

9. Technical Specifications & Classifications

9.1 Technical Specifications

Physical Dimensions

Size (H x W x D): 4.0" x 3.0" x 1.0" / 10.16 cm x 7.62 cm x 2.54 cm

Weight: 0.375 lbs / 0.17 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: + 0°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: 3940 Hz

Feed Frequency 2: 4062 Hz

Output Voltage Range: 0 – 20.0 V rms

Maximum Output: 20.0 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 350 Ω to 1200 Ω

Software Version: 3.4

Power Source

3.2 V DC, 1200 mAh rechargeable LiFePO₄ battery
Provides 3 hours of power at 100% output into 500 Ohms
Battery cannot be changed by the user.

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.

AC Charger

The stimulator must only be used with the universal AC Charger provided:
5V DC, 1.0A, Power Output: 5W, Input Voltage: 90-264 VAC, Frequency 50-60Hz
Cord Plug 2.1 mm I.D. x 5.5mm O.D. x 14 mm Female. CE and UL Mark Listed.

Leadwire Cable

Rating complies with 21 CFR Part 898
(performance standards for Pain Relief Pad leadwires)

Applied Parts - BioWave Noninvasive Pain Relief Pads

BioWave Noninvasive Pain Relief Pads 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 Noninvasive Pain Relief Pads are a type BF applied part complying with IEC 60601-1.

Safety

BioWaveGO 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

Risk of injury if used improperly. The stimulator can produce physiological effects.

Bluetooth®

The Bluetooth word, mark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by BioWave Corporation is under license. Communication between the BioWaveGO Device and the Smartphone is via Bluetooth.

9.2 Classifications

 Before using BioWaveGO, read this User's Manual.

 Protection against electric shock classification: TYPE BF

- Protection against liquid ingress: IP22- vertically dripping water when tilted at an angle of up to 15 degrees shall have no harmful effect. Unit is protected against objects >12.5mm.
- Stimulator is internally powered.
- AC Charger (power supply) is classified as Class 2.
- Mode of operation is continuous.

Bluetooth Specifications

| | | | |
|-----------------------|---|------------------|-----------------|
| FCC ID: | 2ASDQBWG-S | FCC Rules: | Part 15C |
| Hardware: | PSOC CY8C4248LQI-BL553 with BLE Low-Energy Radio | Frequency Range: | 2402.0 - 2480.0 |
| Transmit Power: | +0 dBm | Output Watts: | 0.001W |
| Receiver Sensitivity: | -89 dBm | Security: | Encryption |

FCC Statements

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radi-ate radio frequency energy and, if not in-stalled and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.