

# Avazzia Neuromodulation Technology

## *Health and Wellness Without Drugs or Surgery*

Avazzia manufactures FDA-cleared microcurrent Biofeedback Electro-Stimulation Technology (BEST) devices which feature non-invasive neuromodulation. This system is based on easily understood concepts: neuro means nerve and modulation means varying the property of a wave or signal. Thus, put together it means changing the signals of nerves.

The human body has three systems for functioning: chemical (changing food into energy, for instance), mechanical (bones and muscles) and electrical (the heart beat is but one example – which is why pacemakers are electrical devices).

Avazzia's BEST devices, all engineered and manufactured in Dallas, TX, use proprietary software and microchips in its neuromodulation applications. This non-pharmaceutical, non-invasive technology is designed to stimulate the body's natural release of nitric oxide, endorphins and neuropeptides into the blood stream.

- Nitric oxide causes vascular dilation and thereby increases blood circulation. This is critical to wound healing, reduction of edema and treatment of diabetic neuropathy.
- Endorphins are the body's natural pain management chemicals.<sup>1,2</sup>
- Neuropeptides are the body's regulatory elements that promote accelerated healing.<sup>3</sup>

Avazzia BEST electrical signals, different than other TENS signals, allow this to happen because:

- They are short duration pulses of high voltage amplitude and very low duty cycle.
- The average currents are in the microcurrent range.
- These are damped biphasic, sinusoidal waveforms.
- The process is further enhanced by signals that change and adapt as the electrical properties of the tissue being treated change (biofeedback readings).

BEST™ devices stimulate the neuro-endocrine system through direct touch to the skin. The BEST™ device electrodes (onboard or through accessories) can detect (via biofeedback) impedance on skin by "sticking" (dramatic increase in friction) to acupuncture or electron deficient sump points when gliding the instrument over the skin.<sup>4,6</sup>

These "sticky" areas may be injured or diseased tissue or may be associated with an organ or corresponding body system. By placing the BEST™ electrodes at a correct spot for treatment, equilibrium between tissues and organs is restored, and the redox (reduction-oxidation) potential of the body is recharged.

Published medical research has identified the electrical signal characteristics that impact "C" fibers,<sup>7</sup> resulting in the stimulation of nitric oxide, hormones, endorphins and neuropeptides. Other publications indicate the signal characteristics and treatment locations that balance the sympathetic and parasympathetic nervous systems.<sup>8</sup>



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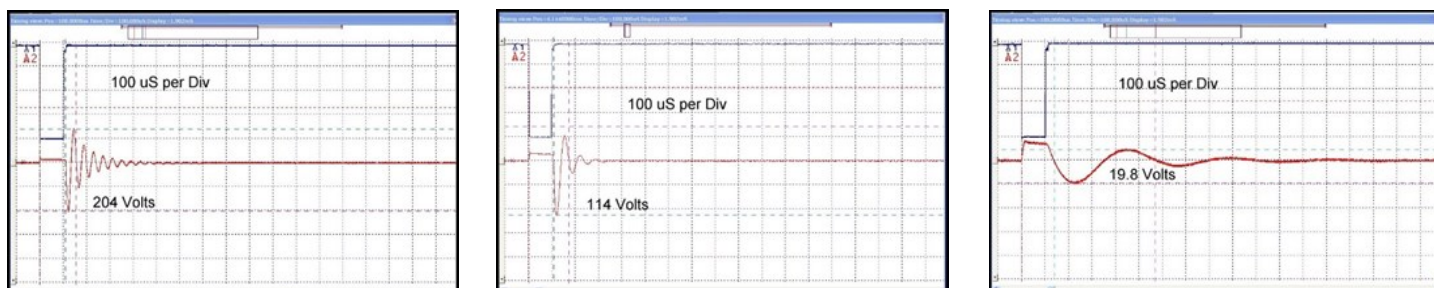
These electrical signal properties are attained by using Avazzia's proprietary algorithms that produce specific patterns of output pulses for specific applications.

#### Results:

- AVAZZIA technology quickly provides relief of chronic and other pains. (Appendix A)
- The pain relief is long lasting, up to 12 hours, and frequently longer.
- BEST technology, through its biofeedback feature, modifies waveforms to eliminate habituation or accommodation by the body.

BEST is a non-invasive microcurrent system that transcutaneously communicates with the internal peripheral nervous system for the purpose of therapeutic intervention.<sup>5</sup> High-speed microprocessors, unknown when electro-stimulation technology was initially created, establish a cybernetic loop between the BEST device and the body. The body's response is measurable, creating information for the loop. When a signal is emitted and penetrates deep into the tissue, the impedance of the tissue (analogous to resistance in DC circuits but dynamic in nature) modulates the next waveform. The degree of modulation is based upon the changes of impedance of skin. This sets up a constantly changing interactive bio-loop processing non-repeating signals. Eventually the change in impedance diminishes in significance until a plateau occurs.

The three charts (below) show Avazzia waveforms of tissue first being treated, midway through treatment and finally, when tissue impedance diminishes and treatment stops.

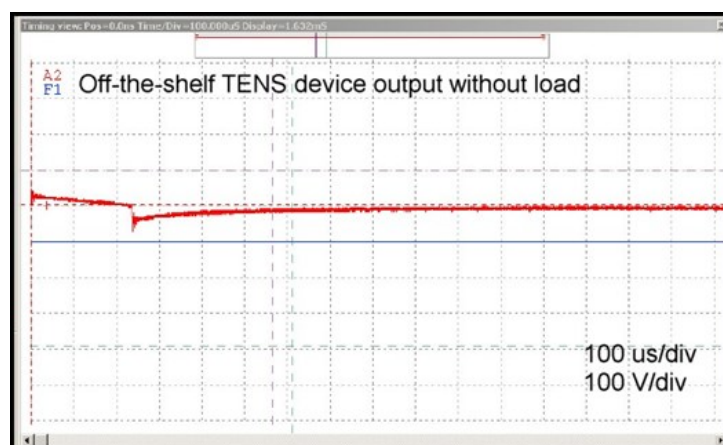


(See Appendix B for comparison chart of BEST and conventional TENS devices.)

#### Avazzia is not just another TENS

TENS was developed for the control of chronic and post-operative pain by saturating subcutaneous nerve receptors with low-intensity electrical stimulation. TENS deliver constant voltage with fluctuating current and resistance/impedance. BEST™ delivers a driving signal based upon the change in microcurrent and impedance over the active pulse interval. Unlike TENS, which relies on constant and externally generated signaling principles, BEST™ is based upon the development of a cybernetic feedback loop.

Conventional TENS work on the pain gate theory by applying a saturating electrical charge to the A and B fibers of the nervous system, thereby blocking the pain message to the brain. Once the stimulation is removed, the pain often returns a short time later. (An oscilloscope reading of a conventional TENS signal is shown, right.)



Avazzia BEST™ (Biofeedback Electro-Stimulation Technology) devices generate electrical impulses that are similar to neurological impulses in the C nerve fibers. These fibers are embedded in tissues and make up 85 percent of all nerves found in the body and to “fast” pain blocking A fibers. (An oscilloscope reading of an Avazzia signal is shown, right.)

### History of TENS Technology

TENS technology can be divided into four eras: early TENS; second generation TENS; third generation (interferential) TENS; and interactive biofeedback TENS.



**Early TENS:** TENS devices developed in the 1930s had mono-phasic square-wave signals and worked at 10 to 500 mA (milliAmpere). This technology has serious drawbacks: habituation (it treated pain for several weeks, after which time the body accommodated or habituated to the stimulation and no longer blocked pain). The other serious drawback was its short period of pain relief (less than one hour). Even though this technology is obsolete, it is still used today and frequently is the only experience patients have with TENS.

**Second Generation TENS:** The technology for this group, developed in the 1970s, has an asymmetrical biphasic square wave output. Biphasic means the signal goes plus and minus relative to a reference voltage. Asymmetrical means the plus and minus signals are not equal in time of application and/or voltage. The improvement over early TENS is that habituation is reduced. Even so, pain relief still is brief (less than an hour). Again, this obsolete technology is still widely available and used today.

**Interferential TENS:** This technology was subsequently developed with asymmetrical, biphasic, and irregular shaped, microcurrent wave outputs. These waveforms result in partial opioid mode and partial pain gate mode. Opioid mode means that the electrical stimulation results in the production by the body of endogenous opioid peptides which mitigate pain. Pain gate mode means the A and B nerve fibers are stimulated to inhibit an individual's perception of pain. This technology improves the duration of pain relief while reducing the likelihood of habituation. This technology is widely used today.



**Interactive Biofeedback Neuromodulation:** This technology, implemented by Avazzia in its premier line of BEST products, incorporates the latest understanding in microcurrent and neuromodulation. It was learned that:

- Pulsed high voltage (>250 volts), low-duty cycle (<10%), microcurrent signals were more effective in stimulating the thin C fibers of the nervous system than square wave signals.
- An asymmetrical wave form reduces habituation.
- The use of electrical biofeedback to adjust the waveform as the electrical properties of the tissue being treated changes further reduces habituation and allows the technology to measure the progress of the treatment and provides information to the medical practitioner.
- Sine wave signals more closely approximate the natural signals in the nervous system.

### MEDICAL PROCEDURES

CHRONIC  
ACUTE  
NEUROPATHY  
ABDOMINAL  
BACK  
SHOULDERS  
NECK  
CARPAL TUNNEL  
REPETITIVE STRAIN INJURIES  
SCAR TISSUE BUILD UP



The following table summarizes the characteristics of the four TENS

Characteristics	Early TENS	2 <sup>nd</sup> Generation TENS	Interferential TENS	Biofeedback Neuro-modulation
				<b>Avazzia's Products</b>
Wave Form				
- Wave Form	Square Wave	Square Wave	Square Wave With Spikes	Damped Sinusoidal
- Biphasic or Monophasic	Monophasic	Biphasic	Biphasic	Biphasic
- Treatment Current	Milliampere	Milliampere	Microampere	Microampere
- Voltage	Low voltage	Low voltage	Pulsed High Voltage	Pulsed High Voltage
- Interactive Biofeedback	No	No	No	Interactive Biofeedback
Habituation	Serious problem	Reduced	Greatly Reduced	Eliminated
Principle Treatment Effects	Pain Gate Mode	Pain Gate Mode	Pain Gate + Opioid Mode	Pain Gate + Opioid Mode
Length of Pain Relief (Hours)	< 1 Hour	< 1 Hour	1 to 2 Hours	12 or More Hours
Diagnostic Indication	No	No	No	Yes

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3. Wolcott LE, Wheeler PC, Hardwicke HM and Rowley BA (1969). "Accelerated healing of skin ulcer by electrotherapy: preliminary clinical results". *Southern Medical Journal* 62 (7): 795–801.PMID 5306004.
4. Johnson C (1999-06-04). "Acupuncture works on endorphins". *News in Science, ABC Science Online*. Australian Broadcasting Corporation. Retrieved 2008-10-15.
5. Boecker H, Sprenger T, Spilker ME, Henriksen G, Koppenhoefer M, Wagner KJ, Valet M, Berthele A, Tolle TR (February 2008). "The Runner's High: Opioidergic Mechanisms in the Human Brain". *Cerebral Cortex* (New York, N.Y. : 1991) 18 (11): 2523–31.
6. Reichmanis M, Marino AA and Becker RO (1975). "Electrical correlates of acupuncture points". *IEEE Transactions on Biomedical Engineering* 22 (Nov;22(6)): 533–5.
7. Purves, Dale; et.al (2004). *Neuroscience*. Massachusetts: Sinauer Associates, Inc.. ISBN 0-87893-725-0.
8. NIH Consensus Development Program (3–5 November 1997). "Acupuncture --Consensus Development Conference Statement". National Institutes of Health. Archived from the original on 14 July 2007. Retrieved 2007-07-17.

#### Appendix A

(See attached "Efficacy of Avazzia BEST Microcurrent Stimulation Device.")

#### Appendix B

(See attached "Avazzia BEST v. Traditional TENS")

