## TYPE
Bone Growth Stimulator

## MANUFACTURER
IGEA S.p.A.  
41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy

## MODEL
OSTEOBIT

### 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 ß – 7000 ß (at nominal frequency)
  - Maximum electrode output current = 1500µA (effective value)

#### Dimensions
- L x W x P = 80 x 100 x 30 mm
- Weight: 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
- IIa

### 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);

#### Mark
- C E 0061

### 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

Written by Viller Righi – Ufficio Tecnico  
Approved by Marco Lusvardi – Direttore Produzione