

# Electromagnetic compatibility (EMC) compliance

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## Guidance and manufacturer's declaration

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

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

The Spot LXi Vital Signs device and accessories comply with all applicable and required standards for electromagnetic interference.

- They do not normally affect nearby equipment and devices.
- They are not normally affected by nearby equipment and devices.
- It is safe to operate them in the presence of high-frequency surgical equipment; however, it is good practice to avoid using the Spot LXi Vital Signs device near other equipment.

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### Electromagnetic emissions

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

<b>Emissions test</b>	<b>Compliance</b>	<b>Guidance</b>
RF emissions CISPR 11	Group 1	The Spot LXi Vital Signs 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 B	The Spot LXi Vital Signs 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	Complies	

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**Electromagnetic immunity**


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<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Guidance</b>
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 line(s) to line(s) ±2 kV line(s) to line(s)	±1 kV line(s) to line(s) ±2 kV line(s) to line(s)	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 for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 seconds	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Spot LXi Vital Signs device requires continued operation during a power mains interruption, it is recommended that the Spot LXi Vital Signs device be powered from an uninterruptible power supply or 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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Immunity test	IEC 60601 test level	Compliance level	Guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of the Spot LXi Vital Signs device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p>
Conducted RF IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			<p>where <b>P</b> is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in meters.</p> <p>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>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>
			

Note 1 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.

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

b 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 Spot LXi Vital Signs device**

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

Rated maximum output power (watts) of transmitter	Separation distance (meters) according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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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