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Acumed Medical, Ltd.
Toronto, Canada

To Whom It May Concern,

I have anaylyzed the device you sent me. It has two distinct modes of operation, a search phase and a treatment phase. The search phase locates points of low skin resistance which often correspond to underlying neural structures. The output of the unit in this mode is an approximate square pulse of 1V amplitude with a resting level of about -2 volts (thumb plate reference).

The treatment mode produces square pulses with a 50% duty cycle which are either positive (tonify) or negative (disperse) in polarity at a frequency of 2.2 Hz. The amplitude of the pulses was 8V when connected to a 100KΩ load.

TENS is an acronym for Transcutaneous Electrical Nerve Stimulation and is defined as a device which provides pain relief through the application of an electrical current to stimulate peripheral nerves (The Biomedical Engineering Handbook, J Bronzino, ED., Boca Raton:CRC Press Inc., 1995). The Dolphin Neurostim fits all of these requirements:

- The device is electrical, powered by a 9 volt battery and delivers a 2 Hz electrical current in treatment mode
- The current is delivered via a non-invasive electrode; thus it is transcutaneous
- The output current is in the tens of microamps range which is sufficient to activate nerves locally but insufficient to interfere with heart function. Activation of afferent nerves produces signals which travel to the central nervous system and induce biochemical responses in the brain, which have a therapeutic effect. At certain skin points, activation of sensory nerves is experienced as a noxious sensation when the unit is in treatment mode.
- The unit has been clinically proven to be an effective tool in pain management

The Dolphin Neurostim fits the criteria of a TENS machine and, thus, should be regarded as such.

In summary, the Dolphin Neurostim satisfies the definition of a TENS device. From an engineering perspective, the device locates points of low skin resistance and produces a nominal 2Hz 8V electrical pulse in treatment mode.

Sincerely

Edward Vigmond

Edward J. Vigmond, Ph.D.