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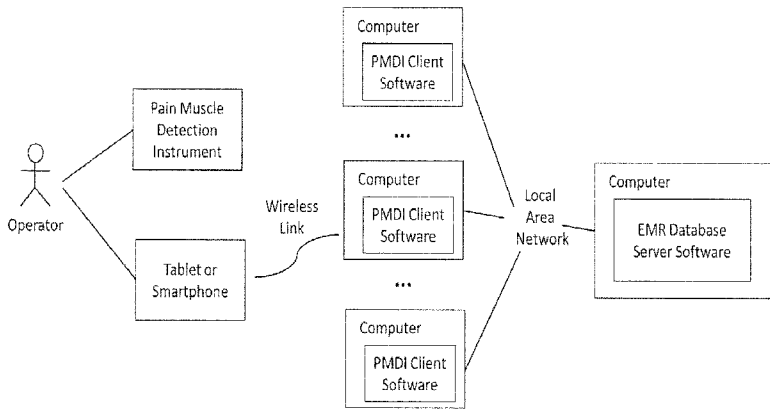

FIG. 1

(57) **Abstract**: Systems and methods for evaluating muscle pain within a patient by determining the minimum stimulation magnitude at which one or more physiological pain signals can be detected within a selected muscle of the patient. Disclosed herein, in one aspect, is a system for evaluating pain within at least one selected muscle of a patient. The system can comprise at least one stimulation source, at least one sensor, and processing circuitry.

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METHOD AND SYSTEM FOR MUSCLE PAIN DIAGNOSIS

FIELD

[0001] The invention relates to systems and methods for identifying and evaluating muscle pain.

BACKGROUND

[0002] Current procedures for identifying muscles as a source of pain are performed through electrical stimulation or palpation of the muscle. The area that is identified as a putative source of pain may be injected with a variety of substances or with a dry needle, generally into a specific spot which is frequently called a trigger point (TrP). Often, the specific muscle in which the TrP resides is not identified. Palpation is often an unreliable means of identifying painful areas, and injections into painful spots within a muscle, identified through palpation without consideration of an entire muscle as the source of the pain, produce suboptimal results. *See* Marcus, NJ., Gracely, E., Keefe, K. (2010). A Comprehensive Protocol to Diagnose and Treat Pain of Muscular Origin May Successfully and Reliably Decrease or Eliminate Pain in a Chronic Pain Population. *Pain Medicine*, 11(1), which is incorporated herein by reference in its entirety.

[0003] Current electrical stimulation systems for muscle pain diagnosis require adjustment of amperage by a clinician of a fixed pulse frequency and waveform to produce enough current to produce a visible contraction in a standard muscle, typically the trapezius. In many patients, particularly those who are deconditioned or obese, the contraction of the muscles may be difficult to observe and therefore excessive amperage beyond the minimum necessary for any contraction may be selected. If significant excess current is used, patients may report a false positive because over-contracting any muscle may produce discomfort. Just as important is the possibility of a false negative, which can occur when unwanted stimulation of cutaneous nerves produces a mild sensation which can mask the concomitant discomfort produced by the contraction of the pain-generating muscle. These problems are largely ignored and/or not addressed by current pain diagnosis systems and methods.

[0004] Thus, there is a need for more sophisticated methods and systems for diagnosing muscle pain.

SUMMARY

[0005] Disclosed herein, in one aspect, is a system for evaluating pain within at least one selected muscle of a patient. The system can comprise at least one stimulation source, at least one sensor, and processing circuitry. Each stimulation source can be configured to selectively apply a selected stimulation to the at least one selected muscle of the patient in accordance with a plurality of stimulation parameters. The plurality of stimulation parameters can comprise a magnitude, a phase, a waveform, and a frequency of the stimulation. Each stimulation parameter of the plurality of stimulation parameters can have a value that is selectively adjustable. The at least one sensor can be configured to detect at least one physiological signal within the at least one selected muscle of the patient. The processing circuitry can be in operative communication with the at least one stimulation source and the at least one sensor. The processing circuitry can be configured to determine a minimum stimulation magnitude for the selected stimulation of at least one stimulation source. The minimum stimulation magnitude can correspond to the lowest possible magnitude of the selected stimulation at which the at least one physiological signal detected by the at least one sensor is indicative of a contraction within the at least one selected muscle of the patient. Methods of using the disclosed systems are also described.

[0006] Additional advantages will be set forth in part in the description which follows or may be learned by practice. The advantages will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments and together with the description, serve to explain the principles of the methods and systems:

[0008] Figure 1 is a schematic diagram illustrating various aspects of an exemplary pain evaluation system as disclosed herein;

[0009] Figure 2 is a schematic diagram illustrating various aspects of an exemplary pain evaluation system as disclosed herein;

[0010] Figure 3 is a circuit diagram illustrating an exemplary waveform generator and controller for use in a pain evaluation system as disclosed herein;

[0011] Figure 4 is a circuit diagram illustrating an exemplary modulator circuit for the stimulus generator of a pain evaluation system as disclosed herein;

[0012] Figure 5 is a circuit diagram illustrating an exemplary differential detecting component of a pain evaluation system as disclosed herein;

[0013] Figure 6 is a schematic diagram illustrating an exemplary differential detecting component of a pain evaluation system as disclosed herein;

[0014] Figure 7 is a circuit diagram illustrating an exemplary differential detecting component of a pain evaluation system as disclosed herein;

[0015] Figure 8 illustrates an exemplary color-coded muscle pain status chart for use in the pain evaluation systems and methods as disclosed herein;

[0016] Figure 9 is an exemplary evaluation chart for use in the pain evaluation systems and methods as disclosed herein;

[0017] Figure 10 illustrates various aspects of an exemplary pain evaluation system as disclosed herein;

[0018] Figure 11 illustrates various aspects of an exemplary pain evaluation system as disclosed herein;

[0019] Figure 12 illustrates various aspects of an exemplary pain evaluation system as disclosed herein;

[0020] Figure 13 illustrates various aspects of an exemplary pain evaluation system as disclosed herein;

[0021] Figure 14 illustrates various aspects of an exemplary pain evaluation system as disclosed herein;

[0022] Figure 15 illustrates various aspects of an exemplary pain evaluation system as disclosed herein;

[0023] Figure 16 is a flowchart illustrating various aspects of an exemplary pain evaluation method as disclosed herein;

[0024] Figure 17 is a schematic diagram depicting an exemplary pain evaluation system as disclosed herein.

[0025] Figure 18 is a perspective view of an exemplary self-contained pain evaluation device as disclosed herein.

[0026] Figure 19 is a block diagram illustrating an exemplary operating environment for performing the disclosed pain detection methods; and

[0027] Figure 20 is a diagram showing the back muscles and thoracolumbar fascia of a subject.

DETAILED DESCRIPTION

[0028] Before the present methods and systems are disclosed and described, it is to be understood that the methods and systems are not limited to specific methods, specific components, or to particular configurations. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting.

[0029] As used in the specification and the appended claims, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" one particular value, and/or to "about" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment. It will be further understood that the endpoints of each of the ranges are significant both in relation to the other endpoint, and independently of the other endpoint.

[0030] "Optional" or "optionally" means that the subsequently described event or circumstance may or may not occur, and that the description includes instances where said event or circumstance occurs and instances where it does not.

[0031] Throughout the description and claims of this specification, the word "comprise" and variations of the word, such as "comprising" and "comprises," means "including but not limited to," and is not intended to exclude, for example, other additives, components, integers or steps. "Exemplary" means "an example of" and is not

intended to convey an indication of a preferred or ideal embodiment. "Such as" is not used in a restrictive sense, but for explanatory purposes.

[0032] Disclosed are components that can be used to perform the disclosed methods and systems. These and other components are disclosed herein, and it is understood that when combinations, subsets, interactions, groups, etc. of these components are disclosed that while specific reference of each various individual and collective combinations and permutation of these may not be explicitly disclosed, each is specifically contemplated and described herein, for all methods and systems. This applies to all aspects of this application including, but not limited to, steps in disclosed methods. Thus, if there are a variety of additional steps that can be performed it is understood that each of these additional steps can be performed with any specific embodiment or combination of embodiments of the disclosed methods.

[0033] The present methods and systems may be understood more readily by reference to the following detailed description of preferred embodiments and the Examples included therein and to the Figures and their previous and following description.

[0034] Disclosed herein, in various aspects, are pain evaluation systems and methods. In exemplary aspects, and with reference to **FIGS. 1-19**, a system for evaluating pain within at least one selected muscle of a patient can comprise at least one stimulation source, at least one sensor, and processing circuitry. In exemplary aspects, the at least one selected muscle can correspond to an area of pain complaint in the upper back, lower back, or thoracolumbar fascia of the patient; however, it is contemplated that the selected muscle can be positioned anywhere within the patient's body.

[0035] In one aspect, each stimulation source of the at least one stimulation source can be configured to selectively apply a selected stimulation to the at least one selected muscle of the patient in accordance with a plurality of stimulation parameters. In this aspect, the plurality of stimulation parameters can comprise at least a magnitude, a phase, a waveform, and a frequency of the stimulation. It is contemplated that each stimulation parameter of the plurality of stimulation parameters can have a value that is selectively adjustable to produce a selected stimulation. In exemplary aspects, the at least one stimulation source can comprise

at least one of a stimulus pad and a stimulator head, such as, for example and without limitation, an aluminum stimulator head.

[0036] In another aspect, the at least one sensor can be configured to detect at least one physiological signal within the at least one selected muscle of the patient. Optionally, in this aspect, each sensor of the at least one sensor is selected from the group consisting of a miniature condenser, an omnidirectional microphone, a microelectromechanical system (MEMS) microphone, a MEMS accelerometer, and an adhesive contact electrical signal sensor pad, such as, for example and without limitation, an electrocardiogram (EKG) sensor pad. Thus, it is contemplated that the at least one sensor can be configured to detect any physiological signal within the at least one selected muscle, such as, for example and without limitation, pressure waves, electrical signals, acoustic signals, acceleration, and the like associated with internal organic or inorganic processes. In exemplary aspects, at least one stimulation source can be positioned anywhere along each selected muscle, from its origin to its insertion. In these aspects, it is contemplated that each selected muscle can be stimulated along its entire length from origin to insertion.

[0037] In a further aspect, the processing circuitry can be in operative communication with the at least one stimulation source and the at least one sensor. In this aspect, the processing circuitry can be configured to determine a minimum stimulation magnitude for the selected stimulation of at least one stimulation source. It is contemplated that the minimum stimulation magnitude can correspond to the lowest possible magnitude of the selected stimulation at which the at least one physiological signal detected by the at least one sensor is indicative of contraction within the at least one selected muscle of the patient. It is further contemplated that upon application of the selected stimulation at the minimum stimulation magnitude, the system and/or a clinician can determine whether the selected muscle is a source of pain.

[0038] Optionally, in one aspect, the at least one stimulation source can comprise at least one of an electrical signal generator and a mechanical force generator.

[0039] Optionally, in an additional aspect, the pain evaluation system can further comprise a housing. In this aspect, the at least one stimulation source and the at least one sensor can be positioned within the housing.

[0040] Optionally, in another aspect, the at least one stimulation source can comprise at

least one external stimulation source provided separately from the at least one sensor.

[0041] Optionally, in a further aspect, each sensor of the at least one sensor can be configured to produce an output indicative of the at least one physiological signal detected by the sensor. In this aspect, the processing circuitry can be configured to receive the output from each sensor of the at least one sensor.

[0042] In one exemplary aspect, the at least one stimulation source can comprise at least one electrical signal generator. Optionally, in this aspect, and with reference to **FIGS. 3-4**, the at least one electrical signal generator can be configured to apply an interferential electrical stimulus waveform to the at least one selected muscle of the patient. The interferential stimulus waveform can optionally comprise at least two electrical signals. It is contemplated that each electrical signal of the at least two electrical signals can have a frequency ranging from about 1 to about 3,000 Hz. In further exemplary aspects, each electrical signal of the at least two electrical signals can have corresponding waveform parameters. In these aspects, the waveform parameters can comprise at least amplitude, frequency, phase values, and amplitude modulation, and at least one of the waveform parameters of each electrical signal can be selectively adjustable. In operation, it is contemplated that the waveform parameters can be selectively adjusted based on one or more of: the internal body process being targeted for identification; the specific muscle or muscle group of the patient being monitored; and the body type and composition of the patient, such as body fat percentage, residual muscle tension, and the like. Optionally, in additional aspects, the at least one electrical signal generator can comprise an electronic circuit. In these aspects, the electronic circuit can comprise at least two semiconductor transistors, and the at least two semiconductor transistors can be configured to multiply the at least two electrical signals into the interferential stimulus waveform. In further aspects, the at least one stimulation source can further comprise at least one electrode positioned in operative electrical communication with the at least one electrical signal generator. In these aspects, the at least one electrode can be configured to receive the interferential stimulus waveform from the electrical signal generator and apply the interferential stimulus waveform to the at least one selected muscle of the patient.

[0043] In another exemplary aspect, the at least one stimulation source can comprise at

least one electrical signal generator. In this aspect, and with reference to **FIGS. 3-4**, the at least one electrical signal generator can comprise an electronic circuit that itself comprises at least two semiconductor transistors. Optionally, the at least two semiconductor transistors can be configured to multiply at least two time-varying electrical signals into a composite interferential stimulus waveform, and the at least one electrical signal generator can be configured to apply the interferential stimulus waveform to the at least one selected muscle of the patient. In additional aspects, the at least one stimulation source can further comprise at least one electrode positioned in operative electrical communication with the at least one electrical signal generator. In these aspects, the at least one electrode can be configured to receive the interferential stimulus waveform from the electrical signal generator and apply the interferential stimulus waveform to the at least one selected muscle of the patient.

[0044] In further exemplary aspects, the electronic circuit of the at least one electronic signal generator can be configured to produce at least two pairs of interferential stimulus waveforms. In these aspects, the at least one stimulation source can be configured to deliver the interferential stimulus waveforms to the at least one selected muscle of the patient. Optionally, at least one pair of interferential stimulus waveforms can be configured to be a reference channel that is compared to other stimulation sources of the at least one stimulation source.

[0045] In yet another exemplary aspect, and with reference to **FIGS. 10-11**, the at least one sensor can comprise a plurality of sensors. In this aspect, the plurality of sensors can cooperate with the processing circuitry to define a plurality of sensing channels and a plurality of processing channels, with each sensing channel being operatively connected to a corresponding processing channel. It is contemplated that each sensing channel can comprise at least one sensor of the plurality of sensors. Optionally, in exemplary aspects, each respective processing channel of the plurality of processing channels can be configured to receive an output of each sensor of the at least one sensor of the corresponding sensing channel. In these aspects, the output of each sensor can be indicative of the at least one physiological signal detected by the at least one sensor of the corresponding sensing channel.

[0046] In an additional exemplary aspect, and with reference to **FIGS. 5-7 and 12-15**, the processing circuitry can comprise a high-common mode rejection ratio instrumentation amplifier positioned in operative communication with the at least one sensor. In this aspect, each sensor of the at least one sensor can be configured to produce an output indicative of the at least one physiological signal detected by the sensor, and wherein the instrumentation amplifier can be configured to receive the output from each sensor of the at least one sensor. Optionally, in further aspects, the processing circuitry can further comprise at least one adaptive averaging circuit. In these aspects, the instrumentation amplifier can be configured to produce an output corresponding to the output received from each sensor of the at least one sensor. In operation, the at least one adaptive averaging circuit can be configured to receive each respective output of the instrumentation amplifier, and the at least one adaptive averaging circuit can be configured to isolate the at least one physiological signal from surrounding noise and thereby produce an isolated output signal. In additional aspects, the at least one adaptive averaging circuit can be configured to compare the isolated output signal to a fixed voltage signal. Optionally, in other exemplary aspects, the pain evaluation system can further comprise at least one display. In these aspects, the at least one adaptive averaging circuit can be positioned in operative communication with the processing circuitry, and the processing circuitry can be configured to produce a visual depiction of the comparison of the isolated output signal and the fixed voltage signal on the display. In still further exemplary aspects, each adaptive averaging circuit can have corresponding signal processing parameters. In these aspects, the signal processing parameters can comprise at least a processing time period and an averaging time period. It is contemplated that at least one of the processing time period and the averaging time period can be selectively adjustable. Optionally, in additional exemplary aspects, the pain evaluation system can further comprise a database in operative communication with the processing circuitry. In these aspects, the database can comprise a plurality of signal processing parameter datasets, and the processing circuitry can be configured to adjust at least one of the processing time period and the averaging time period of each adaptive averaging circuit in accordance with a selected signal processing parameter dataset. Alternatively, it is contemplated that the operator can selectively

manually adjust at least one of the processing time period and the averaging time period of each adaptive averaging circuit.

[0047] In another exemplary aspect, the pain evaluation system can further comprise a memory in operative communication with the processing circuitry. In this aspect, each sensor of the at least one sensor can be configured to produce an output indicative of the at least one physiological signal detected by the sensor, and the processing circuitry can be configured to receive the outputs of the at least one sensor and to produce a plurality of outputs. In operation, at least one output of the plurality of outputs can correspond to an output of the at least one sensor, and at least one output of the plurality of outputs can correspond to the minimum stimulation magnitude for a selected stimulation. The memory can be configured to receive the plurality of outputs from the processing circuitry for storage. In exemplary aspects, the memory can be configured to receive and store diagnostic/treatment data concurrently with the plurality of outputs from the processing circuitry. Optionally, in some aspects, the system can further comprise a display positioned in operative communication with the processing circuitry. In these aspects, the at least one sensor and the display can be operatively secured to a housing. In operation, the display can be configured to visually depict at least one output of the plurality of outputs of the processing circuitry. In some optional aspects, the display can be integrated into or otherwise operatively coupled to a remote computing device that is in operative communication with the processing circuitry. Optionally, in these aspects, the remote computing device can be selected from the group consisting of a smartphone, a tablet, and a computer, and the display can be operatively coupled to a host program and graphical user interface (GUI) stored within the remote computing device. Optionally in one exemplary aspect, the display can be an LED display mounted within the same housing as the at least one sensor.

[0048] In yet another exemplary aspect, and with reference to **FIG. 17**, the pain evaluation system can further comprise a system controller. In this aspect, the system controller can be operatively connected to the at least one stimulation source, the at least one sensor, and the processing circuitry. The system controller can be configured to effect selective adjustment of one or more parameters associated with at least one of the at least one stimulation source, the at least one sensor, and the

processing circuitry. In operation, the system controller can be configured to maintain synchronization of the at least one stimulation source and the at least one sensor. Optionally, in some exemplary aspects, the system can further comprise a remote computing device that is in operative communication with the at least one stimulation source and the system controller. In response to one or more inputs from a user, the remote computing device can be configured to effect selective adjustment of one or more control parameters associated with the operation of the at least one stimulation source. In further optional aspects, each sensor of the at least one sensor can be configured to produce an output indicative of the at least one physiological signal detected by the sensor. In these aspects, the processing circuitry can be configured to receive the outputs of the at least one sensor and to produce a plurality of outputs indicative of processing parameters of the processing circuitry. Following application of a selected stimulation by the at least one stimulation source, the system controller can be configured to evaluate the outputs produced by the at least one sensor and the processing circuitry to determine optimal parameters for at least one of the at least one stimulation source, the at least one sensor, and the processing circuitry. Optionally, the system can further comprise a display in operative communication with the controller, and the controller can be configured to use the display to visually depict the optimal parameters. Optionally, in operation, the controller can be configured to apply a selected stimulation to the at least one selected muscle using the optimal parameters. It is contemplated that the outputs of the at least one sensor upon application of the optimized signal can be monitored as previously described. It is further contemplated that the optimization and monitoring cycle can be continued as necessary to identify the desired parameters. In exemplary aspects, the system controller can comprise software that is configured to permit retrieval of outputs produced by the at least one sensor as well as selective, remote adjustment of the parameters of the at least one sensor. Similarly, in other exemplary aspects, the system controller can comprise software that is configured to permit retrieval of outputs produced by the at least one stimulation source as well as selective, remote adjustment of the parameters of the at least one stimulation source.

[0049] Optionally, in exemplary aspects, the at least one stimulation source can comprise at least one electrode. In these aspects, the at least one electrode can comprise a first electrode spaced from a second electrode. In operation, the second

electrode can optionally be configured to be positioned on the body of the patient at a location different than the location of the first electrode, and the second electrode can be configured to apply a reference stimulation signal to the at least one selected muscle of the patient. In further aspects, it is contemplated that the optimization and monitoring procedure disclosed above with respect to the selected stimulation can be applied to a plurality of stimulations and sensor elements. Thus, it is contemplated that the optimization and monitoring procedure can be applied to both a primary stimulation signal and a reference stimulation signal as disclosed herein.

[0050] In additional optional aspects, and with reference to **FIG. 1**, the pain evaluation system can further comprise a remote computing device and a medical records database. In these aspects, the medical records database can optionally contain historical pain data associated with the patient. The remote computing device can be positioned in operative communication with the medical records database, and the remote computing device can be configured to receive one or more inputs indicative of pain experienced by the patient upon application of a selected stimulation by the at least one stimulation source within the at least one selected muscle of the patient. In operation, the remote computing device can be configured to update the medical records database based upon the one or more inputs. In exemplary aspects, each input of the one or more inputs received by the remote computing device can correspond to one of: no pain; persistent pain; and transient pain. In further exemplary aspects, the remote computing device can be configured to display the historical pain data associated with the patient prior to or during application of the selected stimulation by the at least one stimulation source. In these aspects, the remote computing device can be configured to display at least one of a muscle diagram of the body and diagrams for muscle evaluation and muscle treatment to guide a clinician, such as, for example, during and/or after stimulation of the patient.

[0051] In additional exemplary aspects, the remote computing device can be configured to selectively retrieve historical pain evaluation/treatment data associated with the patient from the medical records database. In still other exemplary aspects, it is contemplated that the medical records database can be accessible by a plurality of remote computing devices at a given time. Optionally, it is contemplated that the remote computing device can retrieve data from the medical records database in the form of printable reports, which can optionally be displayed by the remote

computing device, stored in local memory, and/or delivered to a printer for printing.

[0052] In yet another exemplary aspect, and with reference to **FIG. 8**, the remote computing device of the pain evaluation system can be configured to display a list of muscles of the patient and/or an anatomical depiction of the muscles of the patient. Optionally, in some aspects, each muscle of the list of muscles and/or muscle depictions can be displayed in association with a selected color indicator. In these aspects, each selected color indicator can correspond to a respective muscle pain evaluation/treatment status, such as, for example and without limitation: no pain; persistent pain; transient pain; persistent pain less than three months after injection; and persistent pain more than three months after injection. In operation, the selected color indicator can be selectively adjustable by a clinician during stimulation of the patient.

[0053] In exemplary aspects, and with reference to **FIGS. 11 and 13**, it is contemplated that the at least one stimulation source, the at least one sensor, and the system controller can be provided as separate, individually-packaged units that are operatively connected using conventional wired or wireless connections. In other exemplary aspects, and with reference to **FIGS. 10, 12, and 14**, it is contemplated that at least two of the at least one stimulation source, the at least one sensor, and the system controller can be provided together as an integral, and optionally portable, unit. In still further exemplary aspects, it is contemplated that the at least one stimulation source, the at least one sensor, and the system controller can be provided together as an integral, and optionally portable, unit.

[0054] In exemplary aspects, it is contemplated that the processing circuitry disclosed herein can be configured to develop an algorithm for detecting stimulation of a selected muscle of a patient in accordance with pain stimulation data collected on a pool of patients. In these aspects, it is contemplated that the processing circuitry can be configured to apply the algorithm to evaluate whether a selected muscle is likely a source of pain.

[0055] Although described herein with reference to evaluation of muscle pain, it is contemplated that aspects of the disclosed systems can be used in a variety of applications. For example and without limitation, it is contemplated that aspects of the processing circuitry disclosed herein can be used in other medical applications, fiber optic communications, local area networking, wide area networking, wireless

communications, and the like.

[0056] In use, the disclosed pain evaluation systems can be used to perform a method of evaluating pain within at least one selected muscle of a patient. In exemplary aspects, the method can comprise using the disclosed system to determine the minimum stimulation magnitude for the selected stimulation of at least one stimulation source. In these aspects, it is contemplated that the minimum stimulation magnitude can be zero when the stimulation occurs naturally within the body of the patient.

[0057] Optionally, in some exemplary aspects, the method can comprise selectively adjusting one or more of the stimulation parameters to produce the selected stimulation. In these aspects, the selective adjust can optionally be effected using a remote computing device.

[0058] Optionally, in further exemplary aspects, the method can comprise applying an interferential electrical stimulus waveform to the at least one selected muscle of the patient using at least one electrical signal generator as disclosed herein. Optionally, in still further exemplary aspects, the method can comprise applying a composite interferential stimulus waveform to the at least one selected muscle of the patient using at least one electrical signal generator as disclosed herein. Optionally, in still further exemplary aspects, the method can comprise applying at least two pairs of interferential stimulus waveforms to the at least one selected muscle of the patient using at least one electrical signal generator as disclosed herein.

[0059] Optionally, in still further exemplary aspects, the method can comprise receiving the outputs of the at least one sensor using the processing circuitry. Optionally, in still further exemplary aspects, the method can comprise isolating the at least one physiological signal from surrounding noise to produce an isolated output signal using the processing circuitry as disclosed herein. Optionally, in still further exemplary aspects, the method can further comprise comparing the isolated output signal to a fixed voltage signal as disclosed herein. Optionally, in still further exemplary aspects, the method can further comprise producing a visual depiction of the comparison of the isolated output signal and the fixed voltage signal as disclosed herein. Optionally, in still further exemplary aspects, the method can further comprise using the processing circuitry to adjust at least one of the processing time period and the averaging time period of each adaptive averaging circuit of the

processing circuitry in accordance with a selected signal processing parameter dataset from a database as disclosed herein. Optionally, in still further exemplary aspects, the method can further comprise storing the plurality of outputs from the processing circuitry in a memory. Optionally, in still further exemplary aspects, the method can further comprise visually depicting at least one output of the plurality of outputs of the processing circuitry on a display as disclosed herein.

[0060] Optionally, in still further exemplary aspects, the method can comprise selectively adjusting one or more parameters associated with at least one of the at least one stimulation source, the at least one sensor, and the processing circuitry using the system controller as disclosed herein. Optionally, in still further exemplary aspects, the method can comprise maintaining synchronization of the at least one stimulation source and the at least one sensor using the system controller as disclosed herein. Optionally, in still further exemplary aspects, the method can comprise using the system controller to evaluate the outputs produced by the at least one sensor and the processing circuitry to determine optimal parameters for at least one of the at least one stimulation source, the at least one sensor, and the processing circuitry. Optionally, in still further exemplary aspects, the method can further comprise visually depicting the optimal parameters using a display as disclosed herein. Optionally, in still further exemplary aspects, the method can further comprise applying the selected stimulation to the at least one selected muscle of the patient using the optimal parameters. Optionally, in still further exemplary aspects, the method can comprise applying a reference stimulation signal to the at least one selected muscle of the patient as disclosed herein.

[0061] Optionally, in further exemplary aspects, the method can comprise using the disclosed system to update the historical pain data associated with the patient within the medical records database based upon the presence of at least one of pain and discomfort experienced by the patient upon application of a selected stimulation by the at least one stimulation source. Optionally, in still further exemplary aspects, the method can comprise using a remote computing device to display at least one of a muscle diagram and a treatment diagram to guide a clinician before, during, or after stimulation of the patient. Optionally, in still further exemplary aspects, the method can comprise using the remote computing device to selectively adjust the evaluation/treatment status of pain within each muscle of the patient that is

stimulated. Optionally, in still further exemplary aspects, the method can comprise using the remote computing device to selectively retrieve historical pain evaluation/treatment data associated with the patient from the medical records database.

Exemplary Applications.

[0062] The disclosed pain evaluation system will be generally referred to below as a Painful Muscle Detection Instrument (PMDI). As further disclosed herein the PDMI device represents a multifaceted approach to the evaluation and treatment of functional muscle pain. By providing an automatically generated electrical stimulus, just strong enough to contract a voluntary striated muscle(s), specific muscles can be tested to determine if they are a source of pain. The PMDI device is a departure from the prior art in that it automatically establishes the smallest strength of a stimulus needed to cause a muscle contraction; in contrast, prior art approaches estimate the proper strength of stimulus by observing a muscle twitch. The PMDI device also departs from the prior art in that it comprises embedded software that helps suggest to clinicians all of the muscles that could potentially be pain generators. This provides an educational component that allows a clinician unskilled in muscle anatomy to identify all of the various muscles that could be the source of pain. The software is also configured to provide diagrams to direct the clinician on the proper placement of the instrument to stimulate a specific muscle(s) to determine if it is the source of pain rather than an adjacent muscle(s) that could mistakenly be considered. For example, a point of tenderness on the skin may represent a number of muscles overlying each other. Unless tenderness is elicited along the course of a muscle, from beginning to end (origin to insertion), a clinician cannot accurately know if the suspected muscle is indeed a source of pain. As can be appreciated, this is important because muscle attachment sites as well as TrPs in a muscle, all function as pain generators. Therefore the identification of a specific muscle versus a trigger point (TrP) is necessary to determine where a needle should be placed in the course of treatment. It is contemplated that moving a muscle replicates what occurs in vivo, in contrast to the community standard of identifying a muscle suspected of producing pain through palpation. It is further contemplated that tenderness to palpation in a resting muscle is not a good test for muscle pain because it does not replicate what occurs with most patients who have muscle-based pain (viz., pain

with activity or prolonged positioning). It is still further contemplated that causing a minimal contraction is a more accurate replication of typical pain producing activity. Therefore it is further contemplated that the use of a minimal contraction will provide a more valid indication of the muscle(s) causing pain versus pain caused by pressure, which could be a reflection of pain that is referred from another muscle or a confounded response based on palpation pressing on overlying muscles.

[0063] As further disclosed herein, after the PMDI establishes the minimum stimulation magnitude, it can be configured to automatically shift to a diagnostic mode. The corresponding stimulus can be provided through a stimulation device (e.g., an aluminum stimulator head) along the course of a suspected muscle. One example is an area of pain complaint in the upper back (see **FIG. 20**, showing the Back Muscles and Thoracolumbar Fascia). Overlapping muscles and/or adjacent muscles can be the source of pain. Therefore, the PMDI is placed along the course of the muscle from the origin/insertion of each of the potentially suspect muscles and the muscle is stimulated along its entirety from origin to insertion. Non-limiting examples of muscles that can be tested using the disclosed systems and methods comprise: Rhomboids (from the medial border of the scapula to the thoracic and lower cervical spines); Levator scapula (after palpating the origin on the superior medial angle of the scapula stimulating it up to the cervical spine); and Trapezius (from the acromion to the upper thoracic and cervical spines and occiput). However, it is understood that other muscles can be tested and evaluated using the disclosed systems and methods.

[0064] The operator can record the results of the muscle testing in accordance with the methods disclosed herein, which can optionally comprise pressing appropriate buttons on the PMDI. The information can optionally be transmitted wirelessly to a remote computing device as disclosed herein. Results of the examination can be recorded on the medical records database, such as, for example and without limitation, an electronic medical records (EMR) database, and the results can be used for discussion with the patient or submitted for insurance billing. It is contemplated that, with knowledge of the specific muscle(s) causing pain with movement, a treatment plan can be provided.

[0065] If a muscle is determined to have sustained structuralchanges that would benefit from an injection technique, the PMDI can shift to a treatment mode, either

automatically (based on software) or manually (in response to an input from the operator). In exemplary applications the PMDI can display a diagram and/or video of the selected muscle, along with directions showing the clinician how to insert the needle so as to thoroughly pierce the muscle attachments and tissue in accordance with the method disclosed in U.S. Patent No. 6,432,063, which is hereby incorporated herein by reference in its entirety.

[0066] The muscle injected, the date of injection, and other paint/treatment data can be transmitted to the medical records database for future retrieval. Optionally, the medical records database can be updated to provide a historical picture of the patient's pain/treatment progression. It is contemplated that when pain persists in the region where a specific muscle(s) were injected, it suggests that another un-injected muscle(s) is the source of the pain, in contrast to the conventional, community standard of trigger point injections, where injecting the same painful muscle (or areas) repeatedly is within the standard of care.

[0067] In use, the PMDI can automatically sense barely noticeable muscle contractions of the patient using the at least one sensor as disclosed herein.

[0068] It is contemplated that the PMDI can provide means for a clinician in practice, who may not have an excellent knowledge of muscle anatomy, to accurately identify and test muscles not ordinarily considered in the diagnosis and treatment of common pain syndromes.

[0069] In one exemplary process, when the muscle receives the selected stimulation at the automatically determined minimum stimulation magnitude to provide a contraction, the patient can have one of two responses: (1) No discomfort; or (2) Discomfort that is described as: (a) Bruise-like; (b) Black and Blue; (c) "It feels like you're pressing very hard"; or (d) Tender. If discomfort is produced, the application of the stimulus can continue. If the patient reports reduced and then absence of discomfort after about 30 seconds to about 1 minute, it can be recorded as "Transient" pain. If the discomfort is unchanged or reduces in intensity but nevertheless remains, it can be recorded as "Persistent" pain.

[0070] If the patient presents with pain that is present for less than 3 months or if the pain is transient, physical therapy modalities and exercise may suffice to eliminate the pain, as described in U.S. Patent No. 6,432,063 and Marcus, NJ., Gracely, E., Keefe, K. (2010). A Comprehensive Protocol to Diagnose and Treat Pain of

Muscular Origin May Successfully and Reliably Decrease or Eliminate Pain in a Chronic Pain Population. *Pain Medicine*, 11(1); 25-34, both of which are hereby incorporated by reference herein in their entirety.

[0071] If the pain is present for more than 3 months (or if it is a pain that was intermittently present and has recurred), a needling procedure can be suggested. Clinicians can elect to use various techniques found in the literature. It is contemplated that the PMDI can provide the unique capability of identifying a muscle as a source of pain rather than possibly as a referred pain from another muscle producing the pain. It is further contemplated that palpation cannot make that distinction. In exemplary aspects, it is contemplated that the muscle can be wholly injected into muscle tissue, TrPs, and attachments. However, it is contemplated that partial injection can also be used.

[0072] When the clinician is ready to treat, the PMDI can be selectively moved to a treatment mode. A muscle can be chosen from a list of stored identified muscles, and the selected muscle can be shown on a display. With the selected muscle shown on the display, suggested sites to pierce the muscle can be labeled and/or shown in a diagram or video.

[0073] When the muscle is injected, it can be classified under the treatment module as "injected" for future reference. The pain/treatment status of the identified muscles can be dated and color coded to permit quick review of the patients' muscle status, with different colors corresponding to the following statuses: No pain; Transient Pain; Persistent pain; Persistent pain injected in past 3 months; or Persistent pain injected more than 3 months ago.

[0074] In any examination, the results need to be recorded. With tender muscles this can be crucial because of the dynamic nature of muscle pain. Muscles causing pain can produce both increased (through central sensitization) and decreased (through diffuse noxious inhibitory control-see 0075 below) pain in other muscles. When muscles are a source of persistent pain, they will produce alterations in the spinal cord and brain which cause the nerve cells (neurons) that receive information from the muscles to be more sensitive (central sensitization (CS)). The sensitivity can produce a lowering of the threshold for depolarization of the cell; in other words, a lesser stimulation from a muscle than would normally be required to excite the neuron will now result in cell excitation. Sensitized neurons will open up previously

ineffective connections (nerve pathways) so that neurons receiving signals from other muscles in the body also become more sensitive normally a strong sensation in a muscle is necessary to cause the neuron representing that muscle in the spinal cord to depolarize (fire). When CS exists, as described above, a lesser stimulation will cause firing. Thus, muscle contraction that in a normal muscle was painless, now becomes painful and it is called muscle or mechanical allodynia (pain from a usually non-painful stimulus). This same phenomenon (muscle allodynia) may occur in another muscle to which the stimulus is referred, producing referred muscle pain. The muscle with referred pain, although tender to palpation, will often only be transiently tender to PMDI stimulation because the muscle fibers are not dysfunctional (only the neurons)

[0075] To start injecting muscles, the following rules can be followed: (1) Start with the most painfully tested muscle in the area of the pain complaint; (2) Inject a proximal muscle before a distal muscle (closest to the torso versus most distant from the torso); and (3) Inject a superficial muscle before a deep muscle (a superficial muscle can cause pain in a deep muscle). The injected muscle may no longer be a pain generator, and therefore, if it was a factor in generating pain in other muscles through CS or referral patterns, this may no longer be the case. Therefore, following each muscle injected, the next suspected muscle based on the patient's current report of pain can be retested prior to any injection. This is done because, due to both referred pain and central sensitization, the suspected muscle may now no longer test positive. Therefore, it would have been ill advised to have injected it without a test of its suspected ongoing pain-producing properties.

[0076] On the other hand, a competing phenomenon contributes to the clinical presentation-diffuse noxious inhibitory control (DNIC), currently referred to as conditioned pain modulation (CPM). It is the phenomenon where a pain in one region of the body suppresses pain in another. When the most painful muscle is successfully treated, it is contemplated that re-testing can identify another muscle, not previously identified, as a new painful muscle contributing to the pain syndrome.

[0077] It is contemplated that the collection of serial data can also be important for those clinicians who wish to do clinical research on the pain referral patterns of various muscles which can eventually provide practicing clinicians with a more detailed understanding of the complexity of muscle pain presentations.

[0078] As will be appreciated by one skilled in the art, the methods and systems disclosed herein may take the form of an entirely hardware embodiment, an entirely software embodiment, or an embodiment combining software and hardware aspects. Furthermore, the methods and systems may take the form of a computer program product on a computer-readable storage medium having computer-readable program instructions (e.g., computer software) embodied in the storage medium. More particularly, the present methods and systems may take the form of web-implemented computer software. Any suitable computer-readable storage medium may be utilized including hard disks, CD-ROMs, optical storage devices, or magnetic storage devices.

[0079] Embodiments of the methods and systems are described above with reference to block diagrams and flowchart illustrations of methods, systems, apparatuses and computer program products. It will be understood that each block of the block diagrams and flowchart illustrations, and combinations of blocks in the block diagrams and flowchart illustrations, respectively, can be implemented by computer program instructions. These computer program instructions may be loaded onto a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions which execute on the computer or other programmable data processing apparatus create a means for implementing the functions specified in the flowchart block or blocks.

[0080] These computer program instructions may also be stored in a computer-readable memory that can direct a computer or other programmable data processing apparatus to function in a particular manner, such that the instructions stored in the computer-readable memory produce an article of manufacture including computer-readable instructions for implementing the function specified in the flowchart block or blocks. The computer program instructions may also be loaded onto a computer or other programmable data processing apparatus to cause a series of operational steps to be performed on the computer or other programmable apparatus to produce a computer-implemented process such that the instructions that execute on the computer or other programmable apparatus provide steps for implementing the functions specified in the flowchart block or blocks.

[0081] Accordingly, blocks of the block diagrams and flowchart illustrations support combinations of means for performing the specified functions, combinations of steps

for performing the specified functions and program instruction means for performing the specified functions. It will also be understood that each block of the block diagrams and flowchart illustrations, and combinations of blocks in the block diagrams and flowchart illustrations, can be implemented by special purpose hardware-based computer systems that perform the specified functions or steps, or combinations of special purpose hardware and computer instructions.

[0082] The system has been described above as comprised of units. One skilled in the art will appreciate that this is a functional description and that the respective functions can be performed by software, hardware, or a combination of software and hardware. A unit can be software, hardware, or a combination of software and hardware. The units can comprise the pain diagnosis Software **106** as illustrated in **FIG. 19** and described below. In one exemplary aspect, the units can comprise a computer **101** as illustrated in **FIG. 19** and described below. As an example, the computer **101** can be a pain evaluation system as disclosed herein. As another example, the computer **101** can be a computing device connected to the pain evaluation system.

[0083] **FIG. 19** is a block diagram illustrating an exemplary operating environment for performing at least a portion of the disclosed methods. This exemplary operating environment is only an example of an operating environment and is not intended to suggest any limitation as to the scope of use or functionality of operating environment architecture. Neither should the operating environment be interpreted as having any dependency or requirement relating to any one or combination of components illustrated in the exemplary operating environment.

[0084] The present methods and systems can be operational with numerous other general purpose or special purpose computing system environments or configurations. Examples of well known computing systems, environments, and/or configurations that can be suitable for use with the systems and methods comprise, but are not limited to, personal computers, server computers, laptop devices, and multiprocessor systems. Additional examples comprise set top boxes, programmable consumer electronics, network PCs, minicomputers, mainframe computers, distributed computing environments that comprise any of the above systems or devices, and the like.

[0085] The processing of the disclosed methods and systems can be performed by

software components. The disclosed systems and methods can be described in the general context of computer-executable instructions, such as program modules, being executed by one or more computers or other devices. Generally, program modules comprise computer code, routines, programs, objects, components, data structures, etc. that perform particular tasks or implement particular abstract data types. The disclosed methods can also be practiced in grid-based and distributed computing environments where tasks are performed by remote processing devices that are linked through a communications network. In a distributed computing environment, program modules can be located in both local and remote computer storage media including memory storage devices.

[0086] Further, one skilled in the art will appreciate that the systems and methods disclosed herein can be implemented via a general-purpose computing device in the form of a computer **101**. The components of the computer **101** can comprise, but are not limited to, one or more processors or processing units **103**, a system memory **112**, and a system bus **113** that couples various system components including the processor **103** to the system memory **112**. In the case of multiple processing units **103**, the system can utilize parallel computing.

[0087] The system bus **113** represents one or more of several possible types of bus structures, including a memory bus or memory controller, a peripheral bus, an accelerated graphics port, and a processor or local bus using any of a variety of bus architectures. By way of example, such architectures can comprise an Industry Standard Architecture (ISA) bus, a Micro Channel Architecture (MCA) bus, an Enhanced ISA (EISA) bus, a Video Electronics Standards Association (VESA) local bus, an Accelerated Graphics Port (AGP) bus, and a Peripheral Component Interconnects (PCI), a PCI-Express bus, a Personal Computer Memory Card Industry Association (PCMCIA), Universal Serial Bus (USB) and the like. The bus **113**, and all buses specified in this description can also be implemented over a wired or wireless network connection and each of the subsystems, including the processor **103**, a mass storage device **104**, an operating system **105**, pain diagnosis/evaluation software **106**, pain diagnosis/evaluation/treatment data **107**, a network adapter **108**, system memory **112**, an Input/Output Interface **110**, a display adapter **109**, a display device **111**, and a human machine interface **102**, can be contained within one or more remote computing devices **114a,b,c** at physically separate locations, connected

through buses of this form, in effect implementing a fully distributed system.

[0088] The computer **101** typically comprises a variety of computer readable media. Exemplary readable media can be any available media that is accessible by the computer **101** and comprises, for example and not meant to be limiting, both volatile and non-volatile media, removable and non-removable media. The system memory **112** comprises computer readable media in the form of volatile memory, such as random access memory (RAM), and/or non-volatile memory, such as read only memory (ROM). The system memory **112** typically contains data such as diagnosis and treatment data **107** and/or program modules such as operating system **105** and pain diagnosis software **106** that are immediately accessible to and/or are presently operated on by the processing unit **103**.

[0089] In another aspect, the computer **101** can also comprise other removable/non-removable, volatile/non-volatile computer storage media. By way of example, **FIG. 1** illustrates a mass storage device **104** which can provide non-volatile storage of computer code, computer readable instructions, data structures, program modules, and other data for the computer **101**. For example and not meant to be limiting, a mass storage device **104** can be a hard disk, a removable magnetic disk, a removable optical disk, magnetic cassettes or other magnetic storage devices, flash memory cards, CD-ROM, digital versatile disks (DVD) or other optical storage, random access memories (RAM), read only memories (ROM), electrically erasable programmable read-only memory (EEPROM), and the like.

[0090] Optionally, any number of program modules can be stored on the mass storage device **104**, including by way of example, an operating system **105** and pain diagnosis software **106**. Each of the operating system **105** and pain diagnosis software **106** (or some combination thereof) can comprise elements of the programming and the pain diagnosis software **106**. Diagnosis and treatment data **107** can also be stored on the mass storage device **104**. Diagnosis and treatment data **107** can be stored in any of one or more databases known in the art. Examples of such databases comprise, DB2®, Microsoft® Access, Microsoft® SQL Server, Oracle®, mySQL, PostgreSQL, and the like. The databases can be centralized or distributed across multiple systems.

[0091] In another aspect, the user can enter commands and information into the computer **101** via an input device (not shown). Examples of such input devices

comprise, but are not limited to, a keyboard, pointing device (*e.g.*, a "mouse"), a microphone, a joystick, a scanner, tactile input devices such as gloves, and other body coverings, and the like These and other input devices can be connected to the processing unit **103** via a human machine interface **102** that is coupled to the system bus **113**, but can be connected by other interface and bus structures, such as a parallel port, game port, an IEEE 1394 Port (also known as a Firewire port), a serial port, or a universal serial bus (USB).

[0092] In yet another aspect, a display device **111** can also be connected to the system bus **113** via an interface, such as a display adapter **109**. It is contemplated that the computer **101** can have more than one display adapter **109** and the computer **101** can have more than one display device **111**. For example, a display device can be a monitor, an LCD (Liquid Crystal Display), or a projector. In addition to the display device **111**, other output peripheral devices can comprise components such as speakers (not shown) and a printer (not shown) which can be connected to the computer **101** via Input/Output Interface **110**. Any step and/or result of the methods can be output in any form to an output device. Such output can be any form of visual representation, including, but not limited to, textual, graphical, animation, audio, tactile, and the like.

[0093] The computer **101** can operate in a networked environment using logical connections to one or more remote computing devices **114a,b,c**. By way of example, a remote computing device can be a personal computer, portable computer, a server, a router, a network computer, a peer device or other common network node, and so on. Logical connections between the computer **101** and a remote computing device **114a,b,c** can be made via a local area network (LAN) and a general wide area network (WAN). Such network connections can be through a network adapter **108**. A network adapter **108** can be implemented in both wired and wireless environments. Such networking environments are conventional and commonplace in offices, enterprise-wide computer networks, intranets, and the Internet **115**.

[0094] For purposes of illustration, application programs and other executable program components such as the operating system **105** are illustrated herein as discrete blocks, although it is recognized that such programs and components reside at various times in different storage components of the computing device **101**, and are

executed by the data processor(s) of the computer. An implementation of pain diagnosis software **106** can be stored on or transmitted across some form of computer readable media. Any of the disclosed methods can be performed by computer readable instructions embodied on computer readable media. Computer readable media can be any available media that can be accessed by a computer. By way of example and not meant to be limiting, computer readable media can comprise "computer storage media" and "communications media." "Computer storage media" comprise volatile and non-volatile, removable and non-removable media implemented in any methods or technology for storage of information such as computer readable instructions, data structures, program modules, or other data. Exemplary computer storage media comprises, but is not limited to, RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disks (DVD) or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by a computer.

[0095] The methods and systems can employ Artificial Intelligence techniques such as machine learning and iterative learning. Examples of such techniques include, but are not limited to, expert systems, case based reasoning, Bayesian networks, behavior based AI, neural networks, fuzzy systems, evolutionary computation (e.g. genetic algorithms), swarm intelligence (e.g. ant algorithms), and hybrid intelligent systems (e.g. Expert inference rules generated through a neural network or production rules from statistical learning).

[0096] While the methods and systems have been described in connection with preferred embodiments and specific examples, it is not intended that the scope be limited to the particular embodiments set forth, as the embodiments herein are intended in all respects to be illustrative rather than restrictive.

[0097] Unless otherwise expressly stated, it is in no way intended that any method set forth herein be construed as requiring that its steps be performed in a specific order. Accordingly, where a method claim does not actually recite an order to be followed by its steps or it is not otherwise specifically stated in the claims or descriptions that the steps are to be limited to a specific order, it is no way intended that an order be inferred, in any respect. This holds for any possible non-express basis for interpretation, including: matters of logic with respect to arrangement of steps or

operational flow; plain meaning derived from grammatical organization or punctuation; the number or type of embodiments described in the specification.

[0098] Throughout this application, various publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which the methods and systems pertain.

[0099] It will be apparent to those skilled in the art that various modifications and variations can be made without departing from the scope or spirit. Other embodiments will be apparent to those skilled in the art from consideration of the specification and practice disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit being indicated by the following claims.

What is claimed is:

1. A system for evaluating pain within at least one selected muscle of a patient, comprising:

at least one stimulation source, wherein each stimulation source is configured to selectively apply a selected stimulation to the at least one selected muscle of the patient in accordance with a plurality of stimulation parameters, the plurality of stimulation parameters comprising a magnitude, a phase, a waveform, and a frequency of the stimulation, wherein each stimulation parameter of the plurality of stimulation parameters has a value that is selectively adjustable;

at least one sensor configured to detect at least one physiological signal within the at least one selected muscle of the patient; and

processing circuitry in operative communication with the at least one stimulation source and the at least one sensor, wherein the processing circuitry is configured to determine a minimum stimulation magnitude for the selected stimulation of at least one stimulation source, wherein the minimum stimulation magnitude corresponds to the lowest possible magnitude of the selected stimulation at which the at least one physiological signal detected by the at least one sensor is indicative of pain within the at least one selected muscle of the patient.

2. The system of claim 1, wherein the at least one stimulation source comprises at least one of an electrical signal generator and a mechanical force generator.

3. The system of claim 2, further comprising a housing, wherein the at least one stimulation source and the at least one sensor are positioned within the housing.

4. The system of claim 1, wherein the at least one stimulation source comprises at least one external stimulation source provided separately from the at least one sensor.

5. The system of claim 1, wherein the at least one stimulation source comprises at least one electrical signal generator, and wherein the at least one electrical signal generator is configured to apply an interferential electrical stimulus waveform to the at least one selected muscle of the patient, wherein the interferential stimulus waveform comprises at least two electrical signals, wherein each electrical signal of the at least two electrical signals has a frequency ranging from about 1 to

about 3,000 Hz.

6. The system of claim 5, wherein each electrical signal of the at least two electrical signals has corresponding waveform parameters, the waveform parameters comprising amplitude, frequency, phase values, and amplitude modulation, wherein at least one of the waveform parameters of each electrical signal is selectively adjustable.

7. The system of claim 1, wherein the at least one stimulation source comprises at least one electrical signal generator, the at least one electrical signal generator comprising an electronic circuit, the electronic circuit comprising at least two semiconductor transistors, wherein the at least two semiconductor transistors are configured to multiply at least two time-varying electrical signals into a composite interferential stimulus waveform, and wherein the at least one electrical signal generator is configured to apply the interferential stimulus waveform to the at least one selected muscle of the patient.

8. The system of claim 7, wherein the at least one stimulation source further comprises at least one electrode positioned in operative electrical communication with the at least one electrical signal generator, wherein the at least one electrode is configured to receive the interferential stimulus waveform from the electrical signal generator and apply the interferential stimulus waveform to the at least one selected muscle of the patient.

9. The system of claim 5, wherein the at least one electrical signal generator comprises an electronic circuit, the electronic circuit comprising at least two semiconductor transistors, wherein the at least two semiconductor transistors are configured to multiply the at least two electrical signals into the interferential stimulus waveform.

10. The system of claim 9, wherein the at least one stimulation source further comprises at least one electrode positioned in operative electrical communication with the at least one electrical signal generator, wherein the at least one electrode is configured to receive the interferential stimulus waveform from the electrical signal generator and apply the interferential stimulus waveform to the at least one selected muscle of the patient.

11. The system of claims 7 or 9, wherein the electronic circuit of the at least

one electronic signal generator is configured to produce at least two pairs of interferential stimulus waveforms, and wherein the at least one stimulation source is configured to deliver the interferential stimulus waveforms to the at least one selected muscle of the patient.

12. The system of claim 11, wherein at least one pair of interferential stimulus waveforms is configured to be a reference channel that is compared to other stimulation sources of the at least one stimulation source.

13. The system of claim 1, wherein each sensor of the at least one sensor is selected from the group consisting of a miniature condenser, an omnidirectional microphone, a microelectromechanical system (MEMS) microphone, a MEMS accelerometer, and an adhesive contact electrical signal sensor pad.

14. The system of claim 13, wherein the at least one sensor comprises a plurality of sensors, and wherein the plurality of sensors cooperate with the processing circuitry to define a plurality of sensing channels and a plurality of processing channels, wherein each sensing channel is operatively connected to a corresponding processing channel.

15. The system of claim 14, wherein each sensing channel comprises at least one sensor of the plurality of sensors.

16. The system of claim 15, wherein each respective processing channel of the plurality of processing channels is configured to receive an output of each sensor of the at least one sensor of the corresponding sensing channel, the output being indicative of the at least one physiological signal detected by the at least one sensor of the sensing channel.

17. The system of claim 1, wherein each sensor of the at least one sensor is configured to produce an output indicative of the at least one physiological signal detected by the sensor, and wherein the processing circuitry is configured to receive the output from each sensor of the at least one sensor.

18. The system of claim 1, wherein the processing circuitry comprises a high-common mode rejection ratio instrumentation amplifier positioned in operative communication with the at least one sensor, wherein each sensor of the at least one sensor is configured to produce an output indicative of the at least one physiological signal detected by the sensor, and wherein the instrumentation amplifier is configured

to receive the output from each sensor of the at least one sensor.

19. The system of claim 18, wherein the processing circuitry further comprises at least one adaptive averaging circuit, wherein the instrumentation amplifier is configured to produce an output corresponding to the output received from each sensor of the at least one sensor, wherein the at least one adaptive averaging circuit is configured to receive each respective output of the instrumentation amplifier, wherein the at least one adaptive averaging circuit is configured to isolate the at least one physiological signal from surrounding noise and thereby produce an isolated output signal.

20. The system of claim 19, wherein the at least one adaptive averaging circuit is configured to compare the isolated output signal to a fixed voltage signal.

21. The system of claim 20, further comprising at least one display, wherein the at least one adaptive averaging circuit is positioned in operative communication with the processing circuitry, and wherein the processing circuitry is configured to produce a visual depiction of the comparison of the isolated output signal and the fixed voltage signal on the display.

22. The system of claim 19, wherein each adaptive averaging circuit has corresponding signal processing parameters, the signal processing parameters comprising a processing time period and an averaging time period, wherein at least one of the processing time period and the averaging time period are selectively adjustable.

23. The system of claim 22, further comprising a database in operative communication with the processing circuitry, the database comprising a plurality of signal processing parameter datasets, and wherein the processing circuitry is configured to adjust at least one of the processing time period and the averaging time period of each adaptive averaging circuit in accordance with a selected signal processing parameter dataset.

24. The system of claim 1, further comprising a memory in operative communication with the processing circuitry, wherein each sensor of the at least one sensor is configured to produce an output indicative of the at least one physiological signal detected by the sensor, wherein the processing circuitry is configured to receive the outputs of the at least one sensor and to produce a plurality of outputs, wherein at

least one output of the plurality of outputs corresponds to an output of the at least one sensor, wherein at least one output of the plurality of outputs corresponds to the minimum stimulation magnitude for a selected stimulation, and wherein the memory is configured to receive the plurality of outputs from the processing circuitry for storage.

25. The system of claim 24, further comprising a display positioned in operative communication with the processing circuitry, wherein the at least one sensor and the display are operatively secured to a housing, and wherein the display is configured to visually depict at least one output of the plurality of outputs of the processing circuitry.

26. The system of claim 24, further comprising a remote computing device having a display, the remote computing device being in operative communication with the processing circuitry, wherein the display of the remote computing device is configured to visually depict at least one output of the plurality of outputs of the processing circuitry.

27. The system of claim 26, wherein the remote computing device is selected from the group consisting of a smartphone, a tablet, and a computer.

28. The system of claim 1, further comprising a system controller, wherein the system controller is operatively connected to the at least one stimulation source, the at least one sensor, and the processing circuitry, wherein the system controller is configured to effect selective adjustment of one or more parameters associated with at least one of the at least one stimulation source, the at least one sensor, and the processing circuitry, and wherein the system controller is configured to maintain synchronization of the at least one stimulation source and the at least one sensor.

29. The system of claim 28, further comprising a remote computing device, wherein the remote computing device is in operative communication with the at least one stimulation source, and wherein, in response to one or more inputs from a user, the remote computing device is configured to effect selective adjustment of one or more control parameters associated with the operation of the at least one stimulation source.

30. The system of claim 28, wherein each sensor of the at least one sensor is configured to produce an output indicative of the at least one physiological signal

detected by the sensor, wherein the processing circuitry is configured to receive the outputs of the at least one sensor and to produce a plurality of outputs indicative of processing parameters of the processing circuitry, and wherein, following application of a selected stimulation by the at least one stimulation source, the system controller is configured to evaluate the outputs produced by the at least one sensor and the processing circuitry to determine optimal parameters for at least one of the at least one stimulation source, the at least one sensor, and the processing circuitry.

31. The system of claim 30, further comprising a display in operative communication with the controller, wherein the controller is configured to use the display to visually depict the optimal parameters.

32. The system of claim 30, wherein the controller is configured to apply a selected stimulation to the at least one selected muscle using the optimal parameters.

33. The system of claim 30, wherein the at least one stimulation source comprises at least one electrode, wherein the at least one electrode comprises a first electrode spaced from a second electrode, wherein the second electrode is configured to be positioned on the body of the patient at a location different than the location of the first electrode, and wherein the second electrode is configured to apply a reference stimulation signal to the at least one selected muscle of the patient.

34. The system of claim 1, further comprising a remote computing device and a medical records database, the medical records database contains historical pain data associated with the patient, wherein the remote computing device is positioned in operative communication with the medical records database, wherein the remote computing device is configured to receive one or more inputs indicative of the level of pain experienced by the patient upon application of a selected stimulation by the at least one stimulation source within the at least one selected muscle of the patient, and wherein the remote computing device is configured to update the medical records database based upon the one or more inputs.

35. The system of claim 34, wherein each input of the one or more inputs received by the remote computing device corresponds to one of: no pain; persistent pain; and transient pain.

36. The system of claim 34, wherein the remote computing device is configured to display the historical pain data associated with the patient during

application of the selected stimulation by the at least one stimulation source.

37. The system of claim 36, wherein the remote computing device is configured to display at least one of a muscle diagram and a treatment diagram to guide a clinician.

38. The system of claim 36, wherein the remote computing device is configured to display a list of muscles of the patient, wherein each muscle of the list of muscles is displayed in association with a selected color indicator, each selected color indicator corresponding to a respective muscle pain evaluation/treatment status, and wherein the selected color indicator is selectively adjustable by a clinician during stimulation of the patient.

39. The system of claim 34, wherein the remote computing device is configured to selectively retrieve historical pain evaluation/treatment data associated with the patient from the medical records database.

40. The system of claim 34, wherein the medical records database is accessible by a plurality of remote computing devices at a given time.

41. A method of evaluating pain within at least one selected muscle of a patient, comprising:

using the system of any one of the preceding claims to determine the minimum stimulation magnitude for the selected stimulation of at least one stimulation source.

42. The method of claim 41, further comprising:

updating historical pain data associated with the patient based upon the presence of at least one of pain and discomfort experienced by the patient upon application of a selected stimulation by the at least one stimulation source.

43. The method of claim 41, wherein the minimum stimulation magnitude is zero.

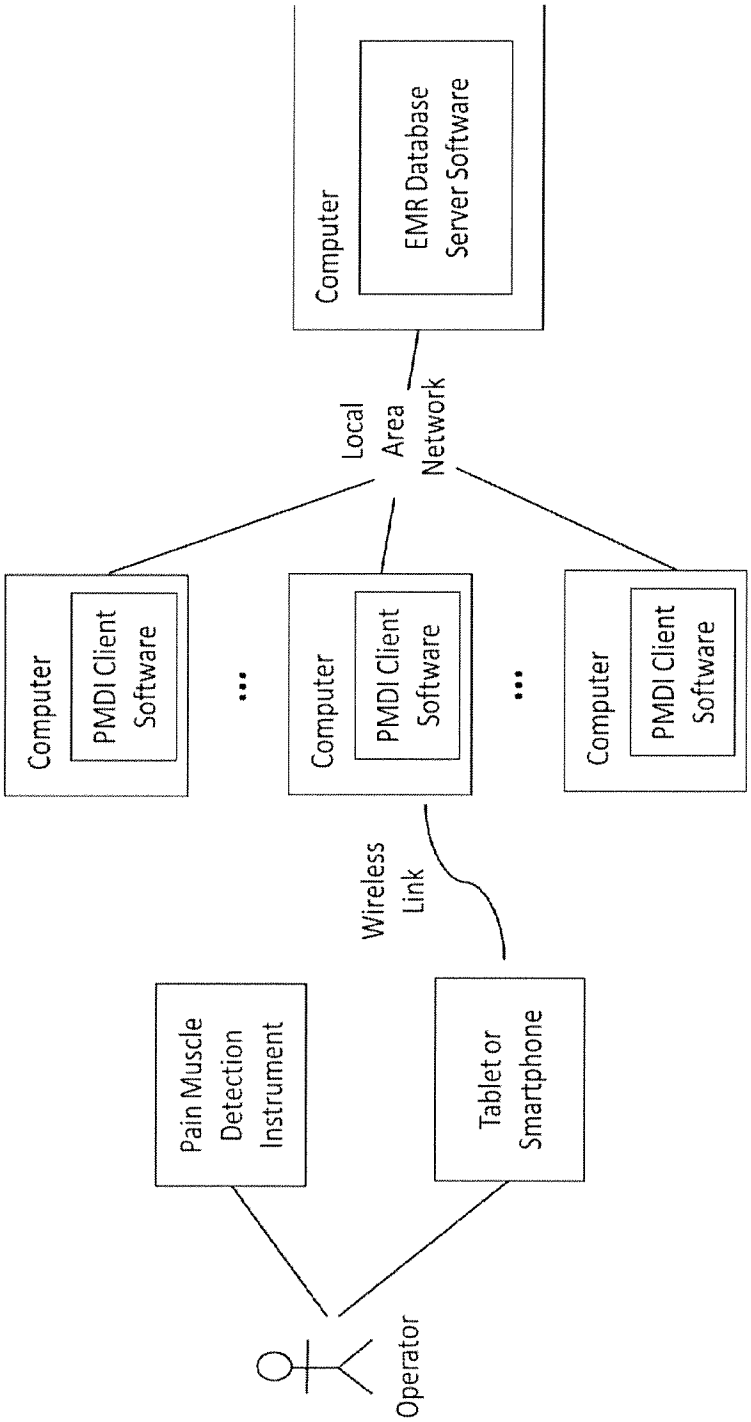

Computer
EMR Database Server Software
Local Area Network
Computer
PMDI Client Software
Computer
PMDI Client Software
Computer
PMDI Client Software
Wireless Link
Pain Muscle Detection Instrument
Tablet or Smartphone
Operator

FIG. 1

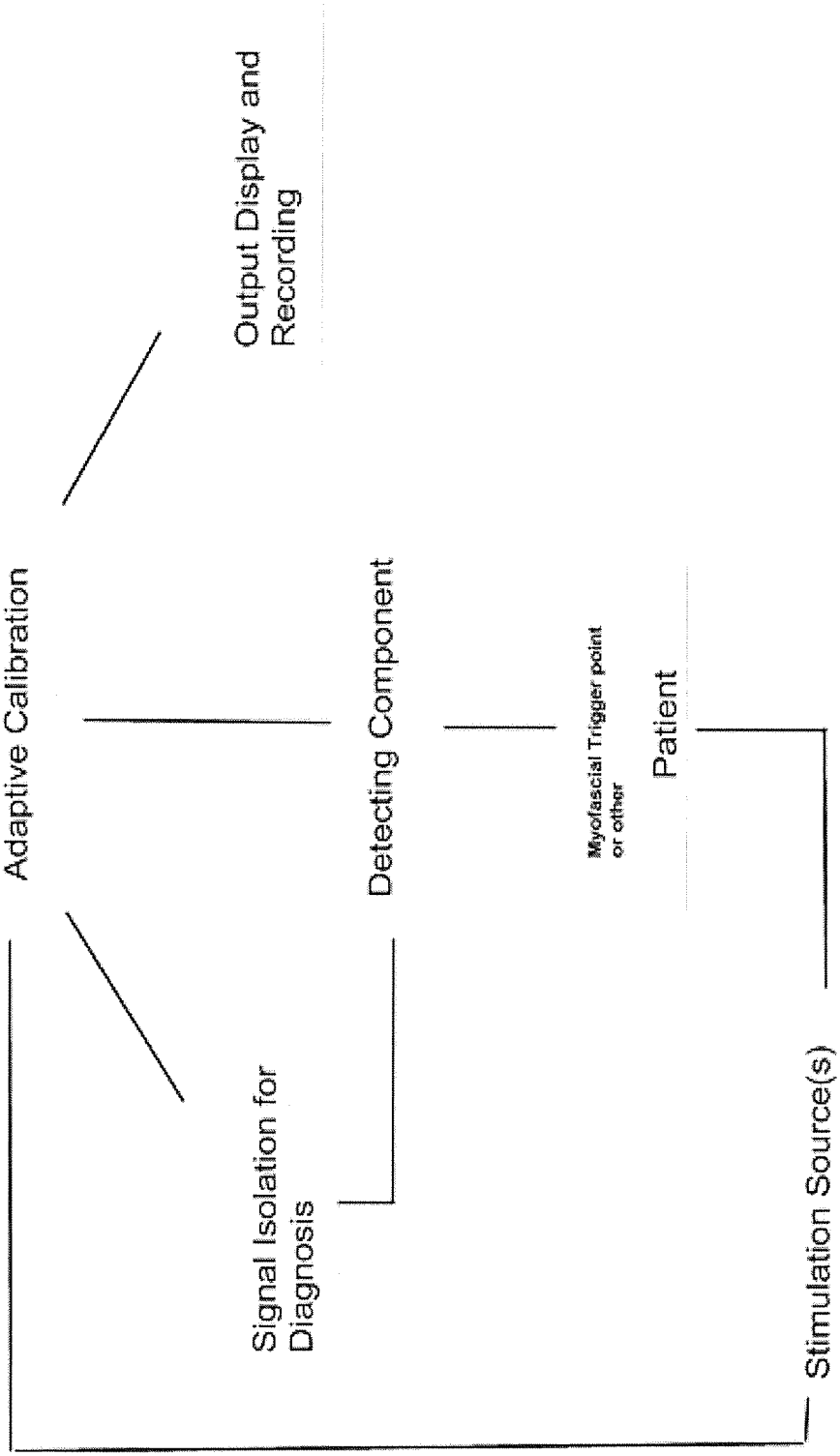

Adaptive Calibration
Output Display and Recording
Signal Isolation for Diagnosis
Detecting Component
Myofascial Trigger point or other
Patient
Stimulation Source(s)

FIG. 2

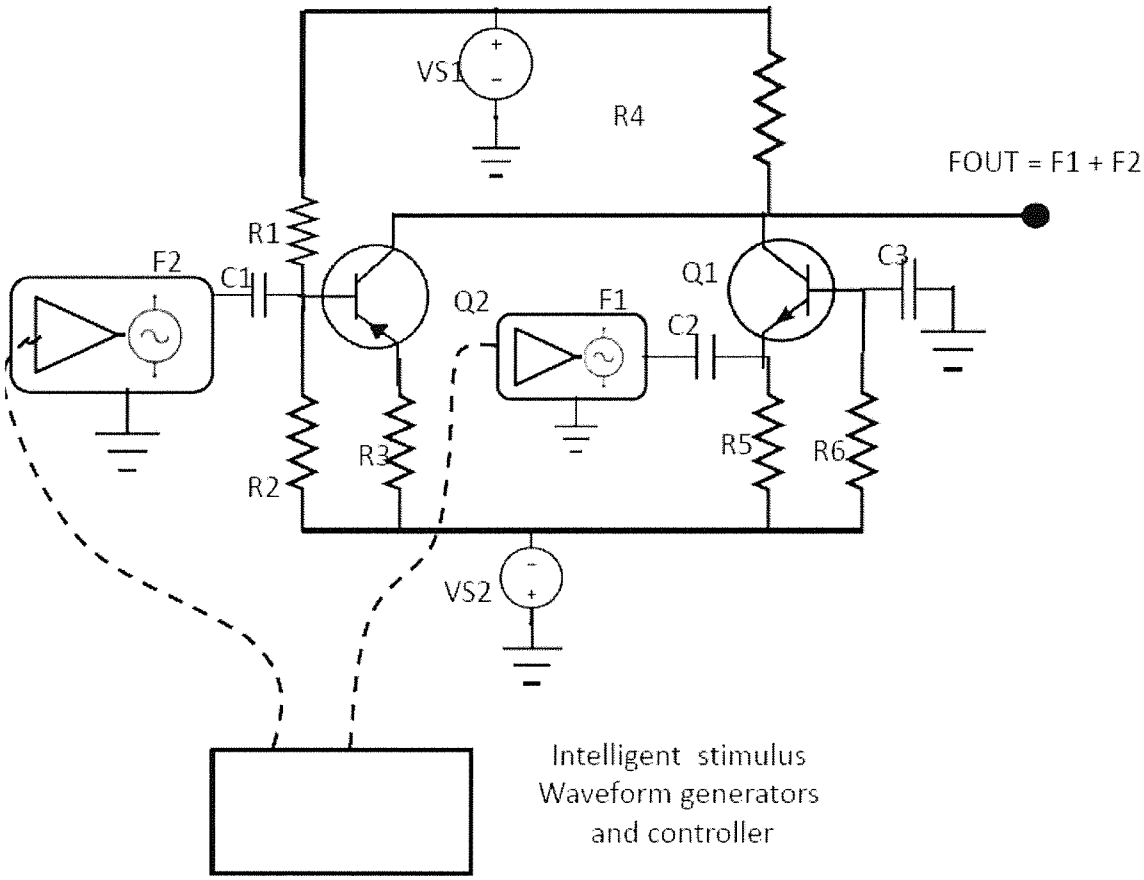

VS1
R4
FOUT = F1 + F2
R1
F2
C1
Q2
F1
Q1
C2
C3
R3
R5
R6
R2
VS2
Intelligent stimulus
Waveform generators
and controller

FIG. 3

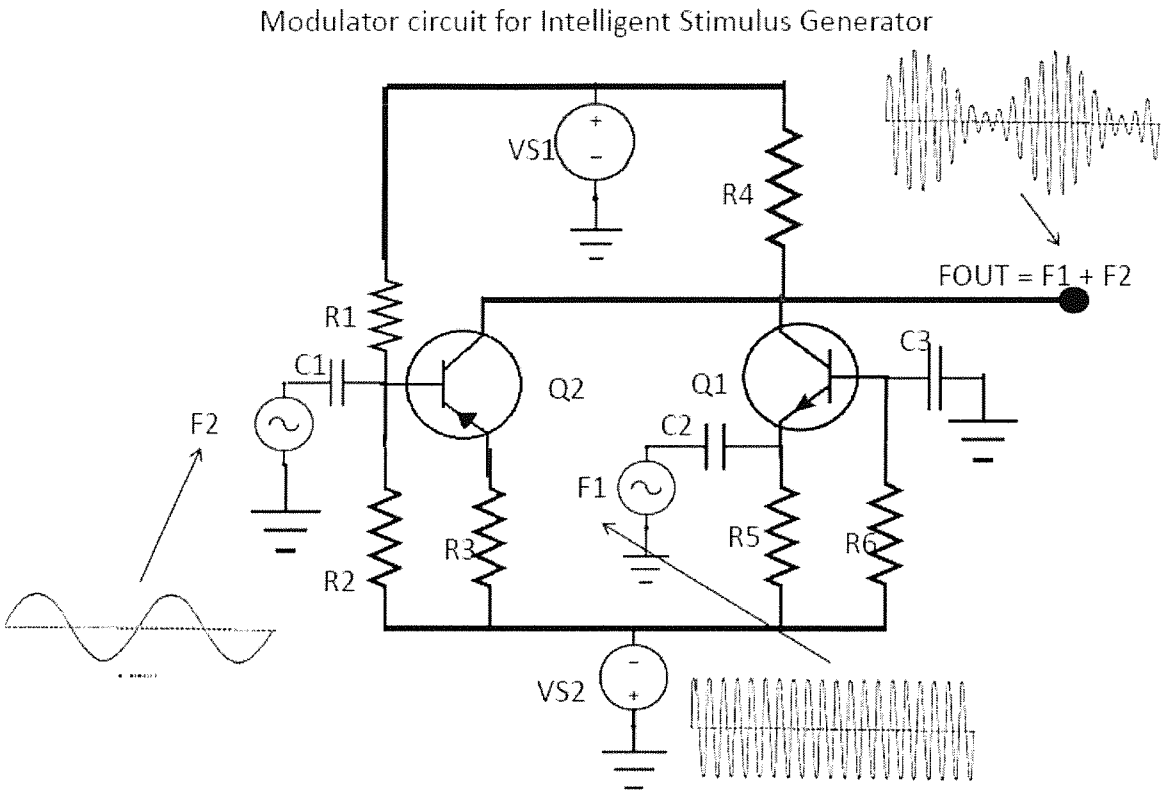
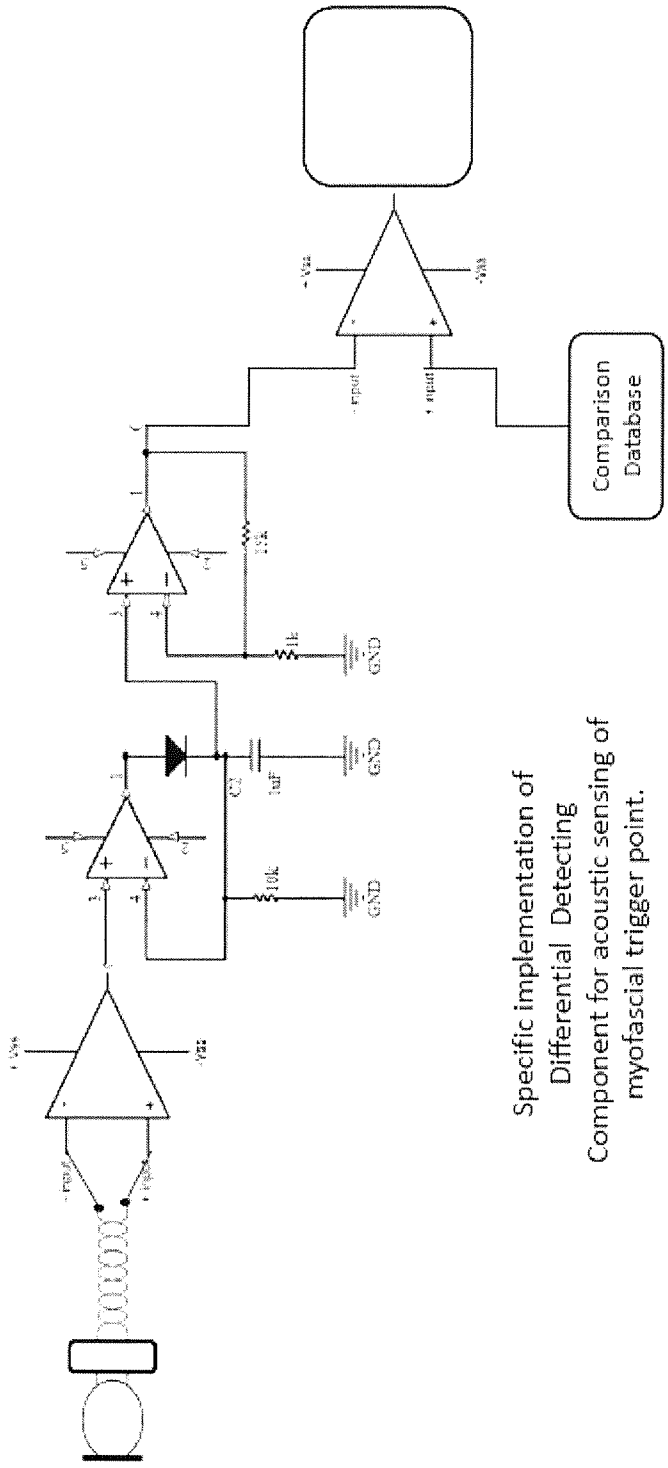

Modulator circuit for Intelligent Stimulus Generator
VS1
R4
FOUT = F1 + F2
R1
C1
Q2
Q1
C3
F2
C2
F1
R3
R5
R6
R2
VS2

FIG. 4



Specific implementation of Differential Detecting Component for acoustic sensing of myofascial trigger point.

FIG. 5

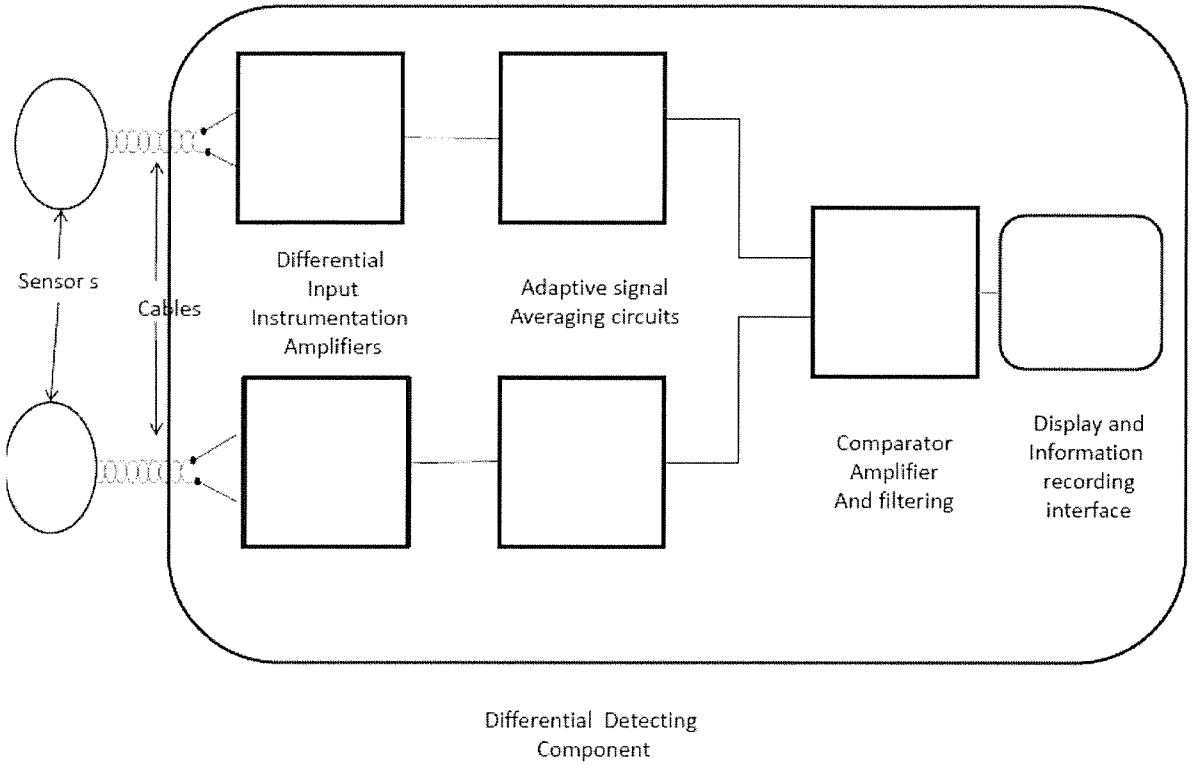

Sensor s
Cables
Differential
Input
Instrumentation
Amplifiers
Adaptive signal
Averaging circuits
Comparator
Amplifier
And filtering
Display and
Information
recording
interface
Differential Detecting
Component

FIG. 6

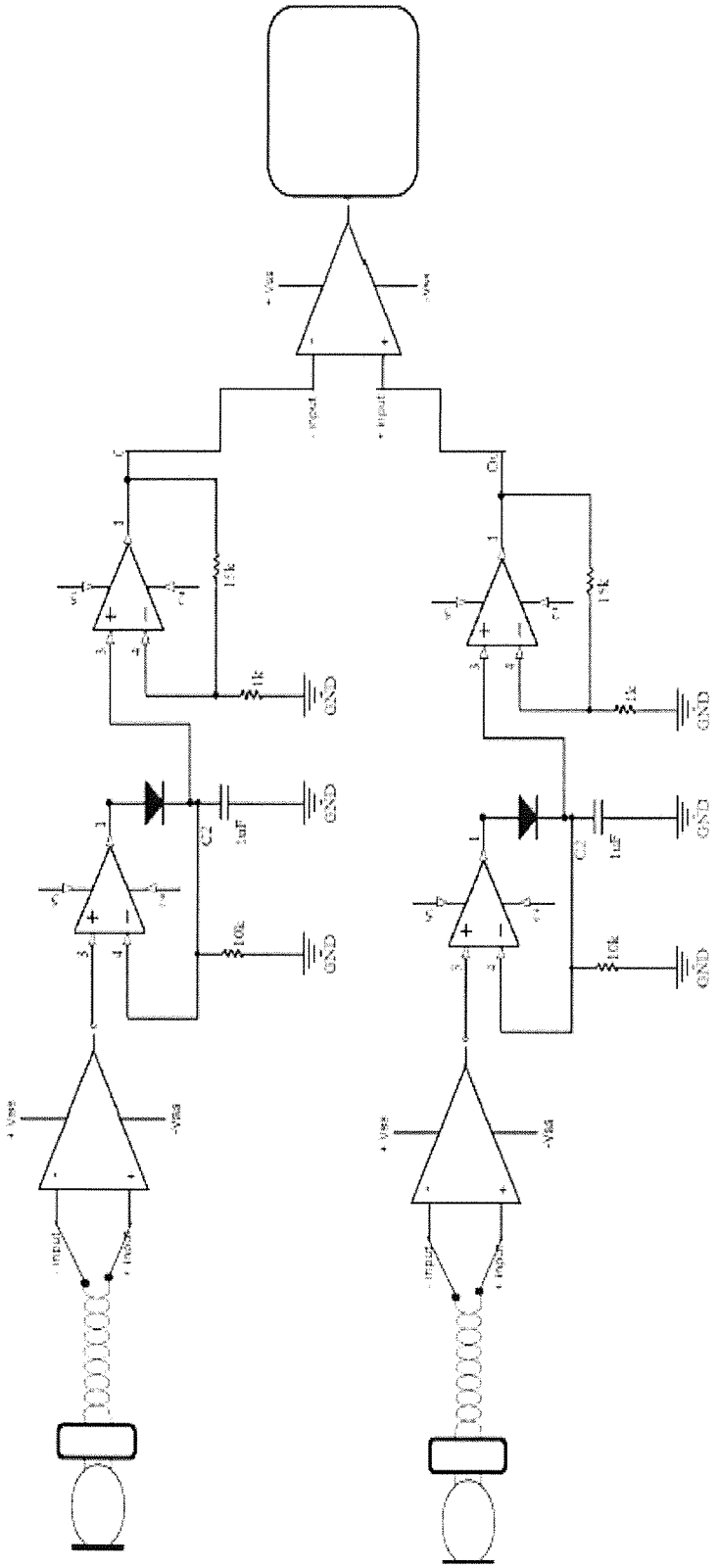

Specific implementation of
Differential Detecting
Component for acoustic sensing of
myofascial trigger point.

FIG. 7

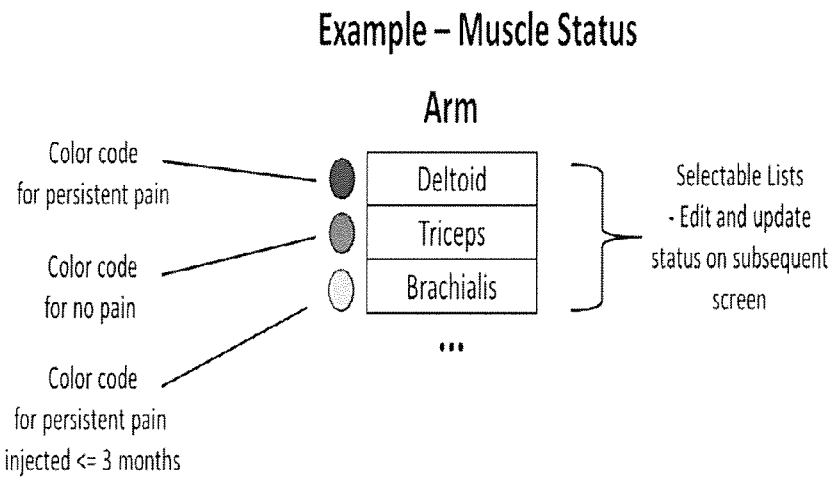

Example – Muscle Status
Arm
Color code
for persistent pain
Color code
for no pain
Color code
for persistent pain
injected <= 3 months
Deltoid
Triceps
Brachialis
...
Selectable Lists
- Edit and update
status on subsequent
screen

FIG. 8

UPPER BODY		Evaluation Date		
		DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY
		N-No Pain		
		T-Transient Pain		
ARM		S-Sustained Pain		
Biceps	C5,6			
Brachialis	C5,6,7			
Brachioradialis				
Coracobrachialis	C5,6,7			
Deltoid	C5,6			
Triceps	C6,7,8			
Wrist extensors	C6,7,8			
Wrist flexors	C6,7,8			
HEAD				
Superior Auricularis				
Temporalis				
Frontalis				
Masseter				
Zygomaticus major/minor				

FIG. 9

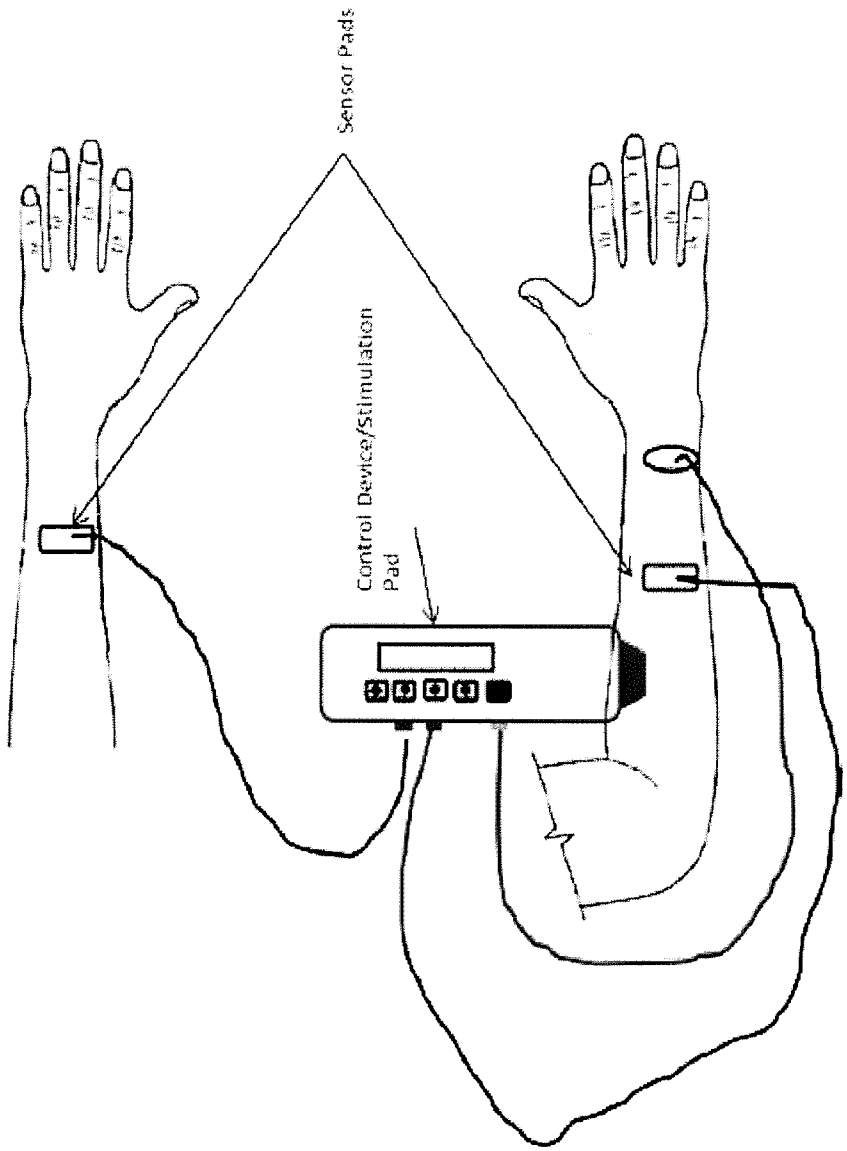


FIG. 10

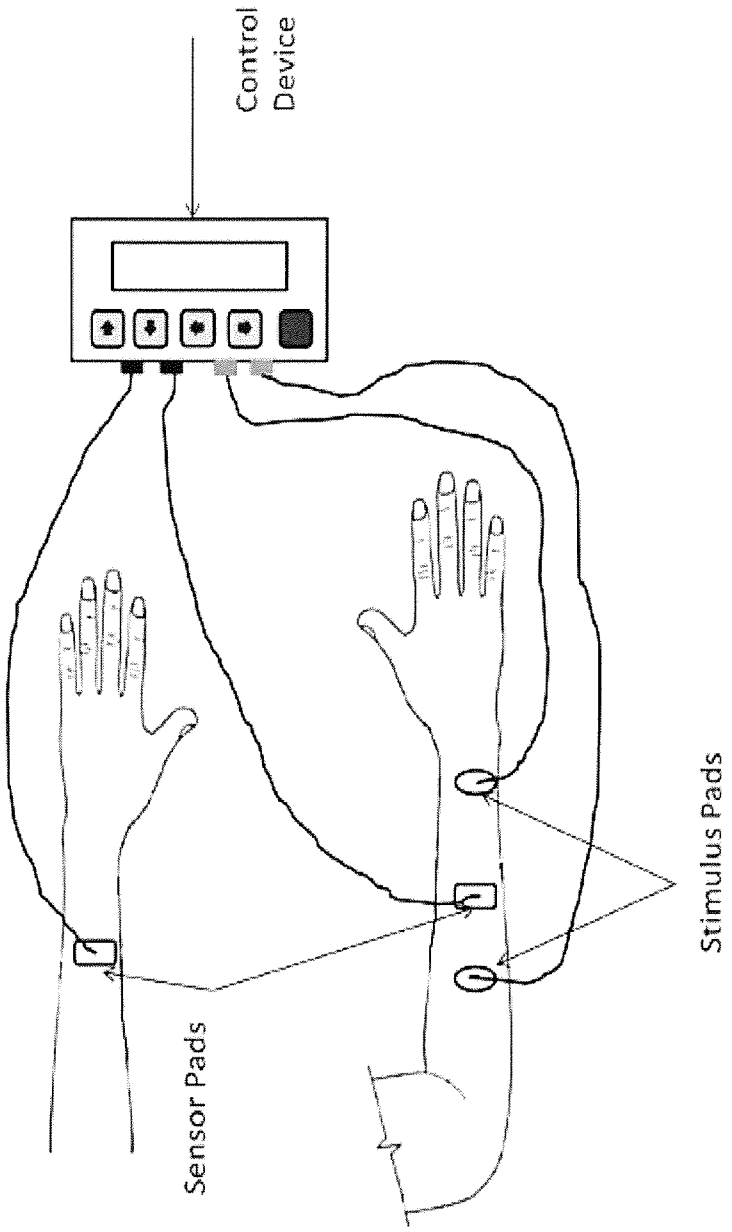


FIG. 11

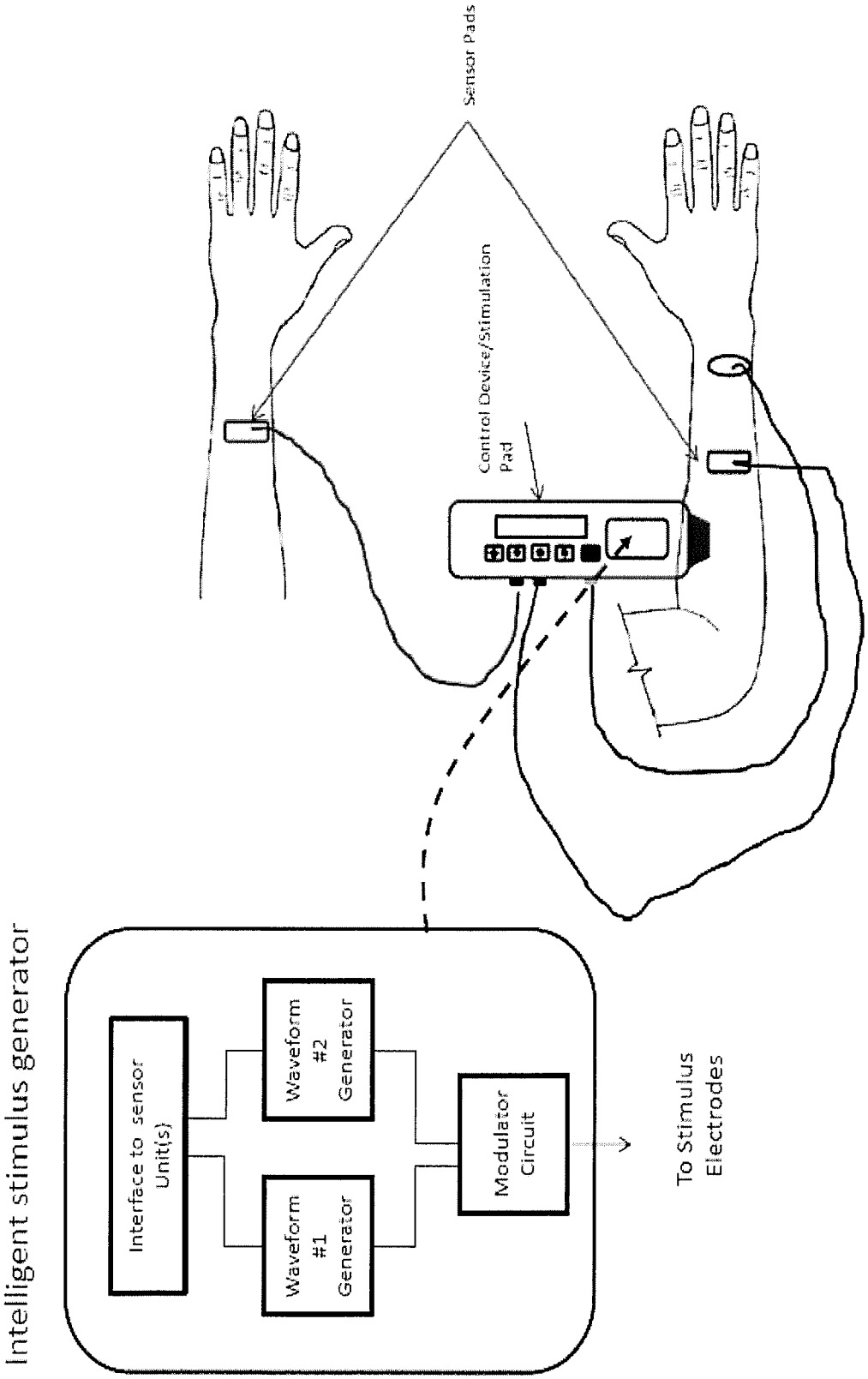

Sensor Pads
Control Device/Stimulation Pad
Intelligent stimulus generator
Interface to sensor Unit(s)
Waveform #2 Generator
Waveform #1 Generator
Modulator Circuit
To Stimulus Electrodes

FIG. 12

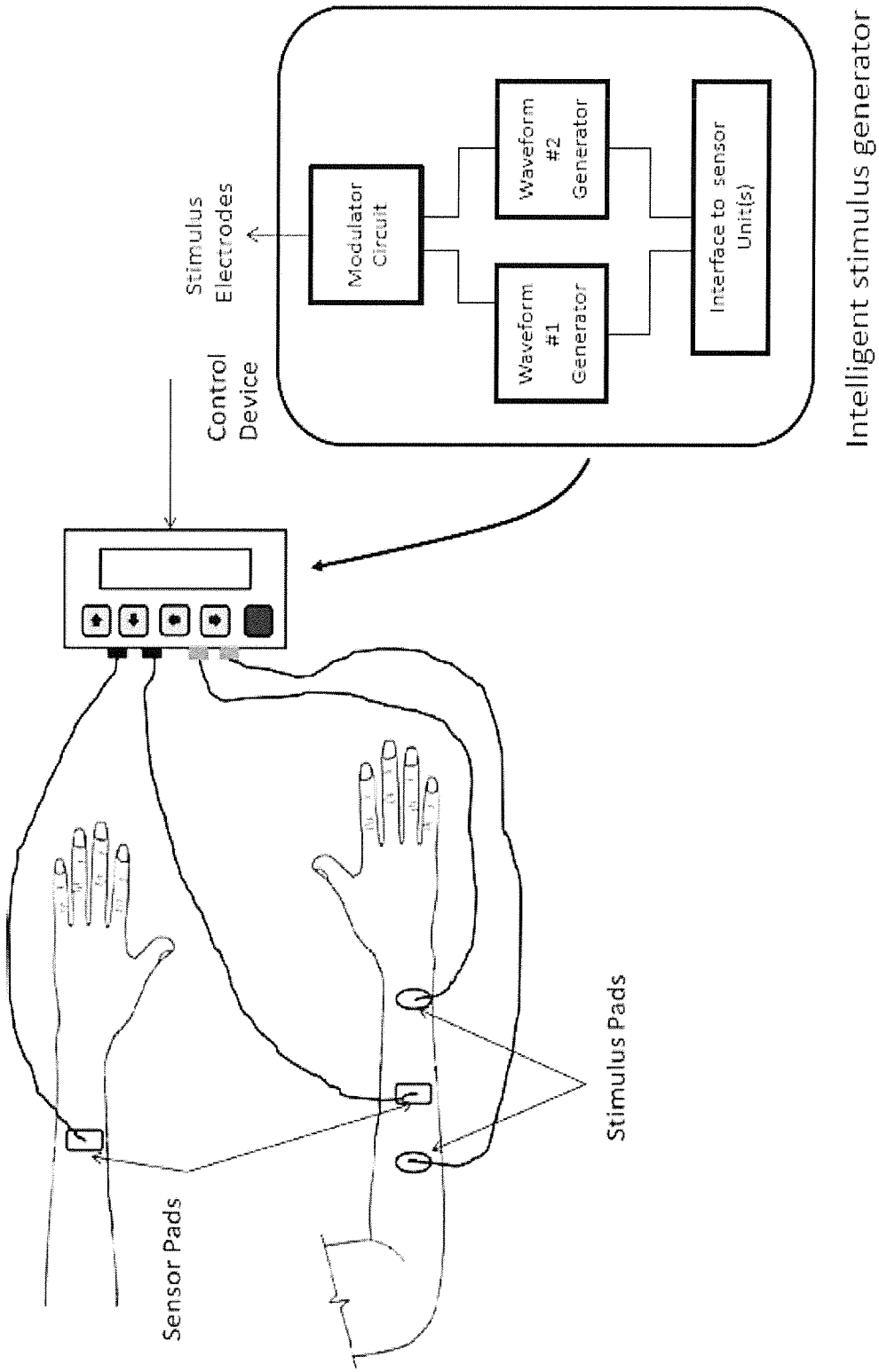

Intelligent stimulus generator
Interface to sensor Unit(s)
Waveform #2 Generator
Waveform #1 Generator
Modulator Circuit
Stimulus Electrodes
Control Device
Stimulus Pads
Sensor Pads

FIG. 13

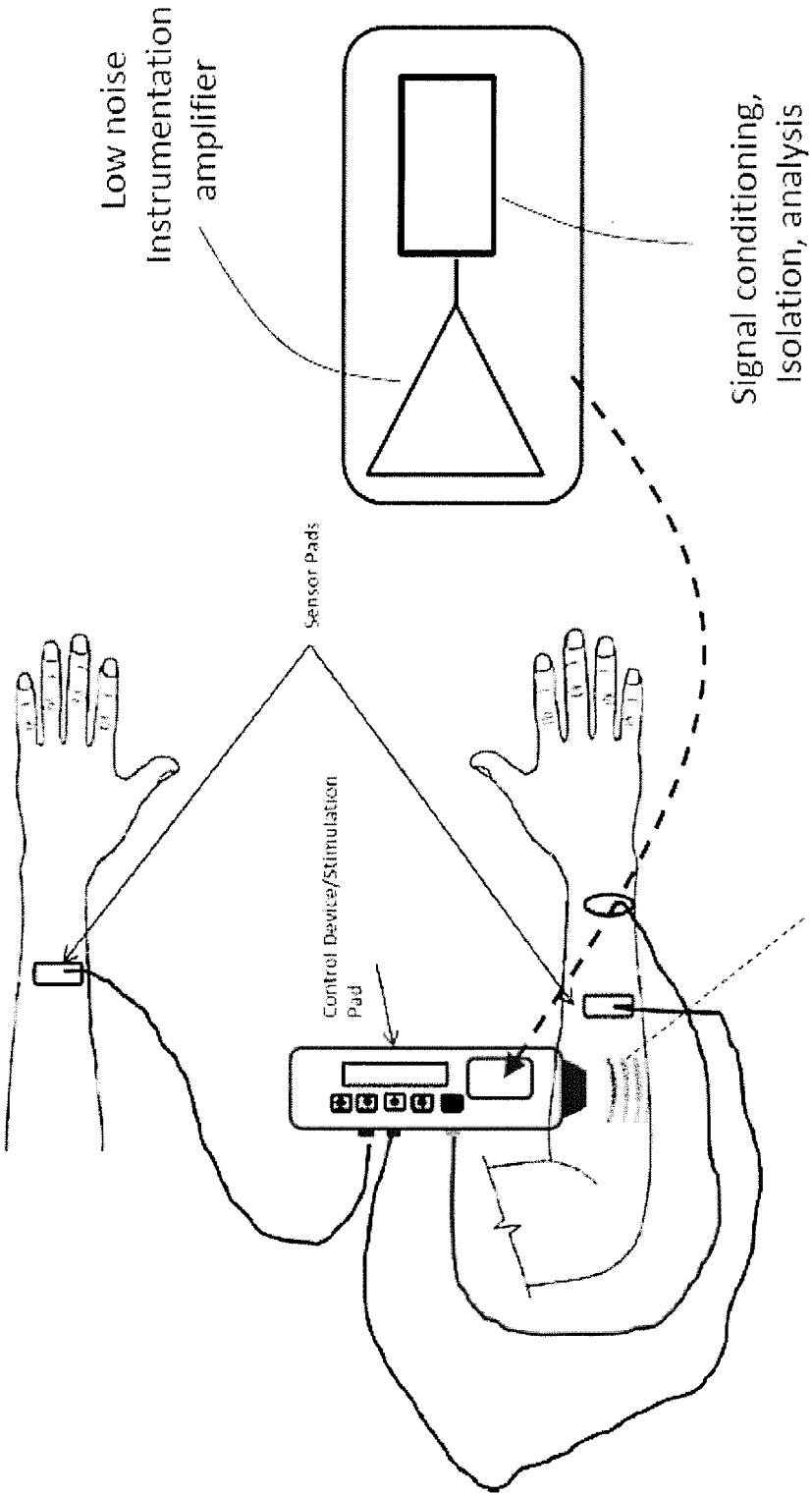

Low noise
Instrumentation
amplifier
Signal conditioning,
Isolation, analysis
Sensor Pads
Control Device/Stimulation
Pad
Pressure waves
From muscle
contraction

FIG. 14

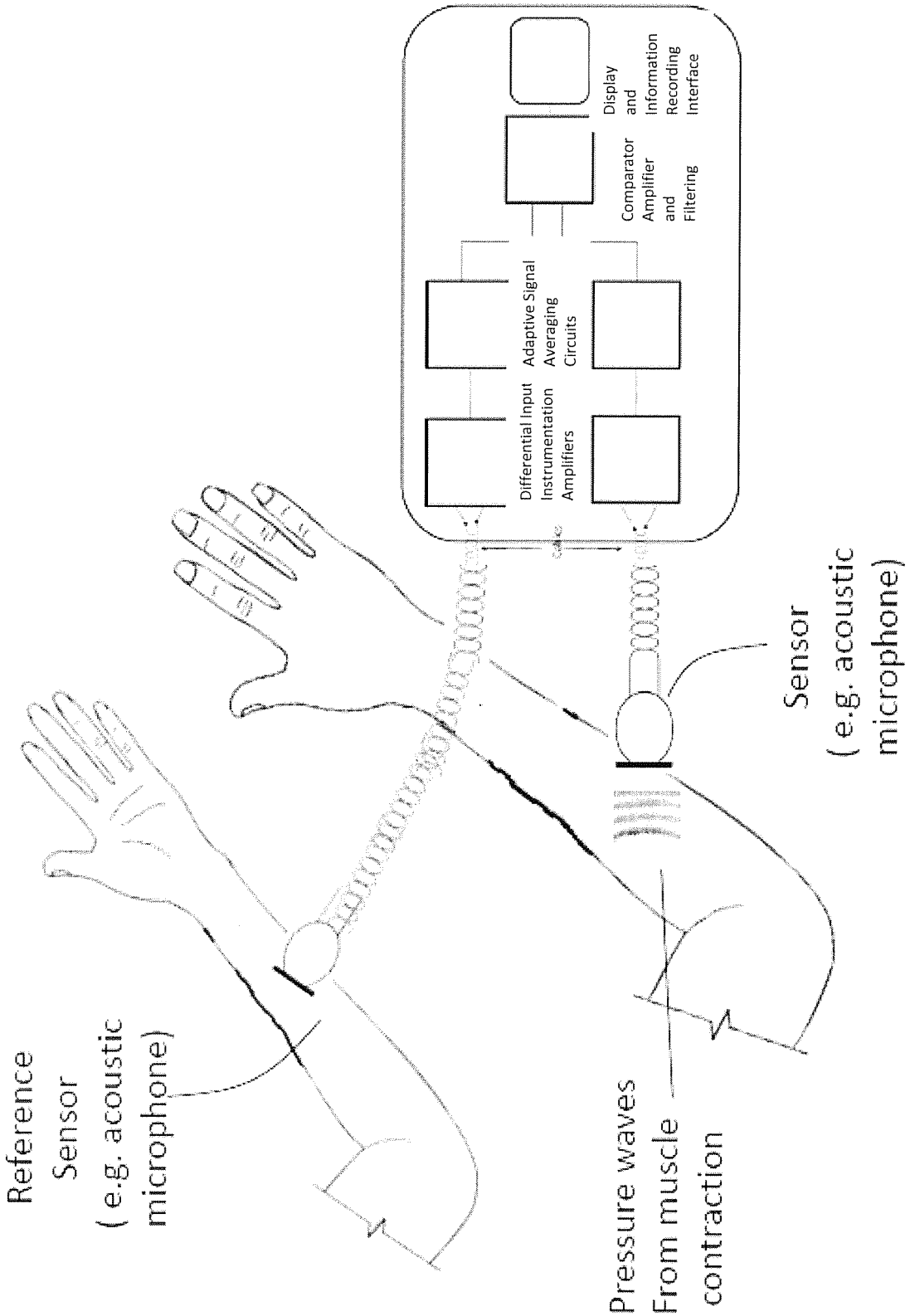

Reference Sensor (e.g. acoustic microphone)
Pressure waves From muscle contraction
Sensor (e.g. acoustic microphone)
Differential Input Instrumentation Amplifiers
Adaptive Signal Averaging Circuits
Comparator Amplifier and Filtering
Display and Information Recording Interface

FIG. 15

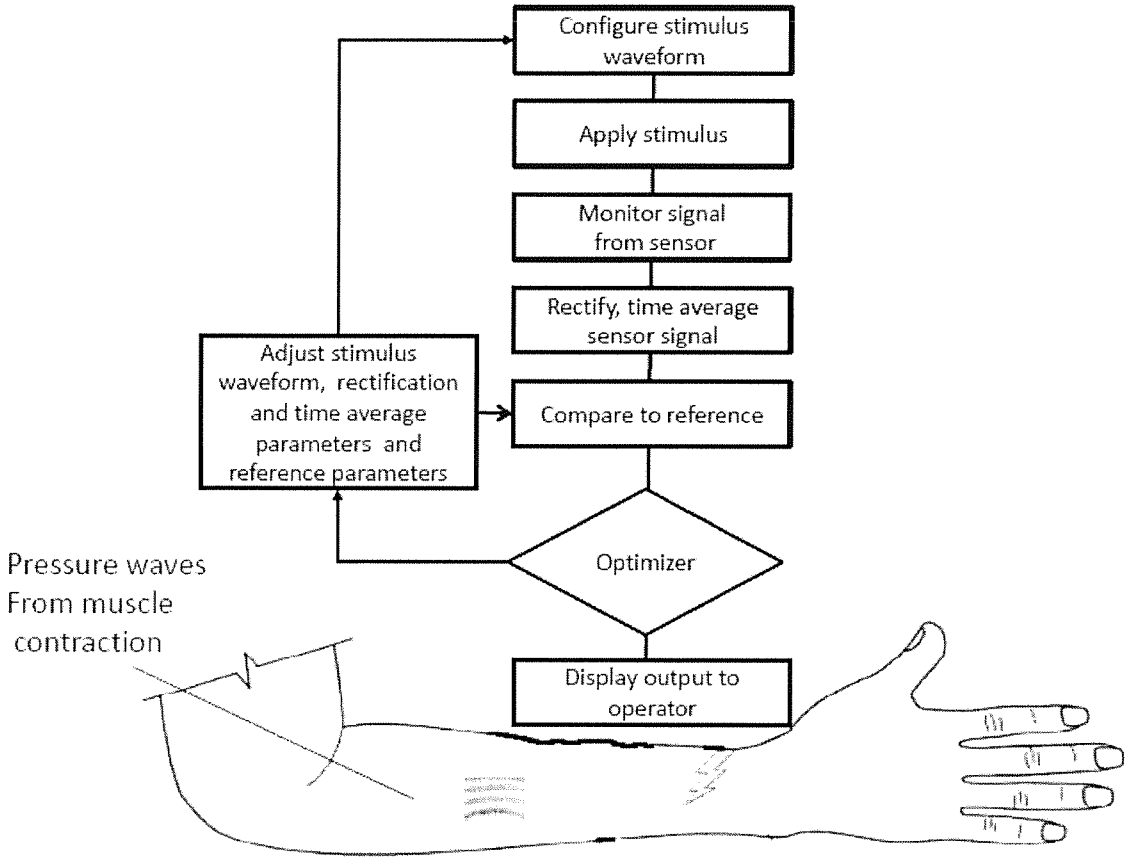

Configure stimulus waveform
Apply stimulus
Monitor signal from sensor
Rectify, time average sensor signal
Compare to reference
Adjust stimulus waveform, rectification and time average parameters and reference parameters
Optimizer
Display output to operator
Pressure waves From muscle contraction

FIG. 16

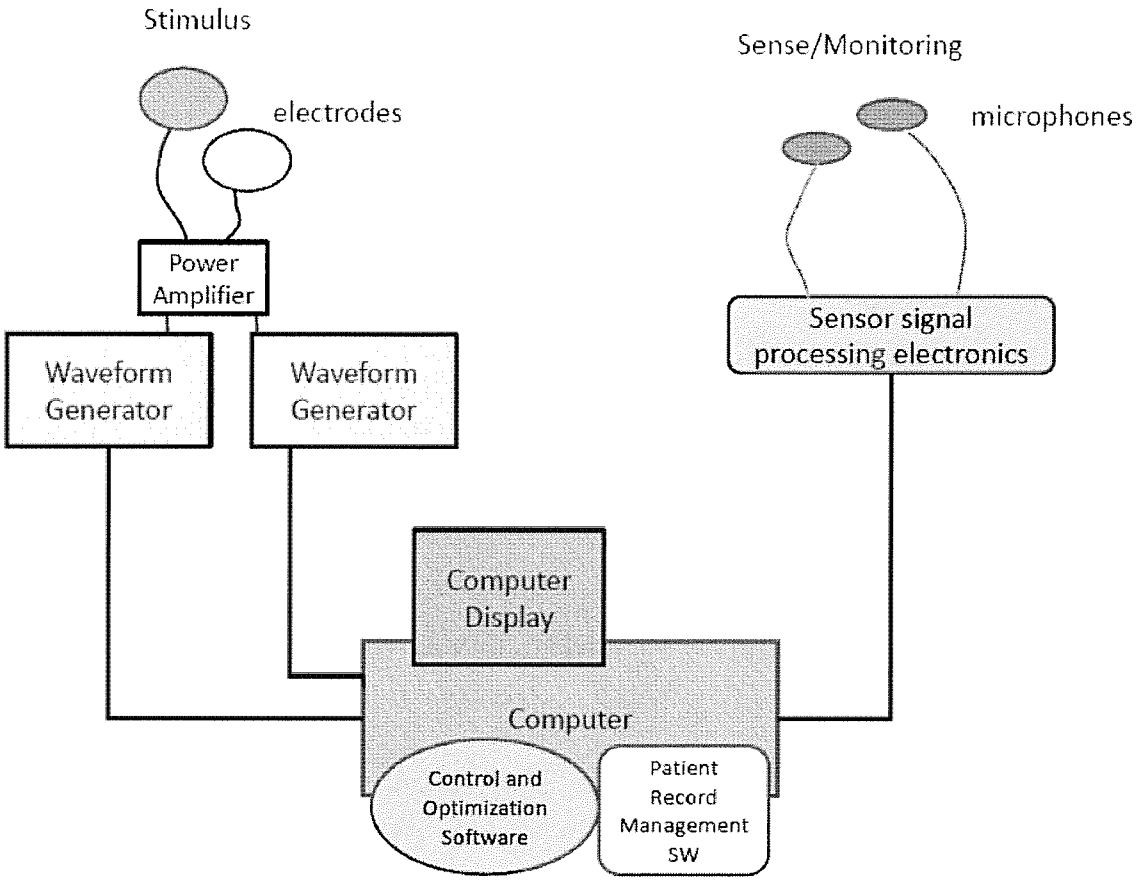

Stimulus
electrodes
Power Amplifier
Waveform Generator
Waveform Generator
Sense/Monitoring
microphones
Sensor signal processing electronics
Computer Display
Computer
Control and Optimization Software
Patient Record Management SW

FIG. 17

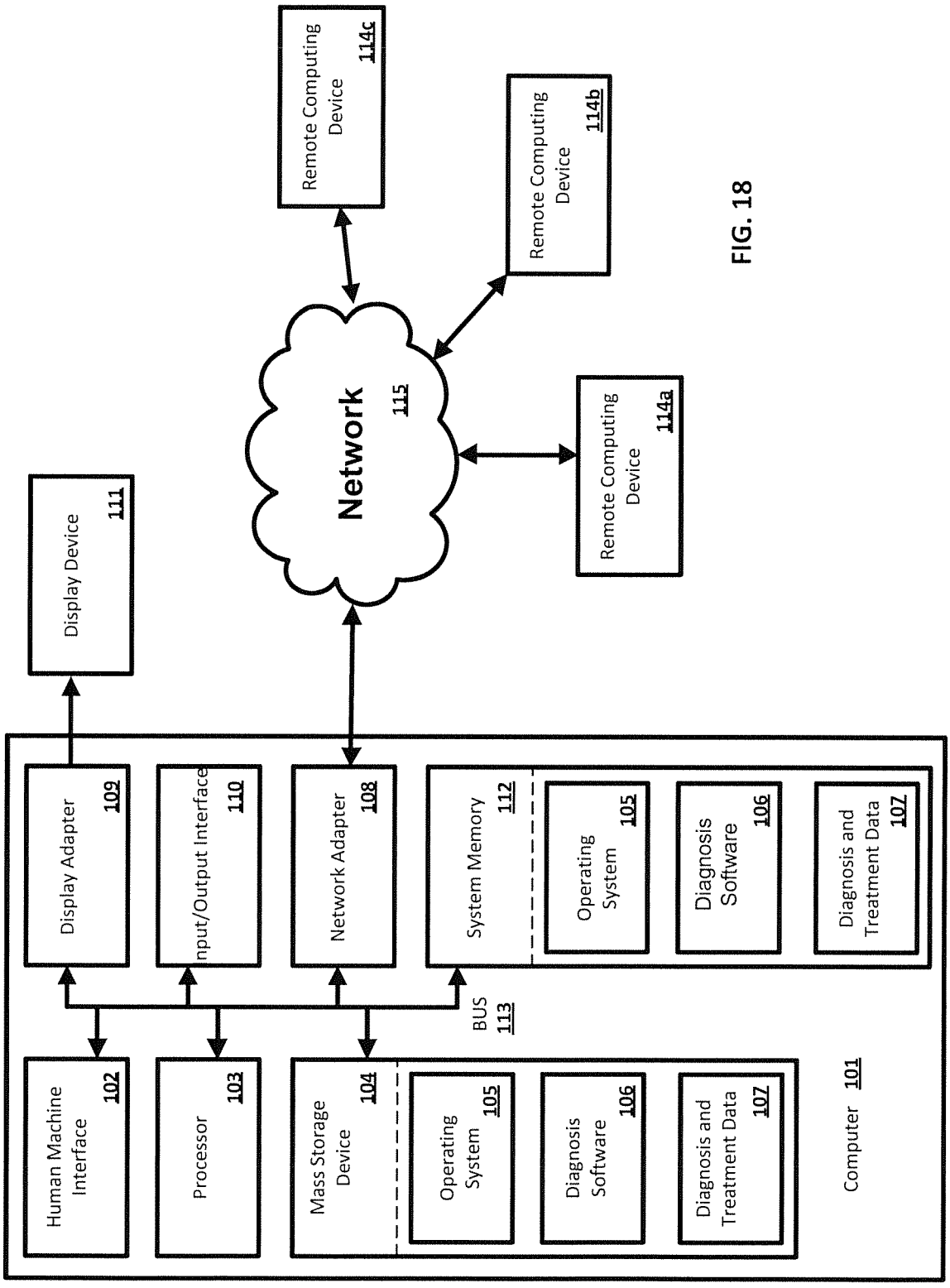

Remote Computing Device 114c
Remote Computing Device 114b
Remote Computing Device 114a
Network 115
Display Device 111
Display Adapter 109
nput/Output Interface 110
Network Adapter 108
System Memory 112
Operating System 105
Diagnosis Software 106
Diagnosis and Treatment Data 107
BUS 113
Human Machine Interface 102
Processor 103
Mass Storage Device 104
Operating System 105
Diagnosis Software 106
Diagnosis and Treatment Data 107
Computer 101

FIG. 18

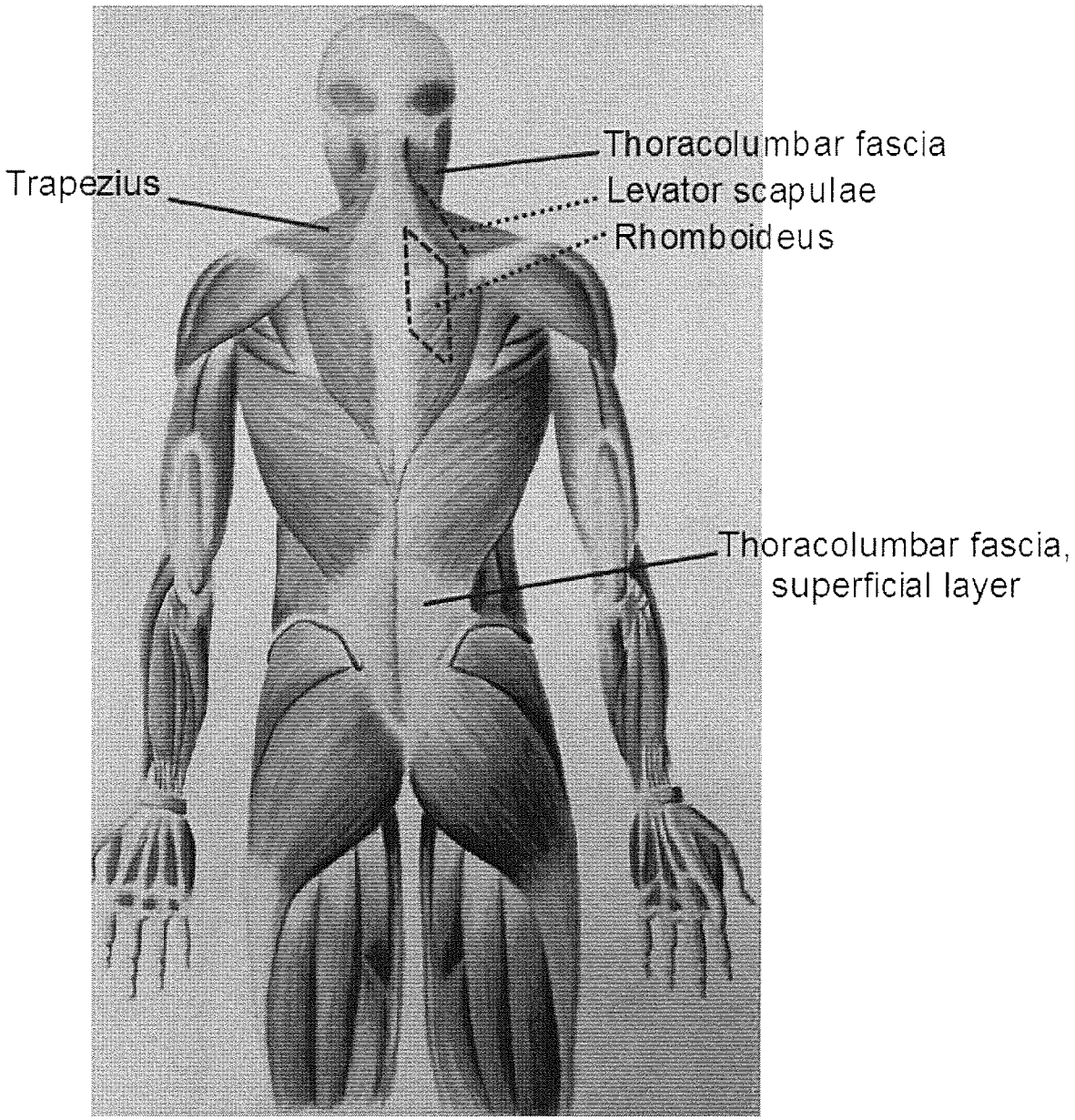

Trapezius
Thoracolumbar fascia
Levator scapulae
Rhomboideus
Thoracolumbar fascia,
superficial layer

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/025987

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/00 (2015.01)
CPC - A61B 5/4824 (2015.04)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00, 5/0478, 5/05, 5/103, 5/11; G06C 3/00 (2015.01)
USPC - 600/544, 545, 546, 557

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 5/00, 5/0478, 5/05, 5/103, 5/11, 5/1107, 5/4824; G06C 3/00 (2015.04) (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google, ProQuest
Search terms used: pain evaluation, measurement, stimulus, stimulation source, muscle, sensor, processor, stimulation parameters, magnitude, phase, waveform, frequency, lowest possible magnitude

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2011/0118661 A1 (PLESS et al) 19 May 2011 (19.05.2011) entire document	1-43
Y	US 2011/0071418 A1 (STELLAR et al) 24 March 2011 (24.03.2011) entire document	1-43
Y	US 5,324,317 A (REISS) 28 June 1994 (28.06.1994) entire document	5-12
Y	US 2002/0113651 A1 (BURT) 22 August 2002 (22.08.2002) entire document	18-23
Y	US 5,230,344 A (OZDAMAR et al) 27 July 1993 (27.07.1993) entire document	19-23
Y	US 2006/0129058 A1 (STRONG et al) 15 June 2006 (15.06.2006) entire document	33
Y	US 2002/0030682 A1 (EBERLEIN) 14 March 2002 (14.03.2002) entire document	37,38

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 June 2015	08 JUL 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774