


FAST TECHNICAL SHEET

DEVICE TYPE	ULTRASOUND BONE GROWTH STIMULATOR
MANUFACTURER	IGEA S.p.A. 41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy
NAME	FAST
MODEL	UBHS-01
TECHNICAL SHEET	
Power Supply	Input voltage : 100-240 VAC (230VAC) Mains frequency : 50-60Hz Max. absorbed power : 0,100 A Max. output voltage : 23,0VA
Applied Part	US transducer (Treatment head)
Features of the US transducer piloting signal	Impulsive square wave signal with a frequency of 1.5 MHz Pulse width = 200 µsec (Duty Cycle = 20%) Modulation: Pulse trains with repetition frequency = 1Khz
Features of US transducer & US Beam	Stainless steel cylindrical Container with a height of 15mm and diameter of 32 mm; Resonant crystal of piezo-composite material of 25 mm in diameter; Bi-polar shielded connecting cable Nominal output power: 149 mW ± 12% Effective radiating area – ERA: 5,1 cm ² ±12% Beam Non-Uniformity Ration BNR: 4,3 Beam Type: Collimated Isata: 30 mW/cm ² Max. temporal Intensity: 0,73 W/ cm ² Maximum power: 3,7 W
Dimensions Weight	L x W x H = 210 x 100 x 70 mm (Generator) 1,150 Kg (Generator+Power Supply)
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 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	
Environmental conditions of transportation and storage	Atmospheric temperature : -40 a +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

