BEST ™* *Avazzia* ™* Technology: a comparison to Trans-cutaneous Electrical Neural Stimulation (TENS)

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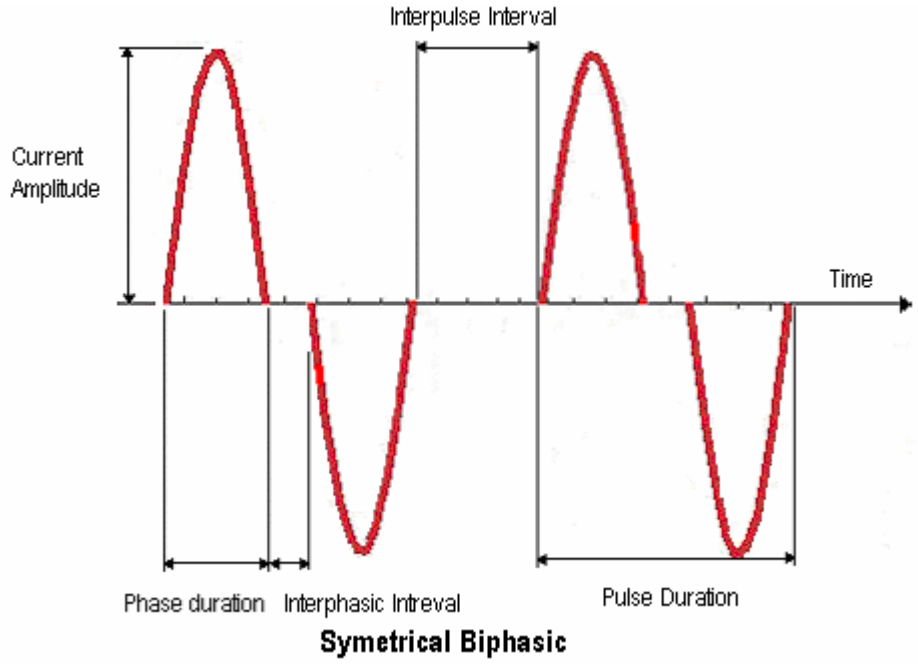
Abstract

Terms to commonly describe electrical waveform components utilized in Trans-cutaneous Electrical Neural Stimulation (TENS) are defined, and a brief description of mechanisms of action of TENS is given. Comparison of Biofeedback Electro Stimulation Technology (BEST™) waveform and neurophysiology is described, and an explanation for its superior therapeutic efficacy based upon up-regulation and enhanced secretion of neuro-peptides from C afferent fibers is affirmed. TENS and BEST are compared and contrasted on a point-by-point basis for the reader to evaluate. BEST is shown to have a direct analgesic effect locally as well as on the CNS. BEST exhibits local and systemic analgesic effects consistent with major aspects of both Gate and DINC theories of pain.

Introduction:



Symetrical Biphasic

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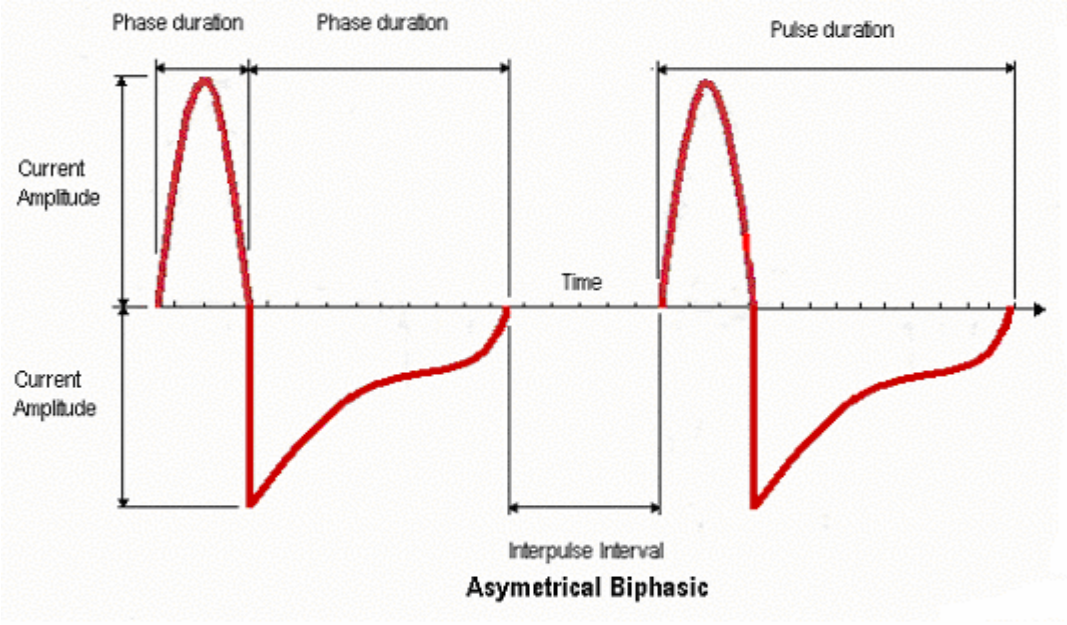
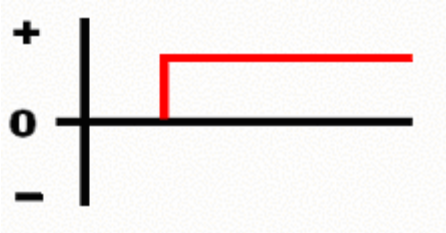


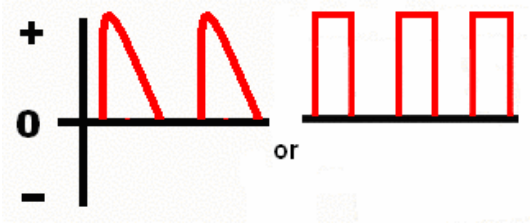
ANATOMY OF A BIOELECTRIC WAVEFORM

An oscilloscope can be utilized to visualize the shape of pulsed electrical currents like those demonstrated above, in order understand and discuss their nature. The following terms are used to define their form and components. TENS units utilize either a monophasic or an asymmetrical biphasic waveform. The phase curves are skewed and asymmetrical with respect to each other. The positive and negative cancel each other out leaving a net skin charge of zero. In the transmitting phase (positive inbound) current travels through the positive electrode into the tissue, and during the balancing (returning) phase the current returns.

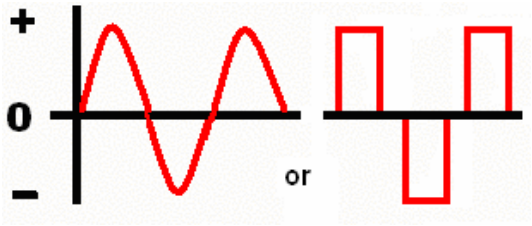
Commonly Utilized Therapeutic Waveforms in Electro-medicine



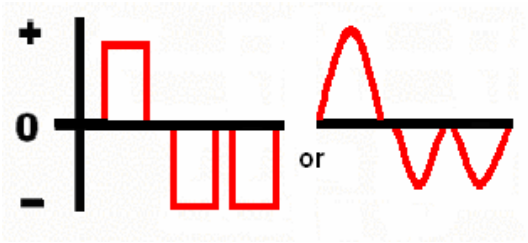
Monophasic direct or galvanic current is a continuous constant voltage and current used for iontophoresis (delivery by electrically driving a drug directly into a targeted tissue) and wound healing. Micro-current stimulation also utilizes this type of signal.



Examples of monophasic pulsed galvanic or interrupted DC current used for powered muscle stimulators, edema reduction, micro-current stimulation (where pulse duration may last for minutes to hours) and wound healing.

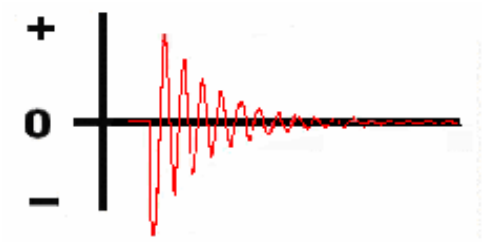


Examples of biphasic symmetrical sinusoidal and square wave AC current used for pain control and/or powered muscle stimulation.

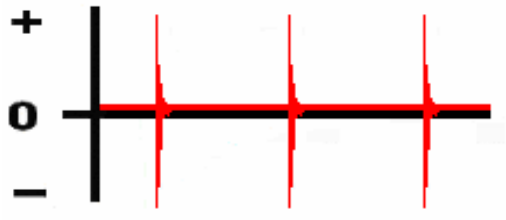


Triphasic symmetrical square or polyphasic asymmetrical sinusoidal and many variations are used for edema and pain control

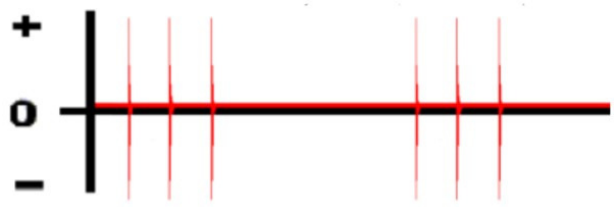
An example of an asymmetrical skewed biphasic sinusoidal wave used for pain control and powered muscle stimulation. The phase interval is not equal but the net charge is zero.



BEST damped, biphasic, asymmetrical sinusoidal high voltage AC signal used for pain control, muscle stimulation, wound healing, high versatility and exceptional resistance to neural accommodation and habituation due to impedance modulation.



BEST damped, biphasic, asymmetrical, sinusoidal, high-voltage AC pulses of intense pulses with a long inter-cluster interval and a short a short duty cycle



BEST damped, biphasic, asymmetrical, sinusoidal, high-voltage AC signals clustered into relatively narrow clusters of intense pulses with a long inter-cluster interval and a short a short duty cycle

DEFINITIONS

Amplitude: The magnitude of the current. Measured in peak milliamps

Phase Duration: The time elapsed from the beginning to the termination of one phase of a pulse. Measured in micro-seconds (µsec.)

Pulse Duration: (Pulse Width): The time elapsed from the beginning to the end of all phases plus the inter-phase interval within one pulse. Measured in micro-seconds (µsec.)

Inter-phase Interval: (Intra-pulse Interval) The time between two successive components of pulse when no electrical activity occurs-measured in microseconds (µsec.)

Inter-pulse Interval: The time between two successive pulses.

Pulse Rate: The number of pulses per measure of time (one second). Also referred to as frequency, measured in hertz (Hz).

Frequency (Rate): defined as cycles or pulses per second (Hertz or Hz.).

Micro-current Therapy (Microamperes): Uses low output current, wide pulse width. Output current is usually less than 600 micro-amps, with some units in the feta amp range.

Micro-coulomb: The total accumulated energy in a pulse determined by amplitude (mA) x the width (µsec.).

M**odulation:** variation in waveform parameters by manual or automatic control (frequency, pulse duration, and/or amplitude) for more efficient stimulation of tissue and prevention of neural accommodation and habituation phenomenon.

Cluster Mode: A series of higher frequency pulses delivered in clusters at a low frequency and a large inter-pulse interval imposing a relatively low on/off duty cycle.

Waveform: A graphic display of stimulation pulses seen on an oscilloscope. Usually depicted as amplitude (current or voltage) vs. time (sec) event.

Amplitude adjustment (intensity): (Toggle Control found on BEST units): Ramps amplitude of stimulation current, both up and down, to improve user comfort and accommodate maximum stimulation.

Faradic Current: Alternating biphasic current (AC) used for pain control and to resists neural accommodation.

Galvanic Stimulation: Pulsed or continuous direct (DC) or mono-phasic current which delivers electrical energy (net DC) to the tissue. Mainly used for edema reduction (increasing lymphatic drainage) and increasing or decreasing perfusion to a local area.

Voltage: Electromotive force that drives charged particles in a current. Measured in volts.

Current: The flow of charged particles past a given point per unit time. Positive current flows from positive to negative potential. Measured in "milliamps" (mA).

Impedance: Analogous to "resistance" in DC circuits but applies to AC circuits whereby resistance becomes a dynamic value based upon changing dielectric properties of the tissues through which current traverses. Measured in "ohm's". Tissues that possess high impedance to the flow of current are skin, fat etc.

Ohm's Law: $\text{Current} = \frac{\text{Voltage}}{\text{Resistance}}$ $\text{Amps} = \frac{\text{Volts}}{\text{Ohms}}$

Neural Accommodation: the rise in the threshold during the passage of a constant, direct electric current because of which only the make and break of the current stimulates the nerve. [3]

Neural Habituation: 1.) The gradual adaptation to a stimulus. 2.) Extinction or decrease of a conditioned neural reflex over time by repetition of the conditioned stimulus.

Law of Dubois-Reymond[◈]**:** To electrically stimulate a nerve, there must be a sudden variation in current flow to prevent neural accommodation.

Cybernetics: the science of communication and control processes within systems. Control is based on communication both within the system and with the external environment and influences the actions of the system to bring it into some desired future state or to maintain homeostasis. Cybernetics includes the concepts of auto-regulation and feedback as well as the transmission and self-correction of information, and can be applied not only to machines like computers but also to living organisms, including humans, and to complex organizations and societies. [i]

DNIC (Diffuse Noxious Inhibitory Control) theory of pain: Based upon the observation that pain in one part of the body inhibits pain responses in other parts. The spinal cord dorsal horn exhibits this effect on a wide range of neurons is termed DNIC (diffuse noxious inhibitory control) or also termed 'counter irritation'.

Although BEST™ appears to generate both ascending stimulation of the CNS through afferent ascending C-fibre pathways into the spine and descending efferent opiod inhibitory pathways (gate theory). Other effects from BEST favour systemic action through neuro-endocrine effects of blood borne neuropetides (NP) particularly on the GI tract as well as electrical stimulation of acupuncture and/or meridian pathways especially when the unit comes in contact with a point or meridian. Some aspects of the DNIC theory are consistent

◈ Father of modern electrophysiology, he conducted foundational research on electrical activity in nerves and muscles. German Physiologist 1818-1896

for explaining BEST, such as activation of 'C' fibres for NP secretion and up-regulated synthesis. (BEST is unlike acupuncture (AP), in that AP generally activates myelinated 'A-delta' and Type III muscle afferents, although BEST may have a "spill over" effect on such fibres). DNIC shows a rapid onset and short after-effect, starting immediately and lasting only several minutes after conditioning stimulus ends. BEST is not consistent with DNIC in the respect that DNIC is relatively short-lived whereas the analgesic effect of BEST can last from 12 hours to several days after one usage, due to the prolonged and continuing NP cascading.

Gate theory of pain postulates that in each dorsal horn of the spinal cord there is a gate-like mechanism which inhibits or facilitates the flow of afferent pain impulses into the spinal cord before it evokes pain perception and response. Opening or closing of the 'gate' is dependent on the relative activity in the large diameter myelinated (A-beta) and small diameter fibres (A-d and C)'. Activity in the large diameter myelinated fibres tend to close the 'gate', and activity in the small diameter fibres tending to open it. TENS unit operation is consistent with this theory. Entry into the CNS can be viewed as a gate which is opened by afferent pain impulses and closed by TENS low intensity stimulation. (See section on mechanisms of pain)

Comparison of TENS to BEST

CONVENTIONAL TENS	BEST
Signals in the frequency tange of 1Hz to 100 Hz, low intensity pulses, activation of Type I and A-β afferent fibers based upon Gate control theory mechanism and signal blocking or diversion	Signals in the frequency tange of 1Hz to 500 Hz, high intensity pulses, direct effect on secretory C fibers, also significant CNS effects via C afferents to spinal ascending and opiod mediated descending inhibitory pathways.
Mono-phasic or asymmetrical biphasic waveform	Damped asymmetrical biphasic sinusoidal waveform
Low intensity activates large muscle (type I) and large skin A-β nerves for Gate effect	High intensity, short duration pulses, induces neuropeptide release, initiates long term cascading effects and up-regulation of NP, endorphin, serotonin, and enkephalin synthesis.
Segmental effects based on Gate Theory: large diameter fibers inhibit pain from small fibers.	Non-segmental and segmental effects: neuropeptide cascade initiated by small C fibers act generally as well as locally: in spine, brainstem and CNS.
Analgesia starts within a few moments of stimulation and disappears within seconds of switching the machine off. TENS must be	Analgesia starts within moments and lasts up to twelve hours with both local and systemic pain relief

used for long periods of time for sustained relief.	
High intensity of most TENS devices can cause burning of skin	BEST will typically not burn the skin as easily.
Pads are placed near the site of pain as large diameter fibers are widely distributed.	No Pads are necessary as the electrode on the unit both transmits and receives. The unit can be placed on acupuncture points or over subcutaneous large diameter nerves as well as directly on areas of interest or pain. Probes for point source delivery are available. For Convenience, pads and conductive garments are attachable.
Tolerance (accommodation and habituation phenomenon) develops over time	Because of dynamic waveform and cybernetic feedback no habituation or accommodation develops
Prolonged duty cycle, long durations of "on" operation compared to off	Short duty cycle with BEST. Typical unit is off over 99% of the time and emits burst signals less than 1%
TENS is constant voltage signal with variable changes in current and resistance/ impedance over the pulse interval	BEST delivers signals with voltages and currents varying as the impedance of the skin is changed as result to prior stimulation pulses.
External control with no bio-feedback modulation of the output signal. TENS signaling is constant although some models have a fixed external program that varies of signaling to resist accommodation or habituation.	Cybernetic loop whereby BEST and the patient's neurological system form a mutually interacting communication and control system via automatic bio-feedback and impedance signaling of affected tissues.

TENS was developed for the control of chronic and post-operative pain by saturating sub-cutaneous nerve receptors with low-intensity, electrical stimulation in order to effect a specific dermatome or anatomical segment where the main source of pain resides. TENS delivers constant voltage with fluctuating current and resistance/impedance where as BEST™ delivers a driving signal based upon the change in micro-current 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.

Cybernetics is the theory of interacting automatic control systems. The nervous system/brain can be viewed as an automatic communication and control system utilizing electrochemical impulses as signals. *BEST*™ is also an electrical control system, external to the body, which interfaces directly with the skin and trans-cutaneously communicates with the internal peripheral nervous system for the purpose of therapeutic intervention. This is possible because of the development of modern high-speed microprocessors, which are able to establish a "cybernetic loop" between electronic instrument and living body. The body's response can be measured with respect to a signal sent out from the instrument to initiate 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. [ii] The degree of modulation is based upon the changes of impedance of skin as signals are applied. This sets up a constantly changing interactive bio-loop possessing non-repeating signals. Eventually the change in impedance diminishes in significance until a plateau occurs.

BEST-Overcoming Neural Habituation/Accommodation to Therapeutic Stimuli

Afferent neurons exhibit phenomenon known as ***neuronal habituation***-where refractoriness develops to repeated stimuli.[3o] The nerve no longer responds to predictable signals and either ignores them or develops alternative neural pathways to circumvent the stimuli and continue to transmit pain, or aberrant signals to the CNS. Therefore, bombarding tissue with repeated, uniform and predictable signals such as those utilized by TENS units eventually become useless in stimulating nerve fibers to release secretions.

Law of Dubois-Reymond[◈]**:** To electrically stimulate a nerve, there must be a sudden variation in current flow to prevent accommodation.

Systematic variation of the pulse amplitude, frequency, interval, and clustering such that no two impulses exhibit the same waveform, discourages neural habituation. In the course of treatment, waveforms emitted from a BEST™ device are continuously changing (if it is repeated it reappears only after a lengthy interval) and is different due to the cybernetics and the changes and responses of the body. Moreover the impedance of the effected tissue is constantly modulating the waveform of the next emitted signal to ensure a different signal until change in impedance is so negligible as to be insignificant. Signal saturation is achieved. Cascading effects and up-regulation of the synthesis function of the C-fiber cell and other types of neurons will continue for many hours to days. An important response to a *BEST*™ impulse is the release of regulative neuro-peptides and cytokines. The signal stream, comprising waveform, signal strength, voltage, current, and frequency, can be varied in a number of ways, either through pre-section by the operator or automatically by the software programmed into the device. The "dosage" can be delivered automatically or over-ridden at the discretion of the operator, with guidance from visual and audio indicators. Digital LED and sound displays or both give guidance to the operator as dynamic real time indicators of function and endpoint achievement of objectives.

A single pulse may be pre-selected for a specific repeat rate over a specific frequency range. The signal may also be "modulated" either by altering the ratio of "time-on" to "time-off"

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signaling or by changing the pulse waveform by selecting one of a series of set damping factors. These "modulations" can either be applied individually or together. Each individual impulse has been adjusted for amplitude, frequency, and dampened waveform.

A cluster of pulses may be packaged into discrete bursts and which may be repeated at a fixed frequency and interval. The individual pulses in these cluster bursts themselves have been modulated for either random or periodic interval spacing to give a concentrated (deep) or diffuse (shallow) penetration.

Automatic cycling of both the pulse interval rate over a set frequency range and the waveform-damping factor is also available. These cyclical modes are applied either individually or together.

The power output can be set by the operator to be detectable but comfortable for the patient. It can also be adjusted during application should this be required. These impulses have been tailored to mimic the electrical discharges of the nervous system, in order to elicit the organism's response with optimum efficiency and minimum disruption to cell function, depending upon the unique requirements of the presenting pain disease dynamics (or lack of same).

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i Dorland's Illustrated Medical Dictionary, WB Saunders and Company, Philadelphia, Penn. 2004

ii B. Scholz, R. Anderson. On Electrical Impedance Scanning-Principals and Simulations, Electromedica 68 – onco 2000