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U.S. PTO 60/848720 100206

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY AND NOTEBOOK PAGES

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ENCLOSED APPLICATION PARTS ***(check all that apply)***

☒ Specification *Number of Pages* 58

☒ Drawing(s) *Number of Sheets* 9

☐ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number

☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.

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☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE

Date 9 / 30 / 06

TYPED or PRINTED NAME Daniel Burnett

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Docket Number:

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Cala Health Ex. 1015
Cala v. EMKinetics
USP 11,628,300

PATENT APPLICATION

METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY

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METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY

[0001] This application claims priority to U.S. Provisional Patent Application Serial No. 60/643,145, filed January 12th, 2005 and is a continuation-in-part of U.S. Pat. No. 6,701,185 entitled "Method and apparatus for electromagnetic stimulation of nerve, muscle, and body tissues" filed February 19th, 2002.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to the field of medical devices, in particular therapeutic intervention devices for central and peripheral nerve modulation therapies, including both excitation and blocking of nerve impulses. Of particular interest is the treatment and prevention of urinary incontinence (UI) and overactive bladder (OAB) with the use of Low Frequency Induction Therapy (LoFIT).

[0003] The OAB and UI market in the United States is well over a $12 billion a year industry. It affects over 16% of all Americans, for a total U.S. market of approximately 34 million men and women each year. Due to social stigmas attached to OAB and UI, as well as misunderstanding of the signs and symptoms associated with OAB and UI, only 40% of those affected (13.6M) seek treatment. Of those 13.6 million individuals, nearly 30% are unsatisfied with their current therapy.

[0004] The use of pulsed electromagnetic stimulation (PES) has been well established as a beneficial therapy in a variety of medical applications. The scientific principle behind this technology is that an electric current passed through a coil will generate an electromagnetic field. These fields, in turn, have been shown to induce current within conductive materials placed within the field. When applied to the human body, pulsed electromagnetic stimulation has been found to be an effective method of stimulating nerves resting within the electromagnetic field. Building on recent data, which highlights the beneficial effects of invasive, needle-based electrostimulation (ES) of the posterior tibial nerve in individuals with OAB and UI, there is

strong evidence for the treatment of these ailments with the use of LoFIT. In particular, ES has been found to modulate bladder dysfunction through its action on the pudendal nerve and the sacral plexus which provides the major excitatory input to the bladder.

[0005] Current treatment options for OAB and UI are exercise and behavioral modifications, pharmacological therapies, surgical intervention, and neuromodulation. Although each of these treatment options targets the UI and OAB populations, each has severe limitations.

[0006] Exercise and behavioral modifications often require patients to adhere to stringent routines, including scheduled voiding, maintenance of a bladder diary, and intense exercise regiments. While this may be a viable option for a small group of highly dedicated individuals, its daily impact on one's life makes it an unattractive option for most individuals.

[0007] Pharmacological intervention is the most widely prescribed therapy for OAB and UI. Unfortunately, as with the ingestion of any chemical, patients are often subject to side effects from their drug therapy. This is especially detrimental in older and elderly patient populations where interaction with other prescribed medications can have adverse effects. Further, there is a high rate of dissatisfaction, approximately 30%, amongst individuals using pharmacological treatment.

[0008] Surgical intervention is an extremely invasive treatment and often results in the long-term, and in some cases permanent, requirement for catheterization. The high expense of these procedures, coupled with the negative impact the procedures have on the patients quality of life, make this an option only when all other treatment options have been exhausted.

[0009] Neuromodulation is another treatment alternative for OAB and UI patients. Sacral nerve stimulation (SNS) has shown itself to be an effective treatment option for those with OAB or UI. However, the procedure requires the permanent implantation of an electrical stimulation device in the patient. One estimate puts the cost at nearly $14,000 with additional routine care costs of $593 per patient per year. Additionally, SNS's risk of battery failure, implant infection, and electrode migration, lead to a high reoperation rate and make this procedure unattractive.

[0010] More recently, the introduction of a posterior tibial nerve stimulator, often referred to as SANS, has shown itself to be another neuromodulation alternative. Yet as is the case with other forms of neuromodulation, this system is invasive in its nature. It requires the insertion of a needle two inches into the patient's ankle region in order to stimulate the posterior tibial nerve.

As well, it requires a minimum of 12 sessions for initial treatment, with the possibility of additional sessions needed for maintenance. Despite its high cost and invasive nature, though, an abundance of published peer-reviewed clinical trials demonstrate the safety and efficacy of the SANS therapy.

REVIEW OF THE PRIOR ART

[0011] U.S. patent number **6,941,171** describes a method and system for treatment of incontinence, urgency, frequency, and/or pelvic pain includes implantation of electrodes on a lead or the 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, and through the lead or catheter, which is tunneled subcutaneously between the stimulator and stimulation site. This device, while holding some therapeutic potential, is invasive in its delivery and requirement for implantation of device components.

[0012] U.S. patent number **5,984,854** describes a method for treating urinary incontinence which consists of delivering a train of current pulses through one or more magnetic stimulation coils to induce a train of magnetic flux pulses, which then induce an eddy current within the body, thereby to stimulate a group of pelvic floor muscles, the pudendal nerve, the external urethral sphincter, or the tibial nerve. While this device describes the employment of pulsed electromagnetic fields in the treatment of urinary incontinence, the application does not contemplate the use of any specific component to facilitate the placement of the magnetic coils over a targeted region of the body. That is, the application describes holding a coil over an intended region of the body, but does not contemplate the use of ergonomic wraps or other means for allowing an untrained user to apply the intended treatments. The application also does not call for the monitoring of the therapy using sensors to ensure that the nerve is actually being stimulated and does not provide for adjustability of the device by the healthcare provider or user in order to accommodate for commonly occurring physiologic and anatomic variations in nerve locations.

[0013] U.S. patent number **6,735,474** describes a method and system for treatment of incontinence and/or pelvic pain includes the injection or laparoscopic implantation of one or more battery- or radio frequency-powered microstimulators beneath the skin of the perineum and/or adjacent the tibial nerve. The devices are programmed using radio-frequency control via an external controller that can be used by a physician to produce patterns of output stimulation pulses judged to be efficacious by appropriate clinical testing to diminish symptoms. The stimulation program is retained in the microstimulator device or external controller and is transmitted when commanded to start and stop by a signal from the patient or caregiver. Again, this application involves the implantation of device components and is thus relatively invasive in nature. This patent also does not call for the monitoring of the therapy using sensors to ensure that the nerve is actually being stimulated and does not provide for adjustability of the device by the healthcare provider or user in order to accommodate for commonly occurring physiologic and anatomic variations in nerve locations.

[0014] U.S. patent application **20050171576** describes an electro-nerve stimulation apparatus 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. The transcutaneous electrode is operably connected to the other end of the first lead wire. An electrically conductive adaptor is secured to the other end of the second lead wire for electrically coupling to the terminal end of the percutaneous needle electrode. The lead wire set includes a single-use mechanism adapted to effectively discourage reuse of the electrodes. In use, the transcutaneous electrode is adhered to the patient's skin distal from the desired internal stimulation site. The percutaneous needle electrode is inserted through the skin in proximity to the desired internal stimulation site. The pulse generator is activated to pass current pulses between the transcutaneous electrode and the percutaneous needle electrode through the internal stimulation site. This device employs pulsed electric stimulation, and does not provide for the delivery of pulsed electromagnetic stimulation. Moreover, the device does not contemplate mechanism for facilitating use of the device by an untrained user (such as a wrap with markings to facilitate correct placement of the appliance). This application also does not call for the monitoring of the therapy using sensors to ensure that the nerve is actually being stimulated and

does not provide for adjustability of the device by the healthcare provider or user in order to accommodate for commonly occurring physiologic and anatomic variations in nerve locations.

[0015] In a paper by Wijkstrda, et al, entitled "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, the authors used an external pulsed magnetic coil in order to stimulate a peripheral nerve for the treatment of urinary incontinence. In this paper, though, the authors used a large magnetic field in order to ensure that the nerve was fired and the resulting nerve conduction was frequently painful or intolerable. Also, the device had major issues with coil alignment in that it utilized an internally implanted coil which had to be aligned with the fully external magnetic field in order to stimulate the nerve. Due to the difficulty in positioning the device, as in the previous applications, the practical application of this therapy would not allow for home healthcare usage without preset alignment and monitoring of the nerve. As with the remainder of the prior art, though, this application does not call for the monitoring of the therapy using sensors to ensure that the nerve is actually being stimulated and does not provide for adjustability of the device by the healthcare provider or user in order to accommodate for commonly occurring physiologic and anatomic variations in nerve locations. This application also does not provide for the use of multiple coils, overlapping or non-overlapping, which may be stimulated simultaneously or in unison in order to focus or locally strengthen the field in order to more accurately target the nerve.

[0016] Lastly, both U.S. patent numbers 6,086,525 and 5,984,854 both utilize pulsed magnetic fields in order to provide neuron-modulation for the treatment of urinary incontinence. While each of these applications have anticipated the use of external pulsed magnetic fields to stimulate the pudendal or sacral nerve offshoots, both are significantly preceded by the Wijkstrda paper mentioned above which was not considered as prior art in their issuance based on the prosecution history. Thus, broad claims such as the found in claim 1 of US Pat No 6,086,525 which are preceded by Wijkstrda are likely to be considered invalid. Regardless of the validity of these patents, though, neither document calls for the monitoring of the therapy using sensors to ensure that the nerve is actually being stimulated and neither provides for the use of a feedback loop with said sensors to ensure that the optimal level of stimulation is being generated despite varying conditions of the targeted region (ie ankle swelling will affect the required power to stimulate the nerve). Furthermore, neither application provides for adjustability of the device by

the healthcare provider or user (including the reversibly and irreversibly locking embodiments) in order to accommodate for customized nerve targeting required based on the commonly occurring physiologic and anatomic variations in nerve locations. These patents also do not provide for the use of multiple coils, overlapping or non-overlapping, which may be stimulated simultaneously or in unison in order to focus or locally strengthen the field in order to more accurately target the nerve.

SUMMARY OF THE INVENTION

[0017] The use of pulsed electromagnetic stimulation (PES) has been well established as a beneficial therapy in a variety of medical applications. The scientific principle behind this technology is that an electric current passed through a coil will generate an electromagnetic field. These fields, in turn, have been shown to induce current within conductive materials placed within the field. When applied to the human body, pulsed electromagnetic stimulation has been found to be an effective method of stimulating nerves resting within the electromagnetic field.

[0018] Building on recent data, which highlights the beneficial effects of invasive, needle-based electrostimulation (ES) of the posterior tibial nerve in individuals with OAB and UI, there is strong evidence for the treatment of these ailments with the use of the proposed Low Frequency Induction Therapy System (LoFIT™ System). In particular, ES has been found to modulate bladder dysfunction through its action on the pudendal nerve and the sacral plexus which provides the major excitatory input to the bladder. ES, and now the LoFIT System, have been built upon animal and human studies demonstrating how electrical stimulation of the pelvic and sacral nerves influence bladder emptying and provide neuromodulation therapies for OAB and UI. While the LoFIT™ System is capable of generating an electrical stimulus identical to that found in ES, it is completely non-invasive and can be applied by an untrained user.

[0019] The LoFIT™ System, consists of two, or more, components: a programmable Logic Controller (LC), which generates the required current, and an ergonomic or body-contoured cradle or wrap containing inductive coils (CW), through which the current is channeled in generating the pulsed electromagnetic fields. The device may also optionally utilize a sensor patch, or other sensing device (SD), which may feed information back to the LC in order to tailor

the strength and of the magnetic field and control coil activation based on nerve conduction. The CW allows for consistent, user-friendly targeting and modulation of peripheral nerves, in particular the pudendal nerve and the sacral plexus, via the posterior tibial nerve, on an outpatient basis. The CW, preferably, may contain multiple coils which may be activated or triggered simultaneously or in unison in order to generate the desired field and the direction and location of each of these coils may be reversibly or irreversibly adjusted by the healthcare provider or user in order to customize the location of stimulation to each user. The patient may then be sent home with their adjusted coil which has been customized to consistently target the target nerve required for neuromodulation. Lastly, the use of the SD to automatically control the activation of the coil, or coils, has not been described in the literature. By using the SD to automatically feed information concerning nerve conduction back to the LC, the amplitude of the current sent to the CW, and the coils to which it is sent, may be tailored based on the information received from the SD indicating whether or not the nerve had fired. This allows for an unparalleled level of control and accuracy in this form of therapy with regards to consistent, repeatable stimulation of the nerve in the home healthcare setting. Aside from the obvious benefit of being able to focus the targeting coils to the patient's nerve in order to accommodate for physiologic variation, the ability to control the pulse amplitude is also of great importance. Take, for example, the patient with leg edema. In this patient, based on whether their legs and ankles are swollen or not swollen, the power required to penetrate to the poseterior tibial nerve, in the case of the urinary incontinence application, varies greatly due to the variable depth of the nerve. Thus, having the SD feedback in this instance is not a luxury, but a necessity. The same is true of small alignment changes and other changes that may be found upon deployment in the variable home healthcare setting.

[0020] The LoFIT™ System is currently protected by 3 patents pending and one issued patent: U.S. Pat. No. 6,701,185 entitled "Method and apparatus for electromagnetic stimulation of nerve, muscle, and body tissues". Through benchtop testing, it has demonstrated that the LoFIT™ System is capable of non-invasively generating electrical currents similar to those found in therapeutic ES.

[0021] In its preferred embodiment, the CW is disposed in a flexible material. Said flexible material will be easily placed onto the body of the user for application of the LoFIT. Markings on this component may indicate how the wrap should be positioned on the body, making the

device easy to use and user-friendly. The device may be used while ambulatory or in a seated position. In another embodiment, the CW is disposed in a footrest or cradle and the user simply places their foot or leg into the rest (and adjacent to the coil) prior to therapy. In other embodiments, the CW may be disposed into back supports, girdles, arm slings, arm cradles, wrist cradles, wrist slings, neck bands, neck rests, headbands or headrests depending on the peripheral nerve to be targeted.

[0022] In one embodiment of the device, the CW will contain an array of overlapping coils. The overlapping coils will help to assure accurate targeting of the posterior tibial nerve with the therapy in a home healthcare setting. In an alternative embodiment of the device, the CW will contain a Helmholtz coil arrangement disposed in the flexible material for the delivery of LoFIT. The coil arrangement may take any shape, though, so long as the stimulation of the nerve is achieved.

[0023] In one embodiment of the device, said CW will be disposed in a material that is intended to be positioned over the ankle. This design will help to stimulate the posterior tibial nerve in the region of the ankle in a location that is easily targeted for therapeutic intervention. This material may be an ergonomic wrap and/or a fixed footrest into which the user may rest their leg and/or ankle and may target the posterior tibial nerve (or other peripheral nerve) anywhere along its length all the way to its sacral or pudendal nerve root origins.

[0024] In this, and other, embodiments, one or more patches or sensors may be placed at a site distant from the region of direct exposure to the magnetic coil impulse. This sensor or patch may be capable of detecting and recording the firing of nerves within the body. In particular, it may be able to accurately record the firing of the target nerve. This patch or sensor may also be used to tailor the firing of the coil (or coils) with increasing pulse amplitude until nerve conduction is detected. This system, then, is capable of reproducibly ensuring that the correct level of stimulation is provided with every session due to the presence or absence of the nerve conduction impulse. The sequence of coil firing, or even pattern of coil firing, can also be tailored to optimize therapy based on sensor input control over power consumption and coil positioning. This automated feedback loop to adjust stimulation of one or more coils within the conductive wrap and/or foot/leg rest to ensure that peripheral nerve conduction is being achieved has not been described in the previous art and is one of the major innovations in the present invention. Ideally, the sensor will be a simple voltage or current detector, ie an EKG patch,

which can be placed anywhere in the vicinity of the nerve to detect its activation. In the ideal embodiment, as well, the amplitude and/or firing sequence of the coil or coils may be ramped to generate more powerful and/or broader magnetic fields until nerve conduction is detected. Once motor nerve conduction is detected, the stimulus may be adjusted or maintained at its current level for the duration of the therapy. In the instance where the sensor does not receive interference from the magnetic pulse, as well, the sensor may be placed directly in the field of stimulation.

[0025] Additionally, the patient may provide feedback to control the level of stimulation. In this embodiment, the patient will activate a switch once a certain stimulus occurs, ie they feel their two twitch or they feel paresthesias over the sole of their foot. The device, then, may be controlled on an outpatient basis not only be the sensors attached to the controller, but also by patient input. In one example of this embodiment, the patient will be asked to activate a button once their toe begins to twitch. The patient will then be asked to continue pressing the button until they can no longer feel their toe twitching and, instead, feel a tingling (or paresthesia) in their foot. This indicates that the optimal therapy may be delivered at this stimulus level and the patient may be instructed to simply retain their foot, knee, etc. within the device until therapy has ended.

[0026] In any of the embodiments mentioned, including the preferred embodiment, the coils may be adjustable within the wrap or device itself. In this preferred embodiment, the coils may be reversibly adjusted and, preferably, locked into place by the physician or healthcare provider prior to initiation of therapy. Once this optimization of the coil configuration has been achieved, the user may then continue their therapy in the home healthcare setting or within the physician or healthcare provider's office using their custom-targeted device with its locked coil configuration.

[0027] In an alternative embodiment of the device, said CW will be disposed in a material that is intended to fit over the knee (or elsewhere along the course of the sacaral or pudendal nerve offshoots) for the delivery of therapeutic stimulation.

[0028] In one embodiment of the device, the LC component is powered by a portable power source (e.g. rechargeable battery) to facilitate mobility with delivery of the intended treatment. In an alternative embodiment of the device, the LC can be powered by a fixed power source (e.g. plugging the device into a traditional outlet in the wall).

[0029] Despite the name LOFIT, it is important to note that any frequency of stimulation may be delivered by the present invention including, but not limited to, low-frequency, high-frequency, mid-frequency, ultrahigh frequency, etc. Furthermore, non-overlapping coils may also be used to generate the desired field, although overlapping or Helmholtz coils are ideal in their ability to target a broader region and achieve more thorough stimulation.

[0030] Furthermore, while this summary has focused on the device and methods for stimulating the posterior tibial nerve and peripheral nerves related to the sacral and pudendal nerves for incontinence therapy, it may also be used for other peripheral and central nerve stimulation, so long as the stimulating coil or coils are at least in part controlled by automated feedback from the nerve conduction sensor and/or patient feedback described above. Thus, the coil or coils may be reversibly locked into an optimally targeted configuration within their ergonomic, body-contoured, wrap or cradle.

[0031] Potential indications for which this therapy has been validated or may hold promise are broad including 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, Burn 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, Urinary incontinence, overactive bladder, 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. Once the target nerve has been identified, ie the vagal nerve for hypertension, the patient need simply apply the device with the ergonomically targeted coils and nerve conduction sensor to allow for repeatable, consistent neuromodulation based on sensor feedback to ensure proper nerve conduction has been achieved for the duration of the therapy. 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. In contrast to existing peripheral nerve stimulation technology (magnetic and electrical), as well, this therapy need not be delivered by a professional healthcare provider and can be controlled to optimize the level of therapy delivered based on power consumption and nerve stimulation requirements.

[0032] The logic controller may also be controlled by the sensing device and or user input to tailor the strength of the current pulse or the sequence of coil firing. For example, in a dual-coil embodiment, the two coils may be placed next to each other or in an overlapping configuration with varying levels of power targeted to each coil in order to provide a variety of field shapes and amplitudes. The sensing element may then feedback to the controller that the nerve has, or has not, been stimulated allowing the controller to try another pulse shape, by varying power to the individual coils, or pulse amplitude, by increasing the current delivered.

[0033] In yet a further embodiment, the neural stimulation technology of the present invention may be utilized with electrical transcutaneous stimulation and/or invasive electrical needle technologies, so long as the method of stimulation is modulated based on information sent back to the stimulator control unit from one or more sensors which may be used to detect, and/or maintain, the correct level of stimulation. The ergonomic applicator and targetable feature of the present invention may also be employed with these technologies, with the emphasis being its use

with the transcutaneous electrical stimulation method of nerve stimulation due to the requirement for precise targeting of the therapy. This targeting could be achieved through fitting the patient with an ergonomic wrap and then simply applying the conductive wrap to the body, applying a sensor along the path of the stimulated nerve (assuming one is not incorporated into the wrap) and then and activating the device to provide the neural stimulation. The transcutaneous electrical stimulation sensor, or sensors, placed on the body or incorporated within the wrap may also provide feedback as to the quality of the electrical connection to the skin which is directly related to the burn risk associated with this therapy. These methods of stimulation are not optimal, though, due to the resulting skin irritation and risk of potential burns, a very serious issue in the large percentage of patients that will already have neuropathy. Even the safeguard above is not a failsafe in that one or more of the patches may still become displaced causing a potential burn. Also the utility of the critical sensor component of the device declines with direct application of potentially interfering electrical impulses to the treatment site, provide a much noisier environment for detection of nerve conduction. That being said, the preferred embodiment of the invention still utilizes the pulsed electromagnetic fields as described above.

[0034] In yet another embodiment, the features of sensory feedback and/or adjustment of an inductive coil, or coils, may be used in a system involving communication between a fully external inductive coil, or coils, and a fully implantable inductive coil, or coils. In this embodiment, which may also involve an ergonomic applicator, the external coil, or coils, within the ergonomic applicator may be adjusted by the user or healthcare provider in order to optimize inductive communication of power between the coils. Sensors may be utilized in order to provide feedback that the coil position has been optimized and the external coil may be reversibly locked into position within the applicator. Two distinct examples of this embodiment are: 1) transfer of power to recharge an implantable device, and 2) transfer of power to activate an implantable device.

[0035] In the first scenario involving an implantable rechargeable device, the external recharging coil, or coils, may be used to recharge any implantable device with an appropriate inductive coil, or coils, to receive the inductive fields generated by the external recharging coil, or coils. The recharging coil, or coils, may, in the case of the purely recharging embodiment, also contain circuitry to determine the amount of resistance encountered by its magnetic field, or other electrical properties that may reflect the quality and degree of magnetic coupling achieved.

Based on this feedback, the coil, or coils, in the applicator may be adjusted manually or automatically in order to optimize the coupling achieved with every recharging session. Alternatively, the sensing element may instead be incorporated into the implantable device which may 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 recharging coil. In any scenario, though, the recharging coil, or coils, may be manually or automatically positioned based on feedback from sensors integrated within the ergonomic coil applicator or external to the applicator (ie within the implantable device). The coil, or coils, within the applicator may then be reversibly locked into place for the duration of the recharge session. The implantable device may also communicate to the external recharging unit that the implantable device has been fully recharged and that the recharging session has been completed. An example of this embodiment involves the use of a magnetic field generator (ie an ergonomic wrap incorporating an inductive coil, or coils) which may be magnetically coupled to an implanted electrical impulse generating device capable of stimulating the posterior tibial nerve. Upon application of the recharging coil, or coils, magnetic coupling may be automatically or manually optimized based on sensor feedback after which the coil, or coils, may be reversibly locked into place for the duration of the recharge. This sensor may be a component of the circuitry within the powering coils, or coils, or the implantable coil, or coils, themselves or may be an external component which may deliver feedback to optimize the recharging of the device. By allowing for intermittent recharging of this, and other, implantable devices, the present invention allows for the implantable device to consume more power in performing its function with less concern over battery laife and more concern over optimizing performance.

[0036] In the second embodiment, in which the inductive coil, or coils, may actively power the device, the powering coil, or coils, may also contain circuitry to determine the amount of resistance encountered by its magnetic field, or other electrical properties that may reflect the quality and degree of magnetic coupling achieved. Based on this feedback, the powering coil, or coils, in the applicator may be adjusted manually or automatically in order to optimize the coupling achieved with every recharging session. Alternatively, the sensing element may instead be incorporated into the implantable device which may 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 any scenario, though,

the powering coil, or coils, may be manually or automatically positioned based on feedback from sensors integrated within the ergonomic coil applicator or external to the applicator (ie within the implantable device or elsewhere on the body). The coil, or coils, within the applicator may then be reversibly locked into place for the duration of the activation of the device. The implantable device may also communicate directly to the external powering unit that the implantable device has been adequately powered and the treatment session is over. An example of this embodiment is the use of a magnetic field generator, ie an ergonomic wrap incorporating an inductive coil, or coils, which may be magnetically coupled to a needle targeting the posterior tibial nerve. Upon application of the powering coil, or coils, magnetic coupling may be automatically or manually optimized based on sensor feedback after which the coil, or coils, may be reversibly locked into place for the duration of the device activation. This sensor may be a component of the circuitry within the powering coils, or coils, or the implantable coil, or coils, themselves or may be an external component such as the conduction sensing patch described previously in which case the power delivered may be automatically adjusted to optimize the stimulation of the nerve based on feedback from the nerve conduction sensors.

[0037] Lastly, the device of the present invention has been described as deploying an ergonomic wrap or cradle. This ergonomic wrap or cradle, though, may not be necessary so long as the external coil may be held in a relatively fixed position during delivery of the therapy to allow for optimization of the positioning of the coil, or coils, based on sensor feedback. It is the optimization of coil positioning based on sensor feedback and/or the ability to reversibly lock the automatically or manually adjustable coil, or coils, into position that are the most critical elements of the present invention.

[0038] While the focus of this specification has been neuromodulation, this technology may be applied to any body tissues, including nerve, muscle, skin, vasculature, or any other organ or tissue within the human body. Although the above is a complete and accurate description of the invention, any of a number of variations, additions and the like may be made to the embodiments described without departing from the scope of the invention. For example, devices and methods described above may be used to treat any suitable condition or perform any suitable function via neuromodulation regardless of whether the stimulation source is electromagnetic fields, direct electric current, ultrasound, RF fields, etc. Therefore, the foregoing description is provided

primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is defined in the claims cited below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] Figure 1 is a perspective view of the LoFIT System illustrating the components for delivery of Low Frequency Induction Therapy in one embodiment of the present invention with the CW incorporating an array of overlapping coils.

[0040] Figure 2 is a perspective view of the LoFIT System illustrating the components for delivery of Low Frequency Induction Therapy in one embodiment of the present invention with the CW incorporating a Helmholtz coil arrangement.

[0041] Figure 3 is a perspective view of the LoFIT System illustrating the components for delivery of Low Frequency Induction Therapy in one embodiment of the present invention with the CW disposed over the knee for delivery of the intended therapy. In this and other embodiments the overlapping or Helmholtz coils are desirable in order to allow application by an untrained user.

[0042] Figure 4 is a perspective view of the ergonomic footrest/cradle and logic controller with embedded coils. Also depicted in this illustration is a sensor (in this case a conductive electrode patch) that may be used to adjust the stimulation parameters of the coils and/or alert the user.

[0043] Figure 5 is a perspective view of the ergonomic knee rest/cradle and logic controller with embedded coils. Also depicted in this illustration is a sensor (in this case a conductive electrode patch) that may be used to adjust the stimulation parameters of the coils and/or alert the user.

[0044] Figure 6 is a perspective view of the function of the foot cradle embodiment of the device employing overlapping coils and a proximally placed nerve conduction sensor.

[0045] Figure 7 is a perspective view of the function of the foot cradle embodiment of the device employing a reversibly lockable, adjustable coil orientation.

[0046] Figure 8 is a perspective view of the function of the foot cradle embodiment of the device employing multiple sensors.

[0047] Figure 9A-D are perspective views of various other embodiments of the body worn ergonomic applicator garments (all shown with optional overlapping coils).

DETAILED DESCRIPTION OF THE DRAWINGS

[0048] The invention is susceptible to many and various embodiments; those embodiments described below should not be interpreted as restrictive, but rather as merely illustrative of the invention. As illustrated in Figure 1, one embodiment of the present invention provides a LoFIT System with a CW 2 disposed over the Tibial Nerve 4 in the region of the ankle. The CW 2 is shown incorporating an array of overlapping coils 1.

[0049] Figure 2 illustrates an alternative embodiment of the present invention, with the CW 2 incorporating a Helmholtz coil arrangement 5 positioned over the Posterior Tibial Nerve 4 for therapeutic stimulation.

[0050] Figure 3 illustrates an alternative embodiment of the present invention, with the CW 6 positioned now over the popliteal fossa in the region of the knee for stimulation of the Posterior Tibial Nerve 4.

[0051] Figure 4 is a perspective view of the ergonomic footrest/cradle and logic controller with embedded coils. Also depicted in this illustration is a sensor (in this case a conductive electrode patch) that may be used to adjust the stimulation parameters of the coils and/or alert the user. In this embodiment, the ankle and heel are captured within an ergonomic footrest which directly apposes the stimulating coils to the site of stimulation. This embodiment allows for increased ease of application and streamlined delivery of therapy for users that prefer to remain seated for the duration of their therapy. This embodiment illustrates overlapping coils and a single sensor patch proximal to the stimulation site. The coil arrangement may also be one of 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 any other coil design that is capable of providing stimulation of the target nerve. Additionally, one or more sensor patches may be applied to the patient (or, alternatively may be incorporated into within the knee rest/cradle itself) to provide information to the patient or logic controller to tailor therapy accordingly.

[0052] Figure 5 is a perspective view of the ergonomic knee rest/cradle and logic controller with embedded coils. Also depicted in this illustration is a sensor (in this case a conductive electrode patch) that may be used to adjust the stimulation parameters of the coils and/or alert the user. In this embodiment, the knee and leg are captured within an ergonomic knee rest which directly apposes the stimulating coil or coils to the site of stimulation. This embodiment allows for increased ease of application and streamlined delivery of therapy for users that prefer to remain seated for the duration of their therapy. This embodiment illustrates overlapping coils and a single sensor patch proximal to the stimulation site. The coil arrangement may also be one of 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 any other coil design that is capable of providing stimulation of the target nerve. Additionally, one or more sensor patches may be applied to the patient (or, alternatively may be incorporated into within the knee rest/cradle itself) to provide information to the patient or logic controller to tailor therapy accordingly.

[0053] Figure 6 is a perspective view of the function of the foot cradle embodiment of the device employing overlapping coils and a proximally placed nerve conduction sensor. Optionally, the patient may also provide input to control therapy, alternative coil designs may be utilized and an alternative application system may be used, ie an ergonomic wrap. Further optionally, the device may be designed to target the nerve, or other nerves, via alternative ergonomic applicators including wraps, cradles, supports for the foot, leg, lower back, arm, hand, neck, thorax, etc.

[0054] Figure 7 is a perspective view of the function of the foot cradle embodiment of the device employing a reversibly lockable, adjustable coil orientation. In this embodiment, which may also be applied to the body-worn wrap embodiment of the device, the user or the provider adjusts positioning of the coils to optimize therapy in office or home-healthcare setting. The position of the coils may be locked once nerve conduction is detected after which the user simply need apply the device and sensing patch (in the external patch embodiment) then activate the controller to provide automated, replicable, consistent therapy to the precisely targeted nerve every time. In an alternative embodiment, the controller may adjust the coil positioning to optimize therapy for each session. While more difficult to implement and more time-intensive, this setup will provide for accurate targeting of the nerve every time, regardless of alterations in

patient positioning or changes to the anatomy (ie a swollen foor, etc.). In this embodiment, the device simply varies the orientation of the coil until stimulation has been sensed. In the illustrated embodiment, the user, healthcare provider or controller simply slides the coil back and forth here shown in one axis, but adjustment along all three axes are possible.

[0055] Figure 8 is a perspective view of the function of the foot cradle embodiment of the device employing multiple sensors. These sensors may detect a variety of physiologic changes, including neural impulses, muscular contraction, twitching, etc. that may occur with neural or muscular stimulation. One or more of the illustrated sensors may be employed in any of the embodiments regardless of the regions of the body being stimulated- back, leg, arm, neck, head, torso, etc. and the sensor may be incorporated within the actual cradle or wrap or, otherwise, applied in conjunction with the cradle or the wrap. In its ideal embodiment, the sensor will be a disposable, single-use EKG-type patch attached to the body outside of the cradle or wrap along the nerve conduction pathway and then connected to the controller prior to therapy initiation. This will allow for intimate body contact of the sensor without the risk of infection, etc. In any embodiment employing the sensors, as well, the sensors may be used both in the initiation and in the monitoring of the therapy. The sensor may be used in the initiation of therapy in order to optimize the strength of the magnetic field and, in one embodiment, to adjust the positioning of the coils within the wrap or cradle. Once therapy has begun, though, the sensor may then continue to monitor for nerve conduction to ensure that the correct level of stimulation is being used throughout. In the event that for some reason the nerve conduction decays during therapy, the controller may also automatically adjust to ensure that the appropriate therapy is delivered for the appropriate amount of time. Any of the sensors may be connected to the controller by any means, including, but not limited to: wireless signals, wired signals, radiofrequencies, Bluetooth, infrared, ultrasound, direct switching of the current circuit, etc. so long as there is communication between the sensor and the device. In an alternative embodiment, though, the physician may simply use the sensor to adjust the device, such as locking the coil or coils into position, in order to optimize future therapies. In this embodiment, the sensor is used to detect the optimal positioning of the coil, or coils, but may not be required for each individual therapy session. Lastly, the sensor, or sensors, in the present invention may also take the form of an inductive coil designed to receive impulses from the underlying nerves. In this manner inductive

technologies may be used to both stimulate the nerve or tissues as well as record the effect to the stimulated nerves or tissues.

[0056] Figure 9A-D are perspective views of various other embodiments of the body worn ergonomic applicator garments (all shown with optional overlapping coils). Each of these embodiments is shown with overlapping coils, although coils of any configuration may be used with these wraps. Each of these wraps, as well, may be translated into a cradle applicator which is not worn, but into which a body part may be placed. These applicators may also contain sensors to provide feedback to the controller, and may include reversibly, or irreversibly, locking coils within the applicator. Contemplated embodiments that are not illustrated include: a headworm garment (such as a cap), a neckworm garment (ie a neck brace and a lower-back garment. Each garment and applicator may also utilize the locking, targeted coil feature without requiring the use of the any sensing components.

[0057] The device of the present invention is unique in that it allows for the stimulation of the posterior tibial nerve, or other peripheral nerves, in a non-invasive manner, using an ergonomically designed wrap to specifically target the posterior tibial nerve in in a consistent and repeatable manner in patients with overactive bladder or incontinence problems due to the novel reversibly lockable movement of the coil or coils, incorporation of one or more sensors and, optionally, patient feedback.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Device for Inductive Neuromodulation and Low Frequency Induction Therapy

[0058] Example Indications for Use:

[0059] 1) Prevention of urinary incontinence (UI) and/or overactive bladder (OAB)

[0060] Example Methods for Use:

[0061] 1) A patient with a condition of UI of OAB, for example, will place a conductive wrap disposed in a flexible material over the region of the ankle (or alternatively the knee). The patient may alternatively use the ergonomic foot/leg rest or cradle with embedded coils to provide the required pulsed magnetic fields.

[0062] 2) A sensor or patch will be placed on the patient's body along the course of the nerve, ideally proximal to the stimulation site to ensure afferent nerve stimualtion, and will be connected to the logic controller.

[0063] 3) The physician or healthcare provider will then adjust the coil or coils until nerve conduction is maximized based on patient and sensor feedback. The coil may then be reversibly locked into this position within the conductive wrap or ergonomic cradle and remain in this position during subsequent use.

[0064] 4) The logic controller component of the device may then be activated and the coil or coils will generate inductive magnetic fields. In the preferred embodiment, these fields will begin at low amplitude and slowly ramp up until nerve conduction is detected by the sensor and/or by the patient (who may signal that motor conduction has occurred by pressing a button, etc.). Alternatively, one or more coils may also be activated to increase the covered area if stimulation does not occur with the initial coil configuration

[0065] 5) Once stimulation is detected, the inductive magnetic pulses will continue for the directed duration of use, 15-30 minutes in the ideal embodiment. Ideally, the sensor will remain in place for the duration of use, as well, to ensure stimulation occurs the entire time and to allow for correction if nerve conduction deteriorates. The logic controller may be powered either by a portable power source (e.g. battery) or a fixed power source (e.g. traditional wall outlet).

[0066] 6) The optimal stimulation will consist of 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.

[0067] 7) The conductive wrap and/or ergonomic cradle will be removed from the body when therapeutic stimulation is not being delivered.

[0068] 8) The conductive wrap and/or ergonomic cradle will be reapplied along with the sensor patch (ideally disposable) as indicated, on a daily basis in the ideal embodiment, and steps 4-8 will be repeated.

Claims:

What is claimed is:

1. A urinary incontinence (UI) or overactive bladder (OAB) treatment device, comprising:

   An electronic controller, which is capable of generating current;

   An ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields, focused on the target nerve,

   One or more sensors which may be placed in contact with the body and connected to said controller, wherein

   Said sensor, or sensors, may provide feedback which may be used to control the positioning, amplitude or firing sequence of the inductive coil, or coils, in generating said inductive magnetic fields, and wherein

   Said inductive coil, or coils, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption on a customized basis

2. A urinary incontinence (UI) or overactive bladder (OAB) treatment device, comprising:

   An electronic controller, which is capable of generating current;

   An ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields, focused on the target nerve,

3. The device of claim 2 wherein one or more sensors which may be placed in contact with the body and connected to said controller

4. The device of claim 3 wherein said sensor, or sensors, may provide feedback which may be used to control the positioning, amplitude or firing sequence of the inductive coil, or coils, in generating said inductive magnetic fields.

5. The device of claim 2 wherein said inductive coil, or coils, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption on a customized basis.

6. The device of claim 2 wherein said ergonomic applicator may be a cradle or fixture into which a body part may be placed.

7. The device of claim 2 wherein said ergonomic applicator may be a body-worn garment or wrap which may be repeatably secured in the correct orientation over the region to be targeted.

8. The device of claim 2 wherein said ergonomic applicator incorporates markings to facilitate user-friendly placement of the appliance over the targeted region of the body for the desired stimulation.

9. The device of claim 2 wherein said ergonomic applicator is intended to be placed over the body in the region of the ankle, where the posterior tibial nerve can be readily targeted for stimulation.

10. The device of claim 2 wherein said ergonomic applicator is intended to be placed over the body in the region of the knee, where the tibial nerve can be readily targeted for stimulation.

11. The device of claim 2 wherein said ergonomic applicator incorporates an array of overlapping coils to facilitate accurate targeting of the posterior tibial nerve in a home healthcare setting.

12. The device of claim 2 wherein said ergonomic applicator incorporates a Helmholtz array of coils for the delivery of stimulation to the tibial nerve.

13. A method for treating urinary incontinence (UI) or overactive bladder (OAB) treatment device, comprising:

    Generating current through an electronic controller,

    Placing a body part into an ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields

14. The method of claim 13 wherein one or more sensors, may be placed in contact with the body and connected to said controller, in order to control or optimize the effect, or effects, of the delivered magnetic field, or fields

15. The method of claim 14 wherein feedback from said sensor, or sensors, may be used to optimize or control the amplitude or firing sequence of the inductive coil, or coils, in generating said inductive magnetic fields.

16. The method of claim 13 wherein said inductive coil, or coils, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption.

17. A inductive neuromodulation treatment device for use in the treatment of medical conditions, comprising:

    An electronic controller, which is capable of generating current;

    An ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields, focused on the target nerve,

    One or more sensors which may be placed in contact with the body and connected to said controller, wherein

    Said sensor, or sensors, may provide feedback which may be used to control the positioning, amplitude or firing sequence of the inductive coil, or coils, in generating said inductive magnetic fields, and wherein

    Said inductive coil, or coils, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption on a customized basis

18. A neuromodulation treatment device, comprising:

    An electronic controller, which is capable of generating current;

An ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields, focused on the target nerve,

19. The device of claim 18 wherein one or more sensors which may be placed in contact with the body and connected to said controller, wherein

20. The device of claim 18 wherein said sensor, or sensors, may provide feedback which may be used to control the positioning, amplitude or firing sequence of the inductive coil, or coils, in generating said inductive magnetic fields.

21. The device of claim 18 wherein said inductive coil, or coils, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption on a customized basis.

22. The device of claim 18 wherein said ergonomic applicator may be a cradle or fixture into which a body part may be placed.

23. The device of claim 18 wherein said ergonomic applicator may be a body-worn garment or wrap which may be repeatably secured in the correct orientation over the region to be targeted.

24. The device of claim 18 wherein said ergonomic applicator incorporates markings to facilitate user-friendly placement of the appliance over the targeted region of the body for the desired stimulation.

25. The device of claim 18 wherein said ergonomic applicator is intended to be placed over the body in the region of the ankle, where the posterior tibial nerve can be readily targeted for stimulation.

26. The device of claim 18 wherein said ergonomic applicator is intended to be placed over the body in the region of the knee, where the tibial nerve can be readily targeted for stimulation.

27. The device of claim 18 wherein said ergonomic applicator incorporates an array of overlapping coils to facilitate accurate targeting of the posterior tibial nerve in a home healthcare setting.

28. The device of claim 18 wherein said ergonomic applicator incorporates a Helmholtz array of coils for the delivery of stimulation to the tibial nerve.

29. A method for delivering a neuromodulation treatment, comprising:

    Generating current through an electronic controller,

    Placing a body part into an ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields

30. The method of claim 29 wherein one or more sensors, may be placed in contact with the body and connected to said controller, in order to control or optimize the effect, or effects, of the delivered magnetic field, or fields

31. The method of claim 29 wherein said sensor, or sensors, may be used to optimize or control the amplitude or firing sequence of the inductive coil, or coils, in generating said inductive magnetic fields.

32. The method of claim 29 wherein said adjustable inductive coil, or coils, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption.

33. The device of claim 18 wherein the target nerve is the posterior tibial nerve.

34. The method of claim 29 wherein the target nerve is the posterior tibial nerve.

35. The device of claim 18 wherein the target nerve is the tibial nerve.

36. The method of claim 29 wherein the target nerve is the tibial nerve.

37. The device of claim 18 wherein the target nerve is the pudendal nerve.

38. The method of claim 29 wherein the target nerve is the pudendal nerve.

39. The device of claim 18 wherein the target nerve is the sacral nerve.

40. The method of claim 29 wherein the target nerve is the sacral nerve.

41. The device of claim 18 wherein the target nerve is the vagus nerve.

42. The method of claim 29 wherein the target nerve is the vagus nerve.

43. The device of claim 18 wherein the target nerve may be any superficial nerve, or deep nerve with a superficial branch, ideally within 3-5 cm of the skin.

44. The method of claim 29 wherein the target nerve is the wherein the target nerve may be any superficial nerve, or deep nerve with a superficial branch, ideally within 3-5 cm of the skin.

45. The device of claim 18 wherein the condition to be treated is urinary incontinence.

46. The method of claim 29 wherein the condition to be treated is urinary incontinence.

47. The device of claim 18 wherein the condition to be treated is fecal incontinence.

48. The method of claim 29 wherein the condition to be treated is fecal incontinence.

49. The device of claim 18 wherein the condition to be treated is obesity.

50. The method of claim 29 wherein the condition to be treated is obesity.

51. The device of claim 18 wherein the condition to be treated is depression.

52. The method of claim 29 wherein the condition to be treated is depression.

53. The device of claim 18 wherein the condition to be treated is fecal incontinence.

54. The method of claim 29 wherein the condition to be treated is fecal incontinence.

55. The device of claim 18 wherein the condition to be treated is hypertension.

56. The method of claim 29 wherein the condition to be treated is hypertension.

57. The device of claim 18 wherein the condition to be treated is pain.

58. The method of claim 29 wherein the condition to be treated is pain.

59. The device of claim 18 wherein the condition to be treated is back pain.

60. The method of claim 29 wherein the condition to be treated is back pain.

61. The device of claim 18 wherein the condition to be treated is restless leg syndrome.

62. The method of claim 29 wherein the condition to be treated is restless leg syndrome.

63. The device of claim 18 wherein the condition to be treated is Guillain Barre syndrome.

64. The method of claim 29 wherein the condition to be treated is Guillain Barre syndrome.

65. The device of claim 18 wherein the condition to be treated is quadriplegia or paraplegia.

66. The method of claim 29 wherein the condition to be treated is quadriplegia or paraplegia.

67. The device of claim 18 wherein the condition to be treated is neuralgia.

68. The method of claim 29 wherein the condition to be treated is neuralgia.

69. The device of claim 18 wherein the condition to be treated may be any disorder with a neural component which may show benefit from neuromodulation.

70. The method of claim 29 wherein the condition to be treated may be any disorder with a neural component which may show benefit from neuromodulation.

71. An electromagnetic therapy device for use in the treatment of medical conditions, comprising:

An electronic controller, which is capable of generating current;

An ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields, focused on the target tissue, wherein

Said inductive coil, or coils, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption on a customized basis

72. A method for delivering a neuromodulation treatment, comprising:

Generating current through an electronic controller,

Placing a body part into an ergonomic applicator containing one or more inductive coils through which the current is channeled in order to generate an inductive magnetic field, or fields

Reversibly, or irreversibly, locking the adjustable coil, or coils, into position to optimize stimulation of the target tissues and/or minimize power consumption.

73. The device of claim 71 wherein the targeted tissue is muscle.

74. The method of claim 72 wherein the targeted tissue is muscle.

75. The device of claim 71 wherein the targeted tissue is brain.

76. The method of claim 72 wherein the targeted tissue is brain.

77. The device of claim 71 wherein the targeted tissue is bone.

78. The method of claim 72 wherein the targeted tissue is bone.

79. The device of claim 71 wherein the targeted tissue is an abdominal organ.

80. The method of claim 72 wherein the targeted tissue is an abdominal organ.

81. The device of claim 71 wherein the targeted tissue is cardiovascular.

82. The method of claim 72 wherein the targeted tissue is cardiovascular.

83. The device of claim 71 wherein the targeted tissue is skin.

84. The method of claim 72 wherein the targeted tissue is skin.

85. The device of claim 71 wherein the targeted tissue is malignant.

86. The method of claim 72 wherein the targeted tissue is malignant.

87. The device of claim 71 wherein the targeted tissue is the lung or diaphragm.

88. The method of claim 72 wherein the targeted tissue is the lung or diaphragm.

89. An energy therapy device for use in the treatment of medical conditions, comprising:

An energy generator

An ergonomic applicator employing energy transmitting elements capable of focusing the energy field, or fields, on the target tissue

90. The device of claim 89 wherein said energy transmitting elements, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption on a customized basis

91. The device of claim 89 wherein one or more sensors, may be placed in contact with the body and connected to said controller, in order to control or optimize the effect, or effects, of the delivered energy field, or fields

92. The device of claim 89 wherein said sensor, or sensors, may be used to optimize or control the amplitude, frequency or waveform of said energy fields

93. The device of claim 89 wherein said energy source is pulsed electromagnetic fields

94. The device of claim 89 wherein said energy source is ultrasound

95. The device of claim 89 wherein said energy source is direct electric current

96. A method for delivering a neuromodulation treatment, comprising:

Generating energy through a controller,

Placing a body part into an ergonomic applicator containing one or more energy transmitting elements capable of generating a stimulatory field, or fields

97. The method of claim 96 wherein one or more sensors, may be placed in contact with the body and connected to said controller, in order to control or optimize the effect, or effects, of the delivered energy field, or fields

98. The method of claim 96 wherein said sensor, or sensors, may be used to optimize or control the amplitude, frequency or waveform of said energy fields

99. The method of claim 96 wherein said energy transmitting elements, may be reversibly, or irreversibly, locked into position to optimize stimulation of the target nerve and/or minimize power consumption.

100. The method of claim 96 wherein said energy source is pulsed electromagnetic fields

101. The method of claim 96 wherein said energy source is ultrasound

102. The method of claim 96 wherein said energy source is direct electric current

METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY

ABSTRACT OF THE DISCLOSURE

The present device of the present invention consists of two, or more, components: an electronic controller which generates the required current, an ergonomic or body-contoured cradle or wrap containing inductive coils, through which the current is channeled in generating the pulsed electromagnetic fields, and a sensing device, which may feed information back to the electronic controller in order to tailor the strength of the magnetic field and control coil activation based on feedback. The ergonomic cradle or wrap allows for consistent, user-friendly targeting and modulation of peripheral nerves, in particular the pudendal nerve and the sacral plexus, via the posterior tibial nerve, on an outpatient basis. The ergonomic cradle or wrap, preferably, may contain multiple coils which may be activated or triggered simultaneously or in unison in order to generate the desired field and the direction and location of each of these coils may be reversibly or irreversibly adjusted by the healthcare provider or user in order to customize the location of stimulation to each user. The patient may then be sent home with their adjusted coil which has been customized to consistently target the target nerve required for neuromodulation.

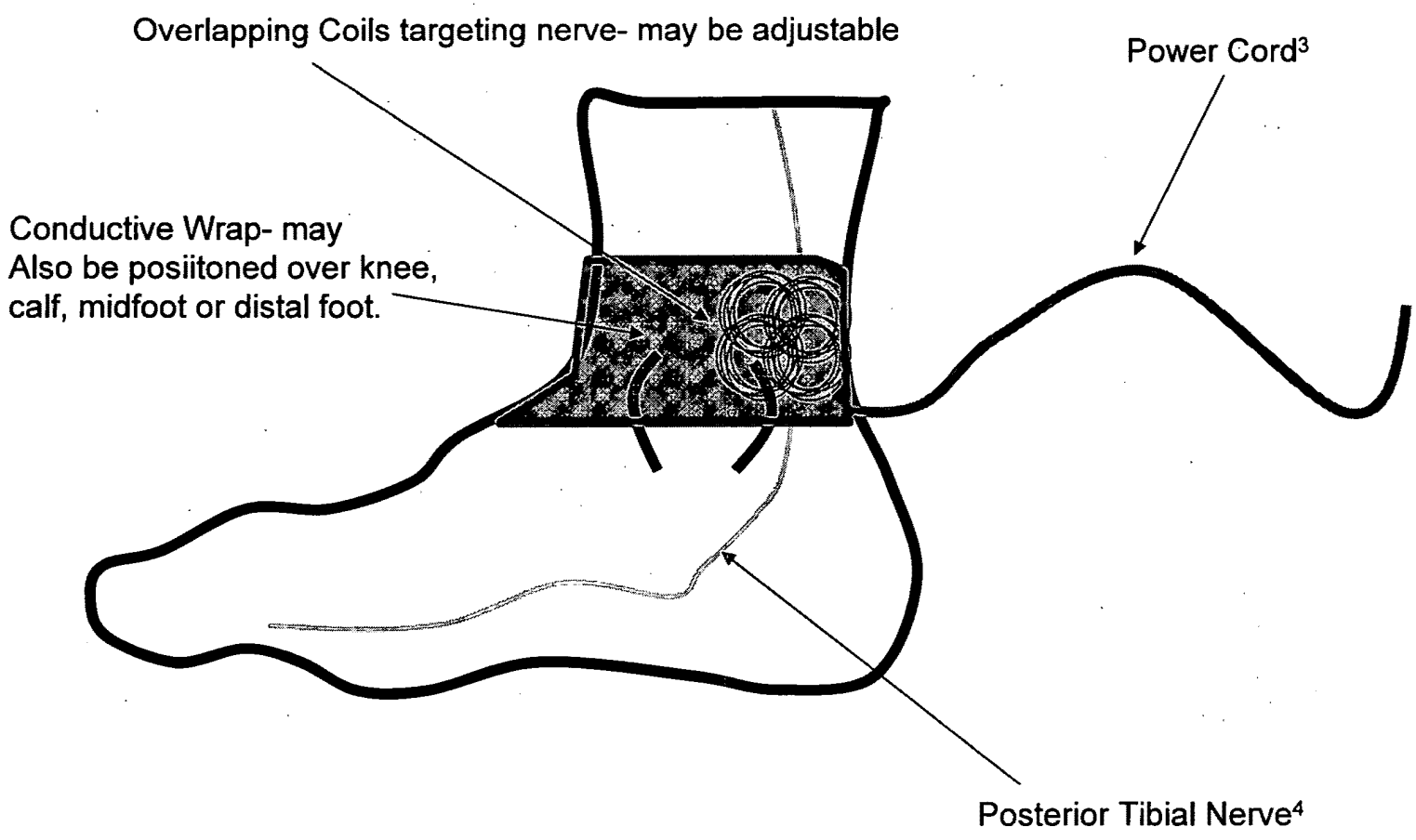

Overlapping Coils targeting nerve- may be adjustable
Power Cord[3]
Conductive Wrap- may
Also be posiitoned over knee,
calf, midfoot or distal foot.
Posterior Tibial Nerve[4]

Figure 1

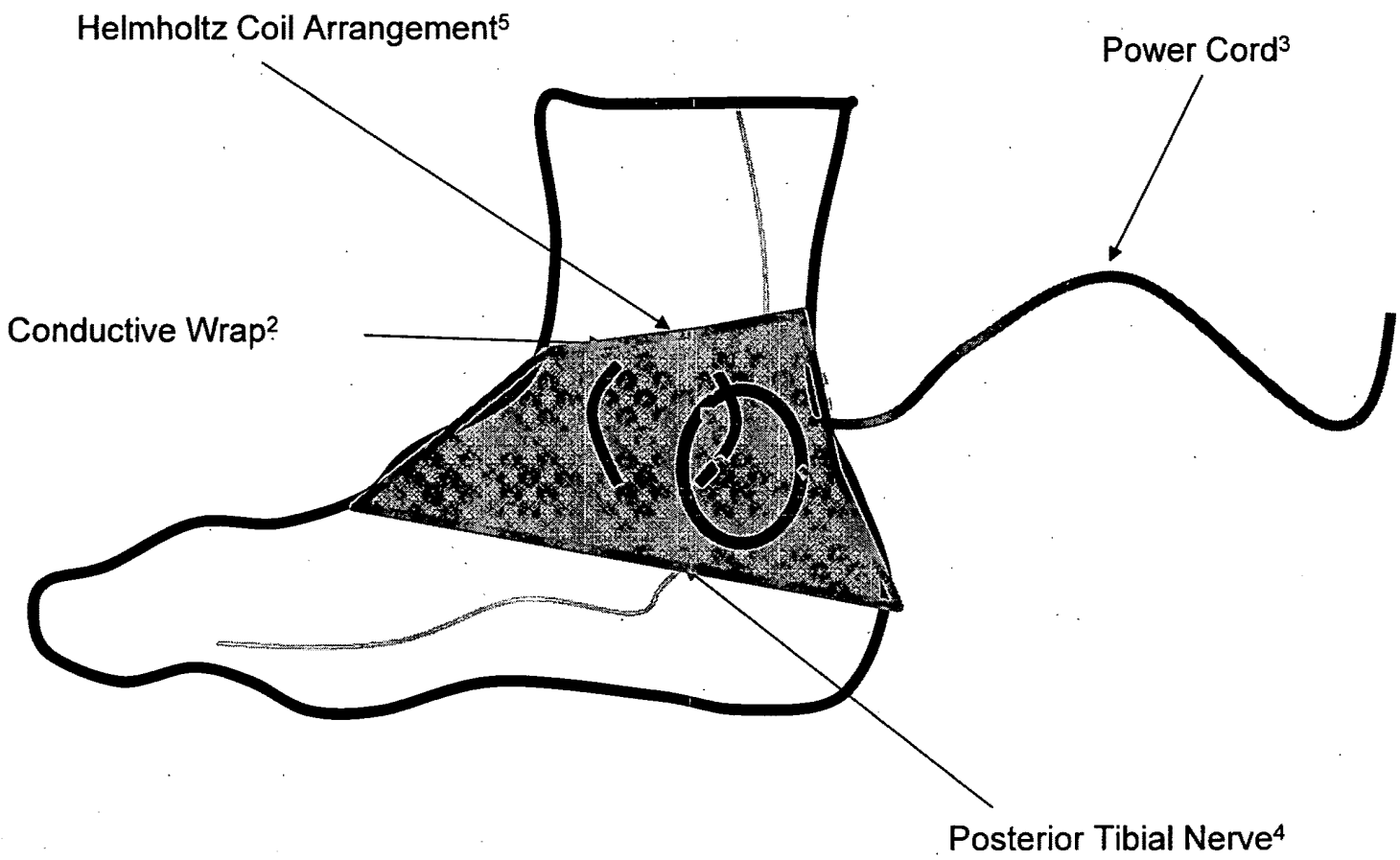

Helmholtz Coil Arrangement[5]
Power Cord[3]
Conductive Wrap[2]
Posterior Tibial Nerve[4]

Figure 2

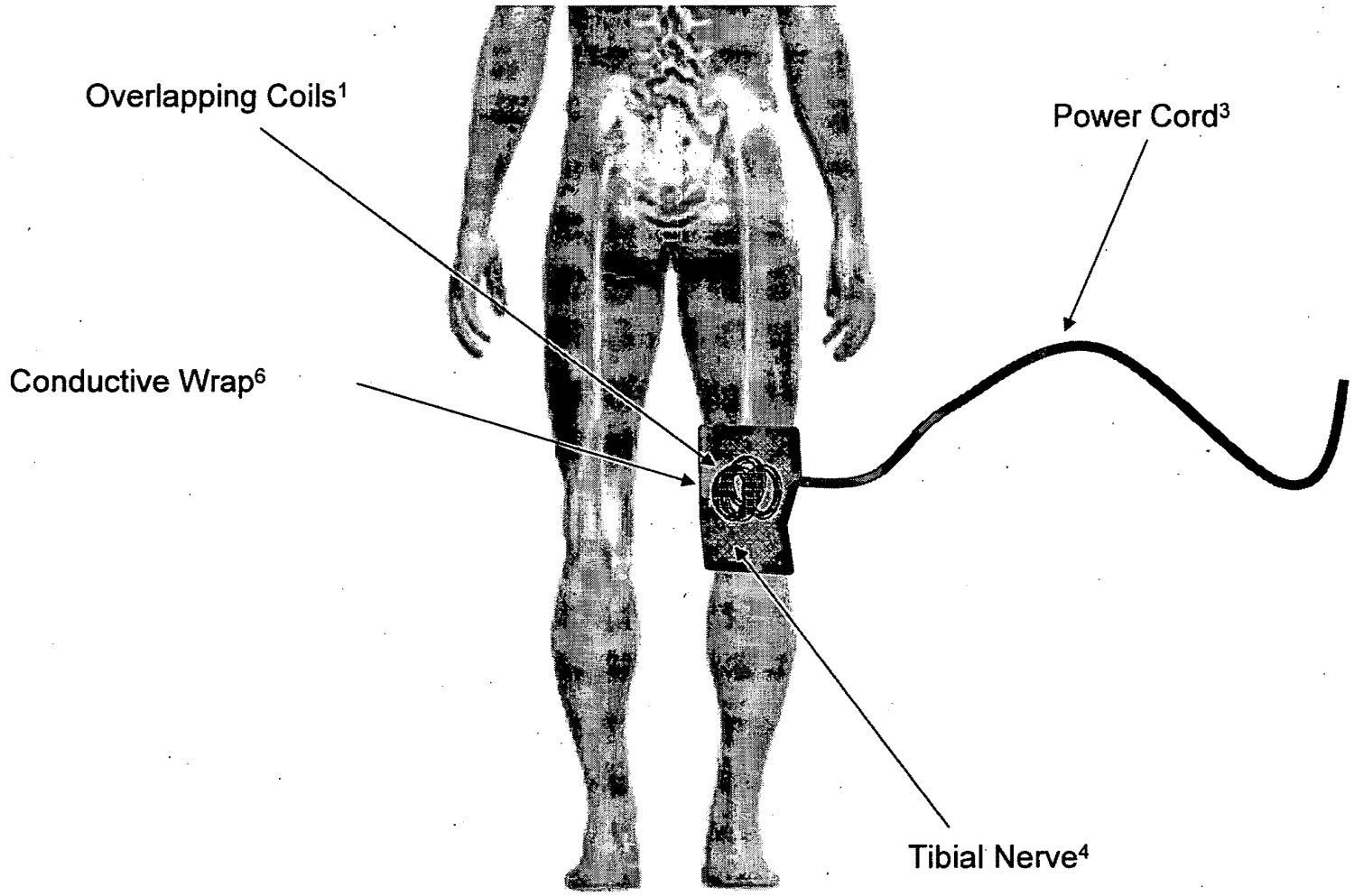
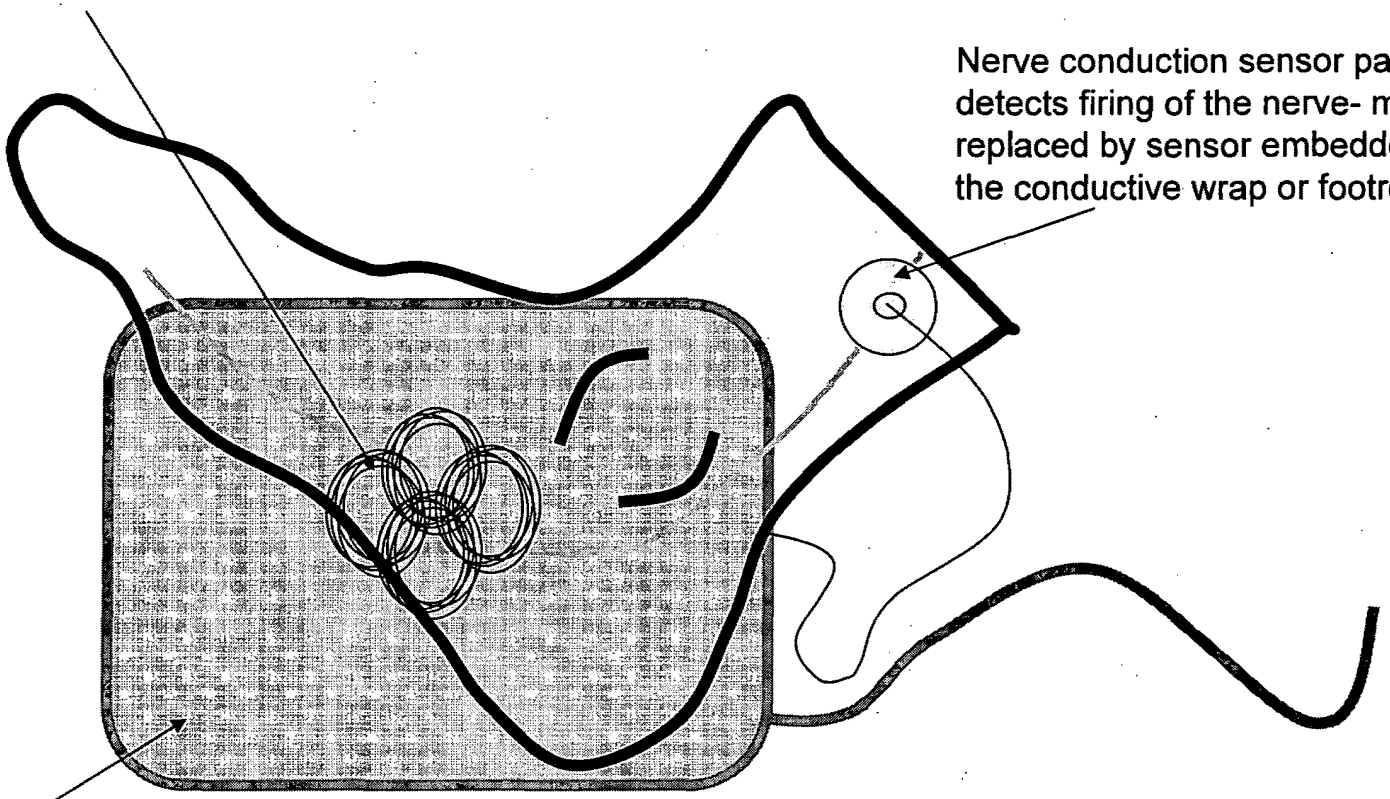

Overlapping Coils[1]
Power Cord[3]
Conductive Wrap[6]
Tibial Nerve[4]

Figure 3

One or more coils within the ergonomic footrest and overlying the target nerve, ideally overlapping to cover more area, that may be fired individually, sequentially or simultaneously based on feedback from the sensor patch indicating whether the target nerve has fired.



Footrest/cradle and logic controller with embedded coils- may also be helmholtz, modified helmholtz, single coil and/or, preferably, adjustable coil that may be aimed and positioned by the healthcare provider. Once positioned, the patient may then simply take the device home and attach the control sensor prior to therapy to deliver a treatment. Coil selection and pulse amplitude may then be tailored based on sensor input to ensure accurate and consistent neuromodulation.

Figure 4

One or more coils within the ergonomic footrest and overlying the target nerve, ideally overlapping to cover more area, that may be fired individually, sequentially or simultaneously based on feedback from the sensor patch indicating whether the target nerve has fired.

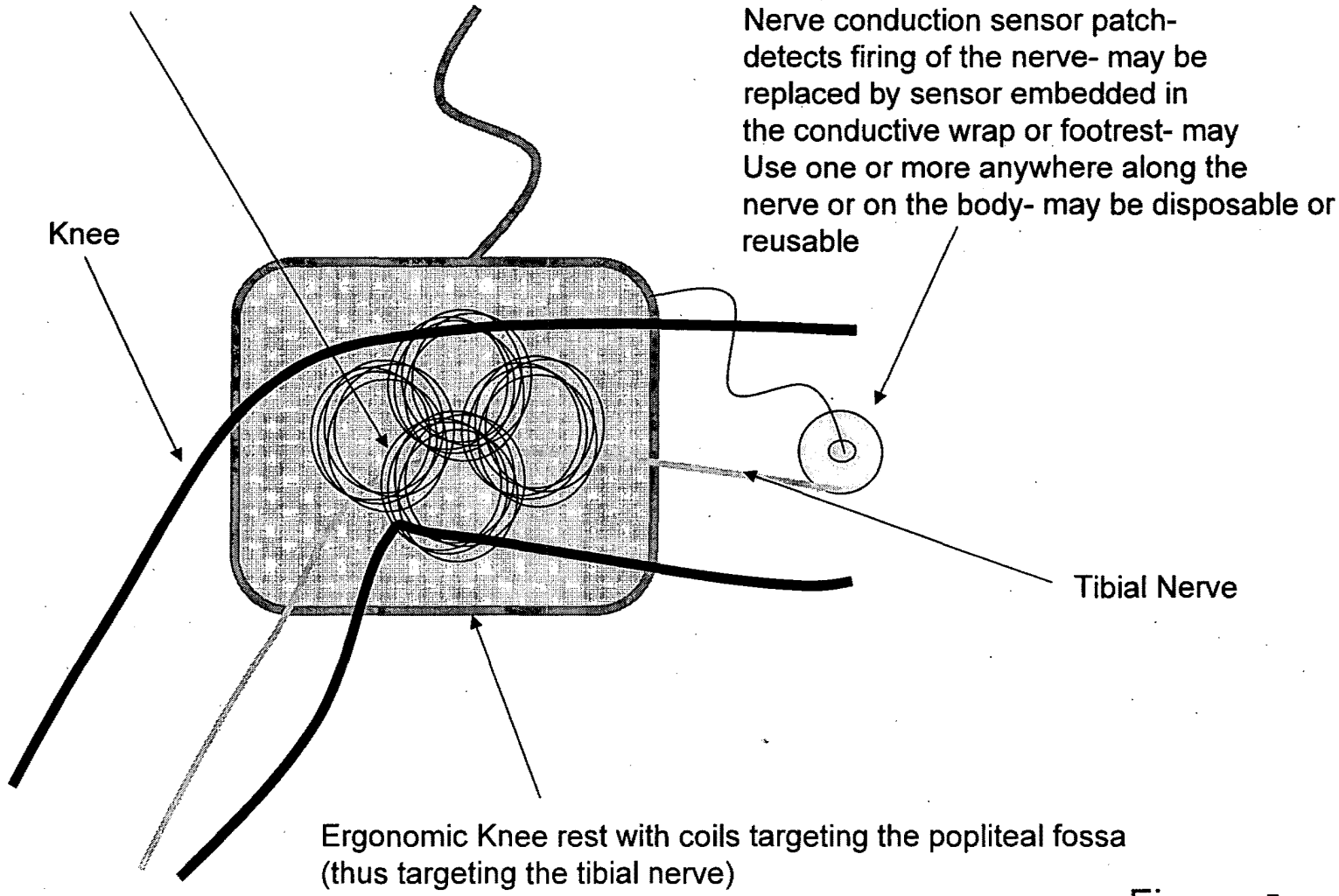


Figure 5

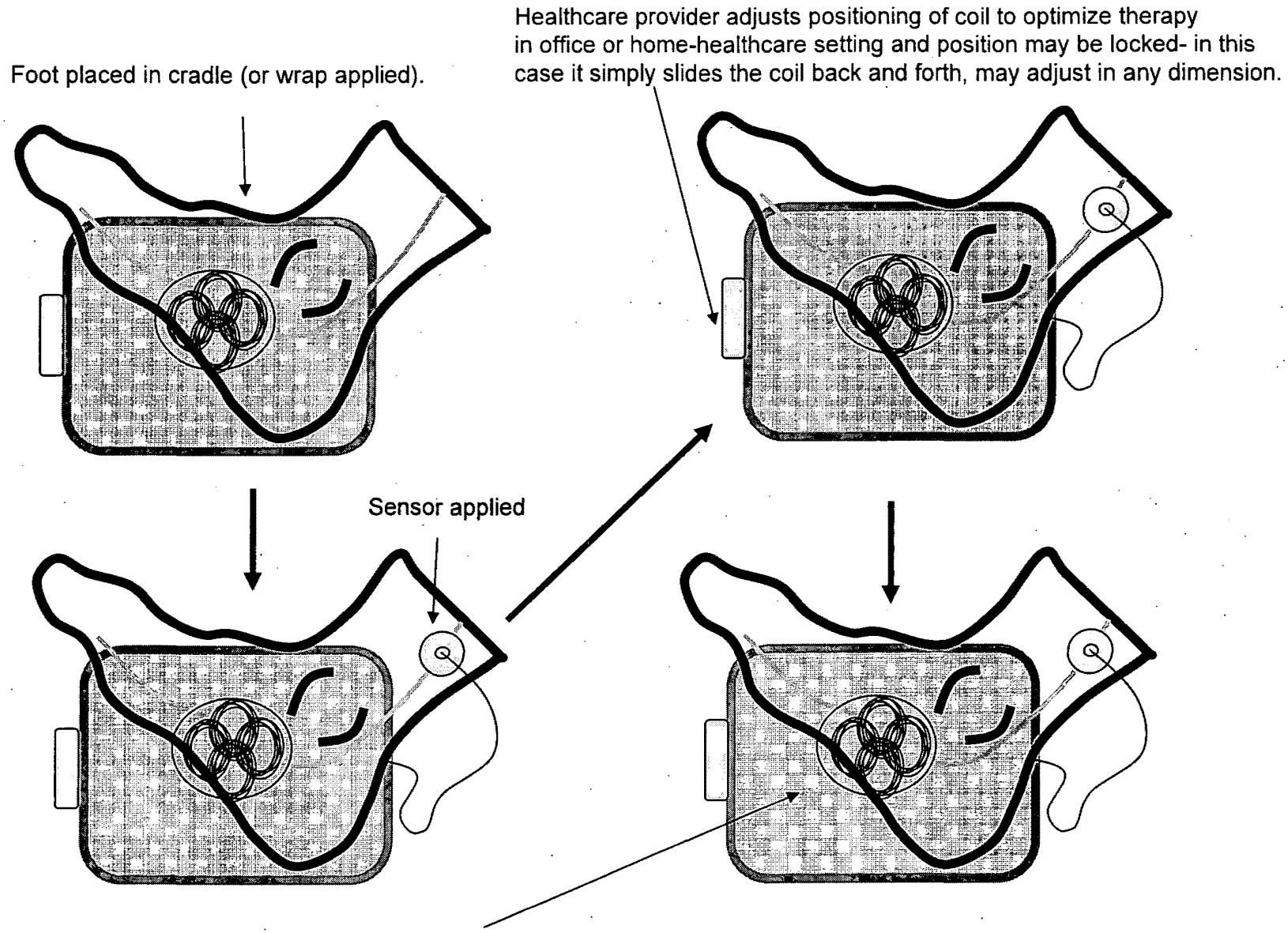

Foot placed in cradle (or wrap applied).
Healthcare provider adjusts positioning of coil to optimize therapy in office or home-healthcare setting and position may be locked- in this case it simply slides the coil back and forth, may adjust in any dimension.
Sensor applied
Therapy delivered in home or office setting and coils energized using increasing field amplitude and increasing field size until nerve conduction is detected. Therapy continues at the optimal level for the duration of the stimulation session.

Figure 6

Healthcare provider adjusts positioning of the coils to optimize therapy in office or home-healthcare setting and position may be locked- in this case it simply slides the coil back and forth, may adjust in any dimension. Adjustment may also be automated by controller

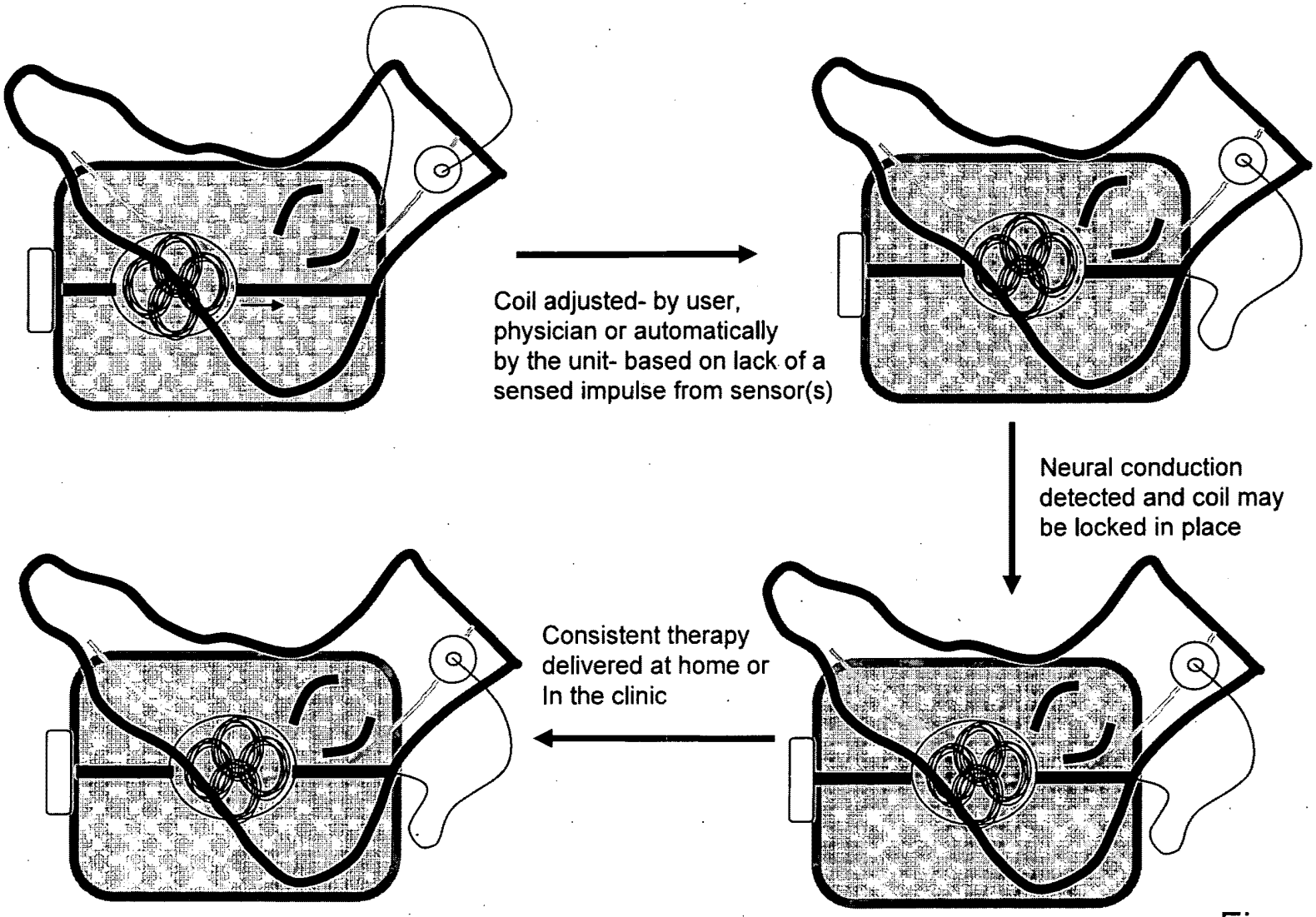


Figure 7

Sensors- conduction, movement, etc.

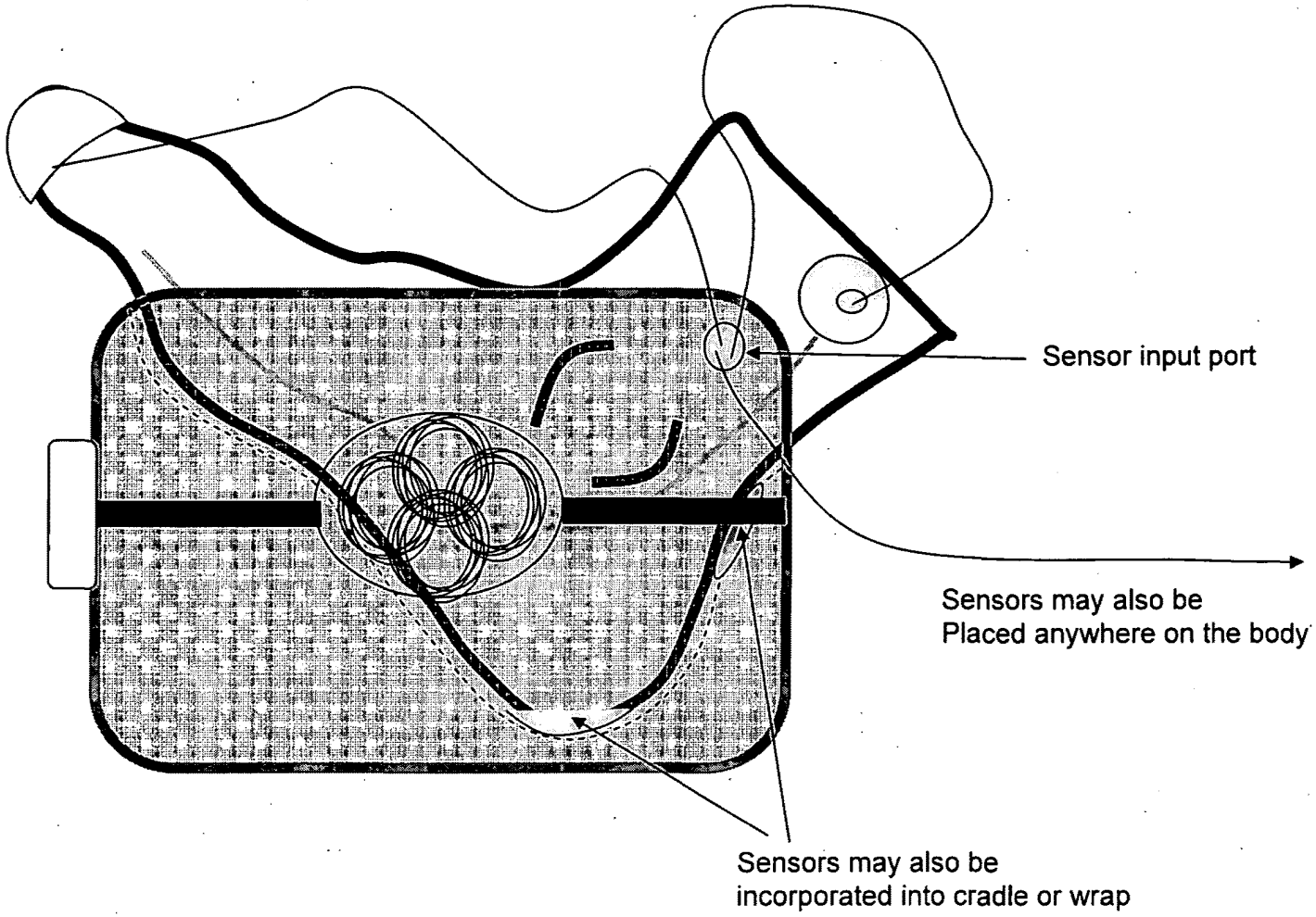
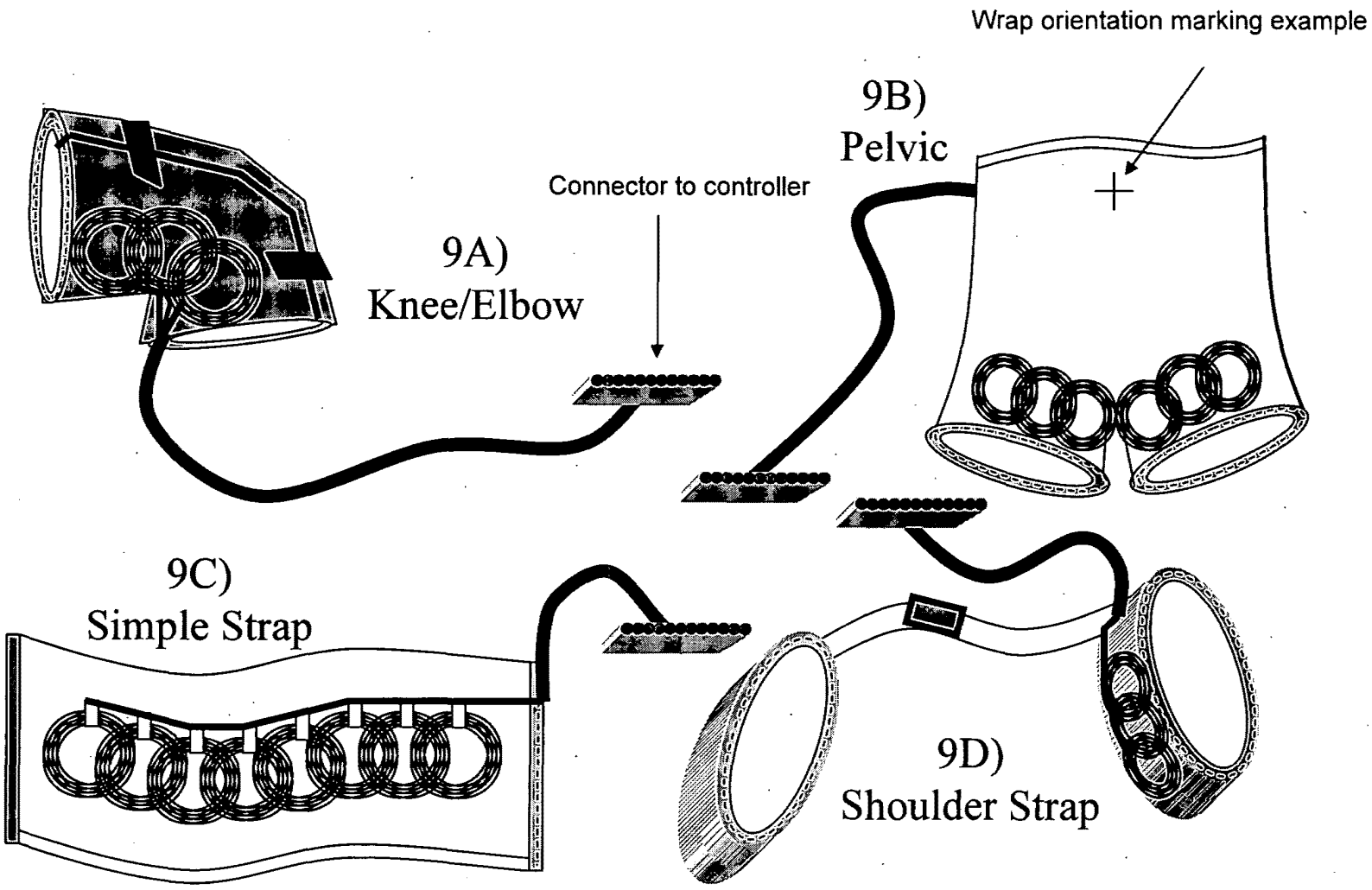


Figure 8


Wrap orientation marking example
9B)
Pelvic
Connector to controller
9A)
Knee/Elbow
9C)
Simple Strap
9D)
Shoulder Strap

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- Based on new interest in PTNS (Percutaneous Tibial Nerve Stimulation) + based on clinical data + a HUGE market, I've decided to reinvigorate the proposed business plan.
- After reviewing the state of the art in magnetic pulsed nerve stimulation, it is clear that the PTNS is a great candidate. The reason it hasn't caught hold, though, is that since the magnetic field generator is so difficult to use, patients are still required to come into the office for a therapy session. A real advance, then, would come with the introduction of user-friendly, home healthcare based system that could treat more frequently + more effectively without the need

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for costly + inconvenient clinic visits. The present invention provides such an advance with its 1) adjustable, locking stimulating coils in a contoured wrap + 2) neural conduction feedback method + device.

- 1) Adjustable Locking Stimulating Coils -

Reference my first issued patent - "Low Frequency Electromagnetic Therapy for the stimulation of nerve, muscle + tissue" for a quick background + the patent for which this application is a continuation. In this patent + in the patent application filed in Yos, I describe an ergonomic wrap capable of holding electromagnetic coils in preset areas dictated by the anatomic landmarks of the

Inventor [signature] Dan Burnett 8/24/08

Witness [signature] C. Heimanson 9/11/6

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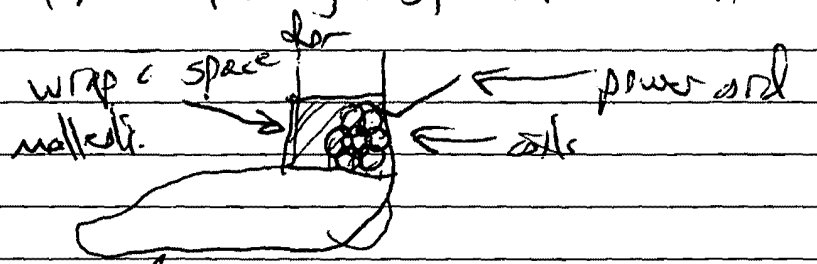
body to which the wrap has been contoured. For example, to target the PTNS, one would utilize coils in wrap for the ankle with stimulating coil located within the region above, behind or below the malleoli of the ankles. This strategy, though is suboptimal if a single-coil is used due to the narrow stimulation field.

Thus, as described in the above-referenced patent, one may use overlapping or adjacent coils which may be fired in series or in parallel in order to provide a more through stimulation zone



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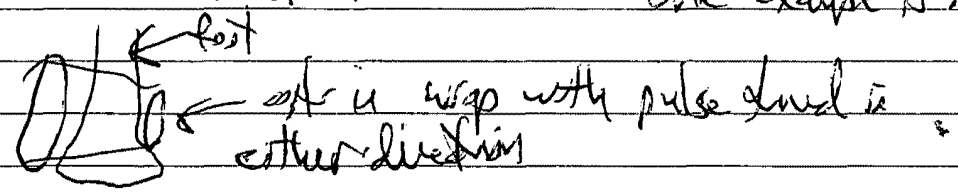
8/24/06 – This configuration, as well as the Helmholtz + adjacent (not overlapping) configuration are both well-detailed in the previous patent + patent applications. The Helmholtz configuration may also be modified to use an inexact Helmholtz (distance separating the coils not = to diameter) or simply coils in the same orientation if possible, differing ever to optimize width + depth of the pulse penetration providing anywhere from 0.1 to 2.0 Tesla at the nerve. One example is:



Even with these configurations, though, the nerve is not optimally targeted, so excess energy (+ overheating of the device) may be necessary. Thus the presentmention

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allows for the physician or a trained user to move the coil or coils within the wrap to optimize the coil orientation. The coils will be in their approximate optimal position, but may then be adjusted (& then locked) into position. The initial therapy, then requires the skill of a trained user after which the therapy may be delivered at home. The ergonomic wrap (or wrap labelled for correct orientation) is still a requirement although a contoured foot stool or cradle would also suffice so long as the precise placement of the user's foot within the device is obvious.

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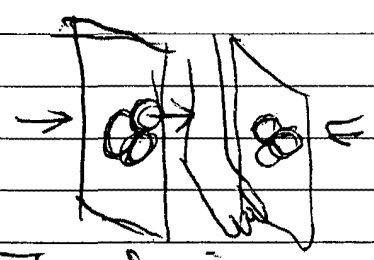
- Further alternatively, the device may consist of two or more plates that are brought in close opposition to the foot + ankle with preset or adjustable coil configurations. Thus, the ergonomic, landmark based application of the design need not be a full wrap or even a wrap at all, so long as it provides anatomic, landmark or anatomic based targeting of the PTNS.



The device may also be a contoured sling that pulls the coil into the correct position when the foot is entered.

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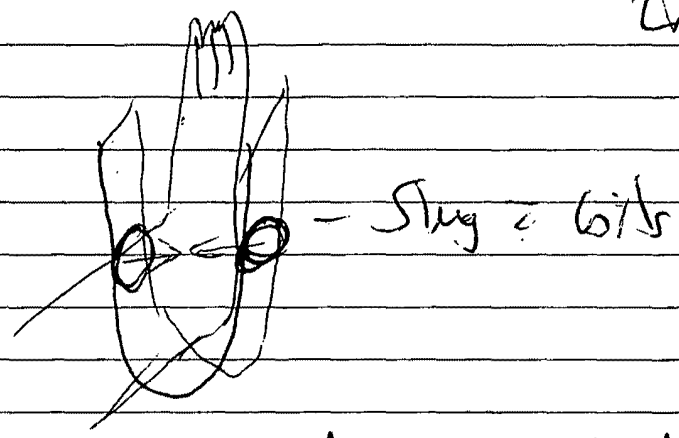

In any and all of these embodiments, the coils targeting the nerve may be freely adjustable by a trained user or by a preset, automated algorithm. Thus, if several coils are used, they may be fired in sequence or sequentially to see if the nerve is stimulated. The coils (or coil if only one is used) may be repositioned (by the trained user or based on a preset algorithm) in an attempt to stimulate the nerve. If no stimulation occurs, the coil(s) may be moved in a lateral or angular configuration to ensure

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that the area of interest is fully saturated. If no stimulation occurs, the power may be increased + the coil repositioning may be repeated until the optimal coil orientation may be obtained to stimulate the nerve (as evidenced by muscular contraction or the twitching of electrical nerve conduction detection) using the smallest possible current + power consumption. The coil may be adjustable side to side (rotating its axis of orientation) or pocked on its axis of orientation to saturate the tissues beneath. The stimulating coil may also be the recording coil that detects whether it has generated a conducting impulse. The coil may then be locked into position once the optimal configuration has been determined for ease of [illegible] 9/11/11

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future use. The patient may then be sent home with a targeted, customized device or their configuration may be stored in an office based device for use in future visits to the clinic. The device may also incorporate a nerve conduction or muscular contraction sensor which reports to the logic controller that the optimal pulse power / coil configuration has been achieved based on detection of neural conduction (with either a conducting contact or magnetic field recorder) or detection of muscular contraction (ie with an accelerometer or position sensor on the toes or other areas). This info may be fed back into the device to indicate that conduction

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has occurred + that therapy may be initiated. The positioning optimization protocol + method may be done once in the physicians office or be done by the logic controller automatically prior to each session. The neural conduction detection and power optimization is preferably performed prior to each session to ensure that the correct level of stimulation is being used (with the actual target being barely sub-contractile stimulatory fields).

— Thus, in its preferred embodiment. The device is positioned in the physicians office by a trained user, the coil(s) is/are locked or set into their optimal configuration +

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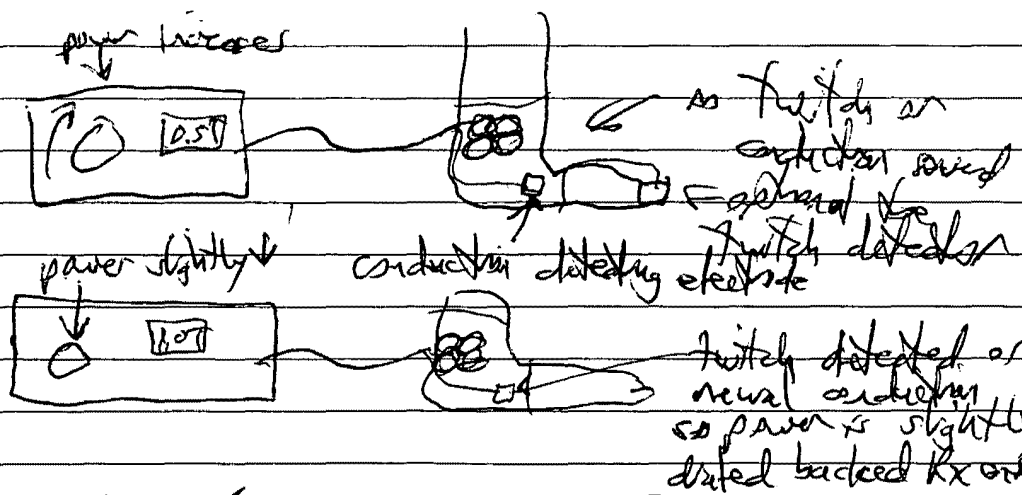
the approximate pulse power required for stimulation is recorded. The patient then may receive a therapy in the clinic or may be sent home to receive therapy there. The device may then be used again in the clinical setting, or optionally, may be used at home with ramping of the pulse amplitude until conduction is detected (by the twitch or by neural conduction detection — shown below).



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The orientation of the coils (as with the power) may be optimized each session (as well) based on feedback from the nerve conduction electrode or twitch monitor but this requires added complexity that may be removed by locking the coils in a customized configuration by a trained user. The nerve conduction sensor or twitch monitor may then be used to tailor the power required only - a factor that changes c̄ ankle swelling, clothing etc. making this optimization necessary with everyhr. This technology, then, allows customized optimization of PTNS to reduce power requirements + patient variability to allow EMT PTNS to be practically deployed in a

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home healthcare setting. The automation of the wrap + or auto-optimization of orientation and/or power of the EMF generating coils may be applied to <u>any</u> EMF stimulation in the body where sensor-based feedback may be incorporated to guide Rx. For example transcranial magnetic stimulation, or TMS, may be optimized by placing adjustable coils within a helmet + sensing (via EEG) whether stimulation at specific coils (or coil orientation) triggers the desired EEG changes + then delivering therapy based on this feedback. The coils may be locked in a configuration in the helmet or the larger controller may remember which coils

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to stimulate such that future Rx may accomplished in a home health setting. This method of customization + auto-optimization is applicable to all pulsed electromagnetic field technologies ~~in ch~~ involved in the stimulation of nerve, muscle or tissue and/or the recharging of internal devices through inductive PEMF. so long as electrical, mechanical or EMF field feedback is available to tailor therapy.

- The device may also be cooled via use of Peltier junctions to ↓ sound + use of cooling fluids, etc. This will allow for ↑ power delivery $\bar{s}$ over-heating of the device.

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—That is it for now. More to come with respect to pulse amplitude + other characteristics + treatment frequency as we test the device on humans.

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- To pick up where I left off:

  Invention = the EMK technology, then is the method of applying pulsed electromagnetic fields to peripheral nerves (in this case the posterior tibial nerve) to achieve central neuromodulation or peripheral neuromodulation in circuits that don't need higher-order input.

- In particular, use of PEMF to stimulate the PTN to affect bladder function is disclosed.

- The method of delivering this therapy using an ergonomic, body-centered element or elements to ensure appropriate orientation of the PEMF is also considered novel + of value.

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— This may be as simple as a single cup to be placed over the malleoli or as complicated as a boot, so long as it targets the appropriate nerve or nerves.

— Also novel + not disclosed in the prior art is the use of multiple coils, overlapping or adjacent, that may be fired concurrently, in unison or selectively to generate unique fields of PEMF penetration to stimulate nerves, and that are incorporated into the ~~wrap~~ shoe ergonomic or body-contoured applicator mentioned above.

— Also not disclosed in prior art + of particular value is the combination of adjustable, locking or varying orientation coils in combination with a feedback sensor, such as neural conducting sensor or toe-twitch monitor, to optimize

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8/28/06 therapy in a user-friendly, effective manner applicable to home-healthcare use.

- Lastly, and in summary, the method of controlling delivery ~~of therapy~~ 8/28/06 of PEMF to the PTN in the treatment of incontinence is highly innovative + unique, wherein the orientation or firing sequence of the coil or coil(s) and/or the amplitude of the PEMF pulse is dictated by feedback from the sensor placed on the user. This sensor requires no user-input (thus no user error) + automatically optimizes therapy for strength of stimulating field + minimal power requirements

- This sensor may be a separate component (ie accelerometer on the toe or conducting patch along the nerve pathway or may be one or more of the →

[signature] Burnett 8/28/06 [signature] 9/5/6

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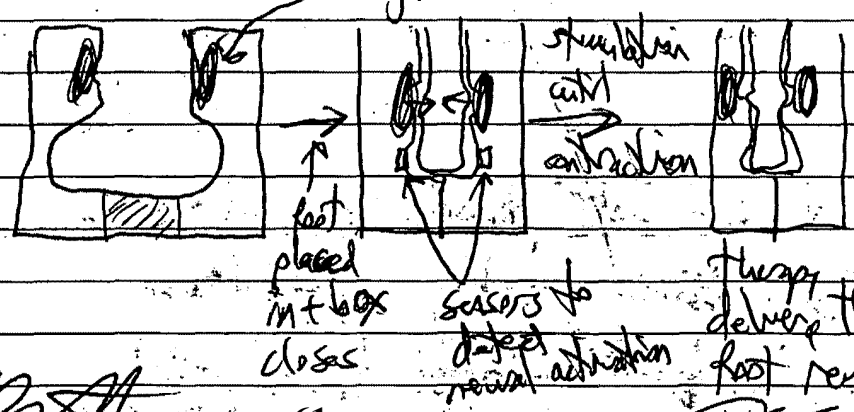
8/28/06 stimulating coils itself (in the receiving mode).

— Thus, by using purely magnetic fields, one can obtain the same (or better) results as the SANS (Stoller Afferent Nerve Stimulator) technology without the need for an insertion of a needle (with subsequent risks) or requirement for physician attendance based Rx — a major downside for this technology.

PTCS

Box Embodiment PEMF coils



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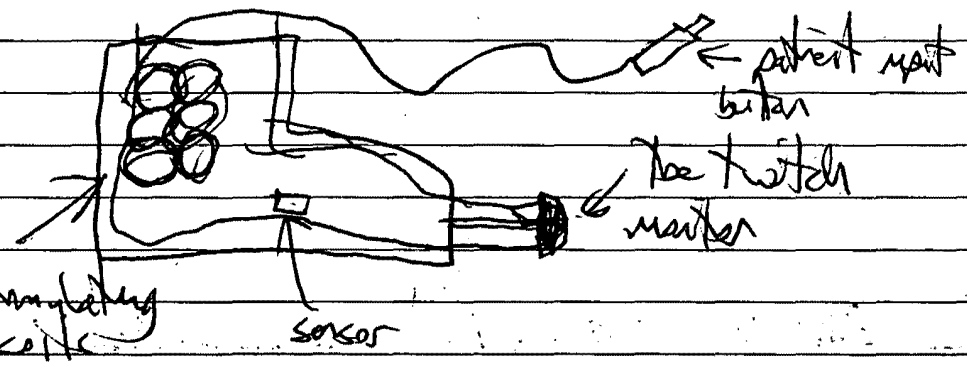
- Sling Embodiment - same as box embodiment, but not in rigid box. Either embodiment may utilize a conducting electrode, a mechanical sensor, toe twitch sensor or patient input (press this button when your toe twitches) to provide feedback for therapy.

- Wrap or pads or boot
  - A wrap or applied garment may be partial wrap or fully circumferential



- In this embodiment, the conduction sensor, toe twitch monitor + patient feedback button are illustrated - although only one would be necessary.

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- In the patient input embodiment, the feedback mechanism would require user input, ideally the pressing of a button. The patient, in one embodiment, would be told to press the button when contraction occurs + until it goes away (which may actively ↓ amplitude within each press).
- While not automatic as with the other embodiments (electrode + toe-twitch sensor) the feedback concept is the same + is central to the value proposition of this therapy.
- Through the use of this novel device, peripheral neuromodulation may be achieved $\bar{s}$ the need for invasive punctures or frequent, inconvenient + expensive clinic or hospital visits.

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EMK

- Based on a quick patent search, the field is slightly crowded, with some patents which would hold up in court (Medtronic's patent is preceded by Nihon Kohden which is preceded by the Heature for peripheral nerve stimulation).
- EMF's technology, though, is a significant advance over previous designs in its ability to reproducibly target the targeted nerve (PTN) in a low power, user friendly manner by incorporating the stimulating coils into an eyeglass wrap capable of being placed by the average user at home with no risk of misplacement due to the use of anterior landmarks on the user's body.

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Blood Glucose

- I've given more thought to my blood glucose patent filing. Initially, I assumed that the rate of recovery of color-sensing neurons, or cones, was the best mechanism for detecting blood glucose levels when used in combination with an optical laser to detect eye movement (ideally focused on the sclera and at an angle that could never directly hit the retina). Recovery from bleaching of cones has been demonstrated in the literature as being hastened by ↑ B6. This is still worth pursuing using the laterally moving bands to induce saccades once the color sensitivity returns + the isochromatic fields are seen as distinct colors. What may also be worth pursuing, though, →

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is the use of an alternating speed wheel that spans the range of human retinal neuron recovery to appear to be standing still. Once the speed of the wheel is 1/8th the speed of neuron recovery (8 pps, I mean 8x the speed of neuron recovery), the wheel with 8 spokes will appear to be standing still. When it is between 7 + 8 times the neural recovery speed, the wheel will appear to be moving forward or backward + the same is true of speeds between 6 + 8 as well as 8-10. Only at 8 will it stand still within this range (2X + 4X will also appear to stand still as well as 16X). Thus any small Δ in the overall speed of recovery can be amplified (8 fold) into a difference → 9/9/06 9/9/06

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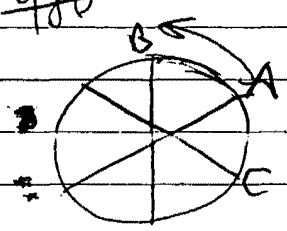
in the overall rate of recovery (processing rate) of the retina may be used in addition to the factor to detect color vision. For example, if the standard frames/second of the human eye is 60 fps, then running an ~~eight~~ six-spoked wheel at ~~480~~ 360 10 revolutions/sec should



make the wheel appear to stand still due to the bar labelled A now being exactly where the bar labelled B was 1/60 of a second ago. In order for C to get to B, though 20 rev/sec are required or, a decrease to 30 fps is required. Thus by measuring the fps at different times

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2:25. I suspect that even small Δs in neuron refresh rate or effective fps of the retina, can be detected using this manipulation of the physics principle called 'aliasing'. I will perform some experiments, altering my own blood sugar, to detect if overall retinal refresh rate is altered by blood glucose using a wheel with exquisite speed control to detect changes in fps. This is also directly applicable to my optical laser detection of eye movement, as well, so long as only a portion (ie 1/4) of the wheel is shown so movement of the bars is in one direction thereby generating the automatic eye tracking/saccades

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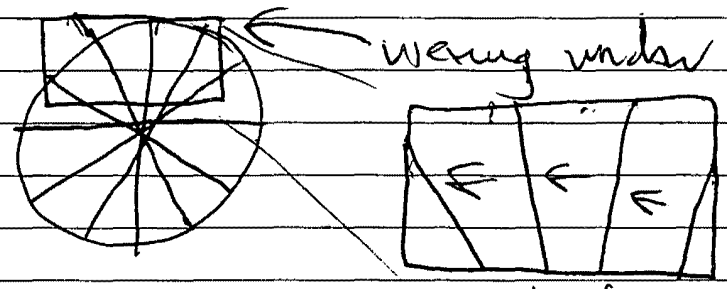
as depicted here in a 12 spoke embodiment



eye tracks in lateral direction until aligning has been achieved + eye stops moving (as detected by eye movement sensor)

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