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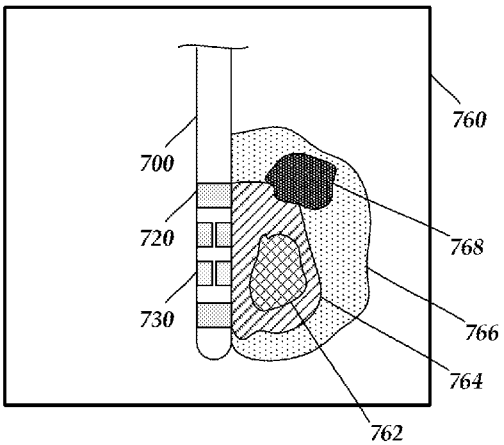

Fig. 7

(57) Abstract: A system for visualizing clinical effects can perform the following actions: obtain, for each of multiple stimulation instances, an estimation of a region stimulated during the stimulation instance and at least one assessment for at least one stimulation effect or stimulation side effect; assign, for each of the stimulation instances, a tag, selected from multiple tags, to each one of multiple voxels within the region stimulated during the stimulation instance, where the tag is selected based on the at least one assessment for the stimulation instance; and assign a voxel type, selected from multiple voxel types, to each of multiple voxels based on the tags assigned to the voxels. Optionally, the actions can also include display, on a display, a representation of multiple voxels with each of the displayed voxels having a graphical feature associated with the voxel type assigned to that voxel.

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SYSTEMS AND METHODS FOR VISUAL ANALYTICS OF CLINICAL EFFECTS

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. 62/354,628, filed June 24, 2016, 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 for visualizing clinical effects for multiple sets of stimulation parameters, as well as methods of making and using the systems.

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), one or more leads, 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. These electrical pulses can produce beneficial stimulation effects, but may also produce side effects. Different stimulation parameters and stimulation electrode selections are often tested to identify a suitable stimulation program.

BRIEF SUMMARY

One embodiment is a system for visualizing clinical effects that includes a display and a computer processor coupleable to the display and configured and arranged to

perform the following actions: obtain, for each of multiple stimulation instances, an estimation of a region stimulated during the stimulation instance and at least one assessment for at least one stimulation effect or stimulation side effect; assign, for each of the stimulation instances, a tag, selected from multiple tags, to each one of multiple voxels within the region stimulated during the stimulation instance, where the tag is selected based on the at least one assessment for the stimulation instance; and assign a voxel type, selected from multiple voxel types, to each of multiple voxels based on the tags assigned to the voxels. Optionally, the actions can also include display, on the display, a representation of multiple voxels with each of the displayed voxels having a graphical feature associated with the voxel type assigned to that voxel.

Another embodiment is a non-transitory computer-readable medium having processor-executable instructions for visualizing clinical effects, the processor-executable instructions when installed onto a device enable the device to perform actions, including: obtain, for each of multiple stimulation instances, an estimation of a region stimulated during the stimulation instance and at least one assessment for at least one stimulation effect or stimulation side effect; assign, for each of the stimulation instances, a tag, selected from multiple tags, to each one of multiple voxels within the region stimulated during the stimulation instance, where the tag is selected based on the at least one assessment for the stimulation instance; and assign a voxel type, selected from multiple voxel types, to each of multiple voxels based on the tags assigned to the voxels. Optionally, the actions can also include display a representation of multiple voxels with each of the displayed voxels having a graphical feature associated with the voxel type assigned to that voxel.

Yet another embodiment is a method for visualizing clinical effects that includes obtaining, for each of multiple stimulation instances, an estimation of a region stimulated during the stimulation instance and at least one assessment for at least one stimulation effect or stimulation side effect; assigning, for each of the stimulation instances, a tag, selected from multiple tags, to each one of multiple voxels within the region stimulated during the stimulation instance, where the tag is selected based on the at least one assessment for the stimulation instance; and assigning a voxel type, selected from multiple voxel types, to each of multiple voxels based on the tags assigned to the voxels.

Optionally, the method can also include displaying a representation of multiple voxels with each of the displayed voxels having a graphical feature associated with the voxel type assigned to that voxel.

In at least some embodiments, the at least one assessment includes at least one assessment for at least one stimulation effect and at least one assessment for at least one stimulation side effect. In at least some embodiments, the actions or method further include determining a confidence level of the voxel type assigned to at least one of the voxels based on relative amounts of the tags assigned to the voxel. In at least some embodiments, the graphical feature associated with the voxel type assigned to that voxel further represents the confidence level in the assignment of the voxel type.

In at least some embodiments, the actions or the method further include determining a stimulation region based on the assignment of voxel types and generate a set of stimulation parameters to stimulate the stimulation region. In at least some embodiments, the actions or method further include transmitting the set of stimulation parameters so that an implantable pulse generator can receive the set of stimulation parameters and provide electrical stimulation using the set of stimulation parameters.

In at least some embodiments, the tags include a first tag indicating absence of stimulation effects and stimulation side effects and a second tag indicating presence of a stimulation effect and absence of stimulation side effects. In at least some embodiments, assigning a voxel type includes assigning the voxel type for multiple of the voxels based on a ratio of the first and second tags. In at least some embodiments, the tags include a third tag indicating presence of a stimulation effect and presence of a stimulation side effect and a fourth tag indicating absence of stimulation effects and presence of a stimulation side effect. In at least some embodiments, the presence is indicated by presence of the stimulation effect or stimulation side effect, respectively, at or above a predetermined presence threshold and the absence is indicated by the stimulation effects or stimulation side effects, respectively, being below a predetermined absence threshold.

In at least some embodiments, the voxel types include a first voxel type and a second voxel type, where, unless a ratio of fourth tags over combined first and second tags is greater than a side effect threshold, a voxel is assigned the first voxel type when a

ratio of the second tags over the first tags is less than a predetermined first threshold. In at least some embodiments, unless the ratio of fourth tags over combined first and second tags is greater than the side effect threshold, a voxel is assigned the second voxel type when the ratio of the second tags over the first tags is greater than a predetermined second threshold.

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, according to the invention;

FIG. 2 is a schematic side view of one embodiment of an electrical stimulation lead, according to the invention;

FIG. 3 is a schematic block diagram of one embodiment of a system for visualizing clinical effects data, according to the invention;

FIG. 4 is a schematic flowchart of one embodiment of a method of visualizing clinical effects data, according to the invention;

FIG. 5 is a schematic illustration of one embodiment of a set of tags for tagging voxels based on stimulation instances, according to the invention;

FIG. 6 is a schematic illustration of one embodiment of a set of voxel types for assigning to voxels based on the tags of FIG. 5, according to the invention; and

FIG. 7 is a schematic illustration of one embodiment of a user interface illustrating the assignment of voxels to different voxel types, according to the invention.

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 for visualizing clinical effects for multiple sets of stimulation parameters, as well as methods of making and using the systems.

Suitable implantable electrical stimulation systems include, but are not limited to, a least one lead with one or more electrodes disposed on a distal end of the lead and one or more terminals disposed on one or more proximal ends of the lead. Leads include, for example, percutaneous leads and paddle leads. 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 their entirety. 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, microelectrode arrays, leads with direction electrodes (see, for example, Figure 2), arrays of leads, and the like.

A percutaneous lead for electrical stimulation (for example, deep brain or spinal cord stimulation) includes stimulation electrodes that can be ring electrodes or segmented electrodes that extend only partially around the circumference of the lead 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. 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 and tissues.

Turning to Figure 1, one embodiment of an electrical stimulation system 10 includes one or more stimulation leads 12 and an implantable pulse generator (IPG) 14. The system 10 can also include one or more 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 one or more lead extensions 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 implantable pulse generator 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 implantable pulse generator can have eight stimulation channels which may be independently programmable to control the magnitude of the current stimulus from each channel. In some embodiments, the implantable pulse generator can have more or fewer than eight stimulation channels (e.g., 4-, 6-, 16-, 32-, or more stimulation channels). The implantable pulse generator 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 has 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 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 in its entirety. 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 in their entirety.

Figure 2 illustrates one embodiment of a lead 110 with electrodes 125 disposed at least partially about a circumference of the lead 110 along a distal end portion of the lead and terminals 135 disposed along a proximal end portion of the lead.
The lead 110 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 110 can be inserted into the cranium and brain tissue

with the assistance of a stylet (not shown). The lead 110 can be guided to the target location within the brain using, for example, a stereotactic frame and a microdrive motor system. In some embodiments, the microdrive motor system can be fully or partially automatic. The microdrive motor system may be configured to perform one or more the following actions (alone or in combination): insert the lead 110, advance the lead 110, retract the lead 110, or rotate the lead 110.

In some embodiments, measurement devices coupled to the muscles or other tissues stimulated by the target neurons, or a unit responsive to the patient or clinician, can be coupled to the implantable pulse generator 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 tremor frequency or amplitude in response to stimulation of neurons. Alternatively, the patient or clinician can observe the muscle and provide feedback.

The lead 110 for deep brain stimulation can include stimulation electrodes, recording electrodes, or both. In at least some embodiments, the lead 110 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 110 to stimulate the target neurons. Stimulation electrodes may be ring-shaped so that current projects from each electrode equally in every direction from the position of the electrode along a length of the lead 110. In the embodiment of Figure 2, two of the electrodes 120 are ring electrodes 120. Ring electrodes typically do not enable stimulus current to be directed from only a limited angular range around of the lead. Segmented electrodes 130, however, can be used to direct stimulus current to a selected angular range around the lead. When segmented electrodes are used in conjunction with an implantable pulse generator that delivers constant current stimulus, current steering can be achieved to more precisely deliver the stimulus to a position around an axis of the lead (*i.e.*, radial

positioning around the axis of the 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, and one or more ring electrodes 120 and one or more sets 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 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 can either be used or unused (OFF). When the 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 one or more sets 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. 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, all of which are incorporated herein by reference in their entirety.

An electrical stimulation lead can be implanted in the body of a patient (for example, in the brain or spinal cord of the patient) and used to stimulate surrounding tissue. It is useful to estimate the effective region of stimulation (often called a volume of activation (VOA) or stimulation field model (SFM)) given the position of the lead and its electrodes in the patient's body and the stimulation parameters used to generate the stimulation. The term SFM will be used herein, but it will be recognized that a VOA or another region of stimulation as determined by any suitable method can be used instead of a SFM. Any suitable method for determining the SFM or VOA and for graphically displaying the SFM or VOA relative to patient anatomy can be used including those described in, for example, U.S. Patents Nos. 8,326,433; 8,675,945; 8,831,731; 8,849,632; and 8.958,615; U.S. Patent Application Publications Nos. 2009/0287272; 2009/0287273; 2012/0314924; 2013/0116744; 2014/0122379; and 2015/0066111; and U.S. Provisional Patent Application Serial No. 62/030,655, all of which are incorporated herein by reference in their entirety. Several of these references also disclose methods and systems for registering an atlas of body structures to imaged patient physiology.

A SFM can be determined based on a set of stimulation parameters input into the system. The SFM can then be modified by the user by modifying the stimulation parameters and determining the new SFM from the modified stimulation parameters. This allows the user to tailor the stimulation volume. Sets of stimulation parameters, used in the stimulation of one or more patients, and the therapeutic effects or side-effects resulting for the respective set of stimulation parameters can be recorded and associated with the corresponding SFM for that set of stimulation parameters. For example, in some embodiments, stimulation data (e.g., parameters, therapeutic effects, side effects, or the like) for multiple patients can be used. In some embodiments, the data or a corresponding SFM can be registered to an anatomic atlas for comparison between different patients.

As described below, the clinical effects data (therapeutic effects and optionally side-effects) from multiple patients, multiple SFMs, or any combination thereof can be aggregated to provide information about anatomical regions and the likelihood that stimulation of the region will produce a therapeutic effect or side effect. These likelihoods can be visualized, for example, on an anatomical display or in an anatomical atlas to provide guidance to a clinician for selection of anatomical regions to stimulate.

Figure 3 illustrates one embodiment of a system for visualization of clinical effects. 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, the electrical stimulation system 312.

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 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 one or more 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.

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 one or more 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, camera, microphone, or any combination thereof, or the like.

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 some embodiments, the computing device 300 may include part of the electrical stimulation system, such as, for example, the IPG, CP, RC, ETS, 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 communications methods. Wired communication can include communication over a twisted pair, coaxial cable, fiber optic, wave guide, or the like, or any combination thereof. Wireless communication can include RF, infrared, optical, acoustic, near field communication, Bluetooth™, or the like, or any combination thereof.

It would useful to determine desirable regions for delivery of electrical stimulation to provide a therapeutic effect or to determine regions to avoid stimulating to reduce or avoid a side effect. In at least some instances, when an electrical stimulation lead is implanted in a patient, the patient undergoes an assessment in which different sets of stimulation parameters are tested and assessed quantitatively or qualitatively. For example, an assessment could be based on a rating scale (for example, the Unified Parkinson's Disease Rating Scale (UPDRS)).

In addition, in at least some instances, the location of the implanted lead within the patient's body can be determined using postoperative imaging (for example, by a CT scan). In other instances, the location of the lead may be estimated based on the target implantation site. The location of the lead, and its corresponding electrodes, and the stimulation parameters can be used to estimate the volume of tissue that is stimulated using those parameters. In other embodiments, the volume of tissue that is stimulated is associated with a position relative to the lead with or without general or specific anatomical knowledge of the implantation site.

In at least some embodiments, the data from a single patient or from multiple patients can be evaluated to identify which regions (for example, portions of the brain or other body parts or regions around a lead), when electrically stimulated, are likely to affect at least one symptom of a treated condition or disorder or produce some other stimulation effect or produce a stimulation side effect. When data from multiple patients is evaluated, the patients may be drawn from the general population or can be selected based on one or more criteria including, but not limited to, the condition or disorder being treated, age, gender, residence, weight, ethnicity, nationality, or the like or any combination thereof.

By understanding which portions of the body or regions around the lead, when electrically stimulated, are likely to produce at least one stimulation effect (i.e., a therapeutic effect) or at least one side effect, a practitioner can select stimulation parameters that are likely to stimulate (or not simulate) a portion of the body or region around the lead. It will be recognized that these parameters represent estimates and, when implemented, may be revised or modified upon actual testing in the patient's body.

The present invention is directed, at least in part, to evaluating data from multiple sets of stimulation parameters (e.g., multiple instances of stimulation) to predict which portions of the body or regions around the lead when stimulated are likely to produce a stimulation effect or a stimulation side effect. In at least some embodiments, for each stimulation instance, the stimulation region is divided into elements (such as volume elements or voxels) that are stimulated and each of these elements is assigned one of several possible tags based on the existence of the stimulation effect and stimulation side effect. The tags for multiple stimulation instances are then aggregated to characterize the elements based on, for example, the numbers or ratios of the different tags or based on other predefined criteria or processing methodologies.

In the discussion below, the elements (for example, elements of the brain or other organ or body part) into which the stimulation region is divided can be, for example, volume elements called "voxels", but any other suitable elements for dividing the stimulation region can be used. In at least some embodiments, the volume of each voxel is identical. In other embodiments, the voxels may have different volumes. It will be recognized that other selections of voxels, such as by function or by anatomically identified regions (such as known and named regions of the brain or portions of those regions), instead of by volume can also be used. Preferably, the voxels do not overlap, but non-overlap is not necessary.

Figure 4 outlines one embodiment of a method of visualizing clinical effects of stimulation. In step 402, multiple stimulation instances are obtained. In at least some embodiments, each stimulation instance includes one or more assessments directed toward at least one stimulation effect or stimulation side effect or any set of stimulation effects/side effects. For purposes of example, the methods described herein may refer to a single stimulation effect or a single stimulation side effect. It will be understood that,

instead of a single stimulation effect or stimulation side effect, the methods described herein can be used to consider multiple stimulation effects or multiple stimulation side effects or any combination thereof. Moreover, it will be understood that multiple stimulation effects (or multiple stimulation side effects) may be considered in the aggregate (i.e., with one assessment relating to all of the stimulation effects or stimulation side effects), individually, or grouped, or any combination thereof.

The assessments directed toward a stimulation effect or side effect can be, for example, an assessment of the presence or absence of the stimulation effect or side effect; an assessment of the presence of the stimulation effect or side effect at or above a predetermined threshold; an assessment of the absence of the stimulation effect or side effect if it doesn't reach a predetermined threshold; a quantitative or qualitative assessment of the intensity or other measure of the stimulation effect or side effect; or a score for the stimulation effect or side effect; or any other suitable assessment.

In some embodiments, the assessment can be a quantitative measurement such as a measurement of a biopotential, change in biopotential, measurement of movement, vital sign measurement, or the like and may be collected automatically or manually. For example, the system may include a sensor that can make the measurement. The sensor may be disposed on the IPG or lead or the sensor may be separate from the IPG or lead. In some embodiments, the assessment can be a subjective measure such as patient feedback or satisfaction level. The assessment may be collected on a short timescale (e.g., in milliseconds, seconds, or minutes after stimulation), medium timescale (e.g., during one or more programming sessions or over days), or long timescale (e.g., over a longer stimulation period such as weeks or months) or any combination thereof.

Each stimulation instance can also be associated with a set of stimulation parameters (for example, selection of one or more electrodes, selection of electrode polarity, pulse width, pulse duration, pulse frequency, pulse amplitude (or amplitude for each selected electrode), pulse pattern, and the like) and values for those stimulation parameters. As used herein, the term "stimulation parameter" is used to indicate the categorization of a parameter and the terms "stimulation parameter value" or "value" are used to indicate the actual value (for example, a numerical value) for the particular stimulation parameter.

The stimulation instances can be from a single patient or can be from multiple patients. In at least some embodiments, each stimulation instance is directed to treating the same condition or disorder or symptom or portion of the body. In other embodiments, different stimulation instances may be directed to treating different conditions or disorders or symptoms or portions of the body which may be related or unrelated.

In step 404, the stimulation parameters of each stimulation instance are used to estimate a portion of the body or region around the lead that is stimulated by these stimulation parameters. In some embodiments, the estimate is a volume of activation (VOA) or stimulation field model (SFM). Examples of suitable methods for making these estimations include, but are not limited to, those described in U.S. Patents Nos. 8,326,433; 8,675,945; 8,831,731; 8,849,632; and 8.958,615; U.S. Patent Application Publications Nos. 2009/0287272; 2009/0287273; 2012/0314924; 2013/0116744; 2014/0122379; and 2015/0066111; and U.S. Provisional Patent Application Serial No. 62/030,655, all of which are incorporated herein by reference in their entirety. In some embodiments, these estimates can include, for example, estimates of axonal activation or suppression, estimates of cell bodies that are activated or suppressed, estimates of fiber pathways that are activated or suppressed, estimates of a second neural population that is activated or suppressed when a first neural population is stimulated, and the like or any combination thereof. It will be understood that other methods of estimating the stimulation region that do or do not use the stimulation parameters can also be employed. For example, the estimates may utilize tractography or other connectivity models to estimate a stimulation region.

In other embodiments, the stimulation instances are provided to the system with an identification of the stimulation region instead of the system computing or estimating the stimulation regions.

In some embodiments, an initial estimate of the stimulation region can be determined using, for example, a quick or less computationally expensive method. A subsequent estimate of the stimulation region may be determined later using a more rigorous or computationally expensive or time consuming method.

The stimulation regions of different stimulation instances are optionally transformed to a common space using the patients' imaging data, using an anatomical atlas, or using any other suitable method for providing a common reference frame for the stimulation regions. This can facilitate combination of all stimulation regions for all stimulation instances into the common reference frame.

In step 406, for each stimulation instance, a tag, from a set of available tags, is assigned to each voxel within the stimulation region for that stimulation instance. The selection of which tag to assign for the stimulation instance can be based on, for example, the one or more assessments for that stimulation instance. Additionally or alternatively, there may be one or more criteria such as, for example, the existence of a stimulation effect or side effect or combinations thereof, the level or score for the stimulation effect or side effect, whether the level or score meets a threshold, or the like or any combination thereof (which may also include multiple stimulation effects and side effects). Each available tag will have different criteria for assignment of that tag to the stimulation instance. In some embodiments, only one tag is assigned for a stimulation instance. In other embodiments multiple tags may be assigned. For example, one tag can be assigned for each effect or side effect or one tag can be assigned based on stimulation effects and another tag assigned based on side effects.

As an example, one embodiment employs four tags (T1, T2, T3, T4) as illustrated in Figure 5. T1 represents a stimulation instance in which neither stimulation effects nor stimulation side effects are present (or, alternatively, are below a predefined threshold level or score); T2 represents a stimulation instance in which stimulation effects are present (or, alternatively, are present at or above a predefined threshold level or score) and stimulation side effects are not present (or, alternatively, are below a predefined threshold level or score); T3 represents a stimulation instance in which both stimulation effects and stimulation side effects are present (or, alternatively, are present at or above a predefined level or score); and T4 represents a stimulation instance in which stimulation side effects are present (or, alternatively, are present at or above a predefined level or score) and stimulation effects are not present (or, alternatively, are below a predefined threshold level or score).

In at least some embodiments, the likelihood of assigning a particular tag may also be taken into account. For example, clinicians or patients will often not increase amplitude once a side effect is encountered or the side effect reaches a threshold level. Accordingly, there will likely be fewer stimulation instances that meet criteria relating to presence of side effects. In the example above, such a situation will likely result in the low occurrence of tags T3 and T4 relative to the number of T1 and T2 tags. Therefore, the actual voxels that result in side effects will likely only be stimulated in a few stimulation instances. Because side effects will often be observed, in at least some stimulation instances, at a relatively high amplitude, the corresponding stimulation region will also likely be large due to the relatively high amplitude and many voxels (e.g., voxels) will have at least some tags T3 or T4 even though only a relatively few voxels actually result in side effects.

In the illustrated example, the tags are assigned based on the presence or absence of stimulation effects and side effects. In other embodiments, different tags may be assigned based on the magnitude of stimulation effects or side effects. For example, a first tag may be assigned when stimulation effects meet, or exceed, a first threshold level but are below a second threshold level and a second tag may be assigned when the stimulation effects are meet, or exceed, both the first and second threshold levels and a third tag may be assigned when the stimulation effects are below both the first and second thresholds.

In step 408, each voxel (e.g., voxel) is assigned a voxel type based on the ratios or numbers (or any other suitable analysis) of each type of tag associated with that voxel. Figure 6 illustrates one example of categorizations of the voxels into four voxel types, V1, V2, V3, and V4.

In the illustrated embodiment, the V2 elements are those which are likely to contribute to stimulation effects without producing stimulation side effects. V3 elements are those that may or may not produce stimulation effects, but do not produce stimulation side effects. V1 elements are those which likely do not produce stimulation effects or stimulation side effects. V4 elements are those that are more likely than V1-V3 elements to produce stimulation side effects.

In the illustrated embodiment, the number of tags is either "Many" or "Few". The boundary between "Many" and "Few" may vary depending, for example, on the number stimulation instances, the number of different tag types, the number of the particular tags (e.g., the number of T1 tags), the ratio or percentage of total tags that are the particular tag (e.g., T1/(T1+T2+T3+T4) as a ratio or multiplied by 100 for percentage) and the like. The boundaries between different voxels types may be preset, set after determining some or all the tags, or determined heuristically.

The following are examples of criteria for determining voxels types V1, V2, V3, and V4. It will be recognized that other criteria or methods of selecting voxel type can be used and may be predetermined or determined during or after processing the tags, or determined using a heuristic or by user experience or experiment.

As described above, in at least some embodiments, the number of T1 and T2 tags are expected to be substantially larger than the number of T3 and T4 tags. Accordingly, as one example, ratios of tags or differences between the numbers of tags can be used as assignment rules to determine voxel type. For example, T2/T1<L1 can indicate voxel type V1. (Unless otherwise indicated, any of the < or > signs in the relationships indicated here may instead by $\leq$ or $\geq$, respectively.) In some embodiments, (T2+T3)/(T3+T4)>L2 or T2/(T3+T4)>L2 or T2/T1>L2 can indicate voxel type V2. L1 and L2 are two threshold values. For example, L1 may be 1, 0.5, 0.33, 0.25, 0.2 or less or any other suitable number and L2 may be 1, 2, 3, 4, 5, or more or any other suitable number. As other examples, a voxel may be assigned voxel type V1 if T1 exceeds a threshold value or if the difference, T1-T2, is positive or exceeds a threshold value. A voxel may be assigned voxel type V2 if the difference, (T2+T3)-(T3+ T4), or the difference, T2-T4, is positive or exceeds a threshold value.

A voxel may be assigned voxel type V4 when (T3+T4)/(T1+T2)>L3. L3 is selected to indicate that there are similar numbers of T1 and T2 tags as T3 and T4 tags. For example, L3 is 0.2, 0.25, 0.33, 0.5, 1, 2, or any other suitable number. As another example, a voxel may be assigned voxel type V4 if (T3+T4) is greater than or equal to (T1+T2+T3) or if the difference, (T3+T4)-(T1+T2+T3), or the difference, T4-(T1+T2), exceeds a threshold amount. As yet another example, a voxel may be assigned voxel type V4 if T4 exceeds a threshold amount or if (T1+T2+T3) is zero and T4 is non-zero or

exceeds a threshold amount. In at least some embodiments, if the voxel does not meet any of the assignment rules for V1, V2, or V4, then the voxel is assigned to voxel type V3.

In some embodiments, the determination of whether a particular voxel is a particular voxel type may proceed in a particular order of the voxel types with testing for the voxel ending when the voxel qualifies as a particular voxel type. For example, the first test may be whether the voxel is voxel type V4. If not, then the second test is whether the voxel is voxel type V2. If not, then the third test is whether the voxel is voxel type V1. If not, then the voxel is type V3.

In other embodiments, the voxel may be compared with rules for each (or a subset of the voxel types) with the positive and negative results being considered (or possibly weighted) to determine the final voxel type. Alternatively, the positive or negative results may be compared to a rule or condition to determine the voxel type. As yet another alternative, the voxel may be tagged with multiple voxel types, optionally with percentages or weightings associated with each voxel type.

In some embodiments, a user may interact with a user interface to set or change one or more of the rules, ratios, formulas, or weightings to change the distribution of voxels between voxel types.

In some embodiments, the voxel type for each voxel may also be given a confidence level to indicate an estimate of the likelihood that the assignment is correct. For types V1 through V3 in the illustrated embodiment, the confidence level is increased by having a larger number of T1 and T2 tags. For type V4, the confidence level goes up as the total number of T1 and T2 tags is reduced, and goes up as the total number of T3 and T4 tags increases. The number of T1 and T2 tags required for a confidence level may vary based on a total number of stimulation instances and may be determined heuristically or using any suitable formula or the like. For V1 through V3 voxels, having more non-side effect stimulation instances (T1 + T2), the higher the confidence the voxel is not causing side effects. V4 voxels with some side effect tags (T3 + T4) and few or no tags indicating a lack of side effects (T1 + T2) have increased confidence level of side effect contribution as T1+T2 reduces. A voxel with no tags has a zero confidence level.

In step 410, a representation of some or all of the voxels is displayed with the voxels marked according to the voxel type. For example, a representation of some or all of the voxels is displayed with the individual voxels marked according to whether the voxel is V1, V2, V3, or V4 in the example embodiment. For example, voxels of type V2 may be marked with a color indicating a likely desirable stimulation region, voxels of type V3 may be marked with a color indicating a likely acceptable stimulation region were stimulation may or may not produce a desired stimulation effect, voxels of type V1 may be marked (or left unmarked) as a region where stimulation likely produces no effect, and voxels of type V4 may be marked with a color (e.g., red) indicating a likely undesirable stimulation region. The different voxel types can be indicated by differences in, for example, text, color, hatching, shading, intensity, transparency, outlining, or the like or any combination thereof.

In some embodiments, only a subset of the total number of voxel types may be displayed or highlighted. In at least some embodiments, the representation may also have a model of the lead displayed with the representation.

Figure 7 illustrates one embodiment of a user interface 760 with a representation of a portion of a lead 700 with electrodes 720, 730 and a region 762 of voxels of type V2 (desirable stimulation region), a region 764 of voxels of type V3 (may or may not produce a stimulation effect), a region 766 of voxels of type V1 (region produces no stimulation effect), and a region 768 of voxels of type V4 (an undesirable, side effect-producing region). In some embodiments, another region of voxels may be identified as unexplored or undetermined.

In at least some embodiments, the confidence level of the voxel may be indicated by, for example, brightness, tone, shade, transparency, or the like. In some embodiments, if the confidence level is below a predefined threshold (which may be the same or different for each voxel type) the voxel may turn a different color, such as gray, or have different text, hatching, shading, intensity, transparency, outlining, or the like or any combination thereof to indicate substantial uncertainty about the categorization of that voxel. In some embodiments, measures other than confidence level, such as relative numbers of particular tags or measures of magnitude of stimulation effect or side effects, may be indicated by variations in the display characteristic.

The voxels may be displayed in a two-dimensional arrangement, multiple two-dimensional arrangements (for example, axial and coronal slices), or a three-dimensional arrangement. In some embodiments, the user interface of the display may permit a user to rotate the representation around an axis. In at least some embodiments, the representation may also have a model of the lead displayed with the representation. In at least some embodiments, the representation may also be displayed on an anatomical image or other representation of the anatomy. In at least some embodiments, the user interface may allow a user to select one or more of the voxel types and those voxel types will be displayed or highlighted. The user interface may also display a surface of the selected voxel type(s) or a volume of the selected voxel type(s).

In some embodiments, the determination of voxel type can be performed multiple times using different stimulation effects and stimulation side effects. The results for each determination can then be displayed simultaneously, sequentially, overlaid, or in any other suitable manner. Such observations can be useful for identifying biomarkers by, for example, comparing biopotential features with stimulation effects or side effects.

In some embodiments, a user set or change one or more of the rules, ratios, formulas, or weightings to change the distribution of voxels between voxel types and the display can be updated based on the changes.

In some embodiments, the user can erase tags or voxel types for some or all of the voxel elements. In some embodiments, the user can set date limits for the stimulation instances that can be used. For example, the user can insert a date or move a date slider in a user interface.

A user can use the analysis of the voxels to identify a proposed stimulation region. In at least some embodiments, the system can automatically or manually determine stimulation parameters that will stimulate that proposed stimulation region. In at least some embodiments, the user can modify or manually select the stimulation parameters. In at least some embodiments, the stimulation parameters can be provided to an implantable pulse generator or external trial stimulator for generating electrical stimulation. The electrical stimulation can be provided to a patient using any suitable electrical stimulation system including the stimulation system illustrated in Figure 1.

It will be understood that the system can include one or more of the methods and graphical user interfaces (GUIs) described hereinabove with respect to Figures 4 and 7. The methods, systems, and GUIs 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 GUIs 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.

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, one or more processes 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, or any other medium which can be used to store the desired information and which can be accessed by a computing device.

The above specification, examples and data provide a description of the manufacture and use of the composition 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 system for visualizing clinical effects, the system comprising:

a display; and

a computer processor coupleable to the display and configured and arranged to perform the following actions:

obtain, for each of a plurality of stimulation instances, an estimation of a region stimulated during the stimulation instance and at least one assessment for at least one stimulation effect or stimulation side effect;

assign, for each of the plurality of stimulation instances, a tag, selected from a plurality of tags, to each one of a plurality of voxels within the region stimulated during the stimulation instance, wherein the tag is selected based on the at least one assessment for the stimulation instance;

assign a voxel type, selected from a plurality of voxel types, to each of a plurality of the voxels based on the tags assigned to the voxels; and

display, on the display, a representation of a plurality of the voxels with each of the displayed voxels having a graphical feature associated with the voxel type assigned to that voxel.

2. The system of claim 1, wherein the at least one assessment comprises at least one assessment for at least one stimulation effect and at least one assessment for at least one stimulation side effect.

3. The system of any one of claims 1 or 2, wherein the plurality of tags comprises a first tag indicating absence of stimulation effects and stimulation side effects and a second tag indicating presence of a stimulation effect and absence of stimulation side effects.

4. The system of claim 3, wherein assign a voxel type comprises assign the voxel type for a plurality of the voxels based on a ratio of the first and second tags.

5. The system of any one of claims 3 or 4, wherein the plurality of tags comprises a third tag indicating presence of a stimulation effect and presence of a stimulation side effect and a fourth tag indicating absence of stimulation effects and presence of a stimulation side effect.

6. The system of claim 5, wherein the presence is indicated by presence of the stimulation effect or stimulation side effect, respectively, at or above a predetermined presence threshold and the absence is indicated by the stimulation effects or stimulation side effects, respectively, being below a predetermined absence threshold.

7. The system of any one of claims 5 or 6, wherein the plurality of voxel types comprises a first voxel type and a second voxel type, wherein, unless a ratio of fourth tags over combined first and second tags is greater than a side effect threshold, a voxel is assigned the first voxel type when a ratio of the second tags over the first tags is less than a predetermined first threshold.

8. The system of claim 7, wherein, unless the ratio of fourth tags over combined first and second tags is greater than the side effect threshold, a voxel is assigned the second voxel type when the ratio of the second tags over the first tags is greater than a predetermined second threshold.

9. The system of any one of claims 1-8, wherein the actions further comprise determine a confidence level of the voxel type assigned to at least one of the voxels based on relative amounts of the tags assigned to the voxel.

10. The system of claim 9, wherein the graphical feature associated with the voxel type assigned to that voxel further represents the confidence level in the assignment of the voxel type.

11. The system of any one of claims 1-10, wherein the actions further comprise determine a stimulation region based on the assignment of voxel types and generate a set of stimulation parameters to stimulate the stimulation region.

12. The system of claim 11, wherein the actions further comprise transmit the set of stimulation parameters so that an implantable pulse generator can receive the set of stimulation parameters and provide electrical stimulation using the set of stimulation parameters.

13. A non-transitory computer-readable medium having processor-executable instructions for visualizing clinical effects, the processor-executable instructions when installed onto a device enable the device to perform actions, including:

obtain, for each of a plurality of stimulation instances, an estimation of a region stimulated during the stimulation instance and at least one assessment for at least one stimulation effect or stimulation side effect;

assign, for each of the plurality of stimulation instances, a tag, selected from a plurality of tags, to each one of a plurality of voxels within the region stimulated during the stimulation instance, wherein the tag is selected based on the at least one assessment for the stimulation instance;

assign a voxel type, selected from a plurality of voxel types, to each of a plurality of the voxels based on the tags assigned to the voxels; and

display a representation of a plurality of the voxels with each of the displayed voxels having a graphical feature associated with the voxel type assigned to that voxel.

14. The non-transitory computer-readable medium of claim 13, wherein the plurality of tags comprises a first tag indicating absence of stimulation effects and

stimulation side effects, a second tag indicating presence of a stimulation effect and absence of stimulation side effects, a third tag indicating presence of a stimulation effect and presence of a stimulation side effect, a fourth tag indicating absence of stimulation effects and presence of a stimulation side effect.

15. A computer implemented method, comprising:

obtaining, for each of a plurality of stimulation instances, an estimation of a region stimulated during the stimulation instance and at least one assessment for at least one stimulation effect or stimulation side effect;

assigning, for each of the plurality of stimulation instances, a tag, selected from a plurality of tags, to each one of a plurality of voxels within the region stimulated during the stimulation instance, wherein the tag is selected based on the at least one assessment for the stimulation instance;

assigning a voxel type, selected from a plurality of voxel types, to each of a plurality of the voxels based on the tags assigned to the voxels; and

display a representation of a plurality of the voxels with each of the displayed voxels having a graphical feature associated with the voxel type assigned to that voxel.

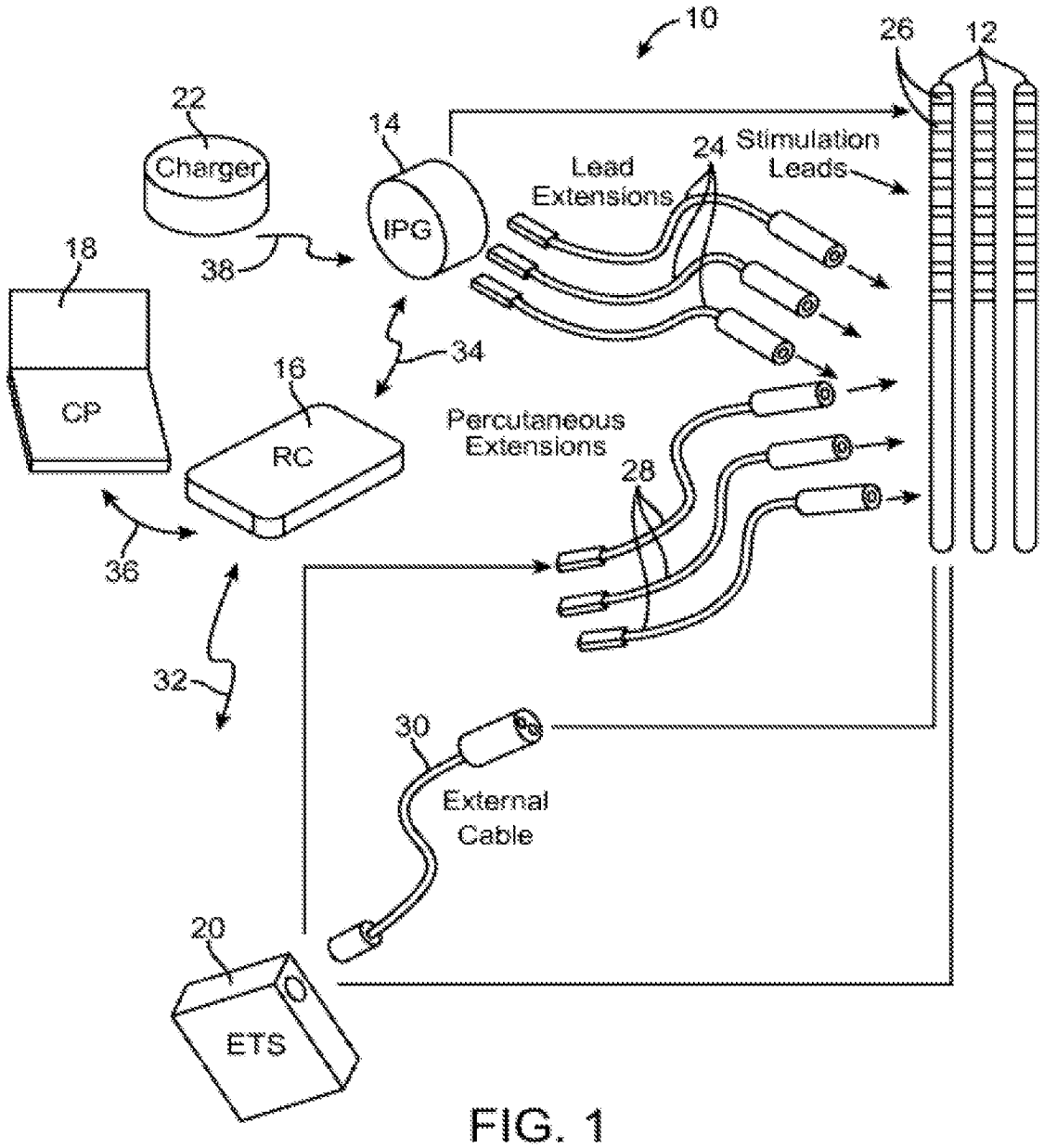
10
26
12
22
Charger
14
IPG
24
Lead Extensions
Stimulation Leads
38
18
CP
34
16
RC
Percutaneous Extensions
28
36
32
30
External Cable
20
ETS

FIG. 1

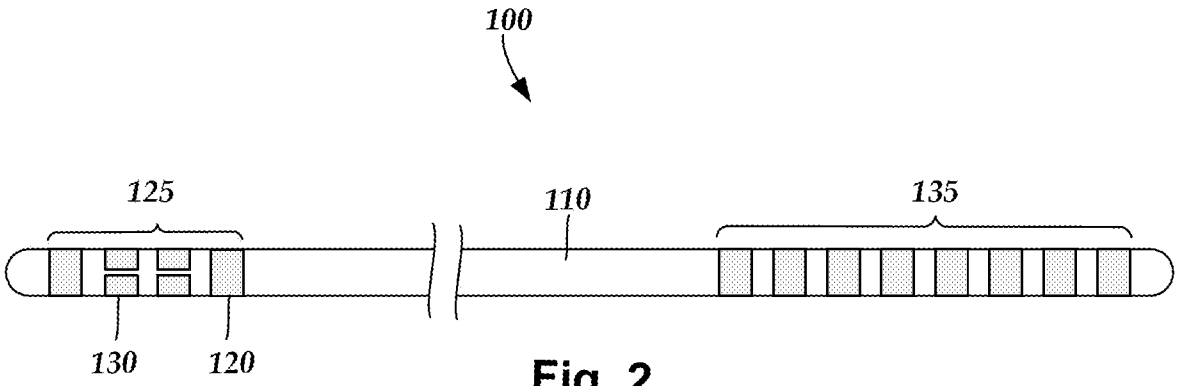
100
125
110
135
130
120

Fig. 2

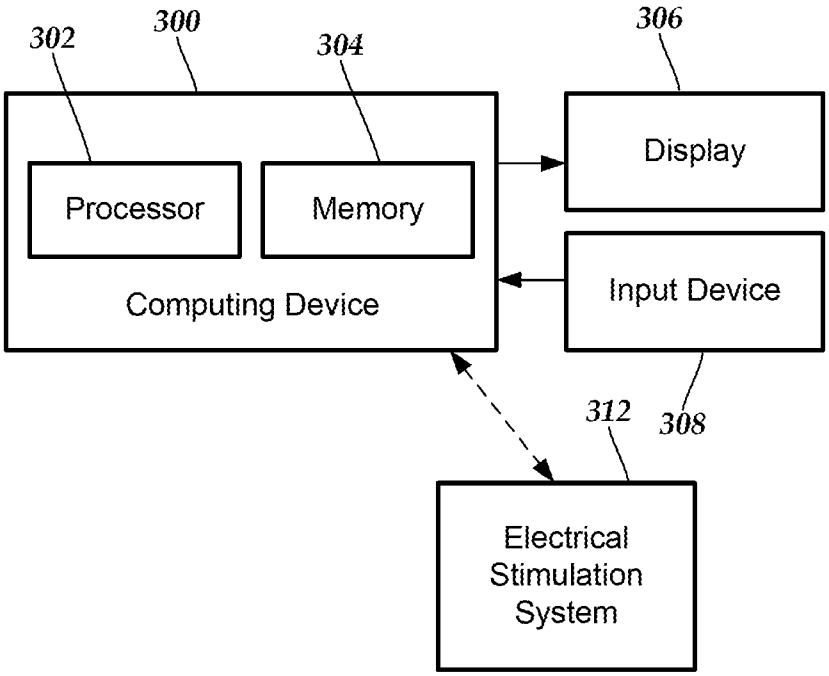
302
300
304
306
Processor
Memory
Display
Input Device
Computing Device
312
308
Electrical Stimulation System

Fig. 3

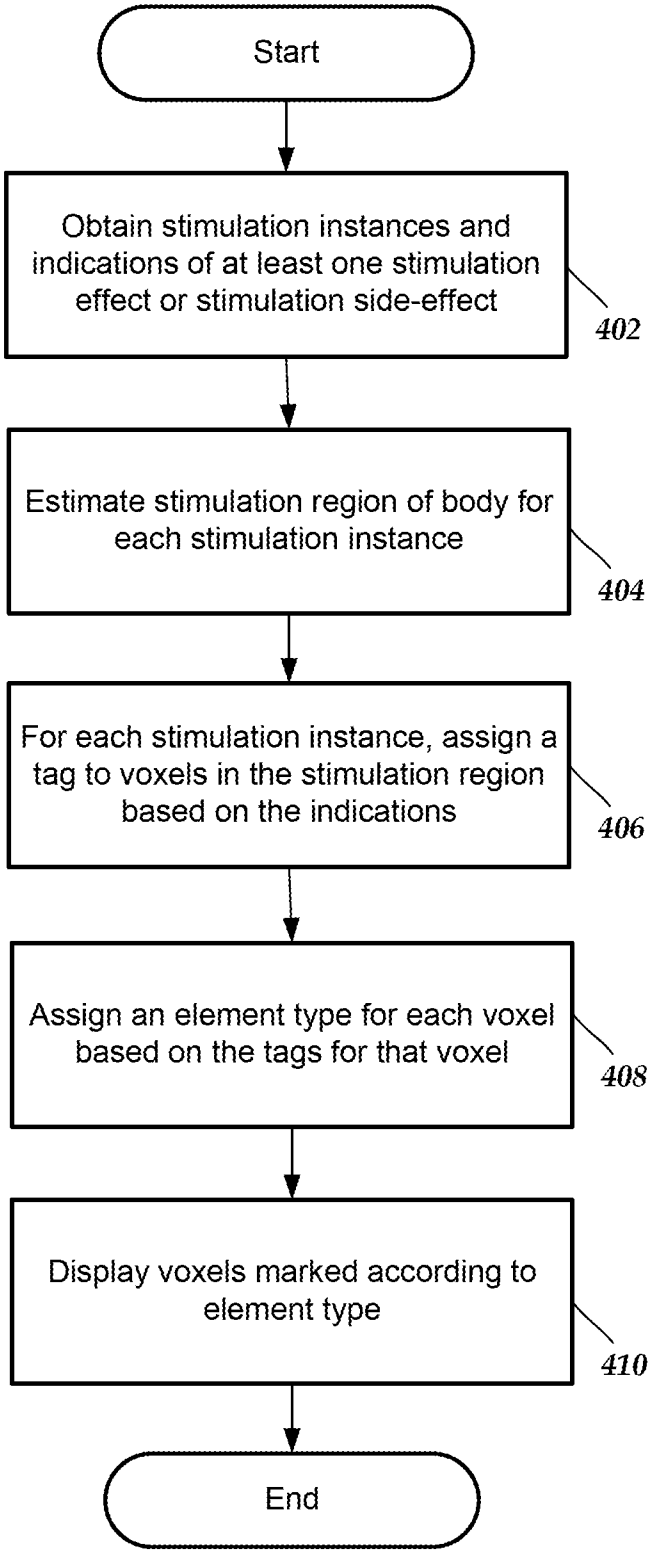

Fig. 4

Tag	Effect	Side Effect
T1	No	No
T2	Yes	No
T3	Yes	Yes
T4	No	Yes

Fig. 5

Element Type	T1	T2	T3	T4
V1	Many	Few	Few	Few
V2	Few	Many	Few	Few
V3	Many	Many	Few	Few
V4	Few	Few	Few	Few

Fig. 6

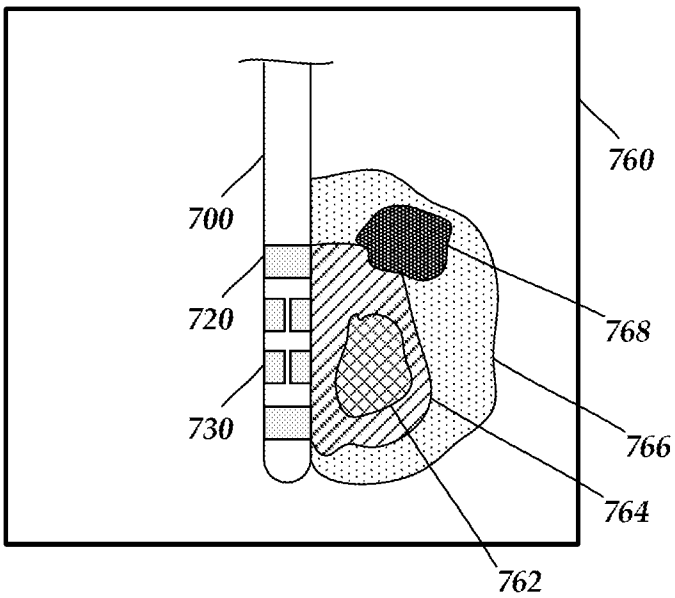

Fig. 7