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(54) **STIMULATIVE ELECTROTHERAPY USING AUTONOMIC NERVOUS SYSTEM CONTROL**

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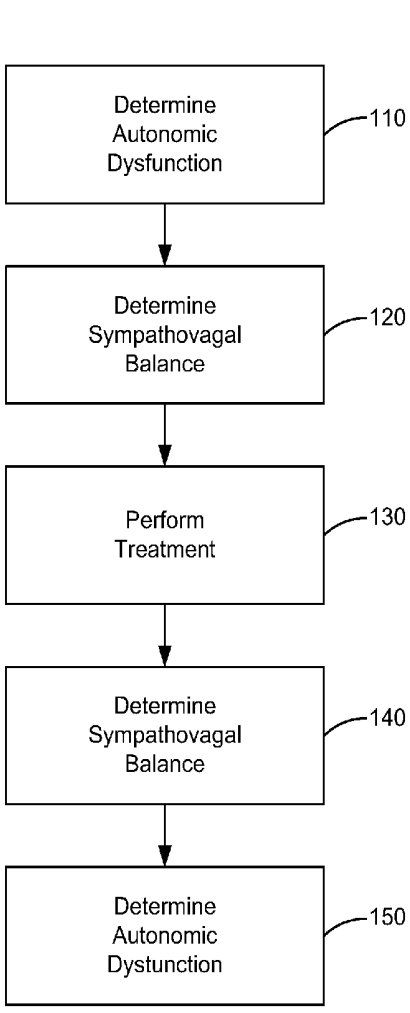
(57) **ABSTRACT**

Methods for caring for a patient are disclosed. In some embodiments, the methods include measuring a first autonomic nervous system condition of the patient, calculating a first autonomic dysfunction based on the measured first autonomic nervous system condition, and calculating a first sympathovagal balance based on the first measured autonomic nervous system condition. The method also includes treating the patient, measuring a second autonomic nervous system condition of the patient, calculating a second sympathovagal balance based on the second measured autonomic nervous system condition, and comparing the second sympathovagal balance with the first sympathovagal balance. The method also includes calculating a second autonomic dysfunction based on the measured second autonomic nervous system condition, and comparing the second autonomic dysfunction with the first autonomic dysfunction.



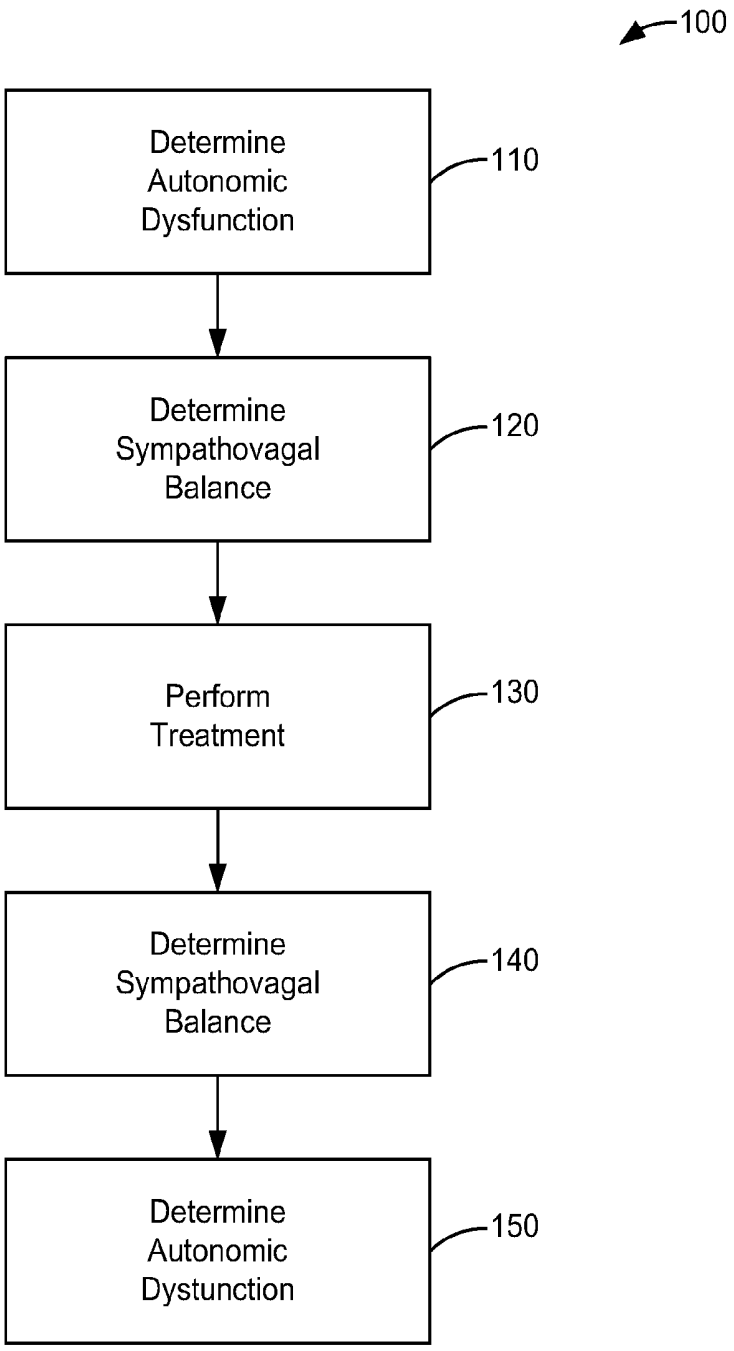

100
Determine Autonomic Dysfunction
110
Determine Sympathovagal Balance
120
Perform Treatment
130
Determine Sympathovagal Balance
140
Determine Autonomic Dystunction
150

Figure 1

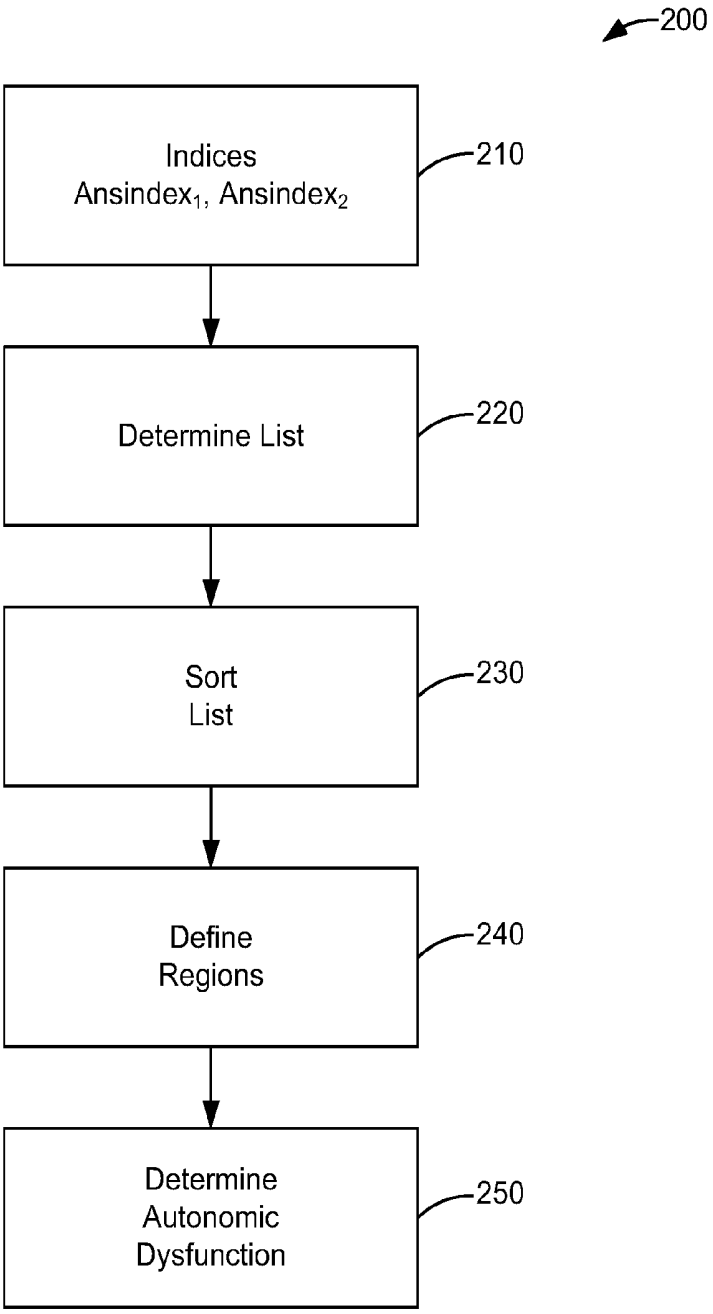
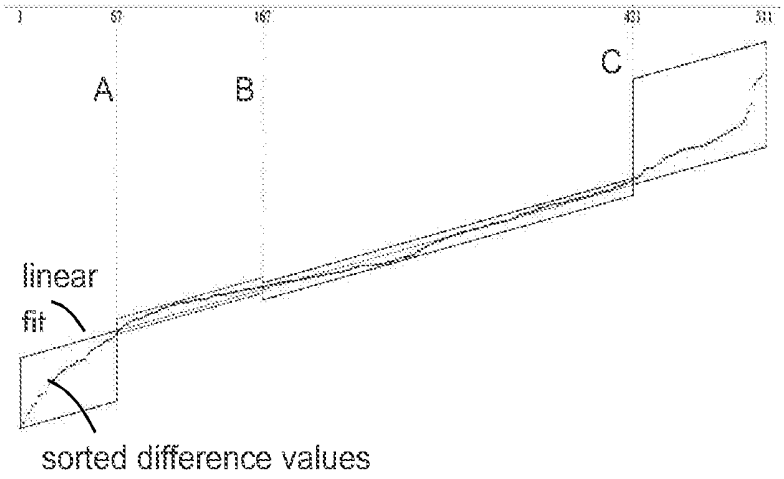

200
Indices
Ansindex1, Ansindex2
210
Determine List
220
Sort
List
230
Define
Regions
240
Determine
Autonomic
Dysfunction
250

Figure 2A



Plot 1

Figure 2B

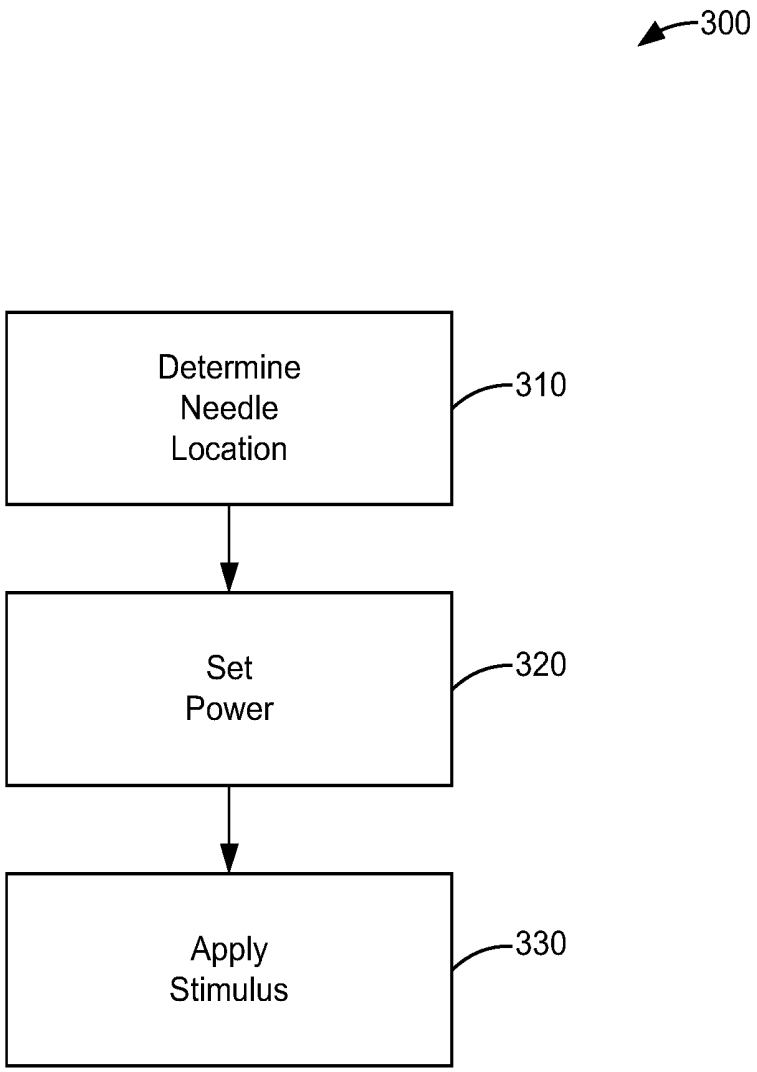

300
Determine Needle Location
310
Set Power
320
Apply Stimulus
330

Figure 3

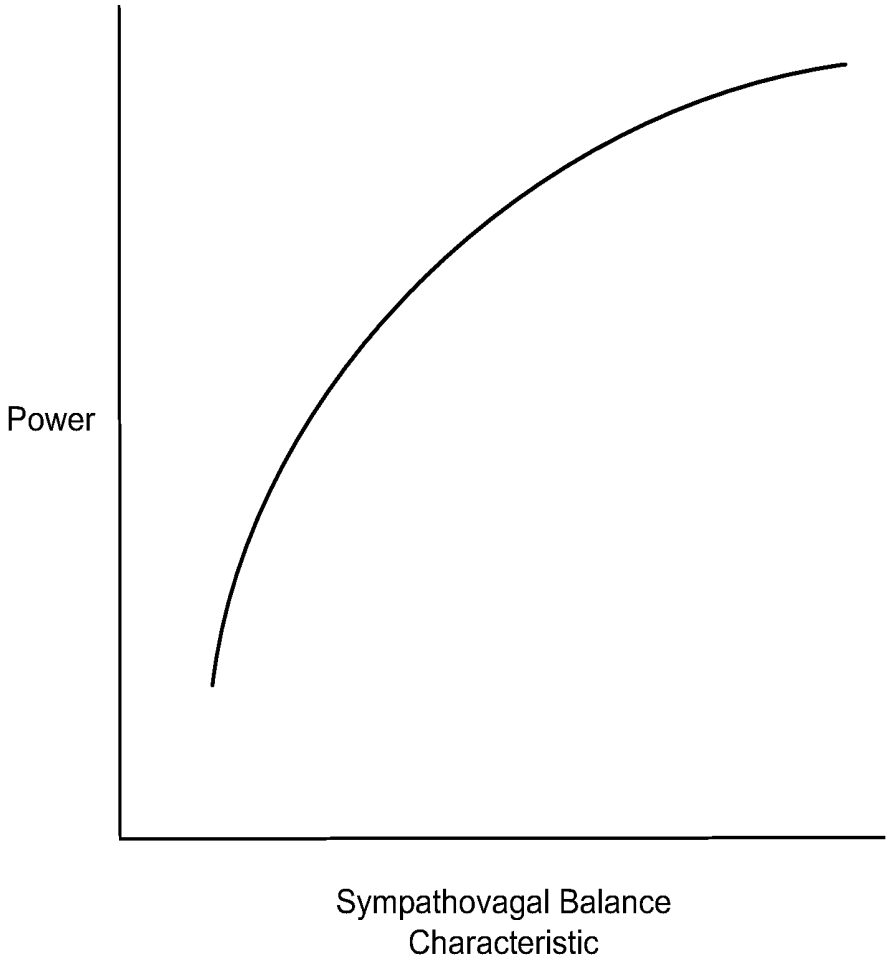


Figure 4

STIMULATIVE ELECTROTHERAPY USING AUTONOMIC NERVOUS SYSTEM CONTROL

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a Continuation of U.S. application Ser. No. 13/917,471, filed Jun. 13, 2013, the contents of which are incorporated herein by reference in their entirety.

[0002] This application is also 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 Attorney Docket No. 89562-000400US-874044, titled "METHOD AND APPARATUS FOR AUTONOMIC NERVOUS SYSTEM SENSITIVITY-POINT TESTING", U.S. patent application Attorney Docket No. 89562-000500US-874022, titled "COMPUTER IMPLEMENTED TRAINING OF A PROCEDURE," and Attorney Docket No. 89562-001000US-876815, titled "METHOD AND APPARATUS FOR STIMULATIVE ELECTROTHERAPY," the contents of all of which are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

[0003] The present invention generally pertains to a method and apparatus for extracting information from a chaotic time series of data generated based on the autonomic nervous system of a patient, and using the information to enhance therapy administered to the patient. More precisely, the present invention pertains to a method and apparatus for analyzing the state of a patient before and after treatment.

BACKGROUND OF THE INVENTION

[0004] The autonomic nervous system (ANS), with its sympathetic and parasympathetic subsystems, governs involuntary actions of the cardiac muscle and every visceral organ in the body. The ANS 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 ANS further plays an adaptive role in the interaction of the organism with its surroundings.

[0005] Heart rate variability has been shown to be a powerful means of assessing the influence of the ANS on the cardiac system. Heart rate variability is therefore a powerful indicator of the state of the ANS, and can be used as an effective means of assessing the state of physiological conditions related to the ANS, such as chronic pain.

[0006] In many diseases, the sympathetic and/or parasympathetic subsystems of the ANS are affected, leading to autonomic dysfunction. It is then important to have reliable and representative measures of the activity and the state of the ANS.

[0007] Three main classes of methods are used to recover information about the ANS from the heart rate variability: spectral analysis (also called time domain analysis), statistics and calculation of a correlation dimension (or any related dimension). These methods do not give easy interpretable outcomes. Moreover, they lack reliability and are often not mathematically appropriate in their considered application.

[0008] Without reliable and representative measures of the ANS, effects of treatment for certain conditions can be measured only subjectively. For example, to measure pain, a patient may be asked to rate their pain level on a scale of 1-10.

BRIEF SUMMARY OF THE INVENTION

[0009] One inventive aspect is a method of caring for a patient. The method includes measuring a first autonomic nervous system condition of the patient, calculating a first autonomic dysfunction based on the measured first autonomic nervous system condition, and calculating a first sympathovagal balance based on the first measured autonomic nervous system condition. The method also includes treating the patient, measuring a second autonomic nervous system condition of the patient, calculating a second sympathovagal balance based on the second measured autonomic nervous system condition, and comparing the second sympathovagal balance with the first sympathovagal balance. The method also includes calculating a second autonomic dysfunction based on the measured second autonomic nervous system condition, and comparing the second autonomic dysfunction with the first autonomic dysfunction.

[0010] Another inventive aspect is a method of caring for a patient. The method includes measuring a first autonomic nervous system condition of the patient, calculating a first sympathovagal balance based on the first measured autonomic nervous system condition, and treating the patient. The method also includes measuring a second autonomic nervous system condition of the patient, calculating a second sympathovagal balance based on the second measured autonomic nervous system condition, and comparing the second sympathovagal balance with the first sympathovagal balance.

[0011] Another inventive aspect is a method of caring for a patient. The method includes measuring a first autonomic nervous system condition of the patient, calculating a first autonomic dysfunction based on the measured first autonomic nervous system condition, and treating the patient. The method also includes measuring a second autonomic nervous system condition of the patient, calculating a second autonomic dysfunction based on the measured second autonomic nervous system condition, and comparing the second autonomic dysfunction with the first autonomic dysfunction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. **1** is a flowchart illustrating a method of caring for a patient.

[0013] FIG. **2**A is a flowchart illustrating a method of calculating autonomic dysfunction, which can be used in the method of FIG. **1**. FIG. **2**B illustrates Plot 1, which is an example of a set of sorted difference values.

[0014] FIG. **3** is a flowchart illustrating a method of treating a patient, which can be used in the method of FIG. **1**.

[0015] FIG. **4** is a chart which can be used to determine a parameter value for use in the method of FIG. **3** based on a measured characteristic of the ANS of the patient.

DETAILED DESCRIPTION OF THE INVENTION

[0016] Particular embodiments of the invention are illustrated herein in conjunction with the drawings.

[0017] Various details are set forth herein as they relate to certain embodiments. However, the invention can also be implemented in ways which are different from those described herein. Modifications can be made to the discussed embodiments by those skilled in the art without departing from the invention. Therefore, the invention is not limited to particular embodiments disclosed herein.

[0018] Particular biological events produced by a patient are governed by the ANS of the patient. Thus, a condition of the ANS of the patient may be determined through appropriate analysis of data representing the particular events. Furthermore, because the condition of the ANS of the patient may be related to one or more conditions for which the patient may seek treatment, the analysis of the data representing the biological events may be used as a quantitative measurement of the one or more conditions.

[0019] For example, the biological events may be related to the cardiac system of the patient. Thus, data representing heart rate or heart rate variability of the patient may be used to determine a measurement of pain experienced by the patient. Additionally or alternatively the biological events may be related to the respiratory system or to brain activity of the patient.

[0020] In some embodiments, conditions correlated with the biological events include one or more of chronic pain, anxiety, depression, and sleep problems.

[0021] FIG. **1** is a flowchart illustrating a method **100** of caring for a patient. The patient may be seeking treatment for one or more conditions which may be measured through analysis of data related to biological events governed by the ANS of the patient. For example, the patient may be experiencing chronic pain.

[0022] According to the method **100**, before treatment, autonomic dysfunction and Sympathovagal balance are determined. In addition, following treatment, autonomic dysfunction and Sympathovagal balance are again determined. A difference between before and after values of the autonomic dysfunction and Sympathovagal balance of the patient may be used as an indication of the efficacy of the treatment.

[0023] In step **110**, autonomic dysfunction is determined.

[0024] In some embodiments, one or more methods and/or systems described in appendix 1 is used to determine autonomic dysfunction. For example, data representing biological events produced by the patient, which are governed by the ANS of the patient may be recorded using an apparatus described in appendix 1. In addition, one or more data analysis methods and systems described in appendix 1 may be used to calculate an autonomic dysfunction of the patient based on the recorded biological event data.

[0025] In some embodiments, methods and/or systems not described in the appendix 1 may be used to the autonomic dysfunction of the patient. For example, a method of determining an autonomic dysfunction of the patient described below with reference to FIG. **2**A may be used.

[0026] In step **120**, Sympathovagal balance is determined.

[0027] In some embodiments, one or more methods and/or systems described in appendix 1 is used to determine Sympathovagal balance. For example, data representing biological events produced by the patient, which are governed by the ANS of the patient may be recorded using an apparatus and/or method described in appendix 1. In addition, one or more data analysis methods and systems described in appendix 1 may be used to calculate a Sympathovagal balance of the patient based on the recorded biological event data. In some embodiments, the recorded biological event data used to calculate the autonomic dysfunction of the patient is also used to calculate the Sympathovagal balance of the patient.

[0028] In some embodiments, a balance curve is calculated using one or more methods and systems described in appendix 1, and Sympathovagal balance is determined based on one or more parameters extracted from balance curve. For example, one or more of the minimum, the maximum, the midpoint, the mean, and the median for either the horizontal or vertical axis values may be used as the Sympathovagal balance. Additionally or alternatively, the presence of loops or upholding of long flat transitions may be used as the Sympathovagal balance.

[0029] In some embodiments, methods and/or systems not described in the appendix 1 may be used to the Sympathovagal balance of the patient.

[0030] In step **130**, a treatment is performed on the patient. In some embodiments, the treatment comprises providing electrical stimulus to selected sites on the body of the patient. Alternatively, one or more other treatments may be performed on the patient. For example, physical therapy, other forms of stimulation, manipulation, and pain medication, such as opioids.

[0031] In some embodiments, a method of treating the patient described below with reference to FIG. **3** may be used.

[0032] In step **140**, following the treatment, Sympathovagal balance of the patient is again determined. The Sympathovagal balance determined after the treatment may be compared with the Sympathovagal balance determined prior to the treatment. The comparison may be used to judge efficacy of the treatment.

[0033] In some embodiments, in step **140**, the Sympathovagal balance of the patient is determined using systems and methods substantially identical to the systems and methods used in step **120** to determine the Sympathovagal balance of the patient prior to the treatment. In some embodiments, the methods and systems used in step **140** to determine the Sympathovagal balance of the patient after the treatment may be different from the methods and systems used in step **120** to determine the Sympathovagal balance of the patient prior to the treatment.

[0034] In step **150**, following the treatment, an autonomic dysfunction of the patient is again determined. The autonomic dysfunction determined after the treatment may be compared with the autonomic dysfunction determined prior to the treatment. The comparison may be used to judge efficacy of the treatment.

[0035] In some embodiments, in step **150**, the autonomic dysfunction of the patient is determined using systems and methods substantially identical to the systems and methods used in step **110** to determine the autonomic dysfunction of the patient prior to the treatment. In some embodiments, the methods and systems used in step **150** to determine the autonomic dysfunction of the patient after the treatment may be different from the methods and systems used in step **110** to determine the autonomic dysfunction of the patient prior to the treatment.

[0036] In some embodiments, the method of FIG. **1** is repeated. For example, the method of FIG. **1** may be used in a first treatment session. As part of the first treatment session, an efficacy of the first treatment may be judged based on the comparisons of the autonomic dysfunction and Sympathovagal balance values before and after the first treatment. Likewise, the method of FIG. **1** may be used in a second treatment session. Similar to the first treatment session, as part of the second treatment session, an efficacy of the second treatment may be judged based on comparisons of the autonomic dysfunction and Sympathovagal balance values before and after the second treatment. In some embodiments, the second treatment session includes about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, or 12 minutes, hours, days, weeks, months, or years after the first treatment session.

[0037] In addition, autonomic dysfunction and Sympathovagal balance values determined as part of the second treatment session may be be compared with autonomic dysfunction and Sympathovagal balance values determined as part of the second treatment session. Such a comparison may indicate efficacy of the treatment over multiple treatment sessions.

[0038] FIG. **2**A is a flowchart illustrating a method **200** of calculating an autonomic dysfunction of a patient. The method **200** can be used, for example, in the method **100** illustrated in FIG. **1**. In some embodiments, the method **200** illustrated in FIG. **2**A is performed separately and distinct from the method **100** illustrated in FIG. **1**. In addition, the method **100** illustrated in FIG. **1** may use a method of calculating autonomic dysfunction which is different from the method **200** illustrated in FIG. **2**A.

[0039] According to the method **200**, an autonomic dysfunction is calculated based on recorded data representing biological events which are governed by the ANS of the patient.

[0040] In step **210**, a first index ANSindex1 and a second index ANSindex2, are calculated according to methods and systems described in appendix 1. In alternative embodiments, ANSindex1 and ANSindex2 may be calculated using different methods and systems. In some embodiments, ANSindex1 and ANSindex2 may be calculated in response to each of a plurality of successive biological events. For example, in response to each of a number of heartbeats as measured, for example, with an EKG, ANSindex1 and ANSindex2 values may be calculated. In some embodiments, ANSindex1 and ANSindex2 values may be calculated in response to each of a series of 400 heartbeats. In some embodiments, ANSindex1 and ANSindex2 values may be calculated in response to each of a series of 512 heartbeats. In some embodiments, the data from a certain number of heartbeats, for example 60, are used for calibration, or other purposes. In some embodiments, the heartbeats are successive.

[0041] In step **220**, a set of difference values (DV) is calculated. Each difference value of the set is calculated based on the ANSindex1 and ANSindex2 values calculated in response to one of the successive biological events, as described with reference to step **210**. For example, in step **210**, for each of the successive biological events, an ANSindex1 value and an ANSindex2 value are calculated, and in step **220** a difference value between the ANSindex1 value and the ANSindex2 value for each successive biological event is calculated. The difference values calculated for all of the biological events forms the set of difference values.

[0042] For example, in some embodiments,

$$DV_i = ANSindex2_i - ANSindex1_i,$$

where i is an index indicating data points.

[0043] In step **230**, the set of difference values is sorted. For example, the set of difference values may be sorted from lowest difference value to highest difference value. In other embodiments the second difference values may be sorted from highest difference value to lowest difference value.

[0044] FIG. **2**B illustrates Plot 1, which is an example of a set of sorted difference values. The difference values are plotted in the sorted order, with the lower difference values being plotted to the left of the higher difference values, and where the distance from the horizontal axis corresponds with the value of each of the sorted difference values. Plot 1 also shows a linear fit reference line.

[0045] In step **240**, the sorted difference values are separated into different regions. For example, four regions may be defined. Indicators A, B, and C identify boundaries between adjacent regions of the example set of difference values shown in Plot 1. In this example, the indicators A, B, and C align with difference values 67, 167, and 421, respectively. In some embodiments, the regions are determined based on the linearity or second derivative of the sorted difference values. For example, each region may include the difference values which correspond to points where the second derivative differs by less than a threshold. In some embodiments, regions may be determined by alternate crossing of a middle portion linear or cubic fit, and/or a distance within various thresholds to a linear or cubic fit.

[0046] Each of the regions may correspond with a certain characteristic of the ANS of the patient. For example, the first and last, lower and upper regions may correspond respectively to a profound altered state and a superficial transient change of autonomic function whereas the quasi-linear middle regions may indicate a melded durable state of autonomic homeostasis.

[0047] In step **250**, information represented in the set of sorted difference values is used to calculate an autonomic dysfunction of the patient. Various mathematical methods may be used.

[0048] For example, a value V_r may be determined for each of the four regions. In some embodiments, the value for each region is determined by summing the difference values of the region. Alternatively, the value for each region may be determined by summing the difference values of the region raised to an exponent. For example, the exponent may be 2, 3, 4, 5, or another value. In some embodiments, the exponent may not be a whole number, may be irrational, and/or may be negative. As a nonlimiting example, the value for each of the regions may be determined by summing the difference values of the region raised to the fourth power.

[0049] For example, in some embodiments,

$$V_r = \Sigma_1^n (DV_i)^4,$$

where i is a summing index indicating data points in the region, n is the number of points in the region, and r identifies the region.

[0050] In some embodiments, the values for the regions are each multiplied by a coefficient (c) specific to the region associated therewith. For example, the value associated with the first region may be multiplied by a coefficient equal to −8.2045, the value associated with the second region may be

multiplied by a coefficient equal to 1.769, the value associated with the third region may be multiplied by a coefficient equal to 0.90025, and the value associated with the fourth region may be multiplied by a coefficient equal to 1.903. Alternatively, the coefficient for the first region may be equal to −9.215, the coefficient for the second region may be equal to −530, the coefficient for the third region may be equal to 0.7, and the coefficient for the fourth region may be equal to 1.23. Other coefficient values may be used.

[0051] In some embodiments, the values multiplied by their respective coefficients are summed. Further, a constant C may be added to the summed values multiplied by their respective coefficients. For example, −2600 may be added to the summed values multiplied by their respective coefficients. Alternatively, the constant C may be equal to −1650.

[0052] In some embodiments, the coefficient values {a->−8-2045, b->1.769, c->0.90025, d->1.903, offset->−2600} are used with a lower sampling rate for the input EKG signal (for example, 300 Hz), and the coefficient values {a->−9.215, b->−530, c->0.7, d->1.23, offset->−1650} are used with a higher sampling rate for the input EKG signal (for example, 600 Hz or 1.2 kHz).

[0053] To calculate the autonomic dysfunction AD, the result of the summing may be raised to an exponent equal to the inverse of the exponent used for determining the values associated with each region.

[0054] For example, in some embodiments,

$$AD=(C+\Sigma_1^n c_i V_i)^{1/4},$$

[0055] where i is a summing index indicating regions, and n is the number of regions.

[0056] In some embodiments, a value representing the calculated autonomic dysfunction is graphically shown on a display associated with an apparatus used for calculating the autonomic dysfunction.

[0057] FIG. **3** is a flowchart illustrating a method **300** of treating a patient. The method **300** can be used in the method **100** illustrated in FIG. **1**. In some embodiments, the method **300** illustrated in FIG. **3** may be performed separately and distinct from the method **100** illustrated in FIG. **1**. In addition, the method **100** illustrated in FIG. **1** may use a method of treating a patient which is different from the method **300** illustrated in FIG. **3**. For example, physical therapy, other forms of stimulation, manipulation, and pain medication, such as opioids.

[0058] In the method **300**, the patient is treated by electrically stimulating points on the patient's skin to which the autonomic nervous system is sensitive.

[0059] In step **310**, locations on the patient's skin having autonomic nervous system sensitivity are identified. For example, a graphical representation of a least a portion of the patient's body having sensitivity points identified may be referenced. In some embodiments, the locations correspond with locations identified as acupuncture points.

[0060] In step **320**, an electrical stimulus source generator is adjusted so as to provide an appropriate stimulus signal. For example, one or more parameters, such as at least one of a frequency, an amplitude, a DC offset, a power, and a treatment duration may be programmed into the electrical stimulus source generator. In some embodiments, the electrical stimulus source generator is programmed with a value determined based on a value calculated based on biological event data. For example, one or more values associated with autonomic dysfunction or Sympathovagal balance may be used to determine one or more values for the one or more parameters to be program into the electrical stimulus source generator.

[0061] For example, FIG. **4** illustrates a chart which can be used to determine a parameter value for use in the method of FIG. **3** based on a measured characteristic of the ANS of the patient. Specifically, FIG. **4** illustrates a chart which can be used to determine a power setting for the electrical stimulus source generator. In this example, the power setting is determined based on a value related to Sympathovagal balance. In this example, a higher power setting is used for a higher calculated Sympathovagal balance value. Similar charts may be additionally or alternatively used to determine other parameters for programming the electrical stimulus source generator based on a measured characteristic of the ANS of the patient.

[0062] In step **330**, an electrical stimulus is provided to the locations identified in step **310**. For example, a needle may be inserted at each of the identified locations, where the needle is attached to the electrical stimulus source generator. In addition, a circuit completion path, such as a ground path, is provided by attaching a circuit completion electrode from the electrical stimulus source generator to the patient. The electrical stimulus is provided to the patient through the needles inserted at the locations identified in step **310** by the electrical stimulus source generator, which has been programmed with the parameter values of step **320**.

[0063] Though the present invention is disclosed by way of specific embodiments as described above, those embodiments are not intended to limit the present invention. Based on the methods and the technical aspects disclosed above, variations and changes may be made to the presented embodiments by those skilled in the art without departing from the spirit and the scope of the present invention.

What is claimed is:

1. A method of treating a patient, the method comprising:

providing an electrical stimulus source generator capable of sending adjustable electrical signals to various locations on the skin of patient via an interfacing form factor, wherein the adjustable electric signals are characterized by parameters including a frequency, an amplitude, a DC offset, a power, a signal duration, and best locations to perform the electrical stimulations in the patient's skin;

applying the electrical stimulus source generator to the patient via the interfacing formfactor;

adjusting the parameters of the electrical stimulus source generator to generate a plurality of appropriate stimulus signals associated with autonomic nervous system (ANS) data of the patient;

analyzing the acquired signals on a graphic terminal of a computer to determine if the stimulated signals associated with ANS data of the patient are acquired with sufficient sensitivity;

optimizing the adjustable electrical signal parameters on the electrical stimulus source generator on the patient's until ANS data from sufficiently sensitive skin points of the patient are presented on the computer graphic terminal;

storing the optimized values of the adjustable parameters in a computer program;

acquiring from the patient multiple sets of the stimulus electrical signals associated with ANS data overtime; and

comparing and calculating dysfunctional ANS data of the patient to determine whether to treat the patient.

2. A method of claim **1**, wherein acquiring the ANS data of the patient comprises measuring a heart rate of the patient over time.

3. A method of claim **1**, wherein the interfacing form factor comprises insertion of an acupuncture-like needle into the patient skin.

4. A method of claim **2**, wherein comparing and calculating the dysfunctional ANS data further comprising: measuring by the electrical stimulus source generator, the first ANS data, wherein the first ANS data corresponds with a first ANS state of the patient, and wherein measuring of the first ANS data comprises measuring first timing information of the patient's heartbeat;

calculating, by the computing apparatus, a first autonomic dysfunction value based on the measured first ANS data, wherein calculating the first autonomic dysfunction value comprises:

determining first heartbeat data by calculating a plurality of time difference values between a first plurality of pairs of successive heartbeats of the first timing information;

sorting the first heartbeat data based on the plurality of time difference values;

determining a plurality of first continuous regions of the sorted first heartbeat data, wherein the data within each of the first region shares a first common mathematical characteristic, wherein the first common mathematical characteristic is unique to each first region among the first regions;

determining a first value for each of the first continuous regions based on the sorted first heartbeat data; and

determining the first autonomic dysfunction value of the patient based on the first values;

calculating, by the computing apparatus, a first sympathovagal balance based on the first measured autonomic nervous system data;

treating the patient, whereby the treatment causes a transformation in the ANS of the patient;

determining, by the computing apparatus, second autonomic nervous system data, wherein the second autonomic nervous system data corresponds with a second autonomic nervous system state of the patient, and wherein the measuring determining of the second autonomic nervous system data comprises measuring second timing information of the heartbeat of the patient;

calculating, by the computing apparatus, a second sympathovagal balance based on the second determined autonomic nervous system data;

comparing, by the computing apparatus, the second sympathovagal balance with the first sympathovagal balance;

calculating, by the computing apparatus, a second autonomic dysfunction value based on the measured second autonomic nervous system data, wherein calculating the second autonomic dysfunction comprises:

determining second heartbeat data by calculating a second plurality of time difference values between a second plurality of pairs of successive heartbeats of the second timing information,

sorting the second heartbeat data based on the second plurality of time difference values,

determining a plurality of second continuous regions of the sorted second heartbeat data, wherein the data within each of the second regions shares a second common mathematical characteristic, wherein the second common mathematical characteristic is unique to each second region among the second regions,

determining a second value for each of the second continuous regions based on the sorted second heartbeat data, and

determining the second autonomic dysfunction value of the patient based on the second values; and

evaluating, by the computing apparatus, the transformation of the ANS of the patient caused by the treatment, wherein the evaluating comprises:

comparing the second autonomic dysfunction value with the first autonomic dysfunction value, and

comparing the second sympathovagal balance with the first sympathovagal balance.

5. The method of claim **1**, further comprising, by the computing apparatus:

determining third autonomic nervous system data, wherein the third autonomic nervous system data corresponds with a third autonomic nervous system state of the patient, and wherein the determining of the third autonomic nervous system data comprises measuring third timing information of the heartbeat of the patient;

calculating a third autonomic dysfunction value based on the measured determined third autonomic nervous system data;

calculating a third sympathovagal balance based on the measured third autonomic nervous system data;

retreating the patient;

determining fourth autonomic nervous system data, wherein the fourth autonomic nervous system data corresponds with a fourth autonomic nervous system state of the patient, and wherein the determining of the fourth autonomic nervous system data comprises measuring fourth timing information of the heartbeat of the patient;

calculating a fourth sympathovagal balance based on the measured fourth autonomic nervous system data;

comparing the fourth sympathovagal balance with the third sympathovagal balance;

calculating a fourth autonomic dysfunction value based on the measured fourth autonomic nervous system data; and

comparing the fourth autonomic dysfunction value with the third autonomic dysfunction value.

6. The method of claim **5**, wherein determining the first and second autonomic nervous system data of the patient and treating the patient are part of a first patient session, and wherein determining the third and fourth autonomic nervous system data of the patient and retreating the patient are part of a second patient session.

7. The method of claim **5**, further comprising, by the computing apparatus:

calculating a fifth autonomic dysfunction value based on one or more of the first and second measured autonomic nervous system data;

calculating a sixth autonomic dysfunction value based on one or more of the third and fourth measured autonomic nervous system data; and

comparing the six autonomic dysfunction value with the fifth autonomic dysfunction value.

8. The method of claim **7**, further comprising, and by the computing apparatus, determining an efficacy of the treatment based on the comparison of the sixth autonomic dysfunction value with the fifth autonomic dysfunction value.

9. The method of claim **4**, wherein calculating the first autonomic dysfunction value comprises calculating a root of a sum of values, wherein one or more of the values is equal to a sum of time difference values raised to an exponent, wherein the time difference values are each equal to a difference of a first index value and a second index value, and wherein the first and second index values are each calculated based on the first autonomic nervous system state.

10. The method of claim **9**, wherein the time difference values belong to a subset of a set of time difference values, and wherein the subset comprises a plurality of time difference values of the set which are sequential when the set of difference values is sorted by value.

11. The method of claim **10**, wherein the boundaries between subsets are defined based on a second derivative of the set.

12. The method of claim **9**, wherein the exponent is the inverse of the root.

13. The method of claim **4**, wherein calculating sympathovagal balance comprises extracting a horizontal midpoint from a balance curve.

14. The method of claim **4**, wherein treating the patient comprises electrically stimulating points on the patient to which the autonomic nervous system of the patient is sensitive.

15. The method of claim **14**, wherein the power of the electrical stimulation is based on the first sympathovagal balance value.

16. The method of claim **4**, wherein measuring the autonomic nervous system data of the patient comprises measuring a heart rate of the patient over time.

17. The method of claim **4**, wherein measuring the autonomic nervous system data of the patient comprises recording first and second sets of data, wherein the first set of data is used to calculate autonomic dysfunction of the patient, and the second set of data is used to calculate a sympathovagal balance of the patient.

18. The method of claim **1**, the method further comprising:

determining, by the computing apparatus, first autonomic nervous system (ANS) data, wherein the first autonomic nervous system data corresponds with a first autonomic nervous system state of the patient, and wherein the determining of the first autonomic nervous system data comprises measuring first timing information of the heartbeat of the patient:

calculating, by the computing apparatus, a first sympathovagal balance based on the first measured autonomic nervous system data, wherein calculating the first sympathovagal balance includes determining a first autonomic dysfunction value based on:

determining first heartbeat data by calculating a plurality of time difference values between a first plurality of pairs of successive heartbeats of the first timing information,

sorting the first heartbeat data based on the plurality of time difference values,

determining a plurality of first continuous regions of the sorted first heartbeat data, wherein the data within each of the first region shares a first common mathematical characteristic, wherein the first common mathematical characteristic is unique to each first region among the first regions,

determining a first value for each of the first continuous regions based on the sorted first heartbeat data, and

determining the first autonomic dysfunction value of the patient based on the first values;

treating the patient, whereby the treatment causes a transformation in the ANS of the patient;

determining, by the computing apparatus, second autonomic nervous system data, wherein the second autonomic nervous system data corresponds with a second autonomic nervous system state of the patient, and wherein the determining of the second autonomic nervous system data comprises measuring second timing information of the heartbeat of the patient;

calculating a second sympathovagal balance based on the second measured autonomic nervous system data; and

evaluating the transformation of the ANS of the patient caused by the treatment, wherein the evaluating comprises:

comparing the second sympathovagal balance with the first sympathovagal balance.

19. The method of claim **18**, further comprising, by the computing apparatus:

determining third autonomic nervous system data, wherein the third autonomic nervous system data corresponds with a third autonomic nervous system state of the patient, and wherein the determining measuring of the third autonomic nervous system data comprises measuring third timing information of the heartbeat of the patient;

calculating a third sympathovagal balance based on the measured determined third autonomic nervous system data;

retreating the patient;

determining fourth autonomic nervous system data, wherein the fourth autonomic nervous system data corresponds with a fourth autonomic nervous system state of the patient, and wherein the determining measuring of the fourth autonomic nervous system data comprises measuring fourth timing information of the heartbeat of the patient;

calculating a fourth sympathovagal balance based on the measured fourth autonomic nervous system data; and

comparing the fourth sympathovagal balance with the third sympathovagal balance.

20. The method of claim **19**, wherein determining the first and second autonomic nervous system data of the patient and treating the patient are part of a first patient session, and wherein determining the third and fourth autonomic nervous system data of the patient and retreating the patient are part of a second patient session.

21. The method of claim **19**, further comprising, by the computing apparatus:

calculating a fifth sympathovagal balance based on one or more of the first and second measured autonomic nervous system data;

calculating a sixth sympathovagal balance based on one or more of the third and fourth measured autonomic nervous system data; and

comparing the sixth sympathovagal balance with the fifth sympathovagal balance.

22. The method of claim 21, further comprising, by the computing apparatus, determining an efficacy of the treatment based on the comparison of the sixth sympathovagal balance with the fifth sympathovagal balance.

23. The method of claim 18, wherein calculating sympathovagal balance comprises extracting a horizontal midpoint from a balance curve.

24. The method of claim 18, wherein treating the patient comprises electrically stimulating points on the patient to which the autonomic nervous system of the patient is sensitive.

25. The method of claim 24, wherein the power of the electrical stimulation is based on the first sympathovagal balance.

26. The method of claim 21, wherein measuring each autonomic nervous system state of the patient comprises measuring a heart rate of the patient over time.

27. The method of claim 1, the method further comprising:

determining, by the computing apparatus, first autonomic nervous system (ANS) data, wherein the first autonomic nervous system data corresponds with a first autonomic nervous system state of the patient, and wherein the measuring of the first autonomic nervous system data comprises measuring first timing information of the heartbeat of the patient;

calculating, by the computing apparatus, a first autonomic dysfunction value based on the determined first autonomic nervous system data, wherein calculating the first autonomic dysfunction value comprises:

determining first heartbeat data by calculating a plurality of time difference values between a first plurality of pairs of successive heartbeats of the first timing information,

sorting the first heartbeat data based on the plurality of time difference values,

determining a plurality of first continuous regions of the sorted first heartbeat data, wherein the data within each of the first region shares a first common mathematical characteristic, wherein the first common mathematical characteristic is unique to each first region among the first regions,

determining a first value for each of the first continuous regions based on the sorted first heartbeat data, and

determining the first autonomic dysfunction value of the patient based on the first values;

treating the patient, whereby the treatment causes a transformation in the ANS of the patient;

determining, by the computing apparatus, second autonomic nervous system data, wherein the second autonomic nervous system data corresponds with a second autonomic nervous system state of the patient, and wherein the measuring determining of the second autonomic nervous system data comprises measuring second timing information of the heartbeat of the patient;

calculating, by the computing apparatus, a second sympathovagal balance based on the second measured autonomic nervous system data;

comparing, by the computing apparatus, the second sympathovagal balance with the first sympathovagal balance;

calculating, by the computing apparatus, a second autonomic dysfunction value based on the measured determined second autonomic nervous system data, wherein calculating the second autonomic dysfunction value comprises:

determining second heartbeat data representing by calculating a second plurality of time difference values between a second plurality of pairs of successive heartbeats of the second timing information,

sorting the second heartbeat data based on the second plurality of time difference values,

determining a plurality of second continuous regions of the sorted second heartbeat data, wherein the data within each of the second regions shares a second common mathematical characteristic, wherein the second common mathematical characteristic is unique to each second region among the second regions,

determining a second value for each of the second continuous regions based on the sorted second heartbeat data, and

determining the second autonomic dysfunction value of the patient based on the second values; and

evaluating, by the computing apparatus, the transformation of the ANS of the patient caused by the treatment, wherein the evaluating comprises:

comparing the second autonomic dysfunction with the first autonomic dysfunction.

28. The method of claim 27, further comprising, by the computing apparatus:

determining third autonomic nervous system data, wherein the third autonomic nervous system data corresponds with a third autonomic nervous system state of the patient, and wherein the determining of the third autonomic nervous system data comprises measuring third timing information of the heartbeat of the patient;

calculating a third autonomic dysfunction value based on the measured third autonomic nervous system data;

retreating the patient;

determining fourth autonomic nervous system data, wherein the fourth autonomic nervous system data corresponds with a fourth autonomic nervous system state of the patient, and wherein the measuring determining of the fourth autonomic nervous system data comprises measuring fourth timing information of the heartbeat of the patient;

calculating a fourth autonomic dysfunction value based on the measured fourth autonomic nervous system data; and

comparing the fourth autonomic dysfunction value with the third autonomic dysfunction value.

29. The method of claim 28, wherein determining the first and second autonomic nervous system data of the patient and treating the patient are part of a first patient session, and wherein determining the third and fourth autonomic nervous system data of the patient and retreating the patient are part of a second patient session.

30. The method of claim 28, further comprising, by the computing apparatus:

calculating a fifth autonomic dysfunction value based on one or more of the first and second measured autonomic nervous system data;

calculating a sixth autonomic dysfunction value based on one or more of the third and fourth measured autonomic nervous system data; and

comparing the sixth autonomic dysfunction value with the fifth autonomic dysfunction value.

31. The method of claim **30**, further comprising, by the computing apparatus, determining an efficacy of the treatment based on the comparison of the sixth autonomic dysfunction value with the fifth autonomic dysfunction value.

32. The method of claim **27**, wherein calculating the first autonomic dysfunction value comprises calculating a root of a sum of values, wherein one or more of the values is equal to a sum of difference values raised to an exponent, wherein the difference values are each equal to a difference of a first index value and a second index value, and wherein the first and second index values are each calculated based on the first autonomic nervous system state.

33. The method of claim **32**, wherein the difference values belong to a subset of a set of difference values, and wherein the subset comprises a plurality of difference values of the set which are sequential when the set of difference values is sorted by value.

34. The method of claim **33**, wherein the boundaries between subsets are defined based on a second derivative of the set.

35. The method of claim **32**, wherein the exponent is the inverse of the root.

36. The method of claim **27**, wherein treating the patient comprises electrically stimulating points on the patient to which the autonomic nervous system of the patient is sensitive.

37. The method of claim **27**, wherein measuring the autonomic nervous system data of the patient comprises measuring a heart rate of the patient over time.

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专利名称(译)	使用自主神经系统控制的刺激性电疗		
公开(公告)号	US20170143247A1	公开(公告)日	2017-05-25
申请号	US15/425950	申请日	2017-02-06
[标]申请(专利权)人(译)	迪彦希斯有限公司		
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)

公开了护理患者的方法。在一些实施方案中，所述方法包括测量患者的第一自主神经系统状况，基于测量的第一自主神经系统状况计算第一自主神经功能障碍，以及基于第一测量的自主神经系统状况计算第一交感迷走神经平衡。该方法还包括治疗患者，测量患者的第二自主神经系统状况，基于第二测量的自主神经系统状况计算第二交感迷走神经平衡，以及将第二交感迷走神经平衡与第一交感迷走神经平衡进行比较。该方法还包括基于测量的第二自主神经系统状况计算第二自主神经功能障碍，并将第二自主神经功能障碍与第一自主神经功能障碍进行比较。