

APPENDIX E - ELECTROMAGNETIC COMPATIBILITY

Emissions



WARNING: The use of accessories or cables other than those specified by SIGMA may result in increased Emissions or decreased Immunity of this medical device.

CAUTION: Use Caution Near RF Sources

The Spectrum Pump meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2 (2001-09) standard for emissions and immunity. It is good practice to keep the pump separated away from other equipment, such as hand-held transmitters, cellular phones and electrosurgical equipment that may generate strong radio frequency interference (RFI). Refer to the EMC Immunity Section, Separation Distance, in this manual for recommended minimum distance.

Guidance and manufacturer's declaration – electromagnetic emissions		
The SIGMA Model Spectrum Infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the Spectrum should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Spectrum 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 Spectrum 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	

Immunity – ESD, transient/burst, voltage disparity, magnetic

Guidance and manufacturer's declaration – electromagnetic immunity			
The SIGMA Model Spectrum Infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the Spectrum 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	±2 kV contact ±6 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%. See Note 1.
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 Not applicable	Supply 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 Not applicable	Supply 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	<5% 120 VAC (>95% dip in 120 VAC) or 0.5 cycle 40% 120 VAC (60% dip in 120 VAC) for 5 cycles 70% 120 VAC (30% dip in 120 VAC) for 25 cycles <5% 120 VAC (>95% dip in 120 VAC) for 5 sec	<5% 120 VAC (>95% dip in 120 VAC) or 0.5 cycle 40% 120 VAC (60% dip in 120 VAC) for 5 cycles 70% 120 VAC (30% dip in 120 VAC) for 25 cycles <5% 120 VAC (>95% dip in 120 VAC) for 5 sec	Supply power quality should be that of a typical commercial or hospital environment. If the user of the Spectrum requires continued operation during power interruption, it is recommended that the Spectrum be powered from an uninterrupted power supply or the internal battery be fully charged to provide unit power as specified in this operator's manual.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

Note1: For levels 2, 3 & 4 a clearable alarm will occur with interruption of flow.

NOTE: The pump was tested to the requirements of IEC 60601-1-2:2001/A1:2004, Ed 2 and IEC 60601-2-23:1998.

NOTE: The essential performance of the pump is volumetric accuracy.



WARNING: The Spectrum Pump is not designed to be MRI-compatible nor is it intended to be used in this manner. Strong magnetic fields (those beyond the level tested) may cause the device to operate improperly.


Do not expose the SIGMA Spectrum to strong magnetic fields such as is common with MRI equipment. Doing so may cause injury to the patient and/or damage to the equipment.

CAUTION: ECG Artifacts Related to the Use of the Spectrum Pump

Peristaltic infusion pumps may produce what is known as piezoelectric artifact on ECG monitors and similar types of monitoring instruments. The Spectrum Pump may produce this effect when the infusion pump is running at rates in the higher ranges of operation, this may be in the frequency range tracked by the ECG monitor. The appearance of the artifact may be affected by set up and/or connection of electrodes, leads, or equipment. See the ECG monitoring system documentation for recommendations on proper set up including electrode connections, site preparation, monitor system set up, and electrode placement.

CAUTION: Wherever possible, eliminate any electro-static producing materials or conditions (dry, low humidity, synthetic materials such as blankets, carpeting, etc.)

Immunity – Conducted and Radiated

Guidance and manufacturer's declaration – electromagnetic immunity			
The SIGMA Model Spectrum Infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the Spectrum should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz in ISM bands a	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Spectrum, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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 meters (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.^d</p> <p>Interference may occur in the vicinity of the equipment marked with the following symbol:</p>  <p>"This excludes the Wireless Battery Modules, SIGMA P/N 35083 and 35162"</p>
	10 Vrms 150 kHz to 80 MHz in ISM bands a	10 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	

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 The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.756 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

^b The ISM compliance level in the ISM frequency band between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason an additional factor of 3K is used in calculating the recommended separation distance for transmitters in these frequency ranges.

^c Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, 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 Spectrum is used exceeds the applicable RF compliance level above, the Spectrum should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Spectrum.

^d Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Immunity – Separation Distances

Recommended separation distance between portable and mobile RF communications equipment and the Spectrum				
The SIGMA Model Spectrum is intended for use in an electromagnetic environment in which the RD disturbances are controlled. The customer or user of the Spectrum can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the Spectrum as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	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	0.12	.23
0.1	0.38	0.38	0.38	.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23
<p>For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where power P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.756 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.</p> <p>NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for the transmitters in the ISM frequency band between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.</p> <p>NOTE 4 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>				



WARNING:

The Spectrum Pump is not designed to be exposed to linear accelerator radiation nor is it intended to be used in this manner. Exposure to radiation of this type may cause the device to operate improperly.

Do not expose the SIGMA Spectrum to linear accelerator radiation. Doing so may cause injury to the patient and/or damage to the equipment.