

INSTRUCTIONS FOR USE

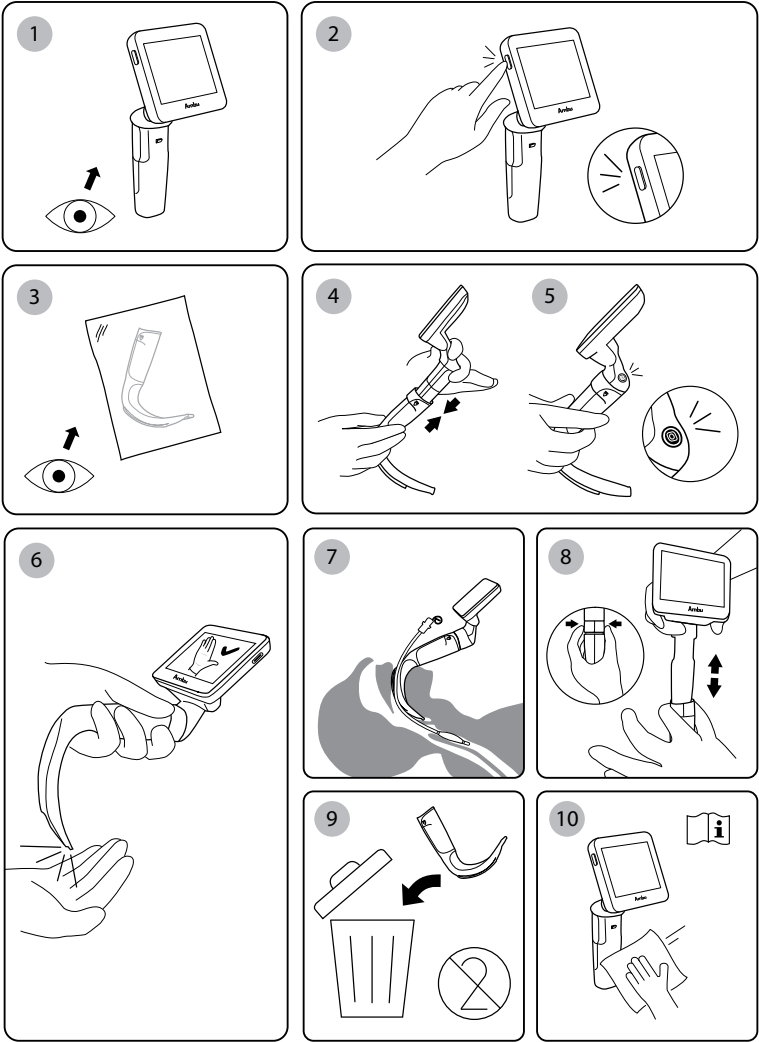
Ambu® SureSight® Mobile

For use by individuals who have been trained
and authorized to use video laryngoscopes.
For use in hospital and pre-hospital environments.

Ambu



QUICK GUIDE



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1. Important information – Read before use

In this document the term *Mobile* refers to Ambu® SureSight® Mobile, *Video Laryngoscope* refers to Ambu® SureSight® Mobile Video Laryngoscope, *Battery Charger* refers to Ambu® SureSight® Battery Charger, *Battery* refers to Ambu® SureSight® Battery, *Data Cable* refers to Ambu® SureSight® Data Cable, and *Blade* refers to Ambu® SureSight® Blade.

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

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

In this document *Mobile* refers to instructions that apply to *Mobile* only, and *Video Laryngoscope* refers to information relevant to the system. The Video Laryngoscope consists of *Mobile* connected to *Blade*. Instructions for use for *Blade* are provided separately. These Instructions for use can be updated without further notice. Copies of the current version are available on request.

1.1. Intended use

Mobile is a reusable mobile display intended to display a live video image from the *Blade* camera module, enabling the user to visualize the upper airway.

Mobile is a part of the Video Laryngoscope which is intended to visualize and aid tracheal intubation procedures and visual examination of the upper airway.

1.1.1. Intended patient population

Adults and pediatrics.

1.1.2. Intended use environment

Hospital and pre-hospital settings.

1.2. Indications for Use

The use of the Video Laryngoscope is indicated for:

- Patients with or without difficult airway anatomy who need tracheal intubation.
- Conditions where visual examination of the upper airway is needed.

1.3. Intended user

The Video Laryngoscope is intended to be used by individuals who have been trained in the use of video laryngoscopes and who are authorized according to local medical regulations.

1.4. Contraindications

No contraindications identified.

1.5. Warnings and cautions

WARNINGS

1. Do not use *Mobile* if the cleaning and disinfection is not performed as instructed in section 6. Insufficient cleaning and disinfection may cause risk of infection.
2. Prior to use, inspect that the light on the *Blade* is activated, live image on the displaying unit is clear, and if applicable, that the battery level is sufficient. Do not use the device if any part of the inspection fails, as it may delay intubation or cause patient harm.

3. The Video laryngoscope is intended to be used by individuals trained in use of Video Laryngoscopes and authorized according to local medical regulations. Incorrect use of the device could lead to potential adverse events.
4. Do not expose the Battery to temperatures above 70 °C/158 °F, submersion in water, short circuiting, or mechanical abuse, as this may result in patient or user injury.
5. Only use Mobile with the compatible Ambu devices, as described in section 2.2. Failure to do so may result in damage to the device or in patient or user injury.
6. Only use the Battery with the compatible Ambu devices, as described in section 2.2. Failure to do so may result in damage to the device or in patient or user injury.
7. Ensure the Blade connector on Mobile is dry before using it. Failure to do so may cause the device to malfunction or cause electric shock.
8. Ensure the pin area and terminals on Mobile and Battery are dry before connecting the Battery. Failure to do so may cause the device to malfunction.
9. The Battery must be charged regularly to prevent degradation and to prolong battery life. Failure to do so may damage the devices and expose the user to battery acid leakage, which can cause skin irritation.
10. The Battery Charger and power adaptor must be placed out of the patient's reach, at least 1.5 meters (5 feet) away. Failure to do so may expose the patient to electrical shock.

CAUTIONS

1. Do not clean and disinfect the Mobile or accessories using other methods than instructed in section 6, as this may cause the device to malfunction.
2. An extra Blade should be available for immediate use in case of device malfunction.
3. Do not expose the product to extreme temperatures, humidities or mechanical abuse, as this may cause malfunction of the device.
4. The Battery is not a serviceable component. Do not try to open as it may cause an electrical or mechanical malfunction of the device.
5. Only use the Battery Charger with a compatible power adaptor as described in section 2.2. Failure to do so may result in damage to the device.
6. Do not use or store the Battery Charger in Emergency Medical Service vehicles (such as ambulances and helicopters), as the vibrations, drops from heights, and other impacts associated with these modes of transportation may damage the device.

1.6. Potential adverse events

Potential adverse events in relation to the use of Video Laryngoscopes (not exhaustive): Mucosal injuries, edema, sore mouth/throat, inadvertent nerve stimulation or injury, dental trauma, dysphagia, esophageal intubation, emesis with concurrent aspiration.

1.7. General notes

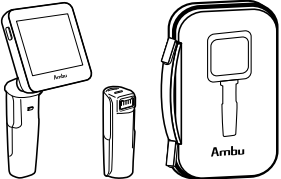
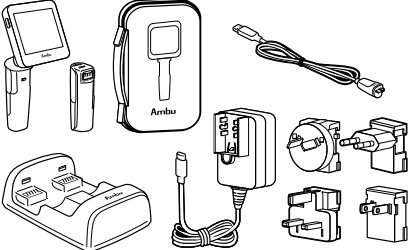
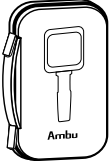
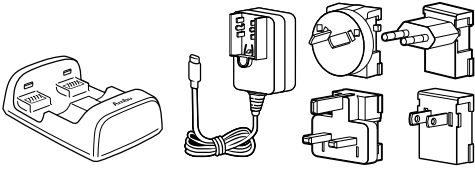
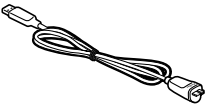
If, during the use of this device or because of its use, a serious incident occurs, report it to the manufacturer and to your national authority.

2. Device description

Mobile is a reusable mobile display, with rechargeable batteries. Mobile displays a live video image from Blade, enabling the user to see the upper airway.

Battery is charged in the Battery Charger, with a capacity for charging two simultaneously. Data is transferred from the Mobile to a PC through Data Cable.

2.1. System overview

Ambu® SureSight® Mobile Mini Kit	Item numbers
	390481000
Ambu® SureSight® Mobile Kit	Item numbers
	390471000
Ambu® SureSight® Carry Case	Item numbers
	390641000
Ambu® SureSight® Battery	Item numbers
	390611000
Ambu® SureSight® Battery Charger (incl. Power adaptor)	Item numbers
	390621000
Ambu® SureSight® Data Cable	Item numbers
	390631000

2.2. Product compatibility

Ambu® SureSight® Mobile is compatible with the following:

Ambu products
Ambu® SureSight® Data Cable
Ambu® SureSight® Battery
Ambu® SureSight® Blade
Agents and lubricants
Water-based lubricants
Isotonic saline solution
Water
70 % ethanol
70 % isopropyl alcohol
Gel and solutions
Disodium tetraborate
Subtilisin
Quaternary ammonium compounds
n-Alkyl Dimethyl Benzyl Ammonium Chloride

Ambu® SureSight® Battery is compatible with the following:

Ambu products
Ambu® SureSight® Mobile
Ambu® SureSight® Battery Charger
Agents and lubricants
Water-based lubricants
Isotonic saline solution
Water
70 % ethanol
70 % isopropyl alcohol
Gel and solutions
Disodium tetraborate
Subtilisin
Quaternary ammonium compounds
n-Alkyl Dimethyl Benzyl Ammonium Chloride

Ambu® SureSight® Battery Charger is compatible with the following:

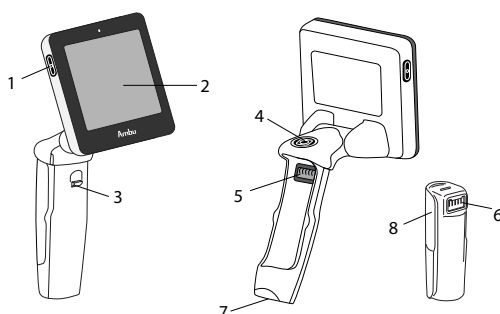
Ambu products
Ambu® SureSight® Battery
Products
Power adaptors with output: 5.0 V  3.0 A, 15.0 W The Adaptor shall comply with IEC 60601-1 (medical graded) or as a minimum comply with IEC 60950-1 or IEC 62368-1
Agents and lubricants
Water-based lubricants
Isotonic saline solution
Water
70 % ethanol
70 % isopropyl alcohol
Gel and solutions
Disodium tetraborate
Subtilisin
Quaternary ammonium compounds
n-Alkyl Dimethyl Benzyl Ammonium Chloride

Ambu® SureSight® Data Cable is compatible with the following:

Ambu devices
Ambu® SureSight® Mobile
Agents and lubricants
Water-based lubricants
Isotonic saline solution
Water
70 % ethanol
70 % isopropyl alcohol
Gel and solutions
Disodium tetraborate
Subtilisin
Quaternary ammonium compounds
n-Alkyl Dimethyl Benzyl Ammonium Chloride

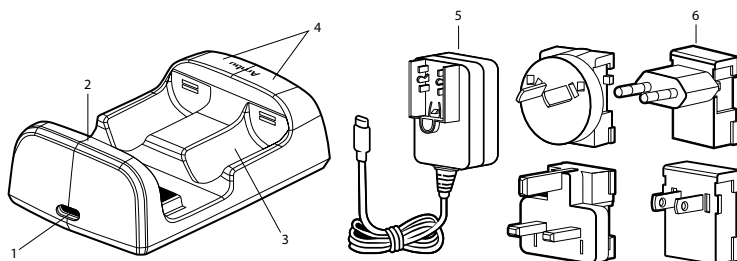
Note: The compatibility with cleaning agents is only for cleaning according to section 6. None of the products should be submerged.

2.3. Mobile parts



No.	Part	Function
1	Power button 	Press and hold to turn Mobile on and off. The button light will indicate the current battery level.
2	Screen	Touch screen that displays the live image and facilitates navigation in settings, playback and brightness adjustments.
3	Blade interface	Functions as a handle and connecting interface to the Blade.
4	Image capture button 	Press to capture image and record live video: – Short press (<1s) button to capture an image. – Long press (>1s) button to start/stop video recording.
5	Pin area	Electrical connection between Battery and Mobile.
6	Terminals	Electrical connection between Battery and Mobile.
7	Blade connector and Data Cable connector	Connector interface for Blade and Data Cable.
8	Battery	Battery to be inserted into Mobile and power the device. It is charged with Battery Charger.

2.4. Battery Charger parts



No.	Part	Function
1	USB-C insert	Electrical connection between the power adaptor (5) and Battery Charger.
2	Power LED	Green LED that indicates the Battery Charger is connected to power.
3	Battery inserts	Electrical connection between Battery and Battery Charger.
4	Battery charging indicator	LEDs to show the battery charging status: - Green – Battery is fully charged. - Blinking orange – Battery is charging.
5	Power adaptor	Providing power to Battery Charger from external power source.
6	Wall plugs	Wall plugs for the power adaptor.

3. Getting started

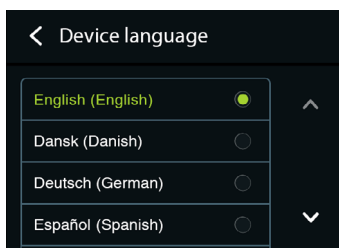
3.1. First-time setup

Follow the steps below before using the Mobile for the first time.

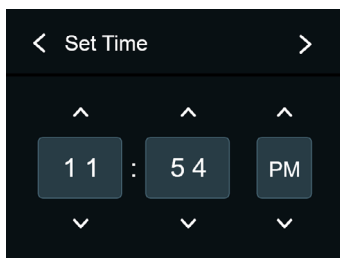
1. Unpack Mobile and verify that no parts are missing. Refer to the parts described in section 2.1.
2. Closely examine Mobile, Battery and other parts for any damage. Do not use Mobile or Battery if they are damaged in any way.
3. Remove protection between Mobile and Battery.
4. Charge Battery to full capacity before first-time use.
5. Insert Battery by aligning battery terminal with Mobile pin area.
6. Turn on Mobile by pressing the power button and holding until the screen turns on. The button light will indicate the current battery level.

For first time setup, the language, time and date must be set. Follow the flow on the screen.

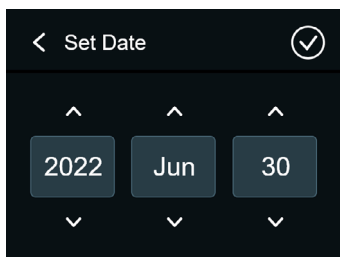
1. Select the desired language. The default language is English.



2. Set the time.



3. Set the date.



3.2. General settings

When no Blade is connected, the settings menu can be entered by tapping the screen for the settings icon  to be visible. The Settings menu consists of General settings and About. In **General settings** the following functionalities can be found:

Recording:

Autostart Recording – select if the recording is to be started automatically when Blade is attached.
Storage Information – see number of stored photos and videos, and the percentage free and used storage.

Brightness:

Auto Adjust Brightness – select if the screen brightness is to be adjusted automatically.

Note: The brightness can be adjusted manually in the main menu both with and without an attached Blade.

Battery:

Battery Health – check the status of the battery capacity, see section 3.4.1.

Power management – select if Mobile screen is to be turned off after 5 minutes of inactivity, according to the following scenarios:

Scenarios	Power management enabled
Blade attached	Mobile will not turn off, if use or movement of the device is detected. Tap the screen or move Mobile to prevent it from turning off.
No Blade attached	Mobile will turn off after 5 minutes of not being used, regardless of any movement. Tap the screen to prevent Mobile from turning off.
Connected to external device for accessing files	Mobile will not turn off.

Language & Time:

Device Language

Set Time

Set Date

In **About**, system information with Software version and Boot code version can be found.

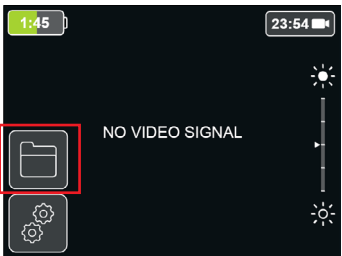
3.3. Replay the latest images and videos

When no Blade is connected, the Replay function can be entered by tapping the screen for the Folder icon  to be visible.

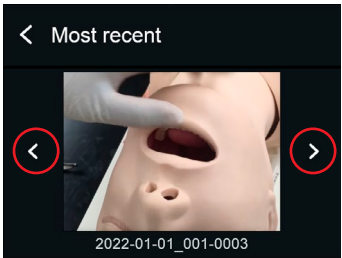
Note: This feature is not available if Blade is attached to the device.

Note: Only images and/or videos recorded while using the latest connected Blade can be accessed on Mobile. All images and videos recorded can be accessed via the file archive on an external device (see section 5.1)

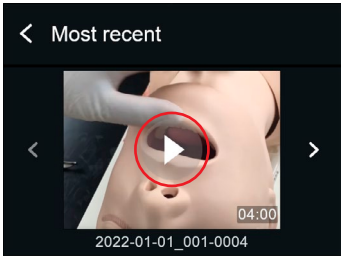
- On the **Main** menu, tap the Folder icon.



- Move between the files by using the arrows.



- For videos tap the play icon to replay the video.



- If no files are available from the last procedure, the folder will be empty.

3.4. Battery

The remaining battery power is shown by the battery icon on the screen and by the color of the power button. The remaining battery time (hrs:min) is shown on the battery icon. Battery level can be quickly assessed when Mobile is OFF by pressing the power button shortly. For information about charging the battery, see section 7.2.

Power button light indicator*	Battery icon on screen	Remaining battery power
Green	Green 	> 40 %
Orange	Orange 	< 40 %
Blinking orange	Red 	< 20 %

*Activate with a short press when Mobile is OFF to see remaining battery power

Note: The power button light indicator will not show any light when Mobile is connected to an external device for file handling, see section 5.1.

3.4.1. Battery health

In the settings menu under **Battery**, the **battery health** information can be accessed. The percentage shows the battery capacity compared to when it was new. Depending upon the length of time between when Battery is made and when it is activated, the battery capacity might show as slightly less than 100 percent.

The battery health is divided into three different statuses:

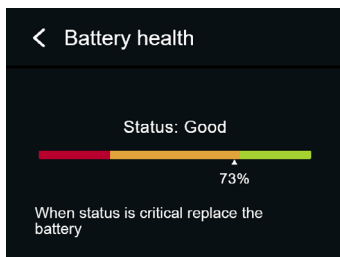
Green (Excellent): The battery capacity is optimal.

Yellow (Good): Monitor the battery capacity and consider replacing the Battery.

Red (Critical): Replace and dispose of the Battery.

For Battery maintenance, see section 7.1.

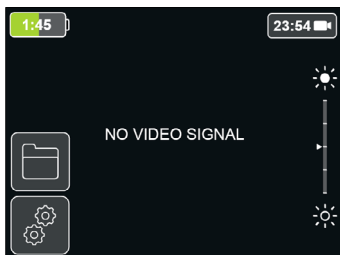
Battery must be disposed of or recycled in accordance with local regulations and guidelines.



4. Use Mobile

4.1. Prepare and inspect Mobile

1. Inspect the device for any visual damage. Do not use the device if it is damaged.
2. Insert the Battery in Mobile. To insert Battery, align battery terminal with Mobile pin area.
3. Briefly press the power button to activate power button light for battery status. Replace with fully charged Battery if the battery level is low.
4. Turn on Mobile by pressing the power button and holding it until the screen turns on.
5. When the device is ready, this screen appears:



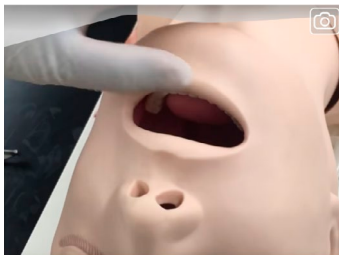
6. Prepare and inspect Blade. To ensure correct and safe use of the device, read Blade's Instructions for use.
7. Attach Blade to Mobile. Blade is attached to Mobile when you hear a "click".
8. Point the end of Blade towards an object, e.g., the palm of your hand to verify that the light and live image are functioning as expected on the Mobile screen. If there is no image, or if the image is blurred, **see Troubleshooting in section 12**.
9. Tap brightness icons on touchscreen to adjust live image brightness.
10. If used in bright ambient light, Sunlight Mode may be activated by pressing the Sunlight Mode icon. 
11. Perform the procedure.

Note: A live image is displayed on Mobile within 3 seconds after connecting Blade and turning on Mobile.

4.2. Image and video capture

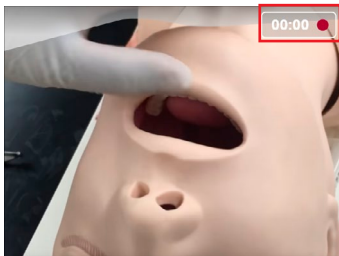
Capture images during the procedure:

Shortly press the image capture button on Mobile (<1 second). A white frame will briefly appear around the edge of the live image to confirm image capture.



Record videos during the procedure:

Start a video recording by a long press on the image capture button (>1 second). When not recording, the Recording icon shows the remaining recording time based on available storage. When recording a video, the recording icon shows a red dot and the recording time.



Stop the video recording by another long press.

An image can be captured during video recording.

For image capture during video recording, see image capture instructions.

Images and videos are stored on Mobile. The images and videos from the last procedure can be seen on Mobile in the **replay menu**, see section 3.3.

Images and video can be seen by connecting Mobile to an external device by using the dedicated Data Cable. When connected to an external device, the files can be transferred to the device or deleted, see section 5.

4.3. After use

1. Detach the Blade by pressing the release marks on the sides of Blade.
2. Dispose of Blade. Read the Blade's Instructions for use.
3. Turn off Mobile by pressing and holding the Power button until the Mobile turns off.
4. Clean and disinfect the Mobile according to the instructions in section 6 and store the device.

5. File handling in Archive

5.1. Accessing files

Images and videos can be viewed on an external device, e.g. a PC. File handling and data transfer is done through the external device.

1. Connect the Mobile to an external device by using Data cable. When connected, the following screen is shown.
2. Open the folder **SureSight**.
3. Select the designated image and video folder named DCIM. In the image and video folder the files are arranged in subfolders by the date of the procedure and the procedure number of that day (YYYY-MM-DD XXX).



The files and folders can be transferred to the external device from Mobile by copying them to the device. The files and folders can be deleted by right clicking on the file/folder and selecting *delete*.

During transfer from Mobile to an external device, the following data is in transit:

Item in transit	Export to	Format	Comments
Photo	external device via USB Mass Storage	JPG	–
Video		MP4	H.264 video compression
Ambu System log		Clear text	System log file is located in a hidden system folder on the device and is intended for troubleshooting by Ambu staff. The log does not contain patient information.

Software Bill of Materials (SBOM) is available on ambu.com

5.2. Software updates

An Authorized Ambu representative will schedule a software update when a new release is available.

6. Clean and disinfect

6.1. Mobile and Battery

Mobile is a reusable medical device. According to the Spaulding classification, Mobile is categorized as a non-critical device.

Mobile should be cleaned and disinfected after each use following the procedure described below. Any deviation from these instructions shall be properly evaluated for effectiveness and related potential consequences by the person responsible for cleaning and disinfection to ensure that Mobile continues to fulfil its intended purpose.

Cleaning/disinfection procedures are recommended to be carried out as soon as possible after each use.

Limitations: Cleaning and disinfection wipes shall be moist but not dripping. Refrain from wiping the pin area (See Section 2.3, #5) as this may damage the device. Refrain from using wipes containing chlorine and hydrogen peroxide, as these chemicals may damage the surface of the devices over time. The devices are not compatible with ultrasonic or automatic cleaning procedures. The devices shall not be immersed or submerged.

Procedure 1 – Enzymatic detergent cleaning and isopropyl alcohol disinfection

Cleaning

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

1. Soak clean lint-free gauze in the enzymatic alkaline detergent and make sure that the gauze is moist but not dripping.
2. If the device is heavily soiled, thoroughly wipe all surfaces of Mobile before removing Battery to prevent soiling of the pin area.
3. Remove Battery from the battery insert.
4. Wipe Mobile and Battery until all visible soil is removed. The gauze must remain moist. Avoid the pin area.
5. Soak clean lint-free gauze in distilled water and make sure that the gauze is moist but not dripping.
6. Wipe the surfaces of the Mobile and Battery to remove any detergent residue. Avoid the pin area.

Disinfection

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

1. Wipe the surfaces of the Mobile and the Battery for 5 minutes. The wipe must remain moist. Avoid the pin area.
2. Soak sterile gauze in distilled water and make sure that the gauze is moist but not dripping.
3. Wipe the surfaces of Mobile and Battery to remove any disinfectant residue. Avoid the pin area.
4. Let Mobile and Battery air dry separately.

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

Cleaning and disinfection

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

1. If the device is heavily soiled, thoroughly wipe all surfaces of Mobile before removing Battery to prevent soiling of the pin area. The wipe must remain moist.
2. Remove Battery from the battery insert.
3. Wipe the surfaces of Mobile and Battery until all visible soil is removed. The wipe must remain moist. Avoid the pin area.
4. To disinfect, wipe the surfaces of Mobile and Battery for 5 minutes. The wipe must remain moist. Avoid the pin area.
5. Soak sterile gauze in distilled water and make sure that the gauze is moist but not dripping.
6. Wipe the surfaces of Mobile and Battery to remove any residue. Avoid the pin area.
7. Let Mobile and Battery air dry separately.

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

6.2. Battery Charger and Data Cable

A cleaning procedure is not specified for the Battery Charger and the Data Cable. It is recommended to apply any wipe containing mild detergent/disinfectant for cleaning purpose, following the instructions and warnings from the wipe manufacturers.

Limitations: Cleaning wipes shall be moist but not dripping. Refrain from using wipes containing chlorine and hydrogen peroxide, as these chemicals may damage the surface of the devices over time. The devices are not compatible with ultrasonic or automatic cleaning procedures. The devices shall not be immersed or submerged.

7. Maintenance

Mobile shall be inspected prior to use according to section 4.1.

Mobile shall be cleaned and disinfected according to section 6.

7.1. Battery maintenance

To prolong battery life, it is recommended to fully charge Battery every 3 months. If Battery is discharged, it can take up to 3 hours to charge it fully. Battery should be charged at temperatures between 10 – 40 °C (50 – 104 °F).

Battery should be fully charged upon receipt and then every 3 months, to prolong battery life.

7.2. Charge Battery

1. Remove Battery from Mobile.
2. Place Battery in Battery Charger.
3. Connect Battery Charger to a power outlet using the power adaptor. Only use a power adaptor compatible with Battery Charger, as specified in section 9. The power LED shows a steady green light when the charger is ready to use.

The Battery Charger LEDs show the battery charging status:

- Green – Battery is fully charged.
- Blinking orange – Battery is charging.

8. Disposal

Clean and disinfect before disposing of the device in accordance with local guidelines.

Note: Before disposing of Mobile, it is advised to delete all data.

9. Technical product specifications

Ambu® SureSight® Mobile has the following main specifications:

Display	
Resolution	640 x 480 pixels
Orientation	Landscape
Display type	3.5" color TFT touch LCD
Start-up time	3 seconds
Electrical System	
Battery type	3.6 Vdc 2200 mAh
Battery operation time	100 minutes
User interface	Image capture / video recording button Power ON/OFF button TFT touch LCD screen
Memory	
Storage capacity	64 GB
Transport Conditions	
Temperature [°C, (°F)]	-10 – 55 (14 – 131)
Relative humidity [%]	10 – 95
Atmospheric pressure [kPa, (psi)]	50 – 106 (7 – 15)
Storage Conditions	
Temperature [°C, (°F)]	10 – 25 (50 – 77)
Relative humidity [%]	10 – 85
Atmospheric pressure [kPa, (psi)]	50 – 106 (7 – 15)
Operating Environment	
Temperature [°C, (°F)]	0 – 40 (32 – 104)
Relative humidity [%]	15 – 95
Atmospheric pressure [kPa, (psi)]	62 – 106 (9 – 15)
Altitude [m]	≤ 4000
Transient Operating Environment (< 20 min)	
Temperature [°C, (°F)]	-20 – 50 (-4 – 122)
Relative humidity [%]	15 – 90
Atmospheric pressure [kPa, (psi)]	62 – 106 (9-15)
Altitude [m]	≤ 4000
Transient Transport & Storage Conditions (between uses)	
Temperature [°C, (°F)]	-40 – 70 (-40 – 158)
Relative humidity [%]	≤ 90
Atmospheric pressure [kPa, (psi)]	62 – 106 (9-15)
Altitude [m]	≤ 4000
General	
Use (lifetime)	Reusable (5 years)
IP Classification (SureSight System)	IP34
Biocompatible	Yes

Ambu® SureSight® Battery has the following main specifications:

Electrical System	
Battery type	Li-Ion 3.6 Vdc 2200 mAh
Battery operation time	100 minutes
Charging time (100 %)	3 hours
Transportation Conditions	
Temperature [°C, (°F)]	-10 – 55 (14 – 131)
Relative humidity [%]	10 – 95
Atmospheric pressure [kPa, (psi)]	50 – 106 (7 – 15)
Storage Conditions	
Temperature [°C, (°F)]	10 – 25 (50 – 77)
Relative humidity [%]	10 – 85
Atmospheric pressure [kPa, (psi)]	50 – 106 (7 – 15)
Operating Environment	
Temperature [°C, (°F)]	0 – 40 (32 – 104)
Relative humidity [%]	15 – 95
Atmospheric pressure [kPa, (psi)]	62 – 106 (9 – 15)
Altitude [m]	≤ 4000
Transient Operating Environment (< 20 min)	
Temperature [°C, (°F)]	-20 – 50 (-4 – 122)
Relative humidity [%]	15 – 90
Atmospheric pressure [kPa, (psi)]	62 – 106 (9 – 15)
Altitude [m]	≤ 4000
Transient Transport & Storage Conditions (between uses)	
Temperature [°C, (°F)]	-40 – 70 (-40 – 158)
Relative humidity [%]	≤ 90
Atmospheric pressure [kPa, (psi)]	62 – 106 (9 – 15)
Altitude [m]	≤ 4000
General	
Use (lifetime)	Reusable (2 years)
Biocompatible	Yes

Ambu® SureSight® Battery Charger has the following main specifications:

Electrical System	
Power requirement	5.0 Vdc, 3.0 A, 15.0 W
Power adaptor	
Input (mains)	100 – 240 V ~ 50/60 Hz, 0.32 – 0.19 A
Output (USB 4.0 Type C)	5.0 Vdc, 3.0 A, 15.0 W
Interchangeable wall plugs types	US/Japan, Europe, UK & Australia

Transportation Conditions	
Temperature [°C, (°F)]	-10 – 55 (14 – 131)
Relative humidity [%]	10 – 95
Atmospheric pressure [kPa, (psi)]	50 – 106 (7-15)
Storage Conditions	
Temperature [°C, (°F)]	10 – 25 (50 – 77)
Relative humidity [%]	10 – 85
Atmospheric pressure [kPa, (psi)]	50 – 106 (7-15)
Operating Environment	
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa, (psi)]	80 – 106 (12 – 15)
Altitude [m]	≤ 2000
General	
Use (lifetime)	Reusable (5 years)
Biocompatible	Yes

Ambu® SureSight® Data Cable has the following main specifications:

Cable Specification	
Cable Length	1.2 meters (3.93 ft)
Transportation Conditions	
Temperature [°C, (°F)]	-10 – 55 (14 – 131)
Relative humidity [%]	10 – 95
Atmospheric pressure [kPa, (psi)]	50 – 106 (7 – 15)
Storage Conditions	
Temperature [°C, (°F)]	10 – 25 (50 – 77)
Relative humidity [%]	10 – 85
Atmospheric pressure [kPa, (psi)]	50 – 106 (7 – 15)
Operating Environment	
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa, (psi)]	80 – 106 (12 – 15)
Altitude [m]	≤ 2000
General	
Use (lifetime)	Reusable (5 years)
Biocompatible	Yes

10. Standards applied

Mobile 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 60601-1-12 Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical service environment.
- IEC 60601-2-18 Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

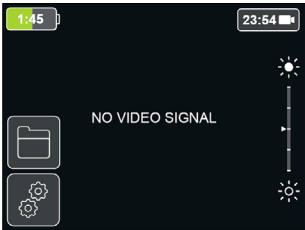
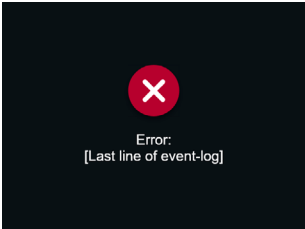
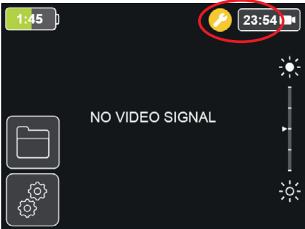
Battery conforms with:

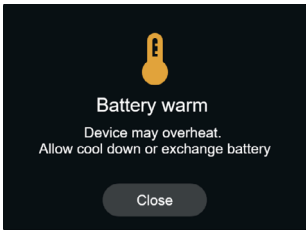
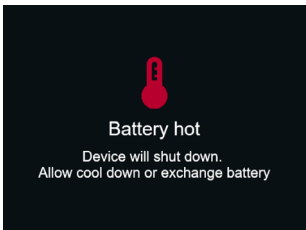
- IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.

Battery Charger 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.

11. Notifications

Icon	Description
	No signal from the Blade. If Blade is connected, see troubleshooting in section 12. Otherwise, connect Blade or Data Cable.
	An error occurred. The error message is shown on the screen. See troubleshooting in section 12.
	A device error has occurred. For details see the error message in Mobile log file. The log file can be accessed by connecting Mobile to an external device with Data Cable.
	Out of storage. Delete data to reactivate image and video capture function. Refer to section 5.1.
	The battery health is critical. Replace battery. For information on battery health see section 3.4.1
	It is not possible to capture images.

Icon	Description
	It is not possible to record videos.
	Battery is warm. Allow Battery to cool down to avoid the device from overheating or exchange Battery to continue safe use of Mobile.
	Battery is hot. The device will shut down automatically after 10 seconds. Allow Battery to cool down or exchange Battery to continue safe use of Mobile.

12. Troubleshooting

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

Many problems can be solved by restarting the Mobile unit by turning it ON and OFF.

Problem	Possible cause	Recommended action
Mobile does not turn ON when the power button is pressed.	No power is left on the Mobile Battery.	Replace Battery with a new fully charged. Verify Battery is fully inserted into Mobile.
	Battery has gotten wet	Ensure Battery is dry, then place Battery in Battery Charger before reinserting into Mobile.
	The power button is not pressed long enough.	Press the power button for one second.
No live image OR No LED light in the distal end of the visualization device.	Mobile is turned off.	Turn on Mobile.
	No Blade is connected.	Attach Blade to Mobile.
	Failure in the connection between Blade and Mobile.	Detach and reattach Blade.
	Blade is damaged.	Replace Blade with a new one.
	The Mobile and the Blade have communication problems.	Detach and replace Blade with a new one. Turn off Mobile by pressing and holding the Power button until the Mobile turns off. Turn the Mobile back on by pressing the power button and holding it until the screen turns on.

Problem	Possible cause	Recommended action
Low quality of the live image.	The image cannot be seen clearly upon inspection prior to the procedure.	Wipe the camera at the tip of Blade.
	Blood, saliva etc. on the camera.	Remove Blade from the patient and wipe the camera at the tip of Blade.
	Blade is damaged.	Replace Blade with a new one.
	The brightness level is too high or too low.	Adjust the brightness manually or make sure the auto brightness adjustment is turned on.
Battery health is low.	The battery health has degraded due to wear and tear.	Check the battery health in the battery health menu. If critical, replace the Battery with a new one.
Mobile turns off unexpectedly.	Power management is enabled.	Change Power management settings.
	Failed connection between Mobile and Battery.	Check the placement of the Battery.
Failed connection from Mobile to external device.	Data cable is not fully connected to either Mobile or the external device.	Detach and reattach Data cable.
No light in power LED on Battery Charger.	No power to Battery Charger.	Inspect that the power outlet is turned on and the power adaptor is correctly connected.
Error message on the screen.	"Device communication failure"	Restart device or replace and dispose of Blade.
	"Battery error".	Replace and dispose of Battery.
	"SD Card not found"	Contact your local Ambu representative. Mobile log files and captured images and videos cannot be accessed. It is not possible to capture images and videos. Tap the Close button to continue use of Mobile without access to these features.
The remaining battery time is not displayed on the battery icon.	The calculation of remaining battery time (hrs, min) has been affected by the battery's exposure to very cold temperatures and are therefore not displayed.	Use the color of the battery icon or power button to see the remaining battery power. These are not affected by exposure to very cold temperatures.
	The calculation of remaining battery time (hrs:min) has been affected by changing power consumption, and is therefore not displayed.	Use the color of the battery icon or power button to see the remaining battery power. These are not affected by changing power consumption.

13. Warranty and replacement

Limited warranty

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

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

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

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

The warranty applies only if it can be established that:

- a) The device has not been disassembled, repaired, tampered with, altered, changed, or modified by persons other than technical personnel and
- b) The defects or damage to the device does not result from abuse, incorrect use, negligence, improper storage, inadequate maintenance or use of unauthorized accessories, spare parts, consumables, or supplies.

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

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

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

14. Symbol explanation

Symbol	Title	Symbol	Title
	Medical – general medical equipment as to electric shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1:2005/AMD2:2021+ CAN/CSAC22.2 NO. 606011:14/AMD2:2022(MOD) +IEC 60601-2-18:2009		UL Recognized Component Mark for Canada and the United States
IP34	Protection against solid foreign objects and water ingress	US: Rx Only	Caution: United States Federal law restricts this device to sale by or on the order of a licensed health care practitioner
	"CCC" certification mark. Chinese national compulsory standard GB 31241 "lithium-ion cells and batteries used in portable electronic equipment - Safety technical specifications		

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

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	Applicable for	Electromagnetic environment guidance
Radiated emission CISPR 11	Group 1	SureSight Mobile SureSight Battery Charger	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 B	SureSight Mobile SureSight Battery Charger	
Radiated emission	RTCA DO-160G Section 21 CAT M	SureSight Mobile	The medical device has been tested and complies with the applicable limits for conducted emissions as per DO-160G, ensuring its safe and reliable operation in the intended electromagnetic environment, including use in airborne ambulances, as it meets the stringent electromagnetic compatibility (EMC) requirements for helicopter environments.
Harmonic emission IEC/EN 61000-3-2	Complies	SureSight Battery Charger	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.
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	SureSight Battery Charger	
Conducted Emission IEC 60601-1-2 CISPR 11	Complies	SureSight Battery Charger	The medical device has been tested and complies with the applicable limits for conducted emissions ensuring its safe and reliable operation in the intended electromagnetic environment.

Note 1: The emissions Characteristics of this equipment makes it suitable for use in residential environment, industrial areas, and hospitals (CISPR 11 class B).

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.				
Immunity test	IEC 60601-1-2 test level	Compliance Level Electromagnetic	Applicable for	Environment Guidance
Electrostatic discharge (ESD) Immunity IEC 61000-4-2	Contact discharge: ±8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact discharge: ±8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	SureSight Mobile SureSight Battery Charger	If floors are covered with synthetic material the relative humidity shall be least 30 %.
Electrical fast transient/burst IEC 61000-4-4	5/50 (Tr/Th) ns ±2 kV for power supply lines +/-1 kV for input/output lines	5/50 (Tr/Th) ns ±2 kV for power supply lines	SureSight Battery Charger	Mains power quality shall be that of a typical commercial or hospital environment.

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.

Immunity test	IEC 60601-1-2 test level	Compliance Level Electromagnetic	Applicable for	Environment Guidance
Surge Transient IEC 61000-4-5	1.2/50 (8/20) (Tr/Th) Line to line: ± 0.5 kV, ± 1 kV, Line to earth: ± 0.5 kV, ± 1 kV, ± 2 kV	1.2/50 (8/20) (Tr/Th) Line to line: ± 0.5 kV, ± 1 kV, Line to earth: ± 0.5 kV, ± 1 kV, ± 2 kV	SureSight Battery Charger	Mains power quality shall be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field Immunity Test IEC 61000-4-8	50 Hz, or 60 Hz, 30 A/m	50 Hz, or 60 Hz, 30 A/m	SureSight Mobile	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
CS (Conducted disturbance by radio frequency) IEC 61000-4-6	80 % AM (1kHz): 3 V, 0.15 – 80MHz 6 V, ISM and amateur radio bands.	80 % AM (1kHz): 3 V, 0.15 – 80 MHz 6 V, ISM and amateur radio bands.	SureSight Battery Charger	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. 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.
RS (Electro-magnetic immunity test) IEC 61000-4-3	80 – 2700 MHz 10 V/m 80 % AM (1 kHz) 385 MHz 50 % Pulse (18 Hz) 450 MHz 28 V/m FM 5 kHz deviation 1 kHz Sine 710 MHz, 745 MHz, 780 MHz 9 V/m 50 % Pulse (217 Hz) 810 MHz, 870 MHz, 960 MHz 28 V/m 50 % Pulse (217 Hz) 1720, 1845, 1970, 2450 MHz 28 V/m 50 % Pulse (217 Hz) 5240, 5500, 5785 MHz 9 MHz 50 % Pulse (217 Hz)	80 – 2700 MHz 10 V/m 80 % AM (1 kHz) 385 MHz 50 % Pulse (18 Hz) 450 MHz 28 V/m FM 5 kHz deviation 1 kHz Sine 710 MHz, 745 MHz, 780 MHz 9 V/m 50 % Pulse (217 Hz) 810 MHz, 870 MHz, 960 MHz 28 V/m 50 % Pulse (217 Hz) 1720, 1845, 1970, 2450 MHz 28 V/m 50 % Pulse (217 Hz) 5240, 5500, 5785 MHz 9 MHz 50 % Pulse (217 Hz)	SureSight Mobile SureSight Battery Charger	



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.				
Immunity test	IEC 60601-1-2 test level	Compliance Level Electromagnetic	Applicable for	Environment Guidance
Radiated Immunity RTCA DO-160G Section 20 CAT T	Frequency Range: 100 Hz – 8000 MHz	Frequency Range: 100 Hz – 8000 MHz	SureSight Mobile	The medical device has been tested and complies with the applicable limits for conducted emissions as per DO-160G, ensuring its safe and reliable operation in the intended electromagnetic environment. Additionally, the device is immune to the frequencies generated by helicopters, as it complies with DO-160G Section 20 Category T (CAT T) requirements, making it suitable for use in airborne ambulances and other helicopter-based medical transport scenarios.
Immunity to Proximity Magnetic Fields, IEC 61000-4-39:2017	134,2 kHz Pulse Modulation 2,1 kHz 65 A/m* 13,56 MHz Pulse Modulation 50 kHz 7,5 A/m* *r.m.s before modulation is applied.	134,2 kHz Pulse Modulation 2,1 kHz 65 A/m* 13,56 MHz Pulse Modulation 50 kHz 7,5 A/m* *r.m.s before modulation is applied.	SureSight Mobile SureSight Battery Charger	Proximity magnetic fields should be at levels characteristic of a typical location in a hospital environment.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	60601-1-2 Table 9	60601-1-2 Table 9	SureSight Mobile	The medical compliance with RF electromagnetic fields, ensuring reliable operation in environments with RF interference.

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.				
Immunity test	IEC 60601-1-2 test level	Compliance Level Electromagnetic	Applicable for	Environment Guidance
				This compliance confirms the device's ability to function safely and effectively in the presence of electromagnetic disturbances, such as those from wireless communication equipment and other RF sources.

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.

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

Note 3: Abnormal performance caused by EMC disturbance can be observed in the live image on the displaying unit as horizontal lines flashing or image flickering. The system will automatically try to recover by restarting. No user interaction is required. If this abnormal performance is observed on a regular basis, additional measures may be necessary such as reorienting or relocating the system.

Appendix 2: Cybersecurity

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

Considerations:

- The unit does not allow input from external devices.
- The unit is not networking connectable and essential functionality is not dependent on network connectivity.
- Exporting from the device requires a bespoke USB adapter cable.
- The displaying unit stores photos and videos captured during a procedure and present these on a USB mass storage device, when using the USB adapter cable.

Due to limited functionality and being designed for specific use, the product is of low security risk. However, due to the potential misuse of the device as a mass storage device transporting malicious files, it is recommended that the devices together with the USB adapter cable are not publicly available without supervision.

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