9. Technical Specifications and Classifications

9.1 Technical Specifications

Physical Dimensions
Size (H x W x D): 6.0" x 3.75" x 1.75" / 15.24 cm x 9.53 cm x 4.45 cm
Weight: 1.0 lbs / 0.45 kg

Transport and Storage
– 25°C to + 5°C, and
+ 5°C to + 35°C at a relative humidity up to 90 %, non-condensing;
> 35°C to 70°C at a water vapour pressure up to 50 hPa

Environmental Conditions
Operating Temperature: + 5°C to + 40°C;
Relative Humidity: 15 % to 90 %, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa; and
Atmospheric Pressure: 700 hPa to 1060 hPa.

Signal Output
Feed Frequency 1: 3858 Hz
Feed Frequency 2: 3980 Hz
Output Voltage Range: 0 – 27.5 V rms
Maximum Output: 27.5 VAC RMS at 110 mA AC RMS for a 250 Ω load
Waveform: Sum of 2 sine waves. The output waveform retains its integrity, harmonic content and instant voltage level into a biological load with an impedance range from 250 Ω to 1000 Ω

Power Source
2 - 3.2 V DC, 3300 mAh rechargeable $LiFePO_4$ batteries
Provides 2 hours of power at 80% output into 500 Ohms

Expected Service Life
Expected service life of the device is 5 years. When exhausted, dispose of device properly and in accordance with local codes and regulations.

Leadwire Cable
Rating complies with 21 CFR Part 898
(performance standards for electrode leadwires)

AC Charger
The stimulator must only be used with the universal AC Charger provided:
V-Infinity Model # EPSA090130U-P5P-EJ Power Adapter, or
Globtek Model # WR9HD1500C9PG2970(R).
9V DC, 1.3-1.5A, Power Output 12W, Cord Plug 2.1mm I.D. x 5.5mm O.D. x 9.5mm Female. Operating Altitude: 5000m. CE and UL Mark Listed.

Applied Parts

BioWave Noninvasive Electrodes
BioWave® Noninvasive Electrodes are of a silver/carbon construction with a pre-applied hydrogel and are cleared for marketing under 510(k) numbers K052289, K072123 and K152437.

BioWave Percutaneous Electrodes
BioWave Percutaneous Electrodes are supplied sterile via gamma radiation and are comprised of a 1.5 inch diameter microneedle array within a 2.5 inch diameter hydrogel-based electrode. The microneedle array is comprised of 1014 microneedles, 0.74 mm in length, made from 316L surgical stainless steel. Cleared for marketing under 510(k) number K061166.

Software Version: 25.2

9.2 Classifications

Before using BioWaveHOME, read this User's Manual.

Protection against electric shock classification: TYPE BF

Rx ONLY For sale by or on the order of a physician.

- Neurotimulator is internally powered.
- AC Charger (power supply) is classified as Class 2.
- Mode of operation is continuous.
- Stimulator is not protected for use with flammable anesthetics.
- Protection against liquid ingress: IP21- dripping water (vertically falling drops) shall have no harmfull effect. Unit is protected against objects >12.5mm.
- Neurotimulator conforms to all requirements of the following standards:

  EN 60601-1:2006+A1:2013
  EN 60601-2-10:2015+A1:2016
  EN 60601-1-6:2010
  EN 60601-1-11:2010
  EN 60601-1-2:2015
  UL 60601-1 CSA C22.2 No. 601.1