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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 June 2023 (15.06.2023)

WIPO | PCT

(10) International Publication Number
WO 2023/107449 A2

(51) International Patent Classification:
A61N 1/372 (2006.01)

(21) International Application Number:
PCT/US2022/051956

(22) International Filing Date:
06 December 2022 (06.12.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/288,153 10 December 2021 (10.12.2021) US

(71) Applicant: **BOSTON SCIENTIFIC NEUROMODULATION CORPORATION** [US/US]; 25155 Rye Canyon Loop, Valencia, CA 91355 (US).

(72) Inventor: **JUAREZ PAZ, Leon, Mauricio**; Uhlandstr. 19, 10623 Berlin (DE).

(74) Agent: **BLACK, Bruce, E.**; Branch Partners PLLC, 600 University Street, Suite 620, Seattle, WA 98101 (US).

(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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) Title: SYSTEMS AND METHODS FOR GENERATING AND USING RESPONSE MAPS FOR ELECTRICAL STIMULATION

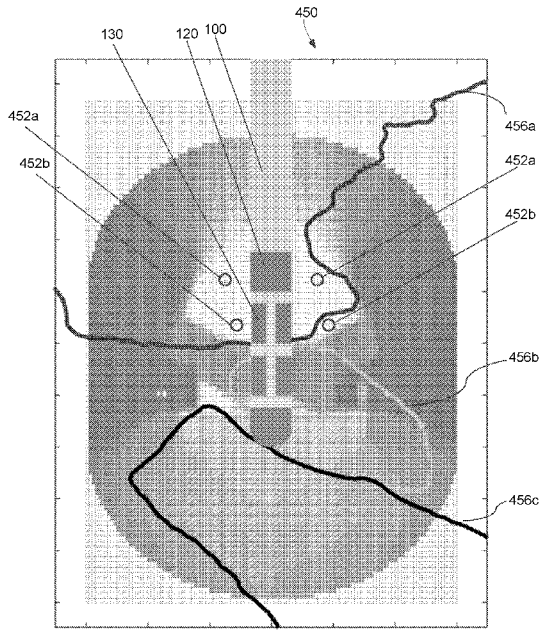

Fig. 4A

(57) Abstract: A method or system for generating a clinical effects map for electrical stimulation includes receiving stimulation parameters and at least one clinical response for each of a plurality of stimulation instances; for each of the stimulation instances, determining a radius of a stimulation field according to the stimulation parameters for the stimulation instance; generating the clinical effects map using the at least one clinical response and the stimulation parameters for each of the stimulation instances, wherein, for each of the stimulation instances, the at least one clinical response for the stimulation instance is assigned to the radius of the stimulation field determined for the stimulation instance; and displaying the clinical effects map.

WO 2023/107449 A2

SYSTEMS AND METHODS FOR GENERATING AND USING RESPONSE MAPS FOR ELECTRICAL STIMULATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Serial No. 63/288,153, filed December 10, 2021, which is incorporated herein by reference.

FIELD

The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to systems and methods for estimating clinical effects of electrical stimulation.

BACKGROUND

Implantable electrical stimulation systems have proven therapeutic in a variety of diseases and disorders. For example, spinal cord stimulation systems have been used as a therapeutic modality for the treatment of chronic pain syndromes. Peripheral nerve stimulation has been used to treat chronic pain syndrome and incontinence, with a number of other applications under investigation. Functional electrical stimulation systems have been applied to restore some functionality to paralyzed extremities in spinal cord injury patients. Stimulation of the brain, such as deep brain stimulation, can be used to treat a variety of diseases or disorders.

Stimulators have been developed to provide therapy for a variety of treatments. A stimulator can include a control module (with a pulse generator), at least one lead, and an array of stimulator electrodes on each lead. The stimulator electrodes are in contact with or near the nerves, muscles, or other tissue to be stimulated. The pulse generator in the control module generates electrical pulses that are delivered by the electrodes to body tissue.

BRIEF SUMMARY

One aspect is a method for generating a clinical effects map for electrical stimulation. The method includes receiving stimulation parameters and at least one clinical response for each of a plurality of stimulation instances; for each of the stimulation instances, determining a radius of a stimulation field according to the

stimulation parameters for the stimulation instance; generating the clinical effects map using the at least one clinical response and the stimulation parameters for each of the stimulation instances, wherein, for each of the stimulation instances, the at least one clinical response for the stimulation instance is assigned to sites corresponding to the radius of at least a portion of the stimulation field determined for the stimulation instance; and displaying the clinical effects map.

In at least some aspects, determining the radius of the stimulation field includes calculating the stimulation field according to the stimulation parameters for the stimulation instance. In at least some aspects, determining the radius of the stimulation field includes comparing the stimulation parameters to a plurality of predefined stimulation fields. In at least some aspects, determining the radius of the stimulation field includes using a parametrical equation and the stimulation parameters to calculate the radius of the stimulation field.

In at least some aspects, the at least one clinical response includes at least one therapeutic response or at least one side effect. In at least some aspects, different colors or shades are used on the generated clinical effects map to distinguish the clinical responses that are therapeutic responses from the clinical responses that are side effects.

In at least some aspects, the clinical effects map is a three-dimensional map. In at least some aspects, the clinical effects map is a two-dimensional map or is displayed as a two-dimensional slice of a three-dimensional map. In at least some aspects, the method further includes a graphical representation of at least one anatomical feature or structure on the clinical effects map. In at least some aspects, generating the clinical effects map includes interpolating at least one clinical response for regions of the clinical effects map between the radii of the stimulation fields of the stimulation instances.

In at least some aspects, the method further includes receiving a selection of a point on the clinical effects map; determining first stimulation parameters that will produce a stimulation field having a radius at the selected point; delivering the first stimulation parameters to a control unit of an electrical stimulation system; and delivering electrical stimulation to the patient from the control unit using the first stimulation parameters.

In at least some aspects, the method further includes, for each of the stimulation instances, stimulating a patient using the stimulation parameters and obtaining the at least one clinical effect resulting from the stimulation. In at least some aspects, generating the clinical effects map includes selecting a shade for at least the radius of the stimulation field based on a strength, value, or intensity of the at least one clinical effect.

Another aspect is a system for generating a clinical effects map for electrical stimulation. The system includes a display and a processor coupled to the display and configured to perform actions including receiving stimulation parameters and at least one clinical response for each of a plurality of stimulation instances; for each of the stimulation instances, determining a radius of a stimulation field according to the stimulation parameters for the stimulation instance; generating the clinical effects map using the at least one clinical response and the stimulation parameters for each of the stimulation instances, wherein, for each of the stimulation instances, the at least one clinical response for the stimulation instance is assigned to sites corresponding to the radius of at least a portion of the stimulation field determined for the stimulation instance; and displaying the clinical effects map.

In at least some aspects, determining the radius of the stimulation field includes calculating the stimulation field according to the stimulation parameters for the stimulation instance. In at least some aspects, determining the radius of the stimulation field includes comparing the stimulation parameters to a plurality of predefined stimulation fields. In at least some aspects, determining the radius of the stimulation field includes using a parametrical equation and the stimulation parameters to calculate the radius of the stimulation field.

In at least some aspects, the at least one clinical response includes at least one therapeutic response or at least one side effect. In at least some aspects, different colors or shades are used on the generated clinical effects map to distinguish the clinical responses that are therapeutic responses from the clinical responses that are side effects.

In at least some aspects, the clinical effects map is a three-dimensional map. In at least some aspects, the clinical effects map is a two-dimensional map or is displayed as a two-dimensional slice of a three-dimensional map. In at least some aspects, the actions further include a graphical representation of at least one anatomical feature or structure on

the clinical effects map. In at least some aspects, generating the clinical effects map includes interpolating at least one clinical response for regions of the clinical effects map between the radii of the stimulation fields of the stimulation instances.

In at least some aspects, the actions further include receiving a selection of a point on the clinical effects map; determining first stimulation parameters that will produce a stimulation field having a radius at the selected point; delivering the first stimulation parameters to a control unit of an electrical stimulation system; and delivering electrical stimulation to the patient from the control unit using the first stimulation parameters.

In at least some aspects, the actions further include, for each of the stimulation instances, stimulating a patient using the stimulation parameters and obtaining the at least one clinical effect resulting from the stimulating. In at least some aspects, generating the clinical effects map includes selecting a shade for at least the radius of the stimulation field based on a strength, value, or intensity of the at least one clinical effect.

A further aspect is a non-transitory computer-readable medium having computer executable instructions stored thereon that, when executed by at least one processor, cause the at least one processor to perform actions including receiving stimulation parameters and at least one clinical response for each of a plurality of stimulation instances; for each of the stimulation instances, determining a radius of a stimulation field according to the stimulation parameters for the stimulation instance; generating the clinical effects map using the at least one clinical response and the stimulation parameters for each of the stimulation instances, wherein, for each of the stimulation instances, the at least one clinical response for the stimulation instance is assigned sites corresponding to the radius of at least a portion of the stimulation field determined for the stimulation instance; and displaying the clinical effects map. Any of the aspects described above also apply to the non-transitory computer-readable medium.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting and non-exhaustive embodiments of the present invention are described with reference to the following drawings. In the drawings, like reference numerals refer to like parts throughout the various figures unless otherwise specified.

For a better understanding of the present invention, reference will be made to the following Detailed Description, which is to be read in association with the accompanying drawings, wherein:

FIG. 1 is a schematic view of one embodiment of an electrical stimulation system;

FIG. 2 is a schematic side view of one embodiment of an electrical stimulation lead;

FIG. 3 is a schematic block diagram of one embodiment of a system for automatically aligning brain atlases using clinical responses;

FIG. 4A illustrates one embodiment of a clinical effects map aligned along a longitudinal axis of the lead;

FIG. 4B illustrates one embodiment of a clinical effects map aligned along a transverse axis of the lead;

FIG. 5A illustrates one embodiment of an outline of a stimulation field generated by a ring electrode;

FIG. 5B illustrates one embodiment of an outline of a stimulation field generated by a segmented electrode;

FIG. 6 is a flowchart of one embodiment of a method of a method of generating a clinical effects map; and

FIG. 7 is a flowchart of one embodiment of a method of using the clinical effects map to stimulate a patient.

DETAILED DESCRIPTION

The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to systems and methods for estimating clinical effects of electrical stimulation.

Suitable implantable electrical stimulation systems include, but are not limited to, a least one lead with at least one electrode disposed on a distal end portion of the lead and at least one terminal disposed on at least one proximal end portion of the lead. Leads

include, for example, percutaneous leads, paddle leads, cuff leads, or any other arrangement of electrodes on a lead. Examples of electrical stimulation systems with leads are found in, for example, U.S. Patents Nos. 6,181,969; 6,516,227; 6,609,029; 6,609,032; 6,741,892; 7,244,150; 7,450,997; 7,672,734;7,761,165; 7,783,359; 7,792,590; 7,809,446; 7,949,395; 7,974,706; 8,175,710; 8,224,450; 8,271,094; 8,295,944; 8,364,278; 8,391,985; and 8,688,235; and U.S. Patent Applications Publication Nos. 2007/0150036; 2009/0187222; 2009/0276021; 2010/0076535; 2010/0268298; 2011/0005069; 2011/0004267; 2011/0078900; 2011/0130817; 2011/0130818; 2011/0238129; 2011/0313500; 2012/0016378; 2012/0046710; 2012/0071949; 2012/0165911; 2012/0197375; 2012/0203316; 2012/0203320; 2012/0203321; 2012/0316615; 2013/0105071; and 2013/0197602, all of which are incorporated by reference. In the discussion below, a percutaneous lead will be exemplified, but it will be understood that the methods and systems described herein are also applicable to paddle leads and other leads.

A lead for electrical stimulation (for example, deep brain or spinal cord stimulation) includes stimulation electrodes that can be ring electrodes, segmented electrodes that extend only partially around the circumference of the lead, or any other type of electrode, or any combination thereof. The segmented electrodes can be provided in sets of electrodes, with each set having electrodes circumferentially distributed about the lead at a particular longitudinal position or across a particular longitudinal region. For illustrative purposes, the leads are described herein relative to use for deep brain stimulation, but it will be understood that any of the leads can be used for applications other than deep brain stimulation, including spinal cord stimulation, peripheral nerve stimulation, or stimulation of other nerves, muscles, and tissues. In particular, stimulation may stimulate specific targets. Examples of such targets include, but are not limited to, the subthalamic nucleus (STN), the internal segment of the globus pallidus (GPi), the ventral intermediate nucleus of the thalamus, the external segment of the globus pallidus (GPe), and the like. In at least some embodiments, an anatomical structure is defined by its physical structure and a physiological target is defined by its functional attributes. In at least some embodiments, the lead may be positioned at least partially within the target, but in other embodiments, the lead may be near, but not inside, the target. The stimulation of tissue can include, but is not limited to, one or more of activation, inhibition, depression, or other modulation of the stimulated tissue.

Turning to Figure 1, one embodiment of an electrical stimulation system 10 includes at least one stimulation lead 12 and an implantable pulse generator (IPG) 14. The system 10 can also include at least one of an external remote control (RC) 16, a clinician's programmer (CP) 18, an external trial stimulator (ETS) 20, or an external charger 22.

The IPG 14 is physically connected, optionally via at least one lead extension 24, to the stimulation lead(s) 12. Each lead carries multiple electrodes 26 arranged in an array. The IPG 14 includes pulse generation circuitry that delivers electrical stimulation energy in the form of, for example, a pulsed electrical waveform (i.e., a temporal series of electrical pulses) to the electrode array 26 in accordance with a set of stimulation parameters. The IPG 14 can be implanted into a patient's body, for example, below the patient's clavicle area or within the patient's buttocks or abdominal cavity. The IPG 14 can have eight stimulation channels which may be independently programmable to control the magnitude of the current stimulus from each channel. In at least some embodiments, the IPG 14 can have more or fewer than eight stimulation channels (for example, 4, 6, 16, 32, or more stimulation channels). The IPG 14 can have one, two, three, four, or more connector ports, for receiving the terminals of the leads.

The ETS 20 may also be physically connected, optionally via the percutaneous lead extensions 28 and external cable 30, to the stimulation leads 12. The ETS 20, which may have similar pulse generation circuitry as the IPG 14, also delivers electrical stimulation energy in the form of, for example, a pulsed electrical waveform to the electrode array 26 in accordance with a set of stimulation parameters. One difference between the ETS 20 and the IPG 14 is that the ETS 20 is often a non-implantable device that is used on a trial basis after the neurostimulation leads 12 have been implanted and prior to implantation of the IPG 14, to test functioning of the system or the responsiveness of the stimulation that is to be provided. Any functions described herein with respect to the IPG 14 can likewise be performed with respect to the ETS 20.

The RC 16 may be used to telemetrically communicate with or control the IPG 14 or ETS 20 via a uni- or bi-directional wireless communications link 32. Once the IPG 14 and neurostimulation leads 12 are implanted, the RC 16 may be used to telemetrically communicate with or control the IPG 14 via a uni- or bi-directional communications link 34. Such communication or control allows the IPG 14 to be turned on or off and to be programmed with different stimulation parameter sets. The IPG 14 may also be operated

to modify the programmed stimulation parameters to actively control the characteristics of the electrical stimulation energy output by the IPG 14. The CP 18 allows a user, such as a clinician, the ability to program stimulation parameters for the IPG 14 and ETS 20 in the operating room and in follow-up sessions.

The CP 18 may perform this function by indirectly communicating with the IPG 14 or ETS 20, through the RC 16, via a wireless communications link 36. Alternatively, the CP 18 may directly communicate with the IPG 14 or ETS 20 via a wireless communications link (not shown). The stimulation parameters provided by the CP 18 are also used to program the RC 16, so that the stimulation parameters can be subsequently modified by operation of the RC 16 in a stand-alone mode (i.e., without the assistance of the CP 18).

For purposes of brevity, the details of the RC 16, CP 18, ETS 20, and external charger 22 will not be further described herein. Details of exemplary embodiments of these devices are disclosed in U.S. Pat. No. 6,895,280, which is expressly incorporated herein by reference. Other examples of electrical stimulation systems can be found at U.S. Patents Nos. 6,181,969; 6,516,227; 6,609,029; 6,609,032; 6,741,892; 7,949,395; 7,244,150; 7,672,734; and 7,761,165; 7,974,706; 8,175,710; 8,224,450; and 8,364,278; and U.S. Patent Application Publication No. 2007/0150036, as well as the other references cited above, all of which are incorporated by reference.

Figure 2 illustrates one embodiment of a lead 100 with electrodes 125 disposed at least partially about a circumference of the lead 100 along a distal end portion of the lead 100 and terminals 135 disposed along a proximal end portion of the lead 100.
The lead 100 can be implanted near or within the desired portion of the body to be stimulated such as, for example, the brain, spinal cord, or other body organs or tissues. In one example of operation for deep brain stimulation, access to the desired position in the brain can be accomplished by drilling a hole in the patient's skull or cranium with a cranial drill (commonly referred to as a burr), and coagulating and incising the dura mater, or brain covering. The lead 100 can be inserted into the cranium and brain tissue with the assistance of a stylet (not shown). The lead 100 can be guided to the target location within the brain using, for example, a stereotactic frame and a microdrive motor system. In at least some embodiments, the microdrive motor system can be fully or partially automatic. The microdrive motor system may be configured to perform at least

one of the following actions (alone or in combination): insert the lead 100, advance the lead 100, retract the lead 100, or rotate the lead 100.

In at least some embodiments, measurement devices coupled to the muscles or other tissues affected by the target neurons or neural structures, or a unit responsive to the patient or clinician, can be coupled to the IPG 14 or microdrive motor system. The measurement device, user, or clinician can indicate a response by the target muscles or other tissues to the stimulation or recording electrode(s) to further identify the target neurons and facilitate positioning of the stimulation electrode(s). For example, if the target neurons are directed to a muscle experiencing tremors, a measurement device can be used to observe the muscle and indicate changes in, for example, tremor frequency or amplitude in response to stimulation of neurons. Alternatively, the patient or clinician can observe the muscle and provide feedback.

The lead 100 for deep brain stimulation can include stimulation electrodes, recording electrodes, or both. In at least some embodiments, the lead 100 is rotatable so that the stimulation electrodes can be aligned with the target neurons after the neurons have been located using the recording electrodes.

Stimulation electrodes may be disposed on the circumference of the lead 100 to stimulate the target neurons. Stimulation electrodes may be ring shaped so that current projects from each electrode radially from the position of the electrode along a length of the lead 100. In the embodiment of Figure 2, two of the electrodes 125 are ring electrodes 120 . Ring electrodes typically do not enable stimulus current to be directed from only a limited angular range around a lead. Segmented electrodes 130, however, can be used to direct stimulus current to a selected angular range around a lead. When segmented electrodes are used in conjunction with an implantable pulse generator that includes multiple independent current sources, current steering can be achieved to more precisely deliver the stimulus to a position around an axis of a lead (i.e., radial positioning around the axis of a lead). To achieve current steering, segmented electrodes can be utilized in addition to, or as an alternative to, ring electrodes.

The lead 100 includes a lead body 110, terminals 135, at least one ring electrode 120, and at least one set of segmented electrodes 130 (or any other combination of electrodes). The lead body 110 can be formed of a biocompatible, non-conducting

material such as, for example, a polymeric material. Suitable polymeric materials include, but are not limited to, silicone, polyurethane, polyurea, polyurethane-urea, polyethylene, or the like. Once implanted in the body, the lead 100 may be in contact with body tissue for extended periods of time. In at least some embodiments, the lead 100 has a cross-sectional diameter of no more than 1.5 mm and may be in the range of 0.5 to 1.5 mm. In at least some embodiments, the lead 100 has a length of at least 10 cm and the length of the lead 100 may be in the range of 10 to 70 cm.

The electrodes 125 can be made using a metal, alloy, conductive oxide, or any other suitable conductive biocompatible material. Examples of suitable materials include, but are not limited to, platinum, platinum iridium alloy, iridium, titanium, tungsten, palladium, palladium rhodium, or the like. Preferably, the electrodes 125 are made of a material that is biocompatible and does not substantially corrode under expected operating conditions in the operating environment for the expected duration of use.

Each of the electrodes 125 can either be used or unused (OFF). When an electrode is used, the electrode can be used as an anode or cathode and carry anodic or cathodic current. In some instances, an electrode might be an anode for a period of time and a cathode for a period of time.

Deep brain stimulation leads may include at least one set of segmented electrodes. Segmented electrodes may provide for superior current steering than ring electrodes because target structures in deep brain stimulation are not typically symmetric about the axis of the distal electrode array. Instead, a target may be located on one side of a plane running through the axis of the lead. Through the use of a radially segmented electrode array ("RSEA"), current steering can be performed not only along a length of the lead but also around a circumference of the lead. This provides precise three-dimensional targeting and delivery of the current stimulus to neural target tissue, while potentially avoiding stimulation of other tissue. Examples of leads with segmented electrodes include U.S. Patents Nos. 8,473,061; 8,571,665; 8,792,993; 9,248,272; 9,775,988; and 10,286,205; U.S. Patent Application Publications Nos. 2010/0268298; 2011/0005069; 2011/0130803; 2011/0130816; 2011/0130817; 2011/0130818; 2011/0078900; 2011/0238129; 2012/0016378; 2012/0046710; 2012/0071949; 2012/0165911; 2012/197375; 2012/0203316; 2012/0203320; 2012/0203321; 2013/0197424; 2013/0197602; 2014/0039587; 2014/0353001; 2014/0358208; 2014/0358209; 2014/0358210;

2015/0045864; 2015/0066120; 2015/0018915; and 2015/0051681, all of which are incorporated herein by reference.

Figure 3 illustrates one embodiment of a system for practicing the invention. The system can include a computing device 300 or any other similar device that includes a processor 302 and a memory 304, a display 306, an input device 308, and, optionally, an electrical stimulation system 312. The system 300 may also optionally include at least one imaging system 310.

The computing device 300 can be a computer, tablet, mobile device, or any other suitable device for processing information. The computing device 300 can be local to the user or can include components that are non-local to the computer including one or both of the processor 302 or memory 304 (or portions thereof). For example, in at least some embodiments, the user may operate a terminal that is connected to a non-local computing device. In other embodiments, the memory can be non-local to the user.

The computing device 300 can utilize any suitable processor 302 including at least one hardware processors that may be local to the user or non-local to the user or other components of the computing device. The processor 302 is configured to execute instructions provided to the processor 302, as described below.

Any suitable memory 304 can be used for the computing device 302. The memory 304 illustrates a type of computer-readable media, namely computer-readable storage media. Computer-readable storage media may include, but is not limited to, nonvolatile, non-transitory, removable, and non-removable media implemented in any method or technology for storage of information, such as computer readable instructions, data structures, program modules, or other data. Examples of computer-readable storage media include RAM, ROM, EEPROM, flash memory, or other memory technology, CD-ROM, digital versatile disks ("DVD") or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by a computing device.

Communication methods provide another type of computer readable media; namely communication media. Communication media typically embodies computer-

readable instructions, data structures, program modules, or other data in a modulated data signal such as a carrier wave, data signal, or other transport mechanism and include any information delivery media. The terms "modulated data signal," and "carrier-wave signal" includes a signal that has at least one of its characteristics set or changed in such a manner as to encode information, instructions, data, and the like, in the signal. By way of example, communication media includes wired media such as twisted pair, coaxial cable, fiber optics, wave guides, and other wired media and wireless media such as acoustic, RF, infrared, and other wireless media.

The display 306 can be any suitable display device, such as a monitor, screen, display, or the like, and can include a printer. The input device 308 can be, for example, a keyboard, mouse, touch screen, track ball, joystick, voice recognition system, or any combination thereof, or the like.

At least one imaging system 310 can be used including, but not limited to, MRI, computed tomography (CT), ultrasound, or other imaging systems. The imaging system 310 may communicate through a wired or wireless connection with the computing device 300 or, alternatively or additionally, a user can provide images from the imaging system 310 using a computer-readable medium or by some other mechanism.

The electrical stimulation system 312 can include, for example, any of the components illustrated in Figure 1. The electrical stimulation system 312 may communicate with the computing device 300 through a wired or wireless connection or, alternatively or additionally, a user can provide information between the electrical stimulation system 312 and the computing device 300 using a computer-readable medium or by some other mechanism. In at least some embodiments, the computing device 300 may include part of the electrical stimulation system, such as, for example, the IPG 14, CP 18, RC 16, ETS 20, or any combination thereof.

The methods and systems described herein may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Accordingly, the methods and systems described herein may take the form of an entirely hardware embodiment, an entirely software embodiment or an embodiment combining software and hardware aspects. Systems referenced herein typically include memory and typically include methods for communication with other devices including mobile

devices. Methods of communication can include both wired and wireless (for example, RF, optical, or infrared) communications methods and such methods provide another type of computer readable media; namely communication media. Wired communication can include communication over a twisted pair, coaxial cable, fiber optics, wave guides, or the like, or any combination thereof. Wireless communication can include RF, infrared, acoustic, near field communication, Bluetooth™, or the like, or any combination thereof.

Given the number of electrodes and the possibility of using multiple electrodes together, along with the directionality provided by segmented electrodes, it can be challenging to identify a suitable set of stimulation parameters to treat a condition or disorder. The number of degrees of programming freedom can be daunting. It is, therefore, useful to identify methods and systems that can facilitate programming and identifying suitable stimulation parameters for stimulation programs.

A clinical effects map that displays therapeutic or side effect results can guide stimulation programming. One example of a two-dimensional clinical effects map is described in U.S. Patent Application Publication No. 2014/0277284, incorporated herein by reference in its entirety. In this particular example, the x axis of the clinical effects map corresponds to stimulation amplitude and the y axis corresponds to the position (or a composite position) of the stimulating electrode(s) along the lead. In this particular example, the y axis provides spatial information regarding the stimulation, but the x axis does not. One example of a three-dimensional clinical effects map is described in U.S. Patent No. 10,071,249, incorporated herein by reference in its entirety. The x and z axes correspond to the electrode selection and the y axis corresponds to the amplitude. Two of the axes provide spatial information but this spatial information corresponds to the position (or a composite position) of one or more stimulating electrodes on the lead.

Clinical effects maps are described herein that map the clinical effects to a radius of the stimulation field. These clinical effects maps provide the clinical effects information with respect to two or three spatial dimensions that represent the region around the distal portion of the lead. In at least some embodiments, the clinical effects map can be a three-dimensional map and, at least in some instances, may be presented on a display as a two-dimensional slice of the three-dimensional map. It will be understood that the clinical effects maps described herein may also be two-dimensional maps that correspond to one or more of these slices.

In at least some embodiments, because the clinical effects are mapped on a representation of the region around the lead using a geometrical parameter (i.e., the radius of the stimulation field), the clinical effects map can represent the clinical effects of stimulation of the tissue around a lead in two or three spatial dimensions. In at least some embodiments, such clinical effects maps can facilitate identifying spatial regions that are beneficial (i.e., therapeutic) to stimulate and regions that produce side effects (or little or no therapeutic effect) when stimulated. In at least some embodiments, because the clinical effects map represents the region around the lead in two or three spatial dimensions, the clinical effects map can also include graphical representations of anatomical structures or features on the map so that, for example, a user can estimate the effects of stimulation of those anatomical structures or features.

The clinical effects map is generated from multiple stimulation instances. Each stimulation instance is defined by one or more stimulation parameters that are used for the stimulation. In addition, one or more clinical effects are observed, measured, or otherwise obtained for each stimulation instance. The clinical effect(s) can be therapeutic effect(s), side effect(s), or any combination thereof.

A stimulation field is an estimated region of tissue that will be stimulated for a particular set of stimulation parameters. The stimulation parameters used for a stimulation instance identify or determine a stimulation field for that stimulation instance. Examples of stimulation parameters include, for example, electrode selection, stimulation amplitude, fractionalization (which, for multi-electrode stimulation, is the distribution of the stimulation amplitude between the selected electrodes), pulse width, pulse duration, and the like or any combination thereof.

The clinical effects map is generated from the clinical effect(s) for multiple stimulation instances where the clinical effect(s) are mapped at the radius of the stimulation field for the stimulation instance. In at least some embodiments, the radius of the stimulation field corresponds to a furthest position away from the stimulating electrode(s) where the tissue is stimulated. For example, the radius can be defined by a threshold value of current or voltage that is estimated to result in stimulation of the tissue. In at least some embodiments, the radius of the stimulation field can correspond to positions where the stimulating field is estimated to a predetermined current or voltage value. This predetermined current or voltage value may correspond to an estimated

threshold value for stimulation of the tissue. Any other suitable predetermined current, voltage, or other value can be used to define the radius of the stimulation field. The radius of the stimulation field typically corresponds to a contour line in two dimensions or a surface of a three-dimensional object in three dimensions.

Figures 4A and 4B illustrate one embodiment of a clinical effects map 450. Figure 4A illustrates a longitudinal slice of the clinical effects map 450 taken along a length of the distal portion of the lead 100 with ring electrodes 120 and segmented electrodes 130. Figure 4B illustrates a cross-sectional slice of the clinical effects map 450.

In Figure 4A, points 452a, 452b correspond to two different stimulation instances, as described in more detail below, and are positioned relative to the lead at the points on the contour line or surface that corresponds to the radius of the stimulation field generated by the particular stimulation instance. Points 452a correspond to stimulation using a ring electrode 120 and are, at least one some embodiments (for example, when the tissue around the lead is considered or modeled as homogenous), symmetrically placed around the lead. Figure 5A illustrates, in longitudinal and cross-sectional views, one example of a contour line/surface 554 defined by the radius 554a of a stimulation field generated by a ring electrode 120 at different sites around the lead. The clinical effect(s) are mapped to one or more sites around the lead having the radius 554a of the stimulation field generated by the ring electrode 120.

Points 452b correspond to stimulation using a segmented electrode 130 and are, at least in some embodiments, asymmetrically placed around the lead. Figure 5B illustrates, in longitudinal and cross-sectional views, one example of a contour line/surface 554 defined by the radius 554b of a stimulation field generated by a segmented electrode 130.

As illustrated in Figure 5B the radius 554b, as measured from the center 553 of the lead or from the electrode generating the stimulation, does not necessarily have a uniform value around the contour line/surface 554. For example, in Figure 5B, the radius, as measured from the center 553 of the lead, at site 555a is larger than the radius at site 555b. In the illustrated example of Figure 5B, the radius at site 555a is the largest radius for the stimulation field and the radius at site 555b is the smallest radius for the stimulation field.

In at least some embodiments, only sites where the radius is at least a threshold percentage (for example, at least 50, 60, 70, 75, 80, or 90%) of the largest radius at site 555a are used to generate the clinical effects map. The clinical effect(s) will only be mapped to those sites.

As an example, in one embodiment, the clinical effects map will only use the portion of the curve 554 in Figure 5B that ranges from site 557a to site 557b inclusive of site 555a (e.g., a portion of the curve 554 on the right side of Figure 5B) where the radius is a selected percentage of the largest radius at site 555a. The remainder of the curve 554 (which includes site 555b) will not be utilized to generate the clinical effects map and those sites will not be mapped to the clinical effect(s) associated with that stimulation field.

In at least some embodiments, if more than one electrode is used to generate the stimulation field, the shape of the stimulation field can be substantially different from the sphere/circle or ovoid/oval stimulation fields illustrated in Figures 5A and 5B. The points 452a, 452b in Figures 4A and 4B are points at the radius. Instead of points, contour lines can also be drawn and are apparent, at least in part, in Figure 4A and 4B by comparing the contours of the regions with different shading.

In at least some embodiments, the stimulation field for a particular stimulation instance can be calculated or otherwise determined using the stimulation parameters for the stimulation instance. The terms "stimulation field", "stimulation field map" (SFM), "volume of activation" (VOA), or "volume of tissue activated (VTA)" are often used to designate an estimated region of tissue that will be stimulated for a particular set of stimulation parameters. Any suitable method for determining the VOA/SFM/VTA can be used including, but not limited to, those described in, for example, U.S. Patents Nos. 8,326,433; 8,675,945; 8,831,731; 8,849,632; 8.958,615; and 10,265,528; U.S. Patent Application Publications Nos. 2009/0287272; 2009/0287273; 2012/0314924; 2013/0116744; 2014/0122379; and 2015/0066111, all of which are incorporated herein by reference in their entireties.

In at least some embodiments, a system may have a collection of predetermined stimulation fields. For a given stimulation instance, the stimulation parameters for the stimulation instance can be compared to the stimulation parameters associated with the

predetermined stimulation fields to identify a predetermined stimulation field that is a match (optionally, matching within a threshold condition) to the stimulation instance. In at least some instances, interpolation or other estimation methods can be used to modify the predetermined stimulation field to better account for the stimulation parameters of the stimulation instance. In at least some embodiments, the predetermined stimulation fields (or at least a radius or other characterization of the radius of the stimulation field) can be contained in a look-up table, database, or the like.

Any other method for assigning, identifying, or other determining a stimulation field for a stimulation instance can be used. It will be understood, that the identification or determining of a radius of the stimulation field may be sufficient to represent the stimulation field. In at least some embodiments, the identification or determination of a radius of the stimulation field can be performed using a parameterized equation or other calculation which relates the stimulation parameters to the radius of the stimulation field. The parameterized equation or other calculation can be determined empirically, experimentally, or using a machine learning or other method. In at least some embodiments, one or more parameters (other than electrode selection) may determine the value of the radius of the stimulation field and the electrode selection may determine the position of the stimulation field (relative to the lead) on the clinical effects map.

Although the Figures and discussion above use the example of electrodes on a single lead, it will be understood that a stimulation field and the radius of the stimulation field can be determined for stimulation instances in which electrodes on two or more leads are used for stimulation.

At least one clinical response is provided for each stimulation instance. The observation, determination, or input of the clinical response may be performed by the user, the patient, or any other suitable person or the clinical response can be observed or determined by a processor of the system or a sensor or other device. Examples of clinical responses include, but are not limited to, manually assessed clinical scores, sensor-derived scores or values, electrophysiological signals, or the like or any combination thereof. For example, a user may input a quantitative or qualitative indication based on visual observation of the patient, a sensor, or data (for example, an EEG or ECG or the like); verbal feedback from the patient; an evoked compound action potential (ECAP) or an evoked resonant neural activity (ERNA)); or the like. As another example, at least one

sensor (for example, a haptic sensor, accelerometer, gyroscope, EEG, EMG, camera, or the like) may be used to observe or determine a clinical response and may provide a quantitative or qualitative value (either directly to the processor or through a programmer, a user, the patient, or another person) that indicates a clinical response. A quantitative or qualitative value can indicate, for example, at least one characteristic of a symptom (for example, tremor), a therapeutic effect or side effect (for example, change in the patient's balance), electrical activity, or the like. The clinical response may be indicative of a therapeutic effect or a side effect or both. Moreover, in at least some embodiments, more than one clinical response can be observed, determined, or input for each stimulation instance.

In at least some embodiments, the stimulation parameters for the stimulation instances can be manually programmed or the stimulation instances can be a set of stimulations performed using an automated programming sequence or any combination thereof. In at least some embodiments, an automated programming sequence may also utilize the clinical effects from preceding stimulation instances to inform or select the next or succeeding stimulation instances. U.S. Patent No. 10,603,498, incorporated herein by reference in its entirety, describes examples of such automated programming.

Returning to Figures 4A and 4B, in at least some embodiments, the clinical effects map utilizes coloring, shading, brightness, or any other suitable graphical elements to identify the clinical effects. For example, the clinical effects map can utilize one color (e.g., green) to signify regions where stimulation produces at least one therapeutic effect and another color (e.g., yellow) to signify regions where stimulation produces at least one side effect. In at least some embodiments, for regions that produce both therapeutic and side effects, the coloring (or other graphical elements) may be weighted based on the intensity or strength of the therapeutic and side effects. In at least some embodiments, the shade or brightness of the color may be used to indicate the strength or intensity of the therapeutic effect(s) or side effect(s).

In at least some embodiments, because the clinical effects map represents the region around the lead, anatomical structures, features, or other elements can be illustrated on the clinical effects map. Such illustrated anatomical structures, features, or other elements can facilitate identifying sites for stimulation. In Figures 4A and 4B, outlines 456a, 456b, 456c represent the position of anatomical structures, features, or

elements. For example, in Figure 4A, outline 456a indicates the boundary of the capsula interna, outline 456b indicates the boundary of the subthalamic nucleus, and outline 456c indicates the boundary of the substantia nigra. Any other suitable graphical indicia can be used to represent the anatomical structures, features, or other elements.

In at least some embodiments, the outlines 456a, 456b, 456c can be based on images such as, for example, magnetic resonance imaging (MRI), computed tomography (CT), X-ray, fluoroscopy, ventriculography, ultrasound, or any other imaging modality or any combination thereof. In other embodiments, the outlines 456a, 456b, 456c can be based on an anatomical atlas and an indication or estimation of the position of the lead within the anatomy. Any combination of imaging or anatomical atlas can also be used.

An anatomical atlas can describe the region of interest in anatomical structures, features, or other elements, such as, for example, anatomical structures, features, or other elements in the brain. An atlas can be based on a single patient (for example, a patient-specific atlas) or many individuals (for example, a general atlas or a population-specific atlas for a particular population of individuals). In some instances, one atlas can be registered to another such as, for example, a patient-specific atlas can be registered to a general atlas in order to identify anatomical structures in the patient-specific atlas. Examples of registration of atlases can be found at, for example, U.S. Patent No. 8,675,945; and U.S. Patent Application Publications Nos. 2009/0118635; 2012/0314919; 2012/0314924; 2012/0330374; 2013/0039550; and 2015/0066111, all of which are incorporated herein by reference in their entireties.

Figure 6 illustrates one method generating a clinical effects map. In step 602, the system receives the stimulation parameters for a stimulation instance. In at least some embodiments, this step can include stimulating the tissue of a patient with an implanted stimulation lead for the stimulation instance. The stimulation parameters can include electrode(s) selection, stimulation amplitude, pulse frequency, pulse duration, or the like or any combination. In at least some embodiments, values of the stimulation parameters are selected manually based on user input or automatically by the processor or any combination thereof.

In step 604, at least one clinical response for the stimulation instance is received. The clinical response may be indicative of a therapeutic effect or a side effect or both. In

at least some embodiments, more than one clinical response can be recorded for each stimulation instance.

In at least some embodiments, step 604 can include observing the stimulation and observing, measuring, or otherwise determining the clinical response(s). The observation of the clinical response may be performed by the user, the patient, or the processor. For example, a user may input a quantitative or qualitative indication based on visual observation of the patient, a sensor, or data (for example, an EEG or ECG or the like); verbal feedback from the patient; neural activity in response to the stimulation (for example, an evoked compound action potential (ECAP) or an evoked resonant neural activity (ERNA)); or the like. As another example, at least one sensor (for example, an accelerometer, gyroscope, EEG sensor, EMG sensor, ECG sensor, camera, haptic sensor, or the like or any combination thereof) may be used to make the observation and may provide a quantitative or qualitative value that indicates a clinical response, for example, a value that indicates at least one characteristic of a symptom, a therapeutic or side effect, electrical activity, or the like.

In step 606, the radius of the stimulation field corresponding to the stimulation instance is determined. In at least some embodiments, the stimulation field is calculated to determine the radius of the stimulation field. In at least some other embodiments, the radius of the stimulation field can be determined from a parametric equation or other calculation, optionally, without further determining or calculating the stimulation field.

In at least some embodiments, the stimulation parameters of the stimulation instance are compared to predetermined stimulation fields to match the stimulation instance to one of the predetermined stimulation fields. In at least some embodiments, once matched, interpolation or other methods can be used to account for difference between the stimulation parameters of the stimulation instance and the predetermined stimulation field.

Any other suitable methods for determining the stimulation field or the radius of the stimulation field can be used.

In step 608, the stimulation parameters and clinical effect(s) are used to generate the clinical effects map. The stimulation parameters and clinical effect(s) can be used to

associate points, contour lines, surfaces of three-dimensional objects, or the like, which correspond to the radius of the stimulation field, with the clinical effect(s). The clinical effects map is a composite of the clinical effects from multiple stimulation instances. In at least some embodiments, the clinical effect(s) for regions between the points, contour lines, of surfaces of three-dimensional objects corresponding to the stimulation instances can be interpolated using the clinical effect(s) from the stimulation instances. The clinical effects map can be displayed on a programming device, such as CP 18, RC 16, or ETS 20, for use by a user to facilitate programming stimulation.

In step 610, the clinical effects map is displayed with the clinical effects map being updated after each stimulation instance is added (or, alternatively, after multiple stimulation instances are added). In at least some other embodiments, step 610 occurs after step 612.

In step 612, there is a query whether another stimulation instance is available or will be performed. If yes, then the method returns to step 602 for the next stimulation instance. If no, then the process ends.

In some embodiments, steps 602 to 612 can be performed automatically where a system automatically proceeds with testing multiple stimulation instances. In some embodiments, the multiple stimulation instances are predetermined. In other embodiments, after each iteration, the system may identify a next stimulation instance to test based on, at least in part, the clinical effect(s) of earlier stimulation instances. In yet other embodiments, the user may select each stimulation instance manually. Any combination of these methods for selection and testing of stimulation instances can also be used.

Figure 7 is a flowchart of one embodiment of a method for using the clinical effects map to stimulate a patient. In step 702, a selection of a point on the clinical effects map is received from a clinician, user, patient, programmer, or other source (which may include an automated system.) In at least some embodiments, the selection of a point may result in the system presenting one or more exemplary outlines (such as outlines 554a, 554b of Figures 5A or 5B) representing possible stimulation field outlines have the selected radius. In at least some embodiments, the individual or source selecting the

radius may be asked to select from different outlines. The outlines represent an estimate of the region of tissue that will be stimulated.

In step 704, stimulation parameters are determined which will produce a stimulation field with a radius at the selected point. In at least some embodiments, this step can be the reverse of step 606 above and may include one or more of stimulation field calculation(s), predefined stimulation fields, or parametric equation(s). In at least some embodiments, more than one set of stimulation parameters may be presented for selection by the clinician, user, patient, programmer, or other individual. In at least some embodiments, one or more outlines (such as outlines 554a, 554b of Figures 5A or 5B) representing the stimulation field outlines corresponding the determined sets of stimulation parameters may be presented for selection by the clinician, user, patient, programmer, or other individual.

In step 706, the determined or selected set of stimulation parameters is delivered or otherwise provided to a control module of an electrical stimulation system (for example, IPG 14 or ETS 20 of Figure 1). In step 708, electrical stimulation, according to the stimulation parameters, is delivered to the patient using one or more leads 12 (Figure 1) and corresponding electrode(s) 26.

It will be understood that each block of the flowchart illustrations, and combinations of blocks in the flowchart illustrations and methods disclosed herein, can be implemented by computer program instructions. These program instructions may be provided to a processor to produce a machine, such that the instructions, which execute on the processor, create means for implementing the actions specified in the flowchart block or blocks disclosed herein. The computer program instructions may be executed by a processor to cause a series of operational steps to be performed by the processor to produce a computer implemented process. The computer program instructions may also cause at least some of the operational steps to be performed in parallel. Moreover, some of the steps may also be performed across more than one processor, such as might arise in a multi-processor computer system. In addition, at least one process may also be performed concurrently with other processes, or even in a different sequence than illustrated without departing from the scope or spirit of the invention.

The computer program instructions can be stored on any suitable computer-readable medium including, but not limited to, RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disks ("DVD") or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, in the cloud or other non-local site, or any other medium which can be used to store the desired information and which can be accessed by a computing device.

A system can include one or more processors that can perform the methods (in whole or in part) described above. In at least some embodiments, some or all of the method may be performed using one or more non-local processor(s) (for example, processors in another device or in the cloud.) The methods, systems, and units described herein may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Accordingly, the methods, systems, and units described herein may take the form of an entirely hardware embodiment, an entirely software embodiment or an embodiment combining software and hardware aspects. The methods described herein can be performed using any type of processor or any combination of processors where each processor performs at least part of the process. In at least some embodiments, the processor may include more than one processor.

The above specification provides a description of the structure, manufacture, and use of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention also resides in the claims hereinafter appended.

CLAIMS

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. A method for generating a clinical effects map for electrical stimulation, the method comprising:

receiving stimulation parameters and at least one clinical response for each of a plurality of stimulation instances;

for each of the stimulation instances, determining a radius of a stimulation field according to the stimulation parameters for the stimulation instance;

generating the clinical effects map using the at least one clinical response and the stimulation parameters for each of the stimulation instances, wherein, for each of the stimulation instances, the at least one clinical response for the stimulation instance is assigned to sites corresponding to the radius of at least a portion of the stimulation field determined for the stimulation instance; and

displaying the clinical effects map.

2. The method of claim 1, wherein determining the radius of the stimulation field comprises calculating the stimulation field according to the stimulation parameters for the stimulation instance.

3. The method of claim 1, wherein determining the radius of the stimulation field comprises comparing the stimulation parameters to a plurality of predefined stimulation fields.

4. The method of claim 1, wherein determining the radius of the stimulation field comprises using a parametrical equation and the stimulation parameters to calculate the radius of the stimulation field.

5. The method of any one of claims 1 to 4, wherein the at least one clinical response comprises at least one therapeutic response or at least one side effect, wherein,

optionally, different colors or shades are used on the generated clinical effects map to distinguish the clinical responses that are therapeutic responses from the clinical responses that are side effects.

6. The method of any one of claims 1 to 5, wherein the clinical effects map is a three-dimensional map, a two-dimensional map, or is displayed as a two-dimensional slice of a three-dimensional map.

7. The method of any one of claims 1 to 6, further comprising including a graphical representation of at least one anatomical feature or structure on the clinical effects map.

8. The method of any one of claims 1 to 7, wherein generating the clinical effects map comprises interpolating at least one clinical response for regions of the clinical effects map between the radii of the stimulation fields of the stimulation instances.

9. The method of any one of claims 1 to 8, further comprising

receiving a selection of a point on the clinical effects map;

determining first stimulation parameters that will produce a stimulation field having a radius at the selected point; and

delivering the first stimulation parameters to a control unit of an electrical stimulation system.

10. The method of any one of claims 1 to 9, further comprising, for each of the stimulation instances, stimulating a patient using the stimulation parameters and obtaining the at least one clinical effect resulting from the stimulation.

11. A system for generating a clinical effects map for electrical stimulation, the system comprising:

a display; and

a processor coupled to the display and configured to perform actions comprising:

receiving stimulation parameters and at least one clinical response for each of a plurality of stimulation instances;

for each of the stimulation instances, determining a radius of a stimulation field according to the stimulation parameters for the stimulation instance;

generating the clinical effects map using the at least one clinical response and the stimulation parameters for each of the stimulation instances, wherein, for each of the stimulation instances, the at least one clinical response for the stimulation instance is assigned to sites corresponding to the radius of at least a portion of the stimulation field determined for the stimulation instance; and

displaying the clinical effects map.

12. The system of claim 11, wherein determining the radius of the stimulation field comprises calculating the stimulation field according to the stimulation parameters for the stimulation instance.

13. The system of claim 11, wherein determining the radius of the stimulation field comprises comparing the stimulation parameters to a plurality of predefined stimulation fields.

14. The system of claim 11, wherein determining the radius of the stimulation field comprises using a parametrical equation and the stimulation parameters to calculate the radius of the stimulation field.

15. A non-transitory computer-readable medium having computer executable instructions stored thereon that, when executed by at least one processor, cause the at least one processor to perform actions comprising:

receiving stimulation parameters and at least one clinical response for each of a plurality of stimulation instances;

for each of the stimulation instances, determining a radius of a stimulation field according to the stimulation parameters for the stimulation instance;

generating the clinical effects map using the at least one clinical response and the stimulation parameters for each of the stimulation instances, wherein, for each of the stimulation instances, the at least one clinical response for the stimulation instance is assigned to sites corresponding to the radius of at least a portion of the stimulation field determined for the stimulation instance; and

displaying the clinical effects map.

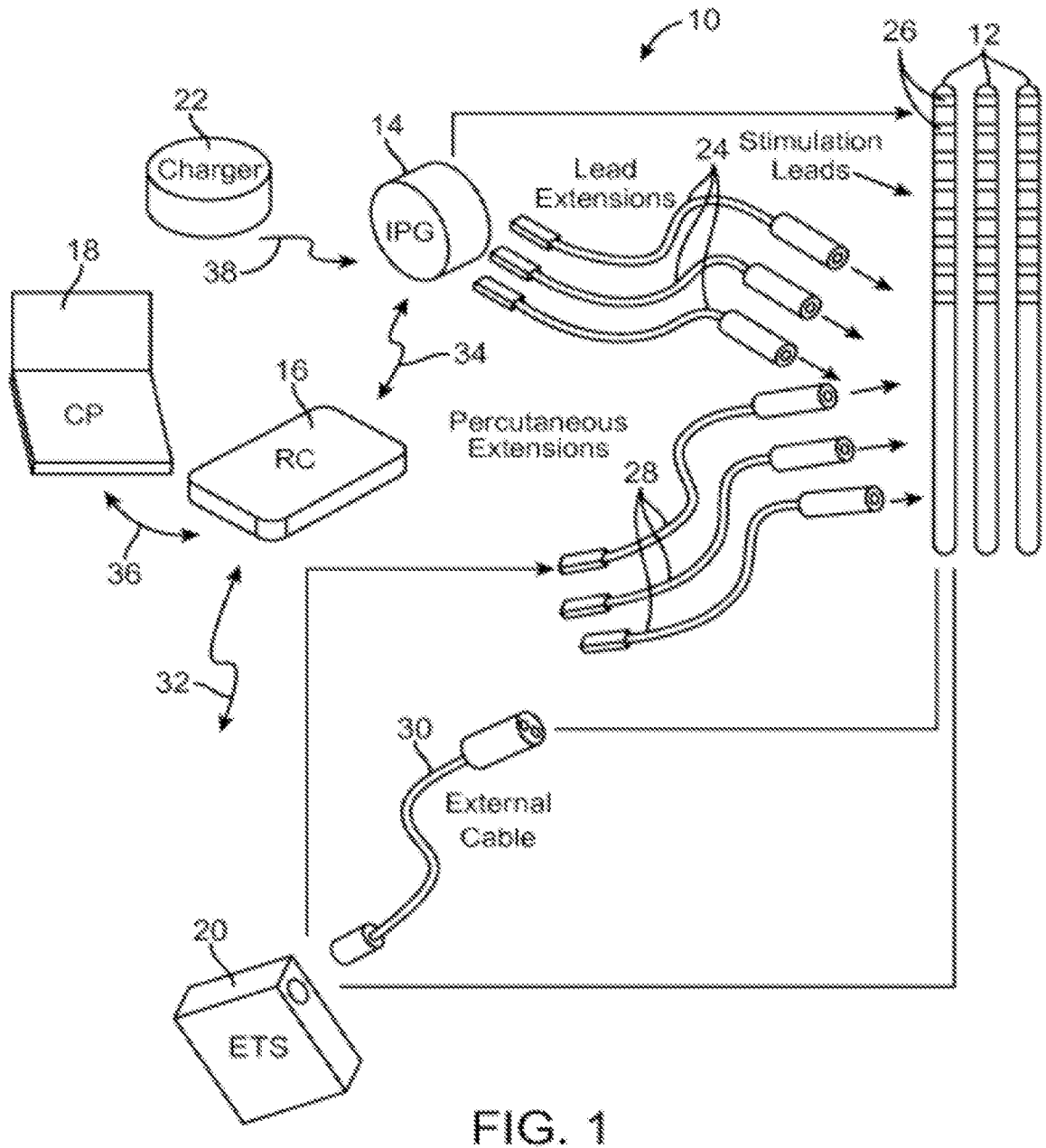
10
26
12
22
Charger
14
IPG
24
Lead Extensions
Stimulation Leads
38
18
CP
34
16
RC
Percutaneous Extensions
28
36
32
30
External Cable
20
ETS

FIG. 1

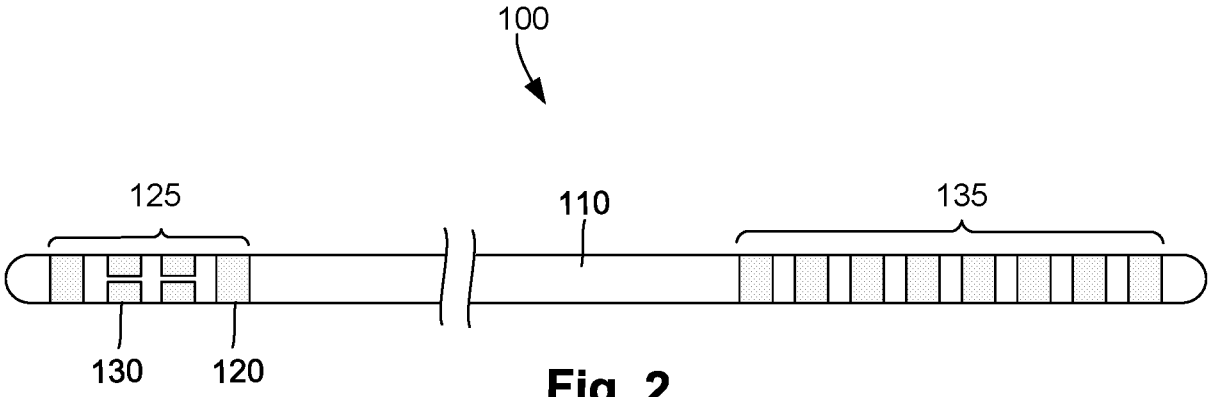
100
125
110
135
130
120

Fig. 2

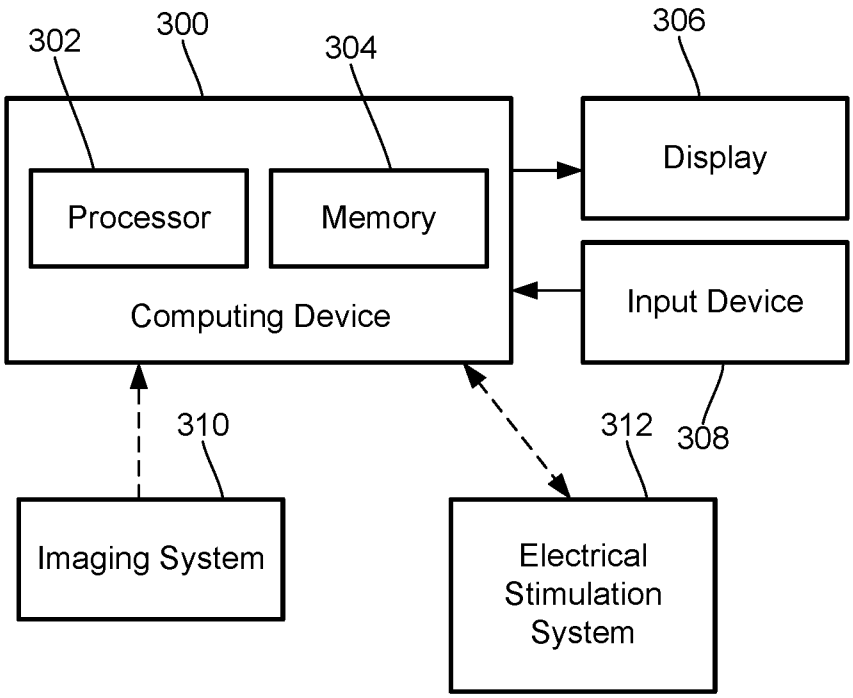
302
300
304
306
Processor
Memory
Display
Input Device
Computing Device
310
312
308
Imaging System
Electrical Stimulation System

Fig. 3

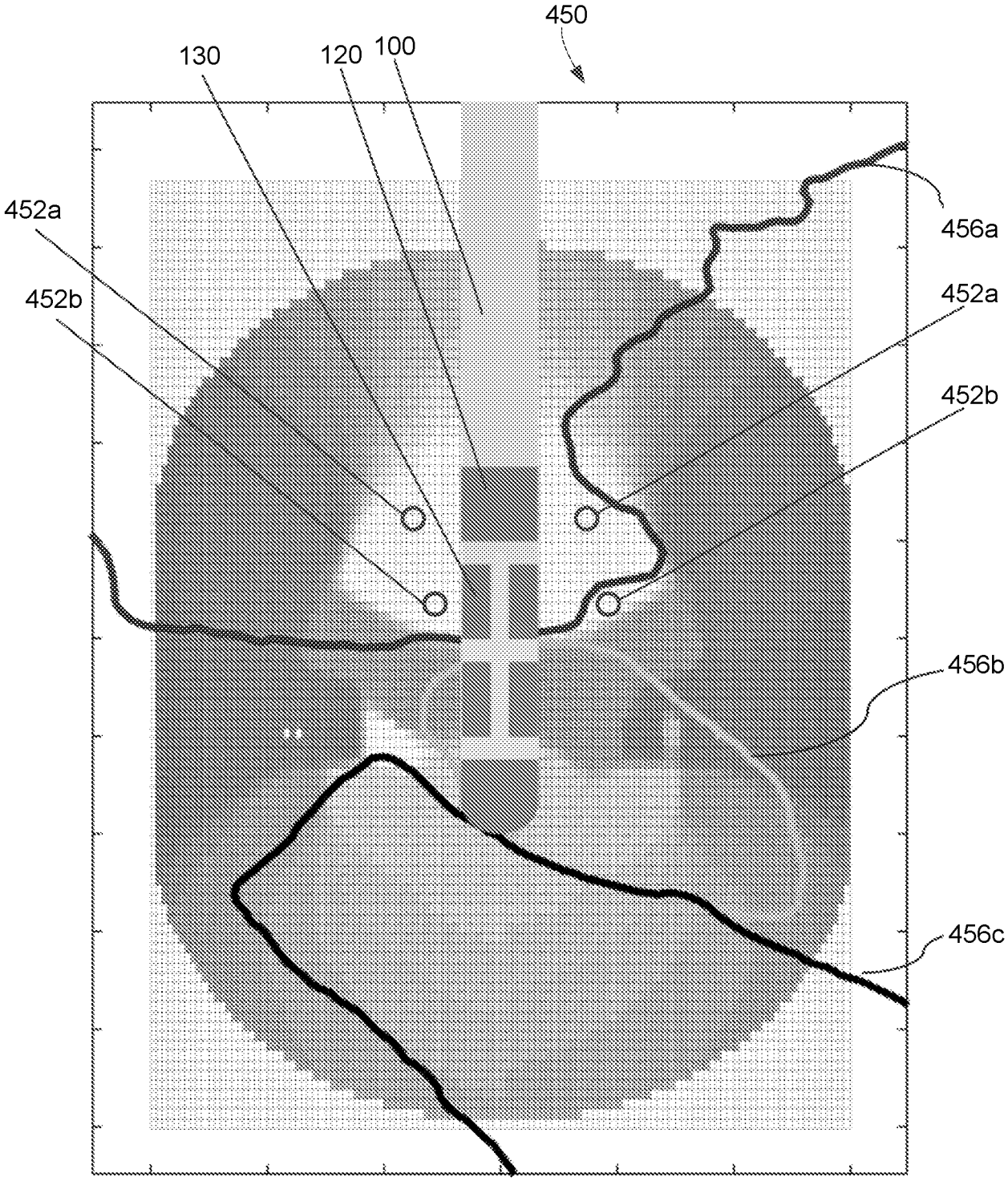

Fig. 4A

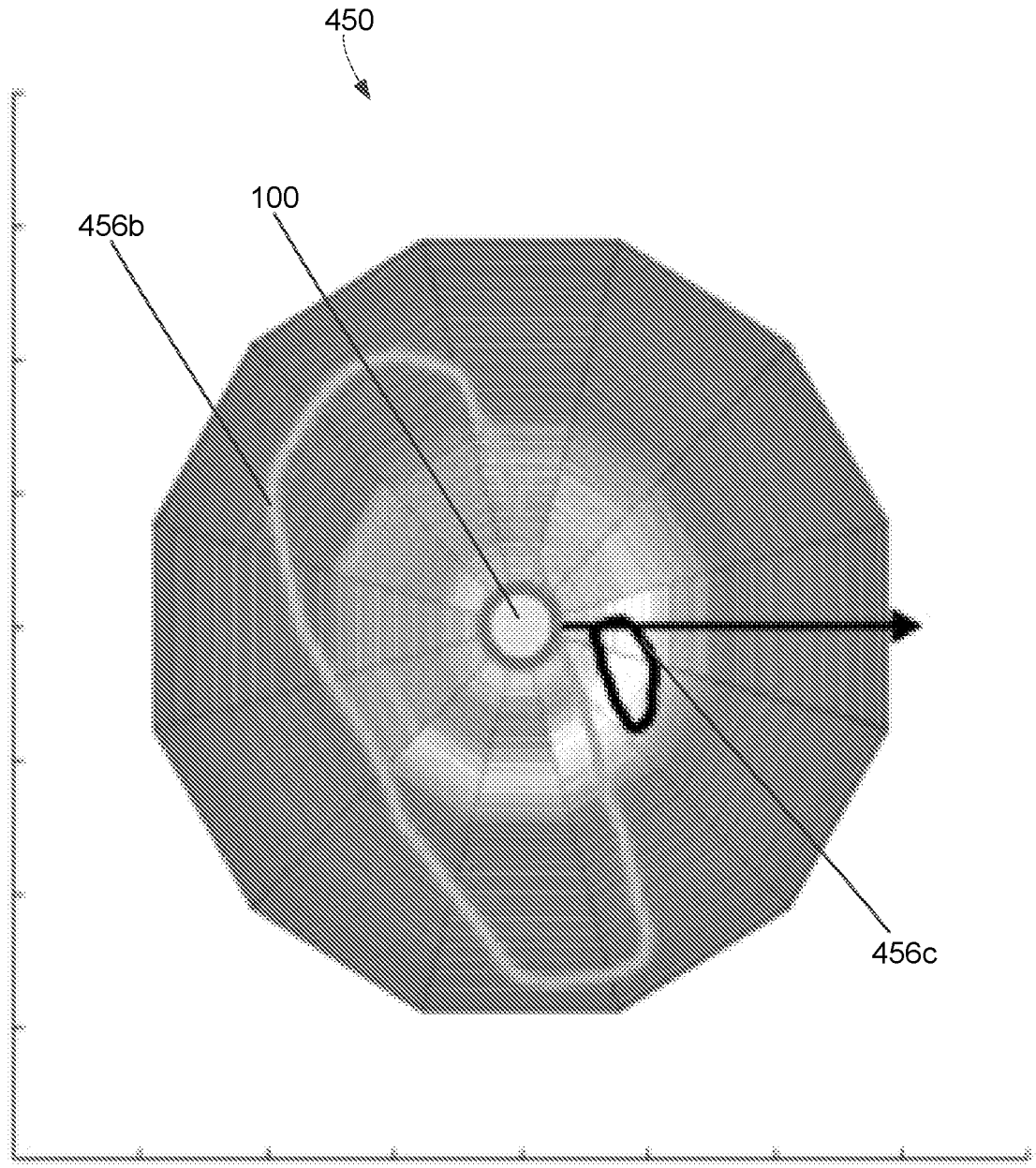

Fig. 4B

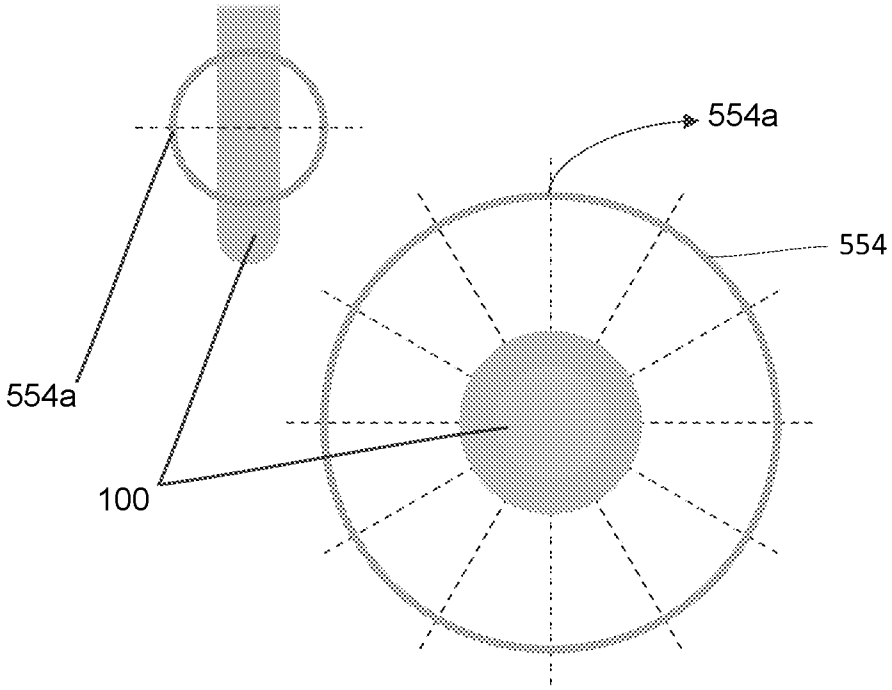

Fig. 5A

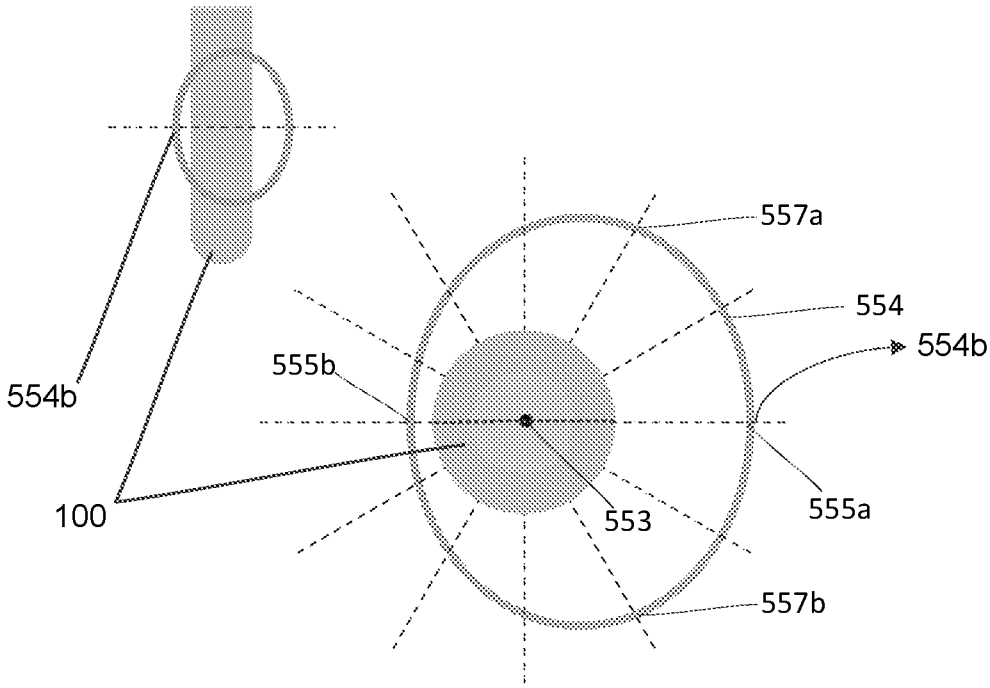

Fig. 5B

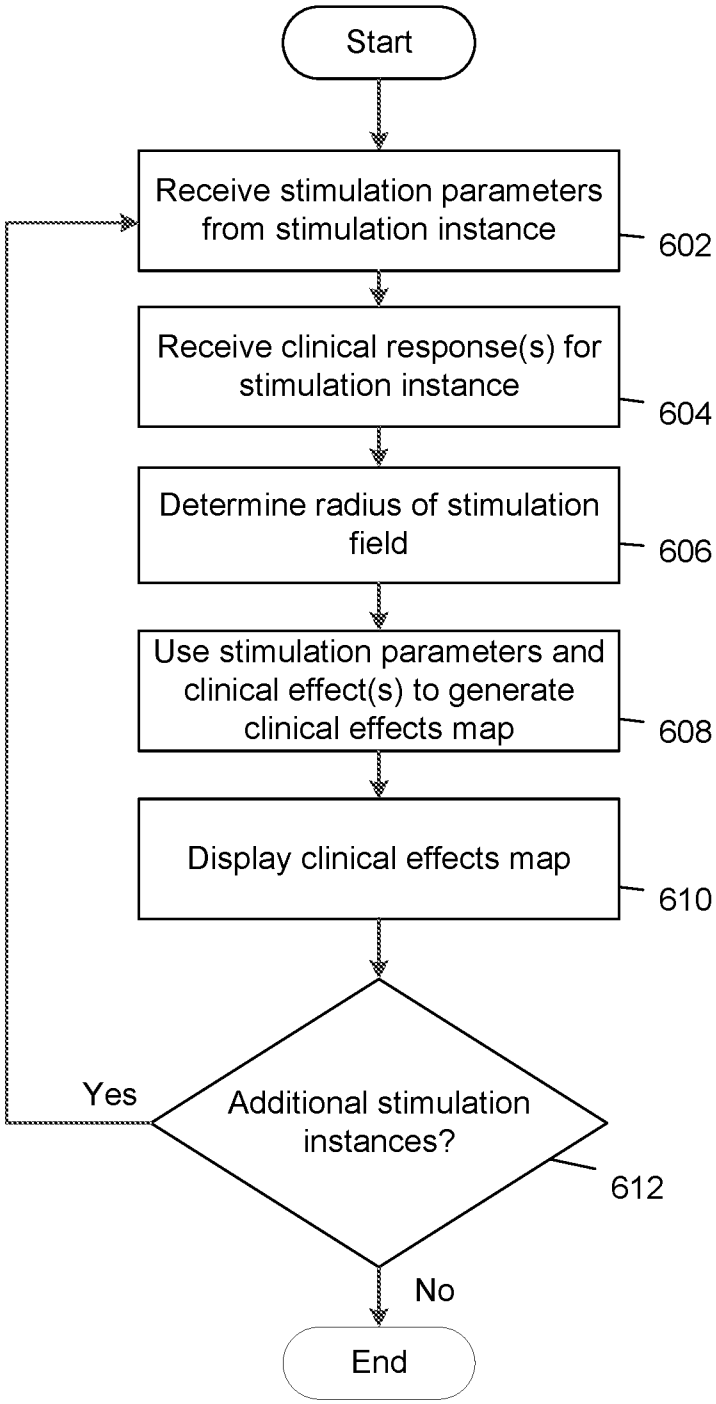
Start
Receive stimulation parameters from stimulation instance
602
Receive clinical response(s) for stimulation instance
604
Determine radius of stimulation field
606
Use stimulation parameters and clinical effect(s) to generate clinical effects map
608
Display clinical effects map
610
Additional stimulation instances?
612
Yes
No
End

Fig. 6

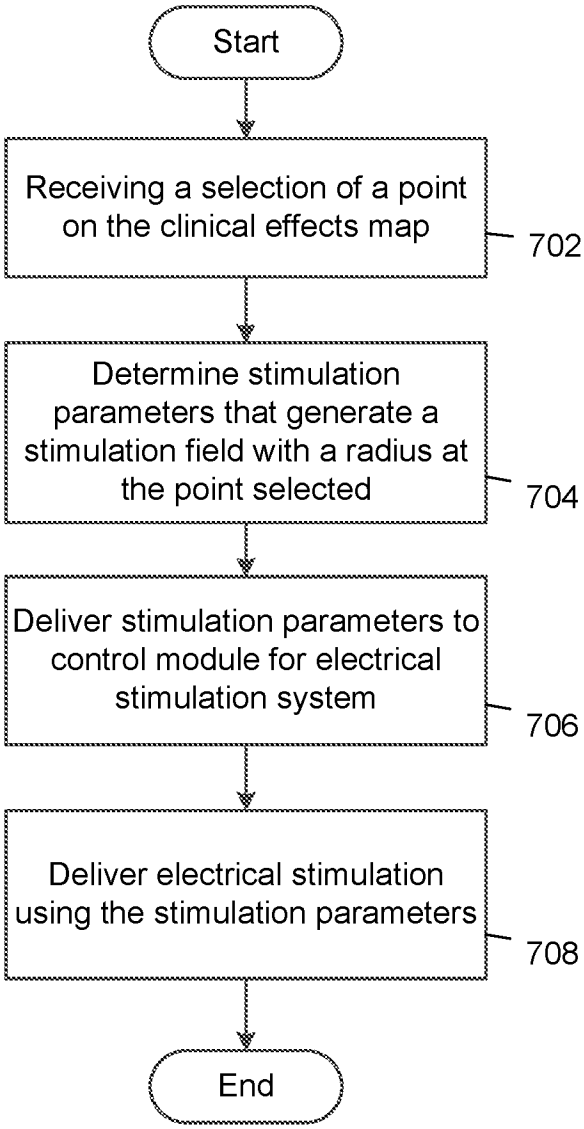
Start
Receiving a selection of a point on the clinical effects map
702
Determine stimulation parameters that generate a stimulation field with a radius at the point selected
704
Deliver stimulation parameters to control module for electrical stimulation system
706
Deliver electrical stimulation using the stimulation parameters
708
End

Fig. 7