UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/085,639	04/07/2015	9002477	EMKNNZ00501	1183

40518 7590 03/18/2015

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

EMKINETICS, INC., San Francisco, CA, Assignee (with 37 CFR 1.172 Interest);
Daniel R. BURNETT, San Francisco, CA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

40518 7590 12/05/2014
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Kim E. Lampkins (via EFS)	(Depositor's name)
/Kim E. Lampkins/	(Signature)
March 3, 2015 (via EFS)	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501	1183

TITLE OF INVENTION: METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	03/05/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
WIELAND, ROBERT N	3762	607-118000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Levine Bagade Han LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: EMKinetics, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): San Francisco, California

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☑ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☑ Issue Fee
- ☑ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies .....

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☑ Payment by credit card. ~~Form PTO-2038 is attached.~~
- ☑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-3973 ~~(enclose an extra copy of this form).~~

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Johney U. Han/ Date March 3, 2015

Typed or printed name Johney U. Han Registration No. 45,565

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 2

Electronic Patent Application Fee Transmittal

Application Number:	14085639
Filing Date:	20-Nov-2013
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Filer:	Johney U. Han/Kim Lampkins
Attorney Docket Number:	EMKNNZ00501

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Utility Appl Issue Fee	2501	1	480	480
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**480**

Electronic Acknowledgement Receipt

EFS ID:	21660517
Application Number:	14085639
International Application Number:	
Confirmation Number:	1183
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Customer Number:	40518
Filer:	Johney U. Han/Kim Lampkins
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00501
Receipt Date:	03-MAR-2015
Filing Date:	20-NOV-2013
Time Stamp:	19:29:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$480
RAM confirmation Number	6108
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	EMKNNZ00501_20150303_issue_fee_transmittal.pdf	286661 fd0f033265757c42915d11b6edff5cf9c044f964	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32420 5b851102942e5655946990c803c91b598bb8e0b3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	319081		

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.

New Applications Under 35 U.S.C. 111
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.

National Stage of an International Application under 35 U.S.C. 371
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.

New International Application Filed with the USPTO as a Receiving Office
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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

40518 7590 12/05/2014
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

EXAMINER
WIELAND, ROBERT N

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/05/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501	1183

TITLE OF INVENTION: METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	03/05/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 7

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

40518 7590 12/05/2014
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501	1183

TITLE OF INVENTION: METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	03/05/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
WIELAND, ROBERT N	3762	607-118000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 8

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501	1183

40518 7590 12/05/2014

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

EXAMINER	
WIELAND, ROBERT N	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/05/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. 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 1.14. 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/085,639	Applicant(s) BURNETT, DANIEL R.	
	Examiner Robert N. Wieland, Esq.	Art Unit 3762	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *an Amendment received 11/25/2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *2-6, 9-11, 15 and 17*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 11/25/2014
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Robert N. Wieland, Esq./
Primary Examiner, Art Unit 3762

DETAILED ACTION

1. This Action is in response to the Amendment filed 11/25/2014.

2. In view of the Amendment, the amendments to the claims are acceptable, and the objection to claim 9 in the Office Action mailed 05/28/2014 is withdrawn.

3. Claims 2-6, 9-11, 15 and 17 are pending.

Notice of Pre-AIA or AIA Status

4. The present application is being examined under the pre-AIA first to invent provisions.

Information Disclosure Statement

5. The information disclosure statement(s) listed on the accompanying PTO-37 was/were filed before the mailing date of the present office action. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Allowable Subject Matter

6. Claims 2-6, 9-11, 15 and 17 are allowed.

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance: The subject matter for the independent claims could not be found or was not suggested in the prior

art. All matters of form have been remedied and applicant's amendment has combined the indicated allowable subject matter with their respective base claims which now places the application in condition for allowance over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT N. WIELAND, Esq. whose telephone number is (571) 270-7399. The examiner can normally be reached on Monday-Thursday, 8:00-6:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number directly to Examiner Wieland is 571-270-8399.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert N. Wieland, Esq./
Primary Examiner, A.U. 3762

CUSTOMIZED PTO/SB/08a/b (07-05)

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	14/085,639
Filing Date	November 20, 2013
First Named Inventor	Daniel R. BURNETT
Art Unit	3762
Examiner Name	Robert N. Wieland
Attorney Docket Number	EMKNNZ00501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	5,158,080	10-27-1992	Kallok	
	2.	2004/0127939	07-01-2004	Grey	
	3.	2007/0021712	01-25-2007	Bernard et al.	
	4.	2008/0058874	03-06-2008	Westlund et al.	
	5.	2008/0177347	07-24-2008	Tehrani et al.	
	6.	2008/0300655	12-04-2008	Cholette	
	7.	2010/0318009	12-16-2010	Stanley	
	8.	2011/0264163	10-27-2011	Tracey et al.	
	9.	2012/0059432	03-08-2012	Emborg et al.	
	10.	2012/0302821	11-29-2012	Burnett	
	11.	2013/0006322	01-03-2013	Tai	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Robert Wieland/	Date Considered	12/04/2014

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.N.W./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14085639	BURNETT, DANIEL R.
	Examiner	Art Unit
	ROBERT N WIELAND	3762

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
607	118	05/22/2014	/RNW/

SEARCH NOTES		
Search Notes	Date	Examiner
Text Searched entire USPC Class	05/22/2014	/RNW/
Searched inventor and assignee names; also for obviousness double patenting	05/22/2014	/RNW/
Placed copy of search report in the record	05/22/2014	/RNW/
Search extended	12/04/2014	/RNW/
Placed copy of interference search report in the record	12/04/2014	/RNW/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
607	118	12/04/2014	/RNW/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	14/085639.app.	US-PGPUB; USPAT	ADJ	ON	2014/12/04 15:41
S1	0	14/085639.app.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:24
S2	12	((emkinetics).as. or burnett.in.) AND (target nerve).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:26
S4	1	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm. and feedback.clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:26
S5	5	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm. and (adjust$4 adj3 current).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:27
S6	6	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm. and (conduction adj5 nerve).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:30
S8	2	((emkinetics).as. or burnett.in.) AND (electrical stimulation).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:45
S10	1	"20040173220" .pn.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:15
S11	167	electrical stimul$5 near9 target near3 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:40
S12	56	electrical stimul$5 near9 target near3 nerve and target near3 nerve same pain AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:40
S13	11	electrical stimul$5 near9 target near3 nerve and target near3 nerve same chronic pain AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:41
S18	57	(transdermal$4 or transcutaneous$4) near9 electrical stimul$5 and stimul$5 near9 nerve same chronic pain AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:53
S19	5	(transdermal$4 or transcutaneous$4) near9 electrical stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:54
S20	5	(transdermal$4 or transcutaneous$4 or skin near6 surface) near9 electrical stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT "L19"	US-PGPUB; USPAT	ADJ	ON	2014/05/21 14:38
S21	24	(transdermal$4 or transcutaneous$4 or skin	US-	ADJ	ON	2014/05/21

		near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial and electrical stimul$5 AND (@ad<"20061002" or @rlad< "20061002") NOT "L19"	PGPUB; USPAT			14:39
S22	21	(transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT S20	US-PGPUB; USPAT	ADJ	ON	2014/05/21 14:40
S23	0	feedback near9 (sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT S20	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:08
S24	0	feedback near9 (electrode or sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT S20	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:08
S25	0	feedback near9 (electrode or sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:09
S26	341	feedback near9 (electrode or sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:10
S27	183	feedback near9 (electrode or sens$4) same adjust$4 and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:11
S28	282	feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:11
S29	0	(tibial nerve same fecal incontinence) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:12
S30	28	(tibial nerve or fecal incontinence) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:12
S31	80	pain same (arm or back or hand) AND	US-	ADJ	ON	2014/05/21

		feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	PGPUB; USPAT			15:20
S32	7	conduction near4 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:22
S33	0	(sens$4 or detect$4) near4 conduction near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:25
S34	1	(sens$4 or detect$4) near4 conduction same nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:25
S35	54	(sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:27
S36	16	(sens$4 or detect$4) near9 nerve same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:14
S37	36	(sens$4 or detect$4) near9 stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:17
S38	54	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:31

		nerve AND (@ad<"20061002" or @rlad< "20061002")				
S39	18	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT S37	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:31
S40	0	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT S37 not S39	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:38
S41	0	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:39
S42	128	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:39
S43	124	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near4 nerve AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:39
S44	59	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near4 nerve same (feedback or closed-loop) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:40
S45	29	(sens$4 or detect$4) near6 nerve near4 (activity or response) same (feedback or closed-loop) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:44

		NOT (S37 or S39)				
S46	88	(sens$4 or detect$4) near6 stimulation same (feedback or closed-loop) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 17:04
S47	11	(US-20040173220-$ or US-20060069415-$ or US-20100114259-$ or US-20080039915-$ or US-20110256097-$ or US-20100016929-$ or US-20020026226-$ or US-20080077192-$).did. or (US-6725094-$ or US-8712546-$ or US-5775331-$).did.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:24
S48	1	S47 and patch "80"	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:25
S49	163	(sens$4 or detect$4) near6 stimulation same (feedback or closed-loop) AND (feedback or sens$4 or control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:30
S50	54	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (pain near9 (arm or back or hand or neck) or tibial nerve or incontinence or restless leg or ejaculation or chronic pain or osteoarthritis or arthritis or neuropathic pain or neuralgia or migraine or atrophy or depression or paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:36
S51	53	stimul$5 same (adjust$4 or feedback or closed-loop) and electrical adj3 stimul$5 near9 nerve and transcutaneous electrical stimulation AND (pain near9 (arm or back or hand or neck) or tibial nerve or incontinence or restless leg or ejaculation or chronic pain or osteoarthritis or arthritis or neuropathic pain or neuralgia or migraine or atrophy or depression or paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 11:02
S52	1	"20050216062".pn.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 11:09
S53	13	(US-20040173220-$ or US-20060069415-$ or US-20100114259-$ or US-20080039915-$ or US-20110256097-$ or US-20100016929-$ or US-20020026226-$ or US-20080077192-$ or US-20070250119-$ or US-20130310909-$).did. or (US-6725094-$ or US-8712546-$ or US-5775331-$).did.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S54	0	LI7 and tibial nerve	US-PGPUB;	ADJ	ON	2014/05/22 12:09

			USPAT			
S55	0	LI7 and tibial near4 nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S56	0	LI7 and tibial near9 nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S57	0	LI7 and tibial same nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S58	1	LI7 and tibial	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S59	0	LI7 and (medial adj3 branch or lateral plantar branch)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:13
S60	34	LI7 and (medial or lateral or plantar)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:17
S61	2	LI7 and (medial branch or lateral branch or plantar)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:18
S62	0	LI7 and (plantar nerve)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:18
S63	1	LI7 and sole	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:19
S64	8	LI7 and foot	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:19
S65	3	S53 and tibial nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:20
S66	2	S53 and restless leg	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:32
S69	0	tibia and restless leg AND transcutaneous electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:40
S70	4	tibial and restless leg AND transcutaneous electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:41
S71	0	tibial and restless leg AND (percutaneous or transcutaneous) electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:43
S72	0	tibial and restless leg AND (percutaneous or transcutaneous or skin near5 surface) electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:44
S73	0	tibial and restless leg AND (percutaneous or transcutaneous or skin near5 surface) near6 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:44
S74	0	tibial and restless leg AND (percutaneous or transcutaneous or skin) near9 electrical	US-PGPUB;	ADJ	ON	2014/05/22 12:45

		stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	USPAT			
S75	1	tibial and restless leg AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:45
S76	4	tibial and restless leg AND transcutaneous electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:33
S77	2	tibial and premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S76	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:33
S78	2	tibial and premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:34
S79	3	premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:38
S80	6	genital near4 nerve AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:41
S81	22	genital near4 nerve AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:41
S82	0	genital near4 nerve and tibial AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:42
S83	5	genital near4 nerve and ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:42
S84	64	premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S83	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:59
S85	6	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 15:12
S86	1	((emkinetics).as. or burnett.in.) AND (electrical stimulation therapy).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 15:13
S87	88	transcutaneous electrical stimulation AND (osteoarthritis or arthritis or neuropathic pain or neuralgia or atrophy or depression or paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 15:31
S88	25	transcutaneous electrical stimulation AND (paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:02
S89	51	transcutaneous electrical stimulation AND (osteoarthritis or arthritis or paralysis) AND	US-PGPUB;	ADJ	ON	2014/05/22 16:02

		(@ad<"20061002" or @rlad< "20061002")	USPAT			
S90	0	transcutaneous electrical stimulation AND (osteoarthritis and arthritis and paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:02
S91	6	transcutaneous electrical stimulation AND (arthritis and paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:02
S92	1	transcutaneous electrical stimulation AND (neuropathic pain and atrophy) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:12
S93	2	transcutaneous electrical stimulation AND (neuropathic pain or neuropathy) same pain$4 and atrophy AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:16
S94	1	percutaneous electrical stimulation AND (neuropathic pain or neuropathy) same pain$4 and atrophy AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:24
S95	24	transcutaneous electrical stimulation AND (neuropathic pain or neuropathy) same pain$4 AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:25
S96	23	transcutaneous electrical stimulation AND (neuropathic pain or neuropathy near9 pain$4) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:25

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	0	(A method of performing electrical stimulation therapy, comprising: non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a posterior tibial nerve or a branch thereof within the first portion of the body is in proximity to the electrical stimulator, passing a current through the electrical stimulator, delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve or branch thereof, detecting electrical conduction through the posterior tibial nerve or branch thereof or detecting a muscular response caused by an electrical conduction through the posterior tibial nerve or branch thereof via at least one sensor positioned along a second portion of the body, receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy, and adjusting the current via a controller in communication with the electrical stimulator based on the feedback).clm.	USPAT; UPAD	ADJ	ON	2014/12/04 15:44

12/4/2014 3:58:30 PM
C:\Users\rwieland\Documents\EAST\Workspaces\14085639.wsp

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14085639	BURNETT, DANIEL R.
	Examiner	**Art Unit**
	ROBERT N WIELAND	3762

CPC							
Symbol						**Type**	**Version**
A61N		1	/	3606		F	2013-01-01
A61N		1	/	36021		I	2013-01-01
A61N		1	/	40		I	2013-01-01
A61N		2	/	006		I	2013-01-01
A61N		1	/	36067		I	2013-01-01
A61N		1	/	36071		I	2013-01-01
A61N		1	/	36075		I	2013-01-01
A61N		1	/	36096		I	2013-01-01
A61N		1	/	36107		I	2013-01-01
A61N		1	/	36139		I	2013-01-01
A61N		1	/	0456		A	2013-01-01
A61N		1	/	0484		A	2013-01-01
A61N		1	/	0502		A	2013-01-01
A61N		1	/	36003		A	2013-01-01
A61N		1	/	36007		A	2013-01-01
A61N		1	/	36017		A	2013-01-01
A61N		2	/	02		A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	10	
/ROBERT N WIELAND/ Primary Examiner.Art Unit 3762	12/04/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14085639	BURNETT, DANIEL R.
	Examiner	**Art Unit**
	ROBERT N WIELAND	3762

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
607	118	A	6	1	N	1 / 00 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	10	
/ROBERT N WIELAND/ Primary Examiner.Art Unit 3762	12/04/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14085639	BURNETT, DANIEL R.
	Examiner	**Art Unit**
	ROBERT N WIELAND	3762

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1	10	17												
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	13														
	14														
9	15														
	16														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	10	
/ROBERT N WIELAND/ Primary Examiner.Art Unit 3762	12/04/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 1183

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/085,639	11/20/2013	607	3762	EMKNNZ00501

APPLICANTS

EMKINETICS, INC., San Francisco, CA, Assignee (with 37 CFR 1.172 Interest);

INVENTORS

Daniel R. BURNETT, San Francisco, CA;

**** CONTINUING DATA ****************************

This application is a CON of 13/456,016 04/25/2012
which is a CON of PCT/US2010/054167 10/26/2010
which claims benefit of 61/279,883 10/26/2009
This application 14/085,639 11/20/2013
is a CIP of 12/508,529 07/23/2009
which is a CIP of 11/866,329 10/02/2007 ABN
which claims benefit of 60/848,720 10/02/2006

**** FOREIGN APPLICATIONS ****************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
12/03/2013

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ROBERT N WIELAND/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	37	~~18~~	1

ADDRESS

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

10 total claims
/RNW/ 12/4/2014

TITLE

METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

FILING FEE RECEIVED		
800	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: November 25, 2014 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	14/085,639
Confirmation No.:	1183
Filing Date:	November 20, 2013
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Robert N. Wieland
Group Art Unit:	3762

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the non-final Office Action dated May 28, 2014 for which a response was due on August 28, 2014. Filed herewith is a Petition and fee for a three-month extension of time, thereby extending the deadline for response to November 28, 2014. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the Remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 4 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

In the claims

1. (Canceled)

2. (Currently Amended): A method of performing electrical stimulation therapy, comprising:

non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a posterior tibial ~~target~~ nerve or branch thereof within the first portion of the body is in proximity to the electrical stimulator;

passing a current through the electrical stimulator;

delivering an electrical stimulus from the electrical stimulator to the posterior tibial ~~target~~ nerve or branch thereof;

detecting electrical conduction through the posterior tibial ~~target~~ nerve or branch thereof or detecting a muscular response caused by an electrical conduction through the posterior tibial ~~target~~ nerve or branch thereof via at least one sensor positioned along a second portion of the body;

receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy; and

adjusting the current via a controller in communication with the electrical stimulator based on the feedback.

3. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to the [[a]] posterior tibial nerve or branch thereof to treat fecal incontinence.

4. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to the [[a]] posterior tibial nerve or branch thereof to treat restless leg syndrome.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 30

5. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to the [[a]] posterior tibial nerve or branch thereof to treat premature ejaculation.

6. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to ~~a target~~ the posterior tibial nerve or branch thereof to treat chronic pain.

7.-8. (Canceled)

9. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to ~~a target~~ the posterior tibial nerve or branch thereof to treat osteoarthritis or arthritis[[,]].

10. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to ~~a target~~ the posterior tibial nerve or branch thereof responsible for neuropathic pain to treat neuropathic pain.

11. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to ~~a target~~ the posterior tibial nerve or branch thereof to treat neuralgia.

12.-14. (Canceled)

15. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to ~~a target~~ the posterior tibial nerve or branch thereof to treat atrophy.

16. (Canceled)

17. (Currently Amended): The method of claim 2, wherein the electrical stimulus is delivered to ~~a target~~ the posterior tibial nerve or branch thereof to treat paralysis.

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Ex. 1002, p. 31

REMARKS

Claims 2-17 were pending in the present application. By virtue of this response, claims 7-8, 12-14, 16 have been cancelled, claims 2-6, 9-11, 15, 17 have been amended. Accordingly, claims 2-6, 9-11, 15, 17 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Claim Objections

Claim 9 is objected to because of an alleged informality.

Claim 9 has been amended to correct for a typographical error. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the objection to the claim.

Rejections under 35 USC § 102

Claims 2, 6-9, 13-14, and 16-17 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated Simon et al. (U.S. Pub. 2013/0310909).

Independent claim 2 has been amended to recite "non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a posterior tibial nerve or branch thereof within the first portion of the body is in proximity to the electrical stimulator" and further "delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve or branch thereof".

On the other hand, Simon et al. fails to disclose delivering an electrical stimulus to the posterior tibial nerve or branch thereof but instead discloses treatment of the vagus nerve as disclosed throughout the description. Hence, independent claim 2 is patentable over Simon et al. and the dependent claims are patentable for at least the same reasons.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 32

Rejections under 35 USC § 103

Claims 3-5, 10-12, 15 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Simon et al., as applied to claim 2, and variously in view of Herregraven et al. (U.S. Pub. 2010/0114259); Cameron et al. (U.S. Pub. 2006/0069415); Boggs et al. (U.S. Pub. 2011/0144468); Naroditsky et al. (U.S. Pub. 2009/0198305); Prochazka (U.S. Pub. 2010/0016929 A1); Wheeler (U.S. Pub. 2006/0047326).

Independent claim 2 has been amended as discussed above. In particular, the claim has been amended to recite "***non-invasively*** positioning a first portion of a patient's body relative to an electrical stimulator such that **a *posterior tibial nerve or branch thereof*** within the first portion of the body is in proximity to the electrical stimulator". (Emphasis added.) Support may be found throughout the specification as-published, e.g., [0088], [0117]-[0118], [0228], [0234], etc.

The claims are patentable over Simon et al. for at least the same reasons above. Each of the additionally cited references also fails to cure the defects of Simon et al. For instance, the specific cited references of Herregraven et al., Cameron et al., and Boggs et al. may teach various treatments of the posterior tibial nerve, as proffered by the Office, yet each of these references teach invasive methods for accessing and treating the posterior tibial nerve. The invasive methods and devices taught by these additional references for applying these treatments to the posterior tibial nerves are integral to the very design and method of operation for these devices.

For example, Herregraven et al. teaches where its "***treatment may be done in a percutaneous manner*** by inserting a fine gauge needle into the posterior tibial nerve just above the ankle and applying an electrical stimulation to the needle." (Emphasis added, Herregraven et al., [0025].) Cameron et al. also teaches where its device "may be used to ***implant an example stimulation system 10 into a person*** for electrical stimulation of the person's nerve tissue, for example, electrical stimulation of target nerve tissue in the brain, the spinal cord, or a peripheral or other nerve." (Emphasis added, Cameron et al., [0050].) Likewise, Boggs et al. teaches where its "[s]timulation may be applied through a lead/electrode … ***inserted via a needle introducer or surgically implanted*** in proximity of the target nerve …. Once proper placement is confirmed, the needle may be withdrawn,

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 33

leaving the electrode in place. Stimulation may also be applied through a ***penetrating electrode*** ...." (Emphasis added, Boggs et al., [0109].)

Hence, none of the cited references cure the defects of Simon et al. and the claims are patentable over each of the references alone or in combination. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 34

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00501**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Johney U. Han/

Johney U. Han
Registration No. 45,565

Customer No. 40518
Levine Bagade Han LLP
2400 Geng Road, Suite 120
Palo Alto, CA 94303
Direct: (650) 242-4217
Fax: (650) 284-2180

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 35

PTO/AIA/22 (03-13)
Approved for use through 3/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): EMKNNZ00501

Application Number: 14/085,639

Filed: November 20, 2013

For: METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

Art Unit: 3762

Examiner: Robert N. Wieland

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 700
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-3973.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 45,565.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Johney U. Han/ — Signature

November 25, 2014 — Date

Johney U. Han — Typed or printed name

(650) 242-4217 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 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: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: November 25, 2014 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	14/085,639
Confirmation No.:	1183
Filing Date:	November 20, 2013
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Robert N. Wieland
Group Art Unit:	3762

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted after receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance. A Certification under 37 C.F.R. § 1.97(e) is provided; accordingly; no fee is believed to be due.

The documents listed on the attached Form PTO/SB/O8a/b were cited in a International Search Report mailed on September 9, 2014, directed to a counterpart international or foreign application and have not been previously cited. I hereby certify that each item of information was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

Under 37 C.F.R. §1.98(a)(3)(i), any patents, publications, or other information listed herein that are not in the English language are relevant, as it is understood in 37 C.F.R. §1.56(c) for reasons self-evident in the English and/or drawing portions and/or due to its citation by a foreign patent office or the U.S. Patent Office or court.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00501**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Johney U. Han/

Johney U. Han
Registration No. 45,565

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Levine Bagade Han LLP
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Petitioner - Avation Medical, Inc.
Ex. 1002, p. 38

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	14/085,639
Filing Date	November 20, 2013
First Named Inventor	Daniel R. BURNETT
Art Unit	3762
Examiner Name	Robert N. Wieland
Attorney Docket Number	EMKNNZ00501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	5,158,080	10-27-1992	Kallok	
	2.	2004/0127939	07-01-2004	Grey	
	3.	2007/0021712	01-25-2007	Bernard et al.	
	4.	2008/0058874	03-06-2008	Westlund et al.	
	5.	2008/0177347	07-24-2008	Tehrani et al.	
	6.	2008/0300655	12-04-2008	Cholette	
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	11.	2013/0006322	01-03-2013	Tai	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	

Electronic Patent Application Fee Transmittal

Application Number:	14085639
Filing Date:	20-Nov-2013
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Filer:	Johney U. Han/Kim Lampkins
Attorney Docket Number:	EMKNNZ00501

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	2253	1	700	700

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**700**

Electronic Acknowledgement Receipt

EFS ID:	20799382
Application Number:	14085639
International Application Number:	
Confirmation Number:	1183
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Customer Number:	40518
Filer:	Johney U. Han/Kim Lampkins
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00501
Receipt Date:	25-NOV-2014
Filing Date:	20-NOV-2013
Time Stamp:	16:02:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$700
RAM confirmation Number	2992
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		01_EMKNNZ00501_20141125_response_to_non-final_office_action.pdf	2044844 7c937ad5330f27c798b1dfc3532192d9edab0a3f	yes	7

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	3
Applicant Arguments/Remarks Made in an Amendment	4	7

Warnings:

Information:

2	Extension of Time	02_EMKNNZ00501_20141125_extension_of_time.pdf	512525 9d8cbc291011c206e1776b6a68dd8c136216b742	no	1

Warnings:

Information:

3	Transmittal Letter	03_EMKNNZ00501_20141125_ids_cover_letter.pdf	702062 43a6317e13b6e7e657634d3a90c7b85377910b2b	no	2

Warnings:

Information:

4	Information Disclosure Statement (IDS) Form (SB08)	04_EMKNNZ00501_20141125_ids_sb08.pdf	446569 9be89852c3bbcf89db880df3ff2b86c23b32a4c0	no	1

Warnings:

Information:

This is not an USPTO supplied IDS fillable form

5	Fee Worksheet (SB06)	fee-info.pdf	30515 ae5bb929208a968b2d99474b1dd24c3934a7f653	no	2

Warnings:

Information:

Total Files Size (in bytes):	3736515

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/085,639	Filing Date 11/20/2013	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	11/25/2014	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 9	Minus	** 20	=	X $ =	
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/TERRANCE LAWRENCE/

This collection of information is required by 37 CFR 1.16. 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 1.14. 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.**

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

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/085,639	Filing Date 11/20/2013	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **11/25/2014**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 10	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/DORRETTA BROOKS/

This collection of information is required by 37 CFR 1.16. 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 1.14. 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.**

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501

CONFIRMATION NO. 1183

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

PUBLICATION NOTICE

OC000000068704860

Title:METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

Publication No.US-2014-0148870-A1
Publication Date:05/29/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501	1183

40518 7590 05/28/2014

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

EXAMINER	
WIELAND, ROBERT N	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
05/28/2014	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 14/085,639	Applicant(s) BURNETT, DANIEL R.	
	Examiner Robert N. Wieland, Esq.	Art Unit 3762	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/07/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *2-17* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *2-17* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *11/20/13, 02/07/14, 05/07/14*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

1. This Action is in response to documents filed 05/07/2014.

2. Claims 2-17 are pending.

Notice of Pre-AIA or AIA Status

3. The present application is being examined under the pre-AIA first to invent provisions.

Claim Objections

4. Claim 9 is objected to because of the following informalities: The comma at the end of the claim seems to be a typographical error, and should be replaced with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 2, 6-9, 13, 14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated Simon et al., U.S. Application Serial No. 2013/0310909 A1.

As to claim 2, Simon et al. discloses a method of performing electrical stimulation therapy, (see ¶ 0097-0100 referring to Fig. 2B, disclosing using an electrode-based nerve stimulating/modulating device 302 for delivering impulses of energy to nerves including a power source 320 coupled to an impulse generator 310, coupled to a control unit 330 and to electrodes 340 having an interface region 351 including an electrically conducting medium 350 configured for contacting a patient's skin surface, for applying signals non-invasively to a target nerve tissue; similarly see ¶ 0150) comprising:

positioning a first portion of a patient's body relative to an electrical stimulator such that a target nerve within the first portion of the body is in proximity to the electrical stimulator, (see ¶ 0100, discussed above);

passing a current through the electrical stimulator; delivering an electrical stimulus from the electrical stimulator to the target nerve, (see ¶ 0097-0100 discussed above);

detecting electrical conduction through the target nerve or detecting a muscular response caused by an electrical conduction through the target nerve via at least one sensor positioned along a second portion of the body, (see ¶ 0104 referring to Figs. 2B and 2C, disclosing nerve stimulating/modulating device 302 acquiring outputs of various sensors which sense prevailing conditions prevailing in target nerve tissue substance, whereby the system automatically adjusts the stimulus output signal by feedback; also see ¶ 0150, disclosing an electrical stimulator configuration; also see ¶ 0204, disclosing the stimulation device wherein parameters of vagus nerve stimulation may be changed automatically, depending on physiological measurements that are made);

receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy, (see immediate above discussion; further see ¶ 0187 referring to Figs. 6 an 7, ¶ 0210-0211 referring to Fig. 8, and also control unit 330 in Fig. 2, disclosing a control theory representation of the inventive stimulation methods, wherein sensed physiological values are used as system input, used to adjust the stimulator system output to a level less than one at which the patient first indicates any discomfort, according to the feedback schema shown in Fig. 8);

and adjusting the current via a controller in communication with the electrical stimulator based on the feedback, (see immediate above discussion regarding Figs. 2 and 8).

As to claim 6, Simon et al. discloses wherein the electrical stimulus is delivered to a target nerve to treat chronic pain, (see reasons for rejection of claim 2 regarding the electrode-based nerve stimulating/modulating device 302 for delivering impulses of energy to nerves, together with the disclosure in ¶ 0074, disclosing electrical stimulation to treat chronic and acute cluster and migraine pain).

As to claim 7, Simon et al. discloses wherein a patient's hand or arm is positioned relative to the electrical stimulator such that the electrical stimulus is focused on a target nerve within the hand or arm, (see reasons for rejection of claim 2 regarding the electrode-based nerve stimulating/modulating device 302 for delivering impulses of energy to nerves, together with ¶ 0126, disclosing application of the stimulation device to tissue contours of the head, arms, legs, neck, etc.).

As to claim 8, Simon et al. discloses wherein a patient's back is positioned relative to the electrical stimulator such that the electrical stimulus is focused on a target nerve within the back, (see reasons for rejection of claim 2 regarding the electrode-based nerve stimulating/modulating device 302 for delivering impulses of energy to nerves, together with ¶ 0126, disclosing application of the stimulation device to tissue contours of the head, arms, legs, neck, etc.).

As to claim 9, Simon et al. discloses wherein the electrical stimulus is delivered to a target nerve to treat osteoarthritis or arthritis, (see ¶ 0018).

As to claim 13, Simon et al. discloses wherein the electrical stimulus is delivered to an occipital nerve to treat migraines, (see reasons for rejection of claim 2 regarding the electrode-based nerve stimulating/modulating device 302 for delivering impulses of energy to nerves, together with ¶ 0074, disclosing electrical stimulation to treat chronic and acute cluster and migraine pain).

As to claim 14, Simon et al. discloses wherein the electrical stimulus is delivered to a target nerve to treat back or neck pain, (see reasons for rejection of claim 2 regarding the electrode-based nerve stimulating/modulating device 302 for delivering impulses of energy to nerves, together with ¶ 0126, disclosing application of the stimulation device to tissue contours of the head, arms, legs, neck, etc.).

As to claim 16, Simon et al. discloses wherein the electrical stimulus is delivered to a target nerve to treat depression, (see reasons for rejection of claim 2 regarding the electrode-based nerve stimulating/modulating device 302 for delivering impulses of

energy to nerves, together with ¶ 0011, disclosing the system configured for treatment of depression).

As to claim 17, Simon et al. discloses wherein the electrical stimulus is delivered to a target nerve to treat paralysis, (see ¶ 0018).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) A patent may not be obtained although the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al., as applied to claim 2, in view of Herregraven et al., U.S. Application Serial No. 2010/0114259 A1.

Simon et al. discloses the electrical stimulus invention substantially as claimed, as discussed in the rejection of claim 2, but does not positively disclose wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat fecal incontinence. However, Herregraven et al. does.

Herregraven et al. teaches wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat fecal incontinence, (see ¶ 0025 and ¶ 0028-0032, referring to Fig. 1, and ¶ 0060).

Since Simon et al. and Herregraven et al. both are concerned with the same field of endeavor, namely the design of transcutaneous electrical stimulation systems, it therefore would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical stimulation therapy parameters as taught by Simon et al., to include the electrical stimulation therapy parameters configured for application to the posterior tibial nerve or branch thereof to treat fecal incontinence, as taught by Herregraven et al., without impermissibly altering the function of the Simon et al. device, since such a combination of known prior art elements would be applied to similar devices and used in a similar way and would provide the system with the predictable result of improved ability to provide the subject therapy.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al., as applied to claim 2, in view of Cameron et al., U.S. Application Serial No. 2006\0069415 A1.

Simon et al. discloses the electrical stimulus invention substantially as claimed, as discussed in the rejection of claim 2, but does not positively disclose wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat restless leg syndrome. However, Cameron et al. does.

Cameron et al. teaches a transcutaneous electrical stimulation system 10, (see ¶ 0079), and further teaches embodiments of the system configured for promoting neuroplasticity effects (see ¶ 0080) by stimulating damaged tissue in instances of impaired neuronal function (see ¶ 0081), and further provides instances of results of such impairment of neuronal function including restless leg syndrome (see ¶¶ 0081). Additionally, at ¶ 0089, Cameron et al. teaches other examples of altering neuroplasticity through electrical stimulation of a peripheral nerve, including the tibial nerves.

Since Simon et al. and Cameron et al. both are concerned with the same field of endeavor, namely the design of transcutaneous electrical stimulation systems, it therefore would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical stimulation therapy parameters as taught by Simon et al., to include the electrical stimulation therapy parameters configured for application to the posterior tibial nerve for treatment of restless leg syndrome, as taught by Cameron et al., without impermissibly altering the function of the Simon et al. device, since such a combination of known prior art elements would be applied to similar devices and used in a similar way and would provide the system with the predictable result of improved ability to provide the subject therapy.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al., as applied to claim 2, in view of Boggs et al., U.S. Application Serial No. 2011/0144468 A1.

Simon et al. discloses the electrical stimulus invention substantially as claimed, as discussed in the rejection of claim 2, but does not positively disclose wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat premature ejaculation. However, Boggs et al. does.

Boggs et al. teaches a transcutaneous electrical stimulation system for stimulation (i.e., activation) of a target nerve A and/or a target nerve B of either the male or the female to provide a sexual restoration function (see ¶ 0025) wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat premature ejaculation, (see ¶ 0091 and ¶ 0095).

Since Simon et al. and Boggs et al. both are concerned with the same field of endeavor, namely the design of transcutaneous electrical stimulation systems, it therefore would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical stimulation therapy parameters as taught by Simon et al., to include the electrical stimulation therapy parameters configured for application to the posterior tibial nerve to treat premature ejaculation, as taught by Boggs et al., without impermissibly altering the function of the Simon et al. device, since such a combination of known prior art elements would be applied to similar devices and used in a similar way and would provide the system with the predictable result of improved ability to provide the subject therapy.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al., as applied to claim 2, in view of Naroditsky et al., U.S. Application Serial No. 2009/0198305 A1.

Simon et al. discloses the electrical stimulus invention substantially as claimed, as discussed in the rejection of claim 2, but does not positively disclose wherein the electrical stimulus is delivered to a target nerve responsible for neuropathic pain to treat neuropathic pain (see ¶ 0066). However, Naroditsky et al. does.

Naroditsky et al. teaches a transcutaneous electrical stimulation arrangement including electrodes in contact with a person's skin for transmitting electrical current to target tissue (see Abstract, and ¶ 0030), configured to deliver electrical stimulus to a target nerve responsible for neuropathic pain to treat neuropathic pain (see ¶ 0066).

Since Simon et al. and Naroditsky et al. both are concerned with the same field of endeavor, namely the design of transcutaneous electrical stimulation systems, it therefore would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical stimulation therapy parameters as taught by Simon et al., to include the electrical stimulation therapy parameters configured for application to a target nerve responsible for neuropathic pain to treat neuropathic pain, as taught by Naroditsky et al., without impermissibly altering the function of the Simon et al. device, since such a combination of known prior art elements would be applied to similar devices and used in a similar way and would provide the system with the predictable result of improved ability to provide the subject therapy.

11. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al., as applied to claim 2, in view of Prochazka, U.S. Application Serial No. 2010/0016929 A1.

As to claim 11, Simon et al. discloses the electrical stimulus invention substantially as claimed, as discussed in the rejection of claim 2, but does not positively disclose wherein the electrical stimulus is delivered to a target nerve to treat neuralgia, or delivered to a trigeminal nerve to treat neuralgia. However, Prochazka does.

Prochazka teaches a transcutaneous electrical stimulation arrangement including electrodes in contact with a person's skin for transmitting electrical current to target nerve tissue, (¶ 0023-0027 and ¶ 0038-0040), the electrical stimulus is delivered to a target nerve to treat neuralgia, or delivered to a trigeminal nerve to treat neuralgia, (see ¶ 0112).

Since Simon et al. and Prochazka both are concerned with the same field of endeavor, namely the design of transcutaneous electrical stimulation systems, it therefore would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical stimulation therapy parameters as taught by Simon et al., to include the electrical stimulation therapy parameters configured for application to a target nerve to treat neuralgia, or delivered to a trigeminal nerve to treat neuralgia, as taught by Prochazka, without impermissibly altering the function of the Simon et al. device, since such a combination of known prior art elements would be applied to similar devices and used in a similar way and would provide the system with the predictable result of improved ability to provide the subject therapy.

As to claim 12, Simon et al. discloses wherein a patient's face or head is positioned relative to the electrical stimulator such that the electrical stimulus is delivered to a trigeminal nerve to treat neuralgia, (see ¶ 0112).

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al., as applied to claim 2, in view of Wheeler U.S. Application Serial No. 2006/0047326 A1.

Simon et al. discloses the electrical stimulus invention substantially as claimed, as discussed in the rejection of claim 2, but does not positively disclose wherein the electrical stimulus is delivered to a target nerve to treat atrophy. However, Wheeler does.

Wheeler teaches a transcutaneous electrical stimulation system configured to deliver electrical stimulus to a target nerve to treat neural atrophy, (see ¶ 0004 and 0007).

Since Simon et al. and Wheeler both are concerned with the same field of endeavor, namely the design of transcutaneous electrical stimulation systems, it therefore would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical stimulation therapy parameters as taught by Simon et al., to include the electrical stimulation therapy parameters configured for application to a target nerve to treat neural atrophy, or delivered to a trigeminal nerve to treat neuralgia, as taught by Wheeler, without impermissibly altering the function of the Simon et al. device, since such a combination of known prior art elements would be

applied to similar devices and used in a similar way and would provide the system with the predictable result of improved ability to provide the subject therapy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT N. WIELAND, Esq. whose telephone number is (571) 270-7399. The examiner can normally be reached on Monday-Thursday, 8:00-6:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number directly to Examiner Wieland is 571-270-8399.

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/Robert N. Wieland, Esq./
Primary Examiner, A.U. 3762

Notice of References Cited	Application/Control No. 14/085,639	Applicant(s)/Patent Under Reexamination BURNETT, DANIEL R.	
	Examiner Robert N. Wieland, Esq.	Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2006/0047326 A1	03-2006	Wheeler, James Walter	607/048
*	B	US-2006/0069415 A1	03-2006	Cameron et al.	607/045
*	C	US-2009/0198305 A1	08-2009	Naroditsky et al.	607/46
*	D	US-2010/0016929 A1	01-2010	Prochazka, Arthur	607/72
*	E	US-2010/0114259 A1	05-2010	Herregraven et al.	607/63
*	F	US-2011/0144468 A1	06-2011	Boggs et al.	600/373
*	G	US-2013/0310909 A1	11-2013	Simon et al.	607/115
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	14/085,639
Filing Date	November 20, 2013
First Named Inventor	Daniel R. BURNETT
Art Unit	2183
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	2002/0183647	12-05-2002	Gozani et al.	
	2.	2007/0265675	11-15-2007	Lund et al.	
	3.	2009/0030337	01-29-2009	Gozani et al.	
	4.	2009/0054950	02-26-2009	Stephens	
	5.	2010/057149	03-04-2010	Fahey	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	6.	WO 2006/061688	06-15-2006	STANDEN LTD.		
	7.	WO 2010/047599	04-29-2010	MED STORM INNOVATION A		

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	8.		

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[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Robert Wieland/	Date Considered	05/22/2014

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.N.W./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	4	tibial and restless leg AND transcutaneous electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:33
L2	2	tibial and premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT L1	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:33
L3	2	tibial and premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:34
L4	3	premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:38
L5	6	genital near4 nerve AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:41
L6	22	genital near4 nerve AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:41
L7	0	genital near4 nerve and tibial AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:42
L8	5	genital near4 nerve and ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:42
L10	64	premature ejaculation AND (percutaneous$4 or transcutaneous$4 or skin) near9 stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT L8	US-PGPUB; USPAT	ADJ	ON	2014/05/22 14:59
L14	6	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 15:12
L15	1	((emkinetics).as. or burnett.in.) AND (electrical stimulation therapy).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 15:13
L16	88	transcutaneous electrical stimulation AND (osteoarthritis or arthritis or neuropathic pain or neuralgia or atrophy or depression or paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 15:31
L17	25	transcutaneous electrical stimulation AND (	US-	ADJ	ON	2014/05/22

		paralysis) AND (@ad<"20061002" or @rlad< "20061002")	PGPUB; USPAT			16:02
L18	51	transcutaneous electrical stimulation AND (osteoarthritis or arthritis or paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:02
L19	0	transcutaneous electrical stimulation AND (osteoarthritis and arthritis and paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:02
L20	6	transcutaneous electrical stimulation AND (arthritis and paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:02
L21	1	transcutaneous electrical stimulation AND (neuropathic pain and atrophy) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:12
L22	2	transcutaneous electrical stimulation AND (neuropathic pain or neuropathy) same pain$4 and atrophy AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:16
L23	1	percutaneous electrical stimulation AND (neuropathic pain or neuropathy) same pain$4 and atrophy AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:24
L24	24	transcutaneous electrical stimulation AND (neuropathic pain or neuropathy) same pain$4 AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:25
L25	23	transcutaneous electrical stimulation AND (neuropathic pain or neuropathy near9 pain$4) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 16:25
S1	0	14/085639.app.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:24
S2	12	((emkinetics).as. or burnett.in.) AND (target nerve).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:26
S4	1	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm. and feedback.clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:26
S5	5	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm. and (adjust$4 adj3 current).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:27
S6	6	((emkinetics).as. or burnett.in.) AND (target nerve).clm. and (muscular response).clm. and (conduction adj5 nerve).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:30
S8	2	((emkinetics).as. or burnett.in.) AND (electrical stimulation).clm.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 09:45
S10	1	"20040173220" .pn.	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:15
S11	167	electrical stimul$5 near9 target near3 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:40
S12	56	electrical stimul$5 near9 target near3 nerve and target near3 nerve same pain AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:40

S13	11	electrical stimul$5 near9 target near3 nerve and target near3 nerve same chronic pain AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:41
S18	57	(transdermal$4 or transcutaneous$4) near9 electrical stimul$5 and stimul$5 near9 nerve same chronic pain AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:53
S19	5	(transdermal$4 or transcutaneous$4) near9 electrical stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 10:54
S20	5	(transdermal$4 or transcutaneous$4 or skin near6 surface) near9 electrical stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT "L19"	US-PGPUB; USPAT	ADJ	ON	2014/05/21 14:38
S21	24	(transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial and electrical stimul$5 AND (@ad<"20061002" or @rlad< "20061002") NOT "L19"	US-PGPUB; USPAT	ADJ	ON	2014/05/21 14:39
S22	21	(transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT S20	US-PGPUB; USPAT	ADJ	ON	2014/05/21 14:40
S23	0	feedback near9 (sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT S20	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:08
S24	0	feedback near9 (electrode or sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002") NOT S20	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:08
S25	0	feedback near9 (electrode or sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and stimul$5 near9 nerve same chronic pain and stimul$5 same tibial AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:09
S26	341	feedback near9 (electrode or sens$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:10
S27	183	feedback near9 (electrode or sens$4) same adjust$4 and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:11
S28	282	feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:11

		stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")				
S29	0	(tibial nerve same fecal incontinence) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:12
S30	28	(tibial nerve or fecal incontinence) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:12
S31	80	pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:20
S32	7	conduction near4 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:22
S33	0	(sens$4 or detect$4) near4 conduction near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:25
S34	1	(sens$4 or detect$4) near4 conduction same nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:25
S35	54	(sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 15:27
S36	16	(sens$4 or detect$4) near9 nerve same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:14

		near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")				
S37	36	(sens$4 or detect$4) near9 stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:17
S38	54	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:31
S39	18	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT S37	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:31
S40	0	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT S37 not S39	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:38
S41	0	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:39
S42	128	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:39
S43	124	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near4 nerve AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:39

		nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)				
S44	59	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near4 nerve same (feedback or closed-loop) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:40
S45	29	(sens$4 or detect$4) near6 nerve near4 (activity or response) same (feedback or closed-loop) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 16:44
S46	88	(sens$4 or detect$4) near6 stimulation same (feedback or closed-loop) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002") NOT (S37 or S39)	US-PGPUB; USPAT	ADJ	ON	2014/05/21 17:04
S47	11	(US-20040173220-$ or US-20060069415-$ or US-20100114259-$ or US-20080039915-$ or US-20110256097-$ or US-20100016929-$ or US-20020026226-$ or US-20080077192-$).did. or (US-6725094-$ or US-8712546-$ or US-5775331-$).did.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:24
S48	1	S47 and patch "80"	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:25
S49	163	(sens$4 or detect$4) near6 stimulation same (feedback or closed-loop) AND (feedback or sens$4 or control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:30
S50	54	stimul$5 same (feedback or closed-loop) AND (sens$4 or detect$4) near9 nerve and pain same (arm or back or hand) AND feedback near9 (electrode or sens$4) same (control$4 or adjust$4) and (transdermal$4 or transcutaneous$4 or skin near6 surface) near9 stimul$5 and electrical adj3 stimul$5 near9 nerve AND (pain near9 (arm or back or hand or neck) or tibial nerve or incontinence or restless leg or ejaculation or chronic pain or osteoarthritis or arthritis or neuropathic pain or neuralgia or migraine or atrophy or depression or paralysis) AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 10:36
S51	53	stimul$5 same (adjust$4 or feedback or closed-loop) and electrical adj3 stimul$5 near9 nerve and transcutaneous electrical stimulation AND	US-PGPUB; USPAT	ADJ	ON	2014/05/22 11:02

		(pain near9 (arm or back or hand or neck) or tibial nerve or incontinence or restless leg or ejaculation or chronic pain or osteoarthritis or arthritis or neuropathic pain or neuralgia or migraine or atrophy or depression or paralysis) AND (@ad<"20061002" or @rlad<"20061002")				
S52	1	"20050216062".pn.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 11:09
S53	13	(US-20040173220-$ or US-20060069415-$ or US-20100114259-$ or US-20080039915-$ or US-20110256097-$ or US-20100016929-$ or US-20020026226-$ or US-20080077192-$ or US-20070250119-$ or US-20130310909-$).did. or (US-6725094-$ or US-8712546-$ or US-5775331-$).did.	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S54	0	LI7 and tibial nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S55	0	LI7 and tibial near4 nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S56	0	LI7 and tibial near9 nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S57	0	LI7 and tibial same nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S58	1	LI7 and tibial	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:09
S59	0	LI7 and (medial adj3 branch or lateral plantar branch)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:13
S60	34	LI7 and (medial or lateral or plantar)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:17
S61	2	LI7 and (medial branch or lateral branch or plantar)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:18
S62	0	LI7 and (plantar nerve)	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:18
S63	1	LI7 and sole	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:19
S64	8	LI7 and foot	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:19
S65	3	S53 and tibial nerve	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:20
S66	2	S53 and restless leg	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:32
S69	0	tibia and restless leg AND transcutaneous electrical stimulation AND (@ad<"20061002" or	US-PGPUB;	ADJ	ON	2014/05/22 12:40

		@rlad< "20061002")	USPAT			
S70	4	tibial and restless leg AND transcutaneous electrical stimulation AND (@ad<"20061002" or @rlad< "20061002")	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:41
S71	0	tibial and restless leg AND (percutaneous or transcutaneous) electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:43
S72	0	tibial and restless leg AND (percutaneous or transcutaneous or skin near5 surface) electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:44
S73	0	tibial and restless leg AND (percutaneous or transcutaneous or skin near5 surface) near6 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:44
S74	0	tibial and restless leg AND (percutaneous or transcutaneous or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:45
S75	1	tibial and restless leg AND (percutaneous$4 or transcutaneous$4 or skin) near9 electrical stimulation AND (@ad<"20061002" or @rlad< "20061002") NOT S70	US-PGPUB; USPAT	ADJ	ON	2014/05/22 12:45

5/22/2014 5:03:19 PM
C:\Users\rwieland\Documents\EAST\Workspaces\14085639.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14085639	BURNETT, DANIEL R.
	Examiner	Art Unit
	ROBERT N WIELAND	3762

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
607	118	05/22/2014	/RNW/

SEARCH NOTES		
Search Notes	Date	Examiner
Text Searched entire USPC Class	05/22/2014	/RNW/
Searched inventor and assignee names; also for obviousness double patenting	05/22/2014	/RNW/
Placed copy of search report in the record	05/22/2014	/RNW/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 12

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00501

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Examiner Signature	/Robert Wieland/	Date Considered	05/22/2014

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 12

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00501

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Examiner Signature	/Robert Wieland/	Date Considered	05/22/2014

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 12

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00501

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 12

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Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00501

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 12

Complete if Known	
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Art Unit	Not Yet Assigned
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 12

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 7 of 12

Complete if Known	
Application Number	Not Yet Assigned
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First Named Inventor	Daniel R. BURNETT
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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)* Sheet 8 of 12	*Complete if Known*	
	Application Number	Not Yet Assigned
	Filing Date	Concurrently Herewith
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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)* Sheet 11 of 12	*Complete if Known*	
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				Examiner Name	Not Yet Assigned
Sheet	12	of	12	Attorney Docket Number	EMKNNZ00501

	349.	Zoll Lifecor Corporation, "What is the LifeVest Wearable Defibrillator," http://www.lifecor.com/about_lifevest/about.asp#, 1 page, printed on January 7, 2011.	

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[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1

Complete if Known	
Application Number	14/085,639
Filing Date	November 20, 2013
First Named Inventor	Daniel R. BURNETT
Art Unit	2183
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	2008/0065167	03-13-2008	Boggs et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
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NON PATENT LITERATURE DOCUMENTS

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
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=	Allowed	÷	Restricted	I	Interference	O	Objected

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	1.	2002/0183647	12-05-2002	Gozani et al.	
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	3.	2009/0030337	01-29-2009	Gozani et al.	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	6.	WO 2006/061688	06-15-2006	STANDEN LTD.		
	7.	WO 2010/047599	04-29-2010	MED STORM INNOVATION A		

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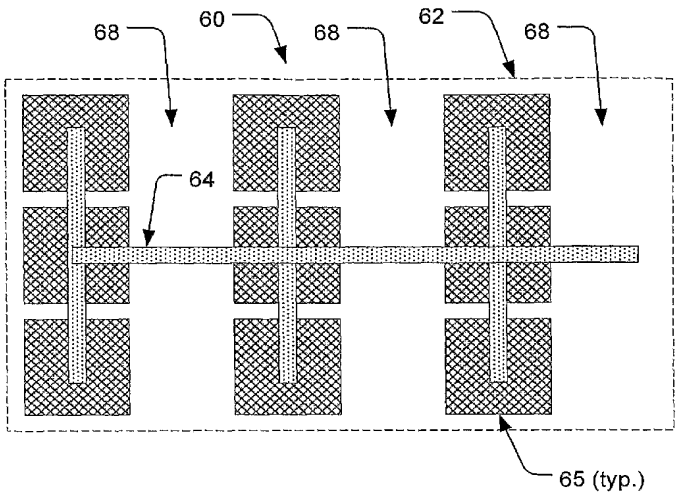
(54) **Title:** ELECTRODES FOR APPLYING AN ELECTRIC FIELD IN-VIVO OVER AN EXTENDED PERIOD OF TIME



(57) **Abstract:** As compared to conventional electrodes, the electrode configurations disclosed herein minimize irritation and damage to the skin when they are placed in contact with a patient's body over extended of time. The electrodes are formed from a conductive substrate coated with a thin dielectric material, and a plurality of open spaces pass through the electrodes. Those open spaces are distributed and sized to permit moisture on the surface of the patient's body to escape when the electrode is placed in contact with the patient's body. One intended use for the electrodes is for treating tumors by applying an AC electric field with specific frequency and field strength characteristics over an extended period of time.

WO 2006/061688 A1

ELECTRODES FOR APPLYING AN ELECTRIC FIELD IN-VIVO OVER AN EXTENDED PERIOD OF TIME

BACKGROUND

[0001] This invention concerns electrodes for applying electric fields in-vivo over an extended period of time, and methods for using such electrodes.

[0002] Living organisms proliferate by cell division, including tissues, cell cultures, microorganisms (such as bacteria, mycoplasma, yeast, protozoa, and other single-celled organisms), fungi, algae, plant cells, etc. Dividing cells of organisms can be destroyed, or their proliferation controlled, by methods that are based on the sensitivity of the dividing cells of these organisms to certain chemical or physical agents. For example, certain antibiotics stop the multiplication process of bacteria.

[0003] It is well known that tumors, particularly malignant or cancerous tumors, grow very uncontrollably compared to normal tissue. Such expedited growth enables tumors to occupy an ever-increasing space and to damage or destroy tissue adjacent thereto. Furthermore, certain cancers are characterized by an ability to spread metastases to new locations where the metastatic cancer cells grow into additional tumors.

[0004] The rapid growth of tumors, in general, and malignant tumors in particular, as described above, is the result of relatively frequent cell division or multiplication of these cells compared to normal tissue cells. The distinguishably frequent cell division of cancer cells is the basis for the effectiveness of many existing cancer treatments, e.g., irradiation therapy and the use of various chemo-therapeutic agents. Such treatments are based on the fact that cells undergoing division are more sensitive to radiation and chemo-therapeutic agents than non-dividing cells. Because tumors cells divide much more frequently than normal cells, it is possible, to a certain extent, to selectively damage or destroy tumor cells by radiation therapy and/or chemotherapy. The actual sensitivity of cells to radiation,

therapeutic agents, etc., is also dependent on specific characteristics of different types of normal or malignant cell types. Thus, unfortunately, the sensitivity of tumor cells is not sufficiently higher than that of many types of normal tissues. This diminishes the ability to distinguish between tumor cells and normal cells, and therefore, existing cancer treatments typically cause significant damage to normal tissues, thus limiting the therapeutic effectiveness of such treatments. Also, certain types of tumors are not sensitive at all to existing methods of treatment.

[0005] Electric fields and currents have been used for medical purposes for many years. The most common is the generation of electric currents in a human or animal body by application of an electric field by means of a pair of conductive electrodes between which a potential difference is maintained. These electric currents are used either to exert their specific effects, i.e., to stimulate excitable tissue, or to generate heat by flowing in the body since it acts as a resistor. Examples of the first type of application include the following: cardiac defibrillators, peripheral nerve and muscle stimulators, brain stimulators, etc. Currents are used for heating, for example, in devices for tumor ablation, ablation of malfunctioning cardiac or brain tissue, cauterization, relaxation of muscle rheumatic pain and other pain, etc.

[0006] Another use of electric fields for medical purposes involves the utilization of high frequency oscillating fields transmitted from a source that emits an electric wave, such as an RF wave or a microwave source, which is directed at the part of the body that is of interest (i.e., a target). In these instances, there is no electric energy conducting between the source and the body; but rather, the energy is transmitted to the body by radiation or induction. More specifically, the electric energy generated by the source reaches the vicinity of the body via a conductor and is transmitted from it through air or some other electric insulating material to the human body.

[0007] Electric fields that can be used in medical applications can thus be separated generally into two different modes. In the first mode, the electric fields are applied to the body or tissues by means of conducting electrodes. These electric fields can be separated into two types, namely (1) steady fields or fields that change at relatively slow rates, and alternating fields of low frequencies that induce corresponding electric currents in the body or tissues, and (2) high frequency alternating fields (above 1 MHz) applied to the body by means of the conducting electrodes or by means of insulated electrodes.

[0008] The first type of electric field is used, for example, to stimulate nerves and muscles, pace the heart, etc. In fact, such fields are used in nature to propagate signals in nerve and muscle fibers, central nervous system (CNS), heart, etc. The recording of such natural fields is the basis for the ECG, EEG, EMG, ERG, etc. The field strength in conductive electrode applications, assuming a medium of homogenous electric properties, is simply the voltage applied to the stimulating/recording electrodes divided by the distance between them. The currents thus generated can be calculated by Ohm's law and can have dangerous stimulatory effects on the heart and CNS and can result in potentially harmful ion concentration changes. Also, if the currents are strong enough, they can cause excessive heating in the tissues. This heating can be calculated by the power dissipated in the tissue (the product of the voltage and the current).

[0009] When such electric fields and currents are alternating, their stimulatory power, on nerve, muscle, etc., is an inverse function of the frequency. At frequencies above 1-10 kHz, the stimulation power of fields approaches zero. This limitation is due to the fact that excitation induced by electric stimulation is normally mediated by membrane potential changes, the rate of which is limited by the RC properties (with time constants on the order of 1 ms) of the membrane.

[0010] Regardless of the frequency, when such current inducing fields are applied, they are often associated with harmful side effects caused by currents. For example, one negative effect is the changes in ionic concentration in the various "compartments" within the system, and the harmful products of the electrolysis biological material, or the medium in which the tissues are imbedded.

[0011] Alternating fields of medium frequencies (about 50 kHz – 1 MHz), which were traditionally assumed not to have any biological effect except due to heating, can be applied to a conductive medium, such as a human body, via insulated electrodes. Under such conditions the electrodes induce in the body only capacitive currents. In contrast to the general belief that such fields have no direct biological effect, in US patent applications # 10/204,334, 10/288,562, 10/285,313 by Palti (each of which is incorporated herein by reference) and in a subsequent publication (Eilon D. Kirson, et al., Disruption of Cancer Cell Replication by Alternating Electric Fields, Cancer Res. 2004 64:3288-3295), such fields have been shown to have the capability to specifically affect cancer cells and serve, among others, for treating cancer.

[0012] Treatment of cancer, other diseases, conditions and patho-physiological states by alternating electric fields may require long term application (e.g., over weeks or months) of the fields to the target location, which involves correspondingly long contact between the electrodes and the body surface (e.g., the patient's skin). Such application may be associated with significant side effects that may result from both chemical and physical reactions. Such reactions have been reported upon application of TENS, muscle stimulation, long term body potential recording (EEG, ECG, etc.).

[0013] Chemical reaction may be due to the contact with the electrode itself, or the materials that are interposed between the electrode and the skin for improving

electric conductivity (for example gel), and the products of the current flow including electrolysis at the electrode surfaces.

[0014] The long-term physical contact of the electrodes against the skin may effect the under-laying skin by the local pressure, by keeping the skin surface wet, or by the fact that the electrodes or gel, etc. occlude the exits of the skin appendages located at the external part of the skin, such as sweat glands, hair follicles, etc. This results in accumulation of water and chemical agents within the appendages and at the skin surface, which can damage the superficial skin layers.

SUMMARY OF THE INVENTION

[0015] The present invention is designed to eliminate, or significantly reduce some of the side effects associated with long term application of electric fields to the skin by using an electrode configuration that permits the skin to "breathe."

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1A is a plan view of a first embodiment of the present invention, which is a multi-segment electrode with the segments arranged in a rectangular array.

[0017] FIG. 1B is a cross section view of the FIG. 1A embodiment, taken along section line A-A.

[0018] FIG. 1C is a cross section view of the FIG. 1A embodiment with an optional wicking feature added.

[0019] FIG. 2 is a plan view of a second embodiment of the present invention, which is a multi-segment electrode with the segments arranged in a hexagonal array.

[0020] FIG. 3 is a plan view of a third embodiment of the present invention, which is a perforated electrode.

[0021] FIG. 4A is a plan view of a fourth embodiment of the present invention, which is an electrode made of a plurality of parallel wires.

[0022] FIG. 4B is a cross section view of the FIG. 4A embodiment, taken along section line B-B used, used with a conductive gel.

[0023] FIG. 5 is a plan view of a fifth embodiment of the present invention, which is an electrode made from a group of parallel wires, with an additional group of parallel wires that are perpendicular to the first group.

[0024] FIG. 6A is a plan view of a sixth embodiment of the present invention, with the electrode located at a first position within an overall footprint.

[0025] FIG. 6B shows the electrode of FIG. 6A located at a second position within an overall footprint.

[0026] FIG. 7A is a pictorial representation showing how a pair of any of the aforementioned electrodes are placed in contact with the skin of a patient during use.

[0027] FIG. 7B is a schematic representation of an electrical circuit that is formed when a pair of any of the aforementioned electrodes are placed in contact with the skin of a patient.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0028] FIGS 1A and 1B depict a first embodiment of a composite electrode that is designed for applying an electric field to an in-vivo tumor for extended periods of time. The composite electrode 10 is made up of a number of individual segments 5, with a number of open spaces 8 disposed between the segments 5. The segments 5 apply an electric field to a desired location within the patient's body. Preferred characteristics of the applied field are described in the three patent applications identified above. Those applications teach that electric fields with frequencies between about 50 kHz to about 500 kHz (and more preferably between

about 100 kHz and 300 kHz) at field strengths of between about 0.1 V/cm to about 10 V/cm (and more preferably between about 1 and about 10 V/cm) have proven effective at slowing or reversing the growth of rapidly dividing cells (e.g., cancer cells). For example, a 120 kHz, 1.4 V/cm field has been shown to be effective against melanoma, and a 170-250 kHz, 2.5 V/cm field has been shown to be effective against glioma.

[0029] Returning to FIGS. 1A and 1B, the segments 5 are preferably free to move about with respect to one another, to permit the electrode 10 to conform to the shape of the body's surface upon which the electrode 10 is placed. The segments 5 may be held together using any of a variety of suitable support structures, such as mounting them on a piece of cloth, netting, or other flexible backing (not shown). All of the segments are preferably electrically connected in parallel using appropriate wiring 4.

[0030] Each segment 5 preferably contains a conductive core 3 that is completely insulated from the surface upon which it is placed by a dielectric insulating material 2. Other surfaces of the segments 5 are preferably covered by any conventional insulating material 9. Because the dielectric insulating material 2 insulates the conductive core 3 from the surface of the patient's skin, any DC component that is present in the signal driving the electrodes will be blocked, and only the AC components at sufficiently high frequencies can pass into the patient's body. This configuration avoids the negative effects that would occur if conductive electrodes were used (e.g., ion concentration changes in the cells and the formation of harmful agents by electrolysis). This is because, in general, when capacitive electrodes are used, no actual transfer of charges takes place between the electrodes and the medium and there is no charge flow in the medium.

[0031] FIG. 7A shows how the above-described electrodes (or the electrodes of the below-described embodiments) are used to apply the desired field to the target

location. A pair of insulated electrodes 74 each contains a conducting portion 74A with an insulating dielectric portion 74B disposed thereon. When such electrodes are placed in contact with the patient's skin 6 and operatively connected to an AC voltage source 72 via leads 73, an electric field 76 is induced in the tissue 78 (which includes a tumor 79) that lies beneath the skin 6. As described in the three patent applications identified above, the equivalent electric circuit when the insulated electrodes are placed on the skin is as depicted in Figure 7B: the dielectric coated electrodes 75 act as capacitors A, E, the skin 6 acts as a resistive load B, D, and the tissue 78 also acts as a resistive load C. Under these conditions, the relative values of the impedances cause the fraction of the potential difference (electric field) that falls on the electrode insulation to be strongly dependent on the capacitance of the electrodes A, E. The potential drop across the capacitive electrode A is A/(A+B+C+D+E), and a similar drop occurs across the other capacitive electrode E. At DC and low frequencies, the impedance of the capacitive electrodes A, E is high, and most of the voltage drop will be across the electrodes. In contrast, for extremely high frequencies, the capacitors have very low impedance and therefore a much larger portion of the voltage drop will appear in the tissue C. At the relevant frequency ranges identified above (i.e., from about 50 kHz to about 500 kHz), the impedance of the capacitive electrodes A, E will lie somewhere between those two extremes.

[0032] The preferred electric field intensity in the target tissue 79 is in the range of about 0.1 V/cm to about 10 V/cm. In order to achieve this voltage drop in the tissue C without increasing the voltage of the AC source 72 to undesirably high levels (which can pose a safety problem and be difficult to generate at the required parameters), the impedance of the capacitors A, E must be minimized, which occurs when the capacitance of the electrodes is maximized. Increasing the capacitance can be achieved by increasing the effective area of the "plates" of the capacitor, decreasing the thickness of the dielectric, or using a dielectric with a high dielectric

constant. Since the electrode area is limited and the insulation thickness can not be reduced in view of potential dielectric breakdown and due to the danger of mechanical damage, the best way to deliver the appropriate fields to their target locations is to use dielectrics with a very high dielectric constant. Examples of suitable dielectrics are: KTN - Potassium Tantalate ($KTa_{1-x}Nb_xO_3$), or PMNT (Lead Magnesium Niobate Titanate), which all have dielectric constants above 1000. Note that with some of these high-K materials, the dielectric constant can vary dramatically depending on the material processing procedures that are used when the material is formed (e.g., crystallization or doping), and it is more preferable to use a variety with a dielectric constant above 10,000. Note, however, that a very thin coating by a strong dielectric material with a standard dielectric constant (e.g., 3-30) may also serve well under some configurations (e.g., if a weaker field or higher voltage is not problematic).

[0033] Returning now to FIGS. 1A and 1B, the electrodes 10 include spaces 8 that are distributed throughout the surface of the electrodes 10. These spaces 8 allow the skin beneath the electrode 10 to "breathe" by allowing air to reach the skin beneath the electrodes. As a result, moisture (e.g., sweat) that might otherwise build up on the surface of the skin can evaporate. This ameliorates the detrimental effects that can accompany long term use of non-perforated electrodes (as described above in the background section). In addition, the presence of the spaces 8 between the active segments 5 of the electrode 10 helps prevent heat (due to, e.g., dielectric losses and current flow) from building up beneath the electrodes 10.

[0034] To ensure that the field is effectively strong the target location, the spacing between the segments 5 of the electrodes 10 is preferably smaller than the distance from the surface to the location that is the target of the treatment (e.g., the tumor 79, shown in FIG. 7A). On the other hand, the spacing between the segments 5 is preferably larger than about 2 mm, and more preferably larger than about 4 mm, to provide adequate ventilation. In terms of area, the area of each space 8 is

preferably larger than about 4 mm², and more preferably larger than about 16 mm². In this embodiment, the area of the segments 5 is roughly the same as the area of the spaces 8.

[0035] FIG. 2 depicts a second embodiment of an electrode 20. This electrode 20 is very similar to the electrode 10 of the FIG. 1 embodiment, except that the segments 25 and the spaces 28 of the FIG. 2 embodiment are hexagonal instead of square. Of course, other shapes besides the depicted squares and hexagons may also be used, and the spacing between the segments may be varied as required. The spacing of the segments in these embodiments is preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin. The segmented structure of these embodiments can be particularly advantageous in anatomical positions where a large degree of flexibility is needed to conform the electrodes to the skin surface.

[0036] FIG. 3 depicts a third embodiment of an electrode 30. This electrode is preferably made of a single piece of conductive material 35, with perforations or holes 38 disposed therein. The lower surface of the electrode 30 (not shown), which contacts the skin of the patient, is preferably coated with a dielectric material similar to the dielectric 2 of the FIG. 1 embodiment. The upper surface of the electrode 30, which faces away from the patient during use, is preferably coated with an insulator similar to the insulator 9 of the FIG. 1 embodiment. The spacing of the holes in this embodiment is also preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin.

[0037] FIGS. 4A and 4B are plan and section views of a fourth embodiment of an electrode 40. This electrode is made of a set of parallel elements 45 that are separated by spaces 48. Each element 45 is made of a conductive wire 43 that is surrounded by a dielectric coating 42, preferably of a material similar to the dielectric 2 of the FIG. 1 embodiment. The conductors 43 are preferably electrically

connected in parallel by wires 44. A suitable backing (not shown) may be affixed to the electrode 40 to maintain the desired spacing of the elements 45 of the electrode 40. Optionally, this backing may be designed to prevent bending of the electrode along the length of the elements 45, which could crack the dielectric coating when a brittle dielectric is used. However, the backing may be configured to permit bending of the electrode 40 about an axis that is parallel to the elements 45, as long as the bending occurs at the spaces 48. The spacing of the open spaces 48 in this embodiment is also preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin. For example, the spaces 48 may be at least 2 mm wide, or more preferably, at least 4 mm wide.

[0038] FIG. 5 is a plan view of a fifth embodiment of an electrode 50. This embodiment is similar to the FIG. 4 embodiment described above, except that in addition to the horizontal elements 55 that correspond to the horizontal elements 45 of the FIG. 4 embodiment, the fifth embodiment also contains a second set of vertical elements 55' with a similar construction. Both sets of elements 55, 55' are preferably wired up in parallel by wires 54. As with the above-describe embodiments, the size of the open spaces 58 are also preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin. For example, the spaces 58 may be at least 2 mm by 2 mm, or more preferably, at least 4 mm by 4 mm.

[0039] In some embodiments, e.g., FIGS. 1 and 4, the pattern of insulated conductors and spaces is configured so that locations that are covered when the electrode is positioned in a first location will become uncovered when the electrode is repositioned to a second location that is offset slightly from the first location, wherein the overall footprint of the electrodes in both locations is substantially the same. When this arrangement is implemented, the electrodes can be shifted back and forth between two positions periodically (e.g., every 2 to 4 days), so that each small patch of skin is alternately covered (in one position) or uncovered (in the other

position). Periodically exposing each patch of skin to the air in this manner gives the skin a chance to recover from any negative effects (e.g., accumulation of moisture or field effects) than may have occurred during the period of time when the skin was covered by the electrode. In applications where the electrodes are applied to the head, the head may be shaved before the electrodes are replaced in their new position, to prevent hair growth from interfering with the fields.

[0040] FIGS. 6A and 6B are plan views of a sixth embodiment of an electrode 60 positioned, respectively, at first and second locations within an overall footprint 62. As such, FIGS. 6A and 6B depict yet another embodiment in which the electrodes can be shifted back and forth between two positions periodically, as discussed above. The electrode 60 of this embodiment is made of a set of square segments 65 that are separated by spaces 68, with the area of the segments 65 roughly the same as the area of the spaces 68. The construction of the individual segments 65 of this embodiment is preferably similar to the segments 5 described above in connection with the FIG. 1 embodiment. Each segment 65 preferably measures at least 2 mm by 2 mm, and more preferably at least 4 mm by 4 mm, with a thickness between about 0.2 and about 1 mm. Note that although square segments are depicted in FIGS. 6A and 6B, other shapes and sizes may also be used, such as rectangular segments (e.g., 5 × 15 mm or 13 × 15 mm), circular segments (e.g., 19 mm in diameter), or other shapes that are designed to conform to a particular anatomical location.

[0041] The segments 65 may be mechanically held in place by any suitable flexible support. For example, they may be mounted on a thin and flexible substrate such as DuPont Kapton® polyimide film (not shown). When such a film is used, flexible wiring 64 may also be integrated onto the substrate to provide a low impedance electrical connection between the segments 65. An adhesive bandage may be used to affix the electrode assembly to the patient's body, in which case the adhesive bandage would also provide additional mechanical support.

[0042] Optionally, temperature sensors (e.g., a thermistor, not shown) may be added to each segment in this embodiment, e.g., by mounting them through a small hole (e.g., 2.5 mm dia.) in the center of each segment. When a polyimide film with flexible wiring is used for the connections to the segments, the wiring for the sensors is preferably implemented on the same polyimide film.

[0043] Fig 1C illustrates an optional additional skin protective system. In this case the spaces between the solid coated portions 3, 2 of the electrodes are filled with a water absorbing material 12 such as cotton, polypropylene, etc. that wicks the wetness off the skin 6 so as to keep it dry, and transfers it to a water storing medium 11 such as a hygroscopic gel, polyacrylate, etc. The water storing medium 11 is preferably positioned on the back of the electrode body so that it does not touch the skin. Note that while FIG. 1C illustrates this optional feature in connection with the FIG. 1A/1B embodiment, this feature may be incorporated into any of the other embodiments described above by making appropriate changes to the shapes and sizes of the water absorbing material 12 and the water storing medium 11.

[0044] FIG. 4B illustrates the use of another option – a conductive gel. (Note that while FIG. 4B is illustrates this optional feature in connection with the FIG. 4A embodiment, this feature may be incorporated into any of the other embodiments described above.) The electric contact between the cylindrical electrodes (which are made of conductors 43 surrounded by a dielectric coating 42) and the body surface 7 or skin can be improved by placing an intervening filler such as a conductive gel 41 between the electrodes and the skin 6. Alternatively, the gel 41' may be applied so as to completely surround the dielectric coating 42 that surrounds the conductor 43, which results in an increase in the area of the effective electrode surface. Optionally, the absorbing material 12 or gel 41' may include or be coated by a medication that prevents or relieves skin irritation and inflammation, such as a steroid paste.

[0045] Unfortunately, long term application of an object or medium that is not permeable to air, such as a gel, often results in skin reaction which may be severe. In addition water based media such as gels keep the skin wet, and long term wetting of the skin causes the external corneal skin layer to swell and lose its skin protective ability. Many gels can also occlude the orifices of the sweat and sebaceous glands, thus worsening the damage to the skin. Accordingly, such gels are preferably used in combination with those above-described embodiments where the electrodes can be shifted back and forth between two positions periodically, to minimize these problems.

[0046] Optionally a temperature sensor (not shown) may be incorporated into the electrode, and an appropriate circuit (not shown) can be used to temporarily turn off the power to the electrode (or to individual affected regions, if the segments are not all wired in parallel) when the output of the sensor indicates that it is too hot.

[0047] The above-described embodiments can generate safely and effectively alternating and transient electric fields in human patients, or other objects, for prolonged periods of time, by means of skin surface electrodes without causing significant side effects. Minor skin reactions that might still occur may be eased by incorporating medication to the conductive gels used. Such medication can include steroids, anti-allergic agents, antihistamines, etc.

[0048] While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details can be made without departing from the spirit and scope of the invention.

I CLAIM:

1. An electrode configured for placement in contact with a surface of a patient's body, the electrode comprising:

a conductive substrate having a first side that faces the patient when the electrode is placed in contact with the patient's body, the conductive substrate having a plurality of open spaces passing therethrough that pass through the first side of the conductive substrate, wherein the open spaces are distributed and sized to permit moisture on the surface of the patient's body to escape via the open spaces when the electrode is placed in contact with the patient's body; and

a thin dielectric material disposed on the first side of the conductive substrate so as to insulate the conductive substrate from the patient's body when the electrode is placed in contact with the patient's body, wherein the dielectric coating has a dielectric constant of at least 1000.

2. The electrode of claim 1, wherein the conductive substrate is a single piece of conductive material.

3. The electrode of claim 1, wherein the conductive substrate comprises a plurality of separate sections that are attached to one another in a manner that permits the sections to move with respect to neighboring sections, by a limited amount.

4. The electrode of claim 1, wherein the conductive substrate comprises a plurality of roughly parallel wires spaced apart by at least 2 mm, and wherein the thin dielectric material surrounds each of the wires.

5. The electrode of claim 1, wherein the open spaces are at least 2 mm wide.

6. The electrode of claim 1, wherein the open spaces are at least 4 mm wide.

7. The electrode of claim 1, wherein the open spaces have an area that is least 4 square mm.

8. The electrode of claim 1, wherein the open spaces have an area that is least 16 square mm.

9. The electrode of claim 1, wherein the open spaces are arranged in a pattern that permits portions of the surface of a patient's body that are covered when the electrode is in the first position to become uncovered when the electrode is moved to a second position, with the overall footprint of the electrode in the first position substantially overlapping the overall footprint of the electrode in the second position.

10. The electrode of claim 9, wherein the combined area of all the open spaces is roughly half the area of the footprint of the electrode.

11. The electrode of claim 1, wherein the dielectric coating has a dielectric constant of at least 10,000.

12. A method of treating a patient with an AC electric field, comprising the steps of:

placing at least two electrodes against a patient's body, the electrodes having a conductive substrate and a thin dielectric layer located between the patient and the conductive substrate, wherein at least one of the electrodes has a plurality of open spaces passing therethrough, the open spaces being distributed and sized to permit moisture that is located beneath the electrode to escape via the open spaces; and

applying an AC voltage across the electrodes to induce an electric field at a target region in the patient's body, the electric field having a frequency between

about 50 kHz and about 500 kHz and a field strength between about 0.1 and about 10 V/cm at the target region.

13. The method of claim 12, wherein the applying step lasts for at least five days.

14. The method of claim 12, wherein the electric field has a frequency between about 170 kHz and about 250 kHz and a field strength between about 1 and about 10 V/cm at the target region.

15. The method of claim 12, wherein the electric field has a frequency of about 120 kHz and a field strength between about 1 and about 10 V/cm at the target region.

16. The method of claim 12, wherein the conductive substrate is a single piece of conductive material.

17. The method of claim 12, wherein the conductive substrate comprises a plurality of separate sections that are attached to one another in a manner that permits the sections to move with respect to neighboring sections, by a limited amount.

18. The method of claim 12, wherein the conductive substrate comprises a plurality of roughly parallel wires spaced apart by at least 2 mm, and wherein the thin dielectric material surrounds each of the wires.

19. The method of claim 12, wherein the open spaces are at least 2 mm wide.

20. The method of claim 12, wherein the open spaces are at least 4 mm wide.

21. The method of claim 12, wherein the open spaces have an area that is least 4 square mm.

22. The method of claim 12, wherein the open spaces have an area that is least 16 square mm.

23. The method of claim 12, further comprising the step of moving the electrodes from a first position in which first portions of the surface of a patient's body are covered by solid portions of the electrodes to a second position in which the first portions are not covered by the solid portions of the electrodes, wherein the overall footprints of the electrodes in the first position substantially overlap the overall footprints of the electrodes in the second position.

24. The method of claim 23, wherein the electrodes are switched between the first position and the second position every 2-4 days.

25. A method of treating a patient with an AC electric field, comprising the steps of:

placing at least two electrodes against a patient's body, the electrodes having a conductive substrate and a thin dielectric layer located between the patient and the conductive substrate, the dielectric layer having a dielectric constant of at least 1000, wherein at least one of the electrodes has a plurality of open spaces passing therethrough, the open spaces being distributed and sized to permit moisture that is located beneath the electrode to escape via the open spaces; and

applying an AC voltage across the electrodes to induce an electric field at a target region in the patient's body, the electric field having a frequency between about 50 kHz and about 500 kHz and a field strength between about 0.1 and about 10 V/cm at the target region.

26. The method of claim 25, wherein the applying step lasts for at least five days.

27. The method of claim 25, wherein the electric field has a frequency between about 170 kHz and about 250 kHz and a field strength between about 1 and about 10 V/cm at the target region.

28. The method of claim 25, wherein the electric field has a frequency of about 120 kHz and a field strength between about 1 and about 10 V/cm at the target region.

29. The method of claim 25, wherein the conductive substrate is a single piece of conductive material.

30. The method of claim 25, wherein the conductive substrate comprises a plurality of separate sections that are attached to one another in a manner that permits the sections to move with respect to neighboring sections, by a limited amount.

31. The method of claim 25, wherein the conductive substrate comprises a plurality of roughly parallel wires spaced apart by at least 2 mm, and wherein the thin dielectric material surrounds each of the wires.

32. The method of claim 25, wherein the open spaces are at least 2 mm wide.

33. The method of claim 25, wherein the open spaces are at least 4 mm wide.

34. The method of claim 25, wherein the open spaces have an area that is least 4 square mm.

35. The method of claim 25, wherein the open spaces have an area that is least 16 square mm.

36. The method of claim 25, further comprising the step of moving the electrodes from a first position in which first portions of the surface of a patient's body are covered by solid portions of the electrodes to a second position in which the first portions are not covered by the solid portions of the electrodes, wherein the overall footprints of the electrodes in the first position substantially overlap the overall footprints of the electrodes in the second position.

37. The method of claim 36, wherein the electrodes are switched between the first position and the second position every 2-4 days.

38. The method of claim 25, wherein the dielectric layer has a dielectric constant of at least 10,000.

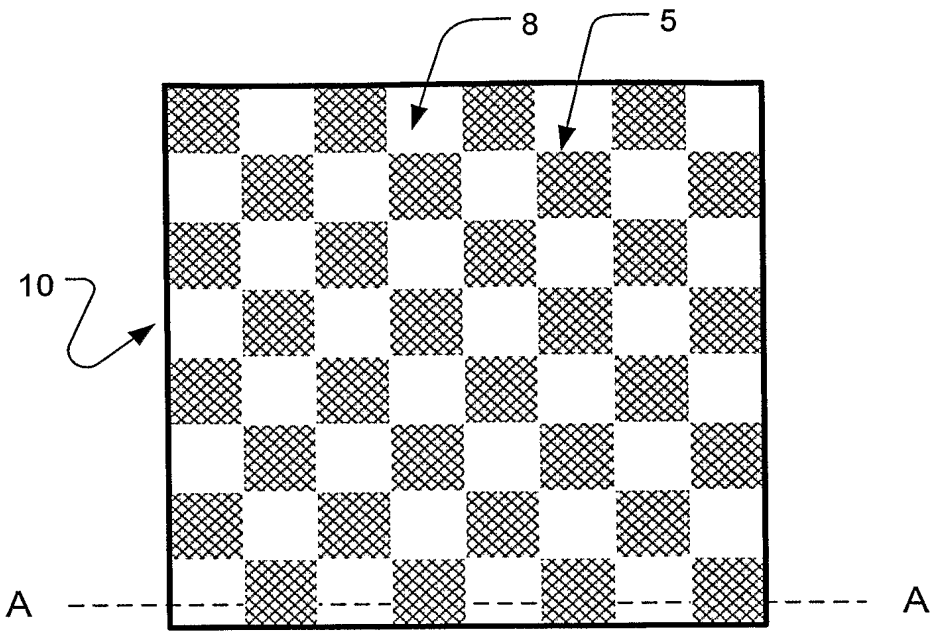


FIG. 1A

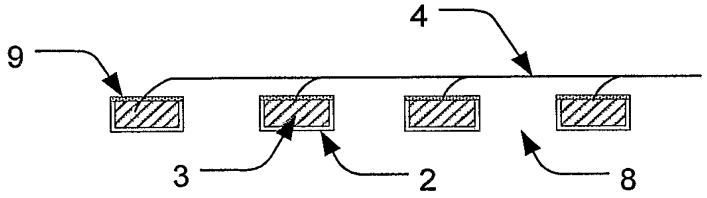


FIG. 1B

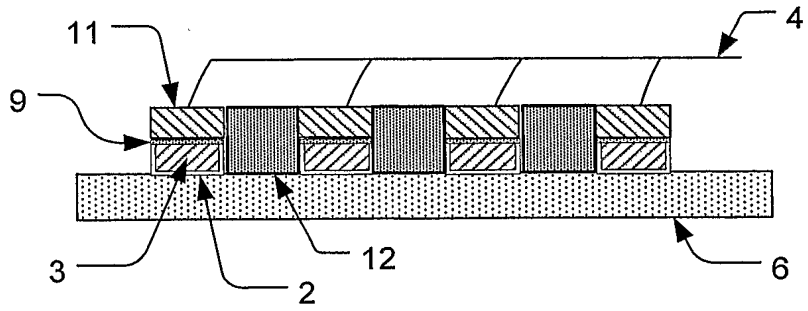


FIG. 1C

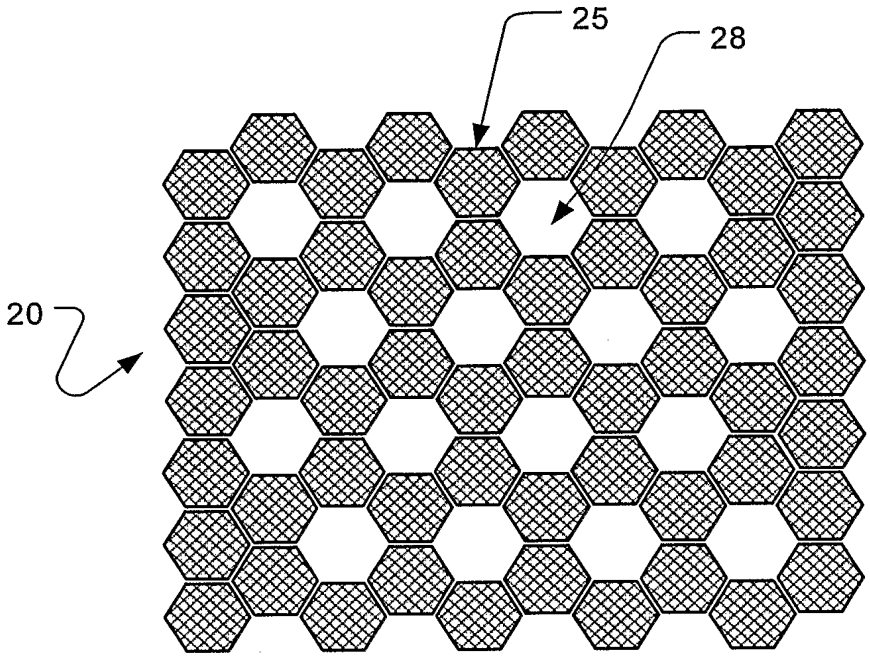


FIG. 2

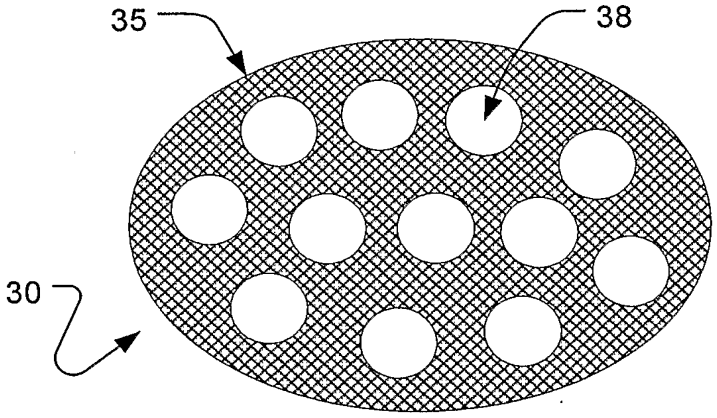


FIG. 3

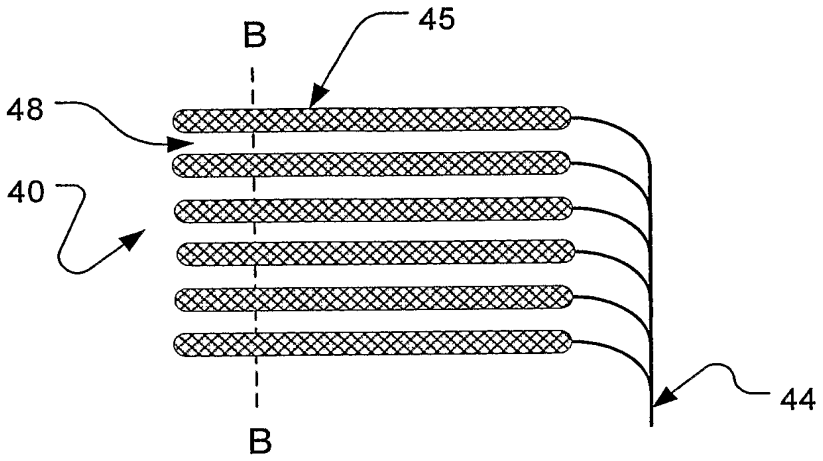


FIG. 4A

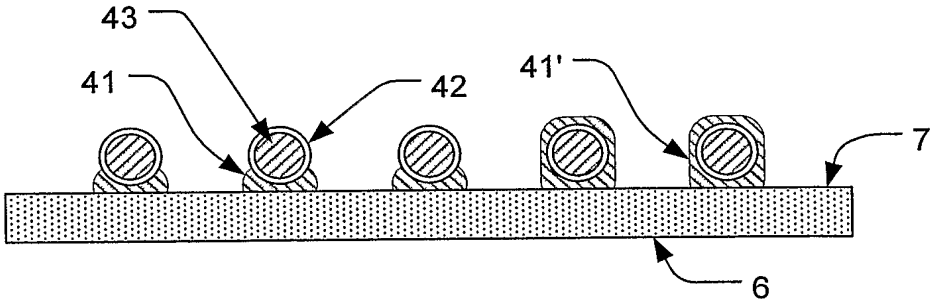


FIG. 4B

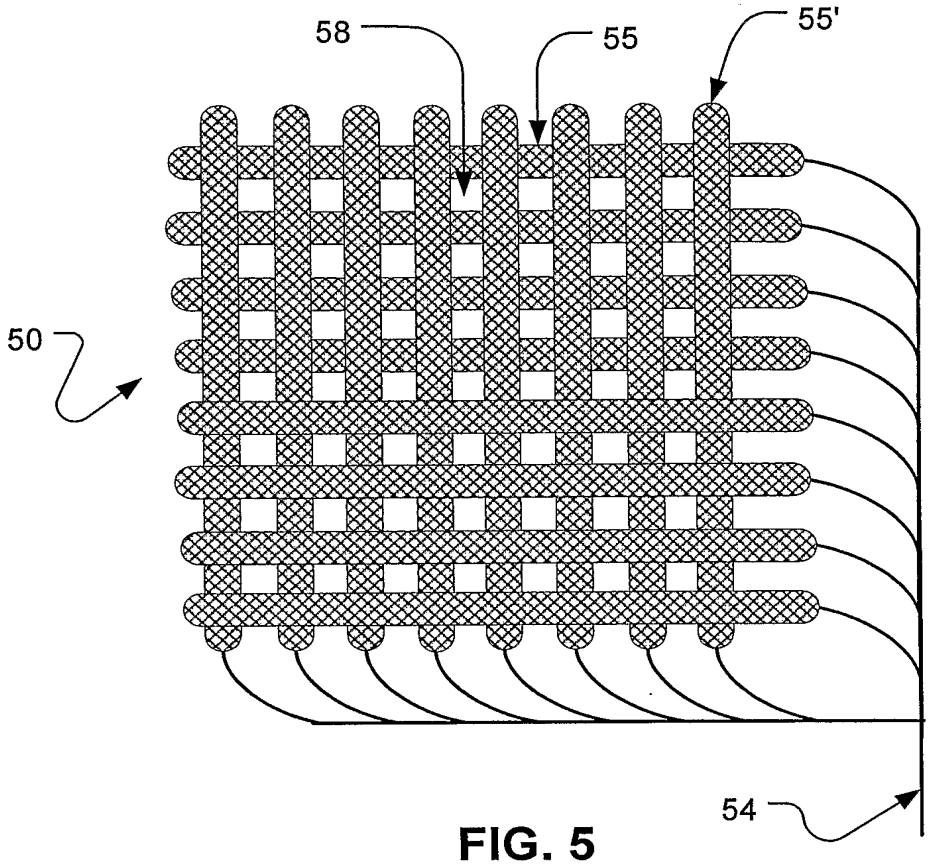


FIG. 5

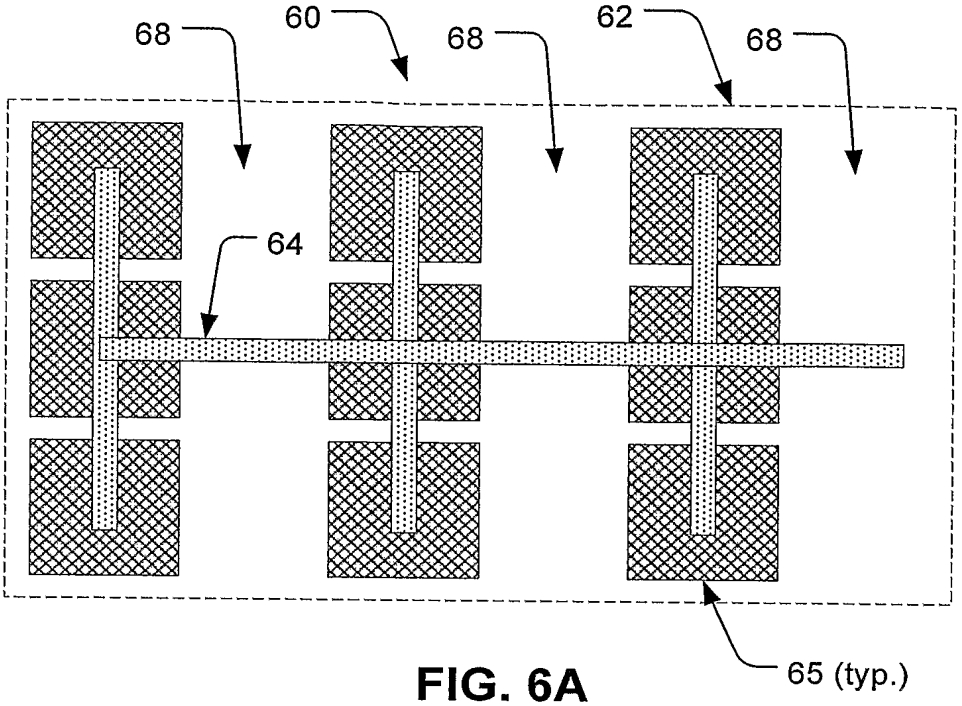


FIG. 6A

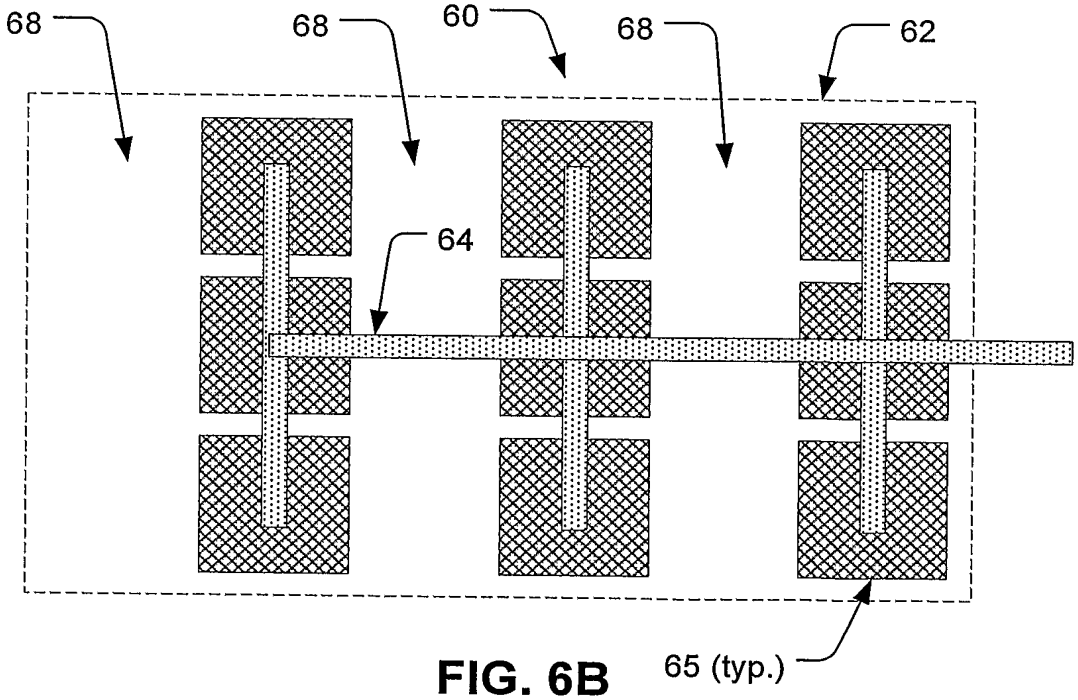


FIG. 6B

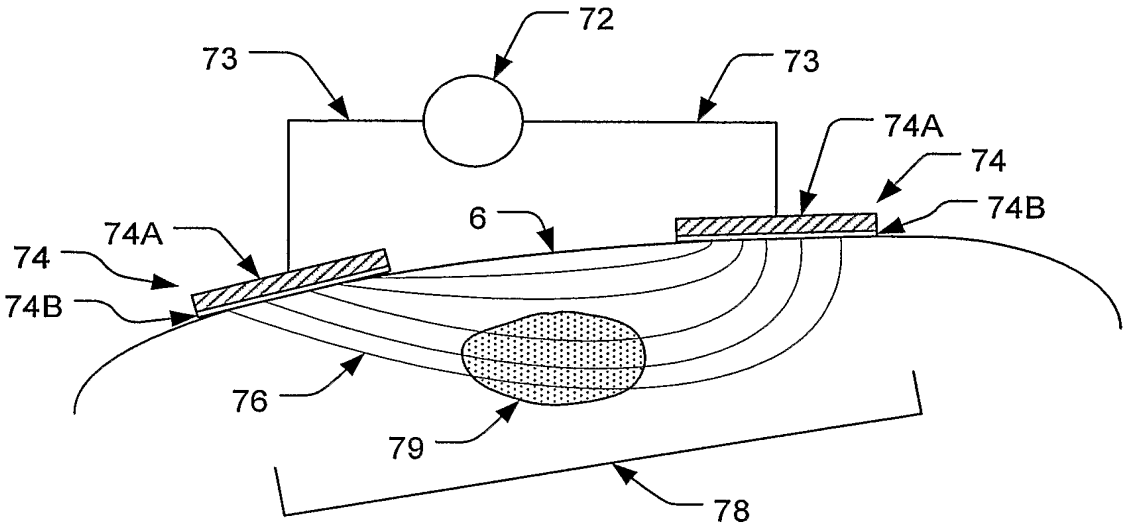

72
73
73
74A
74
74B
6
74A
74
74B
76
79
78

FIG. 7A

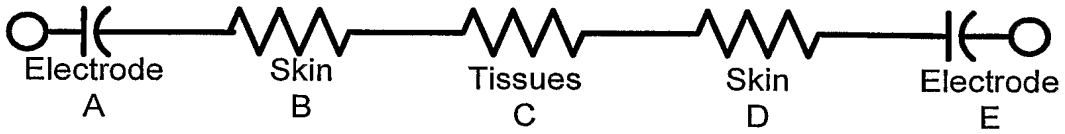

Electrode
A
Skin
B
Tissues
C
Skin
D
Electrode
E

FIG. 7B

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2005/003670

A. CLASSIFICATION OF SUBJECT MATTER
A61N1/04 A61N1/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 130 759 A (ROSE EDGAR J) 20 September 1938 (1938-09-20) the whole document	1,2
A	EP 0 862 924 A (GRAPHIC CONTROLS CORPORATION) 9 September 1998 (1998-09-09) the whole document	1,5-8
A	US 2004/162602 A1 (COHEN SHLOMI) 19 August 2004 (2004-08-19) the whole document	1,2
A	US 5 974 344 A (SHOEMAKER, II ET AL) 26 October 1999 (1999-10-26) the whole document	1,5,7

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 April 2006	25/04/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Sopelana Martínez, J

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2005/003670

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 367 755 A (BAILEY ET AL) 11 January 1983 (1983-01-11) the whole document	1
A	US 2003/055478 A1 (LYSTER THOMAS D ET AL) 20 March 2003 (2003-03-20) the whole document	1
A	US 2004/068297 A1 (PALTI YORAM) 8 April 2004 (2004-04-08) the whole document	1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2005/003670

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12-38
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2005/003670

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 2003055478 A1	20-03-2003	NONE	
US 2004068297 A1	08-04-2004	NONE	

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 118

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(19) World Intellectual Property Organization
International Bureau

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PCT

(10) International Publication Number
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A61B 5/0402 (2006.01)

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PCT/NO2009/000365

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22 October 2009 (22.10.2009)

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(26) Publication Language: English

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(71) Applicant *(for all designated States except US)*: **MED STORM INNOVATION AS** [NO/NO]; Gimle Terrasse 4, N-0264 Oslo (NO).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **STORM, Hanne** [NO/NO]; Gimle Terrasse 4, N-0264 Oslo (NO).

(74) Agents: **ONSAGERS AS** et al.; P.O. Box 6963 St. Olavs plass, N-0130 Oslo (NO).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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[Continued on next page]

(54) **Title**: ELECTRODE ASSEMBLY FOR MEDICAL PURPOSES

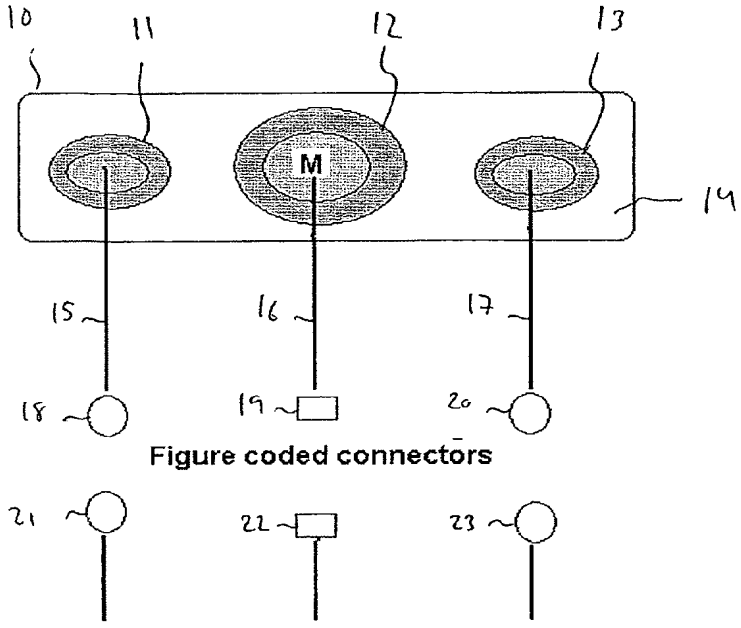

Figure 1

(57) **Abstract**: An electrode assembly 10 for medical purposes comprises a first electrode 11 electrically connected to a first connecting line 15, a second electrode 12 electrically connected to a second connecting line 16, and a third electrode 13 electrically connected to a third connecting line 17. The first, second and third electrodes are arranged in a single patch 14. The shape or area of the second electrode is different from the shape or area of the first and third electrodes. The first, second and third connection lines may be coded by visible or tactile coding means.

WO 2010/047599 A1

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

ELECTRODE ASSEMBLY FOR MEDICAL PURPOSES

Field of the invention

The invention relates to an electrode assembly for medical purposes, particularly to be placed on the skin of a patient.

Background of the invention

Medical electrodes are needed in many applications, e.g. for measurement of electrical activity in the brain (EEG), the heart (ECG), or the muscles (EMG). Medical electrodes may be used for measuring, e.g., electric current, potential/voltage, skin conductance, and skin resistance. Certain medical electrodes may also be used for supplying electrical energy into the patient, e.g. in the case of defibrillators, electroconvulsive therapy and other therapy methods.

Medical electrodes are also used in the fields of electrophysiology and neuroscience. A particular class of equipment and methods utilize measurement of skin conductance for assessing the state of the autonomous nervous system of a patient, such as a sedated patient, e.g. for detecting pain or awakening during anaesthesia.

WO-03/094726 is an example of an apparatus and a method for monitoring the autonomous nervous system of a sedated patient, wherein the skin conductance, measured by use of electrodes placed on the skin of the patient, is measured. Signals indicating pain/discomfort in the patient and awakening in the patient are derived from the skin conductance measurements.

Summary of the invention

The invention is set forth in the appended claims.

Brief description of the drawings

Embodiments, aspects and principles of the invention will now be described in more detail with reference to the attached drawings, in which

figure 1 is a schematic block diagram illustrating an electrode assembly in a first embodiment, and

figure 2 is a schematic block diagram illustrating an electrode assembly in a second embodiment.

Detailed description

Figure 1 is a schematic block diagram illustrating an electrode assembly in a first embodiment.

The electrode assembly 10 comprises a first electrode 11, a second electrode (M) 12, and a third electrode 13, all arranged in a patch 14.

In an aspect, the first electrode 11 is a counter current electrode, the second electrode 12 is a measuring electrode, and the third electrode 13 is a reference voltage electrode.

The first electrode 11 is electrically connected to a first connecting line 15, which is further connected to a first connection device 18. Similarly, the second electrode 12 is electrically connected to a second connecting line 16, further connected to a second connection device 19. Similarly, the third electrode 13 is electrically connected to a third connecting line 17, further connected to a third connection device 20.

In the illustrated example, the area of the second electrode 12 is different from the area of the first 11 and second 13 electrodes.

In an aspect, the shapes of the first and third electrodes are the same. In a particular aspect, the shape of the second electrode may be the same as the shapes of the first electrode and the third electrode. In another particular aspect, the shape of the second electrode may be different from the shapes of the first electrode and the third electrode.

In the illustrated example, the first 11, second 12 and third 13 electrodes have oval shapes. Alternatively, they could have circular shapes, or other shapes such as square, rectangular, triangular, etc.

In an aspect, as illustrated, the area of the first 11 and the third 13 electrodes may be the same, and the area of the second electrode 12 may be larger than the area of the first 11 and second 13 electrodes.

The patch 14 may have an elongated shape, e.g. a substantially rectangular shape as illustrated.

In an aspect, the second electrode 12 is a measurement electrode 12 and is arranged in between the first (counter current) electrode 11 and the third (reference voltage) electrode 13.

In an aspect, the first electrode 11 and the third electrode 13 are arranged substantially symmetrically about a line perpendicular to the length of the longitudinal patch 14.

In an aspect, the first electrode 11, the second electrode 12 and the third electrode 13 are arranged substantially in-line.

In another aspect, the first electrode 11, the second electrode 12 and the third voltage electrode 13 are not arranged in-line.

The first 15, the second 16 and the third 17 connection lines may be coded by visible or tactile coding means.

In an aspect, as schematically illustrated in figure 1, the coding means are both visible and tactile. In this case the first 15, second 16 and third 17 connection lines are figure coded. This is achieved by providing the first 15 and third 17 connection lines with connectors 18, 20 of a first type and by providing the second connection line 16 with a connector 19 which is incompatible with the connectors 18, 20 of the first type.

As an example, the connectors 18 and 20 may be a female connector, i.e. a socket, with a circular cross-section, while the connector 19 is a female connector, i.e. a socket, with a rectangular or square cross-section.

Correspondingly, wires for connection to measurement equipment (not shown) are provided with male connector (plug or pin type) with appropriate circular cross-section (connectors 21, 23), and a male connector (plug or pin type) with appropriate rectangular or square cross-section (connector 22).

Figure 2 is a schematic block diagram illustrating an electrode assembly in a second embodiment.

Please refer to the description of figure 1 for a detailed description of those elements of figure 2 which are identical to (and have the same reference numerals as) those illustrated in figure 1.

In the embodiment of figure 2, the first 15, second 16 and third 17 connection lines are coded by visible coding means. This is achieved by color coding the connection lines. By example, this may be achieved by using different colors of the wires 15, 16, and 17, and/or the connectors 28, 29, 30, and/or the connectors 31, 32, 33.

By example, a blue insulation may be used for the second connection line 32, while red insulation is used for the first 31 and third 33 connection lines.

In such an embodiment, the connectors 28, 29, 30 may be of the same shape and type, e.g. female (socket) connectors, corresponding to male (plug/pin) connectors 31, 32, 33, respectively.

The electrode assembly disclosed in any of the above embodiments may be used in an arrangement for measuring skin conductance, e.g. of a patient.

In such use, the electrode assembly 10 may be placed on an area of the skin on a body part of the patient, for the purpose of measuring the skin's conductance. The

body part may, e.g., be a hand or a foot, and the area of the skin on the body part may, e.g., be the palmar side of the hand or the plantar side of the foot.

The first electrode 11 is a counter current electrode, the second electrode 12 is a measuring electrode 12, and the third electrode 13 is a reference voltage electrode, all arranged in the patch 14, which is placed on the skin area.

The electrode assembly 10 and its connected external equipment may ensure a constant application of voltage over the stratum corneum (the surface layer of the skin) under the measuring electrode.

The resulting current in a closed circuit between the measuring electrode 12 and the counter current electrode 11 may be measured by means of a measurement converter (not shown), connected between the counter current electrode 11 and the measuring electrode 12. The measurement converter may comprise a current to voltage converter, such as a transresistance amplifier or simply a resistance, which converts the current from the measuring electrode 12 to a voltage.

The arrangement of a stiff patch 14 ensures that the second electrode (or measuring electrode) 12 does not suffer from undesired movement, which might lead to artefacts in the resulting measurements.

The arrangement of the measuring electrode 12 in the middle also contribute to reduced artefacts.

Since the skin conductance changes are monitored below the measuring electrode 12, the area below the measuring electrode 12 may be critical.

Further possible values and specifications of the electrode assembly and its elements are given below (for illustration, not for limitation):

Sensor:

Single use self-adhesive Ag/AgCl

Solid gel

The measuring sensor area (M) may be between 260 and 480 mm^2

Operational principle; 3 measuring points, minimum 1 cm between the measuring points.

Dimension:

Electrode size and skin conduct size with adhesive area may have a minimum area of 260 mm^2,

Connecting wire between 1 and 1000 mm.

The electrodes do not necessarily need to be on a line

Materials:

Biocompatible

Color coded or figure coded for ease of identification

Outer carrier, e.g. polyester

Lead-wire insulation, e.g. polyvinyl chloride

Lead-wire connector, e.g polypropylene

The electrode assembly disclosed herein may also be used in an arrangement for monitoring the autonomous nervous system of a patient.

In this case a similar arrangement is used as explained above. In addition, the measuring equipment is connected to a processing device configured for monitoring the autonomous nervous system of the patient, based on measurements of the skin conductance. An example of suitable processing and monitoring means/methods has been disclosed in WO-03/094726 (expressly incorporated by reference).

The inventive concept is not limited to the exemplary embodiments described above. Rather, the scope of the invention is set forth in the following patent claims.

CLAIMS

1. Electrode assembly for medical purposes,
comprising a first electrode electrically connected to a first connecting line,
a second electrode electrically connected to a second connecting line, and
a third electrode electrically connected to a third connecting line,
the first, second and third electrodes being arranged in a single patch,
wherein the shape or area of the second electrode is different from the shape or area of the first and third electrodes, and
wherein the first, second and third connection lines are coded by tactile coding means.

2. Electrode assembly according to claim 1,
wherein the shapes of the first and third electrodes are the same.

3. Electrode assembly according to claim 1 or 2,
wherein the area of the first and third electrodes are the same.

4. Electrode assembly according to one of the claims 1-3,
wherein the area of the second electrode is larger than the area of the first and third electrodes.

5. Electrode assembly according to one of the preceding claims,
wherein said first, second and third connection lines are figure coded,
the first and third connection lines being provided with a connector of a first type and the second connection line being provided with a connector which is incompatible with the connector of the first type.

6. Electrode assembly according to claim one of the preceding claims, wherein said first, second and third connection lines are color coded.

7. Electrode assembly according to one of the preceding claims, wherein
said first electrode is a counter current electrode,
said second electrode is a measuring electrode, and

said third electrode is a reference voltage electrode.

8. Use of an electrode assembly according to one of the preceding claims in an arrangement for measuring skin conductance.

9. Use of an electrode assembly according to one of the claims 1-7 in an arrangement for monitoring the autonomous nervous system of a patient.

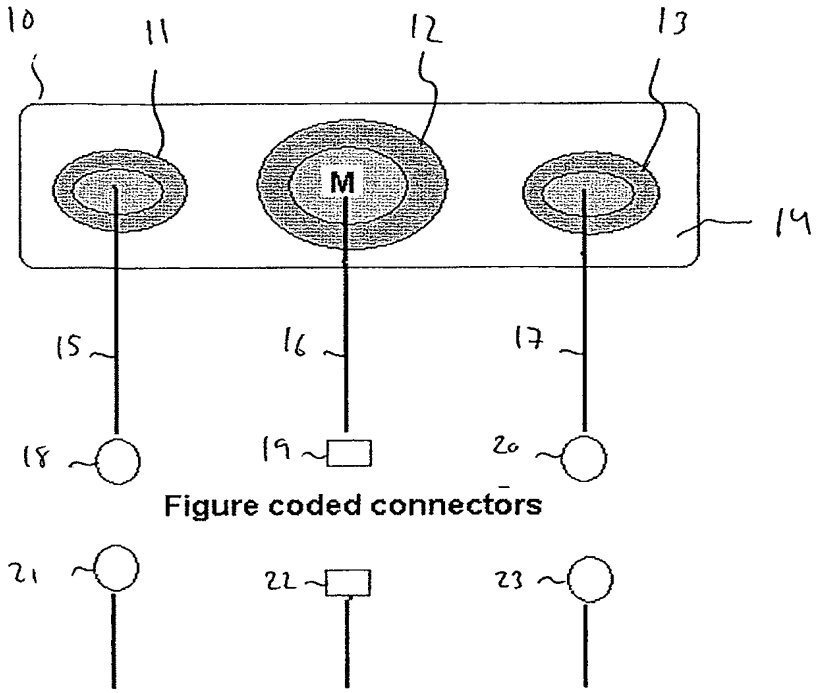

Figure 1

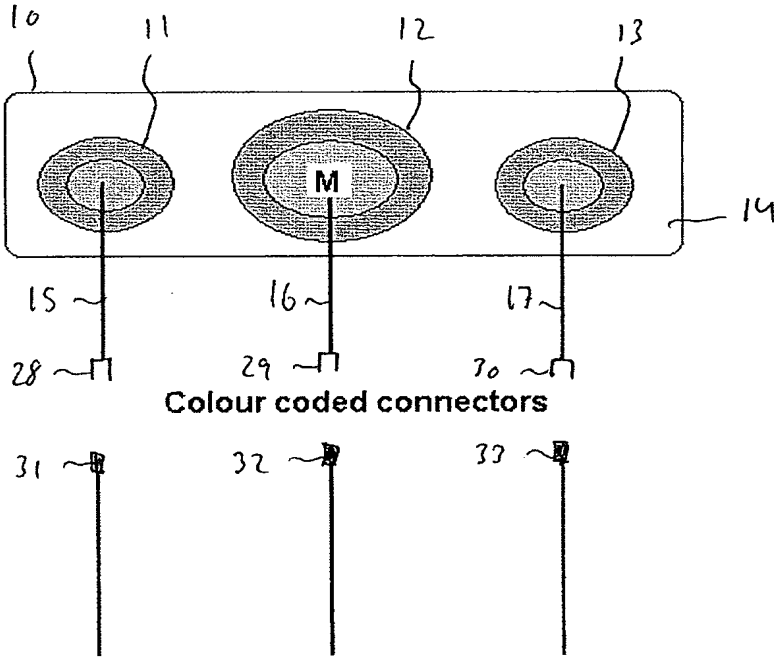

Figure 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/NO2009/000365

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/04 A61B5/0402 A61N1/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/066876 A1 (HALLIN ROLF G [GB]) 22 March 2007 (2007-03-22) paragraphs [0014], [0038], [0039], [0048] - [0059], [0066]; figures 5,6	1-9
Y	WO 2005/114535 A (BAYER HEALTHCARE LLC [US]; THOMPSON BRIAN C [US]) 1 December 2005 (2005-12-01) page 5, line 7 - line 17; figure 1A	1-9
Y	WO 2007/096452 A (BRAINSCOPE OY [FI]; VOIPIO JUHA [FI]) 30 August 2007 (2007-08-30) page 12, lines 1-3	6

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 February 2010	05/03/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schindler, Martin

4

Form PCT/ISA/210 (second sheet) (April 2005)

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 129

INTERNATIONAL SEARCH REPORT

International application No
PCT/NO2009/000365

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 334 068 B1 (HACKER DAVID C [US]) 25 December 2001 (2001-12-25) column 9, line 45 - column 10, line 3; figures 7-10	1-9
A	US 6 394 953 B1 (DEVLIN PHILIP H [US] ET AL) 28 May 2002 (2002-05-28) column 4, line 66 - column 5, line 21; figures 1,5a-c column 6, line 4 - line 13	1-9
A	US 5 632 643 A (SHEPHERD DAVID J [US] ET AL) 27 May 1997 (1997-05-27) column 3, line 58 - column 4, line 24; figure 3	1-9

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 130

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/NO2009/000365

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007066876 A1	22-03-2007	EP 1681995 A1	26-07-2006
		JP 2007508100 T	05-04-2007
		WO 2005037098 A1	28-04-2005
WO 2005114535 A	01-12-2005	AU 2005246302 A1	01-12-2005
		BR PI0510729 A	20-11-2007
		CA 2566471 A1	01-12-2005
		CN 1961320 A	09-05-2007
		EP 1747521 A2	31-01-2007
		JP 2007537016 T	20-12-2007
		US 2007219432 A1	20-09-2007
WO 2007096452 A	30-08-2007	EP 1988827 A1	12-11-2008
		US 2009247835 A1	01-10-2009
US 6334068 B1	25-12-2001	NONE	
US 6394953 B1	28-05-2002	NONE	
US 5632643 A	27-05-1997	EP 0788196 A2	06-08-1997
		NO 970496 A	06-08-1997

Electronic Acknowledgement Receipt

EFS ID:	18971466
Application Number:	14085639
International Application Number:	
Confirmation Number:	1183
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Customer Number:	40518
Filer:	Johney U. Han/Kym Moore
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00501
Receipt Date:	07-MAY-2014
Filing Date:	20-NOV-2013
Time Stamp:	17:22:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	1_EMKNNZ00501_20140507_ids_cover_letter.pdf	73770 5f01b6a760c3d9340b3954e4b4e4d079bea1ab44	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	2_EMKNNZ00501_20140507_ids_sb08.pdf	92313 a0c80519a84dc33cb979574d8a6afefa6847560f	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	3_WO2006061688A1.pdf	843181 4eed955f6d00c4d5fe9c207bdcd1f3c05076ac7b	no	31
Warnings:					
Information:					
4	Foreign Reference	4_WO2010047599A1.pdf	233510 c821d8f2f90cadb9f29b4cc5a53a912e05de7f2b	no	13
Warnings:					
Information:					
		Total Files Size (in bytes):	1242774		

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.		
Date: May 7, 2014	Signature: /Kym Y. Moore/	(Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	14/085,639
Confirmation No.:	1183
Filing Date:	November 20, 2013
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Not Yet Assigned
Group Art Unit:	2183

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents are submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does

not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00501**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

Steven M. Giovannetti
Registration No. 51,739

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Petitioner - Avation Medical, Inc.
Ex. 1002, p. 135

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/085,639

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	16 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501

CONFIRMATION NO. 1183

POA ACCEPTANCE LETTER

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

OC000000066561461

Date Mailed: 02/19/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/07/2014.

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.

/nbekele/

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/085,639	11/20/2013	2183	800	EMKNNZ00501	16	1

CONFIRMATION NO. 1183

UPDATED FILING RECEIPT

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

OC00000066561516

Date Mailed: 02/19/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. 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**

Inventor(s)

Daniel R. BURNETT, San Francisco, CA;

Applicant(s)

EMKINETICS, INC., San Francisco, CA

Assignment For Published Patent Application

EMKINETICS, INC., San Francisco, CA

Power of Attorney: The patent practitioners associated with Customer Number 40518

Domestic Priority data as claimed by applicant

This application is a CON of 13/456,016 04/25/2012
which is a CON of PCT/US2010/054167 10/26/2010
which claims benefit of 61/279,883 10/26/2009
This application 14/085,639
is a CIP of 12/508,529 07/23/2009
which is a CIP of 11/866,329 10/02/2007
which claims benefit of 60/848,720 10/02/2006

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 138

If Required, Foreign Filing License Granted: 12/03/2013

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/085,639**

Projected Publication Date: 05/29/2014

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

Preliminary Class

712

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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 (1-866-999-4258).

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.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: February 7, 2014 Signature: /Kym Y. Moore/ (Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	14/085,639
Confirmation No.:	1183
Filing Date:	November 20, 2013
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Not Yet Assigned
Group Art Unit:	2183

RESPONSE TO NOTICE TO FILE MISSING PARTS

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Notice to File Missing Parts dated December 9, 2013 for which a response is due on February 9, 2014. Accordingly, this response is timely filed.

Applicants respectfully submit:

1. Fully executed Declaration
2. Power of Attorney
3. Statement under 37 CFR 3.73(c) with a copy of an executed Assignment
4. Preliminary Amendment
5. Surcharge for a late declaration and/or fees are being concurrently submitted via EFS-Web.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00501**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

Steven M. Giovannetti
Registration No. 51,739

Customer No. 40518
Levine Bagade Han LLP
2400 Geng Road, Suite 120
Palo Alto, CA 94303
Direct: (650) 646-2570
Fax: (650) 284-2180

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 142

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☑ United States application or PCT international application number 14/085,639 filed on November 20, 2013.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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.

LEGAL NAME OF INVENTOR

Inventor: Daniel R. BURNETT Date (Optional): 11/26/13

Signature: _____

Note: An application data sheet (PTO/AIA/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/SB/AIA01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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. 1002, p. 143

NOTICE REGARDING DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION FILED AFTER SEPTEMBER 16, 2012

By signing the Declaration, I/we acknowledge that I/we have reviewed and understand the contents of the above-identified application, including the claims; and

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	14/085,639
				Filing Date	November 20, 2013
				First Named Inventor	Daniel R. BURNETT
				Art Unit	2183
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	2008/0065167	03-13-2008	Boggs et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	2.					

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	3.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	

Electronic Patent Application Fee Transmittal

Application Number:	14085639
Filing Date:	20-Nov-2013
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Filer:	Steven Michael Giovannetti/Kym Moore
Attorney Docket Number:	EMKNNZ00501

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	70	70
Utility Search Fee	2111	1	300	300
Utility Examination Fee	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
Late Filing Fee for Oath or Declaration	2051	1	70	70
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**800**

Electronic Acknowledgement Receipt

EFS ID:	18150863
Application Number:	14085639
International Application Number:	
Confirmation Number:	1183
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Customer Number:	40518
Filer:	Steven Michael Giovannetti/Kym Moore
Filer Authorized By:	Steven Michael Giovannetti
Attorney Docket Number:	EMKNNZ00501
Receipt Date:	07-FEB-2014
Filing Date:	20-NOV-2013
Time Stamp:	17:11:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$800
RAM confirmation Number	3979
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Applicant Response to Pre-Exam Formalities Notice	1_EMKNNZ00501_20131212_response_to_missing_parts.pdf	84177 ad94790f859b6eb806025020e08c625a65f0ad10	no	2
Warnings:					
Information:					
2	Oath or Declaration filed	2_EMKNNZ00501_20131212_declaration.pdf	57350 3176237ced5cf618757b8ca23049f21a2f217ffe	no	2
Warnings:					
Information:					
3	Power of Attorney	3_EMKNNZ00501_20131212_power_of_attorney.pdf	40330 125b4cf97ee4c239f263cd928f8c73468a70cb2d	no	1
Warnings:					
Information:					
4	Assignee showing of ownership per 37 CFR 3.73.	4_EMKNNZ00501_20131212_statement.pdf	107996 9b5c316d3e048562f05c3a068e57b379d1b57245	no	4
Warnings:					
Information:					
5		5_EMKNNZ00501_20131212_preliminary_amendment.pdf	90821 217c4f9dde20a0642d40be042bca1fdf1e027065	yes	5

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	4
Applicant Arguments/Remarks Made in an Amendment	5	5

Warnings:					
Information:					
6	Transmittal Letter	6_EMKNNZ00501_20131212_ids_cover_letter.pdf	73785 16973f739d88acc0ff47ba9ffc50a8df4fe220ef	no	2
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	7_EMKNNZ00501_20131212_ids_sb08.pdf	91107 8b38787118f66865ce3d5ba7108139d38005cf9e	no	1
Warnings:					
Information:					

This is not an USPTO supplied IDS fillable form

8	Fee Worksheet (SB06)	fee-info.pdf	37069 a4baa04b8dafe8024ce9349b8fa565f8b3764324	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	582635

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

PTO/AIA/80 (07-12)
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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(c).

I hereby appoint:

☑ Practitioners associated with 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 a ssigned only to the undersigned according to the USPTO assignment records or assignments docu ments attached to this form in accordance with 37 CFR 3.73(c).

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

☑ The address associated with Customer Number: 40518

OR

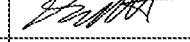
☐	Firm or Individual Name		
	Address		
	City		
	Country		
	Telephone		Email

Assignee Name and Address: EMKinetics, Inc.
2584 Wyandotte St.
Mountain View, CA 94043

A copy of this form, together with a statement under 37 CFR 3.73(c) (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(c) may be completed by one of The practitioners appointed in this form, 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	3-20-13
Name	Daniel Burnett	Telephone	415-926-8616
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.

PTO/AIA/96 (08-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Daniel R. BURNETT

Application No./Patent No.: 14/085,639 Filed/Issue Date: November 20, 2013

Titled: METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

EMKinetics, Inc., a corporation

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

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

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

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.

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**.

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

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

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.

4. 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.

5. 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.

6. 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(c)(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.

/Steven M. Giovannetti/	February 7, 2014
Signature	Date
Steven M. Giovannetti	51,739
Printed or Typed Name	Title or Registration Number

ASSIGNMENT
SOLE

THIS ASSIGNMENT, by Daniel R. BURNETT (hereinafter referred to as the assignor), residing at 588 Teresita Boulevard, San Francisco, CA 94127, US, witnesseth:

WHEREAS, said assignor has invented certain new and useful improvements set forth in an application for Letters Patent of the United States entitled METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS bearing Application No. 14/085,639, filed November 20, 2013; and

WHEREAS, EMKINETICS, INC., a corporation duly organized under and pursuant to the laws of Delaware and having its principal place of business at 101 Mississippi Street, San Francisco, CA 94107, US, (hereinafter referred to as the assignee) is desirous of acquiring the entire right, title and interest in and to said inventions and said application for Letters Patent of the United States, and in and to any Letters Patent or Patents, United States or foreign, to be obtained therefore and thereon:

NOW, THEREFORE, for good and sufficient consideration, receipt of which is hereby acknowledged by assignor, said assignor has sold, assigned, transferred and set over, and by these presents do sell, assign, transfer and set over, unto said assignee, its successors, legal representatives and assigns, the entire right, title and interest in and to, and the right to claim priority to and for the above-mentioned inventions, application for Letters Patent, and any and all Letters Patent or Patents in the United States of America and all foreign countries which may be granted therefore and thereon, and in and to any and all divisions, continuations and continuations-in-part of said application, or reissues or extensions of said Letters Patent or Patents, and all rights under the International Convention for the Protection of Industrial Property, the same to be held and enjoyed by said assignee, for its own use and the use of its successors, legal representatives and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted, as fully and entirely as the same would have been held and enjoyed by the assignor, had this sale and assignment not been made.

AND for the same consideration, said assignor hereby covenants and agrees to and with said assignee its successors, legal representatives and assigns, that, at the time of execution and delivery of these presents, said assignor is the sole and lawful owners of the entire right, title and interest in and to said inventions and the application for Letters Patent above-mentioned, and that the same are unencumbered and that said assignor has good and full right and lawful authority to sell and convey the same in the manner herein set forth.

AND for the same consideration, said assignor hereby covenants and agrees to and with said assignee, its successors, legal representatives and assigns, that said assignor will, whenever counsel of said assignee, or the counsel of its successors, legal representatives and assigns, shall advise that any proceeding in connection with said inventions, or said application for Letters Patent, or any proceeding in connection with Letters Patent for said inventions in any country, including interference proceedings, is lawful and desirable, or that any division, continuation or continuation-in-part of any application for Letters Patent or any reissue or extension of any Letters Patent, to be obtained thereon, is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement,

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 154

maintenance, enforcement and defense of Letters Patent for said inventions, without charge to said assignee, its successors, legal representatives and assigns, but at the cost and expense of said assignee, its successors, legal representatives and assigns. Such cost and expense shall include, but is not limited to, lost normal compensation of the respective assignor.

AND this Assignment is effective on no later than the day of the initial filing of the earliest of the patent applications listed herein. This Assignment shall be governed by and construed in accordance with the laws of the State of California and the federal law of the United States of America without reference to conflict of laws principles.

AND said assignor hereby requests the Commissioner of Patents to issue said Letters Patent of the United States to said assignee as the assignee of said inventions and the Letters Patent to be issued thereon for the sole use of said assignee, its successors, legal representatives and assigns.

11/20/13
Date

Daniel R. BURNETT

Signature on behalf of Assignee:

11/20/13
Date

EMKINETICS, INC.

Name: Daniel R. Burnett

Title: CEO

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.
Date: February 7, 2014 Signature: /Kym Y. Moore/ (Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	14/085,639
Confirmation No.:	1183
Filing Date:	November 20, 2013
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Not Yet Assigned
Group Art Unit:	2183

PRELIMINARY AMENDMENT

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

Prior to examination on the merits, entry of this Preliminary Amendment is respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 156

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

In the claims

1. (Canceled)

2. (New) A method of performing electrical stimulation therapy, comprising:

positioning a first portion of a patient's body relative to an electrical stimulator such that a target nerve within the first portion of the body is in proximity to the electrical stimulator;

passing a current through the electrical stimulator;

delivering an electrical stimulus from the electrical stimulator to the target nerve;

detecting electrical conduction through the target nerve or detecting a muscular response caused by an electrical conduction through the target nerve via at least one sensor positioned along a second portion of the body;

receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy; and

adjusting the current via a controller in communication with the electrical stimulator based on the feedback.

3. (New) The method of claim 2, wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat fecal incontinence.

4. (New) The method of claim 2, wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat restless leg syndrome.

5. (New) The method of claim 2, wherein the electrical stimulus is delivered to a posterior tibial nerve or branch thereof to treat premature ejaculation.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 157

6. (New) The method of claim 2, wherein the electrical stimulus is delivered to a target nerve to treat chronic pain.

7. (New) The method of claim 2, wherein a patient's hand or arm is positioned relative to the electrical stimulator such that the electrical stimulus is focused on a target nerve within the hand or arm.

8. (New) The method of claim 2, wherein a patient's back is positioned relative to the electrical stimulator such that the electrical stimulus is focused on a target nerve within the back.

9. (New) The method of claim 2, wherein the electrical stimulus is delivered to a target nerve to treat osteoarthritis or arthritis,

10. (New) The method of claim 2, wherein the electrical stimulus is delivered to a target nerve responsible for neuropathic pain to treat neuropathic pain.

11. (New) The method of claim 2, wherein the electrical stimulus is delivered to a target nerve to treat neuralgia.

12. (New) The method of claim 11, wherein a patient's face or head is positioned relative to the electrical stimulator such that the electrical stimulus is delivered to a trigeminal nerve to treat neuralgia.

13. (New) The method of claim 2, wherein the electrical stimulus is delivered to an occipital nerve to treat migraines.

14. (New) The method of claim 2, wherein the electrical stimulus is delivered to a target nerve to treat back or neck pain.

15. (New) The method of claim 2, wherein the electrical stimulus is delivered

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 158

to a target nerve to treat atrophy.

16. (New) The method of claim 2, wherein the electrical stimulus is delivered to a target nerve to treat depression.

17. (New) The method of claim 2, wherein the electrical stimulus is delivered to a target nerve to treat paralysis.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 159

REMARKS

Claim 1 was pending in the present application. By virtue of this response, claim 1 has been cancelled and new claims 2-17 have been added. Accordingly, claims 2-17 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Support for the new claims can be found in the specification and claims as originally filed. No new matter has been added.

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00501**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

Steven M. Giovannetti
Registration No. 51,739

Customer No. 40518
Levine Bagade Han LLP
2400 Geng Road, Suite 120
Palo Alto, CA 94303
Direct: (650) 646-2570
Fax: (650) 284-2180

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 160

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.		
Date: February 7, 2014	Signature: /Kym Y. Moore/	(Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	14/085,639
Confirmation No.:	1183
Filing Date:	November 20, 2013
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Not Yet Assigned
Group Art Unit:	2183

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are

accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00501**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

Steven M. Giovannetti
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2400 Geng Road, Suite 120
Palo Alto, CA 94303
Direct: (650) 646-2570
Fax: (650) 284-2180

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 162

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/085,639

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	1 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/085,639	11/20/2013	2183	0.00	EMKNNZ00501	1	1

CONFIRMATION NO. 1183

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

FILING RECEIPT

OC00000065340417

Date Mailed: 12/09/2013

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. 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**

Inventor(s)

Daniel R. BURNETT, San Francisco, CA;

Applicant(s)

EMKINETICS, INC., San Francisco, CA

Assignment For Published Patent Application

EMKINETICS, INC., San Francisco, CA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 13/456,016 04/25/2012
which is a CON of PCT/US2010/054167 10/26/2010
which claims benefit of 61/279,883 10/26/2009
This application 14/085,639
is a CIP of 12/508,529 07/23/2009
which is a CIP of 11/866,329 10/02/2007
which claims benefit of 60/848,720 10/02/2006

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 164

If Required, Foreign Filing License Granted: 12/03/2013

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/085,639**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

Preliminary Class

712

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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 (1-866-999-4258).

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.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/085,639	11/20/2013	Daniel R. BURNETT	EMKNNZ00501

CONFIRMATION NO. 1183

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

FORMALITIES LETTER

Date Mailed: 12/09/2013

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  *Applicant must submit $**70** to complete the basic filing fee for a small entity.*

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- A surcharge (for late submission of the basic filing fee, search fee, examination fee or inventor's oath or declaration) as set forth in 37 CFR 1.16(f) of $ **70** for a small entity in compliance with 37 CFR 1.27, must be submitted.

SUMMARY OF FEES DUE:

Total fee(s) required within **TWO MONTHS** from the date of this Notice is $ **800** for a small entity
- $ **70** Statutory basic filing fee.
- $ **70** Surcharge.
- The application search fee has not been paid. Applicant must submit $ **300** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit $ **360** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):

Daniel R. BURNETT

Applicant may submit the inventor's oath or declaration at any time before the Notice of Allowance and Fee(s) Due, PTOL-85, is mailed.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/tgebre/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	12

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	2,893,392	07-07-1959	Wagner et al.	
	2.	3,034,507	05-15-1962	McConnell et al.	
	3.	3,817,254	06-18-1974	Maurer	
	4.	3,841,305	10-15-1974	Hallgren	
	5.	4,233,965	11-18-1980	Fairbanks	
	6.	4,266,533	05-12-1981	Ryaby et al.	
	7.	4,428,366	01-31-1984	Findl et al.	
	8.	4,456,012	06-26-1984	Lattin	
	9.	4,548,208	10-22-1985	Niemi	
	10.	4,574,809	03-11-1986	Talish et al.	
	11.	4,784,737	11-15-1988	Ray et al.	
	12.	4,804,054	02-14-1989	Howson et al.	
	13.	4,837,049	06-06-1989	Byers et al.	
	14.	4,915,110	04-10-1990	Kitov	
	15.	4,926,878	05-22-1990	Snedeker	
	16.	4,940,453	07-10-1990	Cadwell	
	17.	5,000,178	03-19-1991	Griffith	
	18.	5,014,699	05-14-1991	Pollack et al.	
	19.	5,092,835	03-03-1992	Schurig et al.	
	20.	5,181,902	01-26-1993	Erickson et al.	
	21.	5,309,909	05-10-1994	Gadsby et al	
	22.	5,314,401	05-24-1994	Tepper	
	23.	5,314,453	05-24-1994	Jeutter	
	24.	5,401,233	03-28-1995	Erickson et al.	
	25.	5,449,378	09-12-1995	Schouenborg	
	26.	5,518,495	05-21-1996	Kolt	
	27.	5,562,707	10-08-1996	Prochazka et al.	
	28.	5,690,693	11-25-1997	Wang et al.	
	29.	5,715,837	02-10-1998	Chen	
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(Use as many sheets as necessary)

Sheet 2 of 12

Complete if Known	
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Art Unit	Not Yet Assigned
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 12

Complete if Known	
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Filing Date	Concurrently Herewith
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Art Unit	Not Yet Assigned
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(Use as many sheets as necessary)

Sheet 4 of 12

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(Use as many sheets as necessary)

Sheet 5 of 12

Complete if Known	
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Art Unit	Not Yet Assigned
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 12

Complete if Known	
Application Number	Not Yet Assigned
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Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
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				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Daniel R. BURNETT
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Daniel R. BURNETT
				Art Unit	Not Yet Assigned
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned
Sheet	9	of	12	Attorney Docket Number	EMKNNZ00501

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Examiner Signature		Date Considered	

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Daniel R. BURNETT
				Art Unit	Not Yet Assigned
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned
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Examiner Signature		Date Considered	

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	Not Yet Assigned
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				Art Unit	Not Yet Assigned
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Sheet	11	of	12	Attorney Docket Number	EMKNNZ00501

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Examiner Signature		Date Considered	

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				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Daniel R. BURNETT
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	12	of	12	Attorney Docket Number	EMKNNZ00501

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Electronic Acknowledgement Receipt

EFS ID:	17460620
Application Number:	14085639
International Application Number:	
Confirmation Number:	1183
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Customer Number:	40518
Filer:	Steven Michael Giovannetti/Kym Moore
Filer Authorized By:	Steven Michael Giovannetti
Attorney Docket Number:	EMKNNZ00501
Receipt Date:	20-NOV-2013
Filing Date:	
Time Stamp:	19:06:42
Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	1_EMKNZ00501_20131120_efs_ads.pdf	1509600 9011cb3a12ff2affdbf7bf13037c6fa5ff0164e4	no	7

Warnings:	
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2		2_EMKNZ00501_20131120_specification.pdf	169065 347a677cdf3a118177c51f8c5e89fe8bd475353c	yes	69

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Document Description	**Start**	**End**
Specification	1	67
Claims	68	68
Abstract	69	69

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3	Drawings-only black and white line drawings	3_EMKNZ00501_20131120_drawings.pdf	3936775 d35833051e9ffbc0984d08197b7ef4db269fa8eb	no	37
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4	Transmittal Letter	4_EMKNZ00501_20131120_ids_cover_letter.pdf	72163 316b9dc93ba9f2c594051faa135e5d9f70d08fd4	no	3
Warnings:					
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5	Information Disclosure Statement (IDS) Form (SB08)	5_EMKNZ00501_20131120_ids_sb08.pdf	175980 b174fff25064d857cc4f563b6b9aed1a6533d327	no	12
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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00501
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

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☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Daniel	R.	BURNETT	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Francisco	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

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Address 2			
City	San Francisco	State/Province	CA
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All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

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Email Address	Patent@LBHIP.com	Add Email	Remove Email

Application Information:

Title of the Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS		
Attorney Docket Number	EMKNNZ00501	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	37	Suggested Figure for Publication (if any)	33

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00501
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Domestic Benefit/National Stage Information:

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Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	13456016	2012-04-25
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13456016	Continuation of	PCT/US2010/054167	2010-10-26
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/US2010/054167	non provisional of	61279883	2009-10-26
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation in part of	12508529	2009-07-23
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12508529	Continuation in part of	11866329	2007-10-02
Prior Application Status	Expired		Remove

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00501
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11866329	non provisional of	60848720	2006-10-02

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Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)

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Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00501
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Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. [X]

Organization Name	EMKinetics, Inc.		
Mailing Address Information:			
Address 1	101 Mississippi Street		
Address 2			
City	San Francisco	**State/Province**	CA
Country [i]	US	Postal Code	94107
Phone Number		Fax Number	

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	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Email Address	

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Assignee 1

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If the Assignee is an Organization check here. ☒

Organization Name	EMKinetics, Inc.

Mailing Address Information:

Address 1	101 Mississippi Street		
Address 2			
City	San Francisco	**State/Province**	CA
Country i	US	Postal Code	94107
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

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Signature	/Steven M. Giovannetti/			Date (YYYY-MM-DD)	2013-11-20
First Name	Steven	Last Name	Giovannetti	Registration Number	51739

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	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

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METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application Serial No. 13/456,016 filed April 25, 2012, which is a continuation of PCT International Patent Application Number PCT/US2010/054167, filed October 26, 2010, which claims benefit of priority to U.S. Provisional Patent Application Serial No. 61/279,883 filed October 26, 2009. Each of the above referenced applications is incorporated herein by reference in their entirety. The present application is also a continuation-in part of U.S. Patent Application Serial No. 12/508,529 filed July 23, 2009, which is a continuation-in-part of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007, which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006. Each of the above referenced applications is incorporated herein by reference in their entirety.

[0002] The following applications are also incorporated herein by reference in their entirety for all purposes: U.S. Patent Application Serial No. 12/508,529 filed July 23, 2009, which is a continuation in part of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007, which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006; U.S. Patent Application Serial No. 12/695,087 filed January 27, 2010, which is a continuation of U.S. Patent Application Serial No. 11/332,797 filed January 17, 2006; U.S. Patent Application Serial Nos. 12/509,362 filed July 24, 2009; 12/469,365 filed May 20, 2009 which is a continuation of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007 which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006, and 12/469,625 filed May 20, 2009 which is a continuation of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007 which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006; and 12/509,304 filed July 24, 2009 which is a continuation of U.S. Patent Application Serial No. 12/508,529 filed July 23, 2009 which is a continuation-in-part of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007 which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006; and 12/509,345 filed July 24, 2009 which is a continuation of U.S. Patent Application Serial

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 191

No. 12/508,529 filed July 23, 2009 which is a continuation-in-part of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007 which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006.

BACKGROUND

[0003] The concept of pulsed electromagnetic stimulation (PES) was first observed by the renowned scientist Michael Faraday in 1831. Faraday was able to demonstrate that time varying, or pulsed electromagnetic fields have the potential to induce current in a conductive object. Faraday's experimental setup was simple. He found that by passing strong electric current through a coil of wire he was able to produce pulsed electromagnetic stimuli. This pulsed electromagnetic stimulus was able to induce the flow of current in a nearby electrically conductive body.

[0004] In the years since the discoveries of Faraday, pulsed electromagnetic stimulators have found application in countless areas of scientific investigation. In 1965, the scientists Bickford and Freming demonstrated the use of electromagnetic stimulation to induce conduction within nerves of the face. Later, in 1982 Polson et al., U. S. Patent No. 5,766,124 produced a device capable of stimulating peripheral nerves of the body. This device was able to stimulate peripheral nerves of the body sufficiently to cause muscle activity, recording the first evoked potentials from electromagnetic stimulation.

[0005] One of the earliest practical applications of electromagnetic stimulating technology took the form of a bone growth stimulator – a device that employed low frequency pulsed electromagnetic fields (PEMF) to stimulate bone repair. They first found use approximately 20 years ago in the treatment of non healing fractures, and are slowly becoming the standard of care for this condition.

[0006] As investigators have studied the effects of electromagnetic fields on fracture healing, it has been demonstrated that PEMFs can not only facilitate fracture healing but also promote numerous other positive effects on the human body, including: (1) causing muscles to contract, (2) altering nerve signal transmission to decrease experienced pain, and (3) causing new cell growth in cartilage. These powerful effects of pulsed electromagnetic stimulation have been well established in laboratory studies of animal models and also in

multiple large, double blind, placebo controlled studies of human subjects published in the medical literature.

[0007] Erickson's U.S. Patent 5,181,902, 1/26/1993, which describes a device using a double transducer system with contoured, flat wound transducers intended to generate therapeutic flux-aided electromagnetic fields in the body. The device is suggested to be conformed to the contour of the patient's back and incorporates an adjustable belt into the design. This system, as it is described, is disadvantageous in at least two respects. First, the flat, wound nature of the coil in this device is limited in its delivery of pulsed electromagnetic fields to deep tissues of the body. Second, the rigid nature of this device, intended to provide bracing for patients recovering from spinal fusion surgeries, may prove uncomfortable to some patients, especially in delivering therapy to regions of the body other than the back, such as the knee, elbow, hand, or other joints and tissues.

[0008] U. S. Patent 6,086,525, which discloses a device that has a single coil in the shape of a "C" where the intensity of the electromagnetic field is between the ends of the "C". That point must be employed directly over the target nerve or muscle to be stimulated. The coil is toroidal in configuration and utilizes a unique core of vanadium permendur in the preferred form. One of the disadvantages of this device is that it requires a trained technician to treat the patient and to properly hand hold the open end of the "C" over the targeted nerve or muscle to be stimulated. The device is not portable and is designed for use in hospitals or similar institutions. Also the vanadium permendur core is required to increase the strength of the electromagnetic field to be strong enough to be effectively used. The design, shape and configuration described in Davey and other prior art devices, require the electromagnetic stimulator to be hand operated during use.

[0009] Tepper in U.S. Patent 5,314,401, 5/24/1994 describes a pulsed electromagnetic field transducer that is intended to be conformable to the contour of a patients body. The PEMF transducer in this application is described as having a desired form and sufficient rigidity to maintain an anatomical contour. This system is disadvantageous in a number of respects. First, the desired contouring of this device will require that a significant number of different sizes be manufactured to accommodate the contours of an endless variety of body shapes. Second, the intended device does not incorporate markings to ensure that the device is placed in a correct alignment over the

targeted area of the body. Finally, this proposed device utilizes flat, wound coils, providing PEMFs that do not penetrate as deeply or as uniformly into body tissues as those fields produced by solenoid coils.

[0010] In U.S. Patent 6,179,770 B1, 1/30/2001, Mould describes dual coil assemblies in a magnetic stimulator for neuro-muscular tissue, with cooling provided for the transducer coil. This device is intended to be held by a trained user over the targeted regions of the body in order to deliver PEMF therapy. The design of this device is limited by the difficult nature of manipulating a single coil and the cost-intensive requirement of using highly skilled medical personnel for operation.

[0011] Parker in U.S. Patent 6,155,966, 12/5/2000 describes a wearable article with a permanent magnet/electromagnet combination device to be used for toning tissue with focused, coherent EMF. This device is disadvantageous in several respects. First, this device is intended to be a hand-held application, with the user applying the device to targeted areas of the body. The hand-held nature of this application creates an inherently inconsistent and non-uniform method for delivery, especially difficult with the intention of the device to provide a focused electromagnetic stimulus. Second, the device combines a static magnet with the electromagnet assembly in an attempt to create a unipolar, negative polarity field. This form of electromagnetic field stimulation has not been demonstrated to be effective in the treatment of osteoarthritis, musculoskeletal pain, or atrophy treatment.

[0012] March's U.S. Patent 6,200,259 B1, 3/13/2001 describes a device with electromagnetic field coils applied front and back to a patient for treating cardiovascular disease by angiogenesis. An EMF dosage plan contemplates, multiple coil implants and pulse variables including carrier frequency, pulse shape, duty cycle, and total time exposed. This device describes the placement of coils around the regions of tissues in which collateralization of blood flow (or angiogenesis) is desired. The design contemplates applications including the use of coils embedded in a cloth wrap, which could be worn as a garment surrounding the body area of interest. Alternatively, an applicator with embedded coils to be placed around an arm or a leg to deliver the desired field is described. The use of PEMF in this application for the purpose of modulation of angiogenesis shows significant promise. The description of this device, however, does not suggest any extension of the electromagnetic phenomenon in circumstances where PEMF stimulation can provide

dramatic opportunities for the treatment of osteoarthritis, and musculoskeletal pains including tendonitis, bursitis, and muscle spasms. Furthermore, this device is disadvantageous in the fact that it does not provide for the use of solenoid-type coils for the delivery of PEMF.

[0013] Polson's U.S. Patent 5,766,124, 6/16/1998 describes a magnetic stimulator of neuro-muscular tissue. A reserve capacitor providing more efficiency in the control circuitry is devised. The description of the device, however, describes the stimulating coil in broad, generic terms, and does not contemplate application of the coil in any type of body applicator or other specific method for delivering PEMF to targeted areas of the body. As a result, this device is disadvantageous, in the respect that is does not provide for any method or delivery system to provide consistent, uniform PEMF stimulation.

[0014] Schweighofer's U.S. Patent 6,123,658, 9/26/2000 describes a magnetic stimulation device which consists of a stimulation coil, a high-voltage capacitor, and a controllable network part. This device is intended to differentiate itself from low-voltage, low current devices by using a specific high-voltage, high current design to deliver PEMF for the purpose of triggering action potentials in deep neuromuscular tissue. This coil in this device is described as having a difficult and expensive to use hand-held configuration.

[0015] Lin in U.S. Patent 5,857,957, issued Jan. 12, 1999 teaches the use of functional magnetic stimulation for the purpose of inducing a cough function in a mammalian subject. The description of the device provides for the use of hand-held stimulation coil, intended to be placed over the anterior chest of the subject for the purpose of stimulating nerves to induce a cough. This system is disadvantageous in the requirement of hand-held delivery which is difficult and inconsistent. The description contemplates use of the device in the induction of cough, and does not contemplate extension of the use of the device into other areas of neuromuscular stimulation.

[0016] Tepper in U.S. Patent No. 6,024,691, issued 2/15/2000 describes a cervical collar with integral transducer for PEMF treatment. The description of this device provides for the use of a single coil transducer, formed into the shape of a cervical collar. This system is disadvantageous in several respects. First, this device does not provide for the use of solenoid-type coils in the delivery of PEMF, which can provide a uniform and consistent signal. Second, the semi-rigid design of the collar complicates the delivery of PEMF to

persons of differing body sizes. That is, for a person with a larger than average (or smaller than average) size neck, the design and semi-rigid nature of the device would make an exacting fit difficult, thereby diminishing the effectiveness of any delivered therapy. Furthermore, this device is designed to immobilize the neck and is therefore not applicable to most patients. Lastly, the device must be lowered over the head making application difficult.

[0017] Erickson in U.S. Patent No. 5,401,233, issued 3/28/1995 describes a neck collar device for the delivery of PEMF therapy. The description of this device provides for the use of semi-rigid transducers, intended to be conformable to a selected anatomical contour. This device in disadvantageous in respects similar to those of Pollack 5,401,233, in that the device does not provide for the use of solenoid-type coils. Furthermore, this device is intended to provide bracing (as might be necessary for the treatment of fractures or after surgery). As a result, the rigidity of the device necessary to serve the bracing function makes the device less comfortable to wear, especially for a person who would not require bracing (such as in the treatment of arthritis, muscle spasm, or other forms of musculoskeletal pain).

[0018] Kolt in U.S. Patent No. 5,518,495, issued 5/21/1996 describes a coil wound on a large bobbin that permits the insertion of an arm or a leg into the field of the coil for PEMF type therapy. This device is disadvantageous in several respects. First, the described use of a bobbin, around which the wire for the stimulating coil is wound provides for the treatment of certain areas of the body, but is certainly limited in its ability to deliver therapy to areas of the body such as the hips, shoulder, back, neck, etc. That is, the constraints of our human anatomy make it nearly impossible to approximate a metal bobbin, and thus the stimulating coil, to regions of the body such as the ball and socket joints of the hip or shoulder, where the round metal bobbin would strike the torso before it allowed the stimulating coils to adequately blanket with therapy the arm and/or joint in the hip and shoulder. Similarly, the use of a metal bobbin for the delivery of PEMF stimulation to the back would necessitate a large, cumbersome delivery system (into which the entire body would have to fit) in order to adequately deliver stimulation to targeted areas on the back or torso. Second, the device is described as a rigid bobbin through which the extremity is placed. This format makes application more difficult in that the applicator cannot be worn

and therefore does not provide for consistent ideal placement of the extremity to maximize field effects. In fact, most designs of a similar nature are clinic-based devices and, therefore, would not be amenable to home healthcare applications as with the current invention. Third, the device described magnetic field within the bobbin is intended to have a maximum magnetic flux density in the range of 4.5 to 6 gauss. Studies (such as Trock et al in the Journal of Rheumatology 1994; 21(10): 1903-1911) have shown that PEMF stimulation in the range of 15-25 or more gauss are effective in the treatment of osteoarthritis or other musculoskeletal pain conditions.

[0019] Pollack in U.S. Patent No. 5,014,699, issued 5/14/1991 describes a coil wound around the cast on an appendage for the delivery of PEMF treatment to fractured bone. The described device has shown promise for the treatment of fractured bone, especially nonunion or delayed healing fractures. However, the description of the device does not provide for extension of this application to the treatment of other conditions, such as arthritis, musculoskeletal pain, or atrophy.

[0020] Imran in US Pat App No 2006/0052839 filed 9/7/2005 describe the use of an implantable stimulator for the treatment of chronic back pain. While this modality may be effective at treating back pain, it requires a major surgery and will eventually suffer from habituation as the area around the needle fibroses and the nerve becomes deadened to repeated stimulation.

SUMMARY

[0021] In certain variations, systems for electromagnetic induction therapy may include one or more conductive coils disposed within or along an applicator. The coils may be configured to generate a magnetic field focused on a target nerve, muscle or other body tissues in proximity to the coil. One or more sensors may be utilized to detect electrical conduction in the target nerve, to detect a muscular response caused by an electrical conduction in the target nerve, or to detect stimulation of a nerve, muscle or other body tissues and to provide feedback about the efficacy of the applied electromagnetic induction therapy. A controller in communication with the sensor may be adjustable to vary a current through the at least one coil so as to adjust the magnetic field focused upon the target nerve, muscle or other body tissues. Optionally, a user or patient may detect stimulation of a nerve,

muscle or body tissue and the therapy may be adjusted based on feedback from the user or patient.

[0022] In certain variations, the applicator may be configured to intermittently apply or deliver pulsed magnetic fields to a target nerve, muscle or tissue without causing habituation of the target nerve, muscle or tissue.

[0023] In certain variations, methods of electromagnetic induction therapy may include one or more of the following steps. A first portion of a patient's body may be positioned relative to or in proximity to an applicator or an applicator may be positioned relative to or in proximity to a first portion of a patient's body, such that a target nerve, muscle or tissue within the first portion of the body is in proximity to one or more conductive coils disposed within or along the applicator. A current may be passed through a coil to generate a magnetic field focused on the target nerve, muscle or tissue. An electrical conduction through the target nerve, a muscular response caused by an electrical conduction through the target nerve or stimulation of a nerve, muscle, or body tissue may be detected by a sensor positioned along a second portion of the body. A signal from the sensor indicative of the electrical conduction or stimulation may be received, which provides feedback about the efficacy of the applied electromagnetic induction therapy. The current may be adjusted by a controller in communication with the conductive coils based on the feedback.

[0024] Optionally, a user may detect stimulation of a nerve, muscle or body tissue and the therapy may be adjusted based on feedback from the user. In certain variations, pulsed magnetic fields may be intermittently applied or delivered a target nerve, muscle or tissue without causing habituation of the target nerve, muscle or tissue. Such intermittent magnetic fields may be used to treat chronic conditions, e.g., chronic pain, without causing habituation.

[0025] In certain variations, applicators may be ergonomic or may be designed or configured to accommodate, approximate or be positioned relative to or in proximity to specific regions of the body or anatomy. The specific regions of the body or anatomy may be positioned relative to the applicators, or the applicators may be positioned relative to the specific regions of the body or anatomy to treat various conditions, for example, osteoarthritis, arthritis, back or neck pain, atrophy or paralysis, chronic pain, phantom or neuropathic pain, neuralgia, migraines, orthopedic conditions.

[0026] Other features and advantages will appear hereinafter. The features and elements described herein can be used separately or together, or in various combinations of one or more of them.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The drawings constitute a part of this specification and include exemplary embodiments of the invention, which may be embodied in various forms. It is to be understood that in some instances various aspects of the embodiments may be shown exaggerated or enlarged to facilitate an understanding of the embodiments.

[0028] FIG. 1 is a schematic view of an apparatus for magnetic induction therapy according to a first variation.

[0029] FIG. 2 is a schematic view of an apparatus for magnetic induction therapy according to a second variation.

[0030] FIG. 3 is a schematic view of an apparatus for magnetic induction therapy according to a third variation.

[0031] FIG. 4 is a schematic view of an apparatus for magnetic induction therapy according to a fourth variation.

[0032] FIG. 5 is a schematic view of an apparatus for magnetic induction therapy according to a fifth variation.

[0033] FIGS. 6A-6D are schematic illustrations depicting a first method of use of an apparatus for magnetic induction therapy. This method is based on adjusting the position of the conductive coils so to optimize a magnetic flow applied to a target nerve.

[0034] FIGS. 7A-7D are schematic illustrations of a second method of use of an apparatus for magnetic induction therapy. This method is based on locking the conductive coils in position once electrical conduction in a target nerve has been detected.

[0035] FIG. 8 is a schematic view of a variation that includes a plurality of sensors.

[0036] FIGS. 9A-9D are schematic representations of different garments adapted to operate as apparatus for magnetic induction therapy.

[0037] FIG. 10 is a schematic view of an apparatus for providing electrical stimulation.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 199

[0038] FIG. 11 is a schematic view of another variation of an apparatus for providing electrical stimulation.

[0039] FIG. 12 shows a schematic view of an energy emitting system including a microneedle patch sensor.

[0040] FIG. 13-15 shows magnified bottom views of variations of microneedle patches.

[0041] FIGS. 16-17 shows magnified side views of variations of a microneedle patch.

[0042] FIG. 18 shows a magnified bottom perspective view of a microneedle patch.

[0043] FIG. 19 shows a representative cross sectional view of the skin composed of an outer stratum corneum covering the epidermal and dermal layers of skin and the underlying subcutaneous tissue, with a variation of a microneedle patch attached thereto.

[0044] FIG. 20a shows a magnified side view of a variation of a microneedle patch including multiple electrodes.

[0045] FIG. 20b-20D show variations of a microneedle patches including multiple electrodes.

[0046] FIG. 21 shows a schematic view of an energy emitting system including a microneedle patch sensor placed behind a subject's knee.

[0047] FIGS. 22-23 show schematic views of energy emitting systems including an electrode needle and sensor.

[0048] FIGS. 24-25 show schematic views of energy emitting systems including an electrode needle without a sensor.

[0049] FIG. 26 shows a schematic view of an energy emitting system including a microneedle patch for providing stimulation.

[0050] FIGS. 27-28 show schematic views of energy emitting systems including an electrode needle and microneedle patch for providing stimulation.

[0051] FIG. 29a-29d show a prospective, side, top and rear views of an energy emitting device in the form of a foot cradle.

[0052] FIGS 30A-30B show schematic views of an energy emitting device in the form of a knee support.

[0053] FIGs. 31A-31B show a schematic view of a variation of an arm applicator and a foot, knee or leg applicator.

[0054] FIG. 32 shows a schematic view of a variation of a back applicator.

[0055] FIG. 33 shows a schematic view of a variation of a system including a back applicator, a sensor and logic controller.

[0056] FIG. 34 shows a schematic view of system including multiple back applicators, a sensor and logic controller.

[0057] FIG. 35 shows a schematic view of a variation of a system including a back applicator held on a patient's body by an ergonomic positioning element in the form of a belt and a logic controller.

[0058] FIG. 36 shows a schematic view of a variation of an applicator designed to stimulate a nerve responsible for phantom or neuropathic pain.

[0059] FIG. 37 shows a schematic view of a variation of a facial neuralgia applicator.

[0060] FIG. 38 shows a schematic view of a variation of an applicator which may be placed over the occipital nerve for the treatment of migraines.

[0061] FIG. 39 shows a schematic view of a variation of an applicator which may be placed over the frontal cortex for the treatment of depression.

[0062] FIG. 40 shows a schematic view of a variation an applicator in the form of a stimulatory coil platform for positioning one or more coils in proximity to a knee or popliteal nerve.

[0063] FIG. 41 shows a schematic view of a system including a variation of a back applicator held on a patient's body by an ergonomic positioning element in the form of a shoulder harness, a sensor, and a logic controller.

[0064] Figures 42A and 42B show an example of how the amount of stimulatory power required to achieve a desired stimulus may be automatically adjusted as a result of fibroses.

[0065] Figures 43A and 43B show variations of a coil device positioned on a skull.

DETAILED DESCRIPTION

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 201

[0066] In certain variations, apparatus and methods for magnetic induction therapy, in which dosage of magnetic energy can be regulated according to conduction in a target nerve exposed to the magnetic field are provided.

[0067] In certain variations, apparatus and methods for magnetic induction therapy, in which the flow of magnetic energy can be adjusted directionally by the patient or a healthcare provider without altering the position of a housing containing conductive coils that produce the magnetic field are provided.

[0068] In certain variations, apparatus and methods for treating a variety of ailments by providing energy to a target nerve, for example magnetic energy, electrical energy or ultrasound energy, at a location and in an amount optimized by detecting conduction in the target nerve are provided.

[0069] In certain variations, an energy emitting apparatus for delivering a medical therapy that includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors for detecting electric conduction in a target nerve, which are connected to the logic controller is provided. The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is varied by the logic controller according to an input provided by the one or more sensors based on electric conduction in the target nerve. The feedback provided by the sensors to the logic controller about the efficacy of the applied treatment causes the logic controller to modulate the current transmitted to the coils.

[0070] The applied energy may be a magnetic field, an electrical field, an ultrasound, a visible light, or an infrared or an ultraviolet energy. When a magnetic field is applied, the energy-emitting device is an apparatus that provides a magnetic induction therapy and that includes one or more conductive coils disposed in an ergonomic housing. A logic controller is electrically connected to the one or more coils, and one or more sensors detect electric conduction in the target nerve and are connected to the logic controller so to provide a feedback to the logic controller. The conductive coils receive an electric current from the logic controller and produce a magnetic field focused on a target nerve, and the electric current fed by the logic controller is varied by the logic controller according to an input provided by the sensors, thereby causing amplitude, frequency or direction of the magnetic

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

[0071] The one or more coils may be stationary or movable within the housing, making it possible to optimize the direction of magnetic flow to the target nerve by disposing the coils in the most effective direction. In different variations, the coils may be movable manually by acting on a knob, lever, or similar type of actuator, or may be translated automatically by the logic controller in response to the input provided by the sensors. When a preferred position for the coils has been established, the coils may be locked in position and maintain that position during successive therapy sessions. In other variations, the sensors may be incorporated within the housing, or instead may be disposed on a body part of interest independently of the housing.

[0072] In still other variations, the inductive coils are disposed in a housing that is situated externally to a patient's body, and additional inductive coils are implanted into the body of the patient and are magnetically coupled to the external inductive coils. With this coil arrangement, energy may be transmitted from the external coils to the internal coils either to recharge or to activate an implantable device. In yet other variations, the electric current may varied by the logic controller both on the basis of an input provided by the one or more sensors and also an input provided by the patient according to a muscular response she has perceived, for example, the twitching of a toe after application of the magnetic field.

[0073] In yet other variations, the source of energy for nerve stimulation may be electrical energy and nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli. In these variations, direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues. Furthermore, these variations enable a reduction in power requirement, because control of the signal is provided by the sensor to the signal generator loop.

[0074] In other variations, an energy emitting system for providing a medical therapy is provided. The system may include one or more conductive coils disposed within or along a housing and configured to generate a magnetic field focused on a target nerve in proximity to coils; one or more sensors in the form of microneedle patch configured to detect electrical conduction in the target nerve; and a controller coupled to the conductive coils and optionally in communication with the sensor.

[0075] In other variations, an energy emitting system for providing a medical therapy is provided. The system may include one or more microneedle patches having one or more microneedle arrays deposited on a surface of one or more electrodes and configured to generate or deliver an electrical or magnetic stimulus or field focused on a target nerve in proximity to the microneedle patch; one or more sensors configured to detect electrical conduction in the target nerve; and a controller coupled to the conductive coils and optionally in communication with the sensor. Optionally, the above variations may incorporate an electrode needle. Optionally, the above variations or systems may be utilized without a sensor or mechanism for detecting conduction or stimulation.

[0076] Methods of use of the above apparatus, systems and variations thereof for treating various conditions are also described herein.

[0077] Referring first to FIG. 1, a first variation includes a coil wrap 20, which is depicted as disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24. Because tibial nerve 24 is targeted, this variation is particularly suited for the treatment of OAB and VI. In other variations, coil wrap 20 may be configured to surround other body parts that contain a portion of tibial nerve 24 or of other nerves branching from or connected to tibial nerve 24, still making these variations suitable for treating OAB and VI. In still other variations, coil wrap 20 may be configured for surrounding body parts that contain other nerves when treatments of other ailments are intended.

[0078] Coil wrap 20 may be manufactured from a variety of materials suitable for wearing over ankle 22. Preferably, coil wrap is produced from a soft, body-compatible material, natural or synthetic, for example, cotton, wool, polyester, rayon, Gore-Tex®, or other fibers or materials known to a person skilled in the art as non-irritating and preferably breathable when tailored into a garment. Coil wrap 22 may even be manufactured from a molded or cast synthetic material, such as a urethane gel, to add extra comfort to the patient

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 204

by providing a soft and drapable feel. Additionally, coil wrap 20 may be produced from a single layer of material or from multiple material layers and may include padding or other filling between the layers.

[0079] Coil wrap 20 contains one or more conductive coils 26 arranged to produce a pulsed magnetic field that will flow across tibial nerve 24 and generate a current that will flow along tibial nerve 24 and spread along the length of tibial nerve 24 all the way to its sacral or pudendal nerve root origins. Coils 26 may be a single coil shaped in a simple helical pattern or as a figure eight coil, a four leaf clover coil, a Helmholtz coil, a modified Helmholtz coil, or may be shaped as a combination of the aforementioned coils patterns. Additionally, other coil designs beyond those mentioned hereinabove might be utilized as long as a magnetic field is developed that will encompass tibial nerve 24 or any other target nerve. When a plurality of coils is utilized, such coils may be disposed on a single side of ankle 22, or may be disposed on more than one side, for example, on opposing sides, strengthening and directionalizing the flow of the magnetic field through tibial nerve 24 or other peripheral nerves of interest.

[0080] Coil wrap 20 is preferably configured as an ergonomic wrap, for example, as an essentially cylindrical band that can be pulled over ankle 22, or as an open band that can be wrapped around ankle 22 and have its ends connected with a buckle, a hoop and loop system, or any other closing system known to a person skilled in the art. By properly adjusting the position of coil wrap 20 over ankle 22, a patient or a health care provider may optimize the flow of the magnetic field through tibial nerve 24, based on system feedback or on sensory perceptions of the patient, as described in greater detail below.

[0081] The electric current that produces the magnetic field by flowing through coils 26 is supplied by a programmable logic controller 28, which is connected to coils 26, for example, with a power cord 32. A sensor 30 that feeds information to logic controller 28 is also provided, in order to tailor the strength of the magnetic field and control activation of coils 26 based on nerve conduction. The purpose of sensor 30 is to detect and record the firing of the target nerve and to provide related information to logic controller 28, so to render the intended therapy most effective. For example, sensor input may cause logic controller 28 to alter the strength or pulse amplitude of the magnetic field based on sensor input, or fire the coils in a certain sequence.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 205

[0082] In this variation, as well as in the other variations described hereinafter, sensor 30 may include one or more sensor patches and may be placed at different distances from the region of direct exposure to the magnetic field. For example, sensor 30 may be configured as a voltage or current detector in the form of an EKG patch and may be placed anywhere in the vicinity of the target nerve to detect its activation. For ease of description, the term "coils" will be used hereinafter to indicate "one or more coils" and "sensor" to indicate "one or more sensors," unless specified otherwise.

[0083] By virtue of the above described arrangement, coil wrap 20 provides a reproducibly correct level of stimulation during an initial therapy session and during successive therapy sessions, because the presence or absence of nerve conduction is detected and, in some variations, measured when coil wrap 20 is first fitted and fine-tuned on the patient. In addition to properly modulating the applied magnetic field, the positioning of coils 26 over ankle 22 may also be tailored according to the input provided by sensor 30, so to fine-tune the direction of the magnetic field. Such an adjustment of the direction, amplitude, and level of the stimulation provided to the target nerve through the above described automated feedback loop, to ensure that peripheral nerve conduction is being achieved, is one of the key features.

[0084] If the magnetic pulse does not substantially interfere with sensor 30, sensor 30 may be placed directly within the field of stimulation, so that power supplied to the system may be conserved. This is particularly important for battery-powered systems. Alternatively, sensor 30 may also be placed at a distance from the magnetic field and still properly detect neural stimulation.

[0085] In a method of use of coil wrap 20, the amplitude and/or firing sequence of coils 26 may be ramped up progressively, so that the magnetic field is increased in strength and/or breadth until nerve conduction is detected, after which the applied stimulus is adjusted or maintained at its current level for the remainder of the therapy. The level of stimulation may be also controlled through a combination of feedback from sensor 30 and feedback based on perceptions of the patient. For example, the patient may activate a switch once she perceives an excessive stimulation, in particular, an excessive level of muscular stimulation. In one instance, the patient may be asked to push a button or turn a knob when she feels her toe twitching or when she experiences paresthesia over the sole of her foot. The

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 206

patient will then continue pressing the button or keep the knob in the rotated position until she can no longer feel her toe twitching or paresthesia in her foot, indicating that that level of applied stimulation corresponds to an optimal therapy level. From that point on, the patient may be instructed to simply retain her foot, knee, or other limb within coil wrap 20 until therapy has been terminated while the system is kept at the optimal level. Adding patient input enables control of coil wrap 20 during outpatient treatments, because the patient is now able to adjust the intensity of the magnetic field herself beyond the signals provided to logic controller 28 by sensor 30.

[0086] Detecting and, if the case, measuring conduction in one or more nerves along the conduction pathways of the stimulated nerve confirms that the target nerve has been stimulated, providing an accurate assessment of the efficiency of the applied therapy on the patient. A concomitant detection of muscle contraction may also confirm that the target nerve is being stimulated and provide an indication to the patient or to a healthcare provider as to whether stimulation has been applied at an excessive level in view of the anatomical and physiological characteristics of the patient.

[0087] Based on the foregoing, coil wrap 20 allows for a consistent, user-friendly targeting and modulation of the peripheral nerves via the posterior tibial nerve on an outpatient basis, in particular, the targeting and modulation of the pudendal nerve and of the sacral plexus. When multiple coils 26 are present, coils 26 may be activated simultaneously or differentially to generate the desired magnetic field. The direction and location of each of coils 26 may be reversibly or irreversibly adjusted by the healthcare provider or by the patient, customizing the location of the applied stimulation to the anatomy and therapy needs of each patient. After a healthcare provider has optimized position and firing sequence for each of coils 26, the patient may be sent home with coil wrap 20 adjusted to consistently target the desired nerve. In one variant of the present variation, an automatic feedback system adjusts one or more of firing sequence, firing strength or position of coils 26 within coil wrap 20 during the initial setup and also during successive therapy sessions.

[0088] In summary, certain variations include the creation of a loop consisting of feeding information on nerve conduction to logic controller 28 and on logic controller 28 tailoring the electrical current sent to coil wrap 20 according to the information received from sensor 26 based on whether or not the nerve is receiving the desired stimulation and, in

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 207

some variations, the desired amount of stimulation. This arrangement offers an unparalleled level of therapy control and flexibility within a home care setting, because a consistent, repeatable stimulation of the target nerve can be attained. Aside from adjusting the position of coils 26 in accordance with the patient's anatomy and physiological variations, controlling pulse amplitude is also of great importance even during different therapy sessions with the same patient. For example, a patient with leg edema will encounter difficulties in properly adjusting coil wrap 20 based on whether her legs and ankles are swollen or not swollen, and the power required to penetrate to posterior tibial nerve 24 (in the case of a VI therapy) will vary greatly due to the variable depth of the nerve. Thus, having feedback provided by sensor 26 becomes a necessity for achieving an accurate dosage of the treatment rather than an option. Benchtop testing has demonstrated that a system constructed as described herein is capable of non-invasively generating electrical currents similar to those found in therapeutic electro-stimulation and to do so in different settings.

[0089] Referring now to FIG. 2, a second variation will be described with reference to a coil wrap 34 disposed over ankle 36 for the purpose of treating VI by targeting tibial nerve 38. In this second variation, one or more Helmholtz coils 40 are disposed within coil wrap 34 to create a more narrowly directed magnetic field over tibial nerve 38. Like in the all other variations described herein, more than one coil (in the present variation, more than one Helmholtz coil 40) may be placed within coil wrap 34 and be disposed in different positions within coil wrap 34, in order to optimize magnetic flux over tibial nerve. For example, two Helmholtz coils may be disposed one opposite to the other within coil wrap 34.

[0090] Having coil windings arranged along a common longitudinal axis, as required in a Helmholtz coil configuration, generates a more focused magnetic field and a more accurate targeting of tibial nerve 38 or of any other nerve. Like in the previous variation, the operation of coils 40 is controlled by a logic controller 42, which is in turn connected to sensor 44 that monitors conduction in tibial nerve 44 and that generates a feedback to logic controller 42 about the efficiency of the therapy in progress. Therefore, like in the previous variation, the coupling of sensor 44 with logic controller 42 optimizes operation of coil wrap 34 according to results measured at the level of tibial nerve 38. Also like in the previous variation, manual adjustments to the parameters of electric current provided by logic

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 208

controller 42 to Helmholtz coil 40 may also be made manually by the patient or by a healthcare provider, and coil wrap 34 may be structured so that the position of Helmholtz coil 40 within coil wrap 34 is adjusted as desired either manually by the patient or by a healthcare provider, or automatically by logic controller 42.

[0091] Referring now to FIG. 3, a third variation includes a coil wrap 46 configured for wrapping over the popliteal fossa of a patient, in the region of the knee, to stimulate the posterior tibial nerve (not shown). The configuration and structure of coil wrap 46 reflect the body portion covered by coil wrap 46, but the key system components of coil wrap 46, such as the type, number and disposition of the coils (for example, the use of overlapping coils); the connections of the coils with a logic controller; and the use of one or more sensors (also not shown) to detect nerve conduction are all comparable to those in the previously described variations.

[0092] Referring now to FIG. 4, a fourth variation includes a footrest or foot cradle 48, which is structured to contain at least a portion of a foot 50. One or more coils 52 are enclosed within cradle 48, and a sensor 54 is disposed along the pathway of tibial nerve 55, sensing conduction in tibial nerve 55, and is also connected to a logic controller 56. Coils 52, sensor 54 and logic controller 56 may be arranged in different configurations, in the same manner as in the preceding variations.

[0093] Cradle 48 may be made from a variety of materials and may be monolithic, or have a hollow or semi-hollow structure to enable the movement of coils 52 within cradle 48, as described in greater detail below. Preferably, cradle 48 has an ergonomically design allowing the ankle and heel of the patient to be retained within cradle 48, in a position that matches the positions of stimulating coils 52 to the area of stimulation. The design of cradle 48 provides for a particularly comfortable delivery of therapy to patients that prefer to remain seated during their therapy, and enables the patient to perform the required therapy within a health care facility, or to take cradle 48 home, typically after an initial session and appropriate training in a health care facility. In that event, the patient will be trained to apply sensor 54 autonomously and to adjust stimulation to a comfortable level.

[0094] FIG. 4 shows coils 52 disposed as overlapping and the use of a single sensor patch 54 positioned proximally to the stimulation site. However, coil 52 may be configured as a single coil, a figure eight coil, a four leaf clover coil, a Helmholtz coil, a modified

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 209

Helmholtz coil or a any combination of the aforementioned coils, or as any other coil design providing an effective stimulation to the target nerve. In addition, coils 52 may be fired individually, sequentially or simultaneously according to the feedback provided by sensor 54.

[0095] In one variant of this variation, sensor 54 may include a conductive electrode patch that provides a feedback to logic controller 56 for adjusting, if necessary, the stimulation parameters of coils 52. Alternatively, sensor 54 may be a sensor patch that is either applied to the skin of the patient or is incorporated within the structure of cradle 48.

[0096] Referring now to FIG. 5, a fifth variation includes a knee rest or knee cradle 58 that contains one or more conductive coils 60, one or more sensors 62 and a logic controller 64. The components of this variation are similar to those described with reference to the preceding variations, as regards the structure and materials of cradle 58, the nature and disposition of coils 60, the type and operation of sensor 62, and the function and operation of logic controller 64. Cradle 58 is configured to target the popliteal fossa of the patient, thus to target tibial nerve 66. In that respect, the present variation is similar to the variation illustrated in FIG. 3, but while the variation of FIG. 3 is configured as a wrap that may be worn while the patient is standing, the present variation is configured as a cradle that is more suited for treatment while the patient is sitting or laying down.

[0097] A method of use of the foot cradle depicted in FIG. 4 is described with reference to FIGS. 6A-6D. During a first step illustrated in FIG. 6A, foot 68 is disposed in cradle 70 that contains one or more conductive coils 72, which are connected to a logic controller (not shown) that manages the flow of electric power to coils 72.

[0098] During a second step illustrated in FIG. 6B, a sensor 74 is disposed on foot 68 or on ankle 76 or on another appropriate portion of the patient's body, in order to detect conductivity in tibial nerve 78 or in another target nerve.

[0099] During a third step illustrated in FIG. 6C, a healthcare provider analyzes conductivity measurements provided by sensor 74 (for example, by reading gauge 77) and first adjusts the positioning of coils 72 until conduction in nerve 78 is detected. For example, the healthcare provider may rotate a knob 80, slide a lever or actuate any other displacement system for coils 72 that is known in the art, so that coils 72 are translated until a magnetic field of the proper amplitude and intensity is applied to cause conduction in nerve 78. The

position of coils 72 is then fine-tuned manually until an optimal level of conduction in nerve 78 is attained, and the therapy is continued for a length of time as prescribed by the attending healthcare provider.

[00100] During a fourth, optional step illustrated in FIG. 6D, settings for successive therapy sessions are set, for example by locking knob 80 (in one variation, with a pin 81) so that the healthcare provider or the patient repeat the therapy using the predetermined settings. Alternatively, the patient may be trained to adjust the amplitude and/or strength of the applied magnetic field, as each therapy session requires.

[0100] While the present method has been described with regard to foot cradle 70, the same method steps may be envisioned for coil wraps or cradles of different configurations, for example, for the coil wraps and cradles described with reference to the previous figures.

[0101] In an alternative variation, the logic controller (not shown) may automatically adjust coil positioning to optimize therapy during the initial and successive sessions. While this set-up may be more difficult to implement, it also provides for an accurate targeting of the target nerve during each therapy session, regardless of alterations in patient positioning or changes to the anatomy of the patient (for example, when a foot is swollen). In this variation, the device simply varies the orientation of coils 84 until stimulation has been sensed.

[0102] Further, coils 84 may be translated along a single direction (for example, horizontally) or along a plurality of directions, to provide for the most accurate positioning of coils 84 with respect to the target nerve.

[0103] A second method of use of the foot cradle depicted in FIG. 4 is described now with reference to FIG. 7. While this second method is also described with reference to a foot cradle 82 employing one or more coils 84 that have a reversibly lockable, adjustable orientation, the present method may be equally implemented with a body-worn coil wrap, such as those described with reference to the previous figures, or to other variations. In this method, the patient or the healthcare provider adjusts the positioning of coils 84 to detect conductivity in target nerve 89.

[0104] The position of coils 84 may be translated in different directions (in the illustrated variation, may be translated horizontally) and may be locked in an initial position once conduction in nerve 89 is detected by a sensor (for example, sensing patch 86).

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 211

[0105] More particularly, FIG. 7A illustrates the initial positioning of foot 88 into cradle 82 and of sensor patch 86 on ankle 90 or other appropriate body part of the patient. After proper positioning of foot 88 is attained, a knob 92 (or other equivalent device) may be employed to adjust the position of coils 84, based on the signals (for example, nerve conduction signals) provided by sensor patch 86, as shown in FIG. 7B.

[0106] With reference to FIG. 7C, after neural conduction is detected, coils 84 are locked in place, and, with further reference to FIG. 7D, foot cradle 82 retains coils 84 locked in position for further use in a home or healthcare office environment. Therefore, in the present method, the patient or a healthcare provider simply adjusts coil position by sliding coils 84 back and along one axis until electric conduction in the target nerve is detected, although adjustments along all three axes may be possible in different variants of the present variation.

[0107] Referring now to FIG. 8, a sixth variation relates to the use of multiple sensors. While FIG. 8 depicts a variation shaped as a foot cradle 98, it should be understood that the following description also relates to any other design, whether shaped as a cradle or a wrap or otherwise. The plurality of sensors 94 described herein may detect a variety of physiologic changes, including neural impulses, muscular contraction, twitching, etc. that may occur with neural or muscular stimulation.

[0108] One or more of the illustrated sensors 94 may be employed over body regions being stimulated (for example, back, leg, arm, neck, head, torso, etc.) and may be either incorporated within an actual cradle or wrap or, otherwise, be applied separately from the cradle or the wrap.

[0109] Sensors 94 may be structured as disposable, single-use, EKG-type patches that are attached to the body outside of cradle 98 along the nerve conduction pathway and are then connected to the logic controller (not shown) before beginning therapy. This arrangement provides for an intimate body contact of sensors 94 without the risk of infection or other detrimental side effects that may be present with transcutaneous devices. Sensors 94 may be employed both for beginning and for monitoring the stimulation therapy; more specifically, sensors 94 may be employed during the beginning of the therapy to optimize the strength of the magnetic field and/or to adjust the positioning of coils 96 within the cradle 98. Once therapy has begun, sensors 94 continue to monitor nerve conduction to

ensure that the correct level of stimulation is being provided. In the event that for some reason nerve conduction decays during therapy, the logic controller can automatically adjust the magnetic field, ensuring that the appropriate therapy is delivered for the appropriate amount of time.

[0110] One or more of sensors 94 in this variation, or any of the variations described herein, may take the form of an inductive coil designed to receive impulses from the underlying nerves, so that inductive technologies may be used to both stimulate the nerve or tissues as well as to record the effect of the stimulation on nerves or tissues. Any of sensors 94 may be connected to the logic controller through one or more connection modes, including, but not limited to, wireless signals, wired signals, radio frequencies, Bluetooth, infrared, ultrasound, direct switching of the current circuit, etc., so long as communication between the sensor and the device is effective.

[0111] During implementation of the present method, a healthcare provider may simply elect to use sensors 94 to adjust the device, for example, to lock coils 96 into position, during the first therapy session and not require the use of sensors 94 during each successive therapy session.

[0112] Referring now to FIGS. 9A-9D, there are shown different, non-limiting variations shaped as body worn ergonomic applicator garments. Each of these variations is shown with overlapping coils, although coils of any configurations may be used. Each of the wraps of FIGS. 9A-9D corresponds to a coil wrap, into which a body part may be placed. These garments contain one or more sensors (not shown) that provide feedback to a logic controller (also not shown), or sensors may be applied separately from those garments. Systems may also be included for reversibly or irreversibly locking the coils within the applicator.

[0113] More particularly, FIG. 9A illustrates a variation, in which coils 100 are embedded in a knee wrap 102 and are connected to a logic controller (not shown) by a connector 104. FIG. 9B instead illustrates a variation, in which coils 106 are disposed within an abdominal garment, for example shorts 108 and in which coils 106 are also connected to a logic controller (not shown) by a connector 110. A marking 112 may be added on one side of shorts 108 to indicate wrap orientation. FIG. 9C illustrates a coil wrap shaped like a band 114, in which coils 116 are connected to a logic controller (not shown) by a connector 118.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 213

When this variation is employed, band 114 may be wrapped around a body portion (for example, an arm) and be retained in place by a system known in the art, for example, a hook and loop system, a strap and buckle system, or simply a hook disposed at one end of band 114 for engaging fabric or other material in another portion of band 114. FIG. 9D illustrates a variation shaped as a shoulder strap 120, the length of which may be adjusted by a buckle 122 and which has coils 124 disposed in one or more points, for example, at the joint between an arm and a shoulder as shown. Each of these variations includes one or ore sensors (not shown) that may be coupled to the garment, or that may be applied separately from the garment.

[0114] Other variations that are not illustrated include, bur are not limited to: a head worn garment, such as a cap; a neck worn garment, such as a neck brace; and a lower-back garment. Each garment and applicator may also utilize the locking, targeting coil feature described previously, without requiring the use of the any sensing components after a proper positioning of the coils in relation to the target nerve or nerves has been established.

[0115] Still other variations are depicted in FIGS. 10 and 11. In these variations, the source of energy for nerve stimulation is electrical energy that is dispensed through a percutaneous stimulator, such as a percutaneous needle 124, or a transcutaneous stimulator, such as an electrode 126. As shown in FIG. 10, an electrical pulse controller 128 is electrically connected both to percutaneous needle 124 and to sensor 134, to provide the desired feedback and modulate the power to percutaneous needle 134. In the variation of FIG. 11, electrical pulse controller 130 is connected both to electrode 126 and to sensor 136, and performs a function similar to that of electrical pulse controller 128. With these variations, nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli. Further, direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues. Still further, these variations enable a reduction in power requirement, because control of the signal is provided by the sensor to the signal generator loop.

[0116] As shown, a device constructed according to the principles described herein provides a targeted and precise stimulation of the posterior tibial nerve, or of other

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 214

peripheral nerves, in a non-invasive manner by employing an ergonomic wrap or cradle that specifically targets the posterior tibial nerve in a consistent and repeatable manner. For example, in patients with OAB or VI, the novel, reversibly lockable movement of the coils and the use of a logic controller -sensor loop enables the application of a magnetic field that can be varied in location, amplitude and strength according to the amount of stimulation actually induced in one or more target nerves and of the response of the patient to the therapy. An apparatus according to the variations described herein may deliver any frequency of stimulation, including low frequencies, high frequencies, mid frequencies and ultrahigh frequencies, and overlapping and non-overlapping coils may be used to generate the desired field, although overlapping or Helmholtz coils are preferred due to their ability to target a broader region and achieve more thorough stimulation.

[0117] Ailments that may be treated through the use of apparatus and methods as described herein include not only OAB and VI, but also obesity, depression, urinary incontinence, fecal incontinence, hypertension, pain, back pain, restless leg syndrome, Guillain Barre syndrome, quadriplegia, paraplegia, diabetic polyneuropthy, dyskinesias, paresthesias, dental procedure pain, knee osteoarthritis, anesthesia (pain relief during surgery), Alzheimer's disease, angina (chest pain from heart disease), ankylosing spondylitis, back pain, bum pain, cancer pain, chronic pain, dysmenorrhea (painful menstruation), headache, hemiplegia, hemiparesis (paralysis on one side of the body), labor pain, local anesthesia during gallstone lithotripsy, facial pain, trigeminal neuralgia, bruxism (tooth grinding) pain, myofascial pain, pregnancy-related nausea or vomiting, neck and shoulder pain, pain from broken bones, rib fracture or acute trauma, diabetic peripheral neuropathy, phantom limb pain, post-herpetic neuralgia (pain after shingles), postoperative ileus (bowel obstruction), irritable bowel syndrome, postoperative nausea or vomiting, postoperative pain, post-stroke rehabilitation, rheumatoid arthritis, skin ulcers, spinal cord injury, temporomandibular joint pain, detrusor instability, spinal muscular atrophy (in children), pain during hysteroscopy, gastroparesis, chronic obstructive pulmonary disease rehabilitation, carpal tunnel syndrome, soft tissue injury, multiple sclerosis, intermittent claudication, attention-deficit hyperactivity disorder (ADHD), cognitive impairment, knee replacement pain, achalasia, atopic eczema, bursitis, carpal tunnel syndrome, dementia, depression, dry mouth, dystonia, enhanced blood flow in the brain, enhanced blood

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 215

perfusion of the uterus and placenta, esophageal spasm, fibromyalgia, fracture pain, Guillain-Barre syndrome, hemophilia, herpes, hip pain, interstitial cystitis, irritable bowel syndrome, pruritis, joint pain, labor induction, local anesthesia, menstrual cramps, muscle cramps, muscle spasticity, muscle strain or pain, musculoskeletal trauma, myofascial pain dysfunction syndrome, nerve damage, osteoarthritis, pain medication adjunct, pancreatitis, Raynaud's phenomenon, repetitive strain injuries, sacral pain, schizophrenia, shingles, shoulder subluxation, sickle cell anemia pain, Skin flap ischemia (during plastic surgery), sphincter of Oddi disorders, sports injuries, thrombophlebitis, tinnitus (ringing in the ear), restless legs, tremor, whiplash and neuralgias. In contrast to implantable nerve stimulators, this therapy is completely non-invasive and does not require a major surgery to implant a permanent nerve stimulation device. Moreover, this therapy can be controlled to optimize the level of therapy delivered according to power consumption and nerve stimulation requirements and need not be delivered by a professional healthcare provider.

[0118] In other variations, neural stimulation may be applied as electrical transcutaneous stimulation, for example, by inserting an invasive electrical needle into a target body part and by modulating stimulation is modulated on the basis of information sent back to the logic controller from the one or more sensors that are used to detect and/or maintain the correct level of stimulation. The transcutaneous electrical stimulation sensor may be placed in the body independently or be incorporated within the wrap and may provide, among other things, feedback as to the quality of the electrical connection to the skin, which is directly related to the bum risk inherently associated with this type of therapy. In fact, these methods of stimulation may not be optimal due to the resulting skin irritation and risk of potential bums, a very serious issue in the large percentage of patients that have neuropathies. Even when patches are applied to monitor transcutaneous stimulation very closely, the patches may still become displaced and allow a bum to occur. Moreover, potentially interfering electrical impulses may develop at the treatment site, creating a noisy environment for the detection of nerve conduction.

[0119] In still other variations, an external coil or coils may be inductively connected to an implanted coil or coils may be utilized. In these variations, an ergonomic applicator may be adjusted by the user or by a healthcare provider such to optimize inductive power transmission between the external and implanted coils. One or more sensors may be utilized

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 216

to provide a feedback that the relative coil positions have been optimized, and the external coil may then be reversibly locked into position within the ergonomic applicator. Two applications of this variation relate to the transfer of power to recharge an implantable device, and to the transfer of power to activate an implantable device.

[0120] In the first application, when an implantable rechargeable device is utilized, the external coils may be used for recharging the implanted device by means of inductive fields generated by the external coils. The external coils may include circuitry that determines the amount of resistance encountered by the magnetic field or other electrical properties related to the quality and degree of the magnetic coupling that is being established. Based on this feedback, the position of the external coils may be adjusted manually or automatically to optimize the coupling achieved with during each recharging session. Alternatively, a sensor may be incorporated into the implantable device and may communicate the degree and quality of the magnetic coupling to the external coils and/or the connected circuitry via wireless communication, providing a feedback for the automatic or manual adjustment of the external recharging coils.

[0121] The coils within the ergonomic applicator may be reversibly locked into place for the duration of the recharge session, and the implantable device may also communicate to the external recharging unit that the implantable device has been fully recharged, terminating the recharging session has been completed. By providing for an intermittent recharging of an implanted device, an apparatus according as described herein enables the implantable device to devote more power to performing its intended function optimally and with a lesser concern about protecting or extending battery life.

[0122] In the second application, the powering coils may contain circuitry to determine the amount of resistance encountered by the applied magnetic field, or other electrical properties that may reflect the quality and degree of the magnetic coupling that is being achieved. Based on this feedback, the powering coils in the applicator may be adjusted manually or automatically to activate and optimize the coil coupling at the beginning of each therapy session. Alternatively, a sensor may be incorporated into the implantable device and communicate the degree and quality of the magnetic coupling externally via wireless communication, which may in turn provide feedback for the automatic or manual adjustment

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 217

of the powering coil. In one variant of the present variation, the inductive coils may be magnetically coupled to a needle targeting the posterior tibial nerve.

[0123] An exemplary method of use of an apparatus as described herein on a patient suffering from VI and/or OAB includes the following steps:

[0124] The patient places a conductive wrap contained within a flexible material over a region of the ankle (or alternatively over the knee) to provide the required pulsed magnetic field. Alternatively, the patient may use an ergonomic foot/leg rest or cradle having embedded coils.

[0125] A sensor (for example, a sensor patch) is placed on the patient's body along the path of the nerve, ideally proximal to the stimulation site to ensure afferent nerve stimulation, and is connected to a logic controller.

[0126] A physician or healthcare provider adjusts the coils in the wrap or cradle until nerve conduction is achieved based on patient and sensor feedback. An optimal position is sought, and the coils may be reversibly locked into position within the conductive wrap or ergonomic cradle and remain in this position during subsequent use.

[0127] During the therapy session, the logic controller provides an electric current to the coils, generating an inductive magnetic field. In one variation, this field begins at low amplitude and slowly ramps up until nerve conduction exceeds a threshold level, as signaled by the sensor and possibly by the patient, who may feel motory conduction. Alternatively, one or more coils may also be activated to increase the covered area of stimulation in the event that stimulation does not occur with the initial coil configuration or is inadequate

[0128] The optimal stimulation may be determined in a variety of manners, for example, by measuring exposure to electromagnetic fields capable of generating a square wave electric signal at a frequency of 10-30 Hz at the targeted tissue depth. The square wave configuration of the signal may be generated via Fourier transformation or may be a ramped current generated in any manner.

[0129] The inductive magnetic pulses continue for an appropriate duration of use, for example, for 15-30 minutes. The sensor may remain in place during the entire therapy session to ensure that stimulation occurs consistently and to provide for appropriate corrections if nerve conduction deteriorated. The logic controller may be powered either by

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 218

a portable power source such as a battery, or by or a fixed power source such as a traditional wall outlet.

[0130] The conductive wrap and/or ergonomic cradle is removed from the body when therapeutic stimulation is not being delivered, typically at the end of the therapy session.

[0131] The conductive wrap and/or ergonomic cradle is reapplied along with the sensor patch (ideally disposable) from time to time as indicated, for example, on a daily basis, and steps 4-8 are repeated.

[0132] The devices and methods described herein may be applied to any body tissues, including nerve, muscle, skin, vasculature, or any other organ or tissue within the human body. Further, the devices and methods described herein may be used to treat any conditions suited for neuromodulation regardless of whether the stimulation source is an electromagnetic field, a direct electric current, a RF field, infrared energy, visible light, ultraviolet light, ultrasound, or other energy dispensing device.

[0133] In other variations, as shown in FIG. 12, an energy emitting system 210 for providing a medical therapy includes one or more conductive coils 212 disposed within or along a housing 214, one or more sensors 216 configured to detect electrical conduction in a target nerve or to detect muscle stimulation, and a controller 218 connected or coupled to the conductive coils 212 and optionally in communication with the sensor 216. In certain variations (as shown in Fig. 12), the controller 218 can be integral with the housing 214). The coils 212 are configured such that an electrical current generated by the controller 218 is passed through the coils 212 generating a magnetic field which will stimulate a target nerve, e.g., the tibial nerve 220, a muscle or other body part containing a portion of a target nerve, or any nerves branching off of a target nerve, located in proximity to the coils 212. In this particular variation, the housing 214 is in the form of a foot cradle, as shown in FIG. 4, however, the housing could also be in the form of a flexible wrap, garment or other design suitable for use with a subject. In various variations described herein, sensors may detect voltage or current and may be connected, coupled, wirelessly connected or coupled or otherwise in communication with the housing and/or controller using a variety of methods or techniques known in the art. The sensor may be placed over a muscle to detect muscle stimulation resulting from stimulating the target nerve (as shown in Fig. 12) or over any other portion of the subject's body suitable for detecting conduction of the target nerve.

[0134] Referring to FIG 13 and 16, the sensor may be in the form of a microneedle patch 228, which can be removably attached to the skin surface of a subject. The microneedle patch 228 may include a housing 231, having one or more electrodes 232 and one or more microneedles 235 deposited or arrayed on a surface of the electrode 232, forming one or more microneedle arrays 234. In FIG 13, microneedle patch 228 has the shape of a square, and the microneedles 235 are arrayed on the bottom surface 236 of the electrode 232 in a 16 X 16 configuration. However, as shown in FIGS 14-15, microneedle patches may be designed in a variety of shapes, e.g., round, oval 229, rectangular 230, hexagonal, and a variety of sizes. The microneedles may be arrayed in a variety of arrangements and patterns (e.g., 14 X 14, 12 X 12, etc.) depending on the particular use and needles.

[0135] Additionally, microneedles may be attached, deposited, or arrayed on an electrode surface or patch in a variety of configurations and arrangements, depending on where the particular microneedle patch will be utilized and the treatment to be delivered. The number of microneedles included in an array can vary. For example, the number of microneedles may range from about 5 to 500 or 100 to 400 or about 200 to 300 or about 256. In certain variations where microneedles are composed of strong, highly conductive material, the number of microneedles necessary may be less and may range from about 5 to 100 or 10 to 50 or 5 to 50. However, where microneedles are composed of higher resistance metal, a greater number of needles may be needed, e.g., about 100 to 500 or about 200 to 300 or greater than 500.

[0136] Referring to FIG. 18, a magnified view of a microneedle array 234 composed of one or more microneedles 235 is shown. Microneedles 235 may include a base portion 238 and an upper portion 239. Microneedles 235 may have lengths in the range of about 1 to 400 microns or 10 to 400 microns or preferably about 100 to 150 microns, and a diameter in the range of about 1 to 100 microns. A microneedle 235 may be tapered in diameter, going from a larger to smaller diameter from the base portion 238 to the upper portion 239 where the distal tip 240 of the microneedle is preferably pointed or sharp. The upper portion 239 of the microneedle 235 may have a diameter in the range of about 10-30 microns or about 15 to 25 microns. Optionally, for ease of production, the base portion 238 of the microneedle 235 may be thicker than the distal tip 240 or upper portion 239 of the microneedle 235. In certain variations, as shown in FIG 17, a bulb 237 may be provided at the distal tip 240 of a

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 220

microneedle 235 to provide for effective anchoring of the microneedle 235 in the skin of a patient or subject. Microneedles 335 can include any number of friction or grip increasing features. For example, they may include projections, barbs, bulbs or a roughened surface or tip. Microneedles 235 may take on various configurations, e.g., straight, bent, filtered, hollow or a combination of the above.

[0137] In other variations, microneedles may have lengths that range from about 480 to 1450 microns, widths from about 160 to 470 microns, thicknesses from about 30 to 100 microns and tip angles from about 20 to 90 degrees, and arrays can contain from 5 to 50 microneedles. For example, microneedles having these dimensions have been shown to be less painful than hypodermic needles. Length and number of microneedles can affect the level of pain experienced. Decreasing microneedle length and/or the number of microneedles may be beneficial and act to further reduce pain and provide comfort.

[0138] In certain variations, the one or more microneedles may include an electrically conductive material such that the microneedles may transmit an electrical signal to an overlying electrode or other surface. Microneedles may be constructed of an electrically conductive material and/or coated with an electrically conductive material. Optionally, microneedles may be coated with an electrically conductive material and constructed of a non-conductive material. Microneedles may be fabricated using a variety of materials, e.g., metals, stainless steel, solid or coat of gold over NI, Pd or Pd-Co, Pt, silicon, silicon dioxide, polymers, glass, biocompatible polymers, titanium, silver, or suture materials. Biodegradable polymers may also be used such that if a tip of a microneedle were to snap or break off during insertion, it would easily biodegrade.

[0139] A microneedle array 234 may be constructed or fabricated using any variety of manufacturing methods known to persons of ordinary skill in the art. Microneedles may be arrayed, attached, etched or deposited onto a surface of an electrode. In another variation, microneedles may be etched from or deposited onto a silicon electrode, such that the microneedle patch, including electrode and microneedles, are made from one material creating a durable and stable microneedle patch.

[0140] As shown in FIG 18, microneedles may be fabricated by creating micron sized holes on a silicon substrate and by using a KOH solution to create the needle shape. In other variations, the microneedles may be made of non-conductive material but may still be

utilized to provide superior anchoring properties such that a microneedle patch may effectively adhere or attaché to a subject's skin.

[0141] In certain variations, microneedle arrays are fabricated by patterning SU-8 onto glass substrates and defining needle shapes by lithography. The tips of the needles can be sharpened using reactive ion etching. Optionally, holes may be drilled, e.g., by laser, through the microneedles and base substrate. Holes may be drilled off-center, but parallel to the microneedle axis, terminating in side-opening holes along the needle shaft below the needle tip. If desired, the holes can serve as micro fluidic needle bores for injection or infusion of drugs, medicines, insulin, proteins, nanoparticles that would encapsulate a drug or demonstrate the ability to deliver a virus for vaccinations, etc. to be used separately or in combination with electrical or magnetic therapy. The microneedles may also be coated with nickel by electroplating, which can increase their mechanical strength.

[0142] In certain variations, microneedle patches or microneedle electrode arrays are made by fabricating master structures from which replicates are molded and then made electrically active. For example, SU-8 may be spun on a glass substrate bearing an array mask pattern, baked, and then exposed from the backside to from a tapered needle structure. Microneedles may be sharpened by RIE etching. A PDMS (polydimethylsiloxane) or similar material mold can then be copied from the master. A PMMA (polymethylmethacrylate) microneedle array is formed by solvent-casting and then released from the mold.

[0143] To provide the arrays with electrical functionality, a Ti/Cu seed layer may be deposited on the PMMA array and patterned by excimer laser to electrically isolate adjacent rows. A Ni layer (e.g., about 15 to 30 microns or 20 to 25 microns thick) may be electroplated on the patterned seed layer to enhance structural rigidity. A backside electrical connection to the array may be formed by backside etching of a hole and forming an electrical connection through the hole.

[0144] In another variation, the microneedle array is arranged in a 16 X 16 array (i.e., 256 needles). Each needle has a height of about 400 microns and the base diameter is about 100 microns. The pitch between microneedles can be about 250 microns. The microneedle arrays are then coated with metal and laser-etched to provide electrical functionality. Optionally, rows of microneedles can be electrically isolated from each other so that

alternating rows can provide alternating electrical polarity. The arrays are also interfaced with a power source. Microneedles may be made of polymer, coated with a metal, and etched to act as alternating electrodes. In certain variations, the firing sequence of the microneedles by rows or groups may be varied or configured to alternate.

[0145] In certain variations, a microneedle array may include one or more microneedles having multiple channels. For example, a multichannel silicon microneedle may be constructed to deliver bioactive compounds into neural or other tissue while simultaneously monitoring and stimulating neurons and nerves.

[0146] FIG. 19 shows a cross sectional view of the skin 10 composed of an outer stratum corneum 15 covering the epidermis 16. The skin also includes the dermis 18, subcutaneous tissue/fat 12, and these layers cover muscle tissue 14. As shown in FIG 19, when a microneedle patch 228 is attached to a subject's skin, the microneedles 235 pierce the outer insulating stratum corneum layer 15. The microneedle patch 228 can detect current passing through a stimulated nerve, and provide a superior signal as the current detected is conducted through the microneedles 235, thereby bypassing the poorly conductive stratum corneum layer 15 which generally encompasses the outer 10 to 15 microns of skin. In other variations, microneedles 235 may be fabricated to be long enough to penetrate the stratum corneum 15, but short enough not to puncture nerve endings, thus reducing the risk of pain, infection or injury.

[0147] In certain variations, microneedles are formed such that they are in direct contact with their corresponding or overlying electrodes. For example, a microneedle patch may include an adhesive electrode pad and may utilize a conductive gel to help hold the microneedles in place to prevent shear forces from breaking or bending the microneedles.

[0148] In certain variation, as shown in FIGs. 20a-20d, a microneedle patch or applicator may include multiple electrodes on a single patch or applicator, e.g., positive, negative, and/or control or ground electrodes, where the microneedles will be grouped in multiple arrays such that they conduct to the appropriate electrode. For example, FIGS 20a and 20b show a single patch having positive, negative and control electrodes where a separate array of electrodes is in contact with each respective electrode. This arrangement can be created using a single patch. Alternatively, as shown in FIG. 20c, two patches may be implemented, one including the control electrode with corresponding microneedle array

and the other including the positive and negative electrodes with corresponding microneedle arrays. The various electrodes could be interchanged. Alternatively, as shown in FIG. 20d, three patches may be implemented, each having a separate electrode (control, positive, or negative) with a corresponding microneedle array. In use, in certain variations, the control may be attached above or near bone, while the positive and/or negative electrodes may be attached above nerve or muscle.

[0149] Referring again to FIG. 12, the energy emitting system 210 can be used to treat or prevent various conditions, e.g., urinary incontinence, restless leg syndrome and fecal incontinence, among others. Energy emitting system 210 includes one or more conductive coils 212 disposed within or along a housing 214, one or more sensors 216 configured to detect electrical conduction in the target nerve or to detect muscle stimulation, and a controller 218 coupled to the conductive coils 212 and optionally in communication with the sensor 216. The coils 212 are configured such that an electrical current generated by the controller 218 is passed through the coils 212 generating a magnetic field which will stimulate a target nerve, e.g., the tibial nerve 220, a muscle or other body part containing a portion of a target nerve, or any nerves branching off of a target nerve, located in proximity to the coils 212. In this particular variation, the housing 214 is in the form of a foot cradle, as shown in FIG. 4, however, the housing could also be in the form of a flexible wrap, garment or other design suitable for use with a subject.

[0150] Referring again to FIG. 12, energy emitting system 210 may be used to treat or prevent various conditions, e.g., urinary incontinence, restless leg syndrome or fecal incontinence. In certain variations, a method of using the energy emitting system 210 includes positioning a first portion of a patient's body, for example a foot, ankle, or leg, relative to housing 214 such that a posterior tibial nerve 220 within the first portion of the patient's body is in proximity to one or more conductive coils 212 disposed within or along the housing. In this particular variation, a patient's foot is positioned in a housing which is in the form of a foot cradle 215. A sensor in the form of a microneedle patch 228 may optionally be positioned along a second portion of the patient's body in proximity to the posterior tibial nerve 220. In this particular variation, microneedle patch 228 is attached to the patient's foot over a muscle to detect muscle stimulation. Alternatively, a patch could be placed elsewhere on the patient, for example, on the leg in proximity to the posterior

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 224

tibial nerve 220, proximal to and up-stream from coils 212. Microneedle patch 228 may be composed of one or more microneedle arrays and one or more electrodes, as described supra.

[0151] Once the patient's foot is in position and the microneedle patch 228 (e.g., conductive microneedle patch) is in place, a current is passed from controller 218 through coils 212, and as a result, the coils 212 generate a magnetic field which is focused on the posterior tibial nerve 220. The magnetic field stimulates tibial nerve 220, generating a current that will flow along the tibial nerve 220 and spread along its length, to its sacral or pudendal nerve roots. Microneedle patch 228 detects corresponding muscle stimulation or twitching or electrical conduction through the stimulated posterior tibial nerve. Upon detection, the microneedle array may conduct and transmit an electrical signal to the overlying electrode of microneedle patch 228. The signal may be transmitted to controller 218, which can be integral or a separate controller or device, or a separate controller coupled to controller 218. The controller can then be varied or adjusted (to adjust the current or magnetic field) based on the signal received from microneedle patch 228 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received. Although shown utilizing a sensor, it is also contemplated that the system could be used without a sensor.

[0152] Referring to FIG. 21, the method of using energy emitting system 210 described above with respect to FIG. 12 may be varied such that a conductive microneedle patch 228 is placed in proximity to or proximally over the afferent posterior tibial nerve 220, i.e., behind the patient's knee. In this position, a conductive microneedle patch 228 detects electrical conduction through the afferent posterior tibial nerve, i.e., it detects the electrical signal traveling through the posterior tibial nerve back up to the brain and spinal cord or it may detect corresponding muscle stimulation. The microneedle patch 228 sends the signal to controller 218 or to a separate controller coupled to controller 218. The controller can then be varied or adjusted based on the signal received from microneedle patch 228 to ensure that adequate conduction or stimulation of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received.

[0153] A sensor utilized in the energy emitting system 210 may be a microneedle patch 228 as described above or optionally the sensor may a sensor type known in the art (e.g.,

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 225

EKG sensor) or as described in any of the variations herein. It is also contemplated that energy emitting system 250 can be utilized without a sensor. Optionally, the sensor may be positioned within or along the housing, e.g., the foot cradle, along with the one or more conductive coils, or positioned at a site distant from the housing or conductive coils.

[0154] In certain variations, energy emitting system 210 my optionally include one or more conductive microneedle patches which can be positioned in proximity to the target nerve or muscle and provide an additional or supplemental electrical or magnetic stimulus to the target nerve or muscle.

[0155] Referring to FIG. 22, the energy emitting system 210 described above with respect to FIG. 12 may be varied to create energy emitting system 260. Energy emitting system 260 further includes one or more percutaneous electrode needles 262 or other needles or other percutaneous electrodes coupled to a controller 218 and having an end insertable into a subject's body in proximity to said target nerve or stimulation site. The percutaneous electrode needle 262 is inductively coupled to one or more conductive coils 212. In use, a first portion of a patient's body, for example a foot, ankle, or leg, is positioned relative to housing 214, e.g., foot cradle 215, such that a target nerve, e.g., posterior tibial nerve 220, located within the first portion of the patient's body is in proximity to one or more conductive coils 212 disposed within or along the housing 214. Conductive coils 212 are positioned proximate, optionally down-stream or distal to, a selected stimulation site 261. The percutaneous electrode needle 262 is inserted through the skin at a location and to a depth that brings the tip in close proximity to the stimulation site or target nerve to be stimulated. The controller 218 is activated and a current passes through conductive coils 212. The resulting magnetic field generates a current that traverses the internal stimulation site 261 by passing from conductive coils 212 to the internal percutaneous electrode needle 262, as indicated by arrow i. Also, the percutaneous electrode needle may be positioned within the generated magnetic field, whereby the magnetic field itself generates a current in the percutaneous electrode which stimulates a target nerve or traverses an internal stimulation site. Optionally, a current may be passed from the controller 218 through conductive coils 212 and/or from the controller 218 through percutaneous electrode needle 262, traversing the internal stimulation site as the current passes between the coils and needle.

[0156] In energy emitting system 260, current density and subsequent electric field intensity generated between conductive coils 212 and percutaneous electrode needle 262 is greater than that generated by traditional percutaneous stimulators. A greater electric field intensity makes site location for conductive coils 212 and percutaneous electrode needle 262 easier. Furthermore, the load impedance through the surface of the skin is much higher than the internal impedance, and as such, the relatively high load impedance lessens the likelihood of damage to tissue and nerves due to high current pulses.

[0157] Referring again to FIG. 22, a percutaneous electrode needle for use in any of the energy emitting systems described herein may include a variety of designs. For example, percutaneous electrode needle 262 may include a metal or plastic handle 263 to provide a secure grip for the user, while minimizing the risk of shock to the user. The needle tip can have a terminal portion 264 which may extend between about 0.5 and 10 mm or about 2.0 mm from the needle tip and may be constructed out of medical grade stainless steel or other biocompatible metals. The diameter of the needle can be small (less than about 0.25 mm) which minimizes trauma during insertion. Optionally, needle 262 can be coated with Teflon or similar insulative material 265 except for an exposed tip area 264. This allows for a higher field density at the tip for more precise operation. The exposed needle tip area 264 should have a sufficiently large surface area so as not to create too high a local current field that may cause irritation or pain.

[0158] In another variation, as shown in FIG. 23, percutaneous electrode needle 272 may be used in energy emitting system 260. Percutaneous electrode needle 272 may be constructed out of medical grade stainless steel or other biocompatible electrically conductive metal. Percutaneous electrode needle 272 includes a first end 276 for insertion into the patient's body in proximity to the preselected internal stimulation site or target nerve to be stimulated, and a second end 277. The size of the needle electrode 272 is preferably small, for example 34G needle electrode (0.22x10 mm), to minimize trauma during insertion. Percutaneous electrode needle 272 may also include an electrically conductive adaptor, e.g., an electrically conductive tape member 273. The tape member 273 includes an electrically conductive adhesive portion 274 and an electrically conductive non-adhesive portion 275. Alternatively, the adaptor may include an electrically conductive clip. The second end 277 of the needle electrode 272 preferably includes an enlarged portion to enable

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 227

the electrically conductive tape member 273 to be more easily adhered thereto. Once it is determined that the percutaneous needle electrode 272 is properly positioned, the needle is fixedly adhered to the electrically conductive tape member 273 by folding the ends of the adhesive portion 274 of the electrically conductive tape member 272 over the second end 277 of the needle electrode thereby forming an electrical connection there between. The percutaneous needle electrode 272 is electrically coupled to controller 218 via electrically conductive tape member 273. Various other implantable or insertable electrode needles known to persons of skill in the art may also be utilized in the above described systems.

[0159] In certain variations of energy emitting system 260 as described above and shown in FIGS. 22-23, a sensor 216, such as a conductive microneedle patch 228, may be utilized to detect electrical conduction through the stimulated posterior tibial nerve 220 or to detect muscle stimulation, and transmit the signal to controller 218. The signal may be transmitted to controller 218, a separate controller or device, or a separate controller coupled to controller 218. The controller can then be varied or adjusted based on the signal from microneedle patch 228 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received. It is also contemplated that energy system 260 may be utilized without a sensor 216, see for example FIGS. 24-25. Optionally, other types of sensors may be used in place of a microneedle patch sensor, such as other sensors described herein and sensors known to persons of ordinary skill in the art. The sensor may be placed over a portion of the subject's body suitable for detecting conduction of the target nerve (e.g., on the leg as shown) or over a muscle to detect muscle stimulation resulting from stimulating the target nerve.

[0160] In certain variations, as shown in FIG. 26, an energy emitting system 250 for providing a medical therapy includes a microneedle patch 252 (e.g., conductive microneedle patch) having one or more microneedle arrays deposited on a surface of one or more electrodes; one or more sensors 221 configured to detect electrical conduction in the target nerve or to detect muscle stimulation; and a controller 218 coupled to microneedle patch 252 and in communication with sensor 221. The microneedle patch 252 is configured such that an electrical current generated by the controller 218 is passed through the microneedle patch 252, generating a magnetic field or delivering or generating an electrical or magnetic stimulus to a target nerve, e.g., the tibial nerve 220, a muscle or other body part containing a

portion of a target nerve, or any nerves branching off of a target nerve, located in proximity to microneedle patch 252.

[0161] Referring to FIG. 26, a method of using the energy emitting system 250 may include placing a conductive microneedle patch 252 on a first portion of a patient's body, for example a foot, ankle, or leg, in proximity to posterior tibial nerve 220 within the first portion of the patient's body. Sensor 221 is positioned along a second portion of the patient's body in proximity to the posterior tibial nerve 220. In this particular variation, sensor 216 is attached to the patient's leg in proximity to the posterior tibial nerve 220, proximal to and up-stream from conductive microneedle patch 252. Conductive microneedle patch 252 is composed of one or more microneedle arrays and one or more electrodes, as described in the variations above.

[0162] Once conductive microneedle patch 252 and sensor 221 are in position, a current is passed from controller 218 through conductive microneedle patch 252, resulting in an electrical stimulus of the posterior tibial nerve 220. Alternatively, the microneedle array may be insulated or constructed of non conductive material such that the microneedle patch 252 generates a magnetic field that stimulates tibial nerve 220 in a manner similar to the one or more coils described in the variations above, without an electrical stimulus. Whether the stimulus is electrical or magnetic, either stimulus will generate a current that will flow along the tibial nerve 220 and spread along its length, to its sacral or pudendal nerve roots. Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then transmits the signal to controller 218. In certain variations, the sensor may be in the form of a microneedle patch sensor. The signal may be transmitted to controller 218, a separate controller or device, or a separate controller coupled to controller 218. The controller can then be varied or adjusted based on the signal from sensor 221 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received.

[0163] The sensor utilized in the energy emitting system 250 may be a sensor of the type described above, with respect to other variations. Optionally, for example, the sensor may be a microneedle patch. It is also contemplated that energy emitting system 250 can be utilized without a sensor. The sensor may be placed over a portion of the subject's body

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 229

suitable for detecting conduction of the target nerve (e.g., on the leg as shown) or over a muscle to detect muscle stimulation resulting from stimulating the target nerve.

[0164] In certain variations, energy emitting system 250 my optionally include one or more conductive coils disposed within or along a housing which can be positioned in proximity to the target nerve or muscle and provide an additional or supplemental stimulation of the target nerve or muscle.

[0165] Referring to FIG. 27, the energy emitting system 250 described above with respect to FIG. 26 may be varied to create energy emitting system 280. Energy emitting system 280 further includes one or more percutaneous electrode needles 262 coupled to a controller 218 and having an end insertable into a subject's body in proximity to said target nerve. Optionally, the electrode needle may be non-percutaneous, such that it is insertable in an orifice or opening in the subject, such as a natural orifice. The percutaneous electrode needle 262 is inductively coupled to conductive microneedle patch 252. In use, a microneedle patch 252 is placed on a first portion of a patient's body, for example a foot, ankle, or leg, in proximity to posterior tibial nerve 220 within the first portion of the patient's body and down-stream or distal to a selected stimulation site 261. The percutaneous electrode needle 262 is inserted through the skin at a location and to a depth that brings the tip in close proximity to the target nerve to be stimulated.

[0166] The controller 218 is activated and a current passes through microneedle patch 252 and traverses the internal stimulation site 261 by passing from microneedle patch 252 to the internal percutaneous electrode needle 262, as indicated by arrow i. The current passing through microneedle patch 252 may also generate a magnetic field which can generate a current that traverses the internal stimulation site 261 by passing from microneedle patch 252 to the internal percutaneous electrode needle 262. Also, the percutaneous electrode needle may be positioned within the generated magnetic field, whereby the magnetic field generates a current in the percutaneous electrode which stimulates a target nerve and traverses an internal stimulation site. Optionally, a current may be passed from the controller 218 through microneedle patch 252 and/or from the controller 218 through percutaneous electrode needle 262, traversing the internal stimulation site as the current passes between the patch and needle.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 230

[0167] Referring to FIG. 28, energy emitting system 280 may be modified by using percutaneous electrode needle 272 in place of percutaneous electrode needle 262. Percutaneous electrode needle 272 would be constructed and function as described above with respect to FIG. 23. Various other implantable or insertable electrode needles known to persons of skill in the art may also be utilized in the above described systems. Additionally, energy emitting system 280 may utilize a sensor to detect electrical conduction through the stimulated posterior tibial nerve 220 and send a corresponding signal indicative of the detected conduction to controller 218 or other device such that the electrical or magnetic stimulus can be adjusted as necessary. The sensor may be a sensor 221, or optionally the sensor may be a microneedle patch. It is also contemplated that energy emitting system 280 can be utilized without a sensor. The sensor may be placed over a portion of the subject's body suitable for detecting conduction of the target nerve (e.g., on the leg as shown) or over a muscle to detect muscle stimulation resulting from stimulating the target nerve.

[0168] In any of the above systems, variations are contemplated where the sensors are also coupled or connected to or otherwise in communication with energy emitting devices, e.g., the conductive coils or conductive microneedle patches.

[0169] In certain variations, the one or more microneedles of the microneedle patch may include an electrically conductive material such that the microneedles may transmit an electrical signal to an overlying electrode or other surface. Microneedles may be constructed of an electrically conductive material and/or coated with an electrically conductive material. Optionally, microneedles may be coated with an electrically conductive material and constructed of a non-conductive material. Microneedles may be fabricated using a variety of materials, e.g., metals, stainless steel, solid or coat of gold over NI, Pd or Pd-Co, Pt, silicon, silicon dioxide, polymers, glass, biocompatible polymers, titanium, silver, or suture materials. Biodegradable polymers may also be used such that if a tip of a microneedle were to snap or break off during insertion, it would easily biodegrade. Optionally, the microneedle patch may be non-conductive.

[0170] In certain variations, an electrode patch for improved conductance or conduction is provided. The patch can include at least one electrode having a first surface and/or a second surface. The electrode may optionally be attached to various other materials or adhesive materials. An array of microneedles may be deposited on a surface of the

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 231

electrode, or attached to a patch or other material and indirectly or directly connected to the electrode. The array of microneedles may include a conductive material. Such patches may be used as a sensor to detect muscle stimulation or electrical conduction, or to provide or deliver an electrical stimulus or magnetic field, e.g., to a target nerve, and may optionally be used in any of the variations described herein or in any application where improved conductance or conduction is desired. Microneedles yield improved reduction in impedance compared to simple abrasion and other techniques, and are less painful and more comfortable for the patient.

[0171] In certain variations, typical voltage sensed at the skin and detectable or conductable by a microneedle patch or microneedle array may range from about 1 to 400 microvolts or about 10 to 300 microvolts.

[0172] In certain variations, methods of treating a subject with urinary incontinence or various pelvic floor disorders utilizing the energy emitting systems described herein are contemplated. Symptoms associated with urinary incontinence may be observed, detected, or diagnosed. An energy emitting device having one or more energy generators, e.g., one or more conductive coils or one or more microneedle patches, may be positioned in proximity to a target nerve, e.g., the tibial or posterior tibial nerve or popliteal or sacral nerve or branches thereof of a subject or patient along a first portion of a subject's or patient's body. The subject may or may not be exhibiting symptoms associated with urinary incontinence. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to an energy emitting device such that a target nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device.

[0173] A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic or electromagnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof. This in turn may cause the stimulation of a pudendal nerve, sacral plexus, or other nerves in the pelvic floor. Various nerves innervating the various muscles, sphincters, nerves, organs and conduits of

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 232

the urinary tract and bladder may be stimulated directly or indirectly. In certain variations, a current is passed through one more coils, which generate a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain variations, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain variations, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

[0174] Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body. Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor in the form of a microneedle patch. In certain variations, the sensor may be positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other variations, the sensor may be positioned within or along a housing along with the one or more conductive coils.

[0175] Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of urinary incontinence by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with urinary incontinence. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 233

these symptoms include but are not limited to the inability to control urinary function, urinary leakage, and loss of bladder control.

[0176] In certain variations, the amplitude, frequency, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array may be adjusted. Optionally, the current may be varied according to a muscular response in the patient. Thus, to treat urinary incontinence, the magnetic field or electrical stimulus is applied to a subject or patient until the desired effects (e.g., reduction of symptoms) are achieved.

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

[0178] A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic or electromagnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof. This in turn causes the stimulation of a pudendal nerve, sacral plexus, or nerves in the pelvic floor. Various nerves innervating the various muscles, sphincters, rectum, nerves, organs and conduits associated with bowel movements, fecal control, and the intestines may be stimulated directly or indirectly. Optionally, a current is passed through one more coils, which generate a magnetic or electromagnetic field which stimulates the posterior tibial

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 234

nerve. In certain variations, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain variations, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

[0179] Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body. Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor is in the form a of a microneedle patch. In certain variations, the sensor may be positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other variations, the sensor may be positioned within or along a housing along with the one or more conductive coils.

[0180] Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of fecal incontinence by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with fecal incontinence. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited: the loss of voluntary control to retain stool in the rectum; loss of fecal control; inability to control bowel movements, and fecal leaking:

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 235

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

[0182] In certain variations, methods of treating a subject with restless leg syndrome utilizing the energy emitting systems described herein are contemplated. Victims afflicted with Restless Leg Syndrome (RLS or Ekbom's syndrome), are unable to remain seated or to stand still. Activities that require maintaining motor rest and limited cognitive stimulation, such as transportation, e.g., in a car, plane, train, etc., or attending longer meetings, lectures, movies or other performances, become difficult if not impossible. These sensations become more severe at night and RLS patients find sleep to be virtually impossible, adding to the diminishing quality of their lives. The urge to move, which increases over periods of rest, can be completely dissipated by movement, such as walking. However, once movement ceases, symptoms return with increased intensity. If an RLS patient is forced to lie still, symptoms will continue to build like a loaded spring and, eventually, the legs will involuntary move, relieving symptoms immediately.

[0183] Thus, symptoms associated with restless leg syndrome may be observed, detected, or diagnosed. An energy emitting device having one or more energy generators, e.g., one or more conductive coils or one or more microneedle patches, may be positioned in proximity to a target nerve, e.g., the tibial or posterior tibial nerve, or popliteal or sacral nerve or branches thereof or other nerves associated with restless leg syndrome, of a subject along a first portion of a subject's body. The subject may or may not be exhibiting symptoms associated with restless leg syndrome. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with restless leg syndrome, relative to an energy emitting device such that a target nerve within the first portion of the

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 236

body is in proximity to at least one energy generator disposed within or along the energy emitting device.

[0184] A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof or other nerves associated with restless leg syndrome. This in turn causes the stimulation of a pudendal nerve, sacral plexus or other nerves innervating the pelvic floor or various muscles, nerves, or organs associated with restless leg syndrome. The various nerves may stimulated directly or indirectly. Optionally, a current is passed through one more coils, which generates a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain variations, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain variations, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

[0185] Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body. Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor in the form a of a microneedle patch. In certain variations, the sensor may be positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other variations, the sensor may be positioned within or along a housing along with the one or more conductive coils.

[0186] Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 237

detected by the conductive sensor, in order to optimize or ensure adequate treatment of restless leg syndrome by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with restless leg syndrome. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited to: uncomfortable sensations in the limbs, irresistible urges to move, usually the legs; motor restlessness; when at rest, symptoms return or worsen; and symptoms worsen in the evening and at night.

[0187] In certain variations, the amplitude, frequency, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array may be adjusted. Optionally, the current may be varied according to a muscular response in the patient. Thus, to treat restless leg syndrome, the magnetic field or electrical stimulus is applied to a subject or patient until the desired effects (e.g., reduction of symptoms) are achieved.

[0188] In certain variations, methods of treating a subject suffering from premature ejaculation or various pelvic floor disorders utilizing the energy emitting systems described herein are contemplated. Symptoms associated with premature ejaculation may be observed, detected, or diagnosed. An energy emitting device having one or more energy generators, e.g., one or more conductive coils or one or more microneedle patches, may be positioned in proximity to a target nerve, e.g., the tibial or posterior tibial nerve or popliteal or sacral nerve or branches thereof of a subject along a first portion of a subject's body. The subject may or may not be exhibiting symptoms associated with premature ejaculation. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with premature ejaculation, relative to an energy emitting device such that a target nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 238

[0189] A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic or electromagnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof. This in turn may cause the stimulation of a pudendal nerve, sacral plexus, or other nerves in the pelvic floor or nerves associated with the control of ejaculation. Various nerves innervating the various muscles, sphincters, nerves, organs and conduits of the urinary tract, bladder or reproductive system, or pelvic floor may be stimulated directly or indirectly. Optionally, a current is passed through one more coils, which generates a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain variations, the positioning of the coils relative to the first portion of the subject's body may be adjusted to re-focus the magnetic field on the posterior tibial nerve as needed. In certain variations, a current is passed through a microneedle patch generating or delivering an electrical or magnetic stimulus or field. The positioning of the microneedle patch relative to the first portion of the subject's body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve as needed.

[0190] Optionally, electrical conduction through the target nerve, e.g., the posterior tibial nerve, or muscle stimulation can be detected via at least one sensor. A conductive sensor may be positioned in proximity to the posterior tibial nerve along a second portion of the subject's body. Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or twitching resulting from nerve stimulation. Optionally, the electrical conduction is detected along a second portion of the subject's body which is different from the first portion of the body. Optionally, the sensor in the form of a microneedle patch. In certain variations, the sensor may be positioned behind a subject's knee to detect the electrical conduction along the afferent posterior tibial nerve or on another portion of a patient's leg or foot. In other variations, the sensor may be positioned within or along a housing along with the one or more conductive coils.

[0191] Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of premature

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 239

ejaculation by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels for current, frequency, magnetic field, treatment duration, etc., are levels that result in an observed or detected reduction or prevention of symptoms associated with premature ejaculation. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited to: ejaculation that frequently occurs within one minute or less of penetration; the inability to delay ejaculation on penetrations; or persistent or recurrent ejaculation with minimal stimulation before, on or shortly after penetration.

[0192] In certain variations, the amplitude, frequency, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array may be adjusted. Optionally, the current may be varied according to a muscular response in the patient. Thus, to treat premature ejaculation, the magnetic field or electrical stimulus is applied to a subject or patient until the desired effects (e.g., reduction of symptoms) are achieved.

[0193] Exemplary treatment parameters for treating various conditions, e.g., urinary incontinence, using the systems and methods described herein may include the following. Operation of a conductive coil at about 10 to 20 hertz generating a magnetic field of about .25 to 1.5 tesla, where the coil is administered to a patient for a duration of about 30 minutes/day or 30 minutes per week, depending on the severity of the symptoms, until the symptoms subside. The above treatment parameters or variations on the parameters may be used for treatment of urinary incontinence, fecal incontinence, restless leg syndrome, or premature ejaculation or other conditions. For example, the coil may be operated at various parameter ranges falling with the following ranges: about 5 to 100 hertz, about 1 to 10 tesla, for about 15 minutes to 2 hours per day or week. In treating premature ejaculation, a patient may receive treatment about 4 to 10 hours prior to intercourse. A maintenance phase of treatment, after the initial treatment, may vary for various conditions. For example, the maintenance phase may require application of the systems and methods described herein at the parameters described herein for 30 minutes/week or 30 minutes/month. Any treatment parameter may be varied or modified based on the effect on the patient or sensor or patient

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 240

feedback regarding stimulation, until the desired result of treating or preventing a condition is achieved.

[0194] In certain variations, as shown in FIGs. 29a-29d, energy emitting device may include a controller 289 and a foot cradle 290. Foot cradle 290 may include vertical foot plate 291, and horizontal foot plate 292, where each plate can be adjusted using vertical foot plate knob 293 and horizontal foot plate knob 294. One or more EMG plugs 295 are provided. An air core coil 297 or other type of coil is provided. A display screen 296 may also be provided along with power cord 298. The display screen 296 can display a variety of information to the user and/or practitioner such as the level of power or current applied, treatment time, temperature of the cradle device, detected current levels and/or physiological parameters, etc., to facilitate effective and efficient therapeutic treatment. The information can be used to vary or adjust the controller to ensure that adequate conduction of a target nerve, e.g., posterior tibial nerve 220 or muscle stimulation occurs and an adequate and accurate dosage of treatment is being received. Controls may also be included to affect the following: power, field strength, frequency, pulse, start/pause and cancelation of therapy (as shown) or other parameters one of skill in the art would find necessary or useful to control or monitor. In certain variations, a sensor may be connected, connected or in communication with the foot cradle or other energy emitting apparatus, controller, housing , conductive coils, or microneedle patch.

[0195] In certain variations, as shown in FIGS 30A-30B, an energy emitting device may include a controller and a knee support or knee cradle. The cradle may be configured to provide the conductive coil in proximity to the popliteal fossa or area directly behind the knee. In certain variations, the knee cradle may be configured to cradle or surround at least a portion of the knee or substantially the entire knee without placing direct pressure on the popliteal fossa, thereby minimizing or avoiding venous thrombosis. In one variation, the device may be utilized while the knee is in the flexed position (Fig. 30A). In another variation, the device may be utilized while the knee is in a non-flexed position (Fig. 30B).

[0196] In certain variations, the energy emitting device, e.g., foot support or cradle, knee support or cradle, etc., includes a conductive coil positioned such that a target nerve is automatically targeted. The conductive coil is configured, sized and positioned within the device such that the generated magnetic field may encompass and stimulate the target nerve

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 241

in any patient based on the target nerve's anatomical location, thus providing automatic targeting of the nerve in any patient once the patient positions a particular body portion in the device.

[0197] In certain variations described herein, sensors may detect voltage or current and may be connected, coupled, wirelessly connected or coupled or otherwise in communication with housing, conductive coils, microneedle patch, energy emitting apparatus, energy generators, or electrode needles and/or controller using a variety of methods or techniques known in the art. In various variations described herein, housings, conductive coils, microneedle patches, energy emitting apparatus, energy generators, or electrode needles may be connected, coupled, wirelessly connected or coupled or otherwise in communication with each other, controllers or sensors, using a variety of methods or techniques known in the art.

[0198] Coils used in any of the variations described herein and illustrated in the corresponding figures may take on a variety of shapes, sizes, and configurations. For example, a coil may be shaped as a spiral (as shown) or have a simple helical pattern or be a figure eight coil, a four leaf clover coil, a Helmholtz coil, a modified Helmholtz coil, or may be shaped as a combination of the aforementioned coil patterns. Additionally, other coil designs beyond those mentioned hereinabove might be utilized as long as a magnetic field is developed that will encompass a target nerve.

[0199] The coils may have a variety of dimensions and configurations. In certain variations, a coil may have a central aperture. The diameter of the aperture may range from about 0.5 inch to 2 inches or 1 inch to 1.5 inches or the aperture may have a diameter of about 1 inch. The diameter of the coil body may vary. For example, the diameter may range from about 3.0 to about 7 inches or from about 4 to about 5 inches or the diameter may about 4.5 inches. The coil body may include any suitable number of turns. For example, the coil body may include from about 2 to about 25 turns or from about 10 to about 20 turns or 14 to 17 turns. The adjacent turns may be spaced apart from each other, providing a gap there between. An end or cross section of a turn may have various dimensions. For example, the end or cross section may have a height that is greater than its width. An end or cross section of a turn may have a height ranging from about 1 to 5 cm or from about 10 mm to 51 mm (about .3 inches to 2 inches) or about 25 mm to 40 mm (about 1 inch to 1.5 inches) or about 12 mm to 40 mm (about .5 inch to 1.5 inch) or about .5 inch to

2 inch. The end or cross section of the turn may have a width ranging from about 0.5 mm to about 5mm (about .019 inch to .19 inch) or from about 1mm to about 2 mm (about .03 inch to .07 inch) or about .2 mm to about 1.6 mm (about .01 inch to .06 inch). The above are all exemplary dimensions, where other dimensions are also contemplated depending on the use and configuration of a device.

[0200] In certain variations, a system or device for electromagnetic or magnetic induction therapy may include one or more conductive coils disposed within or along an applicator. The coil may be configured to generate an electromagnetic or magnetic field focused on a target nerve, muscle or other body tissue positioned in proximity to the coil. The system may also include one or more sensors. The sensor may be configured to detect electrical conduction in the target nerve or to detect stimulation of a muscle or other body tissue. The sensor may also detect a muscular response caused by an electrical conduction in a target nerve. The sensor provides feedback about the efficacy of the applied electromagnetic or magnetic induction therapy. Optionally, a user may provide such feedback based on detection by the user, with or without the use of a sensor. The system may also include a controller which is in communication with the sensor. The controller may be adjustable to vary a current through the coil in order to adjust the magnetic field focused upon the target nerve based on feedback from the sensor or user. The various systems or devices described herein may be utilized with or without a sensor.

[0201] A variety of electromagnetic or magnetic induction applicators designed or configured to stimulate various portions of a patient's body for treating various conditions are contemplated herein.

[0202] Figure 31A illustrates a variation of a hand or arm applicator 310. The hand or arm applicator 310 may be ergonomic or contoured to a hand or arm to be positioned relative to or in proximity to a hand or arm to generate an electromagnetic or magnetic field focused on a target nerve, muscle or other tissue within the hand or arm. Optionally, a hand or arm applicator 310 may be designed to stimulate the entire hand or arm of a patient, for example, where the patient has limited or reduced nerve innervation to those portions of the body.

[0203] Figure 31B also illustrates a variation of a foot, knee or leg applicator 320. The foot, knee or leg applicator 320 may be ergonomic or contoured to a foot, knee or leg to be

positioned relative to or in proximity to a foot, knee or leg to generate an electromagnetic or magnetic field focused on a target nerve, muscle or other tissue within the foot, knee or leg. Optionally, a foot, knee or leg applicator 320 may be designed to stimulate the entire foot, knee or leg of a patient, for example, where the patient has limited or reduced nerve innervation to those portions of the body.

[0204] Figure 32 illustrates a variation of a stand alone back applicator 330. The back applicator 330 may be ergonomic or contoured to the back or to a specific area of the back to be positioned relative to or in proximity to the back to generate an electromagnetic or magnetic field focused on a target nerve, muscle or other tissue within the back. A back applicator 330 may be aligned along the spine or positionable in proximity to the spine. The back applicator 330 may be utilized to stimulate nerve offshoots, dorsal ganglion, the spinal cord itself or any other nerve in the body, to treat various conditions, for example, to treat atrophy or paralysis.

[0205] The back applicator 330 may include several coils, which may be pulsed intermittently. In certain variations, a sensor may be placed on muscle in dermatome to provide feedback to ensure stimulation of the proper dorsal root ganglion or vertebral body. The sensor may provide feedback to channel energy or current to the proper or effective coil in an applicator, e.g., in an applicator having multiple coils.

[0206] Figure 33 shows a system including a corded back applicator 340, a sensor 342 and a logic controller 344. Various sensors may be utilized, e.g., a three lead EMG, other EMG electrode, a microneedle electrode, or any sensor for detecting physiologic changes associated with nerve firing and/or muscle contraction. The sensor 342 provides feedback which may be used to monitor and/or control therapy. The sensor 342 may be used to position or optimize therapy in a clinic or home healthcare setting. The applicator 340 may or may not contain a pulse generator and/or logic controller circuitry. Figure 33 shows the logic controller 344 and pulse generator as a separate unit. The logic controller may optimize therapy and minimize energy usage or overheating based on feedback from sensor 342. Optionally, the logic controller 344 may be incorporated into an applicator. The logic controller 344, whether separate from the applicator or incorporated in the applicator, may be controlled based on feedback from the sensor.

[0207] Figure 34 shows a system including a whole back applicator 350, a sensor 352 and a logic controller 354. One or more back applicators 350 may be provided. One or more applicators 350 may include automated therapy targeting. The applicators 350 may include multiple coils, which can be fired sequentially to stimulate the entire spine or chain of dorsal root ganglion (with or without user or sensor feedback) for osteoarthritis therapy, back or neck pain therapy, prevention of muscular atrophy and/or nerve recovery after paralysis, stroke, or after suffering other nerve damaging conditions. In one variation, one or more applicators 350 may include multiple coils fired sequentially in order to determine the optimal coil for stimulation based on user or sensor feedback. Once the optimal coil is determined, that coil may be selected and used for the remainder of the therapy. In another variation, one or more applicators may include one or more coils that are slidable, adjustable or movable within the applicator housing. The coils may be moved within the applicator housing to treat a large area and/or to be focused on the optimal treatment zone based on feedback from the user and/or feedback from the sensor.

[0208] Figure 35 shows a variation of a back applicator 360 which may be positioned in proximity to or aligned along a spine. The back applicator 360 may have ergonomic features or may be placed in proximity to a spine or a spine may be positioned in proximity to the applicator 360. The applicator 360 may include several coils that are pulsed intermittently. As shown in Figure 35, the back applicator 360 or focused back applicator may me held on a patient by an ergonomic positioning element 361 (e.g., a belt) and may be fit such the cervical, thoracic, lumbar, sacral and/or lumbosacral curvatures hold the back applicator 360 in the optimal position. The applicator 360 may be located anywhere along the positioning element 361 depending on the individual and area to be stimulated. Optionally, a sensor lead 362 may be placed over musculature or along a nerve excited by activation of the applicator 360. In one variation, a coil power line 365 for supplying power or current from the logic controller 364 to coils positioned in the applicator 360 may include fluid cooling, e.g., air or liquid cooling.

[0209] Figure 36 shows an applicator 366 designed or configured to generate a magnetic field focused on a target nerve responsible for phantom or neuropathic pain. The applicator 366 or phantom pain therapeutic stimulator unit may be utilized to treat phantom pain or neuropathic pain, to provide phantom pain or neuropathic pain therapy. The applicator 366

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 245

may be ergonomic or contoured to be positioned relative to or in proximity to a nerve responsible for phantom or neuropathic pain.

[0210] Figure 37 shows a facial neuralgia applicator 380. Facial neuralgia applicator 380 may be may be ergonomic or contoured to a face or head to be positioned relative to a face or head to stimulate a nerve responsible for facial neuralgias. The applicator 380 may be designed or configured to be positioned relative to, in proximity to or on a patient's face or head and to generate a magnetic field focused on nerves responsible for facial neuralgias, e.g., the trigeminal nerve, to treat facial neuralgia. Optionally, a sensor may be positioned along a facial nerve to ensure adequate therapy and to provide feedback, e.g., to a logic controller, regarding nerve conduction or body stimulation.

[0211] In certain variations, an applicator may be designed to ergonomically target common nerves responsible for common neuralgias in order to treat such neuralgias. In other variations, an applicator may be used for treating neuralgias virtually anywhere on a patient's body, including in deep nerves due to the ability of magnetic fields generated by the applicator to penetrate painlessly. In certain variations, an applicator may be designed to generate a magnetic field focused on a target nerve to treat central or peripheral neuralgias.

[0212] Figure 38 shows a depression applicator 386 which is designed or configured to be positioned relative to, in proximity to or over a frontal cortex. The applicator 386 may be ergonomic or contoured to a head to be positioned relative to a head to stimulate the frontal cortex. The applicator 386 may generate an electromagnetic or magnetic field focused on the frontal cortex to treat depression. A sensor may be positioned in the offshoots of the motor cortex. The sensor may provide feedback to ensure appropriate placement of the applicator 386 or coil. In one variation, the applicator 386 may include a therapeutic coil and a targeting coil (e.g., a small non-treatment coil), which may be positioned a certain distance behind the therapeutic coil, e.g., about 5 cm behind the therapeutic coil. When firing of the targeting coil is sensed by the sensor (or user-feedback), the therapeutic coil may be positioned in the correct or optimal position over the frontal cortex for depressive therapy.

[0213] Figure 39 shows a migraine applicator 390 which is designed or configured to be positioned relative to, in proximity to or over an occipital nerve. The applicator 390 may be ergonomic or contoured to a face or head to be positioned relative to a face or head to

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 246

stimulate the occipital nerve. The applicator 390 may generate an electromagnetic or magnetic field focused on the occipital nerve to halt, prevent or treat migraines. The applicator 390 may have an ergonomic design to ensure appropriate placement over the occipital nerve. In one variation, the applicator 390 may be a single (or few) pulse device. The applicator 390 may be in a portable format. The applicator 390 may also be without any significant cooling features. Optionally, the applicator 390 may have cooling features. In another variation, an applicator may be a multiple pulse, higher frequency device. Such an applicator may include cooling features, where cooling is provided by utilizing liquids or airflow, such as rapid airflow to cool the coils or applicator.

[0214] Figure 40 shows a variation of an applicator 396 in the form of a stimulatory coil platform which may be ergonomic and contoured to a knee. The applicator 396 is configured to be positioned relative to or in proximity to a knee or the applicator 396 is configured such that a knee may be positioned relative to or in proximity to the applicator 396. The applicator 396 may be configured to generate an electromagnetic or magnetic field focused on the popliteal nerve for peripheral nerve stimulation to treat various conditions, e.g., overactive bladder, neuropathic pain or restless legs. In one variation, a stimulatory coil may target an area behind a patient's knee or the popliteal fossa, and the knee may be rested on a stimulatory coil platform applicator in any position.

[0215] In certain variations, an applicator may include one or two (bilateral) magnetic field generating coils, which may be positioned around the knee when the patient is in a sitting, standing or prostrate position. In certain variations, a pulse generator or logic controller 397 may send energy through one or more coils to create an electromagnetic or magnetic field. The applicator or coils may generate stimulatory or non-stimulatory fields. Sensor or user feedback may provide feedback to logic controller to optimize therapy, e.g., with the stimulatory fields. An applicator may be utilized for generating magnetic fields focused on an area of a patient's body, e.g., the knee, to treat various orthopedic indications, e.g., knee pain or osteoarthritis. An applicator may be utilized for generating magnetic fields focused on a area of a patient's body to treat various non-orthopedic indications, via, e.g., peripheral nerve stimulation.

[0216] Figures 30A-30B, show a variation of an applicator 400 which may be utilized for popliteal nerve stimulation and/or treatment of the knee. The applicator may be designed

or configured to generate an electromagnetic or magnetic field focused on the popliteal nerve for popliteal nerve stimulation or on the knee for treating osteoarthritis. The applicator is configured to be positioned relative to or in proximity to a knee or the applicator is configured such that a knee may be positioned relative to or in proximity to the applicator. A leg may rest on the applicator coil or be positioned above it. Optionally, as shown in Figure 30B, a foot rest 104 may be provided for holding up a foot.

[0217] Figure 41 shows a system including a variation of an ergonomic back applicator 410 held on a patient's body by an ergonomic positioning element 411 in the form of a shoulder harness. A sensor 412, and a logic controller 414 are also provided. The applicator 410 may include various positioning elements 411, e.g., a shoulder harness, an upper torso garment, or an ergonomic back-countered plate. The applicator 410 may be stimulatory or non-stimulatory. In another variation, an applicator may be rested on a seat or chair such that a stimulatory coil reliably overlies the area of the patient's body requiring stimulation. In certain variations, one or more coils may be fixed on the applicator (requiring prior targeting by a healthcare provider or patient) or one or more coils may move freely within or along the applicator and may be locked into position when the desired or optimal position is located. Coils may also move automatically in order to optimize targeting of the coil based on sensor or user feedback. The system may be incorporated into a single unit or, as illustrated, have at least two components including a separate logic controller.

[0218] For any of the applicators described herein, such applicators may include one or more of the following features. The applicators may be ergonomic or contoured to the specific region of the body or anatomy to which the applicator will be delivering stimulation. The applicators may be configured or designed to be positioned relative to, on, around, or in proximity to a specific region of the body or the applicators may be configured or designed such that the targeted region of the body may be positioned relative to, on, around or in proximity to the applicator. The applicators may be openable or adjustable to allow for insertion or entrance of the targeted body part or anatomy into the applicator or to allow for placement of the applicator onto or around the targeted body part or anatomy. The applicators may be flexible or ergonomic to accommodate nearly any type of body habitus. In certain variations, a solenoid-type coil may incorporated into an applicator for delivering PEMF stimulation directly to the targeted areas or regions of a body. In certain variations,

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 248

any of the applicators described herein may approximate the respective targeted body area or anatomy or the applicators may be designed such that the body region or targeted anatomy may approximate the applicator.

[0219] In certain variations, any of the applicators or systems described herein may be used to provide electromagnetic or magnetic induction therapy with or without a sensor.

[0220] In certain variations, electromagnetic stimulating devices or applicators for providing stimulation to tissues of the human body, including nerves, muscles (including superficial and deep muscles), and/or other body tissues for the treatment of various conditions, including, e.g., chronic and acute pain, are provided.

[0221] The devices may utilize an inductive coil encased within an ergonomic, body-contoured applicator to target specific regions of the body. The coils may be designed to target peripheral nerves throughout the body that have been implicated or involved in pain syndromes.

[0222] The various designs and configuration of the devices described herein allow for easier application, more consistent therapy and home use while targeting anatomic regions with therapeutic pulsed electromagnetic fields. The fields may also be delivered or applied in an intermittent manner to allow for convenience and ease of use while providing a durable benefit. With intermittent external stimulation by pulsed electromagnetic or magnetic fields, a nerve or other tissues may be stimulated in manner that provides a continued and lasting effect on nerve, muscle or tissue function, without habituation.

[0223] The electromagnetic or magnetic induction stimulation devices described herein substantially improve the state of the art electromagnetic stimulation technology and may incorporate the delivery of PEMF therapy into a user friendly, body contoured applicator. In certain variations, a delivery system for PEMF therapy may include elements such as, e.g., (1) an ergonomic, body contoured applicator which provides for repetitive application and consistent therapy onto the same body area. The applicator may be coded with clear markings to facilitate repetitive and consistent therapy onto the same body area; (2) the use of a sensor to provide feedback that stimulation is occurring effectively; and/or (3) the use of intermittent stimulation to effectively treat various conditions, e.g., chronic pain, without habituation. These elements individually or the various combinations of these elements

have provided for an easy to use, ergonomically designed system that has applications within a host of clinical and home ease of use health applications.

[0224] In certain variations, an electromagnetic or magnetic induction stimulation device able to provide stimulation to tissues of the human body, including nerves, muscles (including superficial and deep muscles), and/or other body tissues without significant discomfort to the patient is provided. Conductive stimulating coils may be encased in an ergonomic, body-contoured applicator that is coded with clear markings to provide for repetitive application and consistent therapy onto the same body area. The design of the applicator allows for ease of use and also for the targeting of anatomic regions to be exposed to the impulses of the PEMFs. The electromagnetic stimulating device may provide PEMF in a manner that is patient user friendly and the device may be portable. The device may be utilized in a hospital, an outpatient clinic, a therapist's office, or at a patient's home.

[0225] In certain variations, an electromagnetic or magnetic induction stimulation device may stimulate regions of the body to treat conditions requiring both maximal stimulation (i.e., sufficient to cause contraction of muscle fibers and firing of nerves) as well as submaximal stimulation (which will be sufficient to provide therapy but not to cause contraction of muscle fibers).

[0226] The electromagnetic or magnetic induction or stimulating devices described herein may be utilized for various indications. The indications may be divided into maximal and submaximal categories, in which the former requires significantly higher levels of inducting current than the latter. The maximal applications of the device include, but are not limited to: Non-invasive stimulation (intermittent or continuous) of the peripheral nervous system for treating chronic pain; stimulation of a nerve for the up- or down-regulation of hormones or cellular proliferation; treatment and/or prevention of atrophy, which would be therapeutic during recovery after an individual sustains a fracture, experiences paralysis of a limb or other body part, or undergoes surgery, such as ACL repair in the knee; treatment of neurogenic or overactive bladder and bowel; and stimulation of the central nervous system to alter neural pathways or up/down-regulate the aforementioned factors.

[0227] Additional applications of the devices include but are not limited to: treatment of neuropathic pain (e.g., phantom pain in limbs or other neurologic pain) or orthopedic pain

(back and neck pain or skeletal related pain); treatment of overactive bladder and bowel; and treatment of arthritis and/or orthopedic conditions.

[0228] In certain variations, a device is provided for delivering PEMF stimulation to selective anatomic regions of the body, utilizing an ergonomic applicator designed to facilitate accurate and targeted delivery of therapy. The applicator may be coded with clear or solid markings to provide for repetitive application and consistent therapy onto the same body area of the body. This design may facilitate the placement of the device for the stimulation of key nerves, muscles, and/or body tissues.

[0229] In certain variations, a device is provided which may be utilized to electromagnetically stimulate selective nerves, muscles, and/or body tissues, where the device is user friendly and capable of being used even by an unskilled patient in a home healthcare setting.

[0230] In certain variations, a device is provided to electromagnetically stimulate selective nerves, muscles, and body tissues to provide consistent therapy, with an ergonomic applicator targeting key nerves and eliminating the requirement for a highly trained operator to manipulate the device.

[0231] In certain variations, an electromagnetic or magnetic induction system or device may be configured or designed to provide intermittently applied pulsed magnetic fields in the treatment of chronic conditions, such as pain. For example, a device as described herein may provide shorter, intermittent stimulation to treat chronic pain or other chronic conditions. The delivery of pulsed magnetic fields may have a continued and lasting effect on nerve function in treating conditions, such as, overactive bladder as well as other chronic neurological and orthopedic conditions such as neuropathic pain, restless legs and orthopedic pain (e.g., spinal pain, back pain, etc.)

[0232] In certain variations, intermittent pulsed magnetic fields may be utilized for the treatment of chronic and acute non-orthopedic conditions such as neuropathic pain, phantom pain and chronic neuralgias, as well chronic and acute orthopedic conditions, such as back pain and neck pain. The therapeutic magnetic fields may be applied frequently (e.g., several times a day) or less frequently (e.g., once a week or once a month) depending on the durability of the effect for the individual patient. Treatment involving the use of magnetic fields does not require surgery or needles to stimulate a nerve. Also, the deliver of

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 251

intermittent pulsed magnetic fields prevents the nerve from becoming habituated to the stimulator signal by ensuring that there are periods during which the nerve is not subjected to the stimulatory signal. Accordingly, the electromagnetic or magnetic induction systems or devices described herein may provide unparalleled ease of use, non-invasiveness, reliability of therapy based on sensor feedback and/or ergonomic targeting, and/or a lack of habituation due to intermittent stimulation provided by certain systems and devices.

[0233] In certain variations, the electromagnetic or magnetic induction systems or devices described herein may incorporate an air-cooled coil wherein the air coolant, e.g., liquid or air, is drawn through and/or in between the turns of the inductive coil, in direct contact with conductive surfaces of the coil. Drawing air or other fluid through the coil prevents the coil from heating up to the degree that could damage the coil and the electronics of a device, or expose the patient to excessive temperatures.

[0234] In certain variations, the systems and devices described therein may be utilized to stimulate nerves for a variety of conditions, including, e.g., atrophy prevention, nerve repair/regeneration, neuromodulation, chronic pain, up or down regulation of hormones, restless legs, phantom pain, etc. The systems and devices may also be used to stimulate muscles and/or other body tissues to accelerate tissue healing, regeneration and/or growth.

[0235] In certain variations, the electromagnetic or magnetic induction systems or devices described herein and other implantable or extracorporeal devices may allow for the automatic adjusting of nerve stimulation based on feedback.

[0236] In one variation, an extracorporeal or implantable device, e.g., any of the electromagnetic or magnetic induction devices described herein, a pacemaker, defibrillator, or nerve stimulator, may include a feature that allows for automatic adjustment of nerve stimulation based on feedback provided by a sensor or user. This feature may minimize pain and power usage while ensuring optimal therapy delivery. A device may include a stimulator and a sensing component. The stimulator may be automatically adjustable based on feedback from the sensor up to a maximal (safe) threshold. Each therapy may start with lower powered pulses, followed by increasing power pulses until the sensor detects stimulation. The algorithm allows for the minimal amount of power to be used and allows for automatic adjustment of power settings as conditions change.

[0237] In one variation, an implantable device may include a sensor, such that the device can stimulate tissue or nerves and sense stimulation at the same site. For example, the sensor may provide feedback to the implantable device regarding nerve conduction at the site of stimulation. As fibroses develops around an implant, at the site of stimulation, the feedback will indicate whether a target nerve is no longer being effectively stimulated due to the fibroses, which will cause the power or level of stimulation to increase or decrease, as is necessary, to effectively stimulate the target site and overcome any obstruction due to fibroses. As fibroses occurs around an implant, a patient need not report back to a physician or other operator for adjustment of the stimulatory power of the device. The device will automatically adjust the stimulatory power or level based on sensing stimulation of the target nerve or tissue. This eliminate the guesswork involved by the user in monitoring their therapy one day at a time on their own, as they notice the effect of the therapy wear off. This also eliminates the risk of the user being exposed to unnecessarily high power levels that might otherwise by set in order to minimize frequent return visits to a physician or operator for adjustments.

[0238] Figures 42A and 42 show an example of how the amount of stimulatory power required to achieve a desired stimulus may be automatically adjusted as a result of fibroses, according to the above described feature. According to Figure 42A, after the initial implant of the device, the level of stimulatory power is increased until stimulation of the target nerve or tissue is sensed (indicated by square box at, e.g., about 10mV). An effective stimulatory therapy may then be delivered. According to Figure 42B, after fibroses sets in, in order to maintain the desired level of stimulation to provide an effective stimulatory therapy, the level of stimulatory power is increased until stimulation of the target nerve or tissue is sensed (indicated by square box, e.g., at 20 mV). According to the example in Figure 42B, the presence of fibroses required an increase in the stimulatory power level to deliver an effective stimulatory therapy.

[0239] The automatic adjustment feature based on sensor feedback may be utilized in any stimulator or non-stimulatory implant or extracorperal device, where the device incorporates a sensor capable of detecting the desired stimulus and a feedback loop capable of automatically adjusting parameters (e.g., power, frequency, etc.) to ensure appropriate stimulation.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 253

[0240] In certain variations, the electromagnetic or magnetic induction systems or devices described herein and other implantable or extracorporeal devices may include a feature that allows for automatic targeting of coils.

[0241] A device may include multiple inductive coils or one or more movable inductive coils. The device may also include a sensor based feedback algorithm. In one variation, the device includes a targeting or movable coil which may be positioned over or in proximity to a patient's body at a site that elicits a response that can be sensed automatically or detected by a user. Once this response is detected, the coil may either move to its stimulation position, or in the event that a small targeting coil is used, the therapeutic coil may already overlie the treatment area. Once the response is detected, the therapy may automatically begin.

[0242] In one example, relating to the treatment of depression, the motor cortex is stimulated until the thumb is seen to move. The coil may then be advanced, e.g., about 5 cm. to about 5 inches, forward to a position over the frontal cortex. This feature eliminates the guesswork that may otherwise be involved in moving or positioning a coil, and automates therapy based on user feedback or EMG senor or other sensor feedback, e.g., over a thumb.

[0243] Figure 43A shows an example of a device 420 positioned on a skull. The device includes a treatment coil 422 and a targeting coil 423. The treatment coil 422 may be positioned by EMG detection with targeting coil 423 stimulation, where the targeting coil may not move.

[0244] In another variation shown in Figure 43B, an ergonomic fixture or applicator 430 (e.g., a helmet) may be worn and a coil 432 positioned on the applicator may slide or move from its targeting position to its therapeutic position automatically or by user intervention.

[0245] The feature that allows for automatic targeting of coils may be utilized in any device designed to stimulate nerve, body or other tissues with stimulatory or sub-stimulatory fields in which the device may be targeted based on a detectable signal or response.

[0246] Other conditions that may be treated utilizing the various electromagnetic or magnetic induction stimulation systems and methods described herein include but are not limited to: pelvic pain, interstitial cystitis, fibromyalgia, chronic fatigue and preterm labor,

pain syndromes, Irritable Bowel Syndrome, Vulvodynia, Herpetiuc neuralgia, trigeminal neuralgia and Myofascial pain.

[0247] EXAMPLES

[0248] The following Examples are provided for illustration, not limitation. One with skill in the art would be able to use these examples as guidelines for making and using comparable devices.

[0249] In each example, intermittent therapy should be applied and symptoms/scores tracked for a minimum of 6 weeks in order to determine the full extent of the therapies effect.

[0250] Example 1: Empirical Testing of Efficacy in the Treatment of Neuropathic Pain: The optimal stimulus intensity for neuropathic pain treatment; the optimal application parameters, i.e. frequency of stimulation, duration of treatment, location of stimulatory coils in each disposable array of coils; and the optimal coil diameter/placement within the strays can be determined using the following experimental protocol: Before, during and after treatment, patients will report scores of neuropathic pain after weekly stimulation over a minimum of 6 weeks.

[0251] Example 2: Empirical Testing of Efficacy in the Treatment of Neuromuscular Pain: The efficacy of neuromuscular pain treatment can be tested by monitoring patient reported pain scores. A standardized scale may be utilized and, when feasible, local biopsy and blood tests can be useful in determining the impact of the therapeutic fields on circulating factors and local mediators. The optimal pulse amplitude, duration, site of stimulation will be assessed based on reported pain scores and diagnostic tests.

[0252] Example 3: Empirical Testing of Efficacy in the Treatment of Orthopedic conditions (i.e., Arthritis, Back pain and neck pain): The efficacy of arthritis treatment can be tested by monitoring patient reported functionality scores. A standardized subjective functionality scale may be utilized and, when feasible, local biopsy may be useful in determining the impact of the therapeutic fields on the cartilage and arthritic regions treated. As cartilage destruction is a well-studied side-effect of arthritis, reduction of this degeneration will be a valuable marker for efficacy of therapeutic treatments. The optimal pulse amplitude, duration, site of stimulation will be assessed based on reported functionality scores and diagnostic tests. Pain scores may also be measured to determine the

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 255

device's impact on orthopedic conditions such as back pain, neck pain, etc. A standardized pain scale may be used before and after treatment to determine potential benefit.

[0253] It is also contemplated that any of the energy emitting systems or devices described herein can be used with or without a sensor for detecting conduction of a stimulated nerve or muscle of tissue stimulation resulting from the electromagnetic or magnetic field generated by the conductive coil and delivered to a patient or an electrical stimulus delivered to a patient. Also, in any of the above variations, a controller may optionally be connected, coupled, integral to or otherwise in communication with the conductive coils and/or the sensor. Optionally, the sensor may be connected, coupled, integral to or otherwise in communication with the conductive coil.

[0254] Each of the individual variations described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other variations. Modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present invention.

[0255] Methods recited herein may be carried out in any order of the recited events which is logically possible, as well as the recited order of events. Furthermore, where a range of values is provided, every intervening value between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. Also, any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein.

[0256] All existing subject matter mentioned herein (e.g., publications, patents, patent applications and hardware) is incorporated by reference herein in its entirety except insofar as the subject matter may conflict with that of the present invention (in which case what is present herein shall prevail). The referenced items are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such material by virtue of prior invention.

[0257] Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 256

singular forms "a," "an," "said" and "the" include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs.

[0258] This disclosure is not intended to be limited to the scope of the particular forms set forth, but is intended to cover alternatives, modifications, and equivalents of the variations described herein. Further, the scope of the disclosure fully encompasses other variations that may become obvious to those skilled in the art in view of this disclosure. The scope of the present invention is limited only by the appended claims.

CLAIMS

What is claimed is:

1. A system for electromagnetic induction therapy comprising:

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

at least one sensor configured to detect electrical conduction in the target nerve or to detect a muscular response caused by an electrical conduction in the target nerve, the sensor configured to provide feedback about the efficacy of the applied electromagnetic induction therapy; and

a controller in communication with the at least one sensor, where the controller is adjustable to vary a current through the at least one coil so as to adjust the magnetic field focused upon the target nerve.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 258

ABSTRACT OF THE DISCLOSURE

In certain variations, systems and/or methods for electromagnetic induction therapy are provided. One or more ergonomic or body contoured applicators may be included. The applicators include one or more conductive coils configured to generate an electromagnetic or magnetic field focused on a target nerve, muscle or other body tissues positioned in proximity to the coil. One or more sensors may be utilized to detect stimulation and to provide feedback about the efficacy of the applied electromagnetic induction therapy. A controller may be adjustable to vary a current through a coil to adjust the magnetic field focused upon the target nerve, muscle or other body tissues based on the feedback provide by a sensor or by a patient. In certain systems or methods, pulsed magnetic fields may be intermittently applied to a target nerve, muscle or tissue without causing habituation.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 259

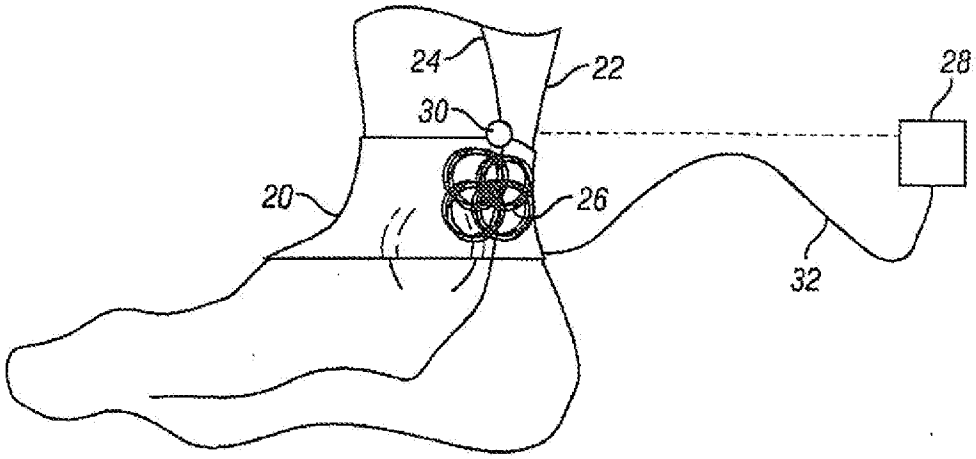


FIG. 1

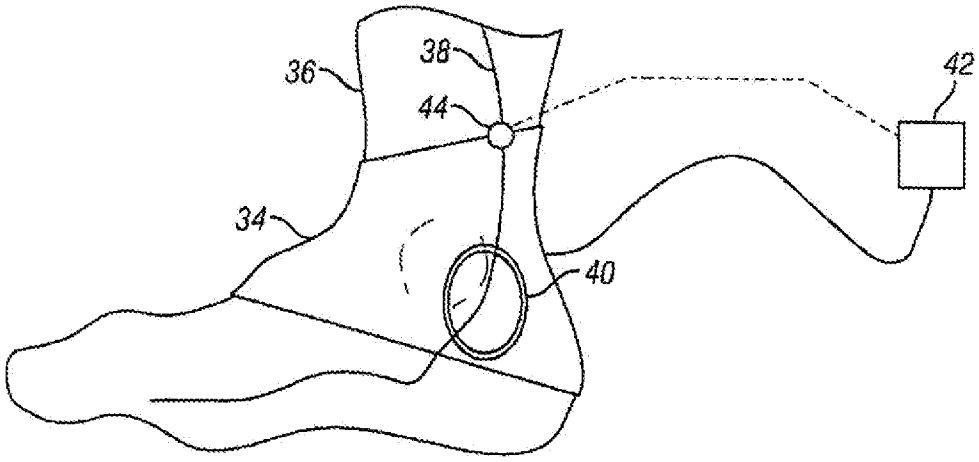


FIG. 2

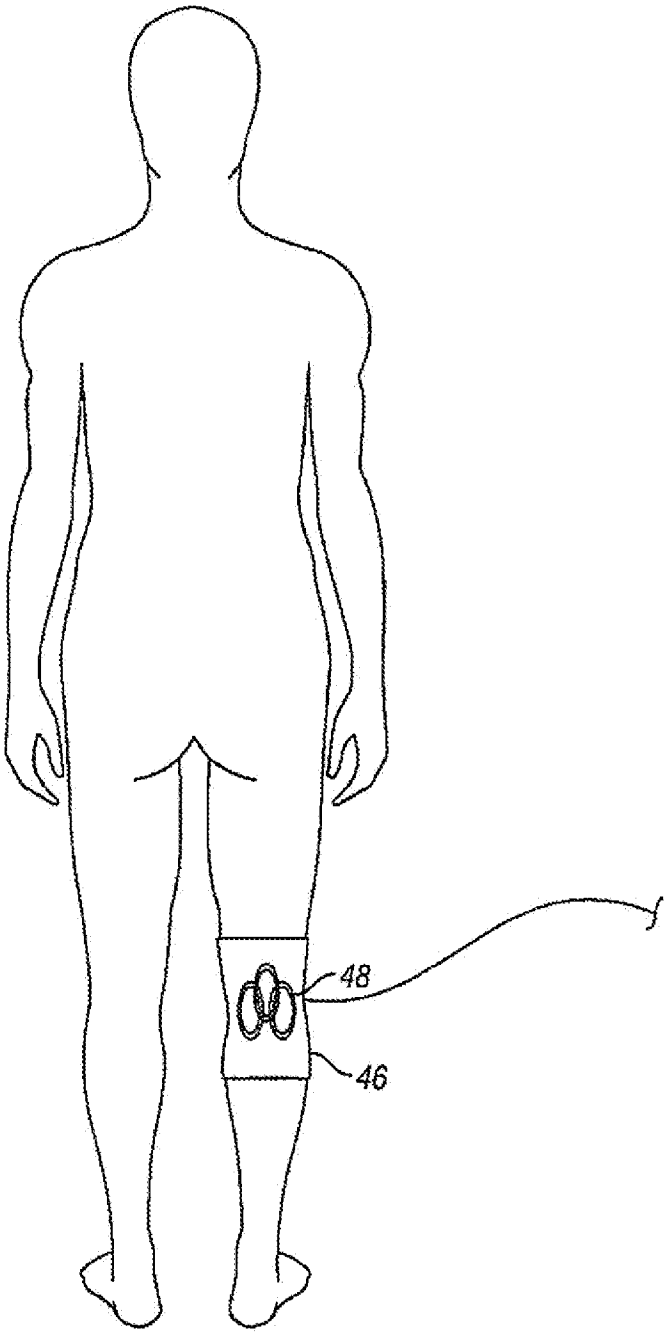


FIG. 3

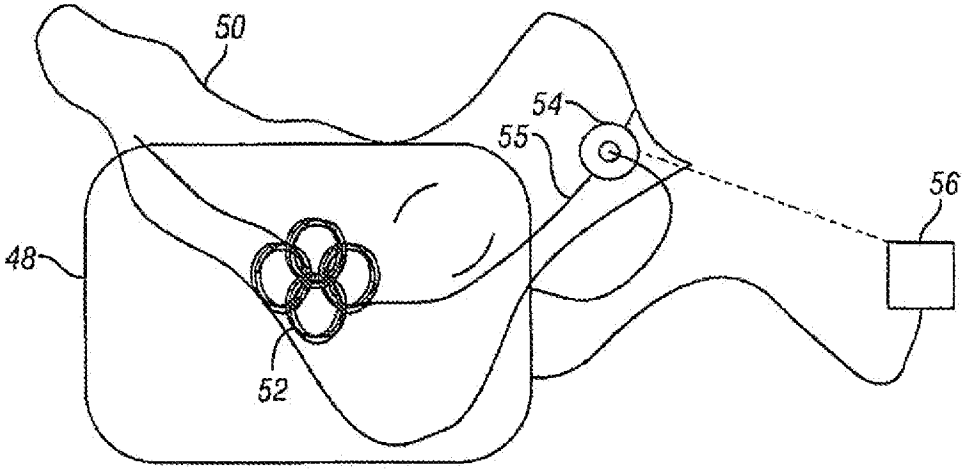


FIG. 4

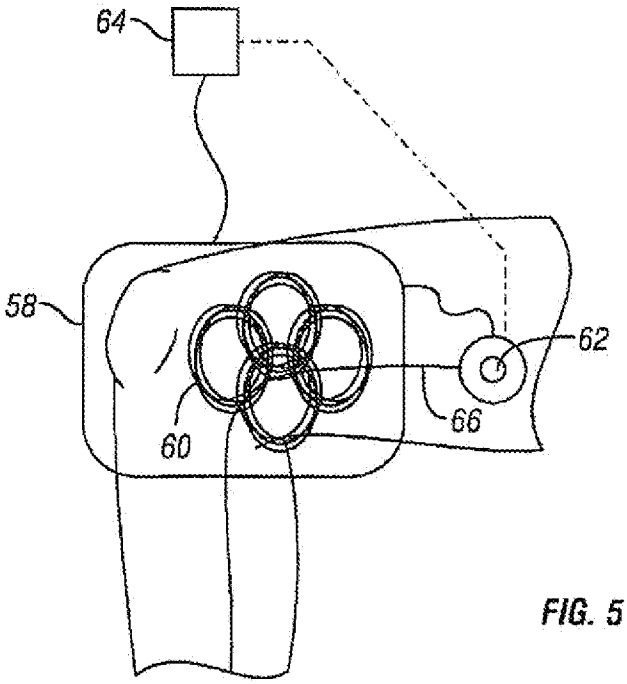


FIG. 5

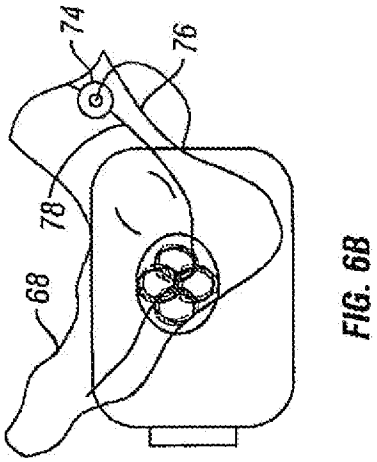


FIG. 6B

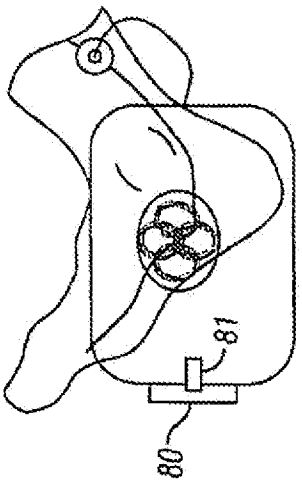


FIG. 6D

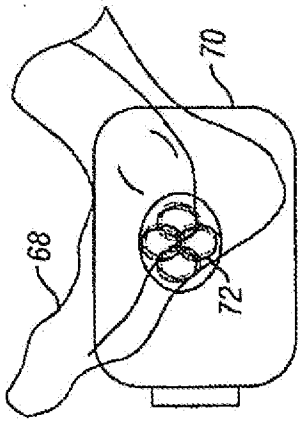


FIG. 6A

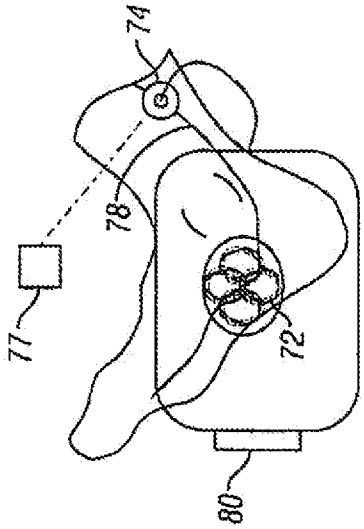


FIG. 6C

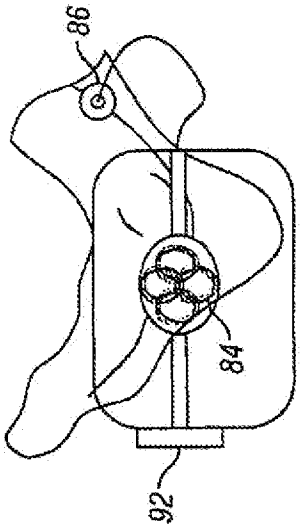


FIG. 7B

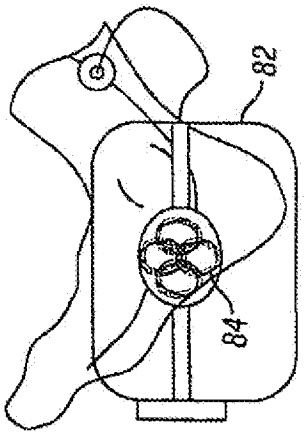


FIG. 7D

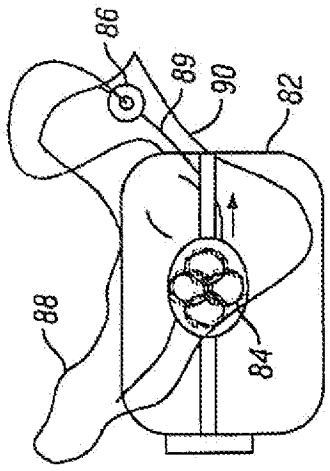


FIG. 7A

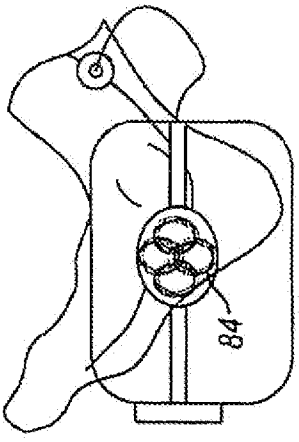


FIG. 7C

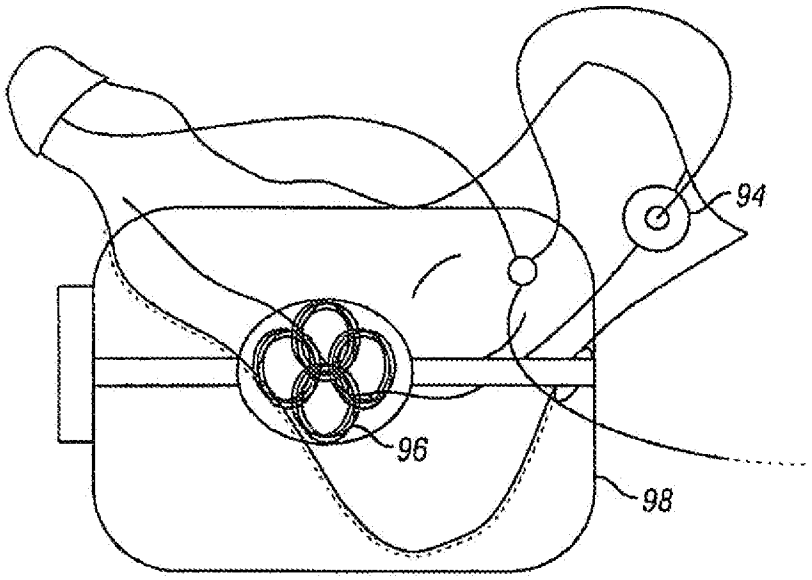


FIG. 8

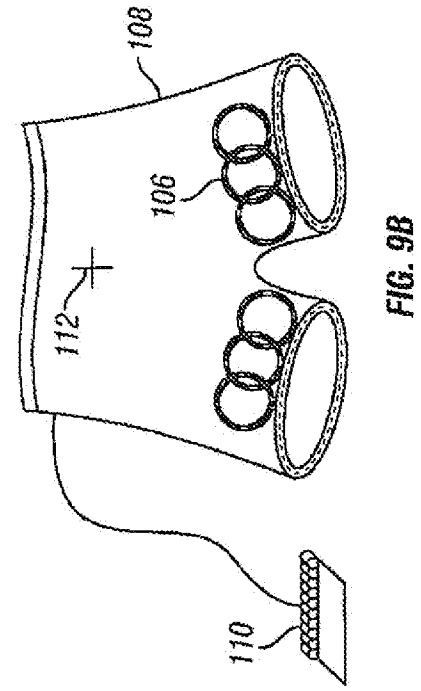


FIG. 9B

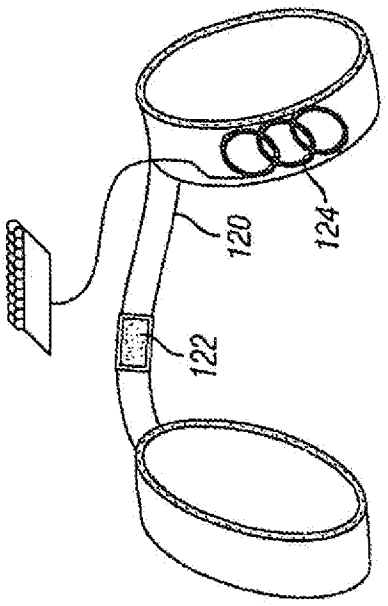


FIG. 9D

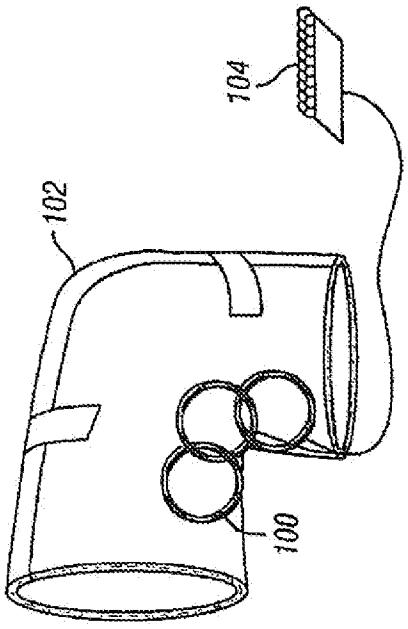


FIG. 9A

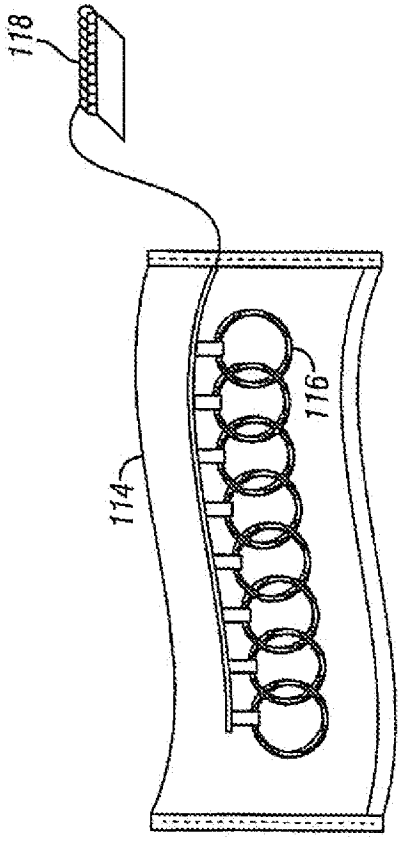


FIG. 9C

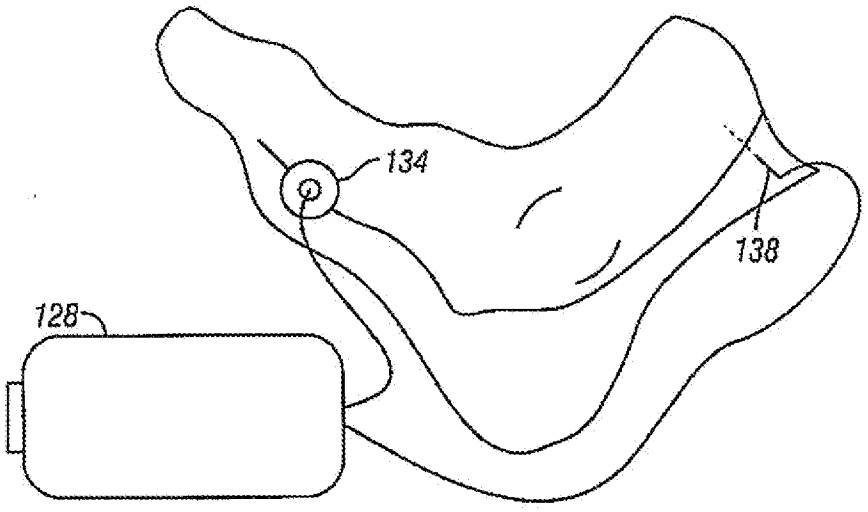


FIG. 10

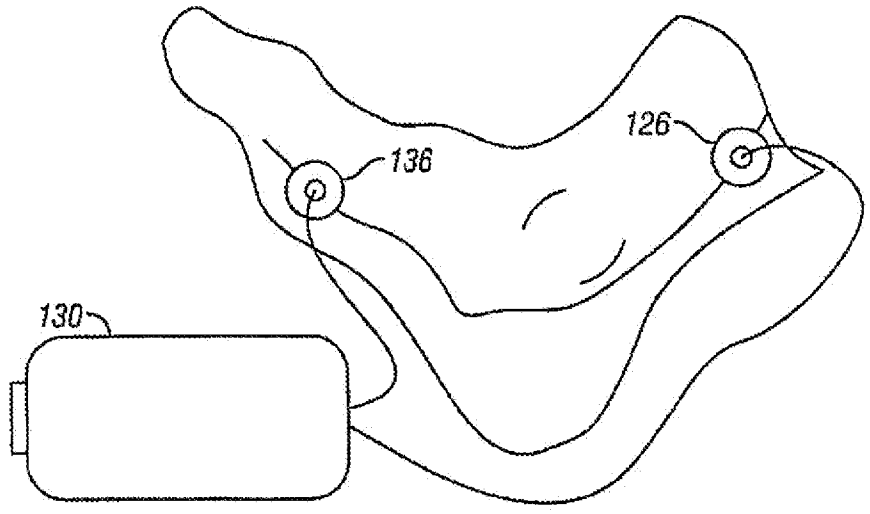


FIG. 11

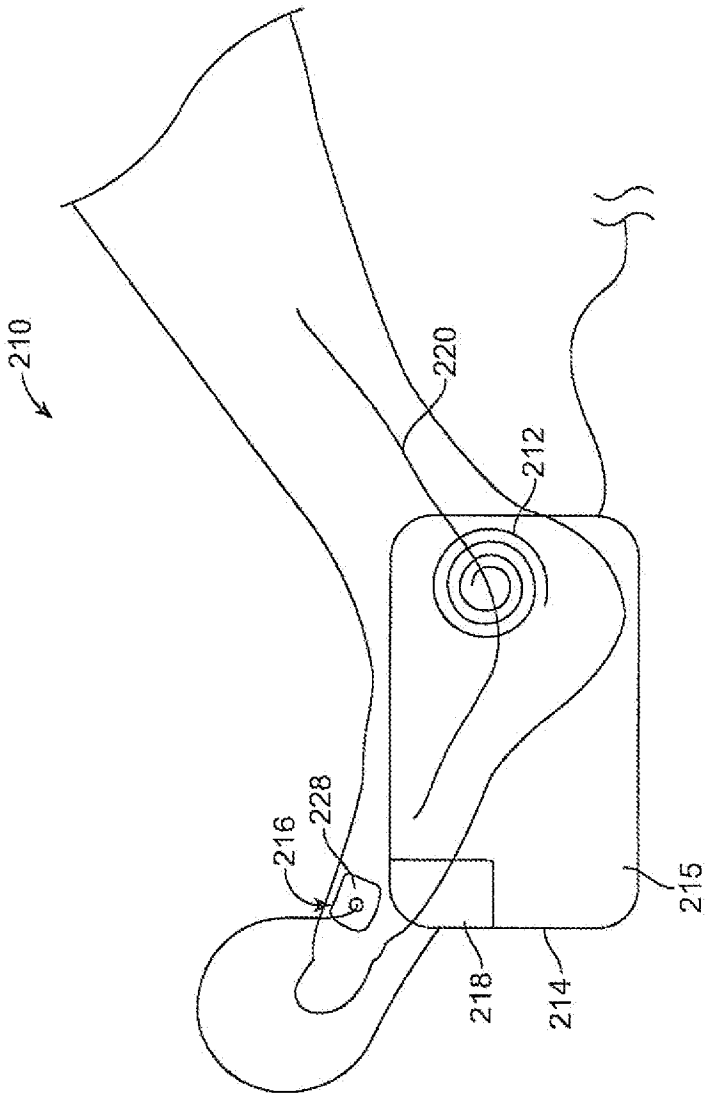


FIG. 12

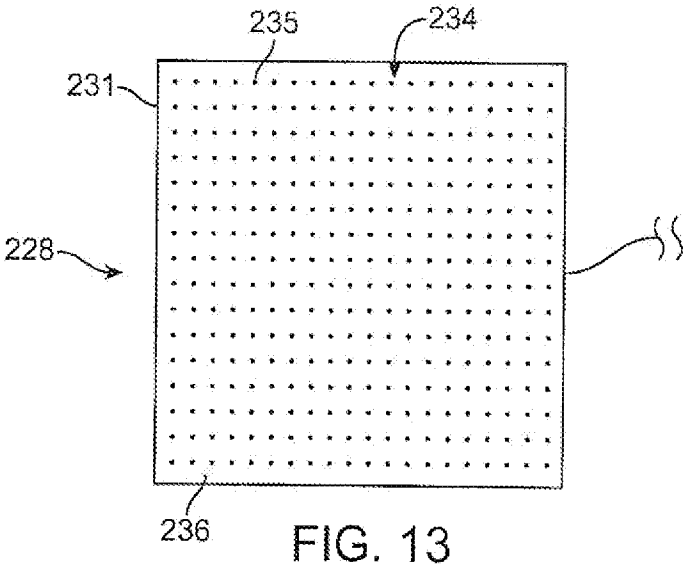


FIG. 13

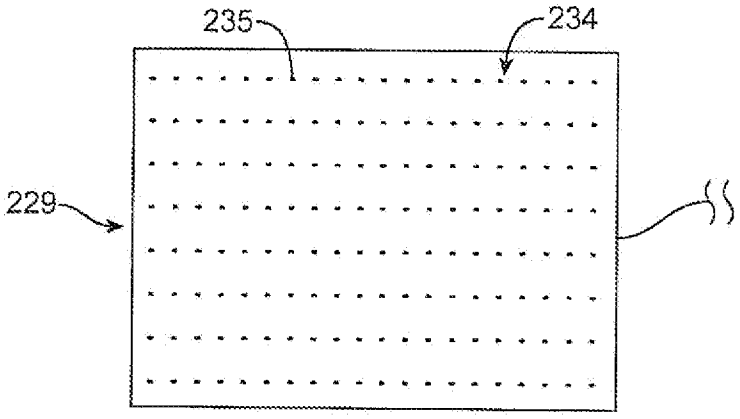


FIG. 14

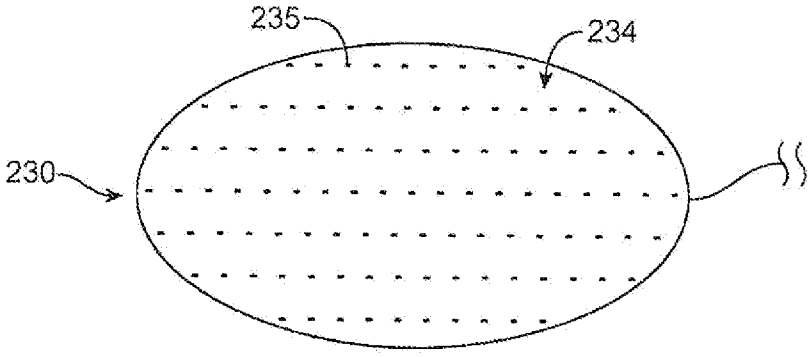


FIG. 15

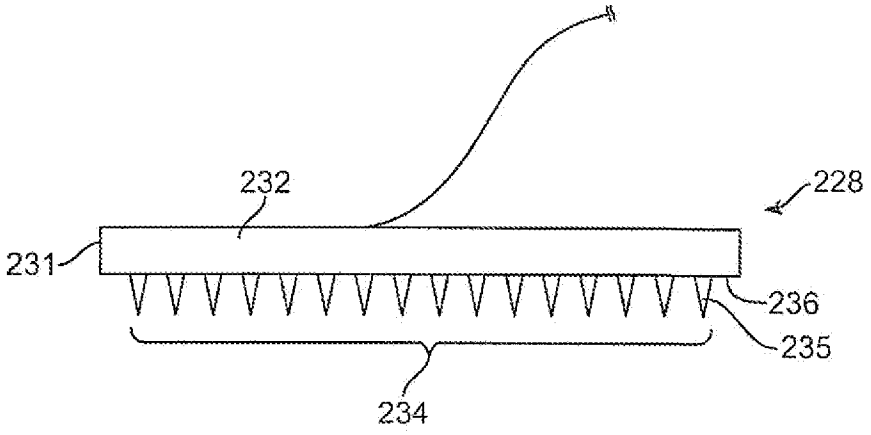


FIG. 16

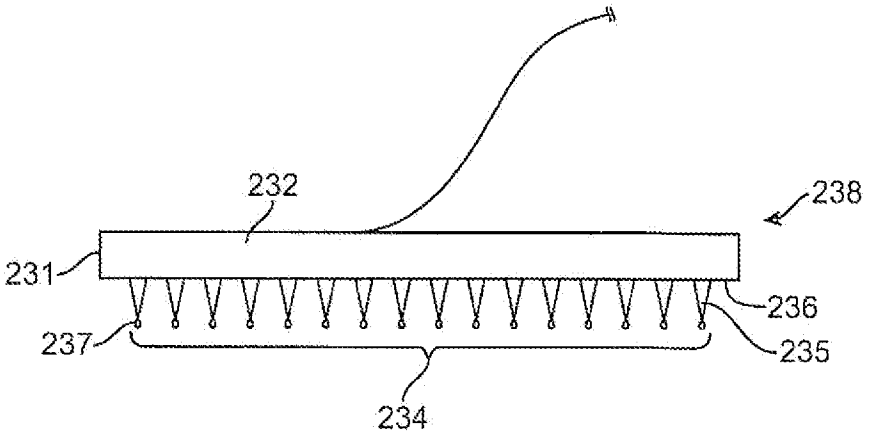


FIG. 17

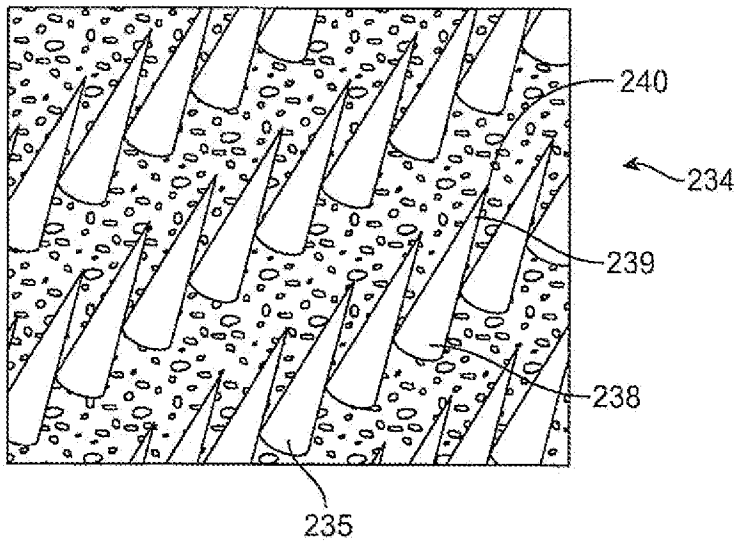


FIG. 18

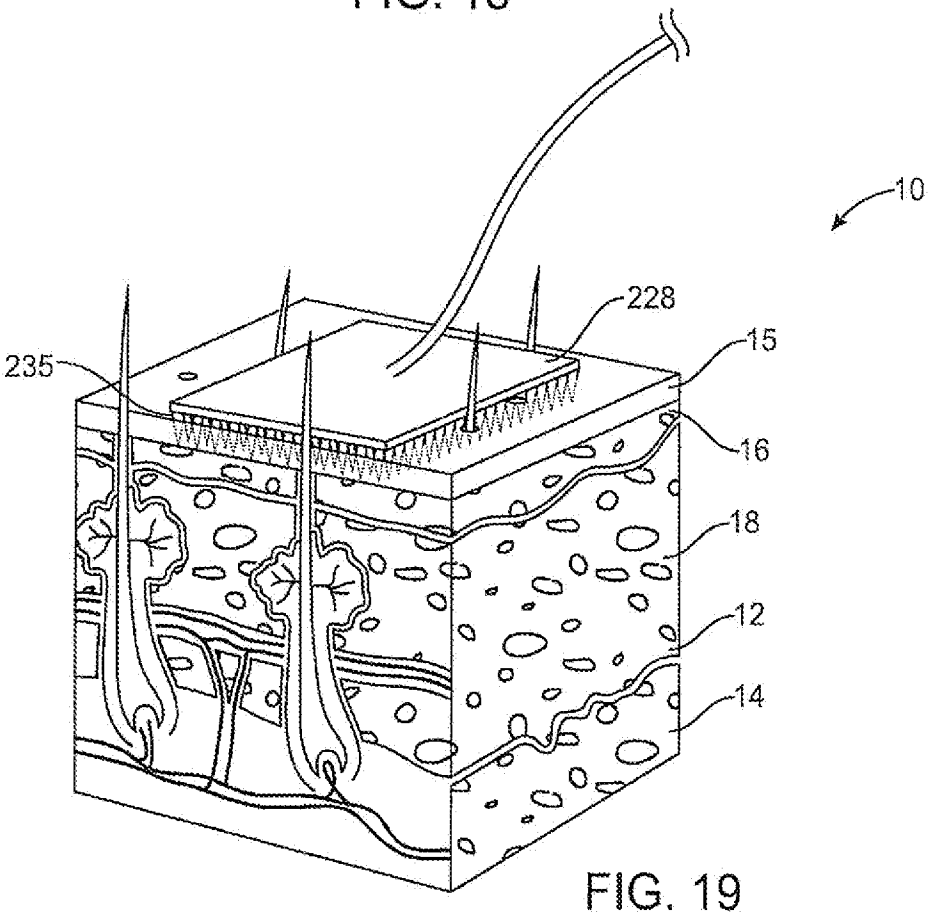


FIG. 19

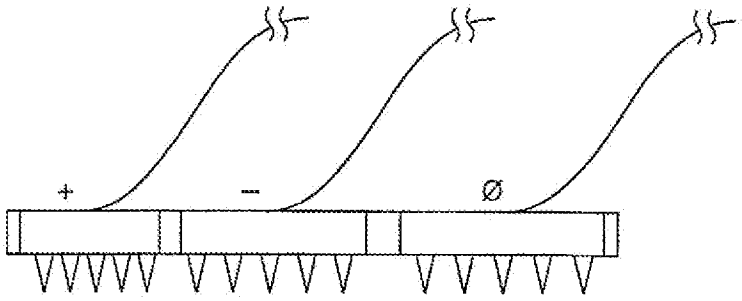


FIG. 20a

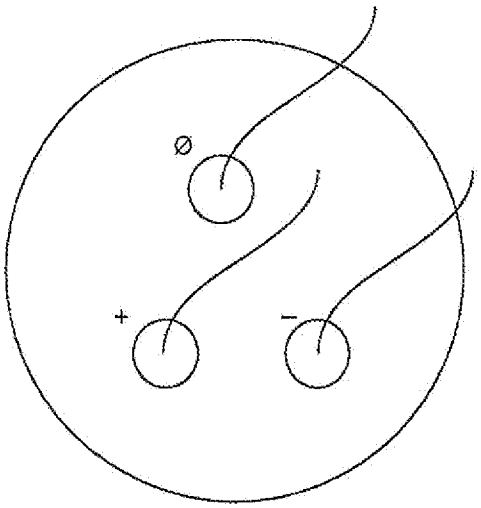


FIG. 20b

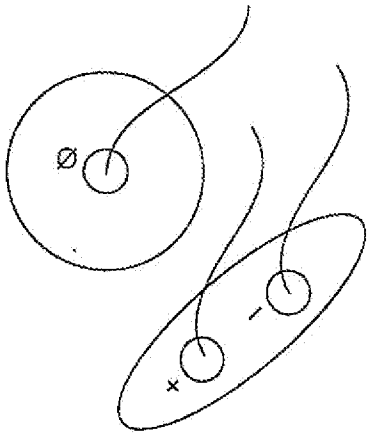


FIG. 20c

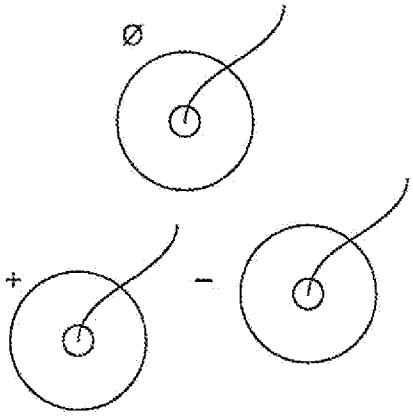


FIG. 20d

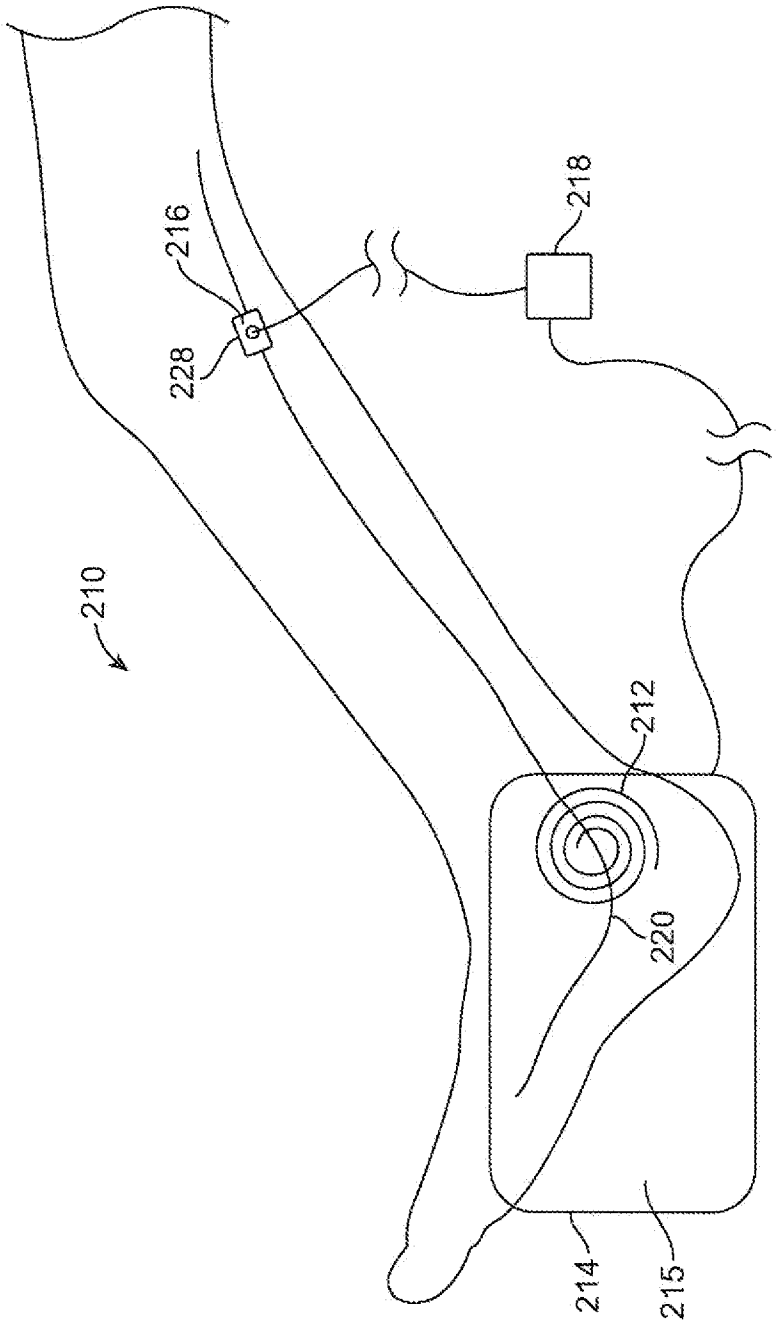


FIG. 21

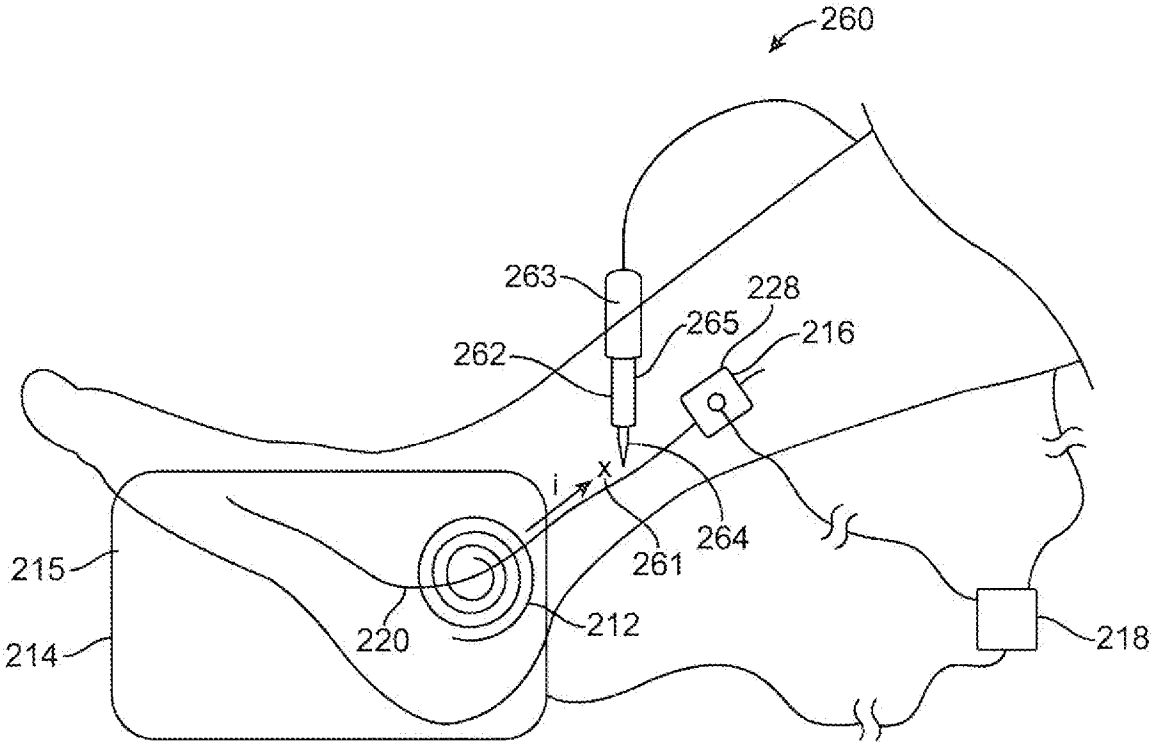


FIG. 22

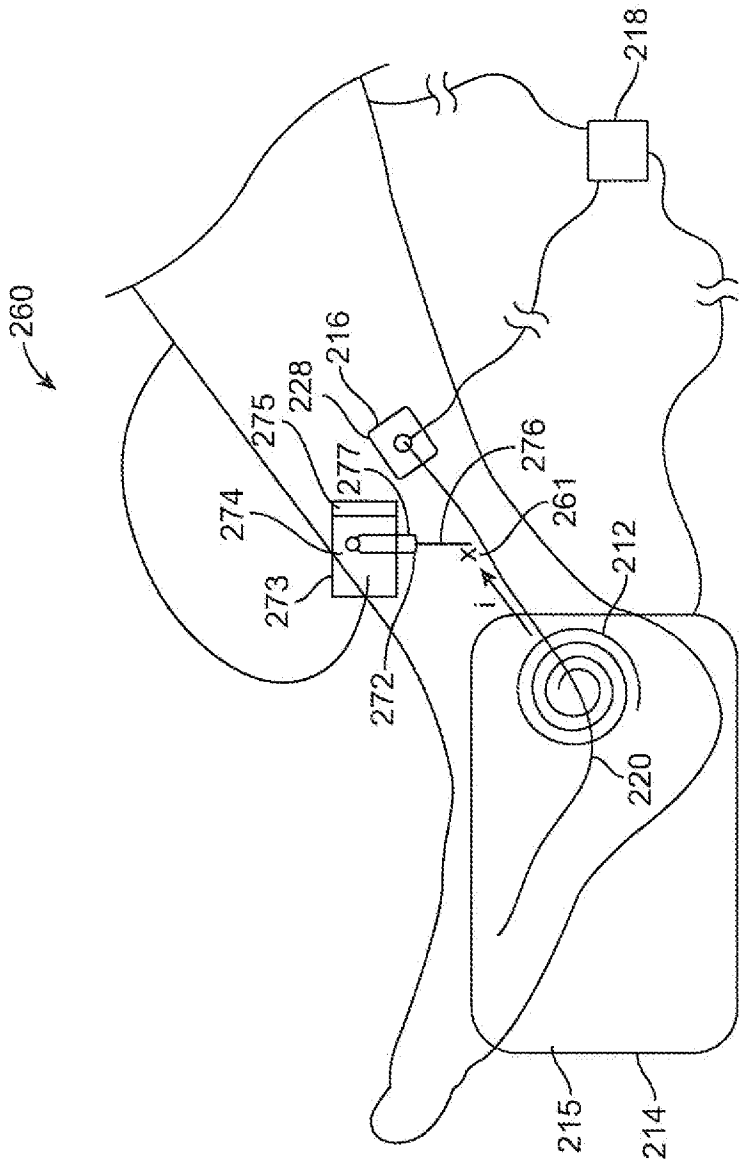


FIG. 23

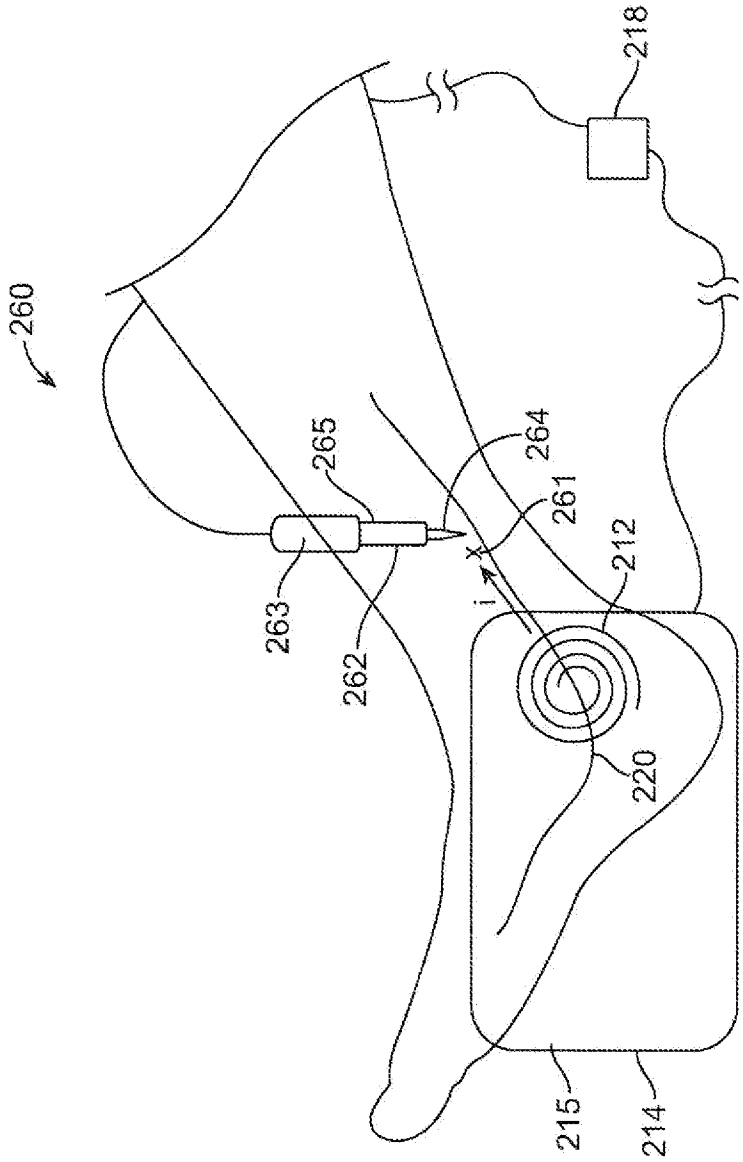


FIG. 24

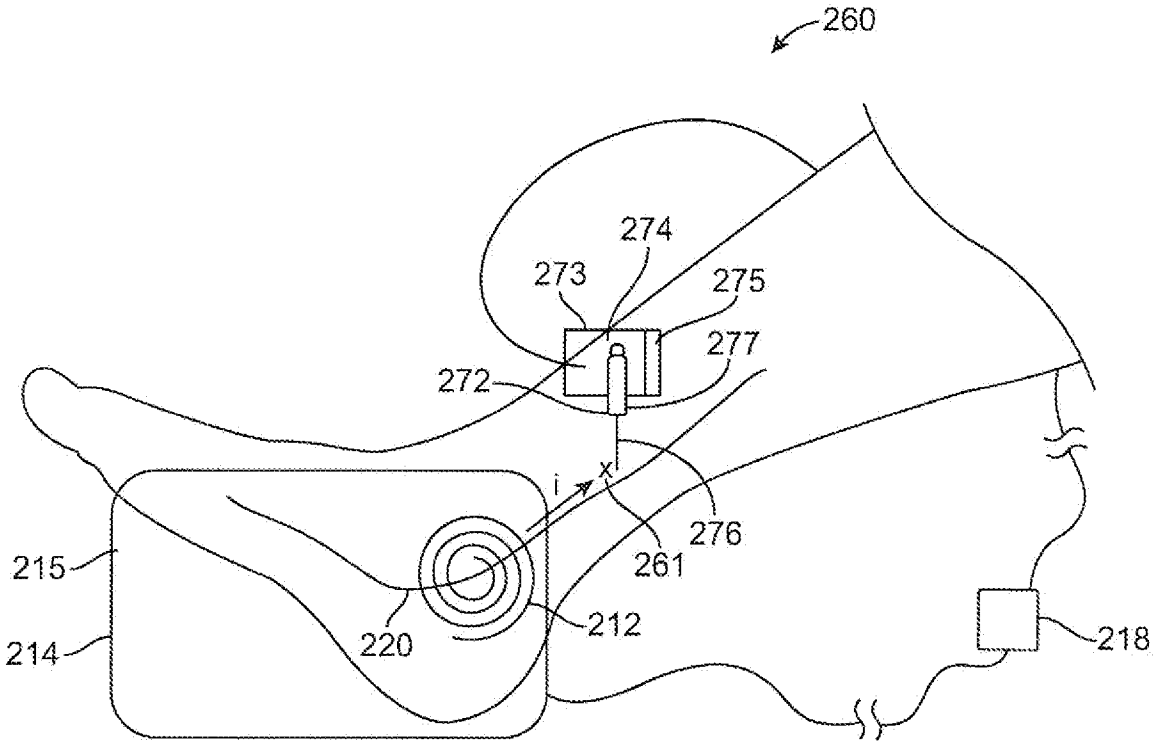


FIG. 25

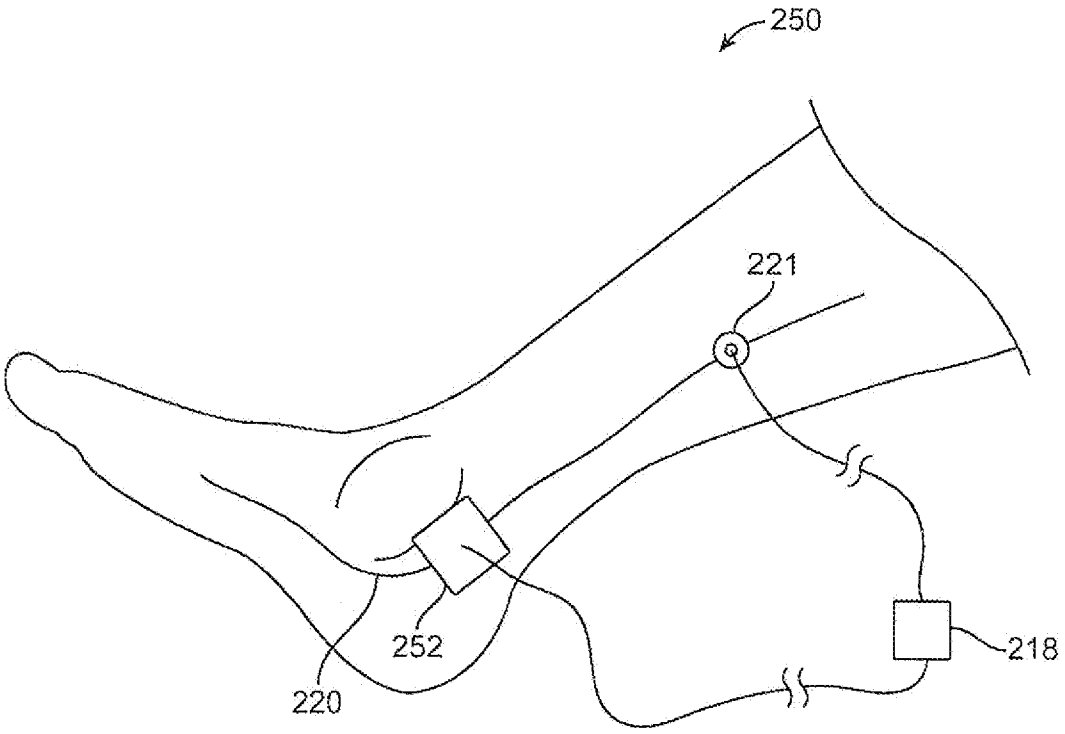


FIG. 26

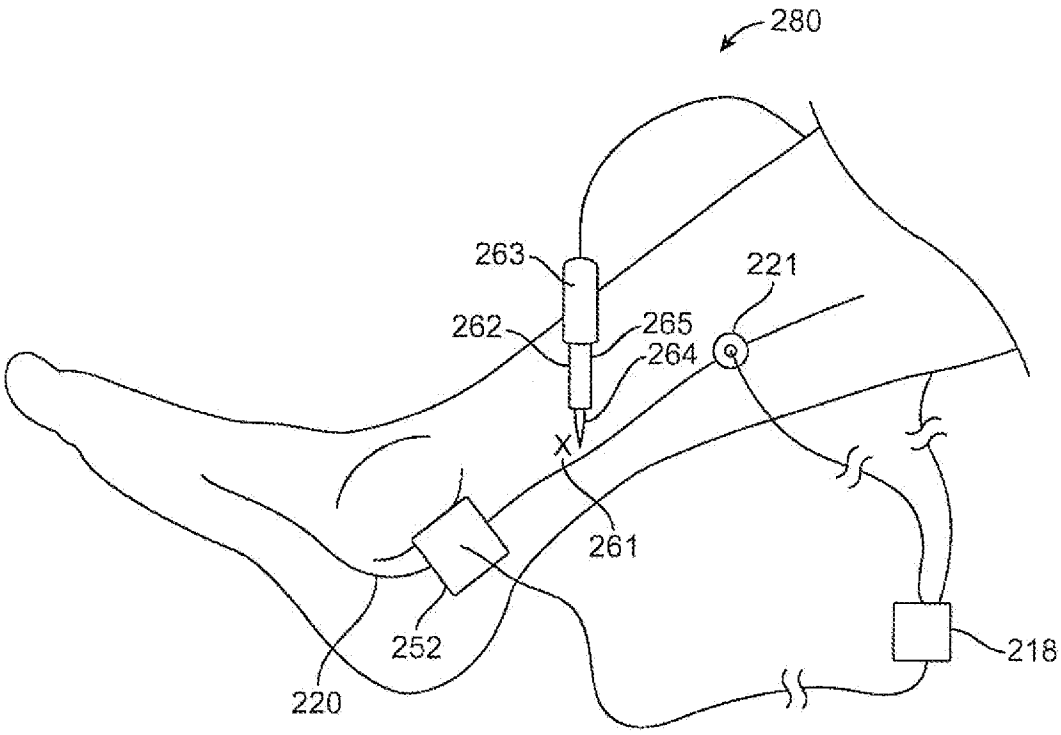


FIG. 27

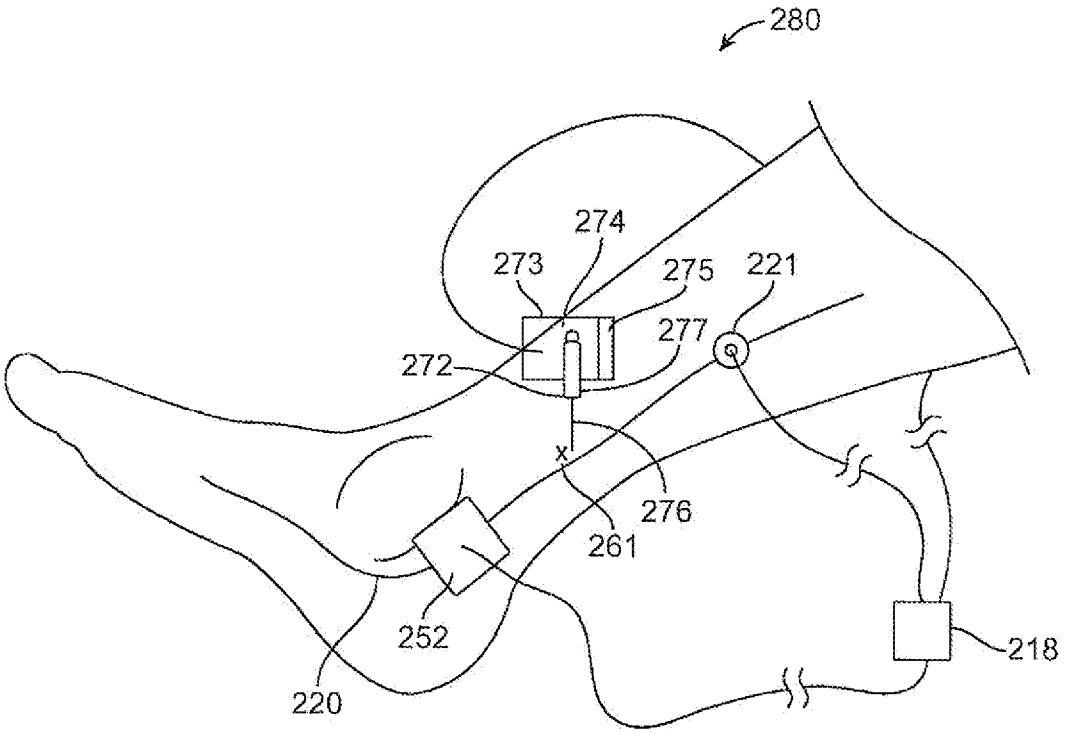


FIG. 28

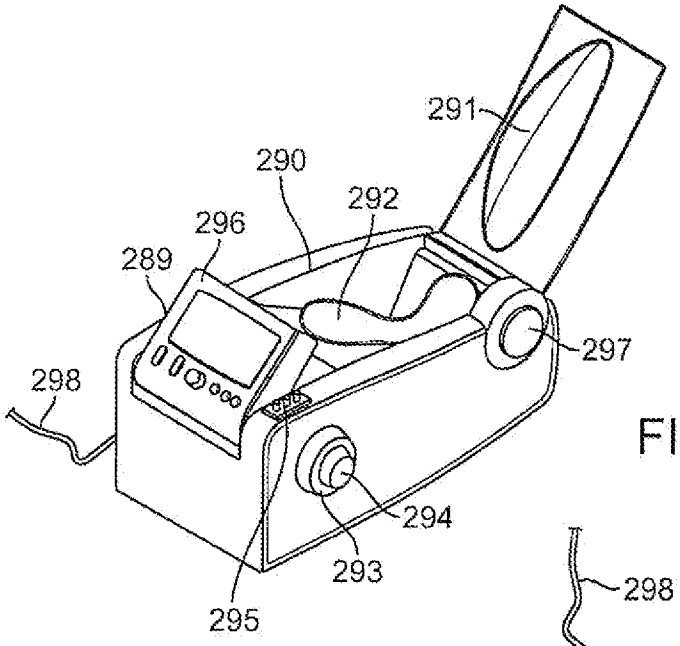


FIG. 29a

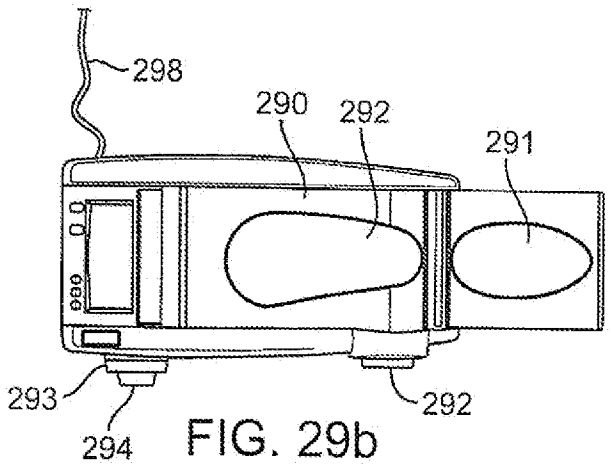


FIG. 29b

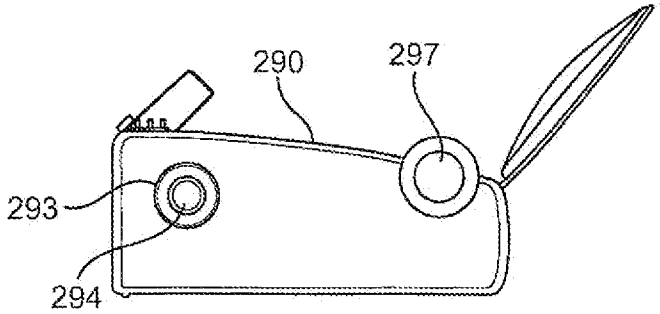


FIG. 29c

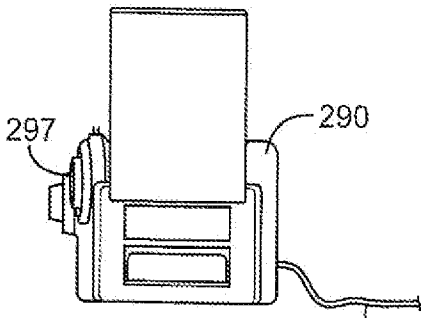


FIG. 29d

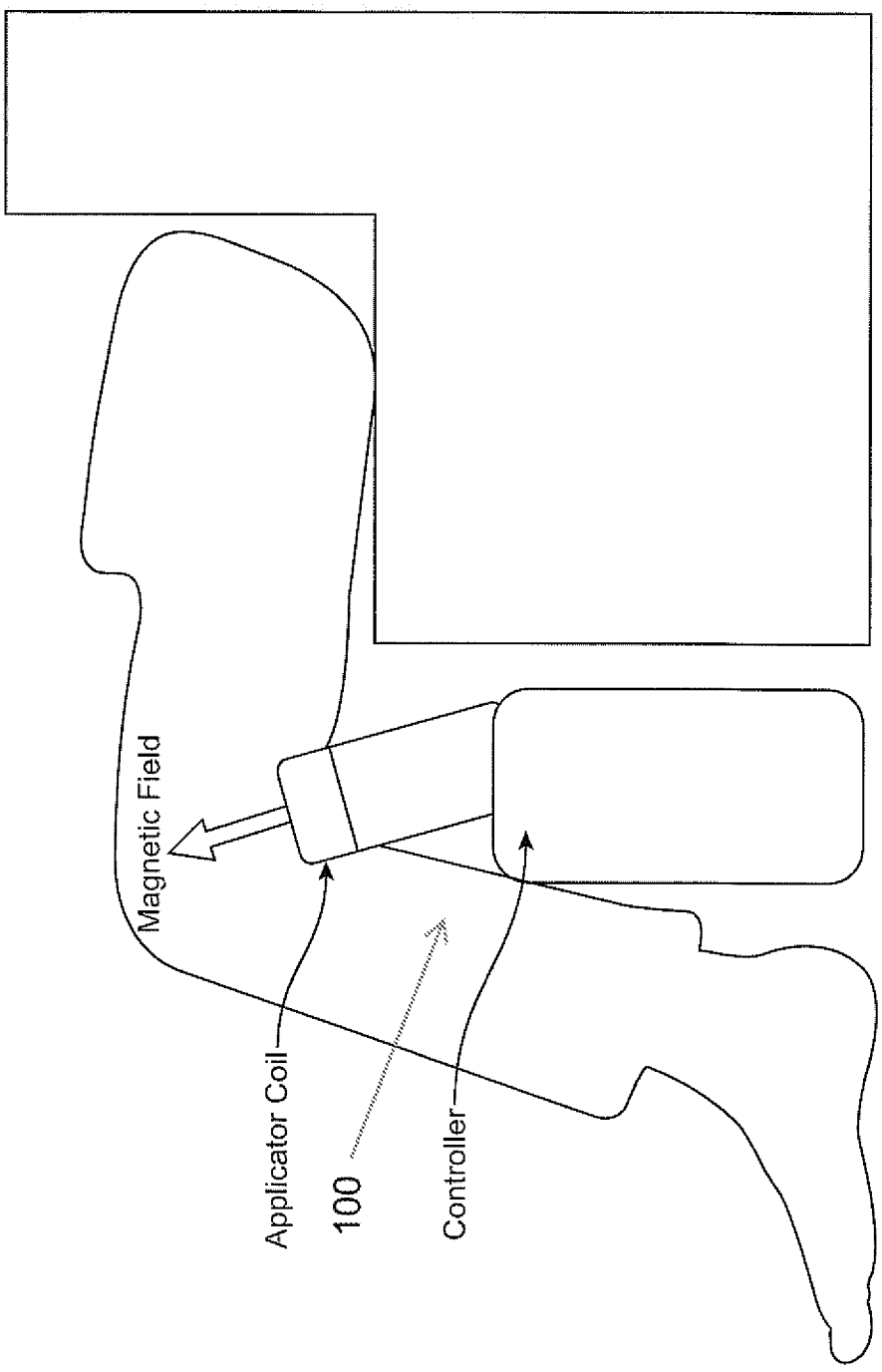


FIG. 30a

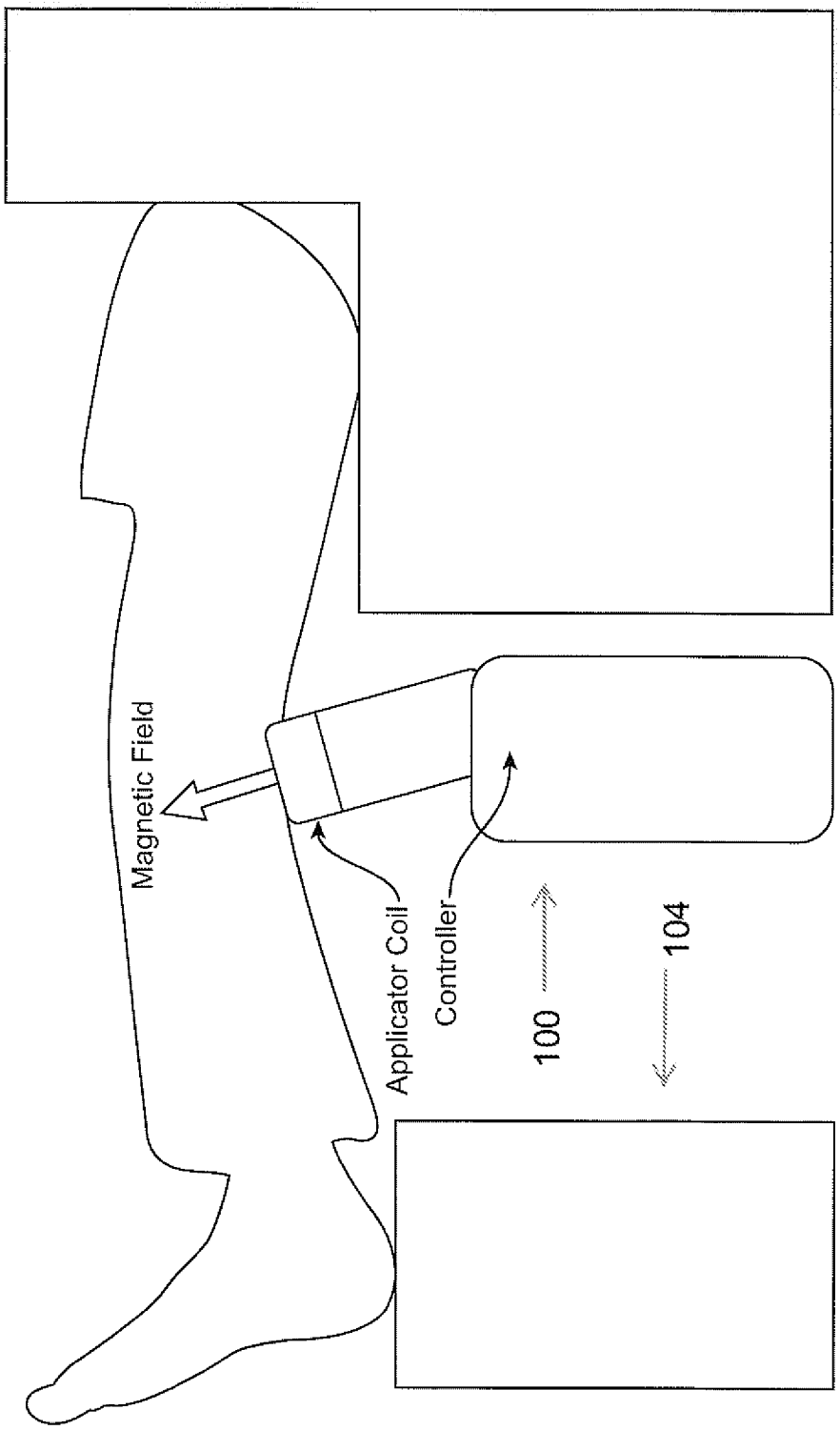


FIG. 30b

Fig. 31b

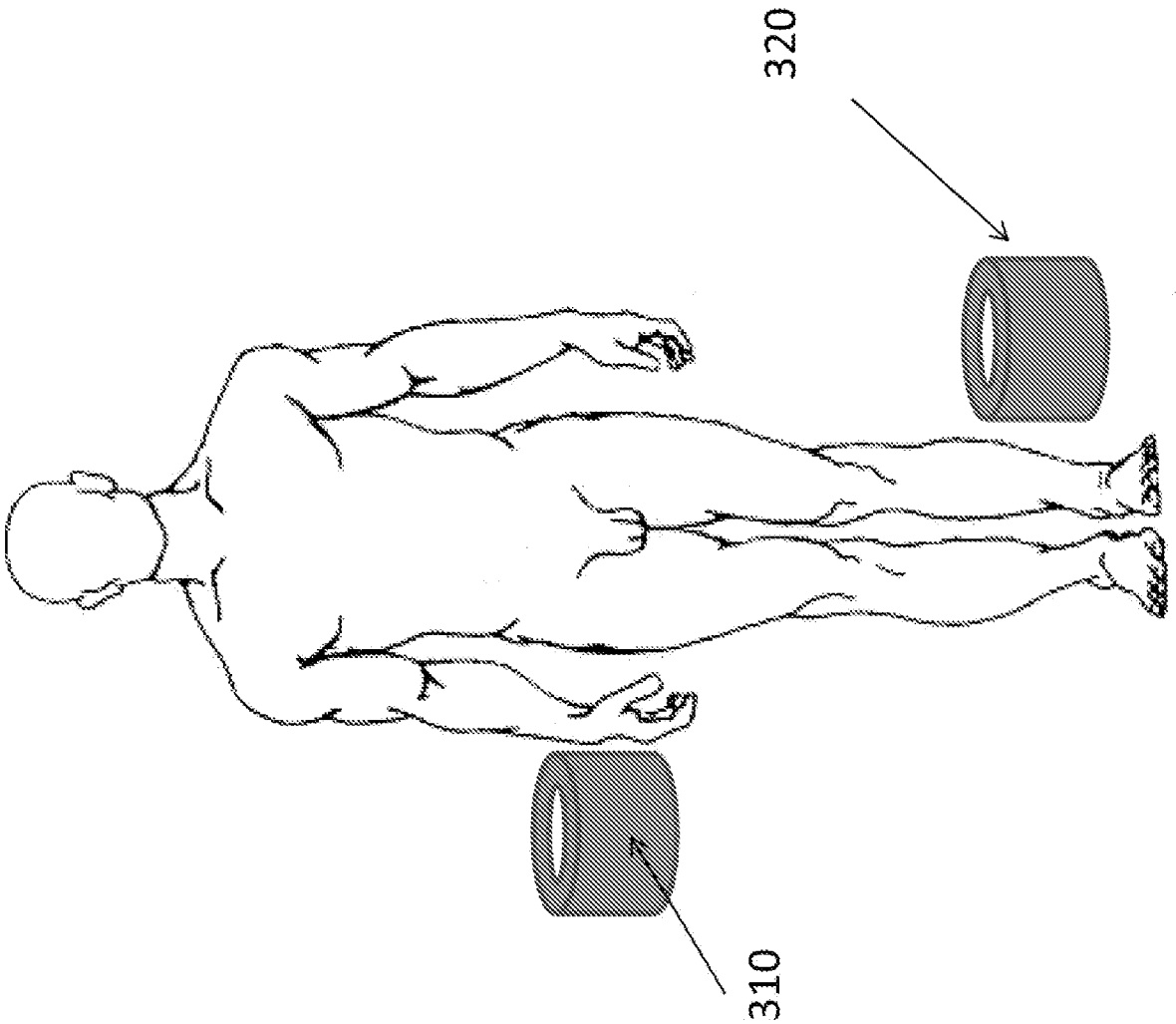


Fig. 31a

Fig. 32

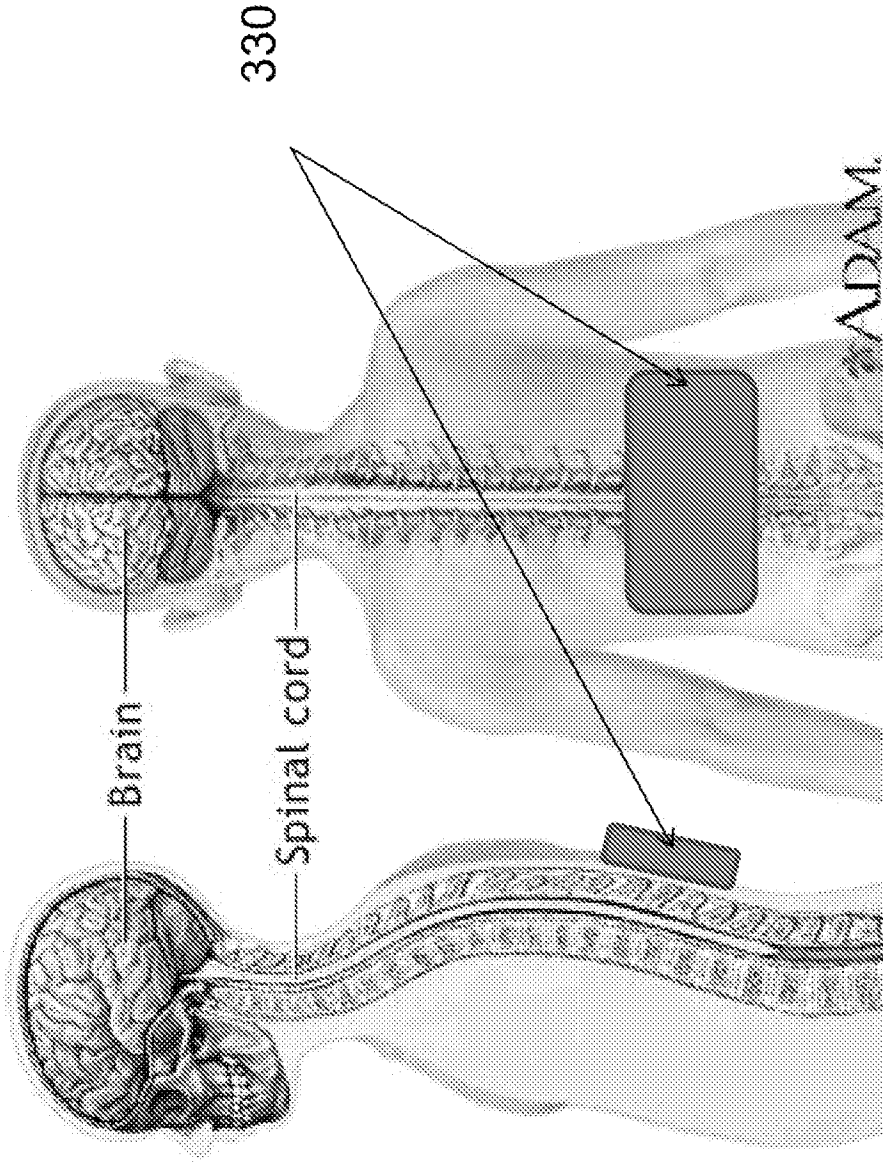


Fig. 33

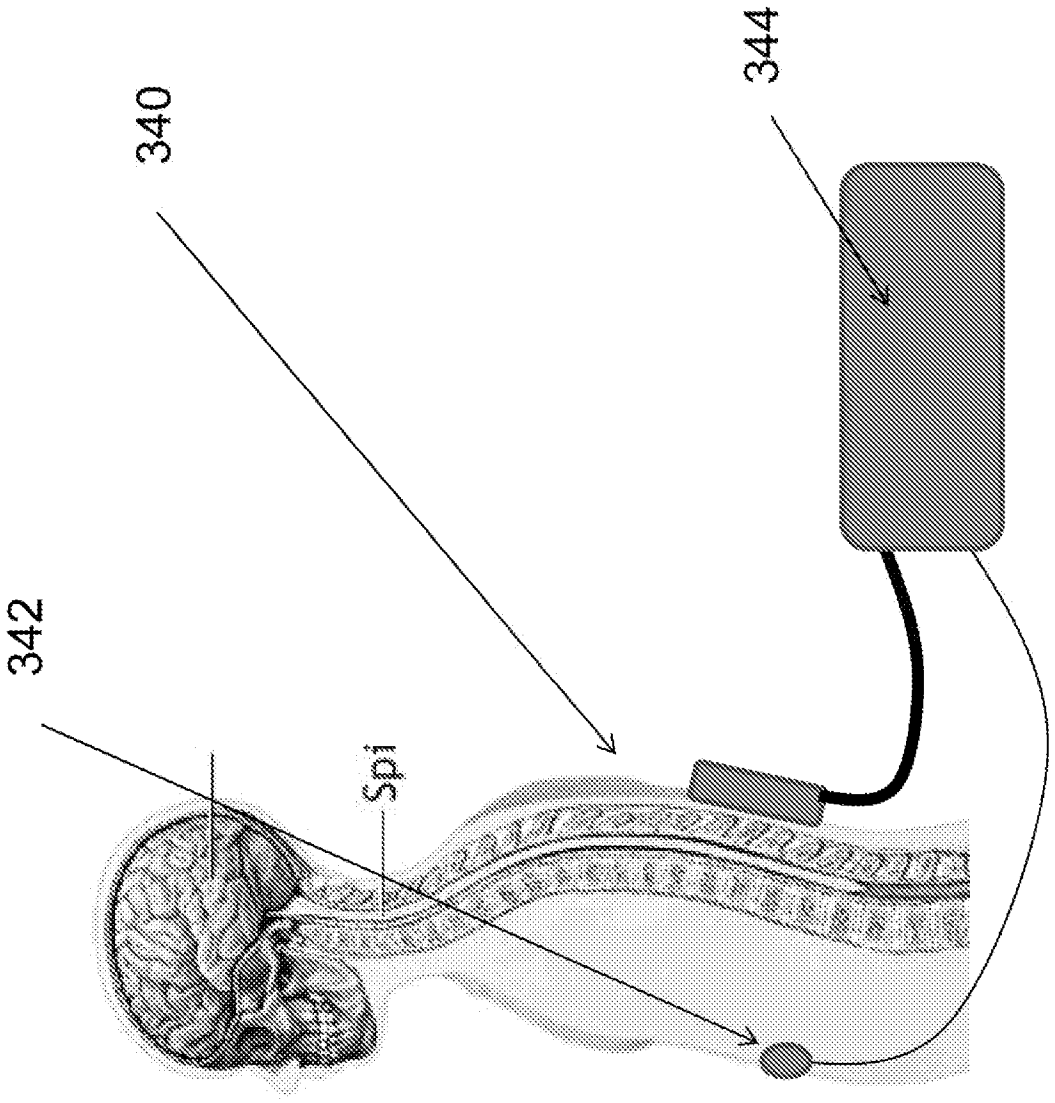
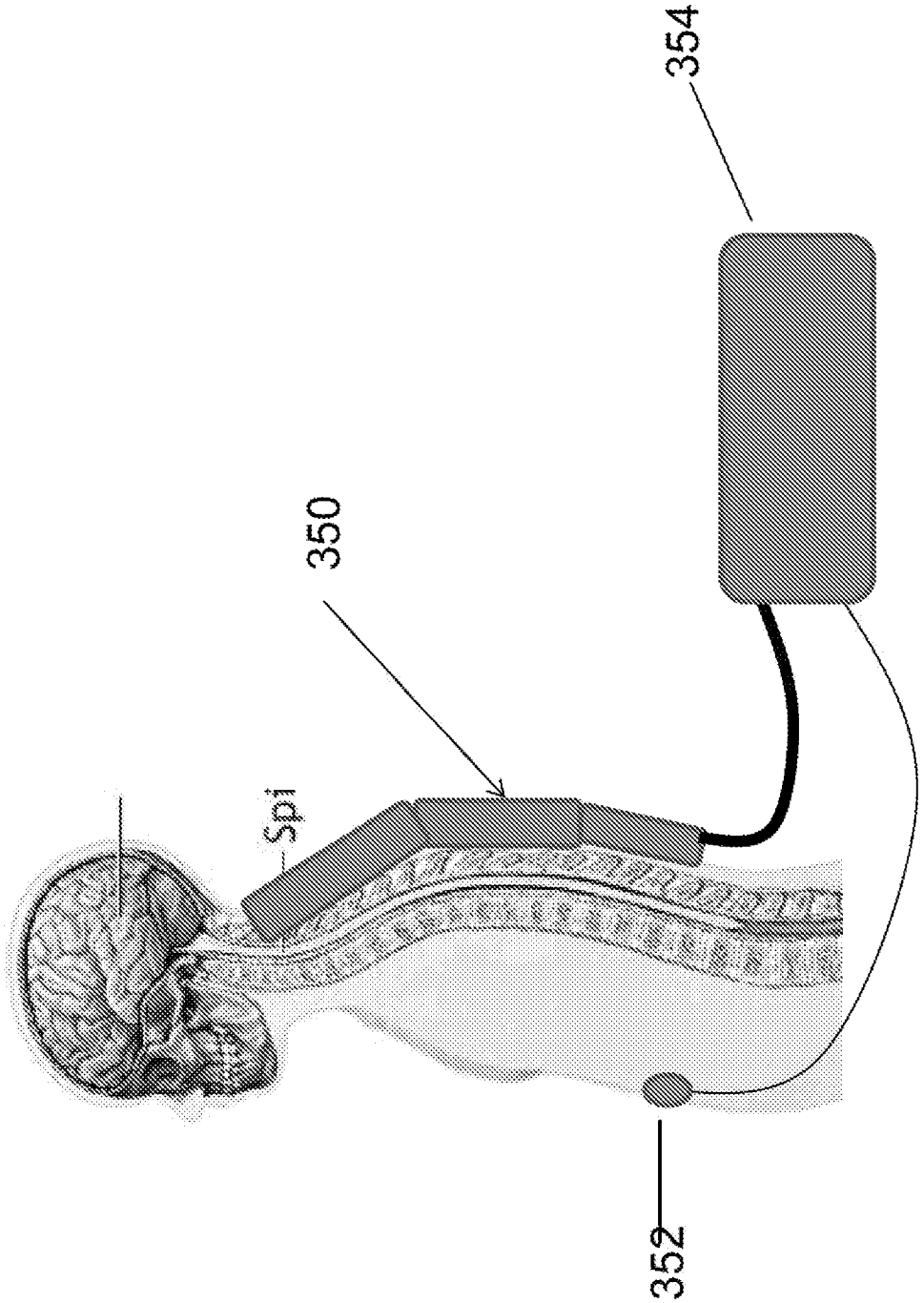


Fig. 34



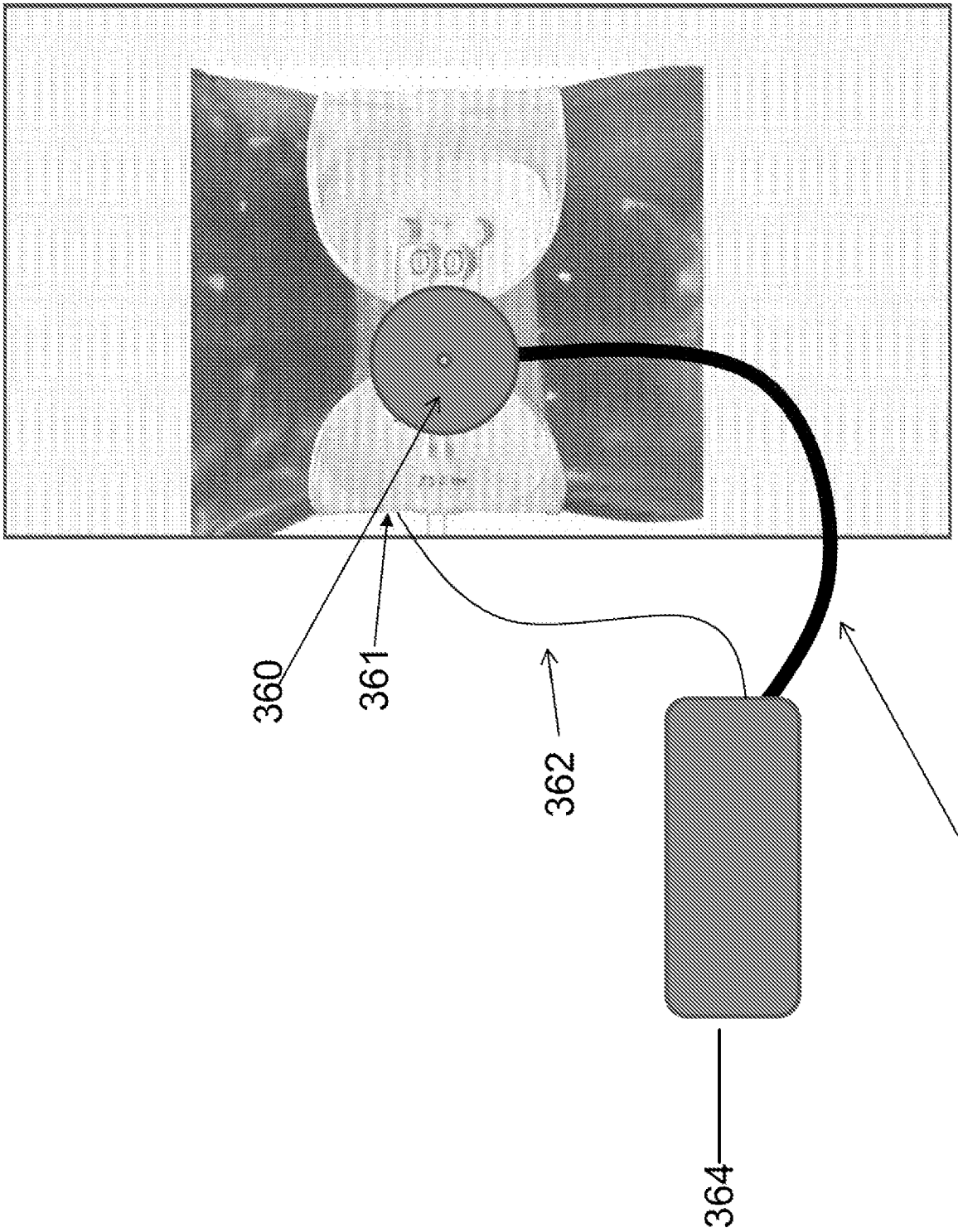


Fig. 35

Fig. 36

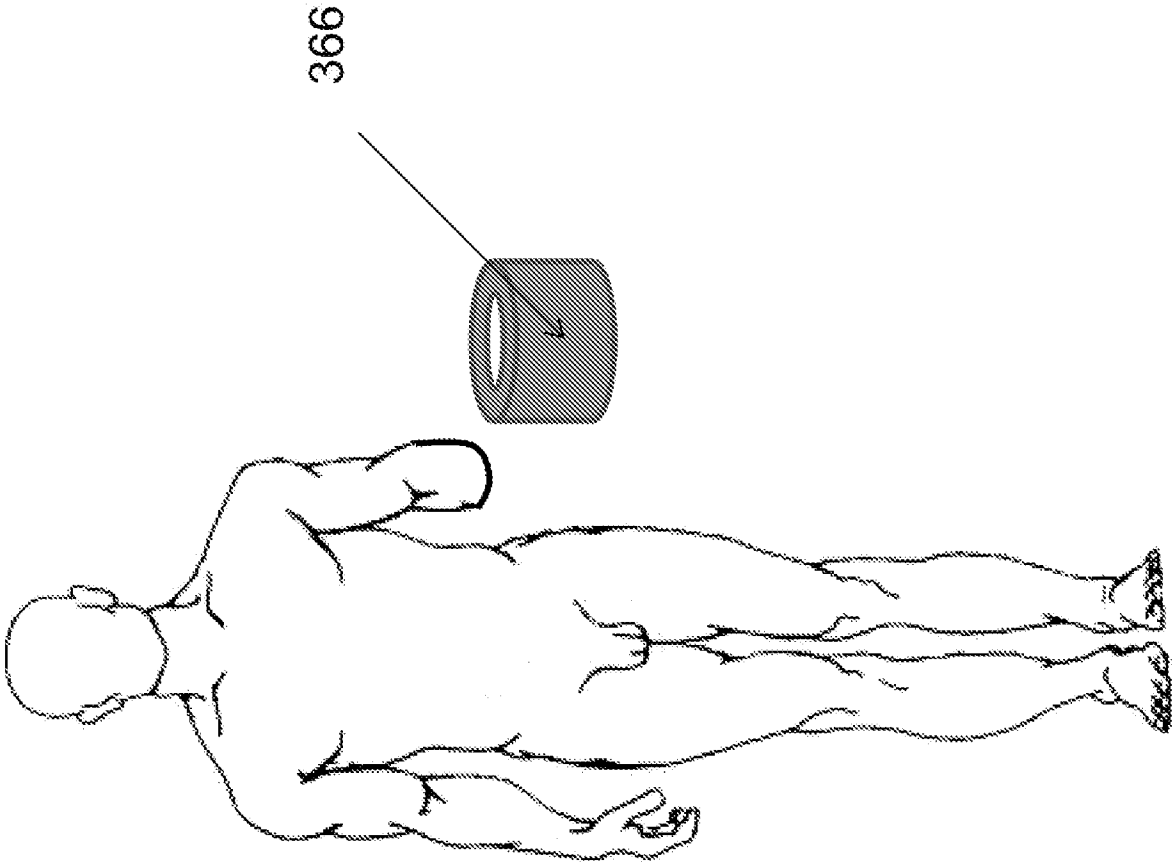


Fig. 37

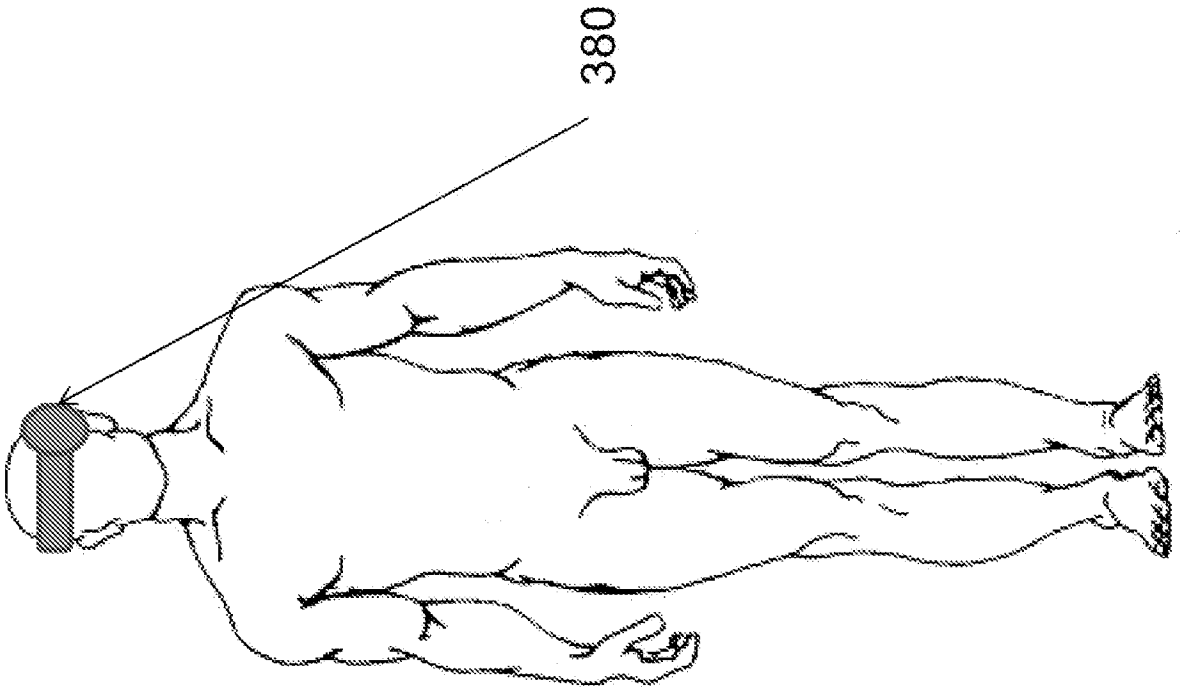


Fig. 38

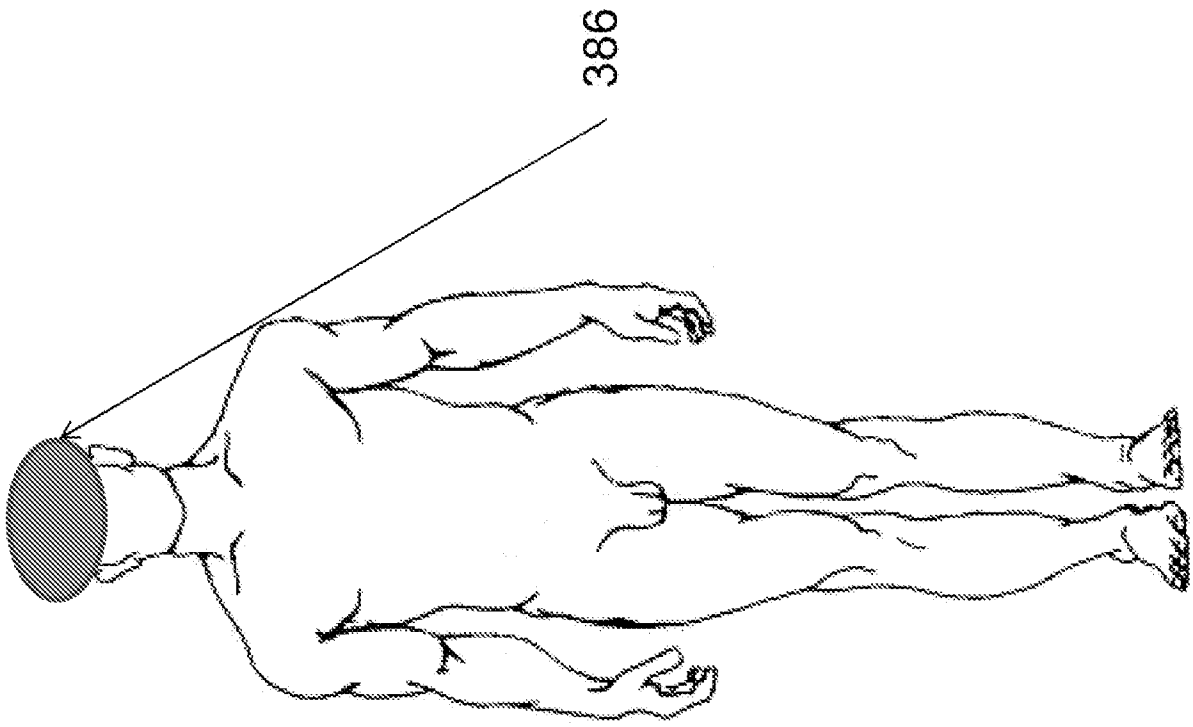


Fig. 39

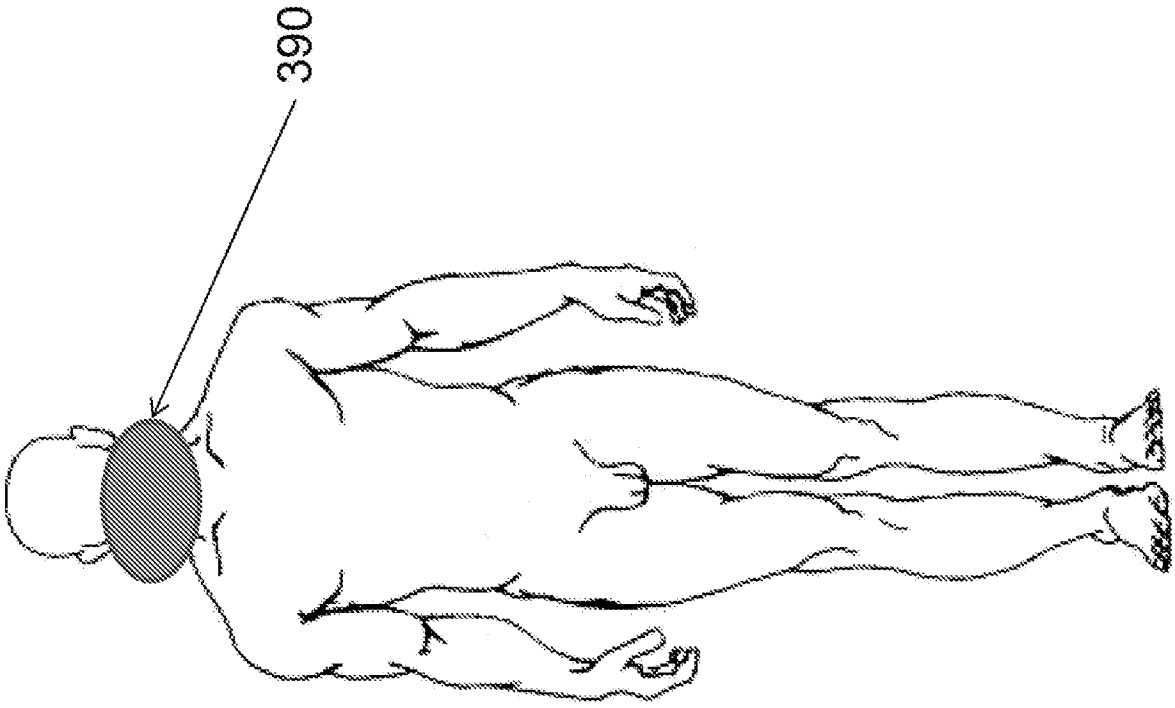


Fig. 40

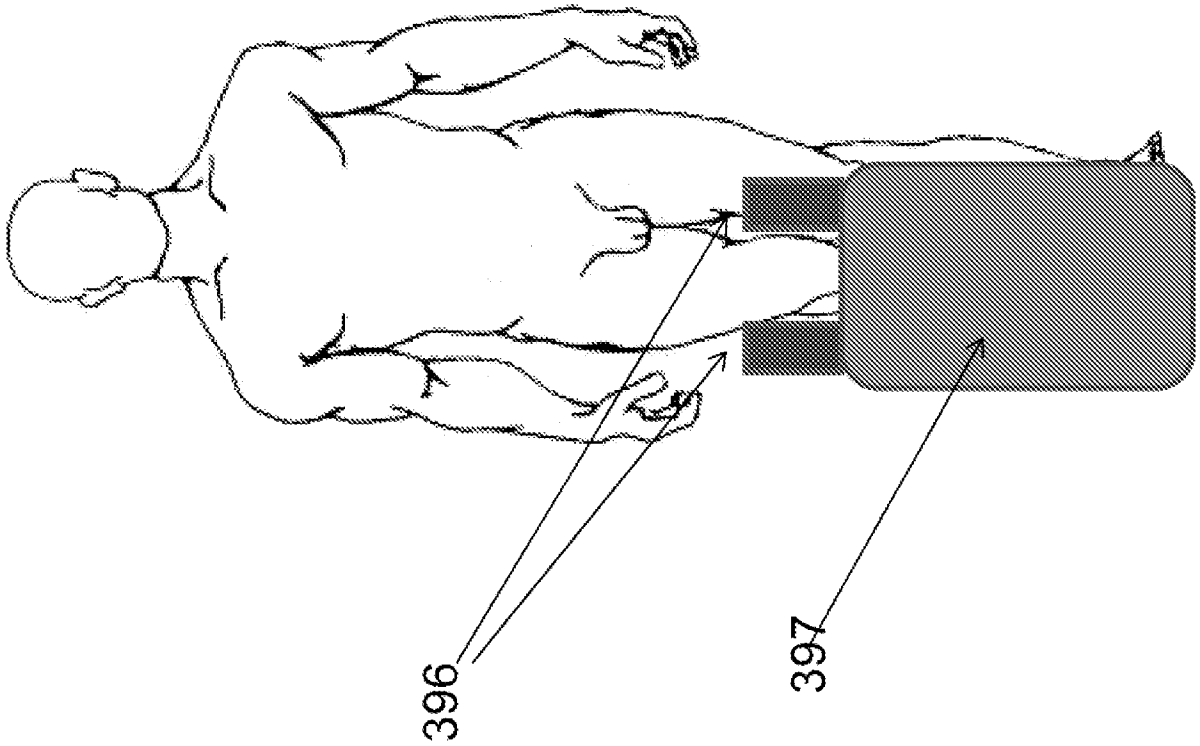
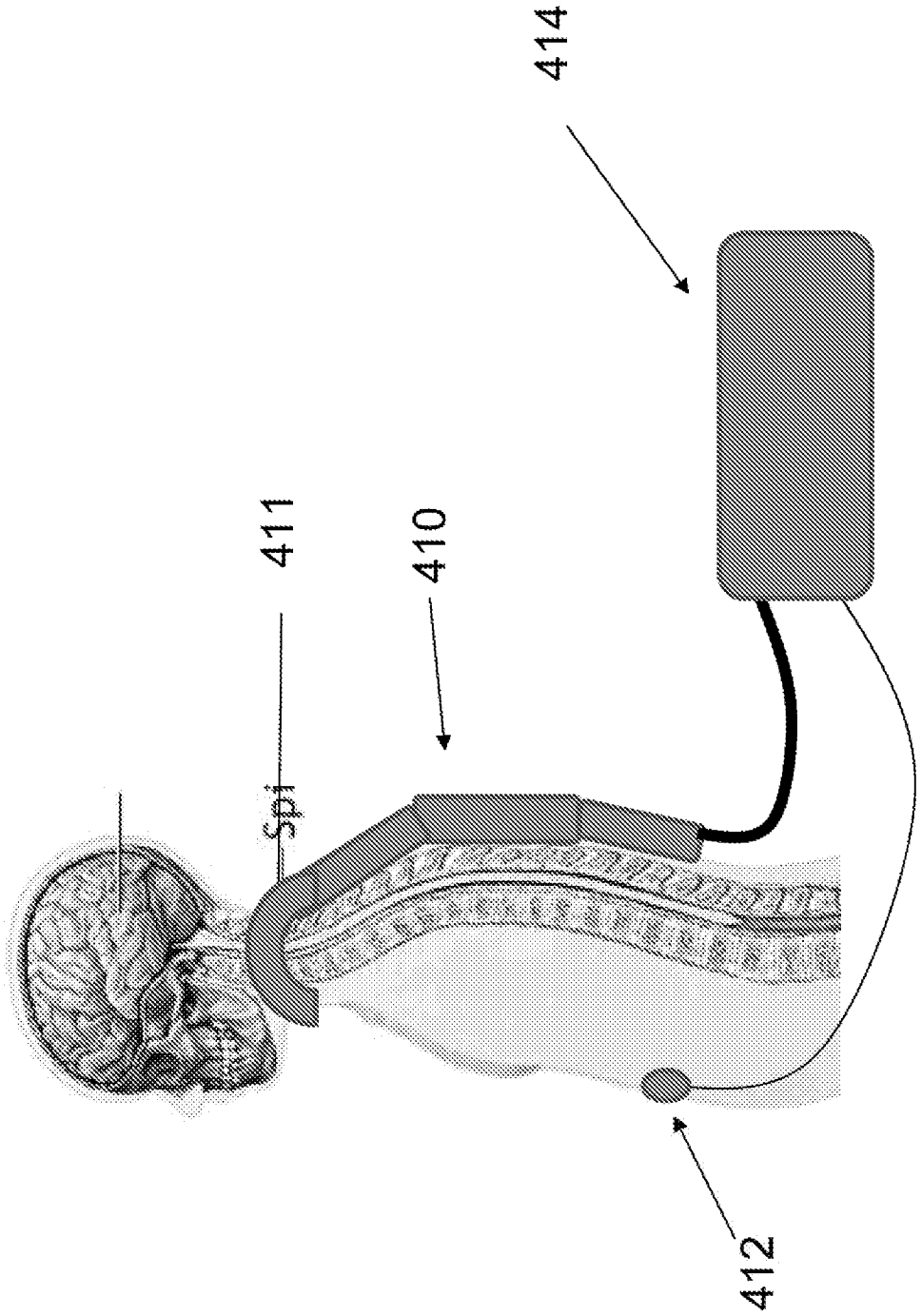


Fig. 41



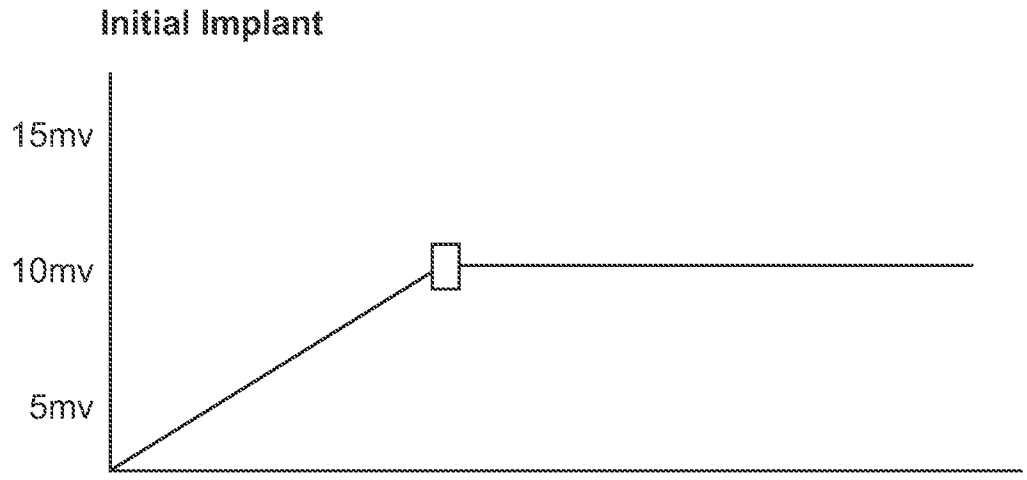


FIG. 42A

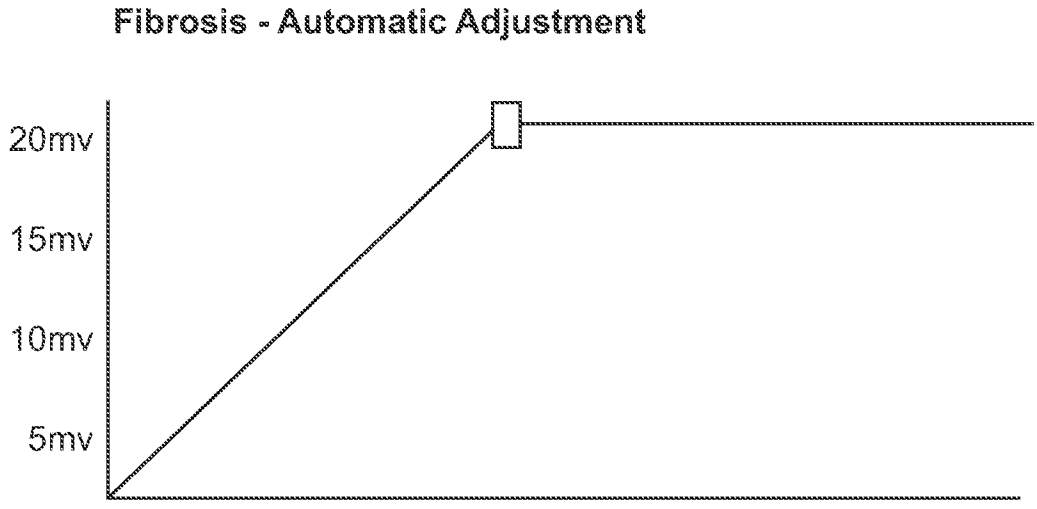


FIG. 42B

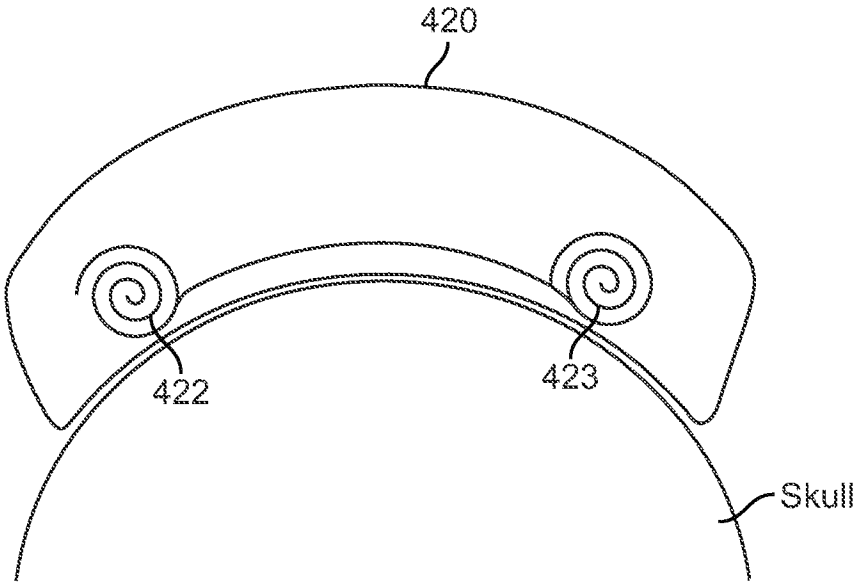


FIG. 43A

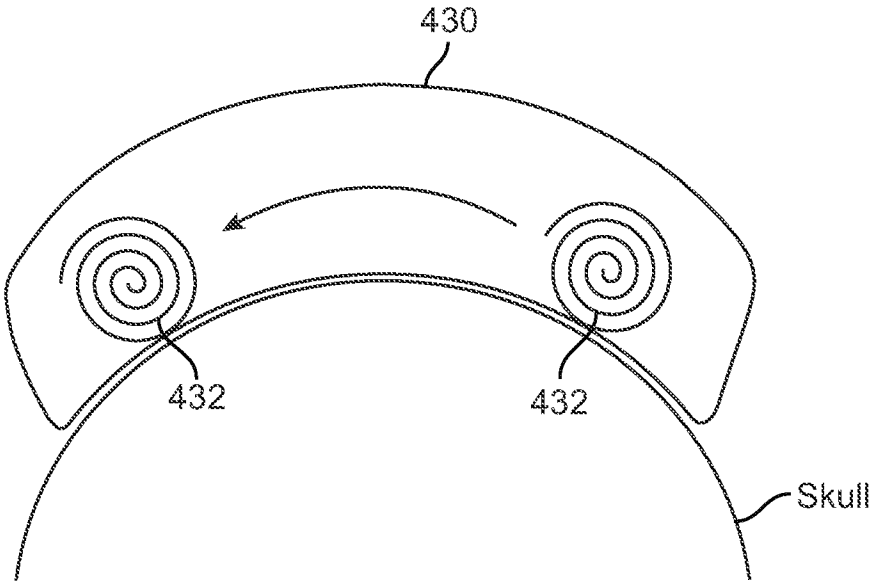


FIG. 43B

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.		
Date: November 20, 2013	Signature: /Kym Y. Moore/	(Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	Not Yet Assigned
Confirmation No.:	Not Yet Assigned
Filing Date:	Concurrently Herewith
Inventor(s):	Daniel R. BURNETT et al.
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Not Yet Assigned
Group Art Unit:	Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related Application Number 13/456,016, filed April 25, 2012, and accordingly, copies are not included herewith. The Examiner is requested to make these documents of record in the application.

Related Applications

Applicants wish to bring to the Examiner's attention, related applications and patents commonly assigned to the assignee of the present invention:

U.S. Application No.: 10/077,434	filed	February 19, 2002
U.S. Application No.: 11/332,797	filed	January 17, 2006
U.S. Application No.: 11/866,329	filed	October 2, 2007
U.S. Application No.: 12/469,625	filed	May 20, 2009
U.S. Application No.: 12/469,358	filed	May 20, 2009
U.S. Application No.: 12/469,365	filed	May 20, 2009
U.S. Application No.: 12/508,529	filed	July 23, 2009
U.S. Application No.: 12/509,304	filed	July 24, 2009
U.S. Application No.: 12/509,345	filed	July 24, 2009
U.S. Application No.: 12/509,362	filed	July 24, 2009
U.S. Application No.: 12/606,941	filed	10/27/2009
U.S. Application No.: 12/695,087	filed	January 27, 2010
U.S. Application No.: 12/790,619	filed	May 28, 2010
U.S. Application No.: 13/456,016	filed	April 25, 2012
U.S. Application No.: 13/457,228	filed	April 26, 2012
U.S. Application No.: 13/840,936	filed	March 15, 2013

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 298

This Information Disclosure Statement is submitted with the application; accordingly, no fee or separate requirements are required.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

/Steven M. Giovannetti/

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Customer No. 40518
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Palo Alto, CA 94303
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Fax: (650) 284-2180

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 299

SCORE Placeholder Sheet for IFW Content

Application Number: 14085639 Document Date: 11/20/2013

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

- Drawings – Other than Black and White Line Drawings

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Form Revision Date: September 30, 2013