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

for the Equipment or System

VM 2500-M and VM 2500-S

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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 monitor even though they meet the requirements of CISPR.
- When the inputted signal of the VM-2500 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 VM-2500.

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

Guidance and manufacturer's declaration Electromagnetic emissions		
The VM-2500-M/S is intended for use in the electromagnetic environment specified below. The customer or the user of the VM-2500-M/S should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group **1**	The VM-2500-M/S 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.
RF emissions CISPR 11	Class **B**	The VM-2500-M/S 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.
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-2500-M/S is intended for use in the electromagnetic environment specified below. The customer or the user of the VM-2500-M/S 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 discharge ± 8 kV Air discharge	± 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 %.
Fast electric transients (burst) IEC 61000-4-4	± 2 kV Power supply lines ± 1 kV Input and output lines	± 2 kV No tests performed on Signal and Data lines due to the length restriction to less than 3m	AC power quality should be that of a typical commercial or hospital environment.
Surge capability IEC 61000-4-5	± 1 kV Differential mode ± 2 kV Common mode	± 1 kV ± 2 kV	AC 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 in UT for 0.5 cycles 60 % Dip in UT for 5 cycles 30 % Dip in UT for 25 cycles > 95 % Dip in UT for 5 cycles	100 % 60 % 30 % 100%	AC power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power outages, the device should be powered by an uninterruptible power supply or a battery.
Magnetic field at power frequency (50/60) Hz 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	V1 = 3 V 150 kHz – 80 MHz E1 = 3 V/m (60601-1-2) 80 MHz – 2.5 GHz for patient transport: E1 = 20 V/m (ISO 9919 and ISO 21647) 80 MHz – 2.5 GHz	3 V 20 V/m a)	Portable and mobile communications equipment should be used no closer to any part of the VM-2500-M/S, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.17 √P d = 0.18 √P 80 MHz to 800 MHz d = 0.35 √P 800 MHz to 2.5 GHz Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, b) should be less than the compliance level in each frequency range c). Interference may occur in the vicinity of equipment marked with the following symbol:  P: Maximal output power rating at transmitter in Watt d: Recommended separation distance in meters

! Take note :
All in this document listed numbers have a point '.' as decimal separator and a comma ',' as thousands separator

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The guidelines may not apply in all situations because electromagnet propagation is affected by absorption and reflection from structures, objects and people.

[a)] Compatibility depends on specific SpO_2 sensor construction. Does not apply to operation with AC-Powered or data transfer via USB.

[b)] Field strength 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 VM-2500 is used exceeds the applicable RF compliance level above, the VM-2500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VM-2500.

[c)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and VM-2500-M/S

VM-2500-M/S is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of VM-2500-M/S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and VM-2500-M/S as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter [W]	**Recommended separation distance according to frequency of the transmitter [m]**		
	150kHz to 80MHz **$d = [3.5/3]\sqrt{P}$**	80MHz to 800MHz **$d = [3.5/20]\sqrt{P}$**	800MHz to 2.5GHz **$d = [7/20]\sqrt{P}$**
0.01	0.12	0.02	0.04
0.1	0.37	0.06	0.11
1	1.17	0.18	0.35
10	3.70	0.57	1.11
100	11.70	1.80	3.50

For transmitters rated 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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The guidelines may not apply in all situations because electromagnet propagation is affected by absorption and reflection from structures, objects and people.

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