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Pannozzo et al.

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[54] **METHOD OF NERVE THERAPY USING TRAPEZOIDAL PULSES**

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[52] **U.S. Cl.** **128/422;** 128/410; 128/411

[51] **Int. Cl.** **A61n 1/36**

[58] **Field of Search** .... 128/2.1 R, 173.1, 404, 128/410, 409, 419 R–423

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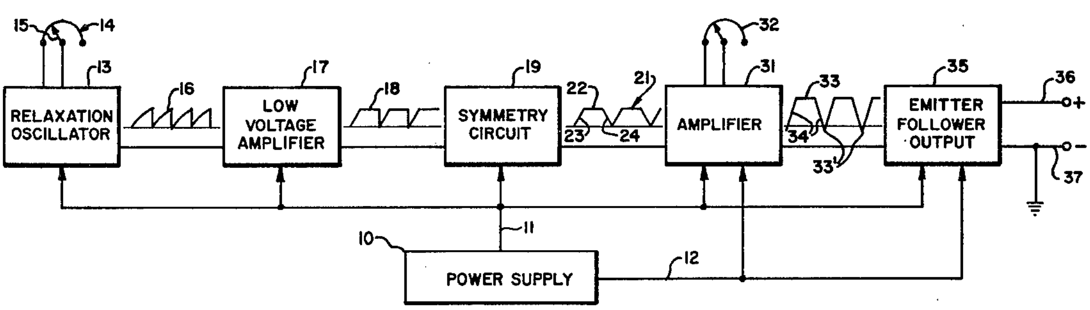
Attorney, Agent, or Firm—Brown, Murray, Flick & Peckham

[57] **ABSTRACT**

A method of nerve therapy for treating nerves by electrical stimulation characterized by using pulses of a trapezoidal waveform such that the waveform, as viewed from a positive electrode has a flat positive potential with a negative pip that is a point made by convergence of the sides with no flat or curved portion. The therapy is carried out by contacting a patient's skin with a pair of electrodes such that the positive electrode is orientated nearest the brain via the nerves conducting channels. The pulses with a trapezoidal waveform occur at a frequency selected within the range of 60 to 250 cycles per second, preferably within the range of 100 to 150 cycles per second with a peak to peak voltage of 55v or less (e.g., 19 to 25 volts.) These pulses are each defined as a pulse having a flat top portion with leading and trailing side portions which slope away from the top portion as the electrical potential drops toward the zero axis and proceeds into the negative pip.

9 Claims, 6 Drawing Figures



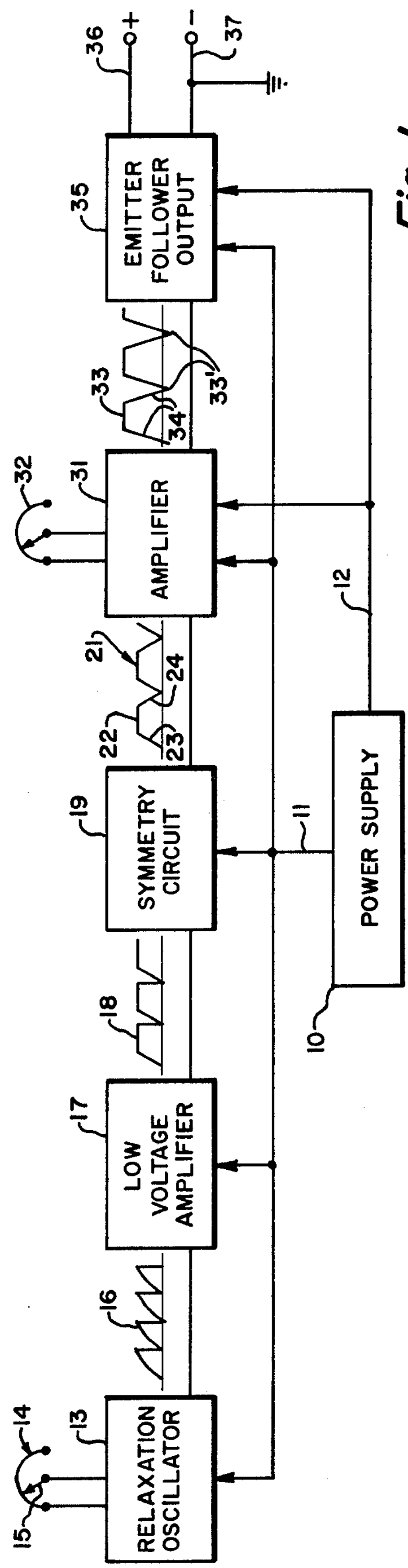


Fig. 1

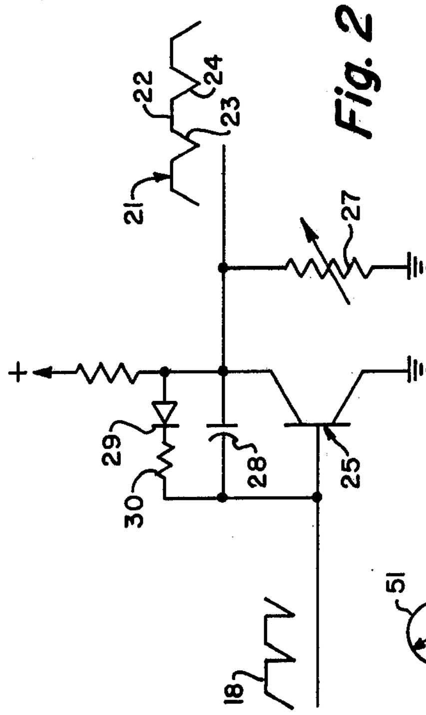


Fig. 2

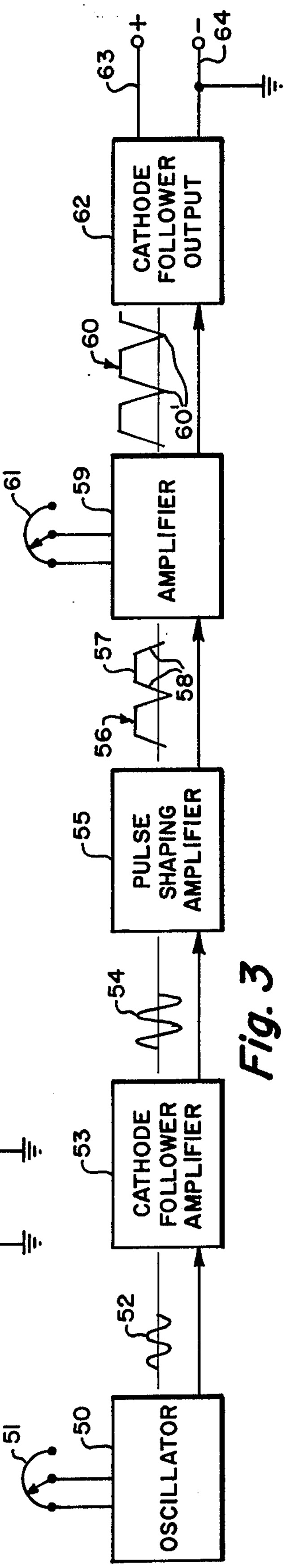


Fig. 3

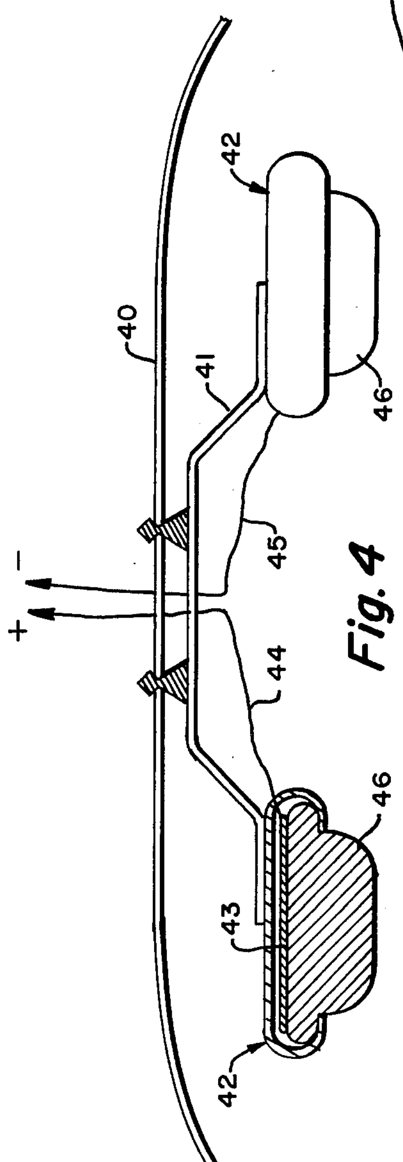


Fig. 4

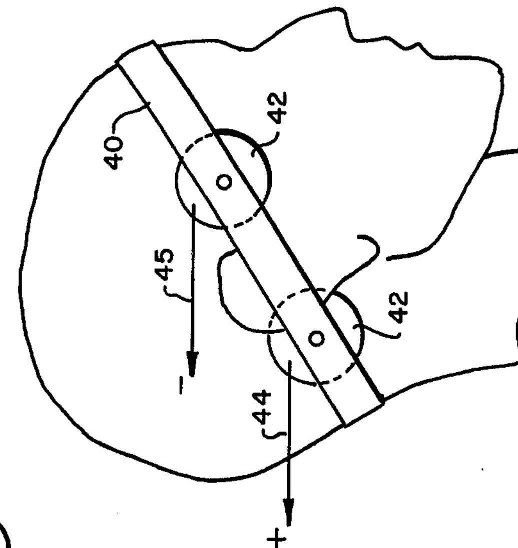


Fig. 5

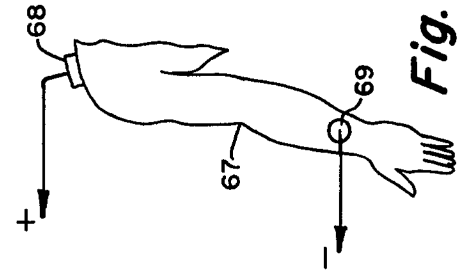


Fig. 6

METHOD OF NERVE THERAPY USING TRAPEZOIDAL PULSES

BACKGROUND OF THE INVENTION

This invention relates to the treatment of afferent and efferent nerves by stimulation using electrical pulses with a trapezoidal waveform. More specifically, the invention relates to a method for electrical stimulation of a damaged nerve in an unique manner to facilitate a healing process along with the reduction of symptoms whereby the affected nerve tissue resorts to a relatively normal or healthy condition.

While the invention described herein can be used to treat any damaged nerve in the human body, it has particular applicability to the problem of hearing loss due to sensorineural damage due to loud noises, and may be applicable to other sensorineural damage due to other causes except congenital hearing loss. The scope of the problem cannot adequately be realized on an individual basis since it permeates every country in the world, and it is estimated that 10 percent of the world population can be considered hard of hearing or deaf. The problem is increasing due to noise pollution of industrial and residential environments. To date, there has not been an adequate medical treatment for this type of hearing loss. It is not completely understood why the eighth cranial nerve or acoustic nerve does not work properly when an insult such as a loud noise is encountered.

In the past, electrical stimulation was adapted for human use and particularly it was employed for the reeducation of paralyzed muscles. It is known to treat Bell's palsy by electrical stimulation at a low frequency. Electrical stimulation is also used to decrease pain; but when the equipment producing such stimulation is turned off, the pain will return. Thus, it is a noncurative type of treatment.

In regards to the organ of hearing, it is known that the acoustic nerve works on bio-electrical principles and that the energy starts as a mechanical impulse from the movement of ossicles in the middle ear and transmitted to the organ of the corti from the movement of fluids. This energy is transformed by the hair cells in the organ of corti into bio-electrical energy. In view of this, the present invention is related to the discovery of an electrical waveform that is helpful to the healing process of an acoustic nerve that is not functioning properly. There is evidence uncovered in regard to sensorineural hearing loss, that is, pathology of the nerve itself. Clinical experience with electrical stimulation equipment indicates that the concept of electrical stimulation of nerves is correct and that a nerve can be stimulated to return to its functional use. The characteristics of the electrical stimulation according to the present invention have been employed or are particularly useful for the treatment of Bell's palsy. Bell's palsy is a swelling of the seventh cranial nerve in the facial canal in the temporal bone. This invention has been used to treat Bell's palsy by applying the stimulation to the fallopian canal or facial canal in the temporal bone. Treatment has been used for nerve deafness, due to loud noises, and may be applicable to other types of sensorineural disease leading to hearing loss, except congenital hearing loss, carpal tunnel syndrome in both pre-operative and post-operative status, tardy ulnar palsy, preoperative and post-operative, all types of neuropathies, swallowing difficulty from nerve damage, compressive neuropathy from any cause at any level, back and neck pain, and disc disease causing nerve pain. It has been found that electrical stimulation according to the concept of the present invention brings about a healing of nerves that are pinched, compressed, swollen or otherwise damaged in any manner, but works best when the compression is relieved, such as in compressive neuropathy.

This method of electrical stimulation according to the present invention is based on the use of pulses having a particular waveform and electrical characteristics. This waveform notably has the form of trapezoidal pulses each having a flat top portion and diverging sides from the top portion. If the entire waveform were on one side of the zero axis, an undesirable electrolytic effect would result. It is not completely understood why pulses with this waveform are of such unique nature that their use to stimulate nerve tissue brings about a return of the nerve to a near normal condition along with a reduction of symptoms. One plausible explanation is based on a chemical imbalance due to lipoproteins and other large molecular proteins in the wall of the nerve axon. It is assumed that the nerve functions by a transmittal of electrical impulses along the nerve, such as wires carry impulses. However, transmission by a nerve is accomplished by chemical means rather than electrical means. The end result is electrical using a method that is chemical. [The propagating electrical pulse by the nerve occurs by the passage of potassium out of the cell; while sodium and chloride ions pass into the cell. The electrical stimulation according to the present invention is related to the ability to transfer molecules across the cell membrane of a nerve. It is to be understood that the transfer of sodium and potassium ions is actively done by the cell wall of the axon.] A most probable explanation is that a nerve is in a dormant state unless stimulated properly. Its relation to nerve damage is such that, for example, a sick ulnar nerve, even after transplantation, gives paresthesia. Paresthesia of the eighth cranial nerve is not completely understood but maybe thought to occur because of tinnitus that is heard, distorted tones and muffled sounds, itching of the ear, and the ear pressure that is felt by those who have nerve deafness. It has nonetheless been found that treatment according to the present invention of the eighth cranial nerve reduces some symptoms in about 4 to 10 days, including tinnitus if treatment continues for 20 to 30 times, as well as the symptoms of peripheral nerves in the same length of time. In the treatment of the eighth cranial nerve, it has been found that increased hearing apparently takes place in all ranges of hearing from 200 to 17,000 cycles per second, although the method of testing above 8,000 cycles per second is, at present, extremely crude. Maximum improvement has been noticed in the upper range which correlates well with the improvement in quantity and accuity of hearing, presumably because of the harmonics that all sounds produce.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a method of treating nerves by electrical stimulation to bring about the return of the nerve tissue to a near normal status.

It is a further object of the present invention to provide a method of electrical stimulation for treating nerves through the use of pulses having a trapezoidal waveform. The electrical stimulation is carried out with the use of electrodes in contact with the body of a patient such that the positive electrode is disposed in relation to the nerve closest to the brain of the patient in regard to the nerve path.

More specifically, the present invention provides a method of treating afferent or efferent nerves of a patient by electrical stimulation which includes the steps of positioning electrodes at spaced locations on the body of the patient such that the current flowing between the electrodes will pass through the nerve, and applying across the electrodes electrical pulses each having a trapezoidal wave shape in which the sides of each pulse diverge away from the top portion of the pulse. These pulses are produced so that the top portions are essentially flat and the negative portion of the wave comes to a point. Stimulating the nerves is carried out using a pulse frequency within the range of 60 to 250 cycles per second at a potential of 55 volts or less between the conducting electrodes. In the preferred embodiment of the invention, trapezoidal wave pulses are used to stimulate nerves at a frequency within the range of 100 to 150 cycles per second with the potential that is appropriate for that portion of the body.

These features and advantages of the present invention as well as others will be more readily understood when the following description is read in light of the accompanying drawings, in which:

FIG. 1 is a schematic illustration of one form of circuitry for the method of electrical stimulation according to the present invention;

FIG. 2 is a detailed description of the symmetry circuit shown in FIG. 1;

FIG. 3 is a schematic illustration of a second form of circuitry for the method of electrical stimulation according to the present invention;

FIG. 4 is an illustration of a holding strap for electrodes to carry out the method of the present invention;

FIG. 5 illustrates the positioning of the electrodes by the holding strap for the treatment of the eighth cranial nerve; and

FIG. 6 illustrates the manner in which electrodes having trapezoidal pulses applied thereto are applied to a body extremity for treatment of nerves therein.

With reference now to FIG. 1, there is illustrated apparatus to produce trapezoidal pulses for nerve stimulation using transistorized components. The apparatus includes a power supply **10** to provide a low voltage direct current in line **11** of the order of 4½ to 6 volts and a high voltage direct current in line **12** of the order of 25 to 55 volts. The low voltage supply in line **11** is connected to a relaxation oscillator **13** having a frequency output of 85 to 300 hertz but preferably locked onto a frequency of 100 hertz. The output of the oscillator may be adjusted by a rheostat **14** having a movable tap **15**. The pulses from the relaxation oscillator have a sawtooth waveform **16** and are delivered to a low voltage amplifier **17**. This amplifier is non-linear and biased to give a pronounced sustained potential of the positive peaks. This is clearly shown by the waveform **18** at the output of the amplifier **17**. Pulses according to waveform **18** are delivered to a symmetry circuit **19** which modifies the input pulses to produce a desired slope to the leading edge of the sawtooth waveform. In addition, the symmetry circuit reduces substantially the slope to the trailing edge of the waveform so that the output pulses are trapezoidal in shape. These pulses are typical of a regular trapezoid. Such trapezoidal pulses are shown by the waveform **21** where it will be observed that each pulse has a flat top portion **22** of constant voltage or amperage in relation to zero ground potential. The top portion **22** is preceded by an inclined leading edge **23** and a mirror image of this leading edge as an inclined trailing edge **24**. The current and voltage increases represented by the edges **23** and **24** raise the output from a zero ground potential to the maximum potential represented by the flat top portion **22** which is maintained for a given period of time according to the desired frequency which is adjustably but preferably locked onto 100 hertz and in accordance with the present invention may be selected within the range of 60 to 250 cycles per second, and more specifically within 100 to 150 cycles per second. The actual form of the symmetry circuit will be described in greater detail in relation to FIG. 2.

In FIG. 2, the symmetry circuit **19** is shown in detail having input pulses comprising the waveform **18** connected to the base terminal of a transistor **25**. The emitter is connected to ground and the collector forms the output. The emitter output is delivered by a line **26** which is connected to ground through a load resistor **27**. The emitter further includes a feedback path from line **26** having a capacitor **28** and in parallel therewith a diode **29** which is in series with a resistor **30** to form an integrator. In this manner, the feedback of the emitter output provides the desired slope to the leading edge **23** of the sawtooth waveform by the integration action. This also reduces the slope to the trailing edge **24** of the sawtooth waveform.

Returning now to FIG. 1, the pulses from the symmetry circuit **19** which as previously indicated have the trapezoidal waveform **21**, are delivered to an amplifier **31** including a rheostat **32** to bias the output and give a wider top to the trapezoidal input waveform. Adjustment by the rheostat **32** is used to bias the amplifier **31** so that the trapezoidal pulse output is of a longer duration at its top portion **33**. The electrical potential of the flat portion **33** is increased to the desired amount, preferably 19–25 volts and at least less than 55 volts. As clearly shown in FIG. 1, the flat top portion **33** is connected by sloping sides **34** which diverge away from the top portion **33**. The pulses from amplifier **31** are connected to an emitter-follower output **35** which is of standard design and has output terminals **36** and **37** of positive and negative polarity, respectively. Terminal **37** is grounded as shown. In this respect, when a "positive electrode" is referred to herein, it means that the electrode is positive with respect to the grounded terminal. Thus, it can be seen that the waveform at the output terminals is selected between 60 to 250 cycles per second and preferably 100 to 150 cycles per second by adjusting the rheostat **14**. The electrical potential is limited to 55 volts or less and as indicated is preferably about 19 to 25 volts. The milliampere output of these pulses is typically selected within the range of 1/10 to 10 milliamperes, although as high as 40 milliamperes may be selected depending upon the weight and other characteristics of the patient to be treated.

On evaluation of the voltage unloaded the wave peak to peak was 70 volts. The loaded voltage that is applied to the body is 55 volts peak to peak. Usually for the ear the voltage is 47 volts peak to peak.

As indicated, the method of treating nerves through electrical stimulation is applied to a nerve with the positive electrode (i.e., that connected to terminal **36**) placed nearest the brain in regard to the nerve channels. This requires that when treating nerves in limbs, the positive electrode is positioned closest to the spinal column in relation to the negative electrode. When treating for nerve deafness, a holding strap may be conveniently employed which is shown in FIGS. **4** and **5.** This holding strap is made up of a band **40** used to support a bracket **41** which, in turn, carries at its opposite ends plastic or rubber cup-like members **42.** Each of the members **42** is of hollow construction within which there is located an electrode plate **43** made of stainless steel or the like and connected to a line **44** which has been arbitrarily noted as the positive electrode. A line **45** is provided for the electrode plate in the remaining cup-like member **42,** thus defining the negative electrode. The plate **43** in each member **42** contacts a sponge **46** which tightly fits within the hollow cavity of each member **42** and is maintained in contact with the plate **43** therein. The sponge may be wet with water to provide a conducting medium for the electrical pulses.

FIG. **5** illustrates schematically the positioning of the holding strap for the treatment of nerve deafness where it will be observed that the members **42** are positioned such as the positive electrode defined by line **44** is positioned behind the ear overlying the mastoid bone area. The lines **44** and **45** are connected to the terminals **36** and **37**, respectively, of the emitter-follower output **35.**

FIG. **3** illustrates a second form of circuitry for the method of treating nerves using electrical stimulation according to the present invention. This embodiment differs from that previously described in regard to FIG. **1** in that FIG. **3** relates to vacuum tube-type components for the production of pulses having a trapezoid waveform. In FIG. **3**, an oscillator **50** is provided in the form of a resistance-capacitance type sine wave oscillator having a variable capacitor or rheostat **51** whereby the frequency of the sine wave may be selected between 55 and 275 hertz. The output from the oscillator **50** has a sinusoidal waveform **52** which is delivered to a cathode-follower amplifier **53.** This amplifier forms an isolation stage for the oscillator and an amplifier for the sine wave which is shown in its amplified state by waveform **54.** The output from amplifier **53** is delivered to a pulse-shaping amplifier **55** which is biased for non-linear response. At the output of amplifier **55**, the negative portion of the pulses **56** has become very small in duration and the positive portion, due to the biasing, has taken the form of a trapezoid whereby the flat top portion **57** of constant potential is preceded and followed by sloping sides **58** due to a saturation of the input to the amplifier **55.** It should be noted that the negative portion of the pulses has become very short in duration. The trapezoidal pulses from the amplifier **55** are applied to an amplifier **59** which provides a further amplification stage and also has a non-linear characteristic which further reduces the negative portions of the pulses and amplifies the trapezoidal shape of the pulses so that each pulse has a wider top portion which is shown at the output of amplifier **59** by the waveform **60** conforming essentially to the characteristic described in regard to the waveform at the output of amplifier **31** (FIG. **1**). The amplifier **59** has an amplitude adjustment control in the form of a rheostat **61** which forms a control for selecting the desired pulse characteristics. The waveform **60** includes negative pips **60'** which come to a point with no flat or round portion. The waveform **60** is then connected to a cathode-follower output **62** which has terminals **63** and **64** of positive and negative potentials, respectively, for connection to the connecting lines used to apply these pulses to the nerves in the manner indicated in FIG. **1.**

FIG. **6** shows the manner in which the invention can be used to treat nerves in a body extremity, namely, the arm **67.** Again, the positive electrode **68** is placed closest to the brain of the patient and is positioned in the example given on the postero-lateral portion of the neck. The negative electrode **69** is placed in the example given on the wrist. With this configuration, trapezoidal pulses of the type described will travel between the electrodes **68** and **69** to produce the therapeutic effect on the arm nerves explained above.

The present invention thus provides a method for treating damaged nerves with the use of trapezoidal pulses in which the opposite sides of the pulse diverge away from an essentially flat top portion to reduce the rate of rise or fall of current at the leading and trailing edges of the pulses. This, among other things, reduces or eliminates any uncomfortable sensation to the patient and facilitates treatment of the nerve which is not possible with pulses having vertical leading and trailing edges and a flat or rounded negative portion. While a frequency in the range of 60 to 250 cycles per second can be employed, depending upon conditions, a frequency of 100 to 150 cycles per second is preferred. Likewise, while a voltage as high as 55 volts across the electrodes can be employed, the preferred range is 19 to 25 volts depending on the size of the patient and the part of the body being treated.

When there is a flat portion in the negative range, or when the waveform has only one polarity an undesirable electrolytic effect will result with an attendant loss in the therapeutic effect of the treatment.

Although the invention has been shown in connection with certain specific embodiments, it will be readily apparent to those skilled in the art that various changes in form and arrangement of parts may be made to suit requirements without departing from the spirit and scope of the invention.

We claim as our invention:

1. A method of treating nerves of a patient by electrical stimulation which includes the steps of:

positioning electrodes at spaced locations on the body of the patient such that current flowing between said electrodes will pass through a nerve;

generating electrical pulses each having a trapezoidal wave shape defined by a top portion of essentially greatest electrical potential and sloping sides diverging from said top portion as the electrical potential falls to zero and below to form a negative pip that comes to a point, and

applying said electrical pulses across said electrodes.

2. The method of claim **1** wherein said positioning electrodes is further defined to include positioning the positive electrode nearest the brain of the patient with respect to the remaining electrode.

3. The method according to claim **1** wherein said pulses are generated at a frequency selected within the range of 60 to 250 cycles per second.

4. The method according to claim **3** wherein said pulses are generated at a frequency selected within the range of 100 to 150 cycles per second.

5. The method according to claim **1** wherein said pulses each having a trapezoidal wave shape are further defined as pulses with a flat top portion of a constant and greatest electrical potential with sloping sides diverging from said top portion as the electrical potential falls to zero and below to form a negative pip that comes to a point.

6. The method according to claim **5** wherein the wave shape of said pulses defines a primarily flat portion in the positive potential with a pointed pip in the negative potential.

7. The method according to claim **6** wherein said pulses have a maximum 55 peak to peak voltage between said electrodes.

8. The method according to claim **7** wherein said pulses have an effective electrical potential within the range of 19 to 25 volts between said electrodes.

9. The method according to claim **1** wherein the steps of positioning said electrodes is further defined to include positioning the positive one of said electrodes in contact with the patient's skin at the mastoid bone area, and positioning the negative electrode in contact with the patient's skin remote to the mastoid bone area, said electrical pulses being applied to said electrodes to stimulate the eighth cranial nerve.

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