

# Guidance and manufacturer's declaration

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## EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC EN 60601-1-2:2007.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document and the directions for use for the device.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the device in the presence of high-frequency surgical equipment.
- It is good practice to avoid using the device in extremely close proximity to other equipment.

## Emissions and immunity information

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### Electromagnetic emissions


**The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.**

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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 emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:

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### Electromagnetic emissions

**The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.**

Emissions test	Compliance	Electromagnetic environment - guidance	
Harmonic emissions IEC 61000-3-2	Class A	 <b>WARNING</b> This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

### Electromagnetic immunity

**The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.**

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should 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	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50–60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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### Electromagnetic immunity

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**The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.**

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
<b>Recommended separation distance</b>			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = (1.17) \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = (1.17) \sqrt{P}$ 80 to 800 MHz

$$d = (2.33) \sqrt{P} \text{ 800 MHz to 2,5 GHz}$$

where  $P$  is the maximum output power rating of the transmitter in watts (W) and  $d$  is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>. Interference may occur in the vicinity of equipment marked with the following symbol:



Note1: At 80 MHz and 800 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.

<sup>a</sup>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 should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

<sup>b</sup>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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**Recommended separation distances between portable and mobile RF communications equipment and the device**

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

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**Separation distance according to frequency of transmitter (m)**

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<b>Rated max. output power of transmitter (W)</b>	<b>150 kHz to 80 MHz</b> $d = (1.17) \sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = (1.17) \sqrt{P}$	<b>800 MHz to 2.5 GHz</b> $d = (2.23) \sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.3333

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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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