Ambu
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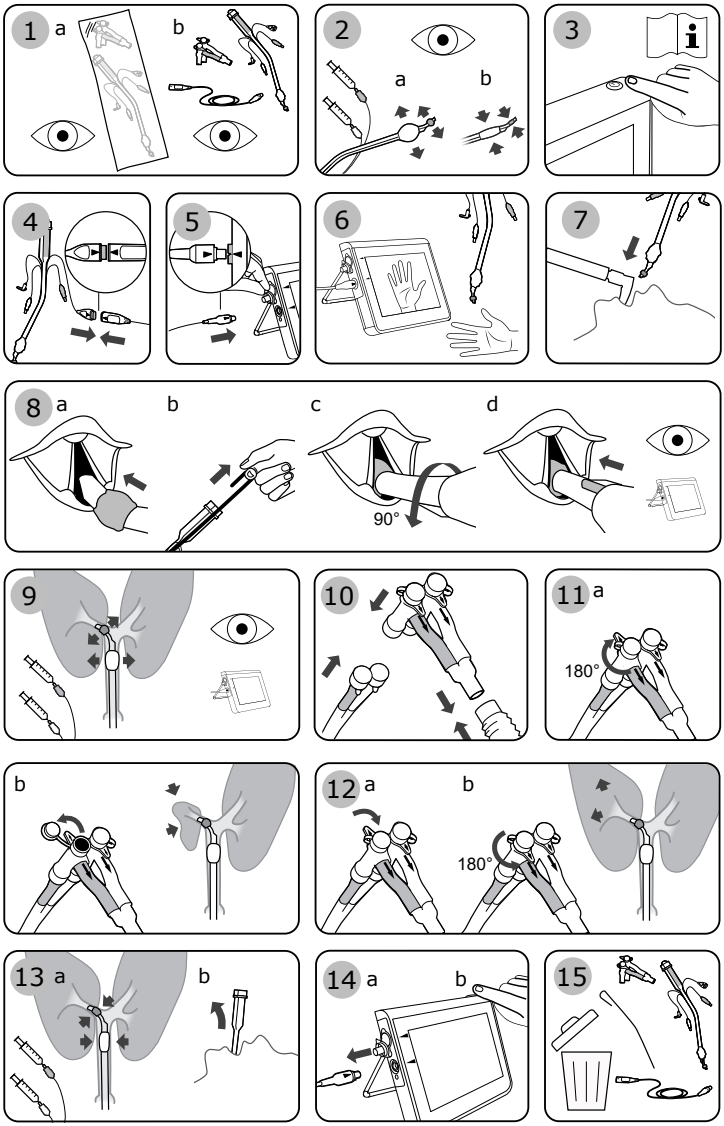
Instruction for Use

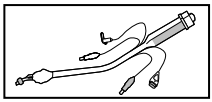
Ambu® VivaSight™ 2 DLT

Abridged version

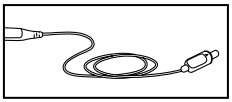
For use by trained clinicians/physicians only.
For use with Ambu® displaying units.



Ambu® VivaSight™ 2 DLT



Ambu® VivaSight™ 2 Adapter Cable



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US Patents for Ambu® VivaSight™ 2 DLT: 10,149,602, 10,245,402 and 10,406,309
Ambu is a registered trademark and VivaSight is a trademark of Ambu A/S.

Contents **Page**

1. Important Information – Read Before Use

Read these safety instructions carefully before using the Ambu® VivaSight™ 2 DLT. The instruction for use may be updated without further notice. Copies of the current version are available upon request. Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operation and precautions related to the use of VivaSight 2 DLT. Before initial use of VivaSight 2 DLT, it is essential for operators to have received sufficient training in oral intubation procedures and to be familiar with the intended use, warnings and cautions described in these instructions.

There is no warranty on VivaSight 2 DLT.

In this document the term *VivaSight 2 DLT* refers to the Ambu® VivaSight™ 2 DLT and the term *adapter cable* refers to the Ambu® VivaSight™ 2 Adapter Cable. The *VivaSight 2 DLT system* refers to information relevant for VivaSight 2 DLT, adapter cable and Ambu displaying unit.

1.1. Intended Use

VivaSight 2 DLT is a sterile, single-use double lumen endobronchial tube intended to be used for isolation of the left or right lung of a patient for one lung ventilation.
The VivaSight 2 DLT system is intended to be used for verifying tube placement and repositioning.

Intended patient population
VivaSight 2 DLT is intended for adult patients.

Intended use environment
The VivaSight 2 DLT system is for use in operating rooms and intensive care units.

Intended user profile
Medical doctors or nurses under medical responsibility trained within mechanical lung ventilation and anaesthesia. The VivaSight 2 DLT system must be handled in accordance with the local medical procedures for performing lung ventilation.

1.2. Indications for Use

Intubation with VivaSight 2 DLT is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery.

1.3. Contraindications

Use of double lumen tubes is relatively contraindicated in patients with a difficult airway anatomy, preexisting tracheostomy and limited mouth opening and contraindicated in patients with distorted airway anatomy and obstruction or stenosis in trachea or left main bronchus.

1.4. Clinical benefits

- Rapid intubation and successful lung isolation for One Lung Ventilation (OLV).
- Reduced need to use a bronchoscope to confirm tube position at intubation and during procedures.
- Continuous monitoring of tube position during procedures and rapid detection of tube dislodgement or malposition.
- Increased patient safety through early detection and adjustment of tube malposition.

1.5. 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 system or patient injury resulting from incorrect use.**

WARNINGS ⚠

1. Do not intubate, reposition, or extubate VivaSight 2 DLT without deflating the cuffs completely. Movement of VivaSight 2 DLT with inflated cuffs may result in trauma to the soft tissue.
2. The surface temperature of the VivaSight 2 DLT may reach above 43 °C when the tube is placed outside the patient. Therefore, switch off the displaying unit or disconnect the VivaSight 2 DLT from the displaying unit after the pre-use test. Switch the displaying unit back on or reconnect the tube immediately before use to prevent the risk of having an impact on the tissue.
3. Do not use an intubation stylet other than the one provided. Using a stylet that protrudes beyond the tube tip can cause damage to vocal cords during intubation.
4. Ensure cables and tubes from VivaSight 2 DLT do not fall onto patient's eyes during intubation and use, as this can lead to eye damage.
5. If stylet is reinserted, make sure only to insert in the bronchial lumen of the VivaSight 2 DLT. Do not insert the stylet in the tracheal lumen of the VivaSight 2 DLT as it will protrude the tracheal tube exit, which can lead to damage to trachea or vocal cords during intubation.
6. VivaSight 2 DLT camera images must not be used for diagnostic purposes. Doing so may result in incorrect or missing diagnosis, or damage to mucosal membrane or tissue due to excessive movement of tube.
7. The cuff pressure should not exceed 30 cm H_2O as over-inflation of the cuffs can damage the tracheal or bronchial mucosa.
8. Do not use VivaSight 2 DLT with flammable anaesthetic gases or agents in the immediate area of VivaSight 2 DLT as this can lead to patient injury, damage VivaSight 2 DLT or disturb image on displaying unit.
9. Do not use VivaSight 2 DLT with laser equipment and electrosurgical equipment in the immediate area of VivaSight 2 DLT as this can lead to patient injury, damage VivaSight 2 DLT or disturb image on displaying unit.
10. Patient leakage currents may be additive and too high when using an energised endoscope in VivaSight 2 DLT. Only energised endoscopes classified as "type CF" or "type BF" applied part shall be used with VivaSight 2 DLT to minimise total patient leakage current.
11. Do not attempt to clean and reuse any part of the VivaSight 2 DLT product as they are single use devices. Reuse of the product can cause contamination leading to infections.
12. Do not reuse the adapter cable on another patient as it is a single patient use device. Reuse of the adapter cable can cause contamination leading to infections.
13. Do not use the product if the Preparation and Inspection (section 4.1.) of the product fails as it can cause patient injury.
14. Do not use VivaSight 2 DLT with other connectors than standard 15 mm connectors for connection to ventilation equipment and circuits, as this can lead to insufficient ventilation.
15. MR Ambu VivaSight 2 DLT is MR Unsafe.

CAUTIONS

1. Do not use the product if the cuff damaged as it may result in insufficient ventilation, hypoxia and reintubation. Care must be taken to avoid damaging the cuff during intubation as teeth or any intubation aid with sharp surfaces can damage the cuff.
2. Before use, always check for compatibility between VivaSight 2 DLT and the external device (e.g. bronchoscope, suction catheter) to avoid devices not being able to pass through lumen.
3. Do not use the flush tube for suctioning as this can occlude the flush tube.

1.6. Potential Adverse Events

Potential adverse events in relation to the use of double lumen tubes (not exhaustive): hoarseness, sore throat, oral laceration, vocal cord injury, mucosal injury, tracheobronchial injury, arytenoid injury, laryngitis, Laryngospasm, bronchospasm, aspiration of gastric content, hypoxemia, hypotension, pneumothorax, arrhythmia, cardiac arrest.

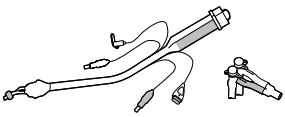
1.7. General Notes

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. System Description

VivaSight 2 DLT can be connected to the Ambu displaying units. For information about the Ambu displaying units, please refer to the Ambu displaying unit's instruction for use.

2.1. Product Parts

Ambu® VivaSight™ 2 DLT	**REF Numbers:**
	412350000 Ambu® VivaSight™ 2 DLT 35 Fr - LEFT 412370000 Ambu® VivaSight™ 2 DLT 37 Fr - LEFT 412390000 Ambu® VivaSight™ 2 DLT 39 Fr - LEFT 412410000 Ambu® VivaSight™ 2 DLT 41 Fr - LEFT All tubes are delivered with a Y-connector (ID 2x15 mm, OD 1x15 mm) and a stylet.

Tube Sizes	**Size [Fr]**	**Outside Bronchial Diameter [mm]**	**Effective Inside Diameter* Bronchial [mm]**	**Effective Inside Diameter* Tracheal [mm]**
Ambu® VivaSight™ 2 DLT 35 Fr	35	Max. 10.5	Min. 4.4	Min. 4.4
Ambu® VivaSight™ 2 DLT 37 Fr	37	Max. 11.0	Min. 4.6	Min. 4.6
Ambu® VivaSight™ 2 DLT 39 Fr	39	Max. 11.5	Min. 4.8	Min. 4.8
Ambu® VivaSight™ 2 DLT 41 Fr	41	Max. 12.0	Min. 5.0	Min. 5.0

*See explanation of "effective inside diameter" in section 2.2

Ambu® VivaSight™ 2 Adapter Cable	**REF Numbers:**
	412030000 Ambu® VivaSight™ 2 Adapter Cable Cable length: 2000 mm ± 50 mm

2.2. Product Compatibility

Ambu® Displaying Units	**REF Numbers**
	VivaSight 2 DLT and adapter cable must be powered by and used in conjunction with: 405002000 Ambu® aView™ 405011000 Ambu® aView™ 2 Advance For Ambu displaying unit model no., please check the backside label on the displaying unit. Please refer to the Ambu displaying unit instruction for use.

Devices to be Used within the Lumens of VivaSight 2 DLT

Ambu® VivaSight™ Suction Catheter	**REF Number:**
	412100000

Other Devices

- Other suction catheters
- Bronchoscopes
- Airway exchange catheters
- Airway intubation catheters

Size guide for selection of appropriate size of devices to be used within the VivaSight 2 DLT lumens:

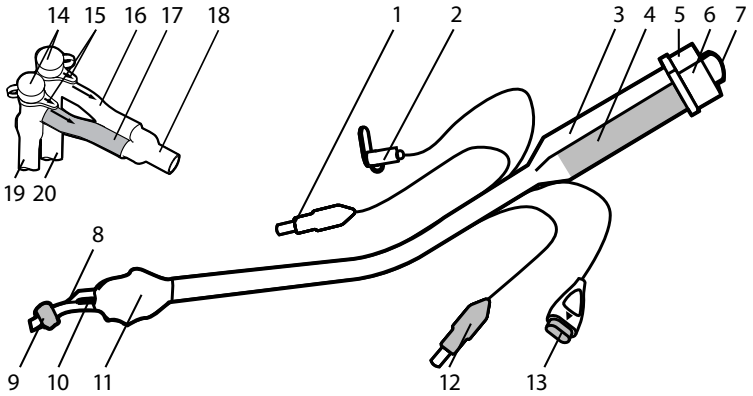
Tube Sizes	**Effective Inside Diameter* Bronchial [mm]**	**Effective Inside Diameter* Tracheal [mm]**
Ambu® VivaSight™ 2 DLT 35 Fr	Min. 4.4	Min. 4.4
Ambu® VivaSight™ 2 DLT 37 Fr	Min. 4.6	Min. 4.6
Ambu® VivaSight™ 2 DLT 39 Fr	Min. 4.8	Min. 4.8
Ambu® VivaSight™ 2 DLT 41 Fr	Min. 5.0	Min. 5.0

*The effective inside diameter is intended as a guide for selecting the appropriate diameter of a bronchoscope or other device to be passed through the lumens. The effective inside diameter differs from the ID by taking into account the restriction on the lumen at the camera position.

Ventilation Equipment
Lung ventilation systems with 15 mm female conical connectors in compliance with ISO 5356-1.

Accessories
- Standard 6 % conical Luer syringes.
- Manometer pressure gauges.

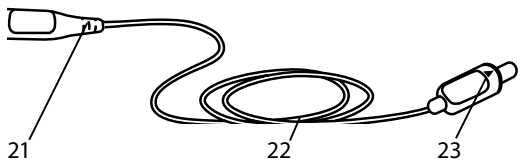
2.3. VivaSight 2 DLT Parts



No.	Part	Function
1	Tracheal pilot balloon with check valve	Provides luer compatible port for tracheal cuff inflation/deflation and indicates state of tracheal cuff inflation/deflation
2	Flush port	Provides luer compatible port for injection of air and saline for cleaning of camera lens
3	Tracheal tube	Channels air for ventilation or deflation of right lung

No.	Part	Function
4	Bronchial tube	Channels air for ventilation or deflation of left lung
5	Tracheal tube connector (Male)	Connects the tracheal tube to the Y-connector
6	Bronchial tube connector (Male)	Connects the bronchial tube to the Y-connector
7	Stylet	Gives shape to the tube for navigation during intubation
8	Flush exits	Channels air and saline for cleaning of camera lens
9	Bronchial cuff	High volume low pressure (HVLP) cuff providing sealing against bronchial wall
10	Video camera and LED light source	Provides visual feedback aiding the user to verify endobronchial tube placement
11	Tracheal cuff	High volume low pressure (HVLP) cuff providing sealing against tracheal wall
12	Bronchial pilot balloon with check valve	Provides luer compatible port for bronchial cuff inflation/deflation and indicates state of bronchial cuff inflation/deflation
13	Video connector	Connects to the tube connector on the adapter cable for connection of VivaSight 2 DLT and adapter cable
14	Endoscopic caps	Provides exit for air during lung deflation and access for devices through the lumens of VivaSight 2 DLT
15	Rotating switches	Enable opening and closing of ventilation flow
16	Tracheal airway tube	Channels air for ventilation of right lung
17	Bronchial airway tube	Channels air for ventilation of left lung
18	Ventilation connector	Connects VivaSight 2 DLT to the ventilation system
19	Bronchial tube connector (female)	Connects the Y-connector to the bronchial tube
20	Tracheal tube connector (female)	Connects the Y-connector to the tracheal tube

2.4. Adapter Cable Parts



No.	Part	Function
21	Tube connector	Connects to VivaSight 2 DLT
22	Cable	Connects VivaSight 2 DLT to the Ambu displaying unit for live video image
23	Displaying unit connector	Connects to the Ambu displaying unit

3. Explanation of Symbols Used

Symbols	Indication	Symbols	Indication
∅ Fr	Outside diameter in Fr	∅ EFF Tr. ID	Effective inside diameter of the endotracheal tube
∅ Br. OD	Outside diameter of the endobronchial tube	∅ EFF Br. ID	Effective inside diameter of the endobronchial tube
MD	Medical Device	GTIN	Global Trade Item Number
MY	Country of manufacturer		Do not use if package is damaged
1	Single Patient Use	STERILE EO	Sterile barrier. Sterilised using ethylene oxide.
	Defibrillation-proof type BF applied part	NON STERILE	Non-sterile product
c UL us	UL Recognized Component Mark for Canada and the United States		

A supplementing list of symbol explanations can be found on:
https://www.ambu.com/symbol-explanation

4. Use of VivaSight 2 DLT

The numbers in gray circles below refer to illustrations on page 2.

4.1. Preparation and Inspection

1. Choose the VivaSight 2 DLT size according to patient anatomy.
2. Check that the seal of the sterile pouch is intact. **1a**
3. Check that all product parts are present and that there are no impurities or damage to the product, such as rough surfaces, sharp edges or protrusions which may harm the patient. **1b**
4. If using devices inside the tube, check their compatibility by verifying that the devices can pass through the tubes without resistance.
   Use the effective inside diameter presented in the table in section 2.2 as a guide for choosing device size. There is no guarantee that devices selected solely using VivaSight 2 DLT effective inside diameter will be compatible in combination with VivaSight 2 DLT.
5. Check the cuffs for integrity by inflating and deflating them completely. **2**
6. VivaSight 2 DLT may be lubricated if needed; avoid the area around the camera lens at the end of the tube.
7. Turn ON the Ambu displaying unit by pressing the power button. Refer to the Ambu displaying unit instruction for use. **3**
8. Connect the adapter cable to the tube and the displaying unit. Be careful to align the arrows. **4** **5**

9. Verify that a correctly oriented live video image appears on the screen by pointing the distal end of VivaSight 2 DLT towards an object, e.g. the palm of your hand **6**. Adjust the image preferences if necessary (please refer to the Ambu displaying unit instruction for use). If the object cannot be seen clearly, wipe the lens at the distal end using a sterile cloth or a swab containing alcohol.

4.2. Operating VivaSight 2 DLT

Intubation

1. Prior to intubation, secure the wire and tubes around or in your hand to prevent the connectors from falling into the patient's face or eyes during intubation.
2. Introduce VivaSight 2 DLT orally. **7**
3. Advance VivaSight 2 DLT with the tip facing upward until the bronchial cuff is just through the vocal cords. **8a**
4. Remove the stylet. **8b**
5. Turn the tube 90 degrees counterclockwise until you can see the vocal cords facing upwards on the displaying unit. **8c**
6. While observing the live image on the displaying unit, advance the tube further until the final position is reached with the bronchial tube placed in the left main bronchus. **8d**
7. Inflate the cuffs up to a maximum pressure of 30 cm H_2O. Verify the position of the tube on the displaying unit **9**. If the patient is moved after intubation, make sure to re-verify the position of the tube on the displaying unit.
8. Secure the VivaSight 2 DLT and the breathing circuit according to local guidelines.

Using the Y-connector

1. Connect the Y-connector to VivaSight 2 DLT. Ensure that the blue bronchial airway tube on the Y-connector is connected to the blue bronchial tube on VivaSight 2 DLT and the transparent tracheal airway tube on the Y-connector is connected to the transparent tracheal tube on VivaSight 2 DLT. **10**
2. Connect the Y-connector to the ventilation system. **10**
3. The Y-connector has an arrow printed on both the tracheal and the bronchial airway tube indicating the flow of air. An identical arrow is printed on the rotating switch connected to each of the two tubes. When the arrow on the rotating switch and the arrow on the tube are pointing in the same direction, the tube is open for ventilation.
4. Stop ventilation of one lung by turning the rotating switch 180° until the arrows are pointing in opposite directions. **11a**
5. To deflate the non-ventilated lung, open the cap on top of the Y-connector. **11b**
6. If applicable, resume lung ventilation of the collapsed lung by closing the cap **12a** and turning the rotating switch 180° until the arrows are pointing in the same direction **12b**.

Cleaning the Camera Lens

If the VivaSight 2 DLT camera lens becomes soiled or obscured by secretions, it can be cleaned by injecting air and saline, where permitted by institutional policy, into the flush port.

1. Open the flush port lid.
2. With a 5 ml syringe, inject 3 ml air into the flush port and then check image clarity.
3. With a 5 ml syringe, inject 3 ml saline into the flush port and then check image clarity.
4. If the live image on the Ambu displaying unit is still unclear repeat step 2 and 3.
5. Close the flush port lid.

Use of Accessories and Other Devices

When using devices inside VivaSight 2 DLT, always perform a compatibility check between VivaSight 2 DLT and the device according to section 4.1 step 4. Inspect the accessory or other device before using it. If there is any irregularity in its operation or external appearance, replace it.

Extubation

1. Disconnect the lung ventilation system.
2. Deflate the cuffs completely. **13a**
3. Slowly withdraw the tube. **13b**

Duration of use
VivaSight 2 DLT can be used for up to 8 hours in total.

4.3. After Use

Visual Check
Examine the integrity of the product and check if there are any missing or broken parts. In case any corrective actions are needed, act according to local hospital procedures.

Final Steps
1. Disconnect the adapter cable from the Ambu displaying unit. **14a**
2. Turn off the Ambu displaying unit by pressing the power button. **14b**
3. VivaSight 2 DLT and the stylet are single-use devices and the adapter cable is for single-patient use. **Do not soak, rinse, sterilise or reuse the devices as this may leave harmful residues or cause malfunction of the devices.** The design and materials used are not compatible with conventional cleaning and sterilisation procedures. **15**

Disposal
VivaSight 2 DLT is a single use device and must be disposed of after use. VivaSight 2 adapter cable is a single-patient use device and must be disposed of with its designated tube after use. VivaSight 2 DLT and VivaSight 2 adapter cable, is considered contaminated after use and must be disposed of in accordance with local guidelines for collection of infected medical devices with electronic components.

5. Technical Product Specifications

5.1. Standards Applied

VivaSight 2 DLT function conforms with:
– EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
– EN 60601-2-18 Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

5.2. Specifications of VivaSight 2 DLT and Adapter Cable

VivaSight 2 DLT and Adapter Cable	**Specification**	
Power	VivaSight 2 DLT and adapter cable can only be powered by compatible Ambu displaying units. See section 2.2 Product Compatibility.	
Environmental Conditions	**Operation**	**Storage**
Ambient temperature	10 - 35 °C (50 - 95 °F)	10 - 25 °C (50 - 77 °F)
Ambient relative humidity	30 - 75 %	-
Ambient atmospheric pressure	70 - 106 kPa	-
Storage recommendation	-	Store in a dry, cool and dark place

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 manual.

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 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-orientation the equipment.
Harmonic emission IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Complies	

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	for power supply +/- 1 kV line to line +/- 2 kV line to earth for input /output +/- 1 kV line to line +/- 2 kV line to earth	for power supply lines +/- 1 kV line to line +/- 2 kV line to earth for input / output N/A	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	Voltage dips: 0 % U_T, 0.5 & 1 cycle 70 % U_T, 25 cycles Voltage interruptions: 0 % U_T, 250 cycles	Voltage dips: 0 % U_T, 0.5 & 1 cycle 70 % U_T, 25 cycles Voltage interruptions: 0 % U_T, 250 cycles	Mains power quality shall be that of a typical commercial or hospital environment. If the use of the system requires continued operation during power mains interruptions the system can be powered by the built in rechargeable battery.
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.
NOTE : U_T is the a.c. mains voltage prior to application of the test level.			

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	For power lines 3 V RMS 0,15 MHz – 80 MHz 6 V RMS in ISM bands 80 % AM at 1 kHz	For power lines 3 V RMS 0,15 MHz – 80 MHz 6 V RMS in ISM bands 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a) Should be less than the compliance level in each frequency range. b) Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated Radio Frequency IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz Proximity to RF wireless communications equipment 385MHz-5785MHz, up to 28V/m	3 V/m 80-2700 MHz 80 % AM at 1 kHz Proximity to RF wireless communications equipment 385MHz-5785MHz, up to 28V/m	

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 (celluar/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey shall be considered. If the measured field strength in the location in which the 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.

Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and system

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

Rated maximum output power (W) of transmitter	**Separation distance (m) according to frequency of transmitter**		
	150 kHZ to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.33 m
10	3.70 m	3.70 m	7.37 m
100	11.7 m	11.7 m	23.3 m

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Ambu A/S
Baltorpbakken 13,
DK-2750 Ballerup, Denmark
T +45 72 25 20 00
F +45 72 25 20 50
www.ambu.com

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