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(54) **SYSTEMS AND METHODS FOR VISUALIZING AND DIRECTING STIMULATION OF NEURAL ELEMENTS**

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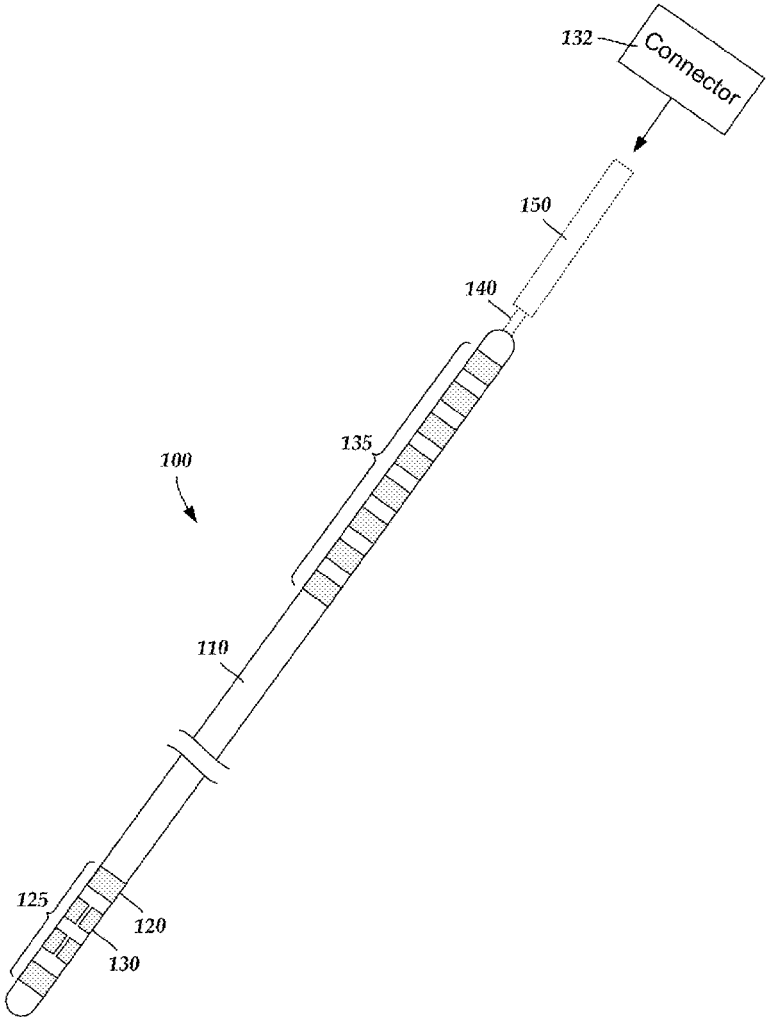
(57) **ABSTRACT**

Method and systems for determining a set of stimulation parameters for an implantable stimulation device include receiving a set of stimulation parameters including at least one electrode for delivery of stimulation and a stimulation amplitude for each electrode; determining, using the set of stimulation parameters, an axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead; and outputting the first axial stimulation field for viewing by a user; receiving, by the computer processor. The methods and systems can be used to model other neural elements oriented non-orthogonally with respect to the longitudinal axis of the lead and determine a non-orthogonal stimulation field.



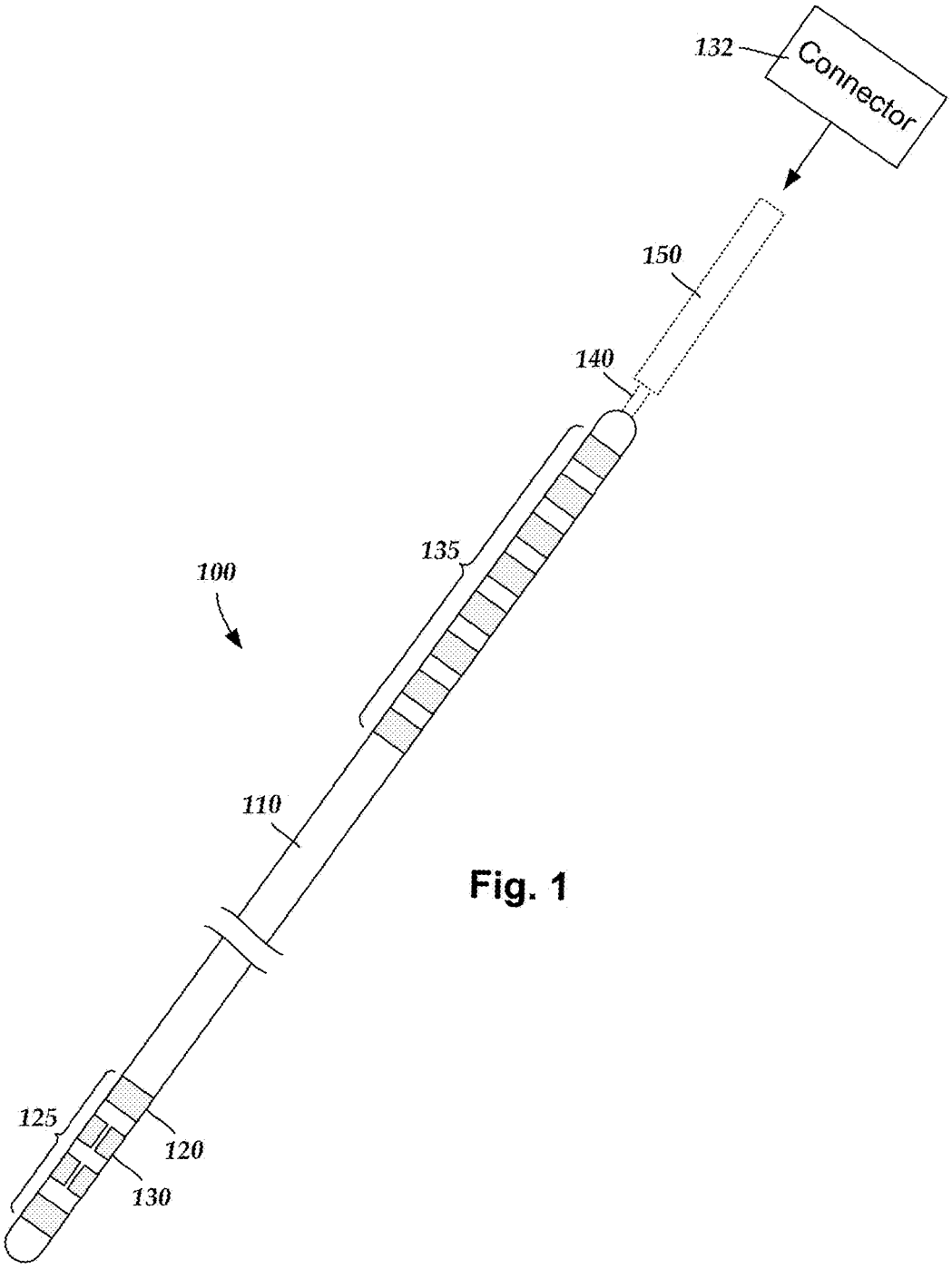


Fig. 1

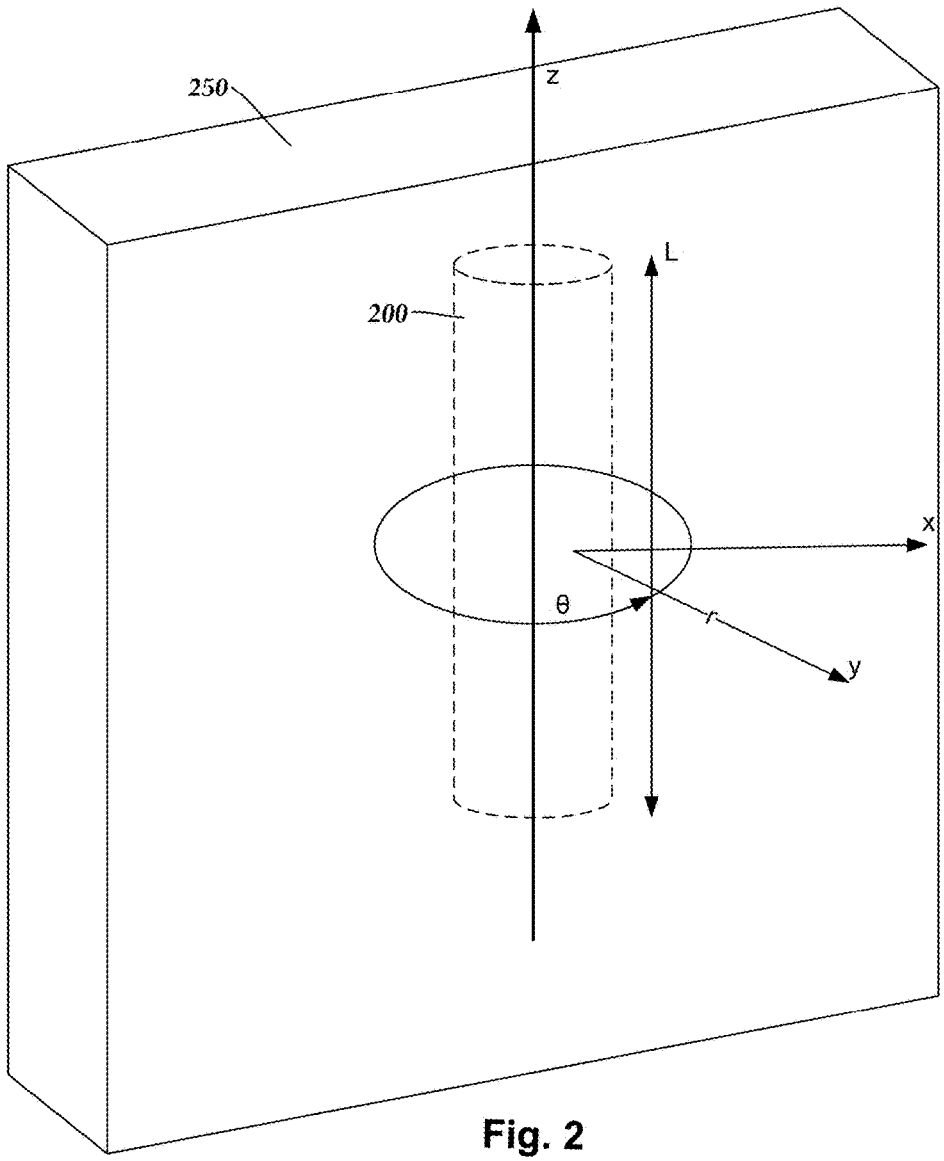


Fig. 2

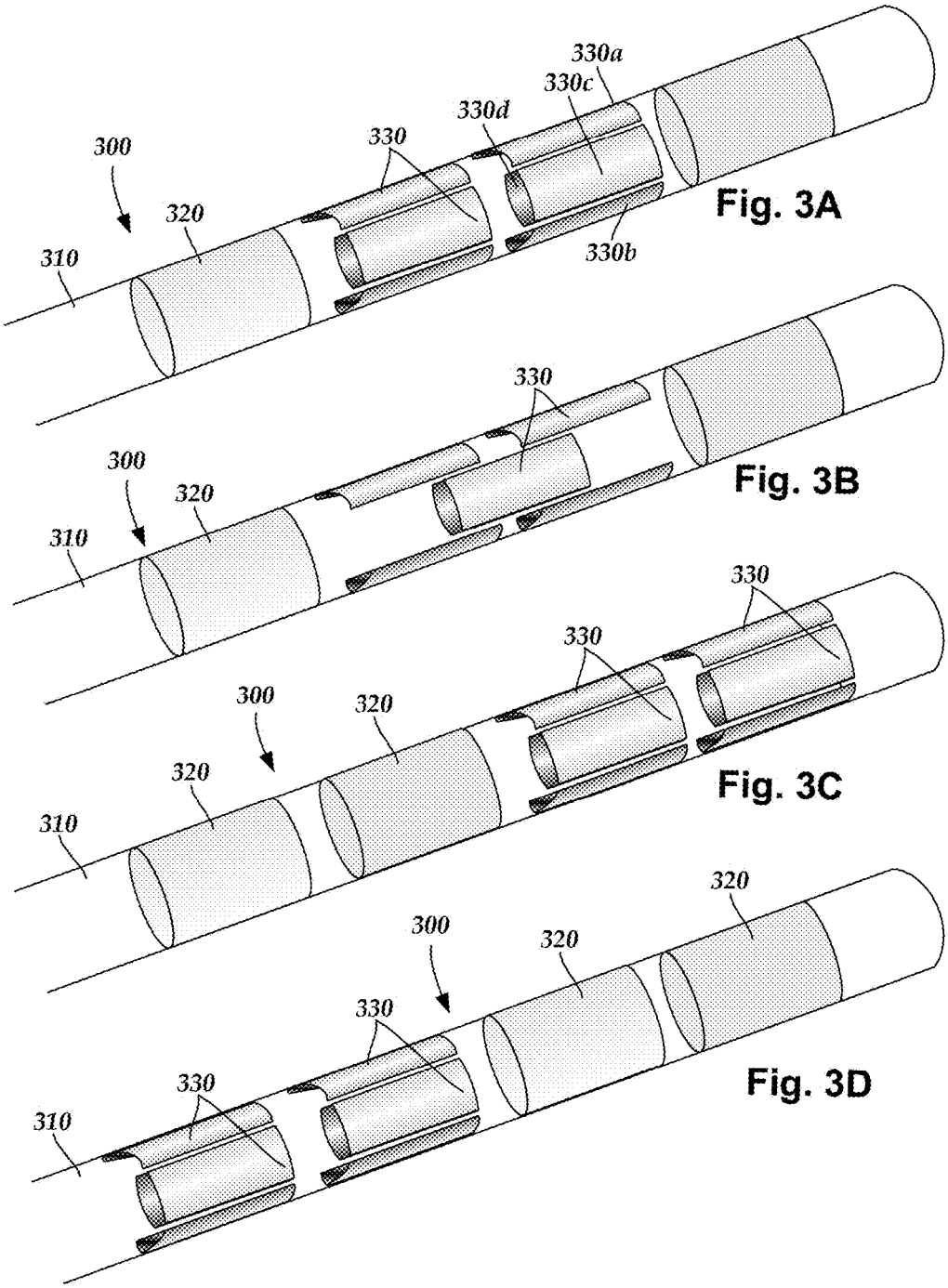


Fig. 3A

Fig. 3B

Fig. 3C

Fig. 3D

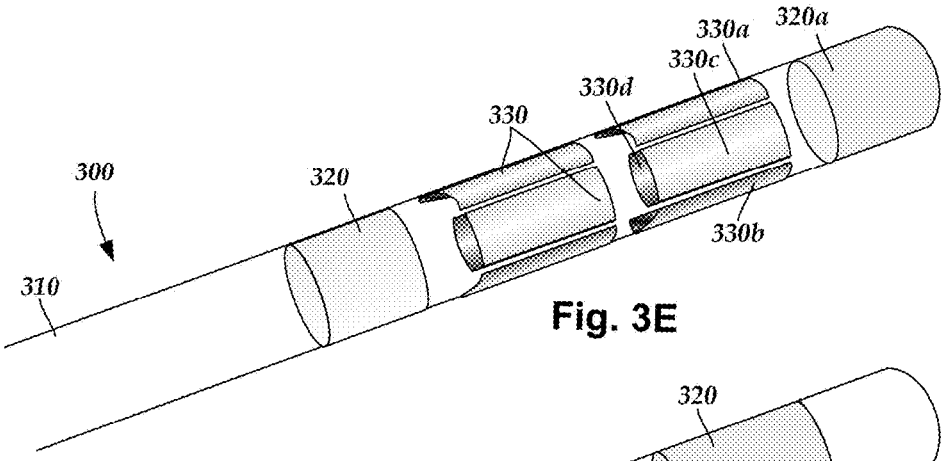


Fig. 3E

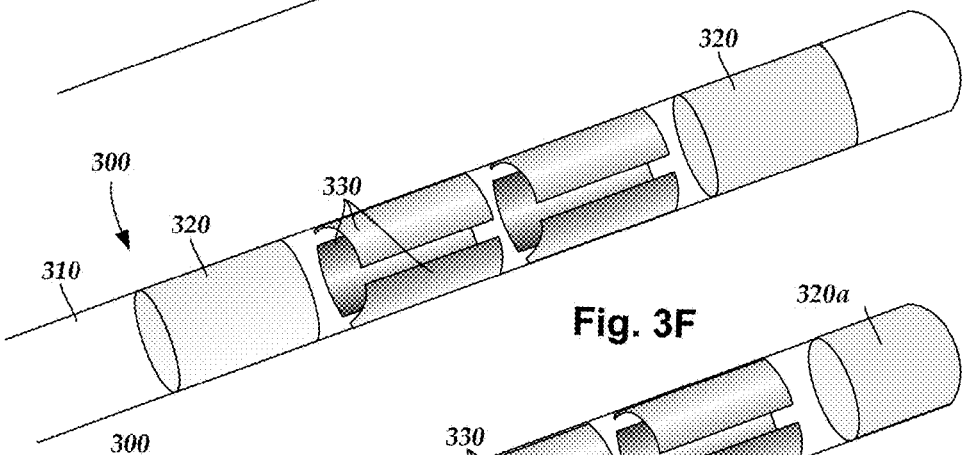


Fig. 3F

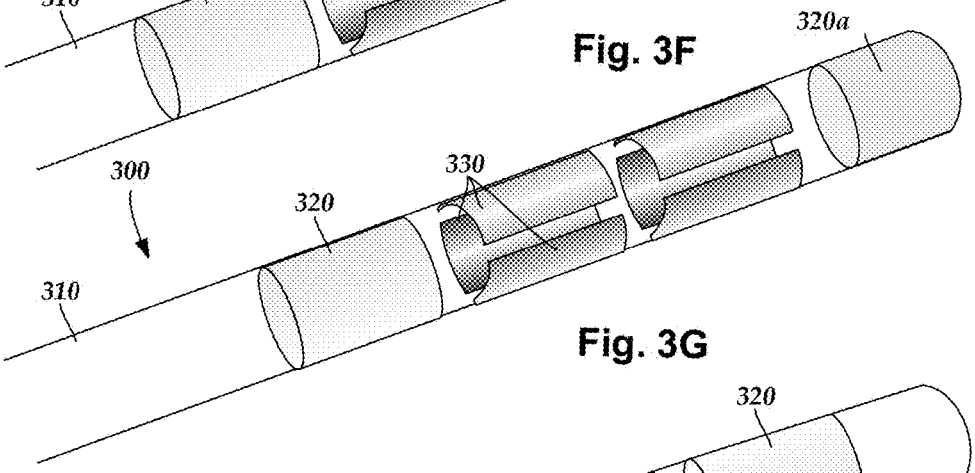


Fig. 3G

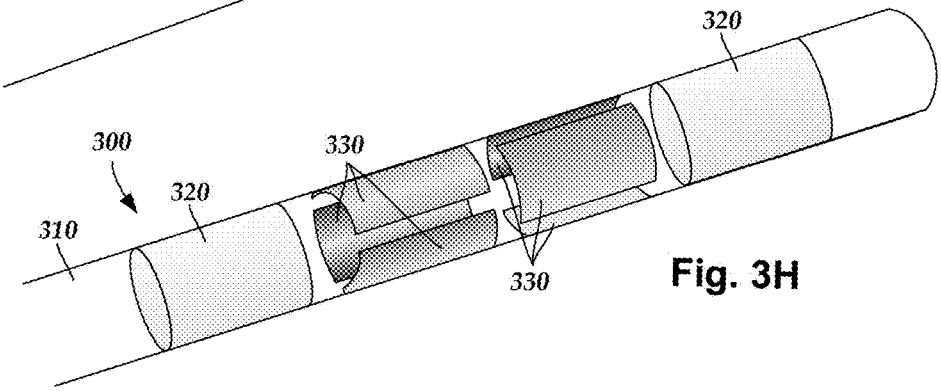


Fig. 3H

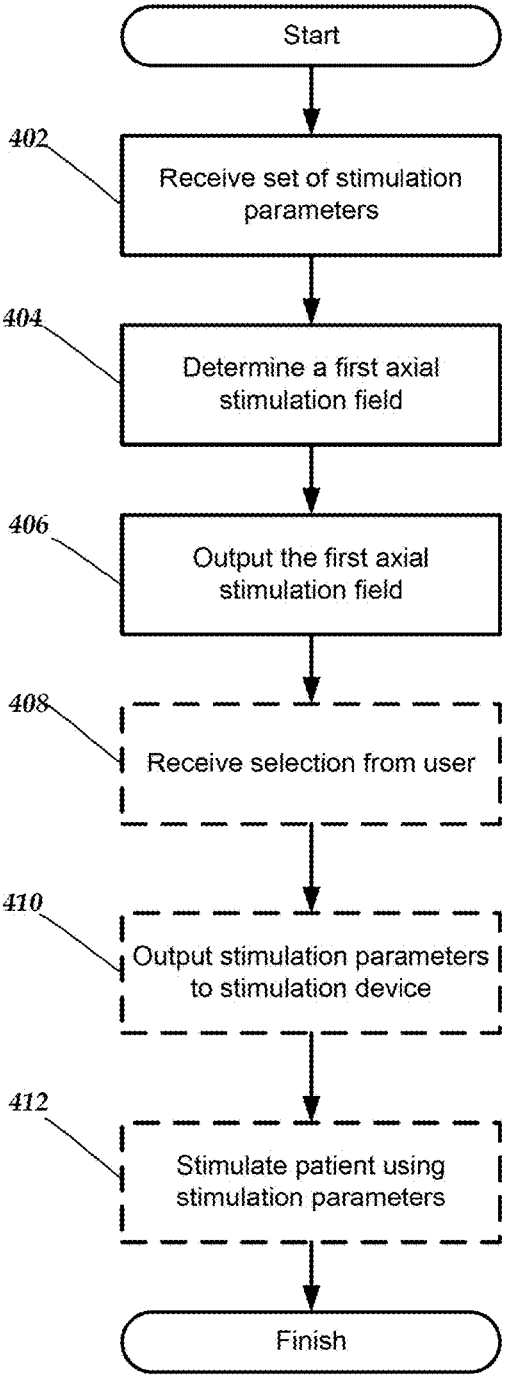

Start
402
Receive set of stimulation parameters
404
Determine a first axial stimulation field
406
Output the first axial stimulation field
408
Receive selection from user
410
Output stimulation parameters to stimulation device
412
Stimulate patient using stimulation parameters
Finish

Fig. 4

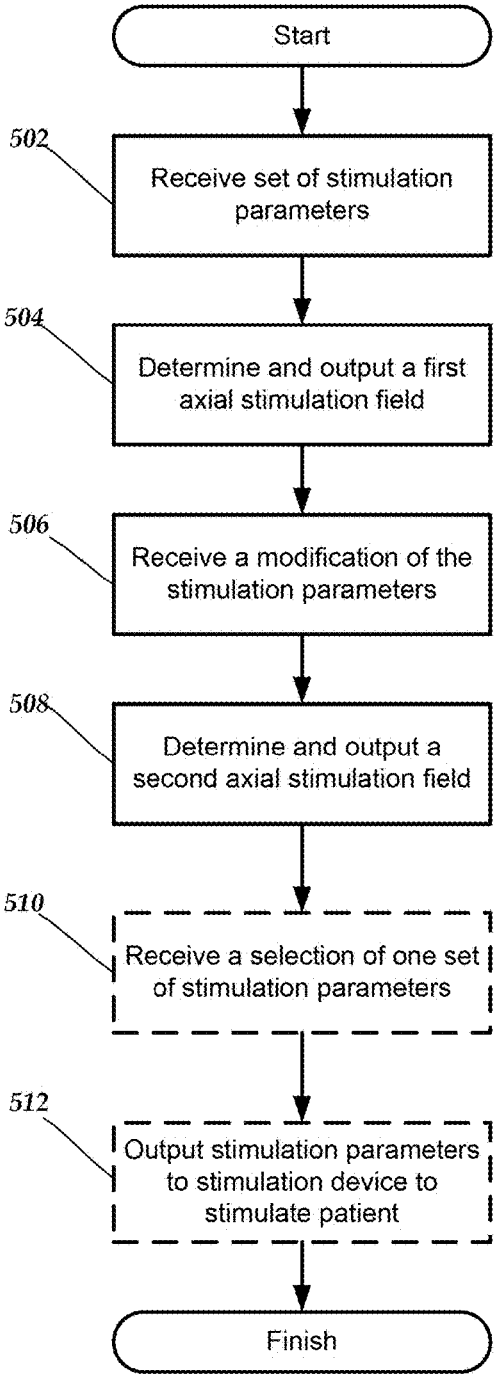

Start
502
Receive set of stimulation parameters
504
Determine and output a first axial stimulation field
506
Receive a modification of the stimulation parameters
508
Determine and output a second axial stimulation field
510
Receive a selection of one set of stimulation parameters
512
Output stimulation parameters to stimulation device to stimulate patient
Finish

Fig. 5

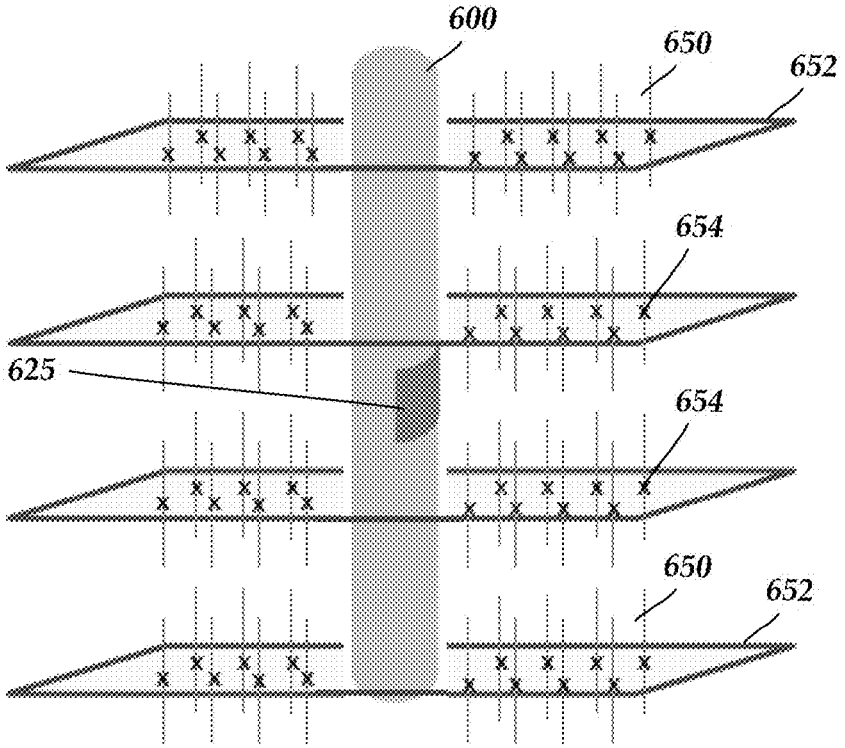

600
650
652
654
625
654
650
652

Fig. 6A

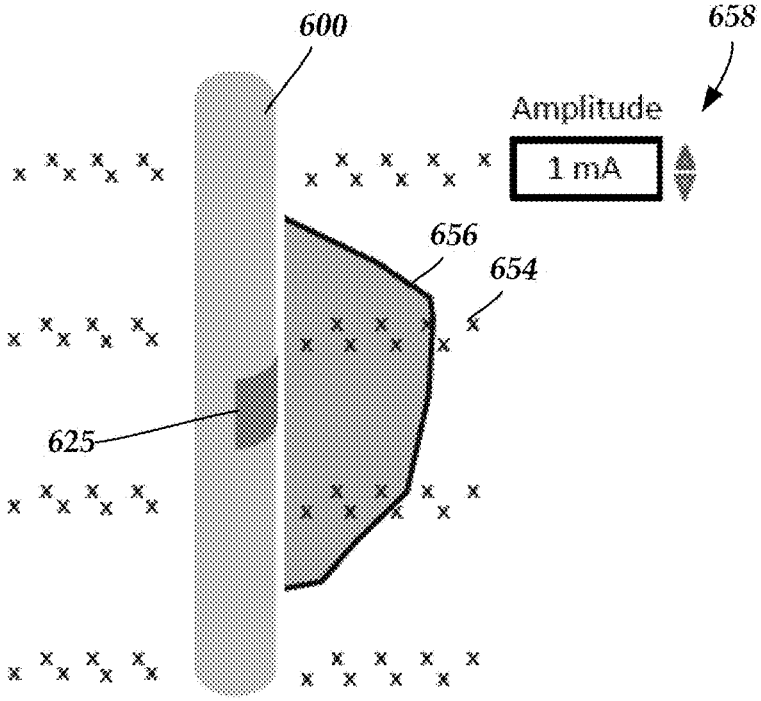

600
658
Amplitude
1 mA
656
654
625

Fig. 6B

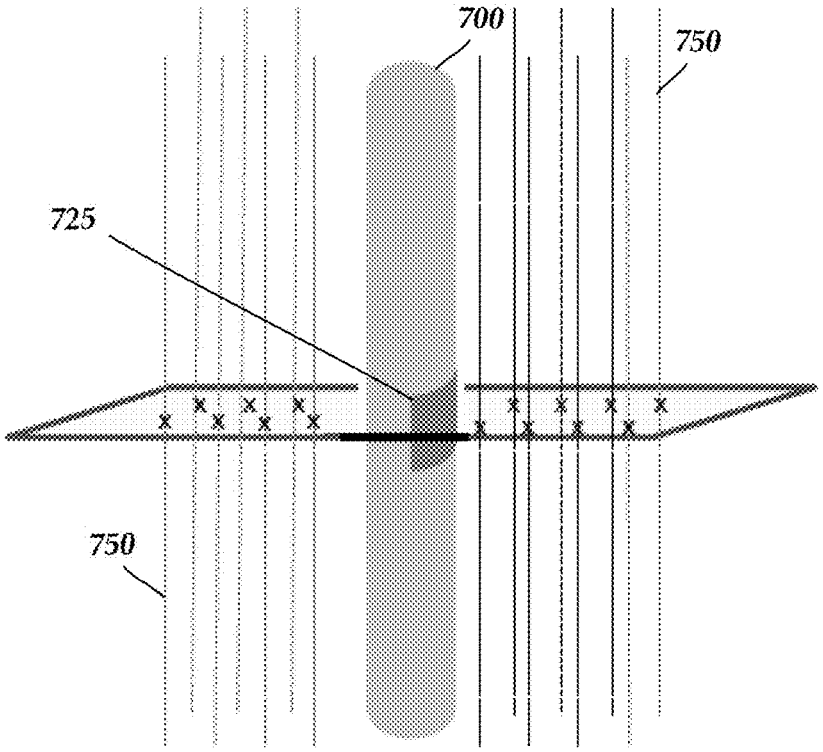


Fig. 7A

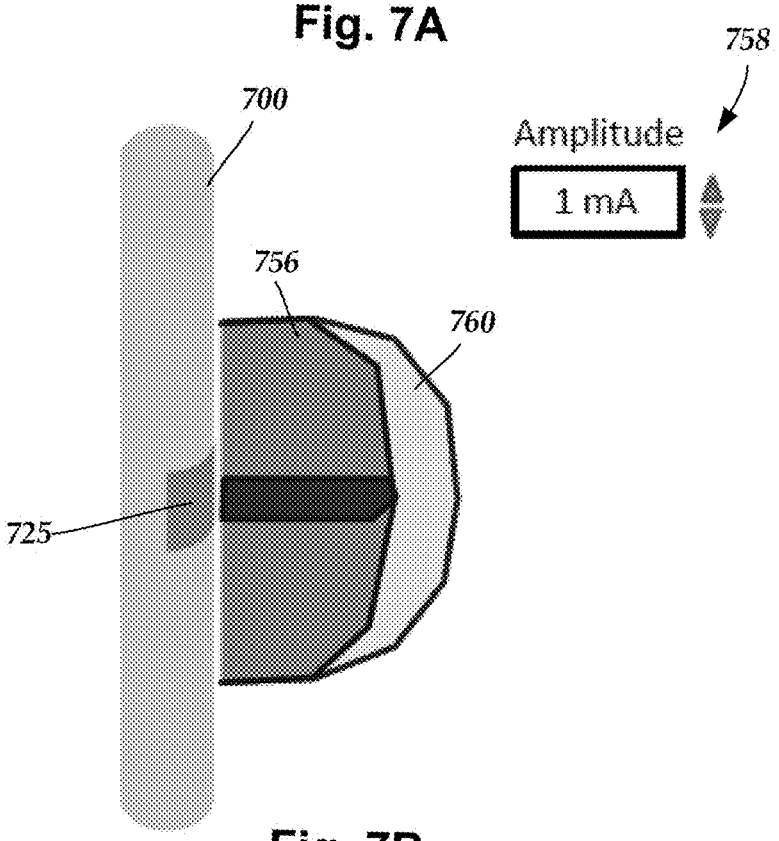


Fig. 7B

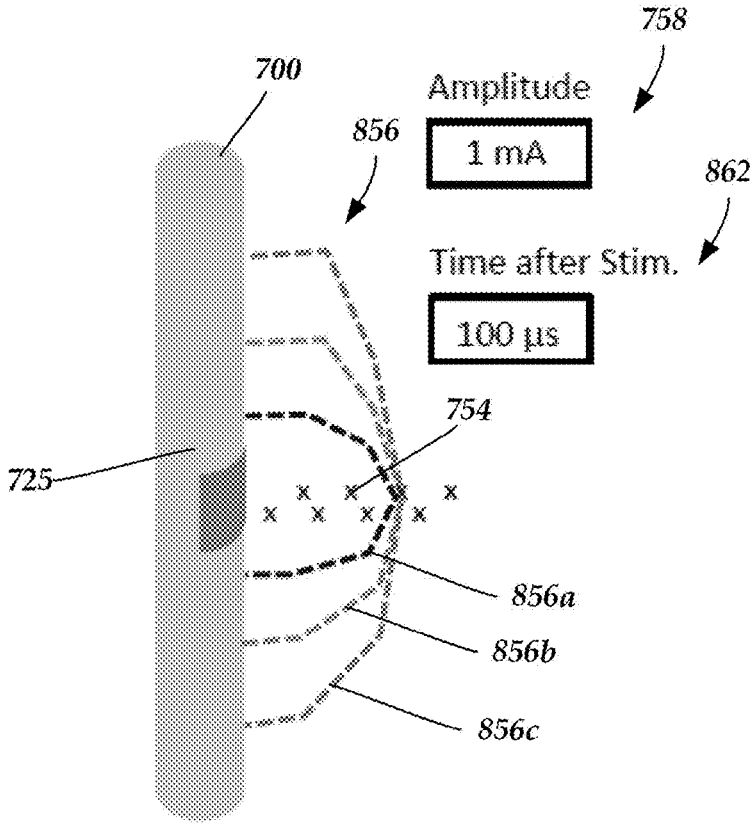

758
700
Amplitude
856
1 mA
862
Time after Stim.
100 µs
754
725
856a
856b
856c

Fig. 8

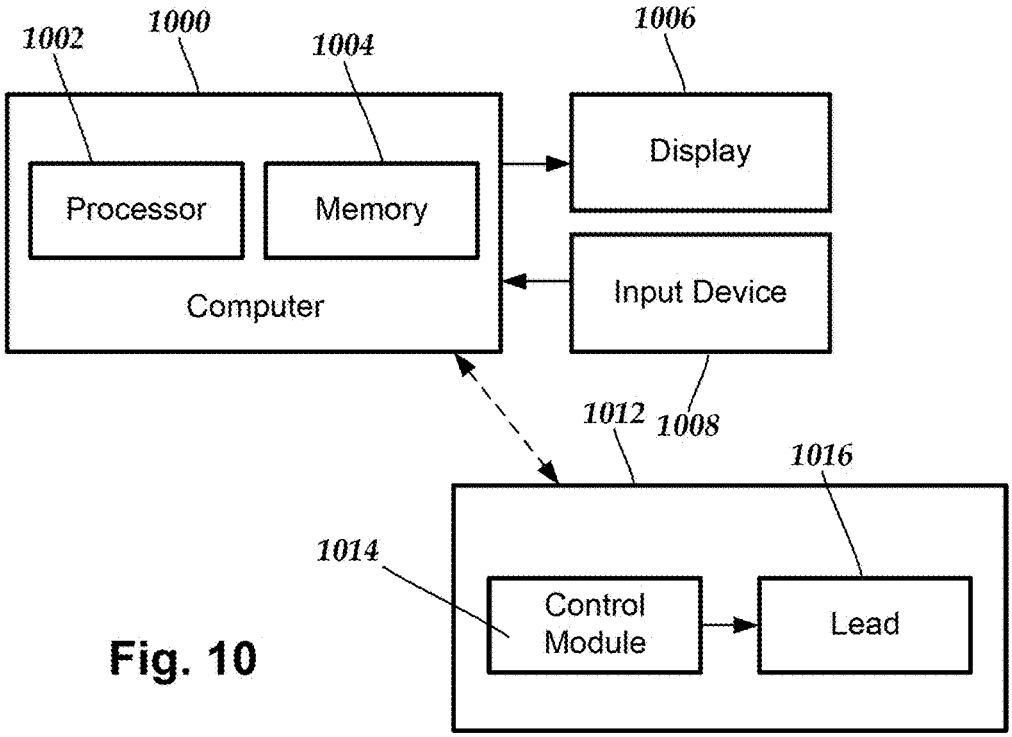

1002
1000
1004
1006
Processor
Memory
Display
Computer
Input Device
1012
1008
1016
1014
Control Module
Lead

Fig. 10

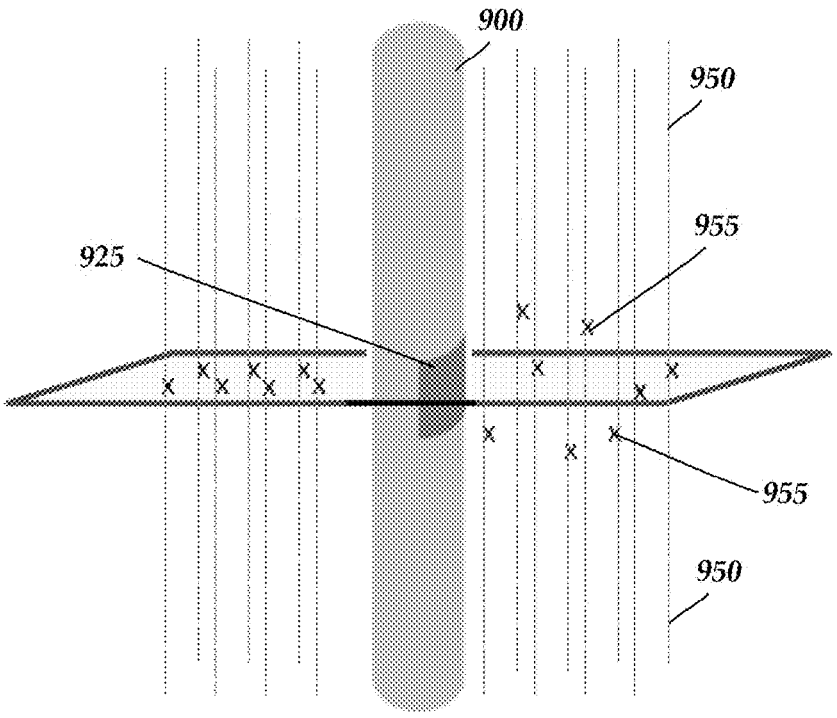


Fig. 9A

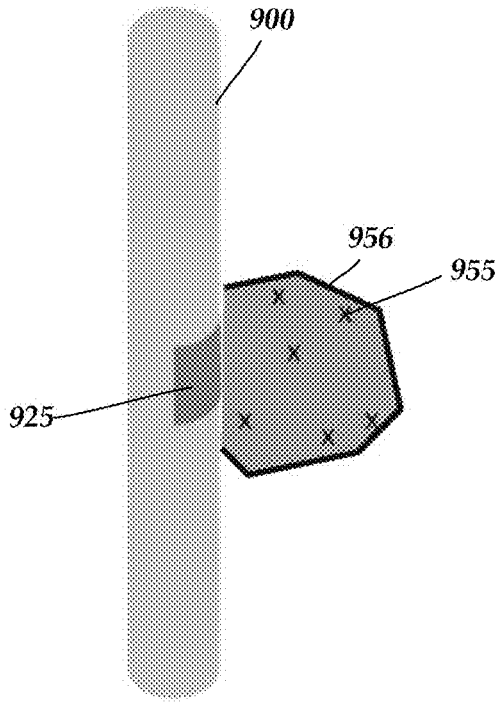


Fig. 9B

SYSTEMS AND METHODS FOR VISUALIZING AND DIRECTING STIMULATION OF NEURAL ELEMENTS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application Ser. No. 62/383,200, filed Sep. 2, 2016, which is incorporated herein by reference.

FIELD

[0002] The invention is directed to the area of electrical stimulation systems. The present invention is also directed to systems and methods for visualizing and directing electrical stimulation of neural elements, as well as methods of making and using systems.

BACKGROUND

[0003] Electrical stimulation can be useful for treating a variety of conditions. Deep brain stimulation can be useful for treating, for example, Parkinson's disease, dystonia, essential tremor, chronic pain, Huntington's disease, levodopa-induced dyskinesias and rigidity, bradykinesia, epilepsy and seizures, eating disorders, and mood disorders. Typically, a lead with a stimulating electrode at or near a tip of the lead provides the stimulation to target neurons in the brain. Magnetic resonance imaging ("MRI") or computerized tomography ("CT") scans can provide a starting point for determining where the stimulating electrode should be positioned to provide the desired stimulus to the target neurons.

[0004] After the lead is implanted into a patient's brain, electrical stimulus current can be delivered through selected electrodes on the lead to stimulate target neurons in the brain. The electrodes can be formed into rings or segments disposed on a distal portion of the lead. The stimulus current projects from the electrodes. Using segmented electrodes can provide directionality to the stimulus current and permit a clinician to steer the current to a desired direction and stimulation field.

BRIEF SUMMARY

[0005] One embodiment is a computer-implemented method for determining a set of stimulation parameters for an electrical stimulation lead. The method includes receiving, by a computer processor, a set of stimulation parameters including at least one electrode for delivery of stimulation and a stimulation amplitude for each electrode; determining, by the computer processor and using the set of stimulation parameters, a first axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead; and outputting, by the computer processor, the first axial stimulation field for viewing by a user. The method may also include receiving, by the computer processor, a modification of the set of stimulation parameters; determining, by the computer processor and using the modified set of stimulation parameters, a second axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead; outputting, by the computer processor, the second axial stimulation field for viewing by a user; receiving, by the computer processor, a selection of either the set of stimulation parameters or the modified set of stimulation parameters as a selected set of stimulation parameters; and outputting, by the computer processor, the selected set of stimulation parameters to be received by an electrical stimulation device for delivery of electrical stimulation to a patient via an electrical stimulation lead.

[0006] Another embodiment is a system for determining a set of stimulation parameters for an electrical stimulation lead. The system includes a display; and a computer processor coupled to the display and configured and arranged to perform the following actions: receiving a set of stimulation parameters including at least one electrode for delivery of stimulation and a stimulation amplitude for each electrode; determining, using the set of stimulation parameters, a first axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead; and outputting the first axial stimulation field for viewing by a user on the display. The actions may also include receiving a modification of the set of stimulation parameters; determining, using the modified set of stimulation parameters, a second axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead; outputting the second axial stimulation field for viewing by a user on the display; receiving a selection of either the set of stimulation parameters or the modified set of stimulation parameters as a selected set of stimulation parameters; and outputting the selected set of stimulation parameters to be received by an electrical stimulation device for delivery of electrical stimulation to a patient via an electrical stimulation lead. The system optionally includes an implantable lead and an implantable control module coupleable to the lead and configured and arranged to receive the set of stimulation parameters from the computer processor and to deliver electrical stimulation to a patient using the lead according to the set of stimulation parameters.

[0007] Yet another embodiment is a non-transitory computer-readable medium having processor-executable instructions for determining a set of stimulation parameters, the processor-executable instructions when installed onto a device enable the device to perform actions, including: receiving a set of stimulation parameters including at least one electrode for delivery of stimulation and a stimulation amplitude for each electrode; determining, using the set of stimulation parameters, a first axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead; and outputting the first axial stimulation field for viewing by a user. The actions may also include receiving a modification of the set of stimulation parameters; determining, using the modified set of stimulation parameters, a second axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead; outputting the second axial stimulation field for viewing by a user; receiving a selection of either the set of stimulation parameters or the modified set of stimulation parameters as a selected set of stimulation parameters; and outputting the selected set of stimulation parameters to be received by an electrical stimulation device for delivery of electrical stimulation to a patient via an electrical stimulation lead.

[0008] A further embodiment is a modification of the methods, systems, and computer-readable media described above where, instead of first and second axial stimulation fields for neural elements oriented axially with respect to a longitudinal axis of the lead, the methods, systems, and computer-readable media determine and output first and

second non-orthogonal stimulation fields for neural elements oriented non-orthogonally with respect to a longitudinal axis of the lead at a specified non-orthogonal angle or over a specified range of non-orthogonal angles.

[0009] In at least some embodiments, determining a first axial or non-orthogonal stimulation field includes selecting a plurality of planes orthogonal to the lead; modeling the neural elements as fixed length elements that intersect only one of the planes; and determining, for each plane and using the stimulation parameters, which of the fixed length elements intersecting the plane are activated using the stimulation parameters.

[0010] In at least some embodiments, determining a first axial or non-orthogonal stimulation field includes modeling the neural elements as extending axially or non-orthogonally relative to the lead; and determining, using the stimulation parameters, which of the neural elements are activated using the stimulation parameters. In at least some embodiments, the method, system, or computer-readable mediums further includes determining, by the computer processor, a time sequence of activation along the neural elements that are activated using the stimulation parameters and outputting, by the computer processor, the first axial or non-orthogonal stimulation field indicating different states of the first axial or non-orthogonal stimulation field over time based on the time sequence. In at least some embodiments, the method, system, or computer-readable mediums further includes receiving, by the computer processor, a time selection and outputting, by the computer processor, the first axial or non-orthogonal stimulation field at the time selection based on the time sequence.

[0011] In at least some embodiments, determining a first axial or non-orthogonal stimulation field includes modeling the neural elements as extending axially or non-orthogonally relative to the lead; and determining, using the stimulation parameters, which of the neural elements are activated using the stimulation parameters and at what point along each of the neural elements that that neural element is first activated.

[0012] In at least some embodiments, the method, system, or computer-readable mediums further includes determining, by the computer processor and using the set of stimulation parameters, a first transverse stimulation field for neural elements oriented orthogonal with respect to a longitudinal axis of the lead; and outputting, by the computer processor, the first transverse stimulation field for viewing by a user. In at least some embodiments, outputting the first axial or non-orthogonal stimulation field and outputting the first transverse stimulation field includes outputting the first axial or non-orthogonal stimulation field and first transverse stimulation field simultaneously. In at least some embodiments, the method, system, or computer-readable mediums further includes receiving, by the computer processor, a user command to toggle either the first axial or non-orthogonal stimulation field or first transverse stimulation field either on or off.

[0013] In at least some embodiments, receiving a modification of the set of stimulation parameters includes receiving a modified stimulation amplitude. In at least some embodiments, receiving a modification of the set of stimulation parameters includes receiving a modified selection of the at least one electrode for delivery of stimulation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] 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.

[0015] 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:

[0016] FIG. **1** is a schematic side view of one embodiment of a device for brain stimulation, according to the invention;

[0017] FIG. **2** is a schematic diagram of radial current steering along various electrode levels along the length of a lead, according to the invention;

[0018] FIG. **3**A is a perspective view of an embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0019] FIG. **3**B is a perspective view of a second embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0020] FIG. **3**C is a perspective view of a third embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0021] FIG. **3**D is a perspective view of a fourth embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0022] FIG. **3**E is a perspective view of a fifth embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0023] FIG. **3**F is a perspective view of a sixth embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0024] FIG. **3**G is a perspective view of a seventh embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0025] FIG. **3**H is a perspective view of an eighth embodiment of a portion of a lead having a plurality of segmented electrodes, according to the invention;

[0026] FIG. **4** is a schematic flowchart of one embodiment of a method of determining a set of stimulation parameters, according to the invention;

[0027] FIG. **5** is a schematic flowchart of another embodiment of a method of determining a set of stimulation parameters, according to the invention;

[0028] FIG. **6**A is a schematic illustration of one embodiment of a model for determining a stimulation field for neural elements arranged parallel to the lead, according to the invention;

[0029] FIG. **6**B is a schematic illustration of the stimulation field for the model of FIG. **6**A, according to the invention;

[0030] FIG. **7**A is a schematic illustration of one embodiment of another model for determining a stimulation field for neural elements arranged parallel to the lead, according to the invention;

[0031] FIG. **7**B is a schematic illustration of the stimulation field for the model of FIG. **7**A, according to the invention;

[0032] FIG. **8** is a schematic illustration of the stimulation field for the model of FIG. **7**A showing the propagation of the stimulation field over time, according to the invention;

[0033] FIG. **9**A is a schematic illustration of one embodiment of a third model for determining a stimulation field for neural elements arranged parallel to the lead, according to the invention;

[0034] FIG. **9**B is a schematic illustration of the stimulation field for the model of FIG. **9**A, according to the invention; and

[0035] FIG. **10** is a schematic illustration of one embodiment of a system for practicing the invention.

DETAILED DESCRIPTION

[0036] The invention is directed to the field of electrical stimulation systems. The present invention is also directed to systems and methods for visualizing and directing electrical stimulation of neural elements, as well as methods of making and using systems.

[0037] A lead for electrical stimulation can includes one or more stimulation electrodes. In at least some embodiments, one or more of the stimulation electrodes are provided in the form of segmented electrodes that extend only partially around the circumference of the lead. These segmented electrodes can be provided in sets of electrodes, with each set having electrodes radially 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, dorsal root ganglia stimulation, vagal nerve stimulation, basoreceptor stimulation, or stimulation of other nerves, organs, or tissues.

[0038] Suitable implantable electrical stimulation systems include, but are not limited to, at 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. Examples of electrical stimulation systems with leads are found in, for example, U.S. Pat. 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.

[0039] In at least some embodiments, a practitioner may determine the position of the target neurons using recording electrode(s) and then position the stimulation electrode(s) accordingly. In some embodiments, the same electrodes can be used for both recording and stimulation. In some embodiments, separate leads can be used; one with recording electrodes which identify target neurons, and a second lead with stimulation electrodes that replaces the first after target neuron identification. In some embodiments, the same lead can include both recording electrodes and stimulation electrodes or electrodes can be used for both recording and stimulation.

[0040] FIG. **1** illustrates one embodiment of a device **100** for electrical stimulation (for example, brain or spinal cord stimulation). The device includes a lead **110**, a plurality of electrodes **125** disposed at least partially about a circumference of the lead **110**, a plurality of terminals **135**, a connector **132** for connection of the electrodes to a control module, and a stylet **140** for assisting in insertion and positioning of the lead in the patient's brain. The stylet **140** can be made of a rigid material. Examples of suitable materials for the stylet include, but are not limited to, tungsten, stainless steel, and plastic. The stylet **140** may have a handle **150** to assist insertion into the lead **110**, as well as rotation of the stylet **140** and lead **110**. The connector **132** fits over a proximal end of the lead **110**, preferably after removal of the stylet **140**. The connector **132** can be part of a control module or can be part of an optional lead extension that is coupled to the control module.

[0041] The control module (for example, control module **1014** of FIG. **10**) can be an implantable pulse generator that can be implanted into a patient's body, for example, below the patient's clavicle area. The control module can have eight stimulation channels which may be independently programmable to control the magnitude of the current stimulus from each channel. In some cases, the control module can have more or fewer than eight stimulation channels (e.g., **4**-, **6**-, **16**-, **32**-, or more stimulation channels). The control module can have one, two, three, four, or more connector ports, for receiving the plurality of terminals **135** at the proximal end of the lead **110**. Examples of control modules are described in the references cited above.

[0042] In one example of operation, 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 the stylet **140**. 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**, retract the lead **110**, or rotate the lead **110**.

[0043] 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 control module 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.

[0044] 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.

[0045] Stimulation electrodes may be disposed on the circumference of the lead **110** to stimulate the target neu-

rons. 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**. Ring electrodes typically do not enable stimulus current to be directed from only a limited angular range around of the lead. Segmented electrodes, however, can be used to direct stimulation energy to a selected angular range around the lead. When segmented electrodes are used in conjunction with an implantable control module 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).

[0046] To achieve current steering, segmented electrodes can be utilized in addition to, or as an alternative to, ring electrodes. Though the following description discusses stimulation electrodes, it will be understood that all configurations of the stimulation electrodes discussed may be utilized in arranging recording electrodes as well. A lead that includes segmented electrodes can be referred to as a directional lead because the segmented electrodes can be used to direct stimulation along a particular direction or range of directions.

[0047] The lead **100** includes a lead body **110**, one or more optional ring electrodes **120**, and a plurality of sets of segmented electrodes **130**. 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.

[0048] The electrodes 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.

[0049] 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.

[0050] Stimulation electrodes in the form of ring electrodes **120** can be disposed on any part of the lead body **110**, usually near a distal end of the lead **100**. In FIG. **1**, the lead **100** includes two ring electrodes **120**. Any number of ring electrodes **120** can be disposed along the length of the lead body **110** including, for example, one, two three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen or more ring electrodes **120**. It will be understood that any number of ring electrodes can be disposed along the length of the lead body **110**. In some embodiments, the ring electrodes **120** are substantially cylindrical and wrap around the entire circumference of the lead body **110**. In some embodiments, the outer diameters of the ring electrodes **120** are substantially equal to the outer diameter of the lead body **110**. The length of the ring electrodes **120** may vary according to the desired treatment and the location of the target neurons. In some embodiments the length of the ring electrodes **120** are less than or equal to the diameters of the ring electrodes **120**. In other embodiments, the lengths of the ring electrodes **120** are greater than the diameters of the ring electrodes **120**. The distal-most ring electrode **120** may be a tip electrode (see, e.g., tip electrode **320***a* of FIG. **3**E) which covers most, or all, of the distal tip of the lead.

[0051] 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, 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 Applications Publication Nos. 2010/0268298; 2011/0005069; 2011/0078900; 2011/0130803; 2011/0130816; 2011/0130817; 2011/0130818; 2011/0078900; 2011/0238129; 2011/0313500; 2012/0016378; 2012/0046710; 2012/0071949; 2012/0165911; 2012/197375; 2012/0203316; 2012/0203320; 2012/0203321; 2013/0197602; 2013/0261684; 2013/0325091; 2013/0317587; 2014/0039587; 2014/0353001; 2014/0358209; 2014/0358210; 2015/0018915; 2015/0021817; 2015/0045864; 2015/0021817; 2015/0066120; 2013/0197424; 2015/0151113; 2014/0358207; and U.S. Pat. No. 8,483,237, all of which are incorporated herein by reference in their entireties. Examples of leads with tip electrodes include at least some of the previously cited references, as well as U.S. Patent Applications Publication Nos. 2014/0296953 and 2014/0343647, all of which are incorporated herein by reference in their entireties.

[0052] The lead **100** is shown having a plurality of segmented electrodes **130**. Any number of segmented electrodes **130** may be disposed on the lead body **110** including, for example, one, two three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen or more segmented electrodes **130**. It will be understood that any number of segmented electrodes **130** may be disposed along the length of the lead body **110**. A segmented electrode **130** typically extends only 75%, 67%, 60%, 50%, 40%, 33%, 25%, 20%, 17%, 15%, or less around the circumference of the lead.

[0053] The segmented electrodes **130** may be grouped into sets of segmented electrodes, where each set is disposed around a circumference of the lead **100** at a particular longitudinal portion of the lead **100**. The lead **100** may have any number segmented electrodes **130** in a given set of segmented electrodes. The lead **100** may have one, two, three, four, five, six, seven, eight, or more segmented electrodes **130** in a given set. In at least some embodiments, each set of segmented electrodes **130** of the lead **100** contains the same number of segmented electrodes **130**. The segmented electrodes **130** disposed on the lead **100** may

include a different number of electrodes than at least one other set of segmented electrodes **130** disposed on the lead **100**.

[0054] The segmented electrodes **130** may vary in size and shape. In some embodiments, the segmented electrodes **130** are all of the same size, shape, diameter, width or area or any combination thereof. In some embodiments, the segmented electrodes **130** of each circumferential set (or even all segmented electrodes disposed on the lead **100**) may be identical in size and shape.

[0055] Each set of segmented electrodes **130** may be disposed around the circumference of the lead body **110** to form a substantially cylindrical shape around the lead body **110**. The spacing between individual electrodes of a given set of the segmented electrodes may be the same, or different from, the spacing between individual electrodes of another set of segmented electrodes on the lead **100**. In at least some embodiments, equal spaces, gaps or cutouts are disposed between each segmented electrode **130** around the circumference of the lead body **110**. In other embodiments, the spaces, gaps or cutouts between the segmented electrodes **130** may differ in size or shape. In other embodiments, the spaces, gaps, or cutouts between segmented electrodes **130** may be uniform for a particular set of the segmented electrodes **130**, or for all sets of the segmented electrodes **130**. The sets of segmented electrodes **130** may be positioned in irregular or regular intervals along a length the lead body **110**.

[0056] Conductor wires that attach to the ring electrodes **120** or segmented electrodes **130** extend along the lead body **110**. These conductor wires may extend through the material of the lead **100** or along one or more lumens defined by the lead **100**, or both. The conductor wires couple the electrodes **120**, **130** to the terminals **135**.

[0057] When the lead **100** includes both ring electrodes **120** and segmented electrodes **130**, the ring electrodes **120** and the segmented electrodes **130** may be arranged in any suitable configuration. For example, when the lead **100** includes two ring electrodes **120** and two sets of segmented electrodes **130**, the ring electrodes **120** can flank the two sets of segmented electrodes **130** (see e.g., FIGS. **1**, **3**A, and **3**E-**3**H—ring electrodes **320** and segmented electrode **330**). Alternately, the two sets of ring electrodes **120** can be disposed proximal to the two sets of segmented electrodes **130** (see e.g., FIG. **3**C—ring electrodes **320** and segmented electrode **330**), or the two sets of ring electrodes **120** can be disposed distal to the two sets of segmented electrodes **130** (see e.g., FIG. **3**D—ring electrodes **320** and segmented electrode **330**). One of the ring electrodes can be a tip electrode (see, tip electrode **320***a* of FIGS. **3**E and **3**G). It will be understood that other configurations are possible as well (e.g., alternating ring and segmented electrodes, or the like).

[0058] By varying the location of the segmented electrodes **130**, different coverage of the target neurons may be selected. For example, the electrode arrangement of FIG. **3**C may be useful if the physician anticipates that the neural target will be closer to a distal tip of the lead body **110**, while the electrode arrangement of FIG. **3**D may be useful if the physician anticipates that the neural target will be closer to a proximal end of the lead body **110**.

[0059] Any combination of ring electrodes **120** and segmented electrodes **130** may be disposed on the lead **100**. For example, the lead may include a first ring electrode **120**, two sets of segmented electrodes; each set formed of four segmented electrodes **130**, and a final ring electrode **120** at the end of the lead. This configuration may simply be referred to as a 1-4-4-1 configuration (FIGS. **3**A and **3**E—ring electrodes **320** and segmented electrode **330**). It may be useful to refer to the electrodes with this shorthand notation. Thus, the embodiment of FIG. **3**C may be referred to as a 1-1-4-4 configuration, while the embodiment of FIG. **3**D may be referred to as a 4-4-1-1 configuration. The embodiments of FIGS. **3**F, **3**G, and **3**H can be referred to as a 1-3-3-1 configuration. Other electrode configurations include, for example, a 2-2-2-2 configuration, where four sets of segmented electrodes are disposed on the lead, and a 4-4 configuration, where two sets of segmented electrodes, each having four segmented electrodes **130** are disposed on the lead. The 1-3-3-1 electrode configuration of FIGS. **3**F, **3**G, and **3**H has two sets of segmented electrodes, each set containing three electrodes disposed around the circumference of the lead, flanked by two ring electrodes (FIGS. **3**F and **3**H) or a ring electrode and a tip electrode (FIG. **3**G). In some embodiments, the lead includes 16 electrodes. Possible configurations for a 16-electrode lead include, but are not limited to 4-4-4-4; 8-8; 3-3-3-3-3-1 (and all rearrangements of this configuration); and 2-2-2-2-2-2-2-2.

[0060] FIG. **2** is a schematic diagram to illustrate radial current steering along various electrode levels along the length of the lead **200**. While conventional lead configurations with ring electrodes are only able to steer current along the length of the lead (the z-axis), the segmented electrode configuration is capable of steering current in the x-axis, y-axis as well as the z-axis. Thus, the centroid of stimulation may be steered in any direction in the three-dimensional space surrounding the lead **200**. In some embodiments, the radial distance, r, and the angle θ around the circumference of the lead **200** may be dictated by the percentage of anodic current (recognizing that stimulation predominantly occurs near the cathode, although strong anodes may cause stimulation as well) introduced to each electrode. In at least some embodiments, the configuration of anodes and cathodes along the segmented electrodes allows the centroid of stimulation to be shifted to a variety of different locations along the lead **200**.

[0061] As can be appreciated from FIG. **2**, the stimulation can be shifted at each level along the length L of the lead **200**. The use of multiple sets of segmented electrodes at different levels along the length of the lead allows for three-dimensional current steering. In some embodiments, the sets of segmented electrodes are shifted collectively (i.e., the centroid of simulation is similar at each level along the length of the lead). In at least some other embodiments, each set of segmented electrodes is controlled independently. Each set of segmented electrodes may contain two, three, four, five, six, seven, eight or more segmented electrodes. It will be understood that different stimulation profiles may be produced by varying the number of segmented electrodes at each level. For example, when each set of segmented electrodes includes only two segmented electrodes, uniformly distributed gaps (inability to stimulate selectively) may be formed in the stimulation profile. In some embodiments, at least three segmented electrodes in a set are utilized to allow for true 360° selectivity.

[0062] Turning to FIGS. **3**A-**3**H, when the lead **300** includes a plurality of sets of segmented electrodes **330**, it may be desirable to form the lead **300** such that correspond-

ing electrodes of different sets of segmented electrodes **330** are radially aligned with one another along the length of the lead **300** (see e.g., the segmented electrodes **330** shown in FIGS. **3**A and **3**C-**3**G). Radial alignment between corresponding electrodes of different sets of segmented electrodes **330** along the length of the lead **300** may reduce uncertainty as to the location or orientation between corresponding segmented electrodes of different sets of segmented electrodes. Accordingly, it may be beneficial to form electrode arrays such that corresponding electrodes of different sets of segmented electrodes along the length of the lead **300** are radially aligned with one another and do not radially shift in relation to one another during manufacturing of the lead **300**.

[0063] In other embodiments, individual electrodes in the two sets of segmented electrodes **330** are staggered (see, FIG. **3**H) relative to one another along the length of the lead body **310**. In some cases, the staggered positioning of corresponding electrodes of different sets of segmented electrodes along the length of the lead **300** may be designed for a specific application.

[0064] Segmented electrodes can be used to tailor the stimulation region so that, instead of stimulating tissue around the circumference of the lead as would be achieved using a ring electrode, the stimulation region can be directionally targeted. In some instances, it is desirable to target a parallelepiped (or slab) region **250** that contains the electrodes of the lead **200**, as illustrated in FIG. **2**. One arrangement for directing a stimulation field into a parallelepiped region uses segmented electrodes disposed on opposite sides of a lead.

[0065] FIGS. **3**A-**3**H illustrate leads **300** with segmented electrodes **330**, optional ring electrodes **320** or tip electrodes **320***a*, and a lead body **310**. The sets of segmented electrodes **330** each include either two (FIG. **3**B), three (FIGS. **3**E-**3**H), or four (FIGS. **3**A, **3**C, and **3**D) or any other number of segmented electrodes including, for example, three, five, six, or more. The sets of segmented electrodes **330** can be aligned with each other (FIGS. **3**A-**3**G) or staggered (FIG. **3**H)

[0066] Any other suitable arrangements of segmented electrodes can be used. As an example, arrangements in which segmented electrodes are arranged helically with respect to each other. One embodiment includes a double helix.

[0067] In at least some instances, a treating physician may wish to tailor the stimulation parameters (such as which one or more of the stimulating electrode contacts to use, the stimulation pulse amplitude (such as current or voltage amplitude depending on the stimulator being used,) the stimulation pulse width, the stimulation frequency, or the like or any combination thereof) for a particular patient to improve the effectiveness of the therapy. Electrical stimulation systems can provide an interface that facilitates parameter selections. Examples of such systems and interfaces can be found in, for example, U.S. patent applications Ser. Nos. 12/454,330; 12/454,312; 12/454,340; 12/454,343; and 12/454,314 and U.S. Patent Application Publication No. 2014/0277284, all of which are incorporated herein by reference in their entireties.

[0068] Conventional electrical stimulation (such as deep brain or spinal cord stimulation) can include a programming procedure that is often performed in an initial session and, in at least some instances, at later sessions. The procedure can involve, for example, testing different sets of stimulation parameters (which can include variations in the electrodes that are selected as well as different electrical parameters such as amplitude, duration, pulse frequency, and the like) and annotating when there is a beneficial therapeutic effect or an unwanted side effect. In at least some embodiments, the clinician performs a monopolar review testing each electrode individually and recording therapeutic/beneficial effects and side effects for each electrode on the lead corresponding to different values of the stimulation amplitude or other stimulation parameters. The clinician may also perform bipolar or multipolar reviews using two or more electrodes.

[0069] In contrast to these conventional methods, stimulation region visualization systems and methods can be used to predict or estimate a region of stimulation for a given set of stimulation parameters. In at least some embodiments, the systems and methods further permit a user to modify stimulation parameters and visually observe how such modifications can change the predicted or estimated stimulation region. Such algorithms and systems may provide greater ease of use and flexibility and may enable or enhance stimulation therapy. The terms "stimulation field map" (SFM) and "volume of activation" (VOA) 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 can be used including those described in, for example, U.S. Pat. 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 Ser. No. 62/030,655, all of which are incorporated herein by reference.

[0070] Neural elements (e.g., neural fibers, axons, or the like) can be arranged at any angle with respect to the lead including, but not limited to, both perpendicular or parallel to the longitudinal axis of the lead. At least some visualization methods and systems only determine the activation of neural elements that are transverse (i.e., perpendicular or orthogonal) to the longitudinal axis of the lead. Neural elements, such as axons or presynaptic terminals, are referred to in the discussion below, but it will be recognized that other anatomic features, such as cell bodies or the like can be featured in place of the neural elements.

[0071] One example of an activating function that can be employed to approximate the neural element response to electrical stimulation is a second difference of the extracellular potential distribution along a neural element (for example, $\partial^2 V/\partial x^2$ or approximations of this quantity for neural elements such as axons), where V represents the potential along the neural element and x represents a position along the neural element. The second difference provides a quantitative estimate of the polarization of the axon in response to an applied electric field. Another example of a neural element is a presynaptic terminal where likelihood of activation, at least in some instances, is proportional to $\partial V/\partial x$ (e.g., the first derivative of voltage along a direction of propagation in the parent axon) or approximations of this quantity. Combinations of these two quantities or other parameters may be used as well.

[0072] The methods and systems described herein, however, are directed to determining the stimulation region for neural elements that are arranged parallel to the longitudinal axis of the lead or at a non-orthogonal angle (for example,

an angle less than 90 degrees or an angle in a range of 0 to 80 degrees or 0 to 75 degrees or 0 to 45 degrees or 45 to 80 degrees) relative to the longitudinal axis. In particular, in at least some embodiments, the present methods and systems utilize one of several models to represent such neural elements.

[0073] FIG. **4** illustrates one embodiment of a method for determining an axial stimulation field and for providing stimulation parameters to a stimulation device to treat a patient. In step **402**, a set of stimulation parameters is received. Examples of stimulation parameters that can be received include, but are not limited to, selection of one or more electrodes of a lead to provide the stimulation, a stimulation amplitude for each of the selected electrodes (or a total stimulation amplitude or uniform stimulation amplitude), pulse duration, pulse width, pulse pattern, and the like. In at least some embodiments, the set of stimulation parameters include an identification of at least one electrode for stimulation and a stimulation amplitude for each of the electrodes. The stimulation amplitude may also indicate the polarity of the electrode (e.g., whether the electrode is an anode or cathode) to the polarity may be provided separately. The set of stimulation parameters can be received from a user, such as a clinician or patient; or can be generated by, for example, an electrical stimulation system, clinician programmer, patient programmer, or other device; or can be received from a database or other source of stimulation parameters. Any other suitable method or arrangement for receiving the set of stimulation parameters can also be used.

[0074] In step **404**, an axial stimulation field is determined. The axial stimulation field is the region around the electrodes where axially oriented neural elements (i.e., neural elements oriented parallel to the longitudinal axis of the lead) are activated using the received stimulation parameters. A number of models for the axially oriented neural elements are presented below to facilitate the determination. In addition, any suitable method can be used for determining the potential or electrical field generated around the lead using the received stimulation parameters. The selected model and the determined potential or electrical field can then be used to determine the region in which axially oriented neural elements will be activated using the received stimulation parameters. For example, the stimulation field can be determined using SFM or VOA techniques. Alternatively or additionally, a stimulation field for neural elements at another non-orthogonal angle or a range of angles can be determined; in which case, reference to the "axial stimulation field" in the description of the remainder of the steps should be replace with this determined stimulation field.

[0075] In step **406**, the axial stimulation field is output for viewing by the user. For example, the axial stimulation field can be displayed with a model of the distal portion of the lead. In at least some embodiments, the electrode(s) that are to be used for stimulation (or all of the electrodes) are also displayed on the model. As described in more detail below, the display may also include at least some of the stimulation parameters and may also include controls for changing one or more of the stimulation parameters or for modifying the axial stimulation field. In addition, as described in more detail below, the display may also display a transverse stimulation field that is determined, using the stimulation parameters, for neural elements oriented transversely (e.g., perpendicularly) to the longitudinal axis of the lead. Alternatively or additionally, the display may also display one or more non-orthogonal stimulation fields for neural elements oriented at one or more different non-orthogonal angles (or angle ranges) relative to the longitudinal axis of the lead.

[0076] In optional step **408**, the user may select the stimulation parameters for stimulating a patient. In optional step **410**, those stimulation parameters may be output to a stimulation device, such as the control module described above, using, for example, wired or wireless communication. In optional step **412**, the stimulation device can stimulate the patient using an attached lead with electrodes and the selected stimulation parameters.

[0077] FIG. **5** illustrates another embodiment of a method for determining an axial stimulation field and for providing stimulation parameters to a stimulation device to treat a patient. In step **502**, a set of stimulation parameters is received. Examples of stimulation parameters that can be received include, but are not limited to, selection of one or more electrodes of a lead to provide the stimulation, a stimulation amplitude for each of the selected electrodes (or a total stimulation amplitude or uniform stimulation amplitude), pulse duration, pulse width, pulse pattern, and the like. In at least some embodiments, the set of stimulation parameters include an identification of at least one electrode for stimulation and a stimulation amplitude for each of the electrodes. The stimulation amplitude may also indicate the polarity of the electrode (e.g., whether the electrode is an anode or cathode) to the polarity may be provided separately. The set of stimulation parameters can be received from a user, such as a clinician or patient; or can be generated by, for example, an electrical stimulation system, clinician programmer, patient programmer, or other device; or can be received from a database or other source of stimulation parameters. Any other suitable method or arrangement for receiving the set of stimulation parameters can also be used.

[0078] In step **504**, a first axial stimulation field is determined. The first axial stimulation field is the region around the electrodes where axially oriented neural elements (i.e., neural elements oriented parallel to the longitudinal axis of the lead) are activated using the received stimulation parameters. A number of models for the axially oriented neural elements are presented below to facilitate the determination. In addition, any suitable method can be used for determining the potential or electrical field generated around the lead using the received stimulation parameters. The selected model and the determined potential or electrical field can then be used to determine the region in which axially oriented neural elements will be activated using the received stimulation parameters. Alternatively or additionally, a first stimulation field for neural elements at another non-orthogonal angle or a range of angles can be determined; in which case, reference to the "first axial stimulation field" in the description of the remainder of the steps should be replace with this determined first stimulation field.

[0079] Optionally, in step **504**, the first axial stimulation field is output for viewing by the user. For example, the first axial stimulation field can be displayed with a model of the distal portion of the lead. In at least some embodiments, the electrode(s) that are to be used for stimulation (or all of the electrodes) are also displayed on the model. As described in more detail below, the display may also include at least some of the stimulation parameters and may also include controls for changing one or more of the stimulation parameters or

for modifying the first axial stimulation field. In addition, as described in more detail below, the display may also display a transverse stimulation field that is determined, using the stimulation parameters, for neural elements oriented transversely (e.g., perpendicularly) to the longitudinal axis of the lead. Alternatively or additionally, the display may also display one or more non-orthogonal stimulation fields for neural elements oriented at one or more different non-orthogonal angles (or angle ranges) relative to the longitudinal axis of the lead.

[0080] In step **506**, a modification of the stimulation parameters is received. For example, a user may modify one or more of the stimulation parameters through a user interface or the system may automatically or, when requested, modify one or more of the stimulation parameters. In some embodiments, the user can input a new value for one or more stimulation parameters or may use sliders, buttons (for example, increasing or decreasing buttons), or other controls on the user interface to modify or otherwise alter one or more stimulation parameters. For example, the user may increase or decrease a stimulation amplitude, pulse duration, pulse pattern, or the like or select one or more different electrodes for providing the stimulation or any other suitable change to the stimulation parameters.

[0081] In step **508**, a second axial stimulation field is determined using the modified stimulation parameters. Optionally, in step **508**, the second axial stimulation field is output for viewing by the user. In some embodiments, the second axial stimulation field is displayed simultaneously with the first axial stimulation field in separate display regions or overlaid in the same display region. Alternatively or additionally, a second stimulation field for neural elements at another non-orthogonal angle or a range of angles can be determined; in which case, reference to the "second axial stimulation field" in the description of the remainder of the steps should be replace with this determined second stimulation field.

[0082] Steps **506** and **508** can be performed multiple times to produce additional axial stimulation fields. In optional step **510**, the user can select one of the sets of stimulation parameters. Alternatively, the system can select set of stimulation parameters automatically based on one or more criteria, such as, for example, a fit to a target stimulation region. In optional step **512**, the selected stimulation parameters may be output to a stimulation device, such as the control module described above, using, for example, wired or wireless communication. In optional step **512**, the stimulation device can stimulate the patient using an attached lead with electrodes and the selected stimulation parameters.

[0083] It will be understood that the methods described with respect to FIGS. **4** and **5** can be performed multiple times to produce multiple axial stimulation fields. In some embodiments, a user may select from among the multiple axial stimulation fields and corresponding sets of stimulation parameters to obtain a set of stimulation parameters to output to the stimulation device to stimulate the patient.

[0084] In order to determine the axial stimulation field, a model of the axial neural elements is constructed. FIG. **6**A illustrates a model of the distal end of a lead **600** with a stimulating electrode **625**. The neural elements **650** are modeled as short cylinders that are each fixed on one of multiple slices **652** orthogonal to the lead **600**. In some embodiments, the neural elements **650** are centered on the respective slices **652**. In at least some embodiments, each neural element **650** intersects only one slice **652**.

[0085] In at least some embodiments, to determine which neural elements **650** are activated, the stimulation parameters are used to determine the electric field. The electric field at the region **654** for each neural element **650** that intersects the corresponding slice **652** is investigated along the neural element to determine whether that particular neural element is activated or not. As an example, the second difference of the extracellular potential distribution (for example, $\partial^2V/\partial x^2$, $\partial V/\partial x$, or approximations or any combinations of these quantities, where V represents the potential along the neural element and x represents positions along the neural element) of the neural element **650** can be determined along the neural element and, if it meets or exceeds a threshold value, the neural element **650** is activated; if not, the neural element is not activated.

[0086] The composite activated neural elements **650** from each slice **652** are then used to form the axial stimulation field **656**, as illustrated in FIG. **6**B, where the regions **654** of the neural elements **650** within the axial stimulation field **656** are activated and those outside the axial stimulation field **656** are not activated. FIG. **6**B also illustrates one embodiment of a control **658** (in this case, up and down areas and a box containing the parameter value) for altering a stimulation parameter, such as the stimulation amplitude, pulse width, pulse frequency, or the like. As described above, when the stimulation parameter is modified, the illustrated axial stimulation field **656** can be updated in view of the modified stimulation parameter.

[0087] FIG. **7**A illustrates the distal end of a lead **700** with a stimulating electrode **725**. In this embodiment, the neural elements **750** are modeled as long cylinders orthogonal to the lead **700**. In at least some embodiments, to determine which neural elements **750** are activated, the stimulation parameters are used to determine the electric field along neural elements **750**. As an example, the second difference of the extracellular potential distribution (for example, $\partial^2V/\partial x^2$, $\partial V/\partial x$, or approximations or any combinations of these quantities, where V represents the potential along the neural element and x represents positions along the neural element) of the neural element **750** can be determined and, if it meets or exceeds a threshold value, the neural element **750** is activated; if not, the neural element is not activated.

[0088] The composite activated neural elements **750** are then used to form the axial stimulation field **756**, as illustrated in FIG. **7**B, where the neural elements **750** within the axial stimulation field **756** are activated and those outside the axial stimulation field **756** are not activated. FIG. **7**B also illustrates one embodiment of a control **758** (in this case, up and down areas and a box containing the parameter value) for altering a stimulation parameter, such as the stimulation amplitude, pulse width, pulse frequency, or the like. As described above, when the stimulation parameter is modified, the illustrated axial stimulation field **756** can be updated in view of the modified stimulation parameter. FIG. **7**B also illustrates that a transverse stimulation field **760** can be determined, using, for example, conventional SFM or VOA calculations for transverse neural elements, and displayed together with the axial stimulation field **756**. It will be understood that the transverse stimulation field can also be determined and displayed for the embodiment illustrated in FIG. **6**B.

[0089] It will be understood that the stimulation fields illustrated in FIGS. **6**B and **7**B are actually two-dimensional cross-sections of the stimulation fields. In other embodiments, an interface may display a representation that portrays a three-dimensional stimulation field or allow for selection of different two-dimensional cross-sections of the stimulation field.

[0090] In some embodiments, the user interface may also permit the user to switch between displaying both the axial and transverse stimulation field; only the axial stimulation field; or only the transverse stimulation field. The user interface may also present or allow the user to select a display that is a combination (e.g., union) or intersection of the axial and transverse stimulation fields. Color, shading, or the like may be used to distinguish between different stimulation fields. In some embodiments, the interface may also, or alternatively, display one or more additional non-orthogonal stimulation fields and, optionally, any combinations or intersections of the displayed or determined axial, transverse, or non-orthogonal stimulation fields.

[0091] FIG. **8** illustrates another display that utilizes the model described with respect to FIG. **7**A and adds a temporal dimension by considering the time of propagation of the action potential along the neural element **750** from the region **754** of initial activation. FIG. **8** illustrates the axial stimulation field at three different times corresponding to axial stimulation fields **856***a*, **856***b*, **856***c*, respectively. In at least some embodiments, the higher the electrical field at the activation region **764**, the faster the neural element **750** will activate and the action potential will propagate. In at least some embodiments, the higher the electrical field at the activation region **754**, the longer the portion of the neural element **750** that will be activated. FIG. **8** also illustrates a control **862** that may be used to select a time after initiation of stimulation for display of the corresponding axial propagation field **856**. In some embodiments, the user interface may also include a control that the user can operate to view a time progression of the axial stimulation field **856**. In some embodiments, the user interface may permit the user to select multiple times and the user will display the axial stimulation fields **856***a*, **856***b*, **856***c* at those different times in the same display region or different display regions. In some embodiments, the time that can be selected represents the time between firing of adjacent nodes of the neural elements.

[0092] FIG. **9**A illustrates the distal end of a lead **900** with a stimulating electrode **925**. In this embodiment, the neural elements **950** are modeled as long cylinders that are orthogonal to the lead **900**. In at least some embodiments, to determine which neural elements **950** are activated, the stimulation parameters are used to determine the electric field in the region adjacent to the lead **900**. Each neural element **950** is investigated to determine at what point that particular neural element is first activated, as represented by an "x" **955**. As an example, the second difference of the extracellular potential distribution (for example, $\partial^2V/\partial x^2$, $\partial V/\partial x$, or approximations or any combinations of these quantities, where V represents the potential along the neural element and x represents positions along the neural element) of the neural element **950** can be determined in the region adjacent the lead **900** and, if it meets or exceeds a threshold value, along that region the neural element **950** is activated; if not, the neural element is not activated. In at least some embodiments, the time evolution of the electric field, based on the stimulation parameters, is used to determine the first point **955** at which each neural element **950** is activated.

[0093] In at least some embodiments, when an axon is activated, some nodes are activated by the stimulation pulse, and others are activated by the normal course of the activation moving along the axon. Analysis of the difference in the activation times of adjacent nodes can, at least in some instances, produce a determination whether a particular node was activated as a direct result of the stimulation pulse, or if it was activated by the normal course of activation progressing along the axon. In at least some embodiments, when the times of activation of the nodes are determined, a volume of activation can be constructed by using the nodes for which the time difference in activation shows that the activation is the result of stimulation. In at least some embodiments, an activation threshold is defined as the amplitude at which the nearest node fires after the test node has fired with a time difference of less than the propagation delay.

[0094] The composite activated neural elements **950** are then used to form the axial stimulation field **956**, as illustrated in FIG. **9**B, where the regions **954** of the neural elements **950** within the axial stimulation field **956** are activated and those outside the axial stimulation field **956** are not activated. In at least some embodiments, the user interface may also include a control for altering a stimulation parameter, such as the stimulation amplitude, or altering a time during or after the stimulation. As described above, when the stimulation parameter or time is modified, the illustrated axial stimulation field **956** can be updated in view of the modified stimulation parameter. In some embodiments, the time progression of the axial stimulation field can be illustrated as described above with respect to FIG. **8**.

[0095] The models illustrated above in FIGS. **6**A-**9**B have been described relative to modeling axial neural elements and axial stimulation fields. It will be recognized that these same models can be modified using non-orthogonal neural elements to determine non-orthogonal stimulation fields.

[0096] FIG. **10** illustrates one embodiment of a system for practicing the invention. The system can include a computer **1000** or any other similar device that includes a processor **1002** and a memory **1004**, a display **1006**, an input device **1008**, and, optionally, the electrical stimulation system **1012**.

[0097] The computer **1000** can be a laptop computer, desktop computer, tablet, mobile device, smartphone or other devices that can run applications or programs, or any other suitable device for processing information and for presenting a user interface (such as the user interfaces of FIGS. **5**A, **5**B, **6**A-**6**C, **9**, and **10**). The computer can be, for example, a clinician programmer, patient programmer, or remote programmer for the electrical stimulation system **1012**. The computer **1000** can be local to the user or can include components that are non-local to the user including one or both of the processor **1002** or memory **1004** (or portions thereof). For example, in some embodiments, the user may operate a terminal that is connected to a non-local computer. In other embodiments, the memory can be non-local to the user.

[0098] The computer **1000** can utilize any suitable processor **1002** including one or more hardware processors that may be local to the user or non-local to the user or other components of the computer. The processor **1002** is configured to execute instructions provided to the processor, as described below.

[0099] Any suitable memory **1004** can be used for the computer **1002**. The memory **1004** 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 computer.

[0100] 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.

[0101] The display **1006** can be any suitable display device, such as a monitor, screen, display, or the like, and can include a printer. The input device **1008** can be, for example, a keyboard, mouse, touch screen, track ball, joystick, voice recognition system, or any combination thereof, or the like and can be used by the user to interact with a user interface or clinical effects map.

[0102] The electrical stimulation system **1012** can include, for example, a control module **1014** (for example, an implantable pulse generator) and a lead **1016** (for example, the lead illustrated in FIG. **1**.) The electrical stimulation system **1012** may communicate with the computer **1000** through a wired or wireless connection or, alternatively or additionally, a user can provide information between the electrical stimulation system **1012** and the computer **1000** using a computer-readable medium or by some other mechanism. In some embodiments, the computer **1000** may include part of the electrical stimulation system.

[0103] 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 (e.g., 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.

[0104] 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.

[0105] 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 computer.

[0106] The above specification and examples data provide a description 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.

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

1. A computer-implemented method for determining a set of stimulation parameters for an electrical stimulation lead, the method comprising:

receiving, by a computer processor, a set of stimulation parameters comprising at least one electrode for delivery of stimulation and a stimulation amplitude for each of the at least one electrode;

determining, by the computer processor and using the set of stimulation parameters, a first axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead;

outputting, by the computer processor, the first axial stimulation field for viewing by a user;

receiving, by the computer processor, a modification of the set of stimulation parameters;

determining, by the computer processor and using the modified set of stimulation parameters, a second axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead;

outputting, by the computer processor, the second axial stimulation field for viewing by a user;

receiving, by the computer processor, a selection of either the set of stimulation parameters or the modified set of stimulation parameters as a selected set of stimulation parameters; and

outputting, by the computer processor, the selected set of stimulation parameters to be received by an electrical stimulation device for delivery of electrical stimulation to a patient via an electrical stimulation lead.

2. The method of claim **1**, wherein determining a first axial stimulation field comprises selecting a plurality of planes orthogonal to the lead; modeling the neural elements as fixed length elements that intersect only one of the planes; and determining, for each plane and using the stimulation parameters, which of the fixed length elements intersecting the plane are activated using the stimulation parameters.

3. The method of claim **1**, wherein determining a first axial stimulation field comprises modeling the neural elements as extending axially relative to the lead; and determining, using the stimulation parameters, which of the neural elements are activated using the stimulation parameters.

4. The method of claim **3**, further comprising determining, by the computer processor, a time sequence of activation along the neural elements that are activated using the stimulation parameters and outputting, by the computer processor, the first axial stimulation field indicating different states of the first axial stimulation field over time based on the time sequence.

5. The method of claim **4**, further comprising receiving, by the computer processor, a time selection and outputting, by the computer processor, the first axial stimulation field at the time selection based on the time sequence.

6. The method of claim **1**, wherein determining a first axial stimulation field comprises modeling the neural elements as extending axially relative to the lead; and determining, using the stimulation parameters, which of the neural elements are activated using the stimulation parameters and at what point along each of the neural elements that that neural element is first activated.

7. The method of claim **1**, further comprising determining, by the computer processor and using the set of stimulation parameters, a first transverse stimulation field for neural elements oriented orthogonal with respect to a longitudinal axis of the lead; and outputting, by the computer processor, the first transverse stimulation field for viewing by a user.

8. The method of claim **7**, wherein outputting the first axial stimulation field and outputting the first transverse stimulation field comprises outputting the first axial stimulation field and first transverse stimulation field simultaneously.

9. The method of claim **8**, further comprising receiving, by the computer processor, a user command to toggle either the first axial stimulation field or first transverse stimulation field either on or off.

10. The method of claim **1**, wherein receiving a modification of the set of stimulation parameters comprises receiving a modified stimulation amplitude.

11. The method of claim **1**, wherein receiving a modification of the set of stimulation parameters comprises receiving a modified selection of the at least one electrode for delivery of stimulation.

12. A system for determining a set of stimulation parameters for an electrical stimulation lead, the system comprising:

a display; and

a computer processor coupled to the display and configured and arranged to perform the method of claim **16**.

13. The system of claim **12**, further comprising an implantable lead and an implantable control module coupleable to the lead and configured and arranged to receive the set of stimulation parameters from the computer processor and to deliver electrical stimulation to a patient using the lead according to the set of stimulation parameters.

14. A non-transitory computer-readable medium having processor-executable instructions for determining a set of stimulation parameters, the processor-executable instructions when installed onto a device enable the device to perform actions, including:

receiving a set of stimulation parameters comprising at least one electrode for delivery of stimulation and a stimulation amplitude for each of the at least one electrode;

determining, using the set of stimulation parameters, a first axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead;

outputting the first axial stimulation field for viewing by a user;

receiving a modification of the set of stimulation parameters;

determining, using the modified set of stimulation parameters, a second axial stimulation field for neural elements oriented axially with respect to a longitudinal axis of the lead;

outputting the second axial stimulation field for viewing by a user;

receiving a selection of either the set of stimulation parameters or the modified set of stimulation parameters as a selected set of stimulation parameters; and

outputting the selected set of stimulation parameters to be received by an electrical stimulation device for delivery of electrical stimulation to a patient via an electrical stimulation lead.

15. The non-transitory computer-readable medium of claim **14**, wherein determining a first axial stimulation field comprises selecting a plurality of planes orthogonal to the lead; modeling the neural elements as fixed length elements that intersect only one of the planes; and determining, for each plane and using the stimulation parameters, which of the fixed length elements intersecting the plane are activated using the stimulation parameters.

16. The non-transitory computer-readable medium of claim **14**, wherein determining a first axial stimulation field comprises modeling the neural elements as extending axially relative to the lead; and determining, using the stimulation parameters, which of the neural elements are activated using the stimulation parameters.

17. A computer-implemented method for determining a set of stimulation parameters for an electrical stimulation lead, the method comprising:

receiving, by a computer processor, a set of stimulation parameters comprising at least one electrode for delivery of stimulation and a stimulation amplitude for each of the at least one electrode;

determining, by the computer processor and using the set of stimulation parameters, a first non-orthogonal stimulation field for neural elements oriented non-orthogonally with respect to a longitudinal axis of the lead at a specified non-orthogonal angle or over a specified range of non-orthogonal angles;

outputting, by the computer processor, the first non-orthogonal stimulation field for viewing by a user;

receiving, by the computer processor, a modification of the set of stimulation parameters;

determining, by the computer processor and using the modified set of stimulation parameters, a second non-orthogonal stimulation field for neural elements oriented non-orthogonally with respect to a longitudinal axis of the lead;

outputting, by the computer processor, the second non-orthogonal stimulation field for viewing by a user;

receiving, by the computer processor, a selection of either the set of stimulation parameters or the modified set of stimulation parameters as a selected set of stimulation parameters; and

outputting, by the computer processor, the selected set of stimulation parameters to be received by an electrical stimulation device for delivery of electrical stimulation to a patient via an electrical stimulation lead.

18. The method of claim **17**, wherein determining a first non-orthogonal stimulation field comprises selecting a plurality of planes orthogonal to the lead; modeling the neural elements as fixed length elements that intersect only one of the planes; and determining, for each plane and using the stimulation parameters, which of the fixed length elements intersecting the plane are activated using the stimulation parameters.

19. The method of claim **17**, wherein determining a first non-orthogonal stimulation field comprises modeling the neural elements as extending non-orthogonally relative to the lead; and determining, using the stimulation parameters, which of the neural elements are activated using the stimulation parameters.

20. The method of claim **19**, further comprising determining, by the computer processor, a time sequence of activation along the neural elements that are activated using the stimulation parameters and outputting, by the computer processor, the first non-orthogonal stimulation field indicating different states of the first non-orthogonal stimulation field over time based on the time sequence.

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