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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	01/18/2022	11224742	EMKNNZ00505	6227

40518 7590 12/28/2021

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 145 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.

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

Daniel R. BURNETT, San Francisco, CA;

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

EMKinetics, Inc., 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 12/23/2021

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

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
12/23/2021	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENT@LBHIP.COM

Response to Rule 312 Communication	Application No. 15/665,152	Applicant(s)
	Examiner	Art Unit

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

1. ☒ The amendment filed on *30 November 2021* under 37 CFR 1.312 has been considered, and has been:

a) ☒ entered.

b) ☐ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

/ A. Marty Willis /

A. Marty Willis

Publishing Division

Office of Data Management

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 3

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	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	3792
Examiner Name	Michael W. Kahelin
Attorney Docket Number	EMKNNZ00505

Change(s) applied to document, /D.M./ 8/17/2021

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.	5,067,478	~~5,067,478~~	11/1991 ~~5,067,478~~ Berlant	
	2.	8,588,884	~~8,588,884~~	11/2013 ~~8,588,884~~ Hegde, et al.	
	3.	9,002,477	~~9,002,477~~	04/2015 ~~9,002,477~~ Burnett	
	4.	9,005,102	~~9,005,102~~	04/2015 ~~9,005,102~~ Burnett, et al.	
	5.	9,339,641	~~9,339,641~~	05/2016 ~~9,339,641~~ Rajguru, et al.	
	6.	9,387,338	~~9,387,338~~	07/2016 ~~9,387,338~~ Burnett	
	7.	9,630,004	~~9,630,004~~	04/2017 ~~9,630,004~~ Rajguru, et al.	
	8.	9,757,584	~~9,757,584~~	09/2017 ~~9,757,584~~ Burnett	
	9.	10,786,669	~~10,786,669~~	09/2020 ~~10,786,669~~ Rajguru, et al.	
	10.	2004/0237170	~~2004/0237170~~	12/2004 ~~2004/0237170~~ Yamazaki, et al.	
	11.	2005/0240230	~~2005/0240230~~	10/2005 ~~2005/0240230~~ Preston, et al.	
	12.	2005/0283204	~~2005/0283204~~	12/2005 ~~2005/0283204~~ Buhlmann, et al.	
	13.	2006/0015153	~~2006/0015153~~	01/2006 ~~2006/0015153~~ Gliner, et al.	
	14.	2010/0057147	~~2010/0057147~~	03/2010 ~~2010/0057147~~ Fassih, et al.	
	15.	2014/0046423	~~2014/0046423~~	02/2014 ~~2014/0046423~~ Rajguru, et al.	
	16.	2014/0148870	~~2014/0148870~~	05/2014 ~~2014/0148870~~ Burnett	
	17.	2015/0202454	~~2015/0202454~~	07/2015 ~~2015/0202454~~ Burnett	
	18.	2016/0193466	~~2016/0193466~~	07/2016 ~~2016/0193466~~ Burnett	

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	/MICHAEL W KAHELIN/	Date Considered	07/30/2021

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.W.K/

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

Date: November 30, 2021 Signature: /Derrick Tat/ (Derrick Tat)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. §1.312

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

Dear Sir or Madam:

Prior to issuance, entry of this Amendment is respectfully requested.

Amendments to the Specification begin on page 2 of this paper.

Amendment to the Drawings begin on page 3 of this paper.

Remarks begin on page 4 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please amend paragraph **[0053]** as follows:

[0053] FIG. 31 ~~FIGs. 31A-31B~~ show a schematic view of a variation of an arm applicator and a foot, knee or leg applicator.

Please amend paragraphs **[0203]** and **[0204]** as follows:

[0203] Figure 31 ~~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.

[0204] Figure 31 ~~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.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 6

PTO/AIA/22 (10-20)
Approved for use through 11/30/2020. 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): EMKNNZ00505

Application Number: 15/665,152

Filed: July 31, 2017

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

Art Unit: 3792

Examiner: Michael W. Kahelin

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))	$220	$110	$55	$
☑ Two months (37 CFR 1.17(a)(2))	$640	$320	$160	$ 320
☐ Three months (37 CFR 1.17(a)(3))	$1,480	$740	$370	$
☐ Four months (37 CFR 1.17(a)(4))	$2,320	$1,160	$580	$
☐ Five months (37 CFR 1.17(a)(5))	$3,160	$1,580	$790	$

☑ 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 30, 2021 — 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.

Electronic Patent Application Fee Transmittal

Application Number:	15665152
Filing Date:	31-Jul-2017
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/Derrick Tat
Attorney Docket Number:	EMKNNZ00505

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	2252	1	320	320
Miscellaneous:				
			Total in USD ($)	**320**

Electronic Acknowledgement Receipt

EFS ID:	44395411
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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/Derrick Tat
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	30-NOV-2021
Filing Date:	31-JUL-2017
Time Stamp:	15:25:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$320
RAM confirmation Number	E2021ATF27293889
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	Post Allowance Communication - Incoming	01_EMKNNZ00505_20211130_response_to_post_allowance_corrected_application_papers.pdf	21504 bc99e47ea5495624a0e0614999cf90aeacefbf19	no	2
Warnings:					
Information:					
2	Drawings-only black and white line drawings	02_EMKNNZ00505_20211130_replacement_drawings.pdf	950549 3cfedec1c3f234fa37ec7e6cfecd686873ba87c8	no	6
Warnings:					
Information:					
3		03_EMKNNZ00505_20211130_312_amendment.pdf	27178 9eb2f9a06acc869caa8b62b5dd771bab5681b540	yes	4

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment after Notice of Allowance (Rule 312)	1	1
Specification	2	2
Drawings-only black and white line drawings	3	3
Applicant Arguments/Remarks Made in an Amendment	4	4

Warnings:					
Information:					
4	Extension of Time	04_EMKNNZ00505_20211130_extension_of_time.pdf	112386 47c14f677ca98ddfd88c47e6d09dfb58af65a4ab	no	1
Warnings:					
Information:					

5	Fee Worksheet (SB06)	fee-info.pdf	38236 6cc1d1c52587888beccfd7464dcdf81ca57082e9	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	1149853

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 EFS-Web transmitted to the USPTO on the date shown below.
Date: November 30, 2021 Signature: /Derrick Tat/ (Derrick Tat)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

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

Dear Sir or Madam:

This is in response to the Notice to File Corrected Application Papers dated August 18, 2021 for which a response was due on October 18, 2021. Filed herewith is a Petition and fee for a two-month extension of time, thereby extending the deadline for response to December 20, 2021. Accordingly, this response is timely filed. Applicants respectfully submit:

1. Replacement Drawings
2. Amendment After Allowance Under 37 C.F.R. §1.312
3. Petition for Extension of Time

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**.

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. 14

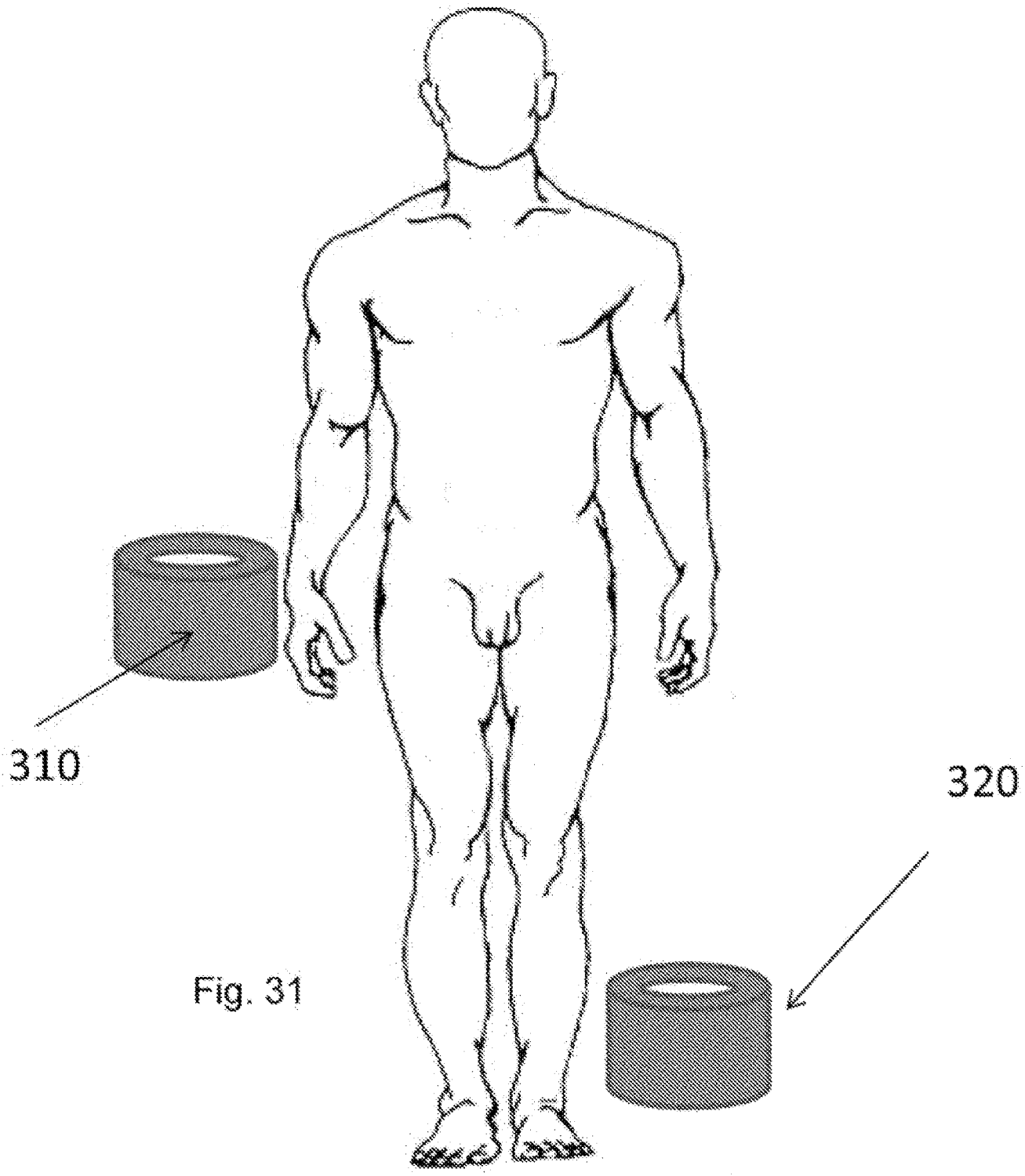


Fig. 31

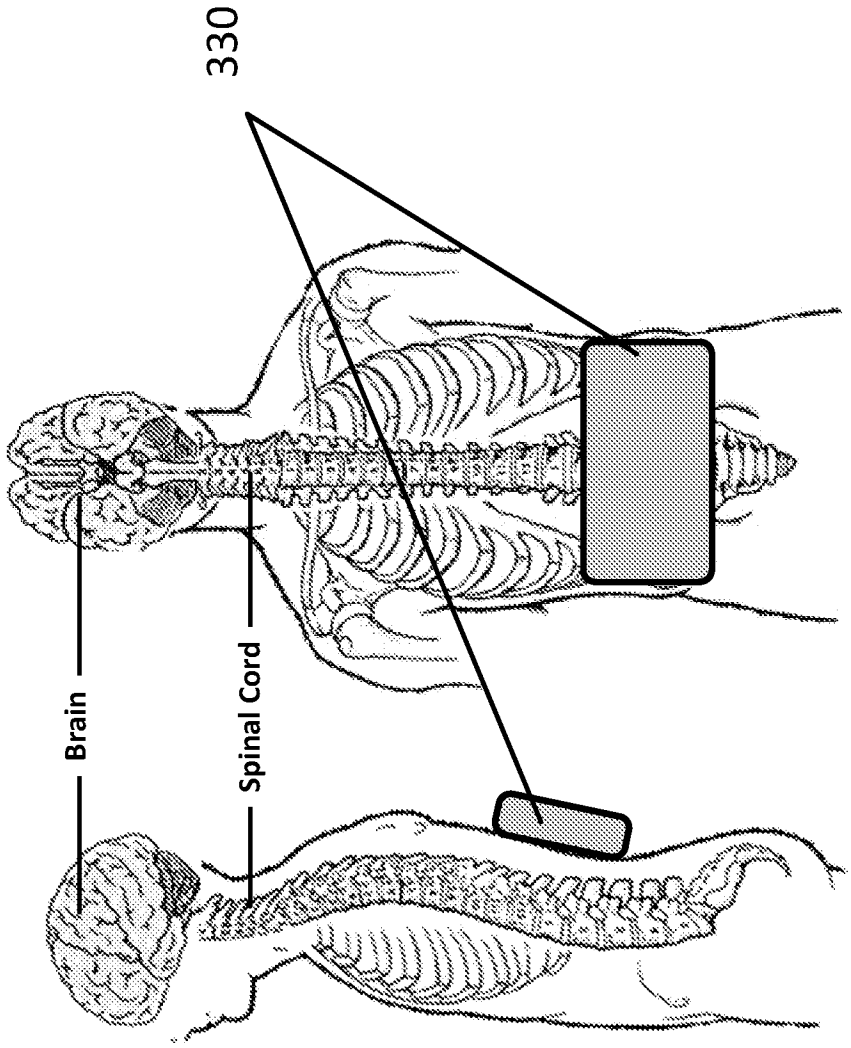


FIG. 32

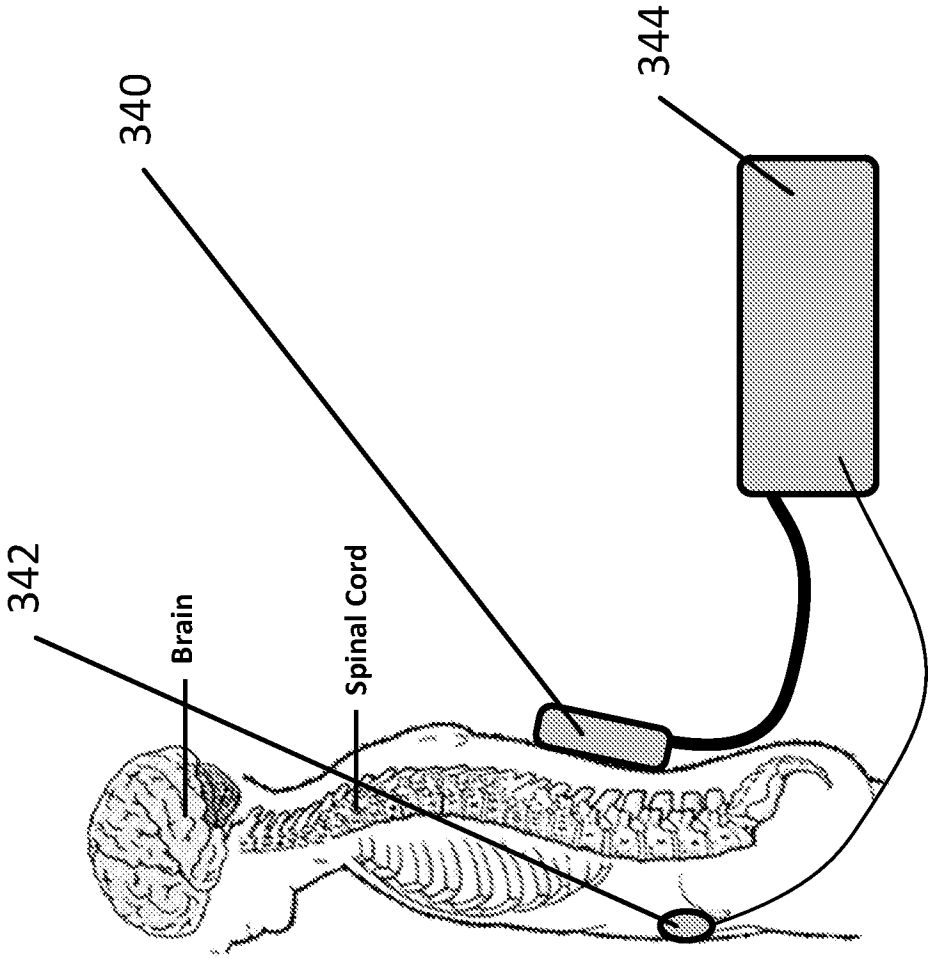


FIG. 33

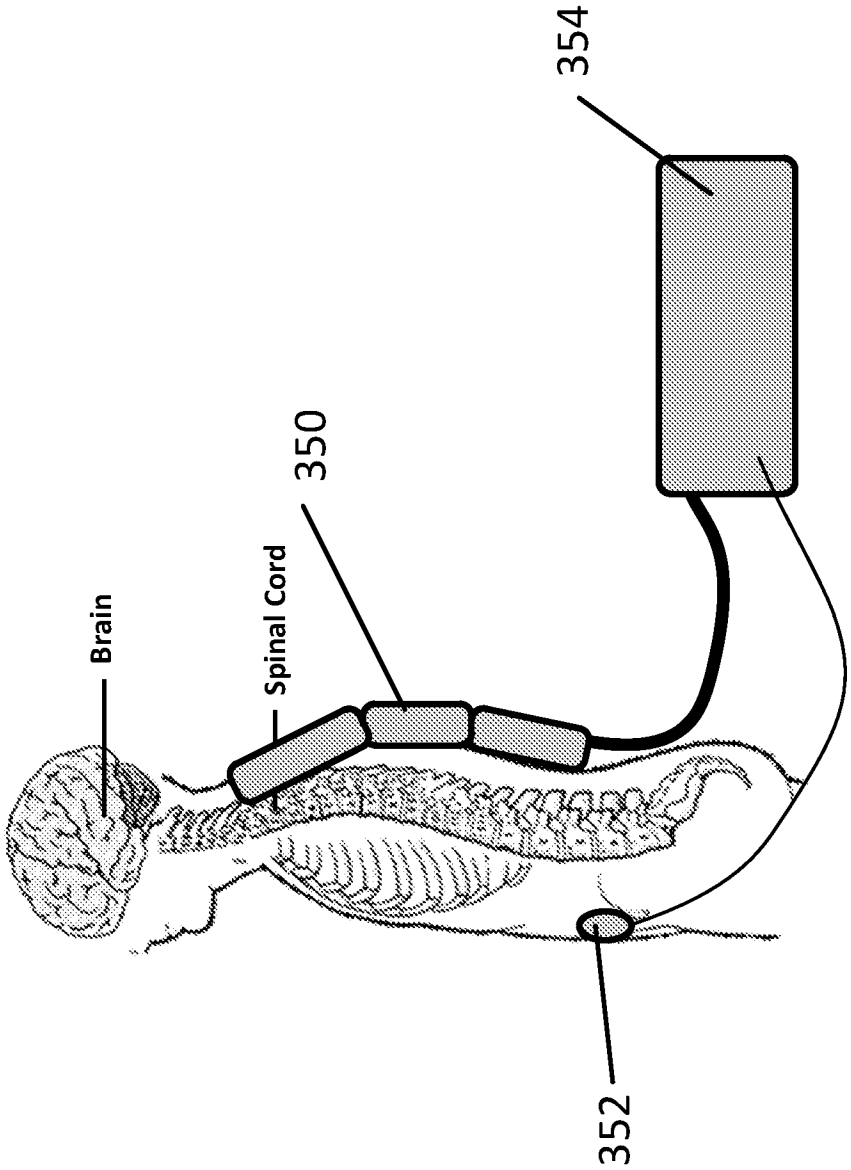


FIG. 34

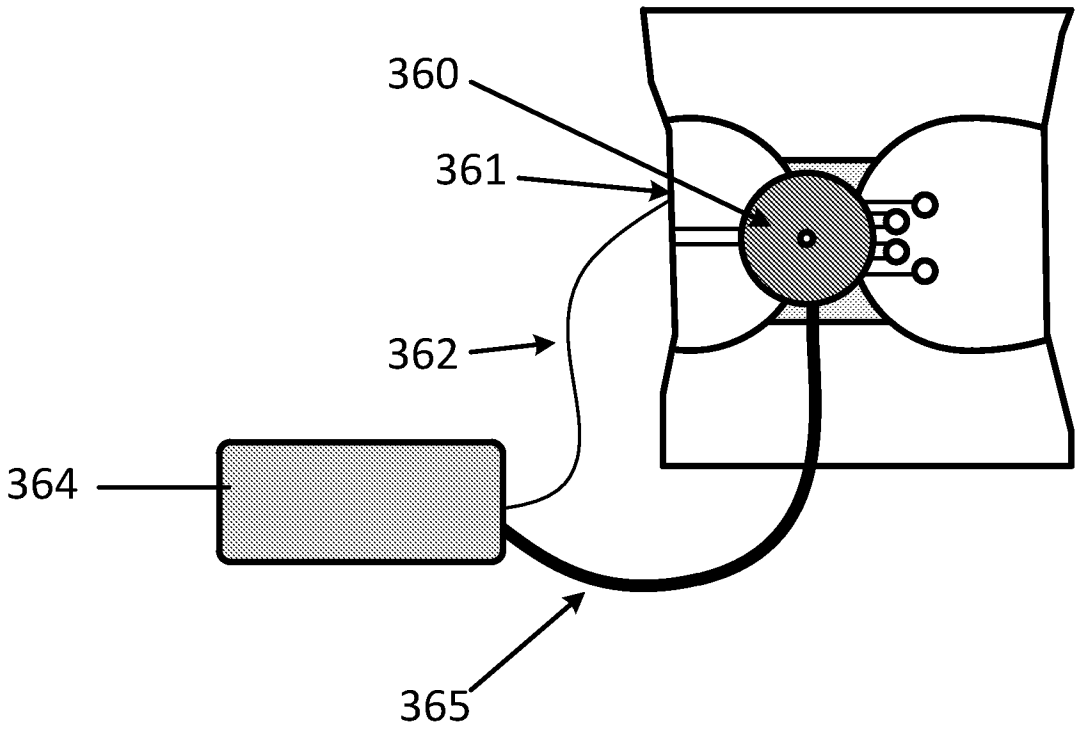


FIG. 35

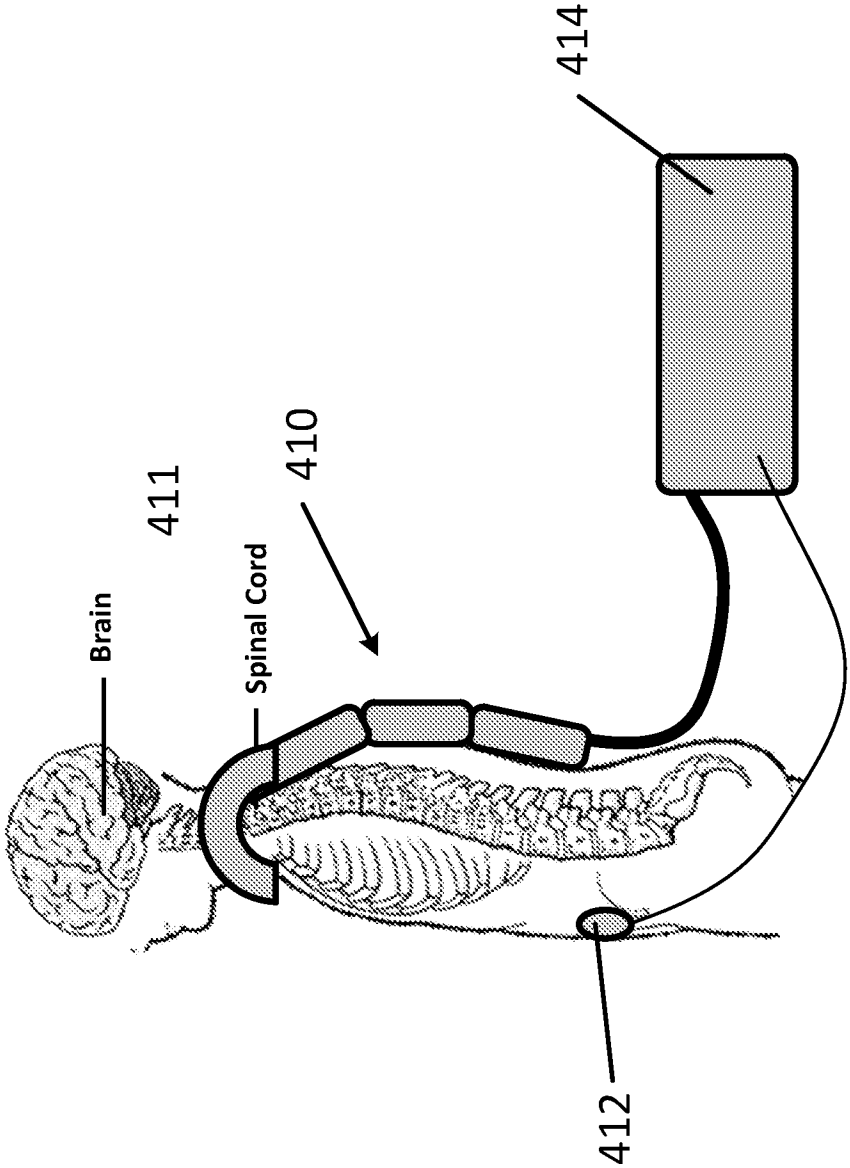


FIG. 41

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include changes to Fig. 31. Figs. 32-35 and 41 have been formalized without amendment. These figures replace the original sheets as filed.

Attachment: Replacement Sheet

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 21

REMARKS

Claims 5-17 were allowed in the present application. By virtue of this amendment, no claims have been cancelled, amended, or added. Accordingly, claims 5-17 remain allowed. 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.

Figs 32-35 and 41 have been formalized and the specification and Fig. 31 have been amended in response to the Notice to File Corrected Application Papers mailed August 10, 2021. 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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**.

Respectfully submitted,

/Johney U. Han/

Johney U. Han
Registration No. 45,565

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

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 11/09/2021

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

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
11/09/2021	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENT@LBHIP.COM

Corrected ***Notice of Allowability***	**Application No.** 15/665,152	**Applicant(s)** BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	**Art Unit** 3792	**AIA (FITF) 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 the claims of 3/19/21 and the letter of 11/1/21.
   ☐ 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 5-17 . 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 _____.
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 _____.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 24

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	**Art Unit**
	MICHAEL W KAHELIN	3792

CPC								
Symbol							**Type**	**Version**
A61N	/	1	/	0502			F	2013-01-01
A61N	/	1	/	36017			I	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	/	2	/	02			I	2013-01-01
A61N	/	1	/	36007			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	/	2	/	008			I	2013-01-01
A61N	/	1	/	0492			I	2013-01-01
A61N	/	1	/	0456			A	2013-01-01
A61N	/	1	/	0484			A	2013-01-01
A61N	/	1	/	36003			A	2013-01-01

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

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	13	
/MICHAEL W KAHELIN/ Primary Examiner, Art Unit 3792	04 November 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	24

U.S. Patent and Trademark Office

Part of Paper No.: 20211104

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 25

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	**Art Unit**
	MICHAEL W KAHELIN	3792

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61N1/05	/	1	/	05
A61N1/36	/	1	/	36

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	13	
/MICHAEL W KAHELIN/ Primary Examiner, Art Unit 3792	04 November 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	24

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 26

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	**Art Unit**
	MICHAEL W KAHELIN	3792

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	13	
/MICHAEL W KAHELIN/ Primary Examiner, Art Unit 3792	04 November 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	24

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 27

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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 08/05/2021
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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Derrick Tat	(Typed or printed name)
/Derrick Tat/	(Signature)
November 1, 2021	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

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	$600	$0.00	$0.00	$600	11/05/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAHELIN, MICHAEL WILLIAM	3792	607-041000

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 03-09 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE	(B) RESIDENCE: (CITY and STATE OR COUNTRY)
EMKinetics, Inc.	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. Fees submitted: ☑ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☑ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 50-3973

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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.
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.
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 November 1, 2021

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

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Petitioner - Avation Medical, Inc.
Ex. 1002, p. 28

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

Date: November 1, 2021 Signature: /Derrick Tat/ (Derrick Tat)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

REQUEST REGARDING REPRESENTATIVE FIGURE

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

Dear Sir or Madam:

Applicants respectfully request that Figure 24 be published as the representative figure for the above referenced issuing application.

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**.

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

Electronic Patent Application Fee Transmittal

Application Number:	15665152
Filing Date:	31-Jul-2017
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/Derrick Tat
Attorney Docket Number:	EMKNNZ00505

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:				
UTILITY APPL ISSUE FEE	2501	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt

EFS ID:	44170624
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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/Derrick Tat
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	01-NOV-2021
Filing Date:	31-JUL-2017
Time Stamp:	13:24:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	E2021A1D24354270
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)	01_EMKNNZ00505_20211101_issue_fee_transmittal.pdf	217632 d23f98e05c8d69efd55d5e327312c657c5af265c	no	1
Warnings:					
Information:					
2	Post Allowance Communication - Incoming	02_EMKNNZ00505_20211101_request_for_representative_figure.pdf	19266 bf2bad8374973fcd13e30ad961dc0f67e35840c5	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	37860 7202bde29ab8431374da24ae09c9061fa1cf64fb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	274758		

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
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.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 08/18/2021

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

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
08/18/2021	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENT@LBHIP.COM

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 15665152
Applicant : Burnett
Filing Date : 07/31/2017
Date Mailed : 08/18/2021

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Naran Hem/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 15665152 **Drawings filed: 07/31/2017**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [X] Drawing sheet or figure is missing. FIG(s) 31b
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [X] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s) 32-35, 41
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as "New" or "Amended" or "Canceled" as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as "Canceled" but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as "Canceled." See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

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
15/665,152	07/31/2017	3792	730	EMKNNZ00505	8	2

CONFIRMATION NO. 6227

CORRECTED FILING RECEIPT

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

OC000000127585303

Date Mailed: 08/10/2021

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Daniel R. BURNETT, San Francisco, CA;

Applicant(s)

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 15/056,910 02/29/2016 PAT 9757584
which is a CON of 14/676,635 04/01/2015 PAT 9387338
which is a CON of 14/085,639 11/20/2013 PAT 9002477
which is a CON of 13/456,016 04/25/2012 ABN
which is a CON of PCT/US2010/054167 10/26/2010
which claims benefit of 61/279,883 10/26/2009
and said 14/085,639 11/20/2013
is a CIP of 12/508,529 07/23/2009 ABN
which is a CIP of 11/866,329 10/02/2007 ABN
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.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 37

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 09/05/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/665,152**

Projected Publication Date: Not Applicable

Non-Publication Request: No

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

METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS

Preliminary Class

607

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

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 38

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).

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 39

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.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 40

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

40518 7590 08/05/2021
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

EXAMINER
KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 08/05/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

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	$600	$0.00	$0.00	$600	11/05/2021

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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 41

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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 08/05/2021

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

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	$600	$0.00	$0.00	$600	11/05/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAHELIN, MICHAEL WILLIAM	3792	607-041000

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 03-09 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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.
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.
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. _____

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 42

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.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 08/05/2021

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

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 08/05/2021

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.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 43

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 30 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.

Petitioner - Aviation Medical, Inc.
Ex. 1002, p. 44

Notice of Allowability	Application No. 15/665,152	Applicant(s) BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	AIA (FITF) 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 the amendment of 3/19/2021.
   ☐ 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 5-17 . 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 _____.
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 _____.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 45

Notice of Pre-AIA or AIA Status

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

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/19/2021 has been entered.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the closest prior art of record fails to disclose or fairly render unpatentable the combination of elements in claim 5 including direct stimulation of a posterior tibial nerve branch to treat overactive bladder or incontinence.

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 MICHAEL WILLIAM KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

CPC - Searched*		
Symbol	Date	Examiner
A61N 1/36007	07/12/2019	MWK
A61N 1/36031,0456	11/19/2019	MWK
updated above	04/09/2020	MWK
updated above	10/05/2020	MWK
updated above	07/30/2021	MWK

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 48

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

Search Notes		
Search Notes	**Date**	**Examiner**
inventor search	07/12/2019	MWK
global dossier search	07/12/2019	MWK
IDS review	07/12/2019	MWK
see attached EAST search history	07/12/2019	MWK
see attached EAST search history	11/19/2019	MWK
NPL search	11/19/2019	MWK
see attached EAST search history	04/09/2020	MWK
see attached EAST search history	10/05/2020	MWK
see attached EAST search history	07/30/2021	MWK
IDS review	07/30/2021	MWK
related application review	07/30/2021	MWK

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61N1$	see attached EAST interference search	07/30/2021	MWK

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 49

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	**Art Unit**
	MICHAEL W KAHELIN	3792

CPC								
Symbol							**Type**	**Version**
A61N	/	1	/	0502			F	2013-01-01
A61N	/	1	/	36017			I	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	/	2	/	02			I	2013-01-01
A61N	/	1	/	36007			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	/	2	/	008			I	2013-01-01
A61N	/	1	/	0492			I	2013-01-01
A61N	/	1	/	0456			A	2013-01-01
A61N	/	1	/	0484			A	2013-01-01
A61N	/	1	/	36003			A	2013-01-01

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

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	13	
/MICHAEL W KAHELIN/ Primary Examiner, Art Unit 3792	30 July 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	11

U.S. Patent and Trademark Office

Part of Paper No.: 20210729

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 50

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	**Art Unit**
	MICHAEL W KAHELIN	3792

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61N1/05	/	1	/	05
A61N1/36	/	1	/	36

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	13	
/MICHAEL W KAHELIN/ Primary Examiner, Art Unit 3792	30 July 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	11

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	**Art Unit**
	MICHAEL W KAHELIN	3792

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	13	
/MICHAEL W KAHELIN/ Primary Examiner, Art Unit 3792	30 July 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	11

U.S. Patent and Trademark Office

Part of Paper No.: 20210729

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 52

Bibliographic Data

Application No: 15/665,152

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /MICHAEL W KAHELIN/ Examiner's Signature | Initials

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

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/31/2017	607	3792	EMKNNZ00505
RULE			

APPLICANTS

INVENTORS

Daniel R. BURNETT, San Francisco, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15056910 02/29/2016 PAT 9757584

15056910 is a CON of 14676635 04/01/2015 PAT 9387338

14676635 is a CON of 14085639 11/20/2013 PAT 9002477

14085639 is a CON of 13456016 04/25/2012ABN

13456016 is a CON of PCT/US2010/054167 10/26/2010

PCT/US2010/054167 has PRO of 61279883 10/26/2009

14085639 is a CIP of 12508529 07/23/2009ABN

12508529 is a CIP of 11866329 10/02/2007ABN

11866329 has PRO of 60848720 10/02/2006

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

09/05/2017

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

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

FILING FEE RECEIVED

$730

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	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	3792
Examiner Name	Michael W. Kahelin
Attorney Docket Number	EMKNNZ00505

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.	5,067,478	5,067,478	5,067,478	
	2.	8,588,884	8,588,884	8,588,884	
	3.	9,002,477	9,002,477	9,002,477	
	4.	9,005,102	9,005,102	9,005,102	
	5.	9,339,641	9,339,641	9,339,641	
	6.	9,387,338	9,387,338	9,387,338	
	7.	9,630,004	9,630,004	9,630,004	
	8.	9,757,584	9,757,584	9,757,584	
	9.	10,786,669	10,786,669	10,786,669	
	10.	2004/0237170	2004/0237170	2004/0237170	
	11.	2005/0240230	2005/0240230	2005/0240230	
	12.	2005/0283204	2005/0283204	2005/0283204	
	13.	2006/0015153	2006/0015153	2006/0015153	
	14.	2010/0057147	2010/0057147	2010/0057147	
	15.	2014/0046423	2014/0046423	2014/0046423	
	16.	2014/0148870	2014/0148870	2014/0148870	
	17.	2015/0202454	2015/0202454	2015/0202454	
	18.	2016/0193466	2016/0193466	2016/0193466	

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]

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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	/MICHAEL W KAHELIN/	Date Considered	07/30/2021

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.W.K./

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 15/665,152	Filing Date 07/31/2017	☐ 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 $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	03/19/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 13	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/JAMES ELLIOTT/
*** 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.	

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.

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	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	3792
Examiner Name	Michael W. Kahelin
Attorney Docket Number	EMKNNZ00505

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.	5,067,478	5,067,478	5,067,478	
	2.	8,588,884	8,588,884	8,588,884	
	3.	9,002,477	9,002,477	9,002,477	
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	5.	9,339,641	9,339,641	9,339,641	
	6.	9,387,338	9,387,338	9,387,338	
	7.	9,630,004	9,630,004	9,630,004	
	8.	9,757,584	9,757,584	9,757,584	
	9.	10,786,669	10,786,669	10,786,669	
	10.	2004/0237170	2004/0237170	2004/0237170	
	11.	2005/0240230	2005/0240230	2005/0240230	
	12.	2005/0283204	2005/0283204	2005/0283204	
	13.	2006/0015153	2006/0015153	2006/0015153	
	14.	2010/0057147	2010/0057147	2010/0057147	
	15.	2014/0046423	2014/0046423	2014/0046423	
	16.	2014/0148870	2014/0148870	2014/0148870	
	17.	2015/0202454	2015/0202454	2015/0202454	
	18.	2016/0193466	2016/0193466	2016/0193466	

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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]

*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]

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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		Date Considered	

Electronic Patent Application Fee Transmittal

Application Number:	15665152
Filing Date:	31-Jul-2017
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00505

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	2253	1	740	740
Miscellaneous:				
RCE- 2ND AND SUBSEQUENT REQUEST	2820	1	1000	1000
		Total in USD ($)		**1740**

Electronic Acknowledgement Receipt

EFS ID:	42231887
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	19-MAR-2021
Filing Date:	31-JUL-2017
Time Stamp:	18:12:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1740
RAM confirmation Number	E20213II13033913
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	Request for Continued Examination (RCE)	01_EMKNNZ00505_20210319_rce_efs.pdf	1323918 c12540d678086ad99f3f06c544e95390142907a6	no	3
Warnings:					
Information:					
2		02_EMKNNZ00505_20210319_response_to_final_office_action.pdf	183242 83f53fb6fa826e74ee543dc7264a4c135a3b07db	yes	9

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Claims	2	4
Applicant Arguments/Remarks Made in an Amendment	5	9

Warnings:					
Information:					
3	Extension of Time	03_EMKNNZ00505_20210319_extension_of_time.pdf	104372 48b7b77d44dc794a0bae02db9a529ddc50be2911	no	1
Warnings:					
Information:					
4	Transmittal Letter	04_EMKNNZ00505_20210319_ids_cover_letter.pdf	22411 18dfbec95299a9ecf81e3f7b34269215b44fab94	no	2
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	05_EMKNNZ00505_20210319_ids_sb08.pdf	26279 6e351d2e6dff649d7a9c610523dfac133c5ec1a4	no	1

Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
6	Fee Worksheet (SB06)	fee-info.pdf	32435 5e134d1e58e914461a913eef35198d5f4559c54b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1692657	

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.

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	15/665,152	Filing Date	2017-07-31	Docket Number (if applicable)	EMKNNZ00505	Art Unit	3792
First Named Inventor	Daniel R. BURNETT			Examiner Name	Michael W. Kahelin		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☒ Other Extension of Time

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 503973

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 63

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. 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 contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Johney U. Han/	Date (YYYY-MM-DD)	2021-03-19
Name	Johney U. Han	Registration Number	45565

This collection of information is required by 37 CFR 1.114. 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.

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

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 the Freedom of Information Act requires disclosure of these records.

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 inspections 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.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 65

I hereby certify that this correspondence is being EFS-Web transmitted to the USPTO on the date shown below.		
Date: March 19, 2021	Signature: /Laura L. Gallagher/	(Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

RESPONSE TO FINAL OFFICE ACTION

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

Dear Sir:

This is in response to the final Office Action dated October 9, 2020 for which a response was due on January 9, 2021. Filed herewith is a Petition and fee for a three-month extension of time, thereby extending the deadline for response to April 9, 2021. 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 5 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.-4. (Canceled)

5. (Currently Amended): A method of treating overactive bladder or incontinence, comprising:

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

passing a current through the electrical stimulator; and

delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve such that the branch directly receives the electrical stimulation to treat overactive bladder or incontinence.

6. (Previously Presented): The method of claim 5, wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator upon a foot of the patient.

7. (Previously Presented): The method of claim 5, further comprising detecting a muscular response caused by an electrical conduction or stimulation of the branch of the posterior tibial nerve.

8. (Previously Presented): The method of claim 5, wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.

9. (Previously Presented): The method of claim 5 further comprising displaying physiological parameters detected from the patient.

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10. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.

11. (Previously Presented): The method of claim 10 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

12. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.

13. (Previously Presented): The method of claim 12 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

14. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.

15. (Previously Presented): The method of claim 14 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

16. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.

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17. (Previously Presented): The method of claim 16 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

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REMARKS

Claims 5-17 were pending in the present application. By virtue of this response, claim 5 has been amended. Accordingly, claims 5-17 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.

Rejections under 35 U.S.C. §102(b)/§103(a)

Claims 5-7, 9, and 14 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Amarenco et al. ("Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, 169, 2210-2215, June 2003), or in the alternative under 35 U.S.C. §103(a) as being obvious over Amarenco et al. in view of Mann et al. (U.S. Pub. 2002/0055761).

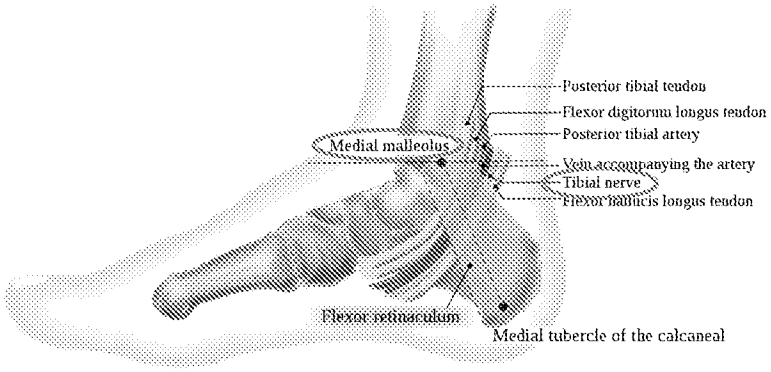
Independent claim 5 has been amended to clarify that "such that a branch of a posterior tibial nerve … is ***directly targeted by*** the electrical stimulator … delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve ***such that the branch directly receives the electrical stimulation***". (Emphasis added.)

The Office proffers that when Amarenco teaches the placement of an "electrode gel on the ankle skin with the negative electrode behind the intneral malleoulus …." (*rf.* Amarenco, p. 2211, col. 1, para. 3), this is equivalent to "delivery stimulation behind that internal malleolus is 'delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve' at least indirectly because the stimulation causes plantar muscle contraction via the plantar nerve branch(es) …." (Office Action, p. 3, para. 2.)

However, Applicant contends that this is factually and physically incorrect as the internal malleolus is located on the inside of the ankle where the tibial nerve resides and not a branch of the tibial nerve. More specifically, the internal malleolus refers to the "pyramid-shaped process of the tibia that projects distally on the medial side of its lower end at the ankle" (https://www.merriam-webster.com/medical/malleolus)

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As shown in the following illustration (https://en.wikipedia.org/wiki/Tarsal_tunnel), the positioning of the posterior tibial nerve is highlighted relative to the medial malleolus which is also highlighted for reference purposes:



The illustration clearly shows how the posterior tibial nerve is positioned relative to the medial malleolus proximal to where the posterior tibial nerve branches. Hence, there is nothing in Amarenco which teaches delivery of stimulation to a branch of the posterior tibial nerve, as presently claimed.

In the alternative, the Office further proffers that Mann teaches that "branches of nerves projecting from the sacral cord would likewise be suitable locations … for stimulation …." (Office Action, p. 3, para. 2.)

However, as previously presented, Mann et al. fails to teach or suggest stimulation to a branch of the posterior tibial nerve anywhere. Mann et al. teaches stimulation of the sacral nerves only in relation to stimulation of the pudendal nerve and/or its branches. (Mann et al., [0079].) Mann et al. refers to the tibial nerve separately from the pudendal nerve and expressly teaches that the "tibial nerve is relatively easily accessible (i.e., relatively near the overlying skin with no muscle between the nerve and the skin) at two sites in the leg …." (*Id.*, [0080].) Yet the stimulation provided by Mann et al. is expressly described for "electrical stimulation to directly activate the pudendal nerve and/or its branches ***by means of an implantable signal generator and electrode(s)*** …." (Emphasis added, *Id.*, [0073].)

Hence, Mann et al. may teach the electrical stimulation of the tibial nerve, which is readily accessible near the overlying skin, it does so by the use of an implantable signal generator and electrodes but fails to teach or suggest stimulation ***to a branch of the posterior tibial nerve*** anywhere.

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The Office further proffers that since "the plantar muscles are innervated by branches of the posterior tibial nerve, this is 'delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve' in the efferent direction …." (Office Action, p. 5, para. 2 – p. 6, para. 1.)

The independent claim 5 has been amended to clarify that the electrical stimulation directly targets the branch of a posterior tibial nerve rather than the plantar muscles which may or may not be innervated.

Thus, Mann et al. necessarily fails to cure the defects of Amarenco et al. and the combination of references fails to teach each and every limitation of independent claim 5 which is patentable over each of the references alone or in combination. 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)/§103(a).

Rejections under 35 U.S.C. §103(a)

A. Claim 8 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Amarenco et al. in view of Mann et al. (U.S. Pub. 2002/0055761).

Dependent claim 8 depends from independent claim 5 and is patentable over Amarenco et al. for at least the same reasons above. Mann et al. fails to cure the defects of Amarenco et al. and the claim is patentable over each of the cited references alone or in combination.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

B. Claims 10-13 and 15-17 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Amarenco et al. in view of Lund et al. (U.S. Pub. 2007/0265675).

Dependent claims 10-13 and 15-17 depend ultimately from independent claim 5 and are patentable over Amarenco et al. for at least the same reasons above. Lund et al. fails to cure the defects of Amarenco et al. and the claims are patentable over each of the cited references alone or in combination.

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Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

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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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**.

Respectfully submitted,

/Johney U. Han/

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PTO/AIA/22 (10-20)
Approved for use through 11/30/2020. 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): March 19, 2021

Application Number: 15/665,152

Filed: July 31, 2017

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

Art Unit: 3792

Examiner: Michael W. Kahelin

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))	$220	$110	$55	$
☐	Two months (37 CFR 1.17(a)(2))	$640	$320	$160	$
☑	Three months (37 CFR 1.17(a)(3))	$1,480	$740	$370	$ 740
☐	Four months (37 CFR 1.17(a)(4))	$2,320	$1,160	$580	$
☐	Five months (37 CFR 1.17(a)(5))	$3,160	$1,580	$790	$

☑ 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

March 19, 2021 — 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 EFS-Web transmitted to the USPTO on the date shown below.			
Date: March 19, 2021	Signature:	/Kevin D. Ho/	(Kevin D. Ho)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop RCE
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 with the filing of a Request for Continued Examination under § 1.114; accordingly, no fee or separate requirements are required.

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**. However, the Commissioner is not authorized to charge the surcharge for late filing of an Oath or Declaration until issuance of a pre-exam formalities Notice.

Respectfully submitted,

/Johney U. Han/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 10/09/2020

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

EXAMINER
KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
10/09/2020	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENT@LBHIP.COM

Office Action Summary	Application No. 15/665,152	Applicant(s) BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	AIA (FITF) 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 8/21/2020.

☐ 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) 5-17 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) 5-17 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 _____.

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

4) ☐ Other: _____.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of pre-AIA 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.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, 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 negatived by the manner in which the invention was made.

Claim(s) 5-7, 9, and 14 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Amarenco et al. ("Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, 169, 2210-2215, June 2003; hereinafter "Amarenco"), or in the alternative under section 103(a) as being obvious over Amarenco in view of Mann et al. (US 2002/0055761, hereinafter "Mann").

In regards to claim 5, Amarenco discloses non-invasively positioning a first portion of a patient's body with respect to an electrical stimulator such that a branch of a posterior tibial nerve is in proximity (abstract); passing a current through the stimulator; and delivering electrical stimulus from the electrical stimulator to the branch of the nerve (page 2211, "Procedure," "The correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction") to treat overactive bladder or incontinence (page 2211, "Procedure," second full paragraph). The examiner's position is that delivering stimulation behind that internal malleolus is "delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve" at least indirectly because the stimulation causes plantar muscle contraction via the plantar nerve branch(es) (i.e., in the efferent direction). Alternatively and additionally, Amarenco discloses the essential features of the claimed invention including afferent posterior tibial nerve stimulation that provides central inhibition of the preganglionic bladder motor neurons through a direct route in the sacral cord (page 2214, second full paragraph), but does not expressly disclose directly and exclusively stimulating a branch of the posterior tibial nerve in the afferent direction. However Mann, in the same field of endeavor of incontinence control teaches that the tibial nerve is a suitable target for incontinence control through the sacral cord (pars. 0079 and 0080) and the branches of nerves projecting from the sacral cord would likewise be suitable locations (par. 0079) for stimulation as these also lead to recruitment of the sacral cord and particular branches may offer advantages for the treatment of certain disorders such as avoiding unwanted side effects (par. 0079). Therefore, it would

have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by providing stimulation directly and exclusively to a branch of the posterior tibial nerve to provide the predictable results of effectively recruiting the sacral cord for incontinence control with particular branches that may offer advantages for the treatment of certain disorders such as avoiding unwanted side effects.

In regards to claim 6, positioning comprises positioning an electrode patch upon a foot of the patient (page 2211, "Procedure," "behind the internal malleolus).

In regards to claim 7, the method further comprises detecting a muscular response cause by stimulation (page 2211, "Procedure," "visualization of rhythmic flexion of the toes).

In regards to claim 9, the method further includes displaying physiological parameters detected from the patient (Figs. 3 and 4).

In regards to claims 14 and 16, the method further includes detecting for presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement (page 2211, "Procedure," visualization of rhythmic flexion of the toes).

Claims 8 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco in view of Mann. Amarenco (or modified Amarenco) discloses the essential features of the claimed invention except for activating for a duration of about 30 minutes per week. However, Mann teaches that it was known in the art of tibial nerve stimulation to deliver stimulation for a duration of about 30 minutes per week (par. 0038) to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by stimulating for a duration of about 30 minutes per week to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence.

Claims 10-13 and 15-17 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco (and/or Amarenco and Mann) in view of Lund et al. (US 2007/0265675, hereinafter "Lund"). Amarenco discloses the essential features of the claimed invention including optimizing stimulation parameters by looking at the muscular response of the patient (page 2211, "Procedure"), but does not expressly disclose determining that response with an electrode or that the presence of conduction as an indicator of electrode migration or electrode malfunction. Lund teaches determining stimulation response with EMG electrodes (e.g., 146) as an indicator of electrode migration (par. 0037) or electrode malfunction (by virtue of its migration) to provide the predictable results of optimizing therapy based on feedback from the patient (par. 0035). Furthermore, it is well-known in the art to embody surface EMG electrodes as patches to provide the predictable results of comfortable and self-carrying electrodes that do not require a user to hold them in contact with the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by determining stimulation response with EMG electrodes as an indicator of electrode migration or electrode malfunction to provide the predictable results of optimizing therapy based on feedback from the patient, and embody the surface EMG electrode as a patch to provide the predictable results of comfortable and self-carrying electrodes that do not require a user to hold them in contact with the body.

Response to Arguments

Applicant's arguments filed 8/21/2020 have been fully considered but they are not persuasive. The previous rejection under the 102 rationale remains unaddressed. As set forth above, the examiner's position is that Amarenco anticipates the claimed subject matter because of the disclosure of causing plantar muscle contractions (page 211, "procedure"). Since the plantar muscles are innervated by branches of the posterior tibial nerve, this is "delivering an electrical stimulus from the electrical

stimulator to the branch of the posterior tibial nerve" in the efferent direction, and Amarenco's method is "to treat overactive bladder or incontinence." In regards to the alternative and additional obviousness rejection, Applicant argued that the combination fails to render the claimed subject matter obvious because Mann only teaches stimulation of sacral nerves in relation to the pudendal nerve and/or its branches, and refers to tibial nerve stimulation separately from the pudendal nerve. Further, Applicant argued that Mann is described for stimulation by means of an implantable system. Applicant then concludes that there is no teaching or suggestion for stimulation of a branch of the posterior tibial nerve. The examiner respectfully disagrees. Mann recognizes that incontinence control can be effectuated by recruitment of the relevant sacral nerves via the pudendal nerve and/or its branches (mapping to the S2, S3, and S4 nerves) or to the tibial nerve (which maps to the S1, S2, and S3 nerves; see attached Wikipedia reference to the tibial nerve); and that there is an advantage to stimulating nerve branches to "avoid[] recruitment of nerves unrelated to the desired treatment" (par. 0079). The examiner respectfully maintains that such disclosures would reasonably lead an artisan of ordinary skill to conclude that stimulation of branches of the tibial nerve would also yield the predictable results of avoiding recruitment of nerves unrelated to the desired treatment.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL WILLIAM KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/665,152	Applicant(s)/Patent Under Reexamination BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A					
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	"Tibial Nerve." Wikipedia, accessed 10/5/2020, https://en.wikipedia.org/wiki/Tibial_nerve. (Year: 2020)
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61N 1/36007	07/12/2019	MWK
A61N 1/36031,0456	11/19/2019	MWK
updated above	04/09/2020	MWK
updated above	10/05/2020	MWK

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
inventor search	07/12/2019	MWK
global dossier search	07/12/2019	MWK
IDS review	07/12/2019	MWK
see attached EAST search history	07/12/2019	MWK
see attached EAST search history	11/19/2019	MWK
NPL search	11/19/2019	MWK
see attached EAST search history	04/09/2020	MWK
see attached EAST search history	10/05/2020	MWK

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 87

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 88

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	15/665,152
				Filing Date	July 31, 2017
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3792
(Use as many sheets as necessary)				Examiner Name	Michael W. Kahelin
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00505

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.	2020/0139120	05-07-2020	Rajguru 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]

*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	/MICHAEL W KAHELIN/	Date Considered	10/05/2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.W.K/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	4	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$ or US-20070265675-$).did.	US-PGPUB	OR	ON	2020/10/05 11:22
L2	326	(A61N1$).cpc. and (plantar and (bladder urinary))	US-PGPUB; USPAT; USOCR	OR	ON	2020/10/05 11:22
L3	326	2 and (sural calcaneal plantar)	US-PGPUB; USPAT; USOCR	OR	ON	2020/10/05 11:23
L4	1	1 and (sural calcaneal plantar)	US-PGPUB; USPAT; USOCR	OR	ON	2020/10/05 11:23
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L6	1	("20100004715").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/10/05 11:50
L7	2	(("20120059432") or ("20130006322")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/10/05 11:51
L8	1	("20200139120").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/10/05 11:53
L9	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/10/05 11:54
L10	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/10/05 12:26
L11	3,101	(A61N1/36007 or A61N1/0456).cpc.	US-PGPUB	OR	ON	2020/10/05 13:13
L12	682	(A61N1/36031).cpc.	US-PGPUB	OR	ON	2020/10/05 13:13
L13	3,489	11 12	US-PGPUB	OR	ON	2020/10/05 13:13
S1	294	((("BURNETT") near3 ("Daniel"))).INV.	US-PGPUB; USPAT; USOCR;	OR	ON	2019/07/11 11:46

			EPO; JPO; DERWENT			
S2	10	S1 and (tibial and bladder).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 11:49
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S5	1	("20090076565").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 12:00
S6	1	(11/857872).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:12
S7	478	(A61N1$).cpc. and (tibial and bladder)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:13
S8	550	(A61N1$).cpc. and (tibial and (bladder urinary))	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:14
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S10	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:21
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S15	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:38
S16	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:44

S17	438	S8 and (feedback sensor)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:48
S18	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:23
S19	1	("9757584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:41
S20	2	(14/676635).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:55
S21	33	(11/866329 | 12/469358 | 12/469365 | 12/469625 | 12/508529 | 12/509304 | 12/509345 | 12/509362 | 12/606941 | 12/695087 | 12/790619 | 13/456016 | 13/457228 | 14/085639 | 14/097568 | 14/676635 | 14/685278 | 14/931702 | 14/949735 | 15/056910 | 15/084356 | 15/436538 | 15/474875).APP.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 09:59
S22	4	S21 and percutaneous.clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:00
S23	228	(A61N1/36007).cpc. and tibial	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:02
S24	1	("20140159912").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 11:34
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S26	314	(A61N1$).cpc. and (posterior adj tibial)	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:05
S27	2,677	(A61N1/36007).cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:06
S28	90	S26 and S27	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:06
S29	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/18 14:20
S30	1	("20120296391").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:05

S31	2	(("20120296391") or ("20150012063")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:07
S32	1	(15/696048).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:15
S33	3	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$).did.	US-PGPUB	OR	ON	2019/11/19 12:38
S34	2,804	(A61N1/36007 or A61N1/0456).cpc.	US-PGPUB	OR	ON	2019/11/19 12:39
S35	580	S34 and emg	US-PGPUB	OR	ON	2019/11/19 12:39
S36	155	(A61N1/36031).cpc.	US-PGPUB	OR	ON	2019/11/19 12:56
S37	0	(A61N1$).cpc. and (feedback same emg same (migrat$4 malfunction$4))	US-PGPUB	OR	ON	2019/11/19 13:07
S38	177	(A61N1$).cpc. and (feedback same emg and (migrat$4 malfunction$4))	US-PGPUB	OR	ON	2019/11/19 13:07
S39	2	(("9757584") or ("9387338")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 14:59
S40	2	(("7126483") or ("8328420")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 15:58
S41	1	("7942824").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 17:09
S42	1	("9610459").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/08 12:35
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S44	4	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$ or US-20070265675-$).did.	US-PGPUB	OR	ON	2020/04/08 13:47
S45	1	S44 and plantar	US-PGPUB; USPAT; USOCR	OR	ON	2020/04/08 13:47
S46	297	(A61N1$).cpc. and (plantar and (bladder urinary))	US-PGPUB; USPAT; USOCR	OR	ON	2020/04/08 13:48
S47	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/08 13:52

S48	6	(("6443883") or ("20020111777") or ("20020082465") or ("20040138517") or ("5715837") or ("4915110")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/08 15:29
S49	4	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$ or US-20070265675-$).did.	US-PGPUB	OR	ON	2020/04/08 15:48
S50	2	S49 and branch	US-PGPUB; USPAT; USOCR	OR	ON	2020/04/08 15:48
S51	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/09 12:11

EAST Search History (Interference)

<This search history is empty>

10/5/2020 1:16:35 PM
C:\Users\mkahelin\Documents\EAST\Workspaces\15665152.wsp

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	15/665,152
				Filing Date	July 31, 2017
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3792
(Use as many sheets as necessary)				Examiner Name	Michael W. Kahelin
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00505

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.	2020/0139120	05-07-2020	Rajguru 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]

*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:	15665152
Filing Date:	31-Jul-2017
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00505

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	2252	1	300	300
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	120	120
		Total in USD ($)		**420**

Electronic Acknowledgement Receipt

EFS ID:	40351895
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	21-AUG-2020
Filing Date:	31-JUL-2017
Time Stamp:	15:06:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$420
RAM confirmation Number	E20208KF06337722
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		01_EMKNNZ00505_20200821_response_to_non-final_office_action.pdf	43074 2097a25a97873d21bfec609c0c6db5b182772b5f	yes	7
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Applicant Arguments/Remarks Made in an Amendment		5	7	
	Claims		2	4	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
Warnings:					
Information:					
2	Extension of Time	02_EMKNNZ00505_20200821_extension_of_time.pdf	89124 77c4b1091a7911e24a1da633167d83d32a01dd96	no	1
Warnings:					
Information:					
3	Transmittal Letter	03_EMKNNZ00505_20200821_ids_cover_letter.pdf	22546 c62b0810ae11fff9059a4d6242dc9e2b75c2c54b	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	04_EMKNNZ00505_20200821_ids_sb08.pdf	23914 5d76e36a5aba1cdcc28d9546a255ae58a080be49	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					

5	Fee Worksheet (SB06)	fee-info.pdf	32317 6abacb6e55f6b4469226640365 85d1526123d662	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	210975

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.

REMARKS

Claims 5-17 were pending in the present application. By virtue of this response, no claims have been canceled or amended. Accordingly, claims 5-17 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.

Rejections under 35 U.S.C. §102(b)/§103(a)

Claims 5-7, 9, 14 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Amarenco et al. (Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder, Journal of Urology, 169, 2210-2215, June 2003), or in the alternative under section §103(a) as being obvious over Amarenco et al. in view of Mann et al. (U.S. Pub. 2002/0055761).

Applicant respectfully traverses the rejection and contends that the proffered combination fails to teach or disclose each and every element of independent claim 5, *to wit*, the combination of Amarenco et al. and Mann et al. fails to teach "delivering an electrical stimulus … to the branch of the posterior tibial nerve", as presently claimed.

The Office acknowledges that Amarenco et al. fails to "expressly disclose directly and exclusively stimulating a branch of the posterior tibial nerve in the afferent direction." (Office Action, p. 4, para. 1.) Mann et al. is proffered as teaching that "the tibial nerve is a suitable target … and the branches of nerves projecting from the sacral cord would likewise be suitable locations …." (*Id.*)

A detailed review of Mann et al. teaches stimulation of the sacral nerves only in relation to stimulation of the pudendal nerve and/or its branches. (Mann et al., [0079].) Mann et al. refers to the tibial nerve separately from the pudendal nerve and expressly teaches that the "tibial nerve is relatively easily accessible (i.e., relatively near the overlying skin with no muscle between the nerve and the skin) at two sites in the leg …." (*Id.*, [0080].) Yet the stimulation provided by Mann et al. is expressly described for "electrical stimulation to directly activate the pudendal nerve and/or its branches ***by means of an implantable signal generator and electrode(s)*** …." (Emphasis added, *Id.*, [0073].)

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 101

Hence, while Mann et al. may teach the electrical stimulation of the tibial nerve, which is readily accessible near the overlying skin, it does so by the use of an implantable signal generator and electrodes but fails to teach or suggest stimulation ***to a branch of the posterior tibial nerve*** anywhere.

Thus, Mann et al. necessarily fails to cure the defects of Amarenco et al. and the combination of references fails to teach each and every limitation of independent claim 1 which is patentable over each of the references alone or in combination. 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)/§103(a).

Rejections under 35 U.S.C. §103(a)

A. Claim 8 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Amarenco et al. in view of Mann et al.

Dependent claim 8 depends ultimately from independent claim 1 and is patentable over Amarenco et al. and Mann et al. for at least the same reasons above. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

B. Claims 10-13 and 15-17 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Amarenco et al. in view of Mann et al. and in view of Lund et al. (U.S. Pub. 2007/0265675).

Dependent claims 10-13 and 15-17 depend ultimately from independent claim 1 and are patentable over Amarenco et al. and Mann et al. for at least the same reasons above. Lund et al. fails to cure their defects 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. 102

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**.

Respectfully submitted,

/Johney U. Han/

Johney U. Han
Registration No. 45,565

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Petitioner - Avation Medical, Inc.
Ex. 1002, p. 103

AMENDMENTS TO THE CLAIMS

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

In the claims

1.-4. (Canceled)

5. (Previously Presented): A method of treating overactive bladder or incontinence, comprising:

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

passing a current through the electrical stimulator; and

delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve to treat overactive bladder or incontinence.

6. (Previously Presented): The method of claim 5, wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator upon a foot of the patient.

7. (Previously Presented): The method of claim 5, further comprising detecting a muscular response caused by an electrical conduction or stimulation of the branch of the posterior tibial nerve.

8. (Previously Presented): The method of claim 5, wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.

9. (Previously Presented): The method of claim 5 further comprising displaying physiological parameters detected from the patient.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 104

10. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.

11. (Previously Presented): The method of claim 10 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

12. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.

13. (Previously Presented): The method of claim 12 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

14. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.

15. (Previously Presented): The method of claim 14 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

16. (Previously Presented): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 105

17. (Previously Presented): The method of claim 16 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 106

I hereby certify that this correspondence is being EFS-Web transmitted to the USPTO on the date shown below.		
Date: August 21, 2020	Signature: /Laura L. Gallagher/	(Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

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 April 10, 2020 for which a response was due on July 10, 2020. Filed herewith is a Petition and fee for a two-month extension of time, thereby extending the deadline for response to September 10, 2020. 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 5 of this paper.

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): EMKNNZ00505

Application Number: 15/665,152

Filed: July 31, 2017

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

Art Unit: 3792

Examiner: Michael W. Kahelin

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	$ 300
☐	Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐	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

August 21, 2020 — 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 EFS-Web transmitted to the USPTO on the date shown below.			
Date: August 21, 2020	Signature:	/Laura L. Gallagher/	(Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
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 document listed on the attached Form PTO/SB/08a/b. The Examiner is requested to make this document 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. The required fee is being concurrently submitted via EFS-Web.

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**. However, the Commissioner is not authorized to charge the surcharge for late filing of an Oath or Declaration until issuance of a pre-exam formalities Notice.

Respectfully submitted,

/Johney U. Han/

Johney U. Han
Registration No. 45,565

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Petitioner - Avation Medical, Inc.
Ex. 1002, p. 110

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
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/665,152	Filing Date 07/31/2017	☐ 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 $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	08/21/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 13	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $230 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ANNETTE COWAN/
*** 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.	

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 04/10/2020

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

EXAMINER
KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
3792	

MAIL DATE	DELIVERY MODE
04/10/2020	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. 15/665,152	Applicant(s) BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	AIA (FITF) 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 3/13/2020.

☐ 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) 5-17 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) 5-17 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 _____.

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

4) ☐ Other: _____.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 113

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/13/2020 has been entered.

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of pre-AIA 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.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, 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 negatived by the manner in which the invention was made.

Claim(s) 5-7, 9, and 14 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Amarenco et al. ("Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, 169, 2210-2215, June 2003; hereinafter "Amarenco"), or in the alternative under section 103(a) as being obvious over Amarenco in view of Mann et al. (US 2002/0055761, hereinafter "Mann").

In regards to claim 5, Amarenco discloses non-invasively positioning a first portion of a patient's body with respect to an electrical stimulator such that a branch of a posterior tibial nerve is in proximity (abstract); passing a current through the stimulator; and delivering electrical stimulus from the electrical stimulator to the branch of the nerve (page 2211, "Procedure," "The correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction") to treat overactive bladder or incontinence (page 2211, "Procedure," second full paragraph). The examiner's position is that delivering stimulation behind that internal malleolus is "delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial

nerve" at least indirectly because the stimulation causes plantar muscle contraction via the plantar nerve branch(es) (i.e., in the efferent direction). Alternatively and additionally, Amarenco discloses the essential features of the claimed invention including afferent posterior tibial nerve stimulation that provides central inhibition of the preganglionic bladder motor neurons through a direct route in the sacral cord (page 2214, second full paragraph), but does not expressly disclose directly and exclusively stimulating a branch of the posterior tibial nerve in the afferent direction. However Mann, in the same field of endeavor of incontinence control teaches that the tibial nerve is a suitable target for incontinence control through the sacral cord (pars. 0079 and 0080) and the branches of nerves projecting from the sacral cord would likewise be suitable locations (par. 0079) for stimulation as these also lead to recruitment of the sacral cord and particular branches may offer advantages for the treatment of certain disorders such as avoiding unwanted side effects (par. 0079). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by providing stimulation directly and exclusively to a branch of the posterior tibial nerve to provide the predictable results of effectively recruiting the sacral cord for incontinence control with particular branches that may offer advantages for the treatment of certain disorders such as avoiding unwanted side effects.

In regards to claim 6, positioning comprises positioning an electrode patch upon a foot of the patient (page 2211, "Procedure," "behind the internal malleolus).

In regards to claim 7, the method further comprises detecting a muscular response cause by stimulation (page 2211, "Procedure," "visualization of rhythmic flexion of the toes).

In regards to claim 9, the method further includes displaying physiological parameters detected from the patient (Figs. 3 and 4).

In regards to claims 14 and 16, the method further includes detecting for presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement (page 2211, "Procedure," visualization of rhythmic flexion of the toes).

Claims 8 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco in view of Mann. Amarenco (or modified Amarenco) discloses the essential features of the claimed invention except for activating for a duration of about 30 minutes per week. However, Mann teaches that it was known in the art of tibial nerve stimulation to deliver stimulation for a duration of about 30 minutes per week (par. 0038) to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by stimulating for a duration of about 30 minutes per week to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence.

Claims 10-13 and 15-17 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco (and/or Amarenco and Mann) in view of Lund et al. (US 2007/0265675, hereinafter "Lund"). Amarenco discloses the essential features of the claimed invention including optimizing stimulation parameters by looking at the muscular response of the patient (page 2211, "Procedure"), but does not expressly disclose determining that response with an electrode or that the presence of conduction as an indicator of electrode migration or electrode malfunction. Lund teaches determining stimulation response with EMG electrodes (e.g., 146) as an indicator of electrode migration (par. 0037) or electrode malfunction (by virtue of its migration) to provide the predictable results of optimizing therapy based on feedback from the patient (par. 0035). Furthermore, it is well-known in the art to embody surface EMG electrodes as patches to provide the predictable results of comfortable and self-

carrying electrodes that do not require a user to hold them in contact with the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by determining stimulation response with EMG electrodes as an indicator of electrode migration or electrode malfunction to provide the predictable results of optimizing therapy based on feedback from the patient, and embody the surface EMG electrode as a patch to provide the predictable results of comfortable and self-carrying electrodes that do not require a user to hold them in contact with the body.

Response to Arguments

Applicant's arguments filed 3/13/2020 have been fully considered but they are not persuasive in part and moot in part. Applicant argued that Amarenco discloses stimulating the posterior tibial nerve and not a branch of the posterior tibial nerve. However, this is addressed in the above rejections in light of Amerenco alone indirectly stimulating the branches in an efferent direction; and under a new obviousness rejection in view of Amarenco and Mann.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL WILLIAM KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

CPC - Searched*		
Symbol	Date	Examiner
A61N 1/36007	07/12/2019	MWK
A61N 1/36031,0456	11/19/2019	MWK
updated above	04/09/2020	MWK

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor search	07/12/2019	MWK
global dossier search	07/12/2019	MWK
IDS review	07/12/2019	MWK
see attached EAST search history	07/12/2019	MWK
see attached EAST search history	11/19/2019	MWK
NPL search	11/19/2019	MWK
see attached EAST search history	04/09/2020	MWK

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 120

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 121

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/09 12:11
S1	294	((("BURNETT") near3 ("Daniel"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/07/11 11:46
S2	10	S1 and (tibial and bladder).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 11:49
S3	42	(A61N1$).cpc. and (tibial and bladder).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 11:57
S5	1	("20090076565").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 12:00
S6	1	(11/857872).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:12
S7	478	(A61N1$).cpc. and (tibial and bladder)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:13
S8	550	(A61N1$).cpc. and (tibial and (bladder urinary))	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:14
S9	0	("15665152").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:21
S10	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:21

S11	1114	"urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S12	69178	(A61N1$).cpc. "urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S13	149	(A61N1$).cpc. and "urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S14	302	S8 and week	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:36
S15	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:38
S16	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:44
S17	438	S8 and (feedback sensor)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:48
S18	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:23
S19	1	("9757584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:41
S20	2	(14/676635).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:55
S21	33	(11/866329 | 12/469358 | 12/469365 | 12/469625 | 12/508529 | 12/509304 | 12/509345 | 12/509362 | 12/606941 | 12/695087 | 12/790619 | 13/456016 | 13/457228 | 14/085639 | 14/097568 | 14/676635 | 14/685278 | 14/931702 | 14/949735 | 15/056910 | 15/084356 | 15/436538 | 15/474875).APP.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 09:59

S22	4	S21 and percutaneous.clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:00
S23	228	(A61N1/36007).cpc. and tibial	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:02
S24	1	("20140159912").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 11:34
S25	367	(A61N1$).cpc. and (tibial with posterior)	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:04
S26	314	(A61N1$).cpc. and (posterior adj tibial)	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:05
S27	2677	(A61N1/36007).cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:06
S28	90	S26 and S27	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:06
S29	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/18 14:20
S30	1	("20120296391").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:05
S31	2	(("20120296391") or ("20150012063")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:07
S32	1	(15/696048).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:15
S33	3	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$).did.	US-PGPUB	OR	ON	2019/11/19 12:38
S34	2804	(A61N1/36007 or A61N1/0456).cpc.	US-PGPUB	OR	ON	2019/11/19 12:39

S35	580	S34 and emg	US-PGPUB	OR	ON	2019/11/19 12:39
S36	155	(A61N1/36031).cpc.	US-PGPUB	OR	ON	2019/11/19 12:56
S37	0	(A61N1$).cpc. and (feedback same emg same (migrat$4 malfunction$4))	US-PGPUB	OR	ON	2019/11/19 13:07
S38	177	(A61N1$).cpc. and (feedback same emg and (migrat$4 malfunction$4))	US-PGPUB	OR	ON	2019/11/19 13:07
S39	2	(("9757584") or ("9387338")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 14:59
S40	2	(("7126483") or ("8328420")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 15:58
S41	1	("7942824").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 17:09
S42	1	("9610459").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/08 12:35
S43	4	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$ or US-20070265675-$).did.	US-PGPUB	OR	ON	2020/04/08 12:37
S44	4	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$ or US-20070265675-$).did.	US-PGPUB	OR	ON	2020/04/08 13:47
S45	1	S44 and plantar	US-PGPUB; USPAT; USOCR	OR	ON	2020/04/08 13:47
S46	297	(A61N1$).cpc. and (plantar and (bladder urinary))	US-PGPUB; USPAT; USOCR	OR	ON	2020/04/08 13:48
S47	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/08 13:52

S48	6	(("6443883") or ("20020111777") or ("20020082465") or ("20040138517") or ("5715837") or ("4915110")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/08 15:29
S49	4	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$ or US-20070265675-$).did.	US-PGPUB	OR	ON	2020/04/08 15:48
S50	2	S49 and branch	US-PGPUB; USPAT; USOCR	OR	ON	2020/04/08 15:48

EAST Search History (Interference)

<This search history is empty>

4/9/2020 12:13:48 PM
C:\Users\mkahelin\Documents\EAST\Workspaces\15665152.wsp

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	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	3792
Examiner Name	Michael W. Kahelin
Attorney Docket Number	EMKNNZ00505

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.	9,610,459	04-04-2017	Burnett 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]

*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	/MICHAEL W KAHELIN/	Date Considered	04/09/2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.W.K./

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. 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 contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	15/665,152	Filing Date	2017-07-31	Docket Number (if applicable)	EMKNNZ00505	Art Unit	3792
First Named Inventor	Daniel R. BURNETT			Examiner Name	Michael W. Kahelin		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☒ Other Extension of Time

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 503973

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. 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 contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Johney U. Han/	Date (YYYY-MM-DD)	2020-03-13
Name	Johney U. Han	Registration Number	45565

This collection of information is required by 37 CFR 1.114. 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.

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

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 the Freedom of Information Act requires disclosure of these records.

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 inspections 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.

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

I hereby certify that this correspondence is being EFS-Web transmitted to the USPTO on the date shown below.		
Date: March , 2020	Signature: /Laura L. Gallagher/	(Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

RESPONSE TO FINAL OFFICE ACTION

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

Dear Sir:

This is in response to the final Office Action dated November 20, 2019 for which a response was due on February 20, 2020. Filed herewith is a Petition and fee for a one-month extension of time, thereby extending the deadline for response to March 20, 2020. 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 5 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.-4. (Canceled)

5. (Previously Presented): A method of treating overactive bladder or incontinence, comprising:

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

passing a current through the electrical stimulator; and delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve to treat overactive bladder or incontinence.

6. (Previously Presented): The method of claim 5, wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator upon a foot of the patient.

7. (Previously Presented): The method of claim 5, further comprising detecting a muscular response caused by an electrical conduction or stimulation of the branch of the posterior tibial nerve.

8. (Previously Presented): The method of claim 5, wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.

9. (Previously Presented): The method of claim 5 further comprising displaying physiological parameters detected from the patient.

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10. (Currently Amended): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.

11. (Previously Presented): The method of claim 10 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

12. (Currently Amended): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.

13. (Previously Presented): The method of claim 12 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

14. (Currently Amended): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.

15. (Previously Presented): The method of claim 14 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

16. (Currently Amended): The method of claim 5 further comprising detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.

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17. (Previously Presented): The method of claim 16 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

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REMARKS

Claims 5-17 were pending in the present application. By virtue of this response, claims 10, 12, 14, 16 have been amended. Accordingly, claims 5-17 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.

Rejections under 35 U.S.C. §112(b) (pre-AIA 35 U.S.C. §112, second paragraph)

Claims 10-17 are rejected under 35 U.S.C. §112(b) (pre-AIA 35 U.S.C. §112, second paragraph), as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of dependent claims 10, 12, 14, 16 has been amended to recite "detecting for a ***lack of*** presence of electrical conduction … as an indicator of" to particularly point out and distinctly claim the subject matter.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §112(b) (pre-AIA 35 U.S.C. §112, second paragraph).

Rejections under 35 U.S.C. §102(b)

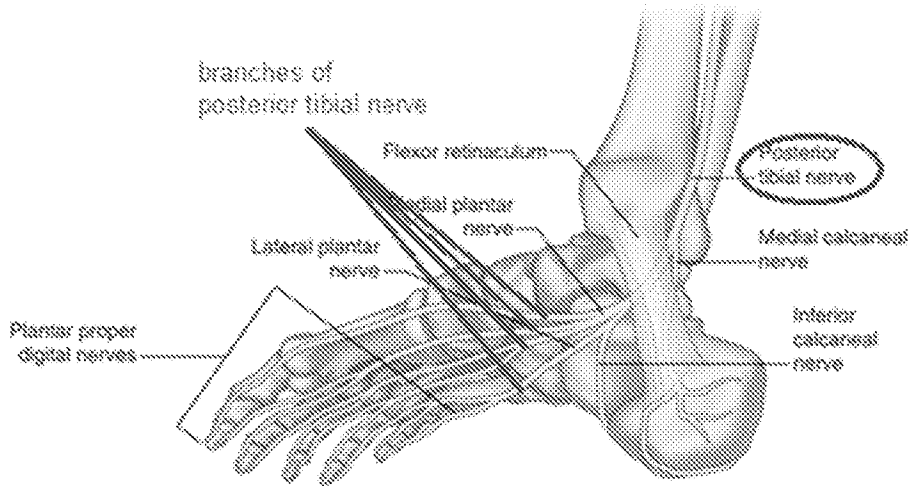
Claims 5-7, 9, and 14 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Amarenco et al. ("Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, 169, 2210-2215, June 2003;).

Applicant respectfully traverses the rejection and contends that Amarenco et al. fails to disclose each and every limitation of independent claim 5, *to wit*, Amarenco et al. fails to disclose "positioning a first portion of a patient's body relative to an electrical stimulator such that ***a branch of a posterior tibial nerve … is in proximity to the electrical stimulator***". (Emphasis added.)

The posterior tibial nerve runs through the ankle of a patient while the branches of the posterior tibial nerve extend inferiorly of the ankle and innervate throughout the foot but the branches are not present within the ankle.

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An example of the anatomy of the posterior tibial nerve and the branches of the posterior tibial nerve are illustrated below with annotations for reference purposes:



(https://link.springer.com/chapter/10.1007/978-3-319-73266-4_10)

Amarenco et al. clearly describes the application of its electrodes behind the ankle for targeting the posterior tibial nerve but Amarenco et al. fails to disclose or teach any targeting of any branch of the posterior tibial nerve. Targeting a branch would instead require the repositioning of its electrodes along regions of the foot itself but not the ankle. For instance, Amarenco et al. discloses "left posterior tibial nerve stimulation using a surface self-adhesive electrode on the ***ankle skin behind the internal malleolus*** [bony prominence on side of ankle]". (Emphasis added, Amarenco et al., Abstract, para. 2.) The cited reference further clarifies that its "Contact electrodes were placed with electrode gel on the ***ankle skin with the negative electrode behind the internal malleolus***". (Emphasis added, *Id.,* p. 2211, col. 1, para. 3.)

Therefore, Amarenco et al. fails to disclose each and every limitation of independent claim 5 which is patentable. 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).

Rejections under 35 U.S.C. §103(a)

A. Claims 8 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Amarenco et al. in view of Mann et al. (U.S. Pub. 2002/0055761).

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Dependent claim 8 depends ultimately from independent claim 5 and is patentable over Amarenco et al. for at least the same reasons above. Mann et al. fails to cure its defects and the claim is patentable over each of the cited references alone or in combination.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

B. Claims 10-13, 15, and 17 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Amarenco et al. in view of Lund et al. (U.S. Pub. 2007/0265675).

Dependent claim 10-13, 15, 17 depend ultimately from independent claim 5 and are patentable over Amarenco et al. for at least the same reasons above. Lund et al. fails to cure its defects and the claims are patentable over each of the cited references alone or in combination.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

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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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**.

Respectfully submitted,

/Johney U. Han/

Johney U. Han
Registration No. 45,565

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Petitioner - Avation Medical, Inc.
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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): EMKNNZ00505

Application Number: 15/665,152

Filed: July 31, 2017

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

Art Unit: 3792

Examiner: Michael W. Kahelin

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	$ 100
☐	Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☐	Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐	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

March 13, 2020 — 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 EFS-Web transmitted to the USPTO on the date shown below.			
Date: March 13, 2020	Signature:	/Laura L. Gallagher/	(Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop RCE
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 document listed on the attached Form PTO/SB/08a/b. The Examiner is requested to make this document of record.

This Information Disclosure Statement is submitted with the filing of a Request for Continued Examination under § 1.114; accordingly, no fee or separate requirements are required.

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**. However, the Commissioner is not authorized to charge the surcharge for late filing of an Oath or Declaration until issuance of a pre-exam formalities Notice.

Respectfully submitted,

/Johney U. Han/

Johney U. Han
Registration No. 45,565

Customer No. 40518
Levine Bagade Han LLP
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Fax: (650) 284-2180

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 141

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	15/665,152
				Filing Date	July 31, 2017
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3792
(Use as many sheets as necessary)				Examiner Name	Michael W. Kahelin
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00505

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.	9,610,459	04-04-2017	Burnett 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]

*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:	15665152
Filing Date:	31-Jul-2017
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00505

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	2251	1	100	100
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	650	650
		Total in USD ($)		**750**

Electronic Acknowledgement Receipt

EFS ID:	38863951
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	13-MAR-2020
Filing Date:	31-JUL-2017
Time Stamp:	16:36:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$750
RAM confirmation Number	E20203CG37198023
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	Request for Continued Examination (RCE)	01_EMKNNZ00505_20200313_rce_efs.pdf	1323908 2b039396d53ca0b768fbba9d069df1830c4529a2	no	3
Warnings:					
Information:					
2		02_EMKNNZ00505_20200313_response_to_final_office_action.pdf	157937 b33a2c8eccee2cbd38d604df5f1ad2d4f38df7f7	yes	8

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Claims	2	4
Applicant Arguments/Remarks Made in an Amendment	5	8

Warnings:					
Information:					
3	Extension of Time	03_EMKNNZ00505_20200313_extension_of_time.pdf	88633 3c24c62caec6f98b20f64fa7b94ec62800298f1f	no	1
Warnings:					
Information:					
4	Transmittal Letter	04_EMKNNZ00505_20200313_ids_cover_letter.pdf	22417 83767d02ca9cad3d3b907572ef98667e84ff5cdd	no	2
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	05_EMKNNZ00505_20200313_ids_sb08.pdf	23910 145df591d71aa76d5055054b627db96aab1fbd22	no	1

Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
6	Fee Worksheet (SB06)	fee-info.pdf	32289 d085f6375b8434f7135b0dda9373fb41a2e8b14b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1649094	

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 15/665,152	Filing Date 07/31/2017	☐ 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 $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	03/13/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 13	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $230 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/POLIN ANG/
*** 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.	

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.

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Ex. 1002, p. 149

UNITED STATES PATENT AND TRADEMARK OFFICE

OPAP AKIMA-7 DEC 0 2 2019 PATENT & 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.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 11/20/2019
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3792	

MAIL DATE	DELIVERY MODE
11/20/2019	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. 15/665,152	Applicant(s) BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	AIA (FITF) 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 11/14/2019.

☐ 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) 5-17 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) 5-17 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 _____.

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

4) ☐ Other: _____.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 151

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-17 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. In regards to claims 10, 12, 14, and 16, it is unclear what, if any, steps are required by "detecting...as an indicator of", or that the method merely requires determining the presence of electrical conduction. Claims 11, 13, 15, and 17 are rejected due to their dependency.

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of pre-AIA 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.

Claim(s) 5-7, 9, and 14 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Amarenco et al. ("Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, 169, 2210-2215, June 2003; hereinafter "Amarenco").

In regards to claim 5, Amarenco discloses non-invasively positioning a first portion of a patient's body with respect to an electrical stimulator such that a branch of a posterior tibial nerve is in proximity (abstract); passing a current through the stimulator; and delivering electrical stimulus from the electrical stimulator to treat overactive bladder or incontinence (page 2211, "Procedure," second full paragraph).

In regards to claim 6, positioning comprises positioning an electrode patch upon a foot of the patient (page 2211, "Procedure," "behind the internal malleolus).

In regards to claim 7, the method further comprises detecting a muscular response cause by stimulation (page 2211, "Procedure," "visualization of rhythmic flexion of the toes).

In regards to claim 9, the method further includes displaying physiological parameters detected from the patient (Figs. 3 and 4).

In regards to claim 14, the method further includes detecting for presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement (page 2211, "Procedure," visualization of rhythmic flexion of the toes).

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, 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 negatived by the manner in which the invention was made.

Claim 8 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco in view of Mann et al. (US 2002/0055761, hereinafter "Mann"). Amarenco discloses the essential features of the claimed invention except for activating for a duration of about 30 minutes per week. However, Mann teaches that it was known in the art of tibial nerve stimulation to deliver stimulation for a duration of about 30 minutes per week (par. 0038) to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by stimulating for a duration of about 30 minutes per week to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence.

Claims 10-13, 15, and 17 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco in view of Lund et al. (US 2007/0265675, hereinafter "Lund"). Amarenco discloses the essential features of the claimed invention including optimizing stimulation parameters by looking at the muscular response of the patient (page 2211, "Procedure"), but does not expressly disclose determining that response with an electrode or that the presence of conduction as an indicator of electrode migration or electrode malfunction. Lund teaches determining stimulation response with EMG electrodes (e.g., 146) as an indicator of electrode migration (par. 0037) or electrode malfunction (by virtue of its migration) to provide the predictable results of optimizing therapy based on feedback from the patient (par. 0035). Furthermore, it is well-known in the art to embody surface EMG electrodes as

patches to provide the predictable results of comfortable and self-carrying electrodes that do not require a user to hold them in contact with the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by determining stimulation response with EMG electrodes as an indicator of electrode migration or electrode malfunction to provide the predictable results of optimizing therapy based on feedback from the patient, and embody the surface EMG electrode as a patch to provide the predictable results of comfortable and self-carrying electrodes that do not require a user to hold them in contact with the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL WILLIAM KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/665,152	Applicant(s)/Patent Under Reexamination BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20070265675-A1	11-2007	Lund; Robert E.	A61N1/36007	607/41
	B					
	C					
	D					
	E					
	F					
	G					
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	J					
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FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Amarenco et al., "Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," June 2003, Journal of Urology, Vol. 169, 2210-2215. (Year: 2003)
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

0022-5347/03/1696-2210/0
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URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER

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ABSTRACT

Purpose: Of the various treatments proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment. However, to our knowledge no data concerning acute stimulation and immediate cystometry modifications have been reported. We verified urodynamic changes during acute posterior tibial nerve stimulation.

Materials and Methods: A total of 44 consecutive patients with urge incontinence, frequency and urgency secondary to overactive bladder were studied. There were 29 women and 15 men with a mean age ±SD of 53.3 ± 18.2 years. Of the patients 37 had detrusor hyperreflexia due to multiple sclerosis (13), spinal cord injury (15) or Parkinson's disease (9), and 7 had idiopathic detrusor instability. Routine cystometry at 50 ml. per minute was done to select the patients with involuntary detrusor contractions appearing before 400 ml. maximum filling volume. Repeat cystometry was performed immediately after the first study during left posterior tibial nerve stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10 Hz. frequency and 200 milliseconds wide. Volume comparison was done at the first involuntary detrusor contraction and at maximum cystometric capacity. The test was considered positive if volume at the first involuntary detrusor contraction and/or at maximum cystometric capacity increased 100 ml. or 50% during stimulation in compared with standard cystometry volumes.

Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 ± 96.4 ml. and it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml. and it was 277.4 ± 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$). The test was considered positive in 22 of the 44 patients.

Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.

KEY WORDS: electrical stimulation, urodynamics, tibial nerve, urinary incontinence

For many years peripheral electrical stimulation has been widely used to treat urinary disorders.[1–4] Different stimulation modalities for various pathological conditions were tested. Chronic perineal muscles stimulation proved to be safe and effective for stress urinary incontinence.[1] Acute perineal nerve stimulation (dorsal nerve of the penis) was effective for decreasing detrusor hyperreflexia in spinal cord injury cases.[5] Chronic electrical stimulation of perineal skin/sacral dermatomes was used to manage urge incontinence and many studies have had good and consistent results.[4,6–8] Recently sacral neuromodulation with surgical implantation of an S3 stimulator was proposed to treat various urinary symptoms, especially intractable urge incontinence and urinary frequency. More recently posterior tibial nerve stimulation has been used as a chronic treatment to improve urge incontinence and frequency.[9,10] Surprisingly sparse urodynamic data on the efficacy of chronic posterior tibial nerve stimulation are available. Moreover, urodynamic parameters evaluations have only been reported before and after chronic treatment with posterior tibial nerve stimulation.[9] Indeed, to our knowledge no study has been performed to determine urodynamic effects following acute posterior tibial nerve stimulation. We studied by urodynamic investigation possible detrusor activity modifications during acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.

Accepted for publication January 17, 2003.

MATERIAL AND METHODS

Study design and subjects. The study group consisted of 44 patients with a history of voiding dysfunction. There were 29 women and 15 men with a mean age ±SD of 53.3 ± 18.2

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years. All patients had irritative symptoms with urge incontinence, urgency and frequency. These patients had demonstrable overactive bladder on routine cystometry with involuntary detrusor contraction appearing before 400 ml. maximum filling volume. The etiology was multiple sclerosis 13 cases, spinal cord injury in 15, brain lesion (brain injury, stroke or Parkinson's disease) in 9 and idiopathic instability in 7 without apparent neurological disease. All patients provided a clinical history and underwent examination, urinalysis and urodynamic studies. All patients provided consent to participate in the study. The study was approved by the local ethics committee.

Procedure. The urodynamic methodology complied with International Continence Society recommendations. Cystometry was performed with the patient supine through a double lumen 8Fr catheter with computerized analysis of results. Cystometry was done using normal saline at 25C to 30C. The filling rate was 50 ml. per minute. The study inclusion criterion was involuntary detrusor contraction during the filling procedure before 400 ml. maximum cystometric volume. Water filling was stopped if leakage occurred or a cystometric volume of 400 ml. was achieved. Volume at the first involuntary detrusor contraction and at maximum cystometric capacity were noted.

Repeat cystometry at a 50 ml. per minute filling rate was performed immediately after posterior tibial nerve stimulation. Stimulation was done using a self-adhesive surface stimulation electrode without an implanted needle electrode. Contact electrodes were placed with electrode gel on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode. The correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction during stimulation delivered at 1 hz. The intensity level was then chosen as the intensity immediately under the threshold determining motor contraction. In addition, no pain was to be noted during the stimulation procedure, which necessarily had to be comfortable for the patient. Stimulation frequency during cystometry was then applied at 10 Hz. and a pulse width of 200 milliseconds in continuous mode. This second cystometry during posterior tibial nerve stimulation was started immediately after determining the chosen stimulation. Neurostimulation was continuous during the whole second study.

A comparison was done between volume at the first involuntary detrusor contraction and at maximum cystometric capacity for standard cystometry and for cystometry during posterior tibial nerve stimulation. If on the second cystometry during stimulation the first involuntary detrusor contraction occurred at a volume that was 100 ml. or 50% more than the first involuntary detrusor contraction volume on standard cystometry, the test was considered positive (fig. 1). Likewise the test was also considered positive if maximum cystometric capacity following posterior tibial nerve stimulation increased more than 100 ml. or more than 50% volume compared with standard cystometry. Otherwise the test was considered negative. For statistical study of different associations the Student test for patient age, and volume at the first involuntary detrusor contraction and at maximum cystometric capacity was used with significance considered at $p < 0.01$.

RESULTS

Mean first involuntary detrusor contraction on standard cystometry was 162.9 ± 96.4 ml., while it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation (table 1, fig. 1). Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml., while it was 277.4 ± 117.9 ml. during stimulation (table 1, fig. 2). During stimulation improvement was significant for the first involuntary detrusor contraction and for maximum cystometric capacity (each $p < 0.0001$).

Regarding the increase of more than 50% in first involuntary detrusor contraction volume during stimulation compared with standard cystometry the test was positive in 21 of

TABLE 1. *Urodynamic parameters before and during posterior tibial nerve stimulation in 44 patients with overactive bladder*

	Mean Vol. ± SD (range) (ml.)
First involuntary detrusor contraction:	
Baseline	162.9 ± 96.4 (2–375)
Posterior tibial nerve stimulation	232.1 ± 115.3 (55–400)*
Max. cystometric capacity:	
Baseline	221 ± 129.5 (14–400)
Posterior tibial nerve stimulation	277.4 ± 117.9* (70–400)

* Student test $p < 0.0001$.

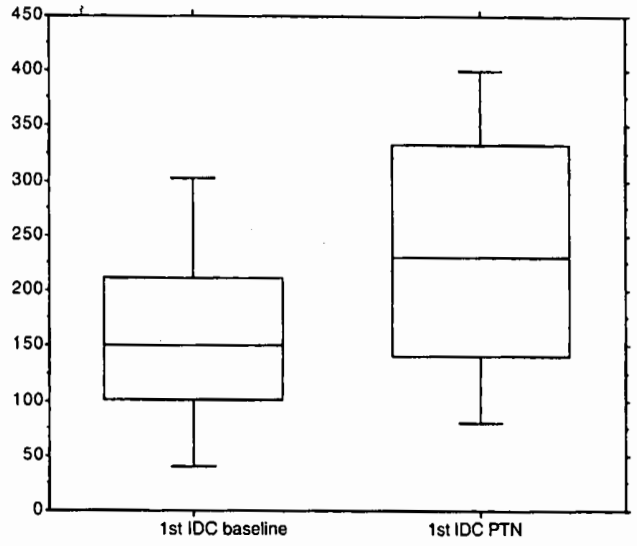


FIG. 1. Improvement in bladder volume at first involuntary detrusor contraction (*1st IDC*) following surface stimulation with 10 Hz. for 200 milliseconds of posterior tibial nerve (*PTN*) at ankle during mid fill cystometry in patients with overactive bladder (Student test $p < 0.0001$).

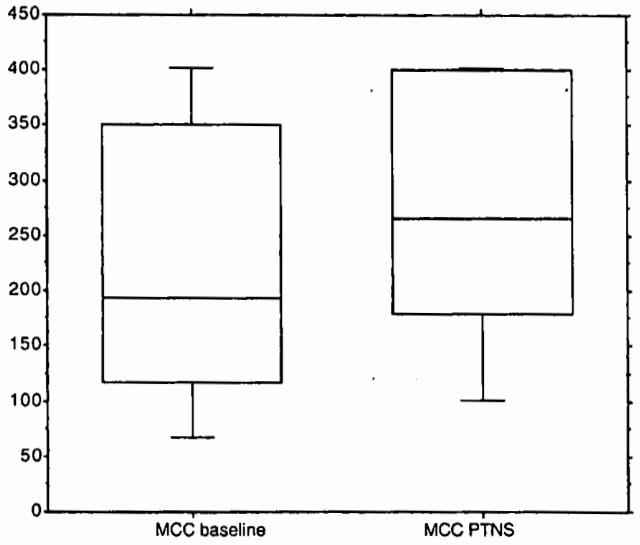


FIG. 2. Improvement in maximum cystometric capacity (*MCC*) following surface stimulation with 10 Hz. for 200 milliseconds of posterior tibial nerve (*PTN*) at ankle during mid fill cystometry in patients with overactive bladder (Student test $p < 0.0001$).

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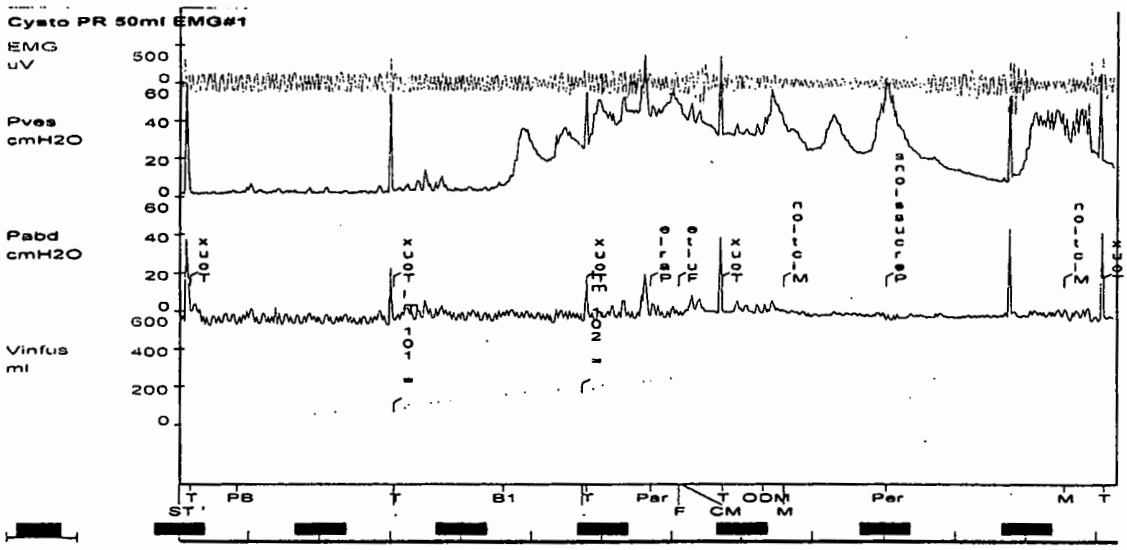


FIG. 3. Standard cystometry in 42-year-old patient with multiple sclerosis presenting with urge incontinence, frequency and urgency shows overactive bladder with noninhibited detrusor contraction.

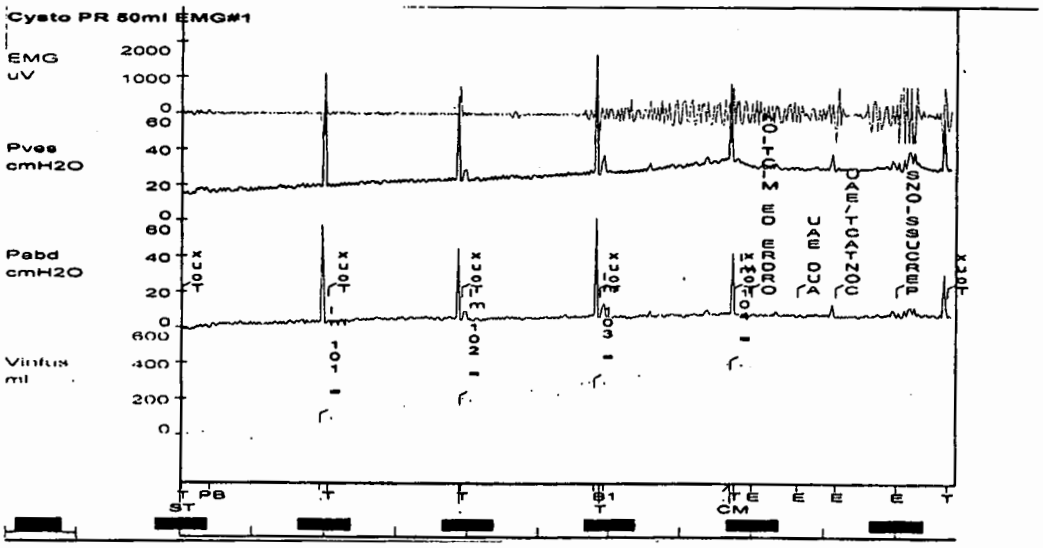


FIG. 4. Cystometry following surface stimulation with 10 Hz. of posterior tibial nerve at ankle demonstrates improvement in urodynamic parameters with suppression of involuntary detrusor contractions.

the 44 cases (figs. 3 and 4). Regarding the increase of more than 100 ml. in first involuntary detrusor contraction volume during stimulation, the test was positive in 13 cases. Regarding the improvement of more than 50% of maximum cystometric capacity during posterior tibial nerve stimulation, the test was positive in 15 cases. Regarding improvement of more than 100 ml. of first involuntary detrusor contraction volume during stimulation, the test was positive in 11 cases. Globally with 1 at least of the 4 previous criteria the test was considered positive in 22 cases (50%). Only 1 patient had improved maximum cystometric capacity without an increase in first involuntary detrusor contraction volume of more than 100 ml. or 50%.

DISCUSSION

Patients with irritative symptoms such as frequency, urgency and urge incontinence secondary to detrusor instability or hyperreflexia are habitually treated with anticholinergic drugs. However, in some patients anticholinergic drugs may have no efficacy for urinary symptoms immediately or after months of treatment. Moreover, these drugs may have side effects (dry mouth, constipation, blurring eyes, hesitancy or urinary retention), which can lead to the cessation of treatment despite its efficacy. Finally detrusor overactivity may persist despite treatment with a high risk of reflux or renal complications in neurologic cases. In all of these cases alternative therapeutic solutions have been proposed before bladder augmentation, such as bladder training and perineal electrical stimulation. Recently local drug treatments have been tested, including intravesical instillation of capsaicin or resiniferatoxin and and botulinum-A toxin injections into the detrusor. Meanwhile, these treatments are actually only proposed in neurological cases, especially spinal cord injury with intractable overactivity, which can lead to ureteral reflux and kidney damage. Moreover, these treatments are only available for pharmaceutical trials and need invasive protocols.

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The use of electrostimulation to improve bladder storage capacity has a long history. Various types of neurostimulation have been tried for urge incontinence treatment, frequency and urgency but also for stress urinary incontinence. Sacral anterior root stimulation and S3 neuromodulation[11] have been well evaluated with real benefits of these devices for bladder overactivity control. These techniques are safe and effective but they require surgical implantation and a test period, which can limit their use. Pudendal nerve stimulation, anal or vaginal stimulation and more generally surface stimulation on the perineal area have been evaluated for various conditions, such as stress urinary incontinence and irritative symptoms. Many clinical studies have demonstrated their efficacy to decrease incontinence episodes, urinary frequency and urge sensation, and increase bladder capacity[4,6,7,12–14] using quality of life instruments, and frequency and volume charts.

On the other hand, urodynamic studies of the effects of chronic electrostimulation are less frequent (table 2).[6,8,12–15] Various sites of stimulation have been tested (perianal skin, sphincter stimulation, dorsal penile or clitoris nerve, quadriceps and hamstring muscles) and different types of patients have been studied with idiopathic detrusor instability or detrusor hyperreflexia, especially concerning spinal cord injury. Thus, transcutaneous electrical stimulation applied to the perianal skin has been demonstrated to be efficacious for abolishing detrusor instability and increasing mean volume at first bladder sensation and mean total bladder capacity.[6,14,15] Meanwhile, other studies have not shown significant changes in cystometric findings after chronic electrostimulation (volume at first involuntary detrusor contraction, duration of phasic contractions or bladder capacity).[8,12,13] However, clinical improvements were noted in these studies, including increased functional capacity, decreased daily number of voids and improved quality of life measures.[8,13]

The urodynamic effects of acute electrical stimulation on detrusor activity is also less reported (table 3).[5,6,16–20] Detrusor hyperreflexia in patients with chronic suprasacral spinal cord injury has especially been studied.[5,16,19,20] Significant differences in bladder capacity were found during electrostimulation of the dorsal penile or clitoris nerve via surface electrodes[5] and during percutaneous sacral nerve neurostimulation.[19] Bladder volume at first uninhibited contraction was also increased and maximum detrusor pressure during uninhibited contractions decreased during sacral root stimulation.[19] Noninvasive third sacral nerve (S3) stimulation and its acute effect on urodynamic parameters were also tested.[16] Transcutaneous electrical stimulation was applied on the skin overlying S3 dermatomes (junction of the buttock and upper thigh) and a statistically significant increase in bladder storage capacity without a corresponding decrease in detrusor pressure was observed in the 74 neurostimulated patients.[16] Electrical current was also delivered to the suprapubic region and third sacral foramen via a transcutaneous electrical nerve stimulator. A decreased mean maximum amplitude of detrusor contraction was noted.[17]

McGuire et al were the first to report the efficacy of direct electrical stimulation of the posterior tibial nerve in patients with urge incontinence.[4] More recently several studies have been done to evaluate intermittent percutaneous posterior tibial nerve stimulation as a treatment in patients who presented with symptoms of bladder overactivity (urgency and frequency syndrome, and/or urge incontinence).[9,10] A statistically significant decrease was observed in leakage episodes, the number of pads used, voiding frequency and nocturia, and an equal increase in the mean and smallest volumes voided. Two-thirds of the cases were classified as treatment

TABLE 2. *Literature on chronic effect of electrostimulation*

References	No. Pts.	Electrostimulation Modality	Disease (No. pts.)	% Overactivity Suppression	Increase (No. pts.)	
					Max. Capacity	First Uninhibited Contraction
Nakamura et al[6]	21	Perianal skin	Detrusor instability	62	—	—
Petersen et al[13]	13	Sphincter stimulation 12 days, 30 mins. twice daily	Detrusor hyperreflexia	0	0	0
Okada et al[15]	19	Quadriceps + hamstring muscles, 20 mins./day, 14 days	Detrusor instability (5) Detrusor hyperreflexia (14)	—	Greater than 50% (11/19)	
Previnaire et al[12]	6	Dorsal penile or clitoris nerve	Detrusor hyperreflexia	0	0	0
Klingler et al[14]	15	Stoller afferent nerve stimulator 4–15 mos.	Detrusor instability	76.9	197 to 252 Ml. (15/15)	
Soomro et al[8]	43	Perianal region	Detrusor instability	0	0	0

TABLE 3. *Literature on acute effect of electrostimulation*

References	Electrostimulation Site	No. Pts.	Disease	Main Results
Nakamura et al[7]	Perianal skin	25	Frequency, urgency or incontinence	Inhibition of detrusor instability in 4/8 pts. + increased max. cystometric capacity in 5/25
Previnaire et al[5]	Dorsal penile or clitoris nerve surface electrodes	10	Spinal cord injury	Significant increase in bladder capacity vs. baseline (318.5 vs. 155.5 ml., $p < 0.007$)
Bower et al[17]	Suprapubic region + third sacral foramina			Decreased mean max. detrusor contraction wt.
Yamanishi et al[18]	Vaginal electrode or surface electrode on dorsal part of penis	33	Detrusor overactivity	Bladder capacity at first desire to void + max. cystometric capacity increased significantly during stimulation ($p = 0.0015 + 0.0229$, respectively)
Chartier-Kastler et al[19]	Sacral neurostimulation (S3)	14	Spinal cord injury	Statistically significant differences in max. bladder capacity (206.8 ml.), bladder vol. at first uninhibited contraction (151.5 ml.) + max. detrusor pressure during uninhibited contractions (−23.4 cm. H_2O)
Walsh et al[16]	Transcutaneous electrical stimulation of third sacral nerve (skin overlying S3 dermatomes, junction of buttock and upper thigh)	74	Idiopathic instability, multiple sclerosis + spinal cord injury	Max. cystometric capacity increased significantly during stimulation ($p = 0.0002$)
Lee and Creasey[20]	Dorsal nerve of penis	1	Incomplete spinal cord injury	Suppressive effect of electric stimulation on hyperreflexic contractions

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successes. In these studies stimulation was delivered using a 34 gauge stainless steel needle inserted about 3 finger breadths cephalad to the medial malleolus, between the posterior margin of the tibia and soleus muscle. We chose another technique that is less invasive using disposable, self-adhesive contact electrodes. This technique is cheap, noninvasive and free of pharmaceutical side-effects. Moreover, stimulation outside of the anogenital region has higher acceptance by patients.

In our series a significant statistical difference was noted between the 2 groups but there were many failures. Comparisons in specific groups (hyperreflexia versus instability, multiple sclerosis versus spinal cord injury, male versus female and so forth, failed to reveal significance. This finding was probably due to poor patients homogeneity, including neuropathic and nonneuropathic groups. The second reason is that many patients had severe detrusor overactivity with low detrusor capacity. This severe detrusor overactivity may be less sensitive to posterior tibial nerve stimulation. In the methodology we chose the limit of 400 ml. maximum filling to standardize the procedure and avoid difficult interpretation of bladder overactivity at high capacities. Another remark concerns the possible effect of habituation due to repeat cystometry on the recorded increase in urodynamic volume parameters. This effect is possible and other studies are necessary to determine its interference.

Posterior tibial nerve stimulation inhibits bladder activity by depolarizing somatic sacral and lumbar afferent fibers.[2] Afferent stimulation provides central inhibition of the preganglionic bladder motor neurons through a direct route in the sacral cord.[1] Meanwhile, the neuromodulation of the micturition reflex allowed by posterior tibial nerve stimulation remains unclear. Modification of perineal spasticity may be one of the different mechanisms involved in neurological cases. Indeed, the effect of afferent cutaneous electrical stimulation on the spasticity of leg muscles is well known. Transcutaneous electrical nerve stimulation at the usual intensity only stimulates sensory fibers. This technique is widely used for pain management and many commercial devices are available. Transcutaneous electrical nerve stimulation applied to the sural nerve may induce short-term post-stimulation inhibitory effects on abnormally enhanced stretch reflex activity in patients with spasticity of cerebral origin. Likewise, transcutaneous electrical nerve stimulation applied in those with spastic hemiparesis caused an immediate increase in soleus H reflex latencies that was evident for up to 60 minutes after stimulation in more than 75%. The short-term effects of transcutaneous electrical nerve stimulation on the H reflex and spinal spasticity was evaluated in spinal cord injured subjects. Although statistical analyses failed to reveal significant effects of transcutaneous electrical nerve stimulation on H reflex amplitude, there was a significant decrease in scores for the Achilles tendon reflex and the modified Ashworth test. In spastic cases the mean peak-to-peak amplitude of H reflexes, F waves, H/M and F/M ratios were significantly decreased and the mean latencies of H reflexes and F waves were significantly increased after the application of transcutaneous electrical nerve stimulation. Other studies have suggested an indirect action of transcutaneous electrical nerve stimulation on the central nervous system, especially a modification on the dorsal column-medial lemniscal pathway. When transcutaneous electrical nerve stimulation was applied to the palm distal to the median nerve stimulation used for somatosensory evoked potentials, cortical N20/P25 amplification disappeared, evidence that transcutaneous electrical nerve stimulation suppresses the central amplification phenomenon, most probably at the level of the cuneate nucleus. A modification of somatovisceral reflexes can be discussed, as previously described for gastric electrical activity modified by transcutaneous electrical nerve stimulation and evaluated by gastric myoelectric activity measured by electrogastrography.

CONCLUSIONS

Posterior tibial nerve stimulation is a minimally invasive technique that can suppress detrusor instability or hyperreflexia. Improved bladder capacity is an encouraging finding that further supports its use as a noninvasive treatment modality in clinical practice. However, there is no argument in this study suggesting that posterior tibial nerve stimulation may predict S3 neuromodulation failure. Thus, S3 neuromodulation remains indicated in patients in whom posterior tibial nerve stimulation has failed. Furthermore, posterior tibial nerve stimulation may be proposed as a test to select candidates for definitive S3 neuromodulation, which is simpler than the several days of clinical evaluation following an S3 stimulation test. However, further studies are required to test this hypothesis.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 11/20/2019

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EXAMINER
KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
3792	

MAIL DATE	DELIVERY MODE
11/20/2019	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. 15/665,152	Applicant(s) BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	AIA (FITF) 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 11/14/2019.

☐ 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) 5-17 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) 5-17 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 _____.

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

4) ☐ Other: _____.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-17 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. In regards to claims 10, 12, 14, and 16, it is unclear what, if any, steps are required by "detecting…as an indicator of", or that the method merely requires determining the presence of electrical conduction. Claims 11, 13, 15, and 17 are rejected due to their dependency.

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of pre-AIA 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.

Claim(s) 5-7, 9, and 14 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Amarenco et al. ("Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, 169, 2210-2215, June 2003; hereinafter "Amarenco").

In regards to claim 5, Amarenco discloses non-invasively positioning a first portion of a patient's body with respect to an electrical stimulator such that a branch of a posterior tibial nerve is in proximity (abstract); passing a current through the stimulator; and delivering electrical stimulus from the electrical stimulator to treat overactive bladder or incontinence (page 2211, "Procedure," second full paragraph).

In regards to claim 6, positioning comprises positioning an electrode patch upon a foot of the patient (page 2211, "Procedure," "behind the internal malleolus).

In regards to claim 7, the method further comprises detecting a muscular response cause by stimulation (page 2211, "Procedure," "visualization of rhythmic flexion of the toes).

In regards to claim 9, the method further includes displaying physiological parameters detected from the patient (Figs. 3 and 4).

In regards to claim 14, the method further includes detecting for presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement (page 2211, "Procedure," visualization of rhythmic flexion of the toes).

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, 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 negatived by the manner in which the invention was made.

Claim 8 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco in view of Mann et al. (US 2002/0055761, hereinafter "Mann"). Amarenco discloses the essential features of the claimed invention except for activating for a duration of about 30 minutes per week. However, Mann teaches that it was known in the art of tibial nerve stimulation to deliver stimulation for a duration of about 30 minutes per week (par. 0038) to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by stimulating for a duration of about 30 minutes per week to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence.

Claims 10-13, 15, and 17 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Amarenco in view of Lund et al. (US 2007/0265675, hereinafter "Lund"). Amarenco discloses the essential features of the claimed invention including optimizing stimulation parameters by looking at the muscular response of the patient (page 2211, "Procedure"), but does not expressly disclose determining that response with an electrode or that the presence of conduction as an indicator of electrode migration or electrode malfunction. Lund teaches determining stimulation response with EMG electrodes (e.g., 146) as an indicator of electrode migration (par. 0037) or electrode malfunction (by virtue of its migration) to provide the predictable results of optimizing therapy based on feedback from the patient (par. 0035). Furthermore, it is well-known in the art to embody surface EMG electrodes as

patches to provide the predictable results of comfortable and self-carrying electrodes that do not require a user to hold them in contact with the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Amarenco by determining stimulation response with EMG electrodes as an indicator of electrode migration or electrode malfunction to provide the predictable results of optimizing therapy based on feedback from the patient, and embody the surface EMG electrode as a patch to provide the predictable results of comfortable and self-carrying electrodes that do not require a user to hold them in contact with the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL WILLIAM KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/665,152	Applicant(s)/Patent Under Reexamination BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20070265675-A1	11-2007	Lund; Robert E.	A61N1/36007	607/41
	B					
	C					
	D					
	E					
	F					
	G					
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	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Amarenco et al., "Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," June 2003, Journal of Urology, Vol. 169, 2210-2215. (Year: 2003)
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

CPC - Searched*		
Symbol	Date	Examiner
A61N 1/36007	07/12/2019	MWK
A61N 1/36031,0456	11/19/2019	MWK

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor search	07/12/2019	MWK
global dossier search	07/12/2019	MWK
IDS review	07/12/2019	MWK
see attached EAST search history	07/12/2019	MWK
see attached EAST search history	11/19/2019	MWK
NPL search	11/19/2019	MWK

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Petitioner - Avation Medical, Inc.
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	(("9757584") or ("9387338")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 14:59
S1	294	((("BURNETT") near3 ("Daniel"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/07/11 11:46
S2	10	S1 and (tibial and bladder).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 11:49
S3	42	(A61N1$).cpc. and (tibial and bladder).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 11:57
S5	1	("20090076565").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 12:00
S6	1	(11/857872).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:12
S7	478	(A61N1$).cpc. and (tibial and bladder)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:13
S8	550	(A61N1$).cpc. and (tibial and (bladder urinary))	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:14
S9	0	("15665152").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:21
S10	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:21
S11	1114	"urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S12	69178	(A61N1$).cpc. "urge incontinence" with "overactive bladder"	US-PGPUB; USPAT;	OR	ON	2019/07/11 13:26

			USOCR			
S13	149	(A61N1$).cpc. and "urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S14	302	S8 and week	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:36
S15	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:38
S16	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:44
S17	438	S8 and (feedback sensor)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:48
S18	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:23
S19	1	("9757584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:41
S20	2	(14/676635).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:55
S21	33	(11/866329 | 12/469358 | 12/469365 | 12/469625 | 12/508529 | 12/509304 | 12/509345 | 12/509362 | 12/606941 | 12/695087 | 12/790619 | 13/456016 | 13/457228 | 14/085639 | 14/097568 | 14/676635 | 14/685278 | 14/931702 | 14/949735 | 15/056910 | 15/084356 | 15/436538 | 15/474875).APP.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 09:59
S22	4	S21 and percutaneous.clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:00
S23	228	(A61N1/36007).cpc. and tibial	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:02
S24	1	("20140159912").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 11:34
S25	367	(A61N1$).cpc. and (tibial with posterior)	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:04
S26	314	(A61N1$).cpc. and (posterior adj tibial)	US-PGPUB;	OR	ON	2019/11/18 14:05

			USPAT; USOCR			
S27	2677	(A61N1/36007).cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:06
S28	90	S26 and S27	US-PGPUB; USPAT; USOCR	OR	ON	2019/11/18 14:06
S29	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/18 14:20
S30	1	("20120296391").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:05
S31	2	(("20120296391") or ("20150012063")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:07
S32	1	(15/696048).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/19 10:15
S33	3	(US-20020055761-$ or US-20030144710-$ or US-20050171576-$).did.	US-PGPUB	OR	ON	2019/11/19 12:38
S34	2804	(A61N1/36007 or A61N1/0456).cpc.	US-PGPUB	OR	ON	2019/11/19 12:39
S35	580	S34 and emg	US-PGPUB	OR	ON	2019/11/19 12:39
S36	155	(A61N1/36031).cpc.	US-PGPUB	OR	ON	2019/11/19 12:56
S37	0	(A61N1$).cpc. and (feedback same emg same (migrat$4 malfunction$4))	US-PGPUB	OR	ON	2019/11/19 13:07
S38	177	(A61N1$).cpc. and (feedback same emg and (migrat$4 malfunction$4))	US-PGPUB	OR	ON	2019/11/19 13:07

EAST Search History (Interference)

< This search history is empty>

11/19/2019 3:09:04 PM
C:\Users\mkahelin\Documents\EAST\Workspaces\15665152.wsp

I hereby certify that this correspondence is being EFS-Web transmitted to the USPTO on the date shown below.		
Date: November 14, 2019	Signature: /Laura L. Gallagher/	(Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Michael W. Kahelin
Group Art Unit:	3792

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 July 15, 2019 for which a response was due on October 15, 2019. Filed herewith is a Petition and fee for a one-month extension of time, thereby extending the deadline for response to November 15, 2019. 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 5 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.-4. (Canceled)

5. (Currently Amended): A method of treating overactive bladder or incontinence, comprising:

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

~~inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve, or a branch thereof, the percutaneous needle electrode including a wire disposed opposite the end;~~

~~securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode, the controller unit including a pulse generator;~~

~~connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller; and~~

~~activating the pulse generator such that~~ passing a current through the electrical stimulator; and ~~pulses flow along the tibial nerve, or a~~

delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve ~~thereof, the current pulses configured~~ to treat overactive bladder or incontinence.

6. (Currently Amended): The method of claim 5, wherein non-invasively positioning ~~inserting an end of the percutaneous needle electrode~~ comprises positioning an electrode patch in communication with the electrical stimulator upon a foot ~~inserting the end near or at an ankle~~ of the patient.

Petitioner - Avation Medical, Inc.
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7. (Currently Amended): The method of claim 5, further comprising detecting a muscular response caused by an electrical conduction or stimulation of the branch of the posterior tibial nerve ~~a nerve, muscle, or body tissue~~.

8. (Currently Amended): The method of claim 5, wherein delivering the electrical stimulus ~~activating the pulse generator~~ comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.

9. (New): The method of claim 5 further comprising displaying physiological parameters detected from the patient.

10. (New): The method of claim 5 further comprising detecting for a presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.

11. (New): The method of claim 10 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

12. (New): The method of claim 5 further comprising detecting for a presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.

13. (New): The method of claim 12 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

14. (New): The method of claim 5 further comprising detecting for a presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.

15. (New): The method of claim 14 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

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16. (New): The method of claim 5 further comprising detecting for a presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.

17. (New): The method of claim 16 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

Petitioner - Avation Medical, Inc.
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REMARKS

Claims 1-8 were pending in the present application. By virtue of this response, claims 1-4 have been canceled, claims 5-8 have been amended, and new claims 9-17 have been added. Accordingly, claims 5-17 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.

Rejections under 35 U.S.C. §102(b)

Claims 1-2, 5-6 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Williams et al. (U.S. Pub. 2005/0171576) as evidenced by Eini et al. (U.S. Pat. 6,432,037)

Claim 5 has been amended to recite a "method of treating overactive bladder or incontinence, comprising: non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a branch of a posterior tibial nerve within the first portion of the body is in proximity to the electrical stimulator; passing a current through the electrical stimulator; and-delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve to treat overactive bladder."

The cited reference of Williams et al. (or Eini et al.) show or describe each of the limitations as presently amended. Therefore, independent claim 5 is patentable over Williams et al. and its dependent claims are patentable for at least the same reasons.

Claims 1-2 have been canceled rendering as moot the rejection to these claims.

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

Rejections under 35 U.S.C. §103(a)

Claims 3-4, 7-8 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Williams et al. in view of Mann et al. (U.S. Pub. 2002/0055761).

Dependent claims 3-4, 7-8 depend ultimately from respective independent claims 1, 5 and are patentable over Williams et al. for the same reasons above. Mann et al. fails to cure the defects of Williams et al. and the claims are therefore patentable over each of the references alone or in combination.

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Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

Double Patenting

Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Pat. 9,387,338.

Applicant will consider the filing of a Terminal Disclaimer upon an indication of allowability of the claims.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 182

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**.

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. 183

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): EMKNNZ00505

Application Number: 15/665,152

Filed: July 31, 2017

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

Art Unit: 3792

Examiner: Michael W. Kahelin

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	$ 100
☐	Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☐	Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐	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 14, 2019 — 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.

Electronic Patent Application Fee Transmittal

Application Number:	15665152
Filing Date:	31-Jul-2017
Title of Invention:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
First Named Inventor/Applicant Name:	Daniel R. BURNETT
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00505

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	2251	1	100	100
Miscellaneous:				
			Total in USD ($)	**100**

Electronic Acknowledgement Receipt

EFS ID:	37758187
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	14-NOV-2019
Filing Date:	31-JUL-2017
Time Stamp:	19:32:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$100
RAM confirmation Number	E2019ADJ32440873
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		01_EMKNNZ00505_20191114_response_to_non-final_office_action.pdf	37646 14d5b2471955f2201c2aa9f334c6b895f8509009	yes	7
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	4	
	Applicant Arguments/Remarks Made in an Amendment		5	7	
Warnings:					
Information:					
2	Extension of Time	02_EMKNNZ00505_20191114_extension_of_time.pdf	89091 b6da56e08b441ca0f3b51db0584f7c201e8cf2c4	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30482 bcafc64f374ed052cabce3543594ce817704676a	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	157219		

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
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.
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505	6227

40518 7590 07/15/2019

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

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3792	

MAIL DATE	DELIVERY MODE
07/15/2019	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. 15/665,152	Applicant(s) BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	AIA (FITF) 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 7/31/2017.

☐ 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) 1-8 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) 1-8 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 7/31/2017 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 _____.

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

4) ☐ Other: _____.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 191

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of pre-AIA 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.

Claim(s) 1, 2, 5, and 6 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Williams et al. (US 2005/0171576, hereinafter "Williams") as evidenced by Eini et al. (US 6,432,037, hereinafter "Eini").

In regards to claims 1 and 5, Williams discloses applying an electrode patch to the outer surface of the skin and the electrode patch (18) is electrically coupled with a controller unit including pulse generator (12); electrically coupling a percutaneous electrode to the controller unit with a wire, the electrode having an end for inserting in proximity to the tibial nerve and inserting the end of the electrode in proximity to the tibial nerve (Figs. 1 and 12; pars. 0030 and 0037); and activating the pulse generator such that current pulses flow along the tibial nerve and configured to treat overactive bladder (par. 0037; see Eini at col. 1, lines 28-29 for evidence that "an overactive bladder [is] (typically referred to as urge incontinence)").

In regards to claims 2 and 6, inserting the electrode comprises inserting the end near an ankle (par. 0037; "medial malleolus").

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, 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 negatived by the manner in which the invention was made.

Claims 3, 4, 7, and 8 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Williams in view of Mann et al. (US 2002/0055761, hereinafter "Mann"). Williams discloses the essential features of the claimed invention except for detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body, tissue; or that the activation of the pulse generator comprises activating for a duration of about 30 minutes per week. However, Mann teaches that it was known in the art of tibial nerve stimulation to detect a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body, tissue (par. 0154) to provide the predictable results of determining the strength and/or duration of electrical stimulation to produce the desired therapeutic effect in a particular patient; and that the activation of the pulse generator comprises activating for a duration of about 30 minutes per week (par. 0038) to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence. Therefore, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify Williams by detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body, tissue to provide the predictable results of determining the strength and/or duration of electrical stimulation to produce the desired therapeutic effect in a particular patient; and that the activation of the pulse generator comprises activating for a duration of about 30 minutes per week to provide the predictable results of a treatment regimen that has been established to be efficacious in reducing symptoms of incontinence.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for

applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-8 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 9,757,584. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims of the instant application are broader than (i.e., "anticipated by") the claims of the issued patent.

Claims 1-8 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 9,387,338. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims of the instant application are broader than (i.e., "anticipated by") the claims of the issued patent. Please see the Eini reference cited above for evidence that "an overactive bladder [is] (typically referred to as urge incontinence)."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL WILLIAM KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/MICHAEL W KAHELIN/
Primary Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/665,152	Applicant(s)/Patent Under Reexamination BURNETT, Daniel R.	
	Examiner MICHAEL W KAHELIN	Art Unit 3792	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/665,152	BURNETT, Daniel R.
	Examiner	Art Unit
	MICHAEL W KAHELIN	3792

CPC - Searched*		
Symbol	Date	Examiner
A61N 1/36007	07/12/2019	MWK

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor search	07/12/2019	MWK
global dossier search	07/12/2019	MWK
IDS review	07/12/2019	MWK
see attached EAST search history	07/12/2019	MWK

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

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Ex. 1002, p. 198

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 13

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	EMKNNZ00505

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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
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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
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
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00505

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Examiner Signature		Date Considered	

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Application Number	Not Yet Assigned
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First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00505

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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
Art Unit	Not Yet Assigned
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				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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				Art Unit	Not Yet Assigned
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Sheet	10	of	13	Attorney Docket Number	EMKNNZ00505

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				Filing Date	Concurrently Herewith
				First Named Inventor	Daniel R. BURNETT
				Art Unit	Not Yet Assigned
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

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Application Number	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	2183
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00505

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				Art Unit	2183
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:23
L2	1	("9757584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:41
L3	2	(14/676635).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/12 09:55
L4	33	(11/866329 | 12/469358 | 12/469365 | 12/469625 | 12/508529 | 12/509304 | 12/509345 | 12/509362 | 12/606941 | 12/695087 | 12/790619 | 13/456016 | 13/457228 | 14/085639 | 14/097568 | 14/676635 | 14/685278 | 14/931702 | 14/949735 | 15/056910 | 15/084356 | 15/436538 | 15/474875).APP.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 09:59
L5	4	4 and percutaneous.clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:00
L6	228	(A61N1/36007).cpc. and tibial	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/12 10:02
S1	294	((("BURNETT") near3 ("Daniel"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/07/11 11:46
S2	10	S1 and (tibial and bladder).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 11:49
S3	42	(A61N1$).cpc. and (tibial and bladder).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 11:57
S5	1	("20090076565").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 12:00
S6	1	(11/857872).APP.	US-PGPUB; USPAT;	OR	OFF	2019/07/11 13:12

			USOCR			
S7	478	(A61N1$).cpc. and (tibial and bladder)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:13
S8	550	(A61N1$).cpc. and (tibial and (bladder urinary))	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:14
S9	0	("15665152").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:21
S10	1	(15/665152).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:21
S11	1114	"urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S12	69178	(A61N1$).cpc. "urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S13	149	(A61N1$).cpc. and "urge incontinence" with "overactive bladder"	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:26
S14	302	S8 and week	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:36
S15	1	("20050171576").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:38
S16	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/07/11 13:44
S17	438	S8 and (feedback sensor)	US-PGPUB; USPAT; USOCR	OR	ON	2019/07/11 13:48

EAST Search History (Interference)

< This search history is empty>

7/ 12/ 2019 10:04:19 AM
C:\ Users\ mkahelin\ Documents\ EAST\ Workspaces\ 15665152.wsp

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

Date: July 31, 2017 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	Not Yet Assigned
Confirmation No.:	Concurrently Herewith
Filing Date:	Not Yet Assigned
Inventor(s):	Daniel R. BURNETT
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

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 the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related Application Number 15/056,910, filed February 29, 2016, and accordingly, copies are not included herewith. The Examiner is requested to make these documents of record in the application.

ALL REFERENCES CONSIDERED EXCEPT WHERE [illegible] /M.E./

Petitioner Avation Medical, Inc.
Ex. 1002, p. 216

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. Patent Application No.: 12/695,087 filed January 27, 2010

U.S. Patent Application No.: 11/866,329 filed October 2, 2007

U.S. Patent Application No.: 12/508,529 filed July 23, 2009

U.S. Patent Application No.: 12/469,625 filed May 20, 2009

U.S. Patent Application No.: 12/469,358 filed May 20, 2009

U.S. Patent Application No.: 12/469,365 filed May 20, 2009

U.S. Patent Application No.: 12/606,941 filed October 27, 2009

U.S. Patent Application No.: 12/509,304 filed July 24, 2009

U.S. Patent Application No.: 12/509,345 filed July 24, 2009

U.S. Patent Application No.: 13/457,228 filed April 26, 2012

U.S. Patent Application No.: 14/097,568 filed December 5, 2013

U.S. Patent Application No. 14/685,278 filed April 13, 2015

U.S. Patent Application No. 14/949,735 filed November 23, 2015

U.S. Patent Application No.: 12/509,362 filed July 24, 2009

U.S. Patent Application No. 15/436,538 filed February 17, 2017

U.S. Patent Application No. 13/456,016 filed April 25, 2012

U.S. Patent Application No. 14/085,639 filed November 20, 2013

U.S. Patent Application No. 14/676,635 filed April 1, 2015

U.S. Patent Application No. 14/931,702 filed November 3, 2015

U.S. Patent Application No. 15/056,910 filed February 29, 2016

U.S. Patent Application No. 12/790,619 filed May 28, 2010

U.S. Patent Application No. 13/840,936 filed March 15, 2013

U.S. Patent Application No. 15/084,356 filed March 29, 2016

U.S. Patent Application No. 15/474,875 filed March 3, 2017

This Information Disclosure Statement is submitted with the application; accordingly, no fee or separate requirements are required.

ALL REFERENCES CONSIDERED EXCEPT WHERE [illegible] /MM/

Petitioner Avation Medical, Inc.
Ex. 1002, p. 217

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**. However, the Commissioner is not authorized to charge the surcharge for late filing of an Oath or Declaration until issuance of a pre-exam formalities Notice.

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

/MICHAEL W KAHELIN/ 07/12/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.K./

Petitioner Avation Medical, Inc.
Ex. 1002, p. 218

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	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00505

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.	2002/0040233	04-04-2002	George et al.	
	2.	2003/0004392	01-02-2003	Tanner et al.	
	3.	2006/0115130	06-01-2006	Kozlay	
	4.	2008/0097142	04-24-2008	Savage	
	5.	2015/0190648	07-09-2015	Fischell 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]

*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	/MICHAEL W KAHELIN/	Date Considered	07/12/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.K./

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
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505

CONFIRMATION NO. 6227

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

POA ACCEPTANCE LETTER

OC000000105544960

Date Mailed: 02/01/2019

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/28/2019.

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.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sibrahim/

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 220

PTO/AIA/80 (07-12)
Approved for use through 11/30/2014. OMB 0651-0035
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.

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 assigned only to the undersigned according to the USPTO assignment records or assignments documents 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.
101 Mississippi Street
San Francisco, CA 94107

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	[signature]	Date	2/22/17
Name	David Burwell	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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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Daniel R. BURNETT

Application No./Patent No.: 15/665,152 Filed/Issue Date: July 31, 2017

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 047935, Frame 0560, 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.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 222

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
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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

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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.

/Johney U. Han/	January 28, 2019
Signature	Date
Johney U. Han	45,565
Printed or Typed Name	Title or Registration Number

Electronic Acknowledgement Receipt

EFS ID:	34981705
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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/Emily Ackerman
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	28-JAN-2019
Filing Date:	31-JUL-2017
Time Stamp:	16:40:19
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	Application Data Sheet	01_EMKNNZ00505_20190128_corrected_ads.pdf	139509 12a56bdf7368e9642704299868c3e8211f8045a8	no	9

Warnings:

Information:					
This is not an USPTO supplied ADS fillable form					
2	Power of Attorney	02_EMKNNZ00505_20190128_power_of_attorney.pdf	789767 d7b68348ef97a10c363a807e66408279641b96d6	no	1
Warnings:					
Information:					
3	Assignee showing of ownership per 37 CFR 3.73	03_EMKNNZ00505_20190128_373c.pdf	69724 f659bfebbf3f3e3dd0c62d19e17829ba7748a91b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	999000	

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/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
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.

Secrecy Order 37 CFR 5.2:

☐ 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	US

Mailing Address of Inventor:

Address 1	588 Teresita Boulevard		
Address 2			
City	San Francisco	State/Province	CA
Postal Code	94127	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	40518		
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	EMKNNZ00505	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	37

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	40518		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15056910	2016-02-29

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15056910	Continuation of	14676635	2015-04-01	9387338	2016-07-12
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14676635	Continuation of	14085639	2013-11-20	9002477	2015-04-07
Prior Application Status	Abandoned		Remove		
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
14085639	Continuation of	13456016	2012-04-25		
Prior Application Status	Expired		Remove		
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
13456016	Continuation of	PCTUS2010054167	2010-10-26		
Prior Application Status	Expired		Remove		
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
PCTUS2010054167	Claims benefit of provisional	61279883	2009-10-26		
Prior Application Status	Abandoned		Remove		
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
14085639	Continuation in part of	12508529	2009-07-23		
Prior Application Status	Abandoned		Remove		
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
12508529	Continuation in part of	11866329	2007-10-02		
Prior Application Status	Expired		Remove		
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
11866329	Claims benefit of provisional	60848720	2006-10-02		

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. 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 contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

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. ☒

Organization Name	EMKinetics, Inc.		
Mailing Address Information For Applicant:			
Address 1	101 Mississippi Street		
Address 2			
City	San Francisco	**State/Province**	CA
Country	US	Postal Code	94107
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	EMKinetics, Inc.

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	101 Mississippi Street		
Address 2			
City	San Francisco	**State/Province**	CA
Country	US	Postal Code	94107
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Johney U. Han/			Date (YYYY-MM-DD)	2019-01-28
First Name	Johney	Last Name	Han	Registration Number	45565

Additional Signature may be generated within this form by selecting the Add button.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	15/665,152
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

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 the Freedom of Information Act requires disclosure of these records.

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 CooperationTreaty.

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 inspections 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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	2183
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00505

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.	2,003,392	06-04-1935	Rucker	
	2.	4,969,468	11-13-1990	Byers et al.	
	3.	5,299,572	04-05-1994	Chen et al.	
	4.	5,374,283	12-20-1994	Flick	
	5.	5,540,735	07-30-1996	Wingrove	
	6.	5,995,873	11-30-1999	Rhodes	
	7.	6,132,386	10-17-2000	Gozani et al.	
	8.	6,379,313	04-30-2002	Gozani et al.	
	9.	6,615,080	09-02-2003	Unsworth et al.	
	10.	6,692,444	02-17-2004	Gozani et al.	
	11.	6,904,614	06-14-2005	Yamazaki et al.	
	12.	7,628,761	12-08-2009	Gozani et al.	
	13.	8,308,665	11-13-2012	Harry et al.	
	14.	8,660,646	02-25-2014	Laing et al.	
	15.	8,805,510	08-12-2014	Chancellor et al.	
	16.	8,812,114	08-19-2014	Van den biggelaar et al.	
	17.	8,818,520	08-26-2014	Laing et al.	
	18.	8,954,153	02-10-2015	Boggs	
	19.	9,056,194	06-16-2015	Van den biggelaar et al.	
	20.	9,076,187	07-07-2015	Laing et al.	
	21.	9,245,265	01-26-2016	Laing et al.	
	22.	9,265,941	02-23-2016	Van den biggelaar et al.	
	23.	2002/0007128	01-17-2002	Ives et al.	
	24.	2002/0055761	05-09-2002	Mann et al.	
	25.	2002/0138116	09-26-2002	Bertolucci	
	26.	2003/0003968	01-02-2003	Muraki	
	27.	2004/0015188	01-22-2004	Coulter	
	28.	2004/0102819	05-27-2004	Zou et al.	
	29.	2006/0155345	07-13-2006	Williams et al.	
	30.	2011/0270140	11-03-2011	Israeli	
	31.	2012/0101326	04-26-2012	Simon et al.	
	32.	2013/0072835	03-21-2013	Harry et al.	
	33.	2014/0249595	09-04-2014	Chancellor et al.	
	34.	2014/0288613	09-25-2014	Laing et al.	
	35.	2015/0227909	08-13-2015	Laing et al.	
	36.	2015/0260471	09-17-2015	Azhocar	
	37.	2018/0050216	02-22-2018	Burnett	
	38.	2018/0133472	05-17-2018	Tai	

Examiner Signature		Date Considered	

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	2183
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00505

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]
	39.	WO 2010/084482	07-29-2010	Israeli		

*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	

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 July 2010 (29.07.2010)

PCT

(10) International Publication Number
WO 2010/084482 A1

(51) International Patent Classification:
A01N 59/22 (2006.01)

(21) International Application Number:
PCT/IL2009/000206

(22) International Filing Date:
24 February 2009 (24.02.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/146,707 23 January 2009 (23.01.2009) US

(72) Inventor; and
(71) Applicant : **ISRAELI, Eran** [IL/IL]; D.N. MISGAV, 98 ANAFA STREET, 20170 ATZMON (IL).

(74) Agent: **BRONSTEIN, Rafi**; Daltan Consulting Ltd., P.O. Box 1146, 44110 Kefar-Sava (IL).

(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, 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, 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.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

[Continued on next page]

(54) **Title**: A METHOD AND DEVICE FOR LESSENING THE EFFECTS OF BENIGN PROSTATIC HYPERPLASIA

(57) **Abstract**: Disclosed is a method for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying by a device including a plurality of protrusions configured to produce at least one stimulating effect on a predefined area of a foot.

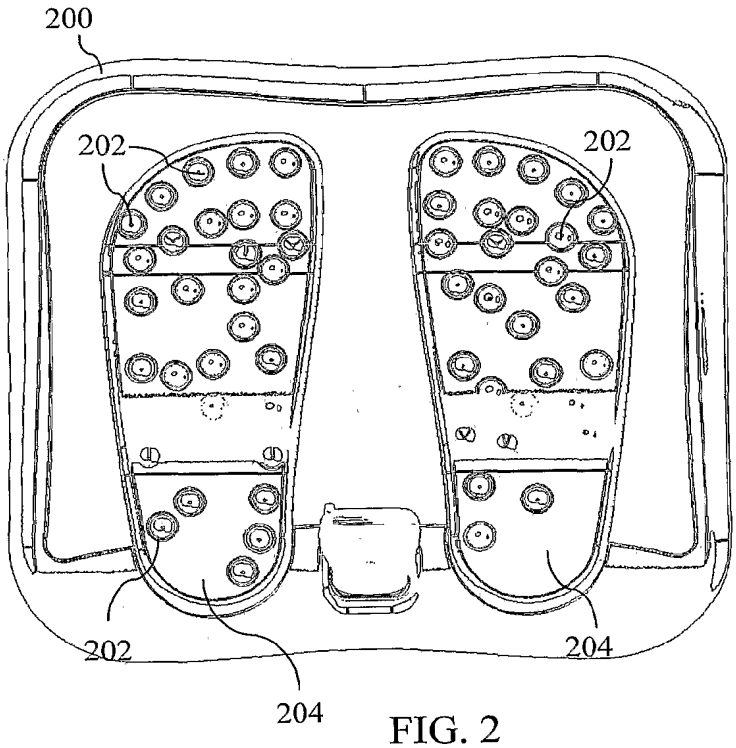


FIG. 2

WO 2010/084482 A1

Published:

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

A METHOD AND DEVICE FOR LESSENING THE EFFECTS OF BENIGN PROSTATIC HYPERPLASIA

TECHNICAL FIELD

[001] The method and device relate to the field of treatments for Benign Prostatic Hyperplasia, and more specifically to lessening the effect of Benign Prostatic Hyperplasia symptoms.

BACKGROUND

[002] Benign Prostatic Hyperplasia (BPH) affects at least 50% of men over the age of 50 years of age. The symptoms include reduced urine flow, urinary hesitancy, frequent urination, incomplete bladder emptying (urine retention), difficulty in bladder emptying and increased risk of urinary tract infections.

[003] BPH refers to the increase in size of the prostate in middle-aged and elderly men. It is characterized by the formation of large nodules in the region of the prostate surrounding the urethral canal. The nodules compress the urethral canal to cause partial, or sometimes virtually complete, obstruction of the urethra, which interferes with the normal flow of urine. This leads to the above described symptoms.

[004] While medication is often prescribed as the first treatment option for those suffering from clinically significant BPH, there are many patients who do not achieve success with this line of treatment. For others, though medication may be a good option, they may not achieve sustained improvement in symptoms or they may stop taking the medication because of side effects.

[005] Patients suffering from clinically significant BPH who elect to avoid medication treatment or are non-responsive to such medication sometimes require painful surgical intervention.

[006] Patients with minor BPH are not treated medically or surgically though still suffer from the symptoms.

[007] Reflexology (zone therapy) is the practice of stimulating, massaging, squeezing, or pushing on predefined areas of the foot, with the goal of encouraging a beneficial effect on other parts of the body, or to improve general health.

[008] According to Reflexology, predefined areas on the tarsal aspect of the foot correspond to specific body organs. By stimulating these predefined areas on the foot, one can induce a beneficial effect on the corresponding body organs. For example, in one exemplary embodiment of the present method, predefined areas of the foot, corresponding to the bladder and urethral canal, are stimulated. This stimulation affects the bladder and the urethral canal and induces increased urine flow through the urethral canal and bladder emptying, thus lessening the effect of BPH.

[009] There is a need for a solution providing relief from the symptoms and lessening the effect of BPH by enabling increased urine flow and bladder emptying, which is painless, non-invasive and non-medicating. There is also a need for a solution providing relief from the symptoms for patients with minor BPH who are not treated medically or surgically though still suffer from the symptoms.

[010] The present method and device provide a solution, alternative to medication or surgery, for such patients seeking relief from the symptoms of BPH.

BRIEF SUMMARY

[011] The present method and device provide an in-home self-treating solution, alternative to medication or surgery, which lessens the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying.

BRIEF LIST OF DRAWING

[012] The method and the device are particularly pointed out and distinctly claimed in the concluding portion of the specification. The method and the device, however, both as to organization and method of operation, may best be understood by reference to the following detailed description when read with the accompanying drawings, in which like reference characters refer to the same parts throughout the different views. The drawings

are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the method.

[013] FIG 1 is a schematic illustration of a Reflexology map of a tarsal aspect of a foot.

[014] FIG 2 is a top view of an exemplary embodiment of the present device for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder
emptying.

[015] FIG 3 is an oblique elevational view of an exemplary embodiment of the present device for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying.

[016] FIG 4 is a schematic illustration of an exemplary embodiment of the present device for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying.

[017] FIG 5 is a schematic illustration of an exemplary embodiment of the user interface for the present device for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[018] In the following detailed description, reference is made to the accompanying drawings that form a part hereof and wherein like reference numerals denote like elements through the several views.

[019] FIG 1 illustrates a reflexology map 102 displaying the tarsal aspect (bottom) of a foot. The map outlines predefined areas corresponding to the bladder 106 and urethral canal 108 and labels 104 that specify the body organs that are affected by stimulation of these outlined predefined areas. According to Reflexology, stimulation of predefined area 106 will induce increasing bladder emptying, and stimulation of predefined area 108 will induce increased urine flow through the urethral canal thus lessening the effects of BPH.

[020] FIG 2 illustrates a top view of an exemplary embodiment of the present device for inducing increased urine flow and bladder emptying and lessening the effect of Benign Prostatic Hyperplasia. The device 200 includes at least one plate 204 containing a plurality of protrusions 202 configured to produce at least one stimulating effect on a predefined area of a foot.

[021] In another embodiment of the present device the plurality of protrusions 202 produce at least one stimulating effect selected from a group consisting of heating stimulation, vibrating stimulation, electric charge stimulation, electromagnetic stimulation and pressure stimulation on said foot in a pattern according to a predetermined protocol.

[022] FIG 3 illustrates an oblique elevational view of an exemplary embodiment of the present device housing 302. The housing 302 contains at least one oblong chamber 304. According to the exemplary embodiment of the device, the chamber 304 contains at least one opening 308 configured to accommodate a human foot and maintain the foot in a constant position relative to the protrusions 202. A chamber floor 306 contains a plurality of protrusions 202 configured to produce at least one stimulating effect on a predefined area of the foot in a pattern according to a predetermined protocol.

[023] FIG 4 is a schematic illustration of another exemplary embodiment of the device. The illustration shows a human foot placed on a plurality of protrusions 202. The axial cross section of the protrusions is of any second or higher degree curve. In the present exemplary embodiment illustrated in FIG. 4 the protrusions are spherical.

[024] Actuators, illustrated in FIG. 4, are selected from a group consisting of a vibrational actuator, a mechanical actuator and an electromagnetic actuator, directly connected to at least one of the plurality of protrusions and configured to communicate with a control unit 412.

[025] In still another illustrated embodiment of the present device, for example, a vibrational actuator 402a is directly connected to at least one protrusion 202a, which is a moveably attached to plate 204 and configured to communicate with the control unit 412. The vibrational actuator, when activated, causes the protrusion to vibrate along a predetermined axis according to a predetermined protocol. A mechanical actuator 402b is directly connected to at least one protrusion 202b which is moveably attached to plate 204

and configured to communicate with the control unit 412. The mechanical actuator, when activated, causes the protrusion 202b to move axially from a resting position and protrude further beyond the plane of plate 204 thus placing pressure on a predetermined area of a foot resting on protrusion 202b. The electromagnetic actuator 402c is directly connected to protrusion 202c and configured to communicate with the control unit 412.

[026] Yet another exemplary embodiment of the present device, illustrated in FIG. 4, contains a heat source 402d which is directly connected to at least one of the plurality of protrusions 202d and configured to communicate with the control unit 412. When activated, the heat source 402d heats the connected protrusion 202d to a predetermined temperature and stimulates a predefined area of a foot resting on protrusion 202d.

[027] Still another exemplary embodiment of the present device contains a source of electricity 402e directly connected to at least one of the plurality of protrusions 202e and configured to communicate with the control unit 412. The source of electricity 402e, when activated, is configured to cause the connected protrusion 202e to produce an electric pulse thus electrically stimulating a predefined area of a foot resting on protrusion 202e. The electric pulse current and voltage levels produced by the source of electricity are configured to be safe for application and at-home use by humans.

[028] Still referring to FIG. 4, another exemplary embodiment of the present device contains a command unit 414 operable configured to activate the device and communicate with the plurality of protrusions 202 and the control unit 412. In yet another exemplary embodiment of the device, the command unit 414 remotely communicates with the plurality of protrusions 202 and the control unit 412.

[029] The command unit 414 and the control unit 412 activate any one of actuators 402a-402e and corresponding protrusions 202a-202e separately, or in combination, according to a predetermined protocol, and cause a stimulating effect on predefined areas of the foot that affect the urethral canal by inducing increased urine flow and the bladder by increasing bladder emptying, thus lessening the effect of Benign Prostatic Hyperplasia.

[030] FIG 5 is a schematic illustration of an exemplary embodiment of the command unit for the present device. In the illustrated embodiment of the device, the command unit 502 contains a touch-screen display 506 of a reflexology map 102 of a tarsal aspect (bottom) of

a foot and a stylus 504 and remotely communicates with the plurality of protrusions 202 and control unit 412.

[031] An exemplary embodiment of the present method teaches placing the foot of a subject on the plurality of protrusions 202 (See Fig. 2) and activating them to produce at least one stimulating effect selected from a group consisting of heating stimulation, vibrating stimulation, electric charge stimulation, electromagnetic stimulation and pressure stimulation on said foot in a pattern according to a predetermined protocol.

[032] Another embodiment of the present method teaches, for example, placing the foot of a subject on the plurality of protrusions 202. Having the subject manipulate command unit 502 with stylus 504 (see Fig. 5) and touch the touch-screen display 506 to select a protocol devised to lessen the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying. The selection is communicated to control unit 412 (See Fig. 4), which activates actuators 402a-402e and the corresponding protrusions 202a-202e, individually or in any combination, to stimulate the predefined areas on the tarsal aspect of the foot that correspond to the bladder 106 and urethral canal 108 and are in contact with the protrusions 202a-202e. Stimulating these predefined areas 106 and 108 affects the bladder and urethral canal by inducing increased urine flow and bladder emptying thus lessening the effect of Benign Prostatic Hyperplasia.

[033] In a similar manner a number of internal diseases, constipation, and insomnia may be treated.

[034] A number of embodiments have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the method. Accordingly, other embodiments are within the scope of the following claims:

What is claimed is:

1. A method for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying, said method comprising:
   - providing a device including at least one plate containing a plurality of protrusions configured to produce at least one stimulating effect on a predefined area of a foot;
   - placing the foot of a subject on said plurality of protrusions and activating them to produce at least one stimulating effect selected from a group consisting of heating stimulation, vibrating stimulation, electric charge stimulation, electromagnetic stimulation and pressure stimulation on said foot in a pattern according to a predetermined protocol,

   wherein said stimulation of said predefined area of said foot lessens the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying.
2. The method according to Claim 1, further comprising a control unit operably configured to activate said device and communicate with said protrusions.
3. The method according to Claim 1, wherein at least one of said plurality of protrusions is moveably attached to said plate.
4. The method according to Claim 1, further comprising a source of electricity directly connected to at least one of said plurality of protrusions.
5. The method according to Claim 1, further comprising at least one actuator selected from a group consisting of a vibrational actuator, a mechanical actuator and an electromagnetic actuator, directly connected to at least one of said plurality of protrusions.
6. The method according to Claim 1, further comprising at least one heat source directly connected to at least one of said plurality of protrusions.
7. The method according to Claim 1, wherein the predetermined protocol is preselected by the subject.

8. A device for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying, said device comprising:
    - at least one plate containing a plurality of protrusions configured to produce at least one stimulating effect on a predefined area of a foot in a pattern according to a predetermined protocol;
    - a command unit operably configured to activate said device and communicate with said plurality of protrusions,

    wherein said stimulating effect on a predefined area of a foot induces increased urine flow and bladder emptying and lessens the effect of Benign Prostatic Hyperplasia.
9. The device according to Claim 8, wherein at least one of said plurality of protrusions is moveably attached to said plate.
10. A device for lessening the effect of Benign Prostatic Hyperplasia by inducing increased urine flow and bladder emptying, said device comprising:
    - at least one oblong chamber, having at least one opening and configured to accommodate at least a human foot, and a floor containing a plurality of protrusions configured to produce at least one stimulating effect on a predefined area of said foot in a pattern according to a predetermined protocol; and
    - a command unit operably configured to activate said device and communicate with said plurality of protrusions,

    wherein said stimulating effect on a predefined area of said foot induces increased urine flow and bladder emptying and lessens the effect of Benign Prostatic Hyperplasia.
11. The device according to Claim 10, wherein said device further comprises a housing configured to contain at least one oblong chamber.

12. The device according to any one of Claims 8 or 10, wherein said device further comprises a control unit configured to communicate with said protrusions and said command unit.
13. The device according to any one of Claims 8 or 10, wherein the axial cross section of said protrusions is of any second or higher degree curve.
14. The device according to any one of Claims 8 or 10, wherein said stimulating effect is at least one effect selected from a group consisting of heating stimulation, vibrating stimulation, electric charge stimulation, electromagnetic stimulation and pressure stimulation.
15. The device according to any one of Claims 8 or 10, further comprising a source of electricity directly connected to at least one of said plurality of protrusions and configured to communicate with said command unit.
16. The device according to any one of Claims 8 or 10, further comprising at least one actuator selected from a group consisting of a vibrational actuator, a mechanical actuator and an electromagnetic actuator, directly connected to at least one of said plurality of protrusions.
17. The device according to any one of Claims 8 or 10, further comprising at least one heat source directly connected to at least one of said plurality of protrusions and configured to communicate with said command unit.
18. The device according to any one of Claims 8 or 10, wherein said command unit remotely communicates with said plurality of protrusions.
19. The device according to any one of Claims 8 or 10, wherein said command unit further comprises a touch-screen display.

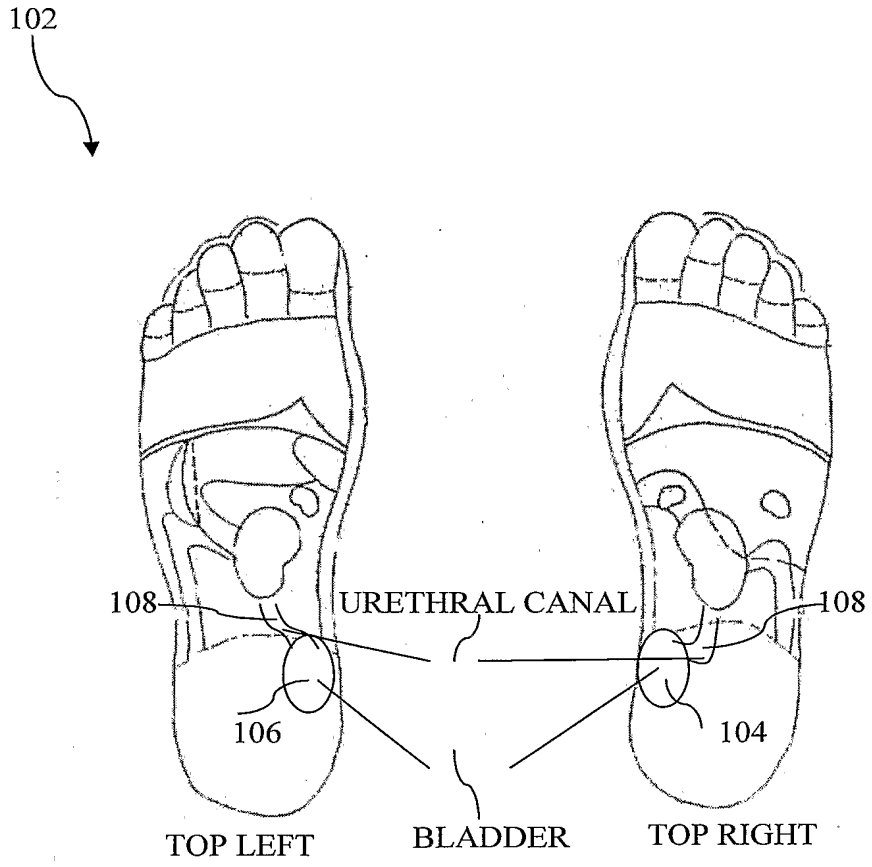


FIG. 1

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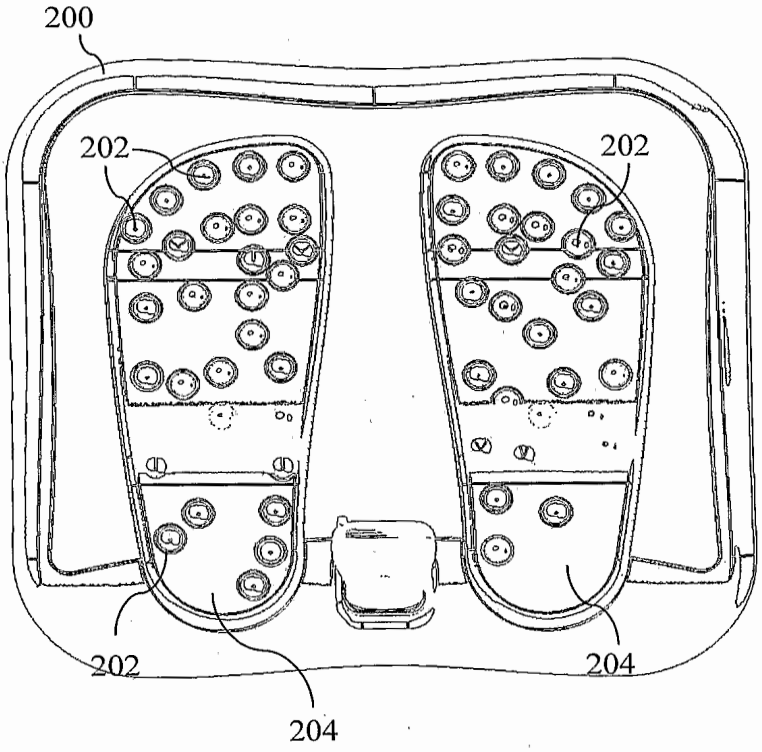


FIG. 2

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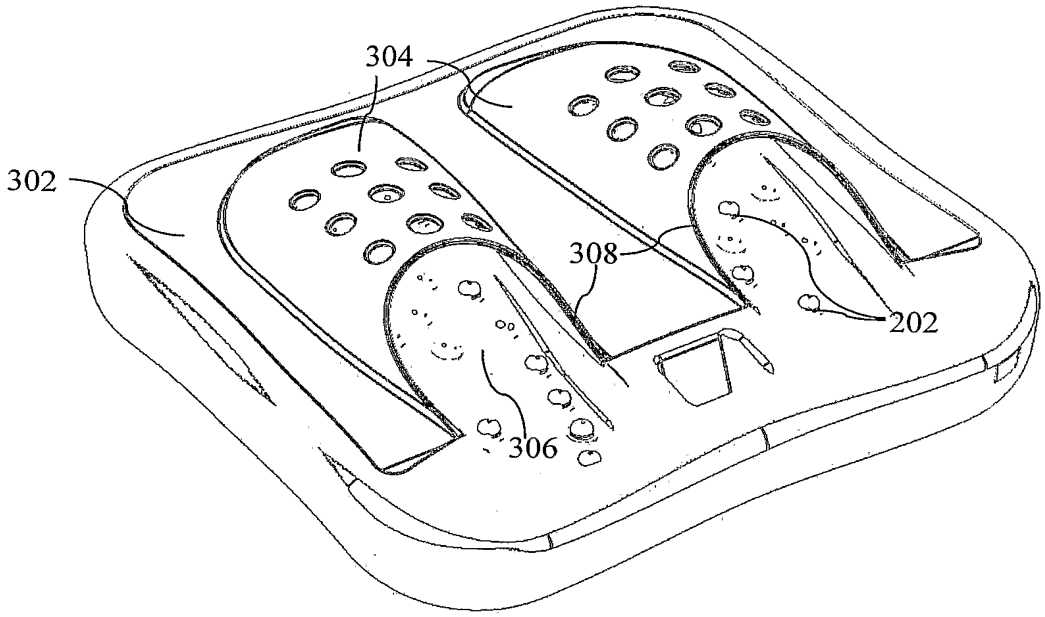


FIG. 3

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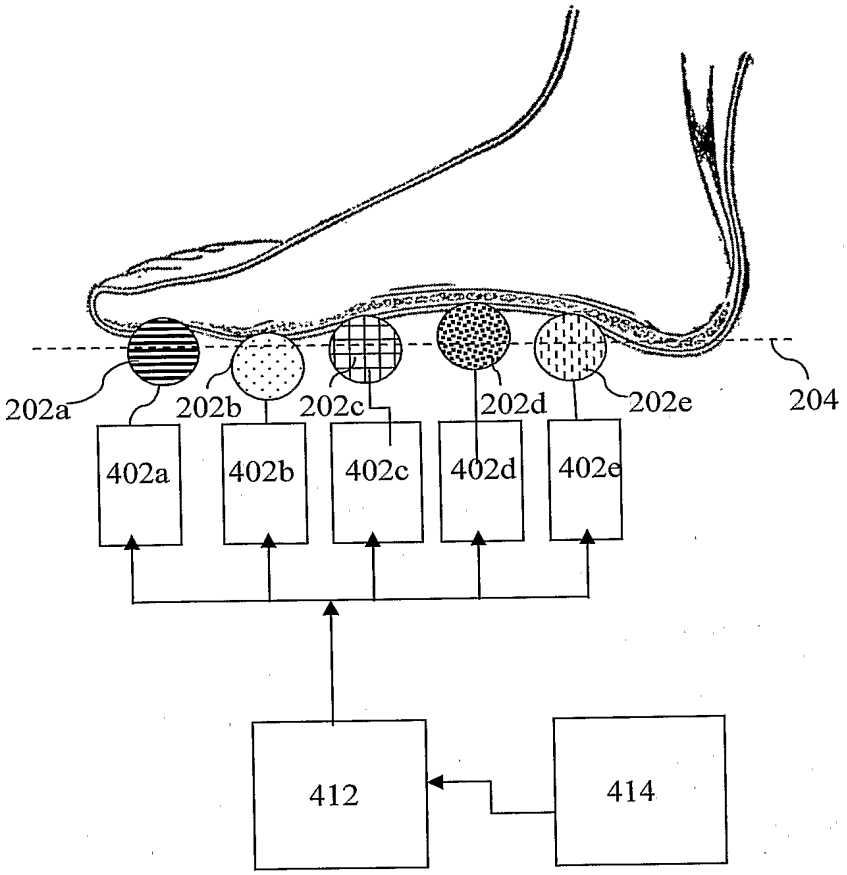


FIG. 4

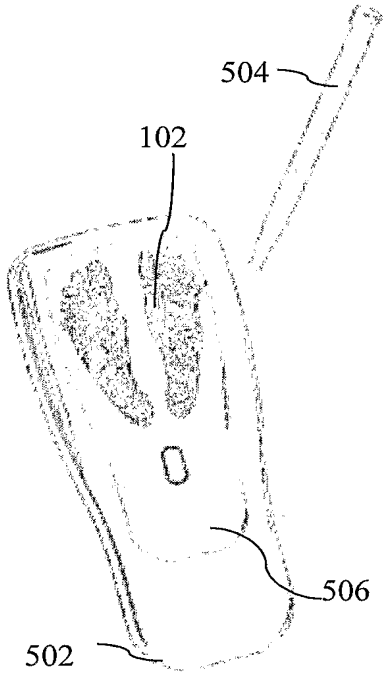


FIG. 5

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 09/00206

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A01N 59/22 (2009.01)
USPC - 424/670
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)
USPC: 424/670

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 practicable, search terms used)
PubWEST (USPT, PGPB, EPAB, JPAB); Google Scholar
Search terms: benign prostatic hyperplasia, urine, bladder, device, protrusions, acuator, foot, reflexology, housing, control unit, vibrational, electricity, electomagnetic, protocol

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0078361 A1 (WONG et al) 05 April 2007 (05.04.2007); entire document, especially astract, para [0020]	1-19
Y	US 2004/0054337 A1 (CHEN) 18 March 2004 (18.03.2004); entire document, especially abstract, para [0081]).	1-19
Y	US 2008/0033513 A1 (MAN et al) 07 February 2008 (07.02.2008); entire document, especially para [0015]).	6, 17

☐ Further documents are listed in the continuation of Box C. ☐

* 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 application or patent 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
30 April 2009 (30.04.2009)	13 MAY 2009

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

Electronic Acknowledgement Receipt

EFS ID:	33344383
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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/Emily Ackerman
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	01-AUG-2018
Filing Date:	31-JUL-2017
Time Stamp:	14:27:22
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	01_EMKNNZ00505_20180801_ids_cover_letter.pdf	22846 53a8562c8911dad84b21ee7229d2d972c93aaa13	no	2

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	02_EMKNNZ00505_20180801_sb08.pdf	32508 60c4989a1010132fae47d8a17c4a58adc245032e	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	03_39_WO2010084482_emkinetics.pdf	606515 72cb7b2ad5a40370d62702df3ffa52178aadc073	no	17
Warnings:					
Information:					
		Total Files Size (in bytes):	661869		

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 EFS-Web transmitted to the USPTO on the date shown below.

Date: August 1, 2018 Signature: /Emily Ackerman/ (Emily Ackerman)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
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 and non-patent literature 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.

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**. However, the Commissioner is not authorized to charge the surcharge for late filing of an Oath or Declaration until issuance of a pre-exam formalities Notice.

Respectfully submitted,

/Johney U. Han/

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/665,152	07/31/2017	Daniel R. BURNETT	EMKNNZ00505

CONFIRMATION NO. 6227

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

PUBLICATION NOTICE



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

Publication No.US-2017-0354831-A1
Publication Date:12/14/2017

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 Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, 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 https://portal.uspto.gov/pair/PublicPair. 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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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/665,152	07/31/2017	2183	730	EMKNNZ00505	8	2

CONFIRMATION NO. 6227

FILING RECEIPT

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

OC000000093851002

Date Mailed: 09/05/2017

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)

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Applicant(s)

Daniel R. BURNETT, San Francisco, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/056,910 02/29/2016 PAT 9757584
which is a CON of 14/676,635 04/01/2015 PAT 9387338
which is a CON of 14/085,639 11/20/2013 PAT 9002477
which is a CON of 13/456,016 04/25/2012 ABN
which is a CON of PCT/US2010/054167 10/26/2010
which claims benefit of 61/279,883 10/26/2009
and said 14/085,639 11/20/2013
is a CIP of 12/508,529 07/23/2009 ABN
which is a CIP of 11/866,329 10/02/2007 ABN
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 Application via Priority Document Exchange: Yes

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Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 09/05/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/665,152**

Projected Publication Date: 12/14/2017

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.

Petitioner - Avation Medical, Inc.
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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

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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.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 262

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/665,152

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))	8 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 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.

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	15/665,152
Filing Date	July 31, 2017
First Named Inventor	Daniel R. BURNETT
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00505

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.	2002/0040233	04-04-2002	George et al.	
	2.	2003/0004392	01-02-2003	Tanner et al.	
	3.	2006/0115130	06-01-2006	Kozlay	
	4.	2008/0097142	04-24-2008	Savage	
	5.	2015/0190648	07-09-2015	Fischell 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]

*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 Acknowledgement Receipt

EFS ID:	30112151
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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/Emily Ackerman
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00505
Receipt Date:	17-AUG-2017
Filing Date:	
Time Stamp:	16:38:49
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	01_EMKNNZ00505_20170817_ids_cover_letter.pdf	498845 d90a1f68ca1d7fb3d74a0a9e51577384276 48d8e	no	2

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	02_EMKNNZ00505_20170817_ids_sb08.pdf	295454 d11adba40cd837fd2458c6370fe8dc63016fedbb	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
			Total Files Size (in bytes):	794299	

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 EFS-Web transmitted to the USPTO on the date shown below.
Date: August 17, 2017 Signature: /Emily Ackerman/ (Emily Ackerman)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/665,152
Confirmation No.:	6227
Filing Date:	July 31, 2017
Inventor(s):	Daniel R. BURNETT
Title:	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS
Examiner:	Not Yet Assigned
Group Art Unit:	Not Yet Assigned

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 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.

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 and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00505**. However, the Commissioner is not authorized to charge the surcharge for late filing of an Oath or Declaration until issuance of a pre-exam formalities Notice.

Respectfully submitted,

/Johney U. Han/

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Registration No. 45,565

Customer No. 40518
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Ex. 1002, p. 268

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 13

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	EMKNNZ00505

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.	4,994,015	02-19-1991	Cadwell	
	18.	5,000,178	03-19-1991	Griffith	
	19.	5,014,699	05-14-1991	Pollack et al.	
	20.	5,092,835	03-03-1992	Schurig et al.	
	21.	5,158,080	10-27-1992	Kallok	
	22.	5,181,902	01-26-1993	Erickson et al.	
	23.	5,309,909	05-10-1994	Gadsby et al	
	24.	5,314,401	05-24-1994	Tepper	
	25.	5,314,453	05-24-1994	Jeutter	
	26.	5,401,233	03-28-1995	Erickson et al.	
	27.	5,449,378	09-12-1995	Schouenborg	
	28.	5,518,495	05-21-1996	Kolt	
	29.	5,562,707	10-08-1996	Prochazka et al.	
	30.	5,690,693	11-25-1997	Wang et al.	
	31.	5,715,837	02-10-1998	Chen	
	32.	5,725,471	03-10-1998	Davey et al.	
	33.	5,749,909	05-12-1998	Schroeppel et al.	
	34.	5,766,124	06-16-1998	Polson	
	35.	5,792,187	08-11-1998	Adams	
	36.	5,792,209	08-11-1998	Varner	
	37.	5,833,600	11-10-1998	Young	
	38.	5,857,957	01-12-1999	Lin	

Examiner Signature		Date Considered	

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 13

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	EMKNNZ00505

	39.	5,976,712	11-02-1999	Suda et al.	
	40.	5,984,854	11-16-1999	Ishikawa et al.	
	41.	6,009,878	01-04-2000	Weijand et al.	
	42.	6,024,691	02-15-2000	Tepper et al.	
	43.	6,029,090	02-22-2000	Herbst	
	44.	6,032,677	03-07-2000	Blechman et al.	
	45.	6,066,084	05-23-2000	Edrich et al.	
	46.	6,086,525	07-11-2000	Davey et al.	
	47.	6,088,619	07-11-2000	Hein et al.	
	48.	6,123,658	09-26-2000	Schweighofer et al.	
	49.	6,143,035	11-07-2000	McDowell	
	50.	6,155,966	12-05-2000	Parker	
	51.	6,179,770	01-30-2001	Mould	
	52.	6,190,893	02-20-2001	Shastri et al.	
	53.	6,200,259	03-13-2001	March	
	54.	6,213,933	04-10-2001	Lin	
	55.	6,219,575	04-17-2001	Nemati	
	56.	6,256,533	07-03-2001	Yuzhakov et al.	
	57.	6,261,221	07-17-2001	Tepper et al.	
	58.	6,312,612	11-06-2001	Sherman et al.	
	59.	6,319,241	11-20-2001	King et al.	
	60.	6,334,856	01-01-2002	Allen et al.	
	61.	6,349,233	02-19-2002	Adams	
	62.	6,366,795	04-02-2002	Brerner et al.	
	63.	6,379,324	04-30-2002	Gartstein et al.	
	64.	6,440,096	08-27-2002	Lastovich et al.	
	65.	6,443,883	09-03-2002	Ostrow et al.	
	66.	6,451,240	09-17-2002	Sherman et al.	
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	68.	6,473,652	10-29-2002	Sarwal et al.	
	69.	6,491,620	12-10-2002	Davey	
	70.	6,493,588	12-10-2002	Malaney et al.	
	71.	6,500,110	12-31-2002	Davey et al.	
	72.	6,503,231	01-07-2003	Prausnitz et al.	
	73.	6,511,463	01-28-2003	Wood et al.	
	74.	6,527,694	03-04-2003	Ishikawa et al.	
	75.	6,533,949	03-18-2003	Yeshurun et al.	
	76.	6,537,242	03-25-2003	Palmer	
	77.	6,553,263	04-22-2003	Meadows et al.	
	78.	6,558,361	05-06-2003	Yeshurun	
	79.	6,565,532	05-20-2003	Yuzhakov et al.	
	80.	6,582,393	06-24-2003	Sage, Jr.	

Examiner Signature		Date Considered	

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 13

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	EMKNNZ00505

	81.	6,591,124	07-08-2003	Sherman et al.	
	82.	6,595,947	07-22-2003	Mikszta et al.	
	83.	6,603,987	08-05-2003	Whitson	
	84.	6,611,707	08-26-2003	Prausnitz et al.	
	85.	6,622,035	09-16-2003	Merilainen et al.	
	86.	6,623,457	09-23-2003	Rosenberg	
	87.	6,652,443	11-25-2003	Struppler et al.	
	88.	6,652,478	11-25-2003	Gartstein et al.	
	89.	6,654,636	11-25-2003	Dev et al.	
	90.	6,656,147	12-02-2003	Gertsek et al.	
	91.	6,663,556	12-16-2003	Barker	
	92.	6,663,820	12-16-2003	Arias et al.	
	93.	6,671,527	12-30-2003	Petersson et al.	
	94.	6,678,556	01-13-2004	Nolan et al.	
	95.	6,684,106	01-27-2004	Herbst	
	96.	6,689,100	02-10-2004	Connelly et al.	
	97.	6,690,959	02-10-2004	Thompson	
	98.	6,697,669	02-24-2004	Dev et al.	
	99.	6,701,185	03-02-2004	Burnett et al.	
	100.	6,735,474	05-11-2004	Loeb et al.	
	101.	6,743,211	06-01-2004	Prausnitz et al.	
	102.	6,767,341	07-27-2004	Cho	
	103.	6,770,022	08-03-2004	Mechlenburg et al.	
	104.	6,770,480	08-03-2004	Canham	
	105.	6,782,283	08-24-2004	Schmidt et al.	
	106.	6,790,372	09-14-2004	Roy et al.	
	107.	6,808,506	10-26-2004	Lastovich et al.	
	108.	6,835,184	12-28-2004	Sage et al.	
	109.	6,866,659	03-15-2005	Nemati	
	110.	6,881,203	04-19-2005	Delmore et al.	
	111.	6,899,838	05-31-2005	Lastovich	
	112.	6,908,453	06-21-2005	Fleming et al.	
	113.	6,926,660	08-09-2005	Miller	
	114.	6,931,277	08-16-2005	Yuzhakov et al.	
	115.	6,939,311	09-06-2005	Geiger	
	116.	6,941,171	09-06-2005	Mann et al.	
	117.	6,960,193	11-01-2005	Rosenberg	
	118.	6,962,772	11-08-2005	Liu et al.	
	119.	6,972,013	12-06-2005	Zhang et al.	
	120.	6,980,855	12-27-2005	Cho	
	121.	7,013,179	03-14-2006	Carter et al.	
	122.	7,027,478	04-11-2006	Ackley	

Examiner Signature		Date Considered	

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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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
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Application Number	Not Yet Assigned
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Art Unit	Not Yet Assigned
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Attorney Docket Number	EMKNNZ00505

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Art Unit	Not Yet Assigned
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				Art Unit	Not Yet Assigned
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(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned
Sheet	12	of	13	Attorney Docket Number	EMKNNZ00505

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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
Sheet	13	of	13	Attorney Docket Number	EMKNNZ00505

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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.

[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:	
Filing Date:	
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:	EMKNNZ00505

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

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:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**730**

Electronic Acknowledgement Receipt

EFS ID:	29940986
Application Number:	15665152
International Application Number:	
Confirmation Number:	6227
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:	EMKNNZ00505
Receipt Date:	31-JUL-2017
Filing Date:	
Time Stamp:	19:05:37
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$730
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	01_EMKNNZ00505_20170731_ads_efs.pdf	1793647 7621de3f4f6d70a843a6d78a554c123ca46ce8bc	no	9
Warnings:					
Information:					
2	Oath or Declaration filed	02_EMKNNZ0050_20170731_declaration_from_parent.pdf	298677 553f171fa88eea729498f3ce74d5073de0bdeba4	no	1
Warnings:					
Information:					
3		03_EMKNNZ00505_20170731_specification.pdf	16401399 2d372e2267e511f687624ffb6e78e0eee4162dbb	yes	69

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	66
Claims	67	68
Abstract	69	69

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4	Drawings-only black and white line drawings	04_EMKNNZ00505_20170731_drawings.pdf	3028287 ab3a21fbaa5b807f36d48468680b11a907cc0658	no	37
Warnings:					
Information:					
5	Transmittal Letter	05_EMKNNZ00505_20170731_ids_cover_letter.pdf	486251 d57f1b8f03118b9ae553d8be7fd70722f88d170c	no	3

Warnings:					
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6	Information Disclosure Statement (IDS) Form (SB08)	06_EMKNNZ00505_20170731_ids_sb08.pdf	2146273 29d5ab180806c40eda7c7c923cda2c6d742f9579	no	13
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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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	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.

Secrecy Order 37 CFR 5.2:

☐ 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	State/Province	Country of Residence
San Francisco	CA	US

Mailing Address of Inventor:

Address 1	588 Teresita Boulevard
Address 2	

City	State/Province	Postal Code	Country
San Francisco	CA	94127	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	40518		
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	EMKNNZ00505	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	37

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	40518		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15056910	2016-02-29

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15056910	Continuation of	14676635	2015-04-01	9387338	2016-07-12

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14676635	Continuation of	14085639	2013-11-20	9002477	2015-04-07

Prior Application Status	Abandoned	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14085639	Continuation of	13456016	2012-04-25

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13456016	Continuation of	PCTUS2010054167	2010-10-26

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCTUS2010054167	Claims benefit of provisional	61279883	2009-10-26

Prior Application Status	Abandoned	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14085639	Continuation in part of	12508529	2009-07-23

Prior Application Status	Abandoned	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
12508529	Continuation in part of	11866329	2007-10-02

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
11866329	Claims benefit of provisional	60848720	2006-10-02

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 289

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

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	EMKNNZ00505
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

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. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Applicant:

Address 1			
Address 2			
City		**State/Province**	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

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Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

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This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Johney U. Han/			Date (YYYY-MM-DD)	2017-07-31
First Name	Johney	Last Name	Han	Registration Number	45565

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00505
	Application Number	
Title of Invention	METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS	

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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.

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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.**

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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. 15/056,910 filed February 29, 2016, which is a continuation of U.S. Patent Application Serial No. 14/676,635 filed April 1, 2015 (now U.S. Pat. No. 9,387,338 issued July 12, 2016), which is a continuation of U.S. Patent Application Serial No. 14/085,639 filed November 20, 2013 (now U.S. Patent No. 9,002,477 issued April 7, 2015), which is a continuation of U.S. Patent Application Serial No. 13/456,016 filed April 25, 2012 (now Abandoned), 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. U.S. Patent Application Serial No. 14/085,639 filed November 20, 2013, is also a continuation-in part of U.S. Patent Application Serial No. 12/508,529 filed July 23, 2009 (now Abandoned), which is a continuation-in-part of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007 (now Abandoned), 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

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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 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.

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[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

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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

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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

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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

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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

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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.

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[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.

[0038] FIG. 11 is a schematic view of another variation of an apparatus for providing electrical stimulation.

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[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.

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[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

[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

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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.

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[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.

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[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 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

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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.

[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.

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[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 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

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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 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

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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 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

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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 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.

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[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.

[0100] 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.

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[0101] 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.

[0102] 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.

[0103] 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.

[0104] 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.

[0105] 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).

[0106] 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.

[0107] 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

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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.

[0108] 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.

[0109] 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.

[0110] 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.

[0111] 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,

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ultrasound, direct switching of the current circuit, etc., so long as communication between the sensor and the device is effective.

[0112] 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.

[0113] 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.

[0114] 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. 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.

[0115] 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

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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.

[0116] 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.

[0117] 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 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.

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[0118] 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 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

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optimize the level of therapy delivered according to power consumption and nerve stimulation requirements and need not be delivered by a professional healthcare provider.

[0119] 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.

[0120] 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 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.

[0121] 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

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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.

[0122] 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.

[0123] In the second application, the powering coils may contain circuitry to determine the amount of resistance encountered by the applied magnetic field, or other electrical properties that may reflect the quality and degree of the magnetic coupling that is being achieved. Based on this feedback, the powering coils in the applicator may be adjusted manually or automatically to activate and optimize the coil coupling at the beginning of each therapy session. Alternatively, a sensor may be incorporated into the implantable device and communicate the degree and quality of the magnetic coupling externally via wireless communication, which may in turn provide feedback for the automatic or manual adjustment of the powering coil. In one variant of the present variation, the inductive coils may be magnetically coupled to a needle targeting the posterior tibial nerve.

[0124] An exemplary method of use of an apparatus as described herein on a patient suffering from VI and/or OAB includes the following steps:

[0125] 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.

[0126] 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.

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[0127] 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.

[0128] 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

[0129] 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.

[0130] The inductive magnetic pulses continue for an appropriate duration of use, for example, for 15-30 minutes. The sensor may remain in place during the entire therapy session to ensure that stimulation occurs consistently and to provide for appropriate corrections if nerve conduction deteriorated. The logic controller may be powered either by a portable power source such as a battery, or by or a fixed power source such as a traditional wall outlet.

[0131] 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.

[0132] 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.

[0133] 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.

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[0134] 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.

[0135] 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.

[0136] 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

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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.

[0137] 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 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.

[0138] 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.

[0139] 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

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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.

[0140] 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.

[0141] 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.

[0142] 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.

[0143] In certain variations, microneedle patches or microneedle electrode arrays are made by fabricating master structures from which replicates are molded and then made electrically

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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.

[0144] 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.

[0145] 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.

[0146] 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.

[0147] 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

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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.

[0148] 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.

[0149] 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.

[0150] 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

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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.

[0151] 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 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.

[0152] 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.

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Although shown utilizing a sensor, it is also contemplated that the system could be used without a sensor.

[0153] 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.

[0154] A sensor utilized in the energy emitting system 210 may be a microneedle patch 228 as described above or optionally the sensor may a sensor type known in the art (e.g., EKG sensor) or as described in any of the 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.

[0155] 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.

[0156] 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

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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.

[0157] 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.

[0158] 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

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a sufficiently large surface area so as not to create too high a local current field that may cause irritation or pain.

[0159] 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 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.

[0160] 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

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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.

[0161] 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.

[0162] 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.

[0163] 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

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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.

[0164] 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 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.

[0165] 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.

[0166] 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.

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[0167] 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.

[0168] 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.

[0169] 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.

[0170] 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.

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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.

[0171] 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 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.

[0172] 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.

[0173] 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

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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.

[0174] 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 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.

[0175] 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.

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[0176] Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of urinary incontinence by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with urinary incontinence. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited to the inability to control urinary function, urinary leakage, and loss of bladder control.

[0177] 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.

[0178] 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

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

[0179] A current is then passed through the energy generator to produce, generate or deliver energy, e.g., a magnetic or electromagnetic field or electrical or magnetic energy or stimulus, focused on the tibial or posterior tibial nerve or branches thereof. This in turn causes the stimulation of a pudendal nerve, sacral plexus, or nerves in the pelvic floor. Various nerves innervating the various muscles, sphincters, rectum, nerves, organs and conduits associated with bowel movements, fecal control, and the intestines may be stimulated directly or indirectly. Optionally, a current is passed through one more coils, which generate a magnetic or electromagnetic field which stimulates the posterior tibial nerve. In certain 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.

[0180] 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.

[0181] 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

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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:

[0182] 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.

[0183] 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.

[0184] 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

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thereof or other nerves associated with restless leg syndrome, of a subject along a first portion of a subject's body. The subject may or may not be exhibiting symptoms associated with restless leg syndrome. In the case of the conductive coils, the coils may be positioned within or along a housing, such as a foot or knee cradle, and a foot or leg may be positioned therein. In the case of a microneedle patch, the patch may be attached to a subject's skin. Optionally, the method involves positioning a first portion of a subject's body, the subject exhibiting symptoms associated with restless leg syndrome, relative to an energy emitting device such that a target nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device.

[0185] 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.

[0186] 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

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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.

[0187] Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the target nerve, e.g., posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of restless leg syndrome by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels or parameters for current, frequency, magnetic field, treatment duration, etc., are those that result in an observed or detected reduction or prevention of symptoms associated with restless leg syndrome. Treatment could also be administered and the appropriate levels and parameters achieved through observing or detecting reduction or prevention of symptoms where a sensor is not used. Examples of these symptoms include but are not limited to: uncomfortable sensations in the limbs, irresistible urges to move, usually the legs; motor restlessness; when at rest, symptoms return or worsen; and symptoms worsen in the evening and at night.

[0188] 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.

[0189] 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

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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.

[0190] 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.

[0191] 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

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foot. In other variations, the sensor may be positioned within or along a housing along with the one or more conductive coils.

[0192] Where a sensor is used, a signal is received from the sensors and the signal is indicative of the electrical conduction of the posterior tibial nerve. The current may be adjusted or varied using a controller which is in communication with the energy generator. Adjustments may be made in response to the nerve or muscle stimulation detected by the conductive sensor, in order to optimize or ensure adequate treatment of premature ejaculation by achieving the appropriate level of conductance and appropriate level of nerve or muscle stimulation. Appropriate levels for current, frequency, magnetic field, treatment duration, etc., are levels that result in an observed or detected reduction or prevention of symptoms associated with premature ejaculation. Treatment could also be 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.

[0193] 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.

[0194] 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

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minutes to 2 hours per day or week. In treating premature ejaculation, a patient may receive treatment about 4 to 10 hours prior to intercourse. A maintenance phase of treatment, after the initial treatment, may vary for various conditions. For example, the maintenance phase may require application of the systems and methods described herein at the parameters described herein for 30 minutes/week or 30 minutes/month. Any treatment parameter may be varied or modified based on the effect on the patient or sensor or patient feedback regarding stimulation, until the desired result of treating or preventing a condition is achieved.

[0195] 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.

[0196] 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

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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).

[0197] 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 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.

[0198] 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.

[0199] 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.

[0200] 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.

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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.

[0201] 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.

[0202] 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.

[0203] 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

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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.

[0204] 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.

[0205] 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.

[0206] 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.

[0207] 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

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separate from the applicator or incorporated in the applicator, may be controlled based on feedback from the sensor.

[0208] 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.

[0209] 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.

[0210] 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

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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 may be ergonomic or contoured to be positioned relative to or in proximity to a nerve responsible for phantom or neuropathic pain.

[0211] 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.

[0212] 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.

[0213] 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.

[0214] 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

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ergonomic or contoured to a face or head to be positioned relative to a face or head to 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.

[0215] 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.

[0216] 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.

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[0217] 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.

[0218] 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.

[0219] 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

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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, 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.

[0220] 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.

[0221] 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.

[0222] 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.

[0223] 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.

[0224] 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.

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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.

[0225] 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.

[0226] 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).

[0227] 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.

[0228] 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

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(back and neck pain or skeletal related pain); treatment of overactive bladder and bowel; and treatment of arthritis and/or orthopedic conditions.

[0229] 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.

[0230] 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.

[0231] 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.

[0232] 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.)

[0233] 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 intermittent pulsed

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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.

[0234] 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.

[0235] 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.

[0236] 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.

[0237] 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.

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[0238] 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.

[0239] 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.

[0240] 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.

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[0241] 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.

[0242] 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.

[0243] 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.

[0244] 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.

[0245] 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.

[0246] 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.

[0247] 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.

[0248] EXAMPLES

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[0249] 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.

[0250] 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.

[0251] 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.

[0252] 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.

[0253] 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 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.

[0254] 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

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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.

[0255] 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.

[0256] 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.

[0257] 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.

[0258] 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 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

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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.

[0259] 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.

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CLAIMS

What is claimed is:

1. A method, comprising:

applying an electrode patch to skin such that the electrode patch is disposed on an outer surface of the skin and the electrode patch is electrically coupled with a controller unit, the controller unit including a pulse generator;

electrically coupling a percutaneous electrode to the controller unit, the percutaneous electrode having an end for inserting in proximity to a tibial nerve, or a branch thereof, of the patient;

inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve, or a branch thereof, of the patient; and

activating the pulse generator such that current pulses flow along the tibial nerve, or branch thereof, the current pulses configured to treat overactive bladder.

2. The method of claim 1, wherein inserting the end of the percutaneous electrode comprises inserting the end near or at an ankle of the patient.

3. The method of claim 1, further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.

4. The method of claim 1, wherein activating the pulse generator comprises activating for a duration of about 30 minutes per week to treat the patient.

5. A method, comprising:

positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve, or a branch thereof;

inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve, or a branch thereof, the percutaneous needle electrode including a wire disposed opposite the end;

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securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode, the controller unit including a pulse generator;

connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller; and

activating the pulse generator such that current pulses flow along the tibial nerve, or a branch thereof, the current pulses configured to treat overactive bladder.

6. The method of claim 5, wherein inserting an end of the percutaneous needle electrode comprises inserting the end near or at an ankle of the patient.

7. The method of claim 5, further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.

8. The method of claim 5, wherein activating the pulse generator comprises activating for a duration of about 30 minutes per week to treat the patient.

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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.

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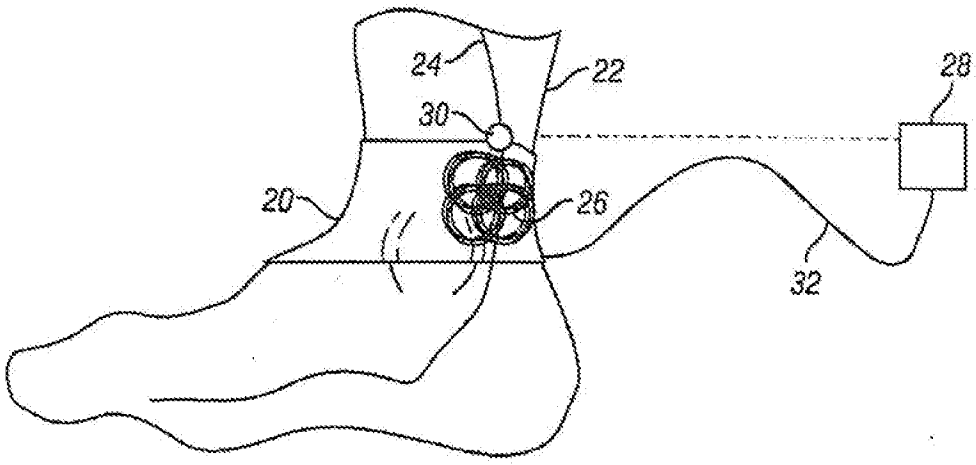


FIG. 1

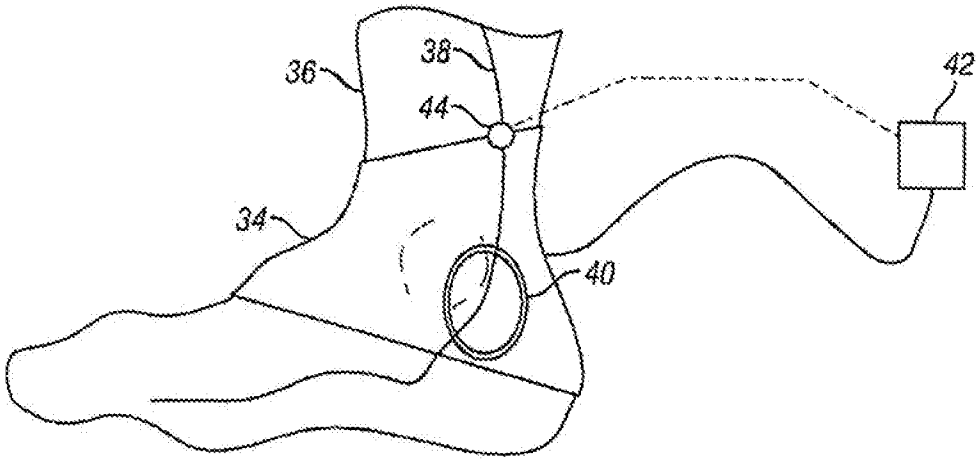


FIG. 2

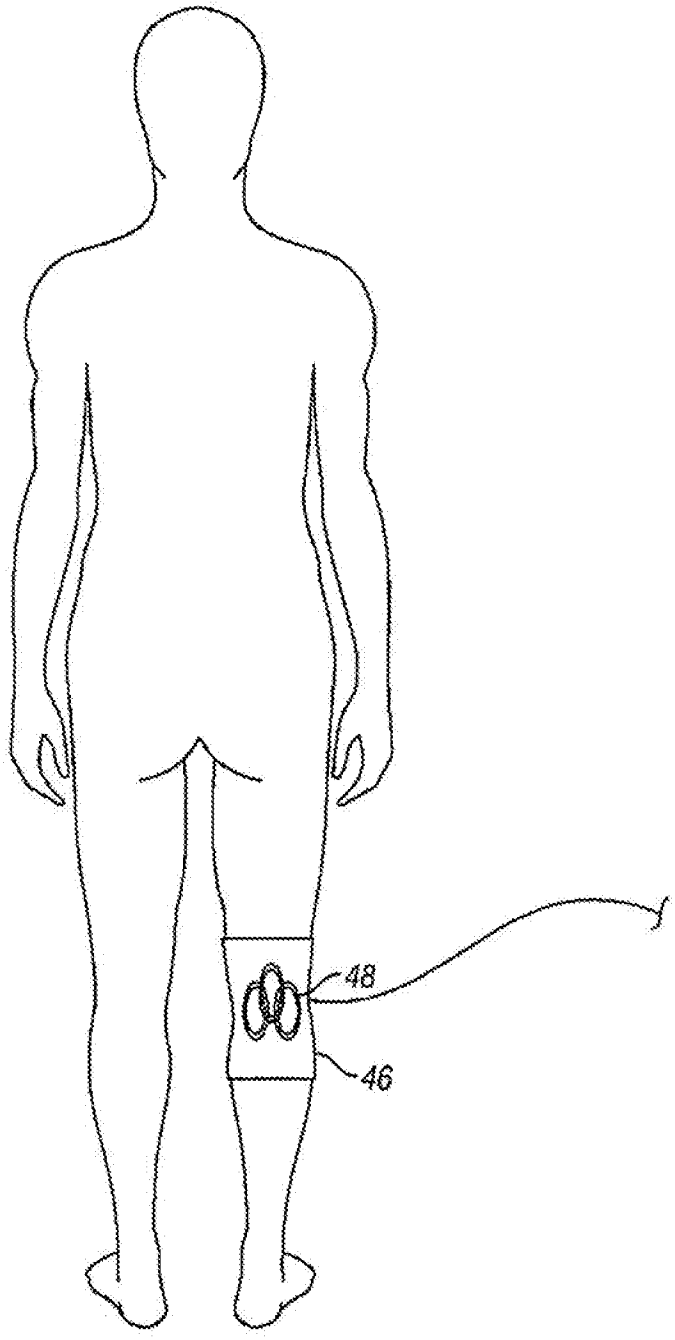


FIG. 3

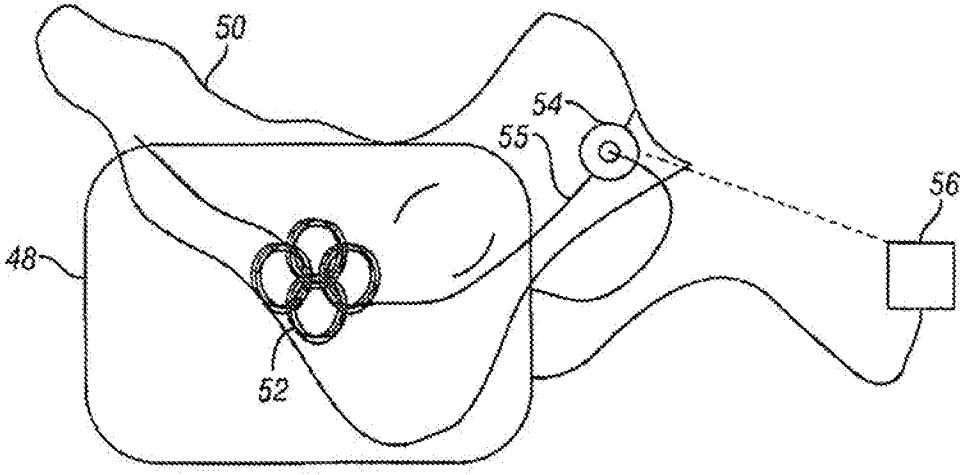


FIG. 4

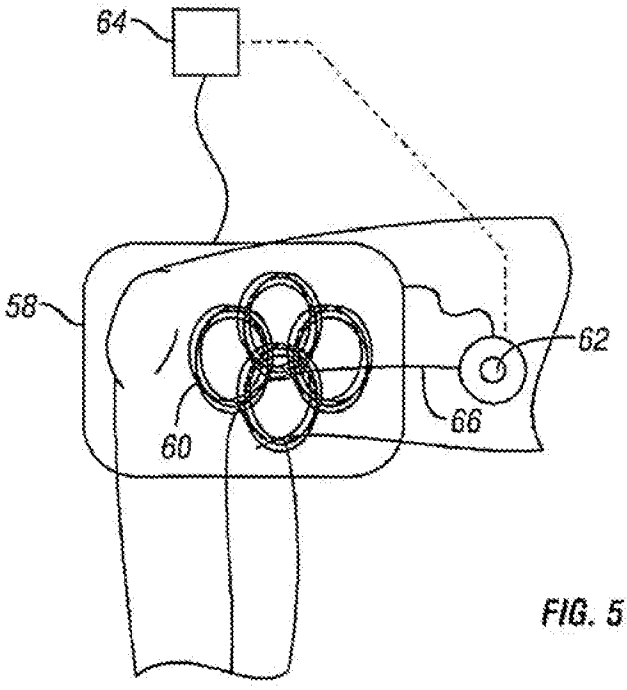


FIG. 5

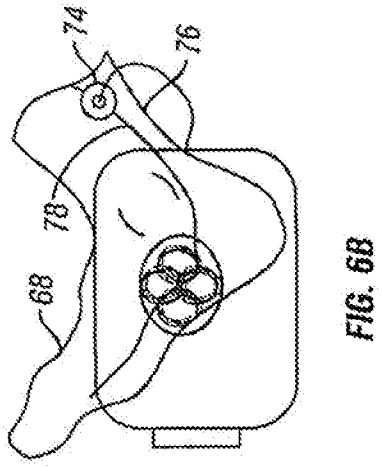


FIG. 6B

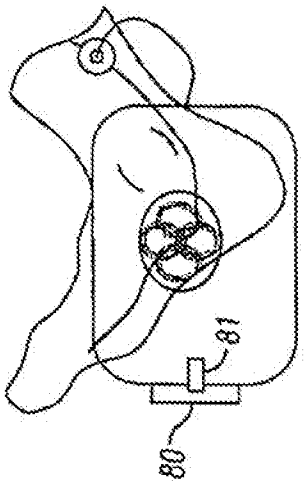


FIG. 6D

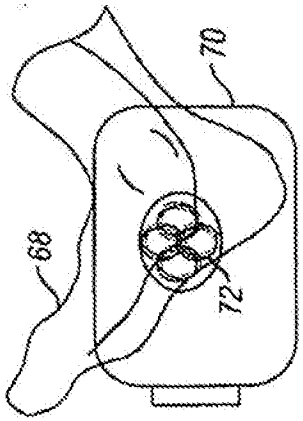


FIG. 6A

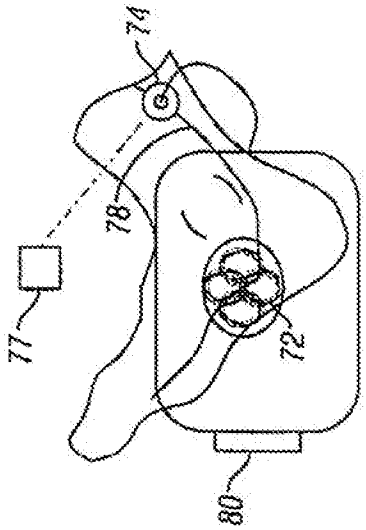


FIG. 6C

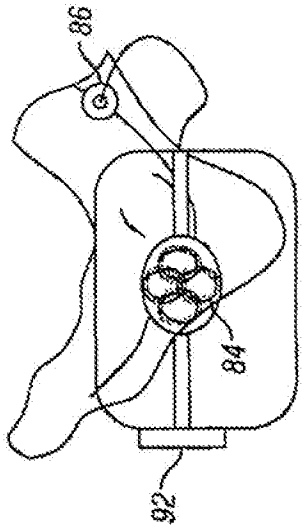


FIG. 7B

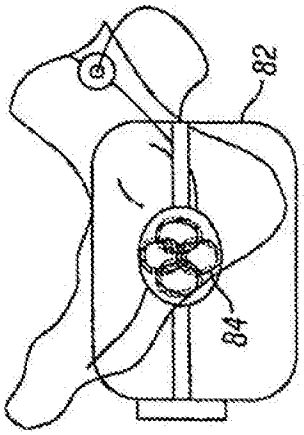


FIG. 7D

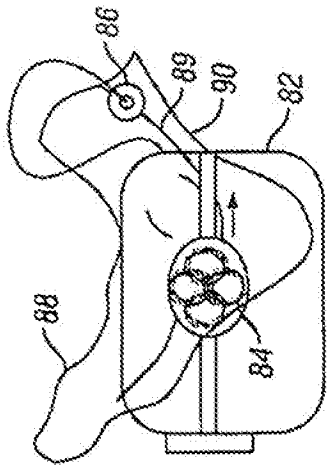


FIG. 7A

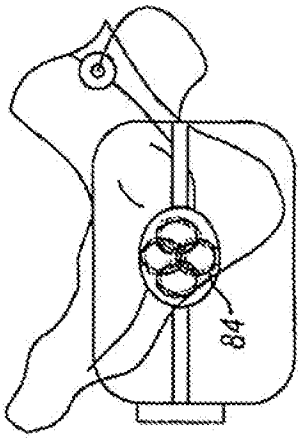


FIG. 7C

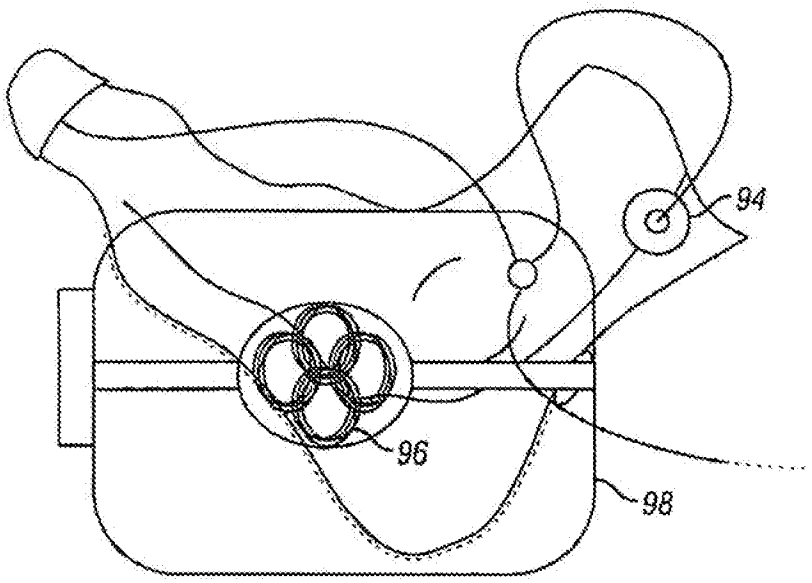


FIG. 8

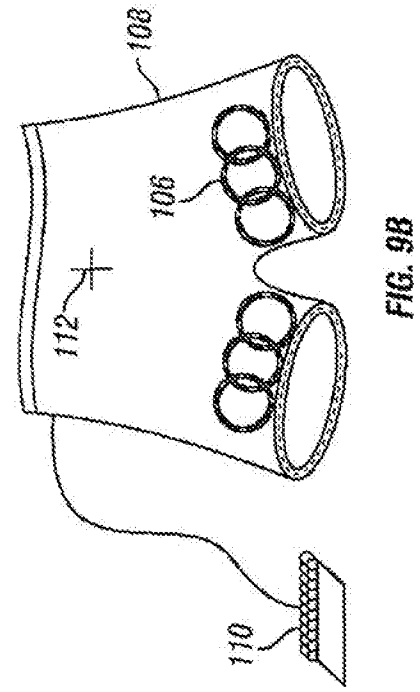


FIG. 9B

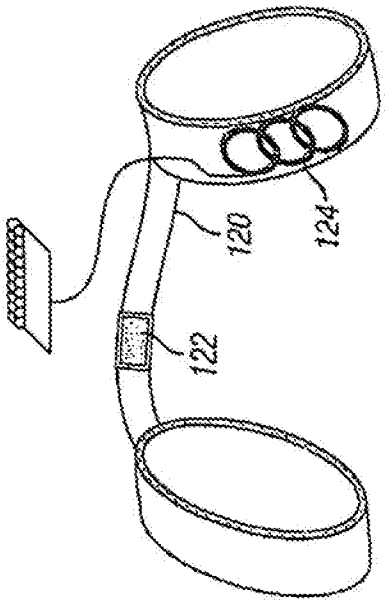


FIG. 9D

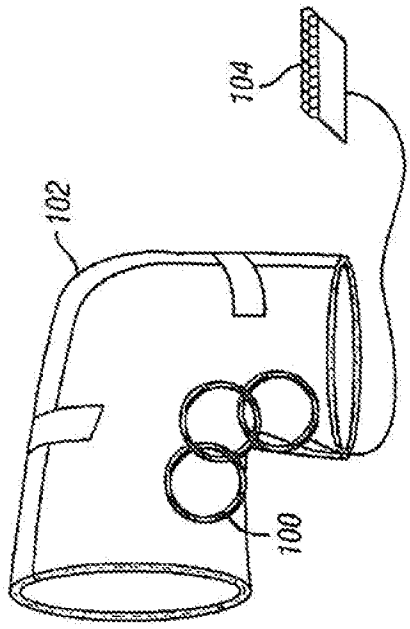


FIG. 9A

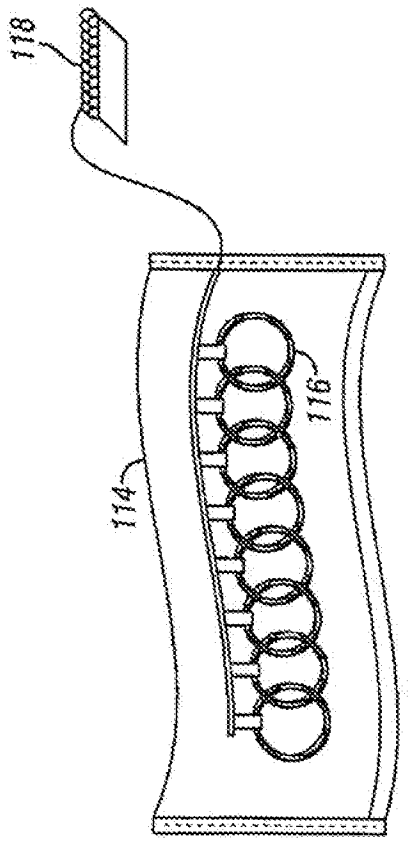


FIG. 9C

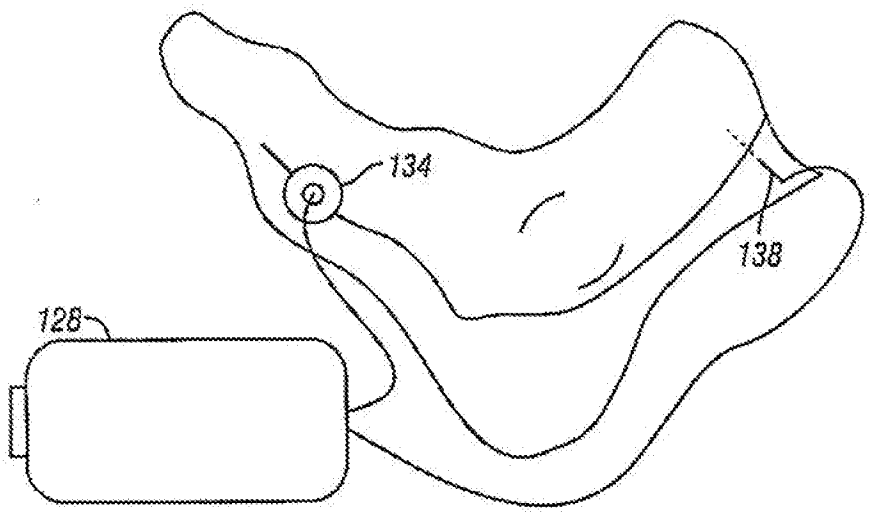


FIG. 10

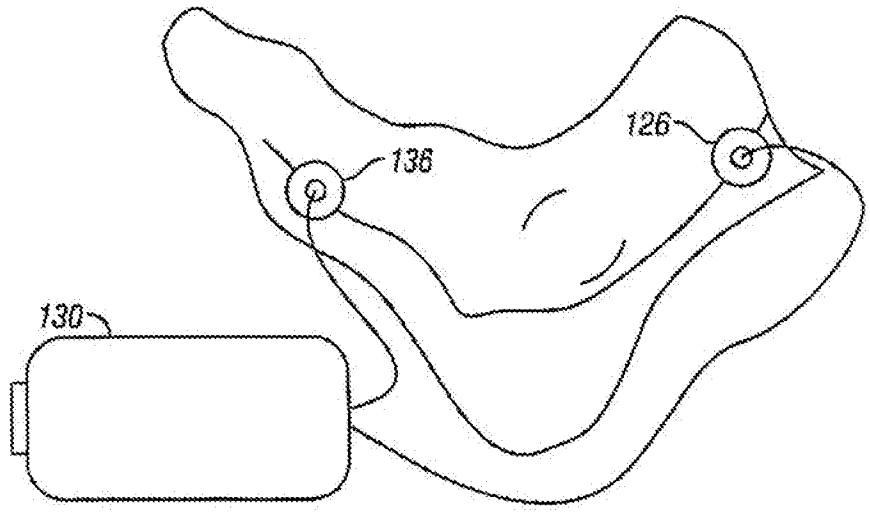


FIG. 11

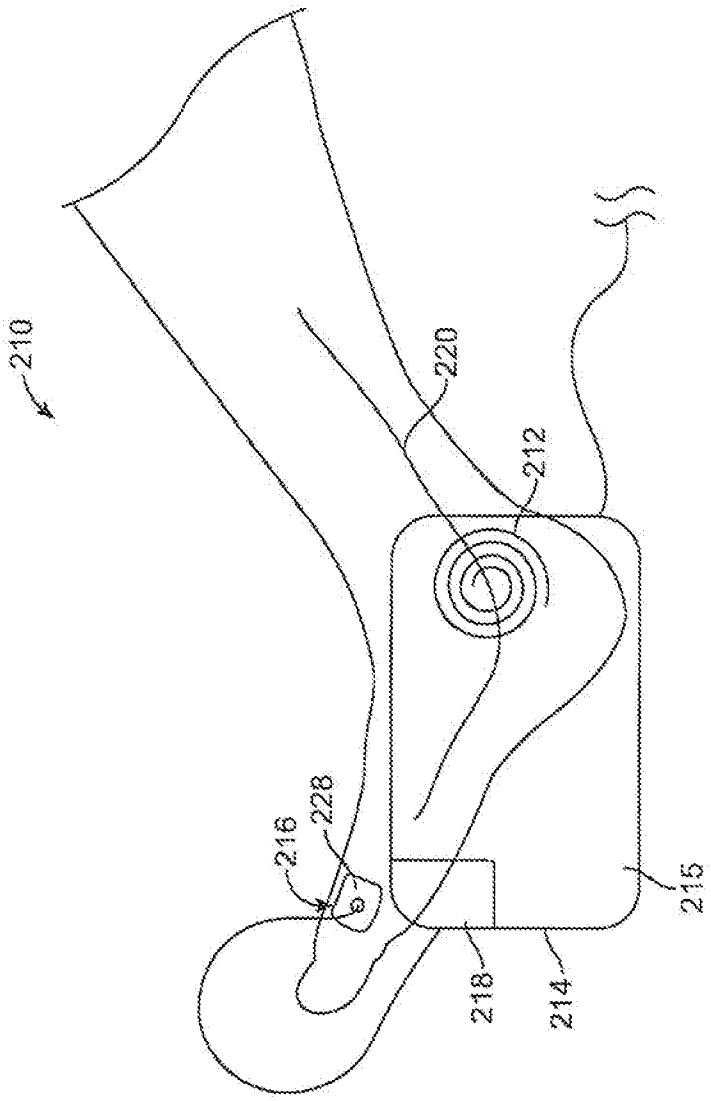


FIG. 12

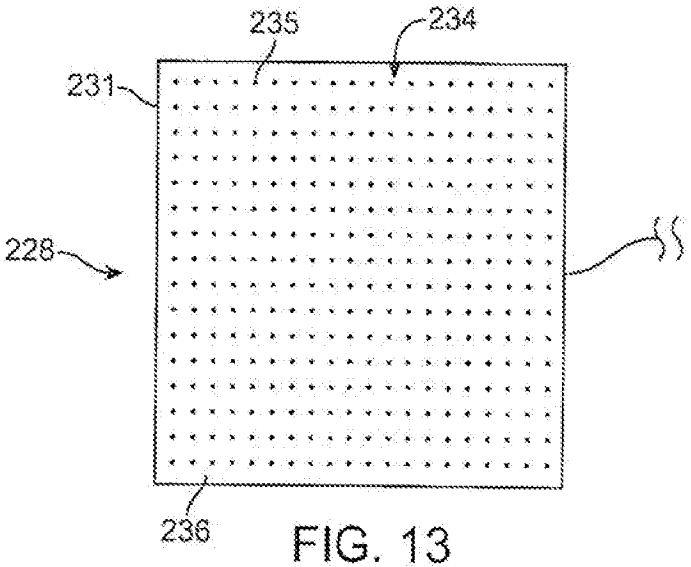


FIG. 13

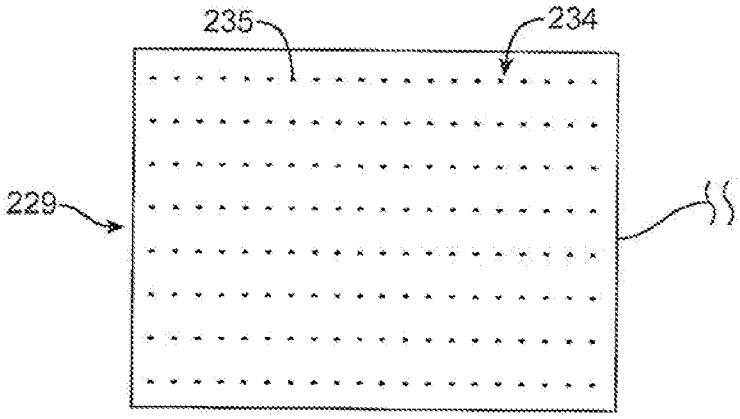


FIG. 14

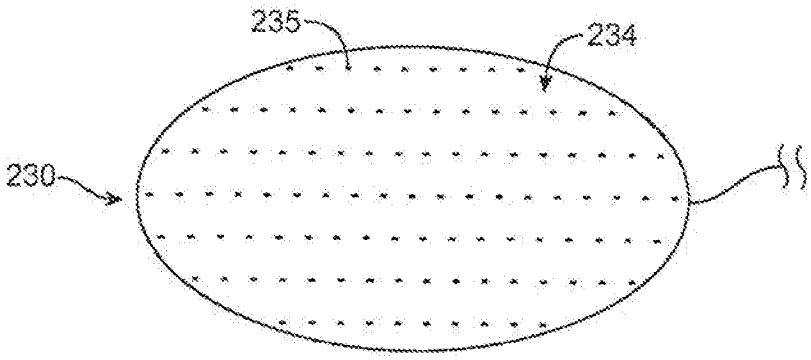


FIG. 15

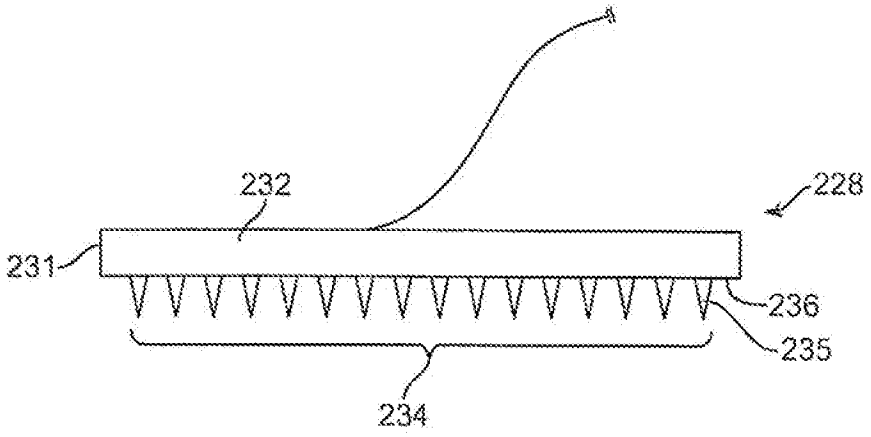


FIG. 16

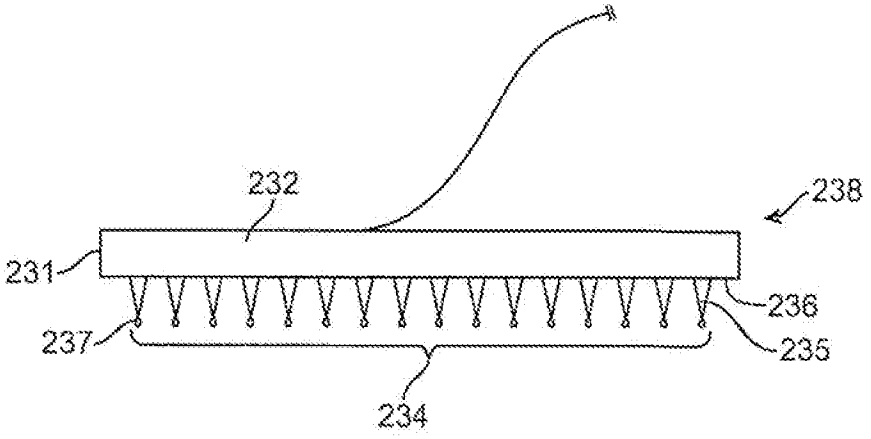


FIG. 17

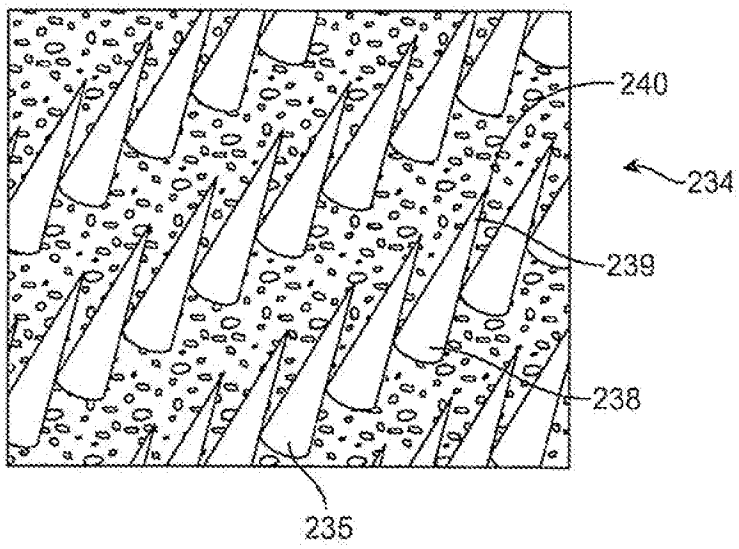


FIG. 18

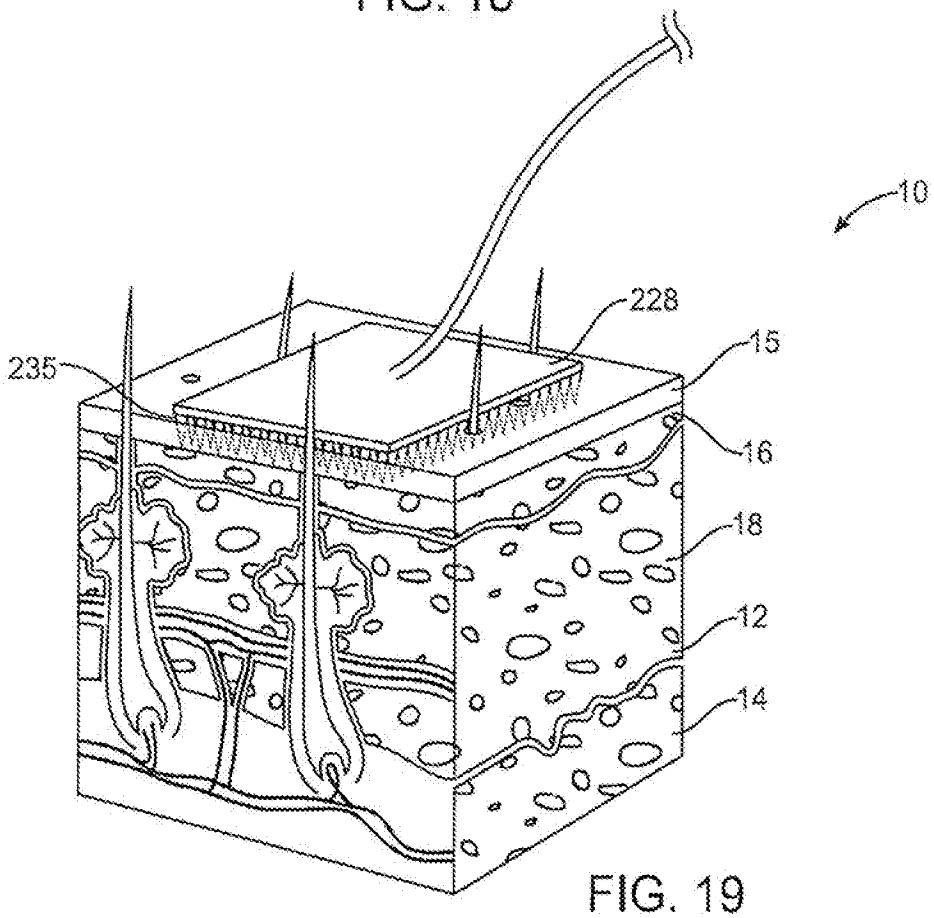


FIG. 19

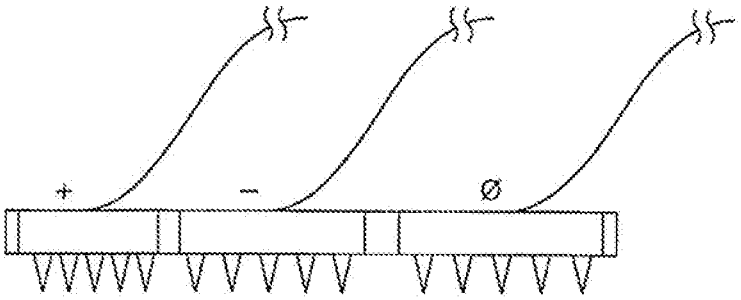


FIG. 20a

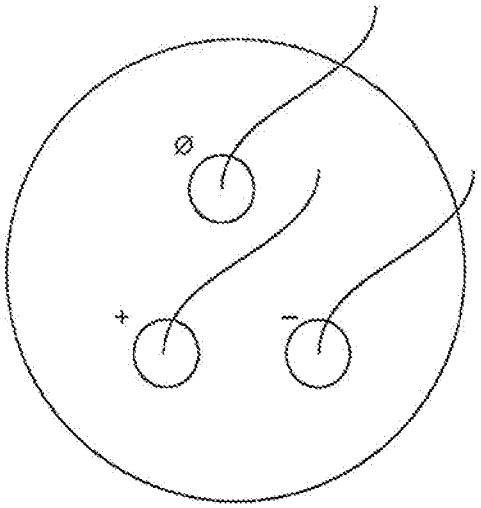


FIG. 20b

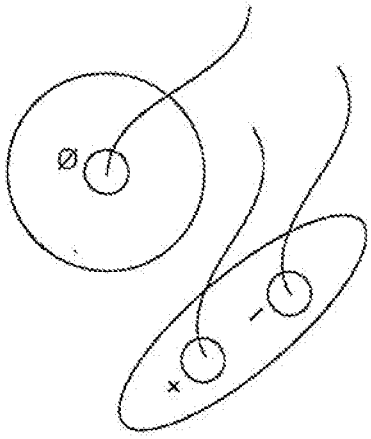


FIG. 20c

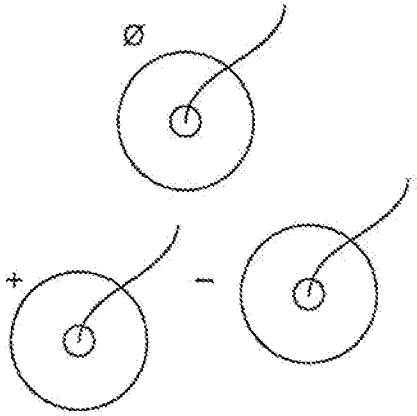


FIG. 20d

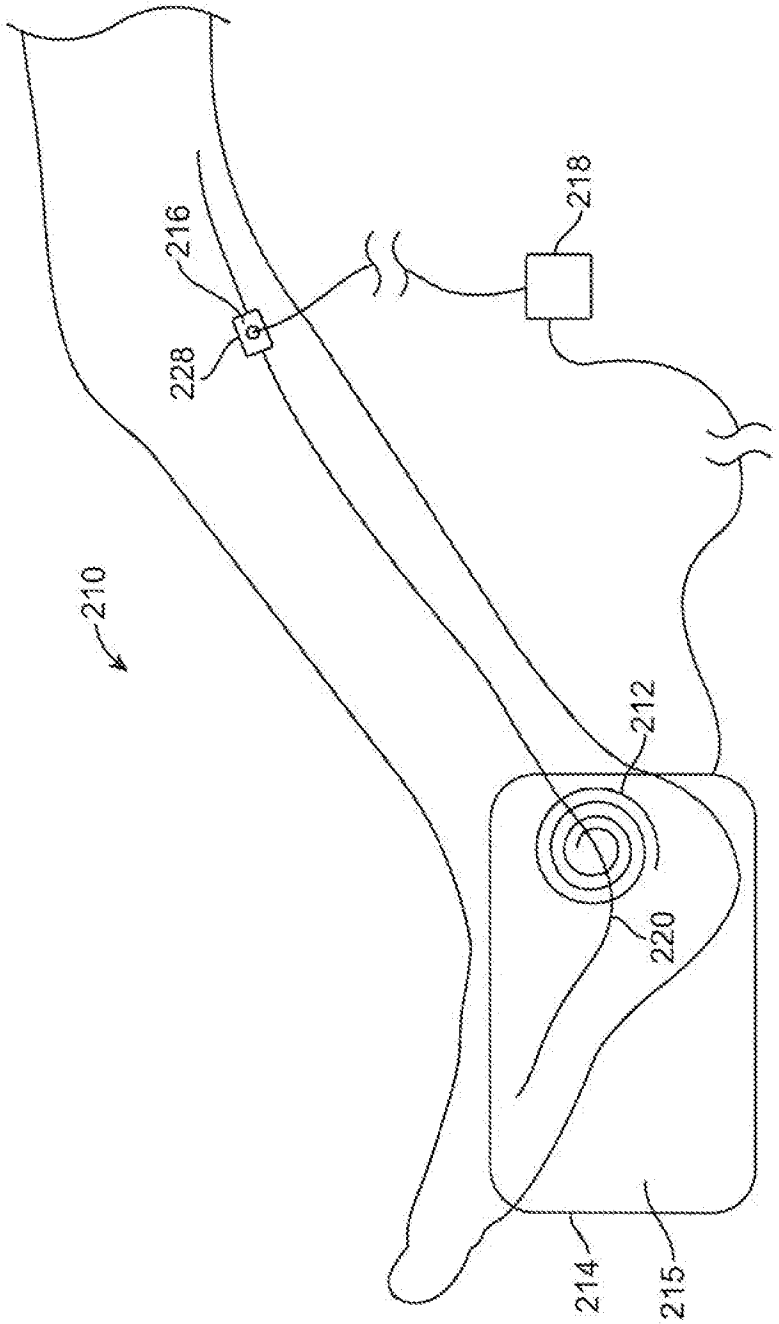


FIG. 21

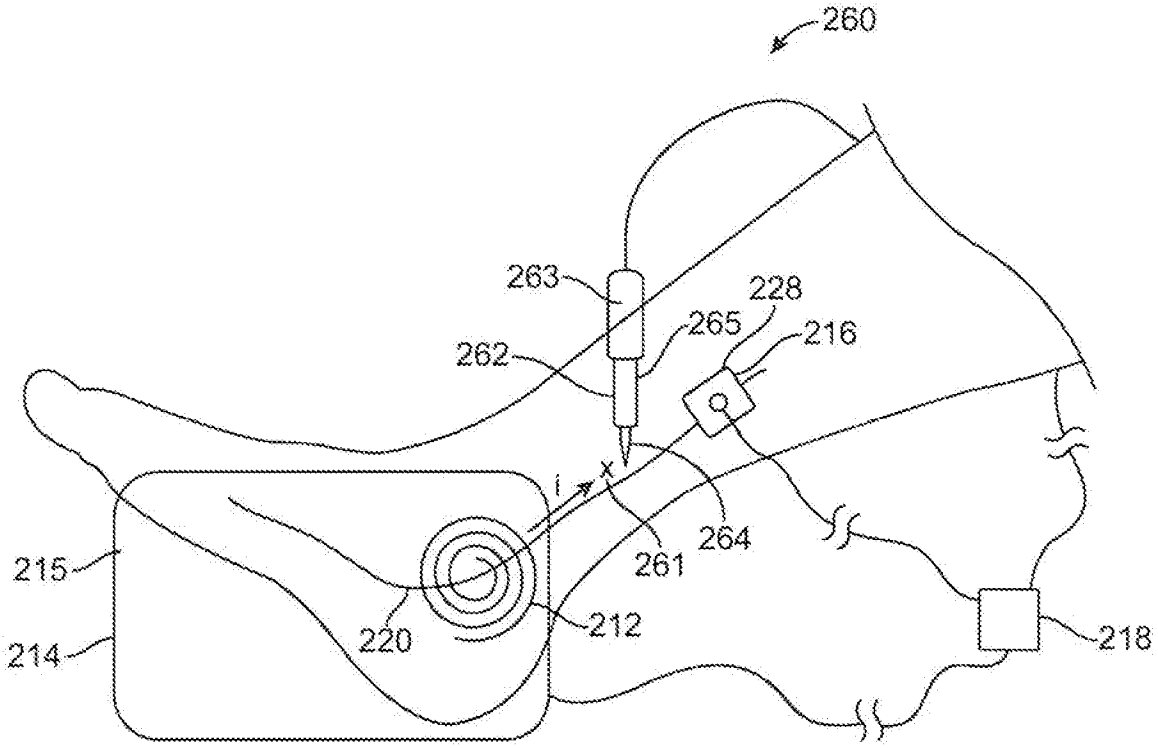


FIG. 22

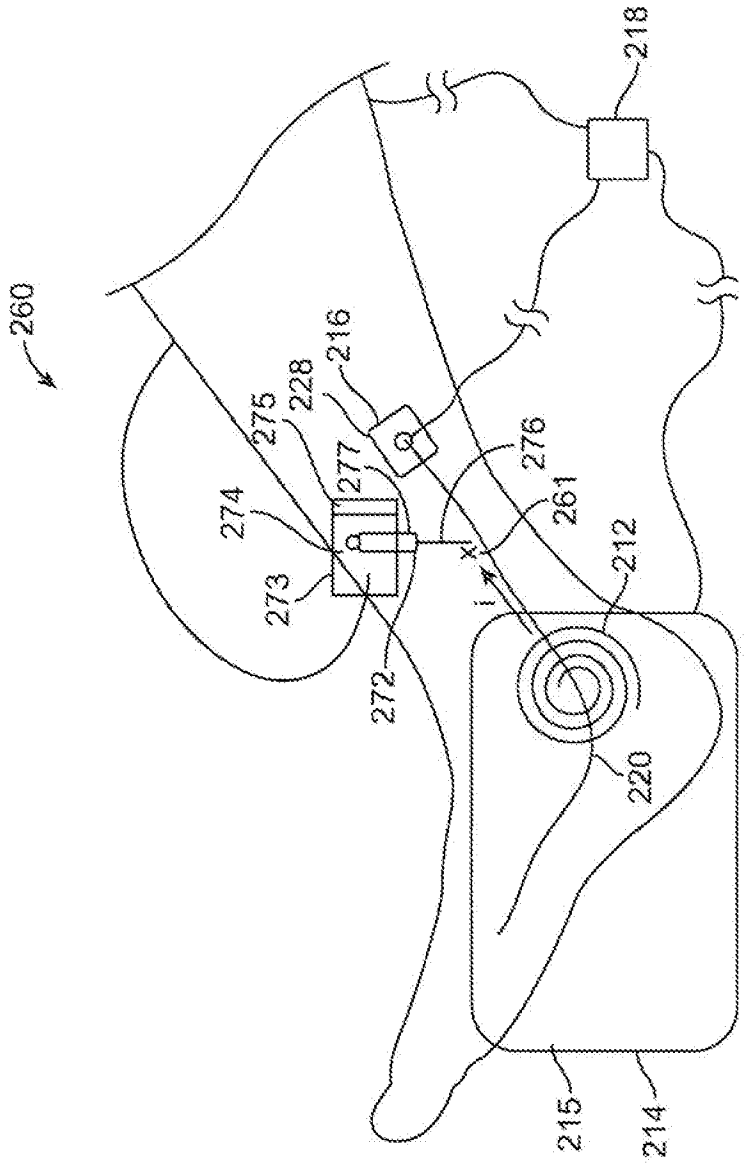


FIG. 23

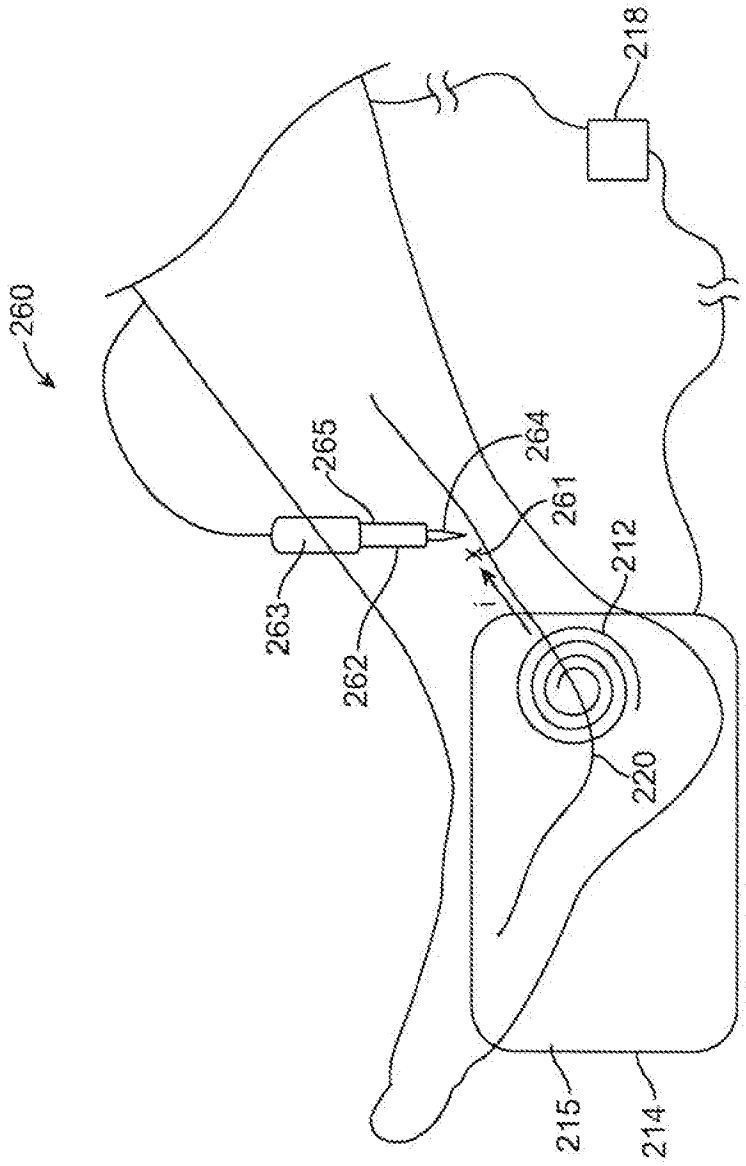


FIG. 24

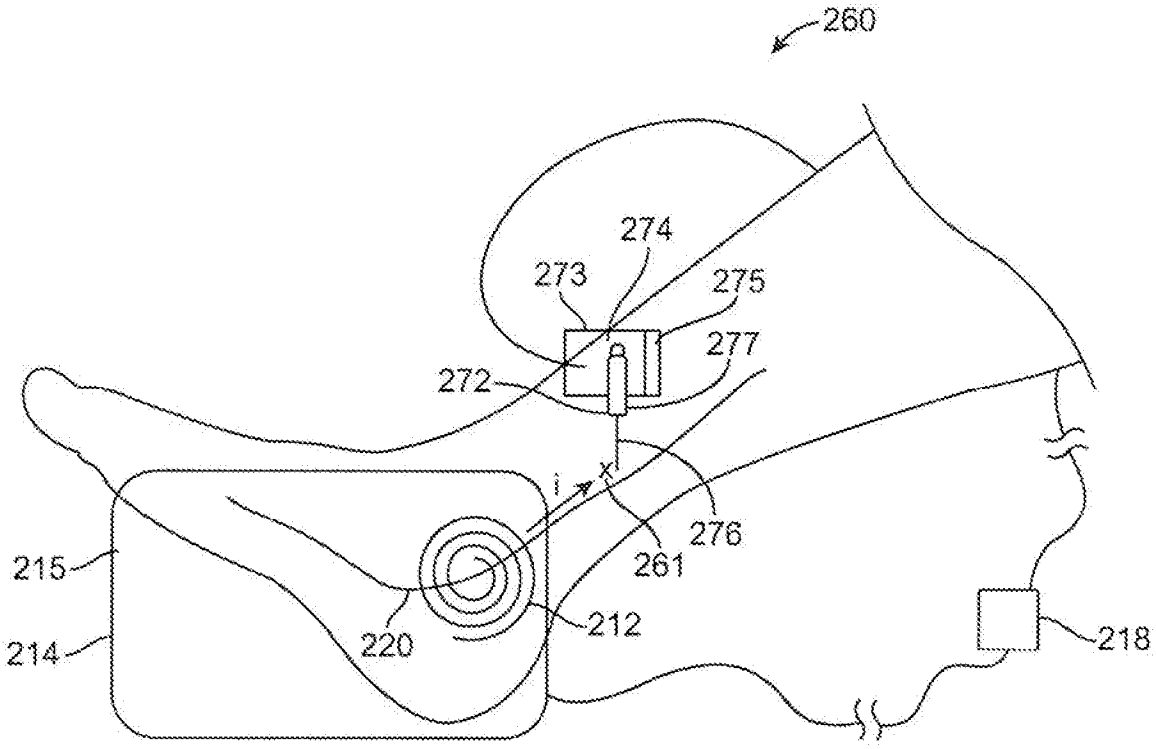


FIG. 25

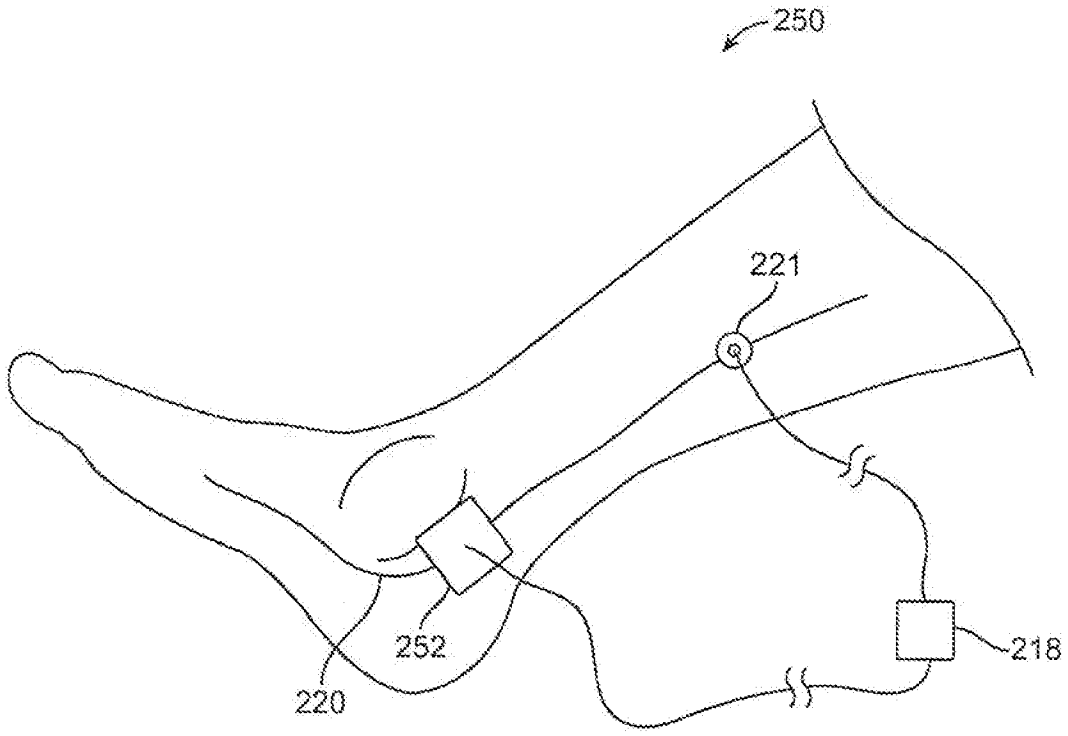


FIG. 26

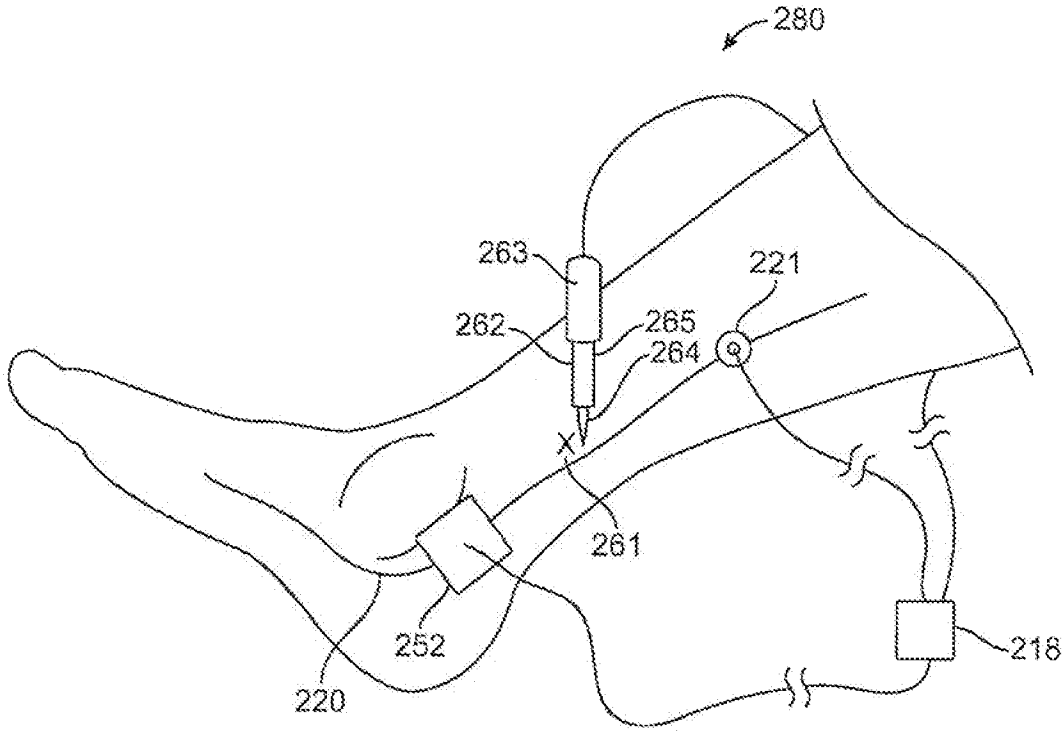


FIG. 27

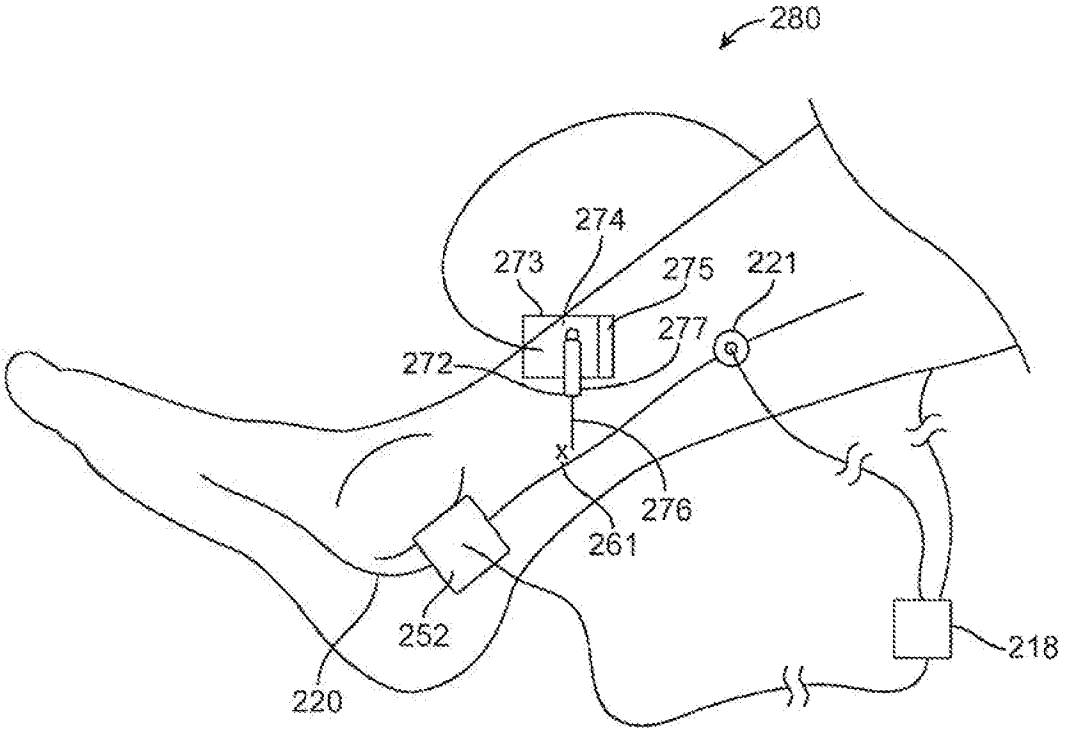


FIG. 28

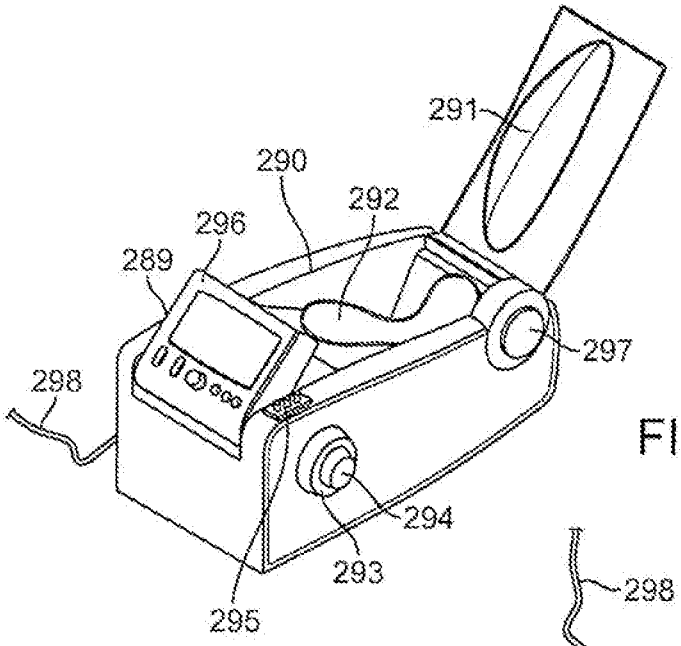


FIG. 29a

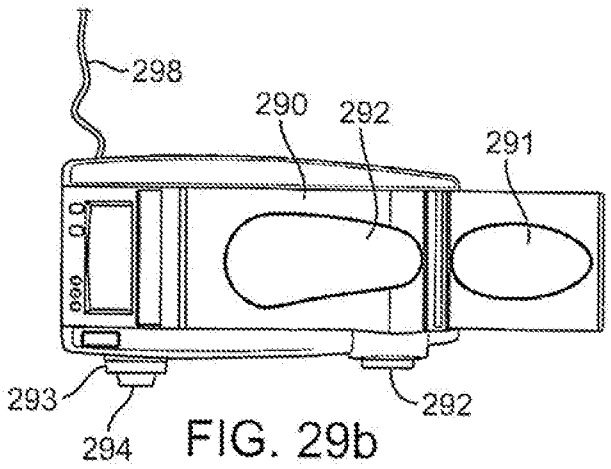


FIG. 29b

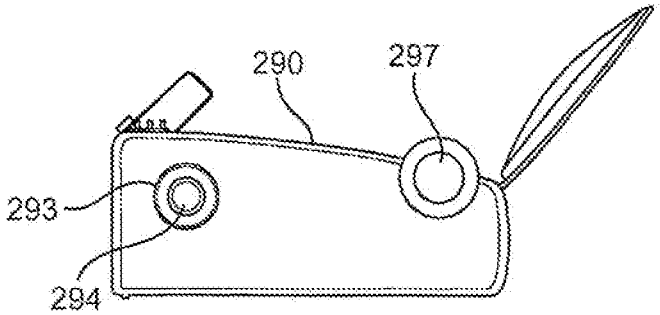


FIG. 29c

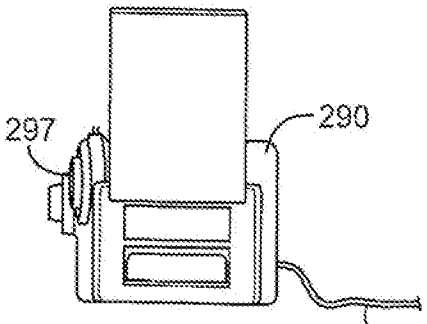


FIG. 29d

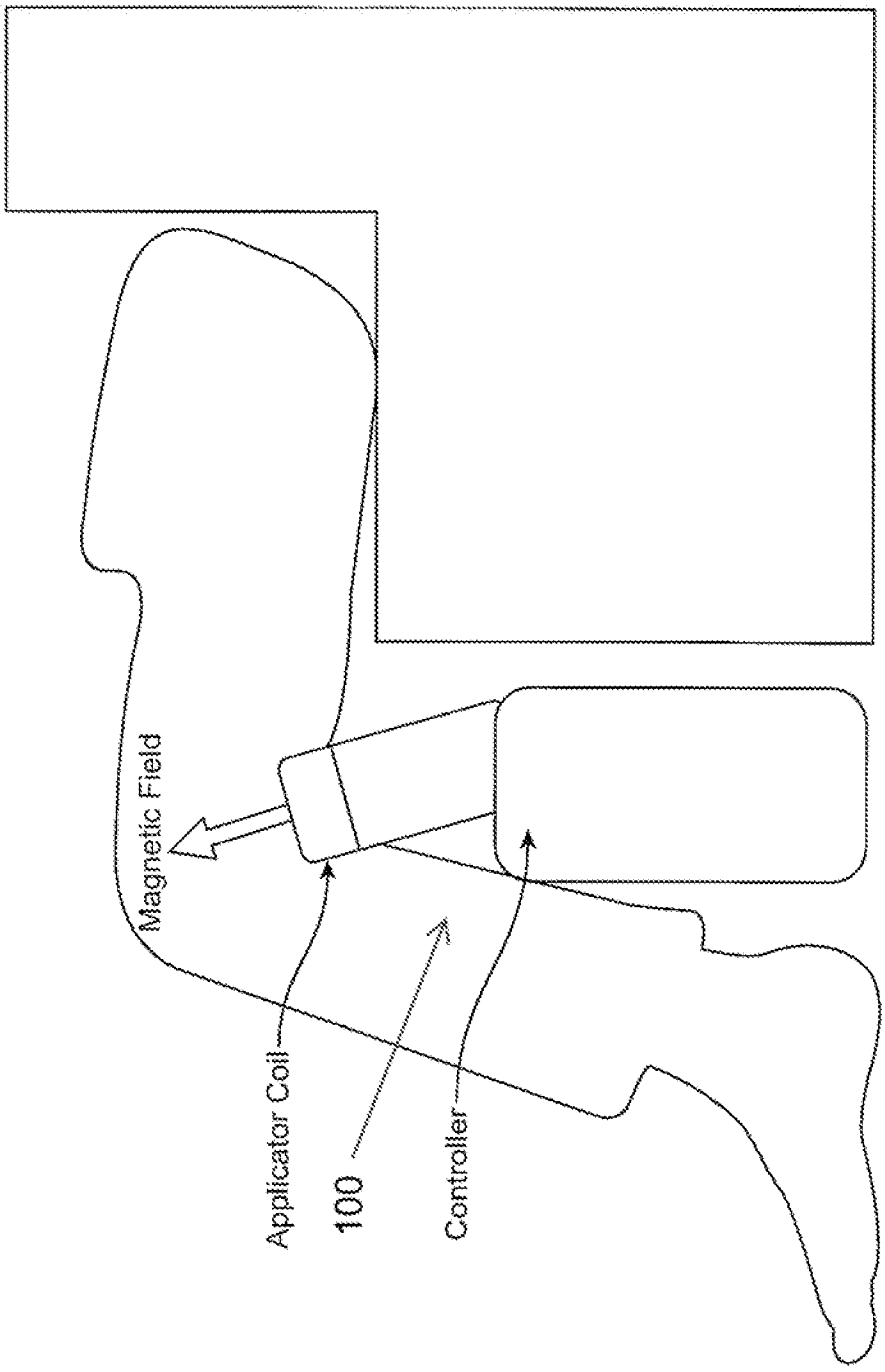


FIG. 30a

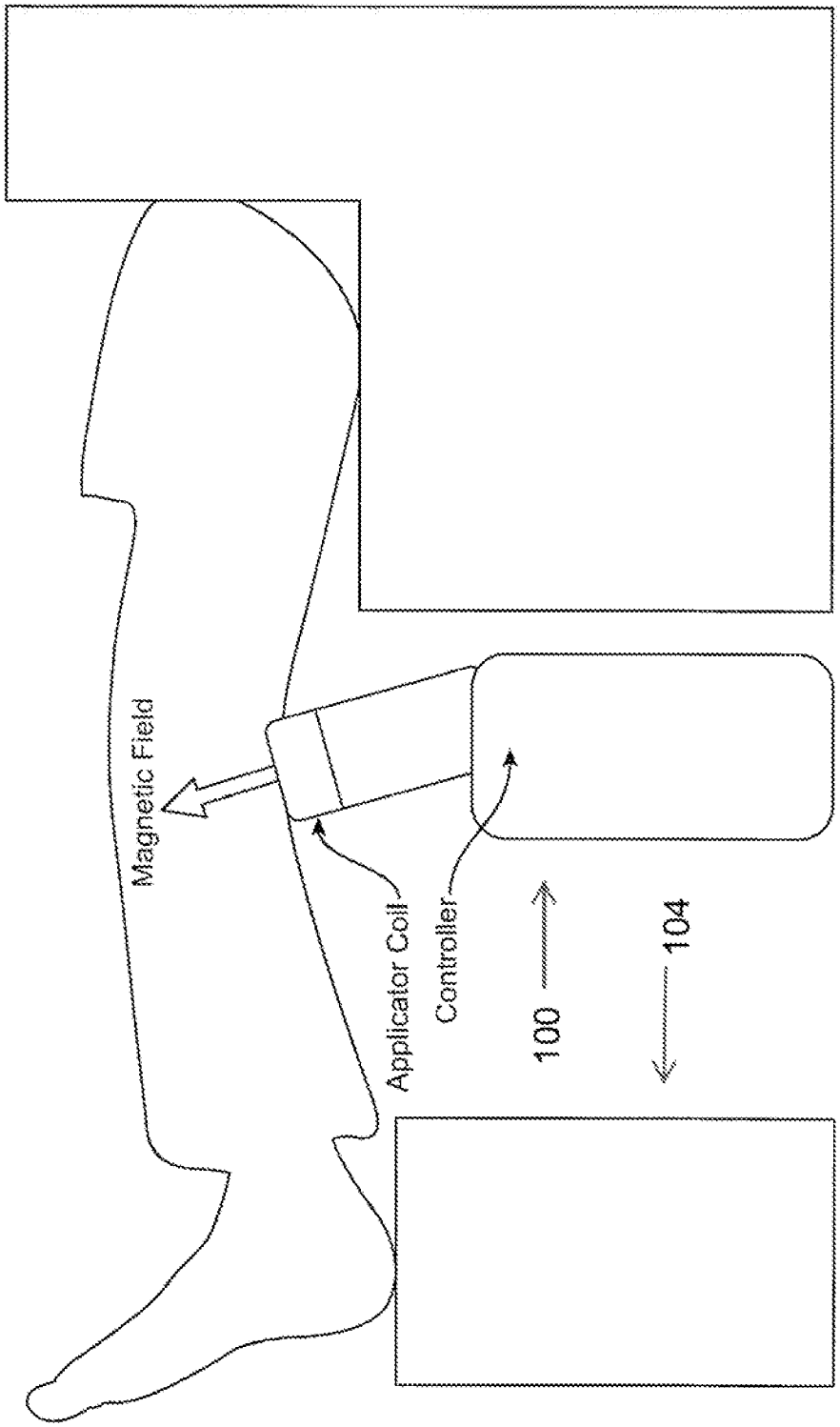


FIG. 30b

Fig. 31b

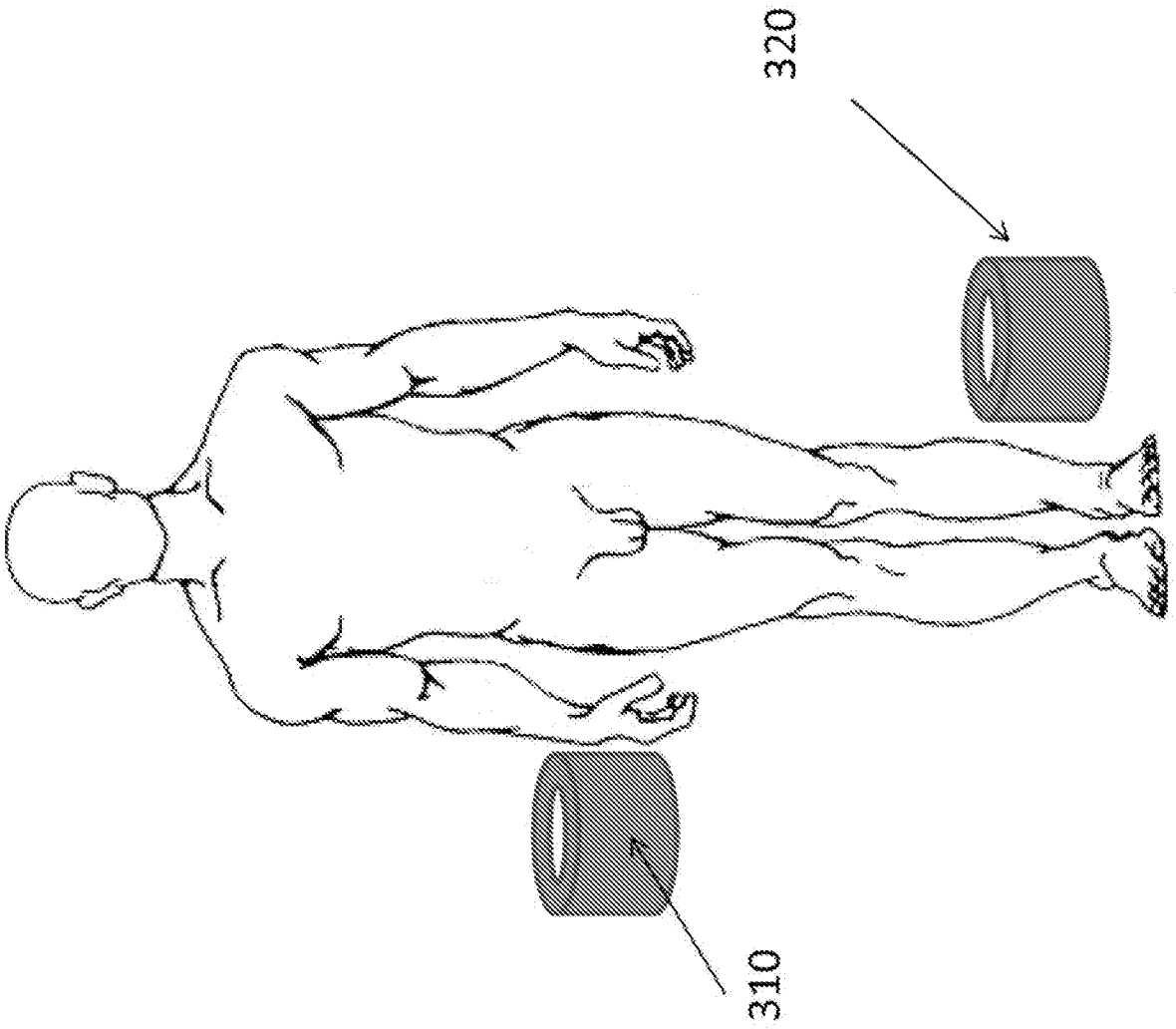


Fig. 31a

Fig. 32

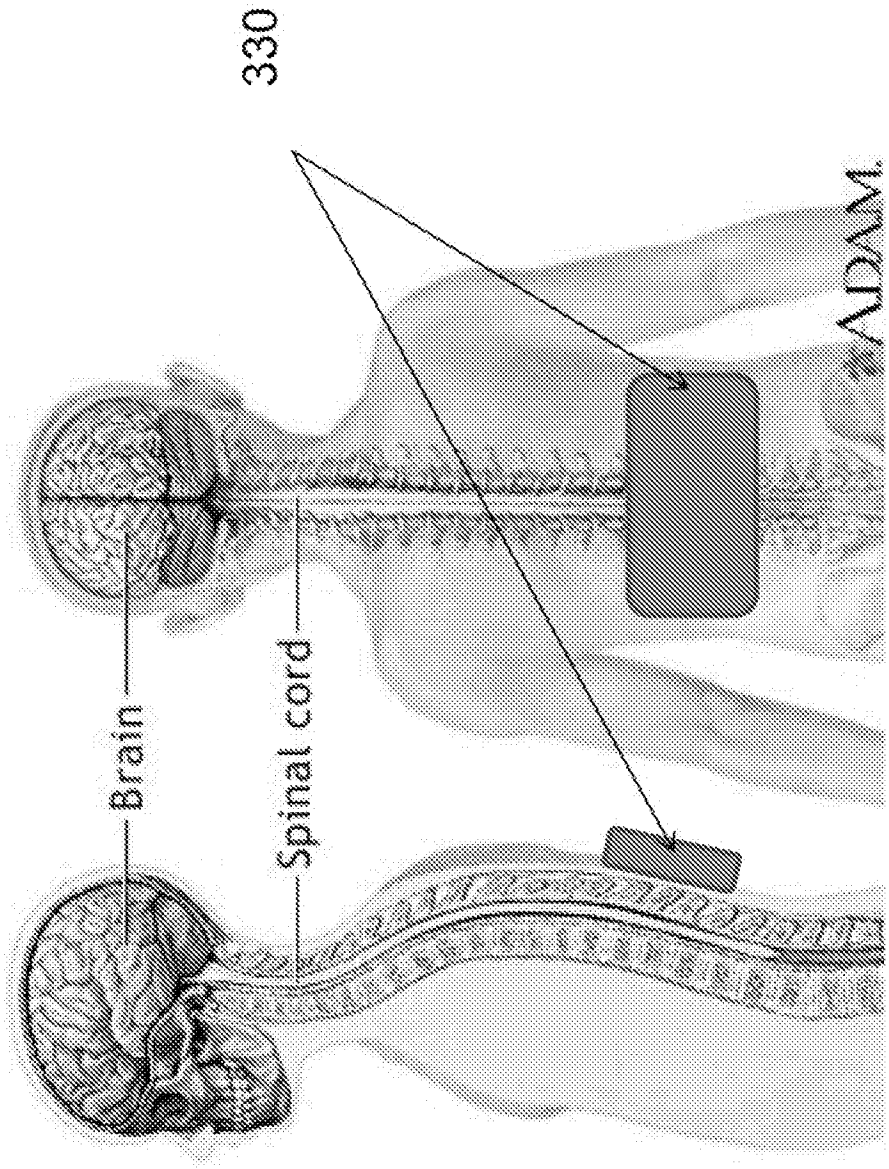


Fig. 33

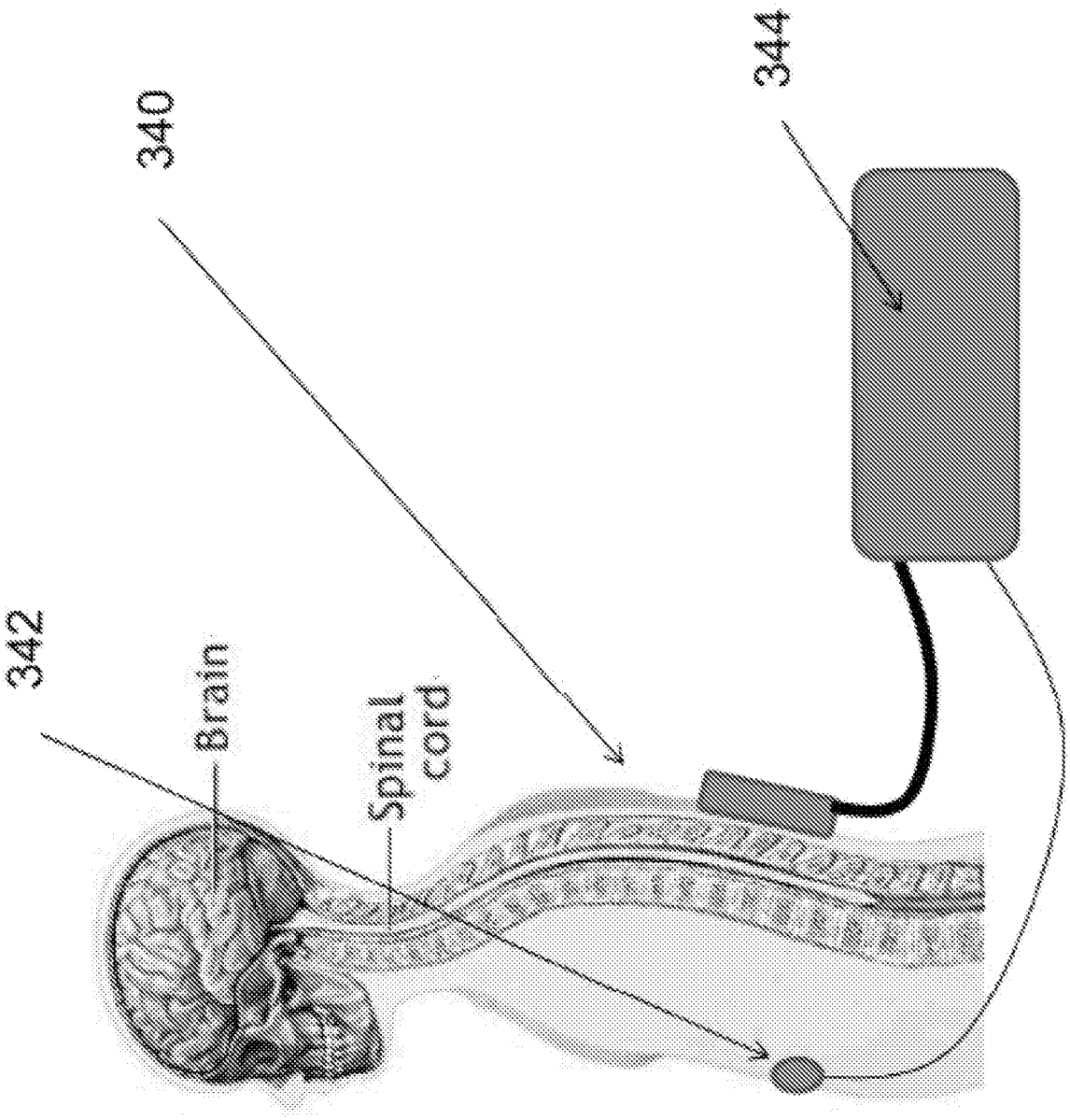
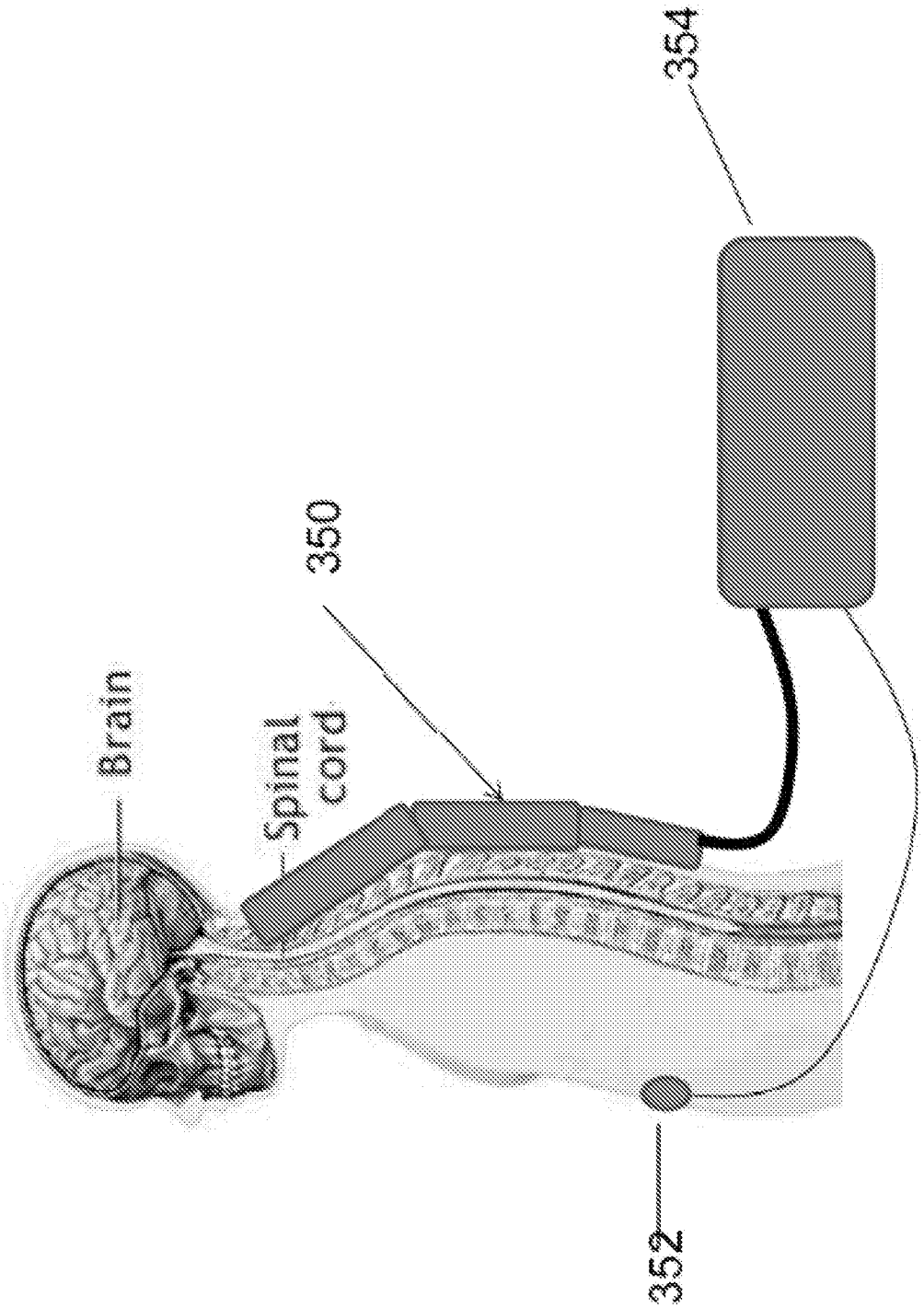


Fig. 34



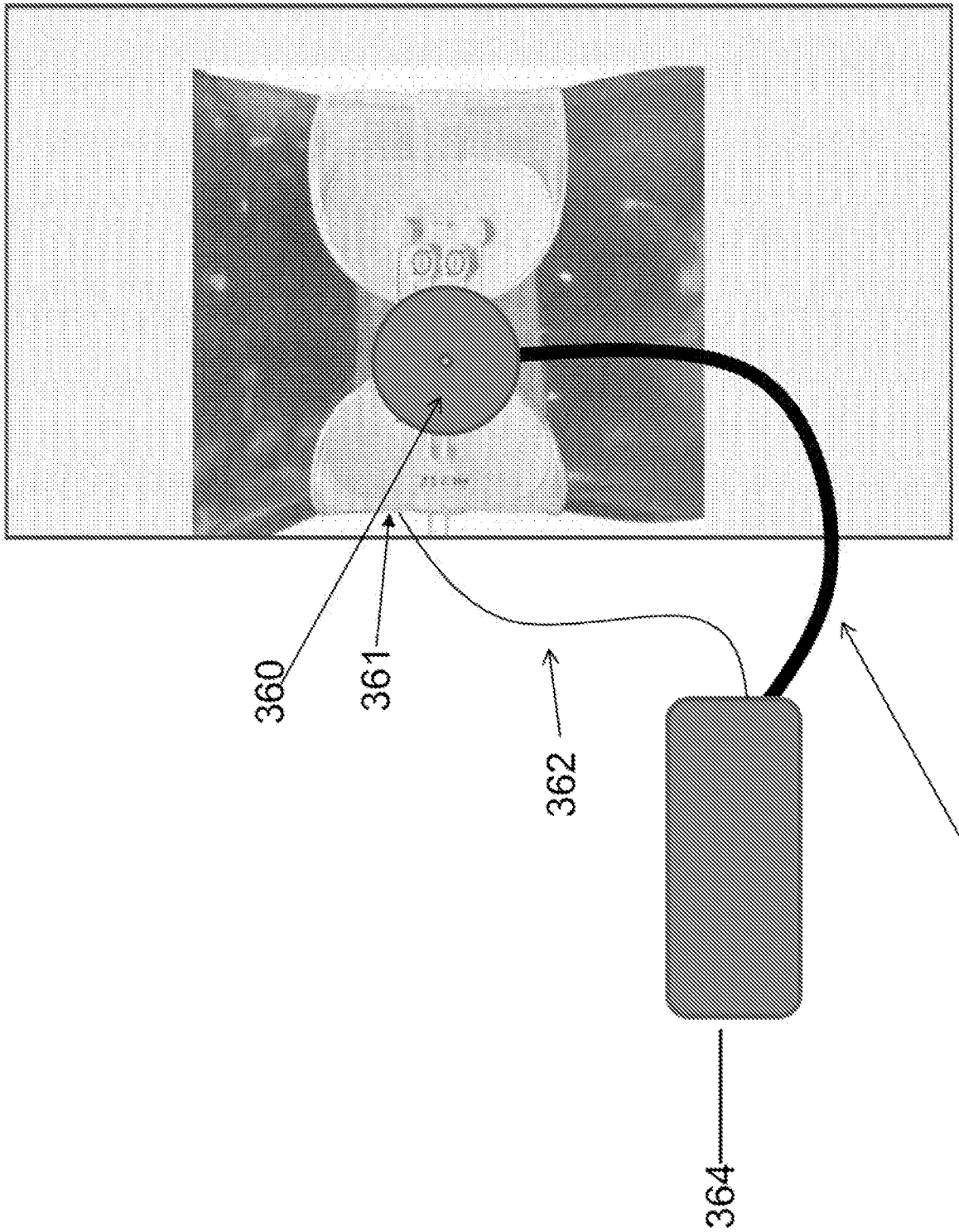


Fig. 35

Fig. 36

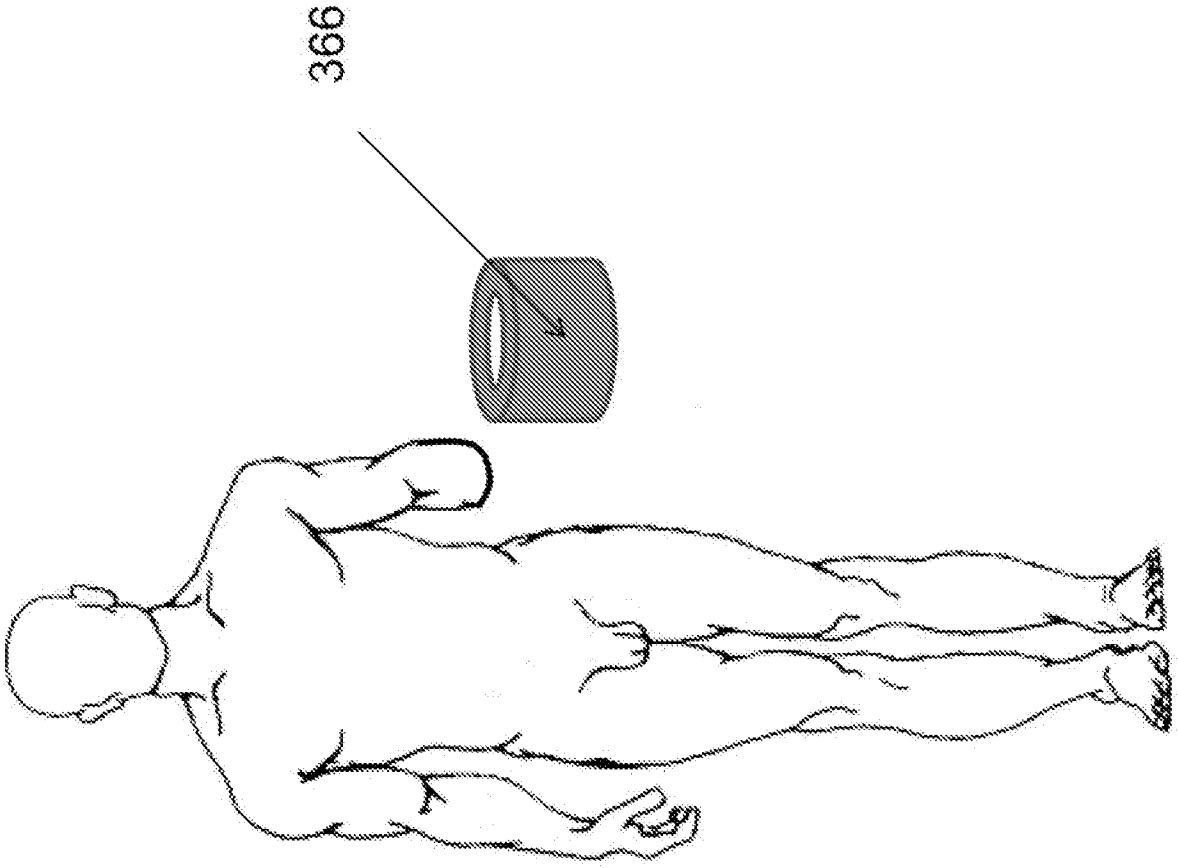


Fig. 37

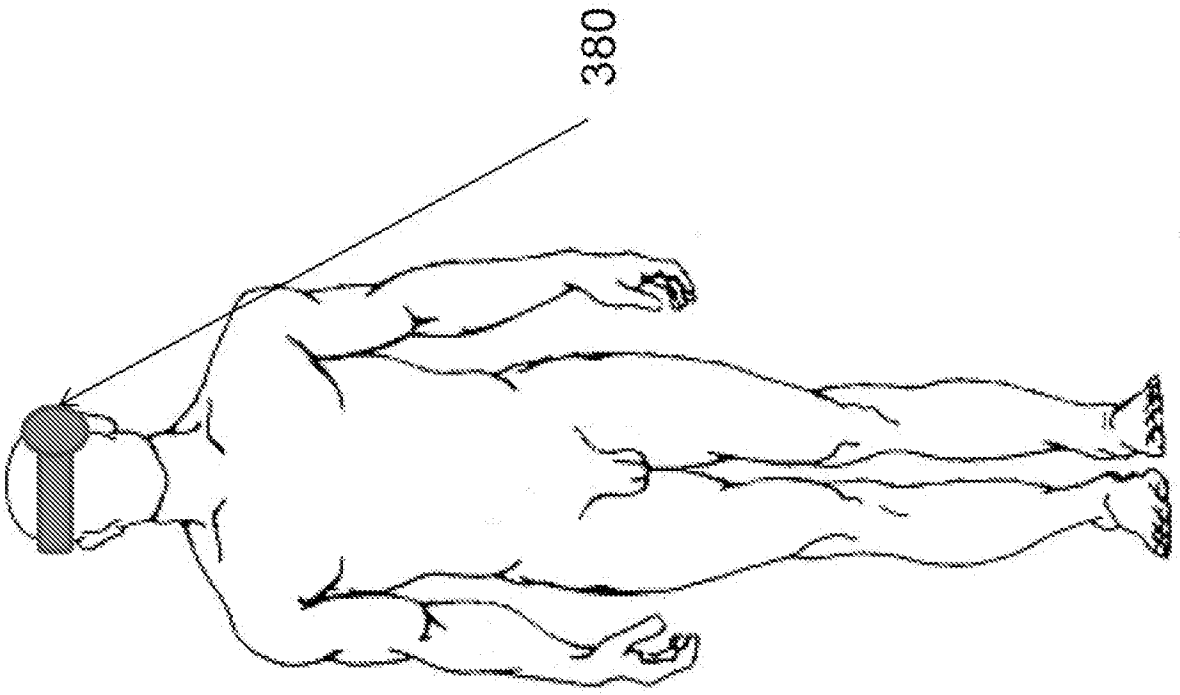


Fig. 38

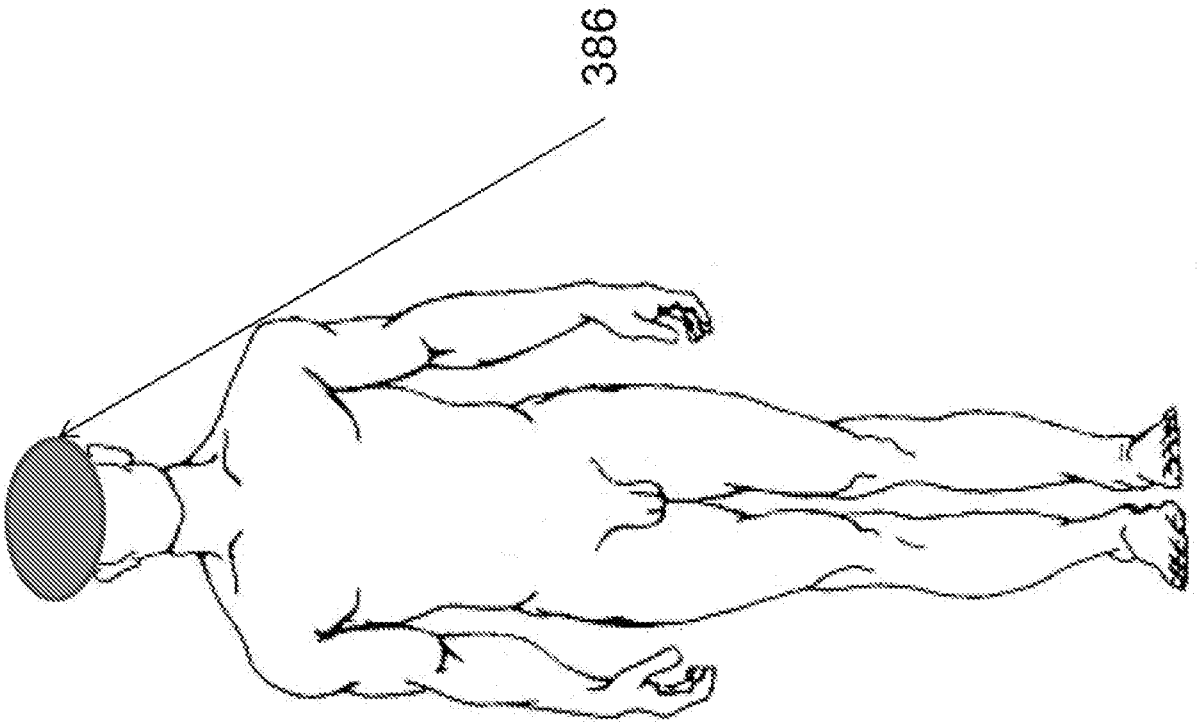


Fig. 39

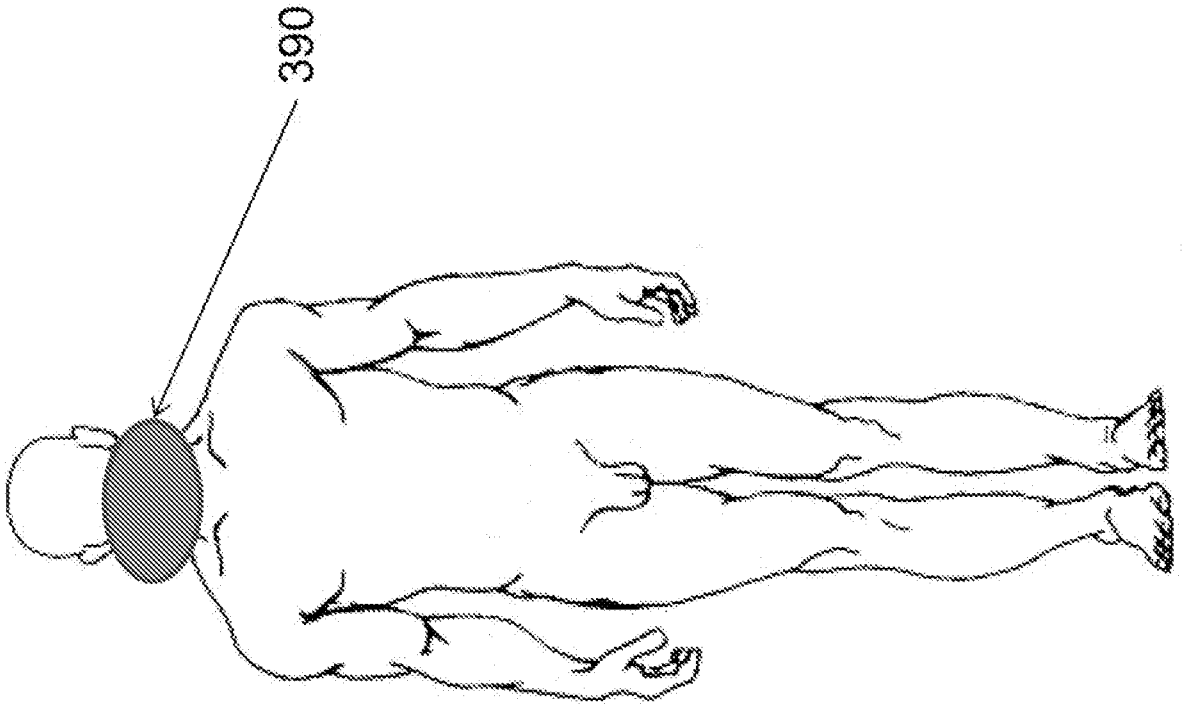


Fig. 40

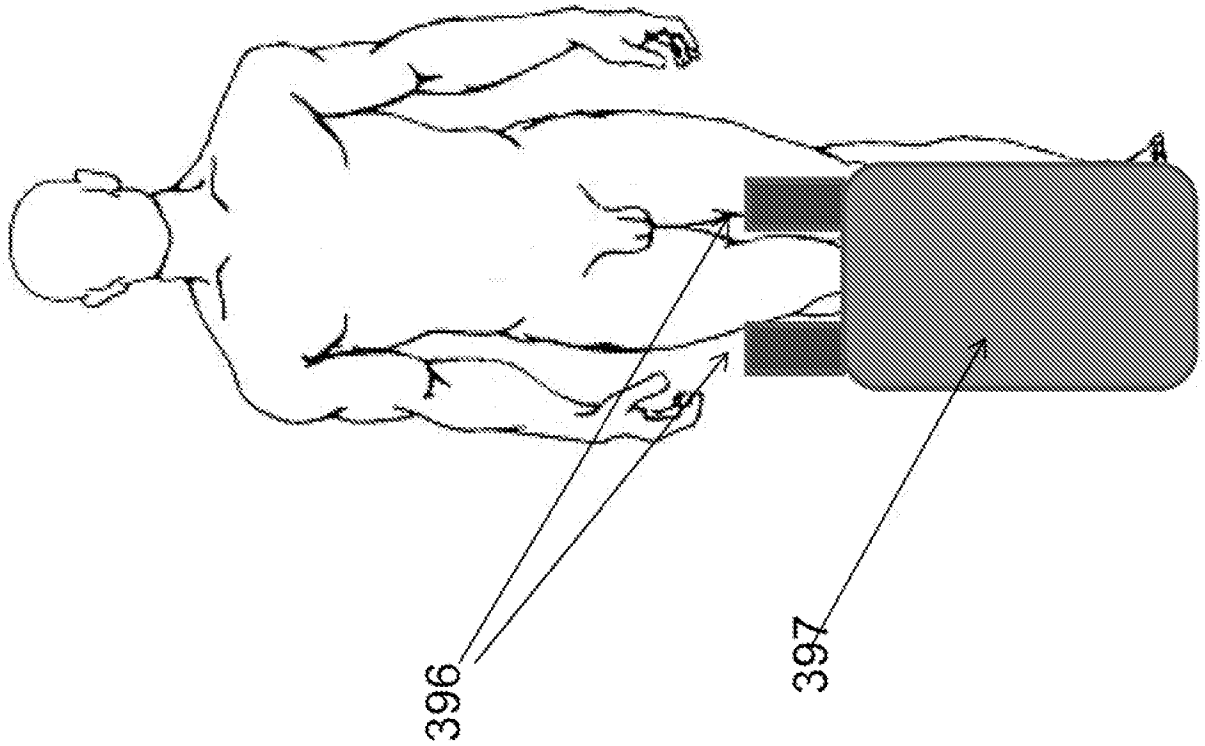
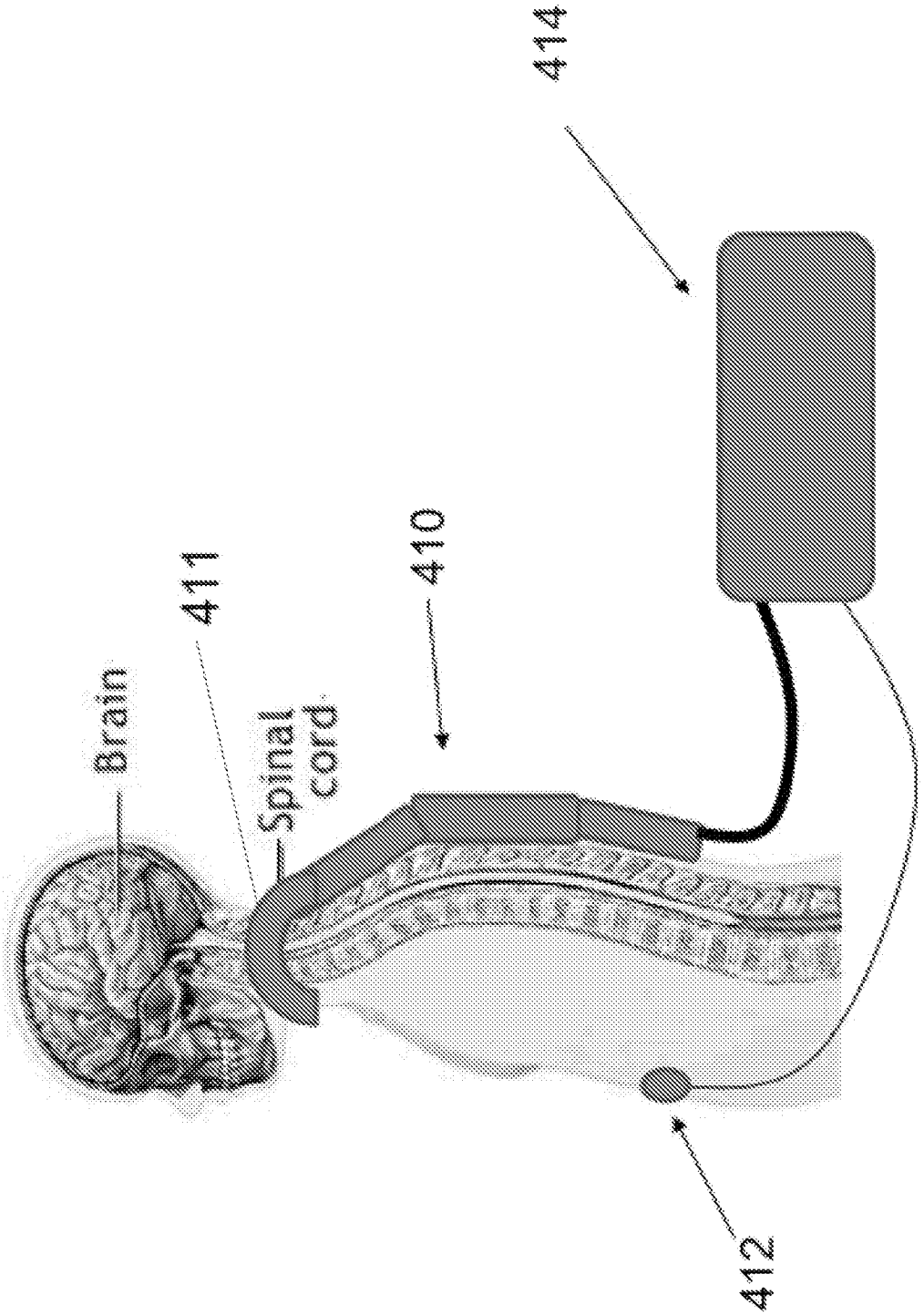


Fig. 41



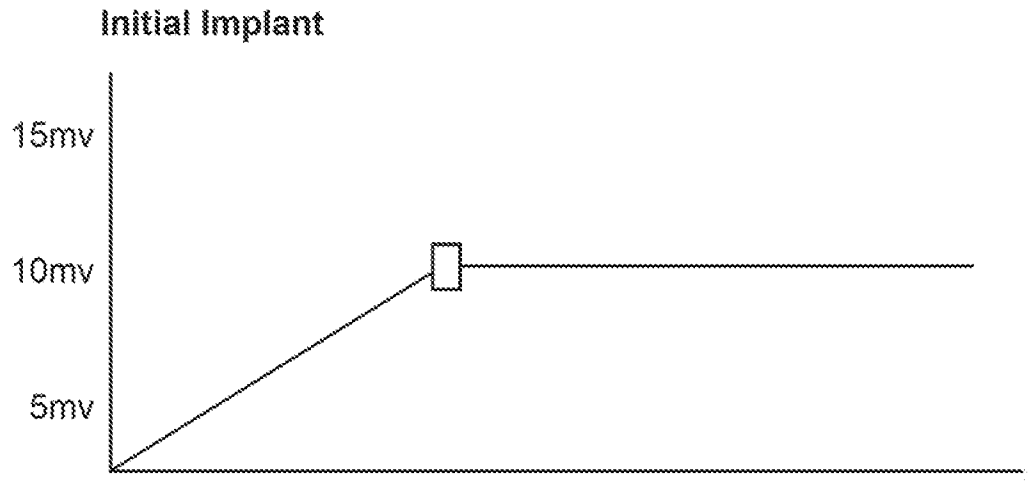


FIG. 42A

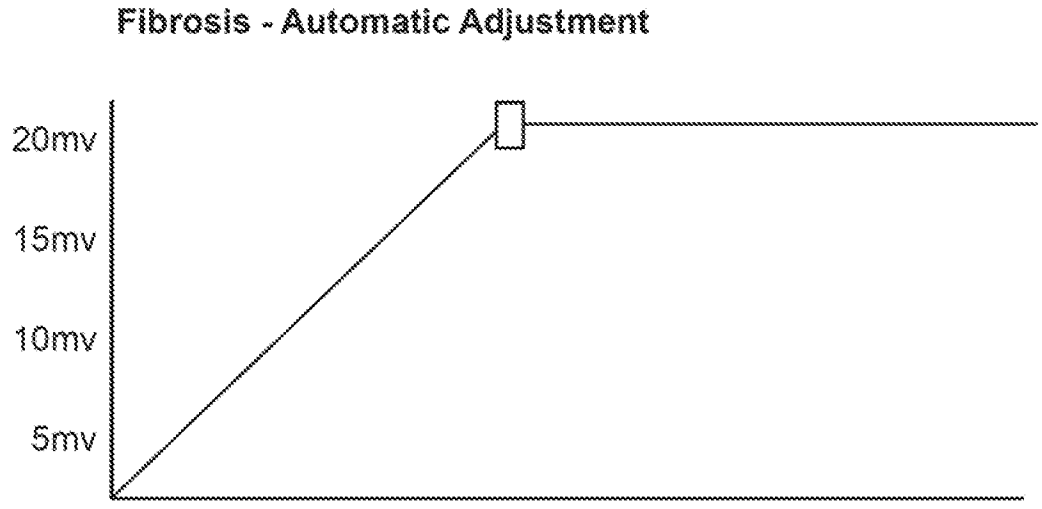


FIG. 42B

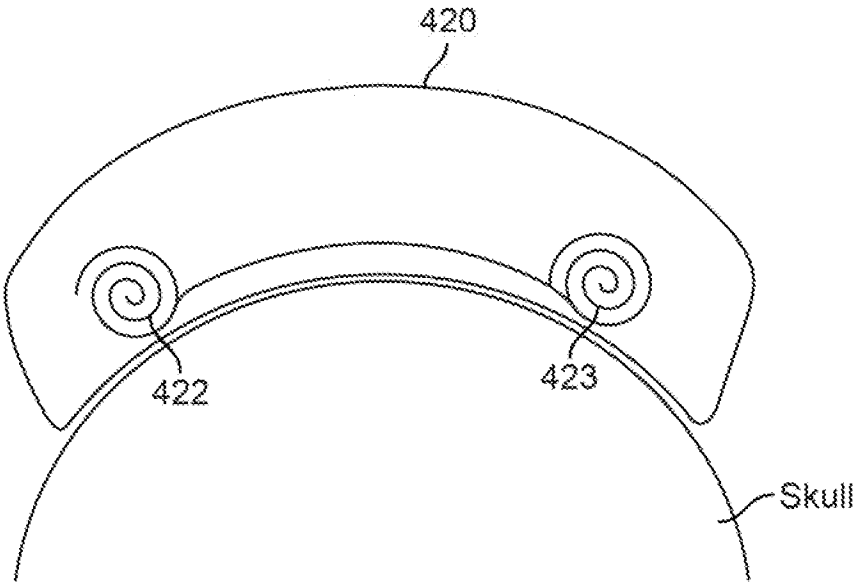


FIG. 43A

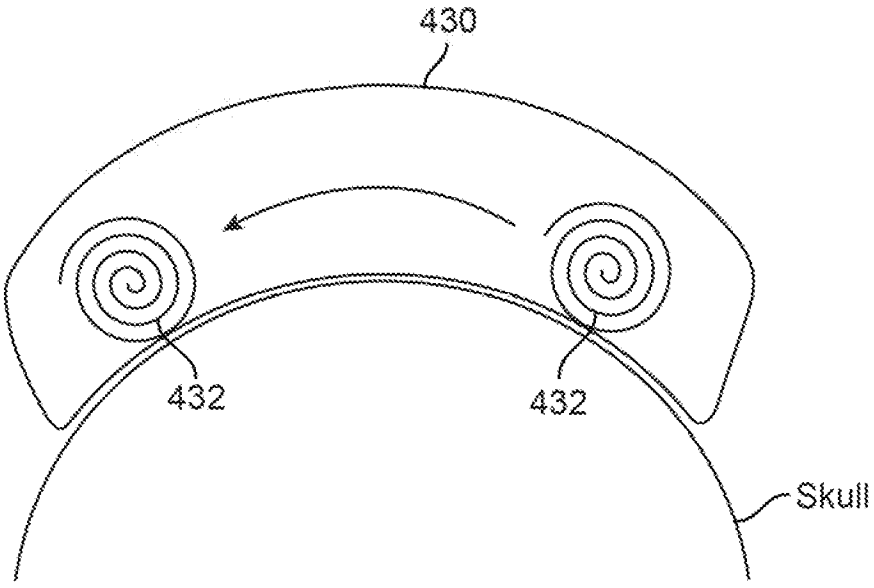


FIG. 43B

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

Date: July 31, 2017 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	Not Yet Assigned
Confirmation No.:	Concurrently Herewith
Filing Date:	Not Yet Assigned
Inventor(s):	Daniel R. BURNETT
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

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 the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related Application Number 15/056,910, filed February 29, 2016, 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. Patent Application No.: 12/695,087 filed January 27, 2010

U.S. Patent Application No.: 11/866,329 filed October 2, 2007

U.S. Patent Application No.: 12/508,529 filed July 23, 2009

U.S. Patent Application No.: 12/469,625 filed May 20, 2009

U.S. Patent Application No.: 12/469,358 filed May 20, 2009

U.S. Patent Application No.: 12/469,365 filed May 20, 2009

U.S. Patent Application No.: 12/606,941 filed October 27, 2009

U.S. Patent Application No.: 12/509,304 filed July 24, 2009

U.S. Patent Application No.: 12/509,345 filed July 24, 2009

U.S. Patent Application No.: 13/457,228 filed April 26, 2012

U.S. Patent Application No.: 14/097,568 filed December 5, 2013

U.S. Patent Application No. 14/685,278 filed April 13, 2015

U.S. Patent Application No. 14/949,735 filed November 23, 2015

U.S. Patent Application No.: 12/509,362 filed July 24, 2009

U.S. Patent Application No. 15/436,538 filed February 17, 2017

U.S. Patent Application No. 13/456,016 filed April 25, 2012

U.S. Patent Application No. 14/085,639 filed November 20, 2013

U.S. Patent Application No. 14/676,635 filed April 1, 2015

U.S. Patent Application No. 14/931,702 filed November 3, 2015

U.S. Patent Application No. 15/056,910 filed February 29, 2016

U.S. Patent Application No. 12/790,619 filed May 28, 2010

U.S. Patent Application No. 13/840,936 filed March 15, 2013

U.S. Patent Application No. 15/084,356 filed March 29, 2016

U.S. Patent Application No. 15/474,875 filed March 3, 2017

This Information Disclosure Statement is submitted with the application; accordingly, no fee or separate requirements are required.

Petitioner - Avation Medical, Inc.
Ex. 1002, p. 404

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.

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Respectfully submitted,

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