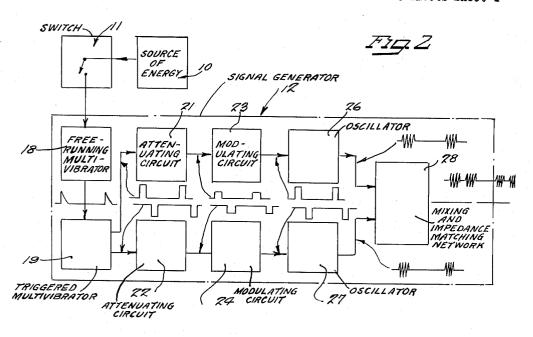
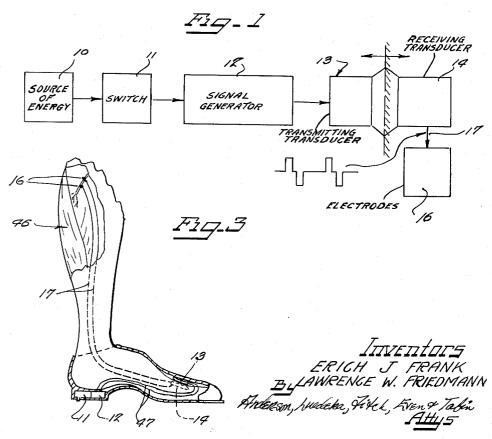
STIMULATING APPARATUS

Filed Feb. 7, 1963

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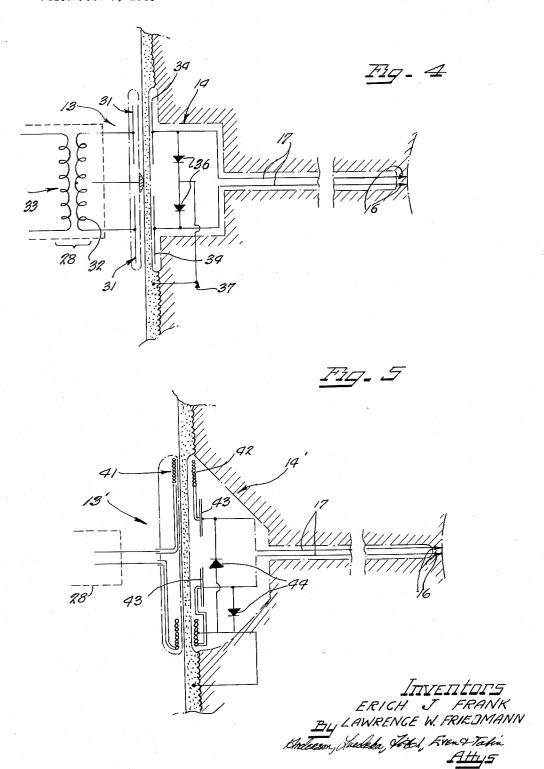




STIMULATING APPARATUS

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STIMULATING APPARATUS
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3 Claims. (Cl. 128—423)

This invention relates to electrophysiological stimulation and more particularly to the controlled stimulation of muscles to effect the movement of body limbs otherwise nonfunctional because of muscle denervation or the like.

Although one skilled in the art will appreciate the factors involved in the normal movement of one's limbs, certain general principles underlying limb-actuating muscle activity should be initially considered. muscles, while undergoing a contractile process initiated by the stimulation of nerves associated therewith, cause the activation of the various lever systems throughout the body whereby desired limb action is effected (e.g. the movement of the arms, legs, etc.). In this connection, the various nerve fibers connected through neuro-muscular junctions to limb actuating muscles supply nerve impulses or action potentials to the neuromuscular junc- 25 tion. When a nerve implse reaches the neuromuscular junction an amount of hormone is released into a small region between the muscle fiber and the nerve fiber. The hormone is present in this region for only a fraction of a second during which time an electro-chemical process takes place and an action potential is induced in the muscle fiber. In this connection, the neuromuscular junction functions essentially as an amplifier so that very small currents generated by normal functioning nerve fibers are translated into currents having sufficient magnitude to excite the muscle fibers. Accordingly, the normal excitation of a muscle is effected by this amplified transmission of a nerve fiber impulse through the neuromuscular junction so that a muscle stimulating action potential is produced to initiate the rather complex contractile proc- 40 ess that leads to the desired limb activity.

Various diseases, malformations, accidents and the like caused damage to or the destruction of the nerve fibers and/or neuromuscular junctions associated with limb actuating muscles so that the process generally outlined 45 above is either substantially inhibited or totally precluded from occurring. Moreover, injury to the corticospinal pathway resulting from a vascular lesion, hemorrhage, thrombosis or the like can effect hypertonia of the muscles thereby precluding normal limb actuating 50 muscle activity although the nerves and junctions associated directly with the muscles are intact. As a result of these and other defects, individuals are left without the use of their arms, legs or other limbs since the necessary actuating stimulus normally provided is either not produced or not transmitted to the muscles. Although various braces, artificial mechanical devices, and other forms of corrective apparatus have been devised in an attempt to provide a means whereby controlled move- 60 ment of one or more of these affected limbs can be produced, such devices have not proven satisfactory from either a functional or a cosmetic standpoint.

Therefore, it is a prime object of the present inven-

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tion to provide an improved method of and apparatus for effecting electrophysiological stimulation of muscles to accomplish the controlled movement of otherwise nonfunctional body members or limbs.

A further object of the invention is to provide an improved method of and apparatus for effecting controlled electrophysiological stimulation to replace defective cerebral control and/or compensate for other inhibitive defects in nerves by supplying variable action potentials to either muscle controlling nerves or the muscles themselves.

Still another object of the invention is to provide an improved method of and means for effecting the controlled stimulation of partially or totally denervated muscles through the utilization of apparatus which is reliable in operation, adaptable for use in a variety of applications and miniaturized for subcutaneous implantation.

Other objects and advantages of the present invention will become apparent from the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIGURE 1 is a simplified schematic illustration of the components of one preferred embodiment of the stimulating apparatus of the present invention;

FIGURE 2 is a schematic diagram which illustrates a preferred embodiment of a signal producing circuit associated with the stimulating apparatus illustrated in FIGURE 1:

FIGURE 3 is an illustration of a preferred embodi-30 ment of the apparatus of the present invention when applied to a limb of an individual;

FIGURE 4 is a diagrammatic illustration of one preferred embodiment of a transducer suitable for use with the apparatus illustrated in FIGURE 1; and

FIGURE 5 is another embodiment of a transducer suitable for use with the apparatus of the present invention

The present invention provides an improved method of an apparatus for effecting the controlled stimulation of muscles by supplying stimulating impulses either to nerve fibers that control limb actuating muscles or directly to the muscles themselves. In this connection, one preferred embodiment of the invention contemplates the subcutaneous implantation of a miniaturized transducer at a location that is normally not exposed to the view of others. Suitable conductors pass beneath the skin between the implanted transducer element and suitable electrodes that are joined to the nerve or muscle to be stimulated. The electrodes are secured to the nerve or muscle to be stimulated so that a desired stimulating action can be realized when a suitable signal pulse or train of pulses is supplied thereto. In this connection, a second transducer or transmitting element, which is also preferably a miniaturized element that can be readily disposed and confined adjacent the implanted transducer, functions to supply the necessary stimulating signal to the implanted transducer element from a signal generating circuit. The signal generating circuit preferably includes compact solid state circuitry that can also be confined on the person and yet hidden from the view of others. Preferably, suitable actuating means under the control of the individual is provided for selectively rendering the signal generating circuit effective so that the desired stimulus is supplied to a selected nerve tract or

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muscle to yield the controlled actuation of an otherwise nonfunctional limb.

As previously set forth, the method and apparatus of the present invention can be employed to effect the controlled stimulation of nerves or muscles themselves so that normally nonfunctional limbs can be activated at will by an individual. However, the following detailed description of one preferred embodiment of the invention will be premised on the application of the method and apparatus to one of the nerve trunks that controls leg action of an individual as shown in FIGURE 3.

More particularly, FIGURE 1 schematically illustrates one preferred embodiment of the electrophysiological stimulating apparatus of the present invention. As shown, the stimulating apparatus includes a suitable source of energy 10 (e.g. a battery) that is connected through a selectively actuable switch means 11 to a variable signal generating circuit 12. The switch means 11 preferably includes a time delay switching mechanism that can be adjusted to yield a predetermined delay in the actuation of the switch means for the purposes hereinafter described. When the switch means 11 is actuated (either immediately or after a desired period of delay), the necessary energy is supplied to the signal generator to render the generator effective, and a selectively variable output signal (i.e. a muscle stimulating pulse or pulse train) is produced thereby.

The output signal from the circuit 12 is fed to a miniaturized transmitting transducer element 13. The transducer 13 is preferably maintained in contact with the surface of the body of an individual adjacent the location whereat a receiving transducer 14 is subcutaneously implanted (e.g. in the foot of an individual for leg muscle stimulation). A signal transmitted through the skin of the individual and received by the transducer 14 is fed through suitable conductors 17 to a pair of stimulating electrodes 16 that are adapted to be connected to the nerve trunk or muscle to be stimulated.

In this connection, the transducer 14, the electrodes 16 and the conductors 17 which are implanted beneath the skin of the individual are preferably coated with a material such as Teflon or the like to preclude the surrounding subcutaneous tissue from being irritated or otherwise adversely affected by these components. Preferably, the conductors 17 and electrodes that are clamped to the member to stimulated are fabricated of a conductive material such as titanium which is not subject to corrosion. Moreover, the transducer element 14 which is connected to the conductors 17 is preferably implanted so that a minimum skin thickness overlies the receptive element 50 thereof.

As shown in FIGURE 2, the signal generating circuit 12 preferably includes the necessary circuit components to render the circuit suitable for use in a variety of applications and render it adaptable for use by a number of 55 different individuals. In this connection, the signal generating circuit 12 includes circuit means for producing an output signal having an adjustable pulse frequency, adjustable pulse amplitude, adjustable pulse duration, adjustable pulse rise and decay times, reversible pulse 60 polarity and which is susceptible to an adjustable degree of modulation. Providing a signal generating circuit capable of being adjusted when necessary is preferable since the strength-duration and strength-capacity characteristics of innervated and denervated muscles (although generally uniform) differ in some individuals and are subject to variation.

More particularly, when the switch means 11 is actuated, the necessary electrical energy is provided for the signal generating circuit 12 from the source 10. Energy supplied to the circuit 12 causes the initiation of the conduction of a conventional signal generating free running multivibrator 18. The output signal from the free running multivibrator 18, which preferably has a frequency within

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the range of 0 to 10 kilocycles per second and which preferably provides a ten percent adjustment in the output frequency within this range, is fed to and controls the conductive state of a conventional triggered multivibrator 19. The multivibrator 19 alternately provides dual rectangular opposite polarity output pulses of an adjustable pulse duration and having an adjustable pulse rise and decay time. In this connection, when muscle stimulation is effected by application of stimulating pulses to the nerves the pulse duration is preferably adjustable between 10 µseconds and 500 µseconds, and a pulse rise and decay time of 1 μ second is preferable. However, when stimulating pulses are supplied directly to the muscle to be stimulated, a pulse duration of between approximately 250 μ seconds and 30 milliseconds is preferable. The dual pulse forming branches of the signal generating circuit 12 preclude the possibility of nerve and/or muscle damage that can result when, for example, a single polarity pulse train is utilized to initiate the aforementioned electrochemical process that induces the limb actuating action potentials within the muscles. That is dual opposite polarity stimulating pulses preclude destructive ionization and permanent polarization from occurring and causing nerve and/or muscle damage.

As shown in FIGURE 2, the output circuits of the triggered multivibrator 19 are connected to a pair of parallelly connected, adjustable attenuating circuits 21 and 22 that provide output signals that yield voltage pulses at the electrodes 16 having a magnitude that is adjustable between 0 and 5 volts. More particularly, the pulse output from the triggered multivibrator 19 when in one state of conduction, is supplied to the attenuator 21. The pulse output corresponding to the alternate state of conduction and having an opposite polarity is fed to the attenuator 22. The output from each of the attenuating circuits 21 and 22 are individually fed through similar conventional, adjustable modulating circuits 23 and 24 and carrier oscillators 26 and 27 to a mixing and impedance matching network 28, which may for example be a transformer. The modulating circuits and carrier oscillators function to produce variable pulse modulated output signals having a carrier frequency of between approximately 1 kilocycle and 50 megacycles.

Although various forms of conventional signal generating circuits may be employed with the apparatus of the present invention, the various aforedescribed circuit components of the signal generator 12 and the arrangement thereof provide a readily adjustable means for producing the desired electrical stimulus for the limb actuating muscles. More particularly, the utilization of variable multivibrator circuits, attenuating circuits, modulators and carrier oscillators renders the illustrated embodiment of the signal generating circuit 12 capable of producing a pulse output of adjustable frequency, amplitude, duration, Accordingly, by employing the signal generator circuit 12 or other similarly adjustable circuitry, various stimulating pulses or pulse trains can be produced with a high reliability and with the necessary adaptability in relation to different patients, changes in power supply potential, displacement of transducer elements, and various other changes in variable parameters. Preferably, any necessary adjustment that is required to calibrate and adapt the apparatus for use on a specific patient is carried out by a skilled physician or technician after the necessary implantation has been carried out as hereinafter described and remains fixedly calibrated during operation on the patient.

As shown in the drawings, the stimulating pulses fed from the network 28 to the transducer 13 are transmitted through the skin to the transducer 14. Although various miniaturized transducer elements may be employed with the apparatus of the present invention, FIGURES 4 and 5 are illustrative of two forms of transducers which are particularly suitable for such use.

More particularly, the embodiments of the transducer elements 13 and 14 shown in FIGURE 4 employ capacitive coupling to transmit the signal pulses therebetween. In this connection, the transducer 13 includes a pair of transmitting capacitor coupling plates 31 that are connected across a center-tapped secondary winding 32 of an output transformer 33 provided by the network 28, the center tap being connected to the skin of the patient as shown. The transmitting capacitor coupling plates 31 are preferably arranged within a suitable compact housing 10 (not shown). That is, this entire transducer element 13 is miniaturized and can be readily mounted in aligned relation adjacent the corresponding receiving transducer element 14 which is implanted beneath the surface of the skin at a desired location.

More particularly, the coupling plates 31 of the transducer element 13 are preferably proportioned to be aligned with a corresponding pair of coupling plates 34 of the receiving transducer element 14. As shown, the coupling plates 34 are connected to the conductors 17 so that the 20 stimulating pulses transmitted thereto are fed directly to the electrodes 16 which are suitably attached to the nerve to be stimulated (FIGURE 3). A suitable demodulating network, which preferably includes a pair of rectifiers 36 that are connected to the skin to provide a point of refer- 25 ence potential 37, is connected across the coupling plates 34 so that signals coupled to the transducer 14 are demodulated prior to the transmission thereof to the electrodes 16 (FIGURE 1).

URE 5 are generally similar to the elements 13 and 14 shown in FIGURE 4 but rely on the principal of inductive coupling. In this connection, the transducer 13' includes a transmitting coil or winding 41 that is connected across the output of the network 28 and confined within 35 a suitable compact housing (not shown). As described in connection with the previous embodiment, the transmitting coil 41 is designed to be situated adjacent the receptive element of the receiving transducer 14' which is a receiving coil or winding 42 that is connected through the conductors 17 to the electrodes 16. The winding 42 is connected to the conductors 17 through coupling capacitors 43 and a demodulating network including rectifiers 44.

The method and apparatus of the present invention 45 whereby otherwise nonfunctional limbs can be rendered effective under the control of an individual can be further appreciated from a consideration of FIGURE 3. Assuming that the controlled contraction of one of the several leg actuating muscles generally designated by the numeral 46 is desired, an incision is made in the skin over the area of the muscle to be stimulated. Similarly, an incision is made preferably in the foot of the individual at a location that is normally covered by a shoe. This latter incision is used to implant the miniaturized receiving transducer 14.

More particularly, the attachment of the electrodes to a nerve trunk associated with the muscle 46 and the implantation of the transducer 14 is initiated by passing a guide wire from the incision at the point of stimulation to the area beneath the incision at the point of implantation of the transducer 14 whereat the ends of the conductors 17 are positioned. The ends of the conductors are then temporarily secured to the end of the guide wire, and the guide wire is withdrawn from this location thereby pulling the conductors 17 beneath the skin to the desired stimulation point and beyond until the transducer 14 is properly implanted in the incision in the foot. After the transducer 14 has been properly implanted, the additional unnecessary length of the conductors 17 extending out of the incision is cut away, and the electrodes 16 are suitably attached to the ends of the conductors. The electrodes 16 are thereafter secured to the nerve trunk at the desired locations to ensure an appropriate interelectrode spacing. After the implantation is carried out 75

the incisions are closed resulting in the receiving transducer 14 being covered by a relatively thin layer of skin.

With the receiving transducer 14 implanted within the foot as described above, the transmitting transducer element 13 is preferably attached to and confined inside the shoe of the individual. In this connection, the transmitting transducer element is preferably located within the shoe so that it will overlie the receiving transducer element 14 when the shoe is worn. Preferably, the transmitting transducer element 13 is coated with one of the non-toxic, non-reactive flexible plastics as a protective measure. Since the receiving transducer will be miniaturized the area of the shoe occupied by this element will not warrant substantial modifications in the shoe structure. Moreover, the transducer will be totally concealed from the view of others which is highly beneficial from a cosmetic standpoint.

The various other circuit components associated with the transmitting transducer 13 are also preferably miniaturized and capable of being confined within another portion of the shoe or strapped to the leg of the individual. In this connection, the switch means 11 might be disposed either in the toe portion or heel portion of the shoe. FIGURE 3 illustrates the utilization of the switch means confined in the heel along with the signal generating circuitry with conductors 47 being employed to connect this circuitry to the remotely positioned transmitting transducer 13.

When employing the switch means in the heel, it is The transducer elements 13' and 14' shown in FIG- 30 preferable that the actuating element of the switch means be located (e.g. protrude from beneath the heel as shown) so that upon movement of the heel away from the ground, operation of the signal generating circuitry can be initiated. More particularly, when using the switch means located within the heel, it is desirable that a delay be provided between the time that the actuating element is released by the upward movement of the heel and the time that the stimulating pulses are supplied to the stimulating electrodes 16.

For example, a time delay of approximately one quarter of a second is sufficient to allow the toe portion of the shoe to be lifted from the ground so that when the musicle is induced to contract, the foot is free to sweep through an arc without dragging across the surface of the ground. However, when the actuating element of the switch means is positioned in the toe portion of the shoe, it is not necessary that any time delay be provided since removal of the toe from the ground is the condition which should exist before the stimulating pulses are produced to effect the controlled contraction of the muscle and cause movement of the leg and foot. In either case, the signal generating circuit is cut off as soon as the foot is returned to the ground and the actuating element is reengaged.

From the foregoing, it should be apparent that a compact arrangement of elements is provided which allows an individual to walk without conscious effort or otherwise actuate nonfunctional limbs. The generated stimulating pulses supplied carry out the aforedescribed normal function of creating an action potential in the muscle which initiates the contractile process.

In one specific application of the invention, the anterior tibial muscle of an individual, which is controlled by the peroneal nerve, was induced to contract by stimulating pulses supplied to the peroneal nerve through the electrodes 16 which were spaced apart a distance of 3/16 inch. In this instance, a train of pulses was successively supplied to the muscle stimulating electrodes 16 by the signal generator at a frequency of 2000 cycles per second. These successive pulses had a pulse duration of 500 useconds, a rise and decay time of 1 usecond, and a magnitude of 70 millivolts at the electrodes. The contractile process initiated thereby resulted in an observable controlled movement of the foot through a distance of 3 inches.

Although the foregoing description has related primarily to the stimulation of nerves that control muscle activity, the invention has equal applicability to the direct stimulation of muscles. Moreover, smooth, balanced and sustained natural motion of one or more body limbs can be effected through the utilization of the present invention by selectively supplying suitable stimulating pulses to a plurality of selected nerve trunks and/or muscles. such a situation, it is desirable to program the operation of the signal generating circuit 12 so that the electrical 10 characteristics and the timing of the stimulating pulses are properly correlated to the controlled motion or motions which one desires to achieve.

It should be understood that the foregoing is merely illustrative of the application of the invention. Various 15 modifications in the structural and functional features of the apparatus and variations from the method can be readily devised by one skilled in the art without departing from the invention, various features of which are set forth in the following claims.

What is claimed is:

1. Apparatus for effecting the stimulation of body members, such as muscles or nerves that control muscle activity, by inducing an action potential therein, the of a leg, which apparatus comprises electrodes adapted to be subcutaneously implanted in contact with a body member which controls leg action of an individual, a receiving transducer element adapted to be subcutaneously implanted beneath the skin in the foot of the leg which is 30 to be moved, a demodulating network having an input coupled to said receiving transducer element, conductors extending between the electrodes and said demodulating network, said electrodes, said receiving transducer element, said conductors and said demodulating network being constructed of a material compatible with the environment of the human body to permit their implantation therein, a footgear for the foot, a transmitting transducer element carried in said footgear in a position such as to be in signal inducing relationship with the implanted 40 receiving transducer element so that signals transmitted through the skin by said transmitting transducer are received by said receiving transducer element, a signal generator means connected to said transmitting transducer element for producing stimulating pulse modulated signals 45 which includes pulse producing means for producing pulses of negative and positive polarity, a first oscillator, first modulating means coupled to said pulse producing means for modulating the output signal of said first oscillator with said pulses of negative polarity, a second 50 oscillator, second modulating means coupled to said pulse producing means for modulating the output signal of said second oscillator with said pulses of positive polarity, and mixing means coupled to said first and said second oscillators for mixing the output signals thereof, said 55 mixing means having its output coupled to said transmitting transducer element, said generator means being carried in the footgear, said demodulating network including means for converting said pulse modulated signals into pulses of opposite polarity, and switch means disposed in the footgear and being responsive to a lifting of the footgear, said switch means being connected to said signal generator for selectively rendering said generator effective when said switch means is operated, whereby said generator supplies stimulating pulse modulated signals through said transducer elements which signals are demodulated by the demodulation means and are coupled to the electrodes to cause movement of the leg.

2. Apparatus for effecting the stimulation of body members, such as muscles or nerves that control muscle activity, by inducing an action potential therein, the stimulation of which body members effects the movement of a leg, which apparatus comprises electrodes adapted to be subcutaneously implanted in contact with a body member which controls leg action of an individual, a 75

transformer including a primary winding and a secondary winding, said secondary winding having a center connection intermediate its end connections and being adapted to be subcutaneously implanted beneath the skin in the foot of the leg which is to be moved, a demodulating network having an input coupled to said secondary winding, said demodulating network including a pair of diodes interconnected in series between said end connections, said center connection being coupled to the connection between said diodes and being adapted to be connected to the skin, conductors extending between the electrodes and the end connections of said secondary winding, said electrodes, said secondary winding, said demodulating network and said conductors being constructed of a material compatible with the environment of the human body to permit their implantation therein, footgear for the foot having a heel, said primary winding being carried in said footgear in position to be in inductive relationship with the implanted secondary winding, a signal generator 20 means connected to said primary winding for producing pulse modulated signals and being carried in the heel of the footgear, said signal generator means including means for producing pulses of negative and positive polarity, a first oscillator, first modulating means coupled to said stimulation of which body members effects the movement 25 pulse producing means for modulating the output signal of said first oscillator with said pulses of negative polarity, a second oscillator, second modulating means coupled to said pulse producing means for modulating the output signal of said second oscillator with pulses of positive polarity, and means coupled to said first oscillator and to said second oscillator for mixing the output signals thereof and coupling the mixed signals to said primary winding, and switch means carried in the footgear and being responsive to a lifting of the footgear, said switch means being connected to said signal generator for selectively rendering said generator effective when said switch means is operated whereby said generator supplies stimulating pulse modulated signals through said transformer which are demodulated and coupled to the electrodes to cause movement of the leg.

3. Apparatus for effecting the stimulation of a nerve trunk that controls the muscle activity of a leg by inducing an action potential therein, which apparatus comprises electrodes adapted to be subcutaneously implanted in contact with the nerve trunk which controls leg action of an individual, a shoe for the foot of the leg to be controlled, said shoe having a heel, a transmitting transducer including a pair of transmitting capacitor coupling plates carried in said shoe, a transformer including a primary winding and a center tapped secondary winding, the center tap of said secondary winding being adapted to be connected to the skin of the leg, the end connections of the secondary winding being connected respectively to the transmitting capacitor coupling plates, a signal generator means connected to said primary winding for producing pulse modulated signals and being carried in the heel of said shoe, said signal generating means including means for producing pulses of negative and positive polarity, a first oscillator, first modulating means coupled to said pulse producing means for modulating the output signal of said first oscillator with said pulses of negative polarity. a second oscillator, second modulating means coupled to said second pulse producing means for modulating the output signal of said second oscillator with pulses of positive polarity, and means coupled to said first oscillator and to said second oscillator for mixing the outputs thereof and supplying the mixed signals to said primary winding, a receiving transducer including a pair of receiving capacitor coupling plates and adapted to be subcutaneously implanted beneath the skin in the foot of the leg in capacitive relationship with the transmitting capacitor coupling plates, conductors coupling the receiving coupling plates to the electrodes, a pair of diodes interconnected in series between said receiving coupling plates, the connection between said diodes being adapted

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to be connected to the skin, said electrodes, said diodes, said conductors and said receiving coupling plates having an external surface constructed of a material compatible with the environment of the human body to permit an implantation therein, and switch means carried in the shoe and being responsive to a lifting of the shoe, said switch means being connected to said signal generating means for selectively rendering said signal generating means effective when said switch means is operated, whereby said generating means supplies stimulating pulse modulated signals through said transmitting and receiving coupling plates, which signals are demodulated and coupled to the electrodes to cause movement of the leg.

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effective when said switch means is operated, whereby said generating means supplies stimulating pulse modulated signals through said transmitting and receiving the signals through the signals through said transmitting and receiving the signals through said transmitting and receiving the signals through the signals through the signal transmitting and transmitting through the signal transmittent transmitt

RICHARD A. GAUDET, Primary Examiner.