. To access this menu, you must be logged in as Administrator (see section 5.2). The following sections provide information on user account privileges and instructions on creating and editing user profiles.

5.3.1. User types
There are four different user profile types. The Default user is active when turning on the displaying unit and does not require login. Login is required for Advanced (blue), Administrator (orange) and Service users (green). Each user profile type has a different level of access to the system. The user profile types, and their system access are shown in the table below.

User Profile Types and System Access					
User Profile Type **Function Access**	**Default User** Instant access without login	**Advanced User** Daily operation	**Administrator** Administrator with full access	**Service User** 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	x	x
Image adjustments	x	x	x	x
Archive	x**	x	x	
Settings	x***	x***	x****	x*****

*The Administrator can enable or disable worklist for the Default users.
**Access to Archive without login can be enabled by Administrator in Settings. By default, the current procedure folder and the bin can be accessed without logging in.
***In the Settings menu, Default and Advanced users only have access to view device information and the current configurations of trigger output channels and visualization device buttons. Log in as Administrator to change settings and reconfigure trigger output channels and visualization device buttons.
****Administrators are also able to reset passwords for all other user profiles.
*****Service users does not have permission to add and change user profiles.

An **Advanced user** profile provides daily users the privileges to access the **Archive** ▢ and to export recorded files to a USB flash drive or a PACS server via DICOM. It is recommended to create at least one **Advanced user** profile (e.g. department login), or individual **Advanced user** profiles for each user of the displaying unit. It is not possible to create additional **Administrator** and **Service user** profiles. The **Administrator** has privileges to change settings for all users. All users can change their own passwords. If the Administrator password is lost and a new one is required, please contact your local Ambu representative.

5.3.2 Create a new Advanced user profile:
To access the User profiles menu:
- Press the **Settings** ⚙ tab in the **tool bar** on the left.
- Press **User profiles.**
- Press **Add user** ⑤.
- Enter **User name** ⑥, **Password** and **Repeat password**. For information on password requirements, please refer to section 5.3.4.
- Press the **Save** ▢ button ⑦.
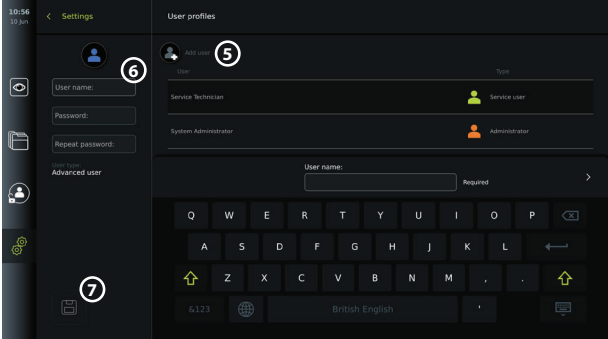
Note: By default, the Archive containing all photos and videos is password protected apart from the current procedure folder and the bin. The Archive can be accessed by an Administrator or an Advanced user profile.

5.3.3. Edit an existing Advanced user profile:

- Press the **Settings** ⚙ tab in the **tool bar** on the left.
- Press **User profiles.**
- Select a user profile from the **User list** ⑧. The **User name**, **User type**, the time it was **Created** for the selected user will be shown on the left side of the screen.
- Press **Edit** ✏ ⑨.
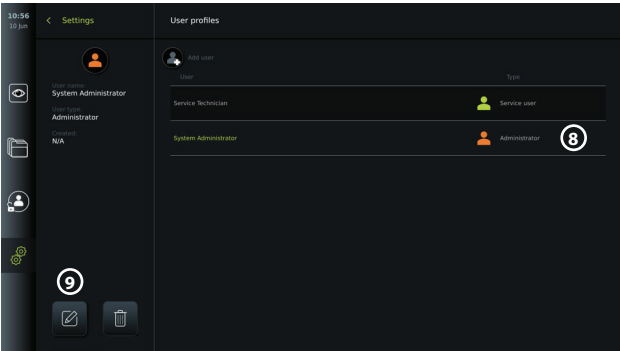
- Type a new name and/or choose a new password ⑩
- Press **Save** 💾 ⑪.
- Press **OK** in the confirmation dialog box to confirm the change.
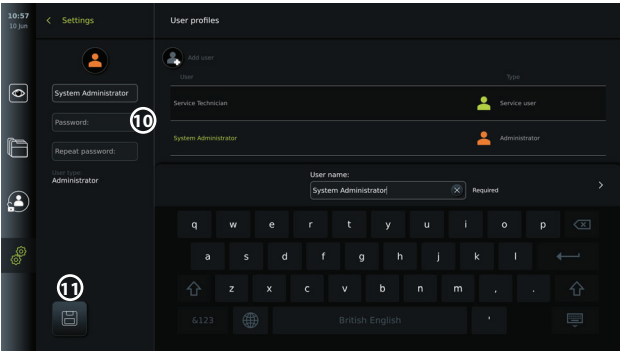
5.3.4. Password requirement

Passwords are required to be at least 8 characters. Any character is allowed. It is recommended to use a combination of upper- and lower-case letter, numbers and symbols to enhance password protection. Ensure to follow local guidelines.

5.4. Language

In the Language settings under the Setup menu, the language for the user interface can be changed. The default language is English. When setting up the displaying unit, select your language preference.

- Press the Settings ⚙ tab in the tool bar on the left ⑫.
- Press Setup ⑬ (the top menu of the menu bar in the Settings ⚙ tab).
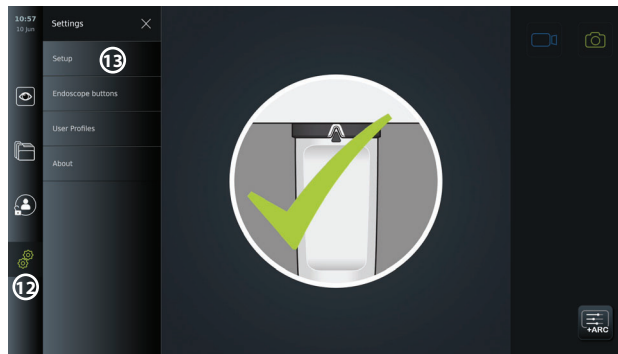
- The **Language** menu opens ⑭.
- Open the **Device language** ⑮ drop-down menu and select language from the list.
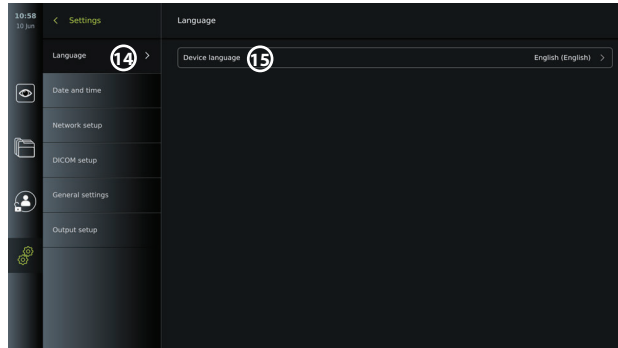
NOTE: The language will change immediately when a new language is chosen.

5.5. Date and Time

- Press the **Settings** ⚙ tab in the **tool bar** on the left.
- Press **Setup** and select **Date and time** ⑯.
- Open the **Time zone setting** drop-down menu ⑰ and select your time zone from the list. It is important to choose the correct time zone as the correct daylight savings is updated automatically.
- Select Time format ⑱.
- Swipe the hours and minutes wheel under **Set time** ⑲ to set the current time.
- Select the current date in the calendar under **Date** ⑳.

14
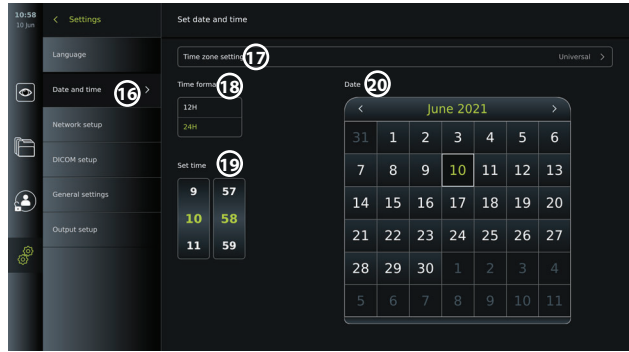
NOTE: The settings are updated as soon as they are chosen.

5.6. Network Setup

In **Network setup** under the **Setup** menu you can setup connection to Wi-Fi and local area network (LAN). For instructions on how to connect LAN cable or Wi-Fi antenna, see section 5.6.1.

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

Setting up LAN connection:
Press the **Settings** ⚙ tab in the **tool bar** on the left.
Press **Setup** and select **Network setup** ㉑.

In the Network setup menu you can see if a LAN (ethernet) cable is connected to the displaying unit ㉒. If no LAN cable is connected, refer to section 5.6.1. for instructions on connection to LAN.

Setting up Wi-Fi connection:
Press the **Settings** ⚙ tab in the toolbar on the left.
Press **Setup** and select **Network setup** ㉑.
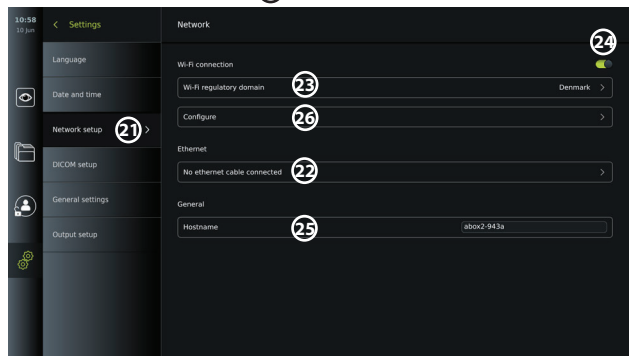
Open the **Wi-Fi regulatory domain** ㉓ drop-down menu and select your region from the list. After selecting a region an ON/OFF slider will appear ㉔. Turn on Wi-Fi by pressing the ON/OFF slider so it switches to green 🔘.

In the **General** menu you can set up the static/fixed **Hostname** ㉕ of the device. This is used if it is required to have a fixed name by which the device is recognized on the network, similar to a static IP address. The **Hostname** can be between 1 and 63 characters (excl. dot "." separator) in the format of xxx.xxx.xxx with dots separating e.g. domain names. The following

15

characters are allowed: a - z (lowercase letters), A - Z (uppercase letters), 0 - 9 (numbers), "-" (hyphens are not allowed as the first and last character).

Press **Configure** (26) and a list of available networks is shown. If a network is already connected, it will be listed under **Currently selected network**. Otherwise the same field will say **No network selected** (27).
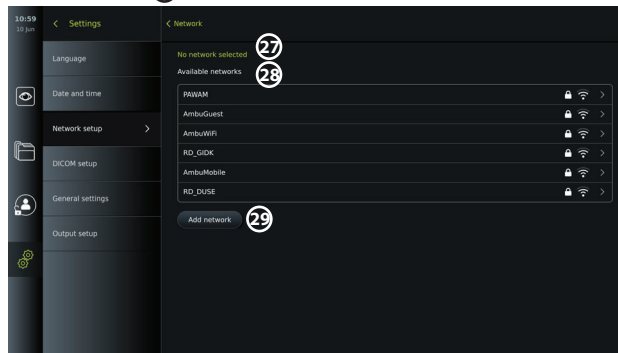
Connecting to a new network:
Choose a new network from the list **Available networks** (28).
Type the **Password** (30) for the selected network. Press **OK** and press **Connect**. IP-address will be assigned automatically.

You can enable automatic connection to a specific network by pressing the ON/OFF slider (31). The displaying unit will automatically remember and connect to this network, when it is recognized.
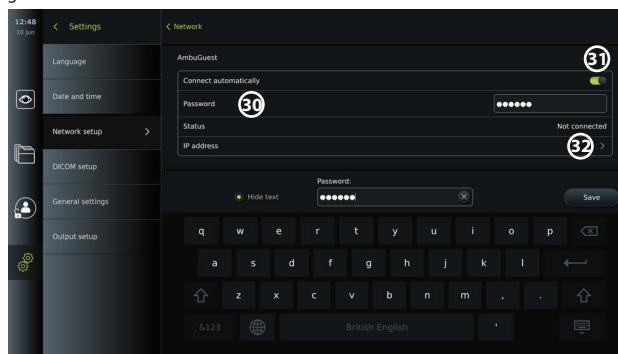
When connection to Wi-Fi is established, a Wi-Fi symbol will appear at the bottom of the **tool bar** on the left (35).

Enable manual configuration of static IP address and/or DNS server
• Press the arrow (32) to enter the IP and DNS configuration.
• Press the ON/OFF slider (33) to enable configuration of a static IP address or the ON/OFF slider (34) for configuration of a DNS server.

16
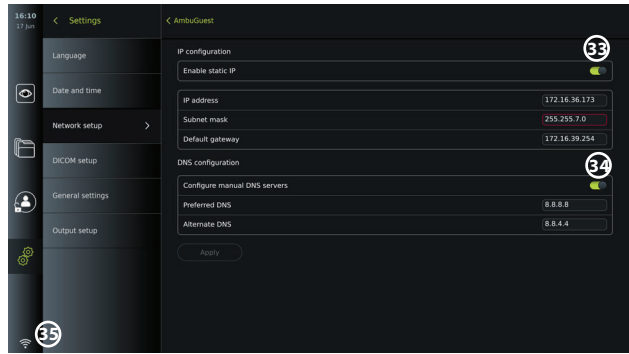
Connecting to a hidden network:
Press the **Add network** button ㉙. Enter the hidden network name and password. The network will hereafter automatically appear on the list of **Available networks** ㉘.

NOTES:
- Wi-Fi networks which require redirection to a login webpage for entering user name and password are not supported on the displaying unit.
- Only WPA and WPA2 are supported.

Disconnecting from network:
Select the connected network and press **Disconnect** ㊱.
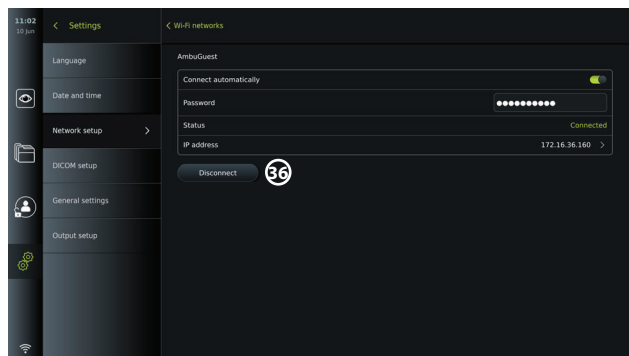
5.6.1. Connecting to Wi-Fi and local area network (LAN)
The displaying unit contains a Wi-Fi module and an ethernet port to connect the device to a local network. This can be used for exporting recorded imaging data to a PACS server (Picture Archiving and Communication System) on the local network (see section 7.3.4.).

A Wi-Fi antenna can be connected to the displaying unit to achieve a better Wi-Fi connection. The displaying unit can be connected to LAN via a LAN cable.

LAN (ethernet)	**Connecting to LAN (Ethernet):** Connect one end of a LAN cable to the ethernet connection port on the back of the displaying unit. Ensure that the other end of the LAN cable is connected to a router or LAN wall connector.

Wi-Fi antenna	**Connecting to Wi-Fi network**
	The supplied Wi-Fi antenna can be connected for better reception.
	Connect the antenna to the Wi-Fi antenna connection on the back of the displaying unit. Orient the antenna to ensure optimal connection to the Wi-Fi signal.
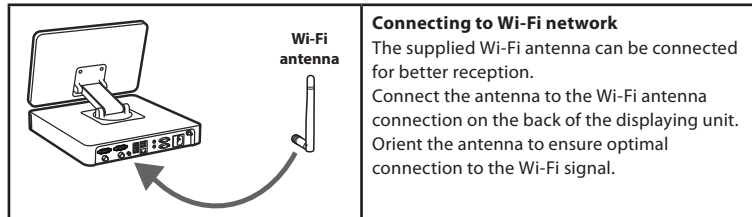
If a network error occurs in your organization, the displaying unit has full functionality while being off-line except for exportation to a PACS server. Imaging data is stored on the local storage of the displaying unit until manually exported to a USB flash drive or a PACS server.

5.7. PACS and Worklist Setup

In **DICOM Setup** under the **Setup** menu, you can configure connection to a PACS (Picture Archiving and Communication System) server to be able to transfer photos and recorded videos in DICOM (Digital Imaging and Communications in Medicine) format over an established Wi-Fi or LAN network (see section 5.6 for network setup).

To set up a PACS server, you may need to involve your IT department or PACS manager of the hospital.
See technical details about establishing connection to a PACS server in Appendix 3.

5.7.1. To access the DICOM setup page:

Press the Settings ⚙ tab in the toolbar on the left.
Press Setup and select DICOM setup �37. Administrator login is required (see section 5.2).
An overview of already configured PACS servers, if any, is shown.
Choose **Device AE** (Application Entity) **title** to enter the name of the displaying unit. The default name is **AmbuMon**. This name will allow the PACS to recognize the displaying unit.
Press the name field �38 to change the name. The maximum length of the name is 16 characters.
Choose if the device "serial number" �39 should be assigned as the **Station name** or create a "custom name" ㊵. The Station name is an optional attribute in DICOM used by PACS to identify the displaying unit.
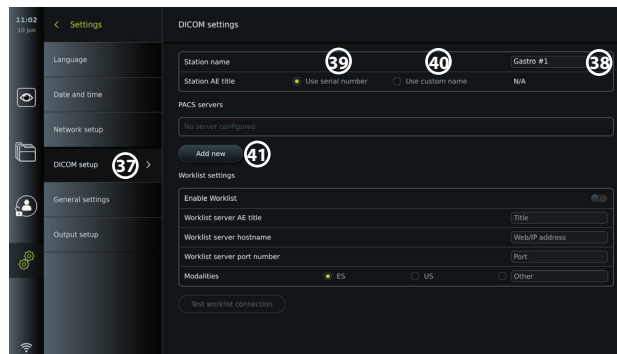
5.7.2. Set up connection to PACS server:

Press **Add new** ㊶, and the **Configure new PACS server** menu will appear.
Press the first field (PACS name) ㊷ and type to add the details.
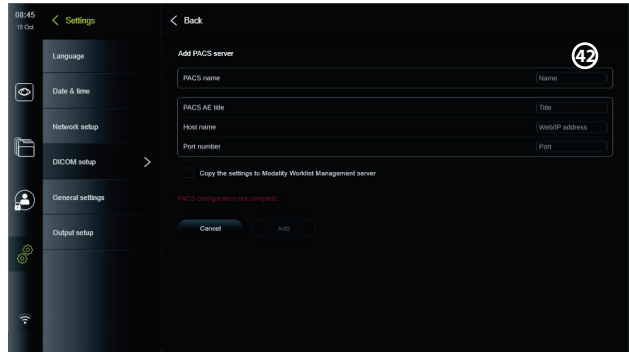
The table below shows the information that must be filled. Please contact your hospital IT or department PACS manager if you do not have this information.

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.

When all the fields have been filled press **Create** to save the PACS configuration. In the following window you can test the PACS connectivity by pressing the "Test connection" button. If the test fails, check if the entered information is correct and try again. For further assistance please contact your local PACS manager.

5.7.3. Worklist settings

Administrators or Service Users can **enable/disable** the user's ability to use the **Worklist** function by pressing the ON/OFF slider ⑬.
Use the **Worklist server AE** (application entity) **title** to uniquely identify the device on the network. Press the Titel box ⑭ and use the keyboard to type the specific name for the device. The **Worklist server hostname** is used to store patient information on a specific server. Find the server by typing the server's Web/IP address in the field ⑮. Type the **Worklist server port number** ⑯ to store patient data on a specific file path of the server. If the server is configured to use different Modalities, this can be changed by picking the **Modalities** used by the server ⑰.
To test if the device is successfully connected, press the **Test worklist connection** button ⑱.
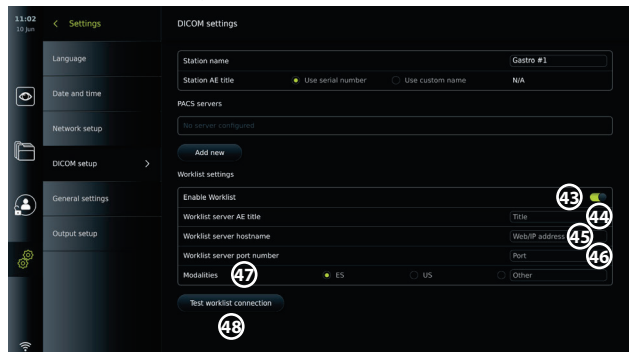
5.8. General Settings

In **General Settings** under the **Setup** menu, the Administrator can enable or disable **Communication Settings, Archive Settings,** the functions **Zoom** and **Stopwatch**, and allow **Access to archive without login** as well as set **User inactivity logout** time.

- Press the Settings ⚙ tab in the toolbar on the left.
- Press Setup and press General settings ㊾.
- Press the ON/OFF sliders ⬤▬ to enable or disable the user's ability to use the functions.
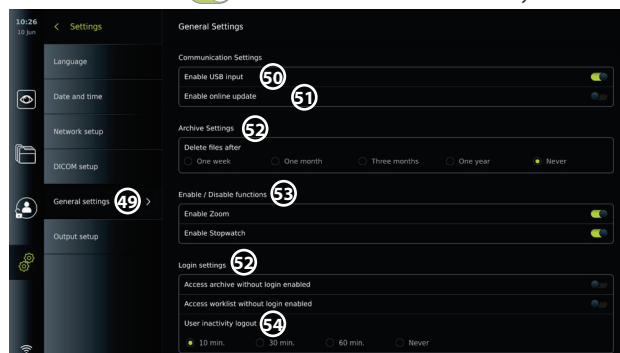
If **USB input** is **disabled** (slider pushed to the left ▬⬤), the USB ports are inactive and cannot be used to export files or perform software updates/upgrades ㊿ . Also, if the **Enable online update** is disabled, the user will not be able to download software updates �51.

In the **Archive settings** �52, the Administrator can choose if and when files should be automatically deleted. If a specific period is chosen, files such as photos and videos will automatically be deleted after the selected period.

Under **Enable/Disable functions** �53, the Administrator can enable/disable the **Zoom** and **Stopwatch** functions. These functions will be available under the **Live view** 👁 tab (see section 7.3. for operating instructions) or directly through the buttons on the visualization device (refer to section 5.10). Shown below is a user interface image where the **Zoom** �54, and **Stopwatch** �55 functions are made available in **General settings**.
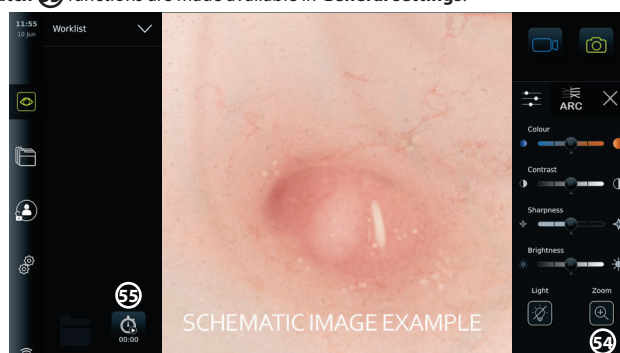
Be aware that if a function is disabled, the symbol is not visible in the menu where it is normally located.

In the **Login settings** �53, the Administrator can enable/disable **Access archive without login** or **Access worklist without login**. When activated, please be aware that the Archive or Worklist is no longer password protected. The Default User is provided Advanced User privileges to access previous procedures and view, delete and export files. Please see section 5.3.1. for further information on user types. The feature is disabled by default.

20

The login settings, also makes it possible to set a time for **User inactivity logout** (54). This will define when the logged in user is automatically logged out if the displaying unit is inactive. The displaying unit is defined as inactive when no visualization device is connected and no functions on the user interface are activated. When the displaying unit is powered ON or has been in STANDBY mode it is necessary to login again, unless **Access archive without login** is enabled.

5.9. Output setup

In **Output setup** in the **Setup** menu, the Administrator can view and reconfigure what **Trigger Outputs** (photo or video functions) (56) are send via which output ports to a connected external medical imaging recorder. 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.

For instructions on how to view and reconfigure endoscope buttons see section 5.10. For instructions on connecting an external imaging recorder refer to chapter 6.

To access the Trigger output menu:

• Press the **Settings** ⚙ tab in the toolbar on the left.

• Press **Setup** and press **Output setup**.

The **Trigger output** menu will open and an overview of the current configuration of the trigger output channels A, B, C and D are shown. 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.
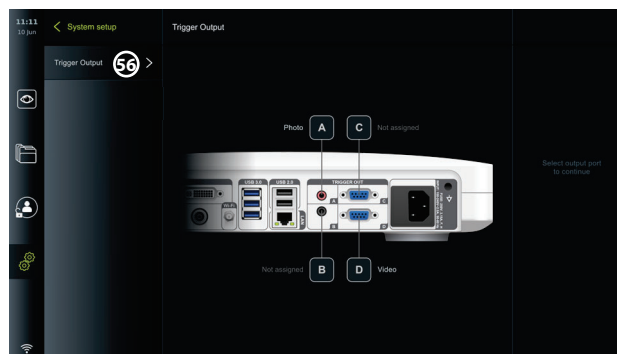
To reconfigure the trigger outputs:

• Log in as Administrator. Refer to section 5.2.

• Navigate to the Trigger output menu in Output setup.

• 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 (57). Here, all available trigger outputs are visible.
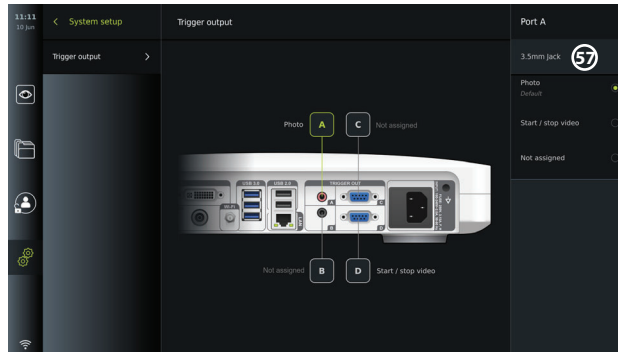
5.10. Endoscope Buttons Configuration

By default, the buttons on a connected endoscope are configured as shown in the table below.

Default Configuration of Endoscope Buttons on Ambu® aScope™ Gastro				
	Button 1	**Button 2**	**Button 3**	**Button 4**
Short press ○	Photo	ARC*	Timestamp	Stopwatch
Long press ⬭	Video	(Disabled)	(Disabled)	(Disabled)

* Advanced Red Contrast, see section 7.3.9.

To view the current configuration of a compatible endoscope type or to reconfigure the buttons, press the **Settings** ⚙ tab in the **tool bar**, press **Endoscope buttons** and select an endoscope type ⑤⑦. An overview will appear.
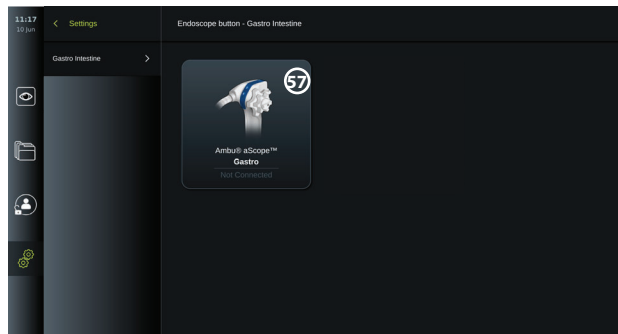
NOTE: With administrator login, Ambu® aScope™ Colon will also be visible on the screen. The aScope™ Colon will only be available for specific markets. Please contact your local Ambu representative for further information.

To reconfigure a button, select the corresponding number ⑤⑧ and select the desired function for long or short press in the selection menu that appears on the right side of the screen. Be aware that Administrator login is required for reconfiguration. Test if the system behaves as expected.

The updated button configuration will automatically be saved on the displaying unit for the type of endoscope selected. For a short description of each function, refer to section 7.3.

NOTE: Some functions may be greyed out in the button configuration menu if disabled by an Administrator. To enable the function, navigate to General settings (see section 5.8.).

6. 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. To avoid risk of electrical shock only connect ancillary equipment approved as medical electrical equipment and always 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.

6.1. 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 1920x1080, 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 [icon] (If enabled in General settings, see section 5.8.)
  - Current procedure folder [icon] 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 section 5.8.)
  - 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 00:39 [icon] will show in the upper right corner

6.2. 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).

6.3. 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 section 5.9 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.

7. Operating the Displaying Unit

This section describes the functions in the user interface of the displaying unit. To use the functions, it is a prerequisite that the system is turned ON and an Ambu visualization device is connected to the appropriate connector port. Letters in grey circles ● refer to the illustrations in the Quick Guide on page 2.

7.1. Preparation and Inspection of the Displaying Unit Before Use

1. Closely examine the displaying unit and other parts for any damage. Do not use the displaying unit if it is damaged in any way. **A**
2. Clean and disinfect the displaying unit (see chapter 9).
3. Connect the displaying unit to a suitable power outlet using the included power cable **B** 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. **D**
5. Turn ON the displaying unit by pressing the power button **E**. 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. Connect the Ambu visualization device to the displaying unit by plugging its connector into the VDI port placed on the front of the base. Make sure that the connector and port colours are matching, and the arrows are aligned. **F**
7. 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. **G**

7.2. Preparing and Operating the Ambu Visualization Device

Please refer to the *Instructions for Use* for the specific visualization device.

7.3. Live View Functions

When the displaying unit is turned ON, the user interface will load after approximately 20 seconds to show the **Live view** 👁 screen. If an Ambu visualization device is not connected, an animation showing how to correctly connect an Ambu visualization device is playing in the live image area. 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.

When the user interface appears, a **tool bar** ① is visible on the left side of the screen which is always accessible. It contains the **Live view** 👁, **Archive** 🗁, **Login** 👤 and **Settings** ⚙ tabs. The **Live View** 👁 tab will initially be active and will be highlighted with a green colour ②.

SCHEMATIC IMAGE EXAMPLE

The icons visible in the Live view screen are described in the table below. The functions are explained in further detail in the following sections.

Explanations of functions in Live View 👁		
Icon	**Name**	**Function**
👁	Live view	This tab shows the live image when an Ambu visualization device is connected.
🎥	Video recording	Press the blue video recording button to start recording video during a procedure. Press again to stop recording.
📷	Photo	Press the green Photo button to take a photo during the procedure. Photos can also be taken during video recording.
📁	Current procedure	View videos and photos recorded in the current procedure. The folder icon appears on the screen if a patient has been selected from the worklist, if a photo or video has been made, or if the stopwatch has been activated. See section 7.3.3
∨	Worklist	Expand the worklist drop down menu to select a patient. Now, patient data will be added to photos and videos. See section 7.3.5.
🗄	Archive	Access photos and videos. Manage and export files. Login is required. See section 7.4.
👤	Login	Login is required to access Settings, Archive and Export files via DICOM.
⚙	Settings	Access system settings. Login as Administrator or Service user to change settings. Default and Advanced users only have access to view device information and the current configuration of the endoscope buttons.
⏱ 00:00	Stopwatch	Press the stopwatch to start a video on the exact procedure time. While the stopwatch is active, multiple timestamps can be recorded during the procedure. See section 7.3.10.
▤ +ARC	Image adjustment	Adjust Colour, Contrast, Sharpness, Brightness. Access the Zoom function and ARC (Advanced Red Contrast) imaging technology. See section 7.3.6.

7.3.1. Taking photos and recording videos
The displaying unit can record still photos and video sequences of the live image using the recording icons in the upper right corner of the user interface (indicated with a red box below) or by using the buttons directly on a connected endoscope (see section 5.10. for endoscope buttons configuration).

SCHEMATIC IMAGE EXAMPLE
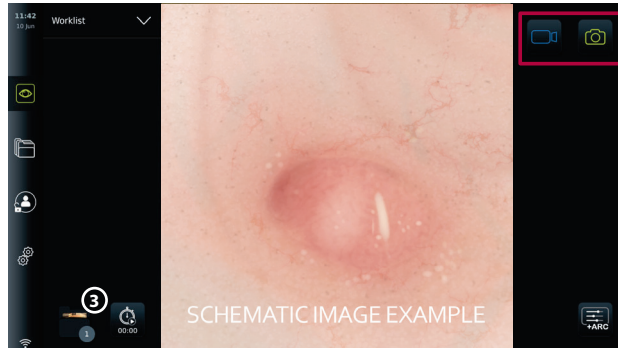
7.3.2. To record a photo or video:

• Press the green **Photo** ⬜ button to take a photo or the **Video recording** ⬜ button to record a video sequence during a procedure.

• It is also possible to take photos while recording a video.

When a photo or video has been recorded it will be stored in the **Current procedure** folder. If a patient has been selected in the Worklist (see section 7.3.5), patient information will be stored with the photos and videos.

Maximum video recording length

The maximum duration of a recorded video sequence is 30 minutes. A notification will be shown in the user interface area when the maximum recording time is almost up. See section 7.4. for information on access to stored photos and videos in the **Archive** ⬜ tab.

7.3.3. Current procedure

When a photo or video has been recorded or a patient has been selected in the Worklist (see section 7.3.5.) a procedure folder for the **Current procedure** is created on the displaying unit. The **Current procedure** ⬜ folder will appear in the lower left corner ③ in the **Live view** ⬿ tab, and will also be accessible under the **Archive** ⬜ tab. A number on the icon informs about the number of photos and videos recorded and stored in the Current procedure.

The **Current procedure** ⬜ folder can be accessed without logging in, but is only accessible during a procedure. When the Current procedure is finished, the procedure folder will move to the **Recent** folder and will require login to access.

SCHEMATIC IMAGE EXAMPLE
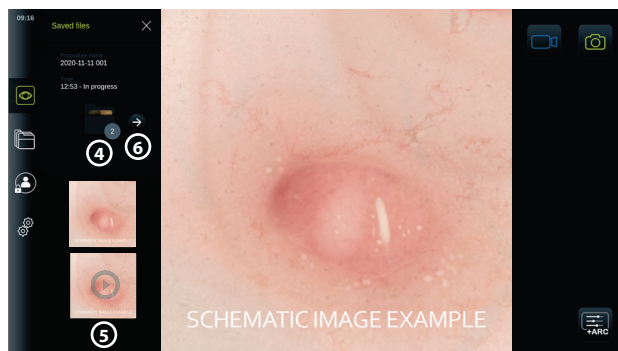
When opening the **Current procedure** folder, the saved files will be shown on the left side of the screen. You can also see the **Procedure name** and the **Time** the visualization device was first connected.

• Scroll down ⑤ to see all available photos or videos from the procedure. The photos or videos are shown in descending order with the newest from the top.

• You can view a specific recorded file by selecting it directly in the **Current procedure** folder. This will open the file in the **Archive** ⬜ tab (see section 7.4).

26

- To access the current procedure overview in the **Archive** 🗁, press the arrow →⑥ (see section 7.4.).
- Press **< Back** ⑥ or press the **Live view** 👁 tab to return to the live image.

Ending the Current procedure:
When the visualization device is disconnected, a pop-up box will show information on the procedure folder, recorded timestamps, and procedure duration before ending the Current procedure.

The user can now choose between the following:

1. End the procedure and export the recorded files by pressing **Finish and export** ⑦. (This will allow the user (regardless of user type) to enter the export menu of the Current procedure and export the files.)
2. End the procedure without exporting files by pressing the X ⑧.
3. Continue procedure by reconnecting the visualization device (or connecting a replacement) and pressing **Continue procedure** ⑨. The displaying unit will return to live view mode.

NOTE: The user are given a certain amount of time to decide an action before the Current procedure is ended automatically. The default **Finish procedure information inactivity timeout** is set at 10 minutes, but can be reconfigured by Administrator in General settings (see section 5.8).

7.3.4. File export
Export photos in the Archive folder 🗁. Select the photo(s) or video(s) and press ⓘ to view photo or video information, press ↑ to enter the export menu or press 🗑 to delete photo(s) or video(s) from the displaying unit.
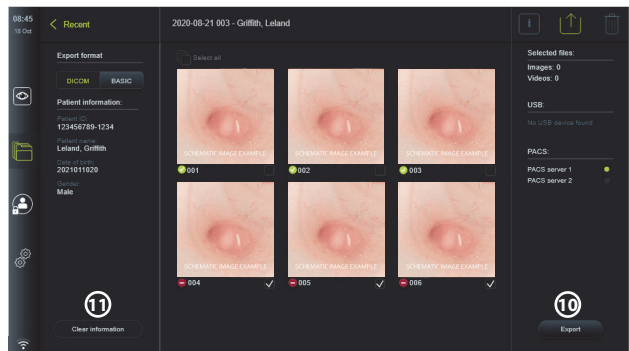
Export the selected photos and videos by pressing the Export button ⑩. After export the symbol ✅ will indicate if the export was successful and the symbol ⛔ will indicate if it

failed.

Press the **Clear information** button ⑪ to reenter patient information manually or with the use of access to the worklist.

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 format.
-	Patient information	Patient data can be retrieved automatically by selecting a patient in the Worklist (refer to section 7.3.5.) or it can be entered manually. Patient data will be saved on the local storage of the displaying unit until the files are deleted, either manually or with auto delete function (can be configured by Administrator in General settings, see section 5.8.).
-	USB	Select a connected USB flash drive to export photo(s) or video(s) to the USB flash drive in BASIC 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 5.7.
Export	Export button	Press the Export button, to export selected photos and videos when all necessary settings have been made.
⌈i⌉	Info	Press Info to view the photo, video or procedure information in the procedure folder.
⌈↑⌉	Export menu	Press the Export menu button to open the Export menu.
⌈🗑⌉	Bin	Press the Bin button to permanently delete photos and videos and any patient data from the displaying unit.
✅➖	Export indicators	To indicate if an export of a photo or video was successful, a green export indicator will appear next to the photo or video. A red indicator means the photo or video was not exported.

*Digital Imaging and Communications in Medicine
**Picture Archiving and Communication System

7.3.5. Worklist

The Worklist contains patient information retrieved from a PACS server (see section 5.7. for information on setting up a connection to PACS server and enable Worklist). When a patient is selected in the Worklist drop-down menu, the selected patient information will be attached to the photos and videos created in the current procedure. Be aware that it is required to log in to access the Worklist. If no patient is selected before starting the export process, it is possible to access the Worklist to assign a patient during export in the Export menu or to enter the patient data manually.

- The Worklist can be found in the **Live View** tab ⌈👁⌉ by pressing the down arrow ⑫. Select a patient by pressing the name, and confirm in the pop-up window.
- To select a different patient, simply press the new patient's name and press **Change** in the pop-up window.
- To deselect a patient, press the selected patient name and press **Deselect** in the pop-up window.

SCHEMATIC EXAMPLE OF VISUALIZATION DEVICE IMAGE

Explanations of functions in Worklist		
Icon	**Name**	**Function**
↻	Update	Press update to retrieve patient information from the hospital system via a PACS* server. The information is downloaded in DICOM** format.
🔍	Search	Press the search field and type to search for a patient name or another parameter. This could be a physicians name a procedure type.
📌	Pin	Press the Pin icon to save a search term. Type a couple of letters and a list will show possible search terms to choose from. Choose one to filter the Worklist for the specific term. To clear a pinned search, press the X. It is only possible to pin one search term at a time. Example: A physician using the displaying unit can pin his/her own name to filter for only his/her patients.

*Picture Archiving and Communication System),

**Digital Imaging and Communications in Medicine).

7.3.6. Adjusting live image appearance

In the **Image adjustment** 📋 menu, you can adjust **Colour**, **Contrast**, and **Sharpness** of the live image as well as the **Brightness** (backlight) of the LCD screen. You can also activate the **Light off** 🔅 function (see section 7.3.8.), **Zoom** 🔍 function (see section 7.3.7.) and **ARC** 📋 (Advanced Red Contrast) imaging technology (see section 7.3.9.).

To change the image parameters:

- In the **Live view** 👁 tab, press the **Image adjustment** 📋 icon to open the menu.
- Adjust the image settings by either pressing an icon at one end of the slider bar ⑬ or drag the slider ⑭ left/right.

SCHEMATIC IMAGE EXAMPLE

NOTE: The displaying unit will save any changes made to the image settings for the type of visualization device that has been connected. As an example, if the settings are changed for a

Ambu® aScope™ Gastro, these will also apply to all other endoscopes of the same type but will not apply to any other aScope variant.

Explanations of functions in Image adjustments ⊞ARC		
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 (see section 7.3.8. for details).
⊕	ZOOM	Zooms in on the live image. A Z icon in the top right corner of the live image indicates that Zoom is active.
⊞ARC	ARC tab	Open the ARC tab to adjust advanced red colour contrast. An A icon in the top right corner of the live image indicates that ARC is active (see section 7.3.9. for details).

7.3.7. Zoom

By using the zoom function, you can expand the size of the live image shown on the screen of the displaying unit or a connected external monitor. The zoom image is enlarged and cropped at the top and bottom. This function can be enabled by Administrator in **General settings** (see section 5.8).

To use the Zoom function:

- Open the **Image adjustment** ⊞ menu and press **Zoom** ⊕ ⑮.
- The live image will expand, and the watermark Z ⑯ will appear in the upper right corner of the live image, indicating that zoom is active. Further, a Zoom crop zoom icon ⑯ will appear, to indicate how the image is cropped to obtain the zoomed view.
- To disable zoom, press **Zoom** ⊕, the black background ⑰ or the zoom crop zoom icon.

SCHEMATIC EXAMPLE OF VISUALIZATION DEVICE IMAGE
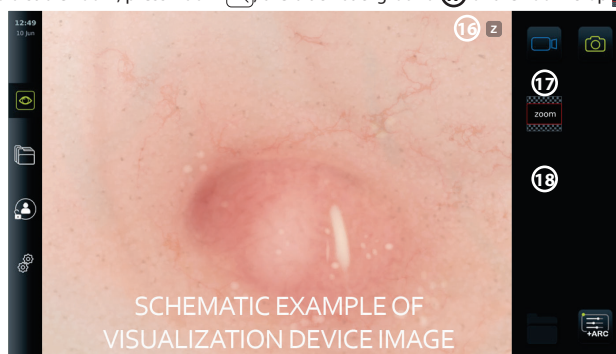
NOTES:

- If photos or videos are recorded while using the zoom function, the original full-size image area is recorded as if the zoom function was not activated.
- The **Stopwatch** ⏱ button, the **Current Procedure** 🗀 folder, and the worklist dropdown menu are not visible when Zoom is activated, but it is still possible to use the

stopwatch function if activated via the buttons on an endoscope (refer to section 5.10. for configuration of endoscope buttons).

• Zoom can be enabled/disabled in **General settings** by Administrator (see section 5.8.).

7.3.8. Light 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. The Light off function allows the user to turn the LED light off and on manually.

• To activate Light off, open the **Image adjustment** [⊞] menu and press the **Light off** [◊] button ⑲.

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 ⑳.
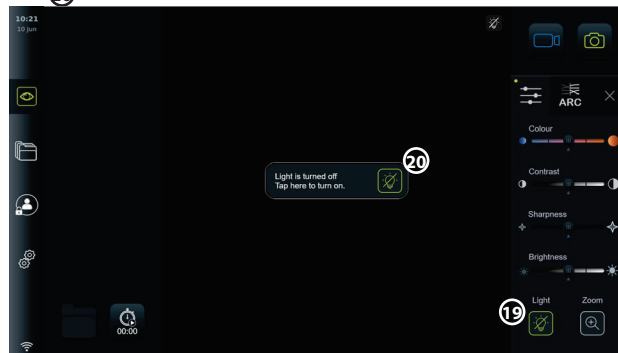
NOTES:

• 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 (off) after a scope has been removed, after a procedure is finished and after reboot.

7.3.9. ARC (Advanced Red Contrast)

ARC is Ambu's proprietary red-colour contrast enhancement algorithm, which amplifies the red colour relative to other colour components at the same location. It is intended to improve the visibility of red colour tones in the image.

• To activate ARC, open the **Image adjustment** [⊞] menu and select the **ARC** [⧉] tab ㉑.

• Press the **ARC** [⧉] button to activate the function. When **ARC** is active, a watermark [A] will show in the top right corner of the live image, the **ARC** [⧉] button will be highlighted in green colour, and a small green dot will appear on the **ARC** [⧉] tab.

• Use the slider bar ㉒ to adjust the strength of the ARC image enhancement.

• Press the **ARC** [⧉] button again to deactivate ARC.

NOTES:

- ARC can be activated by using the buttons on a connected endoscope (see section 5.10.).
- 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.

7.3.10. Stopwatch

Use the **Stopwatch** function to record the exact time used during a procedure. You can find the **Stopwatch** button in the lower left corner of the screen in the **Live view** window. If the **Stopwatch** button is not visible, it has been disabled in the **General settings** menu. Refer to section 5.8. to enable the ability to use the **Stopwatch** function.

To use the Stopwatch during a procedure:

- In the **Live view** window, press the **Stopwatch** button. The stopwatch icon turns green and starts counting in minutes and seconds.
- Press the plus sign (23) to generate timestamps during the procedure. Multiple timestamps can be generated.
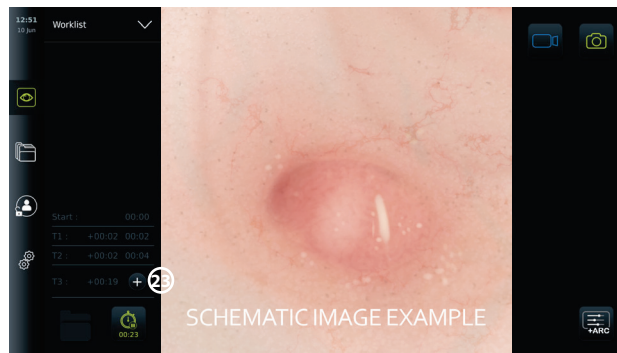
- To stop the stopwatch counter, press the **Stopwatch** button again. The counter on the stopwatch stops and the icon turns white (24).
- To start the stopwatch counter again, press the **Stopwatch** button again. The counter will start from where it was paused.
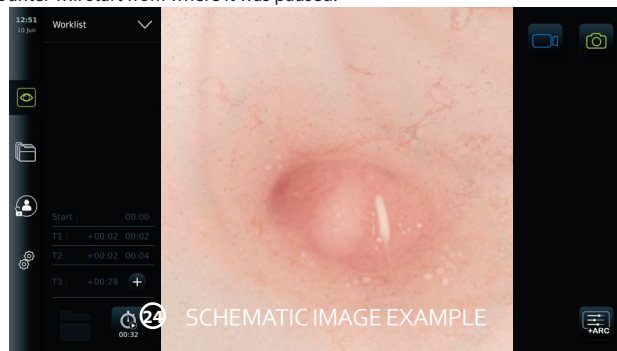
If the visualization device is unplugged before the stopwatch is stopped, the counter will stop and the procedure folder, the timestamps table, and duration of the procedure will pop up, as if the procedure has ended (25). The timestamps and duration of the procedure is saved on the displaying unit and can be viewed in the procedure folder in **Archive** (see section 7.4.).

If the same visualization device is reconnected **within** 60 seconds, the displaying unit will return to live view mode and the counter will continue from the time the device was

disconnected.

If the same visualization device is reconnected **after** 60 seconds, the user must press **Continue procedure** 26 to return to the live view image, continue the procedure and continue the counter from the time the device was disconnected.

When the procedure has ended, the timestamp table will be displayed in a pop-up window and saved to the procedure folder.
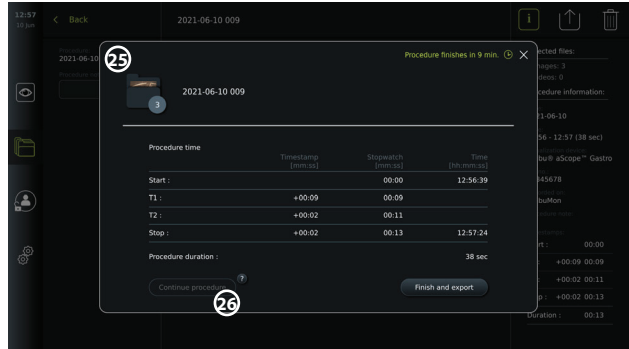
NOTES:

The Stopwatch function can be disabled in the **General settings** menu by an Administrator (see section 5.8.).

7.4. Archive

The **Archive** 🗁 contains photos and videos from all previous procedures. The photos and videos are saved in procedure folders which are unique for each visualization device connected to the displaying unit (see section 7.3.3.).

To access the **Archive** 🗁, log in as **Advanced User** or **Administrator** (see section 5.2.). Press the **Archive** 🗁 tab in the **tool bar** and press **Recent** 27.
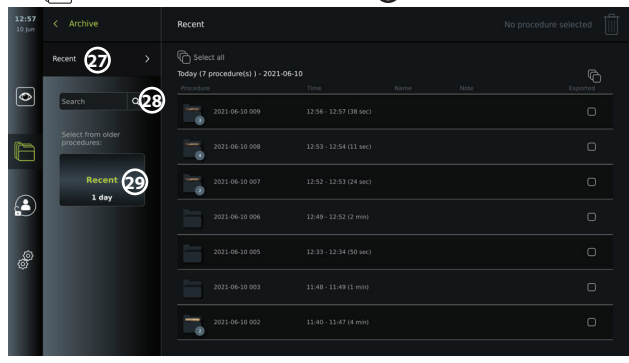
Under **Recent,** all procedure folders are shown in descending order with the most recent at the top. In the list of procedure folders, you will find the **Procedure name**, **Time of procedure**, as well as any **Notes** written for the specific procedure (see section 7.4.2.).
The procedure name consists of the date of the procedure and the procedure number of the day. The format is: YYYY-MM-DD_XXX, where XXX is the procedure number.

NOTE: Ensure that the date is set correctly in the system to have procedures saved with the correct information (see section 5.5.).

The number on the procedure folder icons 🗁 shows number of photos and videos that the particular procedure contains. If the procedure list fills beyond the content of the screen, a scroll bar will appear to the right of the procedure overview.

The **Search** (28) field can be used to find specific procedures. Press the field and type a procedure date or words from a note added to a specific procedure.

You can also choose to filter the procedure list to only see procedures in a given date range.

- Use the **Select range** (29) wheel to select and view a wider or narrower range of procedure folders.
- The list will filter automatically when a range is selected.
- To get a full overview, move the range selector back to **Recent**.

7.4.1 Viewing Procedure folder in Archive

In the **Procedure folder** [icon] an overview of all photos, videos and information from the specific procedure is shown.

- To access, press the **Archive** [icon] tab in the **tool bar** on the left.
- Select a **Procedure folder** [icon] in the procedure list to view the content.
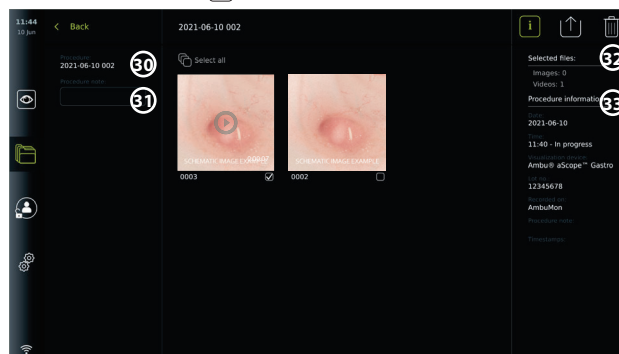
In the left side of the screen the **Procedure name** (30) and a field for **Notes** (31) are shown. The notes field can be used for adding a short descriptions to specific procedures or files.
In the right side of the screen the number of **Selected files** (32) and the **Procedure information** (33) is shown. The **Procedure information** includes:

- **Date** for procedure.
- **Time** of day the procedure was done.
- **Duration** of procedure defined by the time the visualization device was initially connected to the time it was last disconnected.
- The type of **visualization device** used for the procedure.
- The **LOT** number for the visualization device.
- The name of the specific displaying unit (edit name in **DICOM setup** under **Device AE title**, see section 5.7.).
- Any **Procedure notes**.
- Any **Timestamps** recorded using the stopwatch function during the procedure.

All the recorded photos and videos in the procedure are shown in descending order with the most recent photo or video at the top left. Below each photo or video thumbnail is the file name and a **Selection box** [icon] icon. The **Select all** [icon] icon is found above the photos and videos overview. The file name is: XXXX, indicating the image count, starting from 0001.

7.4.2. Adding a note to a procedure, photo or video

- To add a note to a procedure, navigate to the procedure folder and press the **Procedure note** (31) field and use the appearing keyboard to type. To add a note to a photo or video, press the photo or video and press the **File note** (32) field.

The note field is intended for short descriptions about a procedure, photo or video and the space is limited to 40 characters. The note is stored on the displaying unit with the procedure photo or video will become part of the folder name when exporting image data to USB.

7.4.3. Viewing photos and videos

- To view a photo or video, press the thumbnail. The photo or video will expand to full size.
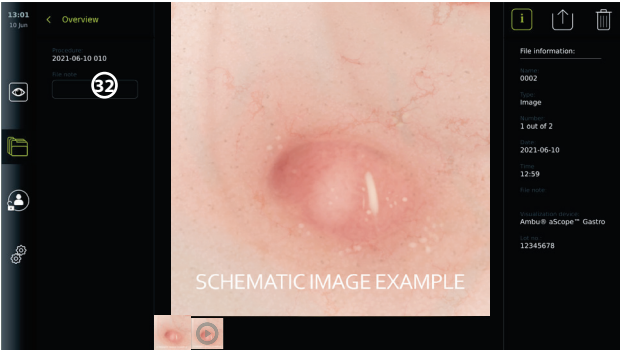
Below the full-size image, all photos and videos from the procedure are shown in descending order with the most recent on the left. Scroll sideways on the thumbnails to see all photos and videos from the procedure.

On the right side of the screen, **File information** is listed for the viewed photo or video. These data are stored on the displaying unit with the files and not exported to USB and PACS. On the left side you will find the procedure name and any notes written for the procedure.

To view a video:
- Press the **play button** 33 in the centre of the full-size video to view it. A **playback bar** is shown below the video.
- To stop/pause the video, press **pause** 33.
- To step forward and backwards, frame-by-frame, in the video use the **arrows** 34 after **pause** has been activated.
- To jump to a specific time in the video, tap the playback bar at the preferred location. You may also slide the **knob** 35 sideways to fast-forward and rewind in the video.
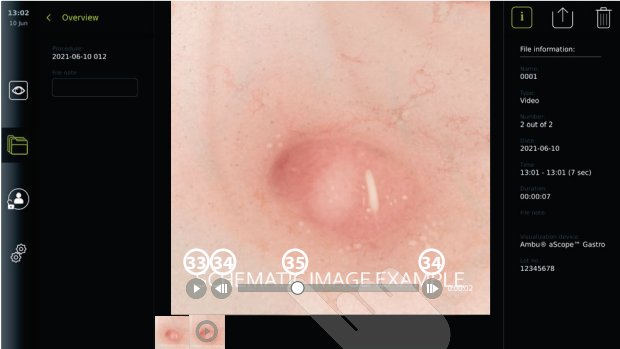
NOTE: It is not possible to take screenshots from a recorded video on the displaying unit. Please use the Photo feature in the Live view during the procedure for taking still photos.

7.4.4. Deleting files
You can delete recorded photo(s) and/or video(s) in any procedure folder or multiple procedure folders at once under **Recent** with **Administrator** access. All user profiles can delete files from the Current procedure folder.
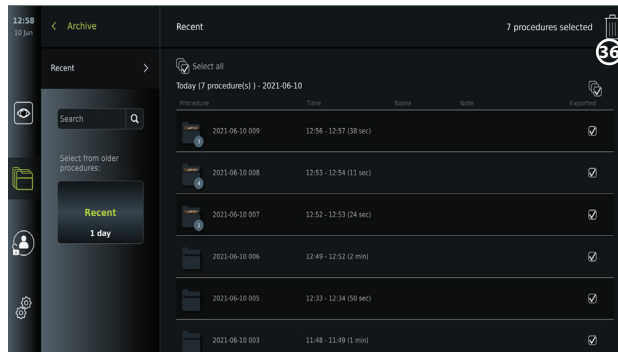
To delete files or procedure folders:

- Select the photo(s), video(s) or folder(s) to be deleted by the specific selection boxes ☑ or press **Select all** ⬚☑. Pressing the same button again will deselect all.

- Press the **Bin** 🗑 ㊱ to delete selected files or folders.

- In the confirmation dialog box press **OK** to confirm or **Cancel** to return to the overview.

NOTE: When a photo or a video has been deleted, it cannot be restored. Administrators can access the **Deleted** folder under **Archive** ▤ to get an overview for all of all deleted procedure folders. The empty procedure folders are not visible to other users.

7.4.5. Export to USB flash drive or PACS

Photos and videos recorded on the displaying unit can be exported to a connected USB flash drive or to a PACS server (Picture Archiving and Communication System – see section 5.7.2. - for setup).

The photos and videos can be exported in two formats: **DICOM** (Digital Imaging and Communications in Medicine) **format** and standard format called **BASIC**.
When photos and videos are exported in BASIC format to the USB flash drive, they are stored in the following formats:

Storage settings	
Image (photo)	PNG (800 x 800 pixels) – no compression
Video	MP4 - compressed

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
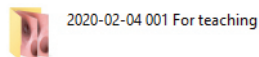
To export files, go to the **procedure folder** to view all photos and videos in the procedure. Use the **Selection boxes** to select individual ☑ or all ⬚☑ files from the procedure to export. When files have been selected, press the **Export** ⬆ icon in the top right corner of the screen.
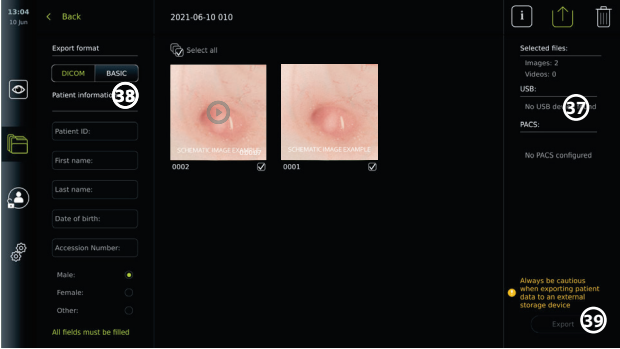
On the left side of the screen, you can choose between the export formats: **DICOM** format or **BASIC** image.

To export in BASIC format (USB flash drive only):

- Press on **BASIC.**
- Select a connected **USB** on the right side of the screen ㊲.
- Press **Export.**

To export in DICOM format to a PACS server or USB flash drive (for manual transfer to PACS):

- Select the **DICOM** tab.
- Enter patient information ㊳. All following fields must be filled:
    - **Patient ID** (e.g. the patients social security number or other ID code)
    - **First name** of the patient
    - **Last name** of the patient
    - The patient's **Date of Birth**
    - **Accession Number**
- Select gender by pressing **Male, Female** or **Other.**
- Select a connected **USB** flash drive (enable USB transfer in **Settings - Setup - General settings**) or **PACS** server (see section 5.7.2. for setting up a PACS server) on the right side of the screen.
- Double check your entered patient data prior to exporting.
- When you are ready to export, press **Export** in the lower right corner ㊴. While the files are being exported a pop up window informs about the export progress. If you need to stop the export, press **Cancel**.

- A pop-up window will indicate that exporting has completed. Press **OK**.

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.

7.5. 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. For disposal of the

visualization device, refer to the *Instructions for Use* of the specific device. **I**

2. Press the power button to switch to STANDBY mode. A confirmation dialog box appears on the screen. Press **OK** to confirm STANDBY. Allow the displaying unit to go into STANDBY mode (orange light in power button) before continuing. **J**

3. Clean and disinfect the displaying unit (see chapter 9). **K**

8. System Information and Upgrade

You can find system information and get access to the software upgrade menu in **About** under the **Settings** ⚙ tab in the **tool bar** on the left.

8.1. Device Information Page

The **Device info** content provides an overview of the systems information and conditions.

• Press the **Settings** ⚙ tab in the **tool bar** on the left.
• Press **About**, and the **Device Info** ① menu will be open.

Here you can view information such as serial number, software (SW) version, build time and disk size. This menu also provides an overview of the current system conditions such as used disk space and device temperature. Ensure to **Refresh info** ② to receive the most updated information.
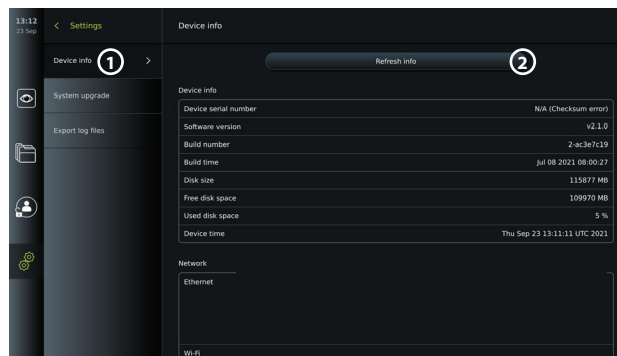
8.2. Software Update/Upgrade

The software upgrade function is located in **System upgrade** in the **About** menu under the **Settings** ⚙ tab. A software upgrade can be supplied and installed either by using a USB flash drive (please contact your local Ambu representative) ③ or downloaded and installed by an Administrator, if the displaying unit is connected to the Internet via Wi-Fi or Ethernet ④.

NOTE: In **General Settings,** USB input or online update must be enabled to allow software update/upgrade (see section 5.8.).
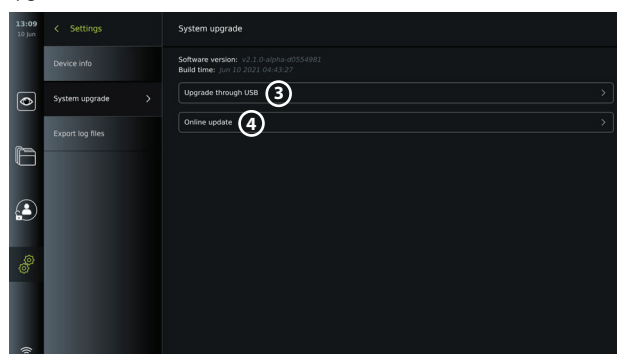
8.2.1. How to update/upgrade Ambu display unit software via the Internet

Downloading the newest Ambu software requires an internet connection using Wi-Fi or Ethernet. The update/upgrade can only be performed by an Administrator. Before starting the download ensure that the network you connect to can reach the address https://api.services. ambu.com ensuring that the displaying unit can retrieve any available update/upgrade.

How to download a software update/upgrade:

1. If a newer software version is available, click **Upgrade software** ⑤ (If you do not have the option to choose **Upgrade software** your system is running on the latest available version) ⑥.

2. The download will start. During the download you can monitor the progress and can at any time cancel the download with no effect on your current software version.

3. When the download has completed you have the options to install or press OK and install it later. It is recommended to stay on the network while installing, but it is not a prerequisite.
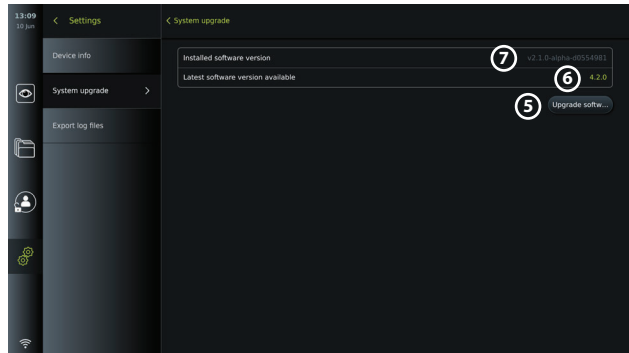
How to install the downloaded software update/upgrade:

1. During the installation ensure there are no interruptions.

2. After the installation has finished, the system will automatically reboot and an *Installation successfully completed* message will appear to confirm a new version update/upgrade has been performed ⑦.

NOTES:

*   The internet access must be enabled in the **General settings** tab (see section 5.8.).

*   An Administrator can grant other users e.g. a Service user to perform updates/upgrades.

*   Downloading or installing updates/upgrades cannot be run in parallel with other procedures.

*   A scope cannot be connected during update/upgrade.

8.3. Reporting a Problem

In case you are experiencing problems with the displaying unit, please follow the troubleshooting guidelines in chapter 13 to find a solution. If this does not help, please contact your local Ambu representative.

8.3.1. Export log files

Log files can be used by Ambu for troubleshooting purposes. This require the log files to be exported from the displaying unit. A log file consists of compressed text files containing information about the displaying unit system.

Please follow these steps to export a log file to a USB device:

*   Connect a portable USB flash drive (see section 6.2.).

*   Go to **Settings** ⚙ and open the **About** menu.

*   Press **Export log files** ⑧, and press the **Export** ⬆ icon ⑨.

A pop-up window will inform you if the export was successful.
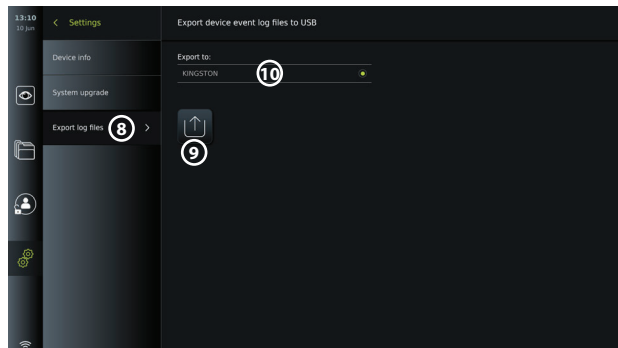
NOTE: Ensure that the connected USB flash drive is displayed below **Export to** ⑩. If it does not show here, USB connectivity might have been disabled in the **General settings** menu. Refer to section 5.8. for information on how to enable USB connectivity.

8.4. Backup

It is recommended to create a backup of your files on a regular basis by exporting photos and videos to an external storage location e.g. USB device or PACS server, in the event a problem occurs with the internal displaying unit storage.

It is not possible to *import* imaging files to store on the internal memory. Setup data cannot be exported. In case Setup data is lost (i.e. time, date, button configuration), it is necessary to re-enter the information.

9. 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 fulfil 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 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 antireflective 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: 80cc of 95% Isopropyl (alcohol) added to 20cc of purified water (PURW). Alternatively, use EPA-registered hospital disinfection wipes containing at least 70% isopropyl. Safety precautions and directions of use of the manufacturer must be followed.

NOTE: After cleaning and disinfection, the displaying unit must be submitted to the pre-check procedure in section 7.1.

10. Maintenance

The displaying unit shall be subject to preventive inspection prior to use according to section 7.1. and shall be cleaned and disinfected according to chapter 9.

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

11. Disposal

At the end of product life, clean and disinfect the displaying unit (see chapter 9).

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.

12. Technical Product Specifications

12.1. Standards Applied

The displaying unit function conforms with:

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

12.2. 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 1080p, 60 fps) and 3G-SDI (1920 x 1080p, 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	100-240VAC ; 2A
Protection against electrical shock	Class I
Operating environment	
Operating temperature	10 - 40°C (50 - 104°F)
Operating relative humidity	30 - 85%
Operating atmospheric pressure	80-106kPa
Operating altitude	≤ 2000 m
Storage environment	
Storage temperature	0 - 40°C (32 - 104°F)
Storage relative humidity	10 - 85%
Storage atmospheric pressure	50-106kPa
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	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
Length of power cables - EU, UK, CH	1830mm (72") including connector
Length of power cables - US, AUS, DK	1800mm (71") including connector

Contact your local Ambu representative for further information.

13. 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
NOTE: Do not power off the displaying unit during the software update/upgrade download and installation process! **Restart the displaying unit** 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). **If the displaying unit does not enter STANDBY mode, force it to completely turn OFF (no light in power button)** 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. **If restart and complete turn OFF does not work, reset displaying unit hardware** 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. Ensure that the light indicator in the power button lights up when the displaying unit is connected to power.	Connect the power cable to the displaying unit and to a power outlet. Make sure the power outlet is turned on.
	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
No live image from the visualization device on the displaying unit screen OR No LED light in the distal end of the visualization device.	A recorded image in the current procedure folder is blocking the live image OR A menu box is blocking the live image.	Return to live image by pressing the Live View tab ⬚. If this does not work perform a **Power OFF Cycle** (follow the procedure above this table).
	LED light switched off by activation of the Light off function.	Deactivate the Light off function (see section 7.3.8.).
	Failure on visualization device connection.	Connect/reconnect visualization device.
	The displaying unit and the Ambu visualization device have communication problems.	Perform a **Power OFF Cycle** (follow the procedure above this table).
	Failure on visualization device or VDI-port on the displaying unit.	Connect a new visualization device. If this does not work, the VDI-port on the displaying unit may be damaged.
Live image on the displaying unit is ONLY working while booting.	Processing failure.	Perform a **Power OFF Cycle** (follow the procedure above this table).
No image or User Interface on the external monitor.	External monitor is turned OFF.	Turn ON external monitor.
	Issue with SDI or VDI cable or cable connection.	Check if the cable is connected properly. If possible, try a new cable. Note: Cable may be damaged, or cabling quality or length may be insufficient. An RG6 grade cable with shielding is recommended.
	SDI – External monitor does not support 3G-SDI.	Make sure that your external monitor supports 3G-SDI (1920 x 1080p 60 fps.).
	Wrong input channel is selected on the external monitor.	Make sure the correct input channel is selected on the external monitor.
	Wrong video output is chosen on the displaying unit.	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.

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 *Instructions for Use* 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. Issue with connection between endoscope and displaying unit.	Unplug and reconnect the endoscope OR Connect a new endoscope. 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).

Problem	Possible cause	Recommended action
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).

14. Warranty and Replacement

Ambu warrants that the displaying unit (as defined in section 2.1.) will conform to the specifications described by Ambu and be free from defects in material and workmanship for a period of one (1) year from the date of invoice.

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

In case of replacement of spare parts, the customer is obligated to provide reasonable assistance to Ambu, including, where relevant, by customer's biomedical technicians pursuant to instruction from Ambu.
Unless otherwise expressly agreed in writing, this warranty is the only warranty which applies to the displaying unit, and Ambu expressly disclaims any other warranty, expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose.
The warranty applies only if it can be established that:

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 9). Ambu is entitled to reject a displaying unit which has not been duly decontaminated, in which case this limited warranty shall not apply.

Appendix 1. Electromagnetic Compatibility

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

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

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

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

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**
Surge IEC 61000- 4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth		Mains power quality shall be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (95% dip in Ut) for 5 sec.	100% reduction 0.5 period 40% reduction for 5 periods 30% reduction for 25 periods 100% reduction for 5 sec.	Mains power quality shall be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic Environment Guidance**
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.
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	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.

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.

c) 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.

d)   Over the frequency range 150kHz to 80MHz, 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**		
	150kHZ to 80MHz $D = 1.17\sqrt{P}$	**80MHz to 800MHZ** $D = 1.17\sqrt{P}$	**800MHz to 2.7GHz** $D = 2.33\sqrt{P}$
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 5.15-5.35GHz 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 models(s), and worst-case tilt angle(s) necessary to remain compliant with the e.i.r.p. elevation mask requirement set forth in section 6.2.2.3 shall be clearly indicated. FR: Le guide d'utilisation des dispositifs pour réseaux locaux doit inclure des instructions précises sur les restrictions susmentionnées, notamment: (i) les dispositifs fonctionnant dans la bande 5150-5250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage p (ii) lorsqu'il y a lieu, les types d'antennes (s'il y en a plusieurs), les numéros de modèle de l'antenne et les pires angles d'inclinaison nécessaires pour rester conforme à l'exigence de la p.i.r.e. applicable au masque d'élévation, énoncée à la section 6.2.2.3, doivent être clairement indiqués
Radiation Exposure Statement/ Déclaration d'exposition aux radiations:
EN: This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with greater than 20cm 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 20cm between the radiator & your body.

Wi-Fi:	
Standard	IEEE802.11ac, IEEE802.11a , IEEE802.11b , IEEE 802.11g , IEEE 802.11n
ISM frequency Band	2.4/ 5 GHz

Data Rate	802.11a: 54, 48, 36, 24, 18, 12, 9, 6 Mbps 802.11b: 11, 5.5, 2, 1 Mbps 802.11g: 54, 48, 36, 24, 18, 12, 9, 6 Mbps 802.11n: MCS 0 to 15 for HT20MHz MCS 0 to 15 for HT40MHz 802.11ac: MCS 0 to 8 for HT20MHz MCS 0 to 9 for HT40MHz MCS 0 to 9 for HT80MHz
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.
LAN communication	IEEE 802.3 IEEE 802.3ab IEEE 802.3az PICMG3.1	The device uses a standard Gigabit Ethernet controller supporting a 1000base-T interface.
Access test	ICMP / ping	Allowing ease-of-discovery for hospital IT infrastructure
Network adaptor configuration	DHCP	Only configurable through DHCP. Special configurations for the network adapter such as static IP are currently not supported.
Re-routing		The device does not support re-routing traffic from Wi-Fi to LAN or vice versa, therefore the device cannot act as a NAT (Network Address Translation) gateway.
PACS servers	DICOM	To support a broad range of network infrastructures and PACS servers, the device supports DICOM without CMS (Cryptographic Message Syntax) encryption for transporting photo(s) and video(s) to the PACS server.
Ports		There are no open ports, the device firewall only accepts TCP responses for DICOM and replies to ICMP ping requests.

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

Appendix 3.2. Data at Rest and In Transit

The displaying unit uses SQLite3 databases to secure information about the scopes,

procedures and network configurations. The SQLite database is not accessible from the GUI, but photos, videos and a limited log can be exported to a PACS server and/or USB device.

The following exportable data are stored:

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

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

Item	Format	Protocols	Comments
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	1.72.0	Boost is used for IO file interaction and asynchronous handling.
libyaml	0.6.2	Is used to parse YAML files on the device. YAML files are used for configuration, including keys and values.
SQLite	3.31.1	Main database.
Linux	Linux Kernel version 4.19.130	The embedded Linux kernel is built custom by Ambu.

Title	Version	Used for
GStreamer	1.18.3	The following plugins are used: v4l2src glupload glcolorconvert 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.
dcmtk	3.6.5	Used for the DICOM protocol communicating to the PACS server.
RAUC	1.4	Used for system upgrades.
yocto	dunfell	Used to build the embedded Linux system
Barebox	v2018.11	Used for bootloading the Embedded system

Ambu