

# Electromagnetic Compatibility Tables

**WARNING:** All medical electronic devices must conform to the requirements of IEC 60601-1-2. Precautions, adherences to the Electromagnetic Compatibility (EMC) guideline information provided in this manual and verification of all medical devices in simultaneous operation are required to ensure the electromagnetic compatibility and co-existence of all other medical devices prior to a surgical procedure.

The following EMC tables are provided for reference: *Electromagnetic Emissions*, *Electromagnetic Immunity*, and *Recommended Separation Distances*.

**Note:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

## Electromagnetic Emissions

Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The product uses RF energy only for its 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 A	The product 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 for the standalone ZeroWire G2. Radiance Ultra displays harmonic Class A.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	All parameters	The following limits apply: <ul style="list-style-type: none"> <li>• The value of Pst. shall not be greater than 1.0</li> <li>• The value of Plt shall not be greater than 0.65</li> <li>• The value of d(t) during a voltage change shall not exceed 3.3% for more than 500ms</li> <li>• The relative steady voltage change, dc, shall not exceed 3.3%</li> <li>• The maximum relative voltage change, dmax, shall not exceed:               <ul style="list-style-type: none"> <li>a) 4% without additional conditions.</li> <li>b) 6% for equipment which is:                   <ul style="list-style-type: none"> <li>- switched manually, or</li> <li>- switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.</li> </ul> </li> </ul> </li> </ul>

# Electromagnetic Immunity

## Guidance and Manufacturer's Declaration: Electromagnetic Immunity

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

Immunity test	Test Level Professional Healthcare
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±2, 4, 6, 8, 15 kV air discharge
Radiated RF field IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM 1 kHz
Proximity fields from wireless transmitters IEC 61000-4-3	80MHz to 2.7 GHz. 3V/m Spot Tests: 385 MHz. at 27V/m; (710, 745, 780, 5240, 5500, 5785) MHz. at 9V/m; (450, 810, 870,930, 1720, 1845, 1970, 2450) MHz. at 28V/m
Electrical fast transient / burst IEC 61000-4-4	±2 kV, AC mains ±1 kV, I/O ports 100 kHz PRR
Surge IEC 61000-4-5 AC mains, Line to Ground AC mains, Line to Line	±0.5, 1, 2 kV ±0.5, 1 kV
Conducted RF IEC 61000-4-6	3 V (0.15 - 80 MHz) 6 V ISM Bands 80% AM 1 kHz
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m - 50 or 60 Hz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% dip, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods (50/60 Hz) Interrupt 100% drop, 5 sec

### Note:

- 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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## Recommended Separation Distances

### Recommended Separation Distances Between Portable/Mobile RF Communications Equipment and the Product

This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product 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)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

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.

#### Separation Distance Notes

**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.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the (ME EQUIPMENT or ME SYSTEM), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**WARNING:** Combinations of accessories that are not listed in the instruction manual may only be used if they are intended exclusively for a given use and do not affect the performance, safety, and EMC characteristics of the medical device.