

APPENDIX


Guidance and manufacture's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration –electromagnetic emission		
The PO 35 Pulse Oximeter is tended for use in the electromagnetic environment specified below. The customer of the user of the PO 35 Pulse Oximeter should assure that it is used in such an environment.		
Emission test	compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The PO 35 Pulse Oximeter uses RF energy only for their 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 PO 35 Pulse Oximeter 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	Not applicable	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration-electromagnetic immunity			
The PO 35 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The user of PO 35 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Guidance and manufacture's declaration-electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration-electromagnetic immunity			
The PO 35 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of PO 35 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Radiated RF ICE 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Portable and mobile RF communication equipment should be used no closer to any part of the PO 35 Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. recommended separation distance $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{2}{E_1} \right] \sqrt{P}$ 800MHz to 2.5GHz 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). 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: 
NOTE 1 At 80MHz and 800MHz, 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 PO 35 Pulse Oximeter is used exceeds the applicable RF compliance level above, the PO 35 Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PO 35.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT or SYSTEM that not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the PO 35 Pulse Oximeter			
The PO 35 Pulse Oximeter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PO 35 Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PO 35 Pulse Oximeter 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)		
	150KHz to 80MHz	80MHz to 800MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{2}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance 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 80MHz and 800MHz, 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.			