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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
61/403,680	09/20/2010	Amit Rajguru	EMKNPZ00700

40518
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

CONFIRMATION NO. 9172
POA ACCEPTANCE LETTER



Date Mailed: 01/11/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/03/2011.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/ddinh/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:



Practitioners associated with the Customer Number:

40518

OR



Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:



The address associated with Customer Number:

40518

(OR)

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

Assignee Name and Address:

EMKINETICS, INC.
49 Westdale Drive
Santa Cruz, CA 95060

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	11/6/15
Name	Christopher Hermanson	Telephone	415 640 7160
Title	CEO		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Petitioner - Avation Medical, Inc.

Ex. 1046, p. 2

STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: Amit RAJGURU et al.Application No./Patent No.: 61/403,680Filed/Issue Date: September 20, 2010Titled: **METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES**

EMKinetics, Inc. _____, a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest in;
2. ☐ an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %); or
3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)
- the patent application/patent identified above, by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 025491, Frame 0765, or for which a copy therefore is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

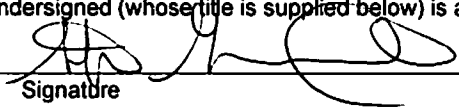
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.


Signature

January 3, 2011

Date

Steven M. Giovannetti

Attorney of Record

Printed or Typed Name

Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Petitioner - Avation Medical, Inc.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	9154723
Application Number:	61403680
International Application Number:	
Confirmation Number:	9172
Title of Invention:	Method and apparatus for transdermal stimulation over the palmar and plantar surfaces
First Named Inventor/Applicant Name:	Amit Rajguru
Correspondence Address:	TheraNova, LLC - 588 Teresita Boulevard - San Francisco CA 94127 US 4155858508 uspto@theranova.net
Filer:	Steven Michael Giovannetti/Kym Moore
Filer Authorized By:	Steven Michael Giovannetti
Attorney Docket Number:	
Receipt Date:	03-JAN-2011
Filing Date:	20-SEP-2010
Time Stamp:	18:17:25
Application Type:	Provisional

Payment information:

Submitted with Payment	no
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File Listing:

Petitioner - Avation Medical, Inc.

Ex. 1046, p. 4

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		EMKNPZ00700_20110103_POA.pdf	119105 709c576cd5dba16ceab0d272aeed2803ce5c4696	yes	2
Multipart Description/PDF files in .zip description					
	Document Description		Start	End	
	Power of Attorney		1	1	
	Assignee showing of ownership per 37 CFR 3.73(b).		2	2	
Warnings:					
Information:					
Total Files Size (in bytes):			119105		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	TOT CLAIMS	IND CLAIMS
61/403,680	09/20/2010		110			

TheraNova, LLC
588 Teresita Boulevard
San Francisco, CA 94127

CONFIRMATION NO. 9172
FILING RECEIPT



Date Mailed: 10/05/2010

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Amit Rajguru, Lafayette, CA;
Daniel Rogers Burnett, San Francisco, CA;
Christopher Hermanson, Santa Cruz, CA;

Power of Attorney: None

If Required, Foreign Filing License Granted: 09/30/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/403,680**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Method and apparatus for transdermal stimulation over the palmar and plantar surfaces

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international

patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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092010 16191 U.S. PTO

U.S. PTO
61/403680
09/20/2010

PTO/SB/16 (12-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

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

Express Mail Label No. _____

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Amit	Rajguru	Lafayette, CA
Daniel Rogers	Burnett	San Francisco, CA
Christopher	Hermanson	Santa Cruz, CA

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

TITLE OF THE INVENTION (500 characters max):

METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ The address corresponding to Customer Number: _____

OR

☒ Firm or Individual Name **TheraNova, LLC**

Address
588 Teresita Boulevard

City San Francisco	State California	Zip 94127
Country USA	Telephone 415-585-8508	Email uspto@theranova.net

ENCLOSED APPLICATION PARTS (check all that apply)

☐ Application Data Sheet. See 37 CFR 1.76	☐ CD(s), Number of CDs _____
☒ Drawing(s) Number of Sheets 3	☐ Other (specify) _____
☒ Specification (e.g. description of the invention) Number of Pages 11	

Fees Due: Filing Fee of \$220 (\$110 for small entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which is \$270 (\$135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.	\$110.00
☒ A check or money order made payable to the Director of the United States Patent and Trademark Office is enclosed to cover the filing fee and application size fee (if applicable).	
☐ Payment by credit card. Form PTO-2038 is attached.	TOTAL FEE AMOUNT (\$)
☐ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: _____	

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Petitioner - Avation Medical, Inc.

Ex. 1046, p. 9

PROVISIONAL APPLICATION COVER SHEET
Page 2 of 2

PTO/SB/16 (12-08)

Approved for use through 06/30/2010. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.



No.

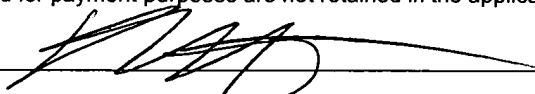


Yes, the name of the U.S. Government agency and the Government contract number are: _____

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

SIGNATURE _____



Date September 20, 2010

TYPED or PRINTED NAME _____

Daniel Rogers Burnett

REGISTRATION NO. _____

(if appropriate)

TELEPHONE _____

415-585-8508

Docket Number: _____

N/A

Petitioner - Avation Medical, Inc.

Ex. 1046, p. 10

PATENT APPLICATION

**METHOD AND APPARATUS FOR TRANSDERMAL LOW FREQUENCY
STIMULATION**

Inventors: AMIT RAJGURU
CHRISTOPHER HERMANSON
DANIEL R. BURNETT

Assignee: EMKinetics

Status: Small Entity

**METHOD AND APPARATUS FOR TRANSDERMAL LOW FREQUENCY
STIMULATION**

BACKGROUND OF THE INVENTION

[0001] 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).

[0002] 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.

[0003] 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.

[0004] 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.

[0005] Exercise and behavioral modifications often require patients to adhere to stringent routines, including scheduled voiding, maintenance of a bladder diary, and intense exercise regimens. While this 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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

[0010] 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.

[0011] 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.

[0012] 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.

[0013] 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.

[0014] 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.

[0015] 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

[0016] 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 transdermal electrical fields. In clinical tests conducted by the inventors, though, transdermal application of motor stimulatory fields at a frequency of 20 Hz to stimulate the posterior tibial nerve near the malleolus were intolerable under all conditions (surface electrode with and without gel, use of a microneedle electrode, strong pressure on electrode, etc.). This clinical data is in keeping with clinical experience associated with attempts at using TENS to achieve posterior tibial nerve stimulation which resulted in burns, intolerance, etc..

[0017] The present invention, then, capitalizes on unique experimental clinical findings that electrical stimulation of nerves underlying glabrous surfaces of the body (palms and soles) may require even greater power, but this stimulation is safe and tolerable. In a short series of 3 test subjects it was found that stimulation of the plantar nerves of the foot via a surface electrode was highly tolerable and resulted in sensation almost identical to that found with needle-based stimulation of the posterior tibial nerve. This similarity also applied to the sensation of cramping musculature with the use of excessive electrical stimulation. The present invention, then provides for not only the unique method of stimulating nerves underlying glabrous surfaces using surface or microneedle electrodes, but also for the devices that would be applied to the feet and/or hand in order to provide this stimulation on an intermittent or continuous basis. This device may also be used in conjunction with implantable or injectable substances in order to improve electrical conductivity to the target nerve. This novel method and device for stimulation may be used to treat virtually any disorder that is impacted by neuromodulation including, but

not limited to: overactive bladder, urinary incontinence, fecal incontinence, chronic pain, depression, migraine, epilepsy, obesity, restless leg, foot drop, etc.

[0018] In its ideal embodiment the current method may be applied either intermittently or, if necessary, on a chronic basis. The ideal applicator will hold the stimulatory electrode surface in contact with the glabrous surface either via an adhesive or an ergonomic applicator.

[0019] Furthermore, the present invention may also include feedback to the stimulator to indicate that stimulation is occurring as intended. This may involve an eMG type measurement device, a motion sensor or other sensing device. This feedback loop may be intermittently queried so that the stimulation may be adjusted to ensure that the minimum amount of energy is being used to stimulate to reduce the risk of burns or intolerance.

[0020] Lastly, the device of the present invention has been described as deploying an ergonomic wrap or cradle. This sensor feedback may also allow for optimization of the positioning of the electrodes based on sensor feedback further reducing the risk of burns/intolerance while increasing the efficacy of the neuromodulation.

[0021] 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

[0022] Figure 1 is a perspective view illustrating the components for delivery of electrical stimulation over the glabrous surfaces.

[0023] Figure 2 is a perspective view illustrating the components for delivery of electrical stimulation over the glabrous surfaces using an ergonomic insole stimulator which may be custom built into an orthotic or other component.

[0024] Figure 3 is a perspective view illustrating the sensor feedback embodiment.

DETAILED DESCRIPTION OF THE DRAWINGS

[0025] 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.

[0026] In Figure 1, the components for delivery of electrical stimulation over the glabrous surfaces are illustrated. In this case the glabrous surface being stimulated is that of the foot. The ground electrode may be located anywhere on the foot with the optimal position being the posterior surface to encourage deeper penetration of the electrical current. The electrodes may be placed anywhere on the glabrous surface of the foot overlying one or more nerves and may consist of dry electrodes, gel electrodes, microneedle electrodes or any other electrode. The electrodes may be adhered to the glabrous surface or may be in contact with the glabrous surface based on a wearable garment (glove or foot) as illustrated in Figure 2. In either embodiment, the use of the palmar and/or plantar surfaces allows for the use of a higher frequency and higher amplitude pulsation than would otherwise be tolerable. To elicit a motor response of the abductor hallucis longus, for example, by stimulating at a site overlying the nerve near the medial malleolus generates a painful shock to the patient. As a single pulse this is tolerable (and is used in EMG diagnostics) but as the frequency increases the shocking sensation builds and quickly becomes too painful to tolerate. Thus stimulating over non-glabrous skin at a frequency within the range that has been found to be effective for posterior tibial nerve stimulation (10-20 Hz) has been found by the inventors to be impractical and not feasible.

[0027] Figure 2 is a perspective view illustrating the components for delivery of electrical stimulation over the glabrous surfaces using an ergonomic insole stimulator which may be custom built into an orthotic or other component. A similar system may be employed to stimulate the hand (with a glove-like adapter) and either of these embodiments may include a durable or

disposable electrode for stimulation, sensing and/or grounding. In this and other embodiments the stimulator itself may be incorporated into an ergonomic insole (or other ergonomic design) or may be distant to the electrodes and attached elsewhere on the body (attached to belt, inside a pocket, strapped to the calf, etc.). For intermittent use the stimulator may simply be a foot plate that the user rests their bare foot on in order to receive therapy (or hand for upper extremity stimulation).

[0028] Figure 3 is a perspective view illustrating the sensor feedback embodiment. In this embodiment the device is capable to sensing stimulation of the nerve underlying the glabrous surface allowing for manual or automatic feedback to adjust the parameters of the stimulation or the position of the area being stimulated to optimize the effect. Sample stimulator electrode here shown attached to an insole but may be simply attached to a wire. In this embodiment this electrode may also be used as a sensor to detect stimulation of the nerve and automatically adjust treatment parameters (or guide manual adjustment). Alternatively an additional dedicated electrode may be used to continuously and/or intermittently sense the stimulation of the nerve.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Device for Neuromodulation and Low Frequency Induction Therapy through the Glabrous (Palmo-platar) Skin Surfaces

[0029] Example Indications for Use:

[0030] 1) Prevention of urinary incontinence (UI) and/or overactive bladder (OAB)

[0031] Example Methods for Use:

[0032] 1) A patient with a condition of UI or OAB, for example, will place the glabrous surface of their foot over an insole or foot to provide contact with a stimulatory electrode. Alternatively a tethered electrode may be used without an applicator (ie an adhesive cutaneous patch).

- [0033] 2) The stimulatory electrode will be positioned over the glabrous surface along the course of the nerve, ideally proximal to the stimulation site to ensure afferent nerve stimulation, and the ground electrode will be placed on the body, as well. One or more sensing electrodes will be placed along the path of the nerve conduction/motor impulse. Stimulatory and sensing electrodes will then be connected to the pulse generator (in the case that the electrodes are not integrated into the insole or foot plate).
- [0034] 3) In the preferred embodiment, electrical stimulation 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.).
- [0035] 4) Once stimulation is detected, the electrical pulses will continue for the directed duration of use, 15-30 minutes in the ideal intermittent embodiment or continuously in the continuous embodiment.
- [0036] 5) 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 the signal deteriorates. The pulse generating/sensing controller may be powered either by a portable power source (e.g. battery) or a fixed power source (e.g. traditional wall outlet).
- [0037] 6) The optimal stimulation will consist of 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.
- [0038] 7) The insole or foot plate will be removed from the body when therapeutic stimulation is not being delivered.
- [0039] 8) The foot plate or insole 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.
- [0040] 9) Stimulation may be delivered such that it provides motor, sensory or subthreshold stimulation.

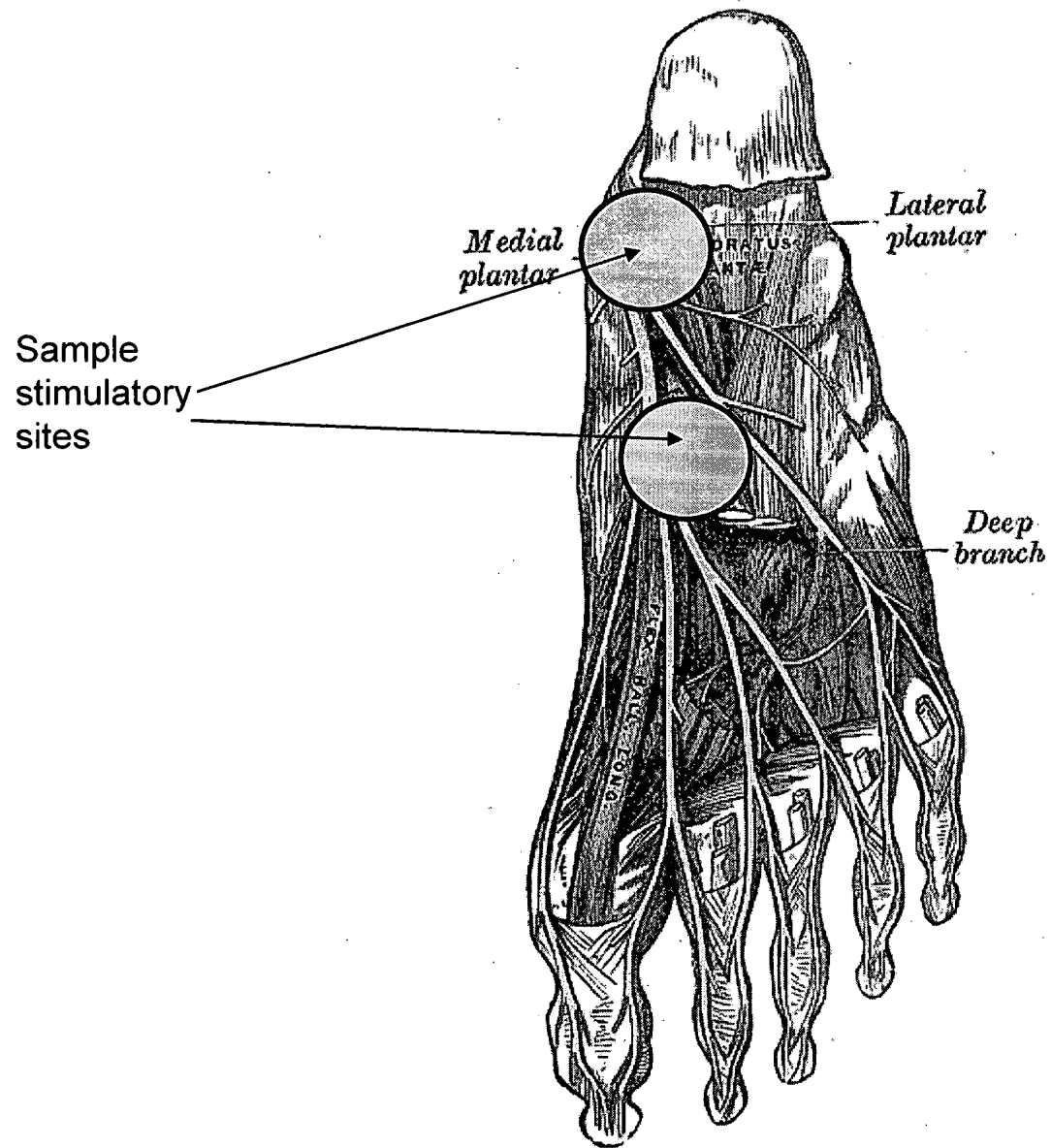


Figure 1

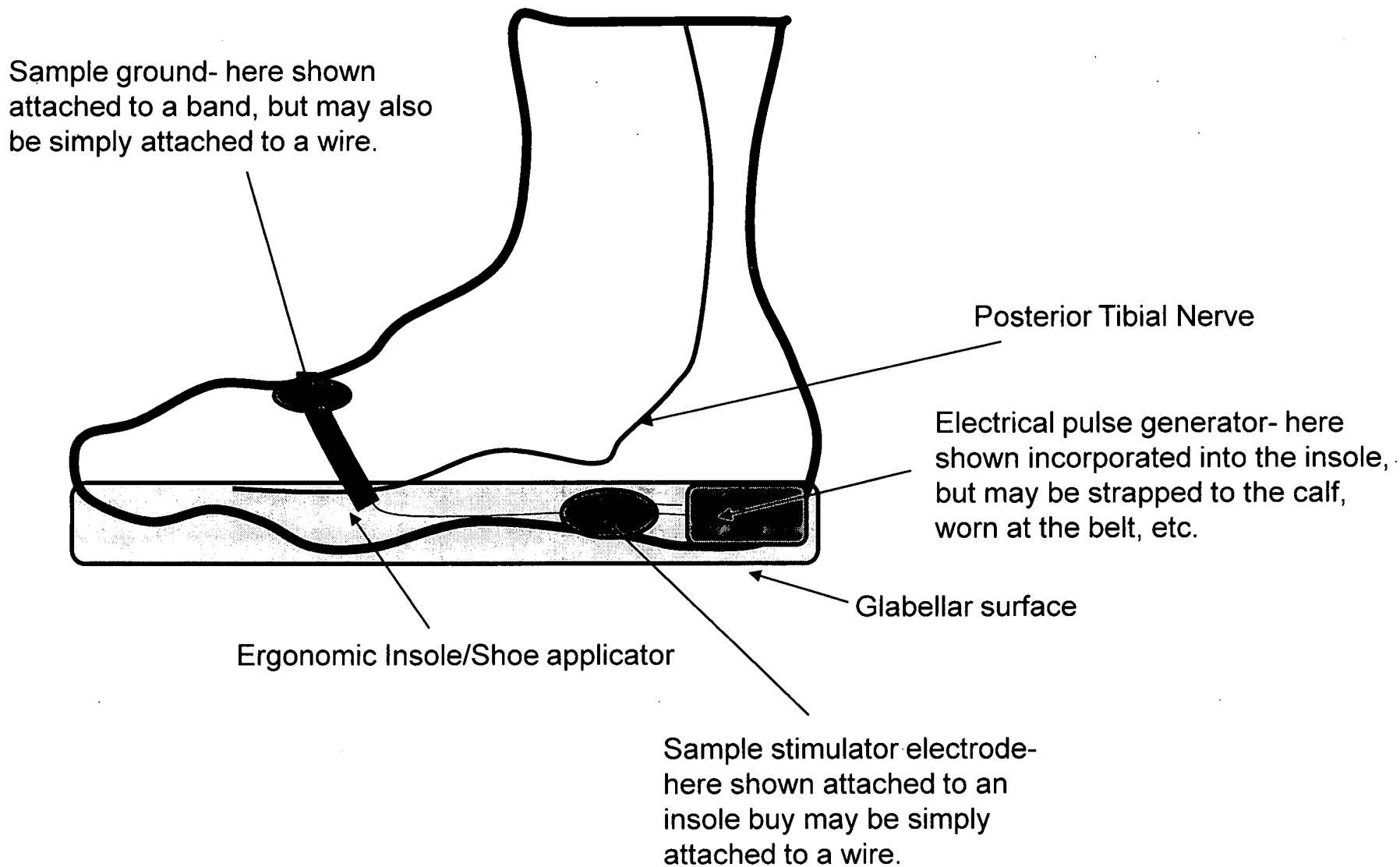


Figure 2

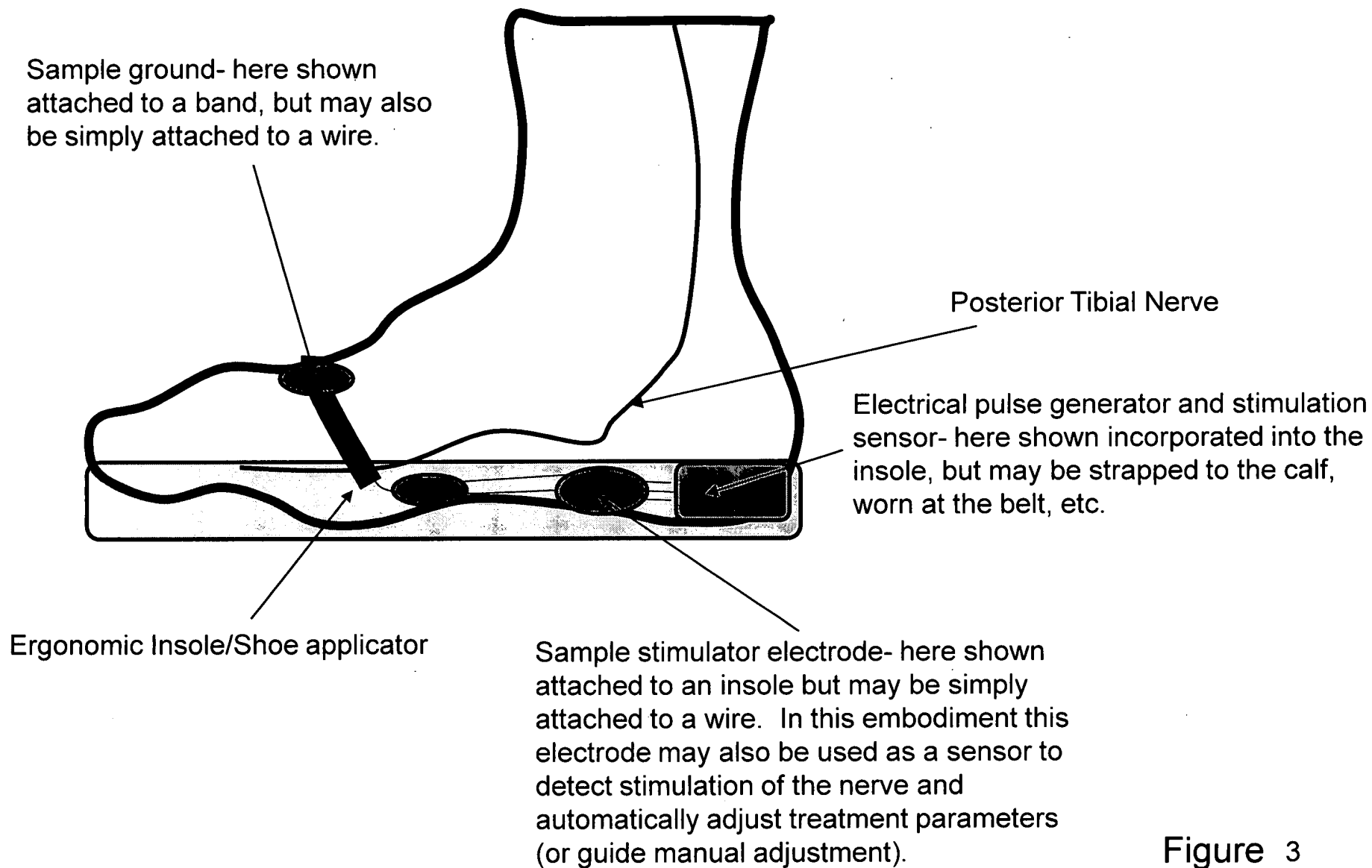


Figure 3

PATENT APPLICATION SERIAL NO. _____

**U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET**

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