

**Table 1 – Guidance and MANUFACTURER’S declaration – ELECTROMAGNETIC EMISSIONS –
for all ME EQUIPMENT and ME SYSTEMS**

Guidance and manufacturer’s declaration - electromagnetic emissions		
The BI-Phasic Impulsator models F00012-HT and F00012 –HT2 is intended for use in the electromagnetic environment specified below. The customer or the user of the BI-Phasic Impulsator should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The models F00012-HT and F00012 –HT2 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 B	The Model models F00012-HT and F00012 –HT2 is suitable for use in all 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	Class A,	Not Applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	Not Applicable

Table 2 – Guidance and MANUFACTURER’S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic immunity			
The Models F00012-HT and F00012 –HT is intended for use in the electromagnet environment specified below. The customer or the end user of the Model F00012-HT and F00012 –HT2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electromagnetic 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 differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ 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 Model F00012-HT and F00012 –HT2 requires continued operation during power mains interruptions, it is recommended that the Model F00012-HT and F00012 –HT2 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.

Table 4 – Guidance and MANUFACTURER’S declaration – electromagnetic IMMUNITY – for BI-Phasic Impulsator models F00012-HT and F00012 –HT2 that are not LIFE-SUPPORTING


Guidance and manufacturer’s declaration - electromagnetic emissions			
The Models F00012-HT and F00012 –HT2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model F00012-HT and F00012–HT2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Models F00012-HT and F00012 –HT2 including cables, than the Recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.7 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz $d = [3.5/V1] \sqrt{P}$ 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 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. Interference may occur in the vicinity of equipment marked with the following symbol: <div style="text-align: center;">  </div>
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz	3 Vrms	
NOTE 1 At 80 MHz and 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.			
^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 Models F00012-HT and F00012 –HT2 is used exceeds the applicable RF compliance level above, the Model EVL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Models F00012-HT and F00012 –HT2 ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for Phasic Impulsator models F00012-HT and F00012 –HT2 that are not LIFE-SUPPORTING

Recommended separation distance between Portable and mobile RF communications equipment and the model @ 3Vrms			
The models F00012-HT and F00012 –HT2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Models F00012-HT and F00012 –HT2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Models F00012-HT and F00012 –HT2 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 $d = \left[\frac{3.5}{v_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.34	0.34	0.74
1	1.7	1.7	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3
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 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 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			