ELECTRICAL STIMULATION APPARATUS AND METHOD

Technical Field of the Invention

This invention relates to the electrical stimulation of tissue for the treatment of selected physiological conditions and, more particularly, to a novel electrical stimulation apparatus and method having an interchangeable electrode module, the electrode module serving as an activation key and being pre-programmable to deliver a predetermined treatment protocol for the particular physiological condition.

Background of the Invention

Various skin lesions such as those resulting from acne and herpes virus are known to be amenable to treatment through the use of electrical stimulation. Although various theories have been advanced to explain this phenomena, to date, no satisfactory explanation has been put forth as a rationale for why these types of skin conditions can be successfully treated using electrical stimulation. In spite of this lack of explanation, various devices have been developed for the delivery of electrical stimulation to tissue. For example, U.S. Patent No. 5,117,826 teaches a device for the combined nerve fiber treatment and body stimulation while U.S. Patent No. 5,133,352 teaches a method for treating herpes simplex. A small size, low frequency curing apparatus is shown in U.S. Patent No. 4,922,906. An electrotherapeutic treatment apparatus is shown in U.S. Patent No. 5,107,835. U.S. Patent No. 4,913,148 discloses the treatment of herpes simplex I and II as well as herpes zoster. A low frequency electrotherapeutic device is disclosed in U.S. Patent No. 5,133,351.

Each of these devices apparently resulted from the search for a device that could be used for the various therapeutic purposes as disclosed in the description of the device and its intended use. It is clear from the foregoing that electrical stimulation can be beneficial if appropriately applied to the area requiring treatment. Appropriate application includes, for example, predetermining the correct voltage of the electrical stimulation, the pulse waveform, if any, the amperage, and the application duration, to name several. Clearly, each application requires that each of the foregoing elements of the electrical stimulation must be tailored to meet the specific requirements for each patient.

In view of the foregoing, it would be an advancement in the art to provide an electrical stimulation apparatus and method wherein the apparatus is pre-programmable to provide each patient with the appropriate electrical stimulation as a function of the patient condition to be treated. It would also be an advancement in the art to provide the electrical stimulation apparatus with a replaceable electrode module. It would be an even further advancement in the art to provide the electrode module with a logic circuit to

allow the electrode module to be pre-programmed with the predetermined operating parameters for the electrical stimulation apparatus. It would be an even further advancement in the art to provide an electrical stimulation apparatus that provides both the patient and the treating physician with the capability of monitoring treatment progress with the electrical stimulation apparatus. Such a novel invention is disclosed and claimed herein.

Brief Summary of the Invention

This invention is a novel electrical stimulation apparatus and method having a hand-held housing and a replaceable electrode module. The housing includes a first electrical circuit and a first battery for the operation of the electrical stimulation function. A second electrical circuit and second battery provides a time/date function. A liquid crystal display (LCD) on the housing is coupled to both the first and second electrical circuits and provides a visual display of the various functions of the electrical stimulation apparatus including a treatment timer, an ON/OFF indicator, a battery status indicator, an indicator for the number of remaining treatments available, a screen prompt, a treatment indicator, treatment cycle indicator, beeper, visual bars, and a time/date display, respectively. The electrode module is provided with a programmable probe control logic circuit to allow the electrical stimulation apparatus to be selectively programmed for each particular application.

In practice, the prescribing physician prescribes the appropriate treatment protocol which is entered into the programmable probe control logic circuit of the electrode module. The patient obtains the pre-programmed electrode module under prescription and plugs it into the hand-held housing where the pre-programmed prescription is relayed to the first electrical circuit in the housing. Ultimately, the electrical stimulation apparatus could be made available OTC. The operational instructions to commence the treatment protocol are visibly displayed on the LCD to instruct the patient in the operation of the stimulation apparatus. Importantly, the electrode module is specifically programmed to meet the treatment requirements of the individual patient during the treatment process and, equally as important, the electrode module is programmed to cease functioning upon completion of its programmed treatment cycle. This latter feature is designed to encourage the patient to return to the prescribing physician for further analysis of the patient's condition and thereby enable the physician to selectively alter the treatment protocol as programmed into the electrode module in order to more suitably treat the patient. It is, therefore, a primary object of this invention to provide improvements in electrical stimulation apparatus.

Another object of this invention is to provide improvements in the method of delivering electrical stimulation.

Another object of this invention is to provide an electrical stimulation apparatus having a replaceable electrode module.

Another object of this invention is to provide a programmable logic circuit in the electrode module.

Another object of this invention is to provide an LCD on the electrical stimulation apparatus as a source of information for the electrical stimulation apparatus.

Another object of this invention is to provide the prescribing physician with the capability to more closely monitor usage of the electrical stimulation apparatus by the patient.

These and other objects and features of the present invention will become more readily apparent from the following description in which preferred and other embodiments of the invention have been set forth in conjunction with the accompanying drawing and appended claims.

Brief Description of the Drawings

FIG. 1 is an exploded, perspective view of the electrical stimulation apparatus of this invention showing the electrode module prior to engagement with the housing;

FIG. 2 is a perspective view of the back side of the electrical stimulation apparatus of FIG. 1;

FIG. 3 is a schematic diagram of the circuitry of the electrical stimulation apparatus of FIGs. 1 and 2;

FIG. 4 is an enlargement of the LCD screen shown in FIG. 1 showing all of the display features of this novel electrical stimulation apparatus;

FIG. 5 is the display of the LCD screen of FIG. 4 prior to insertion of the electrode module;

FIG. 6 is the display of the LCD screen prior to the start of the treatment protocol;

FIG. 7 is the display of the LCD screen during treatment showing the time remaining for the treatment cycle; and

FIG. 8 is the display of the LCD screen upon completion of the treatment cycle.

Description of the Preferred Embodiments

The invention is best understood from the following description with reference to the drawing wherein like parts are designated by like numerals throughout and taken in conjunction with the appended claims.

The novel electrical stimulation apparatus and method described herein are designed to provide the prescribing physician with the capability of selecting a specific treatment protocol for the particular condition to be treated using electrical stimulation.

The electrical stimulation apparatus can be provided as a single unit or as a two-component device, a base unit and an electrode module, the latter configuration being the preferred configuration for several reasons. The electrode module can be made disposable not only for sanitary reasons but also to require the patient to refill the prescription with another electrode module in the event further treatment is required. This procedure not only allows the physician to more closely monitor the patient use of the electrical stimulation apparatus, but it also allows the physician to change the prescription as the treatment progresses.

The electrode module is provided with a logic circuit that allows the electrode module to be pre-programmed with the instructions for the specific treatment parameters. These parameters include the dosage amount (milliamps and microvolts), current profile (whether steady state or pulsatile), waveform, and the number of treatments and the duration of the treatments. Once the prescribed number of treatments have been delivered by the logic circuit, the electrode module is programmed to cease operating, thereby requiring the patient to obtain a replacement electrode module which is available only by prescription. By adopting this procedure, the physician is able to more closely monitor the treatment of the patient as well as reduce instances of the electrical stimulation apparatus being shared among patients, thus reducing cross contamination between patients by infected electrodes. The programmability of the electrode module also allows the physician to selectively prescribe different treatment parameters for the electrical stimulation apparatus as the treatment progresses whether for treating acne, herpes lesions, carpal tunnel syndrome, psoriasis, or the like.

The base unit contains a first battery which provides power to administer the dose of electrical current for the treatment function. A second battery provides electrical energy to a circuit that controls all functions related to the LCD screen, clock, and timer. The LCD screen is capable of displaying a plurality of messages such as a clock/alarm, an ON/OFF notice, an "insert key" notice, a battery level indicator, an alphanumeric remaining dosage indicator, a current power HI/M/LO meter, a "push ACT to Start" notice, a flashing circle to indicate dosage delivery, a dosage bar, and a time/date display.

Operationally, pressing the ON/OFF key to turn on the electrical stimulation apparatus results in the system being activated. In the event the electrode module has not been electrically coupled to the base unit, the LCD screen will flash the message "INSERT KEY." Once the key (electrode module) has been inserted, one of the messages HI, M, or LO will be displayed indicating, respectively, high, medium, or low, to indicate the level of dosage set by the pre-programmed logic circuit in the electrode module. Simultaneously, the alphanumeric indicator will also display the number of remaining treatments, again, as set by the pre-programmed electrode module. A battery symbol will also be displayed to provide a visual indication of the battery status. This

battery status is for the battery that provides current for a dose. If the battery charge is too low, a dose cannot be dispensed. A "PUSH ACT TO START" display flashes to indicate to the patient that the ACT button should be pushed. Once the ACT button has been activated a small circle flashes at a rate of one flash per second to indicate that the electrical stimulation treatment is being delivered to the electrodes. Simultaneously, the alphanumeric display changes from the number of treatments available to display the word "GO" to indicate that the electrical stimulation apparatus is in operation. During treatment, the dosage bar is created as a horizontal array of vertical bars with each vertical bar being created in one second increments until the treatment has concluded and the dosage bar is filled. Also, a short beep tone is generated at the rate of four beeps per second during the treatment.

Completion of the treatment cycle causes the alphanumeric indicator to display the letters "OK," the circle to stop flashing, the dosage bar to be filled, and a long beep tone of one second. After a brief delay, the LCD screen resets to its beginning display.

Detailed Description of the Invention

Referring now to FIGs. 1 and 2, the novel electrical stimulation apparatus 10 includes a housing 12 and an electrode module 20. Housing 12 is configured to be hand portable and has an external dimension comparable to a small pocket calculator thereby rendering electrical stimulation apparatus 10 readily transportable and accessible for immediate use whenever the requirement arises. Housing 12 includes an LCD 40, an ON/OFF switch 42, an ACT switch 44, and a set switch 46, the function of each of which will be discussed more fully hereinafter. Housing 12 also includes battery covers 48 and 49 (FIG. 2), each of which is removable to provide access to the respective batteries, battery 58 and clock battery 66 (FIG. 3) housed within housing 12.

Electrode module 20 includes a body 22 having a base 24 at one end and extending into a generally twin pyramidal configuration formed with a first apex 26 and a second apex 27. First apex 26 serves as a support for a first electrode 28 while second apex 27 serves as a support for a second electrode 29. A first connector 30 extends outwardly from base 24 and serves as an electrical connector for electrically coupling electrode module 20 to housing 12 by engaging a second connector 31 (FIG. 2) in the end of housing 12. A partial enclosure 32 shields a plurality of prongs that constitute first connector 30 against damage and also provides a reliable mechanism for keying electrode module 20 to housing 12 in the correct orientation.

Referring now to FIG. 3, a schematic of the electronic circuitry of electrical stimulation apparatus 10 (FIGs. 1 and 2) is shown generally as circuit 50 and includes an electrode module circuit 52 and a base circuit 54. Electrode module circuit 52 is housed within electrode module 20 (FIGs. 1 and 2) and is electrically coupled to base circuit 54,

housed within housing 12 by electrical contact being made between first connector 30 and second connector 31. Electrode module circuit 52 consists of a probe control logic circuit 56 which is electrically coupled to electrodes 28 and 29. Probe control logic circuit 56 is pre-programmable in order to provide the necessary instructions for the operation of base circuit 54. In particular, probe control logic circuit 56 is selectively pre-programmed with such features as the total number of treatments available with the particular electrode module 20 along with the type, duration, and electrical energy of the specific electrical stimulation. This feature provides the prescribing physician with the ability to closely monitor the treatment program of the particular patient. Control over the number of treatments available significantly reduces the likelihood of cross contamination between patients caused by sharing electrical stimulation apparatus 10 since only a limited number of treatments are available per each prescription as pre-programmed into electrode module 20. The limited number of available treatments also requires the patient to return to the prescribing physician on a regular basis to thereby provide the prescribing physician with the capability of more closely monitoring the treatment progress, and, advantageously, selectively alter the treatment protocol as contained in the memory of probe control logic circuit 56.

Base circuit 54 includes a battery 58, a main control logic circuit 60 and a current regulator 62. Current regulator 62 and main control logic circuit 60 provide the predetermined electrical stimulus to electrodes 28 and 29 as preset in the memory of probe control logic circuit 56. A second battery, battery 66, drives an LCD driver 64 and a clock circuit 68 which provides a continuous time and date display on LCD screen 40. LCD driver 64 provides the necessary electronic processing to present the predetermined information displayed on LCD screen 40 as will be discussed more fully hereinafter.

Referring now to FIG. 4, LCD screen 40 is shown with all of the displays possible thereon. These displays include a horn icon 70; a battery symbol 72; an alphanumeric display 74; an INSERT KEY prompt 76; a dosage power indicator 78 shown as one of "Hi," "M," or "Lo" to indicate high, medium, or low power, respectively; a PUSH ACT TO START prompt 80; a pulse circle 82; a dosage bar 84; and a time and date display 86. Each of these features will be discussed more fully hereinafter with respect to the description of the functions shown in FIGs. 5-8. Time and date display 86 is operational at all times regardless of the status of electrical stimulation apparatus 10 (FIGs. 1 and 2) and regardless whether electrode module 20 is mounted to housing 12.

Referring now to FIG. 5, LCD screen 40 is shown upon initial activation of ON/OFF key 42 (FIG. 1). At this stage battery symbol 72 is displayed along with INSERT KEY prompt 76 which instructs the user to electrically couple electrode module 20 to housing 12. This display on LCD screen 40 occurs only if electrode module 20 is

electrically uncoupled from housing 12 and ON/OFF switch 42 has been activated to the ON position. Otherwise, with electrode module 20 coupled to housing 12 LCD screen 40 displays only time and date display 86 when ON/OFF switch is in the OFF position.

Referring now to FIG. 6, LCD screen 40 is shown at its display configuration when electrode module 20 is electrically coupled to housing 20 with ON/OFF switch turned to the ON position and prior to initiation of the treatment process by electrical stimulation apparatus 10. In particular, battery symbol 72 is displayed to show the status of battery 58 while dosage power indicator 78 displays the symbol "M" to indicate medium dosage power, as pre-programmed into probe control logic circuit 52 (FIG. 3). Alphanumeric display 74 displays the numeral 30 indicating that thirty remaining dosages are available with electrical stimulation apparatus 10. This designation is indicated by the presence of REMAINS reminder 75. PUSH ACT TO START prompt 80 is displayed to alert the user to the next step in the treatment procedure and pulse circle 82 is displayed as a solid display.

Referring now to FIG. 7, LCD screen 40 is shown immediately upon activation of ACT button 44 wherein pulse circle 82 commences flashing or otherwise pulsing in a light and dark manner at one-second intervals while alphanumeric display 74 reads "GO." Simultaneously, dosage bar 84 commences to progressively fill with a plurality of vertical bars advancing from the left toward the right. Each vertical bar represents a one-second period of time in the treatment protocol.

Referring now to FIG. 8, LCD screen 40 is shown immediately upon completion of the treatment cycle in that alphanumeric display 74 now reads OK to indicate successful completion of that particular treatment cycle with electrical stimulation apparatus 10. Further, pulse circle 82 is a steady, solidly colored circle and dosage bar 84 is completed with a plurality of vertical bars. This display is held for several seconds and an audible tone is emitted as visually indicated by the horn icon 70. After a preset period of time, LCD screen returns to a blank screen with the exception of time and date display 86.

The Method

In the practice of the method of this invention using electrical stimulation apparatus 10, the prescribing physician provides to the patient a prescription to enable the patient to obtain electrical stimulation apparatus 10 wherein probe control logic circuit 56 in electrode module 20 has pre-programmed therein all of the predetermined operational parameters for electrical stimulation apparatus 10 as prescribed by the physician. These parameters include, for example, the number of treatments prescribed, their duration and frequency, and the electrical characteristics of the electrical stimulation including the voltage, amperage, waveform, amplitude, and frequency, if any, to name

several. Each of these parameters are predetermined by the prescribing physician in order to meet the particular requirements for treating the physiological condition diagnosed whether acne, herpes simplex, carpal tunnel, eczema, psoriasis, dermatitis, or the like. Advantageously, probe control logic circuit 56 is selectively programmable to provide electrode module 20 with the specific operational instructions to suitably control main control logic circuit 60. Further, since electrode module 20 is pre-programmed for the treatment of a specific condition of a specific patient, there is a significantly reduced likelihood that the patient will share the electrical stimulation apparatus 10 with another patient, thus significantly reducing cross contamination between patients.

After having obtained electrical stimulation apparatus 10 with electrode module 20 and having probe control logic circuit 56 suitably programmed, the patient activates ON/OFF switch 42 where the appropriate prompt is displayed on LCD 40. For example, in the event electrode module 20 is not electrically coupled to housing 12, or more particularly, to base circuit 54, the screen prompt on LCD 40 will display as prompt 76 the words "INSERT KEY" as shown in FIG. 5. The correct coupling of electrode module 20 to housing 12 changes LCD screen 40 to the display shown in FIG. 6. In particular, alphanumeric display 74 reads "30" which is an indication that thirty treatments remain in this particular configuration of electrode module 20 as shown by prompt 75 with the word "REMAINS." Prompt 80 instructs the patient to activate electrical stimulation apparatus 10 by pushing ACT switch 44. The patient places electrodes 28 and 29 in a bracketing position over the particular area to be treated and then pushes ACT switch 44. Alphanumeric display 74 changes from a display of the number of treatments remaining to the word "GO" and dosage indicator 82 starts to flash while dosage bar 84 commences to fill sequentially with a plurality of vertical lines. Each line of dosage bar 81 represents one electrical impulse having the predetermined parameters as set forth herein above and delivered to electrodes 28 and 29. Upon completion of the treatment cycle, dosage bar 84 is filled horizontally, dosage indicator 82 ceases to flash and becomes a solid circle, the word "OK" is displayed by alphanumeric display 74, and a tone is emitted as indicated by horn icon 70. The patient then returns electrical stimulation apparatus 10 to its storage position until it is time to initiate the next treatment sequence. If desired, electrode module 20 may be removed from housing 12 although this step is unnecessary in the event further treatments are available therein as determined by the programming of probe control logic circuit 52. Set switch 46 allows the patient to set the time and date display 86 by suitably controlling clock circuit 68.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the

invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WE CLAIM

1. An electrical stimulation apparatus comprising:

a housing;

display means on said housing for visually displaying selected information;

a first electrical circuit in said housing for supplying a preselected amount of a first electrical energy for said electrical stimulation;

a first battery electrically coupled to said first electrical circuit;

a second electrical circuit and a second battery electrically coupled to said second electrical circuit, said second electrical circuit providing a second electrical energy for operating said display means; and

an electrode module configured to be selectively coupled to said housing and in electrical connection with said electrical circuit, said electrode module comprising a key for activating said first electrical circuit, said key comprising a probe control logic circuit for providing instructions to said first electrical circuit.

2. The electrical stimulation apparatus defined in claim 1 wherein said probe control logic circuit comprises pre-programming means for pre-programming said probe control logic circuit with a pre-selected treatment protocol for said first electrical circuit.

3. The electrical stimulation apparatus defined in claim 2 wherein said key is configured as a disposable element to accommodate disposal of said key upon completion of said preselected treatment protocol.

4. The electrical stimulation apparatus defined in claim 2 wherein said display means includes prompt means for prompting a user of said electrical stimulation apparatus to follow said preselected treatment protocol.

5. The electrical stimulation apparatus defined in claim 2 wherein said display means includes a treatment status display means for displaying the status of the treatment delivered by said electrical stimulation apparatus.

6. The electrical stimulation apparatus defined in claim 1 wherein said display means includes a battery status display means for displaying the status of said first battery.

7. An apparatus for enabling a prescribing physician to selectively prescribe a predetermined prescription of electrical stimulation to a tissue of the patient comprising:

a housing, said housing being configured to be hand portable;

a first electrical circuit in said housing;

a first battery in said housing, said first battery being operable to deliver electrical energy to said first electrical circuit;

an electrode module removably mounted to said housing;

a second electrical circuit in said electrode module, said second electrical circuit being electrically coupled to said first electrical circuit when said electrode module is mounted to said housing;

electrodes on said electrode module, said electrodes extending outwardly from said electrode module to enable said electrodes to be placed in contact with the tissue of the patient, said electrodes being in electrical connection with said second electrical circuit; and

programming means in said second electrical circuit for enabling the prescribing physician to selectively program said electrode module with said predetermined prescription of electrical stimulation for the tissue of the patient.

8. The apparatus defined in claim 7 wherein said housing includes a display means for displaying information relative to said predetermined prescription of electrical stimulation.

9. The apparatus defined in claim 7 wherein said information displayed includes the number of treatments in said predetermined prescription remaining in said electrode module.

10. The apparatus defined in claim 7 wherein said information displayed includes instructions to the patient for the activation of said electrical stimulation.

11. The apparatus defined in claim 7 wherein said information displayed includes the status of said first electrical circuit.

12. The electrical stimulation apparatus defined in claim 7 wherein said display means includes an alarm means to remind the user to use said electrical stimulation apparatus.

13. The electrical stimulation apparatus defined in claim 7 wherein said display means includes an error display means in the event said first electrical circuit is activated in the absence of said electrode module.

14. A method for providing electrical stimulation to tissue comprising the steps of:

preparing a first electrical circuit operable to deliver said electrical stimulation;

interconnecting a first battery to said first electrical circuit;

enclosing said first electrical circuit and said first battery in a housing; and

providing an electrode module for delivering said electrical stimulation to the tissue from said first electrical circuit, said electrode module being selectively mountable to said housing and containing pre-programmable means for programming said first electrical circuit when said electrode module is mounted to said housing in electrical connection to said first electrical circuit.

15. The method defined in claim 14 wherein said providing step includes selectively programming said pre-programmable means with a predetermined treatment protocol for a patient.

16. The method defined in claim 15 wherein said selectively programming step includes modifying said treatment protocol for the patient by reprogramming said pre-programmable means.

17. The method defined in claim 14 wherein said enclosing step includes providing a visual display on said housing for displaying information relative to said electrical stimulation.

18. A method for providing a preselected electrical stimulation to the tissue of a patient comprising the steps of:

preparing a first electrical circuit, said first electrical circuit including a first battery;

enclosing said first electrical circuit in a housing, said housing being configured to be hand portable;

assembling a second electrical circuit, said second electrical circuit including programming means for programming said second electrical circuit;

placing said second electrical circuit in an electrode module;

mounting a pair of electrodes to said electrode module in electrical communication with said second electrical circuit;

programming said programming means in said second electrical circuit with a predetermined treatment protocol for said preselected electrical stimulation;

coupling said second electrical circuit to said first electrical circuit; and

activating said first electrical circuit and said second electrical circuit while contacting the tissue with said pair of electrodes thereby directing said preselected electrical stimulation to the tissue.

19. The method defined in claim 18 wherein said enclosing step includes providing a display means on said housing, said display means displaying information regarding said electrical stimulation.