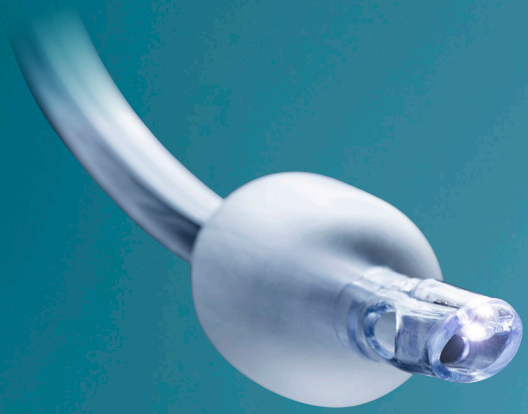
INSTRUCTIONS FOR USE

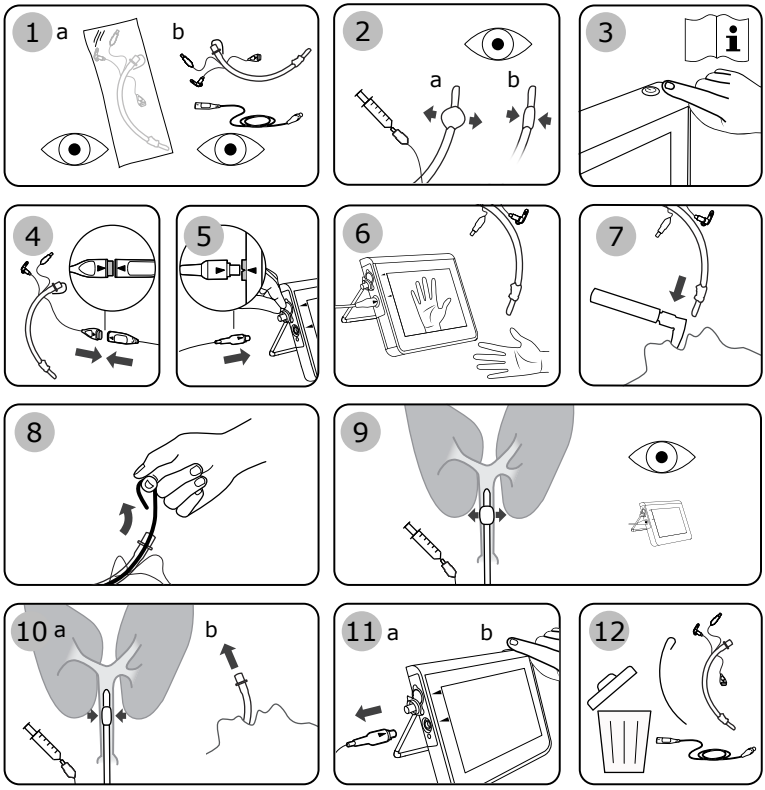
Ambu® VivaSight™ 2 SLT

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

Abridged version

Ambu

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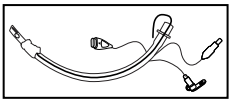

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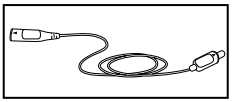
Ambu® VivaSight™ 2 Adapter Cable



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1. Important Information – Read Before Use

Read these safety instructions carefully before using the Ambu® VivaSight™ 2 SLT.
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 SLT. Before initial use of VivaSight 2 SLT, 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 SLT.

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

1.1. Intended Use

VivaSight 2 SLT is a sterile, single-use endotracheal tube intended for oral intubation procedures. It is intended to be used as a temporary artificial airway in adults requiring mechanical ventilation.

The VivaSight 2 SLT system is intended for general inspection of the airways and for visualization during intubation procedures.

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

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

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

1.2. Indications for Use

Intubation with VivaSight 2 SLT is indicated for patients with difficult airway anatomy, pathological lung conditions or other medical conditions that require endotracheal intubation and mechanical ventilation and may in conjunction with an endobronchial blocker include isolation of one lung from the other, e.g. for thoracic surgery.

1.3. Contraindications

Patients suffering from conditions or undergoing specific surgeries making them at risk of or requiring them to undergo an MRI scan.

1.4. Clinical benefits

- Provision of a secure airway, controlled ventilation and airway protection.
- Visualization during oral intubation procedures facilitating surveillance of tube positioning.
- Facilitating lung separation when used in conjunction with an endobronchial blocker.
- Facilitating visualization and real-time monitoring of the medical procedure in lung separation in conjunction with an endobronchial blocker without the use of a bronchoscope.

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 SLT without deflating the cuff completely. Movement of the VivaSight 2 SLT with an inflated cuff may result in trauma to the soft tissue.
2. The surface temperature of the VivaSight 2 SLT may reach above 43 °C when the tube is placed outside the patient. Therefore, switch off the displaying unit or disconnect the Viva Sight 2 SLT 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 the VivaSight 2 SLT do not fall onto patient's eyes during intubation and use, as this can lead to eye damage.
5. VivaSight 2 SLT 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.
6. The cuff pressure should not exceed 30 cmH_2O as over-inflation of the cuff can damage the tracheal mucosa.
7. Do not use VivaSight 2 SLT with flammable anaesthetic gases or agents in the immediate area of VivaSight 2 SLT as this can lead to patient injury, damage Viva-Sight 2 SLT or disturb image on displaying unit.
8. Do not use VivaSight 2 SLT with laser equipment and electrosurgical equipment in the immediate area of VivaSight 2 SLT as this can lead to patient injury, damage VivaSight 2 SLT or disturb image on displaying unit.
9. Patient leakage currents may be additive and too high when using an energised endoscope in VivaSight 2 SLT. Only energised endoscopes classified as "type CF" or "type BF" applied part shall be used with VivaSight 2 SLT to minimise total patient leakage current.
10. Do not attempt to clean and reuse any part of the VivaSight 2 SLT product as they are single use devices. Reuse of the product can cause contamination leading to infections.
11. 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.
12. Do not use the product if the Preparation and Inspection (section 4.1.) of the product fails as it can cause patient injury.
13. Do not use VivaSight 2 SLT with other connectors than standard 15 mm connectors for connection to ventilation equipment and circuits, as this can lead to insufficient ventilation.
14. MR VivaSight 2 SLT is classified as MR unsafe. It is recommended to reintubate the patient with an alternative MR conditional product if MRI scan is clinical indicated.
15. In cases with obstruction of upper airway due to pathology or foreign body, risk of failure with intubation is increased. Consider alternative method or device.

CAUTIONS

1. Do not use the product if the cuff is 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 the SLT and the external device (e.g. endobronchial blocker (EBB), bronchoscope, suction catheter) to avoid devices not being able to pass through lumen.
3. Do not intubate the patient with the VivaSight 2 SLT through a laryngeal mask, as it will not be possible to remove the mask as the video connector is too large to fit through the mask.
4. Caution should be taken when using suction catheter and EBB in VivaSight 2 SLT at the same time, as more devices in the lumen may cause devices to block for each other.
5. Do not use the flush tube for suctioning as this can occlude the flush tube.
6. When intubating patients with soiled airways beware that visualization may be impaired during intubation due to secretion on the camera lens. Recover visualization by flushing camera when possible.

1.6. Potential Adverse Events

Potential adverse events in relation to the use of endotracheal tubes (not exhaustive): hoarseness, sore throat, oral laceration, vocal cord injury, mucosal injury, tracheobronchial injury, laryngospasm, bronchospasm, pneumothorax, dysphonia, esophageal intubation, aspiration of gastric content, ventilator-associated pneumonia, hypoxemia, hypotension, 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 SLT can be connected to 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 SLT	**REF Numbers:**
	412700000 Ambu® VivaSight™ 2 SLT 7.0 412750000 Ambu® VivaSight™ 2 SLT 7.5 412800000 Ambu® VivaSight™ 2 SLT 8.0 All tubes are delivered with a stylet.

Tube Sizes	**Size (inside diameter) [mm]**	**Outside Diameter [mm]**	**Cuff Diameter [mm]**	**Effective Inside Diameter [mm]***
Ambu® VivaSight™ 2 SLT 7.0	7.0	10.0 ± 0.2	25 ± 3.7	Min. 4.6
Ambu® VivaSight™ 2 SLT 7.5	7.5	10.5 ± 0.2	25 ± 3.7	Min. 4.8
Ambu® VivaSight™ 2 SLT 8.0	8.0	11.0 ± 0.2	26 ± 3.9	Min. 5.2

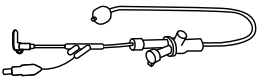
* See explanation of "effective inside diameter" in section 2.2.

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 SLT 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 Lumen of VivaSight 2 SLT

Ambu® VivaSight™ Endobronchial Blocker Tube	**REF Numbers:**
	412900000

Other Devices

- Other endobronchial blockers
- Bronchoscopes
- Airway exchange catheters
- Airway intubation catheters
- Suctions catheters

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

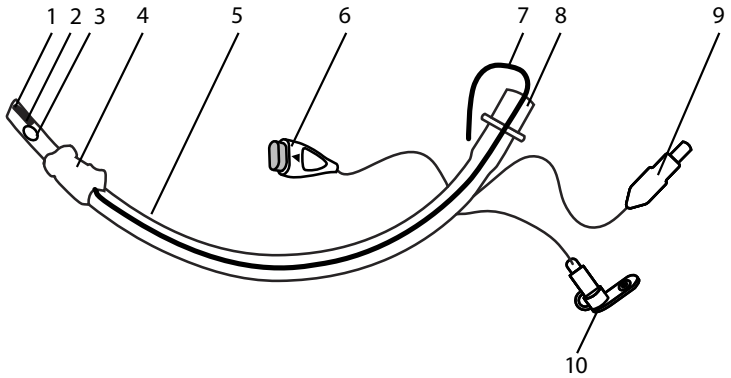
Tube Size	**Effective Inside Diameter [mm]***
Ambu® VivaSight™ 2 SLT 7.0	Min. 4.6
Ambu® VivaSight™ 2 SLT 7.5	Min. 4.8
Ambu® VivaSight™ 2 SLT 8.0	Min. 5.2

* 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 lumen. 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.

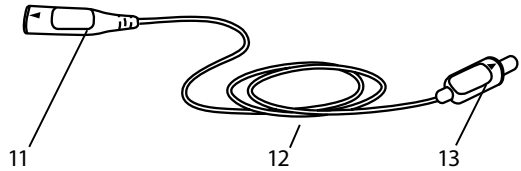
Accessories
- Standard 6 % conical Luer syringes
- Cuff pressure gauges with Luer connector

2.3. VivaSight 2 SLT Parts



No.	Part	Function
1	Flush exits	Channels air and saline for cleaning of camera lens
2	Video camera and LED light source	Provides visual feedback aiding the user to verify endotracheal tube and endobronchial blocker placement
3	Murphy Eye	Ensures flow through the tube if main opening is blocked
4	Tracheal cuff	High volume low pressure (HVLP) cuff providing sealing against tracheal wall
5	Endotracheal tube	Channels air for ventilation of the lungs
6	Video connector	Connects to the tube connector on the adapter cable for connection of VivaSight 2 SLT and adapter cable
7	Stylet	Gives shape to the tube for navigation during intubation
8	Tracheal tube connector	Connects VivaSight 2 SLT to the ventilation system
9	Pilot balloon with check valve	Provides luer compatible port for cuff inflation/deflation and indicates state of cuff inflation/deflation
10	Flush port	Provides luer compatible port for injection of air and saline for cleaning of camera lens

2.4. Adapter Cable Parts



No.	Part	Function
11	Tube connector	Connects to VivaSight 2 SLT
12	Cable	Connects VivaSight 2 SLT to the Ambu displaying units for live video image
13	Displaying unit connector	Connects to the Ambu displaying unit

3. Explanation of Symbols Used

Symbols	Indication	Symbols	Indication
∅ ID	Inside diameter of the endotracheal tube (also referred to as tube size)	∅ EFF ID	Effective inside diameter
∅ OD	Outside diameter of the endotracheal tube	∅ Cuff D	Diameter of the inflated cuff
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
MR	MR Unsafe	c UL us	UL Recognized Component Mark for Canada and the United States

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

4. Use of the VivaSight 2 SLT

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

4.1. Preparation and Inspection

1. Choose the VivaSight 2 SLT size according to patient anatomy.
2. Check that the seal of the sterile pouch is intact **1a**. Do not use the product if the sterile pouch is damaged or has been unintentionally opened before use.
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 tube 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 SLT effective inside diameter will be compatible in combination with VivaSight 2 SLT.
5. Check the cuff for integrity by inflating and deflating it completely. **2**
6. VivaSight 2 SLT 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 SLT towards an object, e.g. the palm of your hand **6**. Adjust the image preferences if necessary (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 SLT

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 SLT orally and advance it through the vocal cords with the tip of the tube facing upwards. **7**
3. Remove the stylet. **8**
4. While observing the live image on the displaying unit, advance the tube further until final positioning above the carina.
5. Inflate the cuff up to a maximum pressure of 30 cmH_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.
6. Connect the ventilation system to the tracheal tube connector. Use capnography for monitoring end-tidal CO_2, auscultation, and observation of chest wall movement to verify correct tube position.
7. Secure the VivaSight 2 SLT and the breathing circuit according to local guidelines.

Cleaning the Camera Lens

If the VivaSight 2 SLT 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 SLT, always perform a compatibility check between VivaSight 2 SLT 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 cuff completely. **10a**
3. Slowly withdraw the tube. **10b**

Long Term Intermittent Monitoring/Duration Of Use

VivaSight 2 SLT can be used for ventilation and intermittent monitoring after surgery. Disconnect the adapter cable from the tube, but keep the adapter cable with the patient in case intermittent monitoring is needed. If necessary, VivaSight 2 SLT and adapter cable can be wiped with water or a swab containing alcohol.

VivaSight 2 SLT can be used for up to 14 days with an intermittent use of the video camera for up to 8 hours in total. When exceeding 8 hours of video camera usage, use the depth marks on VivaSight 2 SLT to monitor tube position.

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.

Disconnect

1. Disconnect the adapter cable from the Ambu displaying unit. **11a**
2. Turn off the Ambu displaying unit by pressing the power button. **11b**
3. VivaSight 2 SLT 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. **12**

Disposal
VivaSigth 2 SLT 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 dis-posed of with its designated tube after use. VivaSight 2 SLT and VivaSight 2 adapter cable, is considered contaminated after use and must be disposed of in accord-ance with local guidelines for collection of infected medical devices with elec-tronic components.

5. Technical Product Specifications

5.1. Standards Applied

VivaSight 2 SLT 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 SLT and Adapter Cable

VivaSight 2 SLT and Adapter Cable	**Specification**	
Power	VivaSight 2 SLT and adapter cable can only be powered by compatible Ambu displaying units. See section 2.2 Product Compatibility.	
Sterility	VivaSight 2 SLT is sterilized using ethylene oxide; the adapter cable is supplied non-sterile.	
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

5.3. Cuff Performance

Endotracheal tube cuff performance (per ISO 5361 method)					
The performance information shown below was collected using a bench test that is intended to provide a comparison of the sealing characteristics of tracheal tube cuffs only in a laboratory setting. The bench test is not configured or intended to predict performance in the clinical setting.					
for size 7.0 mm tracheal tube					
Minimum tracheal diameter: 19 mm			Maximum tracheal diameter: 24 mm		
Cuff pressure	Leakage rate (ml/h)		Cuff pressure	Leakage rate (ml/h)	
hPa (cmH_2O)	50th percentile	90th percentile	hPa (cmH_2O)	50th percentile	90th percentile
27	633.6 ml/h	1225.2 ml/h	27	25.2 ml/h	3754.8 ml/h
for size 7.5 mm endotracheal tube					
Minimum tracheal diameter: 19 mm			Maximum tracheal diameter: 24 mm		
Cuff pressure	Leakage rate (ml/h)		Cuff pressure	Leakage rate (ml/h)	

Endotracheal tube cuff performance (per ISO 5361 method)					
The performance information shown below was collected using a bench test that is intended to provide a comparison of the sealing characteristics of tracheal tube cuffs only in a laboratory setting. The bench test is not configured or intended to predict performance in the clinical setting.					
hPa (cmH_2O)	50th percentile	90th percentile	hPa (cmH_2O)	50th percentile	90th percentile
27	498.0 ml/h	1696.8 ml/h	27	294.0 ml/h	8659.2 ml/h
for size 8.0 mm endotracheal tube					
Minimum tracheal diameter: 20 mm			Maximum tracheal diameter: 25 mm		
Cuff pressure	Leakage rate (mL/h)		Cuff pressure	Leakage rate (mL/h)	
hPa (cmH_2O)	50th percentile	90th percentile	hPa (cmH_2O)	50th percentile	90th percentile
27	0.0 ml/h	594.0 ml/h	27	823.2 ml/h	1423.2 ml/h

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.
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 385 MHz – 5785 MHz, up to 28 V/m	3 V/m 80-2700 MHz 80 % AM at 1 kHz Proximity to RF wireless communications equipment 385 MHz – 5785 MHz, up to 28 V/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.

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