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(54) **METHOD AND APPARATUS FOR
STIMULATIVE ELECTROTHERAPY**

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USPC **607/2**, **46**, **60**, **115**, **149**; **128/907**
See application file for complete search history.

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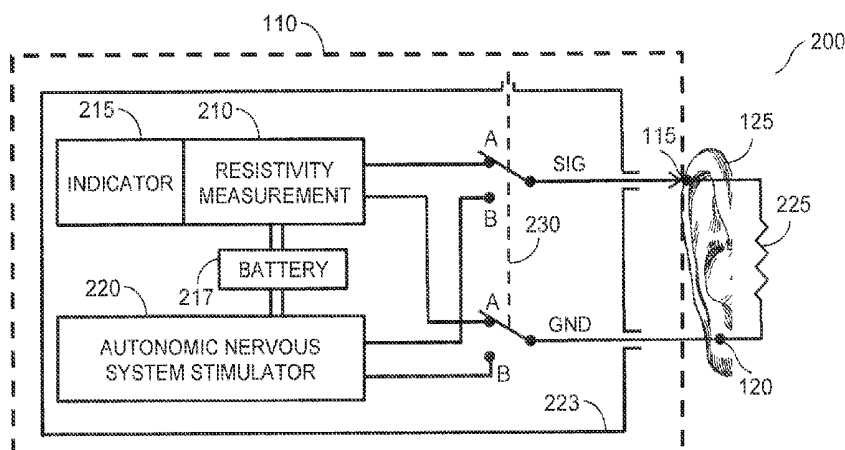
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ABSTRACT

An electrical apparatus includes a battery, a circuit adapted to generate a periodic signal, and a wireless radio transceiver. The electrical apparatus further includes a control circuit adapted to set a characteristic of the periodic signal. The characteristic is received by an input of the wireless radio transceiver. The electrical apparatus further includes a first electrically conductive electrode adapted to electrically contact and puncture a first portion of a surface when the periodic signal is injected below the first portion of the surface. The periodic signal is coupled to the first electrically conductive electrode.

20 Claims, 7 Drawing Sheets



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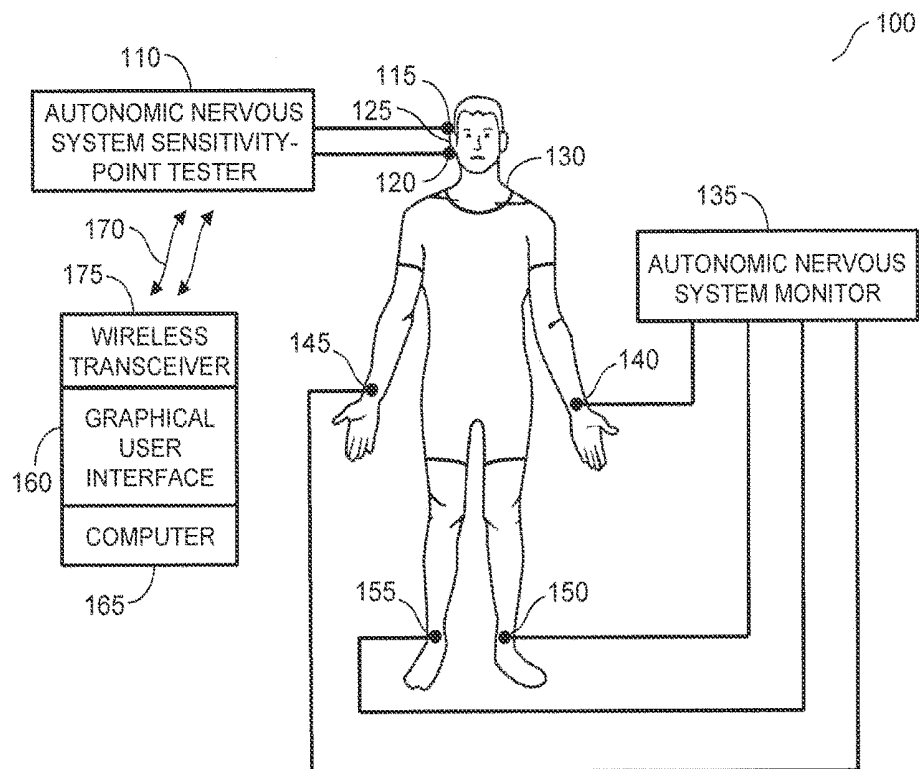


FIG. 1

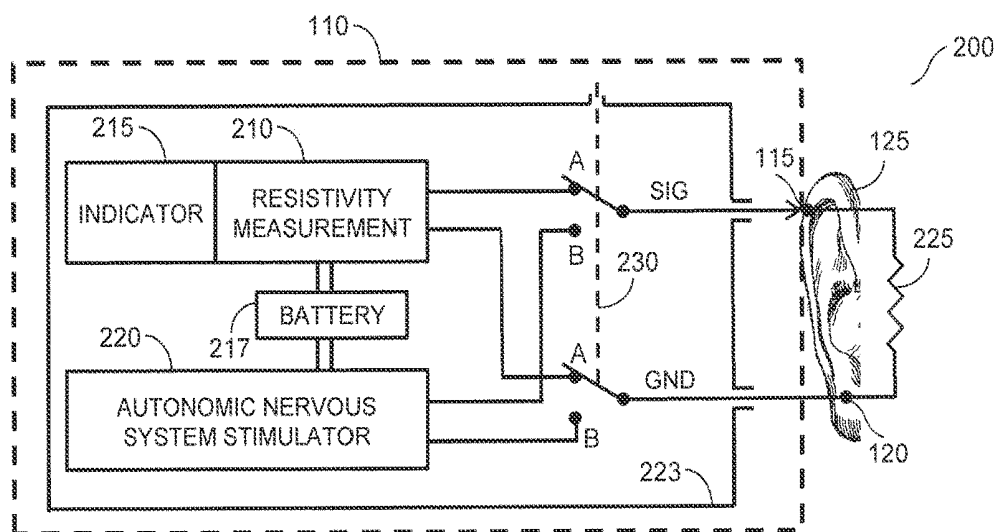


FIG. 2

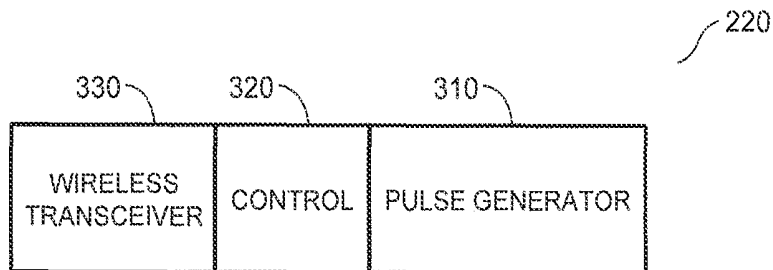


FIG. 3

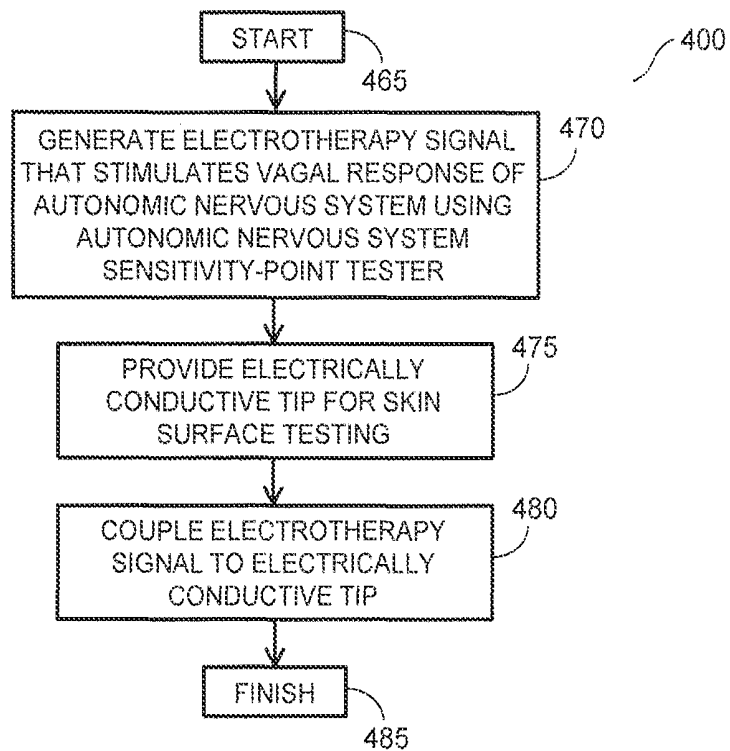


FIG. 4A

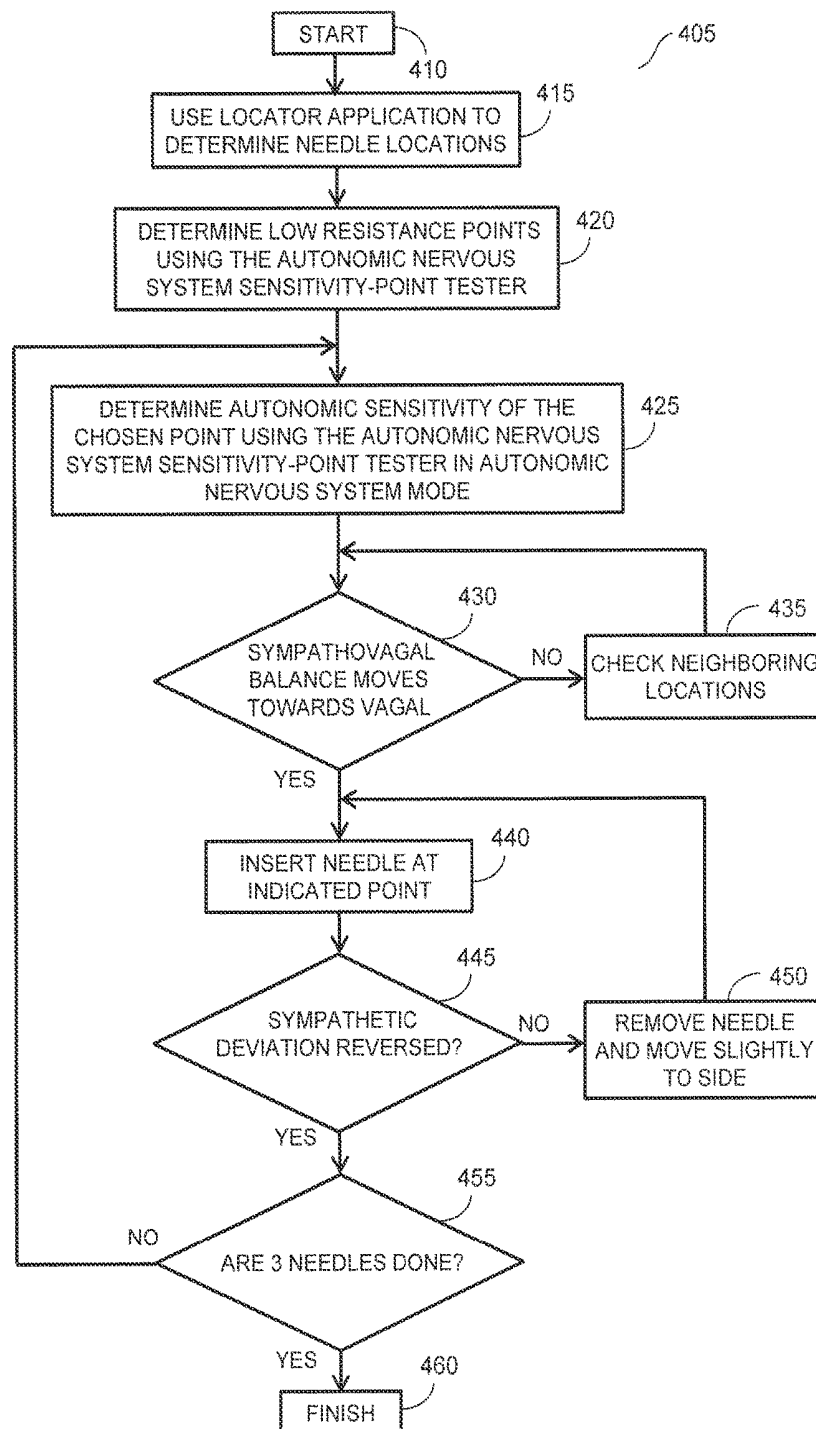


FIG. 4B

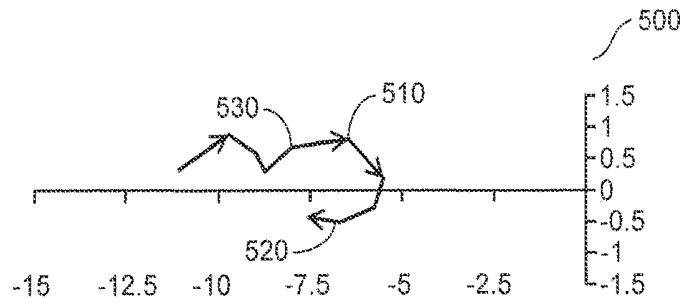


FIG. 5

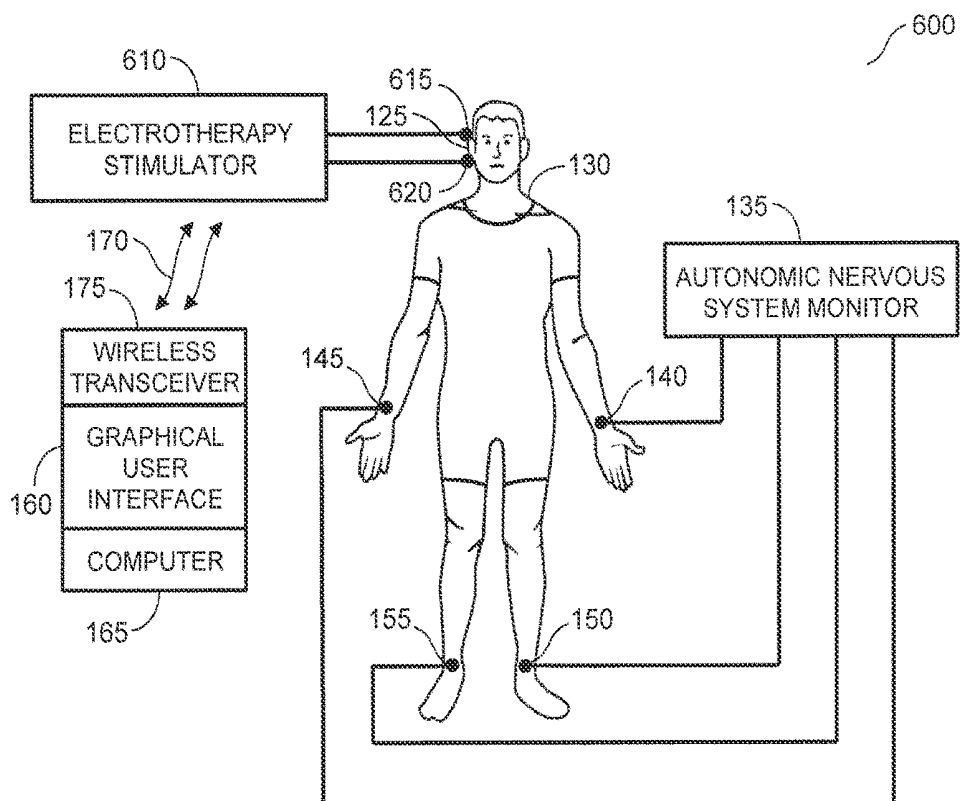


FIG. 6

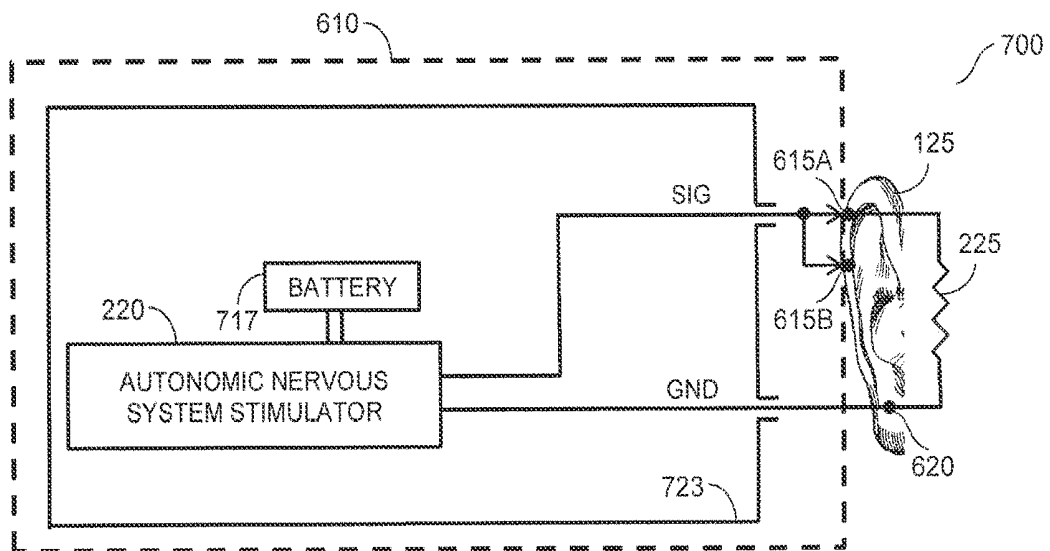
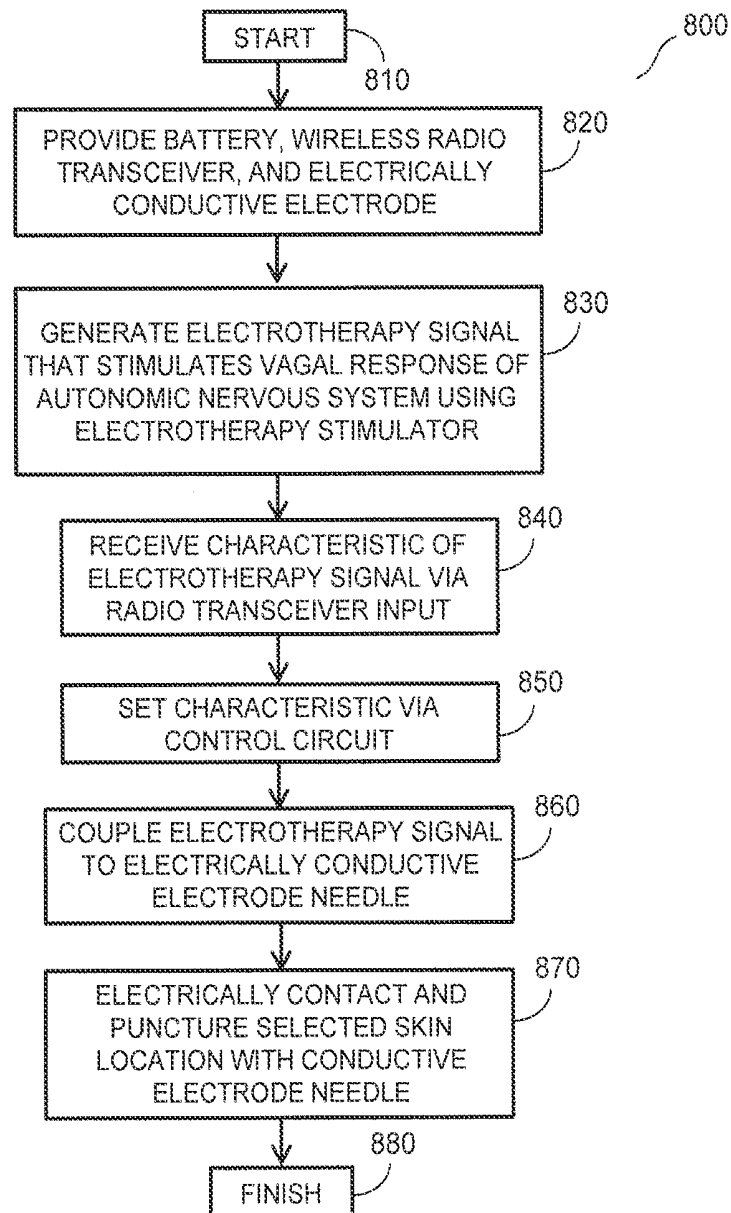


FIG. 7

**FIG. 8**

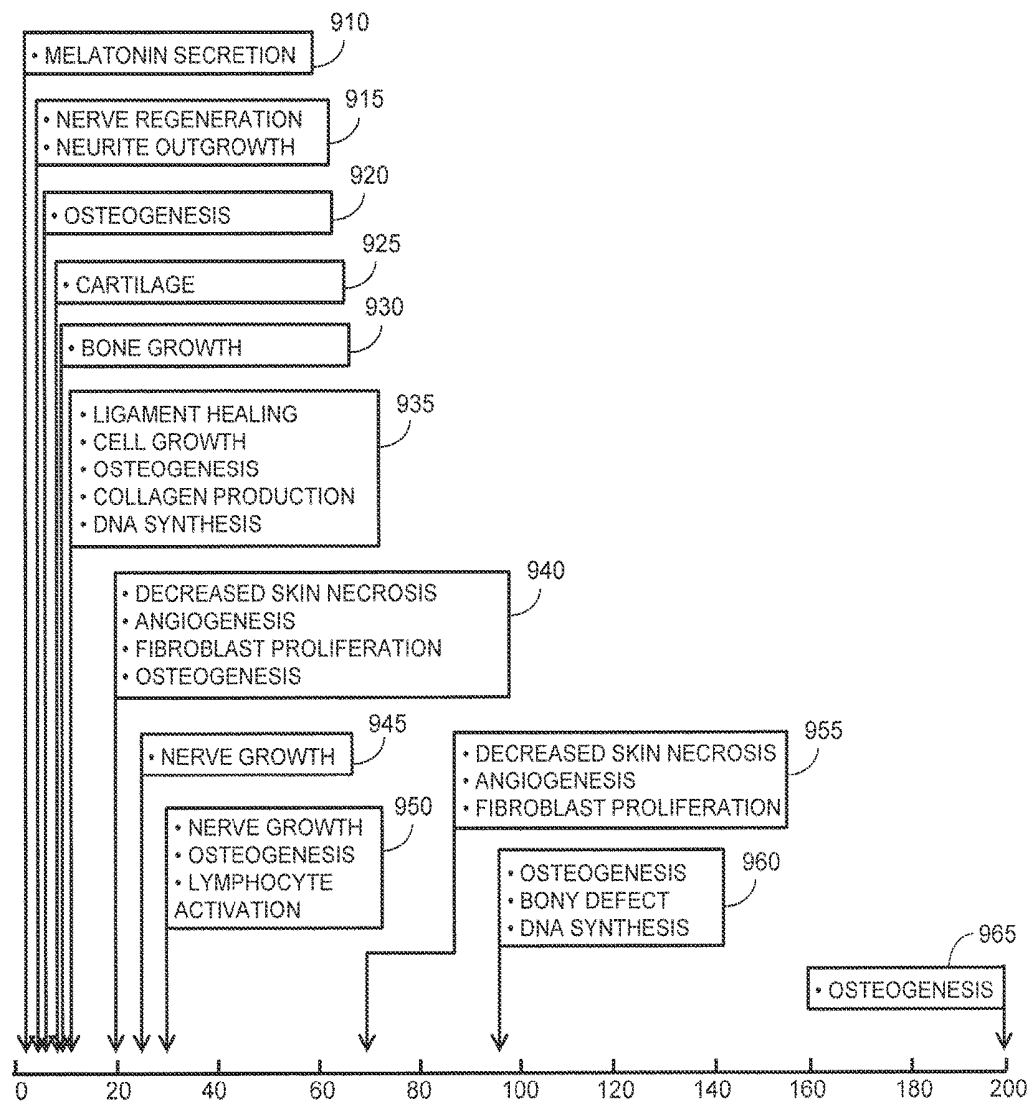


FIG. 9

METHOD AND APPARATUS FOR STIMULATIVE ELECTROTHERAPY

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is related to U.S. Pat. No. 7,092,849, titled "EXTRACTING CAUSAL INFORMATION FROM A CHAOTIC TIME SERIES," granted Aug. 15, 2006, the content of which is incorporated herein by reference in its entirety. This application is also related to the following applications filed herewith: U.S. patent application Ser. No. 13/917,471, titled "STIMULATIVE ELECTROTHERAPY USING AUTONOMIC NERVOUS SYSTEM CONTROL," U.S. patent application Ser. No. 13/916,944, titled "METHOD AND APPARATUS FOR AUTONOMIC NERVOUS SYSTEM SENSITIVITY-POINT TESTING", and U.S. patent application Ser. No. 13/916,975, titled "COMPUTER IMPLEMENTED TRAINING OF A PROCEDURE," the contents of all of which are incorporated herein by reference in their entirety.

BACKGROUND

The present invention relates generally to a method and apparatus for applying an electrical signal to a patient, and in particular, for applying a time varying signal to a nervous system of a patient.

Measures of heart rate variability have been shown to be a powerful means of assessing the influence of the autonomic nervous system on the cardiac system. Indeed, the autonomic nervous system, with its sympathetic and parasympathetic, hereinafter also referred to as "vagal" subsystems, governs involuntary actions of the cardiac muscle and every visceral organ in the body.

The autonomic nervous system is not directly accessible to voluntary control. Instead, it operates in an autonomic fashion on the basis of autonomic reflexes and central control. One of its major functions is the maintenance of homeostasis within the body. The autonomic nervous system further plays an adaptive role in the interaction of the organism with its surroundings.

In many diseases, the sympathetic and/or parasympathetic parts of the autonomic nervous system are affected leading to autonomic dysfunction. It is then important to have reliable and representative measures of the activity and the state of the autonomic nervous system.

U.S. Pat. No. 7,092,849 to Lafitte, et al. describes a method, a system, and a computer code for analyzing the state of the autonomic nervous system from a time-varying signal representing a chaotic series of time intervals between quasi-periodical events produced by the cardiac system governed by the autonomic system. Thus, real-time monitoring of the sympathovagal balance between the parasympathetic and the sympathetic components of the autonomic nervous system is possible.

The autonomic nervous system plays an important role in pain modulation and perception and chronic pain is likely due to a malfunction in the body's central nervous system. While there are many medications and physical therapies that are used to treat pain, they do not cure it and only mask the pain response, sometimes with undesired side effects such as with narcotic medications.

A point stimulation device is a non-narcotic combination of permanent acupuncture-like needles and electrical stimulation used to treat chronic pain over time. A point stimulation device uses auricular acupuncture as a treatment based

on normalizing the body's dysfunction through stimulation of points on the ear. The resulting amelioration of pain and illness is believed to be through the reticular formation and the sympathetic and parasympathetic nervous systems. Specific points in the ear are related to major organs in the body. However, existing medical devices and treatment protocols for testing and locating sensitivity-points on the skin surface for point stimulation needle insertion have not taken advantage of the capabilities of real-time sympathovagal balance monitoring. Present point stimulation devices provide only a fixed electrical stimulation signal.

BRIEF SUMMARY

According to one embodiment of the present invention, an electrical apparatus includes a battery, a circuit adapted to generate a periodic signal, and a wireless radio transceiver. The electrical apparatus further includes a control circuit adapted to set a characteristic of the periodic signal. The characteristic is received by an input of the wireless radio transceiver. The electrical apparatus further includes a first electrically conductive electrode adapted to electrically contact and puncture a first portion of a surface when the periodic signal is injected below the first portion of the surface. The periodic signal is coupled to the first electrically conductive electrode.

According to one embodiment, the electrical apparatus further includes a second electrically conductive electrode adapted to electrically contact but not puncture a second portion of the surface. The second electrically conductive electrode provides a direct electrical contact between the second electrically conductive electrode and the second portion of the surface, which provides a return signal path for the periodic signal when the periodic signal is injected below the first portion of the surface.

According to one embodiment, the electrical apparatus further includes a housing having an insulating surface and at least a first orifice in the insulating surface. The first electrically conductive electrode is adapted to be located outside the housing and coupled through the first orifice to the circuit. The housing encloses the battery and the circuit.

According to one embodiment, the housing is adapted to have a shape being adapted to conform to a third portion of the surface when the periodic signal is injected below the first portion of the surface. According to one embodiment, the housing is adapted to hermetically seal the electrical apparatus.

According to one embodiment, the wireless radio transceiver operates on a transmission standard selected from one of Bluetooth®, 6LoWPAN®, ZigBee®, DASH7®, Z-Wave®, MiWi®, or OSION®. According to one embodiment, the characteristic is selected from one of a frequency, an amplitude, a pulse shape, or a duty cycle.

According to one embodiment, the periodic signal is an electrotherapy signal. The characteristic of the periodic signal is adapted to stimulate a response in a parasympathetic nervous system of a patient. The surface is a skin of the patient when the periodic signal is injected below the first portion of the surface. According to one embodiment, the frequency of the periodic signal is set to a predetermined frequency associated with a treatment of a patient.

According to one embodiment of the present invention, a method for signal injection includes providing a battery, providing a wireless radio transceiver, and providing a first electrically conductive electrode. The method further includes generating a periodic signal in time from a circuit, receiving a characteristic of the periodic signal by an input

of the wireless transceiver, and setting the characteristic via a control circuit. The method further includes coupling the periodic signal to the first electrically conductive electrode, and electrically contacting and puncturing a first portion of a surface when the periodic signal is injected below the first portion of the surface.

According to one embodiment, the method further includes contacting but not puncturing a second portion of the surface by a second electrically conductive electrode. The second electrically conductive electrode provides a direct electrical contact between the second electrically conductive electrode and the second portion of the surface, thereby providing a return signal path for the periodic signal when the periodic signal is injected below the first portion of the surface.

According to one embodiment, the method further includes providing a housing having an insulating surface and at least a first orifice in the insulating surface, and locating the first electrically conductive electrode outside the housing. The method further includes coupling the first electrically conductive electrode through the first orifice to the circuit, and enclosing the battery and the circuit with the housing.

According to one embodiment, the method further includes shaping the housing to conform to a third portion of the surface when the periodic signal is injected below the first portion of the surface. According to one embodiment, the method further includes hermetically sealing the electrical apparatus with the housing.

According to one embodiment, the method further includes selecting the characteristic from one of a frequency, an amplitude, a pulse shape, or a duty cycle. According to one embodiment, the method further includes setting the frequency of the periodic signal to a predetermined frequency associated with a treatment of a patient.

A better understanding of the nature and advantages of the embodiments of the present invention may be gained with reference to the following detailed description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts a simplified block diagram of a patient testing theatre, in accordance with one embodiment of the present invention.

FIG. 2 depicts a simplified block diagram of the autonomic nervous system sensitivity-point tester and the portion of the patient's skin represented in FIG. 1, in accordance with one embodiment of the present invention.

FIG. 3 depicts a simplified block diagram of the autonomic nervous system stimulator represented in FIG. 2, in accordance with one embodiment of the present invention.

FIG. 4A depicts a simplified flowchart of a method for autonomic nervous system sensitivity-point testing on a skin of a patient, in accordance with one embodiment of the present invention.

FIG. 4B depicts a simplified flowchart of a method for autonomic nervous system sensitivity-point testing on a skin of a patient, in accordance with another embodiment of the present invention.

FIG. 5 depicts an exemplary response of a sympathovagal balance used in the method represented in FIG. 4B.

FIG. 6 depicts a simplified block diagram of a patient treatment theatre, in accordance with one embodiment of the present invention.

FIG. 7 depicts a simplified block diagram of the electrotherapy stimulator and the portion of the patient's skin represented in FIG. 6, in accordance with one embodiment of the present invention.

FIG. 8 depicts a simplified flowchart of a method for electrotherapy signal injection into a skin of a patient, in accordance with another embodiment of the present invention.

FIG. 9 depicts a chart showing patient responses to electrotherapy signal injection versus electrotherapy signal frequency from peer-reviewed literature.

DETAILED DESCRIPTION

The present invention relates generally to a method and apparatus for testing a patient's skin, and in particular, to testing a patient's skin to find autonomic nervous system sensitivity-points. Auricular acupuncture electrotherapy treatments involve inserting an electrotherapy needle into the skin of a patient at certain sensitivity-points on the ear associated with a particular therapy regimen and applying an electrotherapy signal to the electrotherapy needle. Finding a location to place the needle may be determined by foreknowledge of general locations and testing or measuring local skin resistance. However, electrotherapy treatment acts through the autonomic nervous system so skin resistivity alone may not be the best test indicator for electrotherapy needle placement.

In accordance with one embodiment of the present invention, a test and measurement for electrotherapy needle placement may generate and apply an electrical signal similar or identical to the electrotherapy signal that would be used during treatment to a portion of the patient's skin surface without puncturing the skin. The skin surface is then probed with the electrotherapy signal via an electrically conductive tip, to identify a location that stimulates a vagal response of the patient's autonomic nervous system by monitoring the sympathovagal balance. The identified location may then be pricked by an electrotherapy needle which is then connected to the electrotherapy signal for a long duration treatment period. Locating the needle sites initially may not constitute therapy but may improve the outcome of planned acupuncture electrotherapy.

FIG. 1 depicts a simplified block diagram of a patient testing theatre 100, in accordance with one embodiment of the present invention. Patient testing theatre 100 includes an autonomic nervous system sensitivity-point tester 110 coupled to an electrically conductive tip 115 and an electrode 120, which in-turn are connected to an ear 125, hereinafter also referred to as "portion of skin", of a patient 130. In one embodiment, an autonomic nervous system monitor 135 is coupled to electrodes 140, 145, 150, 155 respectively on the patient's left arm, right arm, left leg, right leg to receive quasi-periodical electro cardiogram signals from the cardiac system that are in-turn governed by the patient's autonomic nervous system. The patient is preferably in a supine position on an examination table in a clinical environment for autonomic nervous system testing and monitoring.

In the exemplary embodiment depicted in FIG. 1, the patient is represented as a human. It is understood, however, that the patient may be any living creature possessing an autonomic nervous system and cardiac system. In the exemplary embodiment depicted in FIG. 1, autonomic nervous system sensitivity-point tester 110 is shown as connecting to an ear. It is understood, however, that autonomic nervous system sensitivity-point tester 110 may instead be connected

to any portion of skin demonstrated to have nerve connections sensitive enough to affect the autonomic nervous system of the patient.

In one embodiment, the patient testing theatre **100** may include a graphical user interface **160** coupled to a computer **165**, which may be coupled via cable (not shown) or via wireless radio transmission **170** to autonomic nervous system sensitivity-point tester **110**. Preferably, the autonomic nervous system sensitivity-point tester is a wireless hand held device, which may be programmed or have certain characteristics set by a medical practitioner or technician (not shown) via graphical user interface **160** and computer **165**. In one embodiment, computer **165** may be a desktop, laptop, pad, mini-pad, or smart phone that may have a wireless transceiver **175**.

The autonomic nervous system monitor **135** is adapted to convert the patient's electro cardiogram signals to, among other information, a sympathovagal balance between the parasympathetic and the sympathetic components of the autonomic nervous system. U.S. Pat. No. 7,092,849 to Lafitte, et al. and co-pending U.S. patent, titled "STIMULATIVE ELECTROTHERAPY USING AUTONOMIC NERVOUS SYSTEM CONTROL" to Nageshwar, which are incorporated by reference, describe, in part, the theory of operation for autonomic nervous system monitor **135**.

FIG. 2 depicts a simplified block diagram of autonomic nervous system sensitivity-point tester **110** and portion of the patient's skin **125** represented in FIG. 1, in accordance with one embodiment of the present invention. FIG. 2 depicts autonomic nervous system sensitivity-point tester **110**, hereinafter also referred to as "circuit", which includes a resistivity measurement unit **210**, an indicator **215**, an autonomic nervous system stimulator **220**, a switch **230**, an electrically conductive tip **115**, a battery **217**, a housing **223**, and an electrode **120**. Resistivity measurement **210** couples to indicator **215**. Battery **217** provides portable power to the circuit and enables hand-held operation.

Resistivity measurement **210** is adapted to generate an electrical resistance measuring signal to measure a skin resistivity **225** coupled between electrically conductive tip **115** and electrode **120** when the patient is tested. Indicator **215** is responsive to a value of electrical resistance measured by the circuit and may provide a visual indicator, a sonic indicator, and/or a vibrational indicator. For example, indicator **215** may be a buzzer that changes sound pitch in relation to the measured value of skin resistivity **225**, which may change as electrically conductive tip **115** is moved around by the medical practitioner to contact different portions of the patient's skin surface.

Autonomic nervous system stimulator **220** is adapted to generate an electrotherapy signal, hereinafter also referred to as "periodic signal" or "periodic signal in time," coupled to electrically conductive tip **115** that stimulates a vagal response of the patient's autonomic nervous system when the patient is tested. Electrically conductive tip **115** provides electrical contact to but does not puncture a portion of the skin surface of the patient when the patient is tested.

Electrode **120** is applied to a different portion of skin than that portion of skin surface being tested to optimize electrotherapy needle placement. Electrode **120** is adapted to be a return signal path, i.e. ground, for either the electrical resistance-measuring signal or the electrotherapy signal thereby enabling a gloved medical practitioner, hereinafter also referred to as "tester" to facilitate applying the electrical resistance measuring signal or the electrotherapy signal to the patient. Electrode **120** may be a portion of metal foil

taped temporarily on the patient's skin or an electrotherapy needle temporarily placed in the patient's skin.

Housing **223** may have an insulating surface and at least one orifice in the insulating surface through which electrically conductive tip **115** protrudes or extends outside the housing. Housing **223** may enclose battery **217** and the circuit. The housing may have a shape that may be adapted to be hand held when the skin surface is tested. In other words, the housing is shaped to fit the hand grasp of a person using autonomic nervous system sensitivity-point tester **110**. The insulating surface of the housing may have other orifices for example to allow a tester to operate switch **230** and for electrode **120**. Housing **223** may hermetically seal the circuit and seal the orifices, for example by using a flexible gasket around the electrically conductive tip to facilitate cleaning and disinfecting autonomic nervous system sensitivity-point tester **110** between testing uses.

Since electrotherapy needle placement punctures the skin, the medical practitioner may be required to wear gloves during needle placement. Prior sensitivity-point tester designs provide the return signal path via the bare hand of the medical practitioner, which must be placed over a metal contact on the housing of the sensitivity-point tester. In contrast, providing electrode **120** is advantageous over prior sensitivity-point tester designs because the medical practitioner's gloves need not be removed in patient testing theatre **100**.

Resistivity measurement **210** and autonomic nervous system stimulator **220** are coupled to switch **230**, which may be a double-pole, double-throw switch with positions B, A that selectively couple the electrotherapy signal or the electrical resistance measuring signal respectively to electrically conductive tip **115**, while simultaneously coupling the corresponding return signals to electrode **120**. Therefore, circuit **110** is in a resistance-measuring mode when switch **230** is in position A and in an autonomic nervous system mode when switch **230** is in position B.

FIG. 3 depicts a simplified block diagram of autonomic nervous system stimulator **220** represented in FIG. 2, in accordance with one embodiment of the present invention. FIG. 3 depicts autonomic nervous system stimulator **220**, which includes a pulse generator **310**, a control unit **320**, and a wireless transceiver **330**. Pulse generator **310** provides the electrotherapy signal, which includes characteristic such as frequency, amplitude, pulse shape, and duty cycle, which are set by control unit **320**. The electrotherapy signal may be similar or identical to the signal used during long-term electrotherapy treatment. Control unit **320** couples to wireless transceiver **330**, which may receive characteristic settings from computer **165** and set the characteristics in pulse generator **310**. Control unit **320** may also perform power saving functions such as turning off either resistivity measurement **210** or autonomic nervous system stimulator **220** responsive to switch **230** position.

Wireless transceiver **330** need not have high bandwidth or long transmission range capability but because autonomic nervous system sensitivity-point tester **110** may be a hand-held portable device, power savings may be desirable to extend battery life. Therefore, wireless transceiver may operate on low bandwidth, power saving radio transmission standards such as Bluetooth®, 6LoWPAN®, ZigBee®, DASH7®, Z-Wave®, MiWi®, or OSION®.

FIG. 4A depicts a simplified flowchart of a method **400** for autonomic nervous system sensitivity-point testing on a skin of a patient, in accordance with one embodiment of the present invention. Referring simultaneously to FIG. 2 and FIG. 4A, the method starts **465** by the medical practitioner

generating **470** the electrotherapy signal that stimulates a vagal response of an autonomic nervous system of the patient when the patient is tested by using autonomic nervous system sensitivity-point tester **110** in autonomic nervous system mode, i.e. setting switch **230** in position B. The electrically conductive tip **115** is provided **475** that electrically contacts but does not puncture the skin surface when the patient is tested. Setting switch **230** in position B couples **480** the electrotherapy signal to electrically conductive tip **115** as described above. Thus, before finish **485** of this embodiment, the autonomic nervous system sensitivity-point tester **110** is set up to do skin surface testing on the patient.

FIG. **4B** depicts a simplified flowchart of a method **405** for autonomic nervous system sensitivity-point testing on a skin of a patient, in accordance with another embodiment of the present invention. Referring simultaneously to FIG. **1** and FIG. **4B**, the method starts **410** in one embodiment, by using **415** a locator application running on computer **165** to generally determine the needle locations. In other words, choosing a first portion of the patient's skin is done by obtaining a preliminary skin location, e.g. on the ear, from graphical user interface **160** coupled to computer **165** executing a program responsive to a symptom of the patient. For example, the patient may be complaining to the medical practitioner of a pain in the lower back. The medical practitioner may select that symptom on graphical user interface **160**, which responds by displaying the general location on a map of the ear, where acupuncture electrotherapy has been associated with lower back pain treatment.

Referring simultaneously to FIG. **2** and FIG. **4B**, the sensitivity-point location may be further localized by choosing a first portion of skin within the region identified in step **415** by determining **420** low resistance points using autonomic nervous system sensitivity-point tester **110** operating in resistance measuring mode, i.e. by setting switch **230** in position A. Then resistivity measurement **210** generates the electrical resistance-measuring signal, which is coupled to electrically conductive tip **115**. Electrode **120** is applied to a second portion of skin, the electrode being a return signal path for the resistance-measuring signal.

The medical practitioner may then apply the electrical resistance measuring signal to the first portion of skin with electrically conductive tip **115** that electrically contacts but does not puncture the skin when the patient is tested. The electrical resistance at the first portion of skin is measured by resistivity measurement **210** and causes indicator **215** to provide an indication responsive to a value of skin resistivity **225**, i.e. changing an emitted sound pitch correlated with the value. The medical practitioner moves or probes the electrically conductive tip on the skin surface in response to the indication to selectively find a low resistance location of skin near the first portion of skin.

The medical practitioner may then further optimize the electrotherapy needle insertion location by determining **425** the autonomic sensitivity of the chosen point using autonomic nervous system sensitivity-point tester **110** in autonomic nervous system mode, i.e. by setting switch **230** in position B. Then autonomic nervous system stimulator **220** generates the electrotherapy signal, which is coupled to electrically conductive tip **115**. Electrode **120** is applied, if not already applied during step **420**, to another portion of skin, the electrode being a return signal path for the electrotherapy signal.

The medical practitioner may then apply the electrotherapy signal to the selected portion of skin with electrically conductive tip **115** that electrically contacts but does

not puncture the skin when the patient is tested. The electrotherapy signal may stimulate a vagal response of the autonomic nervous system of the patient when electrically conductive tip **115** is located in contact with an autonomic nervous system sensitivity-point on the skin surface when the patient is tested. Referring simultaneously to FIG. **1** and FIG. **4B**, to measure the autonomic nervous system, the medical practitioner couples autonomic nervous system monitor **135** to the patient as described above. Autonomic nervous system monitor **135** analyzes a state of the autonomic nervous system of the patient from a time-varying signal representing a chaotic series of time intervals between quasi-periodical events produced by a cardiac system of the patient, i.e. from the patient's electrocardiogram. Autonomic nervous system monitor **135** also measures and displays a first sympathovagal balance of the patient.

FIG. **5** depicts an exemplary response of a sympathovagal balance **500** used in method **425** represented in FIG. **4B**. FIG. **5** depicts sympathovagal balance **500**, which plots balance trajectory **530** for the patient in real time as shown by the series of arrows on the balance trajectory. The horizontal axis represents a parasympathetic or vagal response in the direction towards higher negative numbers, i.e. towards the left direction on the plot. Conversely, a sympathetic response is represented on the plot's horizontal axis in the direction of smaller negative numbers, i.e. towards the right of the plot. A sympathetic trending balance trajectory **530** over time indicates increasing pain or dysfunction, while a vagal trending balance trajectory indicates pain relief. In this example, the patient may be suffering anxiety to the clinical setting and the patient's balance trajectory **530** starts out generally moving away from the parasympathetic or vagal part of the horizontal axis and towards the sympathetic direction as indicated at point **510**.

Referring simultaneously to FIG. **4B** and FIG. **5**, the medical practitioner determines **430** a response outcome based on the sympathovagal balance. The response outcome is positive when the sympathovagal balance moves towards the vagal response as shown at point **520** indicating the electrically conductive tip **115** is positioned optimally on the skin surface and the patient's autonomic nervous system is responding favorably to the electrotherapy signal. In contrast, the response outcome is negative when the sympathovagal balance does not move towards the vagal response.

When the response outcome is negative, the medical practitioner checks **435** or chooses a slightly different neighboring portion of skin of the patient abutting the earlier portion of chosen skin. The medical practitioner repeats applying the electrotherapy signal, measuring the sympathovagal balance, and determining the response outcome until the response outcome is positive or until a certain predetermined number of portions of skin are tested or time has elapsed.

When the response outcome is positive, the medical practitioner inserts **440** an electrotherapy needle at that portion of skin. The electrotherapy needle location selected with the procedure described above has been tested earlier at step **430** raising the confidence that the same electrotherapy signal applied to that location during the treatment regimen should have the desired beneficial effect on the patient's autonomic nervous system.

The needle insertion will cause a little pain creating a sympathetic deviation such as shown at point **510** on balance trajectory **530** that should quickly subside or reverse. However, the needle insertion location may be at a point that will stimulate an undesired long-term pain response. Therefore,

after needle insertion, the medical practitioner measures a second sympathovagal balance of the patient to determine **445** a sympathetic deviation reversal outcome based on the second sympathovagal balance. The reversal outcome is positive when the second sympathovagal balance reverses from a sympathetic response towards a vagal response as shown at point **520** on balance trajectory **530**. The reversal outcome is negative when the second sympathovagal balance does not reverse from a sympathetic response towards a vagal response.

When the reversal outcome is negative, the medical practitioner removes **450** the electrotherapy needle from the portion of skin and moves the needle slightly to the side to choose another portion of skin abutting the earlier portion of skin. The medical practitioner repeats inserting, measuring the second sympathovagal balance, and determining the reversal outcome until the reversal outcome is positive or until a certain predetermined number of portions of skin are tested or time has elapsed.

The electrotherapy treatment may require more than one stimulation point on the patient's ear. For example, one point may be stimulated to address lower back pain and another point may be stimulated for general pain relief. Accordingly, when the reversal outcome at step **445** is positive, the medical practitioner determines **455** a number of inserted electrotherapy needles. The testing is finished **460** when the number of inserted electrotherapy needles is equal to a predetermined number of electrotherapy needles required for the electrotherapy treatment, e.g. three stimulation needles—one needle located for a specific symptom and two needles located at two different locations for general pain relief. When a number of inserted electrotherapy needles is less than the predetermined number of electrotherapy needles, the medical practitioner repeats choosing the location, applying the electrotherapy signal, measuring the first sympathovagal balance, determining the response outcome, inserting the needle, measuring the second sympathovagal balance, and determining the reversal outcome.

FIG. 6 depicts a simplified block diagram of a patient treatment theatre **600**, in accordance with one embodiment of the present invention. Patient treatment theatre **600** includes the same elements as patient testing theatre **100** represented in FIG. 1 except autonomic nervous system sensitivity-point tester **110**, electrically conductive tip **115**, and electrode **120**, are replaced in FIG. 6 by an electrotherapy stimulator **610**, an electrotherapy needle **615**, and an electrically conductive electrode **620**. Electrotherapy needle **615** and electrically conductive electrode **620** are coupled to electrotherapy stimulator **610**. In contrast to electrically conductive tip **115**, which includes a small but dull tip that prevents skin puncture, electrotherapy needle **615** includes a short, sharp-tipped electrically conductive electrode needle adapted to electrically contact and puncture a portion of the skin surface to inject the electrotherapy signal below the skin surface.

The location where electrotherapy needle **615** is located on ear **125** may be determined by the procedures outlined earlier referenced in FIG. 4A and FIG. 4B using the autonomic nervous system sensitivity-point tester **110** referenced in FIG. 1 and FIG. 2. Unlike autonomic nervous system sensitivity-point tester **110**, which may be a hand-held device used only for testing the location of electrotherapy needle placement, electrotherapy stimulator **610** may be a wearable device that is attached to the patient for a prolonged period of time to deliver electrotherapy signals to the needles emplaced in the skin. Autonomic nervous system monitor **135** may be attached to the patient during the

placement of electrotherapy needle **615** but may be disconnected from the patient during the electrotherapy treatment regimen, thus providing mobility for the patient during treatment. Wireless transceiver **175**, graphical user interface **160** and computer **165** may be used as referenced in FIGS. 1, 2, and 3, to pass electrotherapy signal characteristics to electrotherapy stimulator **610** during set up when the needles are placed into the skin.

Referring to FIG. 6, electrically conductive electrode **620** may be similar to electrode **120** and is adapted to electrically contact but not puncture a different portion of the skin surface than where electrotherapy needle **615** is inserted. Electrically conductive electrode **620** may provide a direct electrical contact between a surface of electrically conductive electrode **620** and the skin surface thereby providing a return signal path for the electrotherapy signal when the periodic signal is injected below the skin surface. The direct electrical contact avoids signal degradation when adhesive glue is instead used between the skin and the electrode. Electrically conductive electrode **620** may be taped to the skin for a prolonged attachment time. Electrically conductive electrode **620** may include a short strip of metal foil that is coupled to electrotherapy stimulator **610** via a flexible wire. Alternatively, electrically conductive electrode **620** may include a thin flexible braided wire directly coupled to electrotherapy stimulator **610**.

FIG. 7 depicts a simplified block diagram of the electrotherapy stimulator **610** and the portion of the patient's skin **125** represented in FIG. 6, in accordance with one embodiment of the present invention. FIG. 7 depicts electrotherapy stimulator **610**, which includes autonomic nervous system stimulator **220**, one or more electrotherapy needles **615A**, **615B**, a battery **717**, a housing **723**, and an electrode **620**. Battery **717** provides portable power to the circuit and enables prolonged operation. Autonomic nervous system stimulator **220** previously described and referenced in FIG. 2 and FIG. 3 may be similar to autonomic nervous system stimulator **220** included in electrotherapy stimulator **610** depicted in FIG. 7. The one or more electrotherapy needles **615A**, **615B** may be coupled in parallel to the electrotherapy signal (SIG) line output of autonomic nervous system stimulator **220**.

Housing **723** may have an insulating surface and at least one orifice in the insulating surface, the electrotherapy needles **615A** may be located outside the housing and coupled through the orifice to the autonomic nervous system stimulator circuit. Housing **723** may hermetically seal or enclose the battery and the autonomic nervous system stimulator circuit. Housing **723** may have a shape being adapted to conform to a portion of the skin surface when the periodic signal is injected below the skin surface. For example, the shape of the housing may have a flat surface when electrotherapy stimulator **610** is mounted on a flat portion of skin or may have a contoured surface when mounted on a portion of skin having a contour. Housing **723** may be attached to the skin via tape or adhesive. For example, housing **723** may be attached by an adhesive layer to the skin on the head behind and below the ear with flexible wires reaching around the ear to the front of the ear surface where electrotherapy needles **615A**, **615B** are attached. Electrode **620** may be taped to the skin surface on the inside or back surface of the ear facing the head.

FIG. 8 depicts a simplified flowchart of a method **800** for electrotherapy signal injection into a skin of a patient, in accordance with another embodiment of the present invention. Referring simultaneously to FIGS. 3, 6, 7, and 8, the method starts **810** by providing **820** battery **717**, wireless

radio transceiver **330**, and one or more electrotherapy needles **615A**, **615B**. The electrotherapy signal is a periodic signal in time that stimulates a vagal response of the autonomic nervous system of the patient is generated **830** using the circuit in electrotherapy stimulator **610**. Electrotherapy stimulator **610** may receive **840** a characteristic of the periodic signal via an input of wireless transceiver **330**. Control circuit **320** may then set **850** the characteristic into the circuit of pulse generator **310**.

The periodic electrotherapy signal is coupled **860** to electrotherapy needle **615**. The periodic signal is injected below the portion of the skin surface by electrically contacting and puncturing **870** the skin surface when electrotherapy needle **615** is inserted into the skin by the medical practitioner. The location of the needle insertion may be determined using the method described in reference to FIGS. **4A**, **4B** and the autonomic nervous system sensitivity-point tester **110** described in reference to FIGS. **1**, **2**, and **3**. After the electrotherapy needles are set in the skin, the electrotherapy stimulator is attached to the patient, and the patient's autonomic nervous system is checked. Then, autonomic nervous system monitor **135** may be disconnected, and the patient may go about his or her routine activities while electrotherapy stimulator **610** delivers periodic pulses that stimulate a vagal response of the autonomic nervous system over a predetermined and/or extended therapy time.

When a round of electrotherapy is done, the patient may return for further monitoring by the medical practitioner using autonomic nervous system monitor **135** to quantitatively determine the treatment outcome by comparing quantitative measurements of the patient's autonomic nervous system before and after the treatment round. The settings of electrotherapy stimulator **610** may be adjusted between the electrotherapy treatment rounds to optimize treatment. For example, the amplitude of the electrotherapy signal may be increased by the medical practitioner as treatment progresses due to desensitization of the nerves at the electrotherapy needle sites, as determined by quantitatively monitoring the patient using autonomic nervous system monitor **135**.

Electrotherapy signal characteristics may affect treatment outcomes. For example, FIG. **9** depicts a chart showing patient responses to electrotherapy signal injection versus electrotherapy signal frequency from peer-reviewed literature. The frequency characteristic is shown along the horizontal axis in a range below 200 Hz. The following therapeutic responses have been observed in ascending frequency order in the range between 1 Hz and 10 Hz respectively; melatonin secretion **910**, nerve regeneration, neurite outgrowth **915**, osteogenesis **920**, cartilage **925**, bone growth **930**, ligament healing, cell growth, osteogenesis, collagen production, and deoxyribonucleic acid (DNA) synthesis **935**. At about 20 Hz decreased skin necrosis, angiogenesis, fibroblast proliferation, and osteogenesis **940** have been observed. At about 25 Hz nerve growth **945** has been observed. Nerve growth, osteogenesis, and lymphocyte activation **950** have been observed at about 30 Hz. Decreased skin necrosis, angiogenesis, and fibroblast proliferation have also been observed at about 70 Hz. Osteogenesis, bony defect, and DNA synthesis **960** have been observed at about 95 Hz. Osteogenesis **965** has also been observed at about 200 Hz. Accordingly, setting the frequency characteristic of the periodic signal generated by pulse generator **310** to a predetermined frequency associated with a therapeutic response mode of the patient may improve or accelerate electrotherapy treatment outcome.

The above embodiments of the present invention are illustrative and not limiting. Various alternatives and equiva-

lents are possible. Although, the invention has been described with reference to a human patient by way of an example, it is understood that the invention is not limited by the type of patient so long as the patient has an autonomic nervous system and cardiac system. Although, the invention has been described with reference to auricular acupuncture electrotherapy by way of an example, it is understood that the invention is not limited by the location of the skin portion being tested or treated so long as the location has autonomic nervous system sensitivity-points. Other additions, subtractions, or modifications are obvious in view of the present disclosure and are intended to fall within the scope of the appended claims.

What is claimed is:

1. An electrical system, consisting essentially of: an electrotherapy stimulator, comprising:

- a battery;
- a circuit adapted to generate a periodic signal;
- a wireless radio transceiver;
- a control circuit adapted to set a characteristic of the periodic signal, the characteristic being received by an input of the wireless radio transceiver;
- a first stimulating electrically conductive electrode adapted to electrically contact and puncture a first portion of a surface of the patient's ear, wherein the periodic signal is configured to be coupled to the first electrically conductive electrode and is configured to cause a monitorable change in the sympathovagal balance between the parasympathetic and the sympathetic components of the autonomic nervous system (ANS) of the patient;
- a second stimulating electrically conductive electrode adapted to electrically contact but not puncture a second portion of a surface of the patient's ear;

and

an electronic ANS monitor, configured to monitor, a third portion of a surface of the patient, the sympathovagal balance between the parasympathetic and the sympathetic components of the ANS of the patient based on a time-varying signal representing a chaotic series of time intervals between quasi-periodic events produced by a cardiac system of the patient and to provide an indication of the monitorable change in the sympathovagal balance caused by the periodic signal; wherein the third portion of the surface of the patient monitored by the electronic ANS monitor is a skin of an arm or a leg.

2. The electrical apparatus of claim 1, the second stimulating electrically conductive electrode provides a direct electrical contact between the second stimulating electrically conductive electrode and the second portion of the surface thereby providing a return signal path for the periodic signal when the periodic signal is injected below the first portion of the surface.

3. The electrical apparatus of claim 1 further consisting of a housing having an insulating surface and at least a first orifice in the insulating surface, the first electrically conductive electrode adapted to be located outside the housing and coupled through the first orifice to the circuit, the housing enclosing the battery and the circuit.

4. The electrical apparatus of claim 3, wherein the housing is adapted to have a shape being adapted to conform to the second portion of the surface when the periodic signal is injected below the first portion of the surface.

5. The electrical apparatus of claim 3, wherein the housing is adapted to hermetically seal the electrical apparatus.

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6. The electrical apparatus of claim 1, wherein the wireless radio transceiver operates on a transmission standard selected from the group consisting of Bluetooth®, 6LoWPAN®, ZigBee®, DASH7®, Z-Wave®, MiWi®, and OSION®.

7. The electrical apparatus of claim 1, wherein the characteristic is selected from the group consisting of a frequency, an amplitude, a pulse shape, and a duty cycle.

8. The electrical apparatus of claim 1, wherein the periodic signal is an electrotherapy signal, the characteristic of the periodic signal is adapted to stimulate a response in a parasympathetic nervous system of a patient, and the second portion of the surface is a skin of the patient when the periodic signal is injected below the first portion of the surface.

9. The electrical apparatus of claim 1, wherein the frequency of the periodic signal is set to a predetermined frequency associated with a treatment of a patient.

10. The electrical apparatus of claim 1, wherein the third portion of the surface is on a right arm, a left arm, a right leg, or a left leg of the patient.

11. A method for signal injection consisting essentially of: generating a periodic signal; wirelessly receiving a characteristic of the periodic signal; setting the characteristic of the periodic signal via a control circuit;

coupling the periodic signal to a first stimulating electrically conductive electrode;

with the first stimulating electrically conductive electrode, electrically contacting a patient through puncturing a first portion of a surface of the patient's ear;

coupling the periodic signal to the first electrically conductive electrode to cause a monitorable change in the sympathovagal balance between the parasympathetic and the sympathetic components of the autonomic nervous system (ANS) of the patient;

contacting but not puncturing a second portion of a surface by a second stimulating electrically conductive electrode;

with an electronic ANS monitor, monitoring from a third portion of a surface of the patient the sympathovagal balance between the parasympathetic and the sympathetic components of the ANS of the patient based on a time-varying signal representing a chaotic series of time intervals between quasi-periodic events produced by a cardiac system of the patient; with the electronic ANS monitor, providing an indication of the monitorable change in the sympathovagal balance caused by the periodic signal, wherein the third portion of the surface of the patient being monitored by the electronic ANS monitor is a skin of an arm or a leg; and

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resetting the characteristic of the periodic signal via the control circuit, wherein the characteristic is reset based at least in part on the change.

12. The method of claim 11 further consisting of: wherein the second stimulating electrically conductive electrode provides a direct electrical contact between the second stimulating electrically conductive electrode and the second portion of the surface, thereby providing a return signal path for the periodic signal when the periodic signal is injected below the first portion of the surface.

13. The method of claim 11 further consisting of: providing a housing having an insulating surface and at least a first orifice in the insulating surface; locating the first stimulating electrically conductive electrode outside the housing;

coupling the first stimulating electrically conductive electrode through the first orifice to the circuit; and enclosing the battery and the circuit with the housing.

14. The method of claim 13 further consisting of: shaping the housing to conform to the second portion of the surface when the periodic signal is injected below the first portion of the surface.

15. The method of claim 13 further consisting of: hermetically sealing the electrical apparatus with the housing.

16. The method of claim 11 further consisting: operating the wireless radio transceiver on a transmission standard selected from the group consisting of Bluetooth®, 6LoWPAN®, ZigBee®, DASH7®, Z-Wave®, MiWi®, and OSION®.

17. The method of claim 11 further consisting of: selecting the characteristic from the group consisting of a frequency, an amplitude, a pulse shape, and a duty cycle.

18. The method of claim 11, wherein the periodic signal is an electrotherapy signal, the characteristic of the periodic signal stimulating a response in a parasympathetic nervous system of a patient, and the second portion of the surface is a skin of the patient when the periodic signal is injected below the first portion of the surface.

19. The method of claim 11 further consisting of: setting the frequency of the periodic signal to a predetermined frequency associated with a treatment of a patient.

20. The method of claim 11, wherein the third portion of the surface is on a right arm, a left arm, a right leg, or a left leg of the patient.

* * * * *

专利名称(译)	用于刺激电疗的方法和设备		
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申请(专利权)人(译)	dyansys , Inc.		
当前申请(专利权)人(译)	dyansys , Inc.		
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摘要(译)

一种电气设备包括电池，适于产生周期信号的电路，以及无线电收发信机。电气设备还包括控制电路，适于设置周期信号的特性。该特性由无线电收发器的输入接收。该电气设备还包括第一导电电极，当周期信号被注入到表面的第一部分下方时，该第一导电电极适于电接触并刺穿表面的第一部分。周期信号耦合到第一导电电极。

