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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 ☐ CD(s), Number _____

☒ Drawing(s) *Number of Sheets* 9 ☐ Other (specify) _____

☐ Application Data Sheet. See 37 CFR 1.76

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Respectfully submitted,

SIGNATURE _____ Date 9 / 30 / 06

TYPED or PRINTED NAME Daniel Burnett

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REGISTRATION NO. *(if appropriate)* _____

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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.

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