


Table 9: Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8kV; Air: ±2kV, ±4kV, ±8kV, and ±15 kV	Contact: ±8kV; Air: ±2kV, ±4kV, ±8kV, and ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	Contact: ±2kV Power input ports Contact: ±1 kV Power input ports	Contact: ±2kV Power input ports N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV and ±1kV line to line ±2 kV line(s) to earth ±2 kV Signal (input/output)to earth	±0.5kV and ±1kV line to line N/A N/A	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3V 0.15 MHz – 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz. And 80% AM at 1 kHz	3V 0.15 MHz – 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz. And 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Vibrant Capsule System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2700 MHz 80% AM at 1 kHz 3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	10 V/m 80 MHz – 2700 MHz 80% AM at 1 kHz 3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	Recommended separation distance 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, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vibrant Capsule System requires continued operation during power mains interruptions, it is recommended that the Vibrant Capsule System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			