
Appendix D – EMC Compliance

This system complies with IEC60601-1-2 (2nd Edition - 2001) EMC standard for medical electrical equipment.

D.1 General Scope

The System is suitable to be used in the electromagnetic environment, within the limits & recommendations shown in the following tables:

- [Table D-1 – Emission Declaration on page D-4.](#)
- [Table D-2 – Immunity Declaration on page D-5.](#)

Note	This system complies with above-mentioned EMC standard when used with the standard supplied cables.
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D.2 Electromagnetic Emission

See [Table D-1 – Emission Declaration on page D-4](#)

D.3 Electromagnetic Immunity

- [Table D-2 – Immunity Declaration on page D-5](#)
- [Table D-3 – Immunity Declaration on page D-6](#)
- [Table D-4 – Separation Distances on page D-7](#)

D.3.1 Limitations Management

Adhering to the distance separation recommended in [Table D-4](#), between 150KHz & 2.5GHz, will reduce disturbances recorded at the image level but may not eliminate all disturbances. However, when installed and operated as specified herein, the system will maintain its essential performance by continuing to acquire, display, and store diagnostic quality images safely.

D.4 Limitations of Use

D.4.1 External Components

The use of accessories, transducers, and cables other than those specified may result in degraded **Electromagnetic Compatibility** of the System

D.5 Installation Requirements & Environment Control

In order to minimize interference risks, the requirements listed below apply.

D.5.1 Cable Shielding & Grounding

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

D.5.2 Radiated Emissions

This product complies with the radiated emission specifications CISPR11 Group1 Class A standard limits.

The System is predominantly intended for use, in non-domestic environments, and not directly connected to the Public Mains Network. The System is predominantly intended for use (e.g. in hospitals) with a dedicated supply system, as described in the site preparation manual.

D.5.3 Power Supply Distribution - Subsystem & Accessories

All components, accessories subsystems, systems which are electrically connected to the System, must have all the AC power supplied by the same power distribution panel & line.

D.5.4 Stacked Components & Equipment

The System should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the System should be observed in order to verify normal operation in the configuration in which it will be used.

D.5.5 Static Magnetic Field Limits

In order to avoid interference on the System system, static field limits from the surrounding environment are specified below.

Static field must be less than <1 Gauss in Examination room and in the Control Area.

Static field must be less than <3 Gauss in the Technical Room.

D.5.6 Electrostatic Discharge Environment & Recommendations

In order to reduce electrostatic discharge interference, install a charge dissipative floor material to avoid electrostatic charge buildup.

The relative humidity shall be at least 30 percent.

The dissipative material shall be connected to the system ground reference, if applicable.


Table D–1: Emission Declaration

EMC Emissions Guidance & Declaration for the System		
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The System 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.
Harmonic emissions IEC 61000-3-2	Not applicable	The System is suitable for use 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.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table D–2: Immunity Declaration

EMC Immunity Guidance & Declaration for System			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line-line ± 2 kV line-earth	± 1 kV line-line ± 2 kV line-earth	Mains 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	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.
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 characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table D–3: Immunity Declaration con't

EMC Immunity Guidance & Declaration for System			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3 (alternative method: IEC 61000-4-21)</p>	<p>3 V_{RMS} 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V_{RMS} 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = \left[\frac{3,5}{3} \right] \sqrt{P}$ <p>(see Table 4)</p> $d = \left[\frac{3,5}{3} \right] \sqrt{P}$ <p>80 MHz to 800 MHz (see Table 4)</p> $d = \left[\frac{7}{3} \right] \sqrt{P}$ <p>800 MHz to 2,5 GHz (see Table 4)</p> <p>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 (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>^a 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 System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Note

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

Table D–4: Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the System			
The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power (P) of Transmitter Watts (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3,5}{3}\right]\sqrt{P}$	$d = \left[\frac{3,5}{3}\right]\sqrt{P}$	$d = \left[\frac{7}{3}\right]\sqrt{P}$
	Separation Distance meters	Separation Distance meters	Separation Distance meters
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3
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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

