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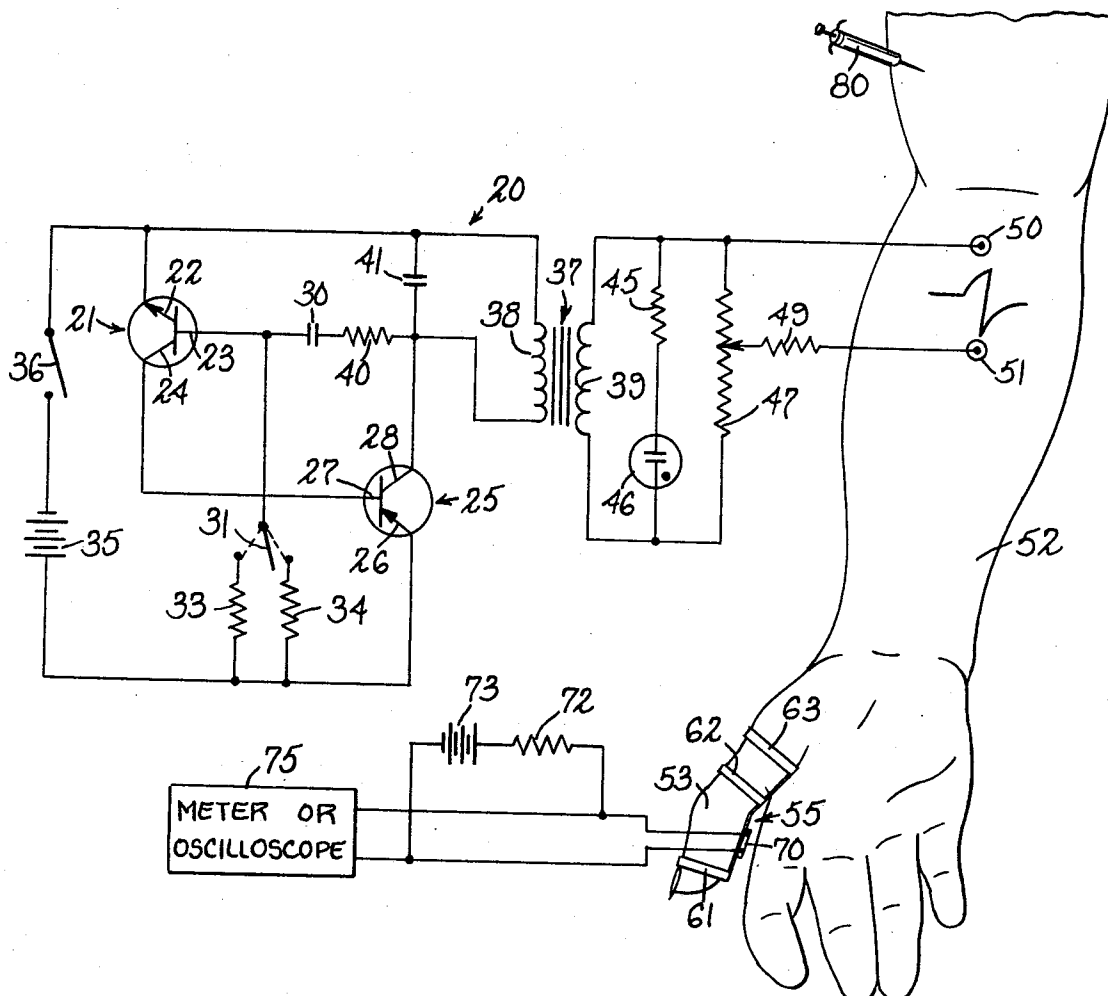
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[54] **NEUROMUSCULAR BLOCK MONITORING APPARATUS**
 10 Claims, 6 Drawing Figs.

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 128/2.1, 331/111, 331/179
 [51] Int. Cl. **H05g/00**
 [50] Field of Search 128/2.1,
 422

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ABSTRACT: A neuromuscular block monitoring device, comprising a battery, an oscillator circuit to translate the power supplied by said battery into electrical impulses and having a variable impedance and switch arranged to set the frequency at either a twitching or a tetanus frequency, a potentiometer coupled to said oscillator circuit to control the amplitude of said impulses to form an electrical signal having the effect of stimulating the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body, and a pair of spaced electrodes to apply the output of the potentiometer to the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body. There is also provided a splint having a strain gage mounted thereon and a display device for displaying the electrical output from said strain gage, the splint being adapted to fit on the thumb of a patient, and said strain gage responsive to the movement of the splint resulting from the application of electrical impulses to the patient.



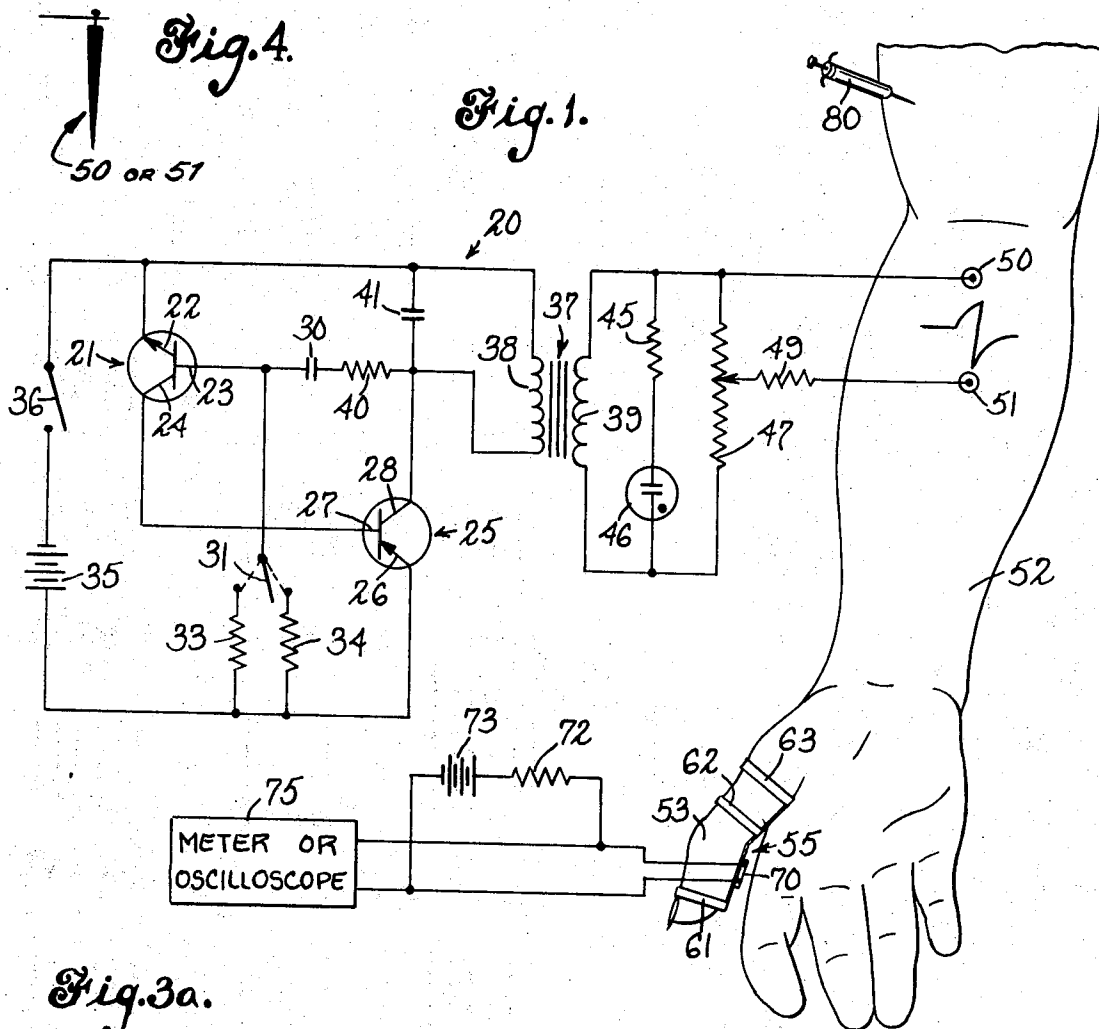


Fig. 3a.

ELECTRICAL STIMULI

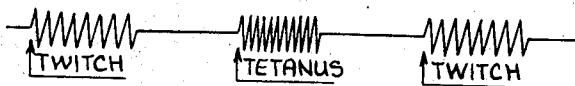


Fig. 3b.

NON-DEPOLARIZING BLOCK
BLOCK POST TETANIC FACILITATION

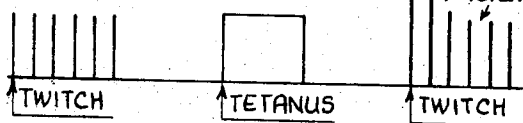


Fig. 3c.

DEPOLARIZING BLOCK

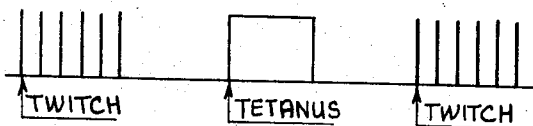
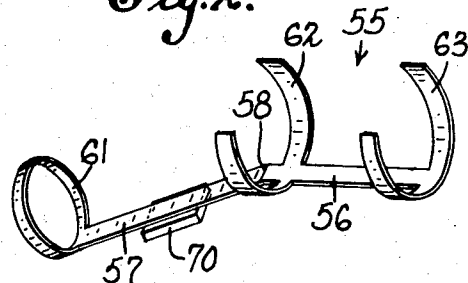


Fig. 2.



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NEUROMUSCULAR BLOCK MONITORING APPARATUS

This invention relates to a monitoring device for applying electrical stimuli to a patient to determine the type of neuromuscular block that exists within the patient.

Anesthesiologists and others have determined that the administration of muscle relaxant drugs, such as succinylcholine, dimethyl tubocurare and hexacarbacholine, produce depolarizing and nondepolarizing neuromuscular blocks in patients. During the course of surgery and after the completion of surgery, it is sometimes required that the patient who has been administered a muscle relaxant drug be stimulated by the administration of an antagonist drug to counteract the effects of the muscle relaxant drug. Commonly used antagonist drugs are physostigmine, eserine and edrophonium. In some instances instead of the antagonist stimulating the patient a continuation of the relaxation of the patient for prolonged periods has occurred. The prolonged period of relaxation has tended to be greater than that which would ordinarily occur without the administration of the antagonist. It is believed that this continuation of relaxation is related to the type of neuromuscular block existing in the patient.

In view of the foregoing, a new and improved apparatus for determining the correct time to administer muscle antagonist drugs was required.

Accordingly, it is an object of this invention to provide a new and improved apparatus for providing electrical stimuli to differentiate between depolarizing and nondepolarizing neuromuscular blocks due to the action of certain muscle relaxant drugs.

It is an additional object of this invention to provide a new and improved and simplified monitoring apparatus for stimulating the patient and to determine the type of neuromuscular block exhibited by the patient.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description taken in conjunction with the accompanying drawings, in which:

FIG. 1 illustrates schematically a transistorized, neuromuscular block monitoring device;

FIG. 2 is an isometric representation of a splint for mounting on a patient to detect response of a patient to electrical stimuli;

FIG. 3a is a graph illustrating the sequential electrical stimuli applied to the patient in accordance with this invention;

FIG. 3b is a graph showing the resultant response of a patient to the electrical stimuli as a result of a nondepolarizing block affecting the nerves of the patient;

FIG. 3c is a graph illustrating a depolarizing block of a patient in response to electrical stimuli; and

FIG. 4 shows one of the electrodes.

Referring now to FIGS. 1 and 2, a monitor oscillator or pulse generator is shown at 20 for generating an electrical stimulus in accordance with this invention. The pulse generator 20 includes a relaxation oscillator circuit having an NPN transistor 21 with an emitter electrode 22, a base electrode 23 and a collector electrode 24, and a PNP transistor 25 with an emitter electrode 26, a base electrode 27 and a collector electrode 28. The collector 24 of transistor 21 is coupled to the base 27 of transistor 25. Connected between the base electrode 23 of transistor 21 and collector electrode 28 of transistor 25 is a capacitor 30. Coupled intermediate the base 23 of transistor 21 and capacitor 30 is a variable resistance network for varying the frequency of the oscillator. The resistance network includes a switch 31 and two resistors 33 and 34. Switch 31 can be connected to either of resistors 33 and 34 to control the frequency of the oscillator. A source of direct current energy 35, such as a battery, is coupled at its positive terminal to emitter 26 of transistor 25 and to the other end of resistors 33 and 34. A switch 36 is provided in the line to place the DC energy source 35 in the circuit. One end of the switch is coupled to the emitter 22 and the other end of the

switch is coupled to the battery 35. A voltage step-up transformer is generally shown at 37. Transformer 37 has its primary winding 38 between the collector 28 of transistor 25 and emitter 22 of transistor 21.

A resistor 40 coupled in series with capacitor 30 and a capacitor 41 connected across winding 38 are preferably included to decrease extraneous voltages in the circuit. The secondary winding 39 of transformer 37 is coupled across a resistor 45 and a gas tube 46. The resistor 45 and gas tube 46 are in parallel with a variable resistor 47. The gas tube 46 indicates when the device 20 is providing a signal of a predetermined voltage level. Coupled in parallel with the top portion of the variable resistor 47 is a first electrode 50 and a second electrode 51 connected to resistor 47 through a resistor 49. The electrodes may be surface-type electrodes which are suitable for applying electrical stimuli to the arm 52 of a patient, but, preferably, needle-type electrodes are utilized which may be of the standard 25 gauge metal needle type.

The electrodes are placed on the arm or the legs of a patient in a well-known manner such that the ulnar nerve and/or the nerve motor point muscle function is stimulated by the signal provided from the oscillator 20. The oscillator 20 operates as follows: upon closure of switch 36 and the connection of switch 31 to one of resistors 33 and 34, the circuit 20 will begin to oscillate. Assume, for example, that switch 31 is coupled to resistor 34. The value of resistor 34 is selected such that the relaxation oscillator 20 will oscillate at a frequency somewhat above zero impulses per second but below 30 impulses per second. This is commonly termed as the frequency which will produce twitching of a digital member of a limb of a patient, as for example, a finger or a toe. This will henceforth be defined as the twitching frequency. The exact impulse frequency range to produce twitching will vary with the patient, and therefore a frequency of 20 impulses per second is preferred. With switch 31 coupled to the resistor 34, a voltage will be applied to transistor base 23 in such a direction as to cause transistor 21 to turn on. The turning on of transistor 21 causes transistor 25 to turn on. This causes a current to flow within the primary 38 of the transformer 37. Transistors 21 and 25 will continue to conduct as long as the transformer 37 is unsaturated. After a period of time, transformer 37 becomes saturated and a voltage across secondary 39 rapidly reverses according to Lenz's law. This causes a potential to be applied to base 23 of transistor 21 of such a polarity as to turn off transistor 21. This, in turn, turns off transistor 25. Capacitor 30 which charged in the reverse direction to cut off transistor 21 due to the saturation of transformer 37 then gradually discharges until the potential at the base electrode 23 of transistor 21 once again becomes of the proper polarity to turn on transistor 21 to restart the cycle.

The resultant output waveform of the oscillator is shown across electrodes 50 and 51. It is to be noted that the topmost portion of the turn-on cycle is slightly clipped due to the presence of gas tube 46. This gas tube flickering indicates to the observer that the impulse generating device 20 is operating. Assume now that the switch 31 is coupled to resistor 33. Resistor 33 is selected such that the impulse frequency rate will be on the order of between 35—120 impulses per second. In the preferred embodiment, 50 impulses per second was chosen. This range of frequencies is generally referred to as the tetanus frequency rate. The tetanus frequency reaction is observed by noticing the involuntary closing of a finger or a toe of a patient. The exact values for the frequency rate for both tetanus and twitching are generally a function of the patient and it is, therefore, to be understood that the ranges described are only illustrative and are not limiting.

Although it is to be understood that many modifications may be made to the above circuit, the following circuit values may be utilized to provide an impulse generating device suitable for generating both tetanus and twitching frequency impulses.

Transistor	21—2N 335
Transistor	25—2N 116

Capacitor	30-20 microfarads
Resistor	33-5.1 K. ohms
Resistor	34-330 K ohms
Battery	35-3 volts
Transformer	37-voltage step-up of approximately 30
Resistor	46-100 ohms
Capacitor	41-15 microfarads
Gas tube	46-NE 51 H

The device 20 is capable of providing approximately a 90 volts rms output signal across electrodes 50 and 51 when used with a 3 volt battery as the energy source for the circuit. This circuit is particularly usable during the administration of an anesthesia and during operations because it is explosion-proof due to the low value of currents and voltages utilized. To detect the response to the electrical stimuli provided across the electrodes 50 and 51, a digital member such as a thumb 53 of arm 52 may be observed. This may be accomplished without the use of any of the auxiliary detecting and monitoring devices shown in FIG. 1. On applying a twitching frequency signal to the electrodes 50 and 51, the twitching signal will produce a periodic contraction of the thumb 53. The application of a tetanus signal will draw the thumb closed. Thus, the twitching and tetanus signals may be observed by watching the motion of a finger or the toes of a patient.

The use of this information will be described at a later time in this specification.

Although the reaction of the patient to the application of tetanus and twitching muscle electrical stimuli may be observed without the use of electrical equipment, it is preferred that some type of electrical monitoring device be utilized to better assist in the recognition of the patient's response.

By the use of a splint, generally shown at 55, which is suitable for mounting on thumb 53, a device for indicating and displaying the response of the patient may be provided. The splint 55 comprises resilient flat portions 56 and 57 having a bend 58 therebetween. Positioned at one end of resilient member 57 is ring 61 suitable for surrounding the tip portion of the patient's thumb 53. Attached to the other member 56 of splint 55 are clamps 62 and 63. These clamps are shaped like rings, but have cutout portions for permitting the clamps to extend over the upper portion of the patient's thumb 53 above the joint. To record the bending of the splint 55, a suitable strain gauge 70 is mounted thereon in a position to record the pressure produced by the thumb against the splint. A strain gauge, such as the type SR-4 available from Baldwin-Lima Hamilton Corp. Waltham, Mass., may be used. Other types of strain or stress transducers such as strain sensitive diodes and transistors may also be utilized as well as piezo-electric devices. Strain gauge 70 is connected to a suitable circuit comprising resistor 72 and battery 73 for providing a current through the strain gauge. The variations of the current flow through the strain gauge, due to a change in resistance of the strain gauge because of flexing of thumb 53, can then be monitored on a meter such as a voltage meter or an oscilloscope 75. Further, other display devices may be utilized, for example, electrical-type brush recorders.

Referring now to FIGS. 3a, 3b and 3c for a description of the method, assume that the patient has been injected with a syringe 80 carrying muscle relaxant drugs such as succinylcholine, or dimethyl tubocurare. Further assume that an anesthesiologist deems it necessary to introduce a muscle antagonistic drug to counteract the effects of the muscle relaxant drug. To determine the proper time to inject the muscle relaxant antagonist, for example, by the use of a syringe 80 as shown in FIG. 1, the neuromuscular block monitoring device 20 is turned on and set to provide electrical stimuli at a twitching frequency. The electrical stimuli are applied at the ulnar nerve at the wrist or elbow or at a motor junction point. It is preferable to use needle electrodes, which may be inserted into the arm of the patient, rather than surface electrodes which tend to cause slight damage to the skin due to irritation by the electrodes after long periods of time as, for example, four hours. FIG. 3a shows the application of the electrical stimuli at a twitching frequency of about 20 impulses per

second, although variations may exist due to the particular patient. The response of the patient is shown in FIGS. 3b and 3c and may be observed on the oscilloscope 75. The spikes in FIGS. 3b and 3c indicate that the patient has reacted to the stimuli such as to produce a twitching of the digital member. This can also be observed by watching the digital member itself. After a period of time as, for example, 20 seconds, monitor oscillating device 20 is then set to provide electrical stimuli at a tetanus frequency. In the preferred embodiment, the monitor is set to provide 50 impulses per second, which is shown in FIG. 3a. The application of electrical impulses at tetanus frequency produces a clamping response of the patient's hand or toes such that the hand or toes tend to close during the application of the tetanus stimuli. This may be observed by noticing the square wave representation in FIGS. 3b and 3c or, again, by watching the digital member.

In the preferred method, the tetanus frequency is held for approximately 2 or to 3 seconds although many variations may be possible depending on the response of the patient. To determine the nature of the neuromuscular block, the monitor 20 is switched to provide electrical stimuli at the twitching frequency once again. FIG. 3b shows the response of the patient's digital members to the reapplication of the twitch frequency when there exists a nondepolarizing neuromuscular block within the patient. This figure further shows what is generally termed post-tetanic facilitation and which is represented by a sudden increase in the amplitude of the twitch response. This has been determined to be the response by the patient to a twitch frequency after the application of tetanus frequency electrical stimuli when there exists a nondepolarizing block within the patient. In FIG. 3c there is shown the response of the patient to the twitch electrical frequency stimuli when there exists a depolarizing neuromuscular block within the patient. In this figure it may be seen that there is no post-tetanic facilitation which is indicative of a depolarizing neuromuscular block.

It has been determined that a muscle antagonist drug should be introduced into the patient only when there exists a nondepolarizing block such as shown by the post-tetanic facilitation of FIG. 3b. The introduction of an antagonist drug when there is a depolarizing block such as shown in FIG. 3c potentiates the depolarizing block rather than counteracting the muscle relaxant drug. If the drug is administered when there is a depolarizing block, the patient generally requires a longer period of time to overcome the relaxant drug than would normally be required if the neuromuscular block were permitted to switch from a depolarizing to a nondepolarizing neuromuscular block by itself. This will generally occur after a predetermined time interval has elapsed to permit the muscle relaxant drug to lose at least some of its potency. It should be understood that a sensor strapped to an arm or leg of the patient could also be utilized, although a sensor strapped to a digital member is preferred.

It will thus be seen that the objects set forth above, a,pmg those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above devices without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

We claim:

1. A neuromuscular block monitoring device comprising a battery, an oscillator circuit to translate the power supplied by said battery into electrical impulses, said oscillator circuit including first circuit elements to produce said electrical impulses at a twitching frequency and second circuit elements to produce said electrical impulses at a tetanus frequency, a switch arranged to select either of said first and second circuit

elements to provide either one or the other of said frequencies, means coupled to said oscillator circuit to control the amplitude of said impulses to form an electrical signal having the effect of stimulating the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body, and a pair of spaced electrodes to apply the output of the control means to the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body.

2. A device in accordance with claim 1, wherein said control means includes a transformer for stepping up the voltage of the electrical impulses to a voltage level required for stimulation.

3. A neuromuscular block monitoring device, comprising a battery, a transistorized relaxation oscillator circuit to translate the power supplied by said battery into electrical impulses, said oscillator including a first amplifying means, a second amplifying means, a capacitor coupled between said first and second means, and first and second circuit means coupled at one end intermediate said first amplifying means and said capacitor and at the other end to said battery to set the frequency of said impulses at either a twitching or a tetanus frequency, said circuit means including a switch for selecting one or the other of said circuit means coupled to said oscillator circuit to control the voltage, current and wave shape of said impulses to form an electrical signal having the effect of stimulating the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body, and a pair of spaced electrodes to apply the output of the control means to the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body.

4. A neuromuscular block monitoring device, comprising a battery, a transistorized relaxation oscillator circuit to translate the power supplied by said battery into electrical impulses, said oscillator including a first transistor amplifying means of a first conductivity type, a second transistor amplifying means of an opposite conductivity type, a capacitor coupled between said first and second amplifying means, and a variable resistance means to provide only two different values of resistance, said variable resistance means coupled between said capacitor and said first means to establish the frequency of said impulses at a twitching frequency or at a tetanus frequency, and a switch arranged to select either one or the other of said values of resistance to select one or the other of said frequencies, a transformer coupled to said first and second means to step up the voltage of said impulses from said oscillator to a level such as to have an effect of stimulating the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body, and a pair of spaced electrodes for applying the electrical impulses to the body of a patient.

5. An ulnar nerve and/or nerve motor point muscle junction of a limb of a body stimulating device, comprising in combination a source of direct current energy, a first transistor of a

first conductivity type having emitter, base and collector electrodes, said emitter of said first transistor coupled to the source of energy, a second transistor of an opposite conductivity type having emitter, base and collector electrodes, said collector of said first transistor coupled to the base of the second transistor, a capacitor coupled to the base of said first transistor and to the collector of said second transistor, and the emitter of said second transistor coupled to said source of energy, a voltage step-up transformer coupled to the emitter of said first transistor and to the collector of said second transistor, means coupled to said transformer for applying the output of said transformer to the ulnar nerve and/or the nerve motor point muscle junction of a limb, and a variable resistance means coupled at one end intermediate the capacitor and the base of the first transistor and at the other end to the source of energy to set the frequency of the device to either a twitching frequency or a tetanus frequency, and a switch arranged to vary said resistance means to select either one or the other of said frequencies.

6. A device according to claim 5, wherein said variable resistance means comprises a first resistor and a second resistor and wherein the switch is connected to select either one or the other of said resistors.

7. A device according to claim 6, wherein said means coupled to said transformer includes a pair of electrodes and a gas tube indicating means coupled across said electrodes.

8. A neuromuscular block monitoring device for providing two different frequency signals to the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body and for monitoring the effect of said signals, said device comprising in combination, a source of direct current energy, an oscillator circuit to translate the power supplied from said energy source into electrical impulses and having means to set the frequency of said impulses only at a twitching frequency rate and or at a tetanus frequency rate, means coupled to said oscillator circuit to control the amplitude of said impulses to form an electrical signal having the effect of stimulating the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body, a pair of spaced electrodes suitable for applying said electrical impulses to the ulnar nerve and/or the nerve motor point muscle junction of a limb of the body, a switch arranged to adjust said frequency setting means to select one or the other of said a detection device adapted to be positioned upon a limb of the body for detecting the degree of flexing of the limb in response to said electrical impulses.

9. A device according to claim 8, wherein said detection device comprises a splint adapted to be mounted on a body limb and a strain gauge supported by said splint to detect bending of said splint.

10. A device according to claim 9, including a display device coupled to said strain gauge for detecting the change in current passing through the gauge.

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Disclaimer

3,565,080.—*Walter S. Ide*, Eastchester, and *William H. Nickerson*, Tuckahoe, N.Y. NEUROMUSCULAR BLOCK MONITORING APPARATUS. Patent dated Feb. 23, 1971. Disclaimer filed Apr. 20, 1978, by the assignee, *Burroughs Wellcome Co.*

Hereby enters this disclaimer to all claims of said patent.

[*Official Gazette June 13, 1978.*]