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(54) Title: METHOD AND APPARATUS FOR PERFORMING MICROCURRENT ELECTROTHERAPY

(57) Abstract: An electrotherapy method and apparatus for healing injuries and tissue diseases to the human or animal body is disclosed. Particularly, the electrotherapy method disclosed herein comprises delivering a current under various conditions, such as, applying microcurrents ranging from 4 miliamperes to 1 femtoamperes, applying an laternating current with a frequency in the range of .00065 Hz to .00085 Hz, utilizing large surface area electrodes to achieve to low current densities of less than 5 microamperes per square inch. The apparatus of the present invention includes a plurality of electrode wraps for applying said electrotherapy method to a body. Each electrode wrap includes a first layer wrap of water absorptive material and a second layer wrap of moderately conductive material. Each electrode wrap is placed on a portion of the body, including, without limitation, arms, legs, hands, feet and torso. The method and apparatus of the present invention are useful in treating wounds, ulcerations, spinal cord injuries, amyotrophic lateral sclerosis, multiple sclerosis, nervous system abnormalities, scar tissue and age lines.

METHOD AND APPARATUS FOR PERFORMING MICROCURRENT ELECTROTHERAPY

The present application is a Continuation-in-Part of U.S. Patent Application Serial No. (To be Assigned), filed on August 24, 2000, which is incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

The present invention relates to a microcurrent electrotherapy method and apparatus for using extremely low level current and current densities to promote the healing process in a subject in need thereof.

DESCRIPTION OF THE PRIOR ART

Electrotherapy is well known to those skilled in the art as a way of assisting the human body's natural healing process. Prior inventions in the field of electrotherapy have been directed at treating such ailments as pains, lacerations, abrasions, sprains, strains, neurolgia, Parkinson's disease, fatigue, hemorrhoids and the like. Several different methods have been developed for applying electrotherapy to the human body. Some techniques, such as that described in U.S. Patent No. 5,935,156, which is incorporated herein by reference, teach applying a direct current to the body. Other techniques, such as that described in U.S. Patent No. 4,960,125, which is incorporated herein by reference, teach applying an alternating current to the body.

The recognized method by which electrotherapy performs its healing functions is by acting on the ions contained within human tissue. Human tissue for the most part is not electrically neutral, but contains charges in the form of positive and negative ions. These positive and negative ions are the life energy force of the body. When an electric current is applied to a body, that current creates a force on the ions in the tissue of that body, causing the ions to be displaced from their original position. The movement of these ions causes, among other things, a warming and stimulation of the tissue, and also assists in the movement of fluids through the body.

However, several problems have been identified with the previously utilized techniques of electrotherapy. It has been recognized that the utilization of direct current through the body can cause the tissue of the body to which the current is applied to break down. Such a result is counter-productive to the goal of increased regeneration and healing of the human body. As an alternative, the application of alternating current to the body is currently the most commonly used method of electrotherapy treatment. However, the application of high-frequency alternating current has been recognized to have minimal therapeutic effect. This is due to the fact that a high frequency alternating current causes the ions of the tissue to oscillate rapidly without being displaced very far from their original positions. Therefore, electrotherapy techniques have been developed that utilize low frequency alternating current. Such a technique is disclosed in U.S. Patent No. 5,476,481, which is incorporated herein by reference. The known techniques of low-frequency alternating current electrotherapy utilize a low-end frequency of around .01 Hz.

The concept of microcurrent electrotherapy is well-known in the art. Microcurrent electrotherapy, also called MENS (microcurrent electrical neuromuscular stimulation), is the use of low-level current to promote healing and regeneration of the human body. The current used in microcurrent electrotherapy is normally in the range of 20 microamperes to 600 microamperes. One benefit of microcurrent electrotherapy over high current electrotherapy techniques is that it results in little or no discomfort to the patient.

Another problem with current electrotherapy techniques is that the current density (current per unit surface area) of these techniques is fairly high. Most electrotherapy techniques, including microcurrent electrotherapy techniques, utilize small electrodes of several square inches of surface area. This translates into a current density of .1 milliamperes per square inch to 5 milliamperes per square inch for high current electrotherapy techniques at the point of current application to the body and as the current travels through the body. Current density yields for microcurrent electrotherapy techniques range from 5 microamperes per square inch to 120 microamperes per square inch. The high current densities achieved by the known techniques overload the body's natural electropotential during application. Applicants have discovered that the resulting overload of the body's natural electropotential is counter-productive to stimulation of the body's natural process of tissue healing and regeneration.

SUMMARY OF THE INVENTION

The present invention is a method and apparatus for electrotherapy. The object of the present invention is to improve upon the known techniques of electrotherapy, as well as overcome some of their limitations. To achieve the foregoing in accordance with the present invention, a method and apparatus is provided for healing injuries to the human body, as well as other types of tissue. It is understood that the method and apparatus of the present invention can also be used for veterinary purposes. A method and apparatus is also provided for stimulating regeneration and growth of otherwise unhealthy tissue. Particularly, the method and apparatus of the present invention is useful in treating wounds, ulcerations, spinal cord injuries, amyotrophic lateral sclerosis, multiple sclerosis, nervous system abnormalities, scar tissue and age lines.

In one aspect of the present invention, a method is disclosed which includes delivering a microcurrent under specific conditions, such as: applying microcurrents ranging from 3 milliamperes to 1 femtoamperes, applying an alternating current with a frequency in the range of .00065 Hz to .00085 Hz and utilizing large surface-area electrodes, referred to herein as electrode wraps, to achieve low current densities. The use of currents lower than 20 microamperes is currently unknown in the prior art. Prior techniques have also not utilized the very low current frequency and current densities of the present invention for any current level.

In another aspect of the present invention, an apparatus is disclosed which includes a plurality of electrode wraps for applying said electrotherapy method to a body. Each electrode wrap includes a first layer wrap of water absorptive material and a second layer wrap of moderately conductive material. Each electrode wrap is placed on a portion of the body, including, without limitation, arms, legs, hands, feet and torso. The first and second layers of the electrode wrap are applied to the selected portion of the body in such a way that each forms a closed surface around the body part to which they are applied. An electropotential is then applied across the electrode wraps to generate a current flow through the body. The area of application of the electrode wraps to the selected portion of the body is large compared to the area covered by known electrotherapy electrodes.

In yet another aspect of the present invention, a means for generating electric current for a microcurrent therapy is disclosed. The current output generator ("COG") is the preferred device for generating a constant current and outputing said current to the electrode wraps according to the method of the present invention. The current is provided

to the electrode wraps from the COG by means for conducting current, such as a rubber-encased copper wire, which is electrically connected to either the positive or negative lead from the current output generator. Particularly, the COG is designed to deliver current according to the method of the present invention.

The method of the present invention teaches a constant current in the range of 3 milliamperes to 1 femtoampere. When these low current levels are utilized with the large surface area of the electrode wraps of the present invention, extremely low current densities are achieved at the points of application of said current and throughout the flow of current through the body, as have heretofore been unknown in the prior art. These extremely low current densities provide for a gentle push and pull on the ions of the tissue to which the current is applied, which does not overload the body's natural potential.

The method of the present invention also utilizes a long duty-cycle of between .00065 Hz and .00085 Hz. While alternating current is known in the prior art, no prior art teaches the utilization of such a long alternating current period. Experimentation by applicants has shown that a duty-cycle of .000732 Hz, or one cycle every 22.77 minutes, increases the body's ability to heal and regenerate tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1(a) is a depiction of the preferred electrode wrap as taught by the present invention.

FIG. 1(b) is a drawing of the preferred method of application of the electrode wrap.

FIG. 2 is a picture of the user interface and display panel of the preferred current output generator of the present invention.

FIG. 3 is a diagram of components of the preferred current output generator of the present invention.

DETAILED DESCRIPTION OF PREFFERED EMBODIMENT OF INVENTION

The present invention provides for an apparatus consisting of various components. One component is an electrode wrap. Referring now to **FIG. 1(a)**, an electrode wrap consists of a first and second layer wrap. The first and second layer wrap is applied to the selected portion of the body to which the current of the electrotherapy method of the present invention, or other electrotherapy method, is to be applied. The first and second

layer wraps are applied in a manner such that a large surface area of the selected portion of the body is covered by said wrap. **101** The first layer wrap consists of a water-absorbent bandage. The bandage may be made of any material that easily absorbs and retains water, and may be of any length and width sufficient to completely wrap the portion of the body to which it is to be applied. **102** The second layer wrap consists of a moderately conductive, synthetic rubber impregnated cloth strap. The strap is of a length sufficient to wrap a large surface area of the selected portion of the body to which it will be applied. In a preferred embodiment, the second layer wrap is approximately two inches wide and twelve feet long, although other width and length wraps are contemplated by the present invention. In a preferred embodiment, the second layer wrap is composed of a cloth impregnated with silicon rubber acting as a flexible carrier for conductive carbon particles dispersed within the silicon rubber. The second layer wrap has a nominal resistance of 2 Kohms across the length of the wrap, as measured by any calibrated galvanic ohm meter.

Referring now to **FIG. 1(b)**, when the **101** first and **102** second layer wrap are applied to the portion of the body to which the electrotherapy current will be introduced, they serve as a conductive surface around the selected portion of the body. Each electrode wrap is attached to either the positive or negative lead of the current output generator by **103** a means for conducting current, including, without limitation, copper wire, silver wire, iron wire, brass wire or aluminum wire. The electrode wraps are attached to the COG by alligator clips, button clips or other means in such a way that a complete circuit can be formed such that current will flow to one or more electrode wraps, then through the body, to the other one or more electrode wraps and then back to the COG. The current thus generated through the body creates a net force on the ions of the body in the path of the generated current through the body, thereby promoting healing and regeneration of the body's tissue. This current also has an effect in stimulating change to the body chemical structure by, among other things, reducing cortisol levels and increasing melatonin levels.

An apparatus is provided for by the present invention that supplies the current to be applied to the electrode wraps according to the method of the present invention. The preferred embodiment for this apparatus, the COG, is described below.

Referring now to **FIG. 2** and **FIG. 3**, the COG has a preferred user interface. The user interface for the COG is contained on the **201** front of the COG casing. The user

interface has a **202** power switch. The power switch can be of any of the various types of switching devices allowing for an on and off position. In a preferred embodiment, the power switch is a latching pushbutton switch. When the power switch is in the off position, no current is drawn from the batteries or other power supply for the COG. When the power switch is in the on position, the COG draws power from the **301** battery or other power supply and can generate a potential difference between the **302** positive and negative COG leads. When the power switch is turned to the on position the COG microprocessors receive power and begin a self- test sequence, as more fully described herein, to verify that the processors and safety monitors are functional. Until the self-test successfully executes, no treatment operation of the COG is possible.

The user interface also preferably contains a plurality of other switches. These switches can be any of the various types of switching devices that allow for two or more possible switching positions, for example, a latching or momentary push-button switch or multi-channel rotating switch. Further, the functionality of all switches may be incorporated into one multi-purpose switching device that can control all the functions of the plurality of independent switches.

A first switch is provided for in the present invention that is used to select the electrotherapy program to be applied as taught by the present invention. Preferably, the **203** program selection switch is a pushbutton thumbwheel switch. The program switch has sixteen different selection positions. Each position corresponds to a given level of current to be applied to the patient.

Another switch is provided for in the present invention that when utilized, in conjunction with the program selection switch, selects normal, Z mode, and three different femto modes of operation of the electrotherapy method of the present invention, allowing different ranges of current to be applied to the patient. Preferably, the **204** mode selection switch is a rotating thumbwheel switch. When utilized, the **204** mode selection switch sends a signal to the **313** option processor to change the operation of the COG to the selected mode. The **204** mode selection switch does not function to change modes of the COG when the COG is currently in a treatment cycle.

The sixteen positions of the **203** program selection switch, when in normal mode, selects one of thirteen possible current levels, comprising: 10 microamperes, 20 microamperes, 30 microamperes, 40 microamperes, 50 microamperes, 60 microamperes, 70 microamperes, 80 microamperes, 90 microamperes, 100 microamperes, 1 milliampere,

2 milliamperes and 3 milliamperes. When in normal mode, the last four positions of the **203** program selection switch all select the 3 milliampere current level. The sixteen positions of the **203** program selection switch, when in Z mode, selects one of ten possible current levels, comprising: 115 nanoamperes, 215 nanoamperes, 310 nanoamperes, 410 nanoamperes, 505 nanoamperes, 605 nanoamperes, 705 nanoamperes, 800 nanoamperes, 900 nanoamperes and 1000 nanoamperes. When in Z mode, the last six positions of the **203** program selection switch do not select any current level.

The **204** mode selection switch also has three possible pico modes. The three pico modes divide the current being supplied to the **302** COG output leads by activating the **317** femto-pico attenuator circuit. The **317** femto-pico attenuator circuit, when activated, divides the current of the Z mode operation by one thousand (pico1 mode), ten thousand (pico2 mode) and one hundred thousand (pico3 mode).

The sixteen positions of the **203** program selection switch, when in pico1 mode, selects one of ten possible current levels, comprising: 115 picoamperes, 215 picoamperes, 310 picoamperes, 410 picoamperes, 505 picoamperes, 605 picoamperes, 705 picoamperes, 800 picoamperes, 900 picoamperes and 1000 picoamperes. When in pico1 mode, the last six positions of the **203** program selection switch do not select any current level.

The sixteen positions of the **203** program selection switch, when in pico2 mode, selects one of ten possible current levels, comprising: 11.5 picoamperes, 21.5 picoamperes, 31 picoamperes, 41 picoamperes, 50.5 picoamperes, 60.5 picoamperes, 70.5 picoamperes, 80 picoamperes, 90 picoamperes and 100 picoamperes. When in pico2 mode, the last six positions of the **203** program selection switch do not select any current level.

The sixteen positions of the **203** program selection switch, when in pico3 mode, selects one of ten possible current levels, comprising: 1.15 picoamperes, 2.15 picoamperes, 3.1 picoamperes, 4.1 picoamperes, 5.05 picoamperes, 6.05 picoamperes, 7.05 picoamperes, 8 picoamperes, 9 picoamperes and 10 picoamperes. When in pico3 mode, the last six positions of the **203** program selection switch do not select any current level.

The **204** mode selection switch also has three possible femto modes. The three femto modes divide the current being supplied to the **302** COG output leads by activating the **317** femto-pico attenuator circuit. The **317** femto-pico attenuator circuit, when

activated, divides the current of the Z mode operation by one million (femto1 mode), ten million (femto2 mode) and one hundred million (femto3 mode).

The sixteen positions of the **203** program selection switch, when in femto1 mode, selects one of ten possible current levels, comprising: 115 femtoamperes, 215 femtoamperes, 310 femtoamperes, 410 femtoamperes, 505 femtoamperes, 605 femtoamperes, 705 femtoamperes, 800 femtoamperes, 900 femtoamperes and 1000 femtoamperes. When in femto1 mode, the last six positions of the **203** program selection switch do not select any current level.

The sixteen positions of the **203** program selection switch, when in femto2 mode, selects one of ten possible current levels, comprising: 11.5 femtoamperes, 21.5 femtoamperes, 31 femtoamperes, 41 femtoamperes, 50.5 femtoamperes, 60.5 femtoamperes, 70.5 femtoamperes, 80 femtoamperes, 90 femtoamperes and 100 femtoamperes. When in femto2 mode, the last six positions of the **203** program selection switch do not select any current level.

The sixteen positions of the **203** program selection switch, when in femto3 mode, selects one of ten possible current levels, comprising: 1.15 femtoamperes, 2.15 femtoamperes, 3.1 femtoamperes, 4.1 femtoamperes, 5.05 femtoamperes, 6.05 femtoamperes, 7.05 femtoamperes, 8 femtoamperes, 9 femtoamperes and 10 femtoamperes. When in femto3 mode, the last six positions of the **203** program selection switch do not select any current level.

When in normal mode, the COG has a tolerance of plus or minus five percent for each current level selected. When in Z mode, pico mode or femto mode operation, the COG has a tolerance level of plus or minus fifteen percent. For the first ten positions of the program selection switch indicated above, whether in Z mode, normal mode or any pico or femto mode, the patient or other operator of the COG can select single cycle or repeating cycle modes. For these positions, the present invention provides for a **217** one cycle switch that selects either one cycle or repeating mode. The **217** one cycle switch is preferably a latching pushbutton switch. The operation of the COG is limited to only one cycle mode for the last six positions of the program selection switch. When utilized, the **217** one cycle switch sends a signal to the **303** option processor indicating that no further treatment cycles should be started after conclusion of the present treatment cycle.

Another switch is provided for in the present invention that begins the treatment cycle of the electrotherapy method of the present invention. Preferably, this **205** switch is

a momentary pushbutton switch. When utilized, the **205** run program switch sends a signal to the **304** system control processor indicating that the treatment cycle should begin. If certain safety conditions described more fully herein are met, the COG will deliver current to the **302** COG output leads according to the mode that has been selected with the other switches.

Another switch is provided for in the present invention that when utilized will pause the electrotherapy treatment cycle. When the **206** pause switch is utilized, a signal is sent to the **304** system control processor to halt output of current to the COG leads. The time remaining in the treatment cycle is stored by **305** the range cycle processor. When the patient or other operator of the COG wishes to resume the paused treatment, the **206** pause switch is again selected to unpause the treatment cycle. A signal is then sent to the **304** system control processor. If certain safety conditions described more fully herein are met, the output of current to the **302** COG leads is resumed and the treatment cycle continues.

Another switch is provided for in the present invention that when utilized will end the electrotherapy treatment cycle. Preferably, the **207** program end switch is a momentary pushbutton switch. When the **207** program end switch is utilized, a signal is sent to the **304** system control processor to reset the COG. The **304** system control processor activates the **306** master reset line. The **306** master reset line is attached to the manual reset pin of each microprocessor of the COG. Activation of the program end switch causes all the COG microprocessors to reset and all current output to cease.

Another switch is provided for in the present invention that when utilized lowers the sound level of the **307** sonic alarm of the COG. Preferably, the **208** quiet switch is a latching pushbutton switch. If the **307** sonic alarm is presently unquieted, when the **208** quiet switch is utilized a signal is sent to the **307** sonic alarm to reduce the voltage provided to the speaker. If the **307** sonic alarm is presently quieted, when the **208** quiet switch is utilized a signal is sent to the **307** sonic alarm to increase the voltage provided to the speaker.

The **201** user interface for the COG also preferably has a status display. **209** A status display aids the patient or other operator in the utilization of the COG and microcurrent electrotherapy method of the present invention. The status display preferably has six status indicators. The status indicators are preferably LED devices, such as a Kingbright ® L-1154 round LED lamp, that light in certain situations. The **209**

status display communicates with and receives commands from the **304** system control processor. In order to conserve battery power, the LED status indicators are not continually lit, but flash for a very short duration, typically 1/100th of a second, every five seconds.

One status indicator **210** is used to indicate when the COG is supplying current to the **302** COG output leads, and the electrotherapy method is in progress. Another status indicator **211** is used to indicate a pause in the electrotherapy method by either the patient or other operator of the COG. Another status indicator **212** is used to indicate when the electrotherapy treatment has been completed and the COG is no longer supplying current to the **302** COG output leads. Another status indicator **213** is used to indicate that the battery supplying the power to the COG is running low and should be replaced or recharged. Another status indicator **214** is used to indicate when the circuit formed by attaching the electrode wraps to the **302** COG leads by means for conducting electrical current is open, and hence the COG cannot supply current to the electrode wraps. Another status indicator **215** is used to indicate that a fault lockout has occurred.

The COG also preferably has a **216** cycle span time display. The cycle span time display indicates to the patient or other operator of the COG the duration and time remaining in the treatment cycle. The **216** cycle span time display is preferably a bar graph segmented LED display, such as a Kingbright ® DC-10 bar graph array. The **216** cycle span time display communicates with and receives instructions from the **308** cycle span display processor. For a ten segment LED display, each segment represents a period of approximately ten percent of the cycle time. Each segment is lit when the time period that the segment represents is entered. Once an LED segment is lit, it remains lit until the entire cycle span time display is reset. For example, at the beginning of the treatment cycle the first LED segment is lit. The second LED segment is lit after ten percent of the cycle time has elapsed, so that the first and second LED segments are now lit. The third LED segment is lit after twenty percent of the cycle time has elapsed, so that the first, second and third LED segments are now lit. This continues until the last LED segment is lit when ninety percent of the cycle time has elapsed, so that all the LED segments are lit. When every LED segment is lit, the patient is thereby informed that the current treatment cycle is nearing completion. If the patient or other operator has selected repeating cycle mode, the **313** option processor will send a command to the **308** cycle span display processor to reset the **216** cycle span time display and begin incrementing again. In order

to conserve battery power, the **216** cycle span time display is not continually lit, but flashes approximately every 20 seconds for a duration of 1 second.

The COG preferably has a **307** sonic alarm. The **307** sonic alarm may consist of a speaker attached electrically to a wave generator. Preferably, the **307** sonic alarm is a piezo-buzzer, that emits a short beep. However, other devices for making sounds are contemplated by the present invention. The **307** sonic alarm communicates with and receives instructions from the certain processors of the COG. Preferably, the processors that communicate with the **307** sonic alarm are the **304** systems control processor, the **313** option processor and the **305** range cycle processor. On the occurrence of certain events, the appropriate systems processor sends an instruction to the **307** sonic alarm indicating that said event has occurred. The **307** sonic alarm processes the incoming signal, and outputs an appropriate signal to the speaker. The speaker then outputs an appropriate aural indicator.

As an example, consider the case where a patient starts an electrotherapy treatment cycle and then falls asleep. If the patient has set the COG to one cycle mode, the COG will automatically terminate after one treatment cycle. When the COG completes the one cycle, a signal is sent from the **305** range cycle processor to the **307** sonic alarm, instructing it to send a signal that one cycle is completed. The **307** sonic alarm then generates a wave signal that is sent to the speaker. The speaker then makes that signal aural, informing the sleeping patient that a cycle has been completed. In this way, a patient that is sleeping, or otherwise unable to see the progress of the treatment cycle on the **216** cycle span time display, can be informed of the end of a treatment cycle.

Other aural indicator functions for the sonic alarm are contemplated by the present invention. These functions include, but are not limited to, low battery power, open circuit, current out of tolerance level, fault lockout and end of program. On the occurrence of any of these events, the appropriate system processor sends a command to the wave generator. The **307** sonic alarm processes the incoming signal, and outputs an appropriate signal to the speaker. The speaker then outputs an appropriate aural indicator.

The COG is preferably supplied power by **301** battery. The **301** battery is preferably a six volt rechargeable battery. The COG does not draw current from the battery until the **202** power switch of the **201** user interface is set in the on position. Once the power switch is in the on position, current flows to the **309** power supply and voltage regulator. The **309** power supply and voltage regulators distributes power and maintains

adequate voltage throughout the circuitry of the COG. The **309** power supply and voltage regulator communicate with and receive instructions from the **305** range cycle processor. The COG operates for approximately 50 hours on one charge of the **301** preferred battery.

The present invention also provides for a **310** constant current source. The **310** constant current source provides a constant current to the **311** polarity switching device. This constant current provided by the **310** constant current source is preferably within the tolerances of the selected program from the **203** program selection switch. The **310** constant current source communicates with and receives instructions from the **305** range cycle processor.

The **310** constant current source preferably consists of a voltage reference, a current sensing device, an amplifier, control element and output current source. The current sensing device signals are sent to the amplifier and then are compared to the reference voltage. A control signal is derived from the comparison and sent to the control element to adjust to the correct voltage value for the selected current range. In the case where the current measured by the current sensing device is outside the tolerance range of the selected program, the amplifier sends a signal to the control element to either increase or decrease the voltage being created between the **302** COG leads, thereby bringing the current being supplied to the **302** COG leads within the tolerance set by the selected program. In this way the constant current source is able to continually adjust to any change in the load present on the **302** COG output leads, thereby maintaining an acceptable current output.

The present invention also provides for **312** a plurality of electrical safety circuits. These circuits are continuously active and constantly measures various performance levels of the COG. In a preferred embodiment the COG internal operating voltage is monitored for a minimum acceptable voltage. If the internal operating voltage falls below this level, the **312** electrical safety circuit sends a signal to the **304** system control processor indicating that low system voltage has been detected. The power source voltage being supplied to the **310** constant current source is also monitored by the **312** electrical safety circuits for an acceptable maximum voltage. If the voltage is above this level, the **312** electrical safety circuit sends a signal to the **304** system control processor indicating that over voltage has been detected. The current being supplied to the **302** COG output leads is also monitored by the **312** electrical safety circuits for maximum safe current levels. In a preferred embodiment the maximum safe current level varies

with the selected treatment current level, i.e. approximately 20% above the current level of the selected treatment program. If the current being supplied to the **302** COG output leads is measured to be above this maximum safe current level, a signal is sent to the **304** system control processor indicating that the current is being supplied to the **302** COG output leads is above the safe current level range.

The present invention provides for a **305** range cycle processor. The **305** range cycle processor is a microprocessor, such as a CMOS microprocessor, programmed to operate according to the method and requirements of the present invention. The **305** range cycle processor receives data from the **203** program selection switch indicating which program should be run. The **305** range cycle processor passes the selected program current level information to the **310** constant current source and to the **304** system control processor. The **305** range cycle processor also controls the cycle time of the COG. Specifically, the **305** range cycle processor sets the cycle time to .000732 Hz. The **305** range cycle processor controls the **311** polarity switching circuit, causing the current flow to be reversed every half-cycle. When the **305** range cycle processor receives a pause signal from the **206** pause switch, the **305** range cycle processor halts the cycle time. When the **305** range cycle processor receives an unpause signal from the **206** pause switch, the **305** range cycle processor continues the cycle time.

The present invention provides for a **303** option board. The **303** option board is comprised of an **313** option processor and a **308** cycle span display processor attached to a circuit board. The **313** option processor is a microprocessor, such as a CMOS microprocessor, programmed to operate according to the method of the present invention. In a preferred embodiment, the **313** option processor receives signals from the **217** one cycle switch and **204** mode switch. When a signal is received from the **204** mode switch, the **313** option processor changes the mode of operation of the COG. When the **313** option processor receives a signal from the **217** one cycle switch, provided certain safety condition as more fully described herein are met, the **313** option processor changes the COG operation from one cycle mode to repeating cycle mode or from repeating cycle mode to one cycle mode as appropriate.

The **308** cycle span display processor is a microprocessor, such as a CMOS microprocessor, programmed to operate according to the method of the present invention. The **308** cycle span display processor monitors the elapsed time in each treatment cycle. The **308** cycle span display processor sends instructions to the **216** cycle span time

display to light the next LED segment after an appropriate time has elapsed, e.g. at the beginning of each 1/10th of the cycle time for a 10 segment LED display. The **308** cycle span display processor also resets the **216** cycle span time display after the termination of each treatment cycle.

Alternatively, the **303** option board may also include a **316** systems operation surveillance circuit. The **316** systems operation surveillance circuit is an inter-microprocessor analog circuit. The **316** systems operation surveillance circuit acts as a surveillance timer for the COG. In a preferred embodiment the **316** systems operation surveillance circuit receives periodic signals from the **304** system control processor, i.e. one signal every 30 seconds. If the **316** systems operation surveillance circuit fails to receive a periodic signal from the **304** system control processor, the **316** systems operation surveillance circuit times out. This time out indicates that the performance of the **304** system control processor cannot be validated. When the **316** systems operation surveillance circuit times out, a manual reset signal is sent to each of the COG processors via the **306** manual reset line to terminate all operations and reset. The COG must then successfully run a self-test in order to restart operations.

The present invention provides for a **304** system control processor. The **304** system control processor is a microprocessor, such as a CMOS microprocessor, programmed to operate according to the method and requirements of the present invention. The **304** system control processor receives from the **312** electrical safety circuits a signal indicating the voltage across the terminals of the **301** COG battery. If the received signal indicates a significant voltage drop across the battery terminals, i.e. voltage lower than 5.8 volts DC for a six volt battery, the **304** system control processor sends a signal to the **307** sonic alarm to aurally indicate that the **301** battery should be recharged and sends a signal to the **213** low battery LED of the **209** status display to light and visually indicate that the **301** battery should be recharged. If the received signal indicates a substantial voltage drop across the battery terminals, i.e. voltage lower than 4.6 volts DC, the **304** system control processor sends a signal, via the **306** master reset line, to reset all COG microprocessors and halt further operation of the COG. The COG will be inoperable until the **301** battery has been replaced or recharged to an acceptable voltage level, i.e. approximately 5.8 volts DC.

The **304** system control processor also operates as an error sensor for the COG. The **304** system control processor receives other signals from the **312** electrical safety

circuits. If an error signal, as discussed above, is received by the **304** system control processor, the **304** system control processor halts system operation. The **304** system control processor then isolates the output to the **302** COG leads from the rest of the COG circuitry so no potential difference exists between said leads. The **304** system control processor then sends a signal to the to the **307** sonic alarm to aurally indicate that a COG fault lockout has occurred and sends a signal to the **215** fault lockout LED of the **209** status display to light and visually indicate that a COG fault lockout has occurred. If a COG fault lockout occurs, the COG remains inoperable until the indicated errors are corrected.

Particularly, a fault lockout will occur if the internal system operating voltage is measured below a minimum acceptable level, i.e. below 5.0 volts DC. A fault lockout will also occur when the current level as measured between the **302** COG leads is above a maximum acceptable level, i.e. 20% above the current level of the selected treatment program current level.

In a preferred embodiment the COG is monitored for an open circuit between the **302** COG output leads. If an open circuit is detected between the **302** COG output leads by the **312** electrical safety circuits, a signal is sent to the **304** system control processor indicating that there is an open circuit between the **302** COG output leads. If the **304** system control processor receives an open circuit signal, the **304** system control processor sends a signal to the **307** sonic alarm to aurally indicate that a complete circuit is not being made between the leads and sends a signal to the **214** open lead LED of the **209** status display to light and visually indicate that a complete circuit is not being made between the leads.

The **304** system control processor also monitors the **205** run, **206** pause and **207** program end switches, and controls the COG operation accordingly. When the **205** run switch is utilized, a signal is sent to the **304** system control processor to begin the selected program treatment. Provided certain safety condition are met, as are herein more fully described, the **304** system control processor begins the selected treatment cycle and sends appropriate signals to the rest of the COG circuitry. The **304** system control processor then sends a signal to the **210** run LED of the **209** status display to light and visually indicate that the COG is providing current to the **302** COG leads. When the **206** pause switch is first utilized, a signal is sent to the **304** system control processor to pause the current treatment cycle. The **304** system control processor then halts the current

treatment cycle and sends appropriate signals to the rest of the COG circuitry. The **304** system control processor then sends a signal to the **211** pause LED of the **209** status display to light and visually indicate that the selected treatment cycle is paused. When the **206** pause switch is utilized again, a signal is sent to the **304** system control processor to unpause the current treatment cycle. The **304** system control processor then resumes the current treatment cycle and sends appropriate signals to the rest of the COG circuitry. The **304** system control processor then sends a signal to the **211** pause LED of the **209** status display to unlight. When the **207** program end switch is utilized, a signal is sent to the **304** system control processor to terminate the current treatment cycle. The **304** system control processor then terminates the current treatment cycle and sends appropriate signals to the rest of the COG circuitry. The **304** system control processor then sends a signal to the **212** program end LED of the **209** status display to light and visually indicate that the current treatment cycle has terminated. The **304** system control processor then begins the system self test and prepares for a new cycle of operation.

In order to receive full efficacy of the present electrotherapy method and apparatus, it is important for the treatment current levels to be within the tolerances of the present invention. If the circuitry of the COG is not operating properly, it is possible that the electric current being provided to the body can be outside the specified ranges. Accordingly, the present invention provides for **312** electrical safety circuits, as detailed above, to monitor and ensure safe system performance. In a preferred embodiment, the COG also provides for a self-test of the **312** electrical safety circuits. The **304** system control processor performs a self-test of the **312** electrical safety circuits monitoring during start-up of the COG and following a manual reset of the COG.

In conducting the self-test, the **304** system control processor instructs the **302** output leads of the COG to be removed from the **310** current source and **311** polarity switching device by activating the **315** test load switches. **314** Test loads are then connected to the **310** current source and **311** polarity switching device. These **314** test loads are designed to cause the current through the test loads to exceed the maximum safety limits of the COG. If the self-test fails, i.e. the **312** electrical safety circuits fail to return an error, the **304** system control processor causes a fault lockout to occur. The **304** system control processor then isolates the **302** output to the COG leads from the rest of the COG circuitry so no potential difference exists between said leads. The system control processor then sends a signal to the **307** sonic alarm to aurally indicate that a COG

fault lockout has occurred and sends a signal to the **215** fault lockout LED of the **209** status display to light and visually indicate that a COG fault lockout has occurred. If a COG fault lockout occurs, the user may not utilize the COG until the error is corrected and the self-test is properly performed.

If the self-test properly executes, i.e. an error signal is generated by the **312** electrical safety circuits and received by the **304** system control processor, the **304** system control processor deactivates the **315** test load switches, reconnecting the output of the **310** constant current source and **311** polarity switching device to the **302** COG output leads. After a successful self-test, the COG is ready for use.

Referring again to **FIG. 1(a)**, the method of the present provides for the application of a large surface-area electrode wrap. Preferably, said electrode wrap comprises a **101** first and **102** second layer wrap. Preferably, the patient soaks the **101** first layer wrap with tap water prior to application. After saturating the **101** first layer wrap with tap water, the patient wraps the **101** first layer wrap around the portion of the body to which the current will be applied. This can be any part of the body, including, without limitation, the head, arm, leg, feet, hand and torso. The application of tap water to the **101** first layer wrap provides good conductivity to the layer being placed closest to the skin. Tap water is a moderately good conductor of electricity on account of the metal ions contained in the tap water.

Once the **101** first layer wrap is applied to the selected portion of the body, the **102** second layer wrap is applied over the **101** first layer wrap. This **102** second layer wrap is a moderately conductive synthetic rubber impregnated cloth strap. In a preferred embodiment, the **102** second layer wrap is composed of a cloth impregnated with silicon rubber acting as a flexible carrier for conductive carbon particles dispersed within the silicon rubber. The **102** second layer wrap has **103** one or more electrodes on its distal ends to which it can be electrically connected with the COG by means for conducting electricity. Referring now to **FIG. 1(b)**, when properly applied, the **101** first and **102** second layer wrap form an cylindrical surface around the selected portion of the body.

Because the first and second layer wraps, as taught by the present invention, are only moderately good conductors, the current is spread out over a large surface-area. Due to this large surface-area and moderate conductivity of the first and second layer wraps, the point of entry and exit of the current is spread across a broad surface area of the selected portions of the body. Thus, a very low current density around the selected

portions of the body is thereby achieved through the present invention. As one example, 500 square inches of body surface is covered by one of the electrode wraps and a current of 500 nanoamperes is applied through the body via the first and second layer wraps, resulting in a current density of 1 nanoampere per square inch at each selected portion of the body. These low current densities are translated into substantially lower current densities through the body as the current travels from the electrode wrap(s) attached to the positive COG lead to the electrode wrap(s) attached to negative COG lead than has been previously achieved by known electrotherapy techniques. These low current densities do not overload the body's natural electropotential, but instead provide a slight push and pull on the body's natural current, thereby aiding the body's natural healing process.

The electrotherapy method of the present invention utilizes a microcurrent to effectuate the healing of the tissue. The microcurrent that is applied to the body is in the range of 3 milliamperes to 1 femtoampere. The use of current lower than 20 microamperes is unknown to the prior art. Specifically, the inventors have discovered that use of current in the range of 100 to 500 nanoamperes results in improved healing of the body tissue in comparison to prior art electrotherapy techniques.

The electrotherapy method of the present invention utilizes a duty cycle in the range of .00065 to .00085 Hz. Preferably, a duty cycle of .000732 Hz is utilized. This translates to a cycle time of 22.77 minutes. Experimentation has shown that a duty cycle of .000732 Hz, plus or minus ten percent, has an improved healing effect on the body tissue over the application of the same current at a different duty cycle, with markedly increased healing being achieved by a duty cycle of .007732 Hz, plus or minus two percent. Experimentation has shown that the efficacy distribution of the method of the present invention is Gaussian in the range of plus and minus ten percent of .000732 Hz.

Experimental

Applicants have performed the following experiments using the electrotherapy apparatus and method of the present invention. Results from these experiments, which are typical of the beneficial results of the present invention, are detailed below in Table 1.

Patient	Disease	Stage	Number Months Present	Time to Heal
1	DM	3	6	70% in 48 hours
2	DM	4	60	50% in 2 weeks
3	DM	4	36	60% in 1 week
4	SCI	3	9	100% in 48 hours
5	SCI	4	3	40% in 12 days
6	PVD	4	9	90% in 72 hours
7	PVD	4	12	100% in 5 days
8	SCI	4	18	75% in 7 days
9	DM	3	8	100% in 72 hours

Table 1

All patients included in Table 1 have decubitus ulcers. The primary disease leading to the ulcers is indicated in the second column, as follows: DM indicates diabetes mellitus, SCI indicates spinal cord injury and PVD indicates peripheral vascular disease. The size of the ulcers is indicated by the stage listed in the third column. The indicated stages are based on the scale developed in 1989 by the National Pressure Ulcer Advisory Panel Consensus. A stage 3 ulcer consists of full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. A stage 3 ulcer present clinically as a deep crater with or without undermining adjacent tissue. A stage 4 ulcer consists of full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone or supporting structures. Stage 4 ulcers may be associated with undermining of adjacent tissue and sinus tracts. The length of time the ulcers have been present in the listed stage is indicated in the fourth column.

Each patient underwent a treatment program utilizing the electrotherapy apparatus and method of the present invention. The typical treatment program consisted of three and one-half hours of treatment per day, five days per week. The results of the treatment program are given in the fifth column of Table 1. The percentage indicated in the fifth column is the approximate percentage of ulcer closure in terms of depth and diameter. As can be seen from Table 1, the use of the electrotherapy apparatus and method of the present invention gives beneficial results in the healing of persistent ulcers of various pathologies.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

All publications, patents, and patent applications are herein incorporated by reference in their entirety to the same extent as if individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference in its entirety.

WE CLAIM:

1. A method for performing electrotherapy comprising applying a current of 1 femtoampere to 20 microamperes to a subject in need thereof.

2. A method for performing electrotherapy comprising applying an alternating current with a duty cycle of .00065 Hz to .00085 Hz to a subject in need thereof.

3. A method of performing electrotherapy comprising applying a current with a current density at the point of application to the body of less than 5 microamperes per square inch to a subject in need thereof.

4. A method of performing electrotherapy comprising applying a current of 1 femtoampere to 20 microamperes, with a duty cycle of .00065 Hz to .00085 Hz and a current density at the point of application to the body of less than 5 microamperes per square inch to a subject in need thereof.

5. The electrotherapy method of any of claims 1, 2, 3 or 4, wherein the current is applied by means of one or more electrode wraps.

6. The electrotherapy method of claim 5, wherein the electrode wrap comprises:

a) a first layer water absorbent bandage of sufficient length to cover 200 or more square inches of skin surface area; and

b) a second layer moderately conductive, synthetic rubber impregnated cloth strap of sufficient length to cover 200 or more square inches of skin surface area, with said second layer wrap being approximately 2 inches wide and having a nominal resistance of .1666 Kohms for each foot of length.

7. The electrotherapy method of any of claims 1, 2, 3 or 4, wherein the current is supplied by means of a current output generator.

8. The electrotherapy method of claim 7, wherein the current output generator comprises:

a) a user interface;

b) a status display;

c) a cycle span time display;

d) a sonic alarm;

e) a power supply;

f) a voltage regulator;

g) a polarity switching circuit;

h) a constant current source;

i) electrical safety circuits;

j) a range cycle processor;

k) an option board;

l) a system control processor; and

m) a femto-pico attentuator.

9. A current output generator comprising:

a) a user interface;

b) a status display;

c) a cycle span time display;

d) a sonic alarm;

e) a power supply;

f) a voltage regulator;

g) a polarity switching circuit;

h) a constant current source;

i) electrical safety circuits;

j) a range cycle processor;

k) an option board;

l) a system control processor; and

m) a femto-pico attentuator.

10. An electrode wrap comprising:

a) a first layer water absorbent bandage of sufficient length to cover 200 or more square inches of skin surface area; and

b) a second layer moderately conductive, synthetic rubber impregnated cloth strap of sufficient length to cover 200 or more square inches of skin surface area, with said second layer wrap being approximately 2 inches wide and having a nominal resistance of .1666 Kohms for each foot of length.

11. An apparatus for performing electrotherapy comprising:

a) the current output generator of claim 10; and

b) the electrode wrap of claim 11.

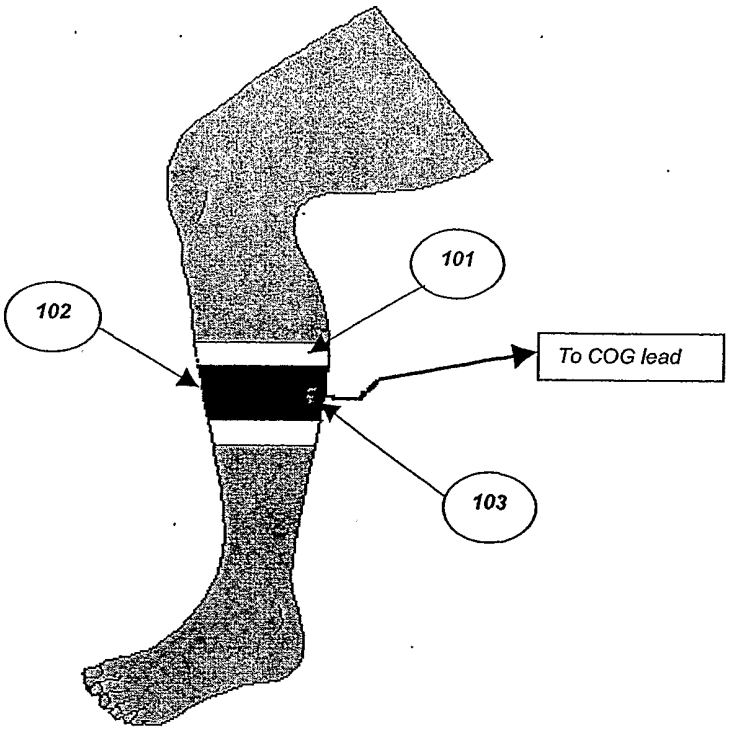


FIG. 1 (a)

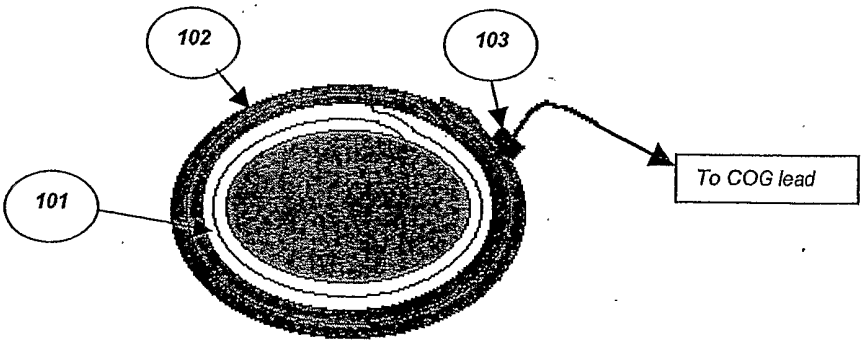


FIG. 1 (b)

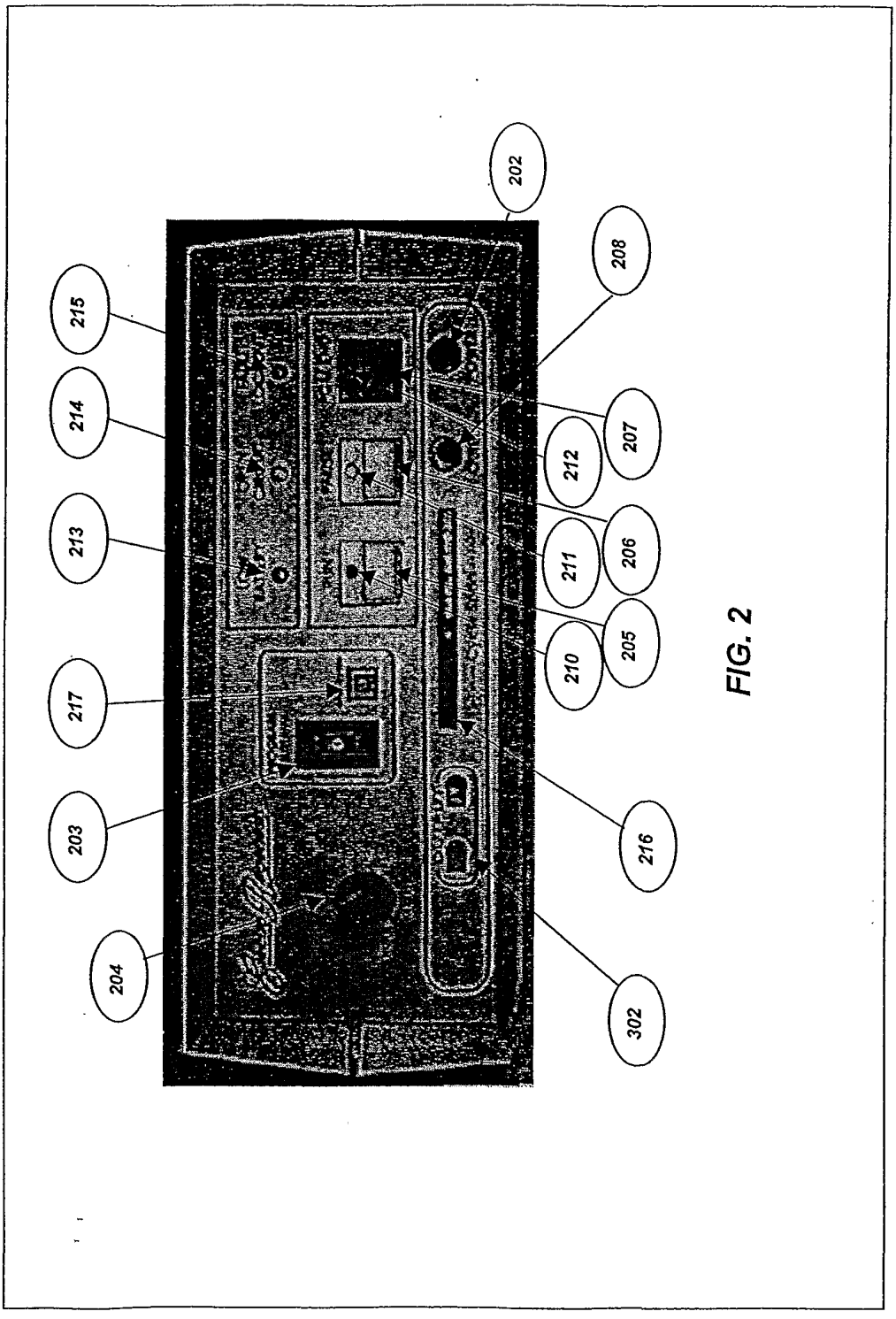


FIG. 2

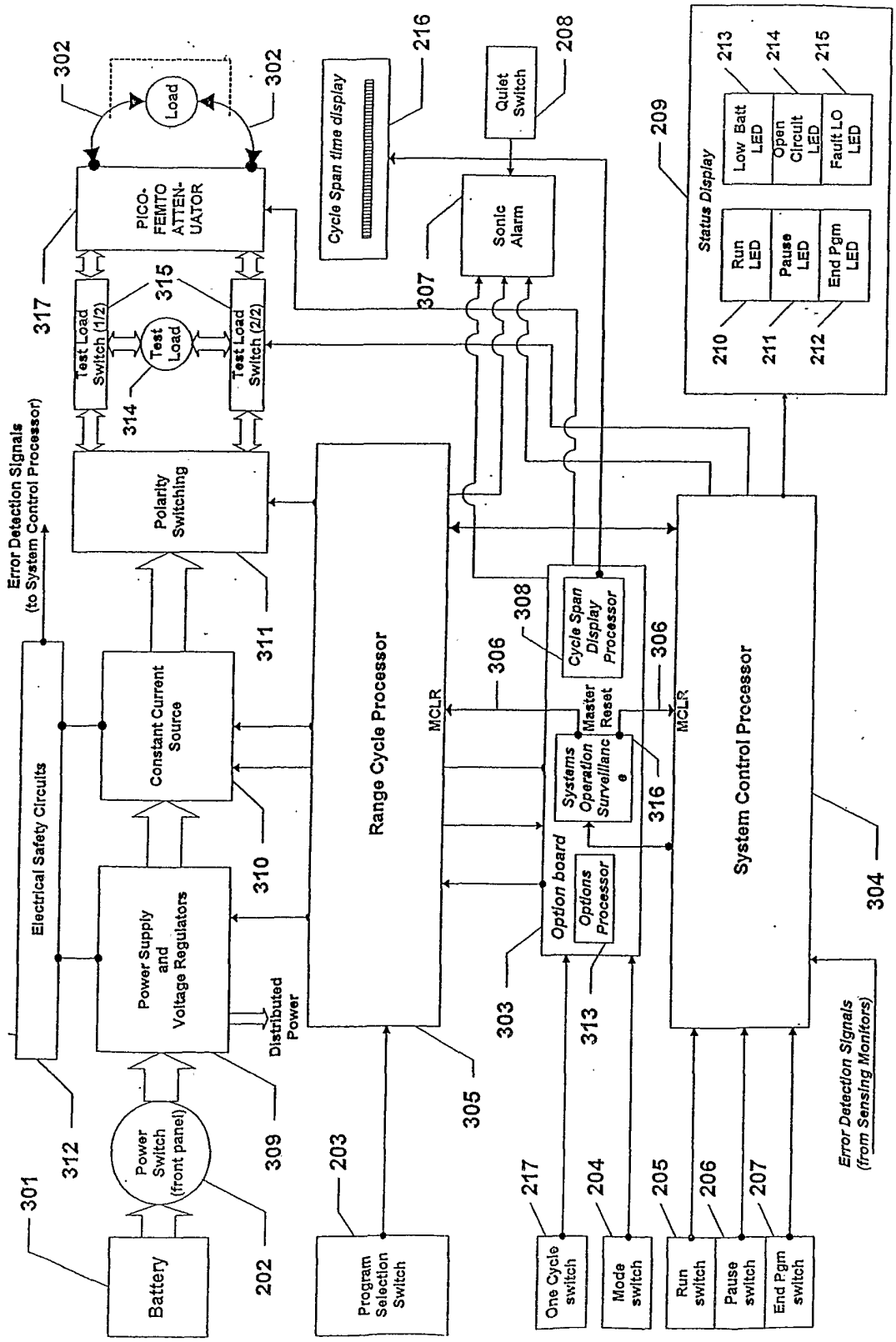

Battery
Power Switch (front panel)
Power Supply and Voltage Regulators
Electrical Safety Circuits
Constant Current Source
Polarity Switching
PICO-FEMTO ATTEN-UATOR
Load
Test Load Switch (1/2)
Test Load
Test Load Switch (2/2)
Error Detection Signals (to System Control Processor)
Distributed Power
Range Cycle Processor
MCLR
Program Selection Switch
Cycle Span time display
Quiet Switch
Sonic Alarm
Option board
Options Processor
Cycle Span Display Processor
Systems Operation Surveillanc e
Master Reset
System Control Processor
Status Display
Low Batt LED
Open Circuit LED
Fault LO LED
Run LED
Pause LED
End Pgm LED
One Cycle switch
Mode switch
Run switch
Pause switch
End Pgm switch
Error Detection Signals (from Sensing Monitors)
301
302
303
304
305
306
307
308
309
310
311
312
313
314
315
316
317
202
203
204
205
206
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FIG. 3