Electromagnetic compatibility
Guidance and manufacturer's declaration

Medical electrical devices are subject to special precautionary measures in particular regarding the EMV with the installation and the operation.
Portable and mobile HF-communication devices e.g. mobile phone can affect medical electrical devices.
A use of other accessories and lines than the indicated, can lead to an increased sending or a reduced noise immunity of the equipment. The equipment has to be operated exclusively with original accessories.
The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such environment.

Emissions test

Emission test	**Compliance**	**Electromagnetic environment – Guidance**
RF emissions CISPR 11	Group A	The device uses RF energy only for its internal function. Therefore, its RF-emission is very low and not likely to cause any interference nearby electronic equipment.
	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Passed	

Immunity test

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	5/50 ns, 100 kHz, ±2 kV	5/50 ns, 100 kHz, ±2 kV	Mains power quality should be similar to that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1.2/50 (8/20) µs LtL: ±1 kV LtG: ±2 kV	1.2/50 (8/20) µs LtL: ±1 kV LtG: ±2 kV	Mains power quality should be similar to that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle (1 phase) 0 % U_T for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % U_T for 250/300 cycles (50/60 Hz)	0 % U_T for 0.5 cycle (1 phase) 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles (50/60 Hz) 0 % U_T for 250/300 cycles (50/60 Hz)	Mains power quality should be similar to that of a typical commercial or hospital environment. When the user of the Medical Electrical Equipment continued function also calls in the event of disruption of supply, it is recommended the EUT from an uninterruptible power supply or a battery.
Power frequency (50 Hz / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Amplitude modulated	150 kHz – 80 MHz 3 V ISM and amateur radio bands 6 V 80 % / 1 kHz	150 kHz – 80 MHz 3 V ISM and amateur radio bands 6 V 80 % / 1 kHz	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device1, including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radio-frequency electromagnetic field Amplitude modulated	IEC 61000-4-3	80 MHz – 2.7 GHz 10 V/m Home Healthcare T Prof. Healthcare 80 % / 1 kHz	
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	380 – 390 MHz 27 V/m; PM 50 %; 18 Hz 430 – 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 – 787 MHz 9 V/m; PM 50 %; 217 Hz 800 – 960 MHz 28 V/m; PM 50 %; 18 Hz 1700 – 1990 MHz 28 V/m; PM 50 %; 217 Hz 2400 – 2570 MHz 28 V/m; PM 50 %; 217 Hz 5100 – 5800 MHz 9 V/m; PM 50 %; 217 Hz	