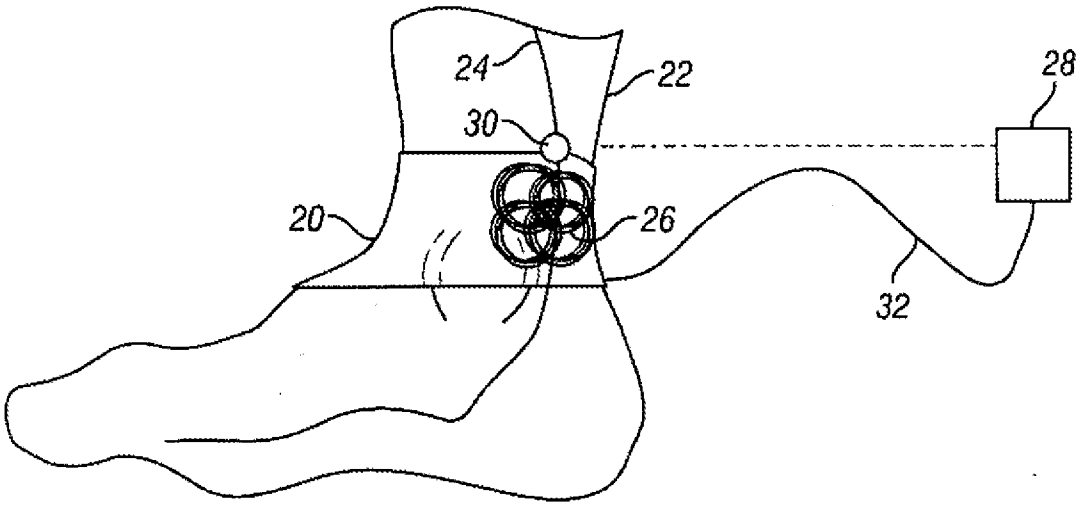



FIG. 1

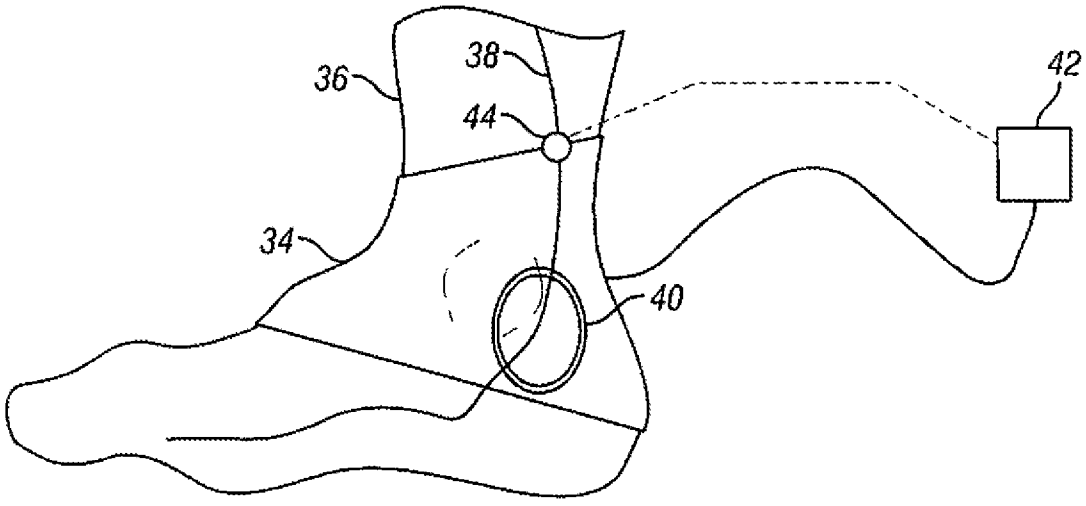



FIG. 2

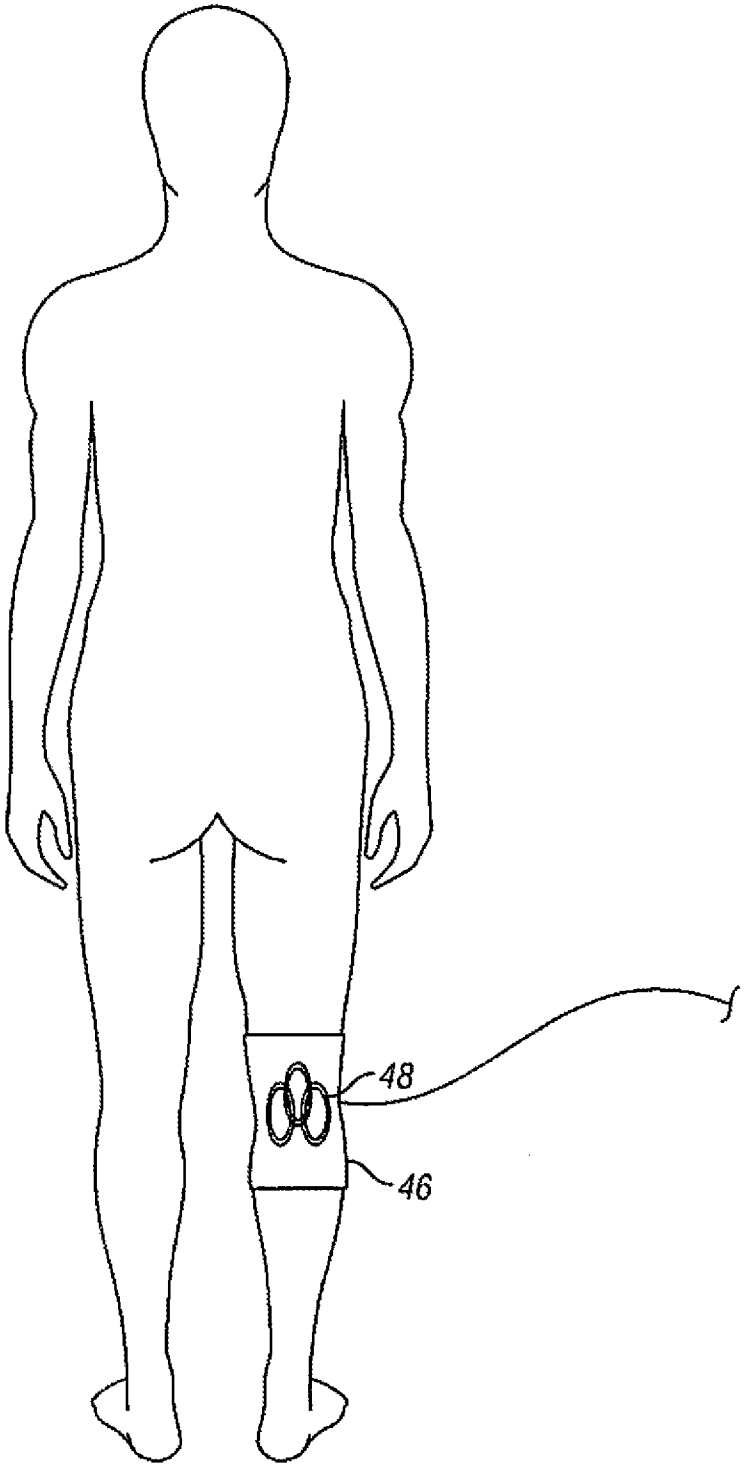



FIG. 3

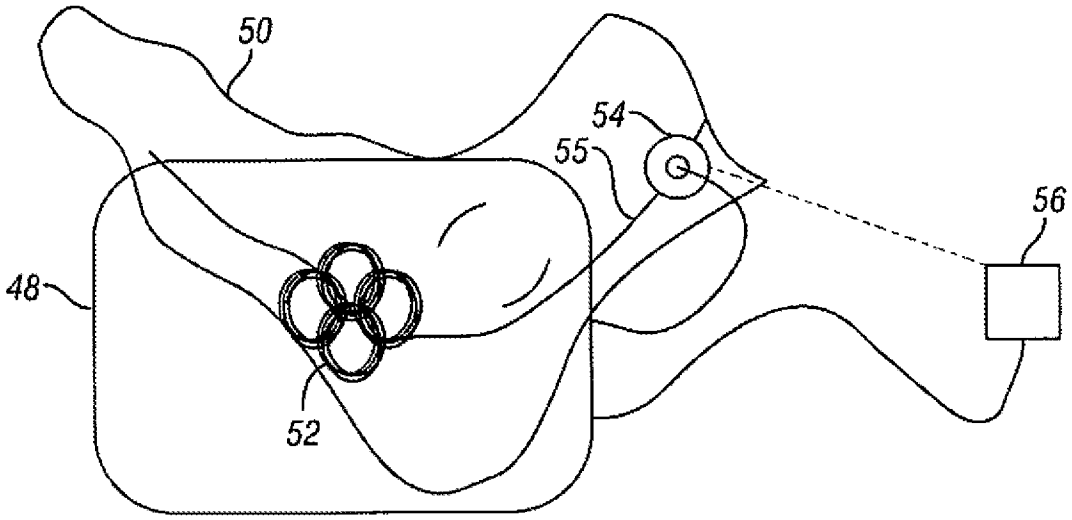



FIG. 4

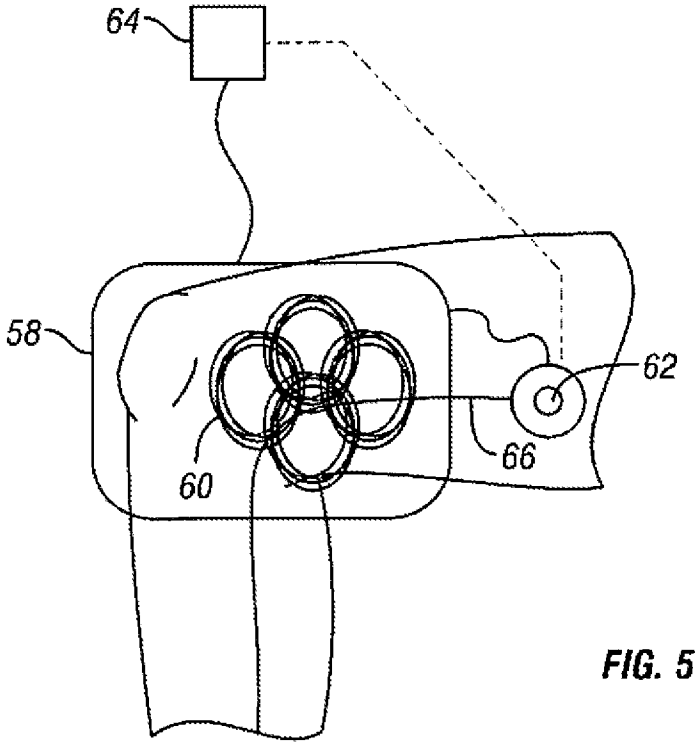



FIG. 5

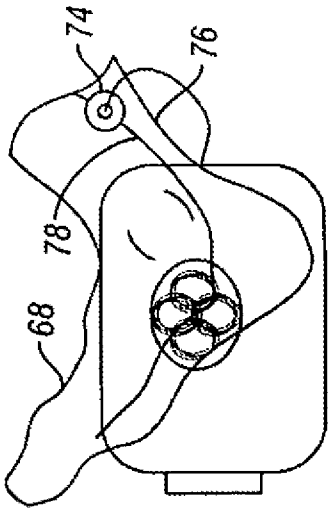



FIG. 6B

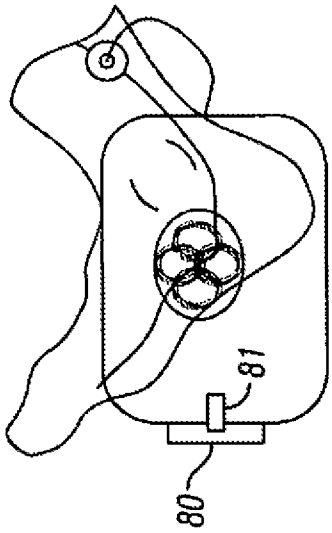



FIG. 6D

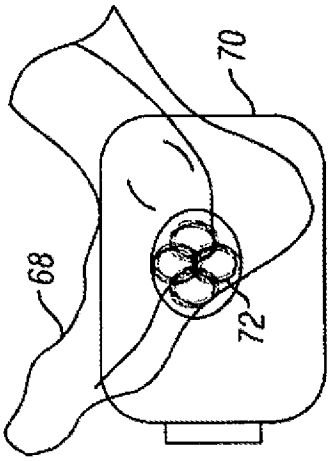



FIG. 6A

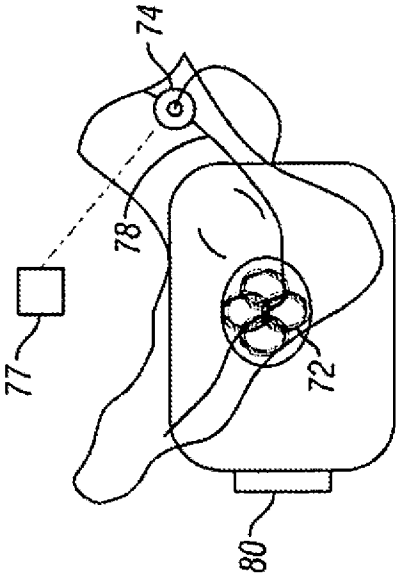



FIG. 6C

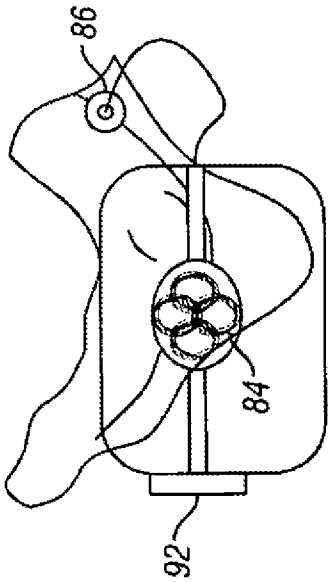



FIG. 7B

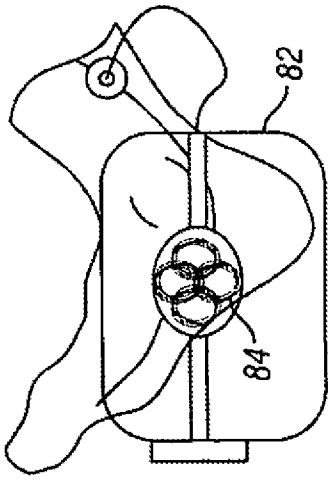



FIG. 7D

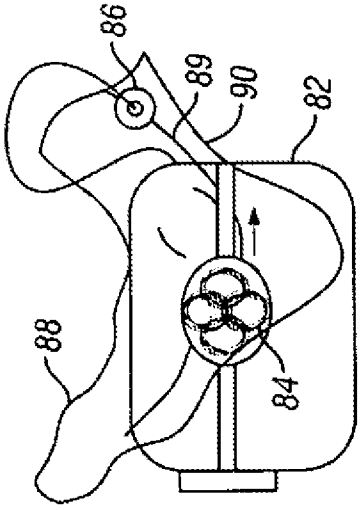



FIG. 7A

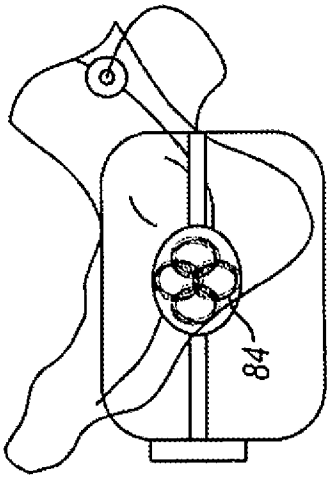



FIG. 7C

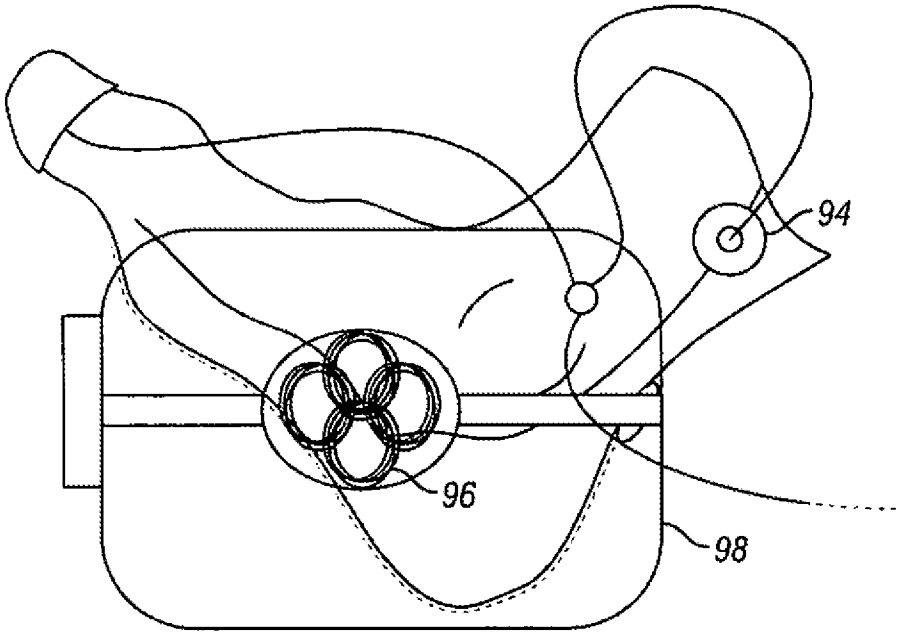



FIG. 8

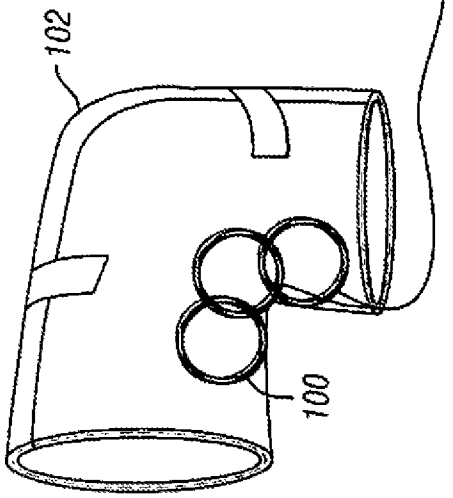



FIG. 9A

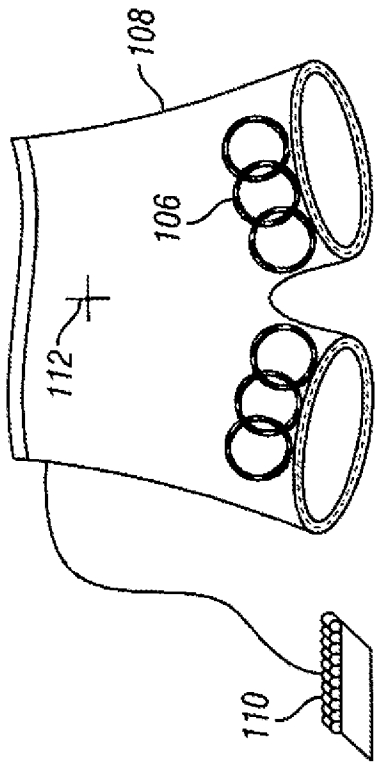



FIG. 9B

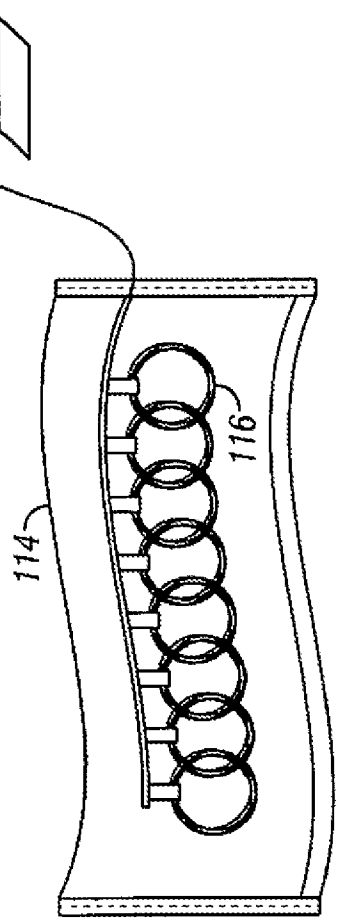



FIG. 9C

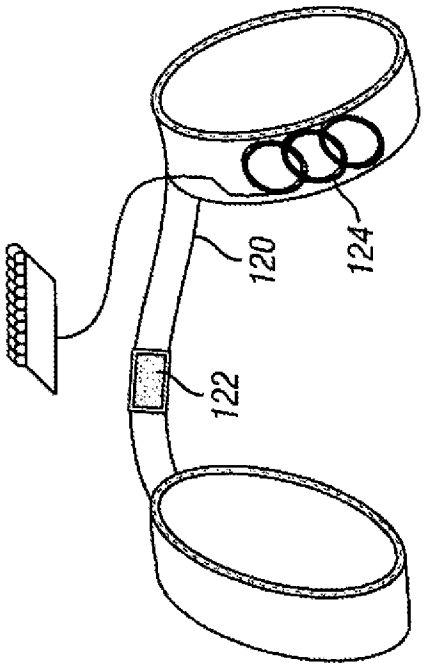



FIG. 9D

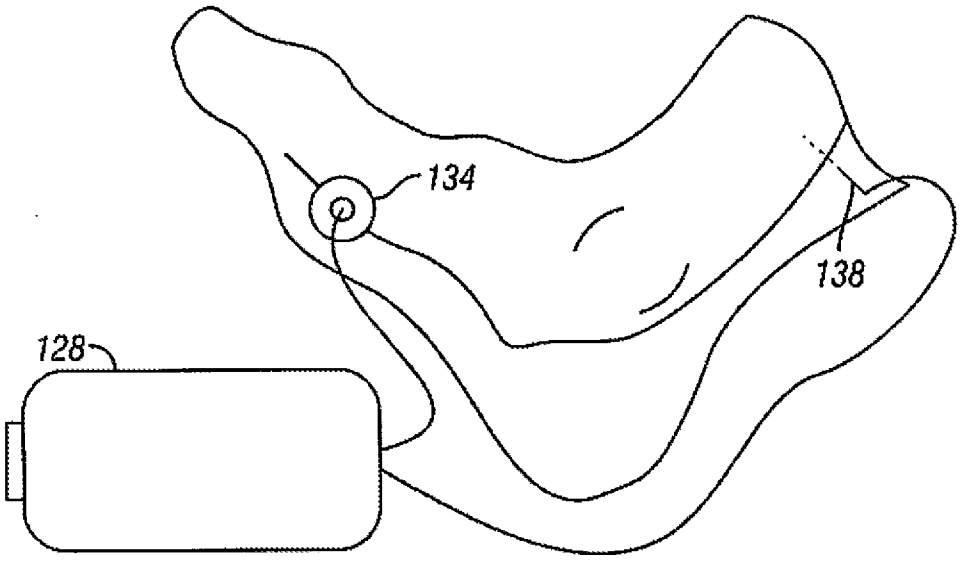



FIG. 10

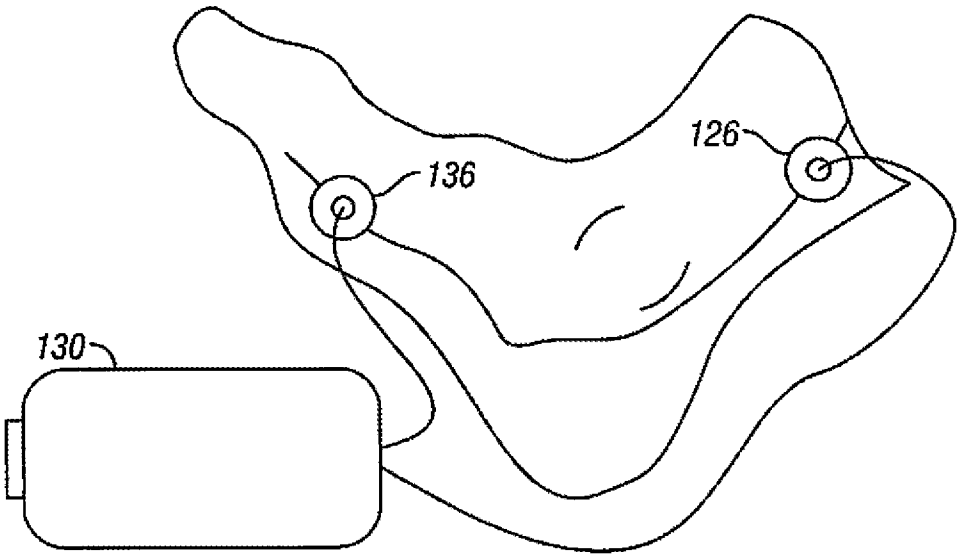



FIG. 11

FIG 12

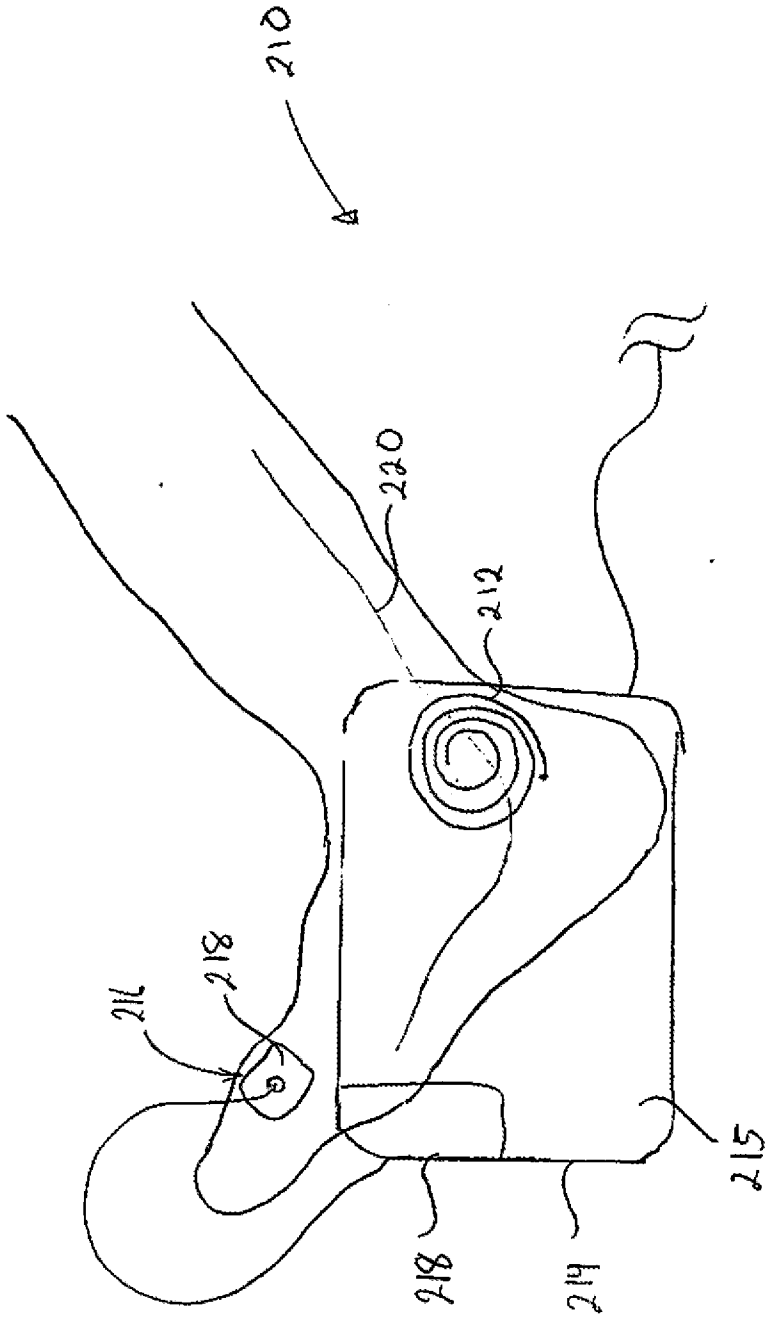


FIG 13

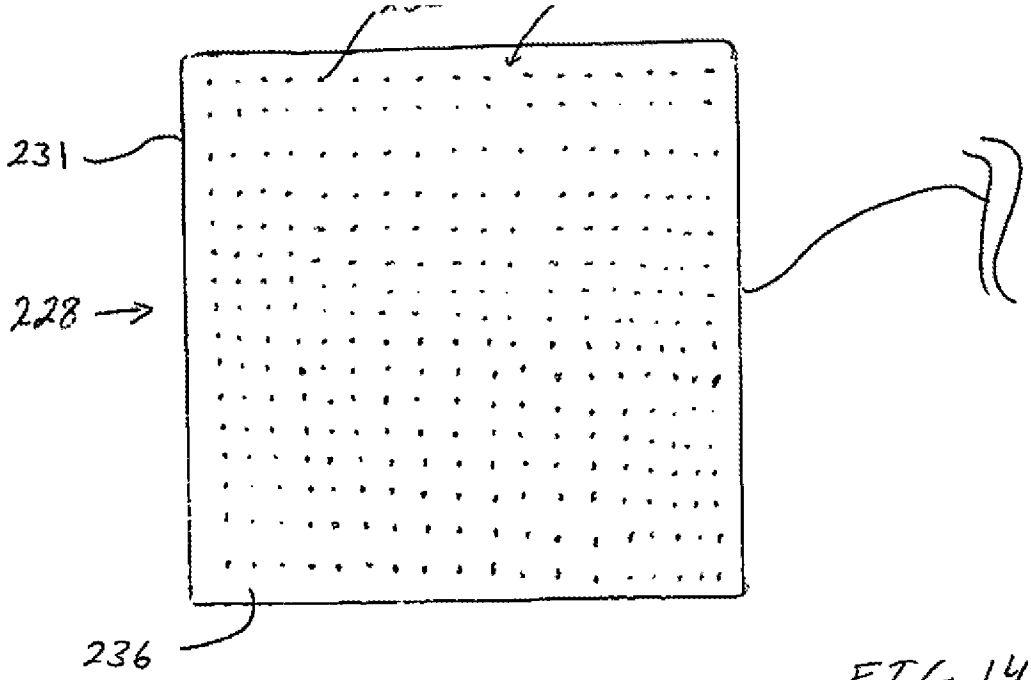



FIG 14

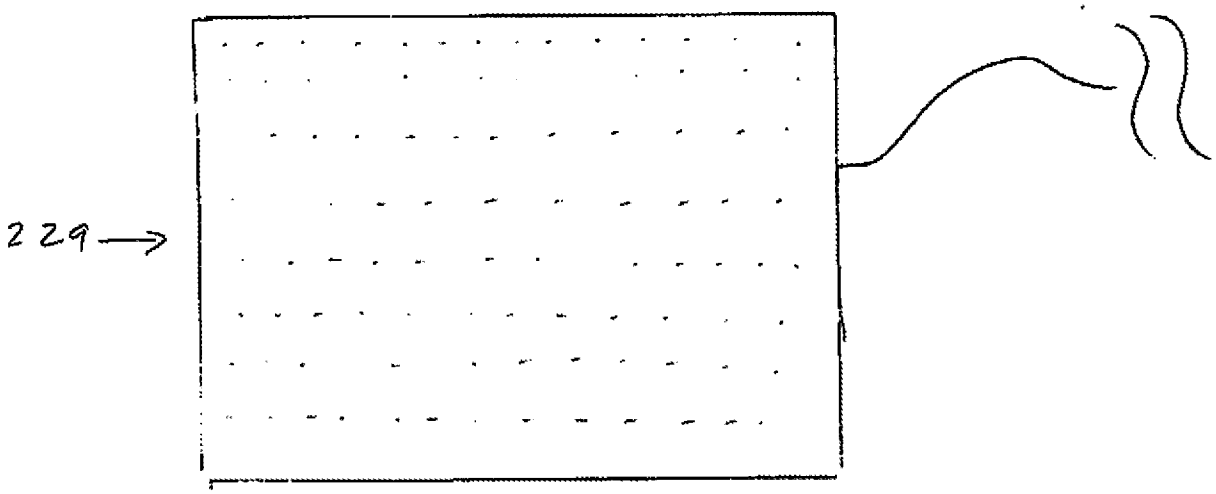



FIG 15

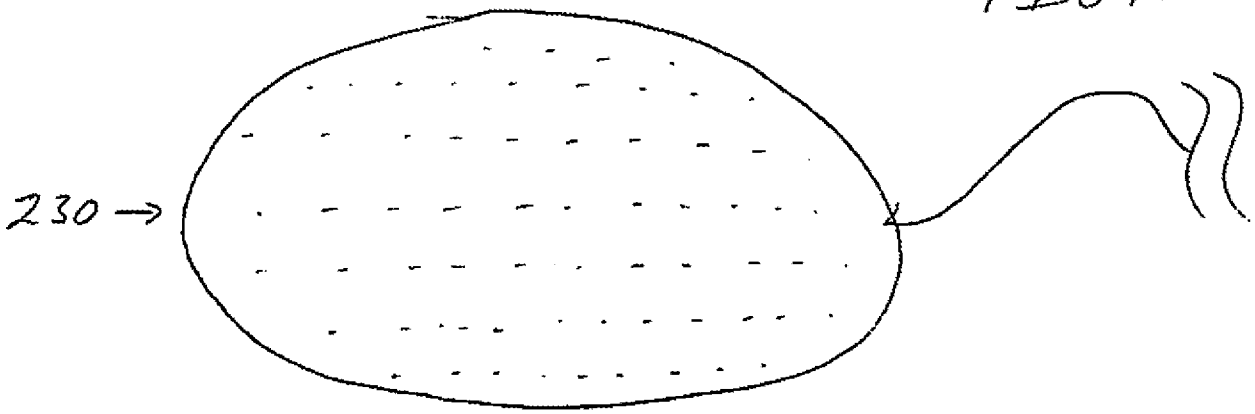


FIG 16

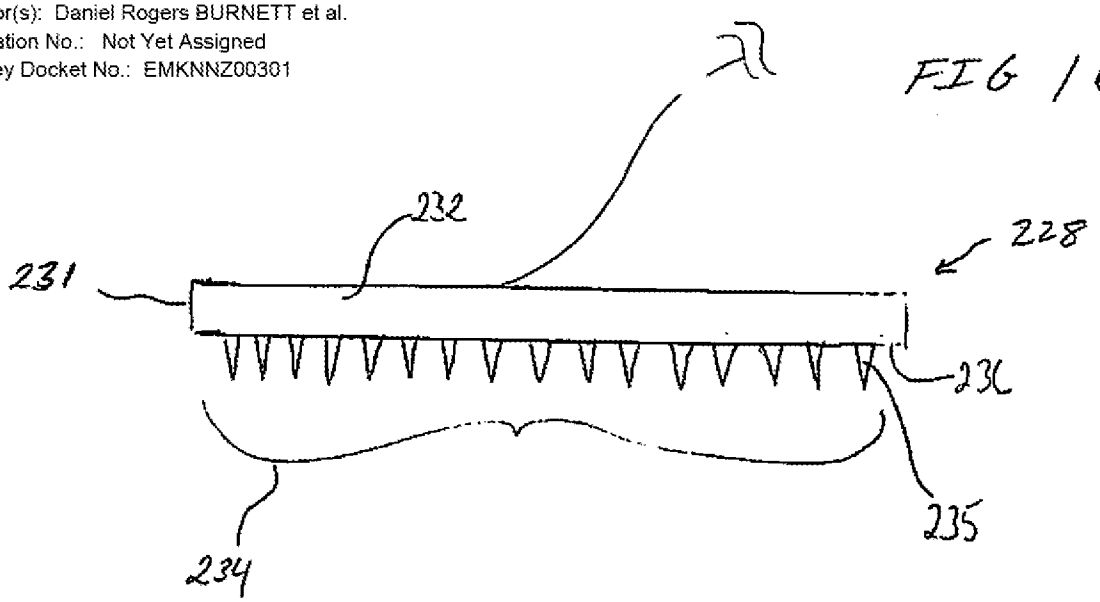
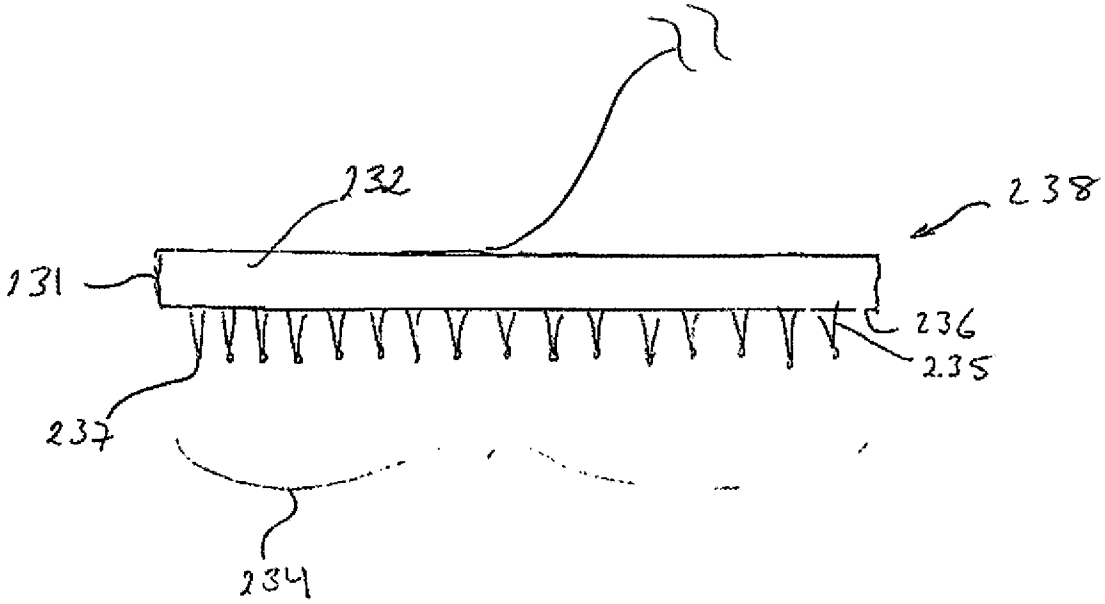



FIG 17



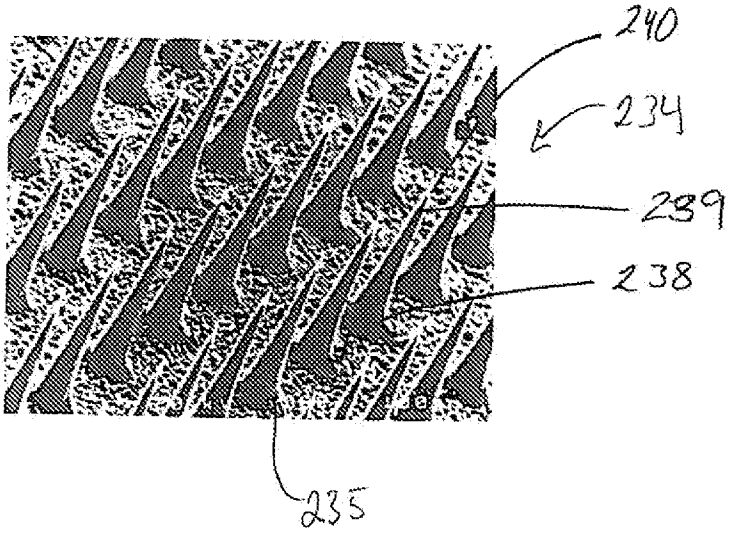



FIG 18

FIG 19

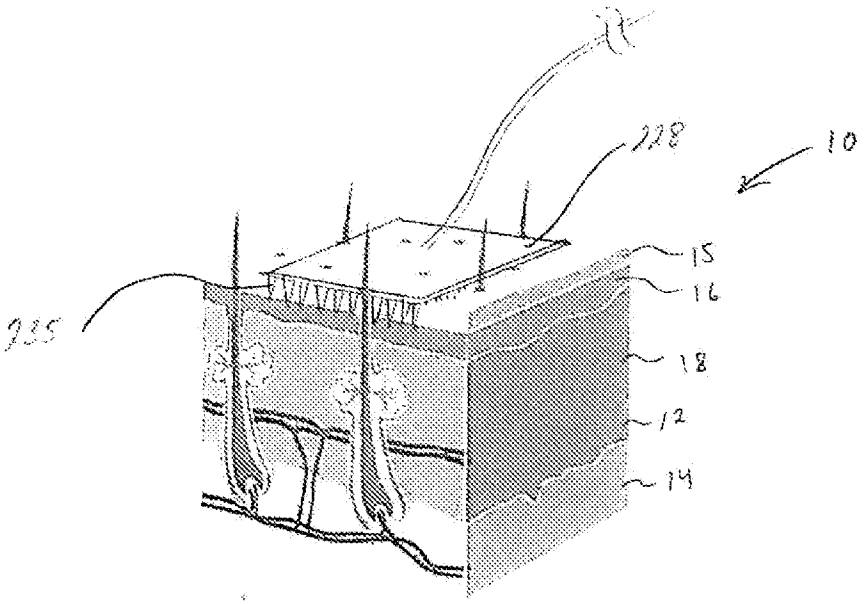
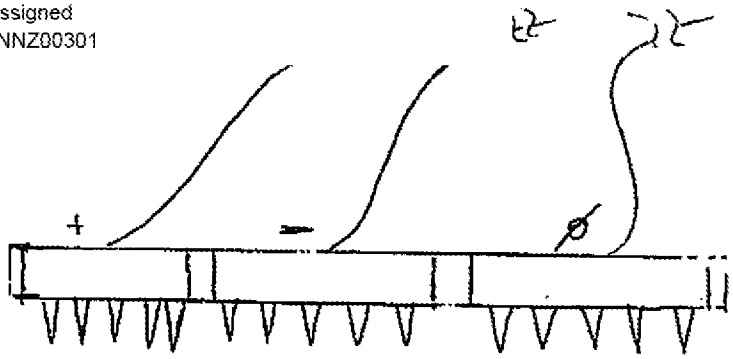


FIG 20a



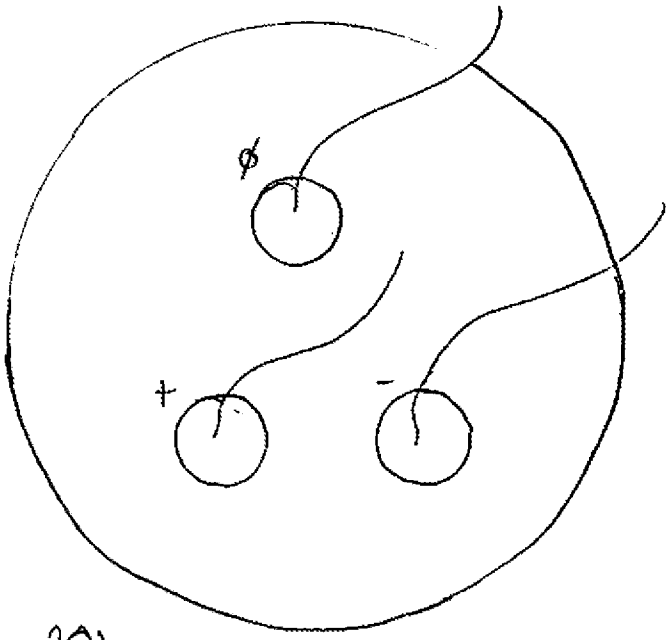
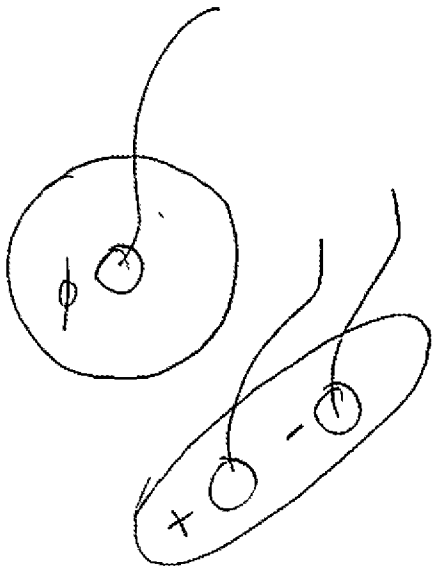




Fig 20b

Fig 20c



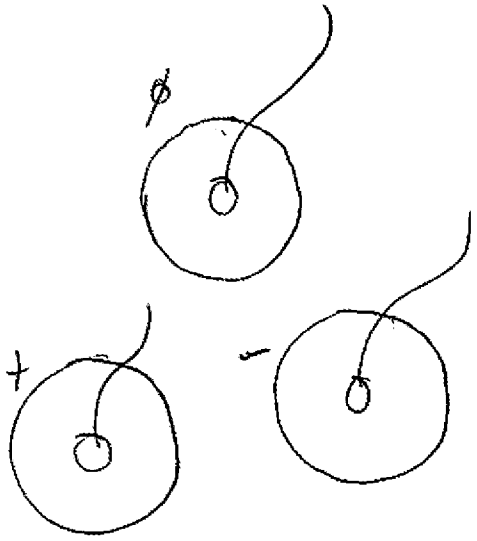




Fig 20d

FIG 21

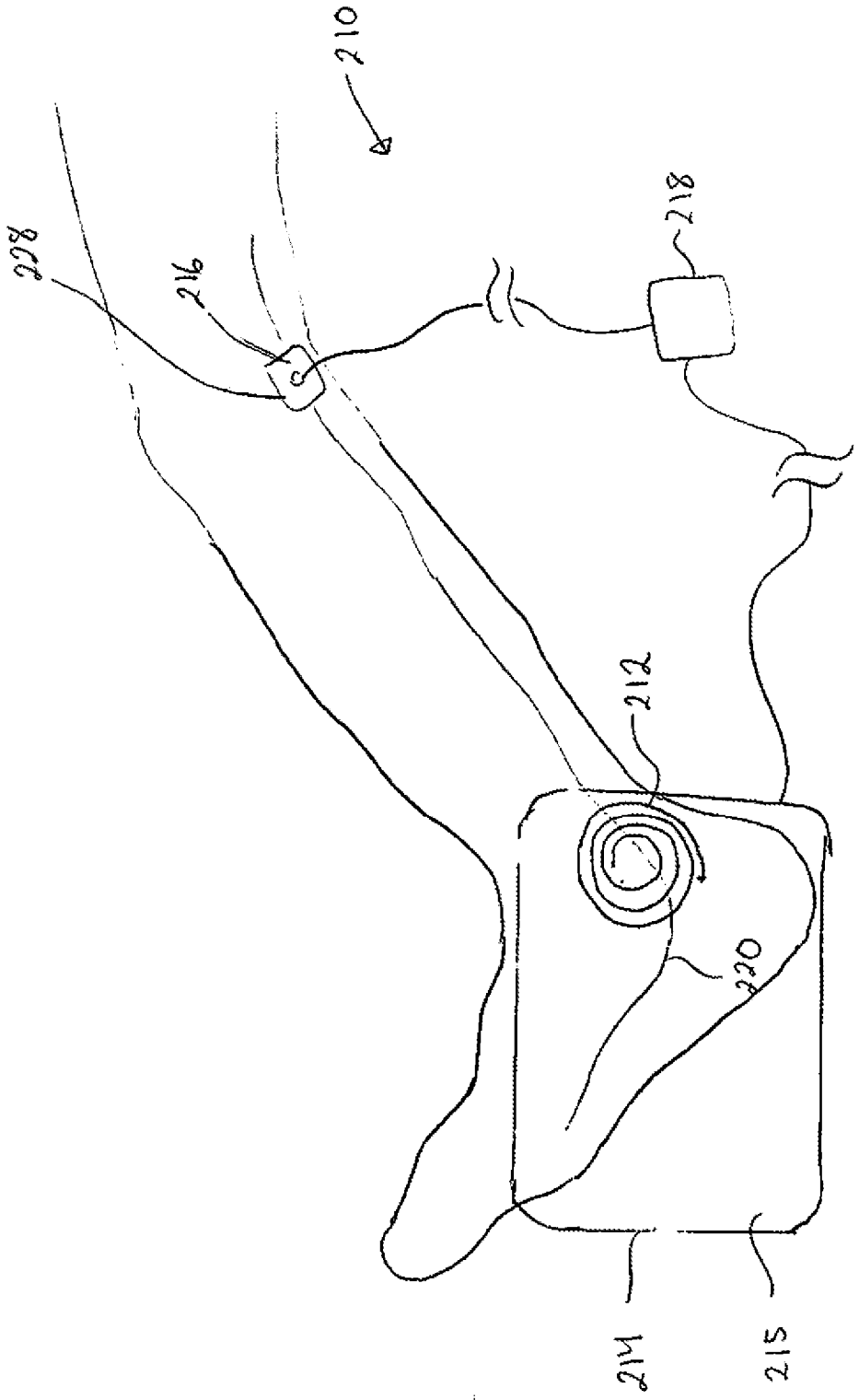


FIG 22

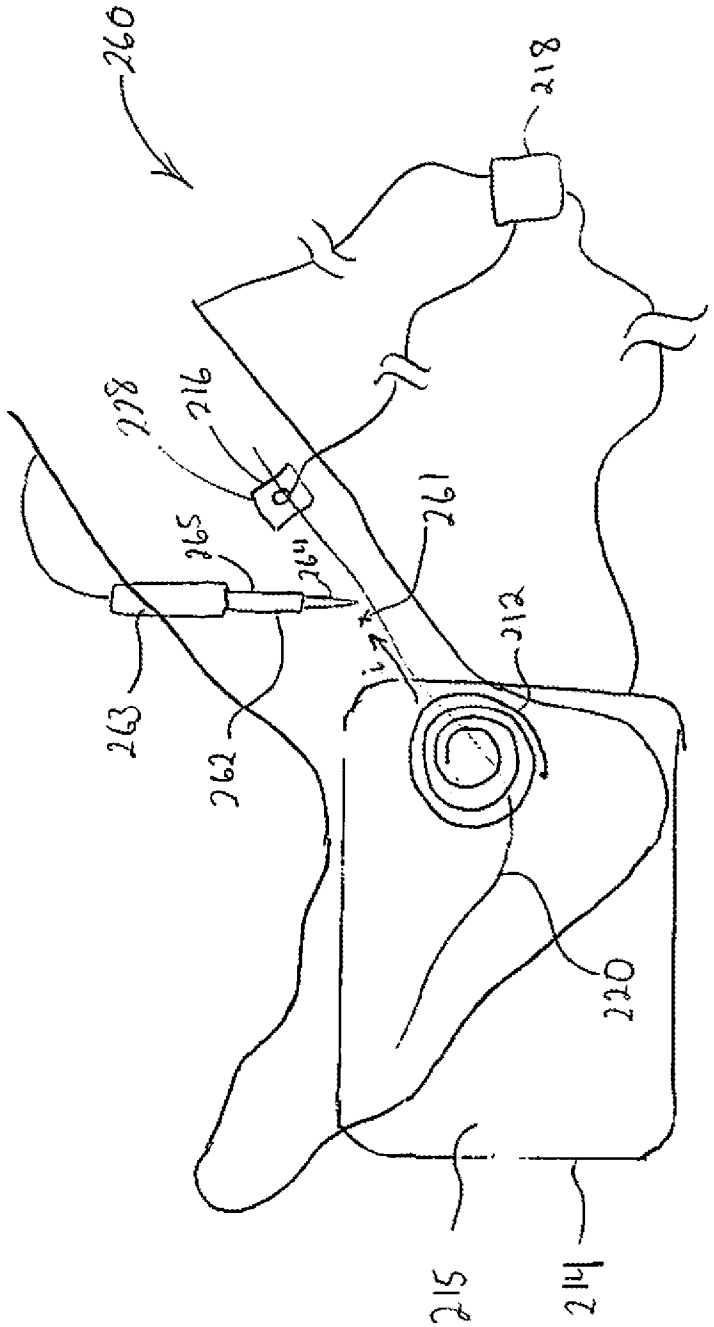


FIG 23

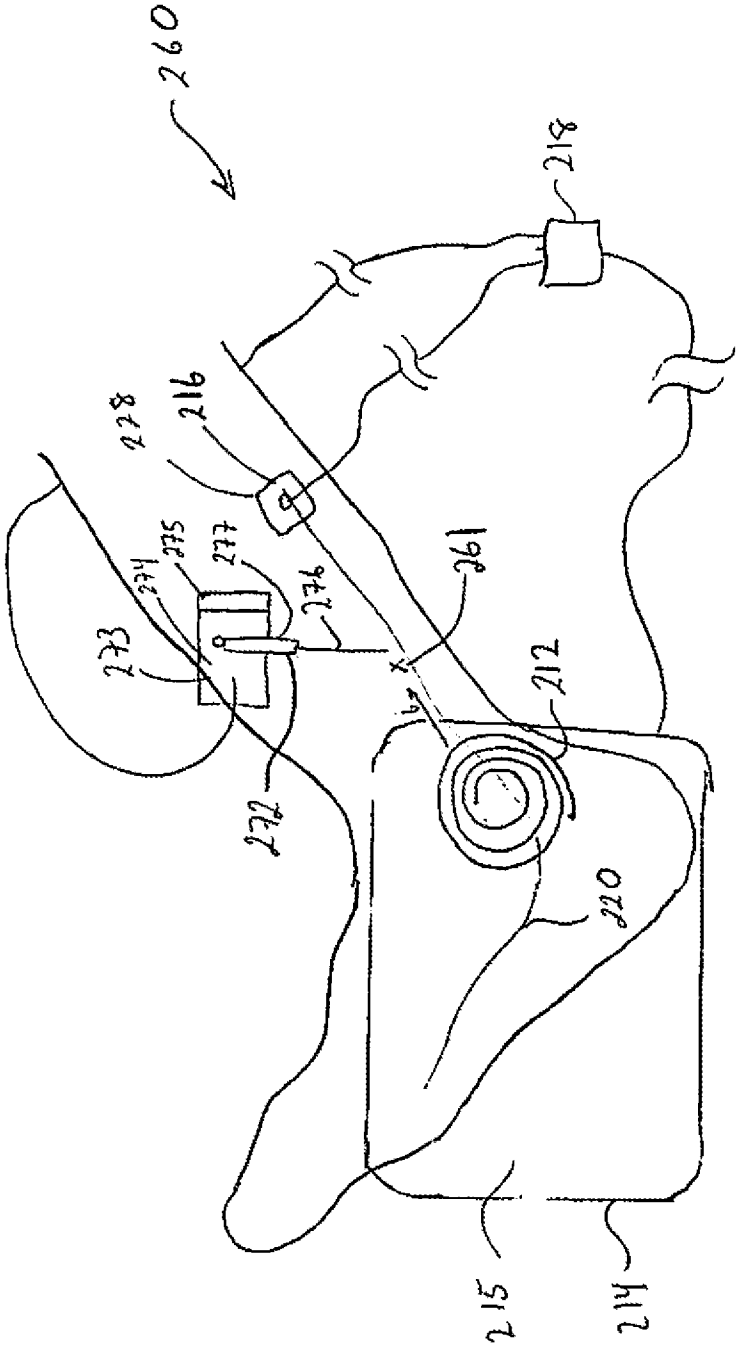


FIG 24

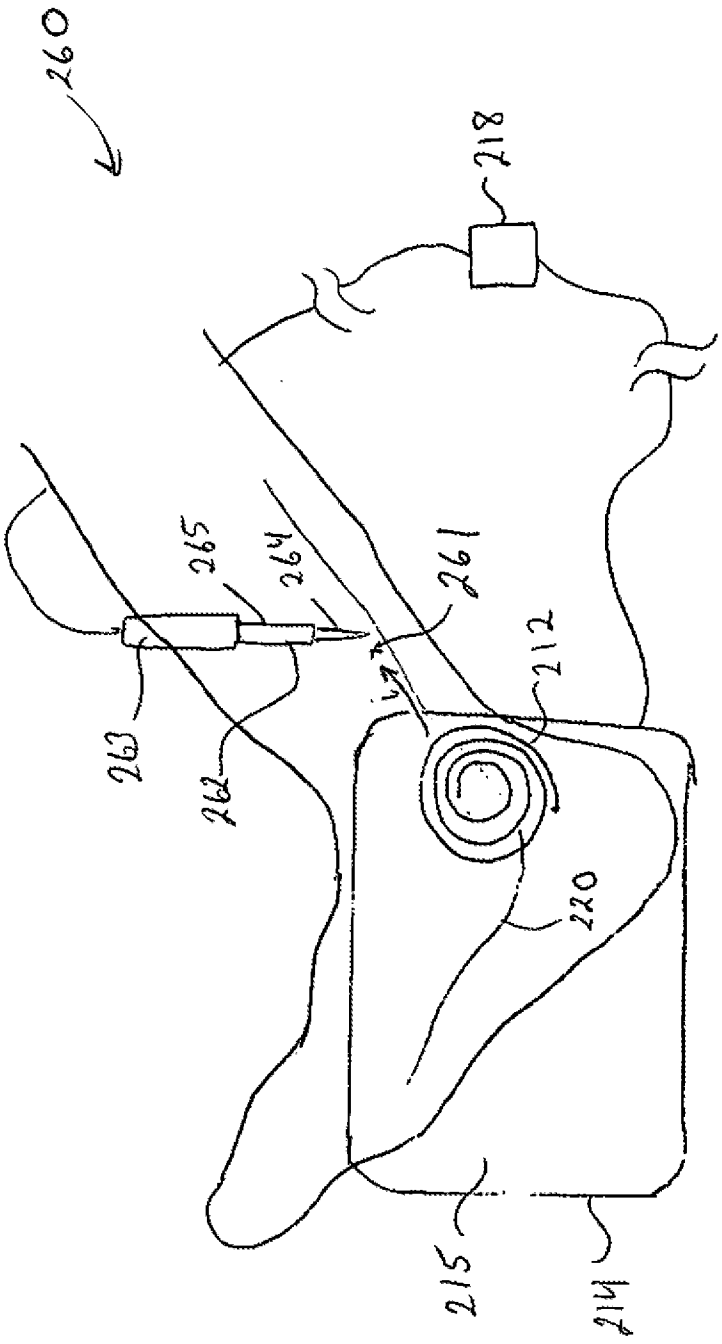


FIG 25

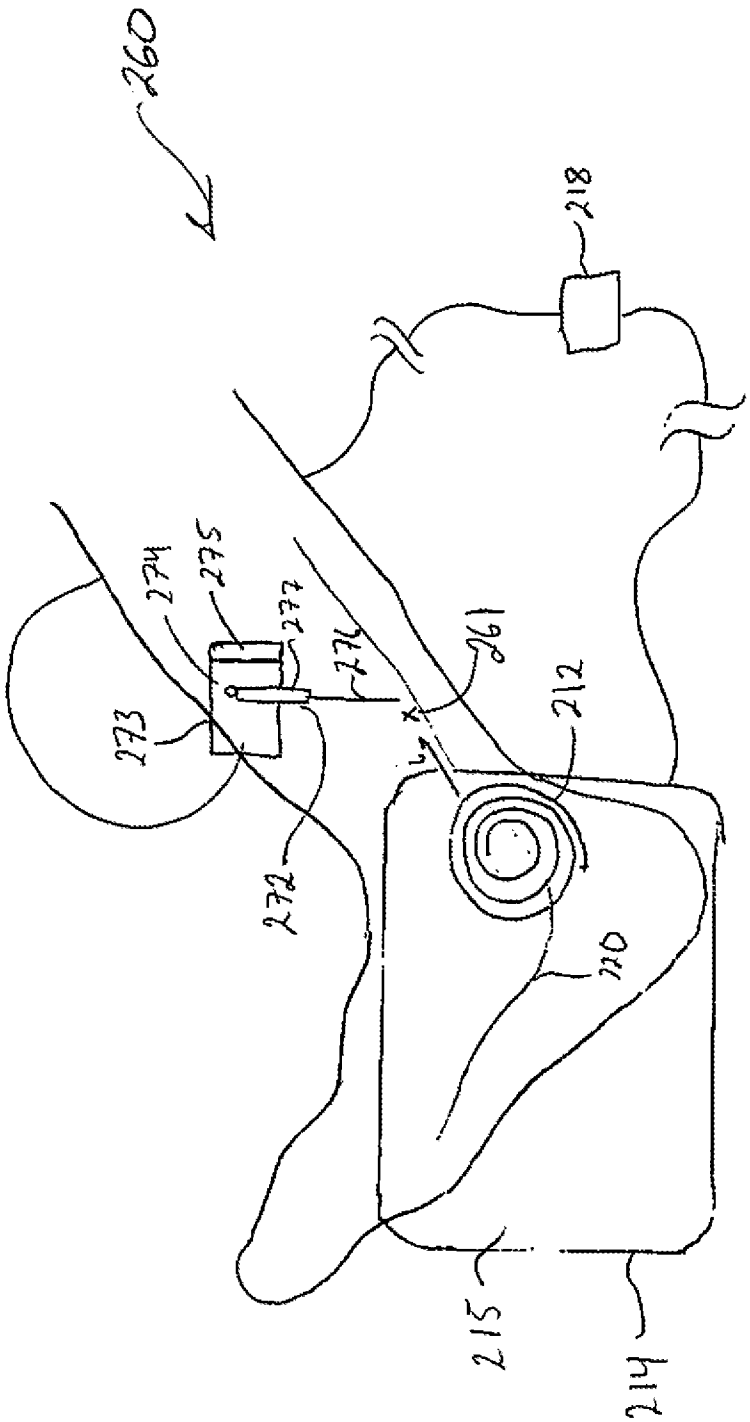


FIG 26

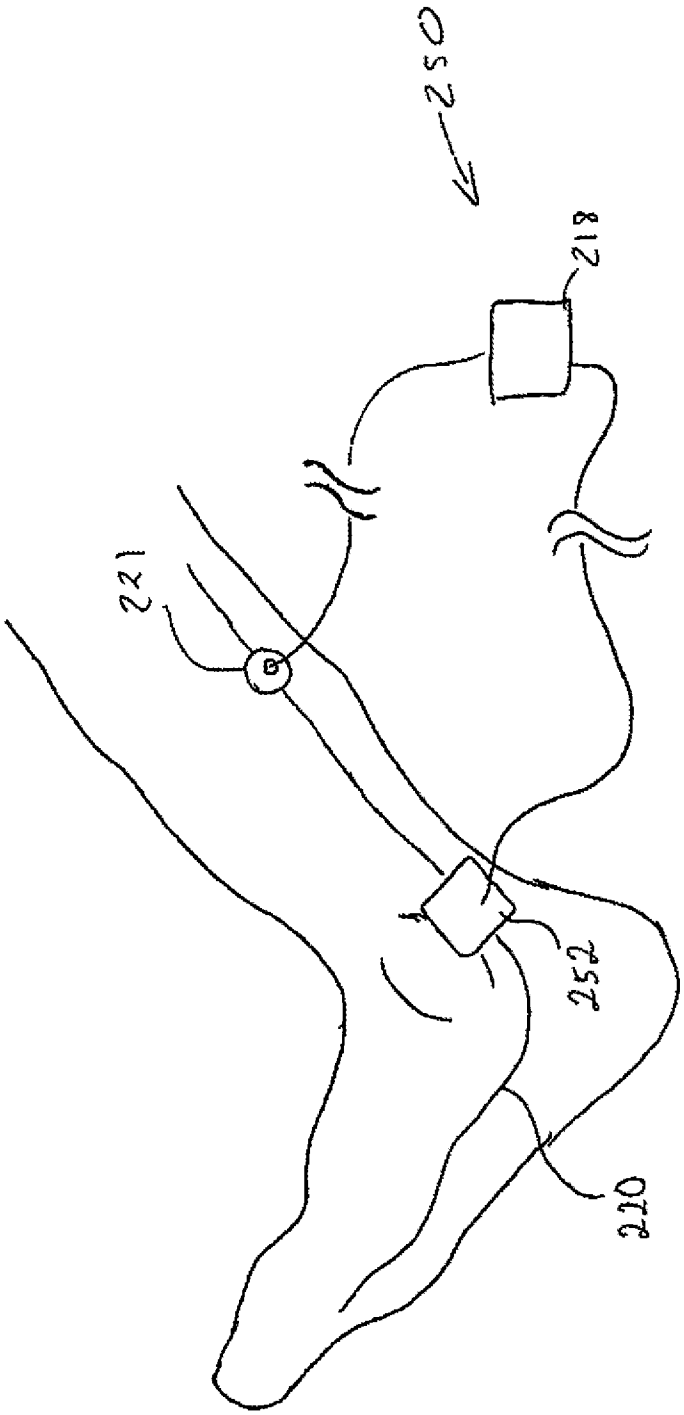


FIG 27

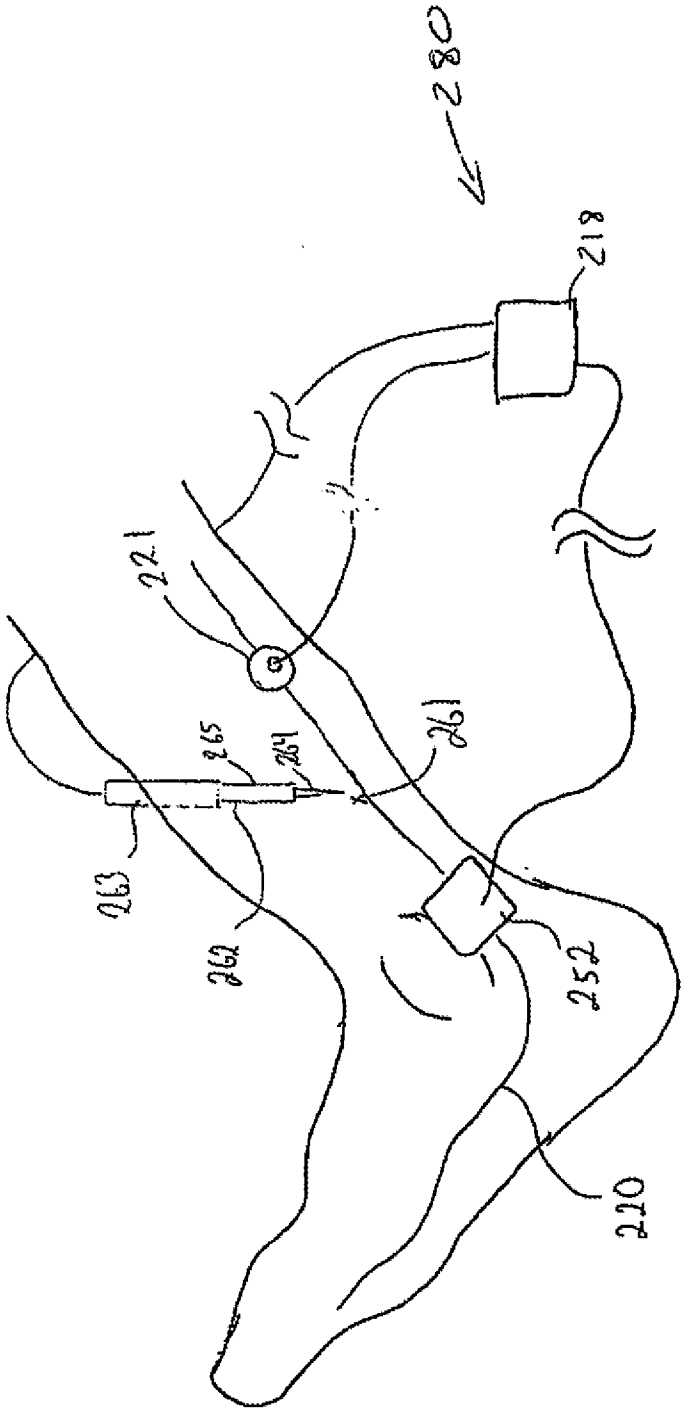
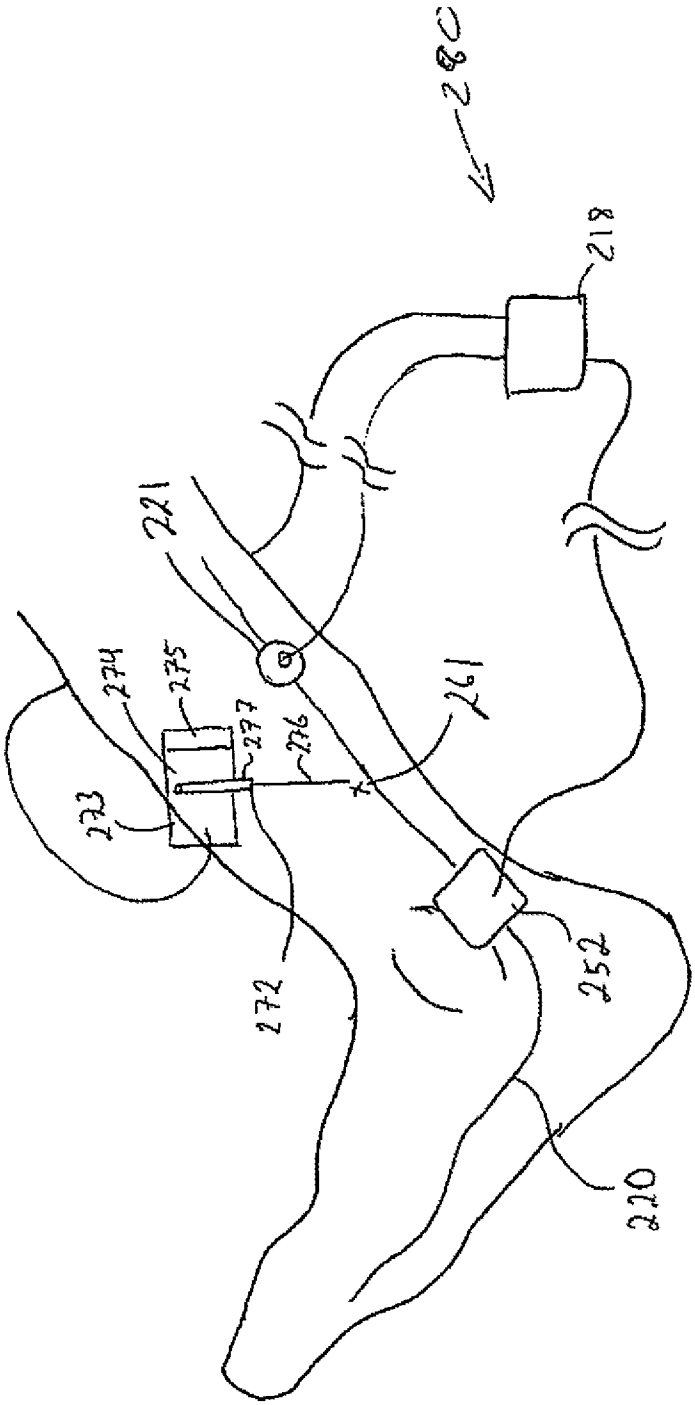


FIG 28



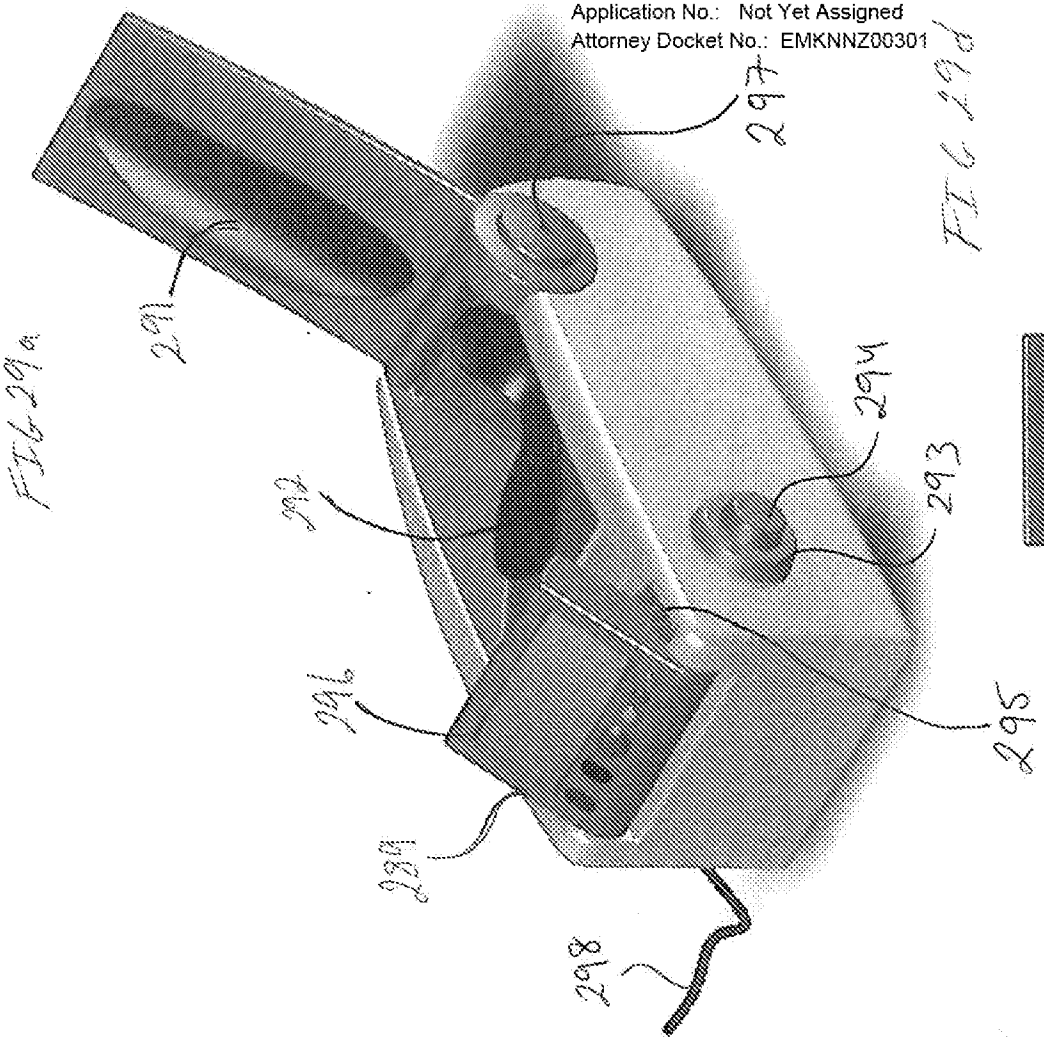



FIG 29a

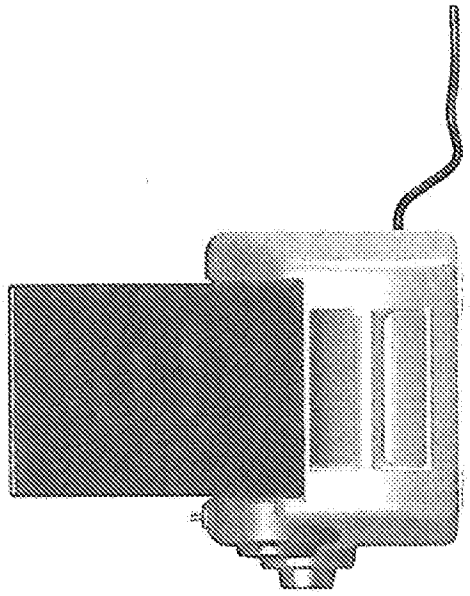


FIG 29d

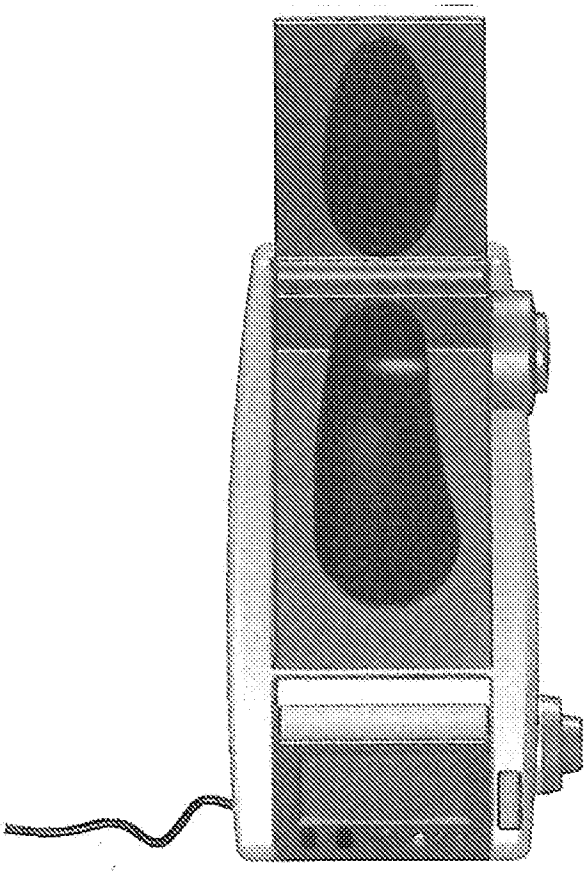


FIG 29b

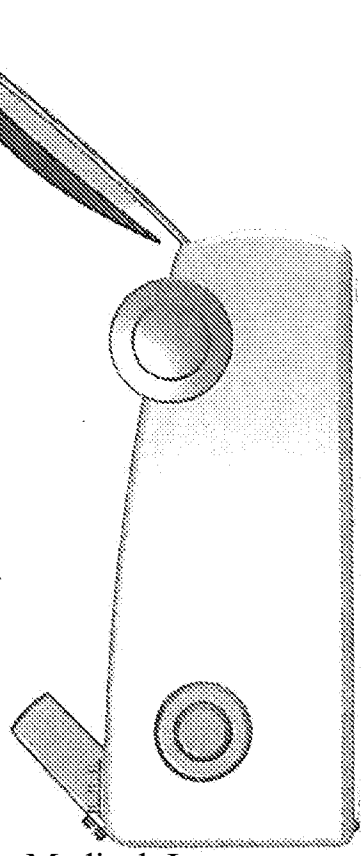
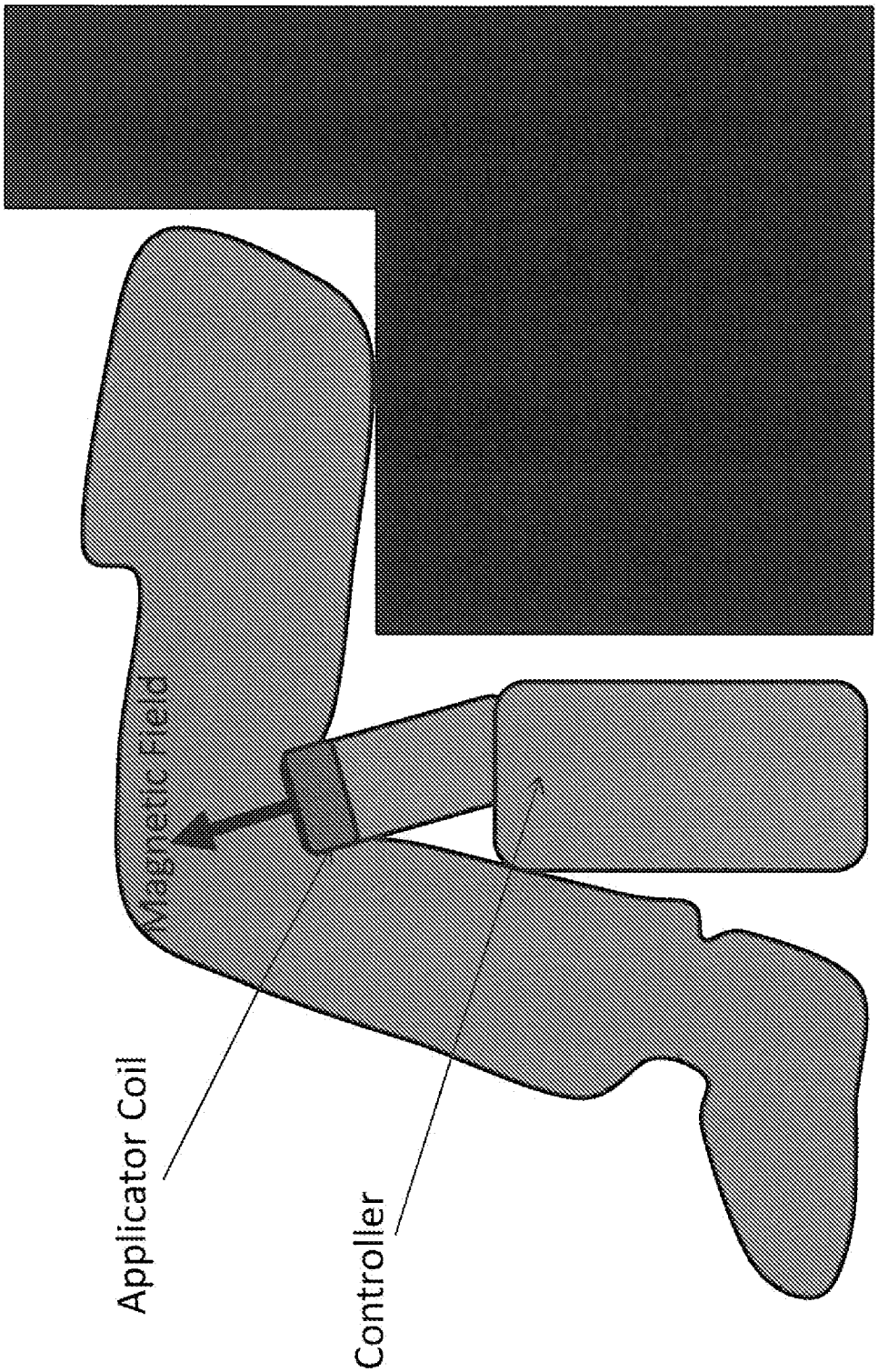
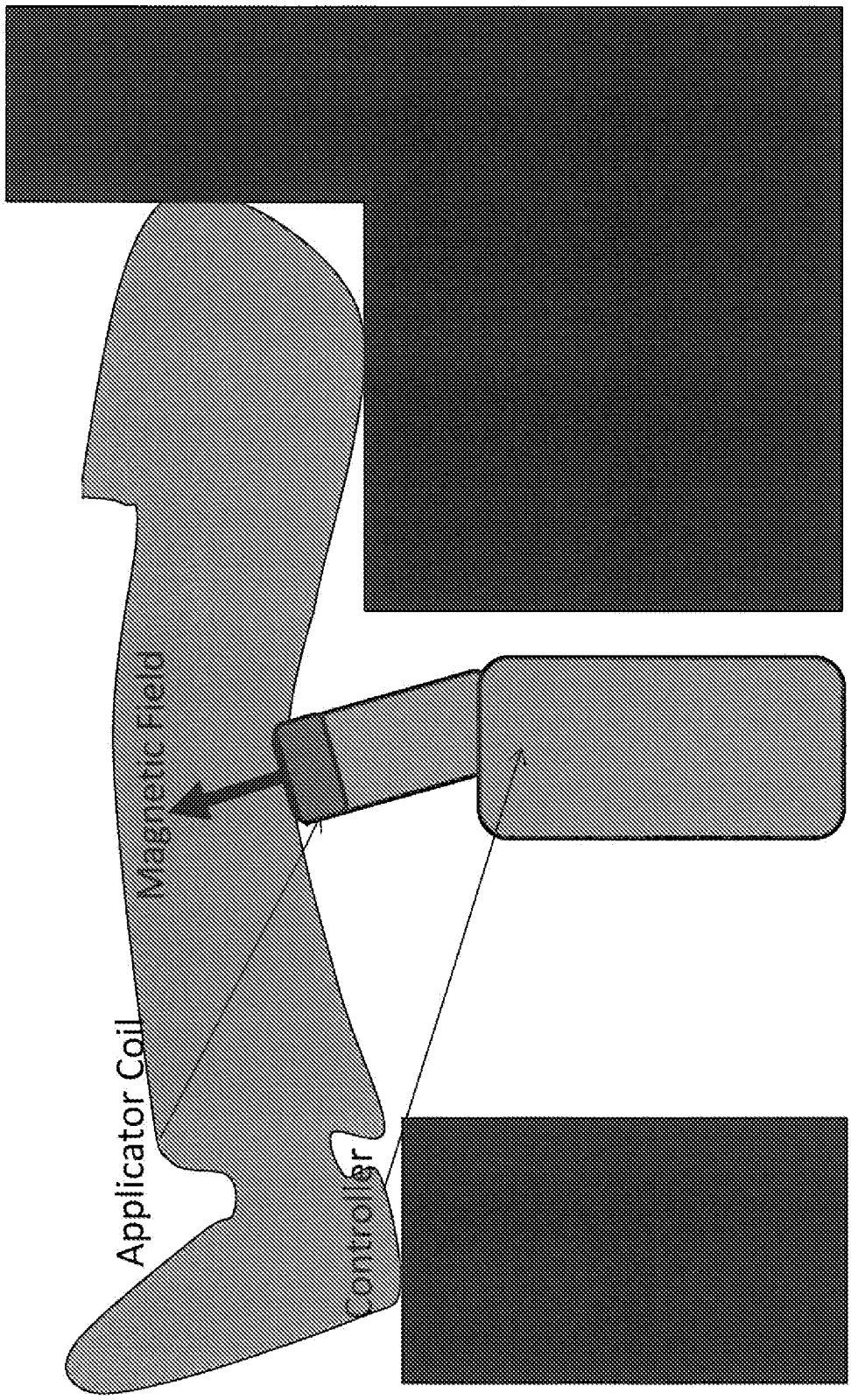


FIG 29c

03 9 52




Magnetic field
Applicator Coil
controller

# METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** The present application is a continuation-in-part of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007, which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006, each of which is incorporated herein by reference in its entirety.

## BACKGROUND

**[0002]** Overactive bladder ("OAB") and urinary incontinence ("UI") affect over 16% of the American population each year, or approximately 34 million men and women. Outside of the United States, OAB and UI affects over 46 million Europeans. The economic cost of OAB and UI is estimated to be in excess of $12 billion a year in the United States alone.

**[0003]** Due to the social stigmas attached to OAB and UI and to misunderstandings related to the symptoms associated with OAB and UI, only 40% of the affected individuals in the United States seek medical treatment. Of those 13.6 million Americans seeking medical treatment, nearly 30% or 4 million individuals are reportedly unsatisfied with their current therapy.

**[0004]** Known treatments for OAB and UI include exercise and behavioral modifications, pharmacological therapies, surgical intervention and neuromodulation, but each of these treatments exhibits severe limitations.

**[0005]** Exercise and behavioral modifications often require patients to adhere to stringent routines, including scheduled voiding, maintenance of a bladder diary, and intense exercise regimens. While this type of treatment may be a viable option for a small group of highly dedicated individuals, its daily impact on a person's life makes it unattractive for most patients.

**[0006]** Pharmacological intervention is the most widely prescribed therapy for OAB and UI. Unfortunately, patients often suffer from side effects related to their drug therapies. Such side effects are sometimes serious and are particularly pronounced in elderly patient populations that tend to use a plurality of medications. In addition, approximately 30% of all patients subjected to pharmacological therapies appear to be dissatisfied with the efficacy of their prescribed treatments.

**[0007]** Surgical intervention IS extremely invasive and often results in a long-term requirement for catheterization that may become permanent in some instances. The negative impact of these procedures on the patient's quality of life and their high expense make surgical intervention a recommended option only when all other treatment options have been exhausted.



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Ex. 1047, p. 25

**[0008]** Neuromodulation is another available therapy for OAB and UI. In general, pulsed electromagnetic stimulation ("PES") has proven to have beneficial effects in a variety of medical applications. The related scientific principle is that an electric current passing through a coil generates an electromagnetic field, which induces a current within a conductive material placed inside the electromagnetic field.

**[0009]** More particularly, PES has been shown to be an effective method of stimulating a nerve positioned within the electromagnetic field, thereby affecting a muscle controlled by that nerve. For example, in the paper titled "Contactless Nerve Stimulation and Signal Detection by Inductive Transducer" presented at the 1969 Symposium on Application of Magnetism in Bioengineering, Maass et al. disclosed that a nerve threading the lumen of a toroid could be stimulated by a magnetic field of 0.7 Volt peak amplitude and a 50 μs duration in a monitor wire, and that such stimulation could generate a contraction of major leg muscles in anesthetized mammals.

**[0010]** Various attempts were made in the prior art to use PES for treating a variety of ailments. For example, U.S. Patent No. 4,548,208 to Niemi discloses an apparatus for inducing bone growth by generating an electric current in the body through the external application of an electromagnetic field. Such apparatus includes opposing clamps disposed on a limb and may optionally include feedback coils and a microprocessor for sensing the magnetic field, so to avoid an overcurrent mode. Therefore, this apparatus optimizes the magnetic field on the basis of measurements of the generated magnetic field.

**[0011]** U.S. Patent No. 4,940,453 to Cadwell discloses a method and apparatus for magnetically stimulating the neural pathways of a higher level organism. In this invention, a sinusoidally fluctuating current flow is created through a coil that overlies neurons to be stimulated, and frequency of the current flow and frequency of the magnetic field produced by the coil predetermined to correspond to the time constant of the neurons to be stimulated. Sensors for sensing coil conditions, such as coil temperature, may also be included.

**[0012]** U.S. Patent No. 5,000,178 to Griffith discloses an electrical to electromagnetic transducer for applying electromagnetic energy to damaged parts of a living body by directing electromagnetic radiation to a certain damaged body part. Electromagnetic radiation is initially generated by a dipole consisting of a bar of high permeability material wrapped with an electrically conductive coil. Magnetic fields, which are generated away from the damaged body part, intersect a conductive shield and establish eddy currents, which in turn generate magnetic fields opposite and nearly equal to the magnetic fields generated by the electromagnetic source. The resultant



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Ex. 1047, p. 26

electromagnetic fields reinforce the electromagnetic field directed towards the damaged body part and diminish the electromagnetic field directed away from the damaged body part.

**[0013]** U.S. Patent No. 5,014,699 to Pollack et al. discloses a non-invasive, portable electromagnetic therapeutic method and apparatus for promoting the healing of damaged or diseased living tissue, including fractured bone. These method and apparatus involve generating a signal that has a series of substantially symmetric voltage cycles of bursted pulses with narrow pulse widths of 0.5 to 20 microseconds, and further involve converting the signal into an electromagnetic field extending into an area that contains tissue to be healed. This invention provides for no feedback on the efficiency of the applied stimulation.

**[0014]** In a paper titled "Selective Stimulation and Blocking of Sacral Nerves: Research Setup and Preliminary Results," published in Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vol. 13, No.2, 1991, Wijkstrda et al. used an external pulsed magnetic coil to stimulate a peripheral nerve for the treatment of urinary incontinence. The authors used a large magnetic field produced by a single coil to ensure that the nerve was fired and the resulting nerve conduction was frequently painful or intolerable. In addition, coil alignment was problematic because an internally implanted coil was utilized, which had to be aligned with the fully external magnetic field to stimulate the nerve. Due to the difficulty in positioning the device, the practical application of this therapy does not permit home healthcare usage without a preset alignment and monitoring of the nerve, and no provision was made to insure that the nerve was actually being stimulated or to adjust the device in response to commonly occurring physiologic and anatomic variations in nerve locations.

**[0015]** U.S. Patent Nos. 5,181,902 Erickson et al. and 5,314,401 to Tepper disclose pulsed electromagnetic field ("PEMF") transducer systems usable to perform PEMF therapies (such as after spinal fusion) by generating flux-aided electromagnetic fields. The drive electronics includes a PEMF processor that executes a PEMF program for controlling the activation of the electromagnetic fields (field strength and cycle).

**[0016]** In a paper titled: "Magnetic Stimulation of the Bladder in Dogs" presented at the 1993 AAEM Annual Meeting, the abstract of which was published in the Muscle & Nerve issue of October 1993, Lin et al. disclosed that magnetic stimulation could be employed to stimulate the cortex, spinal nerves and peripheral nerves of dogs through direct trans-abdominal stimulation of the detrusor muscles or through stimulation of the lumbosacral roots.

**[0017]** As shown, the prior art makes no provision to measure the efficacy of PES treatment, causing patients to be treated improperly, either by an insufficient or excessive exposure to PES. Other attempts to monitor PES dosage in the prior art exhibit serious drawbacks. For



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example, U.S. Patent No. 5,518,495 to Kot discloses an apparatus for the treatment of arthritis utilizing a magnetic field therapy, which includes an adjustable voltage source that is connected to a source of line voltage and a coil connected to the adjustable voltage source. This apparatus has no feedback system to advise a healthcare provider of the efficiency of the treatment.

**[0018]** U.S. Patent No. 5,984,854 to Ishikawa et al. discloses a method for treating urinary incontinence based on delivering a train of current pulses through one or more magnetic stimulation coils so to induce a train of magnetic flux pulses, which then induce an eddy current within the body and stimulates a group of pelvic floor muscles, the pudendal nerve, the external urethral sphincter, or the tibial nerve. While this method includes the use of pulsed electromagnetic for treating urinary incontinence, no specific components are envisioned to facilitate the placement of the magnetic coils over a targeted region of the body or a system for monitoring the efficiency of the therapy being applied.

**[0019]** U.S. Patent No. 6,086,525 to Davey et al. discloses a magnetic nerve stimulator that includes a core constructed from a material having a high field saturation having a coil winding disposed thereon. A thyrister capacitive discharge circuit pulses the device, and a rapidly changing magnetic field is guided by the core, preferably made from vanadium permendur.

**[0020]** U.S. Patent No. 6,701,185 to Burnett et al. also discloses an electromagnetic stimulation device that includes a plurality of overlapping coils, which can be independently energized in a predetermined sequence such that each coil will generate its own independent electromagnetic field and significantly increase the adjacent field. Unfortunately, none of these patents provides a system for monitoring the efficiency of the therapy in progress, either with respect to the proper positioning of the winding over the area to be treated or of the intensity of the magnetic field to be applied.

**[0021]** Other PES therapies require the implantation of devices into the patient, with the consequent discomfort, risk and cost to the patient. For example, U.S. Patent No. 6,735,474 to Loeb et al. discloses a method and system for treating UI and/or pelvic pain by injecting or laparoscopically implanting one or more battery-or radio frequency-powered microstimulators that include electrodes placed beneath the skin of the perineum and/or adjacent the tibial nerve.

**[0022]** U.S. Patent 6,941,171 to Mann et al. describes a method and a system for treating incontinence, urgency, frequency, and/or pelvic pain that includes implantation of electrodes on a lead or a discharge portion of a catheter adjacent the perineal nerve(s) or tissue(s) to be stimulated. Stimulation pulses, either electrical or drug infusion pulses, are supplied by a stimulator implanted remotely through the lead or catheter, which is tunneled subcutaneously between the stimulator and stimulation site.



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**[0023]** Other PES therapies in the prior art involve the use of electrodes placed on or beneath the skin of a patient. Recent data on invasive, needle-based PES of the posterior tibial nerve in individuals with OAB and UI indicates that PES can modulate bladder dysfunction through its action on the pudendal nerve and the sacral plexus, which provide the major excitatory input to the bladder.

**[0024]** In a paper titled "Percutaneous Tibial Nerve Stimulation via Urgent® PC Neuromodulation System -An Emerging Technology for managing Overactive Bladder," which was published in Business Briefing: Global Surgery 2004, CystoMedix, Inc. disclosed that peripheral tibial nerve stimulation ("PTNS") had been found effective in treating OAB. The disclosed procedure involved the use of electrode and generator components, including a small 34-gauge needle electrode, lead wires and a hand-held electrical generator. However, the procedure requires the permanent implantation of an electrical stimulation device in the patient. One estimate put the cost of treatment at nearly $14,000 with additional routine care costs of $593 per patient per year. Additionally, risks of battery failure, implant infection, and electrode migration led to a high re-operation rate and made this procedure unattractive.

**[0025]** U.S. Patent No. 7,117,034 to Kronberg discloses a method for generating an electrical signal for use in biomedical applications that includes two timing-interval generators. In this invention, skin-contact electrodes may be placed over an area of interest and a microprocessor may direct timing and sequencing functions, although such timing and sequencing functions are not related to the actual efficacy of the treatment while treatment is being performed.

**[0026]** U.S. Patent Application Publication No. 2005/0171576 to Williams et al. discloses an electro-nerve stimulation apparatus that includes a pulse generator, a first electrically conductive, insulated lead wire, a second electrically conductive, insulated lead wire, an electrically conductive transcutaneous electrode and an electrically conductive percutaneous needle electrode. Connected to one end of the first and second lead wires is a connector for electrically coupling with the pulse generator. In this invention, a percutaneous needle electrode is inserted through the skin in proximity to the desired internal stimulation site and electric stimulation is employed, rather than pulsed electromagnetic stimulation. Moreover, the Williams invention does not contemplate mechanisms for facilitating use of the device by an untrained user, nor a monitoring of the applied therapy.

**[0027]** A neuromodulation alternative is a posterior tibial nerve stimulator, often referred to as SANS, but as is the case with other forms of neuromodulation, this procedure is invasive in nature and requires the insertion of a needle five centimeters into the patient's ankle region to stimulate the posterior tibial nerve. This procedure also requires a minimum of twelve sessions for initial treatment, possibly with additional sessions required for maintenance.



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[0028] Also, therapies involving the use of traditional insertable or implantable percutaneous needles require penetration into deeper tissues and carry with them the added risk of infection, while causing pain and discomfort to the patient. This often results in ineffective treatment and or reduced patient compliance.

## SUMMARY

[0029] In certain embodiments, apparatus and methods for magnetic induction therapy, in which dosage of magnetic energy can be regulated according to conduction in a target nerve exposed to the magnetic field are provided.

[0030] In certain embodiments, apparatus and methods for magnetic induction therapy, in which the flow of magnetic energy can be adjusted directionally by the patient or a healthcare provider without altering the position of a housing containing conductive coils that produce the magnetic field are provided.

[0031] In certain embodiments, apparatus and methods for treating a variety of ailments by providing energy to a target nerve, for example magnetic energy, electrical energy or ultrasound energy, at a location and in an amount optimized by detecting conduction in the target nerve are provided.

[0032] In certain embodiments, an energy emitting apparatus for delivering a medical therapy that includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors for detecting electric conduction in a target nerve, which are connected to the logic controller is provided. The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is varied by the logic controller according to an input provided by the one or more sensors based on electric conduction in the target nerve. The feedback provided by the sensors to the logic controller about the efficacy of the applied treatment causes the logic controller to modulate the current transmitted to the coils.

[0033] The applied energy may be a magnetic field, an electrical field, an ultrasound, a visible light, or an infrared or an ultraviolet energy. When a magnetic field is applied, the energy-emitting device is an apparatus that provides a magnetic induction therapy and that includes one or more conductive coils disposed in an ergonomic housing. A logic controller is electrically connected to the one or more coils, and one or more sensors detect electric conduction in the target nerve and are connected to the logic controller so to provide a feedback to the logic controller. The conductive coils receive an electric current from the logic controller and produce a magnetic field focused on a target nerve, and the electric current fed by the logic controller is varied by the logic controller



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according to an input provided by the sensors, thereby causing amplitude, frequency or direction of the magnetic field, or the firing sequence of the one or more coils, to be varied according to the efficiency of the treatment provided to the target nerve. In certain embodiments, the housing containing the conductive coils may be a flexible wrap, a cradle or a garment, and the coils may be overlapping and/or be disposed in different positions within the housing, so to generate a magnetic field on different body parts with the desired direction and amplitude.

**[0034]** The one or more coils may be stationary or movable within the housing, making it possible to optimize the direction of magnetic flow to the target nerve by disposing the coils in the most effective direction. In different embodiments, the coils may be movable manually by acting on a knob, lever, or similar type of actuator, or may be translated automatically by the logic controller in response to the input provided by the sensors. When a preferred position for the coils has been established, the coils may be locked in position and maintain that position during successive therapy sessions. In other embodiments, the sensors may be incorporated within the housing, or instead may be disposed on a body part of interest independently of the housing.

**[0035]** In still other embodiments, the inductive coils are disposed in a housing that is situated externally to a patient's body, and additional inductive coils are implanted into the body of the patient and are magnetically coupled to the external inductive coils. With this coil arrangement, energy may be transmitted from the external coils to the internal coils either to recharge or to activate an implantable device. In yet other embodiments, the electric current may varied by the logic controller both on the basis of an input provided by the one or more sensors and also an input provided by the patient according to a muscular response she has perceived, for example, the twitching of a toe after application of the magnetic field.

**[0036]** In yet other embodiments, the source of energy for nerve stimulation may be electrical energy and nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli. In these embodiments, direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues. Furthermore, these embodiments enable a reduction in power requirement, because control of the signal is provided by the sensor to the signal generator loop.

**[0037]** In other embodiments, an energy emitting system for providing a medical therapy is provided. The system may include one or more conductive coils disposed within or along a housing and configured to generate a magnetic field focused on a target nerve in proximity to coils; one or more sensors in the form of microneedle patch configured to detect electrical conduction in the target



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nerve; and a controller coupled to the conductive coils and optionally in communication with the sensor.

**[0038]** In other embodiments, an energy emitting system for providing a medical therapy is provided. The system may include one or more microneedle patches having one or more microneedle arrays deposited on a surface of one or more electrodes and configured to generate or deliver an electrical or magnetic stimulus or field focused on a target nerve in proximity to the microneedle patch; one or more sensors configured to detect electrical conduction in the target nerve; and a controller coupled to the conductive coils and optionally in communication with the sensor. Optionally, the above embodiments may incorporate an electrode needle. Optionally, the above embodiments or systems may be utilized without a sensor or mechanism for detecting conduction or stimulation.

**[0039]** Methods of use of the above apparatus, systems and variations thereof for treating various conditions are also described herein.

**[0040]** Other features and advantages will appear hereinafter. The features and elements described herein can be used separately or together, or in various combinations of one or more of them.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0041]** The drawings constitute a part of this specification and include exemplary embodiments of the invention, which may be embodied in various forms. It is to be understood that in some instances various aspects of the embodiments may be shown exaggerated or enlarged to facilitate an understanding of the embodiments.

**[0042]** FIG. 1 is a schematic view of an apparatus for magnetic induction therapy according to a first embodiment of the invention.

**[0043]** FIG. 2 is a schematic view of an apparatus for magnetic induction therapy according to a second embodiment of the invention.

**[0044]** FIG. 3 is a schematic view of an apparatus for magnetic induction therapy according to a third embodiment of the invention.

**[0045]** FIG. 4 is a schematic view of an apparatus for magnetic induction therapy according to a fourth embodiment of the invention.

**[0046]** FIG. 5 is a schematic view of an apparatus for magnetic induction therapy according to a fifth embodiment of the invention.



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**[0047]** FIGS. 6A-6D are schematic illustrations depicting a first method of use of an apparatus for magnetic induction therapy. This method is based on adjusting the position of the conductive coils so to optimize a magnetic flow applied to a target nerve.

**[0048]** FIGS. 7A-7D are schematic illustrations of a second method of use of an apparatus for magnetic induction therapy. This method is based on locking the conductive coils in position once electrical conduction in a target nerve has been detected.

**[0049]** FIG. 8 is a schematic view of an embodiment of the invention that includes a plurality of sensors.

**[0050]** FIGS. 9A-9D are schematic representations of different garments adapted to operate as apparatus for magnetic induction therapy according to the principles of the present invention.

**[0051]** FIGS. 10 is a schematic view of an apparatus for providing electrical stimulation.

**[0052]** FIG. 11 is a schematic view of another embodiment of an apparatus for providing electrical stimulation.

**[0053]** FIG. 12 shows a schematic view of an energy emitting system including a microneedle patch sensor.

**[0054]** FIG. 13-15 shows magnified bottom views of various embodiments of microneedle patches.

**[0055]** FIGS. 16-17 shows magnified side views of various embodiments of a microneedle patch.

**[0056]** FIG. 18 shows a magnified bottom perspective view of a microneedle patch.

**[0057]** FIG. 19 shows a representative cross sectional view of the skin composed of an outer stratum corneum covering the epidermal and dermal layers of skin and the underlying subcutaneous tissue, with a variation of a microneedle patch attached thereto.

**[0058]** FIG. 20 shows a magnified side view of a variation of a microneedle patch including multiple electrodes.

**[0059]** FIG. 21 shows a schematic view of an energy emitting system including a microneedle patch sensor placed behind a subject's knee.

**[0060]** FIGS. 22-23 show schematic views of energy emitting systems including an electrode needle and sensor.

**[0061]** FIGS. 24-25 show schematic views of energy emitting systems including an electrode needle without a sensor.

**[0062]** FIG. 26 shows a schematic view of an energy emitting system including a microneedle patch for providing stimulation.



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**[0063]** FIGS. 27-28 show schematic views of energy emitting systems including an electrode needle and microneedle patch for providing stimulation.

**[0064]** FIG. 29a-29d show a prospective, side, top and rear views of an energy emitting device in the form of a foot cradle.

**[0065]** FIGS 30-31 show schematic views of an energy emitting device in the form of a knee cradle.

## DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

**[0066]** Detailed descriptions of embodiments of the invention are provided herein. It is to be understood, however, that the present invention may be embodied in various forms. Therefore, the specific details disclosed herein are not to be interpreted as limiting, but rather as a representative basis for teaching one skilled in the art how to employ the present invention in virtually any detailed system, structure, or manner.

**[0067]** Various embodiments of the invention will now be described. The following description provides specific details for a thorough understanding and enabling description of these embodiments. One skilled in the art will understand, however, that the embodiments may be practiced without many of these details. Additionally, some well-known structures or functions may not be shown or described in detail so as to avoid unnecessarily obscuring the relevant description of the various embodiments.

**[0068]** The terminology used in the description presented below is intended to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain specific embodiments of the invention. Certain terms may even be emphasized below. Any terminology intended to be interpreted in any restricted manner, however, will be overtly and specifically defined as such in this detailed description section.

**[0069]** Where the context permits, singular or plural terms may also include the plural or singular term, respectively. Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of items in the list.

**[0070]** Referring first to FIG. 1, a first embodiment of the invention includes a coil wrap 20, which is depicted as disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24. Because tibial nerve 24 is targeted, this embodiment is particularly suited for the treatment of OAB and VI. In other embodiments of the invention, coil wrap 20 may be configured to surround other body parts that contain a portion of tibial nerve 24 or of other nerves branching from or



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connected to tibial nerve 24, still making these embodiments suitable for treating OAB and VI. In still other embodiments of the invention, coil wrap 20 may be configured for surrounding body parts that contain other nerves when treatments of other ailments are intended.

**[0071]** Coil wrap 20 may be manufactured from a variety of materials suitable for wearing over ankle 22. Preferably, coil wrap is produced from a soft, body-compatible material, natural or synthetic, for example, cotton, wool, polyester, rayon, Gore-Tex®, or other fibers or materials known to a person skilled in the art as non-irritating and preferably breathable when tailored into a garment. Coil wrap 22 may even be manufactured from a molded or cast synthetic material, such as a urethane gel, to add extra comfort to the patient by providing a soft and drapable feel. Additionally, coil wrap 20 may be produced from a single layer of material or from multiple material layers and may include padding or other filling between the layers.

**[0072]** Coil wrap 20 contains one or more conductive coils 26 arranged to produce a pulsed magnetic field that will flow across tibial nerve 24 and generate a current that will flow along tibial nerve 24 and spread along the length of tibial nerve 24 all the way to its sacral or pudendal nerve root origins. Coils 26 may be a single coil shaped in a simple helical pattern or as a figure eight coil, a four leaf clover coil, a Helmholtz coil, a modified Helmholtz coil, or may be shaped as a combination of the aforementioned coils patterns. Additionally, other coil designs beyond those mentioned hereinabove might be utilized as long as a magnetic field is developed that will encompass tibial nerve 24 or any other target nerve. When a plurality of coils is utilized, such coils may be disposed on a single side of ankle 22, or may be disposed on more than one side, for example, on opposing sides, strengthening and directionalizing the flow of the magnetic field through tibial nerve 24 or other peripheral nerves of interest.

**[0073]** Coil wrap 20 is preferably configured as an ergonomic wrap, for example, as an essentially cylindrical band that can be pulled over ankle 22, or as an open band that can be wrapped around ankle 22 and have its ends connected with a buckle, a hoop and loop system, or any other closing system known to a person skilled in the art. By properly adjusting the position of coil wrap 20 over ankle 22, a patient or a health care provider may optimize the flow of the magnetic field through tibial nerve 24, based on system feedback or on sensory perceptions of the patient, as described in greater detail below.

**[0074]** The electric current that produces the magnetic field by flowing through coils 26 is supplied by a programmable logic controller 28, which is connected to coils 26, for example, with a power cord 32. A sensor 30 that feeds information to logic controller 28 is also provided, in order to tailor the strength of the magnetic field and control activation of coils 26 based on nerve conduction. The purpose of sensor 30 is to detect and record the firing of the target nerve and to provide related



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information to logic controller 28, so to render the intended therapy most effective. For example, sensor input may cause logic controller 28 to alter the strength or pulse amplitude of the magnetic field based on sensor input, or fire the coils in a certain sequence.

**[0075]** In this embodiment, as well as in the other embodiments described hereinafter, sensor 30 may include one or more sensor patches and may be placed at different distances from the region of direct exposure to the magnetic field. For example, sensor 30 may be configured as a voltage or current detector in the form of an EKG patch and may be placed anywhere in the vicinity of the target nerve to detect its activation. For ease of description, the term "coils" will be used hereinafter to indicate "one or more coils" and "sensor" to indicate "one or more sensors," unless specified otherwise.

**[0076]** By virtue of the above described arrangement, coil wrap 20 provides a reproducibly correct level of stimulation during an initial therapy session and during successive therapy sessions, because the presence or absence of nerve conduction is detected and, in some embodiments, measured when coil wrap 20 is first fitted and fine-tuned on the patient. In addition to properly modulating the applied magnetic field, the positioning of coils 26 over ankle 22 may also be tailored according to the input provided by sensor 30, so to fine-tune the direction of the magnetic field. Such an adjustment of the direction, amplitude, and level of the stimulation provided to the target nerve through the above described automated feedback loop, to ensure that peripheral nerve conduction is being achieved, is one of the key features.

**[0077]** If the magnetic pulse does not substantially interfere with sensor 30, sensor 30 may be placed directly within the field of stimulation, so that power supplied to the system may be conserved. This is particularly important for battery-powered systems. Alternatively, sensor 30 may also be placed at a distance from the magnetic field and still properly detect neural stimulation.

**[0078]** In a method of use of coil wrap 20, the amplitude and/or firing sequence of coils 26 may be ramped up progressively, so that the magnetic field is increased in strength and/or breadth until nerve conduction is detected, after which the applied stimulus is adjusted or maintained at its current level for the remainder of the therapy. The level of stimulation may be also controlled through a combination of feedback from sensor 30 and feedback based on perceptions of the patient. For example, the patient may activate a switch once she perceives an excessive stimulation, in particular, an excessive level of muscular stimulation. In one instance, the patient may be asked to push a button or turn a knob when she feels her toe twitching or when she experiences paresthesia over the sole of her foot. The patient will then continue pressing the button or keep the knob in the rotated position until she can no longer feel her toe twitching or paresthesia in her foot, indicating that that level of applied stimulation corresponds to an optimal therapy level. From that point on, the



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patient may be instructed to simply retain her foot, knee, or other limb within coil wrap 20 until therapy has been terminated while the system is kept at the optimal level. Adding patient input enables control of coil wrap 20 during outpatient treatments, because the patient is now able to adjust the intensity of the magnetic field herself beyond the signals provided to logic controller 28 by sensor 30.

**[0079]** Detecting and, if the case, measuring conduction in one or more nerves along the conduction pathways of the stimulated nerve confirms that the target nerve has been stimulated, providing an accurate assessment of the efficiency of the applied therapy on the patient. A concomitant detection of muscle contraction may also confirm that the target nerve is being stimulated and provide an indication to the patient or to a healthcare provider as to whether stimulation has been applied at an excessive level in view of the anatomical and physiological characteristics of the patient.

**[0080]** Based on the foregoing, coil wrap 20 allows for a consistent, user-friendly targeting and modulation of the peripheral nerves via the posterior tibial nerve on an outpatient basis, in particular, the targeting and modulation of the pudendal nerve and of the sacral plexus. When multiple coils 26 are present, coils 26 may be activated simultaneously or differentially to generate the desired magnetic field. The direction and location of each of coils 26 may be reversibly or irreversibly adjusted by the healthcare provider or by the patient, customizing the location of the applied stimulation to the anatomy and therapy needs of each patient. After a healthcare provider has optimized position and firing sequence for each of coils 26, the patient may be sent home with coil wrap 20 adjusted to consistently target the desired nerve. In one variant of the present embodiment, an automatic feedback system adjusts one or more of firing sequence, firing strength or position of coils 26 within coil wrap 20 during the initial setup and also during successive therapy sessions.

**[0081]** In summary, certain embodiments include the creation of a loop consisting of feeding information on nerve conduction to logic controller 28 and on logic controller 28 tailoring the electrical current sent to coil wrap 20 according to the information received from sensor 26 based on whether or not the nerve is receiving the desired stimulation and, in some embodiments, the desired amount of stimulation. This arrangement offers an unparalleled level of therapy control and flexibility within a home care setting, because a consistent, repeatable stimulation of the target nerve can be attained. Aside from adjusting the position of coils 26 in accordance with the patient's anatomy and physiological variations, controlling pulse amplitude is also of great importance even during different therapy sessions with the same patient. For example, a patient with leg edema will encounter difficulties in properly adjusting coil wrap 20 based on whether her legs and ankles are swollen or not swollen, and the power required to penetrate to posterior tibial nerve 24 (in the case of



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a VI therapy) will vary greatly due to the variable depth of the nerve. Thus, having feedback provided by sensor 26 becomes a necessity for achieving an accurate dosage of the treatment rather than an option. Benchtop testing has demonstrated that a system constructed according to the present invention is capable of non-invasively generating electrical currents similar to those found in therapeutic electro-stimulation and to do so in different settings.

**[0082]** Referring now to FIG. 2, a second embodiment of the invention will be described with reference to a coil wrap 34 disposed over ankle 36 for the purpose of treating VI by targeting tibial nerve 38. In this second embodiment, one or more Helmholtz coils 40 are disposed within coil wrap 34 to create a more narrowly directed magnetic field over tibial nerve 38. Like in the all other embodiments described herein, more than one coil (in the present embodiment, more than one Helmholtz coil 40) may be placed within coil wrap 34 and be disposed in different positions within coil wrap 34, in order to optimize magnetic flux over tibial nerve. For example, two Helmholtz coils may be disposed one opposite to the other within coil wrap 34.

**[0083]** Having coil windings arranged along a common longitudinal axis, as required in a Helmholtz coil configuration, generates a more focused magnetic field and a more accurate targeting of tibial nerve 38 or of any other nerve. Like in the previous embodiment, the operation of coils 40 is controlled by a logic controller 42, which is in turn connected to sensor 44 that monitors conduction in tibial nerve 44 and that generates a feedback to logic controller 42 about the efficiency of the therapy in progress. Therefore, like in the previous embodiment, the coupling of sensor 44 with logic controller 42 optimizes operation of coil wrap 34 according to results measured at the level of tibial nerve 38. Also like in the previous embodiment, manual adjustments to the parameters of electric current provided by logic controller 42 to Helmholtz coil 40 may also be made manually by the patient or by a healthcare provider, and coil wrap 34 may be structured so that the position of Helmholtz coil 40 within coil wrap 34 is adjusted as desired either manually by the patient or by a healthcare provider, or automatically by logic controller 42.

**[0084]** Referring now to FIG. 3, a third embodiment of the invention includes a coil wrap 46 configured for wrapping over the popliteal fossa of a patient, in the region of the knee, to stimulate the posterior tibial nerve (not shown). The configuration and structure of coil wrap 46 reflect the body portion covered by coil wrap 46, but the key system components of coil wrap 46, such as the type, number and disposition of the coils (for example, the use of overlapping coils); the connections of the coils with a logic controller; and the use of one or more sensors (also not shown) to detect nerve conduction are all comparable to those in the previously described embodiments.

**[0085]** Referring now to FIG. 4, a fourth embodiment of the invention includes a footrest or foot cradle 48, which is structured to contain at least a portion of a foot 50. One or more coils 52 are



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enclosed within cradle 48, and a sensor 54 is disposed along the pathway of tibial nerve 55, sensing conduction in tibial nerve 55, and is also connected to a logic controller 56. Coils 52, sensor 54 and logic controller 56 may be arranged in different configurations, in the same manner as in the preceding embodiments.

**[0086]** Cradle 48 may be made from a variety of materials and may be monolithic, or have a hollow or semi-hollow structure to enable the movement of coils 52 within cradle 48, as described in greater detail below. Preferably, cradle 48 has an ergonomically design allowing the ankle and heel of the patient to be retained within cradle 48, in a position that matches the positions of stimulating coils 52 to the area of stimulation. The design of cradle 48 provides for a particularly comfortable delivery of therapy to patients that prefer to remain seated during their therapy, and enables the patient to perform the required therapy within a health care facility, or to take cradle 48 home, typically after an initial session and appropriate training in a health care facility. In that event, the patient will be trained to apply sensor 54 autonomously and to adjust stimulation to a comfortable level.

**[0087]** FIG. 4 shows coils 52 disposed as overlapping and the use of a single sensor patch 54 positioned proximally to the stimulation site. However, coil 52 may be configured as a single coil, a figure eight coil, a four leaf clover coil, a Helmholtz coil, a modified Helmholtz coil or a any combination of the aforementioned coils, or as any other coil design providing an effective stimulation to the target nerve. In addition, coils 52 may be fired individually, sequentially or simultaneously according to the feedback provided by sensor 54.

**[0088]** In one variant of this embodiment, sensor 54 may include a conductive electrode patch that provides a feedback to logic controller 56 for adjusting, if necessary, the stimulation parameters of coils 52. Alternatively, sensor 54 may be a sensor patch that is either applied to the skin of the patient or is incorporated within the structure of cradle 48.

**[0089]** Referring now to FIG. 5, a fifth embodiment of the invention includes a knee rest or knee cradle 58 that contains one or more conductive coils 60, one or more sensors 62 and a logic controller 64. The components of this embodiment are similar to those described with reference to the preceding embodiments, as regards the structure and materials of cradle 58, the nature and disposition of coils 60, the type and operation of sensor 62, and the function and operation of logic controller 64. Cradle 58 is configured to target the popliteal fossa of the patient, thus to target tibial nerve 66. In that respect, the present embodiment is similar to the embodiment illustrated in FIG. 3, but while the embodiment of FIG. 3 is configured as a wrap that may be worn while the patient is standing, the present embodiment is configured as a cradle that is more suited for treatment while the patient is sitting or laying down.



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**[0090]** A method of use of the foot cradle depicted in FIG. 4 is described with reference to FIGS. 6A-6D. During a first step illustrated in FIG. 6A, foot 68 is disposed in cradle 70 that contains one or more conductive coils 72, which are connected to a logic controller (not shown) that manages the flow of electric power to coils 72.

**[0091]** During a second step illustrated in FIG. 6B, a sensor 74 is disposed on foot 68 or on ankle 76 or on another appropriate portion of the patient's body, in order to detect conductivity in tibial nerve 78 or in another target nerve.

**[0092]** During a third step illustrated in FIG. 6C, a healthcare provider analyzes conductivity measurements provided by sensor 74 (for example, by reading gauge 77) and first adjusts the positioning of coils 72 until conduction in nerve 78 is detected. For example, the healthcare provider may rotate a knob 80, slide a lever or actuate any other displacement system for coils 72 that is known in the art, so that coils 72 are translated until a magnetic field of the proper amplitude and intensity is applied to cause conduction in nerve 78. The position of coils 72 is then fine-tuned manually until an optimal level of conduction in nerve 78 is attained, and the therapy is continued for a length of time as prescribed by the attending healthcare provider.

**[0093]** During a fourth, optional step illustrated in FIG. 6D, settings for successive therapy sessions are set, for example by locking knob 80 (in one embodiment, with a pin 81) so that the healthcare provider or the patient repeat the therapy using the predetermined settings. Alternatively, the patient may be trained to adjust the amplitude and/or strength of the applied magnetic field, as each therapy session requires.

**[0094]** While the present method has been described with regard to foot cradle 70, the same method steps may be envisioned for coil wraps or cradles of different configurations, for example, for the coil wraps and cradles described with reference to the previous figures.

**[0095]** In an alternative embodiment, the logic controller (not shown) may automatically adjust coil positioning to optimize therapy during the initial and successive sessions. While this set-up may be more difficult to implement, it also provides for an accurate targeting of the target nerve during each therapy session, regardless of alterations in patient positioning or changes to the anatomy of the patient (for example, when a foot is swollen). In this embodiment, the device simply varies the orientation of coils 84 until stimulation has been sensed.

**[0096]** Further, coils 84 may be translated along a single direction (for example, horizontally) or along a plurality of directions, to provide for the most accurate positioning of coils 84 with respect to the target nerve.

**[0097]** A second method of use of the foot cradle depicted in FIG. 4 is described now with reference to FIG. 7. While this second method is also described with reference to a foot cradle 82



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employing one or more coils 84 that have a reversibly lockable, adjustable orientation, the present method may be equally implemented with a body-worn coil wrap, such as those described with reference to the previous figures, or to other embodiments of the invention. In this method, the patient or the healthcare provider adjusts the positioning of coils 84 to detect conductivity in target nerve 89.

**[0098]** The position of coils 84 may be translated in different directions (in the illustrated embodiment, may be translated horizontally) and may be locked in an initial position once conduction in nerve 89 is detected by a sensor (for example, sensing patch 86).

**[0099]** More particularly, FIG. 7A illustrates the initial positioning of foot 88 into cradle 82 and of sensor patch 86 on ankle 90 or other appropriate body part of the patient. After proper positioning of foot 88 is attained, a knob 92 (or other equivalent device) may be employed to adjust the position of coils 84, based on the signals (for example, nerve conduction signals) provided by sensor patch 86, as shown in FIG. 7B.

**[0100]** With reference to FIG. 7C, after neural conduction is detected, coils 84 are locked in place, and, with further reference to FIG. 7D, foot cradle 82 retains coils 84 locked in position for further use in a home or healthcare office environment. Therefore, in the present method, the patient or a healthcare provider simply adjusts coil position by sliding coils 84 back and along one axis until electric conduction in the target nerve is detected, although adjustments along all three axes may be possible in different variants of the present embodiment.

**[0101]** Referring now to FIG. 8, a sixth embodiment of the invention relates to the use of multiple sensors. While FIG. 8 depicts an embodiment shaped as a foot cradle 98, it should be understood that the following description also relates to any other design, whether shaped as a cradle or a wrap or otherwise. The plurality of sensors 94 described herein may detect a variety of physiologic changes, including neural impulses, muscular contraction, twitching, etc. that may occur with neural or muscular stimulation.

**[0102]** One or more of the illustrated sensors 94 may be employed over body regions being stimulated (for example, back, leg, arm, neck, head, torso, etc.) and may be either incorporated within an actual cradle or wrap or, otherwise, be applied separately from the cradle or the wrap.

**[0103]** Sensors 94 may be structured as disposable, single-use, EKG-type patches that are attached to the body outside of cradle 98 along the nerve conduction pathway and are then connected to the logic controller (not shown) before beginning therapy. This arrangement provides for an intimate body contact of sensors 94 without the risk of infection or other detrimental side effects that may be present with transcutaneous devices. Sensors 94 may be employed both for beginning and for monitoring the stimulation therapy; more specifically, sensors 94 may be employed during the



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beginning of the therapy to optimize the strength of the magnetic field and/or to adjust the positioning of coils 96 within the cradle 98. Once therapy has begun, sensors 94 continue to monitor nerve conduction to ensure that the correct level of stimulation is being provided. In the event that for some reason nerve conduction decays during therapy, the logic controller can automatically adjust the magnetic field, ensuring that the appropriate therapy is delivered for the appropriate amount of time.

**[0104]** One or more of sensors 94 in this embodiment, or any of the embodiments described herein, may take the form of an inductive coil designed to receive impulses from the underlying nerves, so that inductive technologies may be used to both stimulate the nerve or tissues as well as to record the effect of the stimulation on nerves or tissues. Any of sensors 94 may be connected to the logic controller through one or more connection modes, including, but not limited to, wireless signals, wired signals, radio frequencies, Bluetooth, infrared, ultrasound, direct switching of the current circuit, etc., so long as communication between the sensor and the device is effective.

**[0105]** During implementation of the present method, a healthcare provider may simply elect to use sensors 94 to adjust the device, for example, to lock coils 96 into position, during the first therapy session and not require the use of sensors 94 during each successive therapy session.

**[0106]** Referring now to FIGS. 9A-9D, there are shown different, non-limiting embodiments of the invention shaped as body worn ergonomic applicator garments. Each of these embodiments is shown with overlapping coils, although coils of any configurations may be used. Each of the wraps of FIGS. 9A-9D corresponds to a coil wrap, into which a body part may be placed. These garments contain one or more sensors (not shown) that provide feedback to a logic controller (also not shown), or sensors may be applied separately from those garments. Systems may also be included for reversibly or irreversibly locking the coils within the applicator.

**[0107]** More particularly, FIG. 9A illustrates an embodiment, in which coils 100 are embedded in a knee wrap 102 and are connected to a logic controller (not shown) by a connector 104. FIG. 9B instead illustrates an embodiment, in which coils 106 are disposed within an abdominal garment, for example shorts 108 and in which coils 106 are also connected to a logic controller (not shown) by a connector 110. A marking 112 may be added on one side of shorts 108 to indicate wrap orientation. FIG. 9C illustrates a coil wrap shaped like a band 114, in which coils 116 are connected to a logic controller (not shown) by a connector 118. When this embodiment is employed, band 114 may be wrapped around a body portion (for example, an arm) and be retained in place by a system known in the art, for example, a hook and loop system, a strap and buckle system, or simply a hook disposed at one end of band 114 for engaging fabric or other material in another portion of band 114. FIG. 9D illustrates an embodiment shaped as a shoulder strap 120, the length of which may be



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adjusted by a buckle 122 and which has coils 124 disposed in one or more points, for example, at the joint between an arm and a shoulder as shown. Each of these embodiments includes one or ore sensors (not shown) that may be coupled to the garment, or that may be applied separately from the garment.

**[0108]** Other embodiments that are not illustrated include, bur are not limited to: a head worn garment, such as a cap; a neck worn garment, such as a neck brace; and a lower-back garment. Each garment and applicator may also utilize the locking, targeting coil feature described previously, without requiring the use of the any sensing components after a proper positioning of the coils in relation to the target nerve or nerves has been established.

**[0109]** Still other embodiments of the invention are depicted in FIGS. 10 and 11. In these embodiments, the source of energy for nerve stimulation is electrical energy that is dispensed through a percutaneous stimulator, such as a percutaneous needle 124, or a transcutaneous stimulator, such as an electrode 126. As shown in FIG. 10, an electrical pulse controller 128 is electrically connected both to percutaneous needle 124 and to sensor 134, to provide the desired feedback and modulate the power to percutaneous needle 134. In the embodiment of FIG. 11, electrical pulse controller 130 is connected both to electrode 126 and to sensor 136, and performs a function similar to that of electrical pulse controller 128. With these embodiments, nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli. Further, direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues. Still further, these embodiments enable a reduction in power requirement, because control of the signal is provided by the sensor to the signal generator loop.

**[0110]** As shown, a device constructed according to the principles of the present invention provides a targeted and precise stimulation of the posterior tibial nerve, or of other peripheral nerves, in a non-invasive manner by employing an ergonomic wrap or cradle that specifically targets the posterior tibial nerve in a consistent and repeatable manner. For example, in patients with OAB or VI, the novel, reversibly lockable movement of the coils and the use of a logic controller -sensor loop enables the application of a magnetic field that can be varied in location, amplitude and strength according to the amount of stimulation actually induced in one or more target nerves and of the response of the patient to the therapy. An apparatus according to the present invention may deliver any frequency of stimulation, including low frequencies, high frequencies, mid frequencies and ultrahigh frequencies, and overlapping and non-overlapping coils may be used to generate the



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desired field, although overlapping or Helmholtz coils are preferred due to their ability to target a broader region and achieve more thorough stimulation.

**[0111]** Ailments that may be treated through the use of apparatus and methods of the present invention include not only OAB and VI, but also obesity, depression, urinary incontinence, fecal incontinence, hypertension, pain, back pain, restless leg syndrome, Guillain Barre syndrome, quadriplegia, paraplegia, diabetic polyneuropthy, dyskinesias, paresthesias, dental procedure pain, knee osteoarthritis, anesthesia (pain relief during surgery), Alzheimer's disease, angina (chest pain from heart disease), ankylosing spondylitis, back pain, bum pain, cancer pain, chronic pain, dysmenorrhea (painful menstruation), headache, hemiplegia, hemiparesis (paralysis on one side of the body), labor pain, local anesthesia during gallstone lithotripsy, facial pain, trigeminal neuralgia, bruxism (tooth grinding) pain, myofascial pain, pregnancy-related nausea or vomiting, neck and shoulder pain, pain from broken bones, rib fracture or acute trauma, diabetic peripheral neuropathy, phantom limb pain, post-herpetic neuralgia (pain after shingles), postoperative ileus (bowel obstruction), irritable bowel syndrome, postoperative nausea or vomiting, postoperative pain, post-stroke rehabilitation, rheumatoid arthritis, skin ulcers, spinal cord injury, temporomandibular joint pain, detrusor instability, spinal muscular atrophy (in children), pain during hysteroscopy, gastroparesis, chronic obstructive pulmonary disease rehabilitation, carpal tunnel syndrome, soft tissue injury, multiple sclerosis, intermittent claudication, attention-deficit hyperactivity disorder (ADHD), cognitive impairment, knee replacement pain, achalasia, atopic eczema, bursitis, carpal tunnel syndrome, dementia, depression, dry mouth, dystonia, enhanced blood flow in the brain, enhanced blood perfusion of the uterus and placenta, esophageal spasm, fibromyalgia, fracture pain, Guillain-Barre syndrome, hemophilia, herpes, hip pain, interstitial cystitis, irritable bowel syndrome, pruritis, joint pain, labor induction, local anesthesia, menstrual cramps, muscle cramps, muscle spasticity, muscle strain or pain, musculoskeletal trauma, myofascial pain dysfunction syndrome, nerve damage, osteoarthritis, pain medication adjunct, pancreatitis, Raynaud's phenomenon, repetitive strain injuries, sacral pain, schizophrenia, shingles, shoulder subluxation, sickle cell anemia pain, Skin flap ischemia (during plastic surgery), sphincter of Oddi disorders, sports injuries, thrombophlebitis, tinnitus (ringing in the ear), restless legs, tremor, whiplash and neuralgias. In contrast to implantable nerve stimulators, this therapy is completely non-invasive and does not require a major surgery to implant a permanent nerve stimulation device. Moreover, this therapy can be controlled to optimize the level of therapy delivered according to power consumption and nerve stimulation requirements and need not be delivered by a professional healthcare provider.

**[0112]** In other embodiments of the invention, neural stimulation may be applied as electrical transcutaneous stimulation, for example, by inserting an invasive electrical needle into a



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target body part and by modulating stimulation is modulated on the basis of information sent back to the logic controller from the one or more sensors that are used to detect and/or maintain the correct level of stimulation. The transcutaneous electrical stimulation sensor may be placed in the body independently or be incorporated within the wrap and may provide, among other things, feedback as to the quality of the electrical connection to the skin, which is directly related to the bum risk inherently associated with this type of therapy. In fact, these methods of stimulation may not be optimal due to the resulting skin irritation and risk of potential burns, a very serious issue in the large percentage of patients that have neuropathies. Even when patches are applied to monitor transcutaneous stimulation very closely, the patches may still become displaced and allow a bum to occur. Moreover, potentially interfering electrical impulses may develop at the treatment site, creating a noisy environment for the detection of nerve conduction.

**[0113]** In still other embodiments of the invention, an external coil or coils may be inductively connected to an implanted coil or coils may be utilized. In these embodiments, an ergonomic applicator may be adjusted by the user or by a healthcare provider such to optimize inductive power transmission between the external and implanted coils. One or more sensors may be utilized to provide a feedback that the relative coil positions have been optimized, and the external coil may then be reversibly locked into position within the ergonomic applicator. Two applications of this embodiment relate to the transfer of power to recharge an implantable device, and to the transfer of power to activate an implantable device.

**[0114]** In the first application, when an implantable rechargeable device is utilized, the external coils may be used for recharging the implanted device by means of inductive fields generated by the external coils. The external coils may include circuitry that determines the amount of resistance encountered by the magnetic field or other electrical properties related to the quality and degree of the magnetic coupling that is being established. Based on this feedback, the position of the external coils may be adjusted manually or automatically to optimize the coupling achieved with during each recharging session. Alternatively, a sensor may be incorporated into the implantable device and may communicate the degree and quality of the magnetic coupling to the external coils and/or the connected circuitry via wireless communication, providing a feedback for the automatic or manual adjustment of the external recharging coils.

**[0115]** The coils within the ergonomic applicator may be reversibly locked into place for the duration of the recharge session, and the implantable device may also communicate to the external recharging unit that the implantable device has been fully recharged, terminating the recharging session has been completed. By providing for an intermittent recharging of an implanted device, an apparatus according to the present invention enables the implantable device to devote



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more power to performing its intended function optimally and with a lesser concern about protecting or extending battery life.

**[0116]** In the second application, the powering coils may contain circuitry to determine the amount of resistance encountered by the applied magnetic field, or other electrical properties that may reflect the quality and degree of the magnetic coupling that is being achieved. Based on this feedback, the powering coils in the applicator may be adjusted manually or automatically to activate and optimize the coil coupling at the beginning of each therapy session. Alternatively, a sensor may be incorporated into the implantable device and communicate the degree and quality of the magnetic coupling externally via wireless communication, which may in turn provide feedback for the automatic or manual adjustment of the powering coil. In one variant of the present embodiment, the inductive coils may be magnetically coupled to a needle targeting the posterior tibial nerve.

**[0117]** An exemplary method of use of an apparatus according to the present invention on a patient suffering from VI and/or OAB includes the following steps:

**[0118]** The patient places a conductive wrap contained within a flexible material over a region of the ankle (or alternatively over the knee) to provide the required pulsed magnetic field. Alternatively, the patient may use an ergonomic foot/leg rest or cradle having embedded coils.

**[0119]** A sensor (for example, a sensor patch) is placed on the patient's body along the path of the nerve, ideally proximal to the stimulation site to ensure afferent nerve stimulation, and is connected to a logic controller.

**[0120]** A physician or healthcare provider adjusts the coils in the wrap or cradle until nerve conduction is achieved based on patient and sensor feedback. An optimal position is sought, and the coils may be reversibly locked into position within the conductive wrap or ergonomic cradle and remain in this position during subsequent use.

**[0121]** During the therapy session, the logic controller provides an electric current to the coils, generating an inductive magnetic field. In one embodiment, this field begins at low amplitude and slowly ramps up until nerve conduction exceeds a threshold level, as signaled by the sensor and possibly by the patient, who may feel motory conduction. Alternatively, one or more coils may also be activated to increase the covered area of stimulation in the event that stimulation does not occur with the initial coil configuration or is inadequate

**[0122]** The optimal stimulation may be determined in a variety of manners, for example, by measuring exposure to electromagnetic fields capable of generating a square wave electric signal at a frequency of 10-30 Hz at the targeted tissue depth. The square wave configuration of the signal may be generated via Fourier transformation or may be a ramped current generated in any manner.



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**[0123]** The inductive magnetic pulses continue for an appropriate duration of use, for example, for 15-30 minutes. The sensor may remain in place during the entire therapy session to ensure that stimulation occurs consistently and to provide for appropriate corrections if nerve conduction deteriorated. The logic controller may be powered either by a portable power source such as a battery, or by or a fixed power source such as a traditional wall outlet.

**[0124]** The conductive wrap and/or ergonomic cradle is removed from the body when therapeutic stimulation is not being delivered, typically at the end of the therapy session.

**[0125]** The conductive wrap and/or ergonomic cradle is reapplied along with the sensor patch (ideally disposable) from time to time as indicated, for example, on a daily basis, and steps 4-8 are repeated.

**[0126]** The invention described herein may be applied to any body tissues, including nerve, muscle, skin, vasculature, or any other organ or tissue within the human body. Further, the devices and methods described herein may be used to treat any conditions suited for neuromodulation regardless of whether the stimulation source is an electromagnetic field, a direct electric current, a RF field, infrared energy, visible light, ultraviolet light, ultrasound, or other energy dispensing device.

**[0127]** In other embodiments, as shown in FIG. 12, an energy emitting system 210 for providing a medical therapy includes one or more conductive coils 212 disposed within or along a housing 214, one or more sensors 216 configured to detect electrical conduction in a target nerve or to detect muscle stimulation, and a controller 218 connected or coupled to the conductive coils 212 and optionally in communication with the sensor 216. In certain embodiments (as shown in Fig. 12), the controller 218 can be integral with the housing 214). The coils 212 are configured such that an electrical current generated by the controller 218 is passed through the coils 212 generating a magnetic field which will stimulate a target nerve, e.g., the tibial nerve 220, a muscle or other body part containing a portion of a target nerve, or any nerves branching off of a target nerve, located in proximity to the coils 212. In this particular embodiment, the housing 214 is in the form of a foot cradle, as shown in FIG. 4, however, the housing could also be in the form of a flexible wrap, garment or other design suitable for use with a subject. In various embodiments described herein, sensors may detect voltage or current and may be connected, coupled, wirelessly connected or coupled or otherwise in communication with the housing and/or controller using a variety of methods or techniques known in the art. The sensor may be placed over a muscle to detect muscle stimulation resulting from stimulating the target nerve (as shown in Fig. 12) or over any other portion of the subject's body suitable for detecting conduction of the target nerve.



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**[0128]** Referring to FIG 13 and 16, the sensor may be in the form of a microneedle patch 228, which can be removably attached to the skin surface of a subject. The microneedle patch 228 may include a housing 231, having one or more electrodes 232 and one or more microneedles 235 deposited or arrayed on a surface of the electrode 232, forming one or more microneedle arrays 234. In FIG 13, microneedle patch 228 has the shape of a square, and the microneedles 235 are arrayed on the bottom surface 236 of the electrode 232 in a 16 X 16 configuration. However, as shown in FIGS 14-15, microneedle patches may be designed in a variety of shapes, e.g., round, oval 229, rectangular 230, hexagonal, and a variety of sizes. The microneedles may be arrayed in a variety of arrangements and patterns (e.g., 14 X 14, 12 X 12, etc.) depending on the particular use and needles.

**[0129]** Additionally, microneedles may be attached, deposited, or arrayed on an electrode surface or patch in a variety of configurations and arrangements, depending on where the particular microneedle patch will be utilized and the treatment to be delivered. The number of microneedles included in an array can vary. For example, the number of microneedles may range from about 5 to 500 or 100 to 400 or about 200 to 300 or about 256. In certain embodiments where microneedles are composed of strong, highly conductive material, the number of microneedles necessary may be less and may range from about 5 to 100 or 10 to 50 or 5 to 50. However, where microneedles are composed of higher resistance metal, a greater number of needles may be needed, e.g., about 100 to 500 or about 200 to 300 or greater than 500.

**[0130]** Referring to FIG. 18, a magnified view of a microneedle array 234 composed of one or more microneedles 235 is shown. Microneedles 235 may include a base portion 238 and an upper portion 239. Microneedles 235 may have lengths in the range of about 1 to 400 microns or 10 to 400 microns or preferably about 100 to 150 microns, and a diameter in the range of about 1 to 100 microns. A microneedle 235 may be tapered in diameter, going from a larger to smaller diameter from the base portion 238 to the upper portion 239 where the distal tip 240 of the microneedle is preferably pointed or sharp. The upper portion 239 of the microneedle 235 may have a diameter in the range of about 10-30 microns or about 15 to 25 microns. Optionally, for ease of production, the base portion 238 of the microneedle 235 may be thicker than the distal tip 240 or upper portion 239 of the microneedle 235. In certain embodiments, as shown in FIG 17, a bulb 237 may be provided at the distal tip 240 of a microneedle 235 to provide for effective anchoring of the microneedle 235 in the skin of a patient or subject. Microneedles 335 can include any number of friction or grip increasing features. For example, they may include projections, barbs, bulbs or a roughened surface or tip. Microneedles 235 may take on various configurations, e.g., straight, bent, filtered, hollow or a combination of the above.



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[0131] In other embodiments, microneedles may have lengths that range from about 480 to 1450 microns, widths from about 160 to 470 microns, thicknesses from about 30 to 100 microns and tip angles from about 20 to 90 degrees, and arrays can contain from 5 to 50 microneedles. For example, microneedles having these dimensions have been shown to be less painful than hypodermic needles. Length and number of microneedles can affect the level of pain experienced. Decreasing microneedle length and/or the number of microneedles may be beneficial and act to further reduce pain and provide comfort.

[0132] In certain embodiments, the one or more microneedles may include an electrically conductive material such that the microneedles may transmit an electrical signal to an overlying electrode or other surface.- Microneedles may be constructed of an electrically conductive material and/or coated with an electrically conductive material. Optionally, microneedles may be coated with an electrically conductive material and constructed of a non-conductive material. Microneedles may be fabricated using a variety of materials, e.g., metals, stainless steel, solid or coat of gold over NI, Pd or Pd-Co, Pt, silicon, silicon dioxide, polymers, glass, biocompatible polymers, titanium, silver, or suture materials. Biodegradable polymers may also be used such that if a tip of a microneedle were to snap or break off during insertion, it would easily biodegrade.

[0133] A microneedle array 234 may be constructed or fabricated using any variety of manufacturing methods known to persons of ordinary skill in the art. Microneedles may be arrayed, attached, etched or deposited onto a surface of an electrode. In another embodiment, microneedles may be etched from or deposited onto a silicon electrode, such that the microneedle patch, including electrode and microneedles, are made from one material creating a durable and stable microneedle patch.

[0134] As shown in FIG 18, microneedles may be fabricated by creating micron sized holes on a silicon substrate and by using a KOH solution to create the needle shape. In other embodiments, the microneedles may be made of non-conductive material but may still be utilized to provide superior anchoring properties such that a microneedle patch may effectively adhere or attaché to a subject's skin.

[0135] In certain embodiments, microneedle arrays are fabricated by patterning SU-8 onto glass substrates and defining needle shapes by lithography. The tips of the needles can be sharpened using reactive ion etching. Optionally, holes may be drilled, e.g., by laser, through the microneedles and base substrate. Holes may be drilled off-center, but parallel to the microneedle axis, terminating in side-opening holes along the needle shaft below the needle tip. If desired, the holes can serve as micro fluidic needle bores for injection or infusion of drugs, medicines, insulin, proteins, nanoparticles that would encapsulate a drug or demonstrate the ability to deliver a virus for



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vaccinations, etc. to be used separately or in combination with electrical or magnetic therapy. The microneedles may also be coated with nickel by electroplating, which can increase their mechanical strength.

**[0136]** In certain embodiments, microneedle patches or microneedle electrode arrays are made by fabricating master structures from which replicates are molded and then made electrically active. For example, SU-8 may be spun on a glass substrate bearing an array mask pattern, baked, and then exposed from the backside to from a tapered needle structure. Microneedles may be sharpened by RIE etching. A PDMS (polydimethylsiloxane) or similar material mold can then be copied from the master. A PMMA (polymethylmethacrylate) microneedle array is formed by solvent-casting and then released from the mold.

**[0137]** To provide the arrays with electrical functionality, a Ti/Cu seed layer may be deposited on the PMMA array and patterned by excimer laser to electrically isolate adjacent rows. A Ni layer (e.g., about 15 to 30 microns or 20 to 25 microns thick) may be electroplated on the patterned seed layer to enhance structural rigidity. A backside electrical connection to the array may be formed by backside etching of a hole and forming an electrical connection through the hole.

**[0138]** In another embodiment, the microneedle array is arranged in a 16 X 16 array (i.e., 256 needles). Each needle has a height of about 400 microns and the base diameter is about 100 microns. The pitch between microneedles can be about 250 microns. The microneedle arrays are then coated with metal and laser-etched to provide electrical functionality. Optionally, rows of microneedles can be electrically isolated from each other so that alternating rows can provide alternating electrical polarity. The arrays are also interfaced with a power source. Microneedles may be made of polymer, coated with a metal, and etched to act as alternating electrodes. In certain embodiments, the firing sequence of the microneedles by rows or groups may be varied or configured to alternate.

**[0139]** In certain embodiments, a microneedle array may include one or more microneedles having multiple channels. For example, a multichannel silicon microneedle may be constructed to deliver bioactive compounds into neural or other tissue while simultaneously monitoring and stimulating neurons and nerves.

**[0140]** FIG. 19 shows a cross sectional view of the skin 10 composed of an outer stratum corneum 15 covering the epidermis 16. The skin also includes the dermis 18, subcutaneous tissue/fat 12, and these layers cover muscle tissue 14. As shown in FIG 19, when a microneedle patch 228 is attached to a subject's skin, the microneedles 235 pierce the outer insulating stratum corneum layer 15. The microneedle patch 228 can detect current passing through a stimulated nerve, and provide a superior signal as the current detected is conducted through the microneedles 235, thereby bypassing



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the poorly conductive stratum corneum layer 15 which generally encompasses the outer 10 to 15 microns of skin. In other embodiments, microneedles 235 may be fabricated to be long enough to penetrate the stratum corneum 15, but short enough not to puncture nerve endings, thus reducing the risk of pain, infection or injury.

**[0141]** In certain embodiments, microneedles are formed such that they are in direct contact with their corresponding or overlying electrodes. For example, a microneedle patch may include an adhesive electrode pad and may utilize a conductive gel to help hold the microneedles in place to prevent shear forces from breaking or bending the microneedles.

**[0142]** In certain embodiment, as shown in FIGs. 20a-20d, a microneedle patch or applicator may include multiple electrodes on a single patch or applicator, e.g., positive, negative, and/or control or ground electrodes, where the microneedles will be grouped in multiple arrays such that they conduct to the appropriate electrode. For example, FIGS 20a and 20b show a single patch having positive, negative and control electrodes where a separate array of electrodes is in contact with each respective electrode. This arrangement can be created using a single patch. Alternatively, as shown in FIG. 20c, two patches may be implemented, one including the control electrode with corresponding microneedle array and the other including the positive and negative electrodes with corresponding microneedle arrays. The various electrodes could be interchanged. Alternatively, as shown in FIG. 20d, three patches may be implemented, each having a separate electrode (control, positive, or negative) with a corresponding microneedle array. In use, in certain embodiments, the control may be attached above or near bone, while the positive and/or negative electrodes may be attached above nerve or muscle.

**[0143]** Referring again to FIG. 12, the energy emitting system 210 can be used to treat or prevent various conditions, e.g., urinary incontinence, restless leg syndrome and fecal incontinence, among others. Energy emitting system 210 includes one or more conductive coils 212 disposed within or along a housing 214, one or more sensors 216 configured to detect electrical conduction in the target nerve or to detect muscle stimulation, and a controller 218 coupled to the conductive coils 212 and optionally in communication with the sensor 216. The coils 212 are configured such that an electrical current generated by the controller 218 is passed through the coils 212 generating a magnetic field which will stimulate a target nerve, e.g., the tibial nerve 220, a muscle or other body part containing a portion of a target nerve, or any nerves branching off of a target nerve, located in proximity to the coils 212. In this particular embodiment, the housing 214 is in the form of a foot cradle, as shown in FIG. 4, however, the housing could also be in the form of a flexible wrap, garment or other design suitable for use with a subject.



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**[0144]** Referring again to FIG. 12, energy emitting system 210 may be used to treat or prevent various conditions, e.g., urinary incontinence, restless leg syndrome or fecal incontinence. In certain embodiments, a method of using the energy emitting system 210 includes positioning a first portion of a patient's body, for example a foot, ankle, or leg, relative to housing 214 such that a posterior tibial nerve 220 within the first portion of the patient's body is in proximity to one or more conductive coils 212 disposed within or along the housing. In this particular embodiment, a patient's foot is positioned in a housing which is in the form of a foot cradle 215. A sensor in the form of a microneedle patch 228 may optionally be positioned along a second portion of the patient's body in proximity to the posterior tibial nerve 220. In this particular embodiment, microneedle patch 228 is attached to the patient's foot over a muscle to detect muscle stimulation. Alternatively, a patch could be placed elsewhere on the patient, for example, on the leg in proximity to the posterior tibial nerve 220, proximal to and up-stream from coils 212. Microneedle patch 228 may be composed of one or more microneedle arrays and one or more electrodes, as described supra.

**[0145]** Once the patient's foot is in position and the microneedle patch 228 (e.g., conductive microneedle patch) is in place, a current is passed from controller 218 through coils 212, and as a result, the coils 212 generate a magnetic field which is focused on the posterior tibial nerve 220. The magnetic field stimulates tibial nerve 220, generating a current that will flow along the tibial nerve 220 and spread along its length, to its sacral or pudendal nerve roots. Microneedle patch 228 detects corresponding muscle stimulation or twitching or electrical conduction through the stimulated posterior tibial nerve. Upon detection, the microneedle array may conduct and transmit an electrical signal to the overlying electrode of microneedle patch 228. The signal may be transmitted to controller 218, which can be integral or a separate controller or device, or a separate controller coupled to controller 218. The controller can then be varied or adjusted (to adjust the current or magnetic field) based on the signal received from microneedle patch 228 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received. Although shown utilizing a sensor, it is also contemplated that the system could be used without a sensor.

**[0146]** Referring to FIG. 21, the method of using energy emitting system 210 described above with respect to FIG. 12 may be varied such that a conductive microneedle patch 228 is placed in proximity to or proximally over the afferent posterior tibial nerve 220, i.e., behind the patient's knee. In this position, a conductive microneedle patch 228 detects electrical conduction through the afferent posterior tibial nerve, i.e., it detects the electrical signal traveling through the posterior tibial nerve back up to the brain and spinal cord or it may detect corresponding muscle stimulation. The microneedle patch 228 sends the signal to controller 218 or to a separate controller coupled to



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controller 218. The controller can then be varied or adjusted based on the signal received from microneedle patch 228 to ensure that adequate conduction or stimulation of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received.

**[0147]** A sensor utilized in the energy emitting system 210 may be a microneedle patch 228 as described above or optionally the sensor may a sensor type known in the art (e.g., EKG sensor) or as described in any of the embodiments herein. It is also contemplated that energy emitting system 250 can be utilized without a sensor. Optionally, the sensor may be positioned within or along the housing, e.g., the foot cradle, along with the one or more conductive coils, or positioned at a site distant from the housing or conductive coils.

**[0148]** In certain embodiments, energy emitting system 210 my optionally include one or more conductive microneedle patches which can be positioned in proximity to the target nerve or muscle and provide an additional or supplemental electrical or magnetic stimulus to the target nerve or muscle.

**[0149]** Referring to FIG. 22, the energy emitting system 210 described above with respect to FIG. 12 may be varied to create energy emitting system 260. Energy emitting system 260 further includes one or more percutaneous electrode needles 262 or other needles or other percutaneous electrodes coupled to a controller 218 and having an end insertable into a subject's body in proximity to said target nerve or stimulation site. The percutaneous electrode needle 262 is inductively coupled to one or more conductive coils 212. In use, a first portion of a patient's body, for example a foot, ankle, or leg, is positioned relative to housing 214, e.g., foot cradle 215, such that a target nerve, e.g., posterior tibial nerve 220, located within the first portion of the patient's body is in proximity to one or more conductive coils 212 disposed within or along the housing 214. Conductive coils 212 are positioned proximate, optionally down-stream or distal to, a selected stimulation site 261. The percutaneous electrode needle 262 is inserted through the skin at a location and to a depth that brings the tip in close proximity to the stimulation site or target nerve to be stimulated. The controller 218 is activated and a current passes through conductive coils 212. The resulting magnetic field generates a current that traverses the internal stimulation site 261 by passing from conductive coils 212 to the internal percutaneous electrode needle 262, as indicated by arrow i. Also, the percutaneous electrode needle may be positioned within the generated magnetic field, whereby the magnetic field itself generates a current in the percutaneous electrode which stimulates a target nerve or traverses an internal stimulation site. Optionally, a current may be passed from the controller 218 through conductive coils 212 and/or from the controller 218 through percutaneous electrode needle 262, traversing the internal stimulation site as the current passes between the coils and needle.



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[0150] In energy emitting system 260, current density and subsequent electric field intensity generated between conductive coils 212 and percutaneous electrode needle 262 is greater than that generated by traditional percutaneous stimulators. A greater electric field intensity makes site location for conductive coils 212 and percutaneous electrode needle 262 easier. Furthermore, the load impedance through the surface of the skin is much higher than the internal impedance, and as such, the relatively high load impedance lessens the likelihood of damage to tissue and nerves due to high current pulses.

[0151] Referring again to FIG. 22, a percutaneous electrode needle for use in any of the energy emitting systems described herein may include a variety of designs. For example, percutaneous electrode needle 262 may include a metal or plastic handle 263 to provide a secure grip for the user, while minimizing the risk of shock to the user. The needle tip can have a terminal portion 264 which may extend between about 0.5 and 10 mm or about 2.0 mm from the needle tip and may be constructed out of medical grade stainless steel or other biocompatible metals. The diameter of the needle can be small (less than about 0.25 mm) which minimizes trauma during insertion. Optionally, needle 262 can be coated with Teflon or similar insulative material 265 except for an exposed tip area 264. This allows for a higher field density at the tip for more precise operation. The exposed needle tip area 264 should have a sufficiently large surface area so as not to create too high a local current field that may cause irritation or pain.

[0152] In another embodiment, as shown in FIG. 23, percutaneous electrode needle 272 may be used in energy emitting system 260. Percutaneous electrode needle 272 may be constructed out of medical grade stainless steel or other biocompatible electrically conductive metal. Percutaneous electrode needle 272 includes a first end 276 for insertion into the patient's body in proximity to the preselected internal stimulation site or target nerve to be stimulated, and a second end 277. The size of the needle electrode 272 is preferably small, for example 34G needle electrode (0.22x10 mm), to minimize trauma during insertion. Percutaneous electrode needle 272 may also include an electrically conductive adaptor, e.g., an electrically conductive tape member 273. The tape member 273 includes an electrically conductive adhesive portion 274 and an electrically conductive non-adhesive portion 275. Alternatively, the adaptor may include an electrically conductive clip. The second end 277 of the needle electrode 272 preferably includes an enlarged portion to enable the electrically conductive tape member 273 to be more easily adhered thereto. Once it is determined that the percutaneous needle electrode 272 is properly positioned, the needle is fixedly adhered to the electrically conductive tape member 273 by folding the ends of the adhesive portion 274 of the electrically conductive tape member 272 over the second end 277 of the needle electrode thereby forming an electrical connection there between. The percutaneous needle electrode



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272 is electrically coupled to controller 218 via electrically conductive tape member 273. Various other implantable or insertable electrode needles known to persons of skill in the art may also be utilized in the above described systems.

**[0153]** In certain embodiments of energy emitting system 260 as described above and shown in FIGS. 22-23, a sensor 216, such as a conductive microneedle patch 228, may be utilized to detect electrical conduction through the stimulated posterior tibial nerve 220 or to detect muscle stimulation, and transmit the signal to controller 218. The signal may be transmitted to controller 218, a separate controller or device, or a separate controller coupled to controller 218. The controller can then be varied or adjusted based on the signal from microneedle patch 228 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received. It is also contemplated that energy system 260 may be utilized without a sensor 216, see for example FIGS. 24-25. Optionally, other types of sensors may be used in place of a microneedle patch sensor, such as other sensors described herein and sensors known to persons of ordinary skill in the art. The sensor may be placed over a portion of the subject's body suitable for detecting conduction of the target nerve (e.g., on the leg as shown) or over a muscle to detect muscle stimulation resulting from stimulating the target nerve.

**[0154]** In certain embodiments, as shown in FIG. 26, an energy emitting system 250 for providing a medical therapy includes a microneedle patch 252 (e.g., conductive microneedle patch) having one or more microneedle arrays deposited on a surface of one or more electrodes; one or more sensors 221 configured to detect electrical conduction in the target nerve or to detect muscle stimulation; and a controller 218 coupled to microneedle patch 252 and in communication with sensor 221. The microneedle patch 252 is configured such that an electrical current generated by the controller 218 is passed through the microneedle patch 252, generating a magnetic field or delivering or generating an electrical or magnetic stimulus to a target nerve, e.g., the tibial nerve 220, a muscle or other body part containing a portion of a target nerve, or any nerves branching off of a target nerve, located in proximity to microneedle patch 252.

**[0155]** Referring to FIG. 26, a method of using the energy emitting system 250 may include placing a conductive microneedle patch 252 on a first portion of a patient's body, for example a foot, ankle, or leg, in proximity to posterior tibial nerve 220 within the first portion of the patient's body. Sensor 221 is positioned along a second portion of the patient's body in proximity to the posterior tibial nerve 220. In this particular embodiment, sensor 216 is attached to the patient's leg in proximity to the posterior tibial nerve 220, proximal to and up-stream from conductive microneedle patch 252. Conductive microneedle patch 252 is composed of one or more microneedle arrays and one or more electrodes, as described in the embodiments above.



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**[0156]** Once conductive microneedle patch 252 and sensor 221 are in position, a current is passed from controller 218 through conductive microneedle patch 252, resulting in an electrical stimulus of the posterior tibial nerve 220. Alternatively, the microneedle array may be insulated or constructed of non conductive material such that the microneedle patch 252 generates a magnetic field that stimulates tibial nerve 220 in a manner similar to the one or more coils described in the embodiments above, without an electrical stimulus. Whether the stimulus is electrical or magnetic, either stimulus will generate a current that will flow along the tibial nerve 220 and spread along its length, to its sacral or pudendal nerve roots. Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then transmits the signal to controller 218. In certain embodiments, the sensor may be in the form of a microneedle patch sensor. The signal may be transmitted to controller 218, a separate controller or device, or a separate controller coupled to controller 218. The controller can then be varied or adjusted based on the signal from sensor 221 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received.

**[0157]** The sensor utilized in the energy emitting system 250 may be a sensor of the type described above, with respect to other embodiments. Optionally, for example, the sensor may be a microneedle patch. It is also contemplated that energy emitting system 250 can be utilized without a sensor. The sensor may be placed over a portion of the subject's body suitable for detecting conduction of the target nerve (e.g., on the leg as shown) or over a muscle to detect muscle stimulation resulting from stimulating the target nerve.

**[0158]** In certain embodiments, energy emitting system 250 my optionally include one or more conductive coils disposed within or along a housing which can be positioned in proximity to the target nerve or muscle and provide an additional or supplemental stimulation of the target nerve or muscle.

**[0159]** Referring to FIG. 27, the energy emitting system 250 described above with respect to FIG. 26 may be varied to create energy emitting system 280. Energy emitting system 280 further includes one or more percutaneous electrode needles 262 coupled to a controller 218 and having an end insertable into a subject's body in proximity to said target nerve. Optionally, the electrode needle may be non-percutaneous, such that it is insertable in an orifice or opening in the subject, such as a natural orifice. The percutaneous electrode needle 262 is inductively coupled to conductive microneedle patch 252. In use, a microneedle patch 252 is placed on a first portion of a patient's body, for example a foot, ankle, or leg, in proximity to posterior tibial nerve 220 within the first portion of the patient's body and down-stream or distal to a selected stimulation site 261. The



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percutaneous electrode needle 262 is inserted through the skin at a location and to a depth that brings the tip in close proximity to the target nerve to be stimulated.

**[0160]** The controller 218 is activated and a current passes through microneedle patch 252 and traverses the internal stimulation site 261 by passing from microneedle patch 252 to the internal percutaneous electrode needle 262, as indicated by arrow i. The current passing through microneedle patch 252 may also generate a magnetic field which can generate a current that traverses the internal stimulation site 261 by passing from microneedle patch 252 to the internal percutaneous electrode needle 262. Also, the percutaneous electrode needle may be positioned within the generated magnetic field, whereby the magnetic field generates a current in the percutaneous electrode which stimulates a target nerve and traverses an internal stimulation site. Optionally, a current may be passed from the controller 218 through microneedle patch 252 and/or from the controller 218 through percutaneous electrode needle 262, traversing the internal stimulation site as the current passes between the patch and needle.

**[0161]** Referring to FIG. 28, energy emitting system 280 may be modified by using percutaneous electrode needle 272 in place of percutaneous electrode needle 262. Percutaneous electrode needle 272 would be constructed and function as described above with respect to FIG. 23. Various other implantable or insertable electrode needles known to persons of skill in the art may also be utilized in the above described systems. Additionally, energy emitting system 280 may utilize a sensor to detect electrical conduction through the stimulated posterior tibial nerve 220 and send a corresponding signal indicative of the detected conduction to controller 218 or other device such that the electrical or magnetic stimulus can be adjusted as necessary. The sensor may be a sensor 221, or optionally the sensor may be a microneedle patch. It is also contemplated that energy emitting system 280 can be utilized without a sensor. The sensor may be placed over a portion of the subject's body suitable for detecting conduction of the target nerve (e.g., on the leg as shown) or over a muscle to detect muscle stimulation resulting from stimulating the target nerve.

**[0162]** In any of the above systems, embodiments are contemplated where the sensors are also coupled or connected to or otherwise in communication with energy emitting devices, e.g., the conductive coils or conductive microneedle patches.

**[0163]** In certain embodiments, the one or more microneedles of the microneedle patch may include an electrically conductive material such that the microneedles may transmit an electrical signal to an overlying electrode or other surface. Microneedles may be constructed of an electrically conductive material and/or coated with an electrically conductive material. Optionally, microneedles may be coated with an electrically conductive material and constructed of a non-conductive material. Microneedles may be fabricated using a variety of materials, e.g., metals, stainless steel, solid or coat



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of gold over NI, Pd or Pd-Co, Pt, silicon, silicon dioxide, polymers, glass, biocompatible polymers, titanium, silver, or suture materials. Biodegradable polymers may also be used such that if a tip of a microneedle were to snap or break off during insertion, it would easily biodegrade. Optionally, the microneedle patch may be non-conductive.

**[0164]** In certain embodiments, an electrode patch for improved conductance or conduction is provided. The patch can include at least one electrode having a first surface and/or a second surface. The electrode may optionally be attached to various other materials or adhesive materials. An array of microneedles may be deposited on a surface of the electrode, or attached to a patch or other material and indirectly or directly connected to the electrode. The array of microneedles may include a conductive material. Such patches may be used as a sensor to detect muscle stimulation or electrical conduction, or to provide or deliver an electrical stimulus or magnetic field, e.g., to a target nerve, and may optionally be used in any of the embodiments described herein or in any application where improved conductance or conduction is desired. Microneedles yield improved reduction in impedance compared to simple abrasion and other techniques, and are less painful and more comfortable for the patient.

**[0165]** In certain embodiments, typical voltage sensed at the skin and detectable or conductable by a microneedle patch or microneedle array may range from about 1 to 400 microvolts or about 10 to 300 microvolts.

**[0166]** In certain embodiments, methods of treating a subject with urinary incontinence or various pelvic floor disorders utilizing the energy emitting systems described herein are contemplated. Symptoms associated with urinary incontinence may be observed, detected, or diagnosed. An energy emitting device having one or more energy generators, e.g., one or more conductive coils or one or more microneedle patches, may be positioned in proximity to a target nerve, e.g., the tibial or posterior tibial nerve or popliteal or sacral nerve or branches thereof of a subject or patient along a first portion of a subject's or patient's body. The subject may or may not be exhibiting symptoms associated with urinary incontinence. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to an energy emitting device such that a target nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device.

**[0167]** A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic or electromagnetic field or electrical or magnetic energy or stimulus,



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focused on the tibial or posterior tibial nerve or branches thereof. This in turn may cause the stimulation of a pudendal nerve, sacral plexus, or other nerves in the pelvic floor. Various nerves innervating the various muscles, sphincters, nerves, organs and conduits of the urinary tract and bladder may be stimulated directly or indirectly. In certain embodiments, a current is passed through one more coils, which generate a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain embodiments, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain embodiments, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

**[0168]** Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body. Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor in the form of a microneedle patch. In certain embodiments, the sensor may be positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other embodiments, the sensor may be positioned within or along a housing along with the one or more conductive coils.

**[0169]** Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of urinary incontinence by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with urinary incontinence. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited to the inability to control urinary function, urinary leakage, and loss of bladder control.



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**[0170]** In certain embodiments, the amplitude, frequency, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array may be adjusted. Optionally, the current may be varied according to a muscular response in the patient. Thus, to treat urinary incontinence, the magnetic field or electrical stimulus is applied to a subject or patient until the desired effects (e.g., reduction of symptoms) are achieved.

**[0171]** In certain embodiments, methods of treating a subject with fecal incontinence utilizing the energy emitting systems described herein are contemplated. Symptoms associated with fecal incontinence may be observed, detected, or diagnosed. An energy emitting device having one or more energy generators, e.g., one or more conductive coils or one or more microneedle patches, may be positioned in proximity to a target nerve, e.g., the tibial or posterior tibial nerve, or popliteal or sacral nerve or branches thereof, of a subject along a first portion of a subject's body. The subject may or may not be exhibiting symptoms associated with fecal incontinence. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with fecal incontinence, relative to an energy emitting device such that a target nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device.

**[0172]** A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic or electromagnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof. This in turn causes the stimulation of a pudendal nerve, sacral plexus, or nerves in the pelvic floor. Various nerves innervating the various muscles, sphincters, rectum, nerves, organs and conduits associated with bowel movements, fecal control, and the intestines may be stimulated directly or indirectly. Optionally, a current is passed through one more coils, which generate a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain embodiments, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain embodiments, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

**[0173]** Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body.



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Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor is in the form a of a microneedle patch. In certain embodiments, the sensor may be positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other embodiments, the sensor may be positioned within or along a housing along with the one or more conductive coils.

**[0174]** Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of fecal incontinence by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with fecal incontinence. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited: the loss of voluntary control to retain stool in the rectum; loss of fecal control; inability to control bowel movements, and fecal leaking:

**[0175]** In certain embodiments, the amplitude, frequency, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array may be adjusted. Optionally, the current may be varied according to a muscular response in the patient. Thus, to treat fecal incontinence, the magnetic field or electrical stimulus is applied to a subject or patient until the desired effects (e.g., reduction of symptoms) are achieved.

**[0176]** In certain embodiments, methods of treating a subject with restless leg syndrome utilizing the energy emitting systems described herein are contemplated. Victims afflicted with Restless Leg Syndrome (RLS or Ekbom's syndrome), are unable to remain seated or to stand still. Activities that require maintaining motor rest and limited cognitive stimulation, such as transportation, e.g., in a car, plane, train, etc., or attending longer meetings, lectures, movies or other performances, become difficult if not impossible. These sensations become more severe at night and RLS patients find sleep to be virtually impossible, adding to the diminishing quality of their lives. The urge to move, which increases over periods of rest, can be completely dissipated by movement, such as walking. However, once movement ceases, symptoms return with increased intensity. If an



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RLS patient is forced to lie still, symptoms will continue to build like a loaded spring and, eventually, the legs will involuntary move, relieving symptoms immediately.

**[0177]** Thus, symptoms associated with restless leg syndrome may be observed, detected, or diagnosed. An energy emitting device having one or more energy generators, e.g., one or more conductive coils or one or more microneedle patches, may be positioned in proximity to a target nerve, e.g., the tibial or posterior tibial nerve, or popliteal or sacral nerve or branches thereof or other nerves associated with restless leg syndrome, of a subject along a first portion of a subject's body. The subject may or may not be exhibiting symptoms associated with restless leg syndrome. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with restless leg syndrome, relative to an energy emitting device such that a target nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device.

**[0178]** A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof or other nerves associated with restless leg syndrome. This in turn causes the stimulation of a pudendal nerve, sacral plexus or other nerves innervating the pelvic floor or various muscles, nerves, or organs associated with restless leg syndrome. The various nerves may stimulated directly or indirectly. Optionally, a current is passed through one more coils, which generates a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain embodiments, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain embodiments, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

**[0179]** Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body. Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor in the form a of a microneedle patch. In certain embodiments, the sensor may be



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positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other embodiments, the sensor may be positioned within or along a housing along with the one or more conductive coils.

**[0180]** Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of restless leg syndrome by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with restless leg syndrome. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited to: uncomfortable sensations in the limbs, irresistible urges to move, usually the legs; motor restlessness; when at rest, symptoms return or worsen; and symptoms worsen in the evening and at night.

**[0181]** In certain embodiments, the amplitude, frequency, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array may be adjusted. Optionally, the current may be varied according to a muscular response in the patient. Thus, to treat restless leg syndrome, the magnetic field or electrical stimulus is applied to a subject or patient until the desired effects (e.g., reduction of symptoms) are achieved.

**[0182]** In certain embodiments, methods of treating a subject suffering from premature ejaculation or various pelvic floor disorders utilizing the energy emitting systems described herein are contemplated. Symptoms associated with premature ejaculation may be observed, detected, or diagnosed. An energy emitting device having one or more energy generators, e.g., one or more conductive coils or one or more microneedle patches, may be positioned in proximity to a target nerve, e.g., the tibial or posterior tibial nerve or popliteal or sacral nerve or branches thereof of a subject along a first portion of a subject's body. The subject may or may not be exhibiting symptoms associated with premature ejaculation. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with premature ejaculation, relative to an energy emitting device such that a



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target nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device.

**[0183]** A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic or electromagnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof. This in turn may cause the stimulation of a pudendal nerve, sacral plexus, or other nerves in the pelvic floor or nerves associated with the control of ejaculation. Various nerves innervating the various muscles, sphincters, nerves, organs and conduits of the urinary tract, bladder or reproductive system, or pelvic floor may be stimulated directly or indirectly. Optionally, a current is passed through one more coils, which generates a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain embodiments, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain embodiments, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

**[0184]** Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body. Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor in the form of a microneedle patch. In certain embodiments, the sensor may be positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other embodiments, the sensor may be positioned within or along a housing along with the one or more conductive coils.

**[0185]** Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of premature ejaculation by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels for current, frequency, magnetic field, treatment duration, etc., are levels that result in an observed or detected reduction or prevention of symptoms associated with premature ejaculation. Treatment could also be



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administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited to: ejaculation that frequently occurs within one minute or less of penetration; the inability to delay ejaculation on penetrations; or persistent or recurrent ejaculation with minimal stimulation before, on or shortly after penetration.

**[0186]** In certain embodiments, the amplitude, frequency, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array may be adjusted. Optionally, the current may be varied according to a muscular response in the patient. Thus, to treat premature ejaculation, the magnetic field or electrical stimulus is applied to a subject or patient until the desired effects (e.g., reduction of symptoms) are achieved.

**[0187]** Exemplary treatment parameters for treating various conditions, e.g., urinary incontinence, using the systems and methods described herein may include the following. Operation of a conductive coil at about 10 to 20 hertz generating a magnetic field of about .25 to 1.5 tesla, where the coil is administered to a patient for a duration of about 30 minutes/day or 30 minutes per week, depending on the severity of the symptoms, until the symptoms subside. The above treatment parameters or variations on the parameters may be used for treatment of urinary incontinence, fecal incontinence, restless leg syndrome, or premature ejaculation or other conditions. For example, the coil may be operated at various parameter ranges falling with the following ranges: about 5 to 100 hertz, about 1 to 10 tesla, for about 15 minutes to 2 hours per day or week. In treating premature ejaculation, a patient may receive treatment about 4 to 10 hours prior to intercourse. A maintenance phase of treatment, after the initial treatment, may vary for various conditions. For example, the maintenance phase may require application of the systems and methods described herein at the parameters described herein for 30 minutes/week or 30 minutes/month. Any treatment parameter may be varied or modified based on the effect on the patient or sensor or patient feedback regarding stimulation, until the desired result of treating or preventing a condition is achieved.

**[0188]** In certain embodiments, as shown in FIGs. 29a-29d, energy emitting device may include a controller 289 and a foot cradle 290. Foot cradle 290 may include vertical foot plate 291, and horizontal foot plate 292, where each plate can be adjusted using vertical foot plate knob 293 and horizontal foot plate knob 294. One or more EMG plugs 295 are provided. An air core coil 297 or other type of coil is provided. A display screen 296 may also be provided along with power cord 298. The display screen 296 can display a variety of information to the user and/or practitioner such as the level of power or current applied, treatment time, temperature of the cradle device, detected current levels and/or physiological parameters, etc., to facilitate effective and efficient therapeutic treatment. The information can be used to vary or adjust the controller to ensure that adequate



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conduction of a target nerve, e.g., posterior tibial nerve 220 or muscle stimulation occurs and an adequate and accurate dosage of treatment is being received. Controls may also be included to affect the following: power, field strength, frequency, pulse, start/pause and cancelation of therapy (as shown) or other parameters one of skill in the art would find necessary or useful to control or monitor. In certain embodiments, a sensor may be connected, connected or in communication with the foot cradle or other energy emitting apparatus, controller, housing , conductive coils, or microneedle patch.

**[0189]** In certain embodiments, as shown in FIGS 30-31, an energy emitting device may include a controller and a knee cradle. The cradle may be configured to provide the conductive coil in proximity to the popliteal fossa or area directly behind the knee. In certain embodiments, the knee cradle may configured to cradle or surround at least a portion of the knee or substantially the entire knee without placing direct pressure on the popliteal fossa, thereby minimizing or avoiding venous thrombosis. In one embodiment, the device may be utilized while the knee is in the flexed position (Fig. 30). In another embodiment, the device may be utilized while the knee is in a non-flexed position (Fig. 31).

**[0190]** In certain embodiments, the energy emitting device, e.g., foot cradle, knee cradle, etc., includes a conductive coil positioned such that a target nerve is automatically targeted. The conductive coil is configured, sized and positioned within the device such that the generated magnetic field may encompass and stimulate the target nerve in any patient based on the target nerve's anatomical location, thus providing automatic targeting of the nerve in any patient once the patient positions a particular body portion in the device.

**[0191]** In various embodiments described herein, sensors may detect voltage or current and may be connected, coupled, wirelessly connected or coupled or otherwise in communication with housing, conductive coils, microneedle patch, energy emitting apparatus, energy generators, or electrode needles and/or controller using a variety of methods or techniques known in the art. In various embodiments described herein, housings, conductive coils, microneedle patches, energy emitting apparatus, energy generators, or electrode needles may be connected, coupled, wirelessly connected or coupled or otherwise in communication with each other, controllers or sensors, using a variety of methods or techniques known in the art.

**[0192]** Coils used in any of the embodiments described above and illustrated in the corresponding figures may take on a variety of shapes, sizes, and configurations. For example, a coil may be shaped as a spiral (as shown) or have a simple helical pattern or be a figure eight coil, a four leaf clover coil, a Helmholtz coil, a modified Helmholtz coil, or may be shaped as a combination of the aforementioned coil patterns. Additionally, other coil designs beyond those mentioned



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hereinabove might be utilized as long as a magnetic field is developed that will encompass a target nerve.

**[0193]** The coils may have a variety of dimensions and configurations. In certain embodiments, a coil may have a central aperture. The diameter of the aperture may range from about 0.5 inch to 2 inches or 1 inch to 1.5 inches or the aperture may have a diameter of about 1 inch. The diameter of the coil body may vary. For example, the diameter may range from about 3.0 to about 7 inches or from about 4 to about 5 inches or the diameter may about 4.5 inches. The coil body may include any suitable number of turns. For example, the coil body may include from about 2 to about 25 turns or from about 10 to about 20 turns or 14 to 17 turns. The adjacent turns may be spaced apart from each other, providing a gap there between. An end or cross section of a turn may have various dimensions. For example, the end or cross section may have a height that is greater than its width. An end or cross section of a turn may have a height ranging from about 1 to 5 cm or from about 10 mm to 51 mm (about .3 inches to 2 inches) or about 25 mm to 40 mm (about 1 inch to 1.5 inches) or about 12 mm to 40 mm (about .5 inch to 1.5 inch) or about .5 inch to 2 inch. The end or cross section of the turn may have a width ranging from about 0.5 mm to about 5mm (about .019 inch to .19 inch) or from about 1mm to about 2 mm (about .03 inch to .07 inch) or about .2 mm to about 1.6 mm (about .01 inch to .06 inch). The above are all exemplary dimensions, where other dimensions are also contemplated depending on the use and configuration of a device.

**[0194]** It is also contemplated that any of the energy emitting systems or devices described herein can be used with or without a sensor for detecting conduction of a stimulated nerve or muscle stimulation resulting from the magnetic field generated by the conductive coil and delivered to a patient or an electrical stimulus delivered to a patient. Also, in any of the above embodiments, a controller may optionally be connected, coupled, integral to or otherwise in communication with the conductive coils and/or the sensor. Optionally, the sensor may be connected, coupled, integral to or otherwise in communication with the conductive coil.

**[0195]** While the invention has been described in connection with the above described embodiments, it is not intended to limit the scope of the invention to the particular forms set forth, but on the contrary, it is intended to cover such alternatives, modifications, and equivalents as may be included within the scope of the invention. Further, the scope of the present invention fully encompasses other embodiments that may become obvious to those skilled in the art and the scope of the present invention is limited only by the appended claims.



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## CLAIMS

What is claimed is:

1. An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of a microneedle array attachable to a skin surface in proximity to a target nerve or muscle; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

2. The system of claim 1, wherein the magnetic field generated by said at least one conductive coil is varied based on the electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

3. The system of claim 1, wherein the microneedle array is arrayed over a housing.

4. The system of claim 3, wherein the housing is comprised of a patch having at least one electrode and said microneedle array extends from a first surface of the electrode.

5. The system of claim 4, wherein the patch comprises a positive, negative and control electrode, each electrode comprising a microneedle array extending therefrom.

6. The system of claim 4, wherein the microneedle array is etched from a surface of the electrode.

7. The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

8. The system of claim 7, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

9. The system of claim 1, wherein said microneedle array comprises at least one microneedle coated with an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

10. The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

11. The system of claim 1, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.



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12. The system of claim 11, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

13. The system of claim 1, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 100 microns.

14. The system of claim 13, wherein a length of said microneedle is in the range of about 100 to 150 microns.

15. The system of claim 1, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil.

16. The system of claim 15, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said percutaneous electrode needle.

17. The system of claim 16, further comprising at least one conductive microneedle patch positioned distal to said stimulation site and coupled to the controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive microneedle patch and said at least one conductive coil to said electrode needle.

18. An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode and a distal tip having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

19. An energy emitting system for providing a medical therapy comprising:

at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical or magnetic stimulus focused on a target nerve in proximity to the at least one conductive microneedle patch; and

a controller coupled to said at least one microneedle patch.



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20. The system of claim 19, further comprising at least one sensor configured to detect the electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle.

21. The system of claim 20, wherein the electrical or magnetic stimulus generated by said at least one microneedle patch is varied according to the electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

22. The system of claim 19, wherein the microneedle array is etched from a surface of the electrode.

23. The system of claim 19, wherein said microneedle patch comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

24. The system of claim 23, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

25. The system of claim 19, wherein said sensor is comprised of at least one microneedle array.

26. The system of claim 19, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

27. The system of claim 19, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

28. The system of claim 27, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

29. The system of claim 19, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 150 microns.

30. The system of claim 29, wherein a length of said microneedle is in the range of about 100 to 150 microns.

31. The system of claim 19, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive microneedle patch.

32. The system of claim 31, wherein said at least one microneedle patch is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch to said electrode needle.

33. The system of claim 32, further comprising at least one conductive coil positioned distal to said stimulation site and coupled to said controller such that upon activation of said



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controller a current traverses the stimulation site by passing from said at least one microneedle patch and said at least one conductive coil to said electrode needle.

34. An energy emitting system for providing a medical therapy comprising:

at least one conductive microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, wherein said microneedle array comprises an electrically conductive material such that it can transmit an electrical signal to an overlying electrode and a distal tip having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin, said microneedle patch configured to deliver an electrical or magnetic stimulus to a target nerve in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle; and

a controller coupled to said at least one conductive microneedle patch and in communication with said at least one sensor.

35. An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

an electrode needle having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil; and

a controller coupled to said at least one conductive coil and said electrode needle.

36. The system of claim 35, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said electrode needle.

37. The system of claim 35, further comprising at least one sensor in communication with said controller and configured to detect electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle, wherein the magnetic field generated by said at least one conductive coil is varied based on the muscle stimulation or electrical conduction detected by said at least one sensor to ensure adequate therapeutic stimulation.

38. A method of treating a subject with urinary incontinence comprising:

positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to an energy emitting device such that a tibial nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device;



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passing a current through the at least one energy generator to produce a magnetic field or electrical stimulus focused on the tibial nerve;

stimulating a nerve that innervates the pelvic floor of the subject via stimulation of the tibial nerve with the magnetic field or electrical stimulus; and

reducing symptoms associated with urinary incontinence.

39. The method of claim 38, wherein the energy generator comprises a conductive coil for generating a magnetic field.

40. The method of claim 39, wherein positioning comprises placing a foot, ankle, or leg relative to at least one conductive coil disposed within or along a housing.

41. The method of claim 39, wherein positioning comprises placing a popliteal fossa relative to at least one conductive coil disposed within or along a housing.

42. The method of claim 38, wherein the energy generator comprises a microneedle patch for producing a magnetic field or electrical stimulus.

43. The method of claim 38, wherein a nerve that innervates the pelvic floor comprises the pudendal nerve or sacral plexus.

44. The method of claim 38, wherein symptoms associated with urinary incontinence comprise urinary leakage, loss of bladder control and the inability to control urinary function.

45. The method of claim 38, further comprising detecting electrical conduction through the tibial nerve or corresponding muscle stimulation via at least one sensor positioned along a second portion of the body.

46. The method of claim 45, wherein the sensor comprises a microneedle array.

47. The method of claim 45, wherein the sensor is positioned in proximity to the tibial nerve, over a muscle innervated by the tibial nerve, or over the popliteal fossa.

48. The method of claim 45, further comprising adjusting the current via a controller in communication with the energy generator according to a signal received from the sensor indicative of the nerve conduction.

49. The method of claim 48, wherein adjusting comprises adjusting amplitude, frequency, direction of a magnetic field, or firing sequence of the energy generator.

50. The method of claim 48, wherein adjusting comprises adjusting a position of the at least one coil relative to the first portion of the subject's body to re-focus the magnetic field on the tibial nerve.

51. The method of claim 48, wherein adjusting comprises adjusting a position of the microneedle patch relative to the first portion of the subject's body to re-focus the electrical or magnetic stimulus on the tibial nerve.



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52. The method of claim 48, wherein adjusting comprises varying the current according to a muscular response in the patient.

53. The method of claim 39, wherein the conductive coil is operated at about 10 to 20 hertz to generate a magnetic field of about .25 to 1.5 tesla for a duration of about 30 minutes per day.

54. A method of treating a subject with urinary incontinence comprising:

positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to a housing such that a posterior tibial nerve within the first portion of the body is in proximity to at least one conductive coil disposed within or along the housing;

passing a current through the at least one conductive coil to produce a magnetic field focused on the posterior tibial nerve;

detecting electrical conduction of the posterior tibial nerve via at least one microneedle array positioned along a second portion of the body;

receiving a signal from the microneedle array indicative of the electrical conduction;

adjusting the current via a controller in communication with the conductive coil according to the signal received from the microneedle array; and

reducing symptoms associated with urinary incontinence.



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## ABSTRACT OF THE DISCLOSURE

An energy emitting apparatus for providing a medical therapy includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors that are connected to the logic controller for detecting electric conduction in a target nerve. The energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the energy is varied by the logic controller according to an input provided by the one or more sensors. The energy emitting apparatus includes one or more conductive coils that produce a magnetic field focused on the target nerve upon receiving an electric current from the logic controller based on input provided by the sensors. The sensor may also include a microneedle array to detect electrical conduction or an energy emitting apparatus may include a microneedle array to produce or deliver energy, e.g., an electrical or magnetic stimulus or field.




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