

**Manufacturer's Declaration – Electromagnetic Emissions
IEC 60601-1-2:2007**

for the Equipment or System
VM-2160 / VM-2160-L

NOTES


- Using accessories, transducers and cables other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the patient monitoring equipment.
- The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the
- configuration in which it will be used. The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may affect this pulse oximeter even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment will have impact on the performance of the pulse oximeter.

Table 1 – Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration electromagnetic emissions		
The VM-2160 / VM-2160-L is intended for use in the electromagnetic environment specified below. The customer or the user of the VM-2160 / VM-2160-L should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class B	The VM-2160 / VM-2160-L uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The VM-2160 / VM-2160-L is suitable 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. The VM-2160 / VM-2160-L is suitable in all establishments, other than domestic 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 emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacturer's declaration electromagnetic immunity			
The VM-2160 / VM-2160-L is intended for use in the electromagnetic environment specified below. The customer or the user of the VM-2160 / VM-2160-L 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 ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Bursts IEC 61000-4-4	± 2 kV power supply lines ± 1 kV input/output	N/A	The device is battery powered. The usb – cable does not exceed 3m length.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	The device is battery powered.
Voltage dips, short interruptions and voltage variations on power supply input lines	> 95 % dip in U_T / 0,5 cycles 60 % dip in U_T / 5 cycles 30 % dip in U_T / 25 cycles > 95 % dip in U_T / 5 cycles	N/A	The device is battery powered.
magnetic field 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 characteristics of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	$V_1 = 3 \text{ V}$ 150 kHz – 80 MHz $E_1 = 3 \text{ V/m}$ (60601-1-2) 80 MHz – 2,5 GHz $E_1 = 20 \text{ V/m}$ (ISO 9919) for patient transport 80 MHz – 2,5 GHz	3 V 20 V/m*	Portable and mobile communications equipment should be used no closer to any part of the VM-2160 / VM-2160-L including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.17 \sqrt{P}$ for $V_1 = 3 \text{ V}$ $d = [3,5/E_1] \sqrt{P}$ 80 MHz to 800 MHz $d = [7/E_1] \sqrt{P}$ 800 MHz to 2,5 GHz Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment  marked with the following symbol:
		* Compatibility depends on specific sensor construction	

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and The device

The device is suitable for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the 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 communication equipment.

Rated Maximum Output power of Transmitter (W)	Separation Distance (m) Corresponding to Frequency of Transmitter		
	150k to 80MHz $d = [3,5/3] \sqrt{P}$	80M to 800MHz $d = [3,5/20] \sqrt{P}$	800M to 2.5GHz $d = [7/20] \sqrt{P}$
0.01	0,12	0,0175	0,035
0.1	0,37	0,055	0,11
1	1,17	0,175	0,35
10	3,69	0,553	1,11
100	11,67	1,75	3,5

For transmitters at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: From 80 MHz to 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.