

Technical description EN/IEC 60601-1-2, clause 6

Table 201: Emission

Guidance and manufacturer's declaration – electromagnetic emissions		
The therapy device BIOPTRON Pro 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the BIOPTRON Pro 1 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BIOPTRON Pro 1 uses RF energy only for its internal function. Therefore, its RF emissions is very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BIOPTRON Pro 1 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complied	

Table 202: Immunity (all devices)

Guidance and manufacturer's declaration – electromagnetic immunity			
The BIOPTRON Pro 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the BIOPTRON Pro 1 should assure that it is used in such an environment.			
Immunity test standard	IEC 60601 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5s	<5 % U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5s	Mains power quality should be that of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 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.

Table 204: Immunity (not life-supporting devices)


Guidance and manufacturer's declaration – electromagnetic immunity			
The BIOPTRON Pro 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the BIOPTRON Pro 1 should assure that it is used in such an environment.			
Electromagnetic environment - guidance			
Portable and mobile RF communications equipment should be used no closer to any part of the BIOPTRON Pro 1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	V1 = 10 Vrms 150kHz to 80MHz	$d = 0,35 \sqrt{P}$ 150kHz to 80MHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 800MHz	E1 = 10 V/m 80MHz to 800MHz	$d = 0,35 \sqrt{P}$ 80MHz to 800MHz
Radiated RF IEC 61000-4-3	3 V/m 800MHz to 2,5GHz	E2 = 7 V/m 800MHz to 2,7GHz	$d = \sqrt{P}$ 800MHz to 2,7GHz
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).			
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			
Interference may occur in the vicinity of equipment marked with the following symbol:			
			
Note 1:	At 80MHz and 800MHz, 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 BIOPTRON Pro 1 is used exceeds the applicable RF compliance level above, the BIOPTRON Pro 1 or the device, which contains it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device containing the BIOPTRON Pro 1.		
^b	Over the frequency range 150kHz to 80MHz, field strengths should be less than 10 V/m.		

Table 206: Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the BIOPTRON Pro 1			
The BIOPTRON Pro 1 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BIOPTRON Pro 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BIOPTRON Pro 1 as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d = 0,35 \sqrt{P}$	80MHz to 800MHz $d = 0,35 \sqrt{P}$	800MHz to 2700MHz $d = \sqrt{P}$
0,01	3,5cm	3,5cm	10cm
0,1	11cm	11cm	32cm
1	35cm	35cm	1m
10	1,1m	1,1m	3,2m
100	3,5m	3,5m	10m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.			
Note 1:	At 80MHz and 800MHz, 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.		