

TESTING OF ELECTRICAL TRANCUTANEOUS STIMULATORS FOR SUPPRESSING PAIN

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INTRODUCTION

As so many students of bioelectrical phenomena frequently remind us, it was Luigi Galvani who first reported his experiments in applying electrical currents to contract the muscles of frogs and sheep. Numerous attempts have since been undertaken to utilize that phenomenon for a variety of therapeutic purposes, many of them quite successful. One of the most notable is the heart pacemaker.

Electricity interacts with our neuromuscular system in three ways. It may affect the afferent nerves, or efferent nerves, or act directly on the muscles as shown by Galvani. Stimulation of the afferent nerves can introduce signals that are transmitted to the posterior root of the spinal cord and then to the brain, inducing sensations that may overpower other signals or stimulate a reflex arc. Electrical stimulation of the efferent nerves may initiate many physiological changes. We shall confine ourselves to afferent pain phenomena and the influence of electrical stimulation on them.

Pain is Nature's way of telling us that something is wrong. It functions like an early warning signal that is transmitted via the spinal cord, (where it may trigger a reflex arc) to the brain, where it is analyzed and referred. This signal may originate from a damaged area in the body or from an area apparently far from the source. If it is electrically interfered with, at least to some extent, the pain is either reduced or disappears. The electrical stimulus is often described by patients as producing a sensation of buzzing, tingling, vibrating, or numbing.

Alleviation of intractable pain is, of course, an important treatment modality. The VA Prosthetics Center therefore undertook a program to study the effectiveness of several commercially available electrical trans-

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cutaneous nerve stimulators (Fig. 1-5). They were tested for their electrical characteristics and their effectiveness in alleviating severe, interminable pain. The test program was based on one of three most prevalent theories of pain.

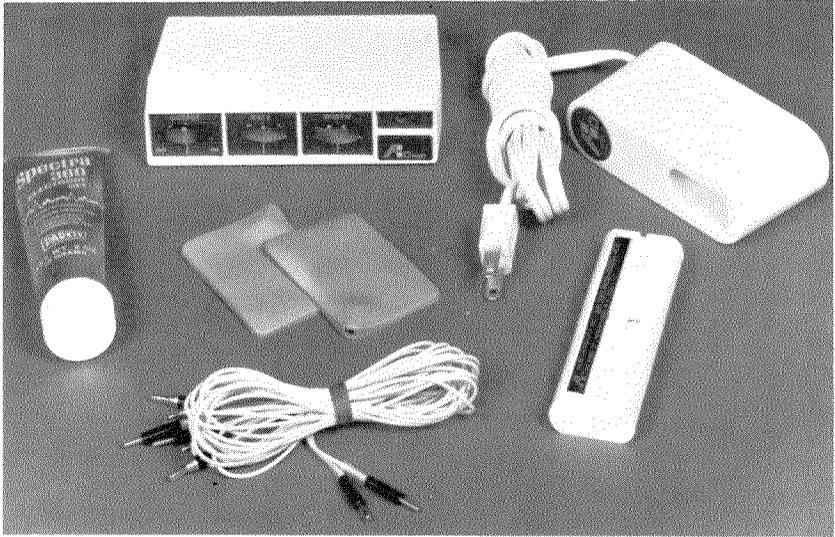


FIGURE 1. — Avery TNS Nerve Stimulator.

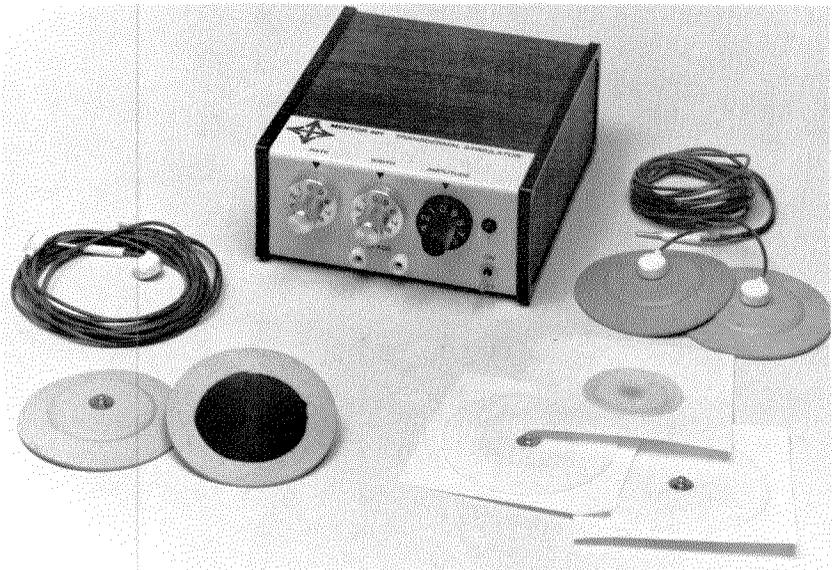


FIGURE 2. — Mentor 401 Nerve Stimulator.



FIGURE 3. — Neuromod TNS Nerve Stimulator.



FIGURE 4. — Neuropac II Nerve Stimulator.

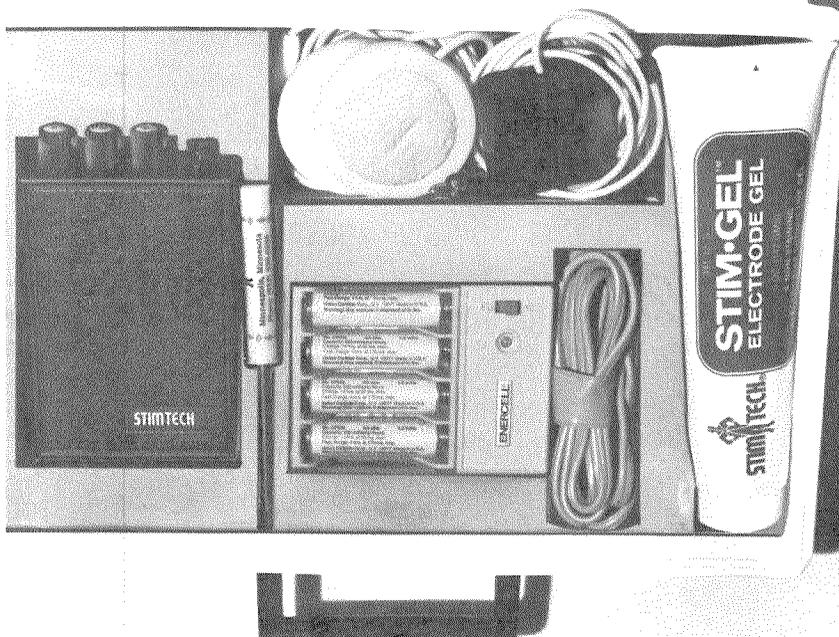


FIGURE 5— Stim-Tech EPC Nerve Stimulator.

THEORIES ON THE TRANSMISSION OF PAIN

Several theories, explaining how nerve firings are transmitted in the body to the brain and interpreted as pain, have gained prominence through the years. Each theory has its learned adherents. Small wonder, then, that it has become increasingly obvious to the pragmatist that this question has not as yet been resolved: with the inconsistencies in all of the presented theories it may not be resolved for many years.

Specificity Theory

The traditional or specificity theory, sometimes referred to as the “one-on-one” theory (single source, single channel, single receptor), holds that a free nerve ending is the probable pain end-organ, and that the pain signal is transmitted through a specific tract to a specific pain center located within the brain. Unanswered questions arise upon application of this theory. For example, how do we distinguish between degrees of pain? How do emotions affect pain? Why are we unable to locate or identify these pain receptors, even with a microscope?

Pattern Theory

More recent is the pattern theory. This theory advances the idea that nerve firings form specific spatial-temporal patterns which are decoded in the brain to be interpreted as pain, variations in pain, and sensations. Microscopically, however, we see a high degree of nerve fiber specialization that would not be necessary if the information were transmitted by a non-specific receptor that generated a pattern in response to a specific stimulus. If signals were transmitted by patterns, one receptor could be adequate for all stimuli.

Gate Control Theory

More recent than the pattern theory is the gate control theory. According to this theory, signals into the central transmission cells of the spinal cord can be inhibited by interactions between large diameter nerve fibers and the *substantia gelatinosa*; this interaction causes signals to be inhibited in small diameter fibers. In like manner, small diameter fibers interact with the *substantia gelatinosa* to inhibit signals in large diameter fibers. An externally applied electrical stimulus appears to affect this interaction and therefore inhibits the transmission of pain. Thus we hypothesized that, on the basis of this theory, a pain suppression stimulator capable of generating a signal that promotes interaction between nerve fibers and the *substantia gelatinosa* is most desirable.

This theory does not explain how pain can be suppressed for long periods of time (3-18 h) after a relatively short (15-45 min) stimulation period.

CHARACTERISTICS OF NERVE TRANSMISSIONS

Specific types of neurons transmit uniquely specific signal patterns. Rates of transmission, pulses per second (pps), and velocities, meters per second (m/s), are determined by the physical diameters and insulation characteristics of the nerves and their respective coverings. Thus, by way of comparison, motor and muscle proprioceptor nerves, type A (α), 1A and 1B, are $13\mu\text{m}$ to $22\mu\text{m}$ in diameter and transmit signals at velocities of from 70 m/s to 120 m/s with a 0.4ms to 0.5ms spike duration (refractory). These are the largest neurons in the human body and are capable of transmitting the most accurate information. Touch kinesthesia transmission nerves, type A (β) II, are $8\mu\text{m}$ to $13\mu\text{m}$ in diameter, and transmit signals at velocities of from 40m/s to 70m/s with a 0.4ms to 0.6ms spike duration. And motor-to-muscle spindle nerves (efferent), type A (γ) II, are $4\mu\text{m}$ to $8\mu\text{m}$ in diameter and transmit signals at 15m/s to 40m/s with a spike duration of 0.5ms to 0.7ms.

For testing purposes, however, we are primarily concerned with class A (δ) III nerves which transmit pain (localized definitive pain), heat, cold, and pressure. These nerve fibers vary in diameter from $1\mu\text{m}$ to $4\mu\text{m}$. They

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are capable of transmitting signals at a velocity of 5m/s to 15m/s with a spike duration of 0.6ms to 1.0ms. We are also concerned with type C IV pain postganglionic (generalized pain) nerve fibers that are the smallest in diameter, 0.2 μ m to 1.0 μ m. These transmit signals at the comparatively slow rate of 0.2m/s to 2.0m/s with a rather long spike duration of 2.0ms.

For comparison, it is interesting to note that muscle fibers transmit signals at a relatively slower rate than nerve fibers and have significantly longer depolarization times (pulse durations). White muscle fiber contraction time is approximately 25ms; tetany is produced at 66pps. White muscle fibers are greater in diameter than most nerve fibers: 10 μ m to 100 μ m. Red muscle fibers can transmit approximately 22pps at a duration time of 75ms.

PRELIMINARY TESTS

Five commercially available electrical stimulators have been tested to date to verify their basic functional capabilities. They are as follows:

- a. Avery TNS (Avery Corporation) (Fig. 1)
- b. Mentor 401 (Mentor Corporation) (Fig. 2)
- c. Neuromod TNS (Metronic, Inc.) (Fig. 3)
- d. Neuropac II (Medical Devices, Inc.) (Fig. 4)
- e. Stim-Tech EPC (Stimulation Technology) (Fig. 5)

Test Conditions

A simulated-body-impedance circuit, as illustrated in Figure 6, was used to test the output parameters of each stimulator separately. As depicted in the diagram, a resistive-capacitive load comprising a 1k Ω (one thousand ohms) resistor connected in parallel with a .047 μ F capacitor was used for voltage output measurements. This was a "worst case" load that was designed to emphasize current regulation. A 1 Ω shunt resistor was used to provide output current measurements. To simulate electrode impedance variations, the value of the load resistor was changed from 1k Ω to 500 Ω , then to 5k Ω during the course of testing.

The following waveform measurements (using a 1k Ω load resistor for the results shown in Fig. 7-11) correspond to given stimulator control settings, as indicated in the associated figures. Each figure presents dual-trace waveforms, the upper waveform depicting current measurements in milliamperes (mA) (shown in millivolts (mV) due to the required 1 Ω shunt resistance) and the lower trace showing voltage measurements in volts. Thus the number in the upper left-hand corner of each diagram applies to the upper trace and indicates the number of milliamperes (indicated in millivolts) per major division. The middle number applies to the lower trace, indicating volts per major division, and the right-hand number denotes time in microseconds (μ s) per major division. All measurements were obtained using a Tektronix 7627A oscilloscope.

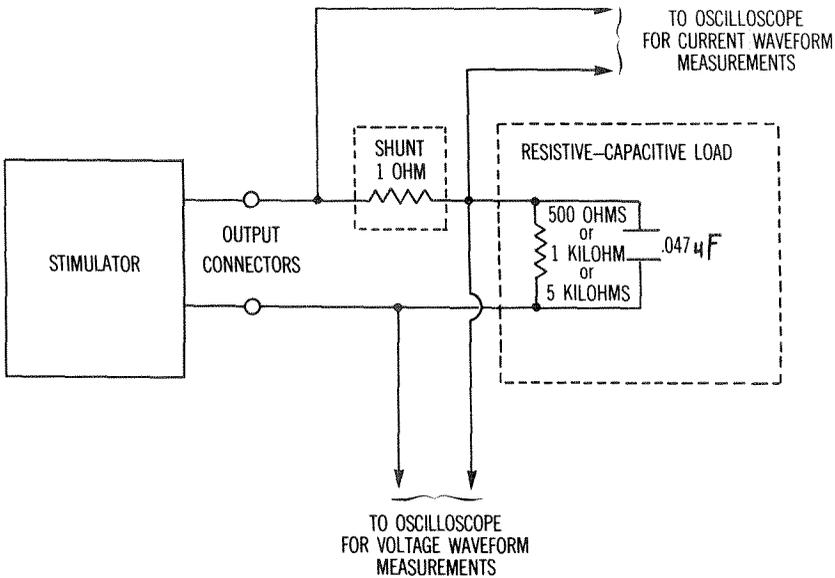


FIGURE 6. — Test setup for waveform measurements.

Test Results

Avery TNS

The Avery TNS utilizes three independent controls, an OUTPUT (current amplitude) control, a RATE (pulse repetition rate) control, and a WIDTH (pulse width) control. This system produces pulses in alternate directions (Fig. 7) that are designed to minimize the polarization at the skin-electrode interface and thereby reduce the electrical energy required for stimulation. The pulse repetition rate varies from 4.5 pps to 290 pps. Pulse duration of $150\mu\text{sec}$ to $400\mu\text{sec}$ occurs with a current reading of 20mA (mid-range setting) to 42mA (maximum setting).

Mentor 401

The Mentor 401 utilizes a RATE (pulse repetition rate) control, a WIDTH (pulse width) control, and an AMPLITUDE (Amp) control. Observe that a current variation of 7mA to 20mA (Fig. 8) occurs as the AMPLITUDE control is positioned from a mid-range setting to the maximum position. There is a minimal effect on the pulse width. When both the RATE control and the AMPLITUDE control are changed from mid-range to maximum, however, the pulse width decreases from 1.9ms to 1.2ms. The overall pulse repetition rate varies from a low (minimum) of

AVERY TNS -- Transcutaneous Nerve Stimulation

Width: .1 ms to .4 ms, Amplitude: .42 mA, Rate: 4.5 pps to 290 pps.

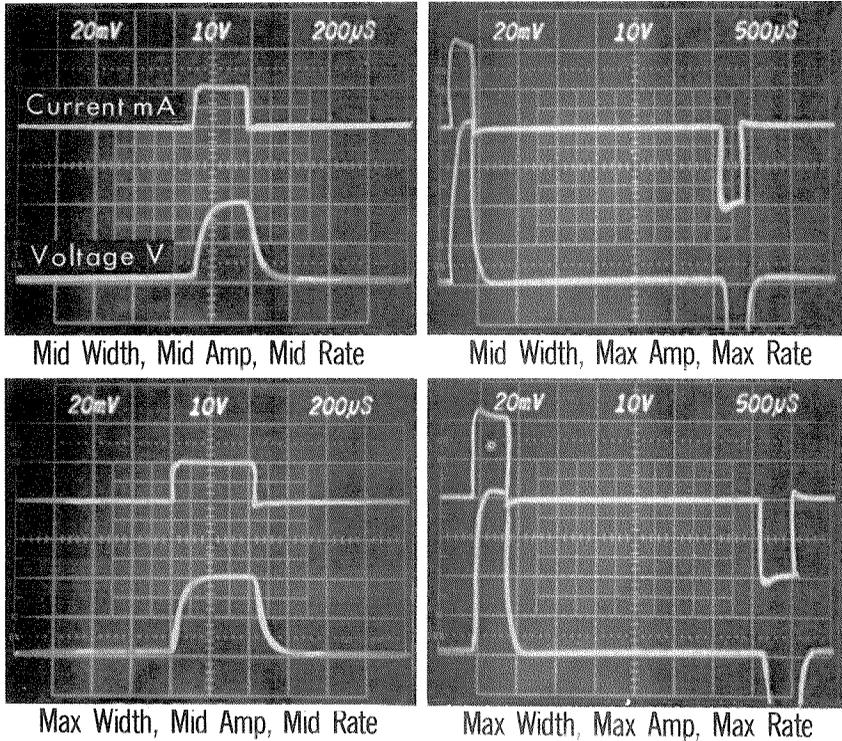


FIGURE 7. -- Avery TNS waveform measurements.

17 pps to a high (maximum) of 210 pps. The WIDTH control can vary the pulse width from approximately 0.5ms to 1.9ms.

Neuromod TNS

The Neuromod TNS features two controls, a RATE (pulse repetition rate) control and an OUTPUT (amplitude and pulse width) control. Observe that the initial pulse remains constant in amplitude at approximately 10mA (Fig. 9) when the output control is varied from a mid-range setting to the maximum position, but that the amplitude of the second pulse increases from approximately 50mA to 80mA for about 200μs. Changing the RATE control from mid-range to maximum has no effect on the amplitude of either the initial output pulse or the second pulse. The RATE control was found to have little effect on the pulse width of either the initial pulse or the second pulse. The overall pulse repetition rate varies from 11 pps to 100 pps.

MENTOR 401 – Transdermal Stimulator

Width: 0.6 ms to 1.9 ms, Amplitude: 20 mA, Rate: 17 pps to 210 pps.

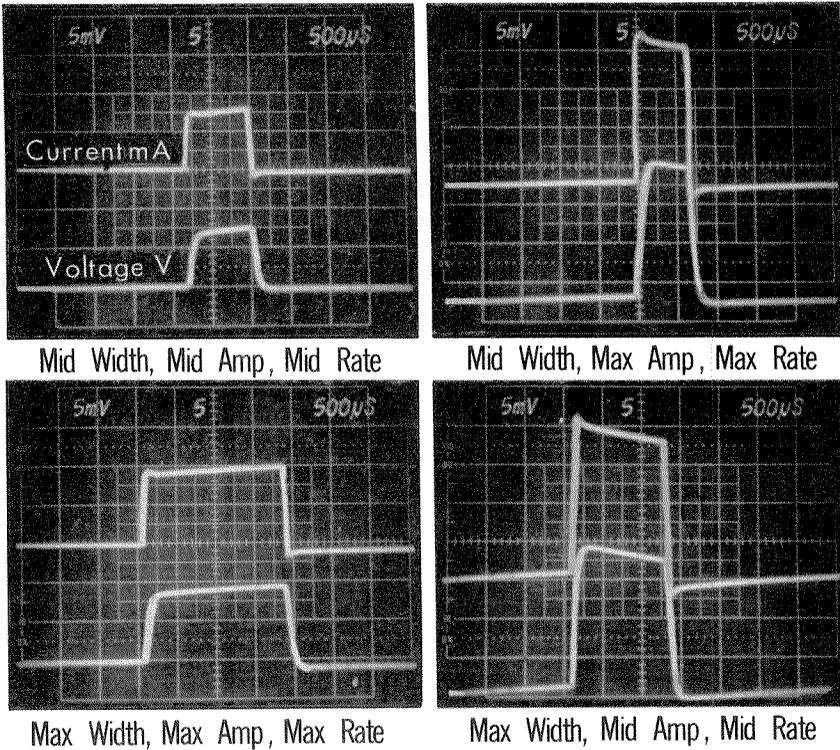


FIGURE 8. — Mentor 401 waveform measurements.

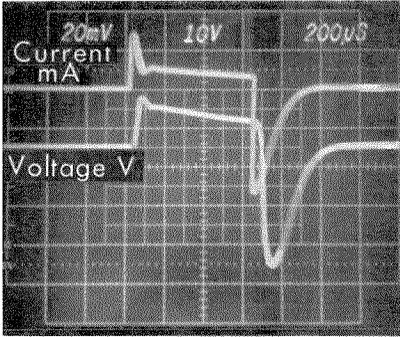
Neuropac II^a

The Neuropac II also employs two controls, a **FREQ** (pulse repetition rate) control and an **AMP** (amplitude) control. Similar to the Neuromod TNS, the output pulse remains constant in amplitude (Fig. 10) at approximately 14mA when the AMP control is varied from a mid-range setting to maximum, but the second pulse increases from approximately 36mA to 68mA. Changing the **FREQ** control setting from mid-range to maximum has a minimal effect on the pulse width of either the initial pulse or the second pulse. The overall pulse repetition rate varies between 42 pps to 110 pps.

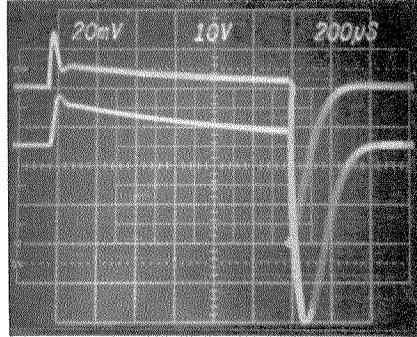
^aThe Neuropac II provides a dual-channel capability for stimulating two areas of the body simultaneously. The majority of the units tested are also available in dual-channel configurations from their respective manufacturers.

NEUROMOD TNS – Transcutaneous Nerve Stimulator

Width: .06 ms to 1.2 ms, Amplitude: 10 mA, Rate: 11 pps to 100 pps.



Mid Amp, Mid Rate

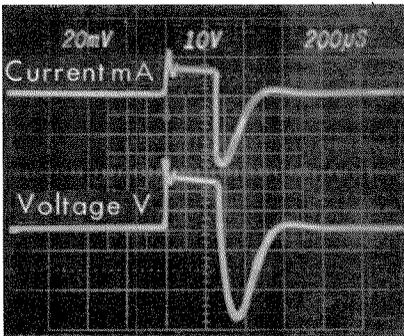


Max Amp, Mid Rate

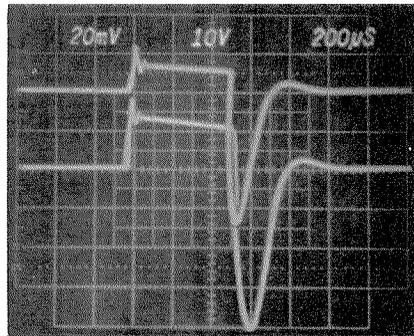
FIGURE 9. – Neuromod TNS waveform measurements.

NEUROPAC II – External Neuropacer

Width: .09 ms to .5 ms, Amplitude: 14 mA, Rate: 42 pps to 110 pps.



Mid Amp, Mid Rate



Max Amp, Mid Rate

FIGURE 10. – Neuropac II waveform measurements.

Stim-Tech EPC

The Stim-Tech EPC utilizes three controls, an R (pulse repetition rate) control, a PW (pulse width) control, and an O (output amplitude) control. Observe an increase in amplitude (Fig. 11) from approximately 28mA to approximately 50mA to 90mA as the O control is varied between a mid-range setting and its maximum setting. The pulse width varies between approximately 100 μ s and 400 μ s. A rate increase of approximate-

ly 11 pps to 115 pps results when the R control is varied from mid-range to maximum. This rate increase has no effect on either the pulse amplitude or the pulse width. There are no significant second pulses produced at any of the various settings.

STIM-TECH EPC – Mini Stimulator

Width: .1 ms to .4 ms, Amplitude: 50 mA, Rate: 11 pps to 115 pps.

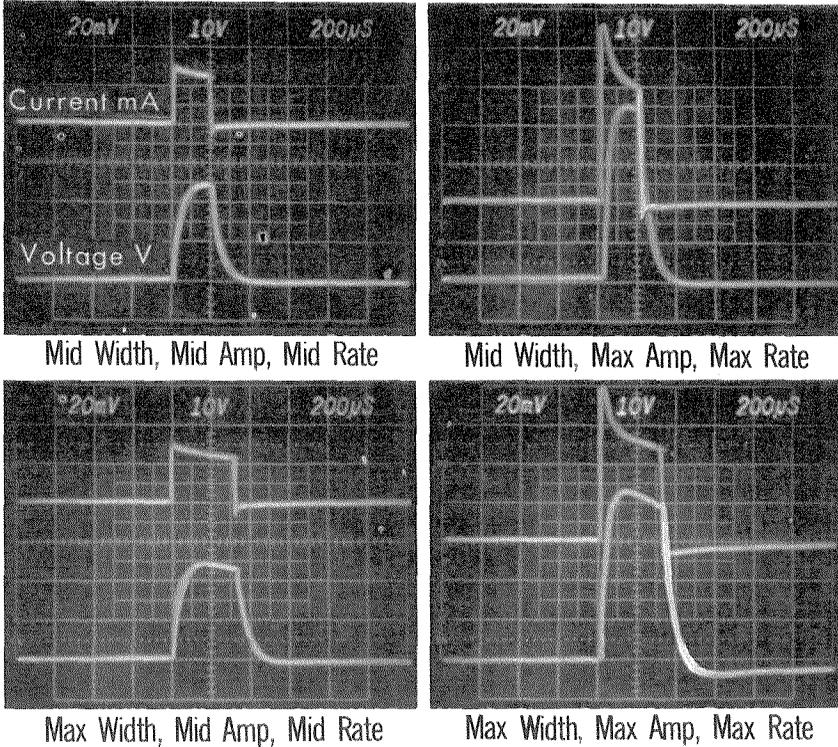


FIGURE 11. — Stim-Tech EPC waveform measurements.

Resistive Load Variations

Figures 12 and 13 illustrate the effects produced by changing the value of the load resistor (which simulates skin electrical impedance) from $1k\Omega$ (typical skin contact) to 500Ω (good skin contact) and $5k\Omega$ (poor skin contact). The purpose of these tests was to determine if varying these impedances would produce current changes and, if so, whether these changes would have a noticeable effect on what the patient felt. The Stim-Tech EPC and Neuromod TNS stimulators were used for these measurements. These measurements are shown in Figures 12 and 13, respectively.

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As observed in Figure 12, no significant changes in current output occur as the load impedance is varied, even though the voltage waveforms display significant changes. The Avery TNS produced similar results. In Figure 13, however, we can observe significant changes in current with corresponding changes in simulated skin impedances, from 18mA with good electrical contact (500Ω) to 3mA with poor electrical contact ($5k\Omega$) and 9mA with typical skin contact ($1k\Omega$). The Neuropac II provided similar results whereas the Mentor 401 demonstrated small changes in output current with impedance variations.

Electrode Interface Variations

Figures 14 and 15 illustrate the effect of changing the skin interface electrolyte from dry skin to wet skin to electrode gel treated skin. In Figure 14, the Stim-Tech EPC demonstrates there was no measurable change in the stimulation current (and the subject reported he felt no difference) when the skin interface electrolyte was changed. There was a slight increase in the impedance for the dry skin as evidenced by the high voltage. In Figure 15, the Neuromod TNS demonstrates that the current changed appreciably with dry skin (and the subject reported he could feel the difference).

CONCLUSION

Although some satisfactory results were obtained with less highly controlled currents, subjective testing to date indicates a preference for stimulators which supply carefully controlled, constant current pulses.

Eight patients, each suffering from irreparable pain, were treated with the stimulators in limited clinical applications. Seven of these patients were regularly medicated for pain, and six suffered from pain associated with lower-limb amputation. While these tests were not designed to prove, nor did they prove, the clear superiority of one system over another, they did indicate that all five stimulators were capable of providing at least some relief from pain in some instances. In two cases, however, we were unable to suppress pain: with the Neuropac II (for one case) and the Neuromod TNS (for the second case). But we did subsequently suppress pain in the same two patients with the Stim-Tech EPC replacing the Neuropac II and the Avery TNS replacing the Neuromod TNS.

Based on the limited subjective tests and the electrical characteristics of stimulation produced by the Stim-Tech EPC and the Avery TNS, we have recommended their general use in VAPC clinics. Despite the absence of definitive "proof," this conclusion is warranted on theoretical grounds, clinical observations, and such factors as cost, weight, and service availability.

STIM-TECH EPC – Mini Stimulator

Mid Width, Mid Amp, Mid Rate

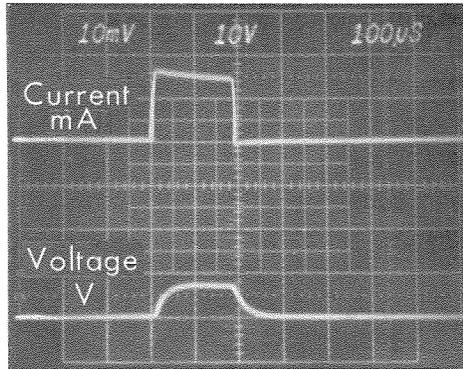
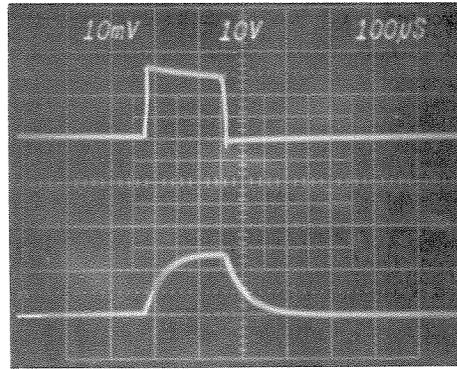
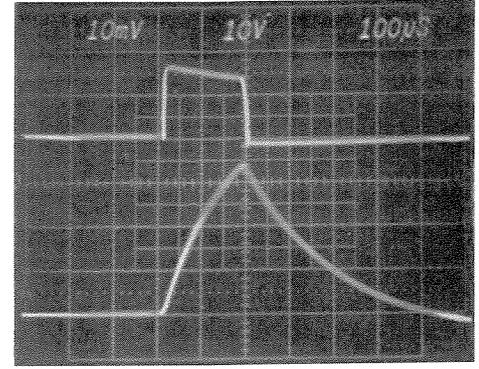
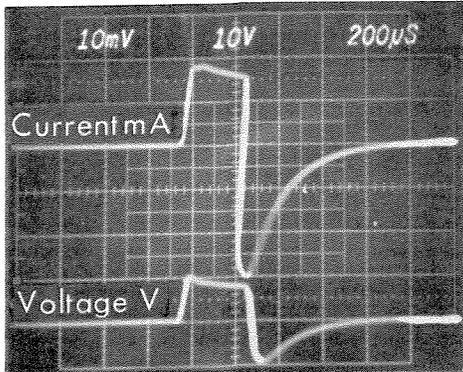
 $.047\mu\text{F}$ Paralleled with 500 Ω  $.047\mu\text{F}$ Paralleled with 1000 Ω  $.047\mu\text{F}$ Paralleled with 5000 Ω

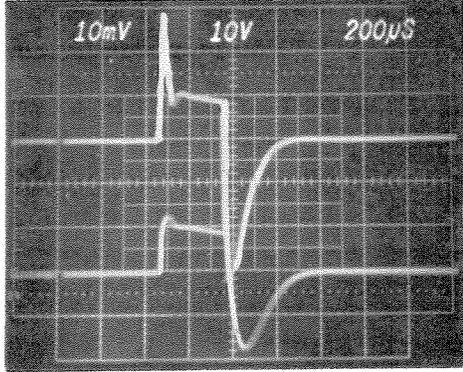
FIGURE 12. – Stim-Tech EPC waveform measurements with resistive load variations.

NEUROMOD TNS – Transcutaneous Nerve Stimulator

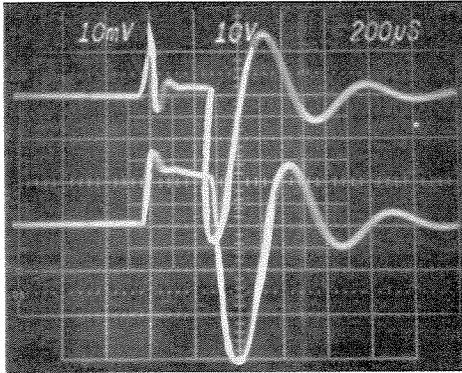
Mid Amp, Mid Rate



.047 μF Paralleled with 500 Ω



.047 μF Paralleled with 1000 Ω

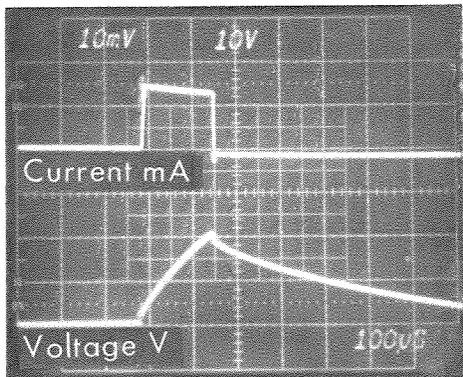


.047 μF Paralleled with 5000 Ω

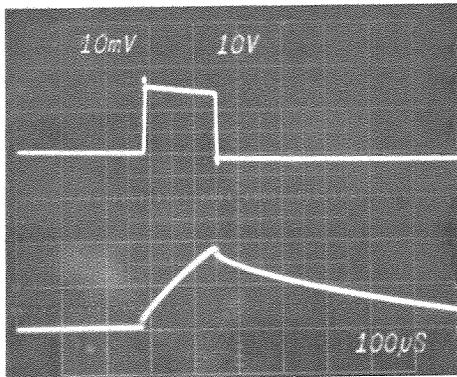
FIGURE 13. – Neuromod TNS waveform measurements with resistive load variations.

STIM-TECH – Mini Stimulator
(With Stim-Tech Rubber Electrodes)

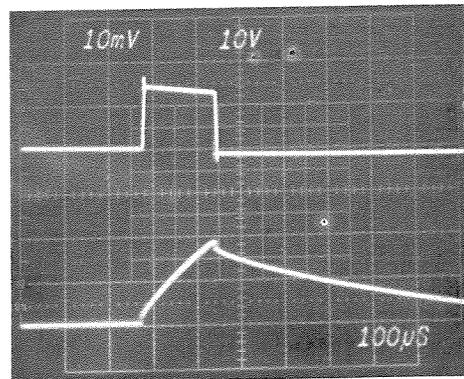
Mid Width, Mid Amp, Mid Rate



Dry Skin



Water-Wet Skin

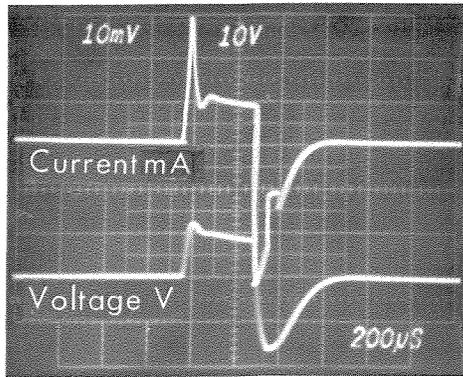


Stim-Gel Wet Skin

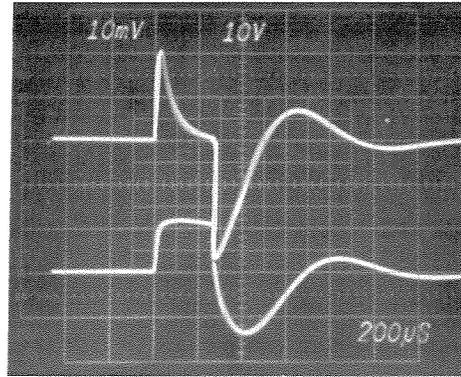
FIGURE 14. — Stim-Tech EPC using electrode interface variations.

NEUROMOD TNS – Transcutaneous Nerve Stimulator
(With Neuromod Rubber Electrodes)

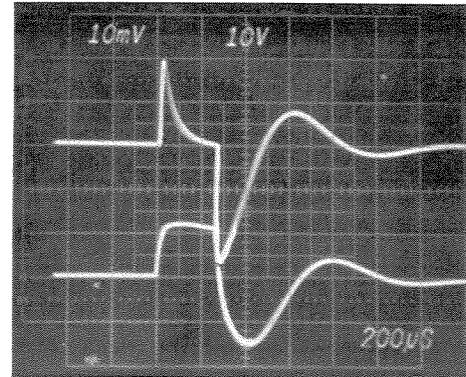
Mid Amp, Mid Rate



Dry Skin



Water-Wet Skin



Spectra '360' Electrodes
Gel on Skin

FIGURE 15. — Neuromod TNS using electrode interface variations.

ACKNOWLEDGMENT

I would like to thank Mr. Herbert Leong, Bioengineering Technician, VAPC Advanced Systems Laboratories, for his many devoted hours of hard work in performing the tests used in this report.