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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/474,875	09/29/2020	10786669	EMKNNZ00703	7884

40518 7590 09/09/2020

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 514 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

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

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

Amit RAJGURU, Lafayette, CA;
EMKinetics, Inc., San Francisco, CA;
Daniel R. BURNETT, San Francisco, CA;
Alexander VERGARA, San Francisco, CA;
Michael HEMATI, San Francisco, CA;

Cala Health Ex. 1004 (Part 1 of 2)
Cala v. EMKinetics
USP 10,786,669

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.

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 7 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	249.	2008/0004484	01-03-2008	Wieraszko et al.	
	250.	2008/0033510	02-07-2008	Herregraven et al.	
	251.	2008/0058874	03-06-2008	Westlund et al.	
	252.	2008/0063866	03-13-2008	Allen et al.	
	253.	2008/0114199	05-15-2008	Riehl et al.	
	254.	2008/0177128	07-24-2008	Riehl et al.	
	255.	2008/0177347	07-24-2008	Tehrani et al.	
	256.	2008/0183070	07-31-2008	Unal et al.	
	257.	2008/0200748	08-21-2008	Testani et al.	
	258.	2008/0224808	09-18-2008	Ghiron et al.	
	259.	2008/0262287	10-23-2008	Dussau	
	260.	2008/0288035	11-20-2008	Gill et al.	
	261.	2008/0300655	12-04-2008	Cholette	
	262.	2008/0306325	12-11-2008	Burnett et al.	
	263.	2008/0312725	12-18-2008	Penner	
	264.	2009/0030337	01-29-2009	Gozani et al.	
	265.	2009/0054950	02-26-2009	Stephens	
	266.	2009/0073991	03-19-2009	Landrum et al.	
	267.	2009/0076336	03-19-2009	Mazar et al.	
	268.	2009/0076340	03-19-2009	Libbus et al.	
	269.	2009/0076344	03-19-2009	Libbus et al.	
	270.	2009/0076345	03-19-2009	Manicka et al.	
	271.	2009/0076363	03-19-2009	Bly et al.	
	272.	2009/0076364	03-19-2009	Libbus et al.	
	273.	2009/0076397	03-19-2009	Libbus et al.	
	274.	2009/0076410	03-19-2009	Libbus et al.	
	275.	2009/0076559	03-19-2009	Libbus et al.	
	276.	2009/0076565	03-19-2009	Surwit	
	277.	2009/0099623	04-16-2009	Bentwich	
	278.	2009/0102819	~~05-27-2004~~ 04/2009	~~Zou et al.~~ Kwak	
	279.	2009/0118777	05-07-2009	Iki et al.	
	280.	2009/0132018	05-21-2009	DiUbaldi et al.	
	281.	2009/0162570	06-25-2009	Swenberg et al.	
	282.	2009/0171236	07-02-2009	Davies	
	283.	2009/0227829	09-10-2009	Burnett et al.	
	284.	2009/0227831	09-10-2009	Burnett et al.	
	285.	2009/0234179	09-17-2009	Burnett et al.	
	286.	2009/0234410	09-17-2009	Libbus et al.	
	287.	2009/0264792	10-22-2009	Mazar	
	288.	2009/0292194	11-26-2009	Libbus et al.	
	289.	2010/0022864	01-28-2010	Cordero et al.	
	290.	2010/0049021	02-25-2010	Jina et al.	

Change(s) applied to document,
/AJ/
8/26/2020

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

40518 7590 08/25/2020

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

EXAMINER
MORALES, JON ERIC C

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
08/25/2020	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

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
15/474,875	03/30/2017	RAJGURU et al.	EMKNNZ00703

	EXAMINER	
LEVINE BAGADE HAN LLP 2400 GENG ROAD, SUITE 120 PALO ALTO, CA 94303	JON ERIC C MORALES	
	ART UNIT	PAPER
	3792	20200820

DATE MAILED: _____

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

Commissioner for Patents

IDS filed on 6/12/2017 has been considered.

/JON ERIC C MORALES/
Primary Examiner, Art Unit 3792

PTO-90C (Rev.04-03)

Attorney Docket No.: EMKNNZ00703

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

Date: June 12, 2017 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Not Ye Assigned
Group Art Unit:	3766

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 15/084,356, filed March 29, 2016, and accordingly, copies are not included herewith. The Examiner is requested to make these documents of record in the application.

/JON ERIC C MORALES/ 08/20/2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.C.M/

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

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.

/JON ERIC C MORALES/ 08/20/2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.C.M/

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.

/JON ERIC C MORALES/ 08/20/2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.C.M/

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. **EMKNNZ00703**. 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

/JON ERIC C MORALES/ 08/20/2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.C.M/

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

Date: August 10, 2020 Signature: /Laura L. Gallagher/ (Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Jon Eric C. Morales
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 48 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. **EMKNNZ00703**.

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

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 08/06/2020
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.

Laura L. Gallagher	(Typed or printed name)
/Laura L. Gallagher/	(Signature)
August 10, 2020	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

TITLE OF INVENTION: METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	11/06/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
MORALES, JON ERIC C	3792	607-144000

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: EMKinetics, Inc.

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

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

4a. 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 August 10, 2020

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

Electronic Patent Application Fee Transmittal

Application Number:	15474875
Filing Date:	30-Mar-2017
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00703

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
UTILITY APPL ISSUE FEE	2501	1	500	500
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**500**

Electronic Acknowledgement Receipt

EFS ID:	40241103
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	10-AUG-2020
Filing Date:	30-MAR-2017
Time Stamp:	16:09:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$500
RAM confirmation Number	E202080G09442367
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_EMKNNZ00703_20200810_request_for_representative_figure.pdf	19339 d433c91617540a4b94ff7869a6af7a73f0e65bb6	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	02_EMKNNZ00703_20200810_issue_fee_transmittal.pdf	186444 0d423e2968b137ff17233a20c30863c9b7ba4037	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31655 684def3231cc93df7aa6c945dd1474f53e445f8c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	237438		

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

40518 7590 08/06/2020

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

EXAMINER
MORALES, JON ERIC C

ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 08/06/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

TITLE OF INVENTION: METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	11/06/2020

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.

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 08/06/2020
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.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

TITLE OF INVENTION: METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	11/06/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
MORALES, JON ERIC C	3792	607-144000

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. _____

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.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

40518 7590 08/06/2020

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

EXAMINER	
MORALES, JON ERIC C	
ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 08/06/2020

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

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

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

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

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 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.

Notice of Allowability	Application No. 15/474,875	Applicant(s) RAJGURU et al.	
	Examiner JON ERIC C MORALES	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 6/26/2020.
   ☐ 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 1-6,10-20 and 22-24 . 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 _____.

/JON ERIC C MORALES/ Examiner, Art Unit 3792	/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Allowable Subject Matter

2. Claims 1-6, 10-20 and 22-24 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: Regarding independent claim 1, for a method of transdermal electrical stimulation therapy to a subject comprising: positioning a stimulator electrode over a skin surface overlying a hand of the subject and providing feedback signals, and adjusting or optimizing the electrical stimulation delivered through the transdermally through the skin surface and to target nerve or tissue, detect a motion from the subject via at least one sensor positioned on the subject has not been suggested or disclosed in the prior art when combined with the rest of the claim limitations of independent claim 1.

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

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JON ERIC C MORALES whose telephone number is (571)272-3107. The examiner can normally be reached on Monday-Friday 830AM-530PM CST.

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, Carl Layno can be reached on 571-272-4949. 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.

/JON ERIC C MORALES/ Examiner, Art Unit 3792	/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792

/J.C.M/
Examiner, Art Unit 3792

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	**Art Unit**
	JON ERIC C MORALES	3792

CPC						
Symbol					**Type**	**Version**
A61N	/	1	/	36021	F	2013-01-01
A61N	/	1	/	0456	I	2013-01-01
A61N	/	2	/	02	I	2013-01-01
A61N	/	1	/	36007	I	2013-01-01
A61N	/	1	/	36057	I	2013-01-01
A61N	/	1	/	3787	A	2013-01-01
A61N	/	2	/	004	A	2013-01-01
A61B	/	5	/	4047	A	2013-01-01
A61N	/	1	/	36017	A	2013-01-01
A61N	/	1	/	0551	A	2013-01-01

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

/JON ERIC C MORALES/ Examiner, Art Unit 3792	27 July 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	27 July 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20200727

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	**Art Unit**
	JON ERIC C MORALES	3792

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61N	/	1	/	34	
A61N	/	1	/	04	

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
607	2

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					
607	40	46	115	144		

/JON ERIC C MORALES/ Examiner, Art Unit 3792	27 July 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	27 July 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	**Art Unit**
	JON ERIC C MORALES	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
1	1	10	13	19	23										
2	2	11	14	20	24										
3	3	12	15												
4	4	13	16												
5	5	14	17												
9	6	15	18												
6	10	16	19												
7	11	17	20												
8	12	18	22												

/JON ERIC C MORALES/ Examiner, Art Unit 3792	27 July 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	27 July 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	JON ERIC C MORALES	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
a61n2/02, 004	6/18/2019	MC
a61n1/3787, 36057, 36021, 36017, 36007, 0551, 0456	6/18/2019	MC
a61b5/4047	6/18/2019	MC

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

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
607	144	6/18/2019	MC

* 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**
Text Limited Search	6/13/2019	MC
Google Patent Search	6/18/2019	MC
Google Scholar Search	6/18/2019	MC
Inventor and Assignee Search	6/18/2019	MC
IDS References Considered	6/18/2019	MC
Text Limited Search	6/19/2019	MC
updated search in EAST	05/28/2020	JECM
applicant and inventor name search in EAST	07/27/2020	JECM

/JON ERIC C MORALES/ Examiner, Art Unit 3792	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	JON ERIC C MORALES	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61N	1/34, 2/02, 1/04, 1/36, 2/02, 1/0456, 1/36021, 1/36057, 1/36007, 2/004, 1/36017, 1/0551, 1/3787	07/27/2020	JECM

/JON ERIC C MORALES/ Examiner, Art Unit 3792	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	(US-9339641-$ or US-9630004-$).did.	USPAT	OR	OFF	2020/07/27 14:08
L3	22	"9339641"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/07/27 14:24
L4	13	hand same tremor same (transdermal or transcutaneous or transcutaneously) same (stimulate or stimulation or stimulating or electric or electrical) same nerve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/07/27 14:28
L5	15	hand same tremor same (transdermal or transcutaneous or transcutaneously) same (stimulate or stimulation or stimulating or electric or electrical) same nerve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/07/27 14:28
L6	25	hand same tremor same (transdermal or transcutaneous or transcutaneously or TENS) same (stimulate or stimulation or stimulating or electric or electrical) same nerve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/07/27 14:29
L7	29	hand same (shaking or shake or tremor) same (transdermal or transcutaneous or transcutaneously or TENS) same (stimulate or stimulation or stimulating or electric or electrical) same nerve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/07/27 14:29
L8	10	((("EMKINETICS") near3 ("INC"))).AS,AANM.	USPAT	OR	OFF	2020/07/27 14:37
L9	323	((("RAJGURU") near3 ("Amit")) OR (("BURNETT") near3 ("Daniel")) OR (("VERGARA") near3 ("Alexander")) OR (("HEMATI") near3 ("Michael"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/07/27 14:37
L11	0	l9 and hand same (shaking or shake or tremor) same (transdermal or transcutaneous or transcutaneously or TENS) same (stimulate or stimulation or stimulating or electric or electrical) same nerve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/07/27 14:38

L12	72	((("EMKINETICS") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/07/27 14:38
L13	0	l9 and hand same (shaking or shake or tremor) same (transdermal or transcutaneous or transcutaneously or TENS) same (stimulate or stimulation or stimulating or electric or electrical) same (neuron or nerve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/07/27 14:38
L14	0	l12 and hand same (shaking or shake or tremor) same (transdermal or transcutaneous or transcutaneously or TENS) same (stimulate or stimulation or stimulating or electric or electrical) same (neuron or nerve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/07/27 14:38
L15	56,002	(A61N1/34; A61N2/02; A61N1/04; A61N1/36; A61N2/02; A61N1/0456; A61N1/36021; A61N1/36057; A61N1/36007; A61N2/004; A61B5/4047; A61N1/36017; A61N1/0551; A61N1/3787).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/07/27 14:41
S1	0	"20040102819".pn.	USPAT	OR	OFF	2020/02/10 17:30
S2	3	"20040102819".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:30
S3	23,847	glabrous	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:31
S4	0	S2 and glabrous	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:31
S5	14	("20040102819" | "20060015153" | "20050283202" | "9630004" | "9339641").pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:33
S6	2	S5 and glabrous	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2020/02/10 17:34

			JPO; DERWENT; IBM_TDB			
S7	1	(US-9339641-$).did.	USPAT	OR	OFF	2020/02/11 14:41
S8	2	(US-9339641-$ or US-9630004-$).did.	USPAT	OR	OFF	2020/05/28 12:07
S9	192	"6892098"	USPAT	OR	OFF	2020/07/23 12:05
S10	3	"6892098".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/07/23 12:05
S11	4	"15474875"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/07/23 16:11

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L10	27	hand same (shaking or shake or tremor) same (transdermal or transcutaneous or transcutaneously or TENS) same (stimulate or stimulation or stimulating or electric or electrical) same nerve	US-PGPUB; USPAT	OR	ON	2020/07/27 14:37
L16	18,247	(A61N1/34; A61N2/02; A61N1/04; A61N1/36; A61N2/02; A61N1/0456; A61N1/36021; A61N1/36057; A61N1/36007; A61N2/004; A61B5/4047; A61N1/36017; A61N1/0551; A61N1/3787).cpc.	US-PGPUB; USPAT	OR	OFF	2020/07/27 14:41
L17	18,247	(A61N1/34; A61N2/02; A61N1/04; A61N1/36; A61N2/02; A61N1/0456; A61N1/36021; A61N1/36057; A61N1/36007; A61N2/004; A61B5/4047; A61N1/36017; A61N1/0551; A61N1/3787).cpc.	US-PGPUB; USPAT	OR	ON	2020/07/27 14:41
L18	17	l17 and hand same (shaking or shake or tremor) same (transdermal or transcutaneous or transcutaneously or TENS) same (stimulate or stimulation or stimulating or electric or electrical) same nerve	US-PGPUB; USPAT	OR	ON	2020/07/27 14:42

7/27/2020 3:32:36 PM
C:\Users\jmorales1\Documents\EAST\Workspaces\15474875 - hand stimulator glabrous skin palm target nerve.wsp

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

Date: June 26, 2020 Signature: /Laura L. Gallagher/ (Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Jon Eric C. Morales
Group Art Unit:	3792

RESPONSE TO FINAL OFFICE ACTION

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

Dear Sir:

This is in response to the final Office Action dated June 2, 2020 for which a response is due on September 2, 2020. This response is filed within two months of the issuance of the final Office Action and therefore qualifies for expedited review. 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.

Bibliographic Data

Application No: 15/474,875

Foreign Priority claimed: ○ Yes ◉ No

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

Verified and Acknowledged: /MICHAEL J CAREY/ Examiner's Signature | Initials

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

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
03/30/2017	607	3792	EMKNNZ00703
RULE			

APPLICANTS

EMKinetics, Inc., San Francisco, CA, UNITED STATES

INVENTORS

Amit RAJGURU, Lafayette, CA, UNITED STATES

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

Alexander VERGARA, San Francisco, CA, UNITED STATES

Michael HEMATI, San Francisco, CA, UNITED STATES

CONTINUING DATA

This application has PRO of 62350610 06/15/2016

This application is a CIP of 15084356 03/29/2016 PAT 9630004

15084356 is a CON of 13840936 03/15/2013 PAT 9339641

13840936 is a CIP of PCT/US2011/052415 09/20/2011

PCT/US2011/052415 has PRO of 61403680 09/20/2010

This application 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**

04/07/2017

**** 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

$970

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	15474875
Filing Date	30-Mar-2017
First Named Inventor	Amit RAJGURU
Attorney Docket Number	EMKNNZ00703
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
EMKinetics, Inc.	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

9339641

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○	I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

◉ Small Entity

○ Micro Entity

○ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 45565

○ A sole inventor

○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

○ A joint inventor; all of whom are signing this request

Signature	/Johney U. Han/
Name	Johney U. Han

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	15474875
Filing Date:	30-Mar-2017
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00703

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 15474875

Filing Date: 30-Mar-2017

Applicant/Patent under Reexamination: RAJGURU

Electronic Terminal Disclaimer filed on June 26, 2020

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	39843917
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	26-JUN-2020
Filing Date:	30-MAR-2017
Time Stamp:	17:31:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$160
RAM confirmation Number	E20206PH31142244
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	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33525 4d4e31a7ce4149716dface21185c8b651a635d17	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30157 e324840d28e028bfb2bcea35bcd26d65f522cf0b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	63682		

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: June 26, 2020	Signature: /Laura L. Gallagher/	(Laura L. Gallagher)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Jon Eric C. Morales
Group Art Unit:	3792

RESPONSE TO FINAL OFFICE ACTION

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

Dear Sir:

This is in response to the final Office Action dated June 2, 2020 for which a response is due on September 2, 2020. This response is filed within two months of the issuance of the final Office Action and therefore qualifies for expedited review. 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. (Previously Presented): A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:

positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject;

delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated; and

detecting a motion from the subject via at least one sensor positioned on the subject.

2. (Original): The method of claim 1, wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject.

3. (Original): The method of claim 1, wherein the stimulator electrode is a surface electrode.

4. (Original): The method of claim 1, wherein the electrical stimulation is delivered intermittently or on a chronic basis.

5. (Previously Presented): The method of claim 1, further comprising:

adjusting or optimizing the electrical stimulation in response to a feedback signal received from the sensor indicative of the detected motion and efficacy of the applied electrical stimulation therapy.

6. (Previously Presented): The method of claim 1, wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.

7.-9. (Canceled)

10. (Previously Presented): The method of claim 5, wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve while reducing the risk of burns or intolerance.

11. (Original): The method of claim 5, wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy.

12. (Original): The method of claim 5, wherein the sensor is a surface electrode.

13. (Previously Presented): The method of claim 1, further comprising positioning a return electrode on the subject to facilitate penetration of an electrical current through the surface to stimulate the target nerve.

14. (Previously Presented): The method of claim 1, wherein the stimulator electrode is attached to the skin surface with an adhesive.

15. (Previously Presented): The method of claim 1, wherein the stimulator electrode is positioned over the skin surface with an ergonomic applicator.

16. (Previously Presented): The method of claim 15, wherein the applicator is a glove or brace configured to be positioned against a skin surface such that the electrode delivers electrical stimulation to the target nerve or tissue.

17. (Original): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes to overcome habituation.

18. (Previously Presented): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes based on feedback provided by the at least one sensor.

19. (Original): The method of claim 1, wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased.

20. (Original): The method of claim 1, wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary.

21. (Canceled)

22. (Previously Presented): The method of claim 1, wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface.

23. (Previously Presented): The method of claim 22, wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.

24. (Previously Presented): The method of claim 22, wherein the at least two electrodes are positioned in opposition relative to one another.

REMARKS

Claims 1-6, 10-20, and 22-24 were pending in the present application. By virtue of this response, no claims have been canceled, amended, or added. Accordingly, claims 1-6, 10-20, and 22-24 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.

Double Patenting

Claims 1-6, 10-20, and 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 11-13, 15-17, 18, and 24 of U.S. Patent No. 9,339,641.

A Terminal Disclaimer is submitted herewith. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection on the ground of nonstatutory obviousness-type double patenting.

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. **EMKNNZ00703**.

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 Acknowledgement Receipt

EFS ID:	39844469
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	26-JUN-2020
Filing Date:	30-MAR-2017
Time Stamp:	17:29:19
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		01_EMKNNZ00703_20200626_response_to_final_office_action.pdf	32800 d45862680c8f90d4ab0f1d378e0d592ea112888e	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	6
Warnings:			
Information:			
	Total Files Size (in bytes):	32800	

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 15/474,875	Filing Date 03/30/2017	☐ 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	06/26/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 21	= 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".	/TAMARA D HARRELL/
*** 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
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.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

40518 7590 06/02/2020

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

EXAMINER	
MORALES, JON ERIC C	

ART UNIT	PAPER NUMBER
3792	

MAIL DATE	DELIVERY MODE
06/02/2020	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. 15/474,875	Applicant(s) RAJGURU et al.	
	Examiner JON ERIC C MORALES	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) 1-6,10-20 and 22-24 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) 1-6,10-20 and 22-24 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 3/13/2020.

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

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Double Patenting

2. 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 time wise 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.

3. Claim(s) 1-6, 10-20, 22-24 is/are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 8, 11-13, 15-17, 18, 24 of U.S. Patent No. 9339641, cited previously. Although the claims at issue are not identical, they are not patentably distinct from each other because both the current application and the US Patent claim a method of transdermal electrical stimulation therapy to a subject comprising: positioning a stimulator electrode over a skin surface overlying a hand of the subject and providing feedback signals, and adjusting or optimizing the electrical stimulation delivered through the glabrous skin surface, the sensor is a motion sensor.

Response to Arguments

4. Applicant's arguments filed 3/13/2020 have been fully considered but they are not persuasive. Examiner still finds that the Double Patenting rejection is still applicable

the amended changes make the claims more broad and the U.S. Patent No. 9339641 still reads on the claims of the current application.

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.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JON ERIC C MORALES whose telephone number is (571)272-3107. The examiner can normally be reached on Monday-Friday 830AM-530PM CST.

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, Carl Layno can be reached on 571-272-4949. 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.

/JON ERIC C MORALES/ Examiner, Art Unit 3792	

/J.C.M/
Examiner, Art Unit 3792

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	JON ERIC C MORALES	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
a61n2/02, 004	6/18/2019	MC
a61n1/3787, 36057, 36021, 36017, 36007, 0551, 0456	6/18/2019	MC
a61b5/4047	6/18/2019	MC

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

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
607	144	6/18/2019	MC

* 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**
Text Limited Search	6/13/2019	MC
Google Patent Search	6/18/2019	MC
Google Scholar Search	6/18/2019	MC
Inventor and Assignee Search	6/18/2019	MC
IDS References Considered	6/18/2019	MC
Text Limited Search	6/19/2019	MC
updated search in EAST	05/28/2020	JECM

/JON ERIC C MORALES/ Examiner, Art Unit 3792	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	JON ERIC C MORALES	3792

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

/JON ERIC C MORALES/ Examiner, Art Unit 3792	

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

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)* Sheet 1 of 1	*Complete if Known*	
	Application Number	15/474,875
	Filing Date	March 30, 2017
	First Named Inventor	Amit RAJGURU
	Art Unit	3792
	Examiner Name	Jon Eric C. Morales
	Attorney Docket Number	EMKNNZ00703

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.	6,432,037	08-13-2002	Eini et al.	
	2.	9,610,459	04-04-2017	Burnett et al.	
	3.	2006/0047326	03-02-2006	Wheeler	
	4.	2006/0069415	03-30-2006	Cameron et al.	
	5.	2008/0065167	03-13-2008	Boggs et al.	
	6.	2009/0198305	08-06-2009	Naroditsky et al.	
	7.	2010/0016929	01-21-2010	Prochazka	
	8.	2010/0114259	05-06-2010	Herregraven et al.	
	9.	2011/0144468	06-16-2011	Boggs et al.	

FOREIGN PATENT DOCUMENTS

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

*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]
	10.	Amarenco et al., "Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, Vol. 169, 2210-2215. (June 2003)	

*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	/JON ERIC C MORALES/	Date Considered	05/28/2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.C.M/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	(US-9339641-$ or US-9630004-$).did.	USPAT	OR	OFF	2020/05/28 12:07

EAST Search History (Interference)

<This search history is empty>

5/28/2020 12:07:36 PM
C:\Users\jmorales1\Documents\EAST\Workspaces\15474875 - hand stimulator glabrous skin palm target nerve.wsp

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.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Jon Eric C. Morales
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 February 12, 2020 for which a response is due on May 12, 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 6 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. (Currently Amended): A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:

positioning a stimulator electrode over a ~~glabrous~~ skin surface overlying a target nerve or tissue which extends through a hand ~~palm~~ of the subject;

delivering electrical stimulation via a pulse generator transdermally through the ~~glabrous~~ skin surface and to the target nerve or tissue ~~within the hand~~ to stimulate the target nerve or tissue ~~within the hand~~ so that tremors experienced ~~pain felt~~ by the subject are mitigated; and

detecting a motion from the subject via at least one sensor positioned on the subject

~~wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude~~.

2. (Original): The method of claim 1, wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject.

3. (Original): The method of claim 1, wherein the stimulator electrode is a surface electrode.

4. (Original): The method of claim 1, wherein the electrical stimulation is delivered intermittently or on a chronic basis.

5. (Currently Amended): The method of claim 1, further comprising:

~~detecting nerve stimulation via at least one sensor positioned on the subject;~~

adjusting or optimizing the electrical stimulation in response to ~~receiving~~ a feedback signal received from the sensor indicative of the detected motion and ~~electrical stimulation thereby providing a feedback about the~~ efficacy of the applied electrical stimulation therapy ~~such that the therapy is adjusted or optimized~~.

6. (Currently Amended): The method of claim 1, wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude ~~5 wherein the sensor senses an M-Wave~~.

7.-9. (Canceled)

10. (Currently Amended): The method of claim 5, wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve ~~within the hand~~ while reducing the risk of burns or intolerance.

11. (Original): The method of claim 5, wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy.

12. (Original): The method of claim 5, wherein the sensor is a surface electrode.

13. (Currently Amended): The method of claim 1, further comprising positioning a return electrode on the subject to facilitate penetration of an electrical current through the ~~glabrous~~ surface to stimulate the target nerve ~~within the hand~~.

14. (Currently Amended): The method of claim 1, wherein the stimulator electrode is attached to the ~~glabrous~~ skin surface with an adhesive.

15. (Currently Amended): The method of claim 1, wherein the stimulator electrode is positioned over the ~~glabrous~~ skin surface with an ergonomic applicator.

16. (Currently Amended): The method of claim 15, wherein the applicator is a glove or brace configured to be positioned against a skin ~~the palmar~~ surface ~~of a hand~~ such that the electrode delivers electrical stimulation to the target nerve or tissue ~~within the hand~~.

17. (Original): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes to overcome habituation.

18. (Currently Amended): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes based on feedback provided by the at least one sensor ~~regarding target nerve stimulation or habituation~~.

19. (Original): The method of claim 1, wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased.

20. (Original): The method of claim 1, wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary.

21. (Canceled)

22. (Previously Presented): The method of claim 1, wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface.

23. (Previously Presented): The method of claim 22, wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.

24. (Previously Presented): The method of claim 22, wherein the at least two electrodes are positioned in opposition relative to one another.

REMARKS

Claims 1-6, 10-20, and 22-24 were pending in the present application. By virtue of this response, claims 1, 5-6, 10, 13-16, 18 have been amended. Accordingly, claims 1-6, 10-20, and 22-24 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.

Double Patenting

Claims 1-6, 20-20, 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 11-13, 15-17, 18, 24 of U.S. Patent No. 9,339,641.

Applicant notes that amendments originally made in the Preliminary Amendment of February 8, 2018 were not reflected in the Response to Non-Final Office Action of November 14, 2019 due to inadvertent typographical errors. Specifically, certain deletions to the claims were not reflected.

Applicant has re-amended the present claims to be consistent with the originally amended claims and further submit that the present claims are still in allowable form. Applicant further submits that the present claims are also patentability distinct over U.S. Patent No. 9,339,641 in view of the corrected claim amendments.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection on the ground of nonstatutory obviousness-type double patenting.

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. **EMKNNZ00703**.

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

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.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Jon Eric C. Morales
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 documents listed on the attached Form PTO/SB/08a/b. A copy of the non-patent literature is submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted after receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance. 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. **EMKNNZ00703**. 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

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	15/474,875
				Filing Date	March 30, 2017
				First Named Inventor	Amit RAJGURU
				Art Unit	3792
(Use as many sheets as necessary)				Examiner Name	Jon Eric C. Morales
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00703

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.	6,432,037	08-13-2002	Eini et al.	
	2.	9,610,459	04-04-2017	Burnett et al.	
	3.	2006/0047326	03-02-2006	Wheeler	
	4.	2006/0069415	03-30-2006	Cameron et al.	
	5.	2008/0065167	03-13-2008	Boggs et al.	
	6.	2009/0198305	08-06-2009	Naroditsky et al.	
	7.	2010/0016929	01-21-2010	Prochazka	
	8.	2010/0114259	05-06-2010	Herregraven et al.	
	9.	2011/0144468	06-16-2011	Boggs et al.	

FOREIGN PATENT DOCUMENTS

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

*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]
	10.	Amarenco et al., "Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder," Journal of Urology, Vol. 169, 2210-2215. (June 2003)	

*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:	15474875
Filing Date:	30-Mar-2017
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00703

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($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	120	120
		Total in USD ($)		**120**

Electronic Acknowledgement Receipt

EFS ID:	38863707
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	13-MAR-2020
Filing Date:	30-MAR-2017
Time Stamp:	16:26:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$120
RAM confirmation Number	E20203CG27127786
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_EMKNNZ00703_20200313_response_to_non-final_office_action.pdf	35624 d68972f28269b4b1e5eb6bf039ae5d0cce0a5e40	yes	7

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	5
Applicant Arguments/Remarks Made in an Amendment	6	7

Warnings:

Information:

2	Transmittal Letter	02_EMKNNZ00703_20200313_ids_cover_letter.pdf	22677 f25953bb50697bf3cd0ee68837f731f21143b00b	no	2

Warnings:

Information:

3	Information Disclosure Statement (IDS) Form (SB08)	03_EMKNNZ00703_20200313_ids_sb08.pdf	25919 90a8b5e1dc8ad688e176d08ce152f775f2bdca57	no	1

Warnings:

Information:

This is not an USPTO supplied IDS fillable form

4	Non Patent Literature	04_Amarenco_2003.pdf	1115388 a9ce4923035f282a07fa391624bef1d4815555d8	no	6

Warnings:

Information:

5	Fee Worksheet (SB06)	fee-info.pdf	30167 01024614e795615d06389808ac636e23939c01d4	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	1229775

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.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

40518 7590 02/12/2020

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

EXAMINER	
MORALES, JON ERIC C	

ART UNIT	PAPER NUMBER
3792	

MAIL DATE	DELIVERY MODE
02/12/2020	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. 15/474,875	Applicant(s) RAJGURU et al.	
	Examiner JON ERIC C MORALES	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 14 November 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) 1-6,10-20 and 22-24 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) 1-6,10-20 and 22-24 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 3/30/2017 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: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Double Patenting

2. 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 time wise 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.

3. Claim(s) 1-6, 10-20, 22-24 is/are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 8, 11-13, 15-17, 18, 24 of U.S. Patent No. 9339641. Although the claims at issue are not identical, they are not patentably distinct from each other because both the current application and the US Patent claim a method of transdermal electrical stimulation therapy to a subject comprising: positioning a stimulator electrode over a glabrous skin surface overlying a palm of the subject and providing feedback signals, and adjusting or optimizing the electrical stimulation delivered through the glabrous skin surface, the sensor is a motion sensor.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JON ERIC C MORALES whose telephone number is

(571)272-3107. The examiner can normally be reached on Monday-Friday 830AM-530PM CST.

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, Carl Layno can be reached on 571-272-4949. 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.

/JON ERIC C MORALES/ Examiner, Art Unit 3792	

/J.C.M/
Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/474,875	Applicant(s)/Patent Under Reexamination RAJGURU et al.	
	Examiner JON ERIC C MORALES	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-9339641-B2	05-2016	Rajguru; Amit	A61N1/0456	1/1
	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	
	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
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	JON ERIC C MORALES	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
a61n2/02, 004	6/18/2019	MC
a61n1/3787, 36057, 36021, 36017, 36007, 0551, 0456	6/18/2019	MC
a61b5/4047	6/18/2019	MC

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

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
607	144	6/18/2019	MC

* 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**
Text Limited Search	6/13/2019	MC
Google Patent Search	6/18/2019	MC
Google Scholar Search	6/18/2019	MC
Inventor and Assignee Search	6/18/2019	MC
IDS References Considered	6/18/2019	MC
Text Limited Search	6/19/2019	MC

/MICHAEL J CAREY/ Primary Examiner, Art Unit 3792	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	JON ERIC C MORALES	3792

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

/MICHAEL J CAREY/ Primary Examiner, Art Unit 3792	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	(US-9339641-$).did.	USPAT	OR	OFF	2020/02/11 14:41
S1	0	"20040102819".pn.	USPAT	OR	OFF	2020/02/10 17:30
S2	3	"20040102819".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:30
S3	23847	glabrous	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:31
S4	0	S2 and glabrous	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:31
S5	14	("20040102819" | "20060015153" | "20050283202" | "9630004" | "9339641").pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:33
S6	2	S5 and glabrous	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/10 17:34

EAST Search History (Interference)

< This search history is empty>

2/ 11/ 2020 2:57:53 PM
C:\ Users\ jmorales1\ Documents\ EAST\ Workspaces\ 15474875 - hand stimulator glabrous skin palm target nerve.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.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Michael J. Carey
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 June 20, 2019 for which a response was due on September 20, 2019. Filed herewith is a Petition and fee for a two-month extension of time, thereby extending the deadline for response to November 20, 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 Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 5 of this paper.

Remarks begin on page 9 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please amend paragraph **[0001]** as follows:

[0001] This application is a continuation-in-part of U.S. patent application No. 15/084,356 filed March 29, 2016 (now U.S. patent 9,630,004) which is a continuation of U.S. patent application 13/840,936 filed March 15, 2013 (now U.S. patent 9,339,641 issued May 17, 2016), which is a continuation in part of PCT International Patent Application Number PCT/US2011/052415, filed September 20, 2011, which claims benefit of priority to U.S. Provisional Patent Application No. 61/403,680 filed September 20, 2010. The present application is also a continuation-in part of U.S. patent application No. 12/508,529 filed July 23, 2009 (now abandoned), which is a continuation-in-part of U.S. patent application No. 11/866,329 filed October 2, 2007 (now abandoned), which claims priority to U.S. Provisional Patent Application No. 60/848,720 filed October 2, 2006. The present application also claims priority to U.S. Provisional Patent Application No. 62/350,610 filed June 15, 2016. Each of the above referenced applications is incorporated herein by reference in their entirety.

Please amend paragraph **[0002]** as follows:

[0002] The following applications are also incorporated herein by reference in their entirety for all purposes: PCT Application Serial No. PCT/US10/54167 filed Oct. 26, 2010; PCT Application Serial No. PCT/US10/054353 filed Oct. 27, 2010; U.S. patent application Ser. No. 12/508,529 filed Jul. 23, 2009 (now abandoned), which is a continuation in part of U.S. patent application Ser. No. 11/866,329 filed Oct. 2, 2007 (now abandoned), which claims priority to U.S. Provisional Patent Application Ser. No. 60/848,720 filed Oct. 2, 2006; U.S. patent application Ser. No. 12/695,087 filed Jan. 27, 2010 (now abandoned), which is a continuation of U.S. patent application Ser. No. 11/332,797 filed Jan. 17, 2006 (now abandoned); U.S. patent application Ser. No. 12/509,362 filed Jul. 24, 2009 (now U.S. patent 9,610,459); Ser. No. 12/469,365 filed May 20, 2009 (now abandoned) which is a continuation of U.S. patent application Ser. No. 11/866,329 filed Oct. 2, 2007 (now abandoned) which claims priority to U.S. Provisional Patent Application Ser. No. 60/848,720 filed Oct. 2, 2006, and Ser. No. 12/469,625 filed May 20, 2009 (now U.S. patent 8,430,805) which is a continuation of U.S. patent application Ser. No. 11/866,329 filed Oct. 2, 2007

(now abandoned) which claims priority to U.S. Provisional Patent Application Ser. No. 60/848,720 filed Oct. 2, 2006; and Ser. No. 12/509,304 filed Jul. 24, 2009 (now abandoned) which is a continuation of U.S. patent application Ser. No. 12/508,529 filed Jul. 23, 2009 (now abandoned) which is a continuation-in-part of U.S. patent application Ser. No. 11/866,329 filed Oct. 2, 2007 (now abandoned) which claims priority to U.S. Provisional Patent Application Ser. No. 60/848,720 filed Oct. 2, 2006; and Ser. No. 12/509,345 filed Jul. 24, 2009 (now abandoned) which is a continuation of U.S. patent application Ser. No. 12/508,529 filed Jul. 23, 2009 (now abandoned) which is a continuation-in-part of U.S. patent application Ser. No. 11/866,329 filed Oct. 2, 2007 (now abandoned) which claims priority to U.S. Provisional Patent Application Ser. No. 60/848,720 filed Oct. 2, 2006.

Please amend paragraph **[0147]** as follows:

[0147] 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® (Bluetooth Sig, Inc., Kirkland, WA), infrared, ultrasound, direct switching of the current circuit, etc., so long as communication between the sensor and the device is effective.

Please amend paragraph **[0376]** as follows:

[0376] FIG. 60C shows another embodiment of a generator/controller. This generator/controller can have all, some of, or additional attributes as those generator/controllers disclosed herein. FIG. 60C has the components in a compact, portable case. It may have advanced features, such as wireless communication, such as Bluetooth®, or other wireless technology, and the ability to communicate with current smartphones or other computers via different applications. For example, any of the embodiments disclosed herein may include a controller which sends, and possible receives, data to/from a centralized server wirelessly. The connection may be via wi-fi, Bluetooth®, cellular connection etc. The controller may be a smartphone, tablet, or other computer and/or may communicate with a

smartphone, tablet, or other computer. The data sent from the controller and/or received by the controller may be anonymous or patient specific data. The data sent/received may be specific to one person or may be aggregate data of more than one user.

AMENDMENTS TO THE CLAIMS

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

In the claims

1. (Previously Presented): A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:

positioning a stimulator electrode over a glabrous skin surface overlying a target nerve or tissue which extends through a hand palm of the subject;

delivering electrical stimulation via a pulse generator transdermally through the glabrous skin surface and to the target nerve or tissue within the hand to stimulate the target nerve or tissue within the hand so that tremors experienced pain felt by the subject are mitigated; and

detecting a motion from the subject via at least one sensor positioned on the subject

wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.

2. (Original): The method of claim 1, wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject.

3. (Original): The method of claim 1, wherein the stimulator electrode is a surface electrode.

4. (Original): The method of claim 1, wherein the electrical stimulation is delivered intermittently or on a chronic basis.

5. (Previously Presented): The method of claim 1, further comprising:

detecting nerve stimulation via at least one sensor positioned on the subject;

adjusting or optimizing the electrical stimulation in response to receiving a feedback signal received from the sensor indicative of the detected motion and electrical stimulation thereby providing a feedback about the efficacy of the applied electrical stimulation therapy such that the therapy is adjusted or optimized.

6. (Previously Presented): The method of claim 1, wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude 5 wherein the sensor senses an M-Wave.

7.-9. (Canceled)

10. (Previously Presented): The method of claim 5, wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve within the hand while reducing the risk of burns or intolerance.

11. (Original): The method of claim 5, wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy.

12. (Original): The method of claim 5, wherein the sensor is a surface electrode.

13. (Previously Presented): The method of claim 1, further comprising positioning a return electrode on the subject to facilitate penetration of an electrical current through the glabrous surface to stimulate the target nerve within the hand.

14. (Previously Presented): The method of claim 1, wherein the stimulator electrode is attached to the glabrous skin surface with an adhesive.

15. (Previously Presented): The method of claim 1, wherein the stimulator electrode is positioned over the glabrous skin surface with an ergonomic applicator.

16. (Previously Presented): The method of claim 15, wherein the applicator is a glove or brace configured to be positioned against a skin the palmar surface of a hand such that the electrode delivers electrical stimulation to the target nerve or tissue within the hand.

17. (Original): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes to overcome habituation.

18. (Currently Amended): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes based on feedback provided by the at least one sensor regarding target nerve stimulation or habituation.

19. (Original): The method of claim 1, wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased.

20. (Original): The method of claim 1, wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary.

21. (Canceled)

22. (Previously Presented): The method of claim 1, wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface.

23. (Previously Presented): The method of claim 22, wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.

24. (Previously Presented): The method of claim 22, wherein the at least two electrodes are positioned in opposition relative to one another.

REMARKS

Claims 1-6, 10-20, 22-24 were pending in the present application. By virtue of this response, claim 18 has been amended. Accordingly, claims 1-6, 10-20, 22-24 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.

Objections to the Specification

The specification is objected to because of informalities.

The specification has been amended in paragraphs [0001] and [0002] to update the status of patent applications. The specification has also been updated in paragraphs [0147] and [0376] with respect to the term Bluetooth.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the objection to the specification.

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

Claim 18 is 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.

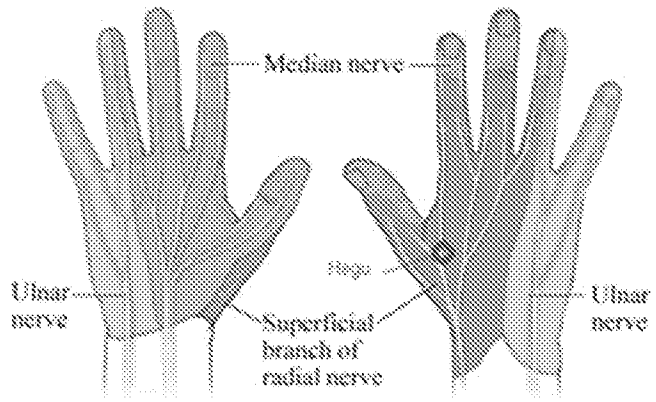
Dependent claim 18 has been amended with respect to the sensor. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §112(b) (pre-AIA 35 U.S.C. §112, second paragraph).

Rejections under 35 U.S.C. §103(a)

A. Claims 1-6, 12-16, 22-24 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zou (U.S. Pub. 2004/0102819) in view of Chang et al. "Effect of Electroacupuncture and Transcutaneous Electrical Nerve Stimulation at Hegu (Ll.4) Acupuncture Point on the Cutaneous Reflex" and in further view of Gliner (U.S. Pub. 2006/0015153).

Applicant respectfully traverses the rejection and contends that the combination of references fail to teach each and every limitation of independent claim 1. The Office indicates that Zou "does not disclose that the stimulation mitigates tremor, detecting motion using a sensor positioned on the subject, or using that sensor reading in a feedback loop to modify stimulation" (*rf.* Office Action, p. 5, para. 7) and further indicates that "Zou discloses stimulating the Hegu acupoint but does not disclose that stimulation mitigates tremor." (*Id.*, para. 8.) The Office then proffers that Chang "discloses a method of transcutaneous electrical stimulation of the Hegu acupoint" and that it would have been obvious to "modify Zou to include stimulating to mitigate tremor as that taught by Chang …." (*Id.*)

The Hegu acupoint of Zou is located specifically along the superficial branch of the radial nerve which extends along the dorsal portion of the back of the hand and along the base of the thumb, as shown below for reference.

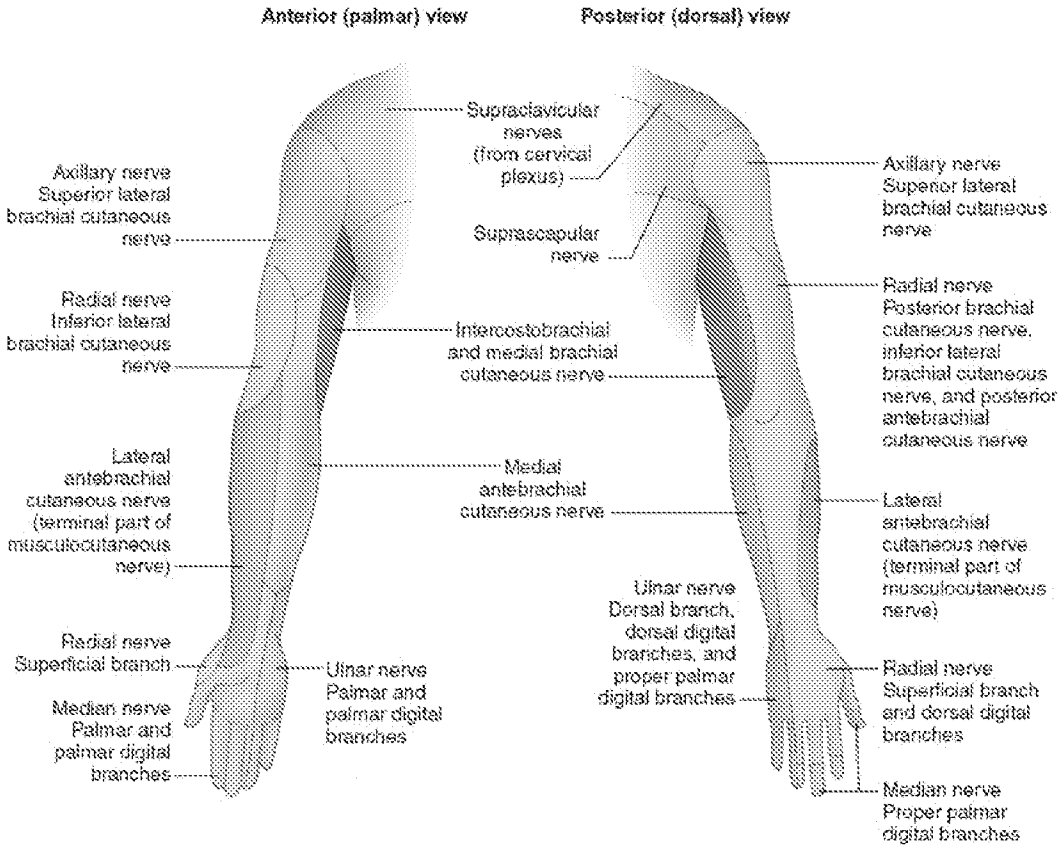


It is also this Hegu point that Chang teaches (acupuncture point LI.4) as the point of application for transcutaneous electrical nerve stimulation. However, the radial nerve does not extend along the palmar surface of the hand and cannot be stimulated by application of electrical stimulation through the glabrous skin surface which overlies the palm of the hand.

Rather, it is the median nerve and the ulnar nerves which innervate the glabrous skin surface and are wholly distinct from the radial nerve. Hence, applying the stimulation at the Hegu point of Chang and Zou both fail to teach delivering electrical stimulation through the glabrous skin surface.

An example of the different nerves innervating the specific areas of the hand is shown below from <www.accessmedicine.com> to illustrate the different regions along the hands which are specific to particular nerves. As shown, the radial nerves do not extend over the

glabrous surfaces of the hands and stimulation applied to the Hegu point cannot the same as delivering stimulation to the glabrous surfaces.



Source: Butterworth JF, Mackey DC, Wasnick JD: *Morgan & Mikhail's Clinical Anesthesiology*, 5th Edition: www.accessmedicine.com

Copyright © The McGraw-Hill Companies, Inc. All rights reserved.

Furthermore, the Office proffers that Chang discloses stimulation to modulate the reflex or tremor caused by Parkinson's disease in the Abstract of Chang but a review of the Abstract shows that there is no teaching or disclosure anywhere of applying stimulation to modulate tremors caused by Parkinson's disease. Hence, Chang further necessarily fails to teach any mitigation of tremors.

Turning now to Gliner, the Office proffers that "Gliner discloses a method of nerve stimulation to mitigate tremor" by "detecting a motion from the subject … adjusting or optimizing the electrical stimulation in response to a feedback signal …." (Office Action, p. 5, para. 9-p. 6, para. 2.) Even assuming, *arguendo*, that Gliner teaches the proffered feedback, Gliner is a completely non-analogous reference to the teachings of either Zou or

Chang and to the claims of the present invention as well. For instance, Gliner teaches the use and implementation of a neural stimulation device which is implanted directly within the brain of a patient where "the first electrode assembly 150 may be positioned to apply stimulation signals to one or more portions of the prefrontal cortex, while the second electrode assembly 152 may be positioned to apply stimulation signals to one or more portions of the motor cortex, the somatosensory cortex, the visual cortex, and/or another neural location." (Gliner, [0053].)

Even as noted in Chang, "either acupuncture or 2Hz EA [electroacupuncture] appeared to have very little effect on spinal cord." (Chang, Abstract.) A treatment as taught by Gliner for implanted direct stimulation within the brain cannot be expected to have the same applicability to a treatment as taught by Chang which has "very little effect on spinal cord" much less effect on the brain of a subject. Thus, Gliner also fails to cure the defects of Zou or Chang.

Therefore, each of the references alone or in combination necessarily fail to teach each and every limitation of independent claim 1 which is patentable. The dependent claims are patentable over each of the references for at least the same reasons.

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

B. Claims 10-11 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zou in view of Chang et al. and in view of Gliner and in further view of Gellman (U.S. Pub. 2005/0283202).

Dependent claims 10-11 depend ultimately from independent claim 1 and are patentable over Zou, Chang et al., and Gliner for at least the same reasons above. Gellman 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).

C. Claims 17-18 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zou in view of Chang et al. and in view of Gliner and in further view of Stephens (WO 2006/092007).

Dependent claims 17-18 depend ultimately from independent claim 1 and are patentable over Zou, Chang et al., and Gliner for at least the same reasons above. Stephens 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).

D. Claims 19-20 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zou in view of Chang et al. and in view of Gliner and in further view of Gellman.

Dependent claims 19-20 depend ultimately from independent claim 1 and are patentable over Zou, Chang et al., and Gliner for at least the same reasons above. Gellman 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).

Double Patenting

A. Claims 1-6, 10-20, 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Pat. 9,630,004.

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

B. Claims 1-6, 10-20, 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Pat. 9,339,641.

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

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. **EMKNNZ00703**.

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

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): EMKNNZ00703

Application Number: 15/474,875

Filed: March 30, 2017

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

Art Unit: 3792

Examiner: Michael J. Carey

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

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:	15474875
Filing Date:	30-Mar-2017
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Filer:	Laura Lan Shires
Attorney Docket Number:	EMKNNZ00703

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 $0 paid	2252	1	300	300
Miscellaneous:				
			Total in USD ($)	**300**

Electronic Acknowledgement Receipt

EFS ID:	37758304
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Laura Lan Shires
Filer Authorized By:	
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	14-NOV-2019
Filing Date:	30-MAR-2017
Time Stamp:	20:00:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$300
RAM confirmation Number	E2019ADK00211066
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_EMKNNZ00703_20191114_response_to_non-final_office_action.pdf	260037 28d68057e5a9202098442a4a2c7ded18f13269f8	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	4
	Claims	5	8
	Applicant Arguments/Remarks Made in an Amendment	9	14

Warnings:

Information:

2	Extension of Time	02_EMKNNZ00703_20191114_extension_of_time.pdf	88389 558bf246d512d84c7179b0f4dd4266f1364da27c	no	1

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	30413 1653c4b60c30237251d950f322e09bcae142b819	no	2

Warnings:

Information:

Total Files Size (in bytes):	378839

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.
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703	7884

40518 7590 06/20/2019

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

EXAMINER	
CAREY, MICHAEL JAMES	

ART UNIT	PAPER NUMBER
3792	

MAIL DATE	DELIVERY MODE
06/20/2019	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. 15/474,875	Applicant(s) RAJGURU et al.	
	Examiner MICHAEL J CAREY	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 2/8/2018.

☐ 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) 1-6,10-20 and 22-24 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) 1-6,10-20 and 22-24 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 6/12/2017 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 6/12/2017, 8/17/2017, 8/1/2018.

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

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Drawings

2. The drawings were received on 6/12/2017. These drawings are acceptable.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. Any application numbers listed in the disclosure should be updated to reflect their patent status (e.g. pending, patented, abandoned) and publication numbers should be provided for any applications that have been published. Specifically, paragraphs [0001] and [0002] need to be corrected. Furthermore, any reference to attorney docket numbers appearing therein should be removed.

5. The use of the term Bluetooth, which is a trade name or a mark used in commerce, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trade names and marks used in commerce (i.e., trademarks, service marks, certification marks, and collective marks) are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as commercial marks.

Claim Rejections - 35 USC § 112

6. 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.

7. Claim 18 is 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. It is unclear if the "a sensor" in line 3 of claim 18 is a new sensor or refers to the previously limited "at least one sensor" in line 9 of claim 1.

Claim Rejections - 35 USC § 103

8. 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.

9. 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.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

12. Claims 1-6, 12-16, and 22-24 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2004/0102819 to Zou (hereinafter "Zou") in view of Chang, Qwang-Yuen, et al "Effect of Electroacupuncture and Transcutaneous Electrical Nerve Stimulation at Hegu (LI.4) Acupuncture Point on the Cutaneous Reflex" (hereinafter "Chang") and U.S. Patent Application Publication 2006/0015153 to Gliner (hereinafter "Gliner"). In regards to claims 1-5, 13-16, and 22-24, Zou discloses a method of providing therapy to a patient comprising:

a. positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject (Fig. 7, 10, [0032]); delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue ([0015])

b. wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject ([0025])

c. wherein the stimulator electrode is a surface electrode ([0031])

d. wherein the electrical stimulation is delivered intermittently or on a chronic basis ([0025])

e. positioning a return electrode on the subject to facilitate penetration of an electrical current through the surface to stimulate the target nerve ([0026])

f. wherein the stimulator electrode is attached to the skin surface with an adhesive ([0015], Claim 1)

g. wherein the stimulator electrode is positioned over the skin surface with an ergonomic applicator (Fig. 8, 2)

h. wherein the applicator is a glove or brace configured to be positioned against a skin surface such that the electrode delivers electrical stimulation to the target nerve or tissue (Fig. 8, 2)

i. wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface (Fig. 7, 10)

j. wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve (Fig. 8, Ulnar and Median nerve are beneath the surface of the palm)

k. wherein the at least two electrodes are positioned in opposition relative to one another (Fig. 7, 10)

However, Zou does not disclose that the stimulation mitigates tremors, detecting motion using a sensor positioned on the subject, or using that sensor reading in a feedback loop to modify stimulation.

In regards to claim 1, Zou discloses stimulating the Hegu acupoint but does not disclose that stimulation mitigates tremor. Chang discloses a method of transcutaneous electrical stimulation of the Hegu acupoint wherein the stimulation modulates the reflex or tremor caused by Parkinson's disease (Abstract). It would have been obvious before the effective filing date of the claimed invention to modify Zou to include stimulating to mitigate tremor such as that taught by Chang in order to enable Parkinson's disease patients with the ability to complete tasks with reduced tremor.

In regards to claims 1, 5, and 12, Gliner discloses a method of nerve stimulation to mitigate tremor comprising:

l. detecting a motion from the subject via at least one sensor positioned on the subject ([0060])

m. adjusting or optimizing the electrical stimulation in response to a feedback signal received from the sensor indicative of the detected motion and efficacy of the applied electrical stimulation therapy ([0060])

n. wherein the sensor is a surface electrode ([0060])

It would have been obvious before the effective filing date of the claimed invention to modify Zou to include a motion sensor and a feedback loop to optimize therapy such as that taught by Gliner in order to recognize the presence of tremor over differing stimulation patterns to determine the best therapy for each patient.

13. Claims 10-11 rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Zou, Chang, and Gliner as applied to claim 5 above, and further in view of U.S. Patent Application Publication 2005/0283202 to Gellman. Zou, Chang, and Gliner do not teach using the feedback loop to provide a minimum amount of stimulation or to optimize the position of the electrode. However, Gellman discloses a method of neural stimulation comprising:

a. wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve while reducing the risk of burns or intolerance ([0036]-[0038])

b. wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy ([0030])

It would have been obvious before the effective filing date of the claimed invention to modify Zou, Chang, and Gliner to include using the feedback loop to provide minimal stimulation and to optimize the electrode position such as that taught by Gellman in order to determine if stimulation is effective and minimize battery drain by producing only the necessary amount of stimulation.

14. Claims 17-18 rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Zou, Chang, and Gliner as applied to claim 1 above, and further in view of WIPO Publication WO 2006/092007 A1 to Stephens (hereinafter "Stephens"). Zou, Chang, and Gliner do not disclose pausing stimulation for a preset amount of time every 10 minutes automatically or in response to sensor feedback. However, in regards to Claims 17 and 18, Stephens discloses a method neural stimulation wherein stimulation is paused every 10 minutes automatically or in response to sensor feedback (paragraph [0043] and Claim 76). It would have been obvious before the effective filing date of the claimed invention to modify Zou, Chang, and Gliner to include a pause in stimulation such as that taught by Stephens in order to avoid overstimulation which may injure the patient or may cause habituation.

15. Claims 19-20 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Zou, Chang, and Gliner as applied to claim 1 above, and further in view of Gellman. Zou, Chang, and Gliner do not disclose adjusting electrical stimulation due to tetany or stimulating in a repeating cycle. However, in regards to claims 50-51 and 61-62, Gellman discloses a neuromodulation method comprising:

a. wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased ([0045])

b. wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary ([0045])

It would have been obvious before the effective filing date of the claim invention to modify Zou, Chang, and Gliner to include adjusting electrical stimulation due to tetany and stimulating in a repeating cycle such as that taught by Gellman in order reduce the amount of power consumed by the device and regulate a patient's nervous system.

Double Patenting

16. 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.

17. Claims 1-6, 10-20, and 22-24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 9,630,004 in view of Chang, Gliner, Gellman, and Zou. The claims of the '004 patent disclose all of the limitations of claims 1-6 and 12-20 of the current application. However, the '004 patent does not disclose that the stimulation mitigates tremor, a motion sensor used in a feedback loop to optimize stimulation, or using at least two electrodes on the skin surface.

In regards to claim 1, Chang discloses a method of transcutaneous electrical stimulation of the Hegu acupoint wherein the stimulation modulates the reflex or tremor caused by Parkinson's disease (Abstract). It would have been obvious before the effective filing date of the claimed invention to modify the '004 patent to include stimulating to mitigate tremor such as that taught by Chang in order to enable Parkinson's disease patients with the ability to complete tasks with reduced tremor.

In regards to claim 1, Gliner discloses a method of nerve stimulation to mitigate tremor comprising: detecting a motion from the subject via at least one sensor positioned on the subject ([0060]). It would have been obvious before the effective filing date of the claimed invention to modify the '004 patent to include a motion sensor and a feedback loop to optimize therapy such as that taught by Gliner in order to recognize the presence of tremor over differing stimulation patterns to determine the best therapy for each patient.

In regards to claims 10-11, Gellman discloses a method of neural stimulation comprising:

a. wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve while reducing the risk of burns or intolerance ([0036]-[0038])

b. wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy ([0030])

It would have been obvious before the effective filing date of the claimed invention to modify the '004 patent to include using the feedback loop to provide minimal stimulation and to optimize the electrode position such as that taught by Gellman in order to determine if stimulation is effective and minimize battery drain by producing only the necessary amount of stimulation.

In regards to claims 22-24, Zou discloses a method of transdermal electrical stimulation:

c. wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface (Fig. 7, 10)

d. wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve (Fig. 8, Ulnar and Median nerve are beneath the surface of the palm)

e. wherein the at least two electrodes are positioned in opposition relative to one another (Fig. 7, 10)

It would have been obvious before the effective filing date of the claimed invention to modify the '004 patent to incorporate two electrodes such as that taught by Zou so that the electrodes could be arranged in a bipolar configuration to stimulate the target nerve.

18. Claims 1-6, 10-20, and 22-24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 9,339,641 in view of Chang, Gliner, and Zou. The claims of the '641 patent disclose all of the limitations of claims 1-6 and 10-20 of the current application. However, the '641 patent does not disclose that the stimulation mitigates tremor, a motion sensor used in a feedback loop to optimize stimulation, or using at least two electrodes on the skin surface.

In regards to claim 1, Chang discloses a method of transcutaneous electrical stimulation of the Hegu acupoint wherein the stimulation modulates the reflex or tremor caused by Parkinson's disease (Abstract). It would have been obvious before the effective filing date of the claimed invention to modify the '004 patent to include stimulating to mitigate tremor such as that taught

by Chang in order to enable Parkinson's disease patients with the ability to complete tasks with reduced tremor.

In regards to claim 1, Gliner discloses a method of nerve stimulation to mitigate tremor comprising: detecting a motion from the subject via at least one sensor positioned on the subject ([0060]). It would have been obvious before the effective filing date of the claimed invention to modify the '004 patent to include a motion sensor and a feedback loop to optimize therapy such as that taught by Gliner in order to recognize the presence of tremor over differing stimulation patterns to determine the best therapy for each patient.

In regards to claims 22-24, Zou discloses a method of transdermal electrical stimulation:

a. wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface (Fig. 7, 10)
b. wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve (Fig. 8, Ulnar and Median nerve are beneath the surface of the palm)
c. wherein the at least two electrodes are positioned in opposition relative to one another (Fig. 7, 10)

It would have been obvious before the effective filing date of the claimed invention to modify the '004 patent to incorporate two electrodes such as that taught by Zou so that the electrodes could be arranged in a bipolar configuration to stimulate the target nerve.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL JAMES CAREY whose telephone number is (571)270-7235. The examiner can normally be reached on Monday-Friday (9am-5pm).

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, Christopher Koharski can be reached on 571-272-7230. 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 J CAREY/
Primary Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/474,875	Applicant(s)/Patent Under Reexamination RAJGURU et al.	
	Examiner MICHAEL J CAREY	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-20040102819-A1	05-2004	Zou, Shazhou	A61N1/36021	607/46
*	B	US-20060015153-A1	01-2006	Gliner; Bradford Evan	A61N1/3606	607/45
*	C	US-20050283202-A1	12-2005	Gellman, Barry N.	A61N1/36007	607/48
*	D	US-9630004-B2	04-2017	Rajguru; Amit	A61N1/0456	1/1
*	E	US-9339641-B2	05-2016	Rajguru; Amit	A61N1/0456	1/1
	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	WO-2006092007-A1	09-2006	WO	STEPHENS TONY	A61N1/0514
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Chang, Qwang-Yuen, et al. "Effect of Electroacupuncture and Transcutaneous Electrical Nerve Stimulation at Hegu (LI.4) Acupuncture Point on the Cutaneous Reflex." 2002. Acupuncture & Electro-Therapeutics Research. Volume 27, Numbers 3-4. Pages 191-202. (Abstract Only) (Year: 2002)
	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
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	MICHAEL J CAREY	3792

CPC - Searched*		
Symbol	Date	Examiner
a61n2/02, 004	6/18/2019	MC
a61n1/3787, 36057, 36021, 36017, 36007, 0551, 0456	6/18/2019	MC
a61b5/4047	6/18/2019	MC

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
607	144	6/18/2019	MC

* 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
Text Limited Search	6/13/2019	MC
Google Patent Search	6/18/2019	MC
Google Scholar Search	6/18/2019	MC
Inventor and Assignee Search	6/18/2019	MC
IDS References Considered	6/18/2019	MC
Text Limited Search	6/19/2019	MC

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

/MICHAEL J CAREY/ Primary Examiner, Art Unit 3792	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	MICHAEL J CAREY	3792

/MICHAEL J CAREY/ Primary Examiner, Art Unit 3792	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/474,875	RAJGURU et al.
	Examiner	Art Unit
	MICHAEL J CAREY	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

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

CLAIM		DATE								
Final	Original	06/19/2019								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	-								
	8	-								
	9	-								
	10	✓								
	11	✓								
	12	✓								
	13	✓								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								
	21	-								
	22	✓								
	23	✓								
	24	✓								

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

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.	5,067,478	11-26-1991	Berlant	
	21.	5,092,835	03-03-1992	Schurig et al.	
	22.	5,158,080	10-27-1992	Kallok	
	23.	5,181,902	01-26-1993	Erickson et al.	
	24.	5,309,909	05-10-1994	Gadsby et al	
	25.	5,314,401	05-24-1994	Tepper	
	26.	5,314,453	05-24-1994	Jeutter	
	27.	5,401,233	03-28-1995	Erickson et al.	
	28.	5,449,378	09-12-1995	Schouenborg	
	29.	5,518,495	05-21-1996	Kolt	
	30.	5,540,735	07-30-1996	Wingrove	
	31.	5,562,707	10-08-1996	Prochazka et al.	
	32.	5,690,693	11-25-1997	Wang et al.	
	33.	5,715,837	02-10-1998	Chen	
	34.	5,725,471	03-10-1998	Davey et al.	
	35.	5,749,909	05-12-1998	Schroeppel et al.	
	36.	5,766,124	06-16-1998	Polson	
	37.	5,792,187	08-11-1998	Adams	
	38.	5,792,209	08-11-1998	Varner	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

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	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	39.	5,833,600	11-10-1998	Young	
	40.	5,857,957	01-12-1999	Lin	
	41.	5,978,712	11-02-1999	Suda et al.	
	42.	5,984,854	11-16-1999	Ishikawa et al.	
	43.	6,009,878	01-04-2000	Weijand et al.	
	44.	6,024,691	02-15-2000	Tepper et al.	
	45.	6,029,090	02-22-2000	Herbst	
	46.	6,032,677	03-07-2000	Blechman et al.	
	47.	6,066,084	05-23-2000	Edrich et al.	
	48.	6,086,525	07-11-2000	Davey et al.	
	49.	6,088,619	07-11-2000	Hein et al.	
	50.	6,123,658	09-26-2000	Schweighofer et al.	
	51.	6,143,035	11-07-2000	McDowell	
	52.	6,155,966	12-05-2000	Parker	
	53.	6,179,770	01-30-2001	Mould	
	54.	6,190,893	02-20-2001	Shastri et al.	
	55.	6,200,259	03-13-2001	March	
	56.	6,213,933	04-10-2001	Lin	
	57.	6,219,575	04-17-2001	Nemati	
	58.	6,256,533	07-03-2001	Yuzhakov et al.	
	59.	6,261,221	07-17-2001	Tepper et al.	
	60.	6,312,612	11-06-2001	Sherman et al.	
	61.	6,319,241	11-20-2001	King et al.	
	62.	6,334,856	01-01-2002	Allen et al.	
	63.	6,349,233	02-19-2002	Adams	
	64.	6,366,795	04-02-2002	Bremer et al.	
	65.	6,379,324	04-30-2002	Gartstein et al.	
	66.	6,440,096	08-27-2002	Lastovich et al.	
	67.	6,443,883	09-03-2002	Ostrow et al.	
	68.	6,451,240	09-17-2002	Sherman et al.	
	69.	6,471,903	10-29-2002	Sherman et al.	
	70.	6,473,652	10-29-2002	Sarwal et al.	
	71.	6,491,620	12-10-2002	Davey	
	72.	6,493,588	12-10-2002	Malaney et al.	
	73.	6,500,110	12-31-2002	Davey et al.	
	74.	6,503,231	01-07-2003	Prausnitz et al.	
	75.	6,511,463	01-28-2003	Wood et al.	
	76.	6,527,694	03-04-2003	Ishikawa et al.	
	77.	6,533,949	03-18-2003	Yeshurun et al.	
	78.	6,537,242	03-25-2003	Palmer	
	79.	6,553,263	04-22-2003	Meadows et al.	
	80.	6,558,361	05-06-2003	Yeshurun	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

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	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	81.	6,565,532	05-20-2003	Yuzhakov et al.	
	82.	6,582,393	06-24-2003	Sage, Jr.	
	83.	6,591,124	07-08-2003	Sherman et al.	
	84.	6,595,947	07-22-2003	Mikszta et al.	
	85.	6,603,987	08-05-2003	Whitson	
	86.	6,611,707	08-26-2003	Prausnitz et al.	
	87.	6,622,035	09-16-2003	Merilainen et al.	
	88.	6,623,457	09-23-2003	Rosenberg	
	89.	6,652,443	11-25-2003	Struppler et al.	
	90.	6,652,478	11-25-2003	Gartstein et al.	
	91.	6,654,636	11-25-2003	Dev et al.	
	92.	6,656,147	12-02-2003	Gertsek et al.	
	93.	6,663,556	12-16-2003	Barker	
	94.	6,663,820	12-16-2003	Arias et al.	
	95.	6,671,527	12-30-2003	Petersson et al.	
	96.	6,678,556	01-13-2004	Nolan et al.	
	97.	6,684,106	01-27-2004	Herbst	
	98.	6,689,100	02-10-2004	Connelly et al.	
	99.	6,690,959	02-10-2004	Thompson	
	100.	6,697,669	02-24-2004	Dev et al.	
	101.	6,701,185	03-02-2004	Burnett et al.	
	102.	6,735,474	05-11-2004	Loeb et al.	
	103.	6,743,211	06-01-2004	Prausnitz et al.	
	104.	6,767,341	07-27-2004	Cho	
	105.	6,770,022	08-03-2004	Mechlenburg et al.	
	106.	6,770,480	08-03-2004	Canham	
	107.	6,782,283	08-24-2004	Schmidt et al.	
	108.	6,790,372	09-14-2004	Roy et al.	
	109.	6,808,506	10-26-2004	Lastovich et al.	
	110.	6,835,184	12-28-2004	Sage et al.	
	111.	6,866,659	03-15-2005	Nemati	
	112.	6,881,203	04-19-2005	Delmore et al.	
	113.	6,899,838	05-31-2005	Lastovich	
	114.	6,908,453	06-21-2005	Fleming et al.	
	115.	6,926,660	08-09-2005	Miller	
	116.	6,931,277	08-16-2005	Yuzhakov et al.	
	117.	6,939,311	09-06-2005	Geiger	
	118.	6,941,171	09-06-2005	Mann et al.	
	119.	6,960,193	11-01-2005	Rosenberg	
	120.	6,962,772	11-08-2005	Liu et al.	
	121.	6,972,013	12-06-2005	Zhang et al.	
	122.	6,980,855	12-27-2005	Cho	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	4	of	13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	123.	7,013,179	03-14-2006	Carter et al.	
	124.	7,027,478	04-11-2006	Ackley	
	125.	7,032,302	04-25-2006	Schmidt et al.	
	126.	7,045,069	05-16-2006	Ozeryansky	
	127.	7,047,070	05-16-2006	Wilkinson et al.	
	128.	7,048,723	05-23-2006	Frazier et al.	
	129.	7,079,355	07-18-2006	Hsiao et al.	
	130.	7,083,592	08-01-2006	Lastovich et al.	
	131.	7,104,947	09-12-2006	Riehl	
	132.	7,115,108	10-03-2006	Wilkinson et al.	
	133.	7,117,034	10-03-2006	Kronberg	
	134.	7,130,696	10-31-2006	Carter et al.	
	135.	7,132,054	11-07-2006	Kravitz et al.	
	136.	7,153,256	12-26-2006	Riehl et al.	
	137.	7,187,976	03-06-2007	Duncan et al.	
	138.	7,226,439	06-05-2007	Prausnitz et al.	
	139.	7,262,068	08-28-2007	Roy et al.	
	140.	7,273,474	09-25-2007	Chang et al.	
	141.	7,285,113	10-23-2007	Yeshurun	
	142.	7,315,758	01-01-2008	Kwiatkowski et al.	
	143.	7,316,665	01-08-2008	Laurent et al.	
	144.	7,320,664	01-22-2008	Riehl et al.	
	145.	7,332,197	02-19-2008	Wood et al.	
	146.	7,332,339	02-19-2008	Canham	
	147.	7,344,499	03-18-2008	Prausnitz et al.	
	148.	7,367,936	05-06-2008	Myers et al.	
	149.	7,396,326	07-08-2008	Ghiron et al.	
	150.	7,410,476	08-12-2008	Wilkinson et al.	
	151.	7,415,299	08-19-2008	Zimmermann et al.	
	152.	7,416,541	08-26-2008	Yuzhakov et al.	
	153.	7,429,333	09-30-2008	Chiou et al.	
	154.	7,473,244	01-06-2009	Frazier et al.	
	155.	7,481,337	01-27-2009	Luharuka et al.	
	156.	7,497,980	03-03-2009	Xu et al.	
	157.	7,500,911	03-10-2009	Johnson et al.	
	158.	7,520,848	04-21-2009	Schneider et al.	
	159.	7,522,061	04-21-2009	Rondoni et al.	
	160.	7,530,968	05-12-2009	Gonnelli	
	161.	7,536,226	05-19-2009	Williams et al.	
	162.	7,556,615	07-07-2009	Pettis et al.	
	163.	7,556,821	07-07-2009	Ameri et al.	
	164.	7,560,036	07-14-2009	Golubovic-Liakopoulos et al.	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	165.	7,570,992	08-04-2009	Nolan et al.	
	166.	7,572,405	08-11-2009	Sherman et al.	
	167.	7,574,256	08-11-2009	Carter	
	168.	7,578,954	08-25-2009	Gartstein et al.	
	169.	7,582,069	09-01-2009	Laurent et al.	
	170.	7,588,552	09-15-2009	Yeshurun et al.	
	171.	7,591,806	09-22-2009	Xu	
	172.	7,627,938	12-08-2009	Kim et al.	
	173.	7,647,112	01-12-2010	Tracey et al.	
	174.	7,648,484	01-19-2010	Yeshurun et al.	
	175.	7,651,946	01-26-2010	Wilke et al.	
	176.	7,658,728	02-09-2010	Yuzhakov	
	177.	7,941,201	05-10-2011	Chiou et al.	
	178.	8,430,805	04-30-2013	Burnett et al.	
	179.	8,435,166	05-07-2013	Burnett et al.	
	180.	2002/0028991	03-07-2002	Thompson	
	181.	2002/0082465	06-27-2002	Bashford et al.	
	182.	2002/0099323	07-25-2002	DEV et al.	
	183.	2002/0111777	08-15-2002	David	
	184.	2002/0133129	09-19-2002	Arias et al.	
	185.	2002/0183647	12-05-2002	Gozani et al.	
	186.	2002/0183804	12-05-2002	Malaney et al.	
	187.	2003/0028072	02-06-2003	Fischell et al.	
	188.	2003/0144625	07-31-2003	Sherman et al.	
	189.	2003/0158583	08-21-2003	Burnett et al.	
	190.	2003/0158585	08-21-2003	Burnett	
	191.	2003/0216729	11-20-2003	Marchitto et al.	
	192.	2003/0217754	11-27-2003	Thomas et al.	
	193.	2004/0010276	01-15-2004	Jacobs et al.	
	194.	2004/0054393	03-18-2004	Stemme et al.	
	195.	2004/0082875	04-29-2004	Donoghue et al.	
	196.	2004/0092860	05-13-2004	Dev et al.	
	197.	2004/0102819	05-27-2004	Zou et al.	
	198.	2004/0111139	06-10-2004	McCreery	
	199.	2004/0122787	06-24-2004	Avanash et al.	
	200.	2004/0127939	07-01-2004	Grey	
	201.	2004/0138517	07-15-2004	Osorio et al.	
	202.	2004/0146611	07-29-2004	Arias et al.	
	203.	2004/0147964	07-29-2004	Nolan et al.	
	204.	2004/0173220	09-09-2004	Harry et al.	
	205.	2004/0210254	10-21-2004	Burnett et al.	
	206.	2004/0210282	10-21-2004	Flock et al.	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	207.	2004/0237170	12-02-2004	Yamazaki et al.	
	208.	2005/0021104	01-27-2005	Dilorenzo	
	209.	2005/0029223	02-10-2005	Yeshurun	
	210.	2005/0033380	02-10-2005	Tanner et al.	
	211.	2005/0099290	05-12-2005	Govari	
	212.	2005/0107654	05-19-2005	Riehl	
	213.	2005/0143783	06-30-2005	Boveja et al.	
	214.	2005/0143789	06-30-2005	Whitehurst et al.	
	215.	2005/0171576	08-04-2005	Williams et al.	
	216.	2005/0203602	09-15-2005	Wallace et al.	
	217.	2005/0240230	10-27-2005	Preston et al.	
	218.	2005/0277998	12-15-2005	Tracey et al.	
	219.	2005/0283202	12-22-2005	Gellman	
	220.	2005/0283204	12-22-2005	Buhlmann et al.	
	221.	2006/0004244	01-05-2006	Phillips et al.	
	222.	2006/0016452	01-26-2006	Goetz et al.	
	223.	2006/0030845	02-09-2006	Leung et al.	
	224.	2006/0047316	03-02-2006	Fischell et al.	
	225.	2006/0049957	03-09-2006	Surgenor et al.	
	226.	2006/0052839	03-09-2006	Kim et al.	
	227.	2006/0084938	04-20-2006	Zhang et al.	
	228.	2006/0122454	06-08-2006	Riehl et al.	
	229.	2006/0122660	06-08-2006	Boveja et al.	
	230.	2006/0135844	06-22-2006	Alekseyenko	
	231.	2006/0161039	07-20-2006	Juliana et al.	
	232.	2006/0173261	08-03-2006	Kali et al.	
	233.	2006/0178576	08-10-2006	Weber et al.	
	234.	2006/0184211	08-17-2006	Gaunt et al.	
	235.	2006/0199159	09-07-2006	Ghiron et al.	
	236.	2006/0276702	12-07-2006	Mcginnis	
	237.	2007/0021712	01-25-2007	Bernard et al.	
	238.	2007/0021803	01-25-2007	Deem et al.	
	239.	2007/0027353	02-01-2007	Ghiron et al.	
	240.	2007/0027354	02-01-2007	Riehl et al.	
	241.	2007/0027355	02-01-2007	Riehl et al.	
	242.	2007/0142885	06-21-2007	Hantash et al.	
	243.	2007/0208212	09-06-2007	Dilorenzo	
	244.	2007/0250162	10-25-2007	Royalty	
	245.	2007/0265489	11-15-2007	Fowler et al.	
	246.	2007/0265675	11-15-2007	Lund et al.	
	247.	2007/0276318	11-29-2007	Henley	
	248.	2007/0282246	12-06-2007	Henley	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 7 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	249.	2008/0004484	01-03-2008	Wieraszko et al.	
	250.	2008/0033510	02-07-2008	Herregraven et al.	
	251.	2008/0058874	03-06-2008	Westlund et al.	
	252.	2008/0063866	03-13-2008	Allen et al.	
	253.	2008/0114199	05-15-2008	Riehl et al.	
	254.	2008/0177128	07-24-2008	Riehl et al.	
	255.	2008/0177347	07-24-2008	Tehrani et al.	
	256.	2008/0183070	07-31-2008	Unal et al.	
	257.	2008/0200748	08-21-2008	Testani et al.	
	258.	2008/0224808	09-18-2008	Ghiron et al.	
	259.	2008/0262287	10-23-2008	Dussau	
	260.	2008/0288035	11-20-2008	Gill et al.	
	261.	2008/0300655	12-04-2008	Cholette	
	262.	2008/0306325	12-11-2008	Burnett et al.	
	263.	2008/0312725	12-18-2008	Penner	
	264.	2009/0030337	01-29-2009	Gozani et al.	
	265.	2009/0054950	02-26-2009	Stephens	
	266.	2009/0073991	03-19-2009	Landrum et al.	
	267.	2009/0076336	03-19-2009	Mazar et al.	
	268.	2009/0076340	03-19-2009	Libbus et al.	
	269.	2009/0076344	03-19-2009	Libbus et al.	
	270.	2009/0076345	03-19-2009	Manicka et al.	
	271.	2009/0076363	03-19-2009	Bly et al.	
	272.	2009/0076364	03-19-2009	Libbus et al.	
	273.	2009/0076397	03-19-2009	Libbus et al.	
	274.	2009/0076410	03-19-2009	Libbus et al.	
	275.	2009/0076559	03-19-2009	Libbus et al.	
	276.	2009/0076565	03-19-2009	Surwit	
	277.	2009/0099623	04-16-2009	Bentwich	
	278.	2009/0102819	05-27-2004	Zou et al.	
	279.	2009/0118777	05-07-2009	Iki et al.	
	280.	2009/0132018	05-21-2009	DiUbaldi et al.	
	281.	2009/0162570	06-25-2009	Swenberg et al.	
	282.	2009/0171236	07-02-2009	Davies	
	283.	2009/0227829	09-10-2009	Burnett et al.	
	284.	2009/0227831	09-10-2009	Burnett et al.	
	285.	2009/0234179	09-17-2009	Burnett et al.	
	286.	2009/0234410	09-17-2009	Libbus et al.	
	287.	2009/0264792	10-22-2009	Mazar	
	288.	2009/0292194	11-26-2009	Libbus et al.	
	289.	2010/0022864	01-28-2010	Cordero et al.	
	290.	2010/0049021	02-25-2010	Jina et al.	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 8 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	291.	2010/0056881	03-04-2010	Libbus et al.		
	292.	2010/0057147	03-04-2010	Fassih et al.		
	293.	2010/0057149	03-04-2010	Fahey		
	294.	2010/0119482	05-13-2010	Yun et al.		
	295.	2010/0160712	06-24-2010	Burnett et al.		
	296.	2010/0161005	06-24-2010	Wahlgren et al.		
	297.	2010/0168501	07-01-2010	Burnett et al.		
	298.	2010/0204538	08-12-2010	Burnett et al.		
	299.	2010/0222629	09-02-2010	Burnett et al.		
	300.	2010/0222630	09-02-2010	Mangrum et al.		
	301.	2010/0318009	12-16-2010	Stanley		
	302.	2011/0021863	01-27-2011	Burnett et al.		
	303.	2011/0264163	10-27-2011	Tracey et al.		
	304.	2011/0295100	12-01-2011	Hedge et al.		
	305.	2012/0059432	03-08-2012	Emborg et al.		
	306.	2012/0302821	11-29-2012	Burnett		
	307.	2013/0006322	01-03-2013	Tai		
	308.	2013/0072746	03-21-2013	Burnett et al.		
	309.	2013/0310909	11-21-2013	Simon et al.		
	310.	2014/0046423	02-13-2014	Rajguru et al.		
	311.	2014/0213842	07-31-2014	Simon et al.		
	312.	2016/0067515	03-10-2016	Burnett et al.		
	313.	2016/0067517	03-10-2016	Burnett		
	314.	2016/0074671	03-17-2016	Burnett et al.		
	315.	D571920	06-24-2008	Juliana 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]
	316.	CN 1083402	03-09-1994	CHEN		
	317.	EP 2456512	05-30-2012	EMKINETICS, INC.		
	318.	EP 2456519	05-30-2012	EMKINETICS, INC.		
	319.	EP 2493551	09-05-2012	EMKINETICS, INC.		
	320.	EP 2493552	09-05-2012	EMKINETICS, INC.		
	321.	GB 0637560	05-24-1950	PANNELL		
	322.	GB 2298370	09-04-1996	THE MAGSTIM COMPANY LIMITED		
	323.	GB 2336544	10-27-1999	THE MAGSTIM COMPANY LIMITED		
	324.	JP 2000-254239	09-19-2000	APOLLO MEC:KK		
	325.	JP 2009-153904	07-16-2009	ITO CO. LTD. et al.		
	326.	WO 2003/070317	08-28-2003	THERA NOVA LLC		

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)* Sheet 9 of 13	*Complete if Known*	
	Application Number	15/474,875
	Filing Date	March 30, 2017
	First Named Inventor	Amit RAJGURU
	Art Unit	3766
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	EMKNNZ00703

	327.	WO 2006/061688	06-15-2006	STANDEN LTD.		
	328.	WO 2008/032279	03-20-2008	KONINKLIJKE PHILIPS ELECTRONICS N.V.		
	329.	WO 2008/042902	04-10-2008	EMKINETICS, INC.		
	330.	WO 2008/115426	09-25-2008	BOSTON SCIENTIFIC NEUROMODULATION CORPORATION		
	331.	WO 2010/047599	04-29-2010	MED STORM INNOVATION A		
	332.	WO 2011/011748	01-27-2011	EMKINETICS, INC.		
	333.	WO 2011/011749	01-27-2011	EMKINETICS, INC.		
	334.	WO 2011/0150502	12-08-2011	TORONTO REHABILITATION INST.		
	335.	WO 2011/053607	05-05-2011	EMKINETICS, INC.		
	336.	WO 2011/053661	05-05-2011	EMKINETICS, INC.		
	337.	WO 2011/150332	12-01-2011	EMKINETICS, INC.		
	338.	WO 2012/040243	03-29-2012	EMKINETICS, INC.		
	339.	WO 2014/0151431	09-25-2014	EMKINETICS, INC.		

*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[6]
	340.	"Bioflex® RX754P, Single Coated Medical Pressure Sensitive Adhesive Tape," *Technical Data*, 2 pages, December 2005.	
	341.	3M Corporation, "3M™ XYZ/Isotropic Electrically Conductive Adhesive Transfer Tape 9707, *3M Electronics Markets Materials Division*, 60-5002-0350-4, 8 pages, 2004, 3M.	
	342.	AARON, Roy K. et al., "Therapeutic Effects of Electromagnetic Fields in the Stimulation of Connective Tissue Repair," *Journal of Cellular Biography*, 52(1):42-6, May 1993, Wiley-Liss, Inc.	
	343.	AmGel Technologies, "AG603 Sensing Gel, Sensing Gel Designed for ECG Applications," AG603-3/10, 1 page, 2010.	
	344.	AmGel Technologies, "AG702 Stimulating Gel, Stimulating Gel Designed for carbon film," AG702-02/06, 1 page, 2006.	
	345.	AmGel Technologies, "AG902-184/229 Grounding Gel, Grounding Gel Designed for Electrosurgical Pads," AG902 Series, 1 page, 2010.	
	346.	AmGel Technologies, "Release Films," 1 Page, July 25, 2006, Revision 1.	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 10 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	347.	BALMASEDA, Marion T. Jr., et al., "Burns in Functional Electric Stimulation: Two Case Reports," *Archives of Physical Medicine and Rehabilitation*, vol. 38., pp. 452-453, July 1987	
	348.	Biowave Corporation, "510(k) Summary for the Biowave Deepwave Neuromodulation Pain Therapy Device," 6 pages, Appendix B, December 13, 2005.	
	349.	Biowave Corporation, "510(k) Summary for the Biowave Deepwave Neuromodulation Pain Therapy Device," 7 pages, Appendix E, August 15, 2006.	
	350.	Biowave Corporation, "Percutaneous Neuromodulation Pain Therapy System," *deepwave*, RevB/080926, 2008.	
	351.	BlueCross BlueShield of Kansas City, "Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)," 7 pages, 1988.	
	352.	BODHALE, D.W. et al., "Design, fabrication and analysis of silicon microneedles for transdermal drug delivery applications," *Proceedings of the 3rd International Conference on the Development of BME in Vietnam*, pages 84-88, January 11-14 2010.	
	353.	BRUCE, C.J. et al., "Intracardiac Echocardiography," *European Journal Echocardiography*, Volume 2, pages 234-244, 2001, The European Society of Cardiology.	
	354.	CABODEVILA, G. et al., "An overview on drug delivery using microneedles", *Institute FEMTO-ST, Dept LPMO,* 24 pages, October 2005, Workshop Micro Dosing Systems.	
	355.	CERTIFIED PULSED SIGNAL THERAPY CENTERS, http://www.certifiedpst.com, 10 pages.	
	356.	CHOI, S. et al., "Microneedle Electrode Array for Electroporation of Skin for Gene Therapy," 2 pages, 2005, Controlled Release Society 32nd Annual Meeting and Exposition TRANSACTIONS.	
	357.	CURLEY, S. et al., "Radiofrequency Ablation of Unresectable Primary and Metastatic Hepatic Malignancies," *Annals of Surgery*, Volume 230(1):1-8, 1999 Lippincott Williams & Wilkins, Inc.	
	358.	CystoMedix, Inc., "Percutaneous Tibial Nerve Stimulation via Urgent ® PC Neuromodulation System - An Emerging Technology for managing Overactive Bladder," *Business Briefing: Global Surgery*, 6 pages, 2004.	
	359.	EBI, L.P., EBI BONE HEALING SYSTEM, http://www.ebimedical.com/products/fracture/bonehealing.html, 5 pages.	
	360.	Fallon Community Health Plan, "Spinal Cord Stimulation," 4 pages, 2006.	
	361.	GRUNDFEST H. et al., "Stainless Steel Micro-Needle Electrodes Made by Electrolytic Pointing," *Review of Scientific Instruments*, Volume 21(4):2 pages, 1950, American Institute of Physics.	
	362.	HARVINDER S. Gill et al., "Effect of microneedle design on pain in human subjects," *NIH Public Access Author Manuscript*, 24(7): 585-594, September 2008, Clinical Journal of Pain.	
	363.	HUBER, D.E. et al., "Popliteal Vein Compression Under General Anaesthesia," *European Journal of Vascular and Endovascular Surgery*, Volume 37, pages 464-	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 11 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

		469, 2009, Elsevier Ltd.	
	~~364.~~	ISSEROFF, Roslyn R. et al., "Beta Adrenergic Receptor (βAR) Signaling as a novel target for optimizing skin wound healing", 5 pages.	
	365.	JACOBSON, Jerry I. et al., "Low-Amplitude, Extremely Low Frequency Magnetic Fields for the Treatment of Osteoarthritic Knees: A Double-Blind Clinical Study," *Electromagnetic Fields and Human Health. Fundamental and Applied Research*, pp. 363-364, September 17-24 2002, Proceedings of the Third International Conference.	
	366.	JASPER, H. et al., "Unipolar Electromyograms of Normal and Denervated Human Muscle," pages 231-244, October 12, 1948, Department of Neurology and Neurosurgery, McGill University, and Montreal Neurological Institute.	
	~~367.~~	KRAVITZ, S. et al., "Microneedles for *In-Situ/In-vivo* Electrochemical Sensor Applications, 1 page, Sandia National Laboratories.	
	368.	KURTZKE, John F., "Epidemiology of Spinal Cord Injury," *IV Panamerican Congress of Neurology*, 18(2-3): 157-90, 93, 1975.	
	369.	LIN et al., "Magnetic Stimulation of the Bladder in Dogs," AAEM Annual Meeting 1993, *Muscle & Nerve*, October 1993 (Abstract)	
	370.	LUTTGE, R. "Microneedle array electrode for human EEG recording," IFMBE Proceedings 22, pages 1246-1249, 2008, Springer-Verlag Berlin Heidelberg 2009.	
	371.	MAASS et al., "Contactless Nerve Stimulation and Signal Detection by Inductive Transducer," *Symposium on Application of Magnetism in Bioengineering*, 1969.	
	372.	MCFARLANE, J.P. et al., "Acute Suppression of Idiopathic Detrusor Instability with Magnetic Stimulation of the Sacral Nerve Roots," *British Journal of Urology*, 80(5): 734-41, November 1997.	
	373.	MORRISON, P.R. et al., "Radiofrequency Ablation of Thoracic Lesions: Part I, Experiments in the Normal Porcine Thorax," *American Journal of Roentgenology*, 2005;184:375–380, February 2005, American Roentgen Ray Society.	
	374.	NeuroStar TMS Therapy, "NeuroStar TMS Therapy® Recipient of Medical Design Excellence Award, *PRNewswire*, 3 pages, April 2009.	
	375.	Newmark, Inc., "Standard Products, Highest Quality Components, Designed & Produced Exclusively for Electrode Manufacturers," *Innovation by Design Newmark*, 2 pages, www.newmarkine.com/std_prods.htm, printed on May 3, 2010.	
	376.	NOBLE, J.H. et al., "Automatic segmentation of the facial nerve and chorda tympani in CT images using spatially dependent features values", Medical Phsysics, Volume 35(12), pages 5375-5384, December 2008, American Association Physical Medicine.	
	377.	PATEL, G. et al., "Microneedles: The option for painless delivery," www.pharmainfo.net/reviews/microneedles-option-painless-delivery, 6 pages, printed on September 9, 2008.	
	378.	*PubMed, U.S. National Library of Medicine National Institutes of Health*, microneedle array electrode - Pub Med results, www.ncbi.nlm.nig.gov/sites/entrez, 2 pages, Search performed on April 22, 2010.	
	379.	*PubMed, U.S. National Library of Medicine National Institutes of Health*, microneedle electrode - Pub Med results, www.ncbi.nlm.nig.gov/sites/entrez, 7 pages, Search performed on April 22, 2010.	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 12 of 13

Complete if Known	
Application Number	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

	380.	SCHAEFER, O. et al., "CT-guided radiofrequency ablation of a bronchogenic carcinoma," *The British Journal of Radiology*, 76 (2003), pages 268-270, 2003, The British Institute of Radiology.	
	381.	SHAFIK, Ahmed, "Magnetic Stimulation: A Novel Method for Inducing Evacuation of the Neuropathic Rectum and Urinary Bladder in a Canine Model," *Urology* 54(2): 368-372, August 1999.	
	382.	SHERIDAN, MT. et al., "Pretreatment apoptosis in carcinoma of the cervix correlates with changes in tumour oxygenation during radiotherapy," *British Journal of Cancer*, 82(6):1177-1182, 2000 Cancer Research Campaign.	
	383.	SIVAGANGABALAN, G. et al., "Comparison of Electroanatomic Contact and Noncontact Mapping of Ventricular Scar in a Postinfarct Ovine Model With Intramural Needle Electrode Recording and Histological Validation," *Circulation: Arrhythmia and Electrophysiology, Journal of the American Heart Association*, Volume 1:363-369, 2008, American Heart Association.	
	384.	SOLBIATI, L. et al., "Percutaneous US-guided Radio-Frequency Tissue Ablation of Liver Metastases: Treatment and Follow-up in 16 Patients," *Radiology*, 202(1):195-203, 1997 L.S. RSNA.	
	385.	The Magstim Company Ltd, "Air Film Coil," *Magstim*, 4 pages, 2007.	
	386.	THON, W.F. et al., "Neuromodulation of voiding dysfunction and pelvic pain," *World Journal of Urology*, Volume 9: pages 138-141, 1991, Springer-Verlag.	
	387.	TROCK, David H., "Electromagnetic Fields and Magnets Investigational Treatment for Musculoskeletal Disorders," *Rheumatic Diseases Clinics of North America*, vol. 26, No. 1., February 2000.	
	388.	TROCK, David H., et al., "The Effect of Pulsed Electromagnetic Fields in the Treatment of Osteoarthritis of the Knee and Cervical Spine. Report of Randomized, Double Blind, Placebo Controlled Trials," *The Journal of Rheumatology*, 1903-1911, 1994.	
	~~389.~~	~~Tyco Adhesives, "2032 Designed Adhesives," Specialty Tape Group, 1 page.~~	
	390.	vanSonnenberg, E. et al., "Radiofrequency Ablation of Thoracic Lesions: Part 2, Initial Clinical Experience—Technical and Multidisciplinary Considerations in 30 Patients," *American Journal of Roentgenology*, 2005;184:381–390, February 2005, American Roentgen Ray Society.	
	391.	WANICH, T. et al, "A Randomized Placebo-Controlled Study To Determine Safety and Efficacy In Terms Of Pain Reduction, Increased Range Of Motion, And Reduced Pain Medications, For A Novel Percutaneous Neuromodulation Pain Therapy Device ("Deepwave®") Following Post-Operative Treatments For Total Knee Replacement Procedures,"American Academy of Orthopaedic Surgeons 2009 Annual Meeting", 6 pages, February 25-28, 2008, Biowave Corporation.	
	392.	WARWICK, K. et al., "The Application of Implant Technology for Cybernetic Systems," *Archives of Neurology*, Volume 60:1369-1373, October 2003, American Medical Association.	
	393.	WIJKSTRDA et al., "Selective Stimulation and Blocking of Sacral Nerves: Research Setup and Preliminary Results," *Annual International Conference of the IEEE*	

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	15/474,875
				Filing Date	March 30, 2017
				First Named Inventor	Amit RAJGURU
				Art Unit	3766
				Examiner Name	Not Yet Assigned
Sheet	13	of	13	Attorney Docket Number	EMKNNZ00703

		Engineering in Medicine and Biology Society, Vol. 13, No. 2, 1991.	
	394.	WILKE, N. et al., "Fabrication and Characterisation of Microneedle Electrode Arrays using Wet Etch Technologies," 5 pages, October 20-21 2004, EMN04, NMRC, University College.	
	395.	ZHAO, M., "Genetic Analysis of Electric Signal-directed Cell Movement," 33 pages, April 8, 2008, Modelling Complex Biological Systems in the Context of Genomics.	
	396.	Zoll Lifecor Corporation, "What is the LifeVest Wearable Defibrillator," http://www.lifecor.com/about_lifevest/about.asp#, 1 page, printed on January 7, 2011.	

*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 J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 September 2006 (08.09.2006)

PCT

(10) International Publication Number
WO 2006/092007 A1

(51) International Patent Classification:
A61N 1/36 (2006.01)

(21) International Application Number:
PCT/AU2006/000258

(22) International Filing Date: 2 March 2006 (02.03.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2005900957 2 March 2005 (02.03.2005) AU

(71) Applicant *(for all designated States except US)*: **CONTINENCE CONTROL SYSTEMS INTERNATIONAL PTY LTD** [AU/AU]; Suite 502, 282 Victoria Avenue, Chatswood, New South Wales 2067 (AU).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **STEPHENS, Tony** [AU/AU]; Continence Control Systems International Pty LTD sUITE 502, 282 victoria Avenue, Chatswood, New South Wales 2067 (AU).

(74) Agent: **GRIFFITH HACK**; Gpo Box 4164, Sydney, New South Wales 2001 (AU).

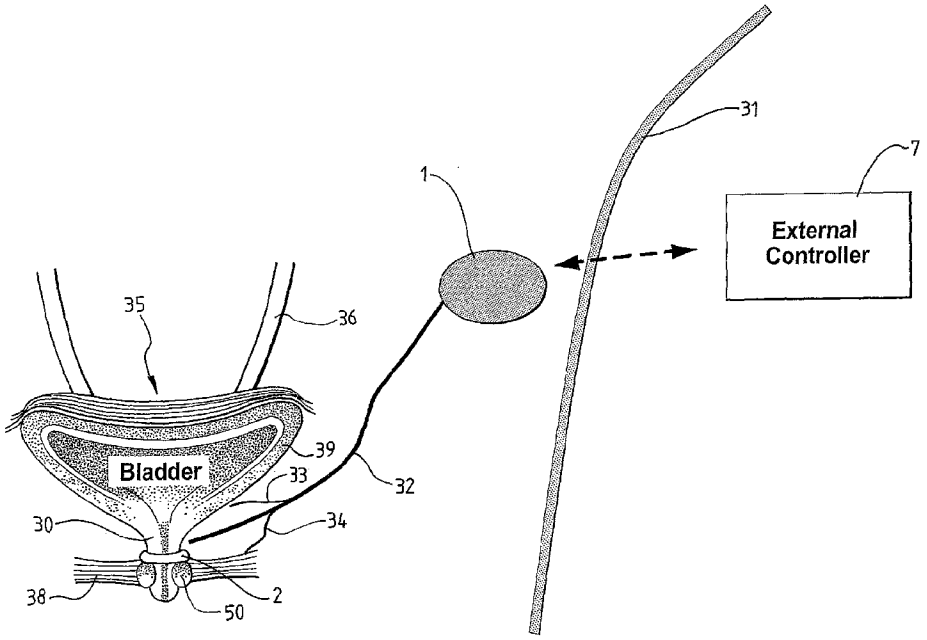
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVED METHOD AND APPARATUS FOR TREATING INCONTINENCE



(57) Abstract: A medical condition is treated using electrical stimulation of contractile tissue, such as a sphincter, as well as electrical stimulation of afferent nerves to illicite a neuro-modulation response. The device (1) and method is particular useful for treating urge incontinence where the tissue is a smooth muscle neo-sphincter (2) about the urethra and the nerves are in the pelvic region.

WO 2006/092007 A1

IMPROVED METHOD AND APPARATUS FOR TREATING INCONTINENCE

The disclosure of International patent applications numbers PCT/AU2005/001698 and PCT/AU00/00925 are herein incorporated in their entirety by reference.

Field of the Invention

The present invention relates to a method and apparatus for treating a disorder by utilising neurological stimulation, and, particularly, but not exclusively, to a method and apparatus for treating incontinence.

Background of the Invention

There are a number of disorders in humans and animals which it is known to treat by stimulation of the nervous system (neurostimulation). In humans, these disorders include incontinence, both fecal and urinary. It is also known to use neurostimulation in the management of pain.

There are a number of known forms of urinary incontinence. Stress incontinence is usually caused by a failure of muscles around the bladder neck and urethra to maintain closure of the urinary outlet. Another form of urinary incontinence, known as urge incontinence may be caused by abnormally heightened activity of the nervous control of the bladder, producing unanticipated bladder contractions. People with urge incontinence may need to urinate frequently. Often, the urge to void cannot be voluntarily suppressed. Conversely, the absence of neural signals to trigger the awareness of fullness to void can result in overflow incontinence. Some people experience

urinary incontinence that includes aspects of both stress and urge incontinence.

A number of treatments have been proposed for urinary incontinence, in particular stress incontinence.

In an earlier patent application, International Patent Application PCT/AU00/00925 (the disclosure of which is incorporated herein by reference) a method and apparatus is proposed for treating incontinence which includes the steps of forming a "neosphincter" from smooth muscle tissue taken from elsewhere in the patient's body, and wrapping the neosphincter around the urethra. An implantable stimulator provides an electrical signal to the neosphincter via two or more electrodes. The electrical signal stimulates the neosphincter to maintain tone about the urethra to reduce leaks from the bladder until the user wishes to urinate. A signal from a control device may cause the stimulator to stop providing the electrical signal to the neosphincter, to allow the neosphincter to relax and enable the individual to urinate.

This is believed to be an effective treatment for stress incontinence, and de facto may reduce the volume of any leaks due to an episode of urge incontinence while the neosphincter is stimulated. It is unlikely, however, to stop symptoms of urge incontinence should they exist, such as a desire to urinate more often than is required.

There is epidemiological evidence that patients who have stress incontinence may progress to also experience urge incontinence. Further, there is also evidence that people who have been surgically treated for symptoms of stress incontinence, may develop "de-novo" urge incontinence. As there are sensory nerves that assess bladder fullness and co-ordinate the act of urination, it

is not surprising that even without treatment, a deficient sphincter function may lead to different perceptions of urge and reflex control of voiding. Additionally, if the patient has undergone surgery involving placement of a foreign body (for example a silicone artificial sphincter or a section of tape to reposition the bladder outlet) to provide a treatment for stress incontinence, it is likely that this may be provocative to the sensory pathways that provide input to bladder control and lead to the development of de-novo urge incontinence.

A technique, referred to as "neuromodulation" is known, in which low level background electrical stimulation of afferent nerve fibres (that is, the sensory nerves that bring information to the central nervous system) is used to modify the response of reflex pathways. This has been commercialised by Medtronic Inc, Minneapolis, Minnesota USA' for treatment of forms of urge incontinence. Medtronic propose treatment by stimulation of the sacral roots to provide background stimulation to modulate the activity of the voiding reflex neural pathways, as the nerves emerge from, and enter into the spinal cord. It has also been proposed to use microstimulators placed in various locations to stimulate sensory pathways at the periphery of the nervous system and modify reflex behaviour (US 2002/0055761, Advanced Bionics Corporation), to address symptoms of incontinence.

Summary of the Invention

In accordance with an embodiment, the present invention provides a method of treating urinary incontinence, including the step of applying an electrical signal to stimulate a sphincter to cause it to contract

about the urethra, and to stimulate one or more afferent nerves to alleviate or avoid symptoms of urge incontinence.

In one embodiment, the one or more nerves are afferent nerves. Stimulation may be by way of electrical stimulation of tissue in the region of the one or more nerves.

Stimulation of the sphincter advantageously provides an effective treatment for stress incontinence and also may prevent extent of leaks which may occur as a result of urge incontinence. Electrical stimulation of one or more afferent nerves (advantageously located near the neosphincter), alleviates symptoms of urge incontinence where urge incontinence exists, or may avoid symptoms of "de-novo" urge incontinence developing, decreasing the frequency and or extent of leaks. It is believed that the novel combination of electrical stimulation of a sphincter to maintain a seal of the bladder, together with afferent nerve stimulation to alleviate symptoms of urge incontinence may prove a most effective treatment for incontinence having both stress and urge aspects.

In an embodiment, the electrical signal may include a first electrical signal for stimulating the sphincter and a second electrical signal for stimulating the one or more nerves.

In an alternative embodiment, a single electrical signal of a pre-determined pattern may be used to stimulate the sphincter and the one or more nerves. In this embodiment, the predetermined pattern may comprise one signal for effecting stimulation of the afferent nerves interspersed with a signal for stimulating the sphincter.

In an embodiment, the same electrode or electrodes may deliver the electrical signal to stimulate the sphincter and to stimulate the one or more nerves.

In an alternative embodiment, separate electrodes may deliver the electrical signal to stimulate the sphincter and to stimulate the one or more afferent nerves.

In an embodiment, the sphincter is an implanted smooth muscle neosphincter, as disclosed in the earlier International Patent Application No. PCT/AU00/00925. Branches of the pudendal nerve innervate many areas of the pelvic floor. Selective, background stimulation of the neosphincter by the electrical signal may therefore elicit a neuromodulation type affect, reducing symptoms of urgency. In one embodiment, therefore, the electrical signal is used to provide stimulation of the afferent nerves in the region of the neosphincter. One or more electrodes may be used to stimulate the one or more nerves and also to stimulate the neosphincter.

In an alternative embodiment, an electrode or electrodes for stimulating the one or more afferent nerves may be placed away from the sphincter. In one embodiment, the electrode or electrodes may be placed within the pelvic anatomy. In one embodiment, an electrode or electrodes may be arranged to provide stimulation to the External Urethral Sphincter to elicit a neuromodulation type affect from this site.

In the method of PCT/AU00/00925, the smooth muscle neosphincter is constantly stimulated to maintain tone, except, in one embodiment, during urination. Neuromodulation to reduce symptoms of urge incontinence may also generally require constant stimulation of the one or more afferent nerves.

In an embodiment, rather than constant stimulation of the one or more nerves, stimulation may be by way of a duty cycle, the nerve stimulation being on for a period and off for a period.

In an embodiment, the step of applying the electrical signal to stimulate one or more nerves may comprise initially applying the electrical signal at a relatively low level and increasing it to the required level. This "ramping up" may reduce annoying perception of the stimulation by the patient. Otherwise they may perceive this stimulation as an unpleasant tingling, for example.

In one embodiment, the stimulation of the sphincter is by a relatively low frequency signal and the stimulation of the one or more nerves is by a relatively high frequency signal.

In one embodiment, a relatively low frequency signal means from 1 to 5 Hz and a relatively high frequency signal means 5 to 200 Hz.

In an embodiment, a relatively low intensity signal is utilised for stimulation of the one or more afferent nerves and a relatively high intensity signal for stimulation of the sphincter.

In an embodiment, the method is implemented with a smooth muscle neosphincter treatment for stress incontinence, as disclosed in the above-referenced International Patent Application. A first electrical signal is utilised to stimulate the smooth muscle neosphincter, in accordance with the disclosure of the above-referenced PCT application, and a second electrical signal or signals is used to stimulate one or more afferent nerves. In an embodiment, the afferent nerves stimulated by the second electrical signal are near the

EUS, or they may be elsewhere within the pelvic or lumbar region.

In the embodiment where a neosphincter is utilised in accordance with the applicant's referenced patent application, the method may include a pre-calibration step. A physician may adjust the electrical signal stimulating the neosphincter to avoid any perceived urgency symptoms, or reduce any perceived urgency symptoms. The physician may also adjust the stimulation of the one or more afferent nerves in order to optimise the effect of the stimulation.

In accordance with a second embodiment, the present invention provides, in a treatment for incontinence which includes a step of stimulating a sphincter to maintain mechanical seal of the bladder, a method of reducing or avoiding symptoms of incontinence comprising the step of providing an electrical signal to stimulate one or more afferent nerves.

In accordance with a third embodiment, the present invention provides an apparatus for treating mixed urinary incontinence in a patient, the apparatus including a stimulator device including signal generator means arranged to provide an electrical signal for stimulation of a sphincter to contract the urethra of the patient, and to stimulate one or more nerves to alleviate or avoid symptoms of urge incontinence.

In an embodiment, the signal generator is arranged to generate a single electrical signal for stimulation of the sphincter and the one or more nerves. The signal may be of a particular signal pattern, for example, interleaving a first electrical signal pattern for stimulating the sphincter with a second electrical signal pattern for stimulating the one or more nerves.

In an alternative embodiment, the signal generator may be arranged to generate separate signals for separate application to the sphincter and one or more nerves, respectively.

In an embodiment, a plurality of separate signals may be generated for a plurality of nerves or for a plurality of positions in the pelvic or lumbar anatomy. In an embodiment, these signals may have different characteristics, depending upon the effect that they are arranged to elicit.

In an embodiment, the stimulator device is arranged to be implanated within the patient's body.

In an embodiment, the apparatus includes at least one electrode for applying the electrical signal.

In an embodiment, the apparatus includes a plurality of electrodes. One or more electrodes may provide stimulation to the sphincter, and one or more other electrodes may provide stimulation to another area for stimulating the one or more nerves. In one embodiment, the one or more other electrodes may be placed elsewhere in the pelvic anatomy. In one embodiment, an electrode is arranged to be positioned to stimulate the afferent nerves in the area of the external urinary sphincter (EUS).

In an embodiment, at least a first electrode is mounted by an electrode mounting arrangement. The electrode mounting arrangement may include a mounting element having an inner surface and an outer surface. The inner surface mounts the first electrode and is arranged to be positioned proximate to the sphincter for stimulation of the sphincter. In an embodiment, a second electrode is also mounted by the electrode mounting arrangement. In an embodiment, the second electrode is mounted on the outer surface of the mounting element, for

stimulating afferent nerves in the region of the sphincter. In an embodiment, one or more electrodes may be arranged to be positioned away from the first electrode elsewhere in the patient's anatomy.

In one embodiment, an electrode may be arranged to be positioned proximate to the pelvic floor in use.

In an embodiment, the signal generator means is arranged to provide a relatively high frequency signal to stimulate the nerves and a relatively low frequency signal for stimulation of the sphincter.

In an embodiment, the signal generator is arranged to provide a relatively low intensity signal to stimulate the nerves and a relatively high intensity signal to stimulate the sphincter.

In accordance with an embodiment, the signal generator means is arranged to generate the signal for stimulation of the one or more nerves as a continuous signal.

In an embodiment, the signal generator means is arranged to provide a signal for stimulating the one or more nerves in accordance with a duty cycle, being on for a period and off for a period.

In an embodiment, the signal generator means is arranged to provide the signal for stimulating the nerves by commencing with a low intensity signal and gradually increasing the signal, thereby, reducing or avoiding patient discomfort.

In an embodiment, the apparatus is arranged to provide electrical stimulation to a neosphincter such as the neosphincter disclosed in the above-referenced PCT application. In an embodiment, the neosphincter is a smooth muscle sphincter.

In an embodiment, the apparatus includes a control device. The control device may be arranged externally from the patient for patient control of the stimulator device. The control device may be adjustable to control a parameter(s) of the electrical signal. As an example, the patient may reduce the stimulation to address unwanted perception of the stimulation or, alternatively, increase stimulation to have greater inhibitory effect on the perception or frequency of urge events while the system is operative. The control device may be arranged to enable the patient to control onset and offset of stimulation.

In an embodiment, the apparatus includes a programmer device. The programmer device is arranged to adjust the parameters of the electrical signal. For example, under control of the physician, the programmer device may be used to calibrate the stimulation, for example, to assess the ability of different parameters of the electrical signal to achieve the intended clinical outcome (for example, extent of urinary leakage observed at a particular stimulus intensity). In an embodiment, the calibration may be done by the physician in response to patient feedback.

In an embodiment, the stimulator device is enclosed in a single housing. Leads may extend from the housing to the electrode(s).

In the above embodiments of the invention, the application is for treating urinary incontinence. The present invention is not limited to the treatment of urinary incontinence, but may be used to treat a number of patient disorders where stimulation of contractile tissue (such as, for example, a sphincter or smooth muscle neosphincter) in conjunction with stimulation of one or more nerves to effect a neurostimulation or

neuromodulation effect, may be useful. Other applications may include faecal incontinence, where a contractile tissue may be used to facilitate closure of the colo-rectum, and neuromodulation may be used further facilitate fecal continence. Neuromodulation may also be used to reduce the perception of pain.

In accordance with a fourth aspect, the present invention provides a method of treating a disorder in a patient, comprising the steps of applying an electrical signal to stimulate contractile tissue to contract and also to effect neuromodulation by stimulation of one or more nerves.

The disorder may be fecal incontinence and the contractile tissue may be a sphincter placed to affect the colorectum or anal canal. The sphincter may be a smooth muscle sphincter.

In accordance with a fifth aspect, the present invention provides an apparatus for treating a disorder in a patient, the apparatus comprising a stimulator device including a signal generator means arranged to provide an electrical signal for stimulation of contractile tissue and also to effect neuromodulation by stimulation of one or more nerves.

In one embodiment, the disorder may be fecal incontinence and the contractile tissue may be a sphincter placed to affect the colo-rectum or anal canal. The sphincter may be a smooth muscle sphincter.

In accordance with a sixth aspect, the present invention provides an electrode arrangement for stimulating contractile tissue and one or more nerves, the electrode arrangement including at least one mounting element mounting a first electrode arranged for stimulation of the contractile tissue, and a second

electrode being arranged for stimulation of the one or more nerves.

In one embodiment, the mounting element is an elongate element having inner surface and an outer surface, the first electrode is mounted on the inner surface and the second electrode is mounted on the outer surface.

In one embodiment, the electrode arrangement includes a pair of mounting elements arranged to be positioned opposite each other with the contractile tissue in between.

The electrode arrangement may include electrodes not mounted by the mounting element, positionable remote from the mounting element.

Brief Description of the Drawings

Features and advantages of the present invention will become apparent from the following description of embodiments thereof, by way of example only, with reference to the accompanying drawings, in which:

Figures 1a and 1b are diagrams of the female and male bladder anatomy, showing a site of implant of a neosphincter;

Figure 2 is a diagram of a female bladder anatomy illustrating an implanted stimulator device in accordance with an embodiment of the present invention;

Figure 3 is a block diagram of the stimulator of Figure 2;

Figure 4 is a block diagram of an apparatus in accordance with an embodiment of the present invention;

Figure 5 is a block diagram of an apparatus in accordance with an embodiment of the present invention;

Figure 6 shows a diagram of the bladder anatomy with a neosphincter and stimulation electrode in accordance with an embodiment of the present invention, in a position of the neosphincter;

Figure 7 is a diagram showing a detail from Figure 6 and illustrating operation of the embodiment of Figure 6;

Figure 8 is a diagram illustrating operation of a further embodiment of the present invention;

Figure 9 is a diagram illustrating operation of yet a further embodiment of the present invention;

Figure 10 is a cross-sectional diagram of the colorectal anatomy showing an implanted stimulator device and sphincter in accordance with a further embodiment of the present invention.

Figures 11a and 11b are perspective views from above and one side of electrode arrangements in accordance with embodiments of the present invention;

Figure 12 is a diagram illustrating the electrode arrangement in accordance with an embodiment of the present invention in position about contractile tissue; and

Figure 13 is a diagram illustrating the interleaving of the electrical stimulation in accordance with an embodiment of the present invention.

Description of Preferred Embodiments

Figures 1a and 1b are diagrams showing aspects of the female and male urinary anatomy. The bladder in each case is designated generally by reference numeral 35. The ureters are designated by reference numeral 36. In the male anatomy the prostate gland is designated by reference numeral 37. Reference numeral 50 indicates the External

Urethral Sphincter (EUS) and reference numeral 38 the pelvic floor. Reference numeral 39 indicates the Detrusor smooth muscle. The urethra in each Figure is denoted by reference numeral 30. A smooth muscle neosphincter 2 has been surgically implanted around the urethra 30 in a position close to the bladder 35. The sphincter 2 has been implanted in accordance with the disclosure of the above-referenced PCT application no. PCT/AU00/00925.

Note that the position of the neosphincter implant may be different from that shown in the diagram in some cases. It may be implanted proximal (close to the bladder) or more distal (close to the pelvic floor).

Referring to Figure 2, which shows the female anatomy only (but it will be appreciated a similar arrangement can be transposed to the male anatomy), in accordance with an embodiment of the present invention, a stimulator device 1 has been implanted in the patient. The stimulator 1 may be implanted in any surgically convenient position, but is preferably implanted between the abdominal muscles and the skin (represented by the line designated by reference numeral 31). The stimulator 1 includes a signal generator means arranged to provide an electrical stimulation signal for stimulating the smooth muscle sphincter 2, and also to provide stimulation for afferent nerves in order to ameliorate or avoid symptoms of urge incontinence. The afferent nerves are not shown in Figure 2, but it will be appreciated that many branches of the pudendal nerve are positioned in the region of the bladder anatomy, close to where the smooth muscle neosphincter is positioned and elsewhere in the pelvic floor. In embodiments, stimulation to the neosphincter may also stimulate the afferent nerves, in an alternative embodiment stimulation may be applied to other areas of the pelvic floor, for

example in the area of the External Urinary Sphincter (EUS) 50. Stimulation may be applied to the Sacral Nerve roots.

In Figure 2, conductors 32, 33, 34 are shown. Conductors 32, 33, 34 are arranged to conduct electrical stimulation signals to implanted electrodes. In another embodiment, conductors 33 and 34 may be joined by "plug-in" sockets to the conductor 32 to permit the surgeon flexibility in choosing a particular configuration suitable for the patient's condition.

In one embodiment, only a single conductor 32 may be required to provide stimulation to the smooth muscle sphincter 2 and to the afferent nerves. As discussed above, as there may be many afferent nerves in the region of the neosphincter 2, the single conductor may be sufficient to provide appropriate stimulation to affect symptoms of urge incontinence.

In another embodiment, one or more electrodes may be implanted in other parts of the pelvic anatomy. In one embodiment, electrodes may be implanted elsewhere to stimulate afferent nerves. Further leads 33 or 34 may be arranged to conduct the electrical signal to the further electrodes.

A plurality of electrodes placed in various positions may be used to provide the electrical signal(s). Each electrode may deliver a distinct electrical signal to a plurality of different sites in order to effect the required nerve stimulation.

The stimulation of afferent nerves in the pelvic anatomy is arranged to suppress symptoms of urge incontinence or avoid such symptoms developing. The symptoms of urge incontinence may be primary symptoms or symptoms developed as a result of stress incontinence

problems. Further, as discussed in the preamble, implantation of the device (such as the electrode 32) has the potential to result in development of urge incontinence as it will be closely placed to sensory nerves of the External Urinary Sphincter.

The electrical stimulating signal may comprise a single signal, or two or more separate or interleaved signals. In one embodiment, a first electrical signal is responsible for stimulation of the smooth muscle sphincter 2 to maintain pressure on the urethra 30, and a second electrical signal is responsible for stimulation of the afferent nerves to ameliorate or avoid symptoms of urge incontinence. Stimulator 1 is arranged to produce all the signals with a single signal generator, although more generally, separate signal generators and even separate stimulators will still fall within the scope of the present invention.

In this embodiment, parameters of the stimulating signal(s) being produced by the stimulator 1 are variable, to enable adjustment of the stimulus, as will be discussed in more detail later.

In accordance with the system disclosed in the above-referenced PCT application, the stimulator 1 may also be arranged to produce a further electrical signal to stimulate the sphincter 2 to relax, to allow urine to flow through the urethra and enable the patient to evacuate their bladder. Instead of a further electrical signal, the stimulator 1 may be arranged to stop producing any electrical signal and it is the absence of a signal that causes the sphincter to relax.

The stimulator 1 is shown in more detail in Figure 3. In this embodiment, a signal generator means arranged to provide the electrical signal for stimulation of the

sphincter and of afferent nerves is in the form of a control unit 9 and stimulus driver 10. The control unit 9 encodes the stimulus and provides a signal to the stimulus driver 10 which provides the stimulation signal at output 6. As discussed above, the output 6 may output to one or more conductors 32, 33, 34 as required and to one or more electrodes. The control unit 9 may be arranged to control the stimulus driver 10 to provide a plurality of stimulation signals e.g. one or more stimulation signals to contract the sphincter 2 and one or more stimulation signals to stimulate afferent nerves to affect symptoms of urge incontinence.

In this embodiment, the control unit 9 and stimulus driver 10 form, together with a demodulator 8, a processing unit for generating the stimulation signal(s) at output 6.

The modulator 8 is arranged to demodulate a signal received by transceiver 5. An external control unit and external programmer unit (both to be described later) are able to communicate via the transceiver with the processing unit 4 in order to control application of stimuli and/or vary the stimuli. In addition, as described in more detail later, the processing unit 4 may transmit, via control unit 9, demodulator 8 and transceiver 5, signals to the control unit or programmer unit. The transmitted signals may deliver telemetry information indicative of parameters of the stimulator, for the purposes of calibration and control.

The entire stimulator 1 (including components 4 and 5), is enclosed in a housing which includes a casing made from a bio-compatible material, such as titanium, silicone rubber or other known inert materials. The frequency of the RF signal for transmission and reception by the

transceiver 5 may depend on the material of the casing of the stimulator.

Figure 4 shows an apparatus in accordance with an embodiment of the present invention. The apparatus incorporates the implanted stimulator 1, including transceiver 5. The electrode(s) 40 is shown schematically together with cables 32, 33, 34. As discussed above, less or more than three conductors may be present, depending upon the number of electrodes present.

The apparatus also comprises an external controller 7 which includes a transmitter 11. The controller 7 is intended for operation by a patient with the stimulator implanted, for control of the stimulator 1.

The controller 7 includes means (such as a button, not shown) operable by the patient to selectively send signals to the implanted stimulator 1, for control of the stimulation signals being sent to the electrodes 40. In this embodiment, the stimulator is "fail safe". Unless a signal is received from the controller 7, the stimulator produces a signal which maintains tone in the smooth muscle implant 2, maintaining pressure on the urethra. The stimulator also provides an electrical signal to stimulate the afferent nerves to reduce or avoid symptoms of urgency incontinence.

When the patient wishes to urinate, they actuate the controller 7 to send, via the transmitter 11, a signal to the stimulator. In response to receiving the signal, the control unit 9 operates to turn the stimulating signal off causing the sphincter to relax and allow the patient to urinate. The signal may also cause the afferent nerve stimulation to turn off. In an alternative embodiment, afferent nerve stimulation may continue or change to a different pattern of stimulation.

The controller 7 may also be arranged to provide a further signal under patient control, once the patient has finished urinating, the further signal causing stimulator 1 to resume providing the stimulation signals to the electrode(s) 40.

In "fail safe" mode, if the further signal is not produced, the stimulator will resume providing the stimulation signal to the electrodes 40 after a pre-determined period of time.

The stimulation signal 6 provided to contract the smooth muscle sphincter 2 is selected so as to provide a substantially continuous tone in the sphincter. A generally rectangular and symmetrically biphasic pulse may be suitable for this. The signal has a substantially constant current less than or equal to 30 mA, and may be in the order of 15 mA. Stimulation pulse frequency provided to sphincter 1 is in the range of 0.25 Hz to 2.5 Hz and is preferably 2 Hz. Stimulation pulse width is in the range of 0.05 m/s to 0.02 m/s and is preferably 0.15 m/s. The stimulator is current regulated, and accordingly the stimulation voltage will vary with the resistance of the muscle tissue between the electrodes. Typical values for the voltage are between 0.2 and 12 Volts. Either a current source (voltage limited) or a voltage source (current limited) stimulator may be used.

Note that it is also possible to use an asymmetric biphasic pulse, in which, for example, the first phase is shorter in duration than the second phase. .

In this embodiment, the signal for stimulating the afferent nerves is a further signal provided at output 6 and may be provided to either the same electrode i.e. interleaved with the signal for stimulating the smooth muscle sphincter 2 or a separate electrode also

stimulating in the sphincter area, or a separate electrode arranged to stimulate in the area of the external urethral sphincter. The further signal may provide a low-level "background" stimulation to large diameter afferent nerve fibres. A narrow width, low amplitude signal may be used to target the lower threshold, large diameter sensory fibres of the external urethral sphincter. The signal may be a long duty cycle stimulation (e.g. five minutes on, five minutes off).

Stimulation of the afferent fibres may therefore be provided in at least these two ways:

1. By the same signal that is used to stimulate the smooth muscle sphincter to contract the smooth muscle sphincter 2. In this case the signal would be arranged to provide the appropriate stimulation to maintain tone in the smooth muscle sphincter 2, as well as stimulation to reduce or avoid symptoms of urge incontinence.

2. Separate signals, one for reducing or avoiding urge incontinence and the other for stimulating the smooth muscle sphincter. The signals may be interleaved or may be provided in separate channels. In either case, the stimulation parameters can be distinct for the different purposes of (i) stimulating the smooth muscle neosphincter and (ii) stimulating the afferent nerves. The signals for stimulating the afferent nerves may be applied to other electrodes in the area of the smooth muscle sphincter 2 or in other regions in the pelvic anatomy, including the EUS.

Figure 13 shows a diagram of an example of an interleaved-type signal. The signal 600 for stimulation of the afferent nerves has a relatively small amplitude and a higher frequency. The signal 601 for stimulating

the neosphincter, has a relatively large amplitude and low frequency.

A relatively high frequency signal may be used to provide the stimulation for the afferent nerves and a relatively low frequency signal to stimulate the sphincter. The relatively high frequency signal may be greater than 5 Hz, preferably greater than 8 Hz and even more preferably 10 Hz or greater. In one embodiment, the high frequency signal is up to 100 Hz.

The low frequency signal, for stimulation of the sphincter, will usually be less than 5 Hz and may be 2 Hz or less.

A relatively low intensity signal may be used to stimulate the afferent nerves and a relatively high intensity signal for the sphincter. The low intensity signal in this embodiment is a pulse signal. The pulse signal may have 300 us or less pulse width and a 3 mA or less current, and in this embodiment 200 us or less and 1 mA current.

The high intensity sphincter stimulating signal may have pulse width greater than 300 us and a current of greater than 3 mA, and in this embodiment is 400 us or more and the current is 4 mA.

The duty cycle for the afferent nerve stimulating signal may vary. As discussed above in this embodiment it is 5 minutes on and 5 minutes off but in other embodiments may be 5 minutes or more on and 15 minutes or more off, 5 minutes or less off and 5 minutes or less on. Duty cycle and other signal characteristics may be adjusted to provide the most effective stimulation. In some embodiments, the duty cycle may be in terms of seconds (e.g. less than 10 seconds on and less than 30 seconds off).

With the afferent nerve stimulation signal, it is possible that the patient may experience some discomfort (e.g. 'tingling') on application of the signal. Where the signal is applied in accordance with a duty cycle, this tingling may be experienced in rhythm with the duty cycle. In one embodiment, the afferent nerve stimulating signal may be "ramped up" from a relatively low intensity to the required intensity each time it is applied. This may reduce unwanted awareness of the stimulation or patient discomfort.

The electrodes employed may incorporate an electrically conductive surface that is in contact with the neosphincter, which also activates afferent nerve fibres. In another embodiment, the electrode for the neosphincter may include one or more additional electrically conductive surfaces that are on the outer surface of the electrode, to stimulate nerve endings in the surrounding pelvic anatomy. In yet a further embodiment, the electrode may be entirely separate to the electrode used to stimulate the neosphincter, but placed conveniently in the adjacent anatomy to facilitate delivery of electrical stimulation to neuromodulate the bladder reflexes.

Referring to Figures 11(a), an electrode arrangement 100 in accordance with an embodiment of the present invention is illustrated. The electrode arrangement 100 includes first and second electrode elements 200, 300, which in this example are in the form of elongate rectangular elements which extend from a mounting 400. Mounting 400 acts to secure the electrode elements 200, 300 at their proximal ends.

The electrode arrangement 100 includes electrodes 500, 600, in this embodiment being in the form

of conductive plates which extend along the inside of the electrode elements 200, 300 opposite to each other. The electrodes 500, 600, may alternatively be in the form of a printed conductive medium printed on the inside surface of the electrode elements 500, 600.

The electrode elements 200, 300 are arranged so that tissue from a human or animal body may be received therebetween within the gap 201, so tissue is "sandwiched" between the electrode 500, 600 exposed surfaces.

In this embodiment, the electrode element 200, 300 are comprised mainly of insulating material 202 so that the outer surface (in this embodiment all surfaces apart from conductive electrodes 500 and 600) are insulated and do not conduct electricity.

In this embodiment the inner surface is also insulating material with an elongate opening in the form of a slit. The electrodes are provided at the slit.

Distal ends 203, 204 of the electrode elements 200, 300 include projecting portions which project inwardly from the electrode elements 200, 300 so that they meet each other. In operation, the ends 203, 204 may be secured together so that the electrode arrangement is firmly secured about the tissue which lies in the gap 201 between the electrode elements 200, 300.

In this embodiment, mounting 400 includes a strain relief member 205 for receiving an electrical conductor 206 within a cable 207 (the cable being insulated), the electrical conductor 206 being arranged for electrical connection between electrodes 500 and 600 and the stimulator 1. The distal ends of the electrode elements may be fixed (if required to be fixed) by a number of means, including suture holes, press studs or any other arrangement that may not require much surgical

access to "lock" the electrode elements closed. Note also, it is not essential for all embodiments that the electrode elements be fixed together at their distal ends.

In embodiments, insulating parts of the electrode elements may be composed of two sheets of bio compatible material (e.g. silicone) - which acts as an insulator, and surrounds and limits the exposed surface of thin flexible platinum foils that forms the electrodes. The silicone may be reinforced with bio compatible mesh (eg a PET or PTFE -like material), so that sutures will not tear through the silicone.

In this embodiment, the electrode elements 200, 300 are arranged to flex such that the arrangement is arranged to conform, at least to some limited extent, with the profile of the received tissue and/or external tissue that they may be seated against. The electrode elements 200, 300, are arranged to flex to conform with any changes in the profile of the received tissue which may be due to electrical stimulation.

In this embodiment, the electrode elements may be sufficiently flexible so that they conform with any changes in the profile of the received tissue and also with the profile of external tissue so they do not irritate or erode the external tissue or receive tissue. This has the advantage of increasing the lifetime of the implant.

The electrode elements may be semi-flexible or in another embodiment totally flexible.

In a further embodiment, electrodes elements are not flexible (non flexible electrode elements are within the scope of the present invention).

The electrode is similar in structure and operation to the electrode disclosed in the Applicant's co-pending

application, number PCT/AU2005/001698, the disclosure of which is incorporated herein by reference. In addition, a further electrode 210 is provided on the outside of at least one of the electrode elements 200. Note the yet a further electrode (not shown) may be provided on the outside of the other electrode element 300, if required. The further electrode 210 is electrically connected to the stimulator 1 via the electrical conductor 206 (note that the cable 207 may in fact house a plurality of electrical conductors if required, or a single electrical conductor may be utilised to transmit interleaved signals. Separate electrical conductors may be convenient for separate electrical signals).

Figure 11(b) shows an alternative embodiment, same reference numerals have been used for similar components and no further description will be given of these components. In this embodiment, no further electrode is mounted on the outside of the elements 200,300, but instead further electrodes are arranged for mounting elsewhere in the patient's anatomy, the further electrodes being designated by reference numerals 211 and 212. Electrodes 211 and 212 may be mounted remote from electrodes 500,600, for stimulation of other areas of the pelvic anatomy. Such electrodes may comprise rounded, conductive button electrodes that may be sutured directly by the surgeon at the required location or catheter electrodes that be placed and secured between fascia or other convenient anatomy, close to the afferent nerve. Such electrodes may be connected to the electrode using an implantable connector, to provide the surgeon the convenience of using these additional electrodes at his or her convenience.

Figure 12 schematically illustrates an electrode in accordance with an embodiment of the present invention in situ about muscle tissue 213. The same reference numerals have been used in Figure 12 as in Figure 11(b), to designate corresponding components.

It can be seen from Figure 12 that the muscle tissue 213 is received between electrode elements 200, 300. The electrodes 500, 600 on the inside surfaces of the electrode elements 200, 300 therefore contact the muscle tissue 213. Electrical signals may be applied to the electrodes 500, 600 resulting in an electrical field applied across the muscle tissue 213.

Tethers (also known as sutures) 214 and 215 may be used to hold the electrode arrangement in place adjacent the tissue within the human or animal body.

In the above embodiments, the electrode arrangement 100 includes mounting elements joined at a base 400. In an alternative embodiment, the mounting elements 200,300 may not be joined at the base but may merely be arranged to be positioned opposite each other without requiring a base. For example, they may be fixed in place in the patient e.g. sutured in place.

Regarding the Figure 11(b) embodiment, note that there may be less or more remote electrodes 211, 212 than shown, depending upon the application and how many electrode are required for appropriate stimulation. Similarly with the embodiment of Figure 11(a) there may be more than one electrode 210 on the outer surface of the mounting element 200,300. Further, in another embodiment, electrodes may be included on the outer surface of the mounting element 200, 300 and also remote electrodes may be provided.

Figure 6 illustrates a stimulation electrode 100 in place at the neosphincter 2. This electrode may be similar to the embodiment of Figure 1.

Figure 7 schematically illustrates a system for management of mixed incontinence which utilises a stimulator 1 which provides single channel stimulation to the electrode 100 to stimulate the neosphincter 2 as well as stimulate afferent nerve fibres to reduce unnecessary symptoms of urge. The continuous or long duty cycle, low level background electrical stimulation of afferent fibres, interleaved with stimulation to the neosphincter 2, reduces symptoms of urge incontinence via neuromodulation of the micturition reflex. Background stimulation delivered to the neosphincter 2 to keep it toned may also elicit low level stimulation of sensory nerve fibres in the EUS 50, causing a neuromodulation effect, reducing symptoms of urge. The stimulus pattern delivered to the afferent nerves may be the same stimulus pattern as delivered to the neosphincter 2 or another stimulus pattern may be delivered to the afferent nerves, interleaved with the stimulation to the neosphincter.

Figure 8 illustrates schematically a two-channel implantable stimulator 1 where one channel is dedicated to stimulate the neosphincter 2 and another channel to stimulate afferent nerves to reduce the symptoms of urge incontinence. Extra conducting electrodes 210a, 210b are provided at the distal edge of the electrode 100 or on its outer surface, to activate nerve fibres near the pelvic floor 38 or EUS 50. So a separate stimulation pattern for neuromodulation can be delivered to afferent fibres in the pelvic floor or EUS from electrode sites at the distal edge or on the outer surface of the electrode 100.

Figure 9 illustrates a system using a two-channel implantable stimulator 1. This embodiment also illustrates an arrangement for delivering a separate stimulation pattern for neuromodulation from one or more dedicated electrodes 211,212 that may be placed in contact with the pelvic floor or other anatomy with afferent fibres (for example, branches of the pudenal nerve).

As well as switching the stimulator 1 on and off, the controller 7 may have further patient control functions. It may, in one embodiment, include "fine" control to vary the parameters of the stimulation being applied by the stimulator 1. For example, before the patient goes to sleep, they may wish to provide a different pattern of stimulation to the afferent nerves. The controller 7 may therefore include a patient manipulator or control to enable the patient themselves to adjust the stimulation.

Figure 5 shows an apparatus in accordance with an embodiment of the present invention, including a programmer unit 13 which may be utilised by a physician to set and adjust parameters of the implanted stimulator 1. The programmer unit 13 may include an appropriate means for communicating with the stimulator via transceiver 11, and may include a computing device. The control unit 9 is also arranged to transmit stimulator telemetry information indicative of one or more of the parameters of the stimulator 1, for detection by the programmer 13 via transceiver 11. The programmer unit 13 can therefore determine parameters of the stimulator from telemetry information and can adjust the parameters by transmitting control signals to the stimulator 1. The signal from the programmer may be able to selectively vary the output current, shape, frequency and/or pulse width or stimulation mode of the stimulation signal(s).

In operation, a physician adjusts parameters of the stimulation signal(s). The physician will note feedback from the patient as to the effect of the stimulus on bladder control, and may subsequently re-adjust the parameters until the stimulation is optimum. For example, patient perceived feedback may be used to set the maximum stimulation threshold of the smooth muscle sphincter (for example, any excess stimulation to the neosphincter may elicit and/or be perceived as an urgency event by the patient).

In the above-described embodiments, signals between the controller or programmer and the stimulator are RF signals. Other types of transmission media other than RF may be used. For example, microwave signals may be used for transmission, optical signals may be used, and in another embodiment magnetic transmission may be used.

Magnetic transmission may be used for the controller unit 7 to cause the stimulator to stop producing stimulation signals and therefore allow the patient to urinate. In this embodiment, the control unit 7 may be a simple magnet which, when passed over a magnetic receiver of the stimulator 1, results in the stimulator ceasing to provide stimulation signals for contracting the sphincter.

The apparatus of the above embodiment provides stimulation signals to a neosphincter in the form of a smooth muscle sphincter which is usually taken from elsewhere in the body and transplanted around the urethra, as taught in International Patent Application publication no. WO 01/10357. The apparatus of the present invention is not limited to providing stimulation signals to such a neosphincter. Signals may instead be provided to other anatomical features. For example, the external urinary sphincter may be stimulated to exert pressure on the

urethra, in the absence of any smooth muscle neosphincter. In addition, of course, in accordance with the present invention stimulation is provided to avoid or ameliorate symptoms of urgency.

The above embodiments have been described for use mainly in applications for treating urinary incontinence. The present invention is not limited to the treatment of urinary incontinence. The present invention may be useful for any disorder where advantage may be gained by stimulating contractile tissue and at the same time stimulating one or more nerves in order to, for example, provide a neuromodulation effect, whether to decrease symptoms of urge or for example, perception of pain.

Another application where the present invention is useful is in the treatment of fecal incontinence. Signal stimulation to existing anal sphincters may be utilised in conjunction with afferent nerve stimulation. Branches of the sacral nerve may also be stimulated, for example as there are afferent nerves that also conveniently located to the anal sphincter.

In the Applicant's co-pending provisional patent application, Australian patent application number 2005905673, the disclosure of which is herein incorporated by reference, a treatment for fecal incontinence is proposed which involves stimulation of a smooth muscle sphincter wrapped about a portion of the anal canal or colo-rectal canal. In accordance with an embodiment of the present invention, neurostimulation can be applied to facilitate anal continence or treat symptoms associated with implantation of the stimulator and sphincter.

Referring to Figure 10, a system and apparatus in accordance with an embodiment of the present invention, for treating anal incontinence, are illustrated in

schematic form. The system includes an apparatus comprising an implantable stimulator 1 and a device comprising contractile tissue 2 which is arranged to be stimulated by a signal that is generated by the stimulator 1 and, in this embodiment, applied to the contractile tissue 2 via an electrode 100 conductively connected between the stimulator 1 and contractile tissue 2.

In this embodiment, the stimulator 1 may be of the same general construction as described above with reference to Figures 3, 4 and 5, with the signal characteristics being provided as appropriate for the anal incontinence application.

The contractile tissue 2 in this embodiment is formed into a sphincter which is implanted about the anal sphincter region, in this embodiment proximate to the anus. In Figure 10, the external anal sphincter is designated by reference numeral 250 and the internal anal sphincter by reference numeral 251. Failure of operation of the external and/or internal anal sphincters (perhaps because of nerve damage, or other reason) have lead to anal incontinence in this patient. Stimulation of the contractile tissue sphincter 2, in operation, causes the contractile tissue 2 to contract and maintain closure of the anal-rectal canal 252, maintaining anal continence.

The stimulator 1 as discussed above includes a signal generator arranged to provide a stimulation signal for stimulating the smooth muscle sphincter 2. A lead 253 extends from the stimulator 1 to the electrode 3 at the smooth muscle sphincter 2, for providing the stimulation signal 2 to the smooth muscle sphincter 2. The stimulation signal may be a signal of frequency and

amplitude determined to maintain contraction of the smooth muscle sphincter 2 to facilitate and anal continence.

The stimulator 1 may also be arranged to produce a further electrical signal to stimulate the sphincter 2 to relax, to enable the patient to defecate. As an alternative to a further electrical signal, the stimulator 1 may be arranged to stop producing any electrical signal, and it is the absence of the signal that causes the sphincter 2 to relax. In this embodiment, the stimulator 1 is arranged to have the stimulation signal varied under control of the patient by way of an external controller.

In addition to the lead 253, and electrode 100 further electrodes 254, 255 and leads 256, 257 are provided to allow background stimulation e.g. neuromodulation, to be provided to other areas of the anatomy.

In the above embodiments, power sources for the implantable stimulator will be provided in the form of batteries. These are not shown in the diagrams. The batteries may be replaceable or may be rechargeable via inductive recharging and are incorporated within the implantable stimulator.

As discussed above, the stimulator implant is preferably sealed and encased in a biologically inert material such as a bio-compatible silicone material. Metallic electrodes and leads are preferably of platinum-iridium alloy. The connecting wires are preferably insulated with a silicone coating. The implant is preferably placed between the abdominal muscle and the skin.

In the above embodiments, a single stimulation single signal generator is used to provide the electrical signal.

Other embodiments may use two or more signal generators. Other embodiments may use two or more stimulators, which may be placed in different locations.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A method of treating urinary incontinence, including the step of applying an electrical signal to stimulate a sphincter to cause it to contract around the urethra, and to stimulate one or more nerves to alleviate or avoid symptoms of urge incontinence.

2. A method in accordance with Claim 1, wherein the electrical signal includes a first electrical signal for stimulating the sphincter and a second electrical signal for stimulating one or more nerves.

3. A method in accordance with claim 2, wherein a plurality of electrical signals are applied for stimulating a plurality of nerves.

4. A method in accordance with claim 3, wherein the plurality of signals have different signal characteristics from each other.

5. A method in accordance with Claim 1, wherein the electrical signal is a single electrical signal having a predetermined pattern for stimulating the sphincter and the one or more nerves.

6. A method in accordance with any one of the preceding claims, wherein the electrical signal is applied by one or more electrodes, and wherein the same electrode or electrodes may deliver the electrical signal to stimulate the sphincter and to stimulate the one or more nerves.

7. A method in accordance with any one of Claims 1 to 4, wherein a plurality of electrodes are used to apply the electrical signal, and wherein separate electrodes are utilised to deliver the electrical signal to stimulate the sphincter and the electrical signal to stimulate the one or more nerves.

8. A method in accordance with any one of the preceding claims, wherein the step of applying an electrical signal includes applying an electrical signal via an electrode placed in the pelvic or lumbar anatomy.

9. A method in accordance with Claim 8, wherein the step of applying an electrical signal includes applying an electrical signal via a first electrode positioned proximate the sphincter to stimulate the sphincter, and applying an electrical signal via a second electrode positioned elsewhere to stimulate the one or more nerves.

10. A method in accordance with Claim 9, wherein the second electrode is positioned close to the first electrode.

11. A method in accordance with Claim 9 or Claim 10, wherein the first and second electrodes are mounted by a single electrode mounting arrangement.

12. A method in accordance with Claim 11, wherein the electrode mounting arrangement includes a mounting element having an inner surface and an outer surface, the inner surface mounting the first electrode.

13. A method in accordance with Claim 9, wherein the second electrode is positioned away from the first electrode, in contact with anatomy having afferent fibres.

14. A method in accordance with Claim 13, wherein the second electrode is positioned proximate a branch of the pudenal nerve.

15. A method in accordance with Claim 13 or claim 14, wherein the second electrode is positioned proximate the pelvic floor.

16. A method in accordance with any one of claims 9 to 15, wherein there are a plurality of second electrodes.

17. A method in accordance with any one of the preceding claims, wherein the sphincter is an implanted neosphincter, composed of contractile tissue.

18. A method in accordance with Claim 17, wherein the neosphincter is a smooth muscle neosphincter.

19. A method in accordance with Claim 17 or Claim 18, wherein the electrical signal provides stimulation to one or more afferent nerves in the region of the neosphincter.

20. A method in accordance with any one of the preceding claims, including the further step of adjusting the electrical signal to reduce or avoid any perceived urgency symptoms.

21. A method in accordance with any one of the preceding claims, wherein the step of applying an electrical signal includes the step of applying a relatively high frequency electrical signal to stimulate the one or more afferent nerves and a relatively low frequency electrical signal to stimulate the sphincter

22. A method in accordance with Claim 21, wherein the relatively high frequency electrical signal is greater than 5Hz.

23. A method in accordance with Claim 22, wherein the relatively high frequency signal is 8Hz or greater.

24. A method in accordance with Claim 23, wherein the relatively high frequency signal is 10Hz or greater.

25. A method in accordance with Claim 24, wherein the relatively high frequency signal is 50Hz or greater.

26. A method in accordance with Claim 25, wherein the relatively high frequency signal is up to 100Hz.

27. A method in accordance with any of Claims 21 to 26, wherein the relatively low frequency signal is equal to or less than 5Hz.

28. A method in accordance with Claim 27, wherein the relatively low frequency signal is 3Hz or less.

29. A method in accordance with Claim 28, wherein the relatively low frequency signal is 1Hz or less.

30. A method in accordance with any one of the preceding Claims, wherein the step of applying an electrical signal includes the steps of applying a relatively low intensity signal to stimulate the one or more afferent nerves and a relatively high intensity signal to stimulate the sphincter.

31. A method in accordance with Claim 30, wherein the relatively low intensity signal is a pulse signal having a 300 us or less pulse width and a 3 mA or less current.

32. A method in accordance with Claim 31, wherein the pulse width is 250 us or less and the current is 1.5 mA or less.

33. A method in accordance with Claim 32, wherein the pulse width is 200 us or less and the current is 1 mA or less.

34. A method in accordance with any one of Claims 30 to 33, wherein the relatively high intensity signal is a pulse signal having a pulse width greater than 300 us and a current of greater than 2 mA.

35. A method in accordance with Claim 34, wherein the pulse width is 350 us or more and the current is 3.5 mA or more.

36. A method in accordance with Claim 35, wherein the pulse width is 400 us or more and the current is 4 mA or more.

37. A method in accordance with any one of the preceding Claims, wherein the electrical signal for stimulating one or more nerves is continuously applied.

38. A method in accordance with any one of Claims 1 to 36, wherein the electrical signal for stimulating the one or more nerves is applied in accordance with a duty cycle, the signal being on for a period and off for a period.

39. A method in accordance with Claim 38, wherein the duty cycle is one minute or more less and 5 minutes or less off.

40. A method in accordance with Claim 39, wherein the duty cycle is 1 minutes or more on and 5 minutes or more off.

41. A method in accordance with Claim 40, wherein the duty cycle is 5 minutes or more on and 15 minutes or more off.

42. A method of reducing or avoiding symptoms of urge incontinence for use in a treatment for urinary incontinence which includes a step of stimulating a sphincter to cause it to contract the urethra, the method comprising the step of providing an electrical signal to stimulate one or more nerves.

43. An apparatus for treating mixed urinary incontinence in a patient, the apparatus including a stimulator device including signal generator means arranged to provide an electrical signal for stimulation of a sphincter to contract the urethra of the patient, and to stimulate one or more nerves to alleviate or avoid symptoms of urge incontinence.

44. An apparatus in accordance with Claim 43, wherein the electrical signal includes a first electrical signal for stimulating the sphincter and a second electrical signal for stimulating the one or more nerves.

45. An apparatus in accordance with Claim 44, wherein a plurality of electrical signals are applied for stimulating a plurality of nerves.

46. An apparatus in accordance with Claim 45, wherein the plurality of signals have different signal characteristics from each other.

47. An apparatus in accordance with Claim 43, wherein the electrical signal is a single electrical signal having a predetermined pattern for stimulating the sphincter and the one or more nerves.

48. An apparatus in accordance with any one of Claims 43 to 47, including at least one electrode which is arranged to apply the electrical signal to stimulate the sphincter and the one or more nerves.

49. An apparatus in accordance with Claim 48, the apparatus including a plurality of electrodes, one or more electrodes being arranged to provide stimulation to the sphincter, and one or more other electrodes being arranged to provide stimulation to the one or more nerves.

50. An apparatus in accordance with Claim 49, wherein an electrode is arranged to be positioned to stimulate an afferent nerve in the area of the external urinary sphincter (EUS).

51. An apparatus in accordance with Claim 49 or Claim 50, the apparatus including an electrode mounting arrangement mounting a first electrode for positioning proximate the sphincter and a second electrode for positioning elsewhere in the pelvic or lumbar anatomy.

52. An apparatus in accordance with claim 51, the electrode mounting arrangement including a mounting element having an inner surface and an outer surface, the inner surface being arranged to be positioned adjacent the sphincter and mounting the first electrode, and the outer surface mounting the second electrode.

53. An apparatus in accordance with Claim 49, the plurality of electrodes including an electrode being

arranged to be mounted proximate the sphincter and an electrode being arranged to be mounted remote from the sphincter elsewhere in the pelvic or lumbar anatomy.

54. An apparatus in accordance with any one of Claims 43 to 53, wherein the sphincter is an implanted neosphincter.

55. An apparatus in accordance with Claim 54, wherein the neosphincter is a smooth muscle neosphincter.

56. An apparatus in accordance with any one Claims 43 to 55, further including a stimulator controller which is operable by a user to adjust the stimulation.

57. An apparatus in accordance with any one of Claims 43 to 56, further including a stimulator programmer, the stimulator programmer being arranged to enable programming of control parameters of the stimulator.

58. An apparatus in accordance with any one of Claims 43 to 57, wherein the signal generator means is arranged to generate a relatively high frequency signal to stimulate the nerves and a relatively low frequency signal to stimulate the sphincter.

59. An apparatus in accordance with Claim 58, wherein the relatively high frequency signal is greater than 5Hz.

60. An apparatus in accordance with Claim 59, wherein the relatively high frequency signal is 8Hz or greater.

61. An apparatus in accordance with Claim 60, wherein the relatively high frequency signal is 10Hz or greater.

62. An apparatus in accordance with Claim 61, wherein the relatively high frequency signal is 50Hz or greater.

63. An apparatus in accordance with Claim 62, wherein the relatively high frequency signal is 100Hz or greater.

64. An apparatus in accordance with any one of Claims 58 to 63, wherein the relatively low frequency signal is 5Hz or less.

65. An apparatus in accordance with Claim 60, wherein the relatively low frequency signal is 3Hz or less.

66. An apparatus in accordance with Claim 65, wherein the relatively low frequency signal is 1Hz or less.

67. An apparatus in accordance with any one of Claims 43 to 66, wherein the signal generator is arranged to provide a relatively low intensity signal to stimulate the nerves and a relatively high intensity signal to stimulate the sphincter.

68. An apparatus in accordance with Claim 67, wherein the relatively low intensity signal is a pulse signal having a pulse duration of 300 us or less and a current of 2 mA.

69. An apparatus in accordance with Claim 68, wherein the signal period is 250 us or less and the current is 1.5 mA or less.

70. An apparatus in accordance with Claim 69, wherein the signal period is 200 us or less and the current is 1 mA or less.

71. An apparatus in accordance with any one of Claims 67 to 70, wherein the relatively high intensity signal is a pulse signal and the period of the signal is greater than 300 us and the current is 3 mA or greater.

72. An apparatus in accordance with Claim 71, wherein the signal period is 350 us or more and the current is 3.5 mA or more.

73. An apparatus in accordance with Claim 72, wherein the signal period is 400 us or more and the current is 4 mA or more.

74. An apparatus in accordance with any one of Claims 43 to 73, wherein the signal generator means is arranged to generate the signal for stimulating the afferent nerves as continuous signal.

75. An apparatus in accordance with any one of claims 43 to 73, wherein the signal generator means is arranged to generate the afferent nerve stimulating signal in accordance with a duty cycle, the signal being on for a period and off for a period.

76. An apparatus in accordance with Claim 75, wherein the on period is 10 minutes or more and the off period is 20 minutes or more.

77. An apparatus in accordance with Claim 76, wherein the on period is 8 minutes or more and the off period is 18 minutes or more.

78. An apparatus in accordance with Claim 77, wherein the on period is 5 minutes or more and the off period is 15 minutes or more.

79. An apparatus in accordance with Claim 78, wherein the on period is less than 1 minute or less and the off period is 5 minutes or less.

80. A method of treating a disorder in a patient, comprising the steps of applying an electrical signal to stimulate contractile tissue to contract and also to effect neuromodulation by stimulation of one or more nerves.

81. A method in accordance with Claim 80, wherein the electrical signal includes a first electrical signal for stimulating the contractile tissue and a second electrical signal for stimulating the one or more nerves.

82. A method in accordance with Claim 81, wherein a plurality of second electrical signals are applied for stimulating a plurality of nerves.

83. A method in accordance with Claim 81, wherein the plurality of signals each have different signal characteristics.

84. A method in accordance with Claim 80, wherein the electrical signal is a single electrical signal having a predetermined pattern for stimulating the contractile tissue and the one or more nerves.

85. A method in accordance with any one of Claims 80 to 84, wherein the electrical signal is generated by a single signal generator.

86. A method in accordance with Claim 85, wherein the signal generator means is mounted in a housing which is implanted in the patient's body.

87. A method in accordance with any one of the Claims 80 to 86, wherein the electrical signal is applied by one or more electrodes, and wherein the same electrode or electrodes may deliver the electrical signal to stimulate the contractile tissue and to stimulate the one or more nerves.

88. A method in accordance with any one of Claims 80 to 87, wherein a plurality of electrodes are used to apply the electrical signal, and wherein separate electrodes are utilised to deliver the electrical signal to stimulate the contractile tissue and the electrical signal to stimulate the one or more nerves.

89. A method in accordance with Claim 88, wherein the electrical signal is applied by a first electrode positioned proximate the contractile tissue and a second electrode positioned elsewhere.

90. A method in accordance with Claim 89, wherein the second electrode is positioned close to the first electrode.

91. A method in accordance with Claim 80, wherein the first and second electrodes are mounted by an electrode mounting arrangement.

92. A method in accordance with Claim 91, wherein the electrode mounting arrangement includes a mounting element having an inner surface and an outer surface, the inner surface mounting the first electrode proximate the contractile tissue and the outer surface mounting the second electrode.

93. A method in accordance with Claim 90, wherein the second electrode is positioned remote from the first electrode and in contact with anatomy bearing afferent nerve fibres.

94. A method in accordance with any one of Claims 80 to 93, wherein the disorder is fecal incontinence.

95. A method in accordance with Claim 94, wherein the contractile tissue is a sphincter positioned about the colo-rectum or anal canal.

96. A method in accordance with Claim 95, wherein the sphincter is a smooth muscle sphincter.

97. A method in accordance with any one of Claims 94 to 96, wherein the electrical signal is applied to stimulate one or more nerves carrying afferent signals to the sphincter muscle complex of the anal rectal barrier.

98. A method in accordance with any one of Claims 80 to 97, wherein the step of stimulating the one or more nerves include stimulating the sacral nerve.

99. A method in accordance with any one of Claims 80 to 98, wherein the stimulation of the one or more nerves is arranged for treatment of pain.

100. A method in accordance with any one of Claims 80 to 93, wherein the disorder is urinary incontinence and the contractile tissue is a sphincter mounted about the urethra.

101. A method in accordance with any one of Claims 80 to 100, wherein the contractile tissue is smooth muscle.

102. An apparatus for treating a disorder in a patient, the apparatus comprising a stimulator device including a signal generator means arranged to provide an electrical signal for stimulation of contractile tissue and also to effect neuromodulation by stimulation of one or more nerves.

103. An apparatus in accordance with Claim 102, wherein the electrical signal includes a first electrical signal for stimulating the contractile tissue and a second electrical signal for stimulating the one or more nerves.

104. An apparatus in accordance with Claim 103, wherein the electrical signal includes a plurality of second electrical signals arranged for stimulation of a plurality of nerves.

105. An apparatus in accordance with Claim 104, wherein the plurality of second electrical signals each have different signal characteristics.

106. An apparatus in accordance with Claim 102, wherein the electrical signal is a single electrical signal having a predetermined pattern for stimulating the contractile tissue and the one or more nerves.

107. An apparatus in accordance with any one of Claims 102 to 106, the signal generator means being mounted in a housing which is implantable in the patient's body.

108. An apparatus in accordance with any one of Claims 103 to 107, further including one or more electrodes, and wherein the same electrode or electrodes may be arranged to deliver the electrical signal to stimulate the contractile tissue and to stimulate the one or more nerves.

109. An apparatus in accordance with any one of Claims 102 to 107, further including a plurality of electrodes, the signal generator means being arranged to utilise separate

electrodes to deliver the electrical signal to stimulate the contractile tissue and the electrical signal to stimulate the one or more nerves.

110. An apparatus in accordance with Claim 109, wherein a first electrode is arranged to be positioned proximate the contractile tissue and a second electrode is arranged to be positioned elsewhere.

111. An apparatus in accordance with Claim 110, wherein the second electrode is arranged to be positioned close to the first electrode.

112. An apparatus in accordance with Claim 111, further including an electrode mounting arrangement mounting the first and second electrodes.

113. An apparatus in accordance with Claim 112, wherein the electrode mounting arrangement includes a mounting element having an inner surface and an outer surface, the inner surface mounting the first electrode for positioning proximate the contractile tissue, and the outer surface mounting the second electrode.

114. An apparatus in accordance with Claim 110, wherein the second electrode is arranged to be positioned remote from the first electrode and in contact with anatomy bearing afferent nerve fibres.

115. An apparatus in accordance with any one of Claims 102 to 114, wherein the disorder is fecal incontinence.

116. An apparatus in accordance with Claim 115, wherein the contractile tissue is a sphincter positioned about the colo-rectum or anal canal.

117. An apparatus in accordance with Claim 116, wherein the sphincter is a smooth muscle sphincter.

118. An apparatus in accordance with any one of Claims 115 to 117, arranged to apply the electrical signal to

stimulate one or more nerves carrying afferent signals to the sphincter muscle complex of the anal-rectal barrier.

119. An apparatus in accordance with any one of Claims 112 to 118, the signal generator means being arranged to provide the electrical signal for stimulating the sacral nerve.

120. An apparatus in accordance with any one of Claims 102 to 119, wherein the stimulation of the one or more nerves is arranged for treatment to reduce the perception of pain.

121. An apparatus in accordance with any one of Claims 102 to 114, wherein the disorder is urinary incontinence and the contractile tissue is a sphincter mounted about the urethra.

122. An apparatus in accordance with Claim 121, wherein the contractile tissue is smooth muscle.

123. An apparatus in accordance with any one of Claims 43 to 78, further include the sphincter.

124. An apparatus in accordance with any one of Claims 102 to 122, further including the contractile tissue.

125. A method of surgically implanting a stimulator device in accordance with any one of Claims 43 to 78, comprising the steps of implanting the apparatus in the patient's body so that it is positioned to provide stimulation to the contractile tissue and the one or more afferent nerves.

126. A method of surgically implanting an apparatus in accordance with any one of Claims 102 to 122, comprising the steps of implanting the stimulator device in the patient's body so that it is positioned to provide stimulation to the contractile tissue and the one or more nerves.

127. An electrode arrangement for stimulating contractile tissue and one or more nerves, the electrode arrangement including at least one mounting element mounting a first electrode arranged for stimulating the contractile tissue, and a second electrode being arranged to be mounted to stimulate the one or more nerves.

128. An electrode arrangement in accordance with Claim 127, wherein the second electrode is also mounted on the mounting element.

129. An electrode arrangement in accordance with Claim 128, wherein the mounting element has an inner face and an outer face, and the first electrode is mounted on the inner face and the second electrode is mounted on the outer face.

130. An electrode arrangement in accordance with any one of Claims 127 to 129, wherein the second electrode is arranged to be mounted remote from the first electrode, elsewhere in the pelvic anatomy.

131. An electrode arrangement in accordance with any one of Claims 127 to 130, wherein there are a plurality of second electrodes.

132. An electrode arrangement in accordance with any one of Claims 127 to 131, wherein the are a plurality of first electrodes.

133. An electrode arrangement in accordance with any one of Claims 127 to 132, wherein the mounting element has a length dimension and a width dimension, the length dimension is greater of the width dimension, so that the mounting element is of an elongate form.

134. An electrode arrangement in accordance with any one of Claims 127 to 133, comprising a further mounting element, in operation the mounting element and further

mounting element arranged to be positioned opposite to each other with the contractile tissue inbetween.

135. An electrode arrangement in accordance with Claim 134, the mounting element and further mounting element being mounted at proximate ends thereto to a base, from which they extend in respect to each other so as to form a gap between them for receiving the contractile tissue.

136. An electrode element in accordance with Claim 135, wherein the gap is open on all sides apart from when the mounting elements are joined at the base, so the arrangement may be placed over the tissue from one end, in an analogous manner to a peg.

137. A method of surgically implanting an electrode arrangement in accordance with any one of Claims 127 to 136, so that the electrode arrangement is positioned to provide stimulation to contractile tissue and the one or more nerves.

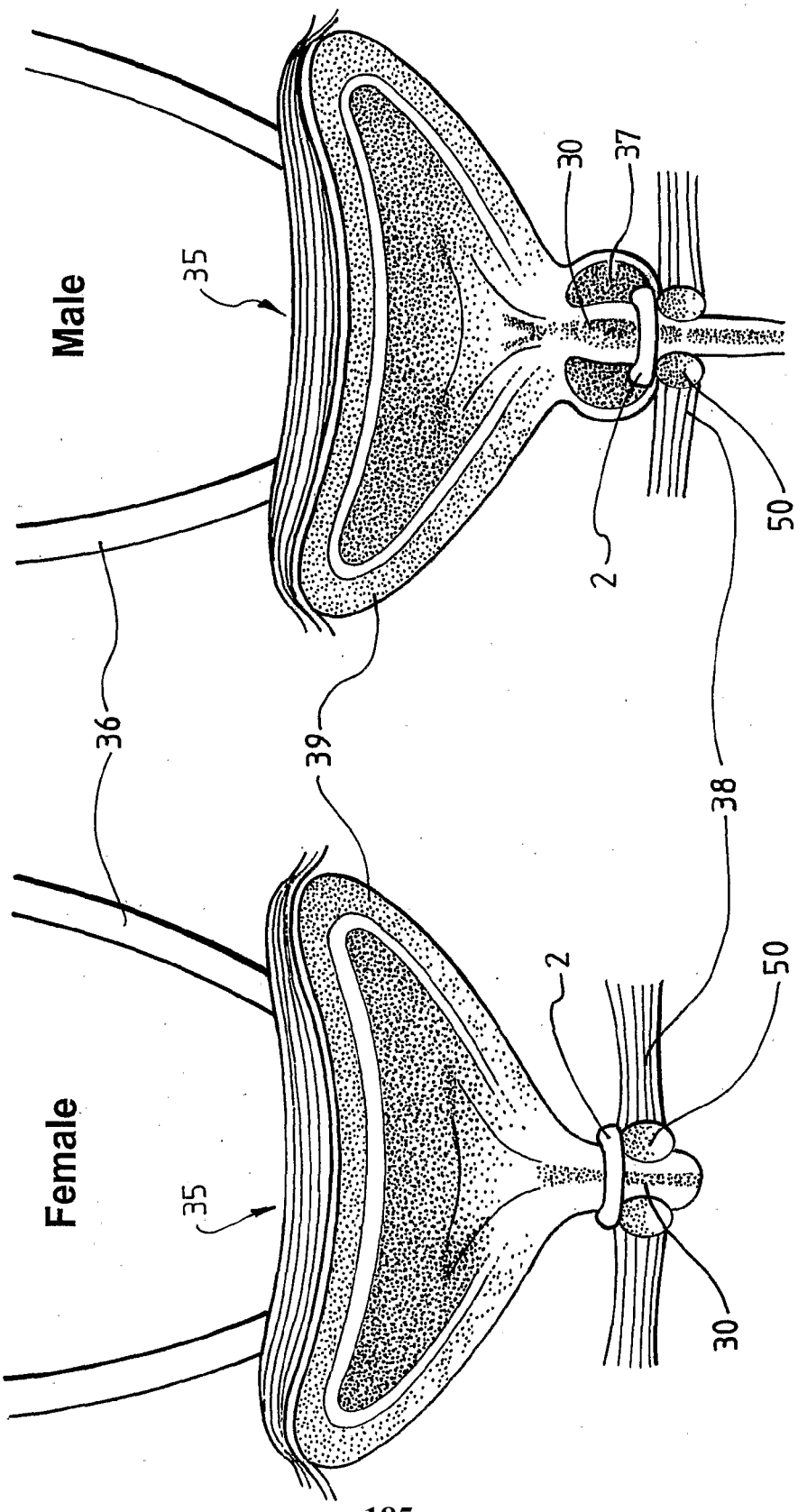


Fig. 1b

Fig. 1a

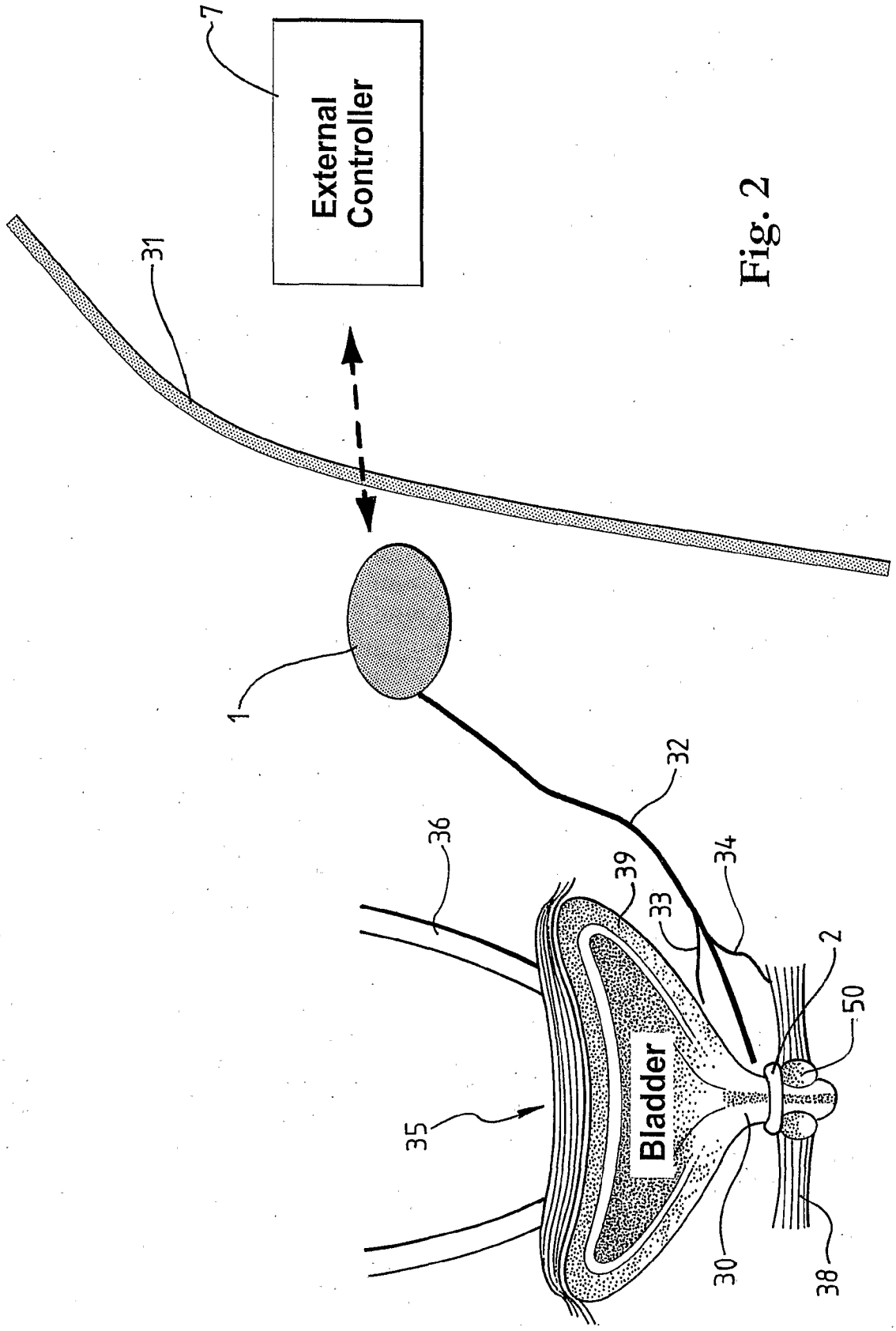


Fig. 2

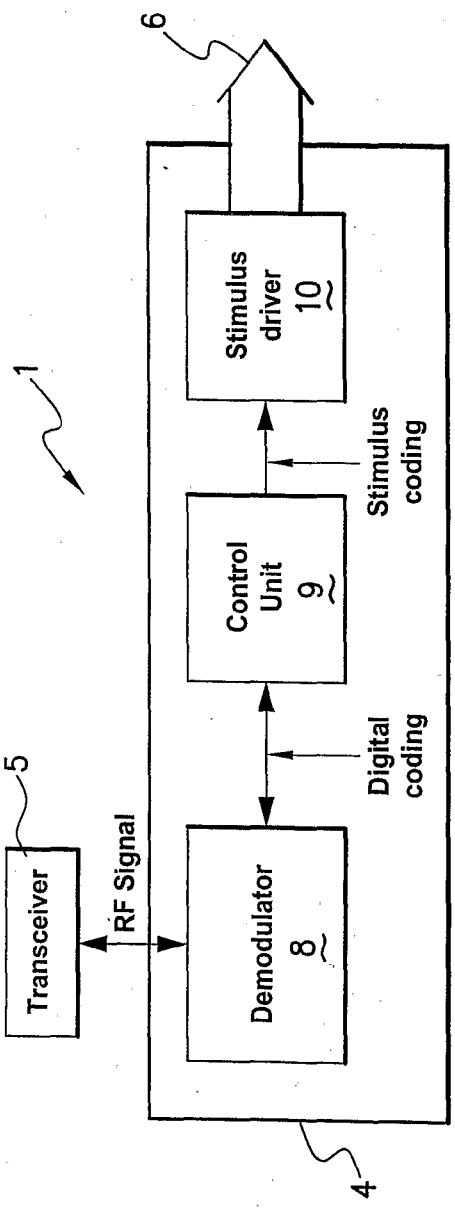


Fig. 3

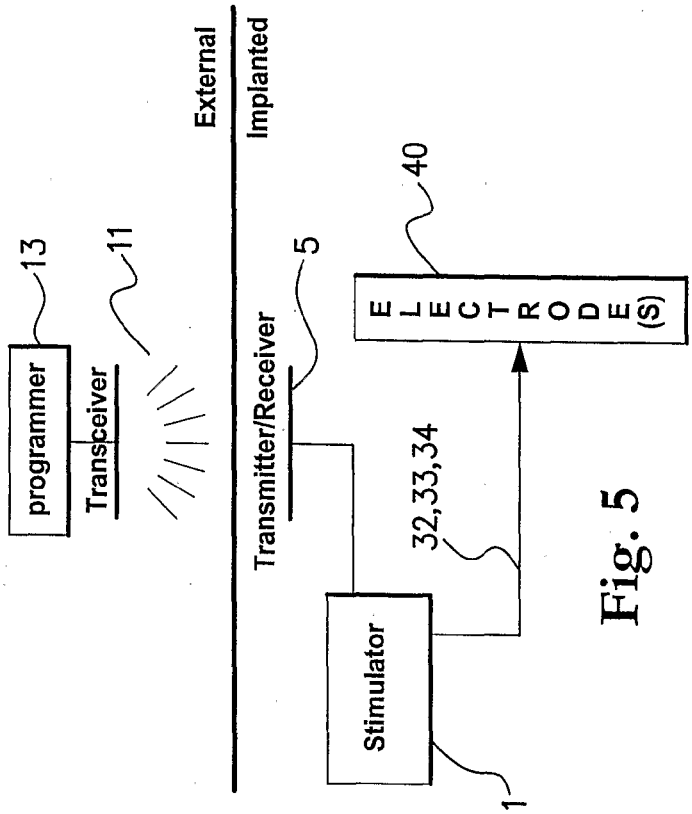


Fig. 5

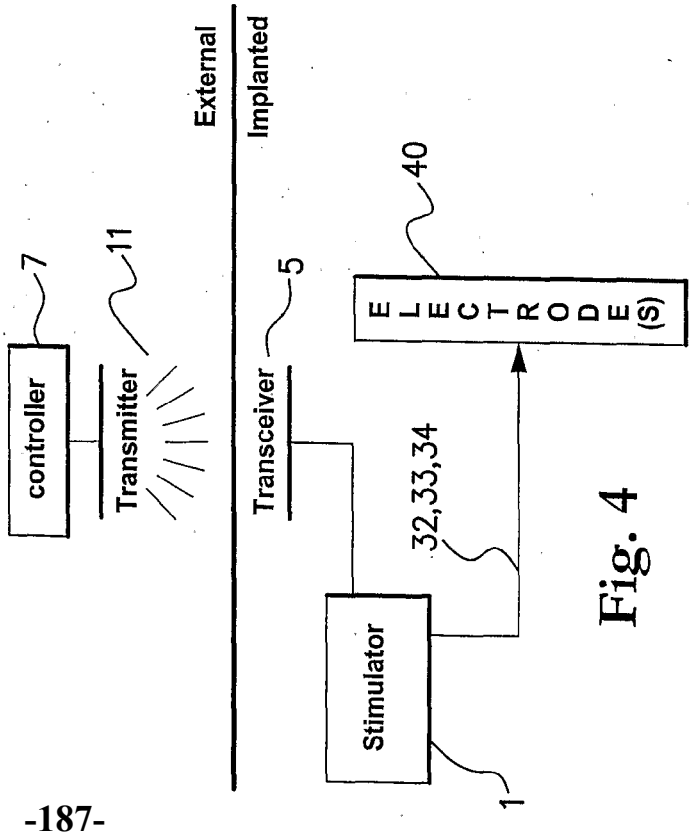


Fig. 4

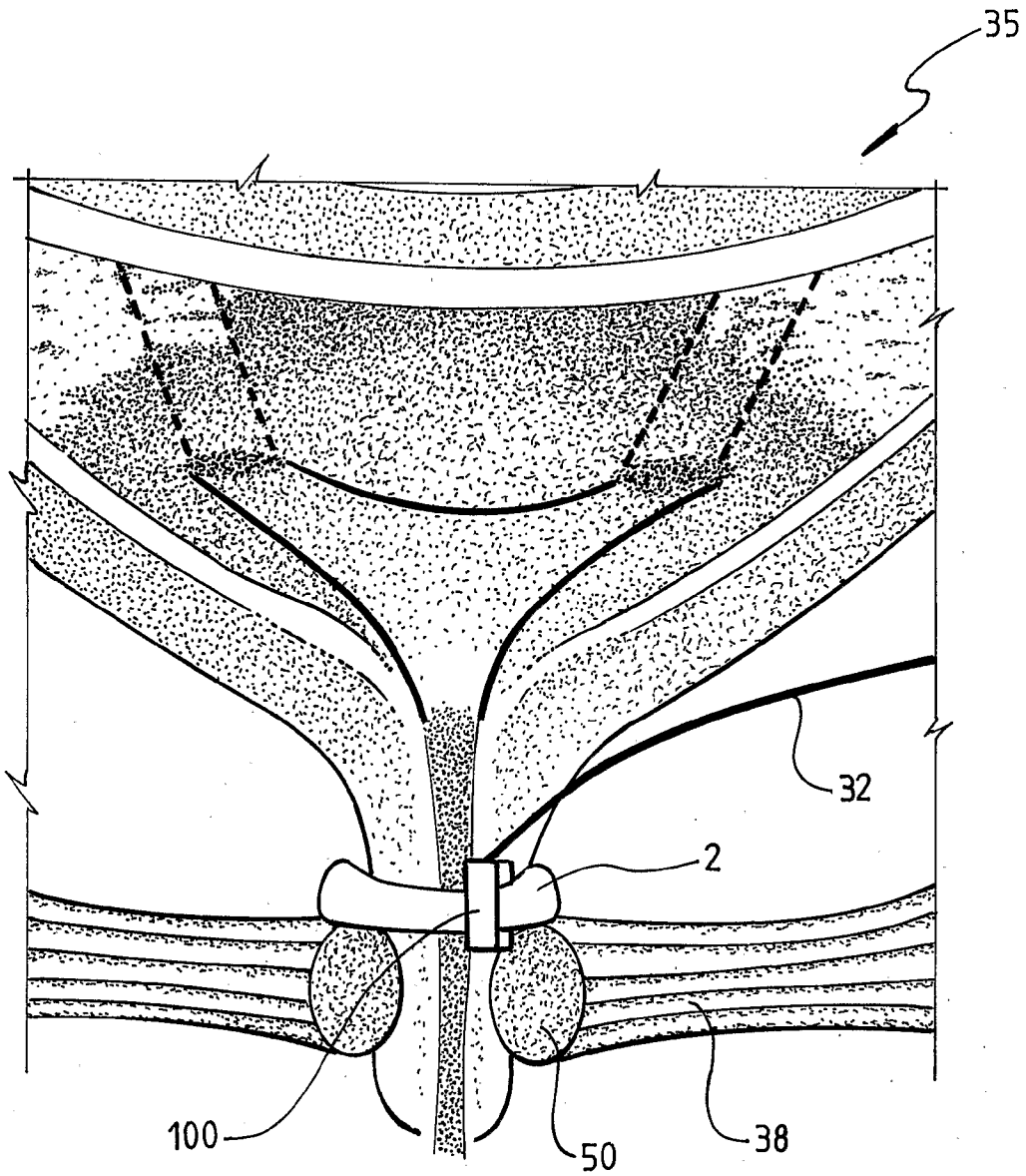


Fig. 6

Fig. 7

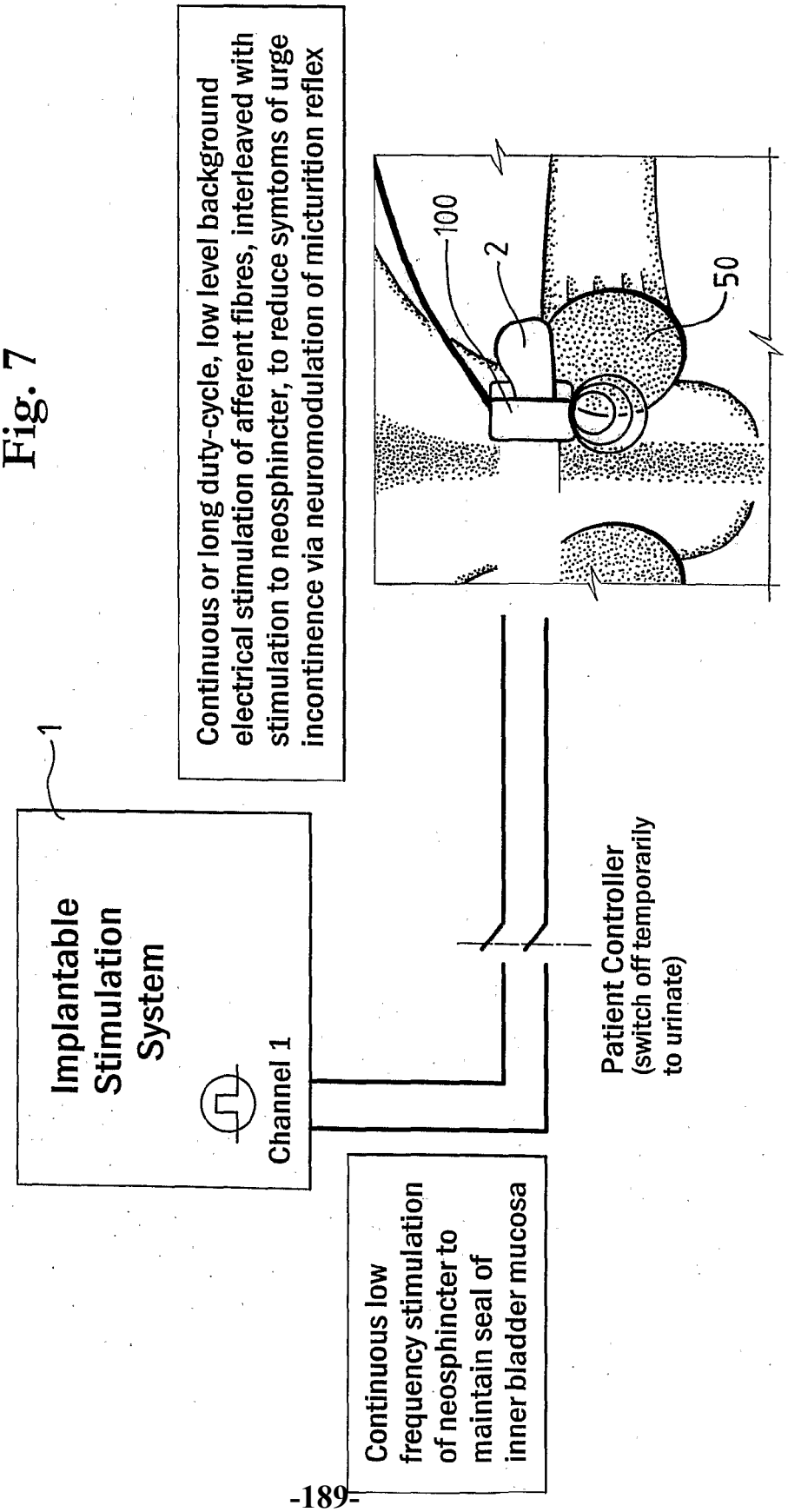

Implantable Stimulation System
1
Channel 1
Continuous or long duty-cycle, low level background electrical stimulation of afferent fibres, interleaved with stimulation to neosphincter, to reduce symtoms of urge incontinence via neuromodulation of micturition reflex
Continuous low frequency stimulation of neosphincter to maintain seal of inner bladder mucosa
Patient Controller (switch off temporarily to urinate)
100
2
50

Fig. 8

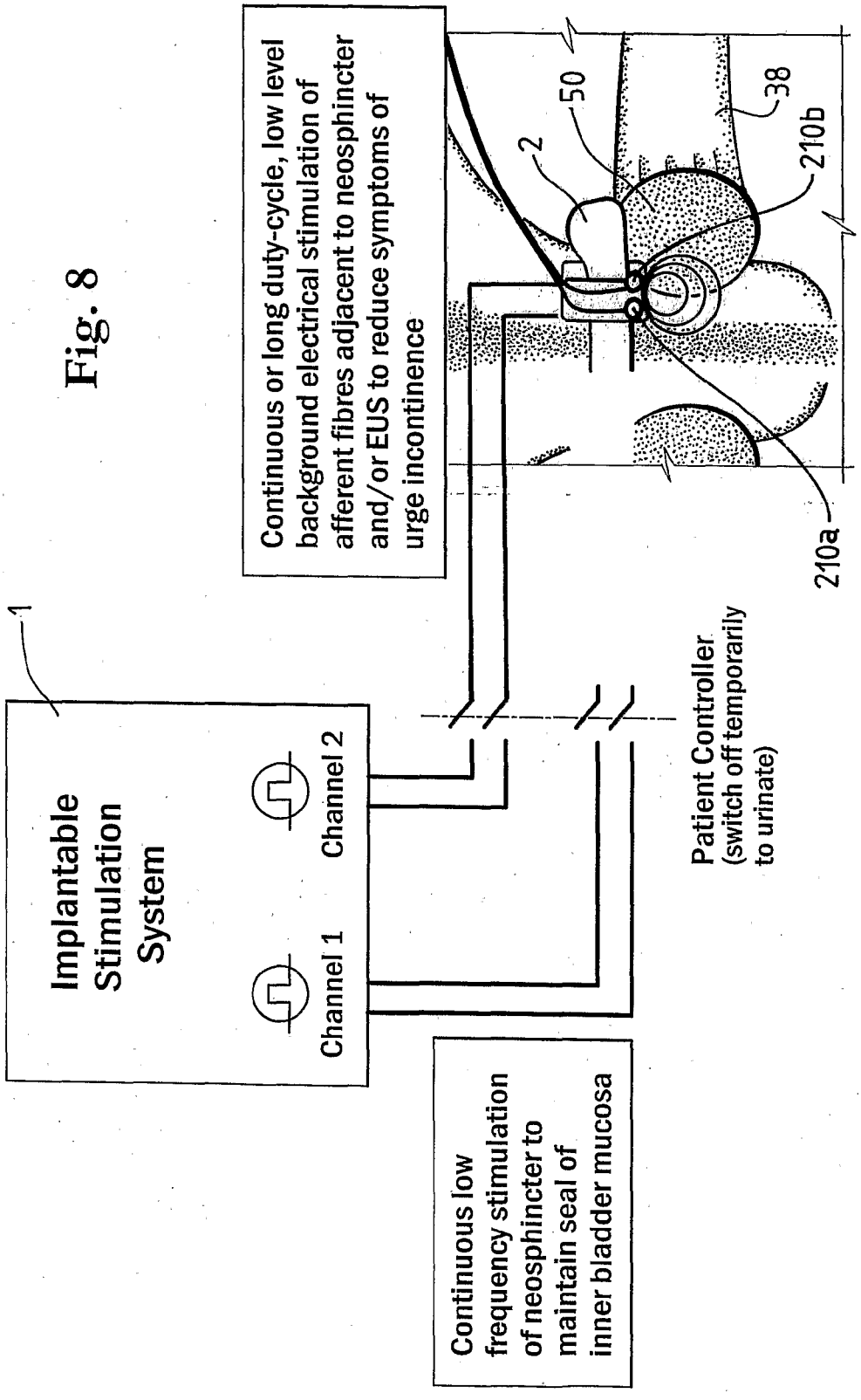
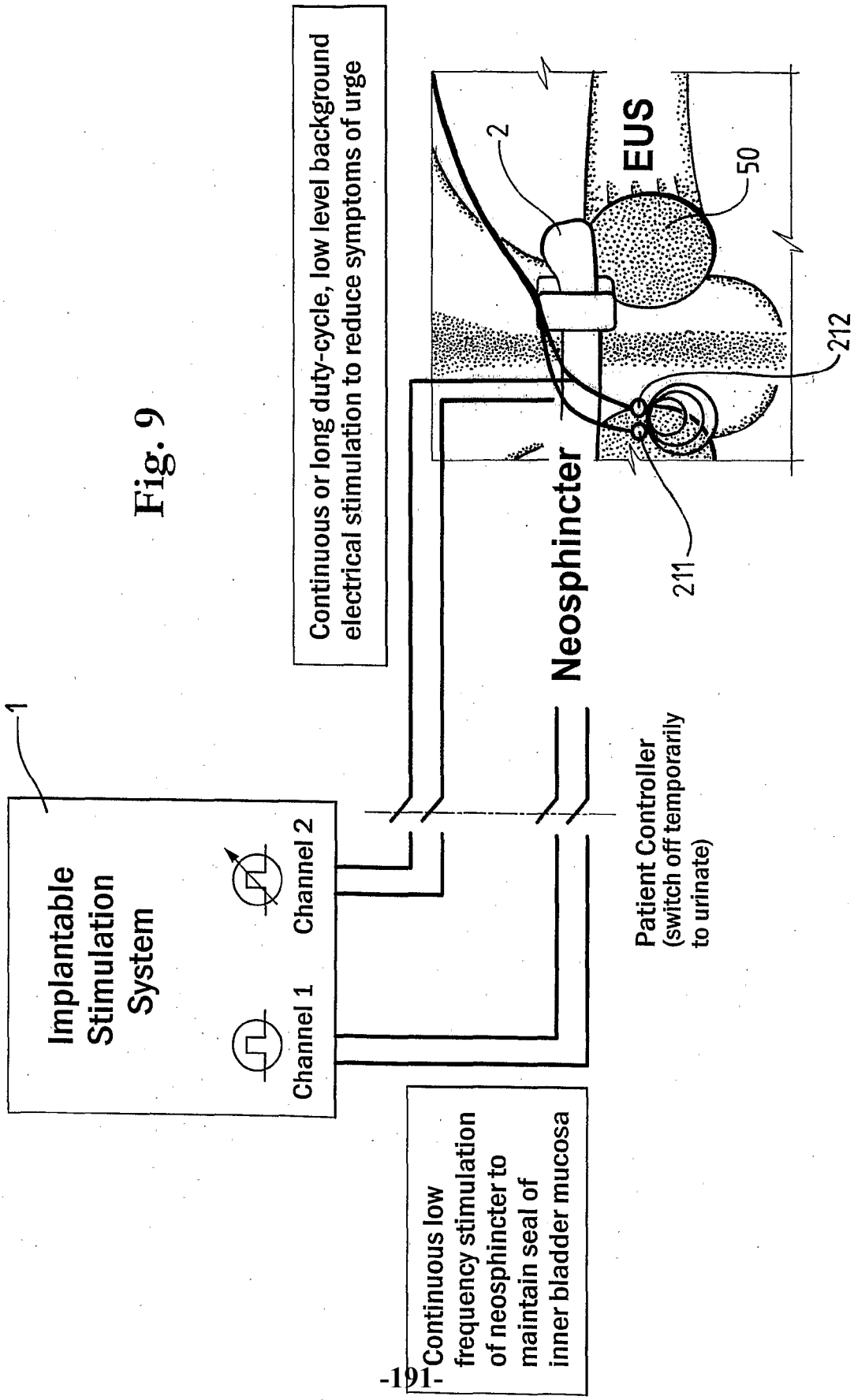

Implantable Stimulation System
1
Channel 1
Channel 2
Continuous or long duty-cycle, low level background electrical stimulation of afferent fibres adjacent to neosphincter and/or EUS to reduce symptoms of urge incontinence
Continuous low frequency stimulation of neosphincter to maintain seal of inner bladder mucosa
Patient Controller (switch off temporarily to urinate)
2
50
38
210b
210a

Fig. 9


Implantable Stimulation System
1
Channel 1
Channel 2
Continuous or long duty-cycle, low level background electrical stimulation to reduce symptoms of urge
Continuous low frequency stimulation of neosphincter to maintain seal of inner bladder mucosa
Neosphincter
Patient Controller (switch off temporarily to urinate)
EUS
2
50
211
212

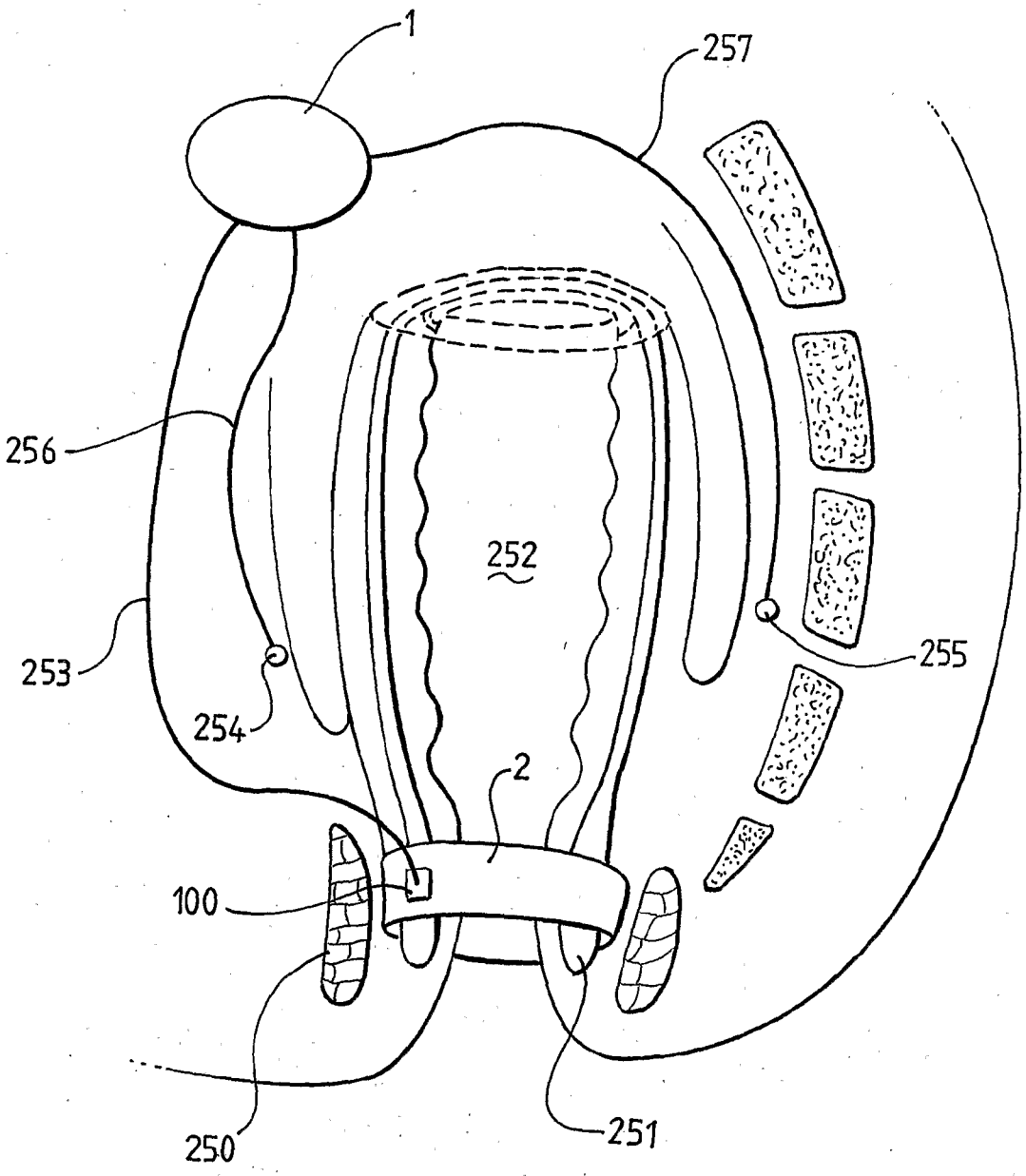


Fig. 10

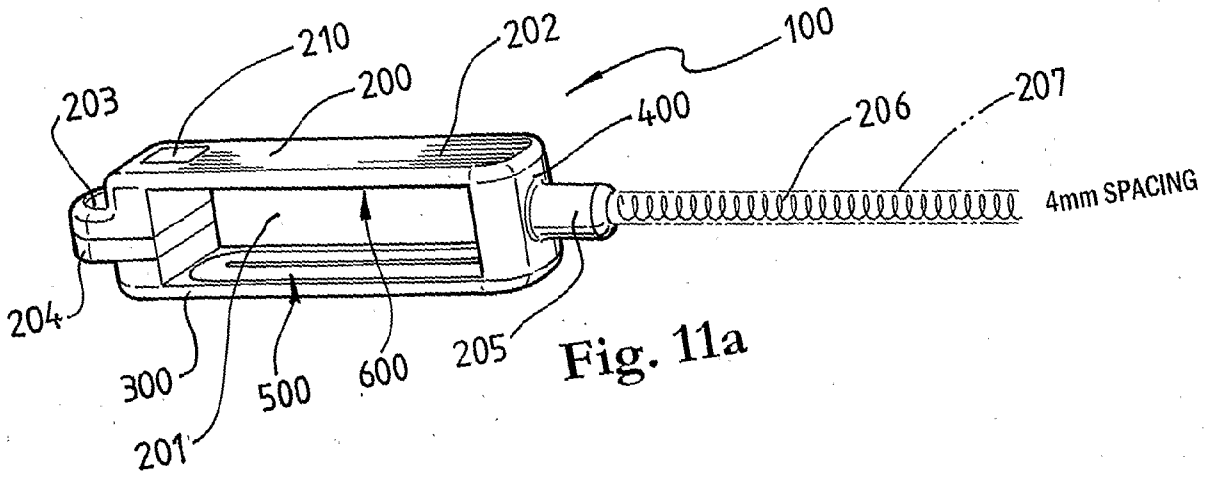


Fig. 11a

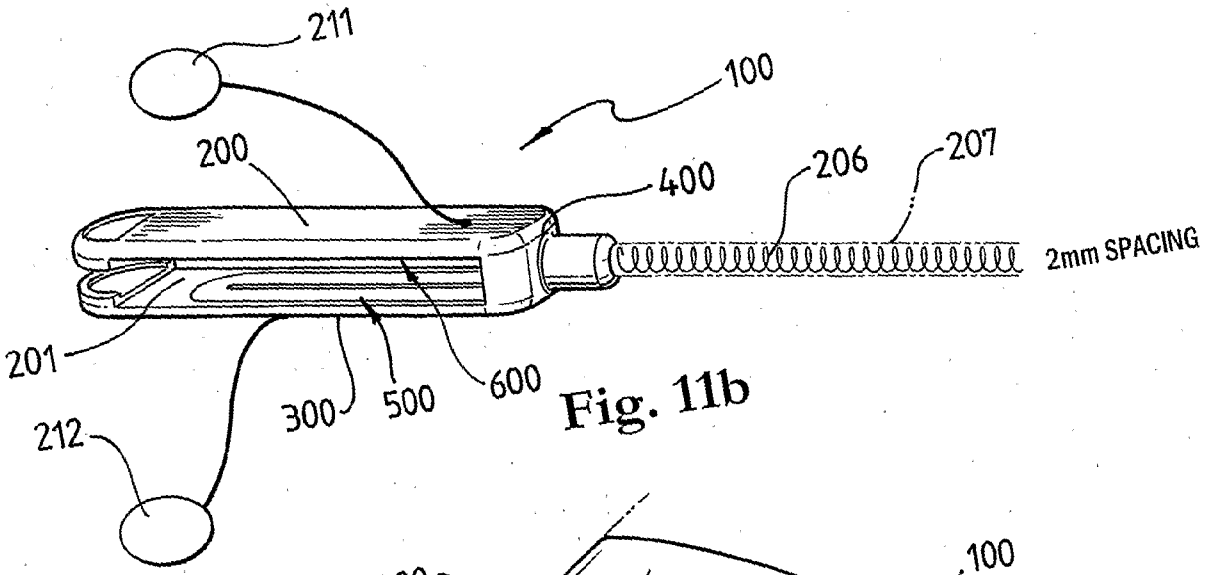


Fig. 11b

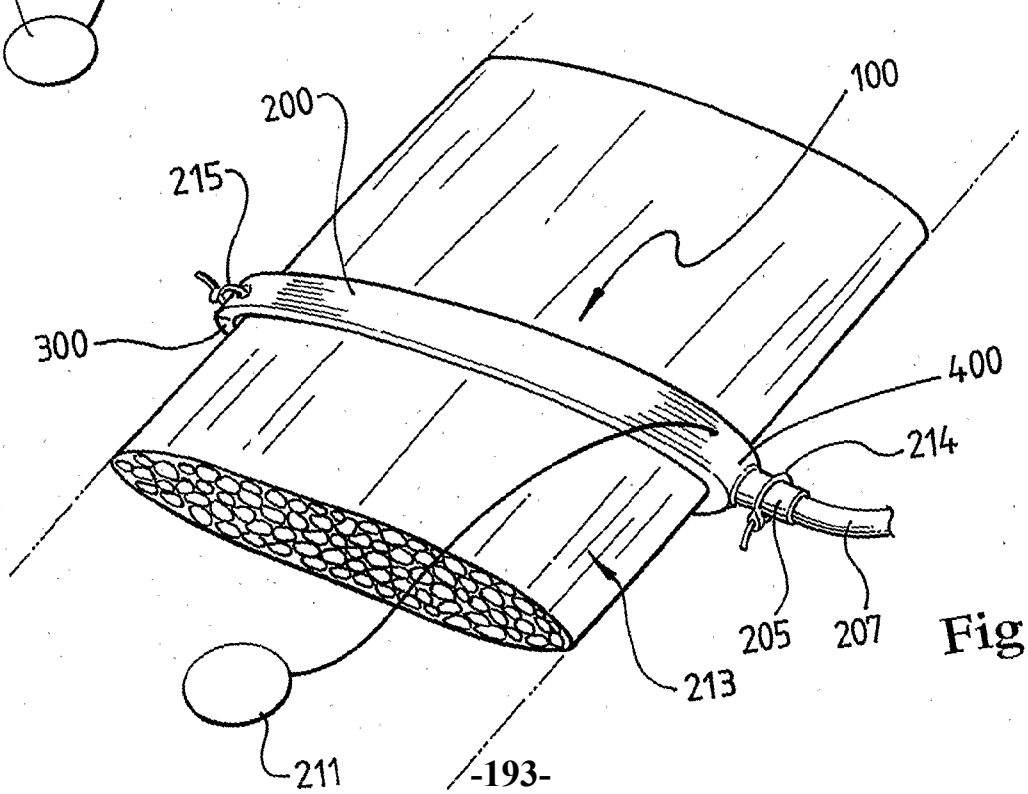
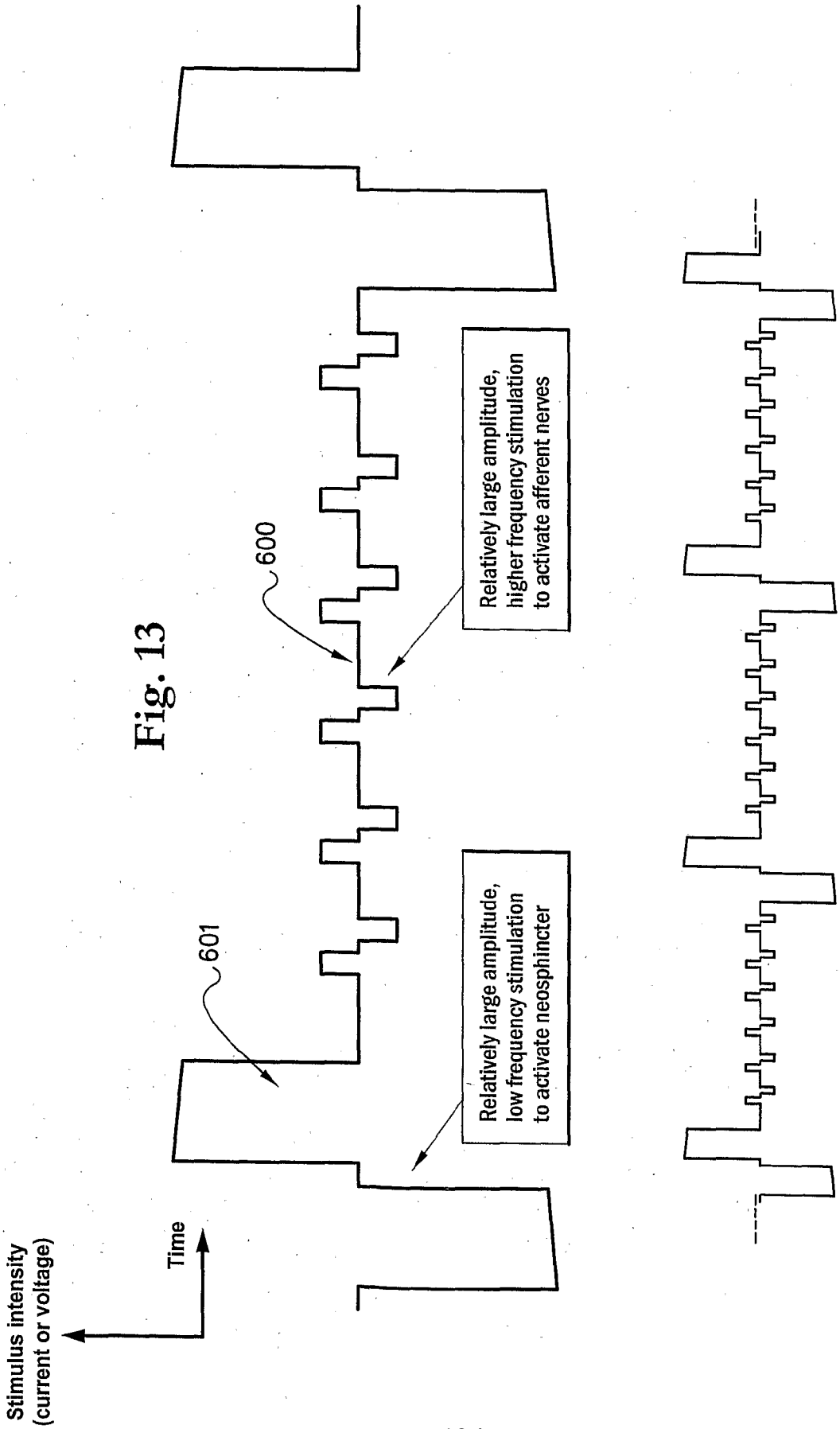


Fig. 12

Fig. 13


Stimulus intensity
(current or voltage)
Time
601
600
Relatively large amplitude,
low frequency stimulation
to activate neosphincter
Relatively large amplitude,
higher frequency stimulation
to activate afferent nerves

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000258

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61N 1/36 (2006.01)

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)

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)

DWPI: A61B A61N nerve neuro neural afferent efferent sphincter urethra contract smooth fes fns stimulate electric trigger signal provoke excite pulse induce incontinence bladder bowel fecal colon defecate urinate reflex urge urging need require

Medline: urge incontinence nerve muscle stimulation neuromodulation FES

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4607639 A (TANAGHO et al) 26 August 1986 Column 3 line 53 to column 4 line 51, column 5 line 28 to 63, column 10 line 6 to column 11 line 35, claim 1	80-82,84,85, 87-104,106, 108-122,124, 126-137
Y		1-79 83,86,105,107

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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

"E" earlier 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
15 June 2006	26 JUN 2006
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**MATTHEW FORWARD** Telephone No : (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000258

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2001/054767 A1 (POLYVALOR L.P. et al) 2 August 2001 Page 6 line 25 to page 8 line 21, page 10 lines 6 to 10, page 13 lines 5 to 16	4, 6, 46, 52, 83, 86, 105, 107
X	US 2004/0186531 A1 (JAHNS et al) 23 September 2004 Paragraphs 0085 to 0101, 0135 to 0136, 0145, figures	80-85, 88-93, 102-106, 109-114, 127, 130
Y		87, 108
Y	Vaizey et al (1999). Effects of short term sacral nerve stimulation on anal and rectal function in patients with anal incontinence. *Gut*, V44, PP407-412 Pages 407 and 411	1-3,5,7-41,44,45,47-51,53-79
Y	US 5964789 A (KARDSON) 12 October 1999 Column 3 lines 7 to 59, column 4 lines 9 to 67	87, 108
Y	WO 2000/001320 A2 (ADVANCED BIONICS CORPORATION) 13 January 2000 Pages 2 and 5	1-3,5,7-41,44,45,47-51,53-79
Y	WO 2002/078592 A2 (CASE WESTERN RESERVE UNIVERSITY) 10 October 2002 Pages 2 to 6	1-3,5,7-41,44,45,47-51,53-79
A	EP 1319422 A2 (NIHON KOHDEN CORPORATION) 18 June 2003 Column 3	
A	US 2005/0010260 A1 (GERBER) 13 January 2005 Paragraphs 0007, claim 1	
P, A	Groen et al (2005). Chronic pudendal neve neuro-modulation in women with idiopathic refractory detrusor overactivity incontinence: results of a pilot study with novel minimally invasive implantable mini-stimulator. *Neurourological Urodynamics*, 24(3), pp 226-230	
P, A	Spinelli et al (2005). A new minimally invasive procedure for pudenal nerve stimulation to treat neurogenic bladder: description of the method and preliminary data. *Neurourological Urodynamics*, 24(4), pp305-309	

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	4607639	EP	0245547	US	4703755	US	4739764
		US	4771779				
WO	0154767	AU	28240/01	CA	2397957	EP	1251907
		EP	1600193	US	6393323	US	2002193840
US	2004186531	AU	20270/02	AU	21183/97	AU	26332/00
		AU	36640/02	AU	71667/01	AU	73088/01
		AU	2003228528	AU	2003294293	CA	2361670
		CN	1347297	EP	1154738	EP	1322382
		EP	1324805	EP	1401358	EP	1583581
		US	6006134	US	6266564	US	6449507
		US	6532388	US	6542774	US	6692513
		US	6718208	US	6735471	US	6769434
		US	6890330	US	6896690	US	6904318
		US	6912419	US	6929653	US	2002026221
		US	2002032468	US	2002042651	US	2002049468
		US	2002095116	US	2002138044	US	2002188325
		US	2003216790	US	2004030362	US	2004034380
		US	2004162584	US	2004172075	US	2004186517
		US	2005010246	US	2005010285	US	2005015112
		US	2005055088	US	2005096707	US	2005131438
		US	2005251216	US	2005261669	US	2005261759
		WO	0044313	WO	0201999	WO	0205888
		WO	0226318	WO	0226320	WO	0234118
		WO	0247539	WO	9740885	WO	03026741
		WO	03088809	WO	2004043293	WO	2005053788
US	5964789	US	5447526	US	5713940		
WO	0001320	AU	49635/99	CA	2336190	EP	1100402
		US	6735474	US	6941171	US	2002055761
		US	2005228451				
WO	02078592	AU	2004277854	CA	2442412	CA	2538799
		EP	1372780	US	6907293	US	7047078
		US	2003004553	US	2005060005	US	2005222636

		WO	2005032332				
EP	1319422	EP	0788813	JP	9276418	US	5984854
US	2005010260	US	2004049240	US	2004193228	US	2005010259
		US	2005015117	US	2005020970	US	2005021008
		US	2005033372	US	2005033373	US	2005033374
		US	2005070969	US	2005113877	US	2005113878

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	5	(("20040102819") or ("20060015153") or ("20050283202") or ("9630004") or ("9339641")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/06/19 07:59
L2	3	wo-2006092007-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/19 08:03
L3	189	(607/144).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/06/19 08:07
L4	46778	(A61N1/36021 or A61N1/36057 or A61N1/0456 or A61N2/02 or A61N1/36007 or A61N1/0551 or A61N1/36017 or A61B5/4047 or A61N2/004 or A61N1/3787).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/19 08:07
L5	46944	L3 or L4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/19 08:07
L6	3941	l5 and (tremor or parkinson$2)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/19 08:07
L7	158	l6 and ((stimulation with feedback) same (motion or tremor))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/19 08:08
L8	79	l7 and (electrode with (hand or palm))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/19 08:08

S1	241	(((hand or palm) with (tremor or parkinson$2)) same stimulation)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/13 16:33
S2	10	((("EMKINETICS") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/06/18 11:13
S3	305	((("RAJGURU") near3 ("Amit")) OR (("BURNETT") near3 ("Daniel")) OR (("VERGARA") near3 ("Alexander")) OR (("HEMATI") near3 ("Michael"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/06/18 11:13
S4	164	("20020007128" | "20020055761" | "20020138116" | "20030000392" | "20030003968" | "20040015188" | "20060155345" | "20110270140" | "20120101326" | "20130072835" | "20140249595" | "20140288613" | "20150227909" | "20150260471" | "20180050216" | "20180133472" | "4969468" | "5299572" | "5374283" | "5995873" | "6132386" | "6379313" | "6615080" | "6692444" | "6904614" | "7628761" | "8308665" | "8660646" | "8805510" | "8812114" | "8818520" | "8954153" | "9056194" | "9076187" | "9245265" | "9265941" | "20020040233" | "20030004392" | "20060115130" | "20080097142" | "20150190648" | "0066177" | "20020082465" | "20020099323" | "20020111777" | "200210028991" | "200210133129" | "200210183647" | "200210183804" | "20030028072" | "20030144625" | "20030158583" | "20030158585" | "20030216729" | "20040054393" | "20040082875" | "20040102819" | "20040122787" | "20040138517" | "20040147964" | "20040173220" | "20040237170" | "20050029223" | "20050033380" | "20050099290" | "20050107654" | "20050143783" | "20050203602" | "20050240230" | "20050283204" | "20060004244" | "20060047316" | "20060049957" | "20060122660" | "20060135844" | "20060161039" | "20060173261" | "20060178576" | "20060184211" | "20060276702" | "20070021712" | "20070027353" | "20070027355" | "20070208212" | "20080004484" | "20080058874" | "20080063866" | "20080114199" | "20080177128" | "20080177347" | "20080224808" | "20080262287" | "20080306325" | "20080312725" | "20090030337" | "20090073991" | "20090076336" | "20090076340" | "20090076344" | "20090076345" | "20090076363" | "20090076364" | "20090076397" |	US-PGPUB; USPAT	OR	ON	2019/06/18 11:14

		"20090076410" | "20090076559" | "20090076565" | "20090102819" | "20090118777" | "20090132018" | "20090162570" | "20090171236" | "20090227829" | "20090227831" | "20090234179" | "20090234410" | "20090264792" | "20090292194" | "20100022864" | "20100049021" | "20100056881" | "20100057149" | "20100119482" | "20100160712" | "20100161005" | "20100168501" | "20100204538" | "20100222630" | "20100318009" | "20110021863" | "20120302821" | "201210059432" | "20130072746" | "20130310909" | "20140046423" | "20160067515" | "20160067517" | "5833600" | "6029090" | "6032677" | "6066084" | "6319241" | "6379324" | "6471903" | "6500110" | "6511463" | "6565532" | "6678556" | "6684106" | "6689100" | "6743211" | "6782283" | "6866659" | "6926660" | "6931277" | "7013179" | "7226439" | "7262068" | "7273474" | "7332197" | "7367936" | "7396326" | "7429333" | "7500911" | "7522061" | "7560036" | "7570992" | "7591806" | "7627938" | "7647112").PN.				
S5	189	(607/144).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/06/18 11:52
S6	46778	(A61N1/36021 or A61N1/36057 or A61N1/0456 or A61N2/02 or A61N1/36007 or A61N1/0551 or A61N1/36017 or A61B5/4047 or A61N2/004 or A61N1/3787).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/06/18 11:52

EAST Search History (Interference)

< This search history is empty>

6/ 19/ 2019 8:25:43 AM
C:\ Users\ mcarey\ Documents\ EAST\ Workspaces\ 15474875.wsp

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

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)* Sheet 1 of 2	*Complete if Known*	
	Application Number	15/474,875
	Filing Date	March 30, 2017
	First Named Inventor	Amit RAJGURU
	Art Unit	3766
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	EMKNNZ00703

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

Examiner Signature	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	15/474,875
				Filing Date	March 30, 2017
				First Named Inventor	Amit RAJGURU
				Art Unit	3766
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	EMKNNZ00703

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]
	37.	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	/MICHAEL J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	15/474,875
				Filing Date	March 30, 2017
				First Named Inventor	Amit RAJGURU
				Art Unit	3766
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00703

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 J CAREY/	Date Considered	06/19/2019

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.J.C/

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	15/474,875
Filing Date	March 30, 2017
First Named Inventor	Amit RAJGURU
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	EMKNNZ00703

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.	5,995,873	11-30-1999	Rhodes	
	6.	6,132,386	10-17-2000	Gozani et al.	
	7.	6,379,313	04-30-2002	Gozani et al.	
	8.	6,615,080	09-02-2003	Unsworth et al.	
	9.	6,692,444	02-17-2004	Gozani et al.	
	10.	6,904,614	06-14-2005	Yamazaki et al.	
	11.	7,628,761	12-08-2009	Gozani et al.	
	12.	8,308,665	11-13-2012	Harry et al.	
	13.	8,660,646	02-25-2014	Laing et al.	
	14.	8,805,510	08-12-2014	Chancellor et al.	
	15.	8,812,114	08-19-2014	Van den biggelaar et al.	
	16.	8,818,520	08-26-2014	Laing et al.	
	17.	8,954,153	02-10-2015	Boggs	
	18.	9,056,194	06-16-2015	Van den biggelaar et al.	
	19.	9,076,187	07-07-2015	Laing et al.	
	20.	9,245,265	01-26-2016	Laing et al.	
	21.	9,265,941	02-23-2016	Van den biggelaar et al.	
	22.	2002/0007128	01-17-2002	Ives et al.	
	23.	2002/0055761	05-09-2002	Mann et al.	
	24.	2002/0138116	09-26-2002	Bertolucci	
	25.	2003/0003968	01-02-2003	Muraki	
	26.	2004/0015188	01-22-2004	Coulter	
	27.	2006/0155345	07-13-2006	Williams et al.	
	28.	2011/0270140	11-03-2011	Israeli	
	29.	2012/0101326	04-26-2012	Simon et al.	
	30.	2013/0072835	03-21-2013	Harry et al.	
	31.	2014/0249595	09-04-2014	Chancellor et al.	
	32.	2014/0288613	09-25-2014	Laing et al.	
	33.	2015/0227909	08-13-2015	Laing et al.	
	34.	2015/0260471	09-17-2015	Azhocar	
	35.	2018/0050216	02-22-2018	Burnett	
	36.	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)*				***Complete if Known***	
				Application Number	15/474,875
				Filing Date	March 30, 2017
				First Named Inventor	Amit RAJGURU
				Art Unit	3766
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	EMKNNZ00703

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]
	37.	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.

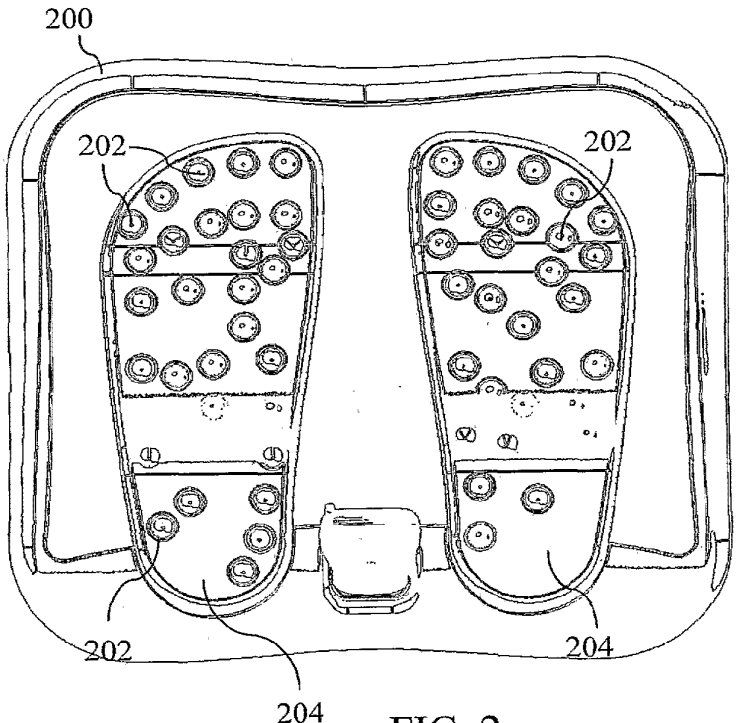


FIG. 2

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.

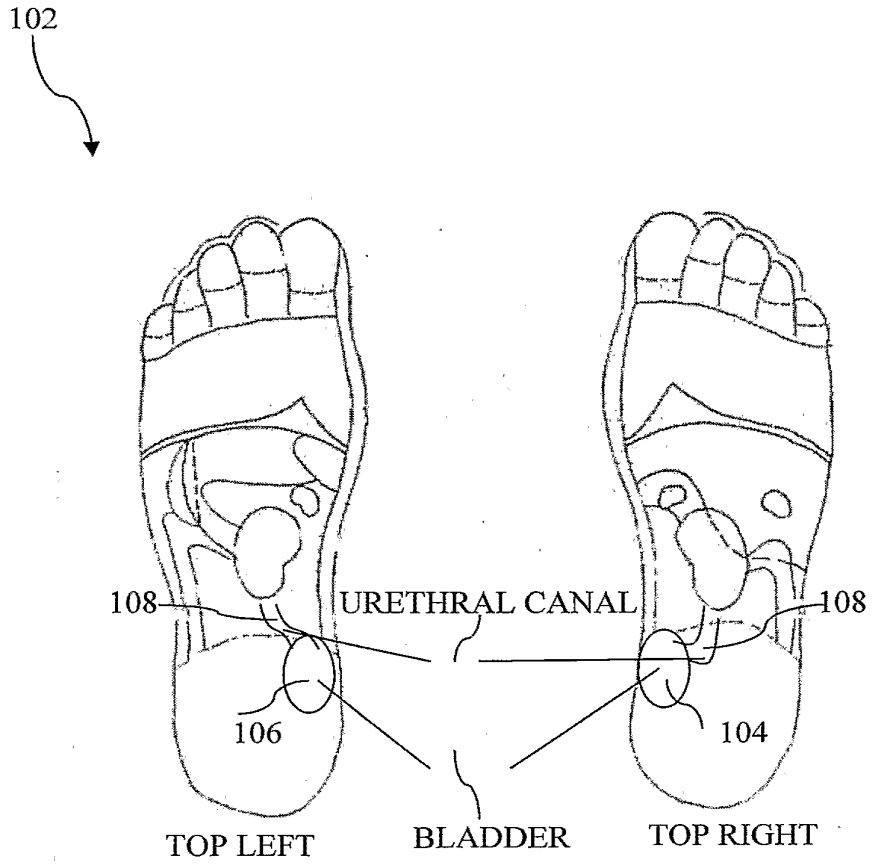

102
108
URETHRAL CANAL
108
106
104
TOP LEFT
BLADDER
TOP RIGHT

FIG. 1

1/5

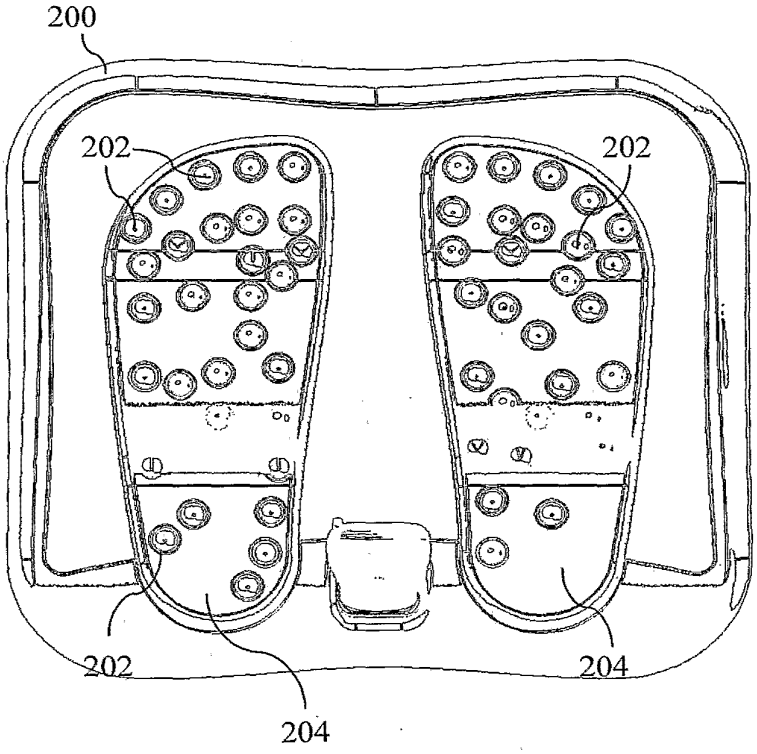


FIG. 2

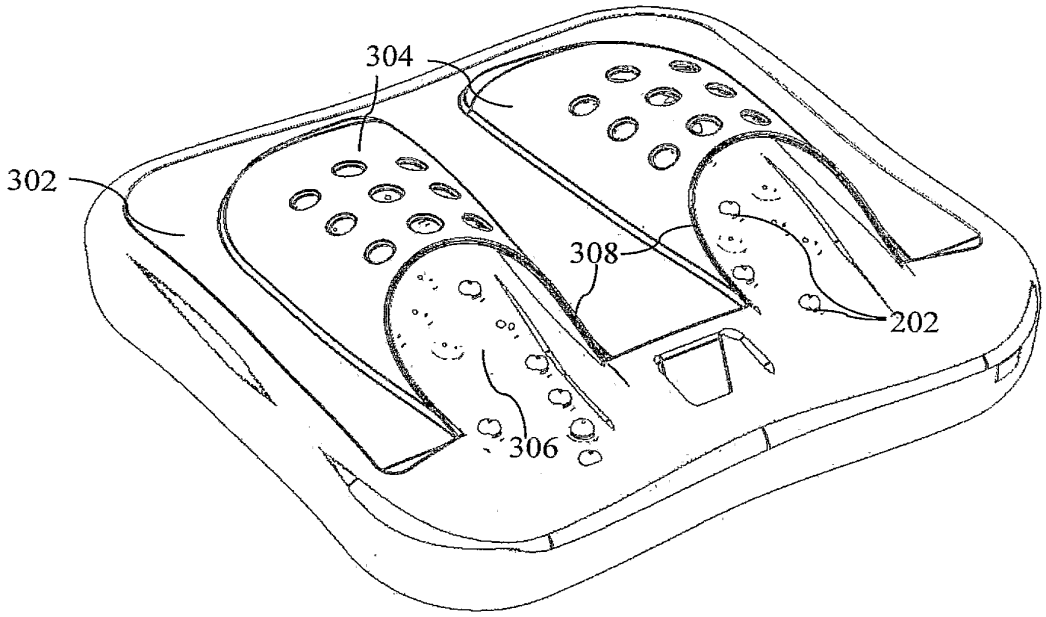


FIG. 3

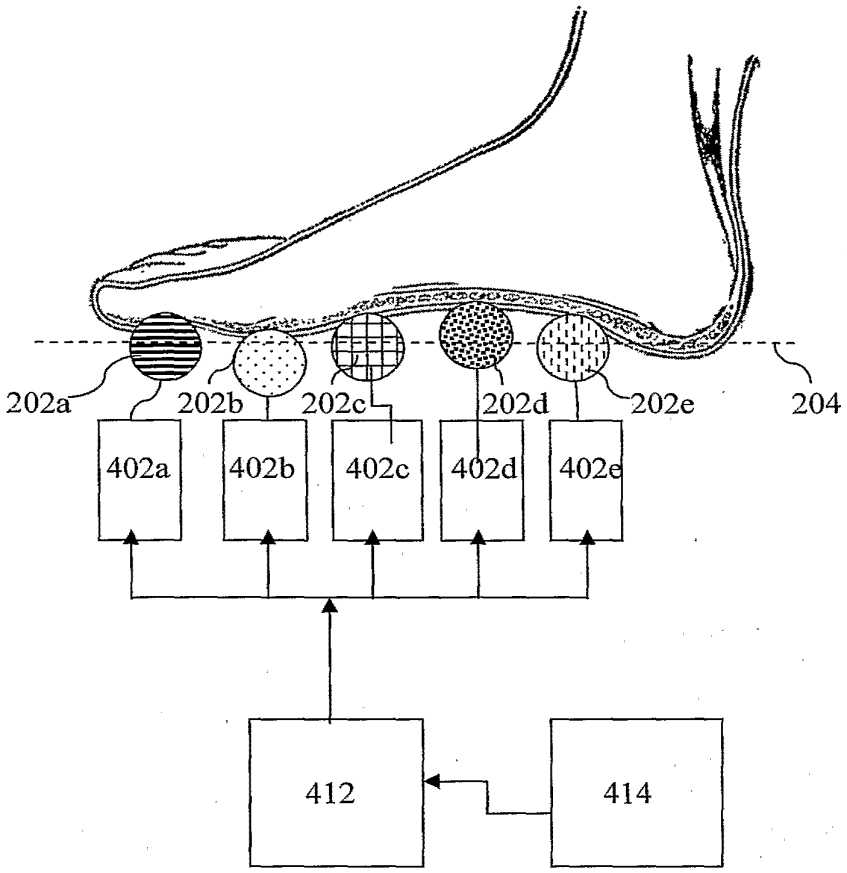


FIG. 4

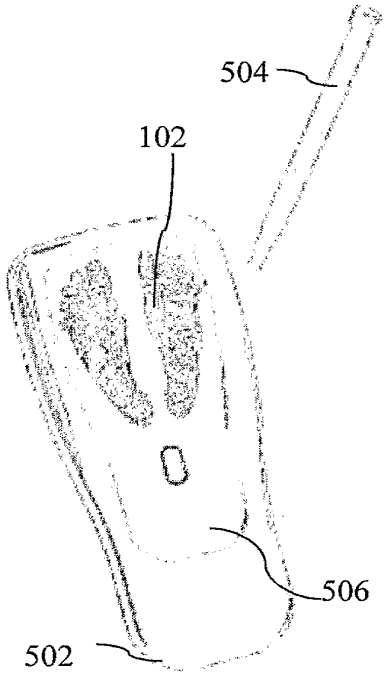


FIG. 5

5/5

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 Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: 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:	33344477
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Johney U. Han/Emily Ackerman
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	01-AUG-2018
Filing Date:	30-MAR-2017
Time Stamp:	14:30:55
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_EMKNNZ00703_20180801_ids_cover_letter.pdf	22836 47cf0164921655be55b757219b0f05d079e2fc70	no	2

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	02_EMKNNZ00703_20180801_sb08.pdf	32274 2fe67a43ef8d4451a24b8c6c0c1404d839306fd5	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	03_37_WO2010084482_emkinetics.pdf	606515 72cb7b2ad5a40370d62702df3ffa52178aadc073	no	17
Warnings:					
Information:					
		Total Files Size (in bytes):	661625		

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.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Not Yet Assigned
Group Art Unit:	3766

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. **EMKNNZ00703**. 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

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 15/474,875	Filing Date 03/30/2017	☐ 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 $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **02/08/2018**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 21	= 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

AMENDMENT

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

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

LIE
THERESA OKON

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.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.
Date: February 8, 2018 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Not Yet Assigned
Group Art Unit:	3766

PRELIMINARY AMENDMENT

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

Dear Sir or Madam:

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

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

Remarks begin on page 6 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. (Currently Amended): A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:

positioning a stimulator electrode over a ~~glabrous~~ skin surface overlying a target nerve or tissue which extends through a hand ~~palm~~ of the subject; [[and]]

delivering electrical stimulation via a pulse generator transdermally through the ~~glabrous~~ skin surface and to the [[a]] target nerve or tissue ~~within the hand~~ to stimulate the target nerve or tissue ~~within the hand~~ so that tremors experienced ~~pain felt~~ by the subject are [[is]] mitigated; and

detecting a motion from the subject via at least one sensor positioned on the subject

~~wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude~~.

2. (Original): The method of claim 1, wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject.

3. (Original): The method of claim 1, wherein the stimulator electrode is a surface electrode.

4. (Original): The method of claim 1, wherein the electrical stimulation is delivered intermittently or on a chronic basis.

5. (Currently Amended): The method of claim 1, further comprising~~:~~

~~detecting nerve stimulation via at least one sensor positioned on the subject;~~

adjusting or optimizing the electrical stimulation in response to ~~receiving~~ a feedback signal received from the sensor indicative of the detected motion and ~~electrical stimulation thereby providing a feedback about the~~ efficacy of the applied electrical stimulation therapy ~~such that the therapy is adjusted or optimized~~.

6. (Currently Amended): The method of claim 1, wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude ~~5 wherein the sensor senses an M-Wave~~.

7.-9. (Canceled)

10. (Currently Amended): The method of claim 5, wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve ~~within the hand~~ while reducing the risk of burns or intolerance.

11. (Original): The method of claim 5, wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy.

12. (Original): The method of claim 5, wherein the sensor is a surface electrode.

13. (Currently Amended): The method of claim 1, further comprising positioning a return electrode on the subject to facilitate penetration of an electrical current through the ~~glabrous~~ surface to stimulate the target nerve ~~within the hand~~.

14. (Currently Amended): The method of claim 1, wherein the stimulator electrode is attached to the ~~glabrous~~ skin surface with an adhesive.

15. (Currently Amended): The method of claim 1, wherein the stimulator electrode is positioned over the ~~glabrous~~ skin surface with an ergonomic applicator.

16. (Currently Amended): The method of claim 15, wherein the applicator is a glove or brace configured to be positioned against a skin ~~the palmar~~ surface ~~of a hand~~ such that the electrode delivers electrical stimulation to the [[a]] target nerve or tissue ~~within the hand~~.

17. (Original): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes to overcome habituation.

18. (Currently Amended): The method of claim 1, wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes based on feedback provided by a sensor ~~regarding target nerve stimulation or habituation~~.

19. (Original): The method of claim 1, wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased.

20. (Original): The method of claim 1, wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary.

21. (Canceled)

22. (New): The method of claim 1, wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface.

23. (New): The method of claim 22, wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.

24. (New): The method of claim 22, wherein the at least two electrodes are positioned in opposition relative to one another.

REMARKS

Claims 1-21 were pending in the present application. By virtue of this response, claims 7-9, 21 have been canceled, claims 1, 5-6, 10, 13-16, 18 have been amended, and new claims 22-24 have been added. Accordingly, claims 1-6, 10-20, 22-24 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.

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. **EMKNNZ00703**. 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

Electronic Acknowledgement Receipt

EFS ID:	31742321
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Johney U. Han/Kim Lampkins
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	08-FEB-2018
Filing Date:	30-MAR-2017
Time Stamp:	16:33:32
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		EMKNNZ00703_20180208_preliminary_amendment.pdf	33444 1f9a330635726e7b50bb77908ea23fc7a00761f9	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	6
Warnings:			
Information:			
	Total Files Size (in bytes):	33444	

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703

CONFIRMATION NO. 7884

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

PUBLICATION NOTICE

OC000000094233415

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

Publication No.US-2017-0266443-A1
Publication Date:09/21/2017

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

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	15/474,875
				Filing Date	March 30, 2017
				First Named Inventor	Amit RAJGURU
				Art Unit	3766
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00703

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:	30112524
Application Number:	15474875
International Application Number:	
Confirmation Number:	7884
Title of Invention:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
First Named Inventor/Applicant Name:	Amit RAJGURU
Customer Number:	40518
Filer:	Johney U. Han/Emily Ackerman
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00703
Receipt Date:	17-AUG-2017
Filing Date:	30-MAR-2017
Time Stamp:	16:54:04
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_EMKNNZ00703_20170817_ids_cover_letter.pdf	499840 7c9e83b44fb8c21bd6769efa6584127f01dd7420	no	2

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	02_EMKNNZ00703_20170817_ids_sb08.pdf	294155 c0068197319074bee9661d86ac8c7438993e8953	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
			Total Files Size (in bytes):	793995	

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.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Not Yet Assigned
Group Art Unit:	3766

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. **EMKNNZ00703**. 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

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
15/474,875	03/30/2017	3766	1040	EMKNNZ00703	21	1

CONFIRMATION NO. 7884

UPDATED FILING RECEIPT

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

OC000000092073058

Date Mailed: 06/14/2017

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)

Amit RAJGURU, Lafayette, CA;
Daniel R. BURNETT, San Francisco, CA;
Alexander VERGARA, San Francisco, CA;
Michael HEMATI, San Francisco, CA;

Applicant(s)

EMKinetics, Inc., San Francisco, CA;

Assignment For Published Patent Application

EMKinetics, Inc., San Francisco, CA

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

Domestic Priority data as claimed by applicant

This application is a CIP of 15/084,356 03/29/2016 PAT 9630004
which is a CON of 13/840,936 03/15/2013 PAT 9339641
which is a CIP of PCT/US2011/052415 09/20/2011
which claims benefit of 61/403,680 09/20/2010
This application 15/474,875
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
This application 15/474,875
claims benefit of 62/350,610 06/15/2016

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

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: 04/07/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/474,875**

Projected Publication Date: 09/21/2017

Non-Publication Request: No

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

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

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 patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

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

NOT GRANTED

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

SelectUSA

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/474,875

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE($)	FEE($)		RATE($)	FEE($)
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))	21 minus 20 =	* 1	x 40 =	40	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			200			
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	970		TOTAL	

APPLICATION AS AMENDED - PART II

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

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

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

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/474,875	03/30/2017	Amit RAJGURU	EMKNNZ00703

CONFIRMATION NO. 7884

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

POA ACCEPTANCE LETTER

OC000000092056909

Date Mailed: 06/14/2017

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/12/2017.

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**.

/ytdemisse/

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

Date: June 12, 2017 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	15/474,875
Confirmation No.:	7884
Filing Date:	March 30, 2017
Inventor(s):	Amit RAJGURU et al.
Title:	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES
Examiner:	Not Yet Assigned
Group Art Unit:	3766

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

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

Dear Sir or Madam:

This is in response to the Notice to Corrected Application Papers dated April 10, 2017 for which a response was due on June 10, 2017, which fell on a Saturday. Accordingly, this response is timely filed. Applicants respectfully submit:

1. Corrected Application Data Sheet
2. Fully executed Declaration
3. Executed Substitute Statement
4. Replacement Drawings
5. Power of Attorney
6. Statement under 37 CFR 3.73(c)
7. Information Disclosure Statement
8. Surcharge for a late declaration and/or fees are being concurrently submitted via EFS-Web.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing and all documents filed herewith to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00703**.

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

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	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

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
	Amit		RAJGURU	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Lafayette	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	30 Chapel Drive		
Address 2			
City	Lafayette	State/Province	CA
Postal Code	94549	Country	US

Inventor 2 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	586 Teresita Boulevard		
Address 2			
City	San Francisco	State/Province	CA
Postal Code	94127	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alexander		VERGARA	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

City	San Francisco	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	3953 21st Street
Address 2	

City	San Francisco	State/Province	CA
Postal Code	94114	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Michael		HEMATI	

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	1000 Chestnut Street 13A
Address 2	

City	San Francisco	State/Province	CA
Postal Code	94109	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@ibhip.com	Add Email	Remove Email

Application Information:

Title of the Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES		
Attorney Docket Number	EMKNNZ00703	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	71	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

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	Patented ~~Pending~~	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
	Continuation in part of	15084356	2016-03-29	9630004	2017-04-25

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15084356	Continuation of	13840936	2013-03-15	9339641	2016-05-17
Prior Application Status	Expired				Remove
Application Number	Continuity Type	Prior Application Number			Filing or 371(c) Date (YYYY-MM-DD)
13840936	Continuation in part of	PCT/US2011/052415			2011-09-20
Prior Application Status	Expired				Remove
Application Number	Continuity Type	Prior Application Number			Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2011/052415	Claims benefit of provisional	61403680			2010-09-20
Prior Application Status	Abandoned				Remove
Application Number	Continuity Type	Prior Application Number			Filing or 371(c) Date (YYYY-MM-DD)
	Continuation in part of	12508529			2009-07-23
Prior Application Status	Abandoned				Remove
Application Number	Continuity Type	Prior Application Number			Filing 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
Prior Application Status	Pending				Remove
Application Number	Continuity Type	Prior Application Number			Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62350610			2016-06-15

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

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

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[j] (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	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

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)
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	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

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.	[X]
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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

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)	2017-06-12
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
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	EMKNNZ00703
	Application Number	15/474,875
Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES	

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.

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

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

Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

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 15/474,875 filed on March 30, 2017.

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

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

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

WARNING:

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

LEGAL NAME OF INVENTOR

Inventor: Amit RAJGURU Date (Optional): _____

Signature: _____

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

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

SUPPLEMENTAL SHEET

(for use with Form PTO/AIA/01 and PTO/SB/01A)

Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES		
Application No.	15/474,875	Filing Date	March 30, 2017

LEGAL NAME OF INVENTOR(S)			
Inventor two:	Daniel R. BURNETT	Date (Optional):	3/31/17
Signature:			
Inventor three:	Alexander VERGARA	Date (Optional):	09/14/17
Signature:			
Inventor four:	Michael HEMATI	Date (Optional):	09/14/17
Signature:			

Doc code: Oath
Document Description: Oath or declaration filed

PTO/AIA/02 (07-13)
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 displays a valid OMB control number.

SUBSTITUTE STATEMENT IN LIEU OF AN OATH OR DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (35 U.S.C. 115(d) AND 37 CFR 1.64)

Title of Invention	METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

This statement is directed to:

☐ The attached application,

OR

☒ United States application or PCT international application number 15/474,875 filed on March 30, 2017.

LEGAL NAME of inventor to whom this substitute statement applies:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Amit RAJGURU

Residence (except for a deceased or legally incapacitated inventor).

City	State	Country
Lafayette	CA	US

Mailing Address (except for a deceased or legally incapacitated inventor):

30 Chapel Drive

City	State	Zip	Country
Lafayette	CA	94549	US

I believe the above-named inventor or joint inventor to be the original inventor or an original joint inventor of a claimed invention in the application.

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

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

Relationship to the inventor to whom this substitute statement applies:

- ☐ Legal Representative (for deceased or legally incapacitated inventor only),
- ☒ Assignee,
- ☐ Person to whom the inventor is under an obligation to assign,
- ☐ Person who otherwise shows a sufficient proprietary interest in the matter (petition under 37 CFR 1.46 is required), or
- ☐ Joint Inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PTO/SB/AIA02 (07-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

SUBSTITUTE STATEMENT

Circumstances permitting execution of this substitute statement:

- ☐ Inventor is deceased,
- ☐ Inventor is under legal incapacity,
- ■ Inventor cannot be found or reached after diligent effort, or
- ☐ Inventor has refused to execute the oath or declaration under 37 CFR 1.63.

If there are joint inventors, please check the appropriate box below:

- ■ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) naming the entire inventive entity has been or is currently submitted.

OR

- ☐ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) has not been submitted. Thus, a Substitute Statement Supplemental Sheet (PTO/AIA/11 or equivalent) naming the entire inventive entity and providing inventor information is attached. See 37 CFR 1.64(b).

WARNING:

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

PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

Name: Daniel R. BURNETT | Date (Optional): 5/5/17

Signature:

APPLICANT NAME AND TITLE OF PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

If the applicant is a juristic entity, list the applicant name and the title of the signer:

Applicant Name: EMKinetics, Inc.

Title of Person Executing This Substitute Statement: CEO

The signer, whose title is supplied above, is authorized to act on behalf of the applicant.

Residence of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent):

City San Francisco | State CA | Country US

Mailing Address of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent)

588 Teresita Boulevard

City San Francisco | State CA | Zip 94127 | Country US

Note: Use an additional PTO/AIA/02 form for each inventor who is deceased, legally incapacitated, cannot be found or reached after diligent effort, or has refused to execute the oath or declaration under 37 CFR 1.63.

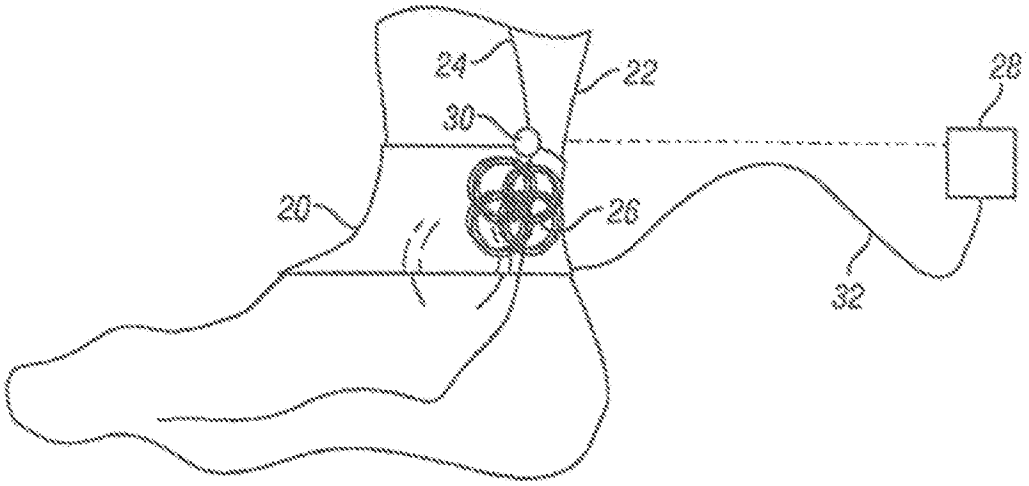


FIG. 1

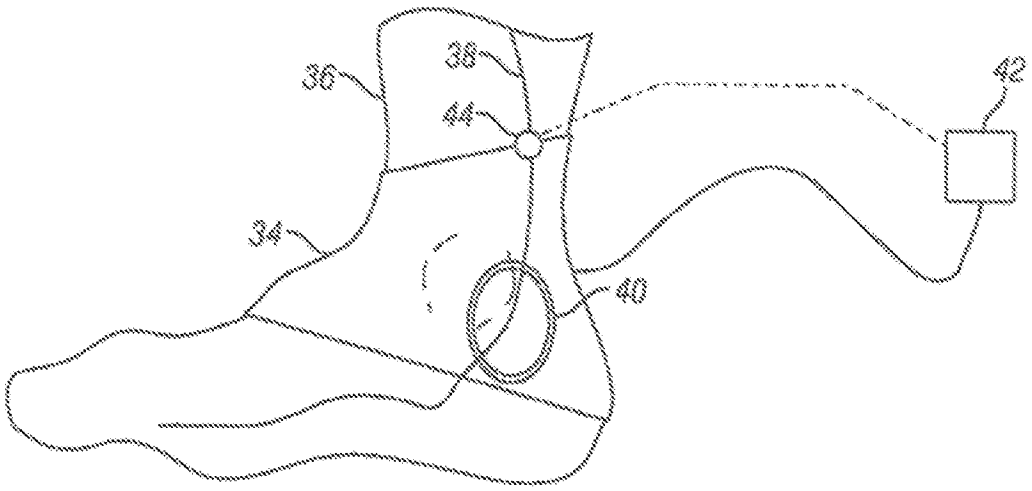


FIG. 2

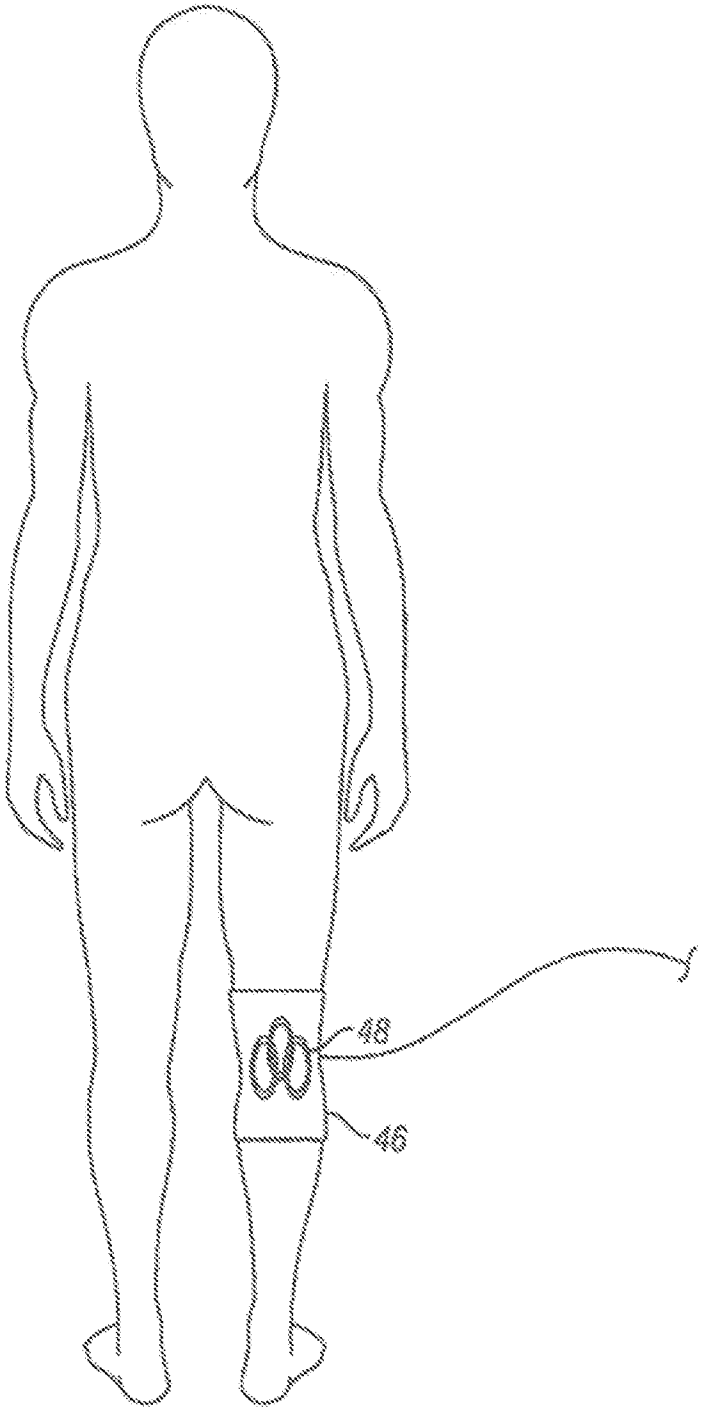


FIG. 3

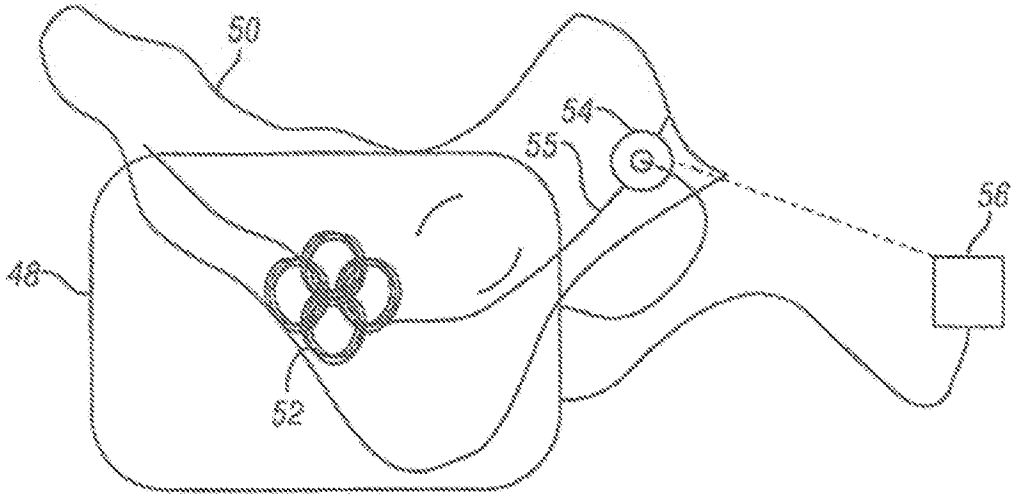


FIG. 4

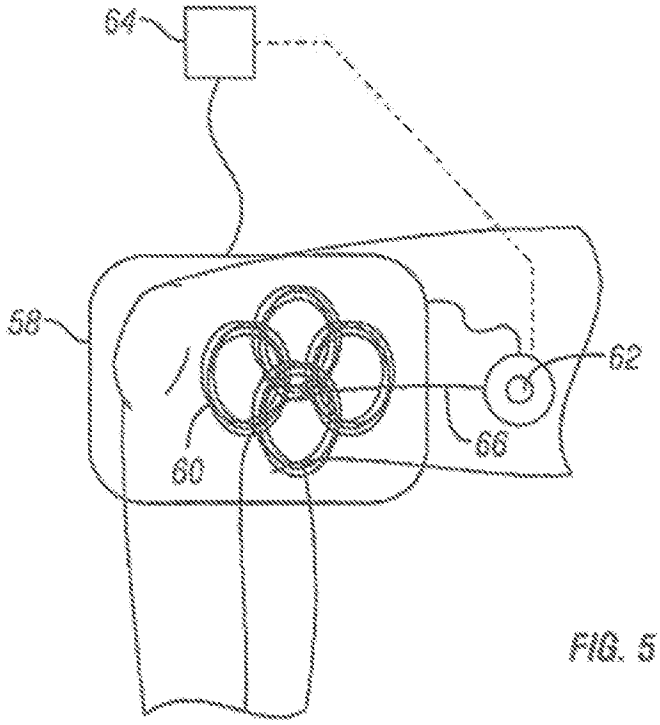


FIG. 5

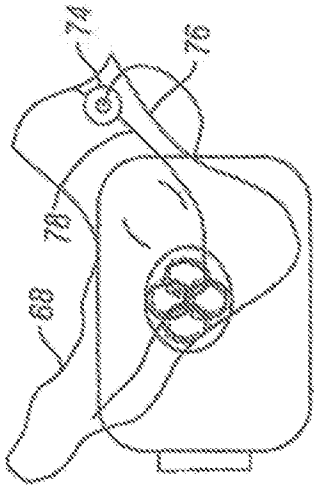


FIG. 6B

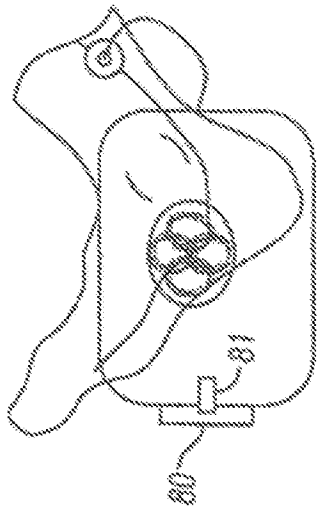


FIG. 6D

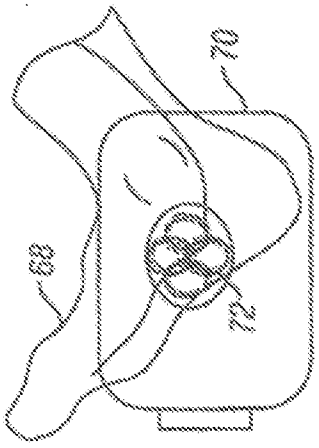


FIG. 6A

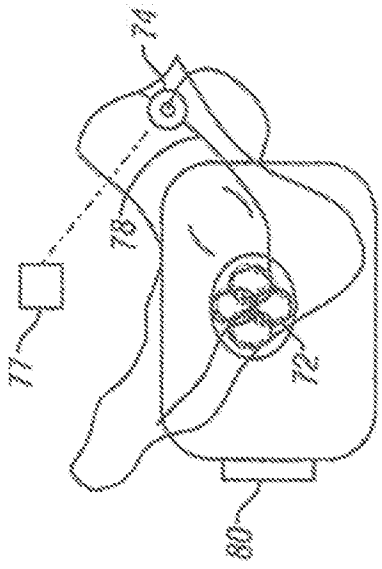


FIG. 6C

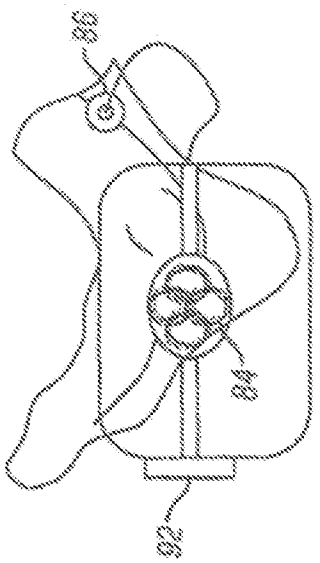


FIG. 7B

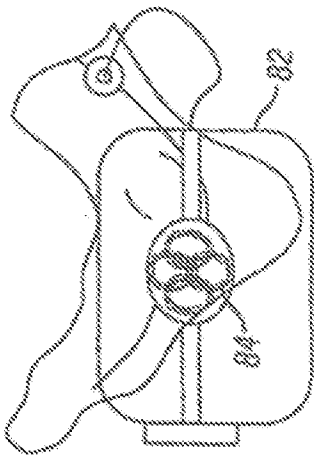


FIG. 7D

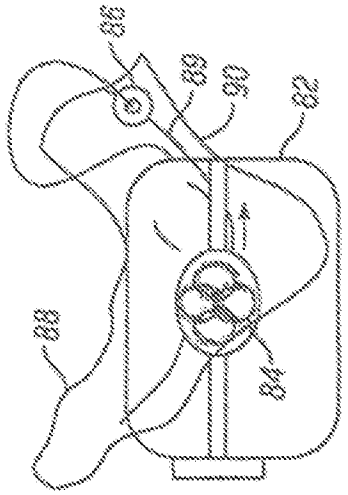


FIG. 7A

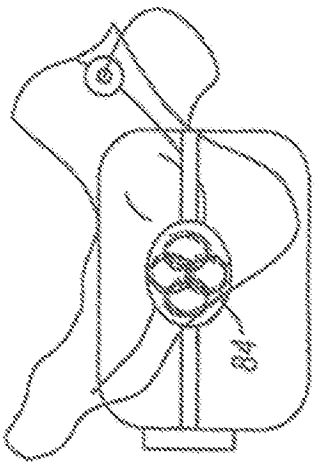


FIG. 7C

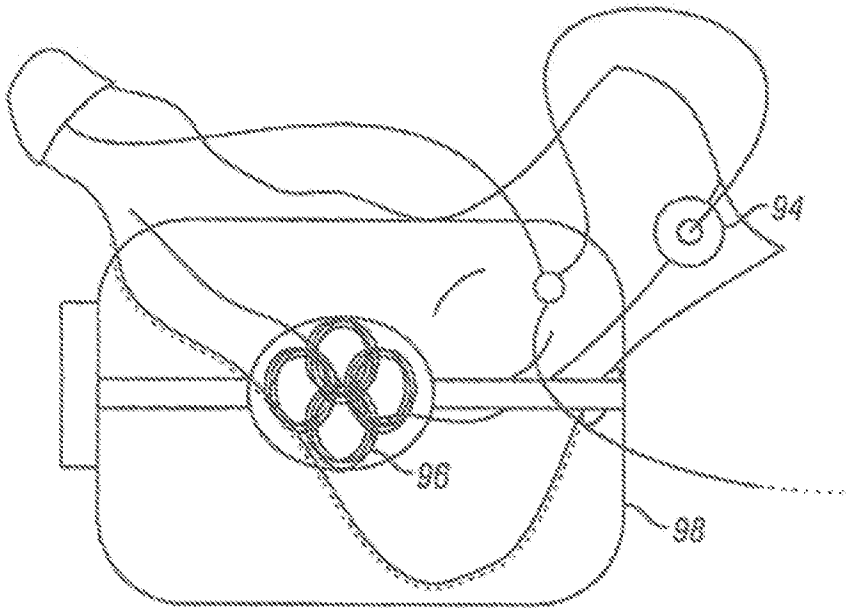


FIG. 8

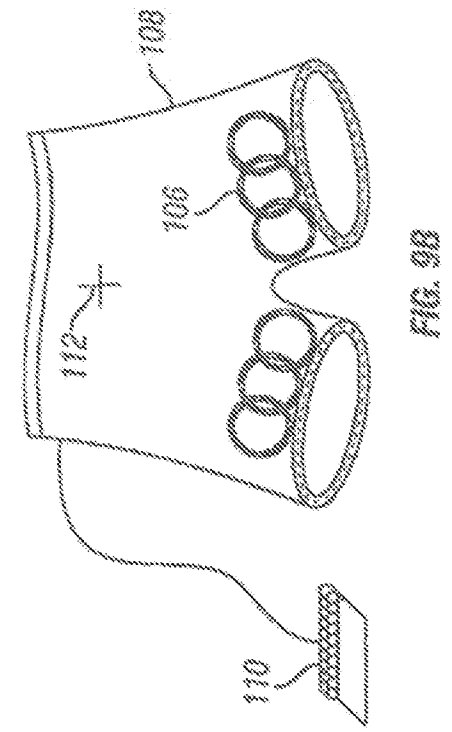


FIG. 9B

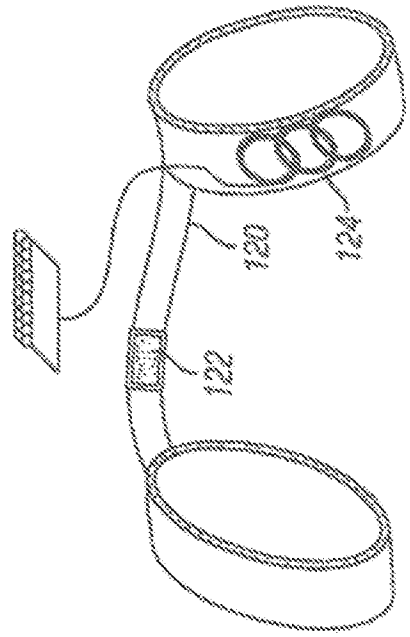


FIG. 9D

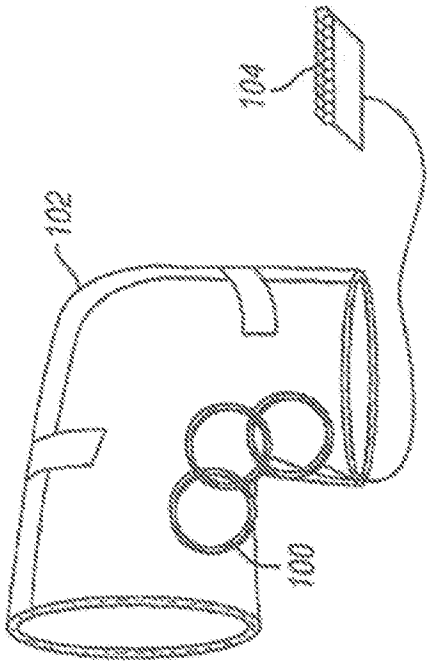


FIG. 9A

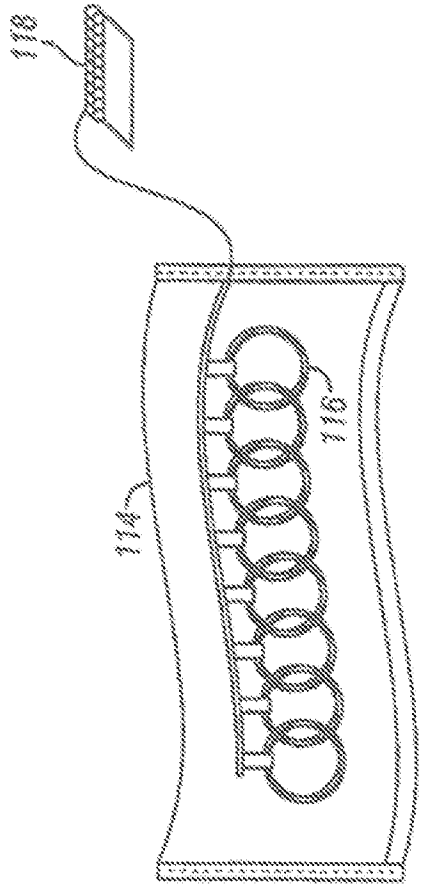


FIG. 9C

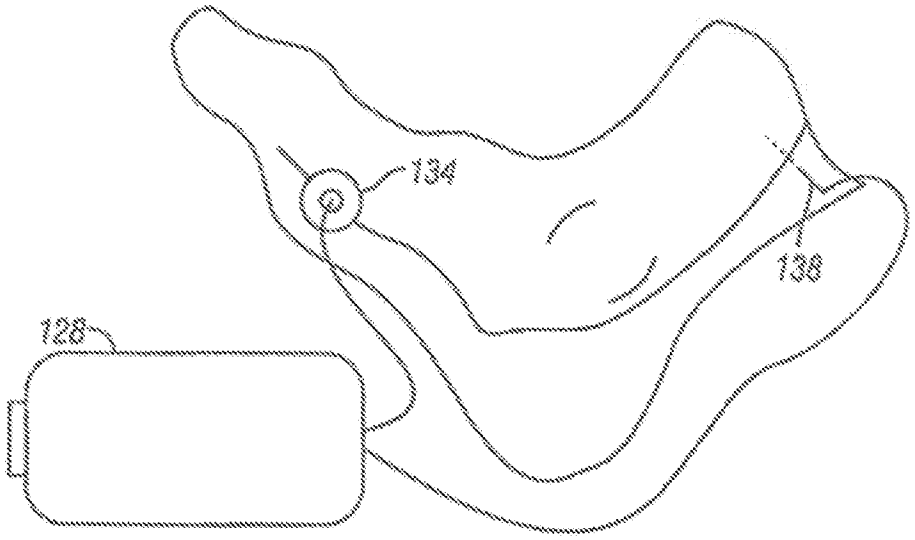


FIG. 10

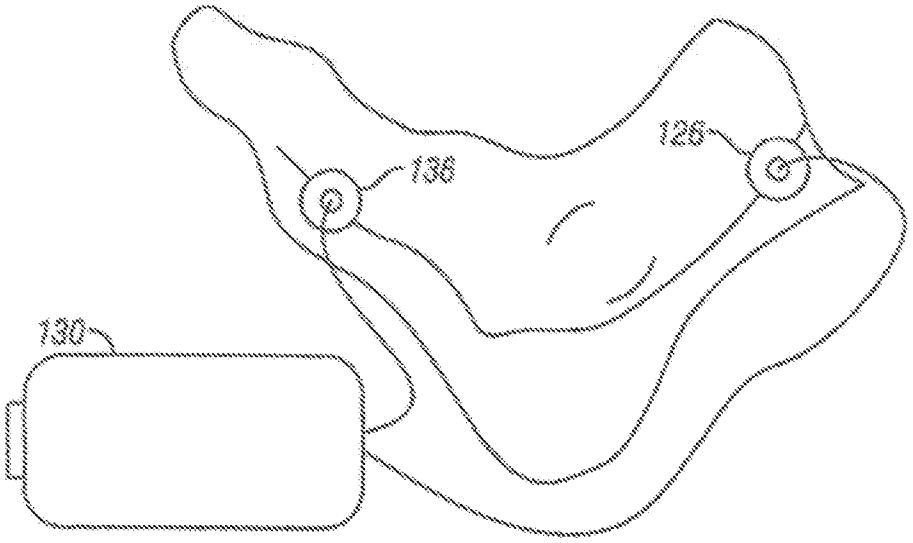


FIG. 11

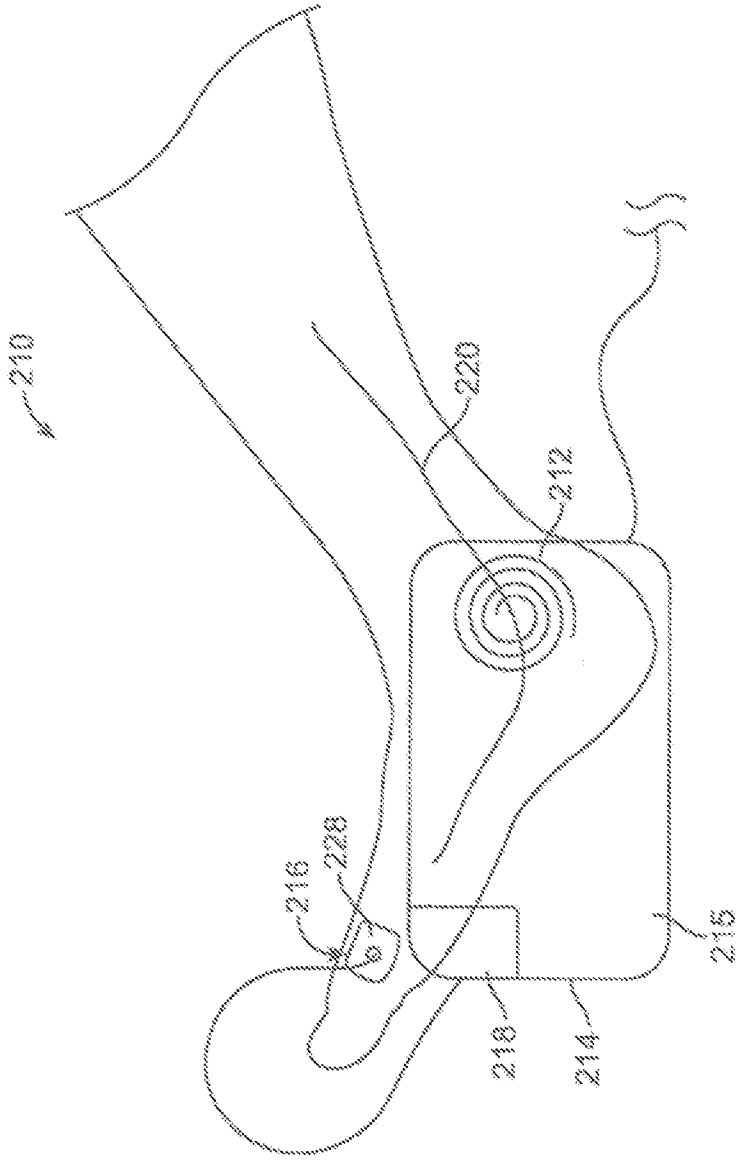


FIG. 12

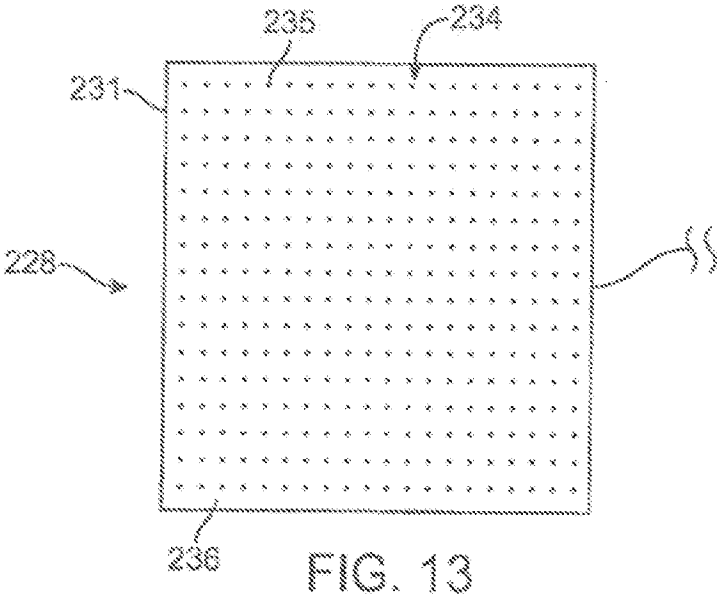


FIG. 13

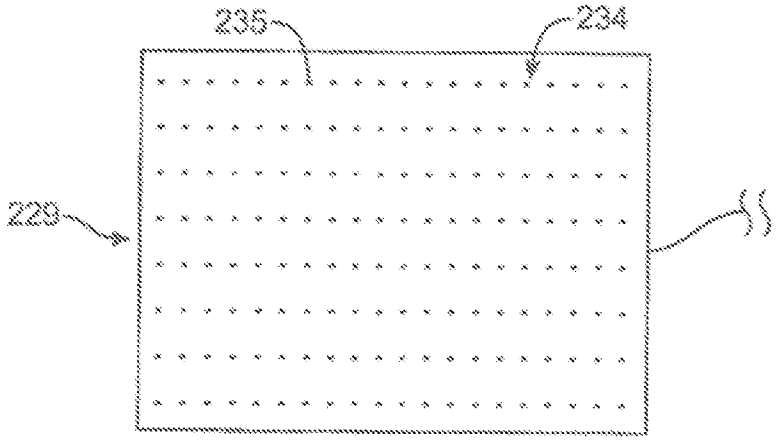


FIG. 14

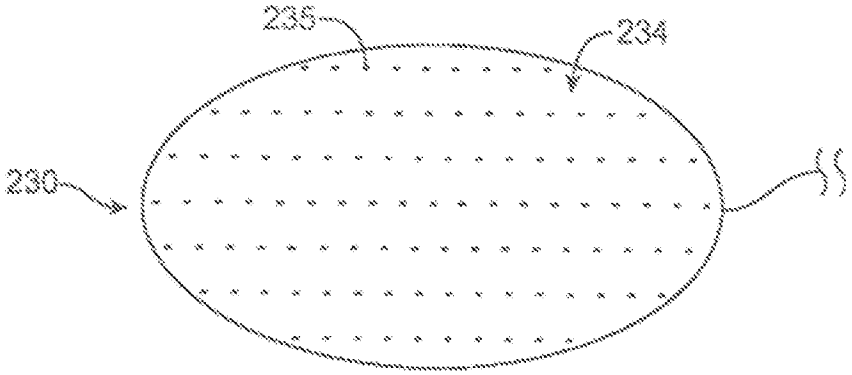


FIG. 15

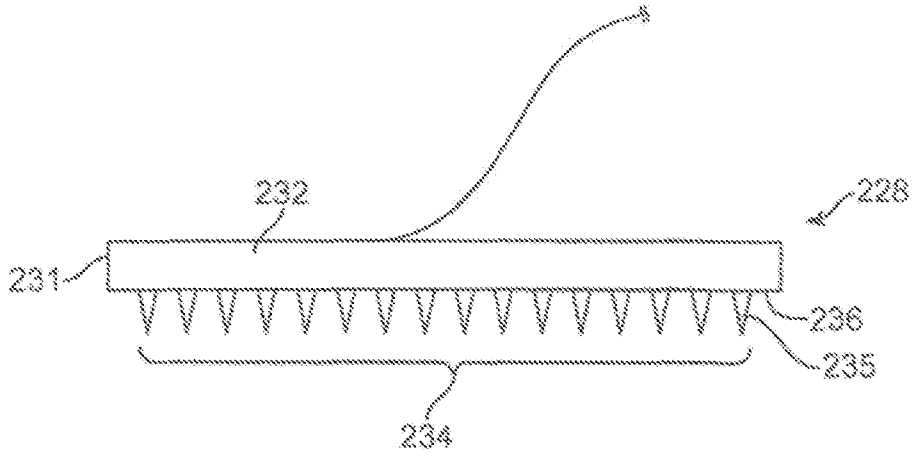


FIG. 16

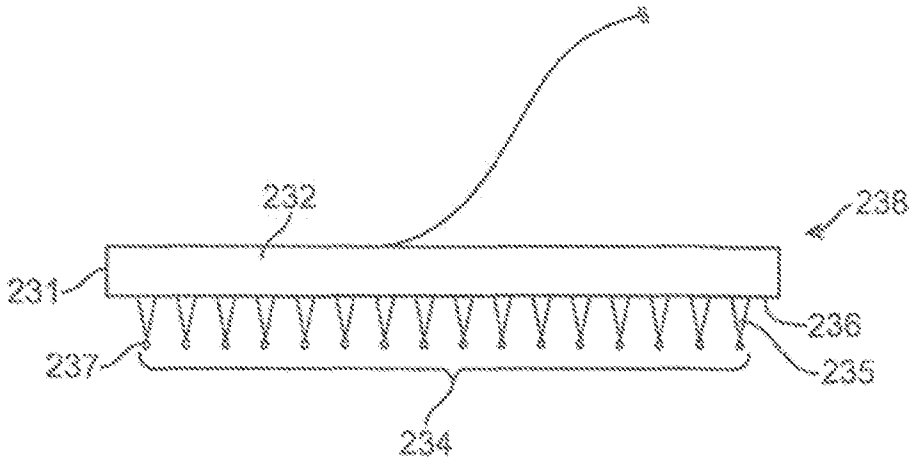


FIG. 17

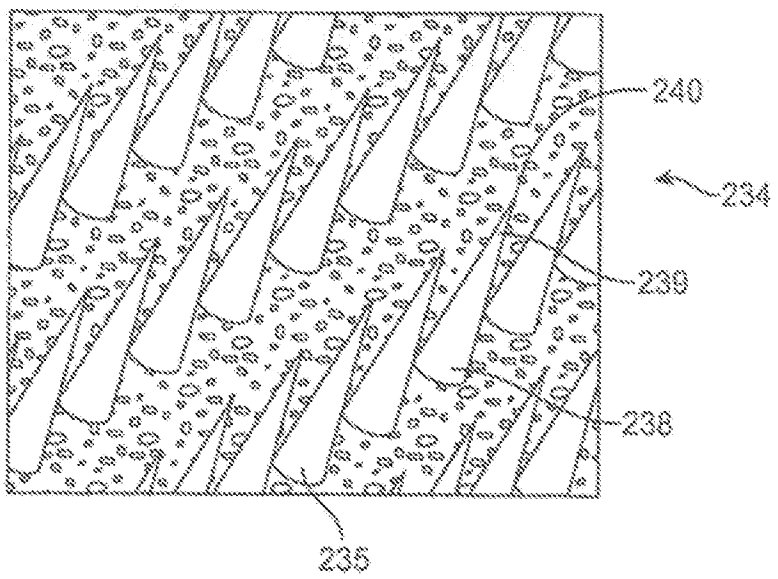


FIG. 18

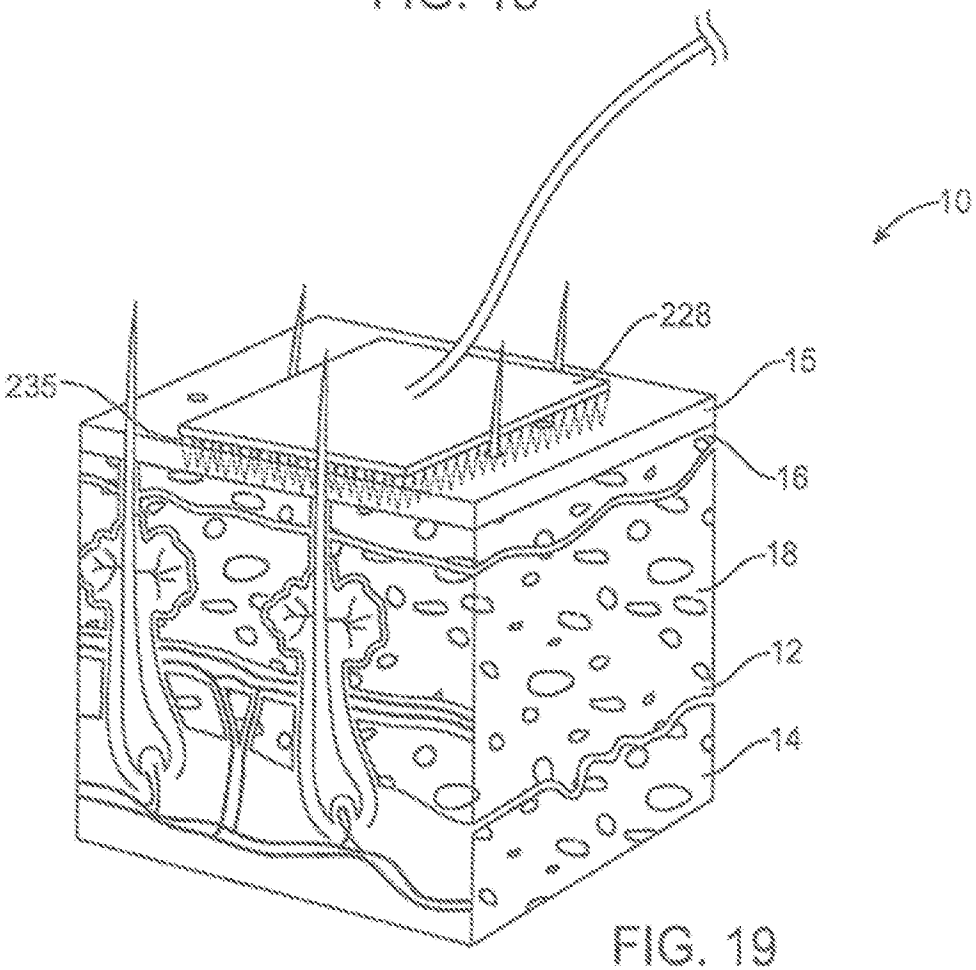


FIG. 19

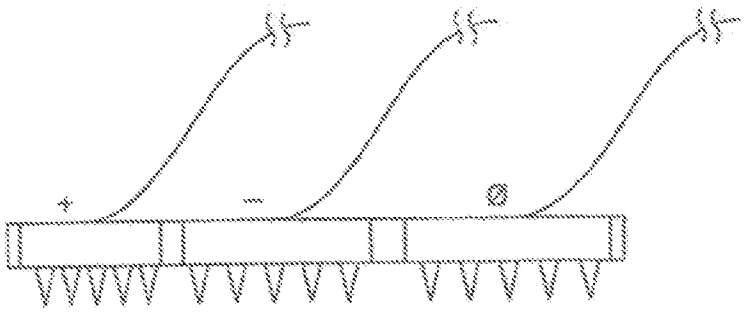


FIG. 20a

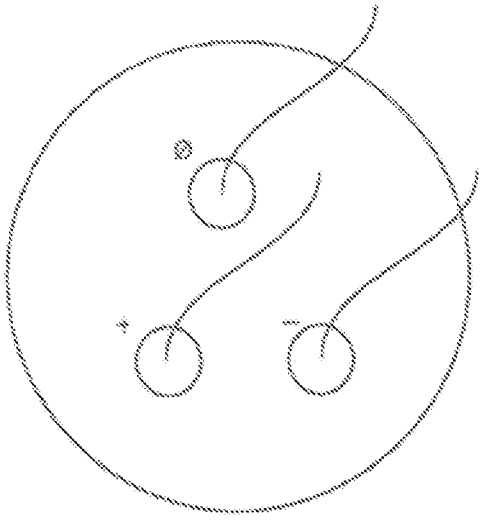


FIG. 20b

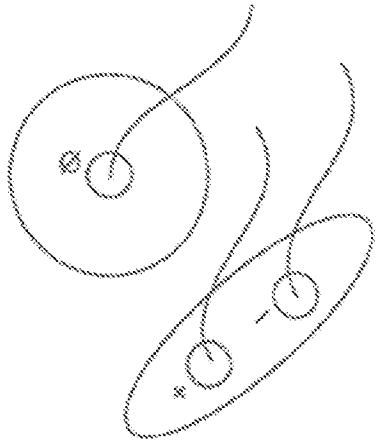


FIG. 20c

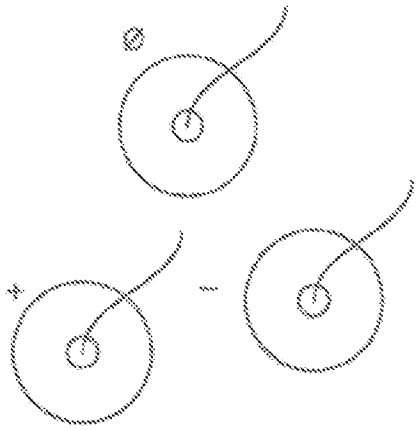


FIG. 20d

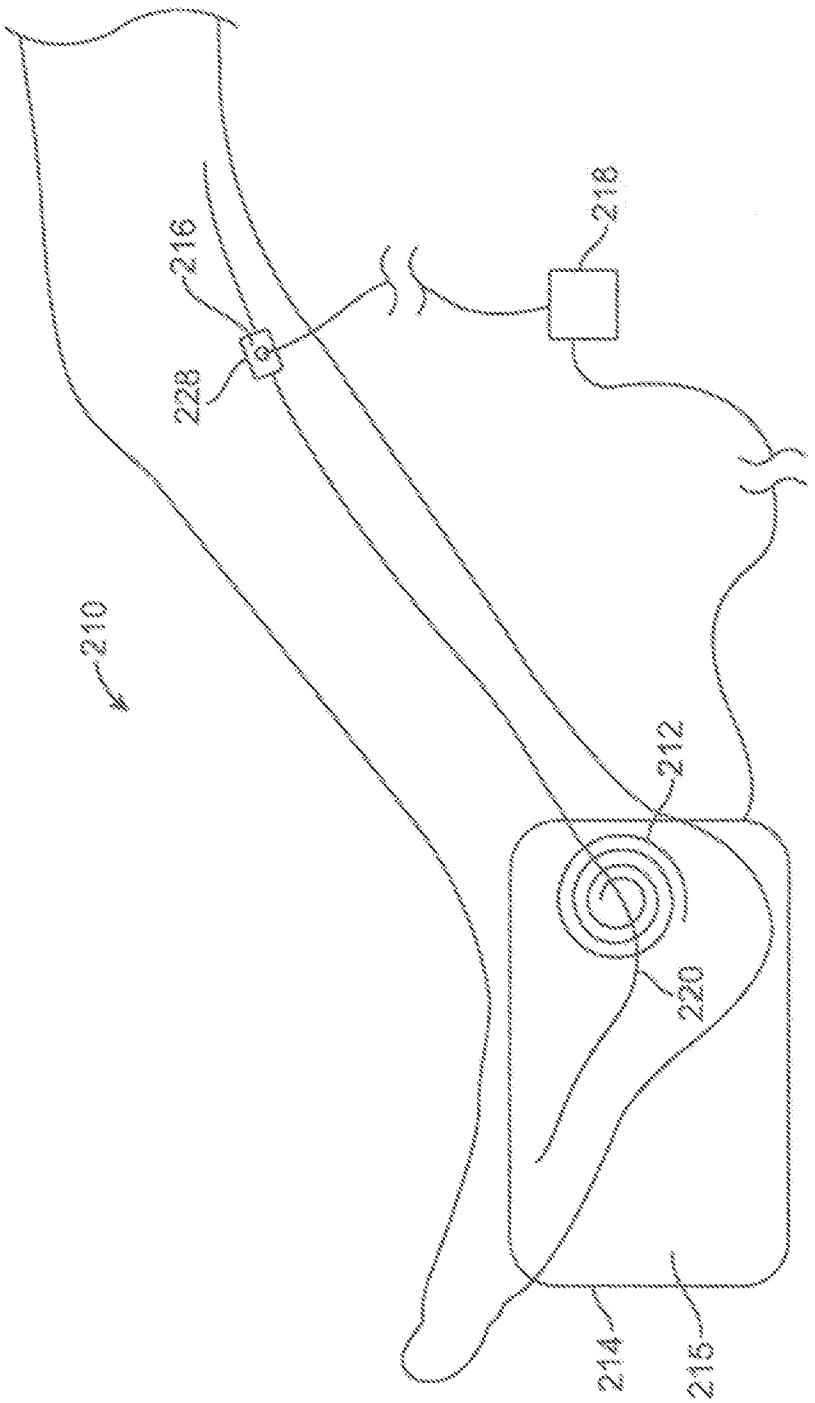


FIG. 21

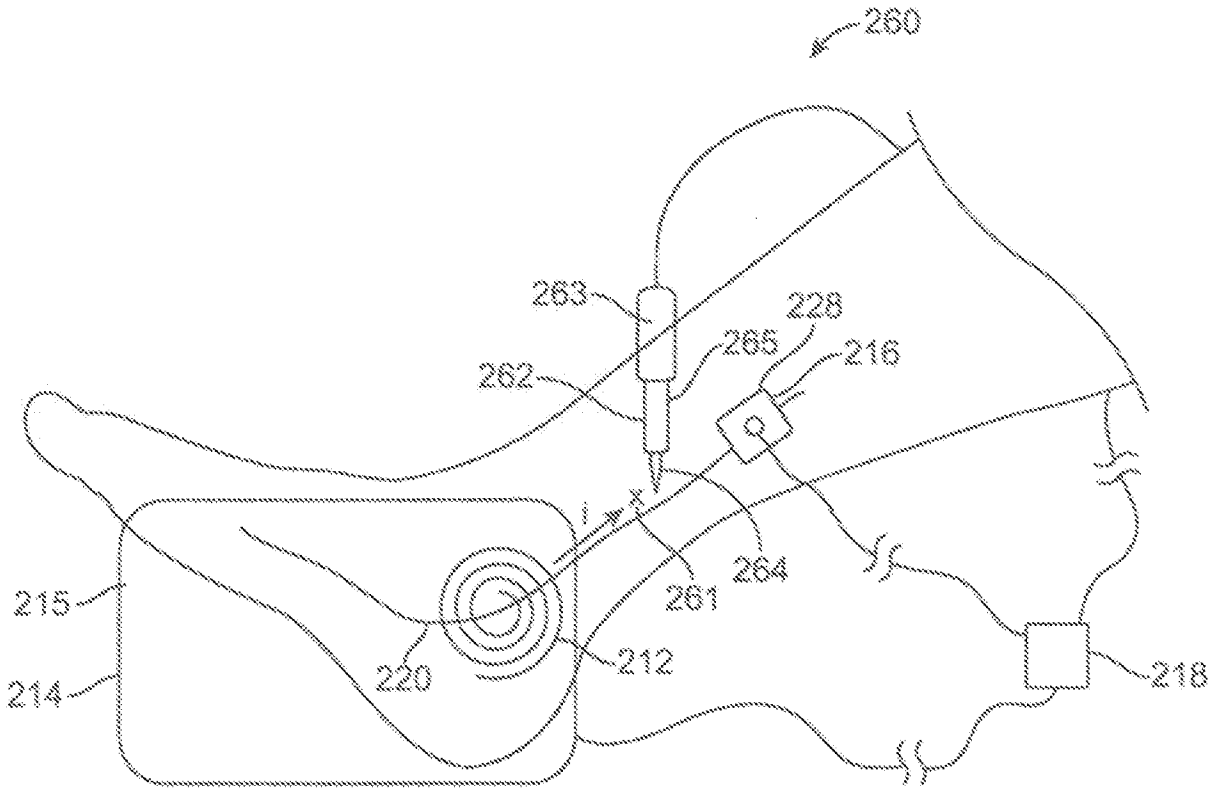


FIG. 22

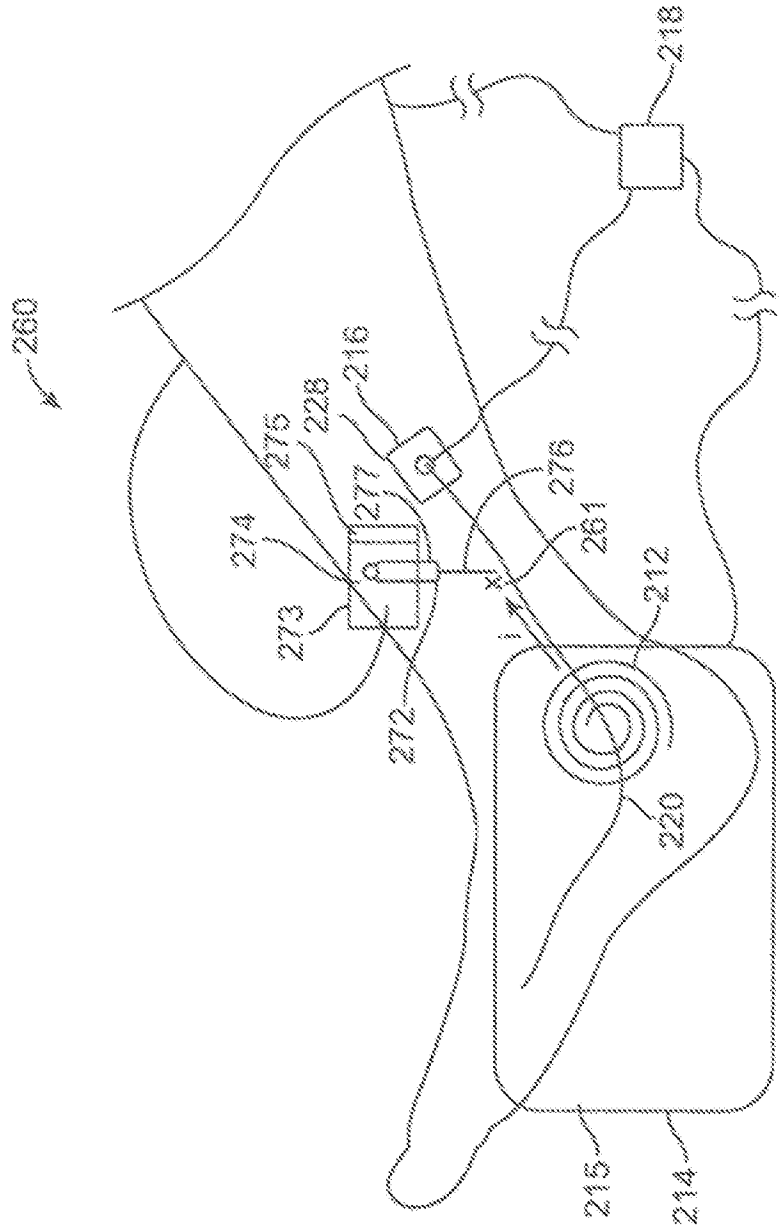


FIG. 23

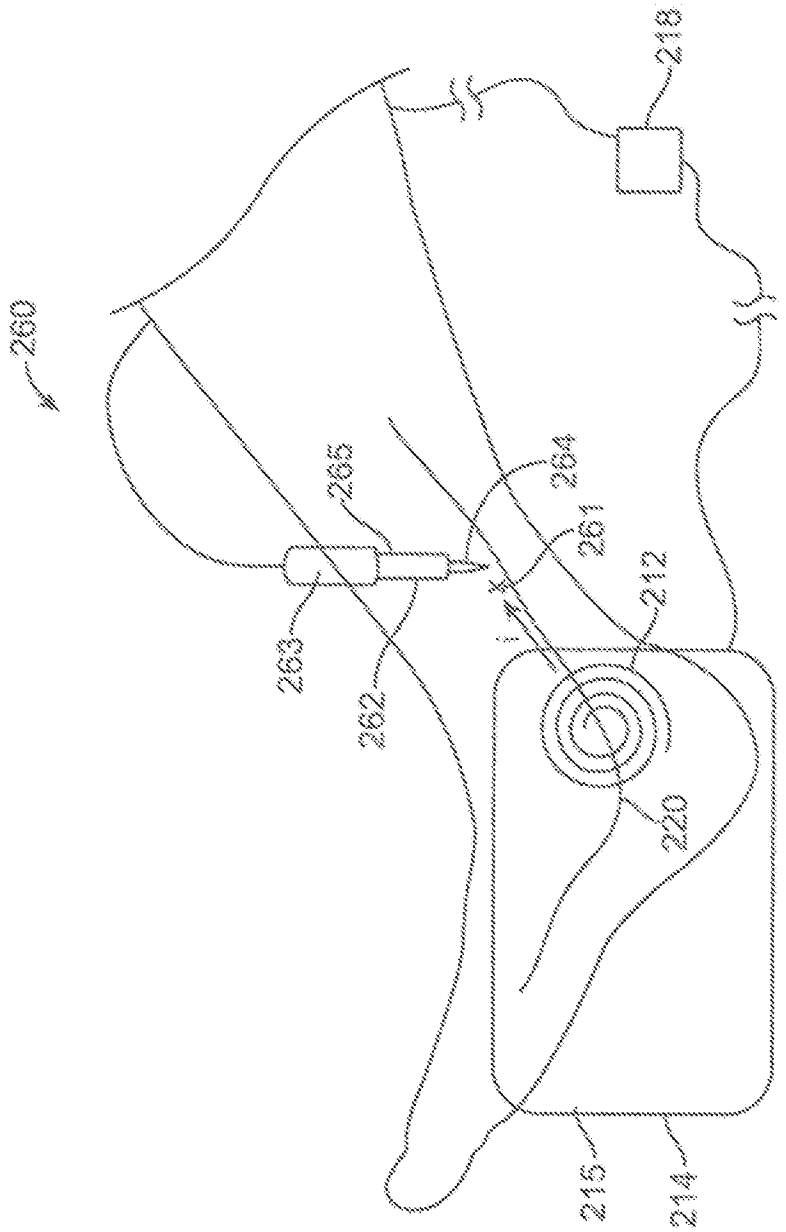


FIG. 24

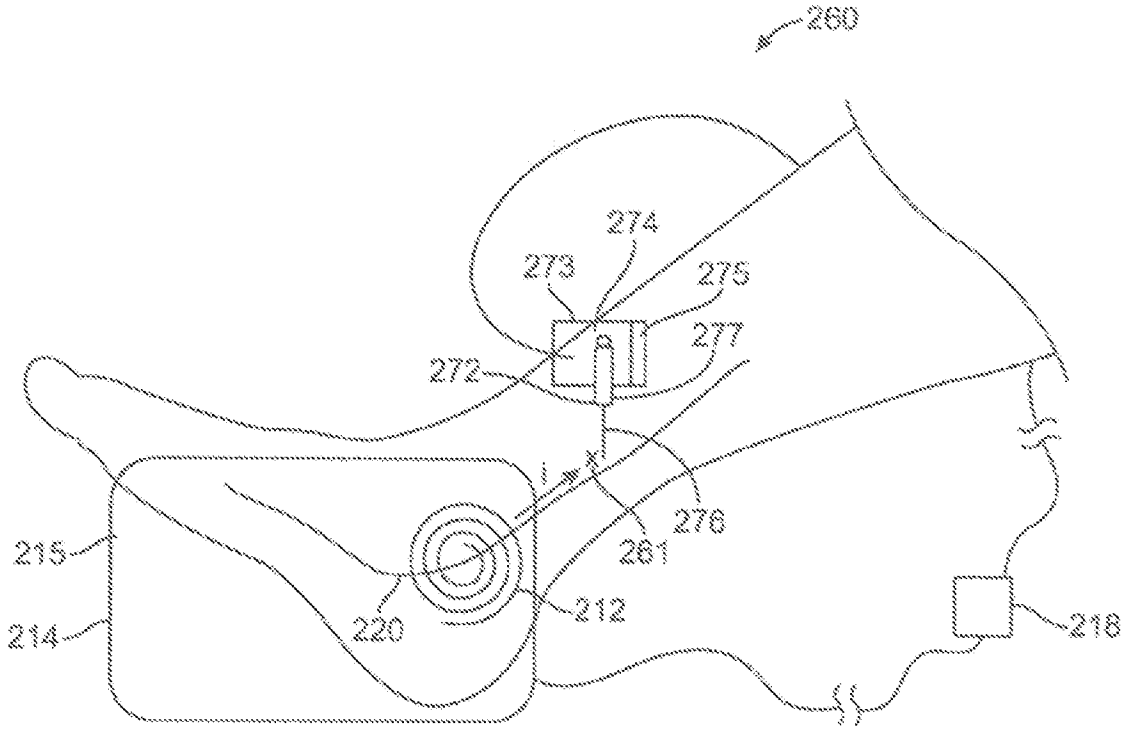


FIG. 25

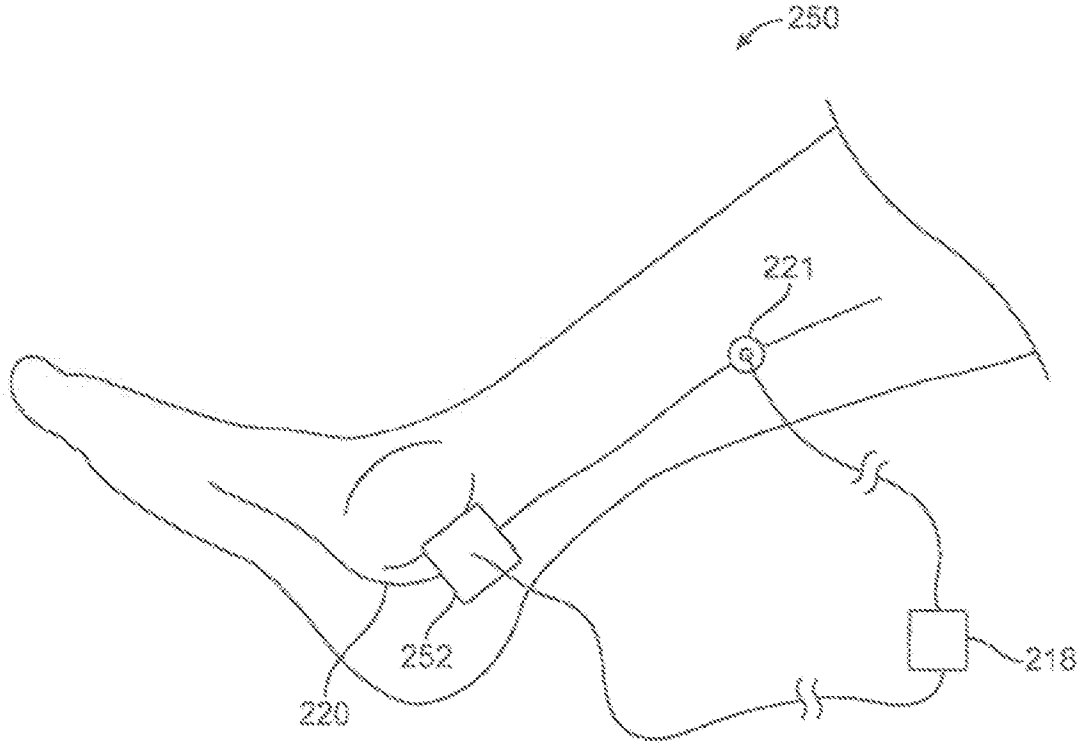


FIG. 26

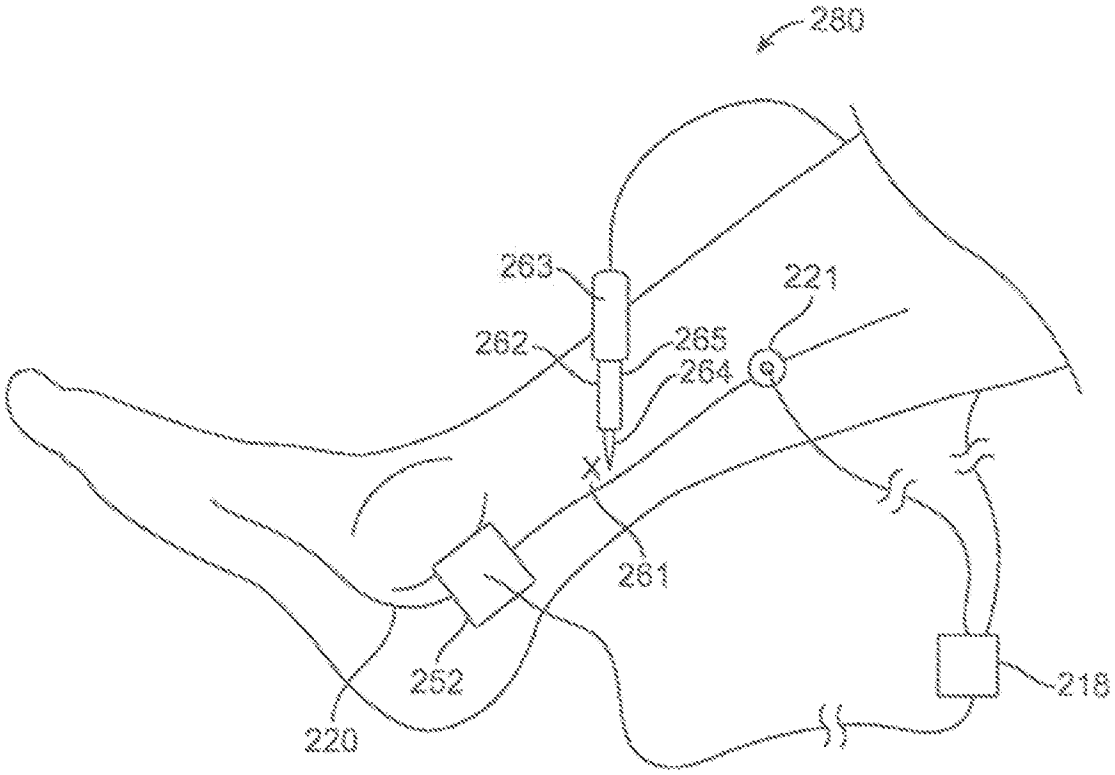


FIG. 27

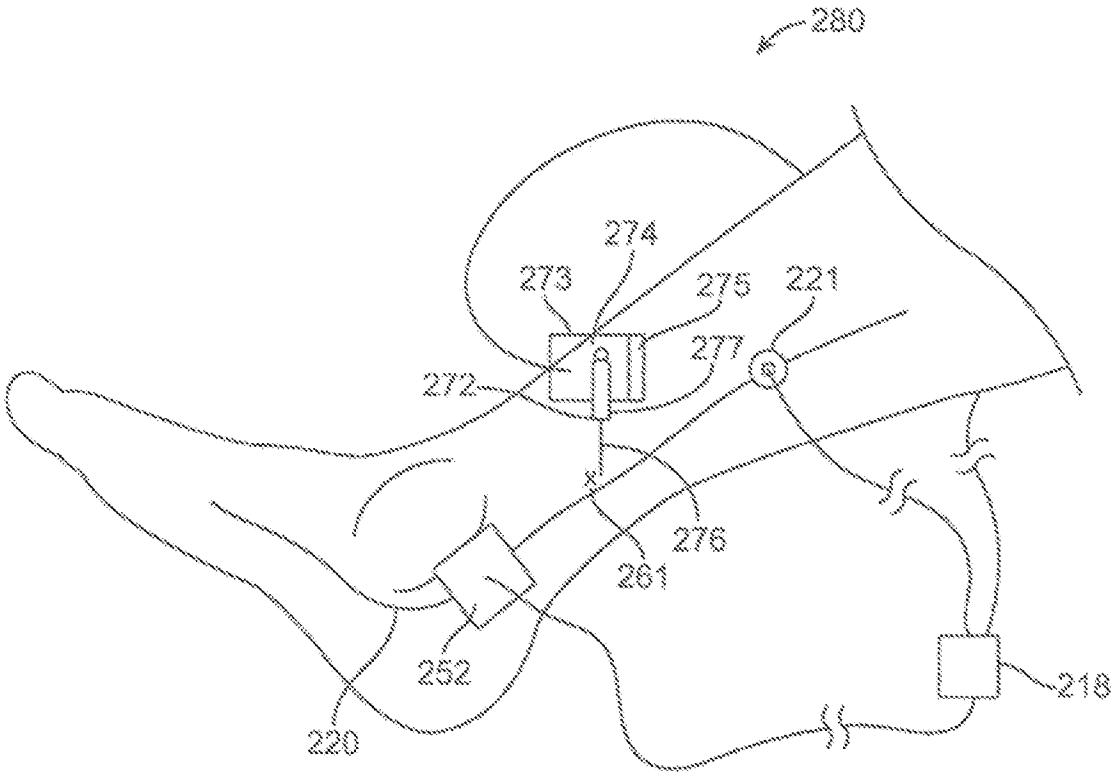


FIG. 28

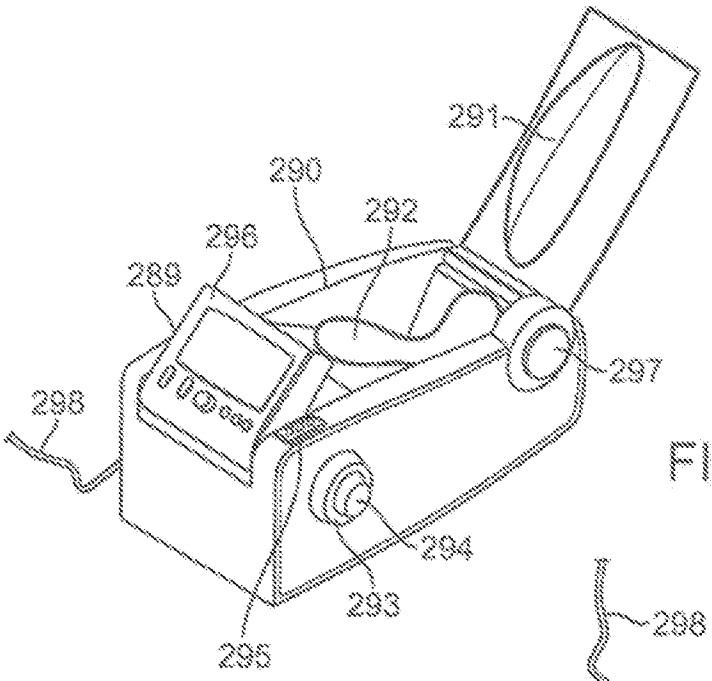


FIG. 29a

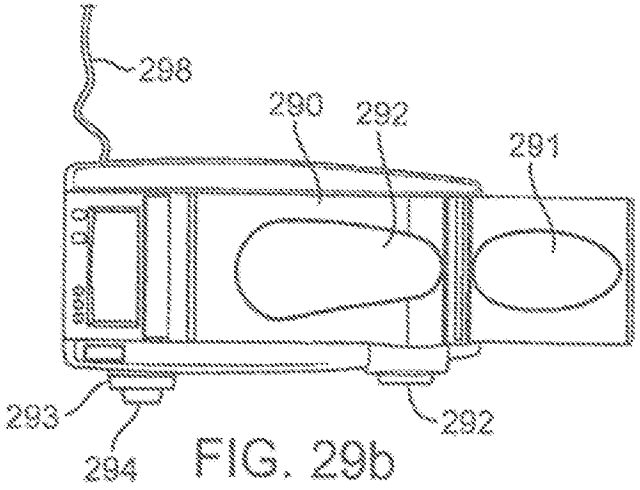


FIG. 29b

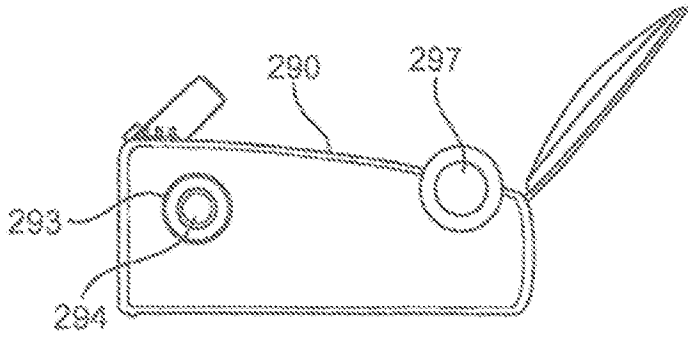


FIG. 29c

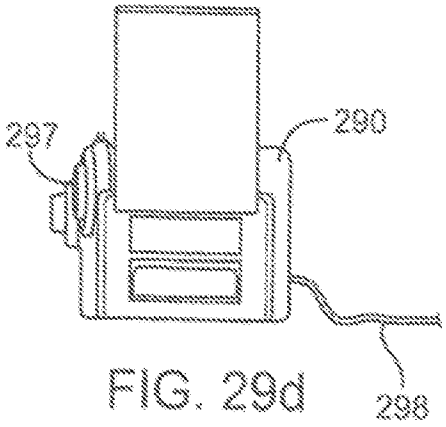


FIG. 29d

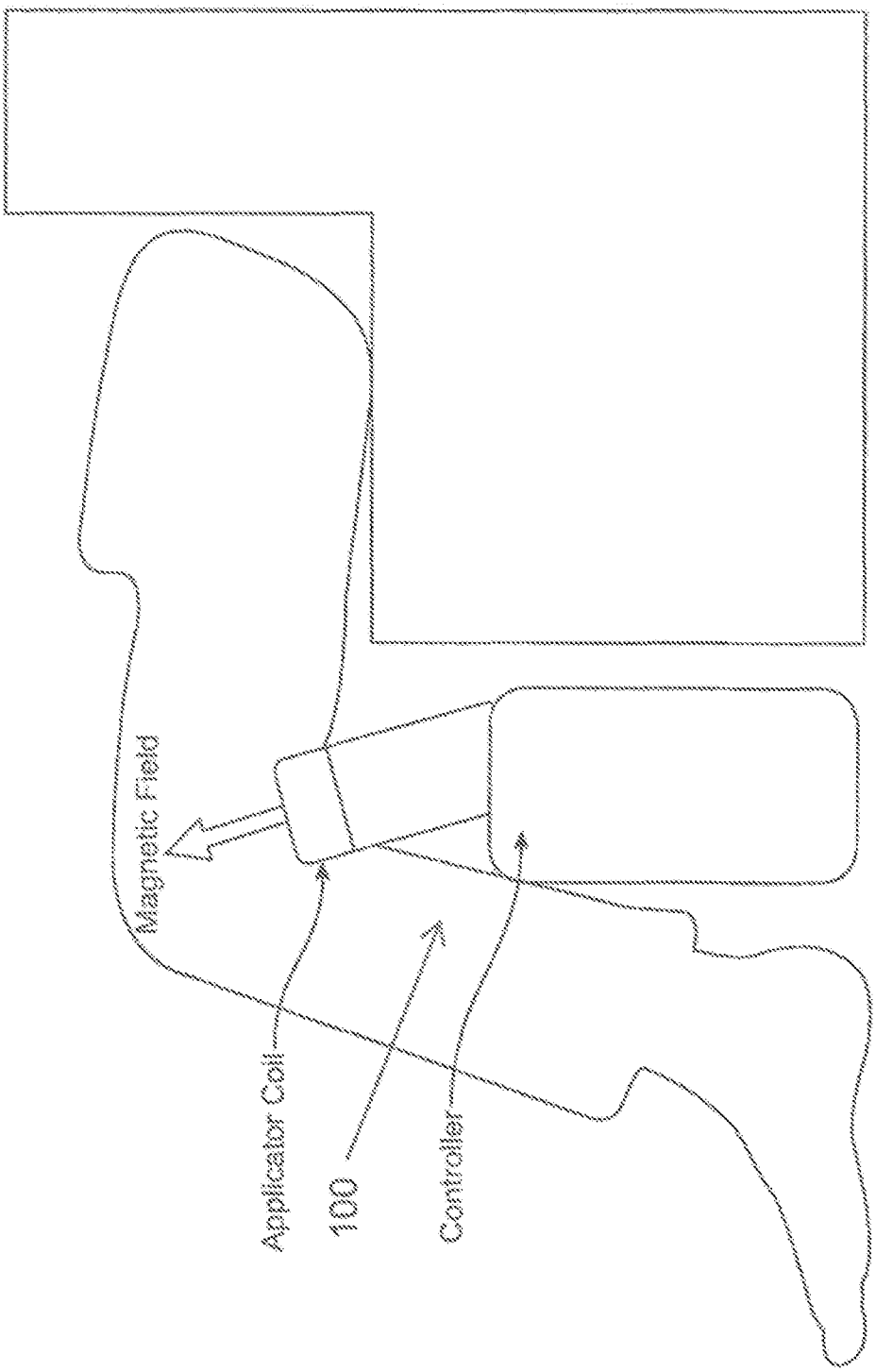


FIG. 30a

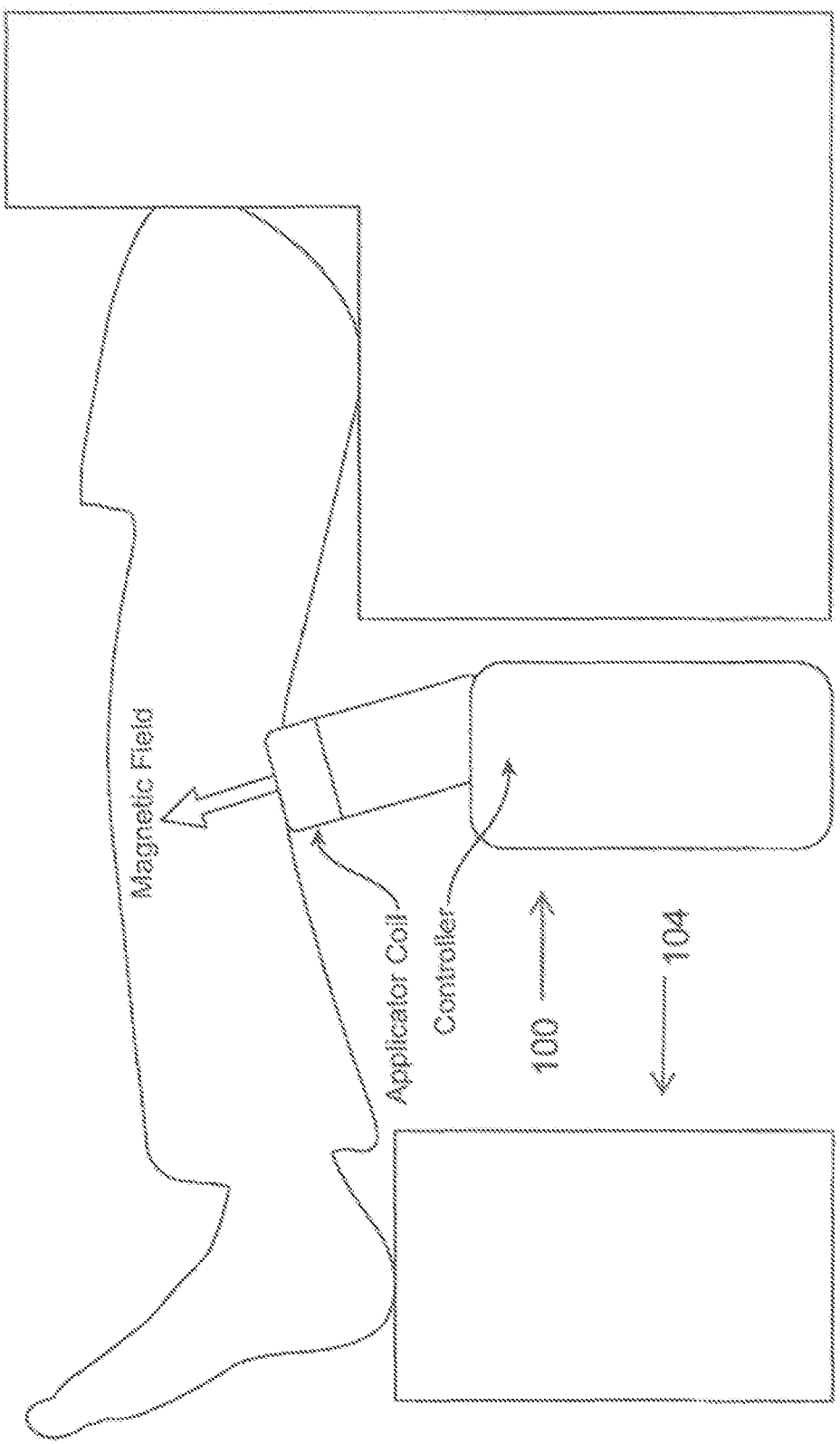


FIG. 30b

Fig. 31b

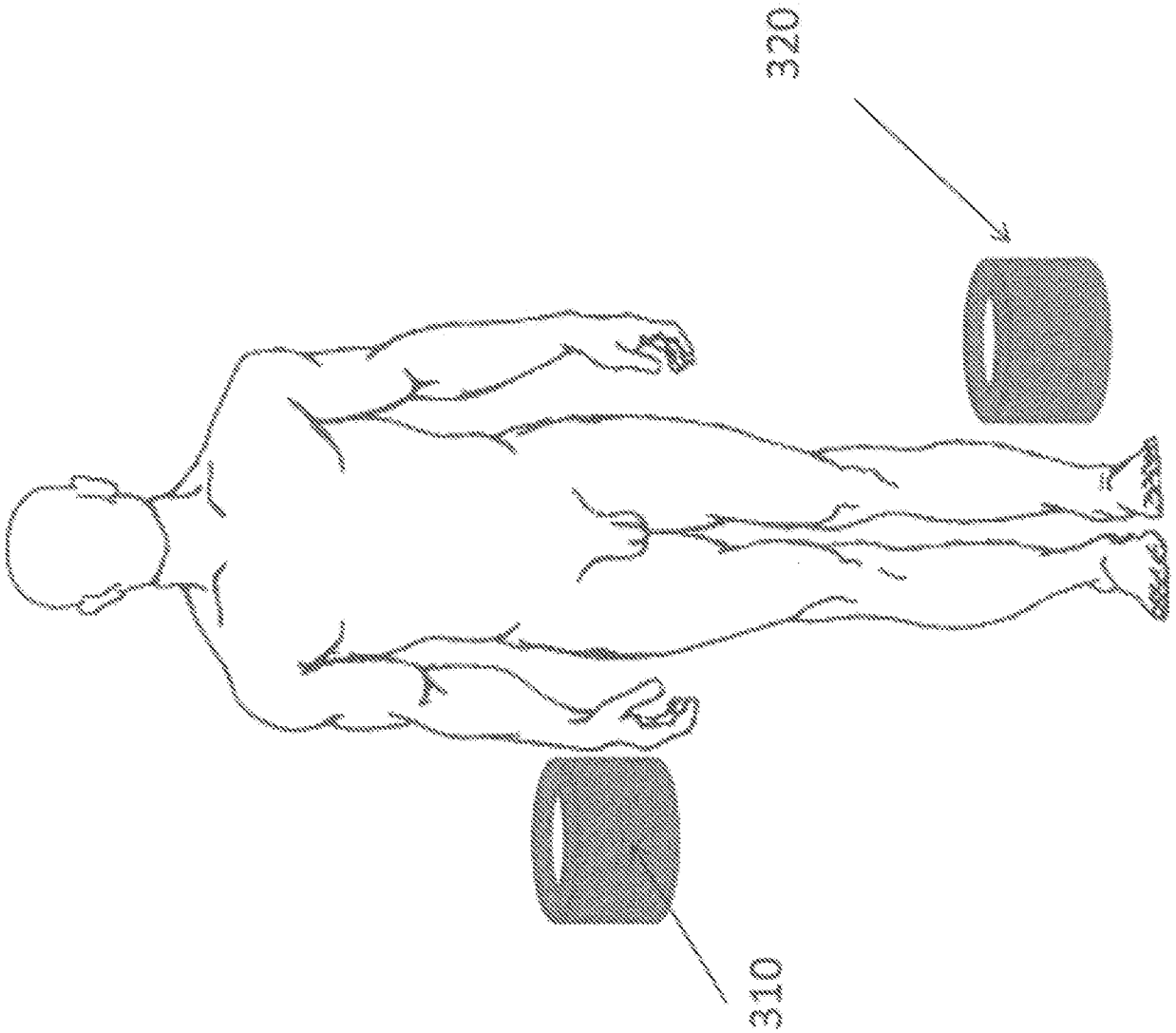


Fig. 31a

Fig. 32

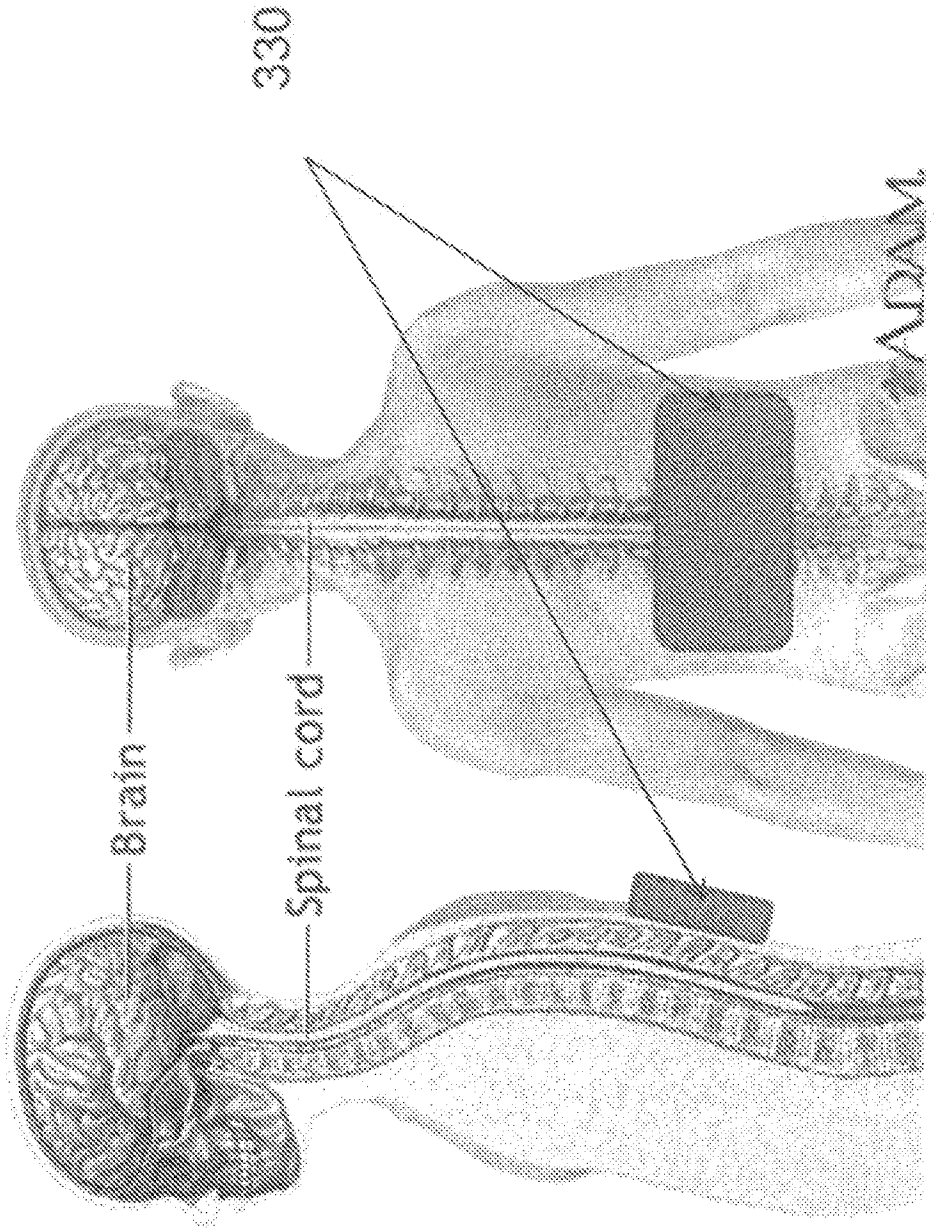


Fig. 33

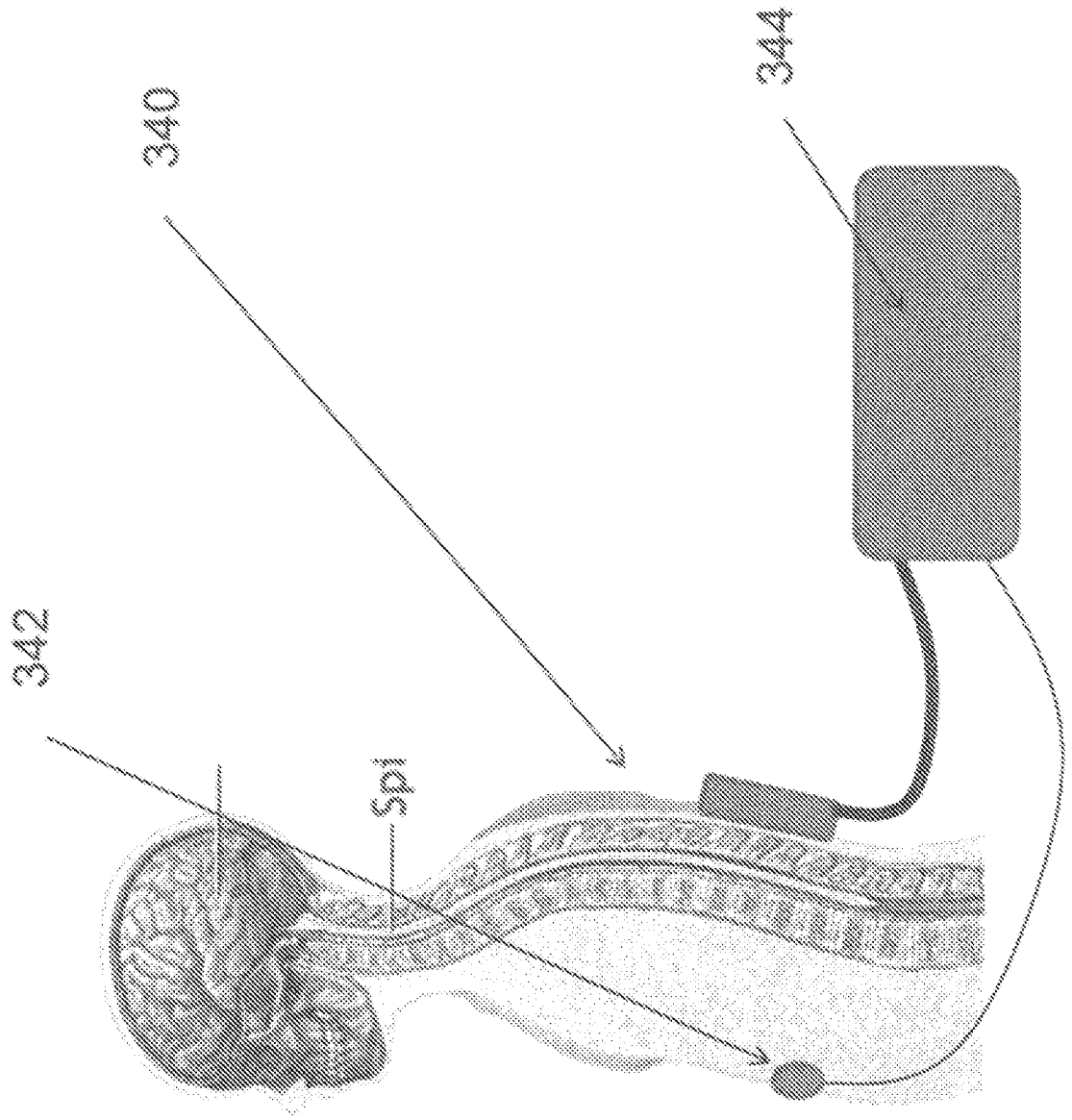
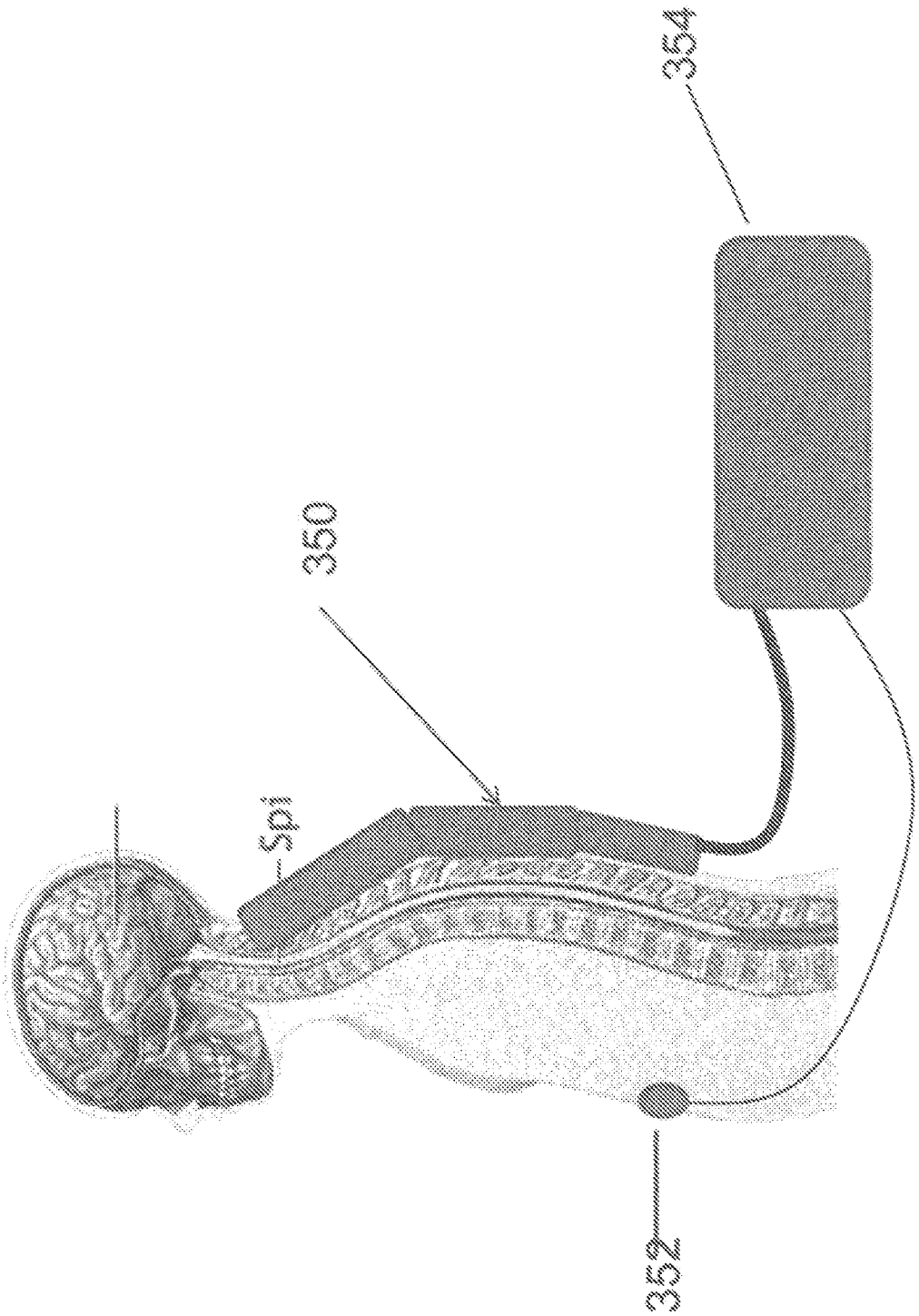


Fig. 34



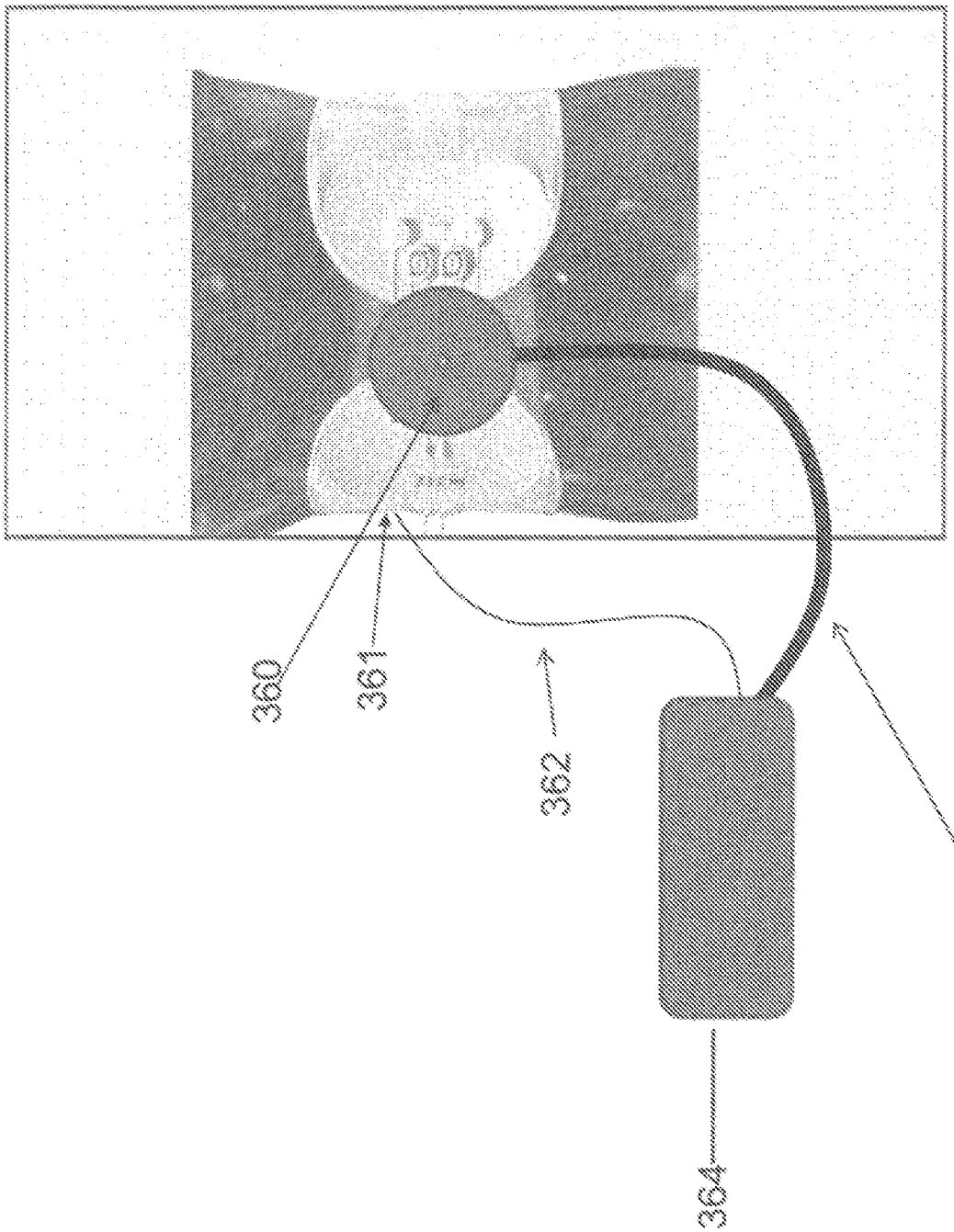


Fig. 35

Fig. 36

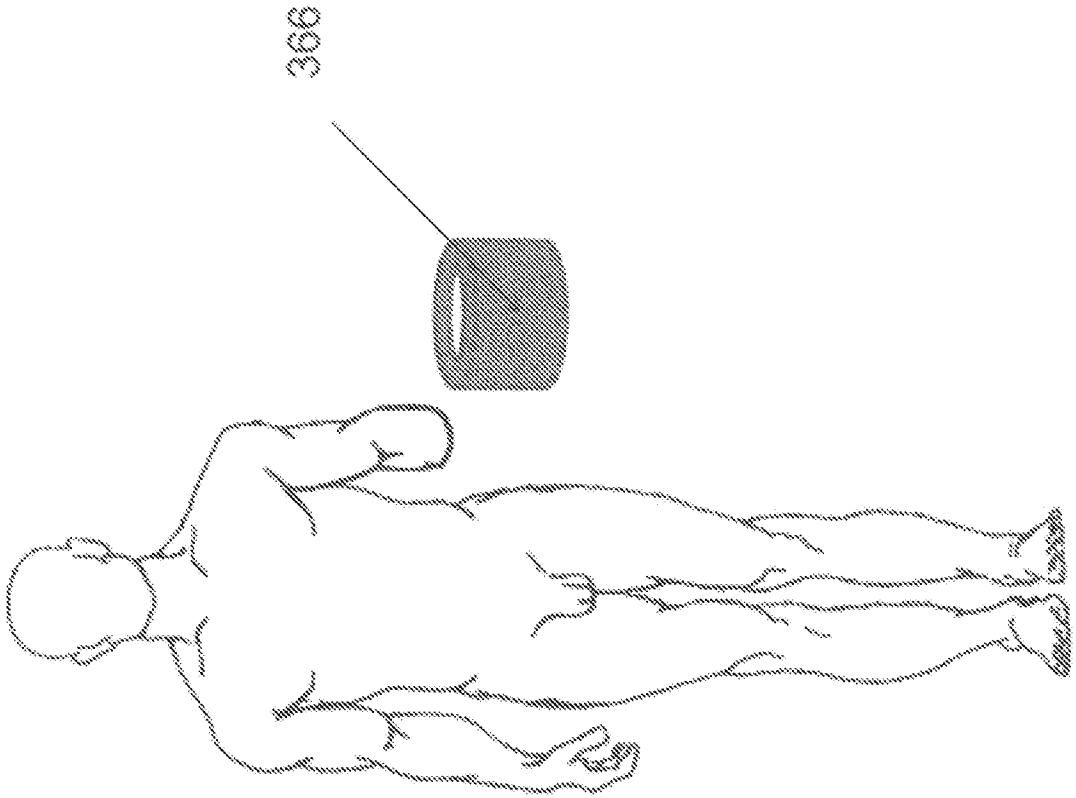


Fig. 37

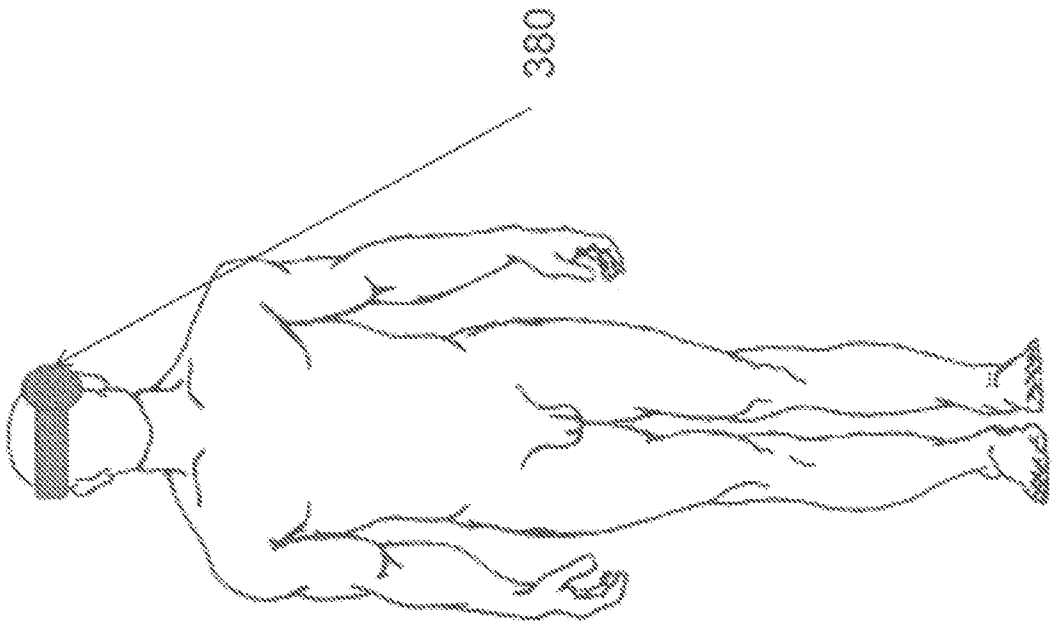


Fig. 38

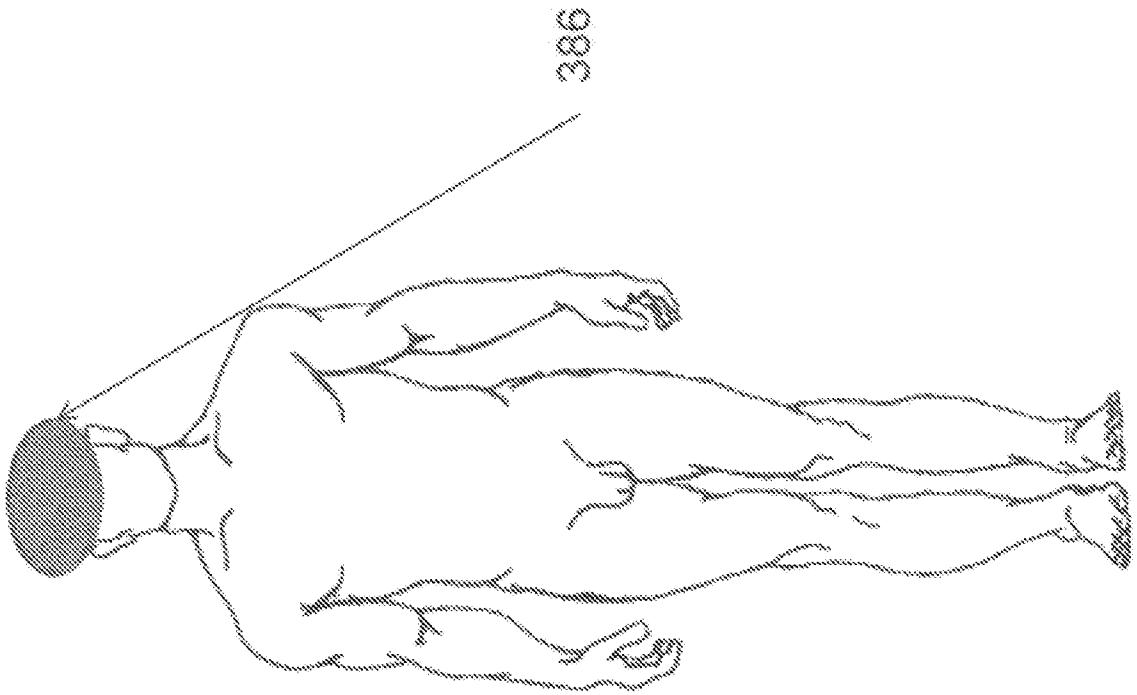


Fig. 39

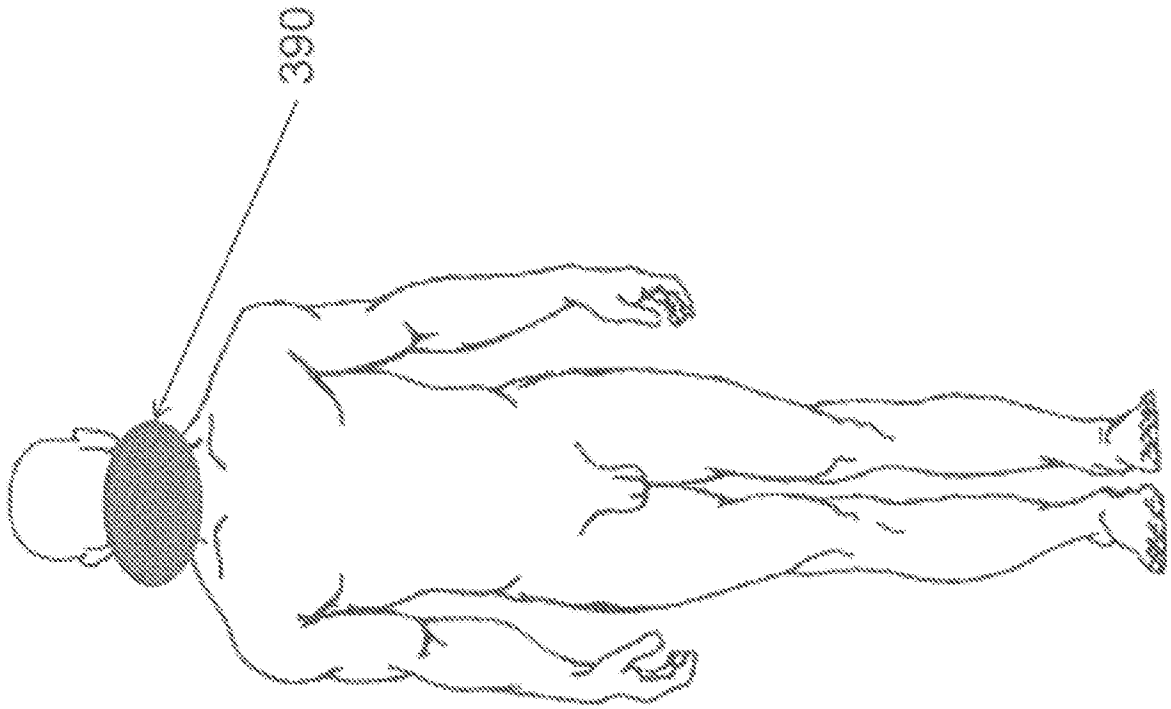


Fig. 40

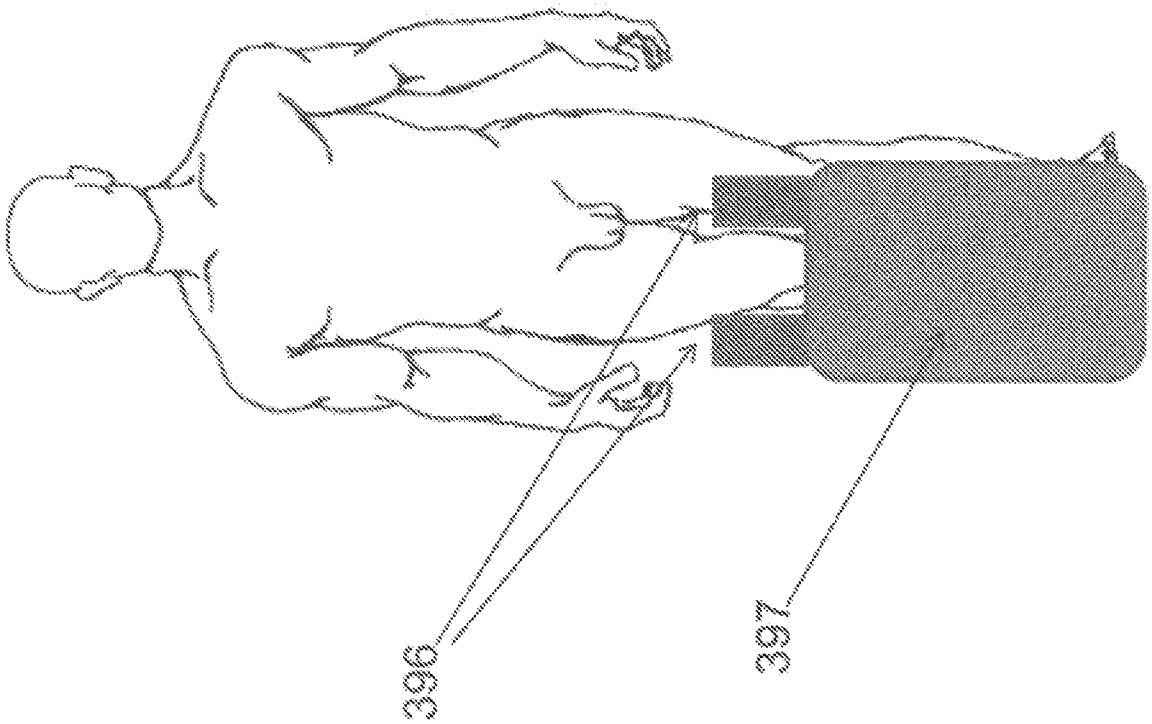
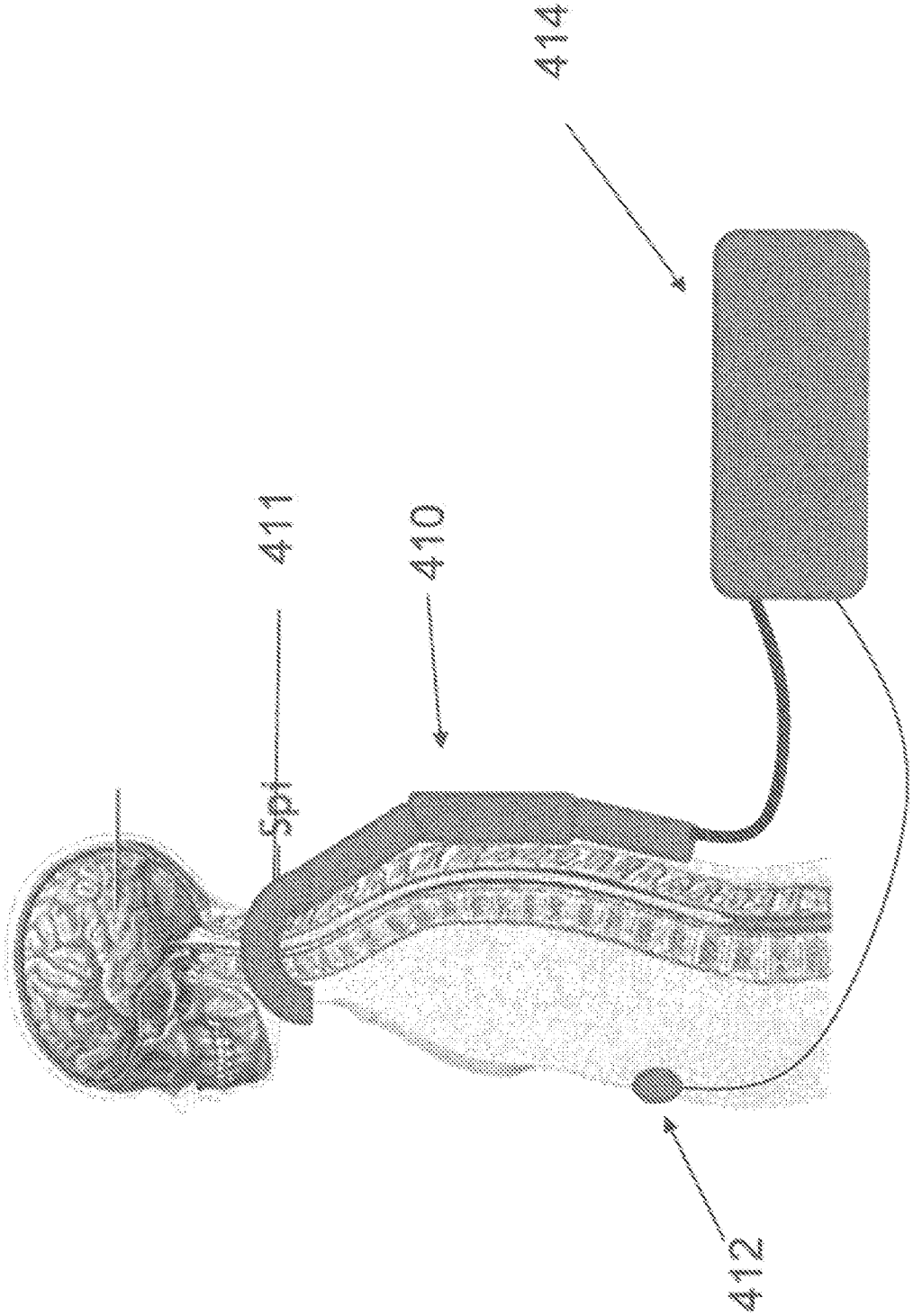


Fig. 41



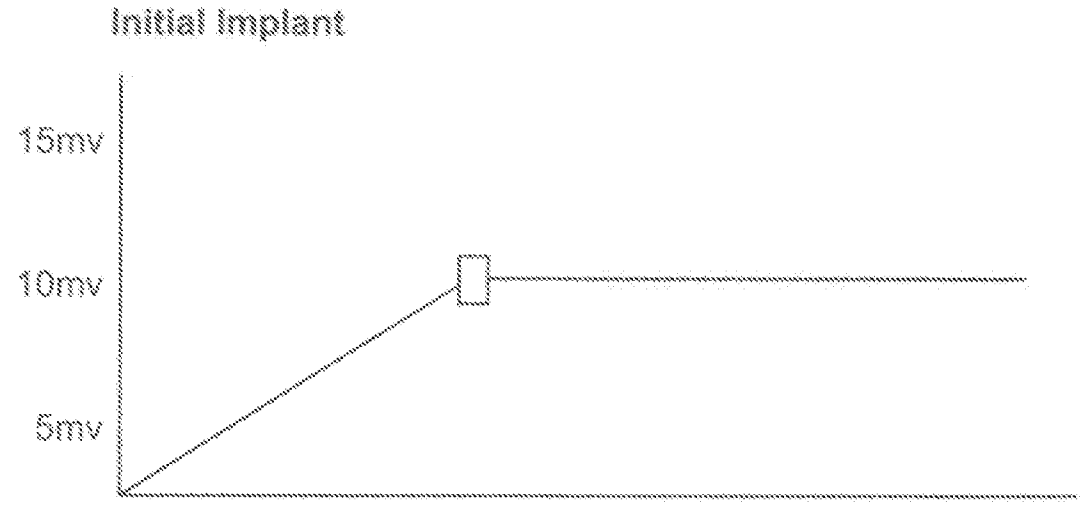


FIG. 42A

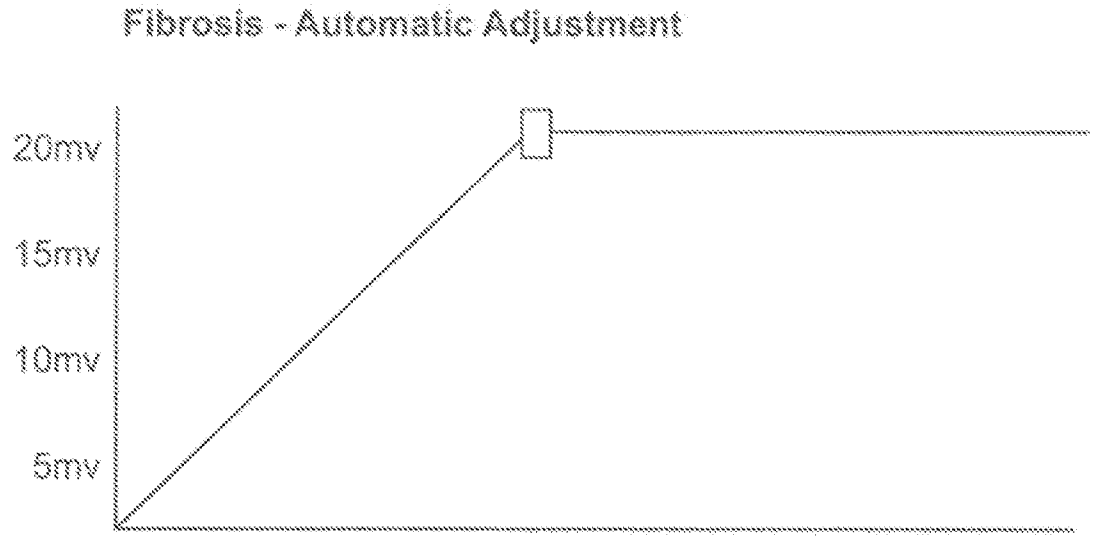


FIG. 42B

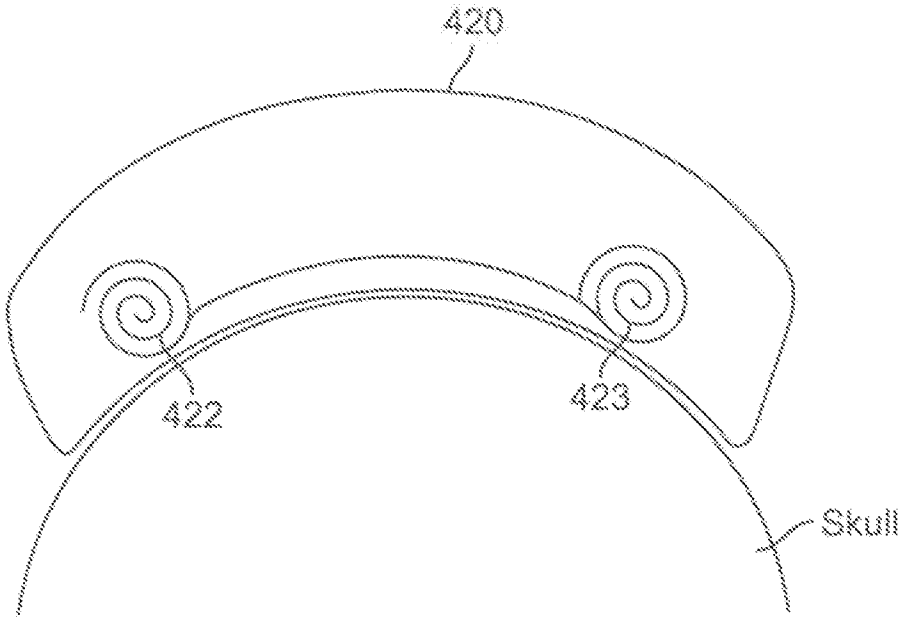


FIG. 43A

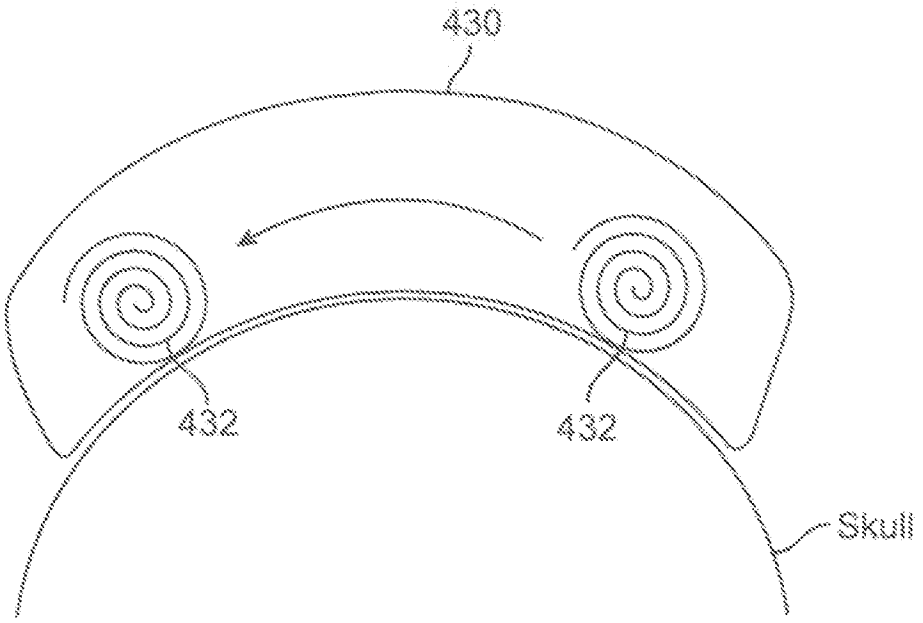
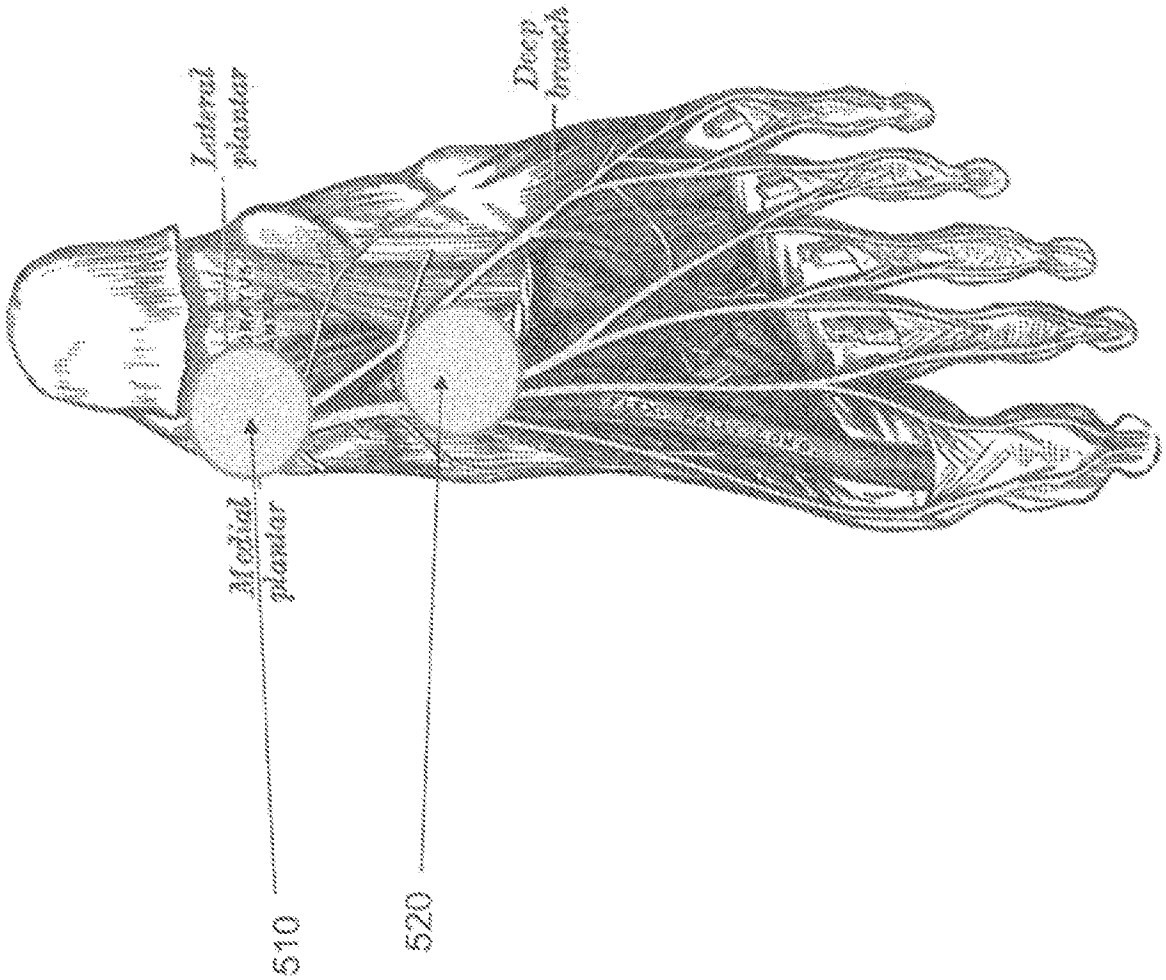


FIG. 43B

Figure 44



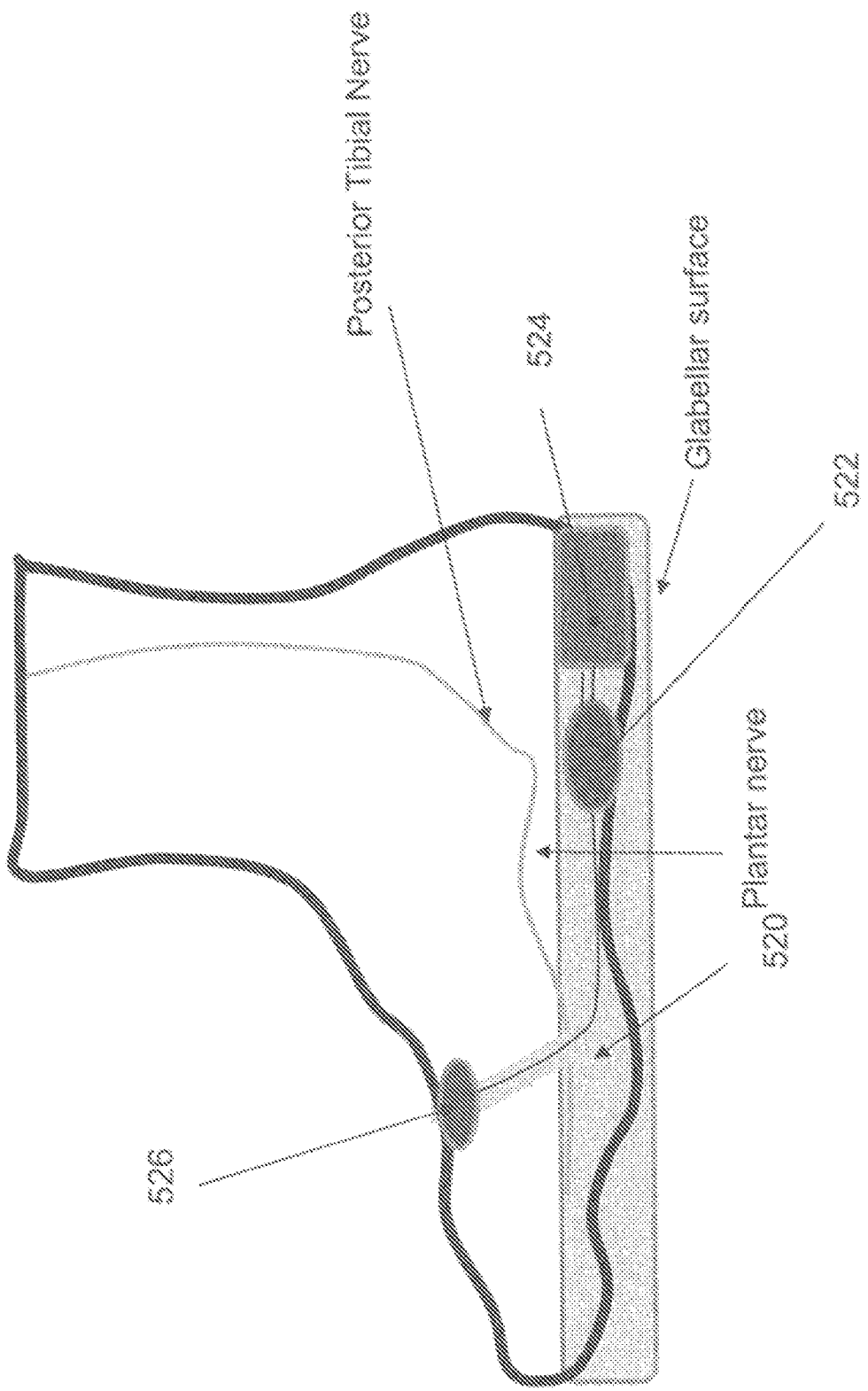

Posterior Tibial Nerve
524
Glabellar surface
522
520 Plantar nerve
526

Figure 45

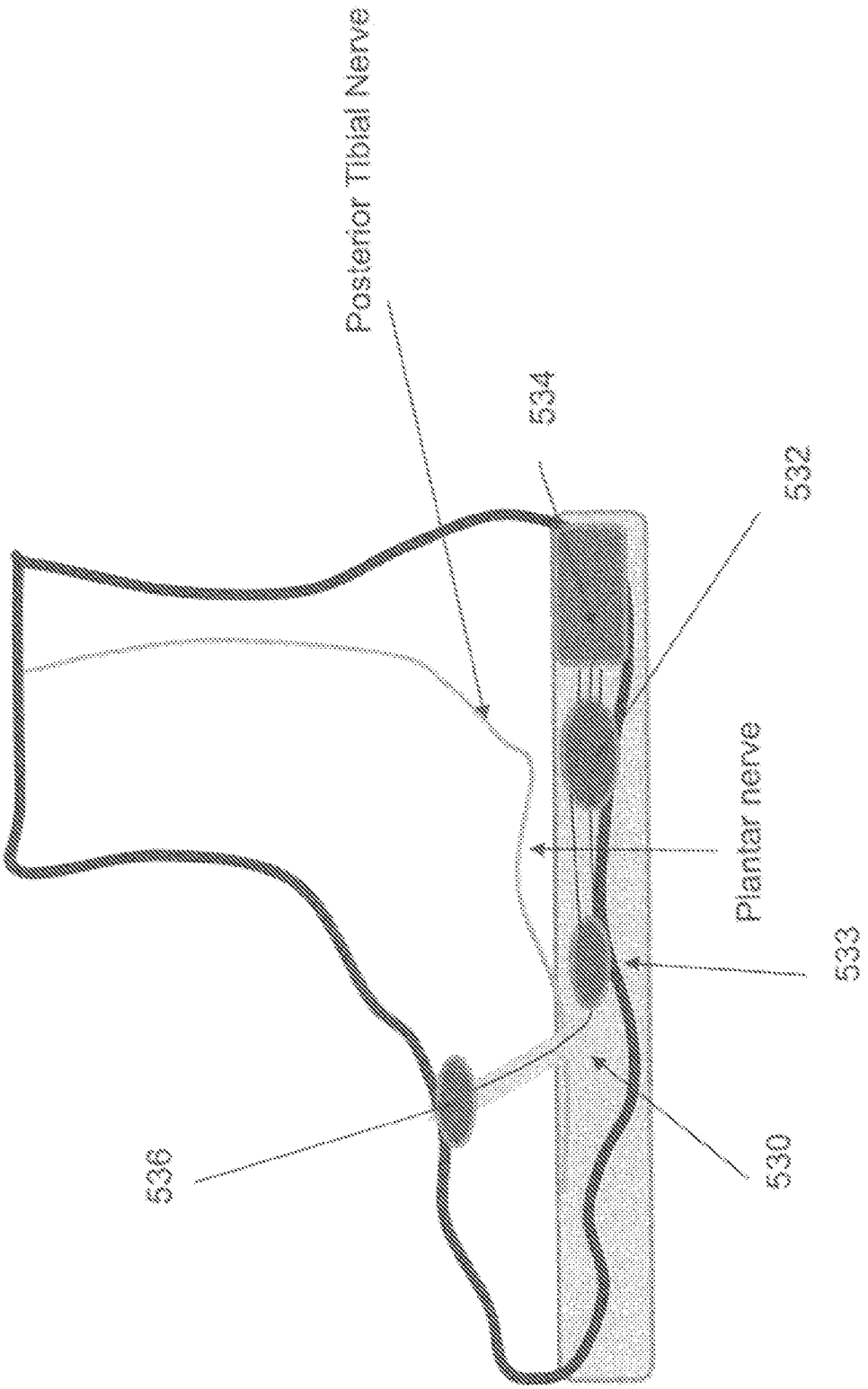


Figure 46

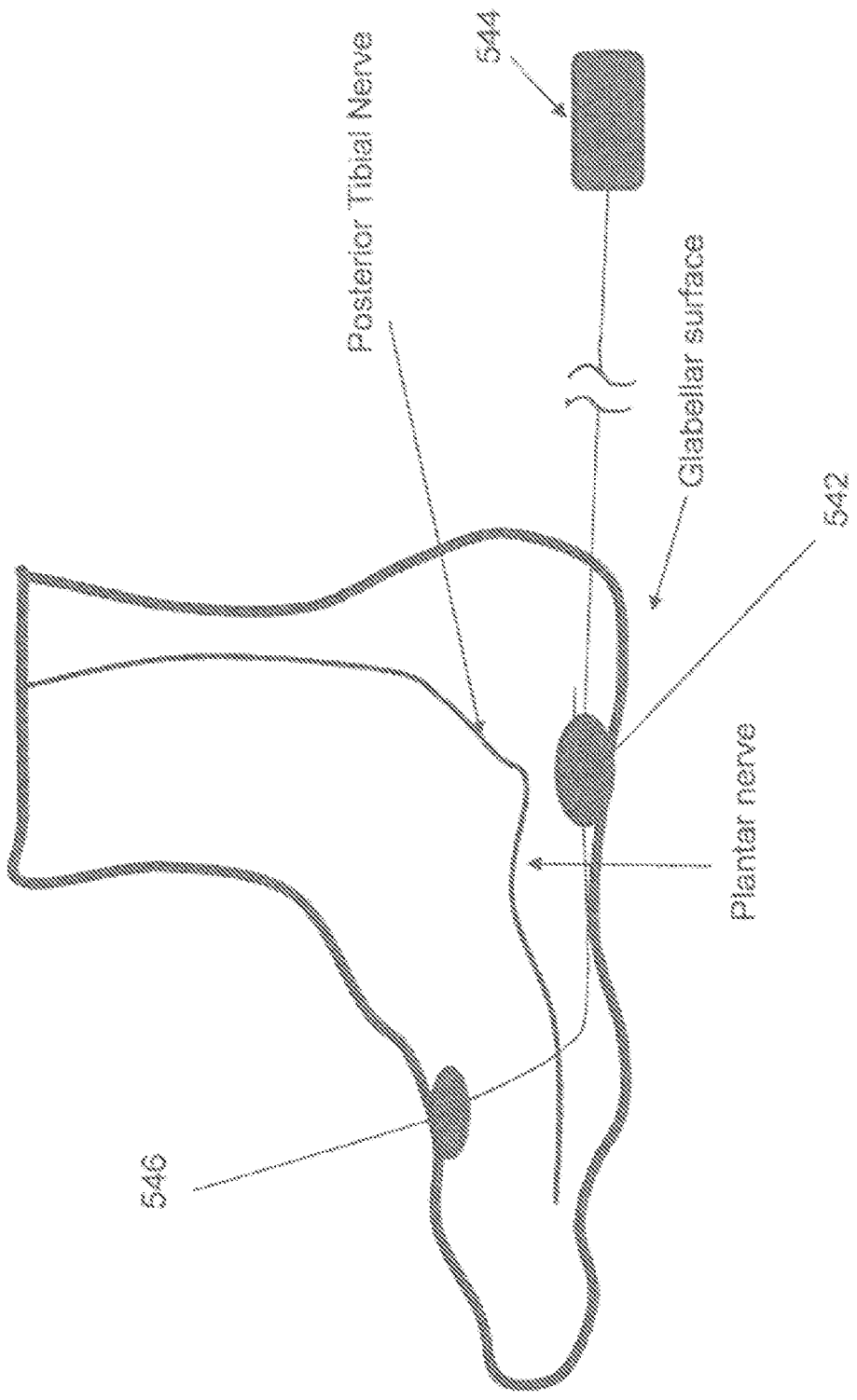

544
Posterior Tibial Nerve
Glabellar surface
542
Plantar nerve
546

Figure 47

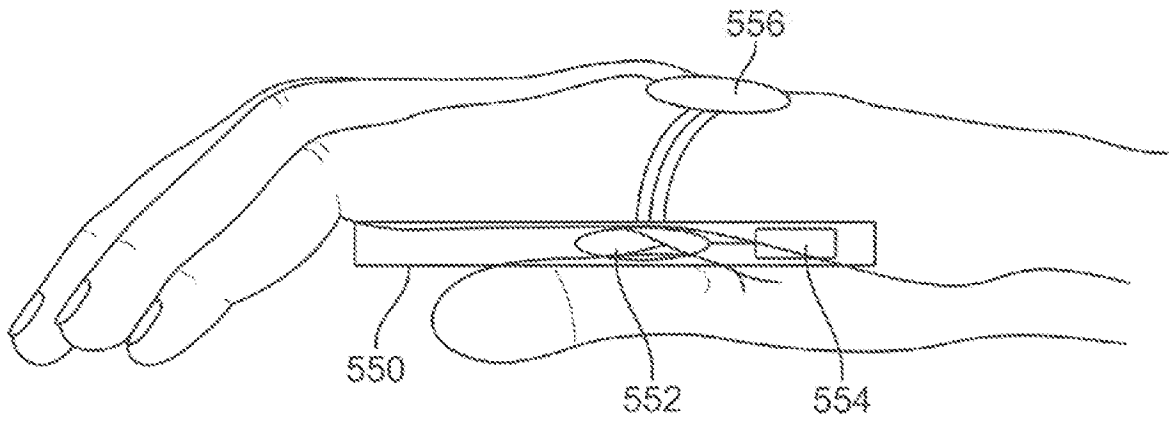


FIG. 48

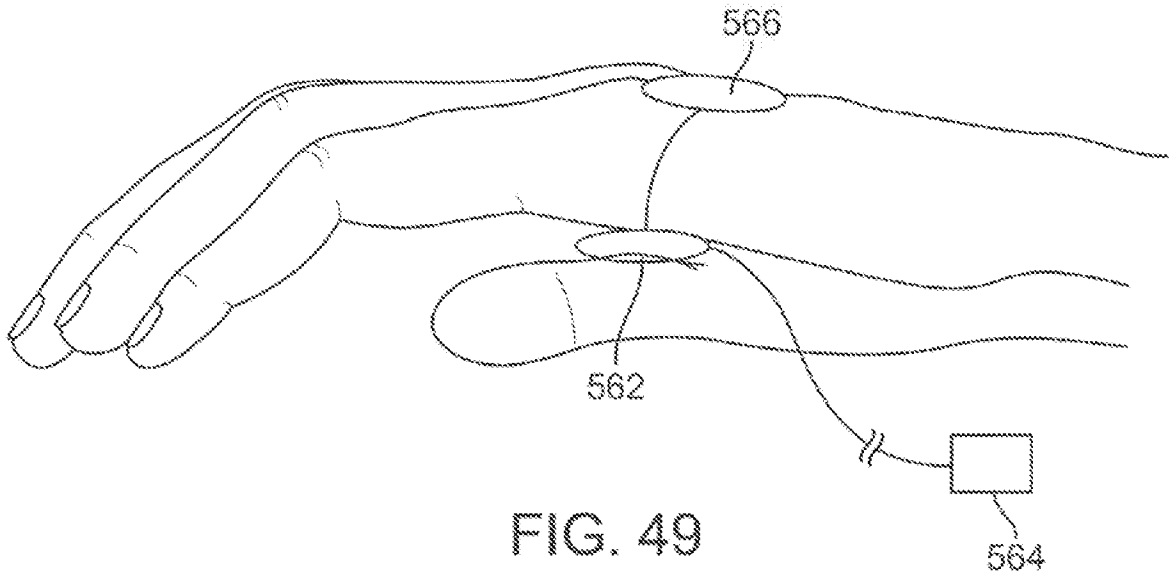


FIG. 49

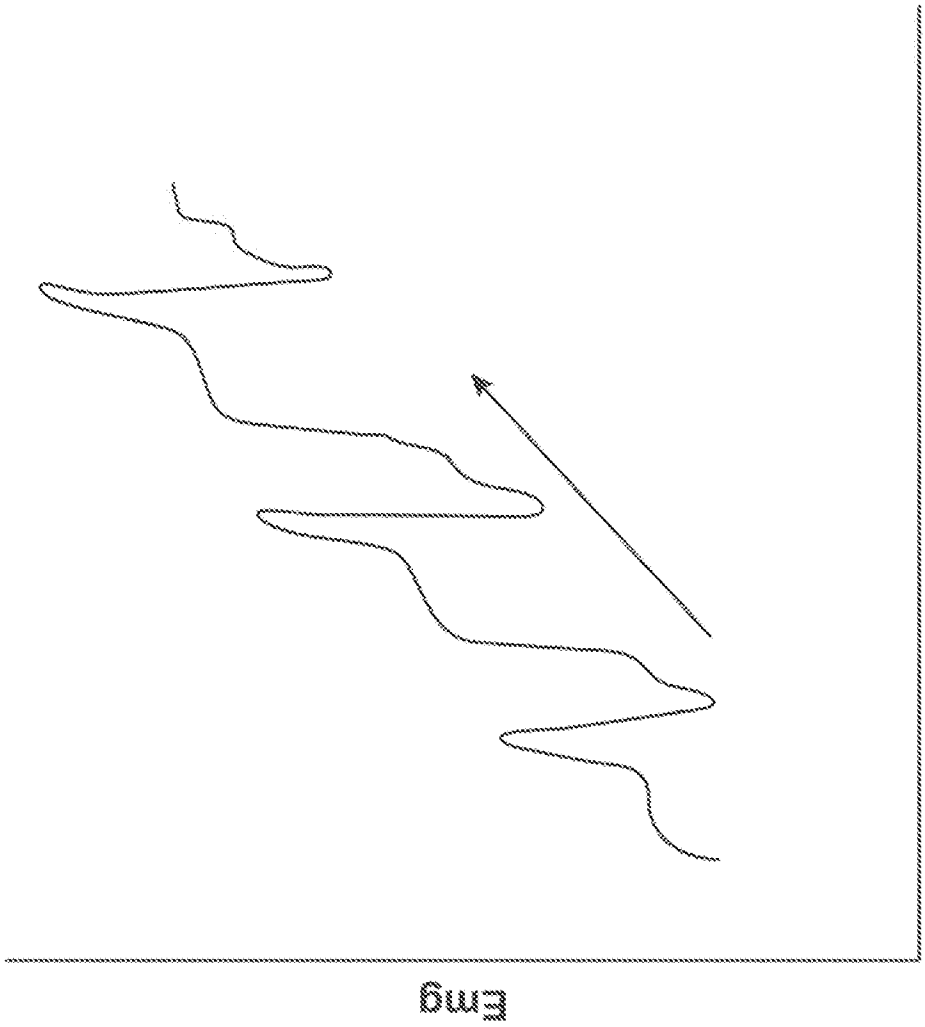


FIG. 50

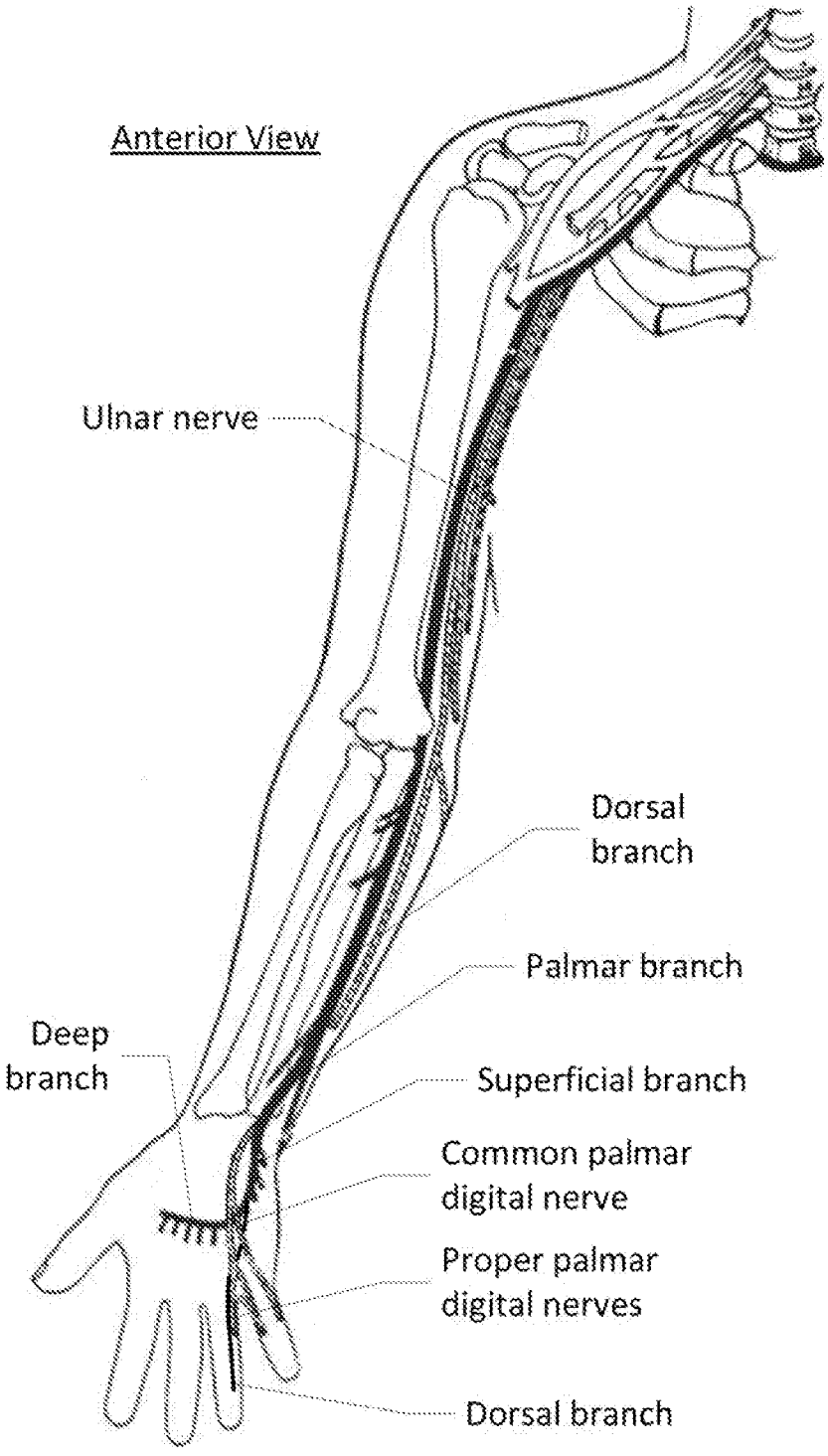


FIG. 51A

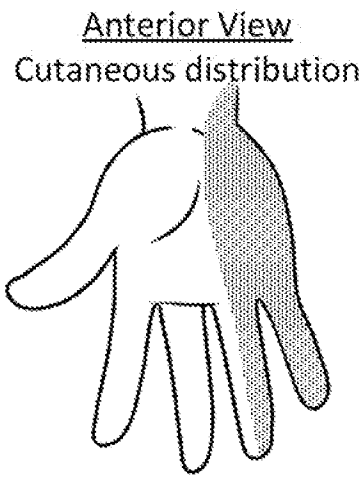


FIG. 51B

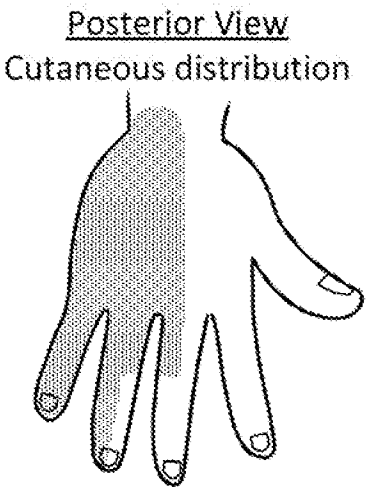


FIG. 51C

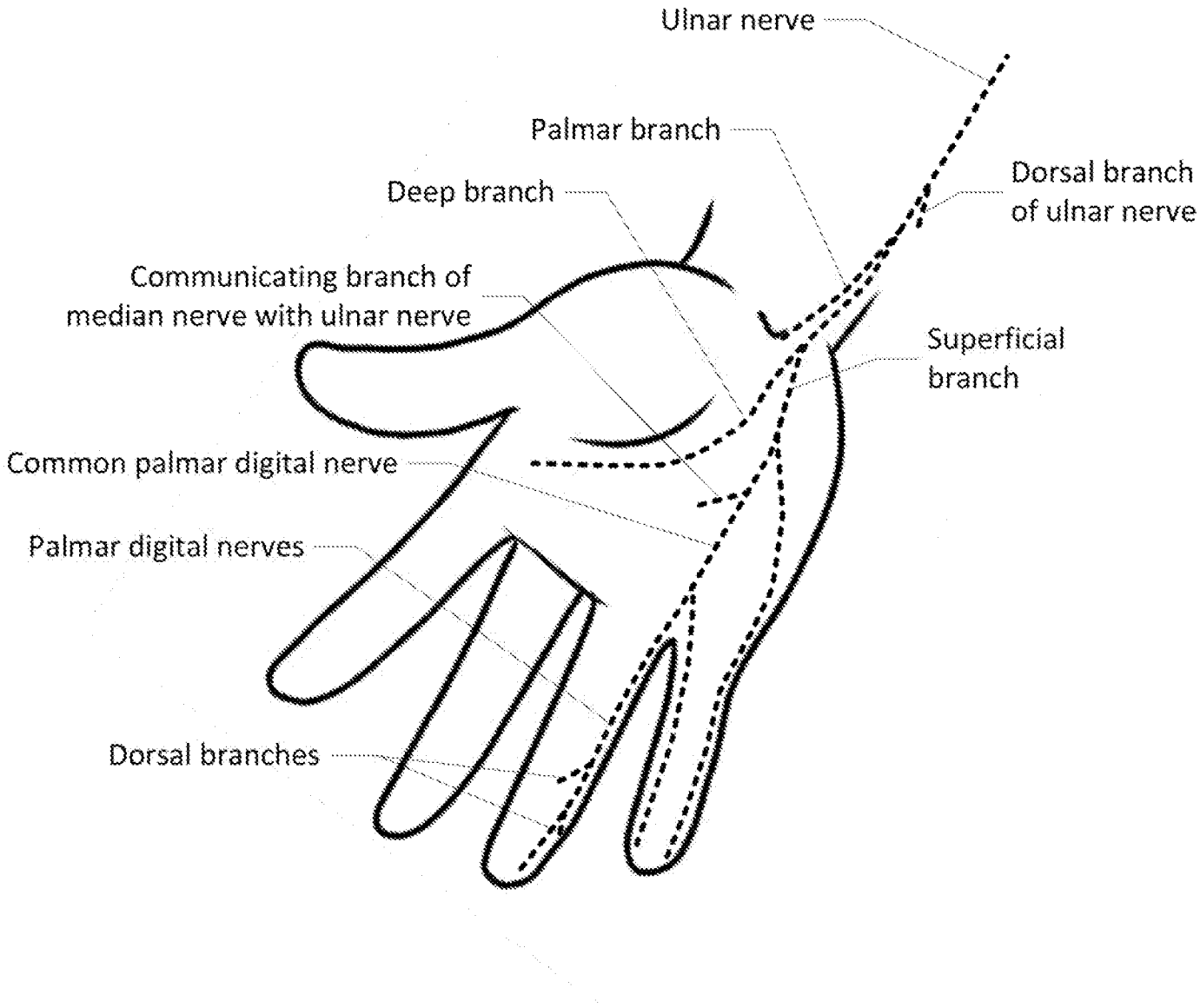

Ulnar nerve
Palmar branch
Deep branch
Dorsal branch of ulnar nerve
Communicating branch of median nerve with ulnar nerve
Superficial branch
Common palmar digital nerve
Palmar digital nerves
Dorsal branches

FIG. 52

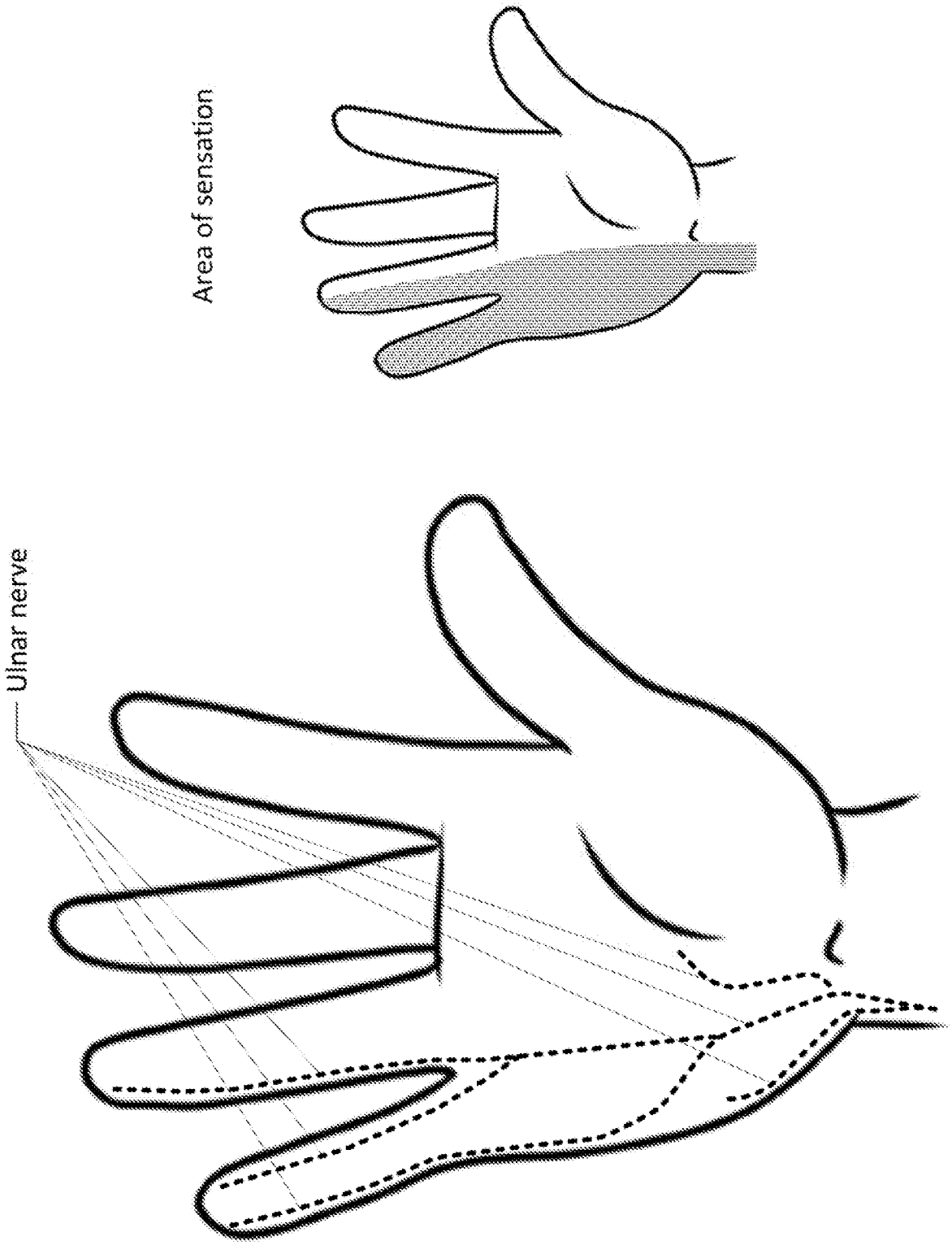


FIG. 53

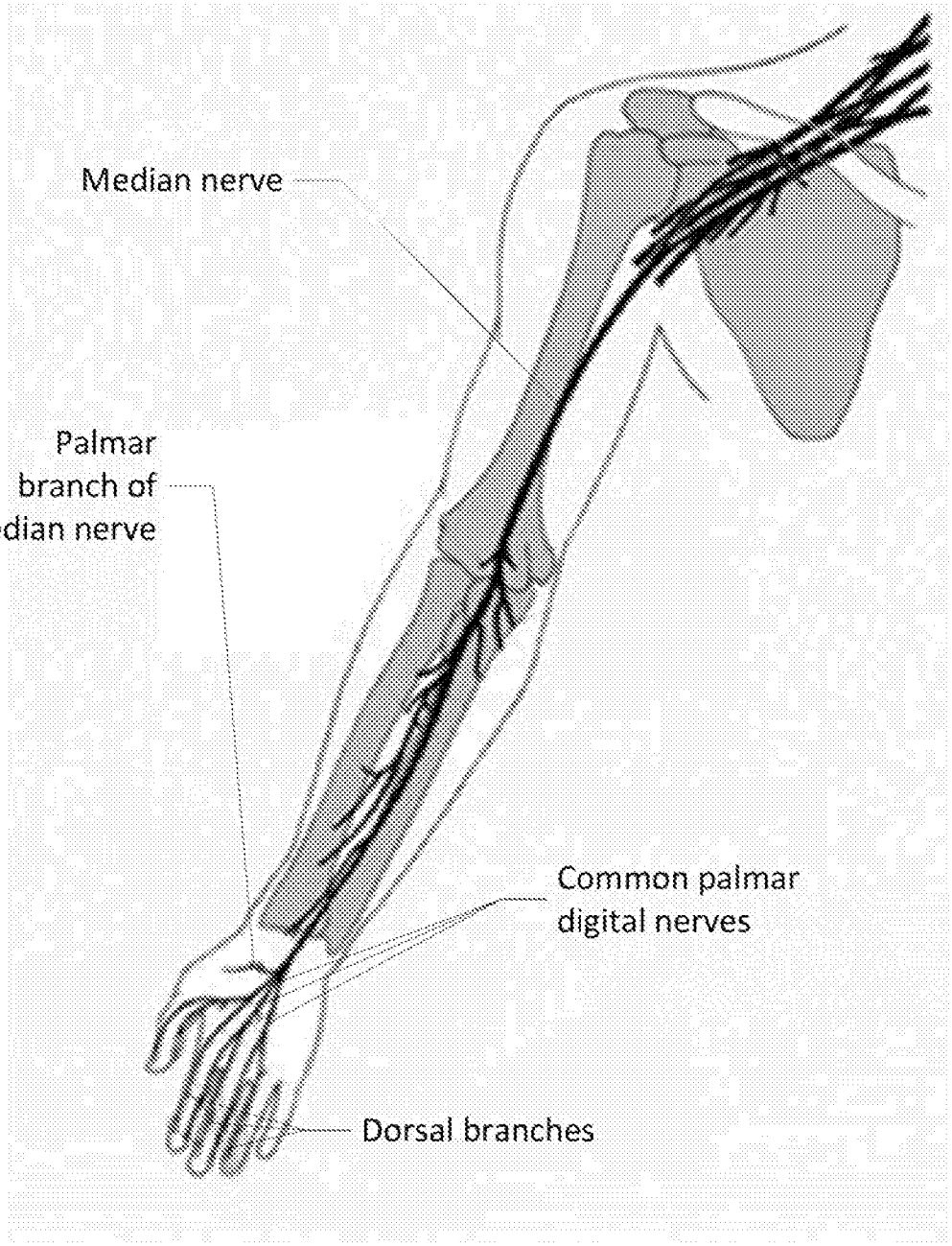


FIG. 54A

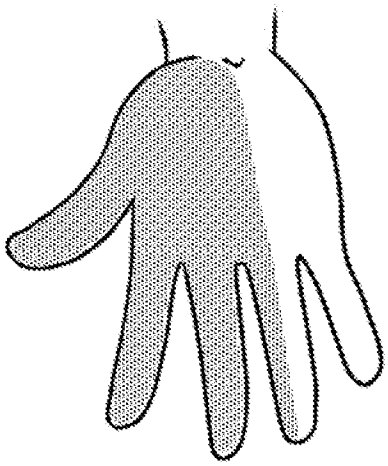


FIG. 54B

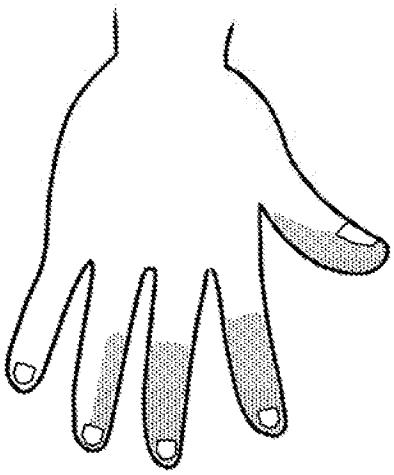


FIG. 54C

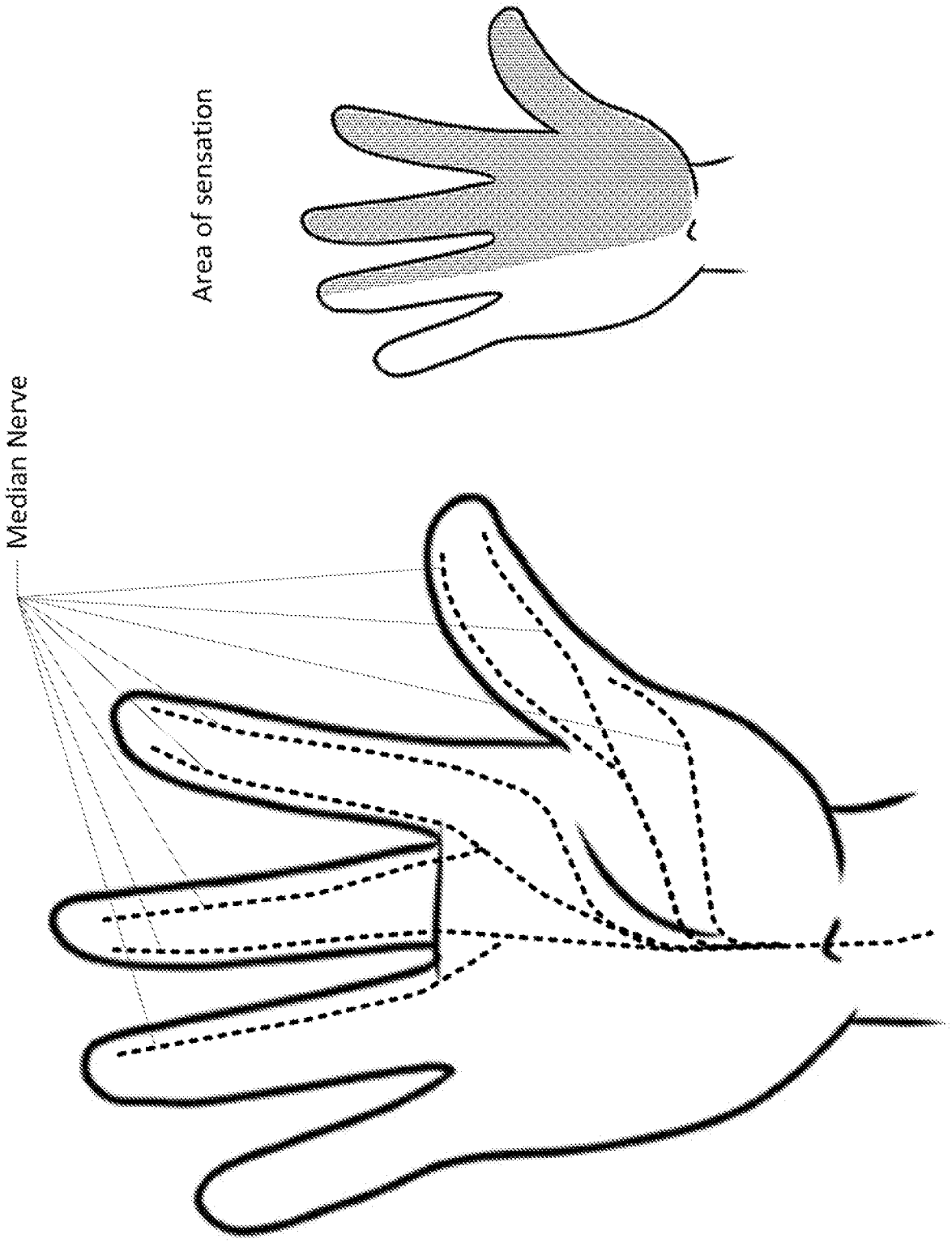


FIG. 55

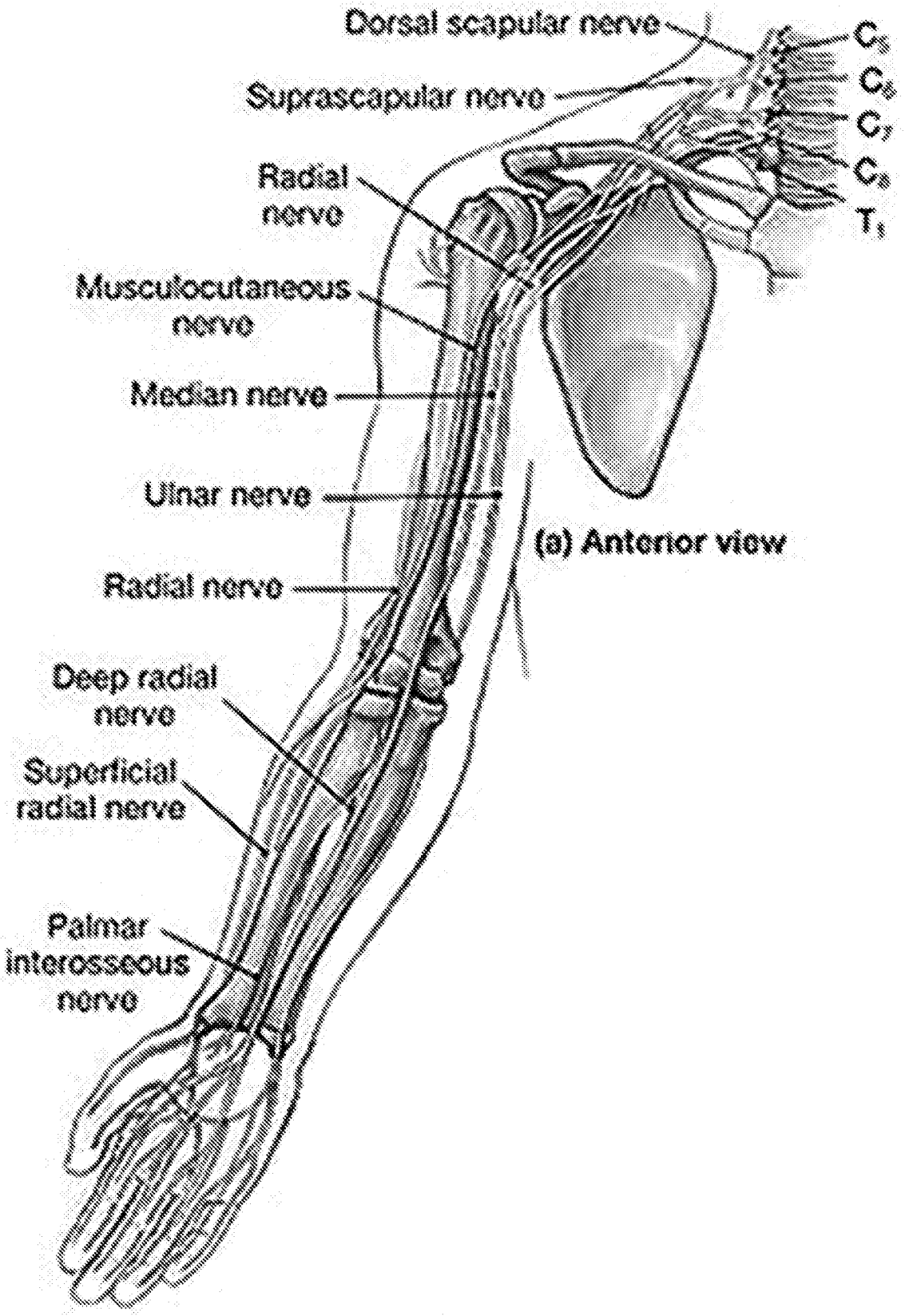
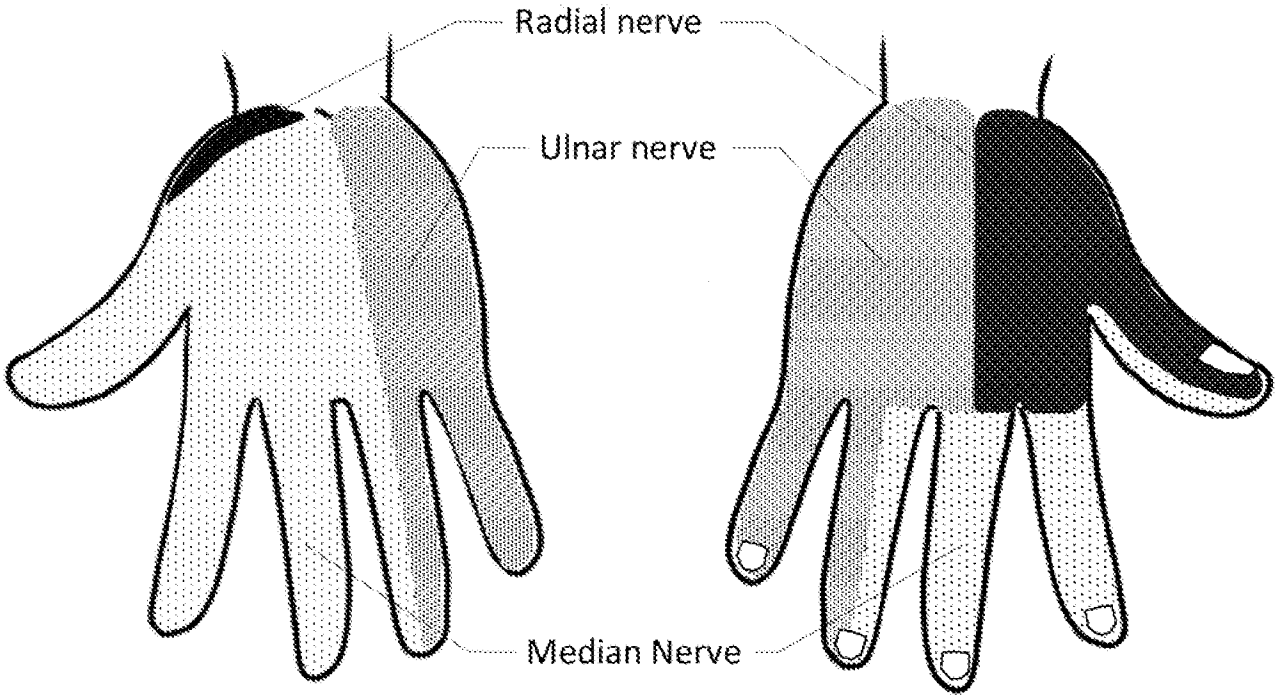

Dorsal scapular nerve
Suprascapular nerve
Radial nerve
Musculocutaneous nerve
Median nerve
Ulnar nerve
Radial nerve
Deep radial nerve
Superficial radial nerve
Palmar interosseous nerve
C5
C6
C7
C8
T1
(a) Anterior view

FIG. 56A



Distribution of cutaneous nerves

FIG. 56B

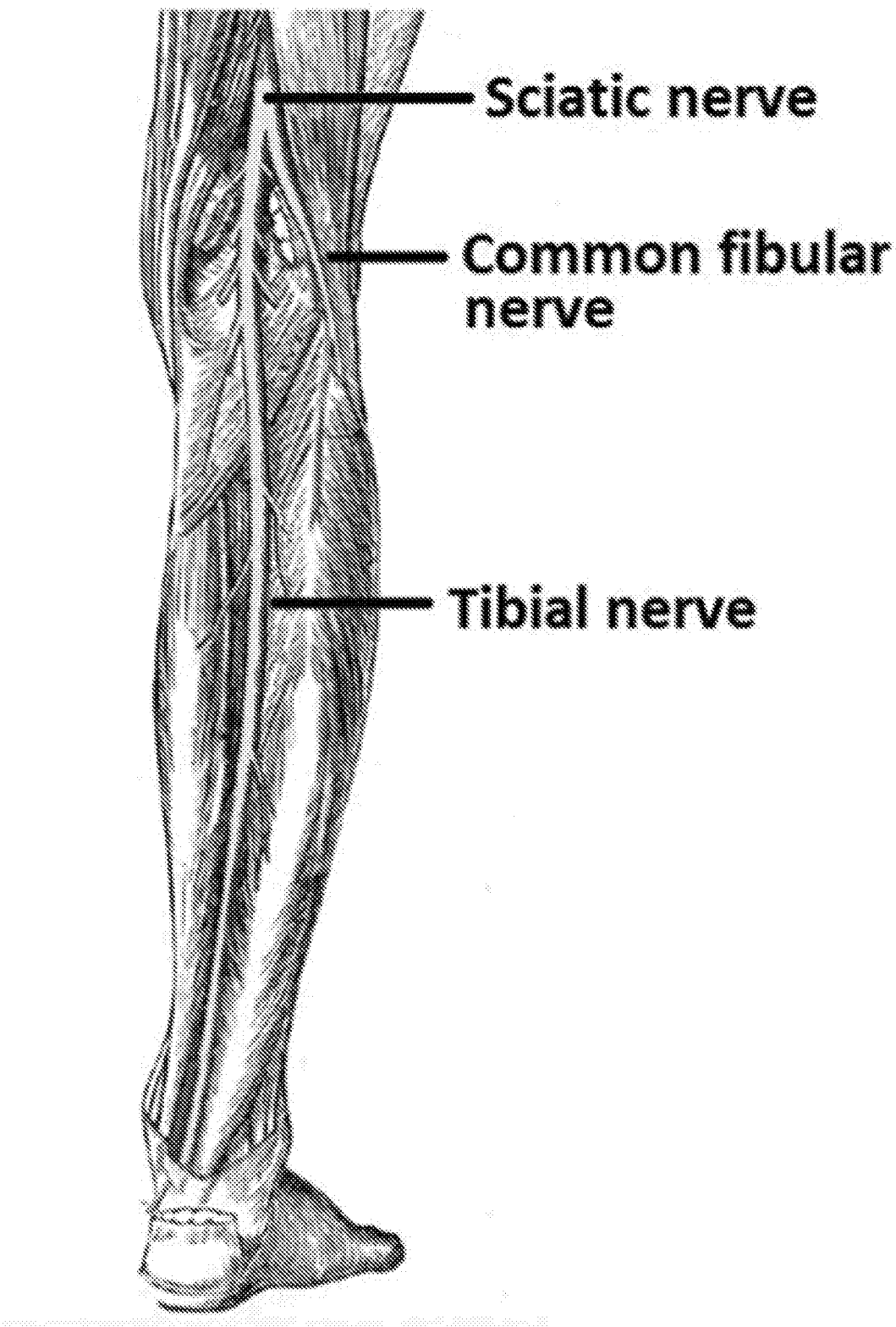


FIG. 56C

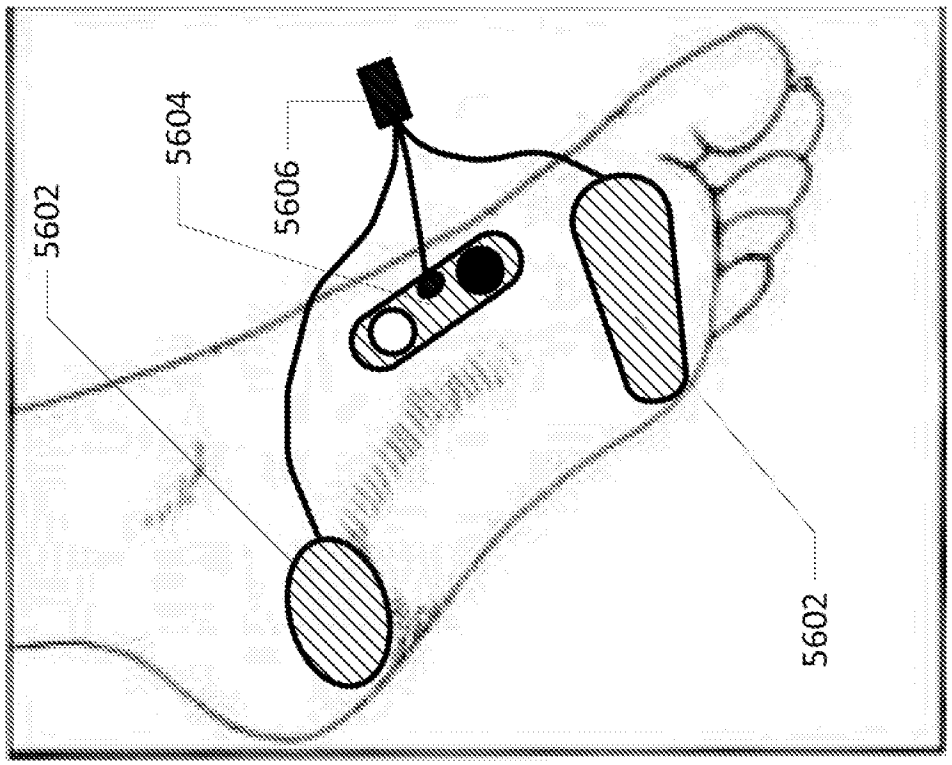


FIG. 56E

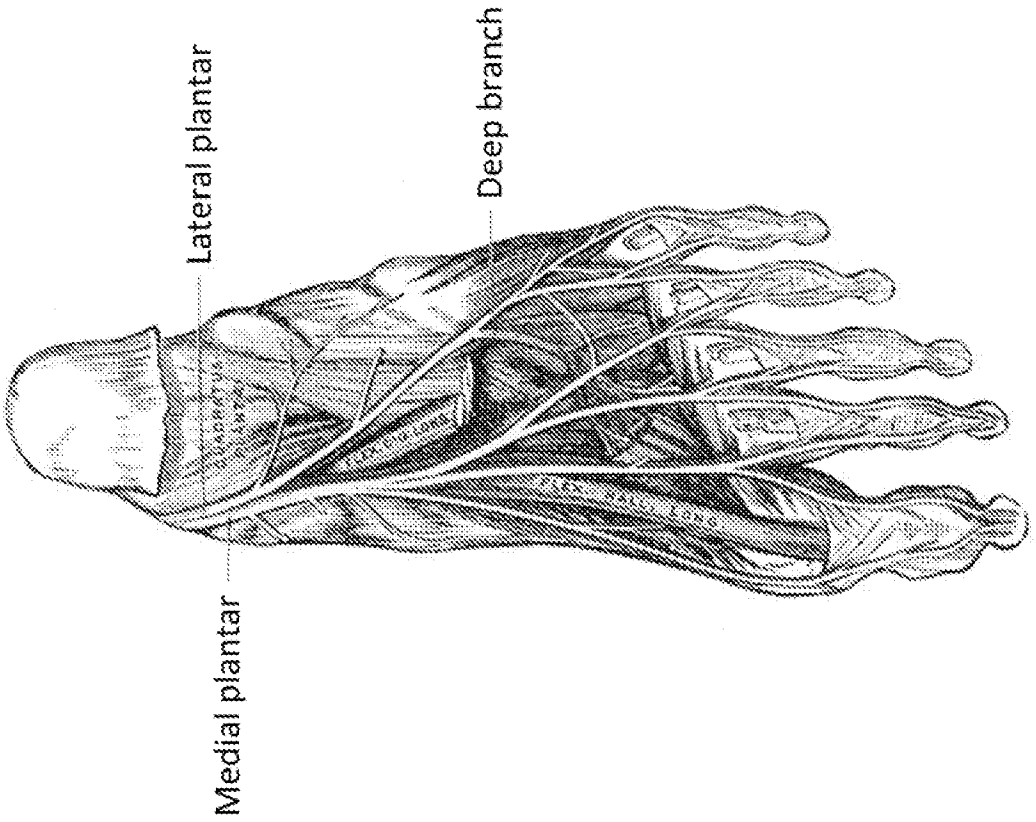


FIG. 56D

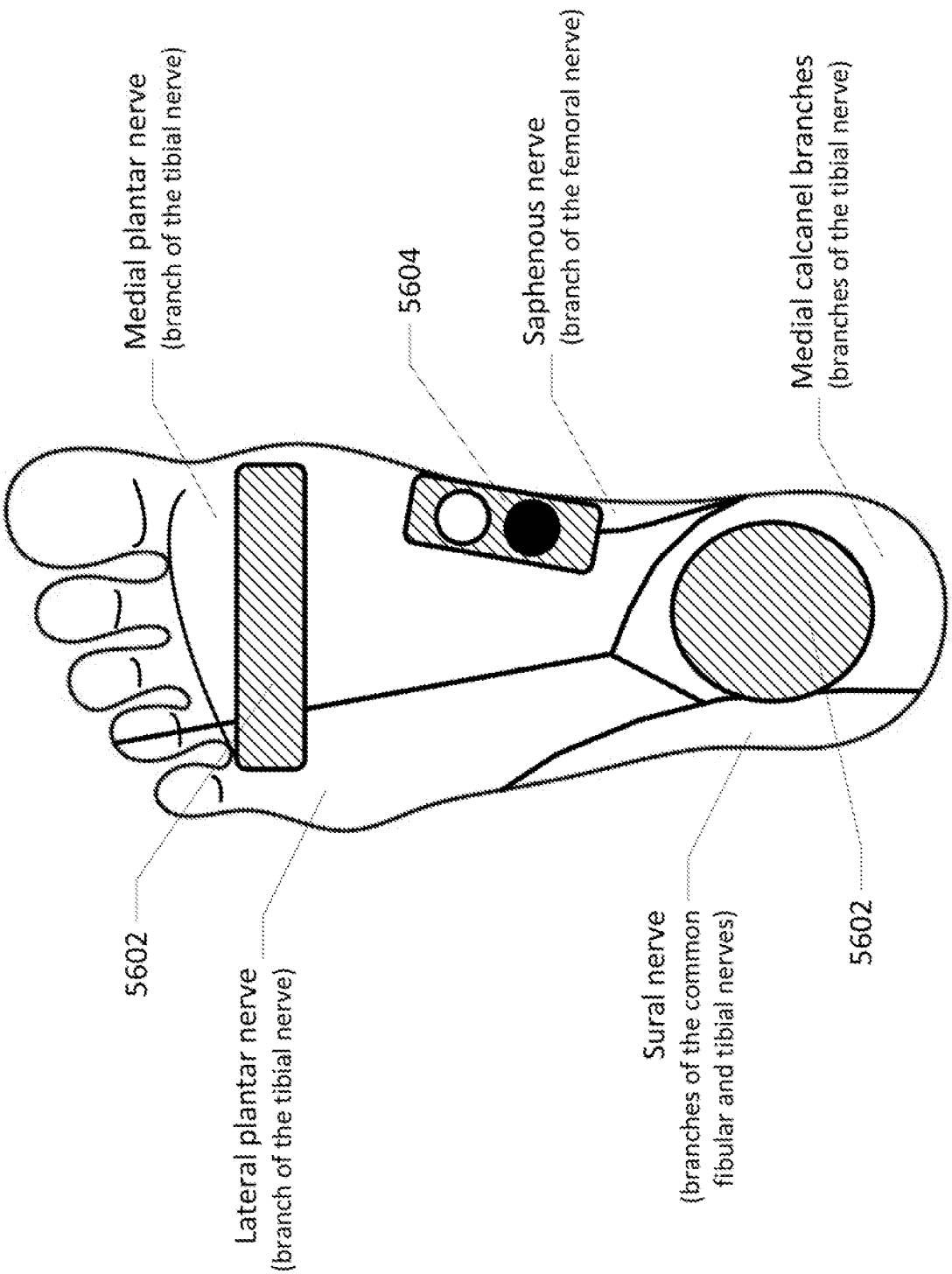

Medial plantar nerve
(branch of the tibial nerve)
5604
Saphenous nerve
(branch of the femoral nerve)
Medial calcanel branches
(branches of the tibial nerve)
5602
Lateral plantar nerve
(branch of the tibial nerve)
Sural nerve
(branches of the common
fibular and tibial nerves)
5602

FIG. 56F

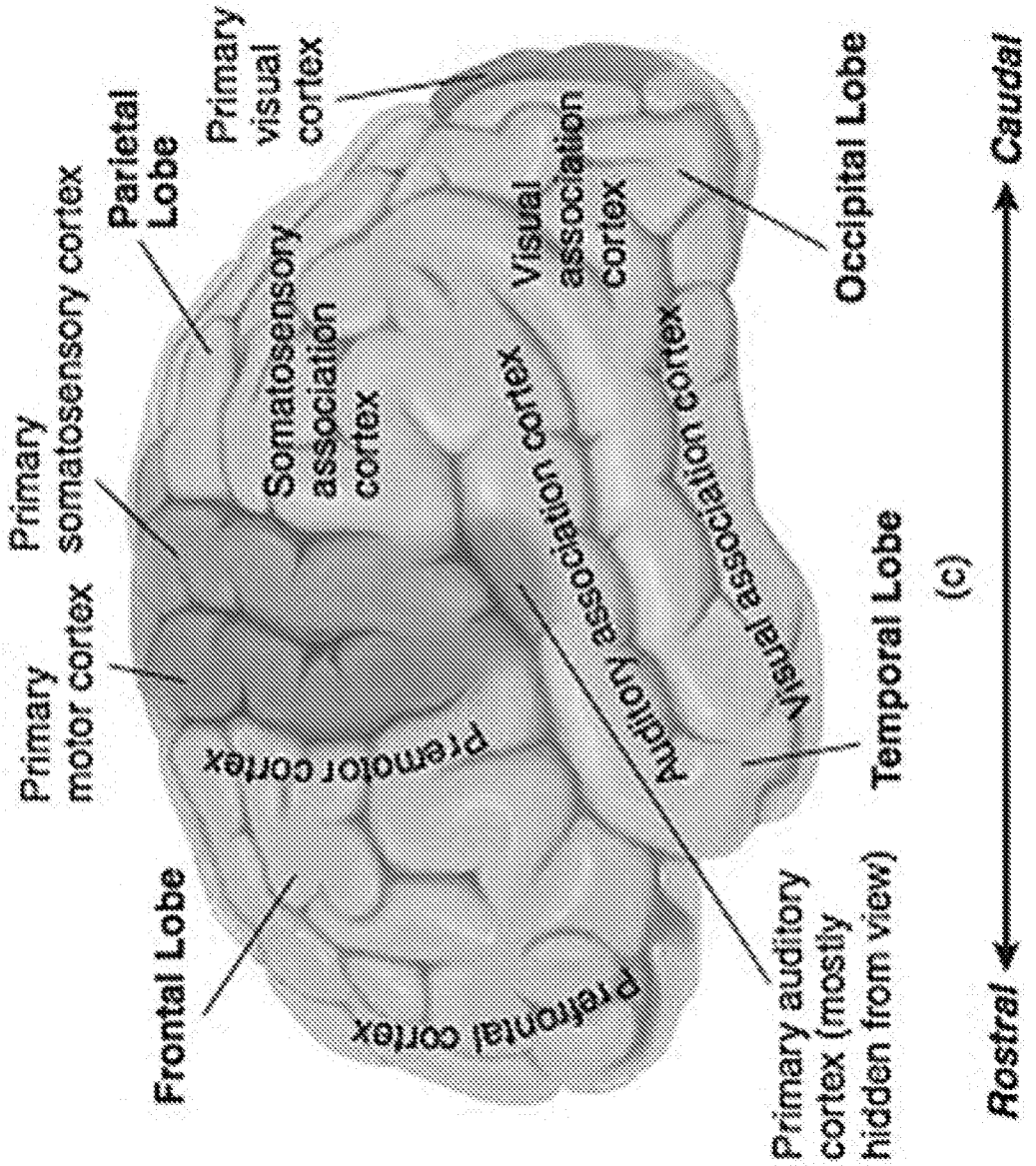

Primary motor cortex
Primary somatosensory cortex
Parietal Lobe
Primary visual cortex
Frontal Lobe
Premotor cortex
Somatosensory association cortex
Visual association cortex
Occipital Lobe
Prefrontal cortex
Auditory association cortex
Visual association cortex
Temporal Lobe
Primary auditory cortex (mostly hidden from view)
(c)
Rostral
Caudal

FIG. 57

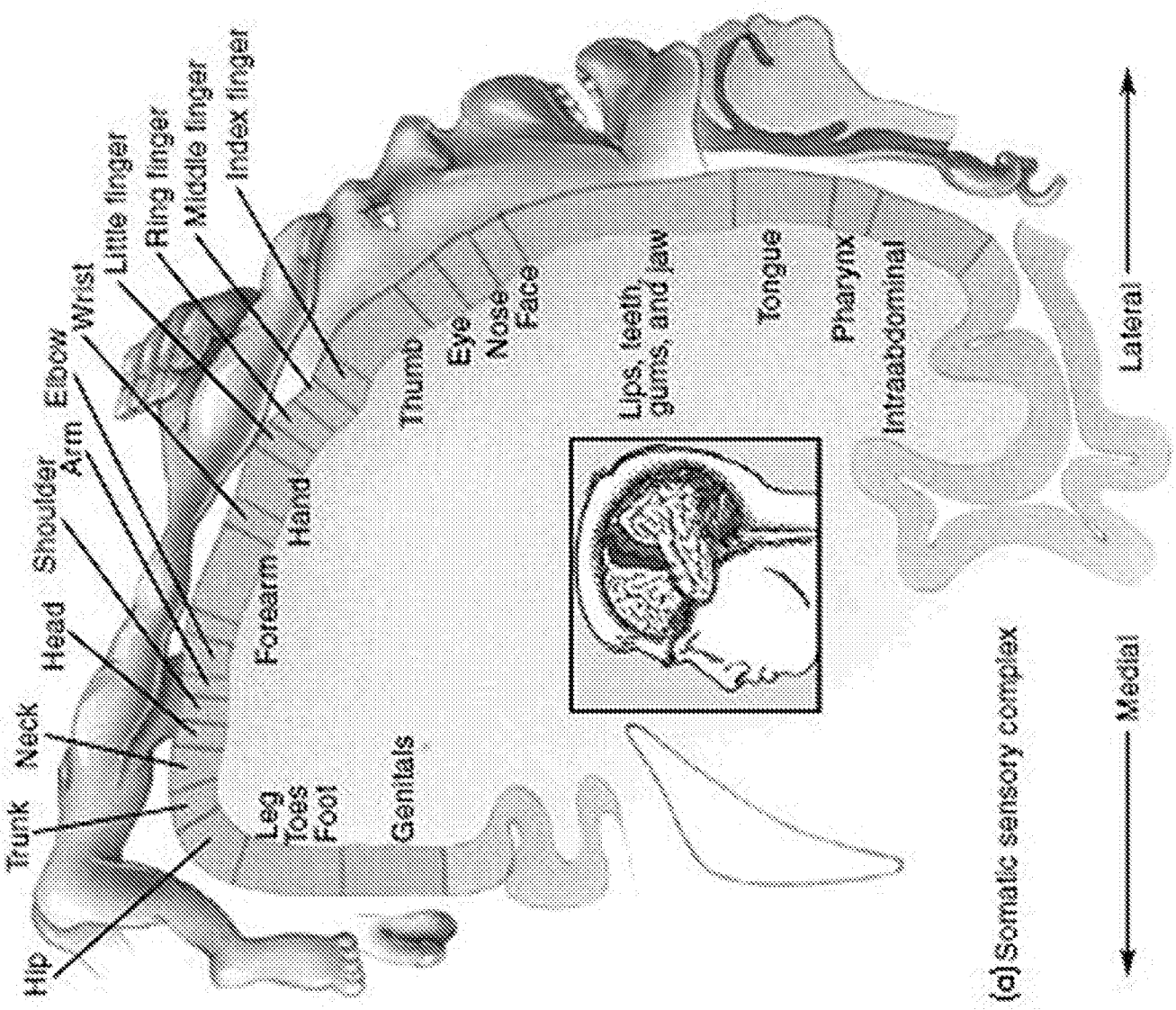

Hip
Trunk
Neck
Head
Shoulder
Arm
Elbow
Wrist
Little finger
Ring finger
Middle finger
Index finger
Thumb
Eye
Nose
Face
Lips, teeth, gums, and jaw
Tongue
Pharynx
Intraabdominal
Hand
Forearm
Leg
Toes
Foot
Genitals
(a) Somatic sensory complex
Medial
Lateral

FIG. 58

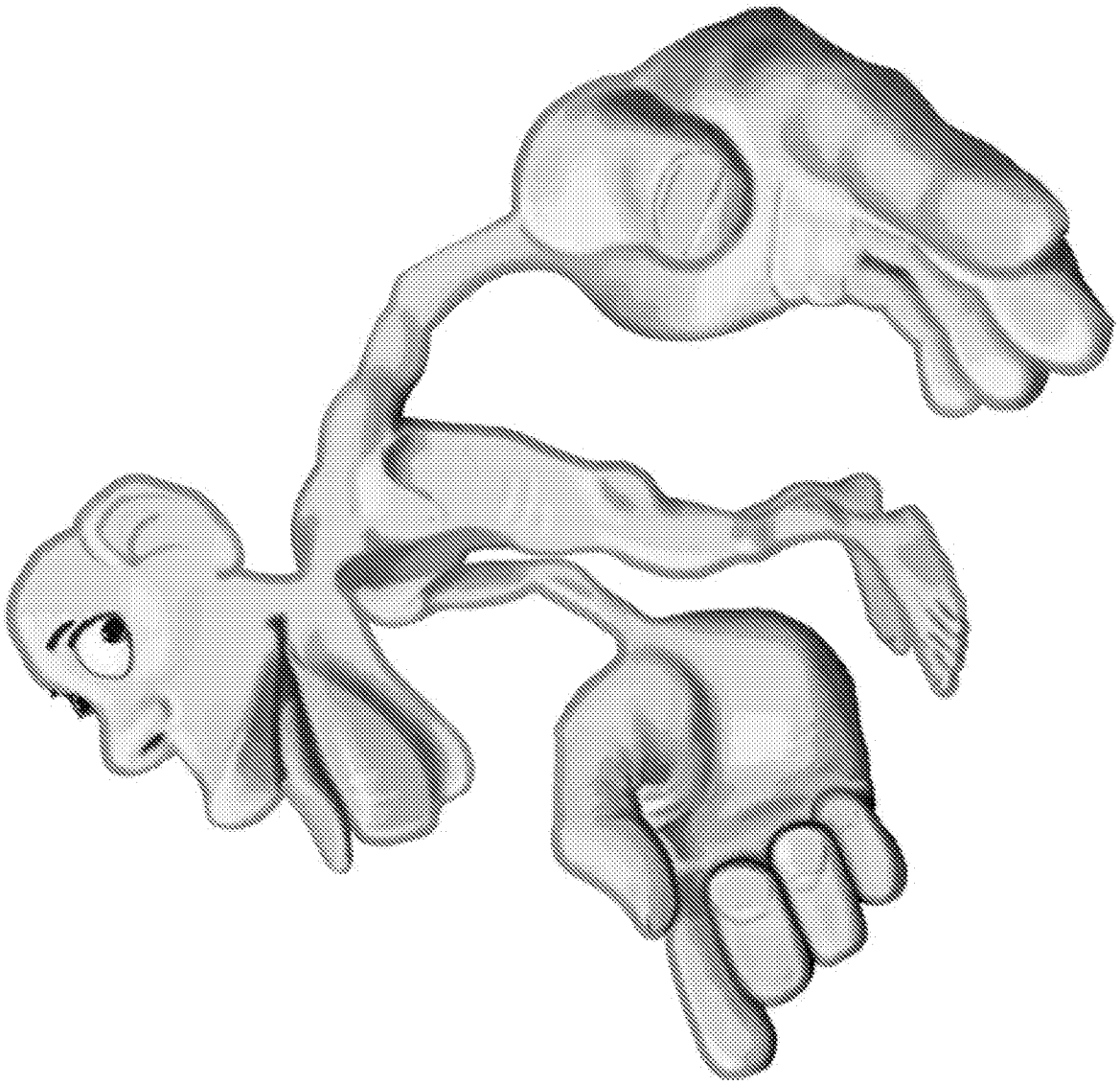


FIG. 59A

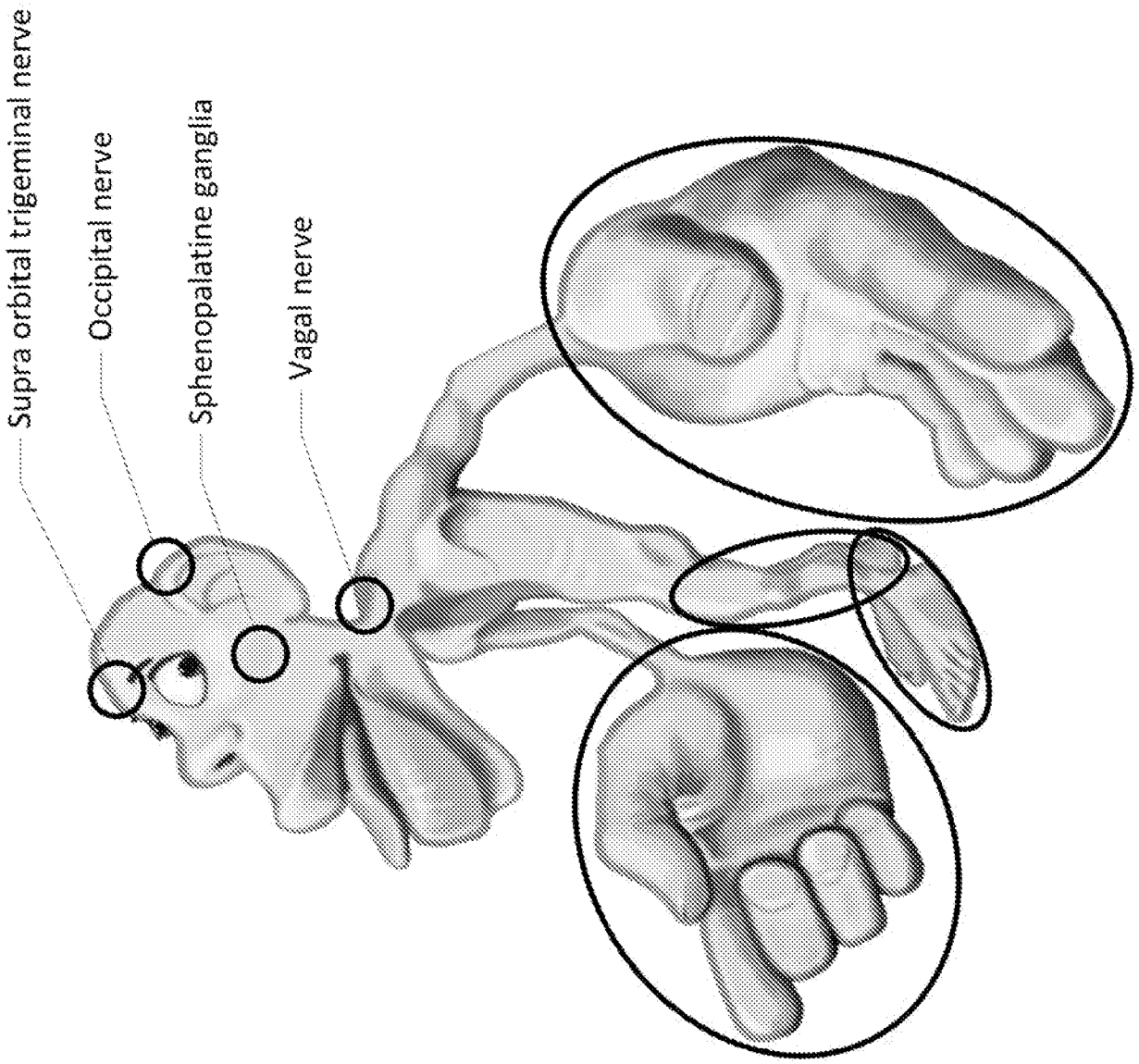

Supra orbital trigeminal nerve
Occipital nerve
Sphenopalatine ganglia
Vagal nerve

FIG. 59B

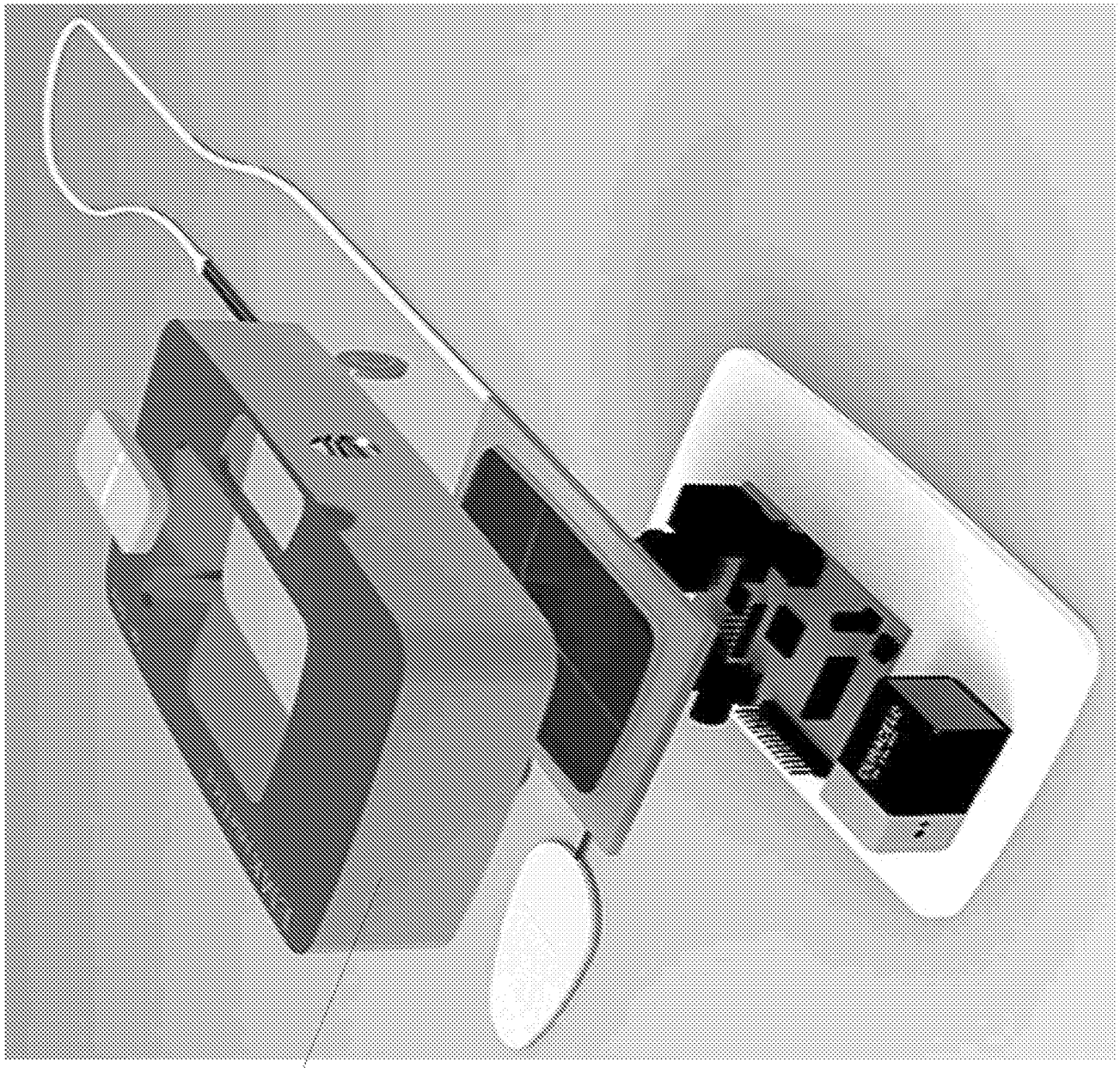


FIG. 60A

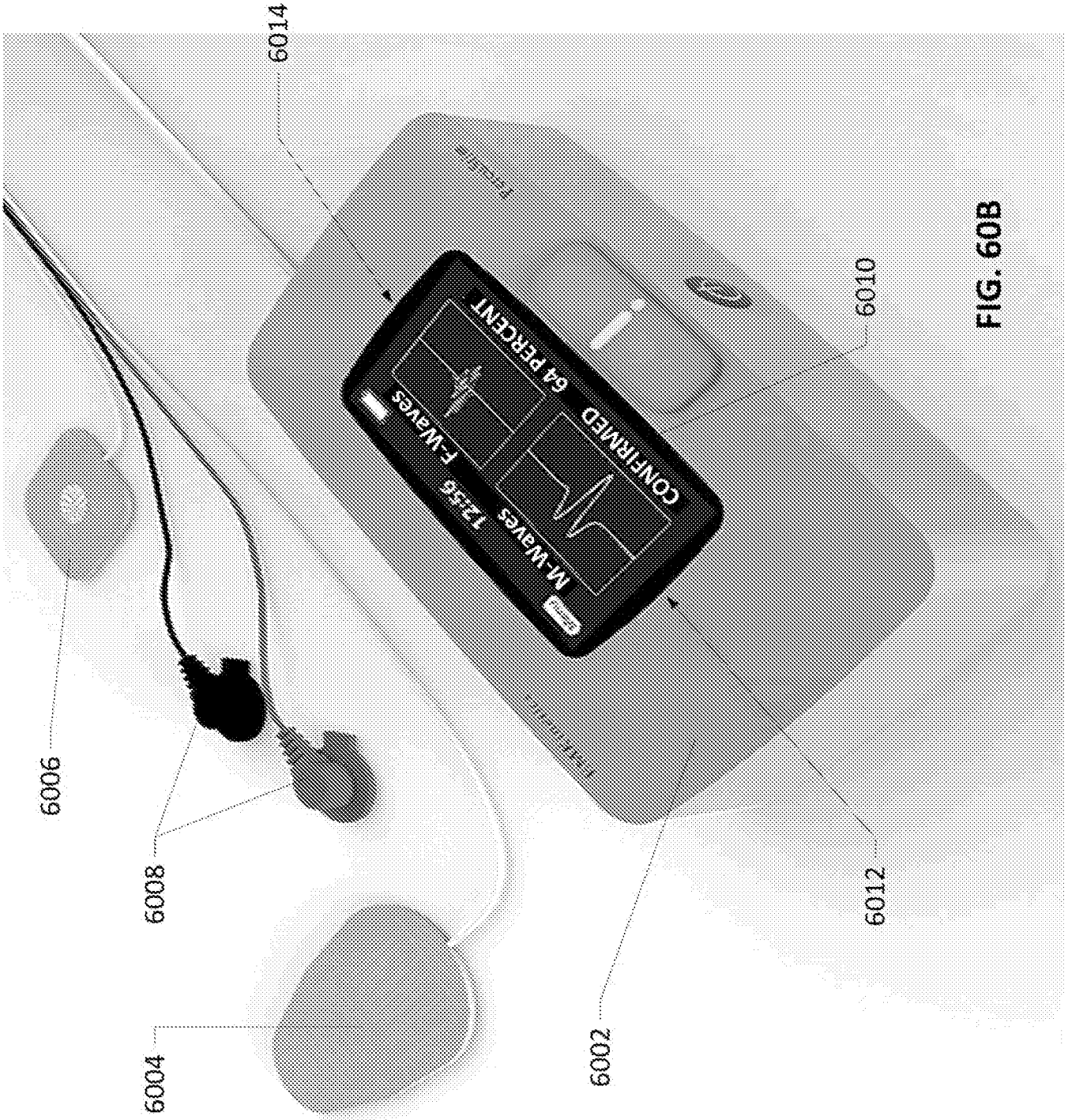

6014
6010
6006
6008
6012
6004
6002
M-Waves
T2455
P-Waves
CONFIRMED
64 PERCENT

FIG. 60B



FIG. 60C

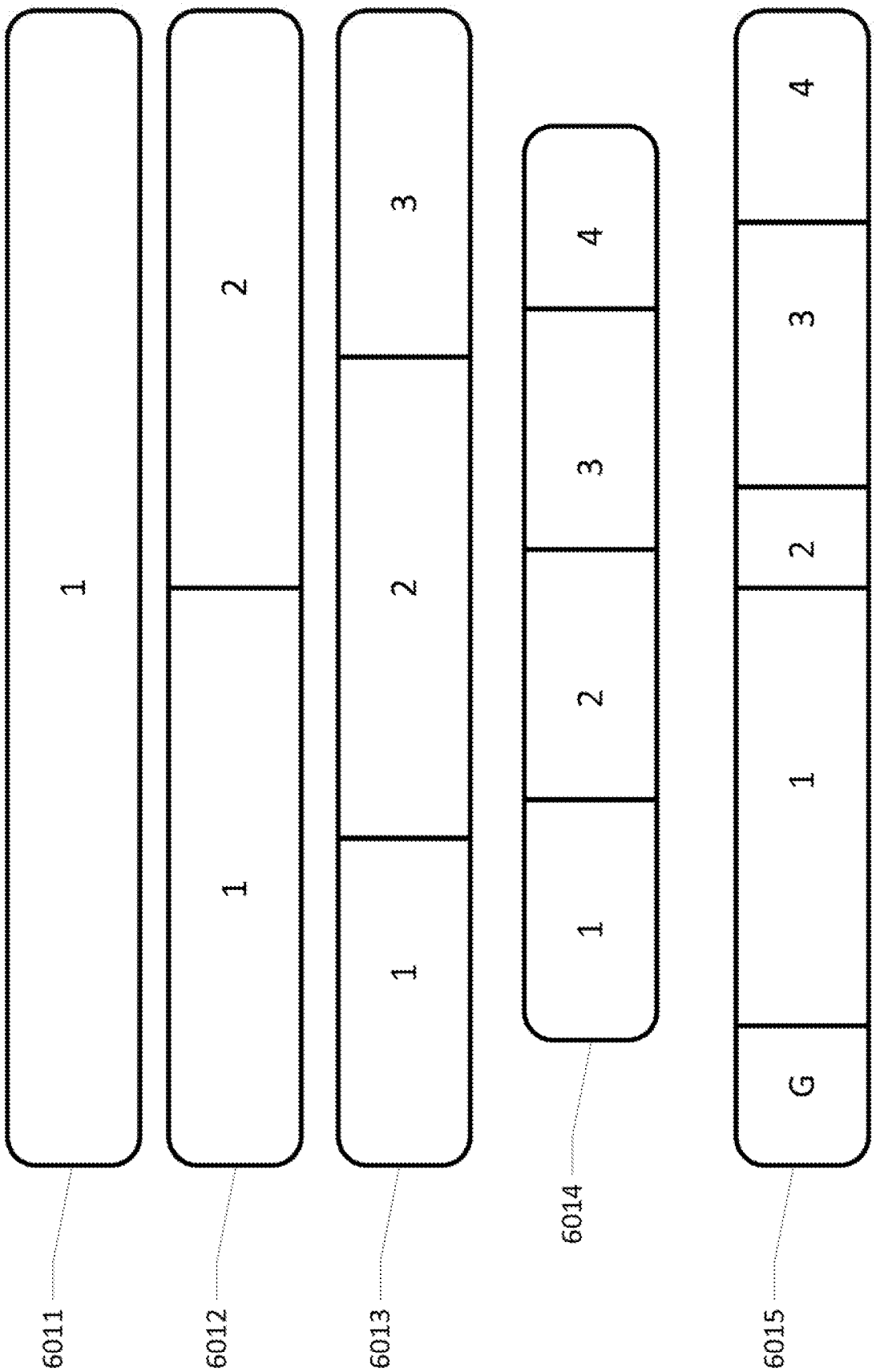


FIG. 60D

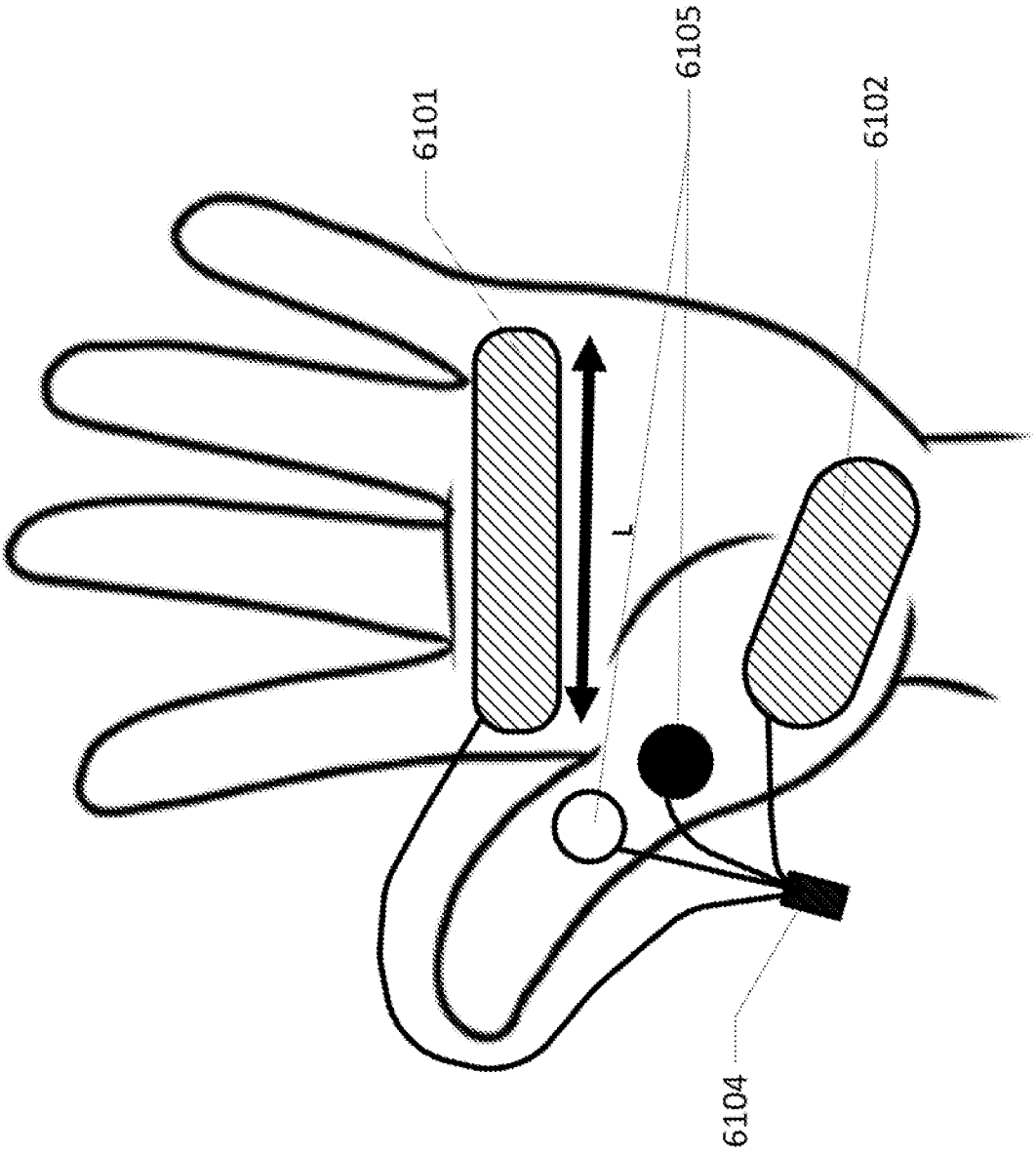


FIG. 61A

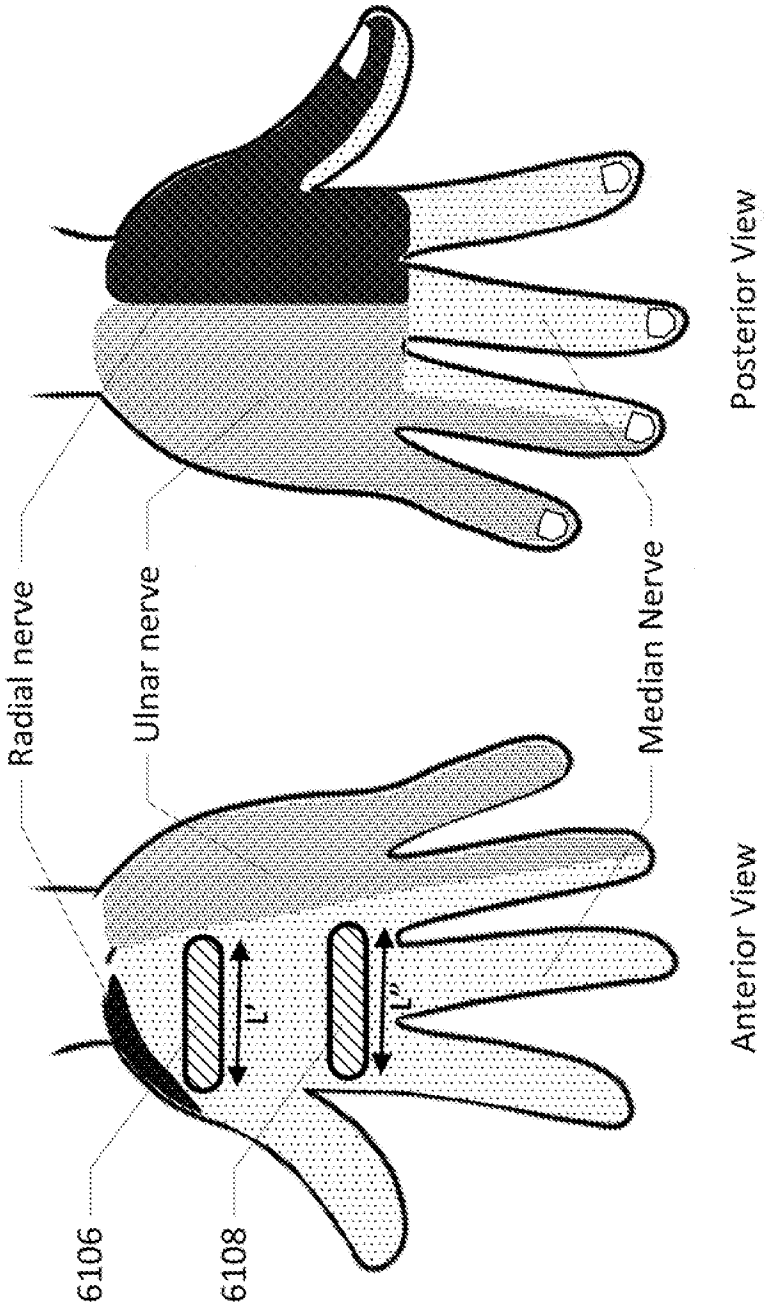

Radial nerve
Ulnar nerve
Median Nerve
Posterior View
Anterior View
L'
L''
6106
6108

FIG. 61B

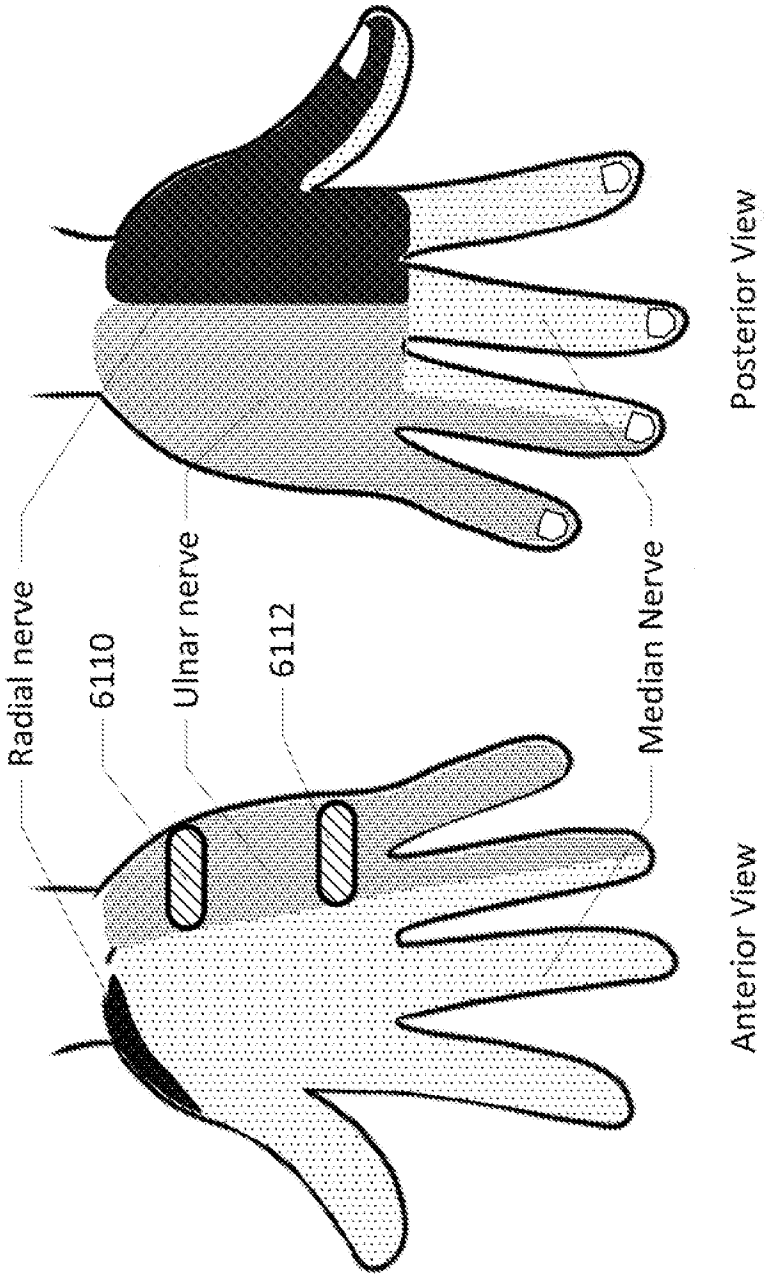

Radial nerve
6110
Ulnar nerve
6112
Median Nerve
Posterior View
Anterior View

FIG. 61C

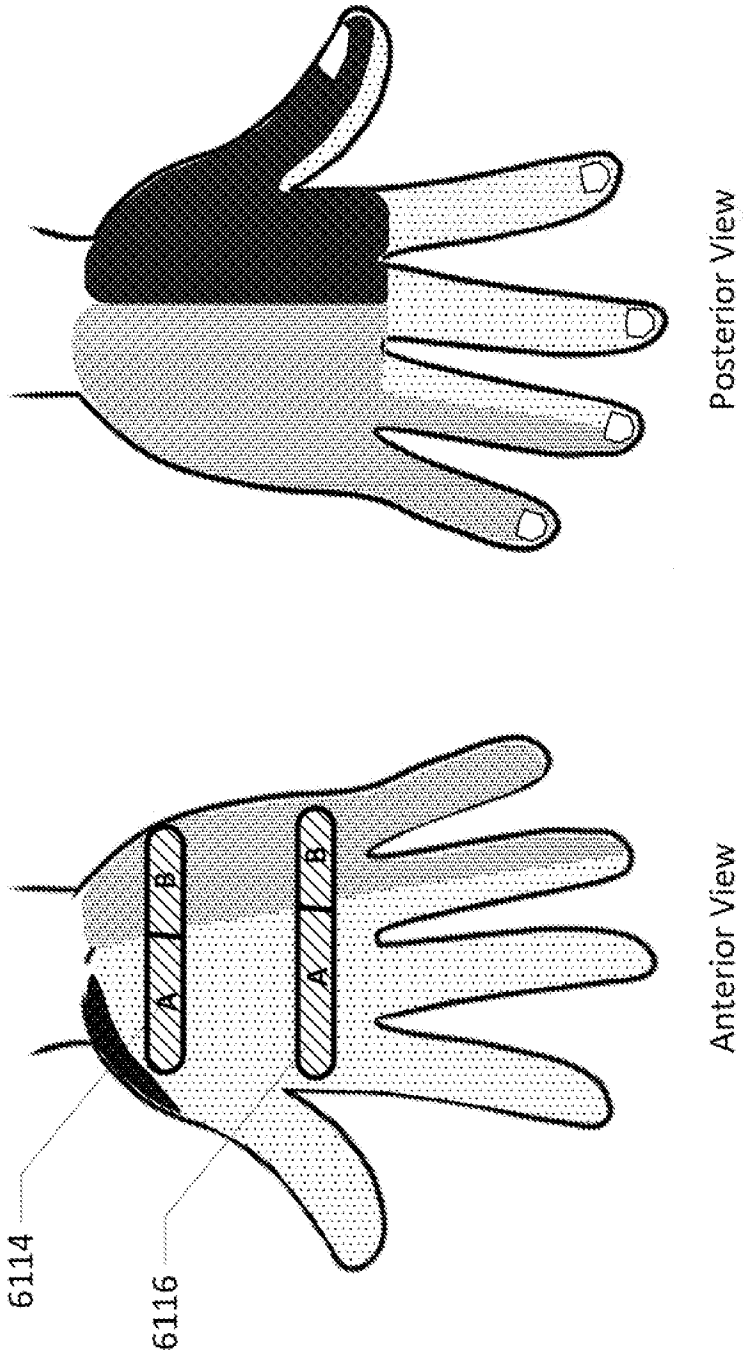


FIG. 61D

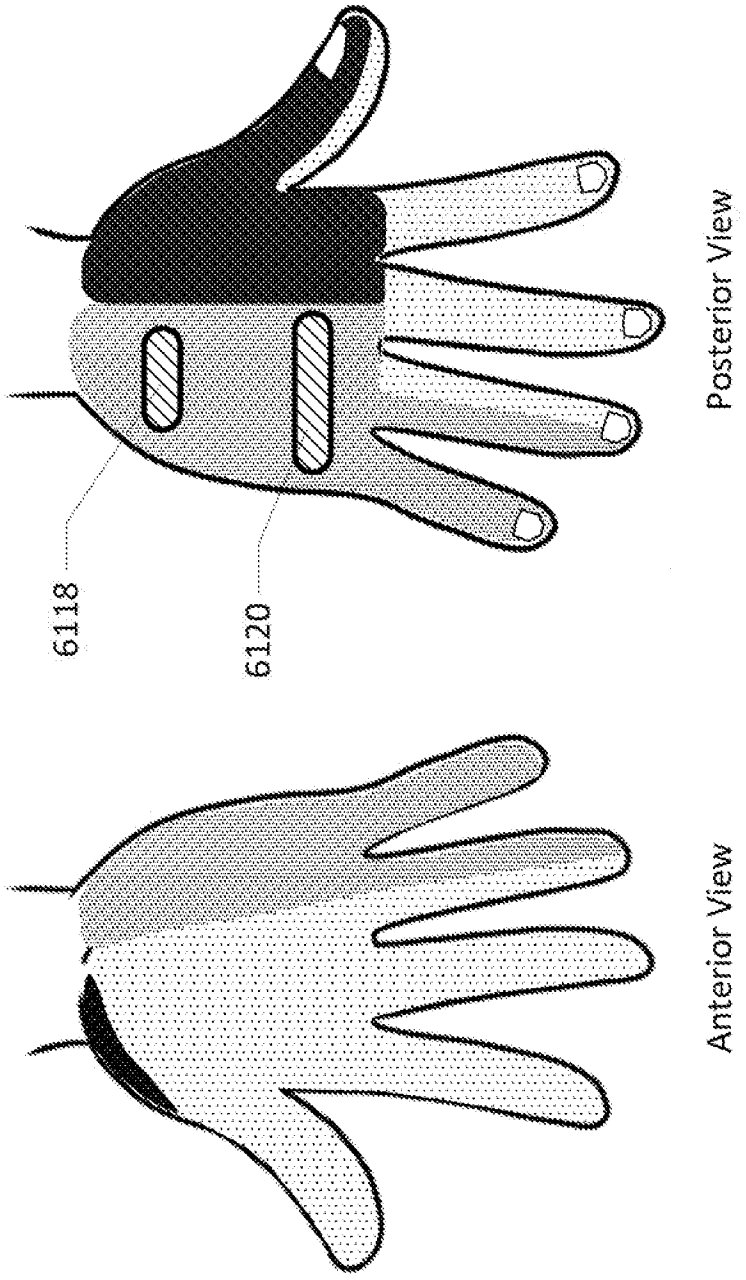

6118
6120
Posterior View
Anterior View
Distribution of cutaneous nerves

FIG. 61E

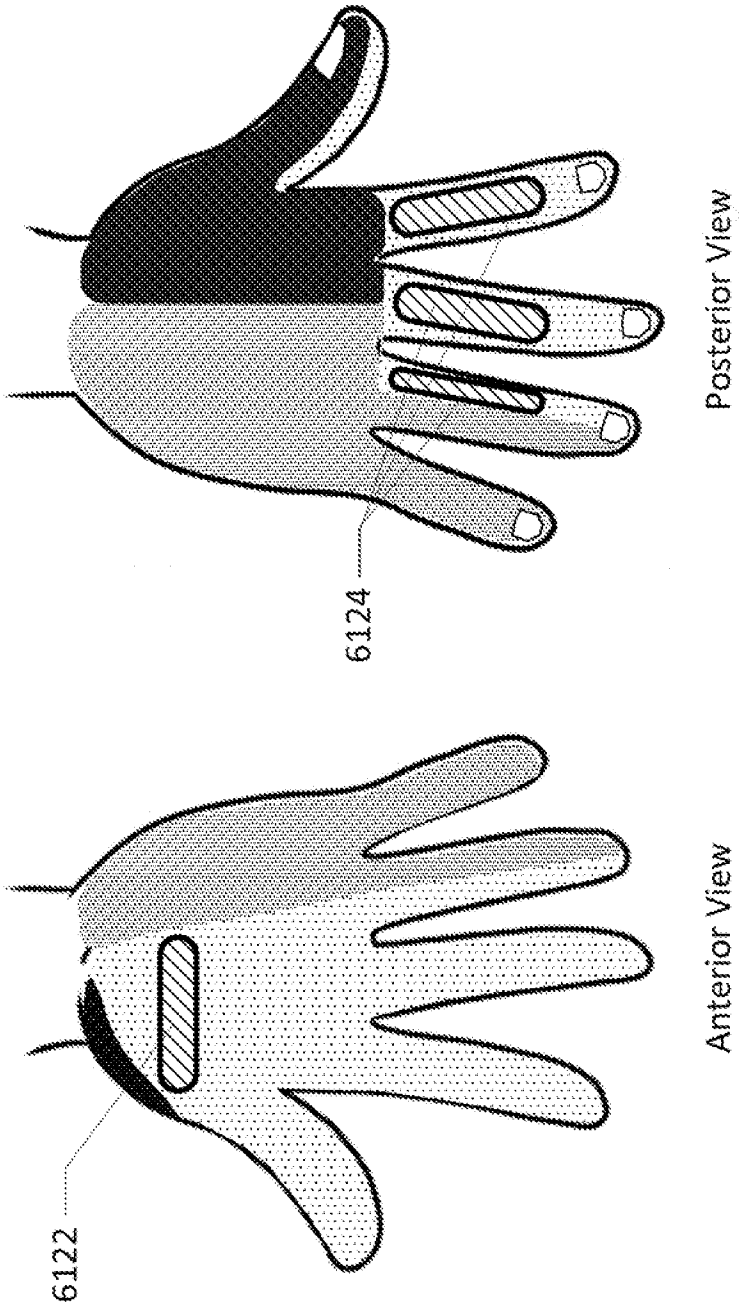


FIG. 61F

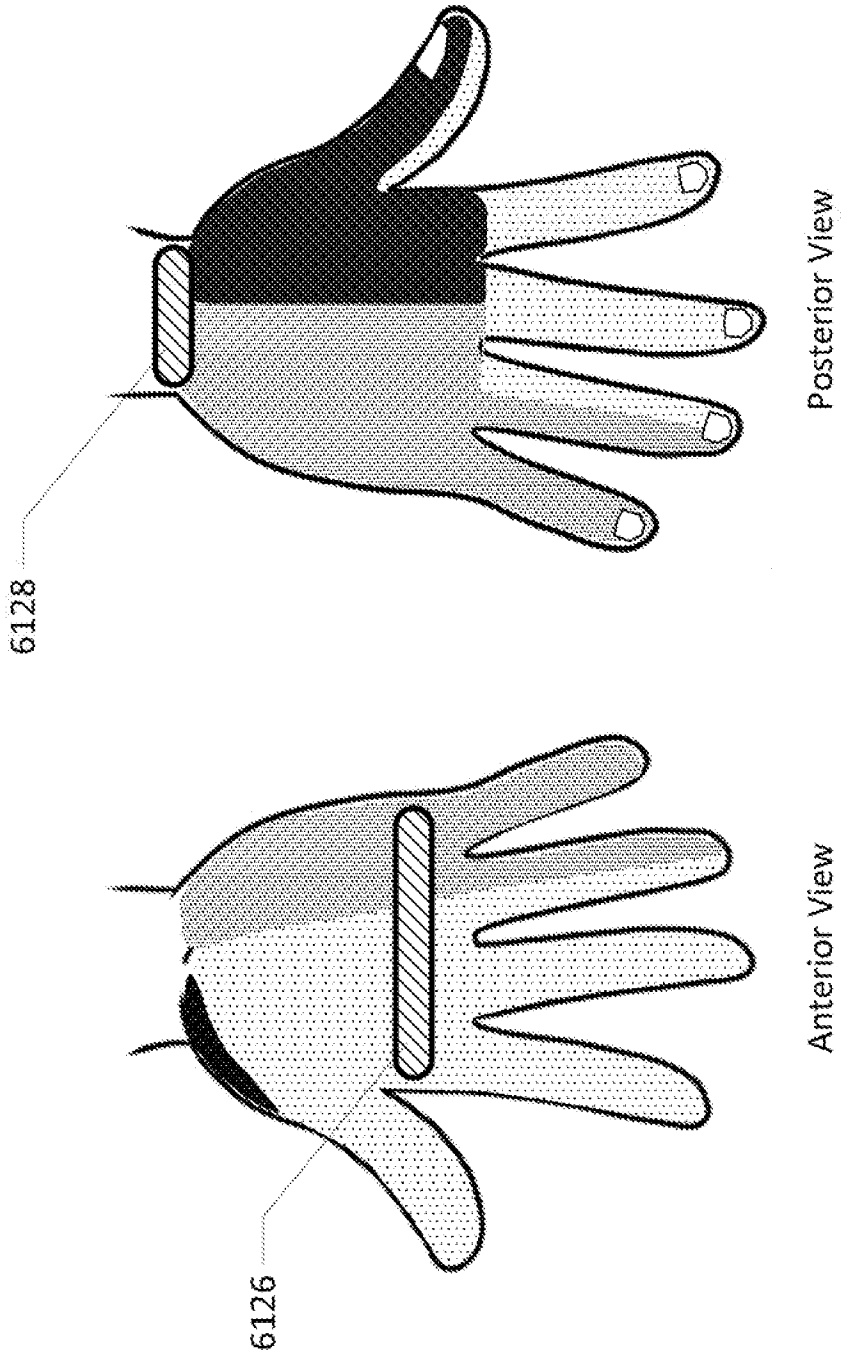
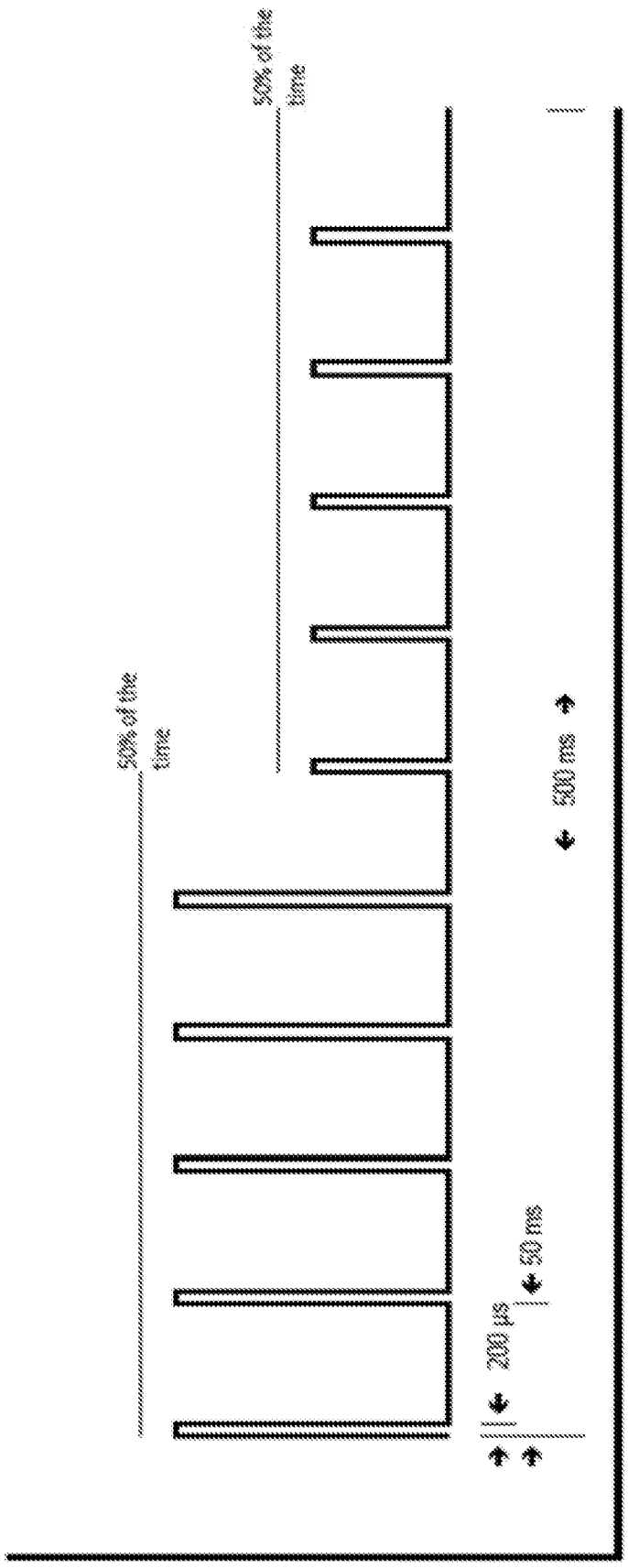


FIG. 61G



Schematic Representation of Output (one 10 pulse period)

FIG. 62

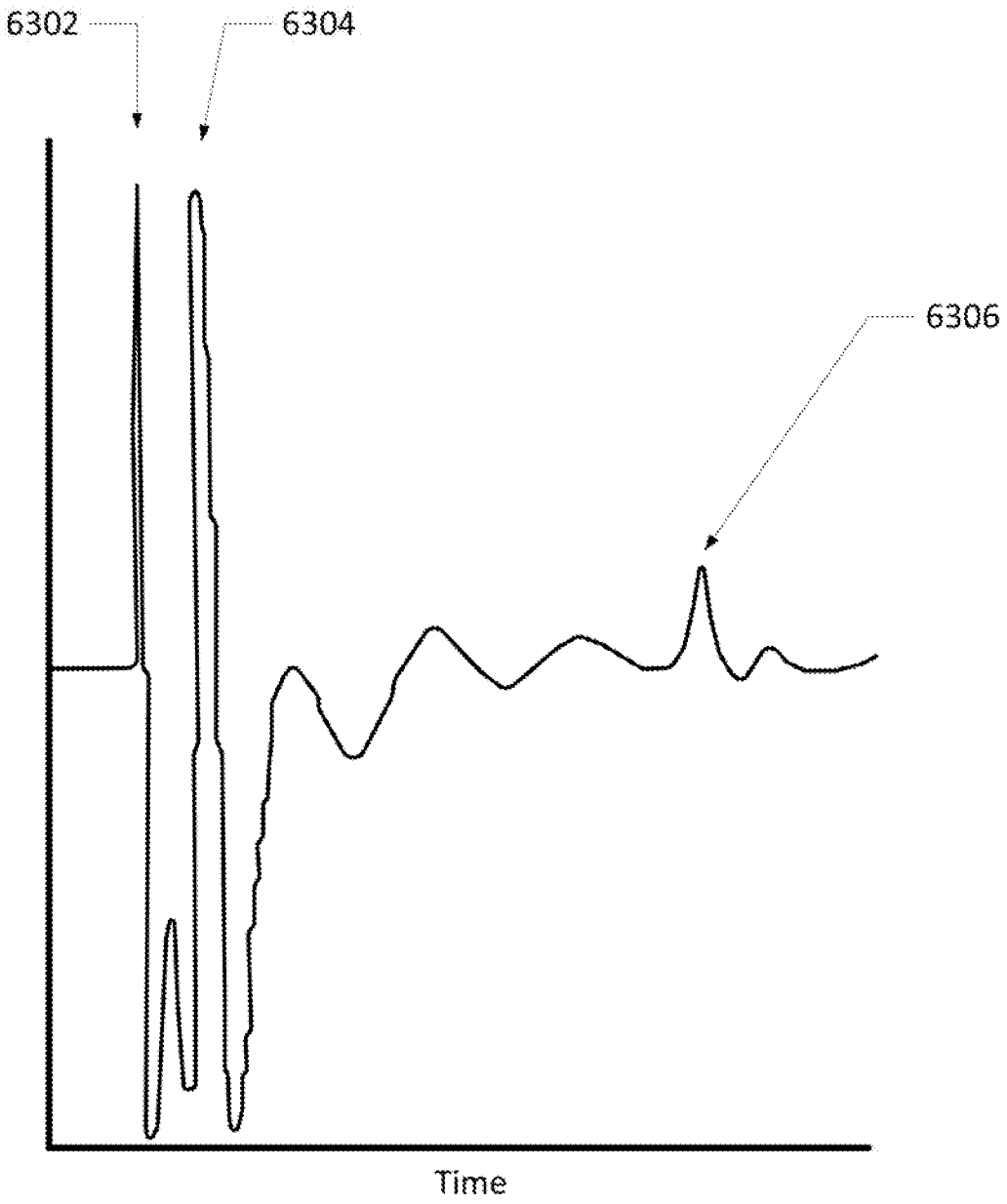
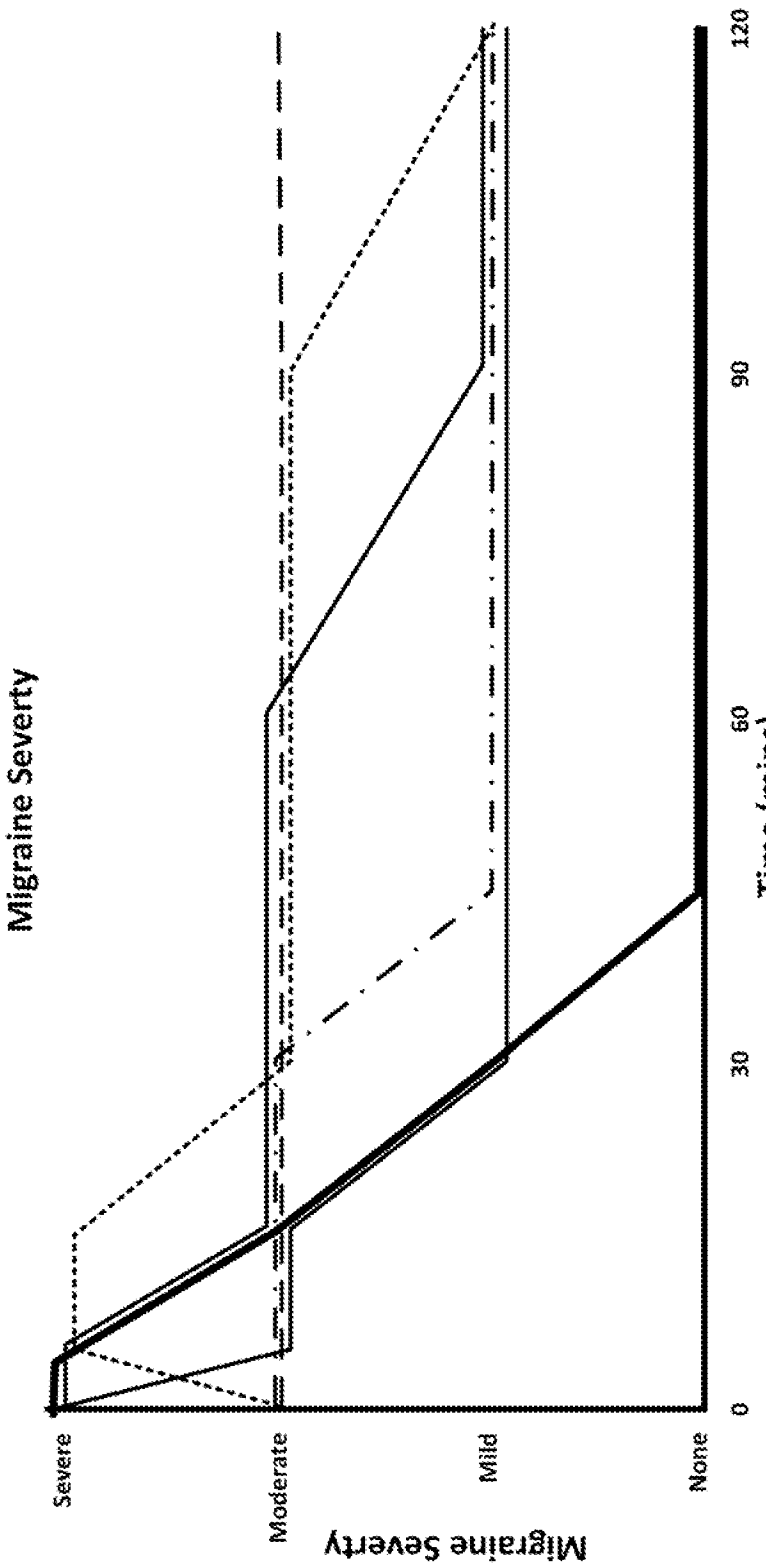


FIG. 63



5/6 met clinical endpoint with some degree of relief and 2/3 improved by two categories on the index

FIG. 64

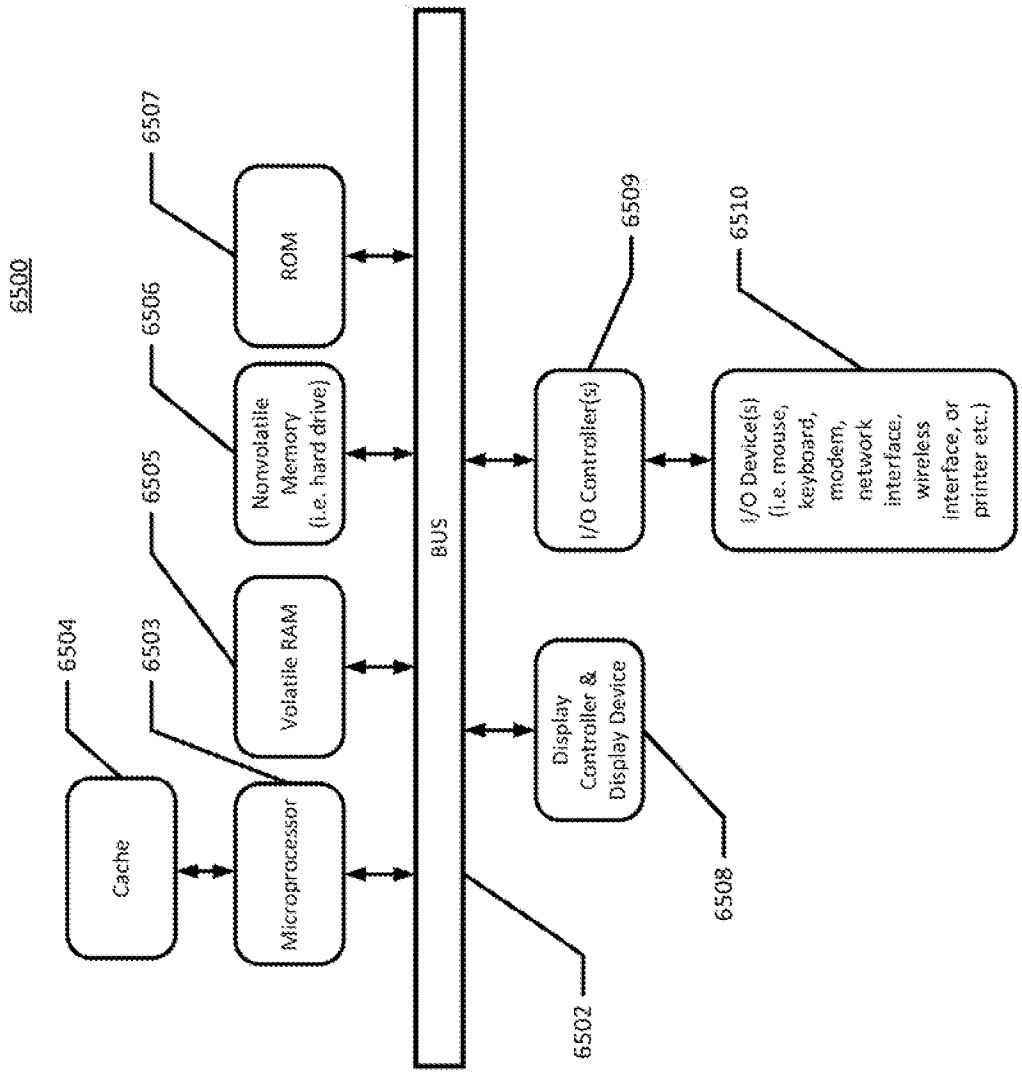

6500
6504
Cache
6503
Microprocessor
6505
Volatile RAM
6506
Nonvolatile Memory (i.e. hard drive)
6507
ROM
BUS
6502
Display Controller & Display Device
6508
I/O Controller(s)
6509
I/O Device(s) (i.e. mouse, keyboard, modem, network interface, wireless interface, or printer etc.)
6510

FIG. 65