


OSTEOSPINE TECHNICAL SHEET

TYPE	Bone Growth Stimulator
MANUFACTURER	IGEA S.p.A. 41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy
MODEL	OSTEOSPINE
TECHNICAL DATA	
Power supply	Equipment supplied by the internal power source: NiMH rechargeable battery Generator supply voltage : 9 VDC (NiMH battery 150mAh) Max. absorbed current : 0,010 A Generator max. power : 1,0VA External power supply : 100-240 VAC 50-60Hz
Applied Part	Biocompatible adhesive electrodes supplied by the Manufacturer IGEA
Output signal	Sinusoidal signal with impulse train: Electrode piloting frequency : 12,5Hz (80 msec) Duty Cycle = 50% (operational time : 40 msec) Therapeutic signal frequency : 59 KHz +/-5% Therapeutic signal Maximum range : 20 Vpp (effectively 7 V) Charge Impedance validity field : 500 Ω – 7000 Ω (at nominal frequency) Maximum electrode output current = 1500µA (effective value)
Dimensions Weight	L x W x P = 80 x 100 x 30 mm 150 g (generator only)
Classification (EN 60601-1)	Class II with Applied Part of Type BF Appliance for continuous use not to be used where there is danger of explosion Equipment supplied by the internal power source Appliance with casing having a degree of protection IP10
Classification Directive 93/42	Ila
Standard Compliance	EN 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance); EN 60601-1-2 (Electromagnetic Compatibility); EN 60601-1-6 (Usability); EN 62304 (medical device software); EN 60601-1-11 (Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment); Medical Device Directive 93/42/CEE e Amending Directive 2007/47/EC
Mark	 0051
Environmental conditions of transportation and storage	Atmospheric temperature : - 20 / +70 °C Relative humidity : 10 % - 90% Atmospheric pressure : 500 - 1060 hPa
Environmental conditions of use	Atmospheric temperature : 0 - 40 °C Relative humidity : 30% - 75% Atmospheric pressure : 700-1060hPa

