Guidance and manufacturer's declaration- electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions	Group 1	The device uses RF energy only for its internal function. Therefore, its RF
CISPR 11		emissions are very low and are not likely to cause any interference in nearby
		electronic equipment.
RF emissions	Class B	The device is suitable for use in all establishments, including domestic
CISPR 11		establishments and those directly connected to the public low-voltage power
Harmonic emissions	N/A	supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2		
Voltage fluctuations/	N/A	
flicker emissions		
IEC 61000-3-3		

Guidance and manufacturer's declaration – electromagnetic immunity

The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the

Pulse Oximeter should assure that it is used in such an environment.

Immunity test	IEC 60601 test	Compliance level	Electromagnetic environment – guidance
	level		
			Floors should be wood, concrete or ceramic tile. If floors are
Electrostatic			covered with synthetic material, the relative humidity
discharge (ESD) IEC	± 8 kV contact ±	± 8 kV contact	should be at least 30%. If ESD interfere with the operation of
61000-4-2	13 KV dii	_ 13 KV uii	equipment, counter measurements such as wrist strap,
			grounding shall be considered.
Electrical fast	± 2 kV for power	± 2 kV for power	The quality of the power supply should meet the
transient/ burst	supply lines	supply lines	requirements of a typical commercial (initial power supply)
IEC 61000-4-4	± 1 kV for input/	\pm 1 kV for input/	or medical environment.

	output lines	output lines		
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line to earth	± 1 kV line to line ±2 kV line to earth	The quality of the power supply should meet the requirements of a typical commercial or medical environment.	
	0% U _T	0% UT		
	(100% dip in U _T)	(100% dip in UT)		
	for 0.5 cycle	for 0.5 cycle		
Voltage dine short	0% U _T	0% UT		
Voltage dips, short	(100% dip in U _T)	(100% dip in UT)	The quality of the power supply should meet the	
interruptions and	for 1 cycle	for 1 cycle	requirements of a typical commercial or medical	
voltage variations on	70% U _T	70% UT	environment.If the user of this product needs to continue	
power supply input	(30% dip in U _T)	(30% dip in UT)	poerating during power interruption,it is recommended to	
lines	for 25/30 cycles	for 25/30 cycles	use uninterruptible power supply or battery power.	
IEC 61000-4-11	0% U _τ	0% UT		
	(100% dip in U _T)	(100% dip in UT)		
	for 250/300	for 250/300		
	cycles	cycles		
Power frequency			Power frequency magnetic fields should be at levels	
(50/60 Hz) magnetic	30 A/m	30 A/m	characteristic of a typical location in a typical commercial or	
field IEC 61000-4-8			hospital environment.	

 $\mathsf{NOTE}: \mathsf{U}_\mathsf{T}$ is the AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter 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	
		N/A	equipment should be used no closer to any part	
			of the device, including cables, than the	
	3V _{rms} 150kHz to 80MHz		recommended separation distance calculated	
Conducted RF			from the equation applicable to the frequency of	
IEC61000-4-6			the transmitter.	
	(6V in ISM and amateur		\sqrt{P} Recommended separation distance:	
	radio bands between 0.15MHz and 80MHz)		d = 1.2	
			\sqrt{P}	
			d= 1.2 80MHz to 800MHz	
			\sqrt{P}	
			d= 2.3 800MHz to 2.5GHz	
		10V/m	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 metres	
	3V/m 80MHz to 2.7GHz		(m). Field strengths from fixed RF transmitters, as	
			determined by an electromagnetic site survey, ^a	
D # 4 105			should be less than the compliance level in	
Radiated RF			each frequency range.b	
IEC61000-4-3			(((••)))	
			Interference may occur in the vicinity of	
			equipment marked with the following symbol:	

Recommended separation distances between portable and mobile RF communications equipment and the Pulse

Oximeter

The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as

recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)				
Rated maximum output power of transmitter (W)	\sqrt{P} 150kHz to 80MHz d = 1.16	\sqrt{P} 80MHz to 800MHz	\sqrt{P} 800MHz to 2.5GHz d =		
			2.33		
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.