


## OSTEOSPINE TECHNICAL SHEET

<b>TYPE</b>	Bone Growth Stimulator
<b>MANUFACTURER</b>	<b>IGEA S.p.A.</b> 41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy
<b>MODEL</b>	<b>OSTEOSPINE</b>
<b>TECHNICAL DATA</b>	
<b>Power supply</b>	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
<b>Applied Part</b>	Biocompatible adhesive electrodes supplied by the Manufacturer IGEA
<b>Output signal</b>	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)
<b>Dimensions</b> <b>Weight</b>	L x W x P = 80 x 100 x 30 mm 150 g (generator only)
<b>Classification (EN 60601-1)</b>	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
<b>Classification Directive 93/42</b>	Ila
<b>Standard Compliance</b>	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
<b>Mark</b>	 0051
<b>Environmental conditions of transportation and storage</b>	Atmospheric temperature : - 20 / +70 °C Relative humidity : 10 % - 90% Atmospheric pressure : 500 - 1060 hPa
<b>Environmental conditions of use</b>	Atmospheric temperature : 0 - 40 °C Relative humidity : 30% - 75% Atmospheric pressure : 700-1060hPa

