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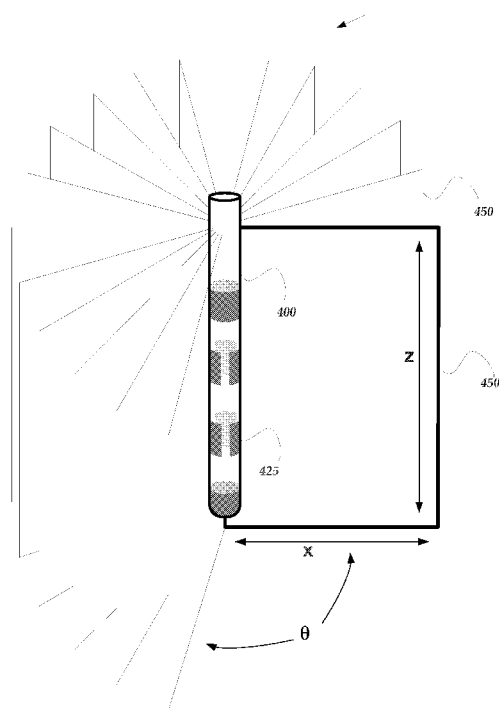


Fig. 4A

(57) Abstract: A system for estimating a volume of activation around an implanted electrical stimulation lead for a set of stimulation parameters includes a display; and a processor coupled to the display and configured to: receive a set of stimulation parameters including a stimulation amplitude and a selection of one of more electrodes of the implanted electrical stimulation lead for delivery of the stimulation amplitude; determine an estimate of the volume of activation based on the set of stimulation parameters using the stimulation amplitude and a database including a plurality of planar distributions of stimulation threshold values and a map relating the planar distributions to spatial locations based on the one or more electrodes of the implanted electrical stimulation lead selected for delivery of the stimulation amplitude; and output on the display a graphical representation of the estimate of the volume of activation.



**SYSTEMS AND METHODS FOR ESTIMATING A VOLUME OF
ACTIVATION USING A COMPRESSED DATABASE OF THRESHOLD
VALUES**

5 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. 62/480,942, filed April 3, 2017, which is incorporated herein by reference.

FIELD

10 The invention is directed to the field of electrical stimulation systems. The present invention is also directed to systems and methods for estimating a volume of activation, as well as methods of making and using systems.

BACKGROUND

Electrical stimulation can be useful for treating a variety of conditions. Deep
15 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
20 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.

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.
25 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

30 One embodiment is a system for estimating a volume of activation around an implanted electrical stimulation lead for a set of stimulation parameters. The system

includes a display; and a processor coupled to the display and configured to: receive a set of stimulation parameters including a stimulation amplitude and a selection of one of more electrodes of the implanted electrical stimulation lead for delivery of the stimulation amplitude; determine an estimate of the volume of activation based on the set of stimulation
5 parameters using the stimulation amplitude and a database including a plurality of planar distributions of stimulation threshold values and a map relating the planar distributions to spatial locations based on the one or more electrodes of the implanted electrical stimulation lead selected for delivery of the stimulation amplitude; and output, on the display, a graphical representation of the estimate of the volume of activation.

10 Another embodiment is a non-transitory computer-readable medium having computer executable instructions stored thereon that, when executed by at least one processor, cause the at least one processor to perform the instructions, the instructions including: receiving a set of stimulation parameters including a stimulation amplitude and a selection of one of more electrodes of the implanted electrical stimulation lead for delivery
15 of the stimulation amplitude; determining an estimate of the volume of activation based on the set of stimulation parameters using the stimulation amplitude and a database including a plurality of planar distributions of stimulation threshold values and a map relating the planar distributions to spatial locations based on the one or more electrodes of the implanted electrical stimulation lead selected for delivery of the stimulation amplitude; and
20 outputting, on the display, a graphical representation of the estimate of the volume of activation.

In at least some embodiments of the system or the non-transitory computer-readable medium, the database consists of the plurality of planar distributions, wherein each of the planar distributions is unique. In at least some embodiments, the database is a lossless
25 compressed database. In at least some embodiments, the database is a lossy compressed database.

In at least some embodiments of the system or the non-transitory computer-readable medium, the map includes a plurality of entries, wherein each entry is indexed to a selection of the one or more electrodes and an angular location around the implanted electrical
30 stimulation lead. In at least some embodiments, the selection of the one or more electrodes is characterized by at least one fractionalization parameter. In at least some embodiments,

the at least one fractionalization parameter includes at least one of an axial position parameter, an angular direction parameter, or an angular spread parameter. In at least some embodiments, the selection of the one or more electrodes is characterized by an axial position parameter, an angular direction parameter, and an angular spread parameter. In at least some embodiments, at least two of the entries of the map point to a same planar distribution. In at least some embodiments of the system or the non-transitory computer-readable medium, the at least two of the entries include a first entry corresponding to a selection of a first one of the electrodes and a first angular location and a second entry corresponding to a selection of a second one of the electrodes and a second angular location, wherein the first angular location and the second angular location differ by a first angle, wherein a location of the first one of the electrodes differs from a location of the second one of the electrodes by the first angle.

Yet another embodiment is a system for estimating a volume of activation around an implanted electrical stimulation lead for a set of stimulation parameters. The system includes a processor configured to: receive a plurality of planar distributions of stimulation threshold values for each of a plurality of sets of stimulation parameters, each of the sets of stimulation parameters includes a stimulation amplitude and a selection of one of more electrodes of the implanted electrical stimulation lead for delivery of the stimulation amplitude; compress the plurality of planar distributions of stimulation threshold values into a compressed database including a plurality of unique planar distributions of stimulation threshold values; and generate a map relating the unique planar distributions of stimulation threshold values to the planar distributions of stimulation threshold values for the multiple sets of stimulation parameters.

In at least some embodiments, the compressing includes compress the plurality of planar distributions of stimulation threshold values into a compressed database using a lossless compression technique. In at least some embodiments, the compressing includes compress the plurality of planar distributions of stimulation threshold values into a compressed database using a lossy compression technique.

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.

5 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 side view of one embodiment of a device for brain stimulation, according to the invention;

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

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

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

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

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

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

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

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

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

FIG. 4A is a graphical illustration of one embodiment of a set of planes relative to a lead for facilitating estimating a volume of activation, according to the invention;

5 FIG. 4B illustrates examples of planar distributions of stimulation threshold values, according to the invention;

FIG. 5 is a schematic illustration of one embodiment of a system for practicing the invention;

10 FIG. 6 is a perspective view of a portion of a lead having a plurality of segmented electrodes for use as an example, according to the invention;

FIG. 7 is a schematic representation of relationship between a full set of I_{th} tables and a compressed set of unique I_{th} tables related by a map, according to the invention;

15 FIG. 8 is a schematic representation of relationship between a full set of I_{th} tables and a compressed set of unique, approximate I_{th} tables related by a map, according to the invention;

FIG. 9 is a schematic flowchart of a one embodiment of a method of estimating a volume of activation, according to the invention;

20 FIG. 10 is a schematic flowchart of one embodiment of a method of compressing a set of planar distributions of stimulation threshold values into a compressed database, according to the invention; and

FIG. 11 is a schematic flowchart of one embodiment of a method of decompressing a compressed database, according to the invention.

DETAILED DESCRIPTION

25 The invention is directed to the field of electrical stimulation systems. The present invention is also directed to systems and methods for estimating a volume of activation, as well as methods of making and using systems.

A lead for electrical stimulation can include 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
5 having electrodes radially distributed about the lead at a particular axial 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
10 stimulation, or stimulation of other nerves, organs, or tissues.

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
15 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;
20 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 at least some embodiments, a practitioner may determine the position of the
25 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
30 lead can include both recording electrodes and stimulation electrodes or electrodes can be used for both recording and stimulation.

Figure 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.

The control module (for example, control module 514 of Figure 5) 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.

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.

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.

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. 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 one or more particular angular ranges around an axis of the lead.

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.

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.

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.

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.

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 Figure 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 320a of Figure 3E) which covers most, or all, of the distal tip of the lead.

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. Patent 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.

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.

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
5 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
10 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.

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
15 circumferential set (or even all segmented electrodes disposed on the lead 100) may be identical in size and shape.

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
20 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,
25 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.

Conductor wires that attach to the ring electrodes 120 or segmented electrodes 130
30 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.

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.*, Figures 1, 3A, and 3E-3H – 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.*, Figure 3C – 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.*, Figure 3D – ring electrodes 320 and segmented electrode 330). One of the ring electrodes can be a tip electrode (see, tip electrode 320a of Figures 3E and 3G). It will be understood that other configurations are possible as well (*e.g.*, alternating ring and segmented electrodes, or the like).

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

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 (Figures 3A and 3E – ring electrodes 320 and segmented electrode 330). It may be useful to refer to the electrodes with this shorthand notation. Thus, the embodiment of Figure 3C may be referred to as a 1-1-4-4 configuration, while the embodiment of Figure 3D may be referred to as a 4-4-1-1 configuration. The embodiments of Figures 3F, 3G, and 3H 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 Figures 3F, 3G, and 3H has two sets of segmented electrodes, each set containing three electrodes
 5 disposed around the circumference of the lead, flanked by two ring electrodes (Figures 3F and 3H) or a ring electrode and a tip electrode (Figure 3G). 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.

10 Figure 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
 15 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
 20 the segmented electrodes allows the centroid of stimulation to be shifted to a variety of different locations along the lead 200.

As can be appreciated from Figure 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.
 25 In some embodiments, the sets of segmented electrodes are shifted collectively (*i.e.*, the centroid of stimulation 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
 30 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.

Turning to Figures 3A-3H, when the lead 300 includes a plurality of sets of segmented electrodes 330, it may be desirable to form the lead 300 such that corresponding 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 Figures 3A and 3C-3G). 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.

In other embodiments, individual electrodes in the two sets of segmented electrodes 330 are staggered (see, Figure 3H) 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.

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 Figure 2. One arrangement for directing a stimulation field into a parallelepiped region uses segmented electrodes disposed on opposite sides of a lead.

Figures 3A-3H illustrate leads 300 with segmented electrodes 330, optional ring electrodes 320 or tip electrodes 320a, and a lead body 310. The sets of segmented electrodes 330 each include either two (Figure 3B), three (Figures 3E-3H), or four

(Figures 3A, 3C, and 3D) 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 (Figures 3A-3G) or staggered (Figure 3H)

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

Figure 5 illustrates one embodiment of a system for practicing the invention. The system can include a computer 500 or any other similar device that includes a processor 502 and a memory 504, a display 506, an input device 508, and, optionally, the electrical
10 stimulation system 512.

The computer 500 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. The computer can be, for example, a clinician programmer, patient programmer, or remote
15 programmer for the electrical stimulation system 512. The computer 500 can be local to the user or can include components that are non-local to the user including one or both of the processor 502 or memory 504 (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.

20 The computer 500 can utilize any suitable processor 502 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 502 is configured to execute instructions provided to the processor, as described below.

Any suitable memory 504 can be used for the computer 502. The memory 504
25 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
5 a computer.

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
10 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
15 acoustic, RF, infrared, and other wireless media.

The display 506 can be any suitable display device, such as a monitor, screen, display, or the like, and can include a printer. The input device 508 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
20 interface or clinical effects map.

The electrical stimulation system 512 can include, for example, a control module 514 (for example, an implantable pulse generator) and a lead 516 (for example, the lead illustrated in Figure 1.) The electrical stimulation system 512 may communicate with the computer 500 through a wired or wireless connection or, alternatively or additionally, a
25 user can provide information between the electrical stimulation system 512 and the computer 500 using a computer-readable medium or by some other mechanism. In some embodiments, the computer 500 may include part of the electrical stimulation system.

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
30 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. Patents Nos. 8,326,433; 8,831,731; 8,849,632; 9,050,470; and 9,072,905; and U.S. Patent Application Publication No. 2014/0277284, all of which are incorporated herein by reference in their entireties.

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 specific targeting of stimulation therapy. The term “volume of activation” (VOA) will be used to designate an estimated region of tissue that will be stimulated for a particular set of stimulation parameters. The terms “stimulation field map” (SFM) and “volume of tissue activation” (VTA) also refer to the VOA. Examples of methods for determining the VOA can be found in, for example, U.S. Patents Nos. 7,346,282; 8,180,601; 8,209,027; 8,326,433; 8,589,316; 8,594,800; 8,606,360; 8,675,945; 8,831,731; 8,849,632; 8,958,615; 9,020,789; and U.S. Patent Application Publications Nos. 2009/0287272; 2009/0287273; 2012/0314924; 2013/0116744; 2014/0122379; 2015/0066111; and 2016/0030749, all of which are incorporated herein by reference.

In at least some methods of estimating or determining a VOA, the electric field arising from the electrical energy delivered according to the stimulation parameters is determined or modeled, the tissue response to an electrical field is also determined or modeled, and then the VOA can be identified or estimated. There are a variety of methods for determining or modeling an electric field including, but not limited to, a finite element analysis model described in, for example, the references cited in the preceding paragraph, although it will be recognized that other models (including other models described in the references cited in the preceding paragraph) can also be used. There are also a variety of method for determining or modeling tissue including, but not

limited to, a neural element model or axon model as described in, for example, the references cited in the preceding paragraph, although it will be recognized that other models (including other models described in the references cited in the preceding paragraph) can also be used.

5 In at least some embodiments, the information based on the electric field model and tissue response model can be used to produce planar distributions of stimulation threshold values for a series of planes 450 distributed around a lead 400 having electrodes 425, as illustrated in Figure 4A. In at least some embodiments, these stimulation threshold values may be dependent on other stimulation parameters, such as stimulation
10 duration (for example, pulse width), stimulation frequency, and the like.

Each of the planes 450 can be divided into multiple regions (for example, squares or rectangles) with an associated stimulation threshold value (such as a threshold current or voltage) which, when applied to the lead will activate or stimulate the tissue at that region, as illustrated in Figure 4B. For discussion purposes, the stimulation threshold
15 value will be considered a threshold current, I_{th} , but it will be recognized that a threshold voltage or other electrical characteristic may be used instead. Each region of each plane 450 can be characterized by an x-value, which corresponds to a radial distance from the lead 400, a z-value, which corresponds to an axial coordinate along the longitudinal axis of the lead, and a θ -value, which corresponds to the relative angle of the plane in which
20 the region resides. These coordinates are labeled in Figures 4A and 4B. Thus, the values of I_{th} can be stored in a database as a series of I_{th} tables, $I_{th}(z, x, \theta)$, which can also be indexed relative to other state variables, as described below. A visual example of these I_{th} tables 450a, 450b, 450n is presented in Figure 4B where each plane 450 of Figure 4A represents one of the tables 450a, 450b, ... 450n wherein the number in each cell of the
25 table represents the current at which a neural fiber located at the center of the cell would be activated. Although the example illustrated in Figure 4B has four z values, 3 x values, and one table for every 60 degrees of θ , it will be recognized that the number of values for z and x and the θ separation for each table can be any number. The tables of Figure 4B are merely provided for illustrative purposes.

30 The I_{th} values may also depend on other stimulation parameters, such as pulse width ("pw"), pulse frequency ("freq"), and the distribution of the electrical energy (or

current or voltage) between the different electrodes (which can be referred to as “fractionalization”). Thus, when these factors are considered, the database is expanded to $I_{th}(z, x, \theta, pw, freq, \text{fractionalization})$. Other stimulation parameters may be added to this set. The database may also be visualized as a set of tables 450a, 450b, ... 450n (as
5 illustrated in Figure 4B) for each unique selection of the pulse width, frequency, and fractionalization parameters.

Fractionalization is the distribution of the electrical energy (or current or voltage) between the electrodes of the lead and can be expressed, for example, by an additional set of parameters: axial position, rotation, and spread. For purposes of illustration of these
10 three parameters, one embodiment of a distal end of a lead 500 is presented in Figure 6. The lead 500 includes a ring electrode 550, a first set of three segmented electrodes 552a, 552b, 552c, a second set of three segmented electrodes 554a, 554b, 554c, and a tip electrode 556. An “axial position” variable can be used to estimate or represent the central axial position of the field relative to the longitudinal axis of the lead. For
15 example, if the stimulation is provided solely by ring electrode 550, then the axial position of the field is centered on the axial position of the ring electrode 550. However, combinations of electrodes can also be used. For example, if the stimulation is provided with 50% of the current amplitude on ring electrode 550 and 50% of the current amplitude on segmented electrode 552a, then the axial position of the field can be
20 described as centered axially between electrode 550 and electrode 552a (although it will be recognized that the field also extends in both axial directions from this axial position.) If the stimulation is provided with 75% of the current amplitude on ring electrode 550 and 25% of the current amplitude on segmented electrode 552a, then the axial position of the field can be described as centered axially between electrode 550 and electrode 552a, but
25 closer to ring electrode 550. In at least some embodiments, a specific number of different axial position values can be defined for the system.

For example, in one embodiment, 31 different axial position values can be defined for the lead illustrated in Figure 6. Four of the axial positions correspond to 1) electrode 550, 2) electrodes 552a, 552b, 552c, 3) electrodes 554a, 554b, 554c, and 4) electrode 556.
30 In addition, nine axial positions can be defined between adjacent pairs of these four axial positions (e.g., 1) 90% of current amplitude on electrode 550 and 10% of current

amplitude on electrodes 552a, 552b, 552c, 2) 80% on electrode 550 and 20% on electrodes 552a, 552b, 552c, ... 8) 20% on electrode 550 and 80% on electrodes 552a, 552b, 552c, and 9) 10% on electrode 550 and 90% on electrodes 552a, 552b, 552c).

Another parameter is “rotation” which represents the angular direction of the field extending away from the lead. In the case of stimulation provided solely by ring electrode 550, the rotation parameter is arbitrary because the stimulation is provided equally in all directions. On the other hand, if the stimulation is provided by segmented electrode 552a, the rotation can be described as directed outward from segmented electrode 552a. Again, combinations of electrodes can be used so that the rotation may be described as centered between electrodes 552a, 552b if 50% of the stimulation amplitude is provided to both electrodes. In at least some embodiments, a specific number of different rotation values can be defined for the system.

For example, in one embodiment, 12 different rotation values are defined for the lead illustrated in Figure 6. For example, three of the rotation values correspond to the angular positions of 1) electrodes 552a, 554a, 2) electrodes 552b, 554b, and 3) electrodes 552c, 554c. In addition, three additional rotation values can be defined between adjacent pairs of these three rotation values (e.g., 1) 75% on electrode 552a and 25% on electrode 552b, 2) 50% on electrode 552a and 50% on electrode 552b; and 3) 25% on electrode 552a and 75% on electrode 552b).

Yet another parameter is “spread” which relates to the angular spread of the field around the circumference of the lead. In the case of stimulation provided solely by ring electrode 550, the spread variable is at a maximum because the stimulation is provided equally in all directions. On the other hand, if the stimulation is provided by segmented electrode 552a, the spread variable is at its minimum because the field is generated using only one segmented electrode 552a. Again, combinations of electrodes can be used. For example, the spread may be described as intermediate between the two previous examples when 50% of the stimulation amplitude is provided on both electrodes 552a, 552b. In at least some embodiments, a specific number of different spread values can be defined for the system.

For example, in one embodiment, 11 different spread values are defined for the lead illustrated in Figure 6. For example, one spread value corresponds an equal field in all directions (such as, the field generated by electrode 550 or electrode 556) and another spread value corresponds to a field generated by one of the segmented electrodes (e.g., electrode 552a). The other nine spread values are between these two extremes.

The stimulation (e.g., stimulation current) can be steered to different positions and arrangements around the lead which results in changes in these fractionalization parameters: axial position, rotation, and spread. For example, the stimulation can be moved up or down the longitudinal axis of the lead thereby changing the axial position parameter. As an example, the stimulation can be initially provided 100% through electrode 550. The stimulation can then be steered distally by directing a portion of the stimulation to the electrodes 552a, 552b, 552c. For example, in a first step, 90% of the stimulation remains on electrode 550 and 10% is divided equally among electrodes 552a, 552b, 552c. The second step can have 80% on electrodes 550 and 20% divided equally among electrodes 552a, 552b, 552c. This can continue until there is no stimulation on electrode 550 and 100% of the stimulation is divided among electrodes 552a, 552b, 552c. The process can proceed to incrementally transfer stimulation from electrodes 552a, 552b, 552c to electrodes 554a, 554b, 554c. Similarly, the stimulation then be incrementally transferred from electrodes 554a, 554b, 554c to electrode 556.

The stimulation can also be rotated. For example, stimulation from electrode 552a can be rotated to electrode 552b in stepped increments. The stimulation field can also be spread. For example, stimulation field from electrode 552a can be spread so that the stimulation arises from both electrodes 552a, 552b. That stimulation field can then be contracted so that the stimulation is only from electrode 552b.

It will be recognized that the resulting I_{th} database can be quite large depending on the number of different values for each of the parameters. As one example, such an I_{th} database can be generated for a set of fractionalization states obtained using 11 different spread values, 12 different rotation values, and 31 different axial position values, as well as multiple values of the other variables (for example, 43 values for z , 16 values for r , 12 values for θ , 12 values for pulse width, and 45 values for frequency).

The database can be compressed using one or more techniques. As one example, the database can be compressed (for example, the amount of stored data decreased) when it is recognized that many fractionalization states are not unique or are not available. The amount of data stored can be reduced by taking advantage of the unavailability of fractionalization states, as well as redundancy and symmetry in the fractionalization states. In at least some embodiments, the database can be reduced to a set of unique I_{th} tables (such as those illustrated in Figure 4B) and a map M which relates the I_{th} tables to the different fractionalizations (i.e., the different axial position, rotation, and spread values) and, optionally, to different pulse widths or frequencies.

Using lead 500 of Figure 6 as an example with 11 different spread values, 12 different rotation values, and 31 different axial position values, as described above, there are potentially 4092 different fractionalization states. However, a number of these states are not actually available or are redundant. For example, any stimulation that utilizes only ring electrode 550 for delivery of the stimulation will have the maximum spread value (because the other spread states, with a smaller degree of spread, cannot be produced using only the ring electrode 550) and rotation value will be irrelevant because there is no identifiable angular direction of the stimulation because stimulation by the ring electrode 550 is cylindrically symmetric. Although there are potentially 121 different possible combinations of spread and rotation for each axial position value, when the axial position value corresponds to stimulation using the ring electrode only, there is only 1 non-redundant fractionalization state. Thus, the number of actual available fractionalization states associated with stimulation using only one of the ring electrodes is reduced by 120.

As another example, when the stimulation is divided equally among 552a, 552b, 552c (i.e., the spread variable value is maximum), then the rotation value is again irrelevant because there is no identifiable angular direction for the stimulation and therefore, although there are 12 potential selections of rotation, there is actually only 1 available rotation state. Thus, the number of actual available states associated with stimulation using maximum spread over all of the segmented electrodes of one set is reduced by 12.

Using similar observations, it is found that, for 31 axial position values, 12 rotation values, and 11 spread values and assuming symmetrical tissue response, the 4092 total states can be reduced to 828 unique fractionalization states that can be selected for the electrodes of the lead in Figure 6.

5 In addition to reducing the number of unique or possible fractionalization states, symmetry can be used to compress the stored data. Assuming that the tissue response is the same in all directions, then the I_{th} values for stimulation using only electrode 552a (fractionalization state 1) will be the same as the I_{th} values for stimulation using only electrode 552b (fractionalization state 2) except for a 120 degree rotation and will be the same as the I_{th} values for stimulation using electrode 552c (fractionalization state 3) except for a -120 degree rotation. In other words, $I_{th,1}(x, z, \theta) = I_{th,2}(x, z, \theta-120) = I_{th,3}(x, z, \theta+120)$ where $I_{th,1}$ = the threshold table for fractionalization state 1, $I_{th,2}$ = the threshold table for fractionalization state 2, and $I_{th,3}$ = the threshold table for fractionalization state 3. Because of this symmetry, only one set of I_{th} tables is stored for these three fractionalization states because the same set of I_{th} tables by mapping the I_{th} tables accounting for the rotation described above. Thus, the number of I_{th} tables needed in the database is less due to the recognition of the symmetry. This equivalence of the I_{th} tables, except for a rotation, for similar states is available for many fractionalizations. For example, a fractionalization that includes stimulation provided by a combination of electrode 556 and electrode 554a (with a particular apportioning of the stimulation between the two electrodes, for example, 70%/30%) is similar to stimulation provided by a combination of electrode 556 and electrode 554b (with the same apportioning of the stimulation between the two electrodes) except for a rotation of 120 degrees. In this example, the same set of I_{th} tables can be used with the mapping taking into account the rotation. As another example, stimulation provided by a combination of electrodes 554a and 554b (with a particular apportioning of the stimulation between the two electrodes, for example, 70%/30%) is similar to a combination of electrodes 554b and 554c (with the same apportioning of the stimulation between the two electrodes) except for a rotation of 120 degrees. Again, in this example, the same set of I_{th} tables can be used with the mapping taking into account the rotation.

Similarly, in many instances the stimulation field will have mirror symmetry about the central radial axis of the stimulation field. In other words, $I_{th}(x, z, \theta) = I_{th}(x, z, -\theta)$ and, therefore, in these instances, only $I_{th}(x, z, \theta)$ for values of θ from 0 to 180 degrees needs to be stored in the database because $I_{th}(x, z, \theta)$ for values of θ between 180 and 360 degrees, non-inclusive of the endpoints, corresponds to one of the stored $I_{th}(x, z, \theta)$. Again, a map can be used to map the stored I_{th} tables to the large set of $I_{th}(x, z, \theta$, fractionalization), but the number of I_{th} tables that are need to be stored in the database is less due to the recognition of the symmetry.

It will be recognized that other symmetries can be identified and that there may also be symmetries that are applicable based on pulse width or frequency stimulation parameters. Therefore, as illustrated in Figure 7, a set of unique $I_{th,unique}$ tables 760 (such as $I_{th,unique}(x, z, \theta)$) form a compressed database and are identified, as well as a map 762 that relates the $I_{th,unique}$ tables to the full set of $I_{th,full}$ tables 764 (such as $I_{th,full}(x, z, \theta$, fractionalization) or $I_{th,full}(x, z, \theta$, fractionalization, pw, frequency)). This arrangement is a lossless compression of the I_{th} data because the full set of I_{th} data can be reconstructed from the $I_{th,unique}$ tables and map.

Alternatively or additionally, lossy compression may also be applied to the $I_{th,unique}$ tables or full I_{th} data. As illustrated in Figure 8, a set of unique, approximate $I_{th,approx}$ tables 861 form a compressed database and are identified with a map 862 that relates the $I_{th,approx}$ tables to the $I_{th,full}$ tables 860. This is a lossy compression because the $I_{th,approx}$ tables 861 are not necessarily the same as the $I_{th,full}$ tables that they represent, but rather the $I_{th,approx}$ tables are sufficiently similar (based on a similarity metric) to the original $I_{th,full}$ tables that they represent to be acceptable to the user.

In some embodiments of lossy compression, a group of similar I_{th} tables are approximated using a single $I_{th,approx}$ table. As an example, a similarity metric may be used to compare a particular I_{th} table with a particular $I_{th,approx}$ table and, when the similarity metric is within a specified tolerance, the original I_{th} table can be represented by the $I_{th,approx}$ table in the compressed I_{th} database. In this manner, the large set of I_{th} tables can be represented by fewer $I_{th,approx}$ tables. Any suitable similarity metric can be used including, but not limited to, the sum of the of the squared differences between

corresponding entries in the I_{th} table and the $I_{th,approx}$ table. Moreover, any suitable number of $I_{th,approx}$ tables can be selected including 10, 50, 100, 200, 300, 400, 500 or more tables.

Another lossy compression method utilizes MPEG compression or a process
5 similar to MPEG compression. MPEG video compression is a procedure that looks at the differences from frame to frame in a video sequence and, instead of generating data describing each frame, generates data describing differences from the previous frame.

In one example of a lossy compression method for I_{th} data, a similarity metric is selected such as the sum of the of the squared differences between corresponding entries
10 in a particular I_{th} table and a selected base I_{th} table. A sequence of I_{th} tables can then be built from this base I_{th} table. In some embodiments, an ordered list is created starting with the I_{th} tables most similar to the base I_{th} table and continuing to less similar I_{th} tables. This can generate a linear succession of I_{th} tables. In other embodiments, a branched sequence of I_{th} tables can be created by building a connected non-looping sequence
15 linking all I_{th} tables to their least different counterparts. From the base I_{th} table, there can be multiple branches with each branch being generated based on similarity of the I_{th} tables along that branch.

In some embodiments, all of the I_{th} tables will be located in a linear or branched sequence using a single base I_{th} table. In other embodiments, two or more base I_{th} tables
20 are selected (preferably, based on substantial differences between the base I_{th} tables) and the remainder of the I_{th} tables are associated with one of the base I_{th} tables (for example, the most similar of the base I_{th} tables) and linear or branched sequences of I_{th} tables are generated using each of the base I_{th} tables.

Once a linear or branched sequence of I_{th} tables is generated, the individual I_{th}
25 tables in the sequence can be considered image frames and compressed into a compressed database using a MPEG compression algorithm that, instead of storing the individual I_{th} tables in the compressed database, stores the base I_{th} table(s) and then proceeds along each linear or branched sequence storing the difference between the current table and the preceding table. Again, a map is used to identify which data also the sequence

corresponds to a particular I_{th} table. When a particular I_{th} table is subsequently needed, the compressed database and map are used to retrieve the I_{th} table from the stored data.

The lossless or lossy compressed databases described above can be stored in any suitable memory and then used to generate a volume of activation. Figure 9

5 illustrates one method of estimating a volume of activation. In step 980, the system receives or is otherwise provided with a set of stimulation parameters with include a stimulation amplitude and a selection of one or more electrodes (referred to above as the “fractionalization”) for delivery of the stimulation and may also include other parameters such as pulse width, frequency, or the like. In step 982, the system determines an
10 estimate of the volume of activation using the set of stimulation parameters, the compressed database (such as database 760 or database 861), and the map (such as map 762 or map 862). For example, the set of stimulation parameters, compressed database, and map are used to obtain I_{th} data corresponding to the set of stimulation parameters. For example, the $I_{th,unique}$ or $I_{th,approx.}$ tables of the compressed database can be identified
15 for the designated fractionalization, pulse width, and frequency. The identified $I_{th,unique}$ or $I_{th,approx.}$ tables provided a spatial distribution in z , x , and θ of the threshold values for stimulation of neural elements. Using the stimulation amplitude and these threshold values, the system can estimate which regions will have neural elements that are stimulated for the given set of stimulation parameters.

20 In step 984, this estimated region can then be displayed graphically for the user. In optional step 986, the user may direct the system to output the stimulation parameters to a stimulation device, for example, the control module 514 of Figure 5, that can produce stimulation signals for delivery to the patient via the lead electrodes. The stimulation device can receive the stimulation parameters and can then operate a stimulation program
25 to deliver electrical stimulation to the patient using the stimulation parameters.

Figure 10 illustrates one method of producing a compressed database. In step 1092, the system receives or produces planar distributions of stimulation threshold values for multiple sets of stimulation parameters. In step 1094, this data is compressed using one or more of the lossless or lossy compression methods described above to produce the
30 compressed database.

A compressed database can be fully or partially decompressed. Figure 11 illustrates one method of decompressing a compressed database. In step 1196, the compressed database and map is provided. In step 1198, the map is used to fully or partially compress the compressed database. For a lossless compressed database, this
5 decompression regenerates the original database or a part of the original database. For a lossy compressed database, the decompression creates a new full or partial uncompressed database that utilizes only $I_{th,approx.}$ tables and, therefore, is an approximation of the original database. In some embodiments, only part of the compressed database is uncompressed. This part may be selected based on selections of certain stimulation
10 parameter values. For example, the portion of the compressed database for a particular selection of electrodes or a particular selection of pulse width or frequency (or ranges of these values) may be decompressed. In some embodiments, this decompression may occur as part of a procedure for estimating a volume of activation (similar to step 982 of Figure 9 except that a portion of the database is decompressed in this step). In some
15 embodiments, decompression of different portions of the database may be performed sequentially during any suitable procedure. In some embodiments, the database may be compressed for storage or transfer to another device and then decompressed upon transfer to the other device or retrieval from storage.

The methods and systems described herein may be embodied in many different
20 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 hardware and software aspects. Systems referenced herein typically include memory and typically include methods for communication with other devices including mobile
25 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,
30 acoustic, near field communication, BluetoothTM, or the like, or any combination thereof.

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
5 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
10 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-
15 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.

20

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

CLAIMS

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

1. A system for estimating a volume of activation around an implanted electrical stimulation lead for a set of stimulation parameters, the system comprising:
a display; and
a processor coupled to the display and configured to:
receive a set of stimulation parameters comprising a stimulation amplitude and a selection of one of more electrodes of the implanted electrical stimulation lead for delivery of the stimulation amplitude;
determine an estimate of the volume of activation based on the set of stimulation parameters using the stimulation amplitude and a database comprising a plurality of planar distributions of stimulation threshold values and a map relating the planar distributions to spatial locations based on the one or more electrodes of the implanted electrical stimulation lead selected for delivery of the stimulation amplitude; and
output, on the display, a graphical representation of the estimate of the volume of activation.
2. The system of claim 1, wherein the database consists of the plurality of planar distributions, wherein each of the planar distributions is unique.
3. The system of claim 2, wherein the map comprises a plurality of entries, wherein each entry is indexed to a selection of the one or more electrodes and an angular location around the implanted electrical stimulation lead.
4. The system of claim 3, wherein the selection of the one or more electrodes is characterized by at least one fractionalization parameter, wherein the at least one fractionalization parameter optionally comprises at least one of an axial position parameter, an angular direction parameter, or an angular spread parameter.

5. The system of claim 3, wherein at least two of the entries of the map point to a same planar distribution,

optionally wherein the at least two of the entries comprise a first entry corresponding to a selection of a first one of the electrodes and a first angular location and a second entry corresponding to a selection of a second one of the electrodes and a second angular location, wherein the first angular location and the second angular location differ by a first angle, wherein a location of the first one of the electrodes differs from a location of the second one of the electrodes by the first angle.

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

receiving a set of stimulation parameters comprising a stimulation amplitude and a selection of one of more electrodes of the implanted electrical stimulation lead for delivery of the stimulation amplitude;

determining an estimate of the volume of activation based on the set of stimulation parameters using the stimulation amplitude and a database comprising a plurality of planar distributions of stimulation threshold values and a map relating the planar distributions to spatial locations based on the one or more electrodes of the implanted electrical stimulation lead selected for delivery of the stimulation amplitude; and

outputting on the display a graphical representation of the estimate of the volume of activation.

7. The non-transitory computer-readable medium of claim 6, wherein the database consists of the plurality of planar distributions, wherein each of the planar distributions is unique.

8. The non-transitory computer-readable medium of claim 7, wherein the map comprises a plurality of entries, wherein each entry is indexed to a particular selection of the one or more electrodes and a particular angular location around the implanted electrical stimulation lead.

9. The non-transitory computer-readable medium of claim 7, wherein the selection of the one or more electrodes is characterized by at least one fractionalization parameter.

10. The non-transitory computer-readable medium of claim 7, wherein at least two of the entries of the map point to a same planar distribution.

11. The system of any one of claims 1-5 or the non-transitory computer-readable medium of any one of claims 6-10, wherein the database is a lossless compressed database.

12. The system of any one of claims 1-5 or the non-transitory computer-readable medium of any one of claims 6-10, wherein the database is a lossy compressed database.

13. A system for estimating a volume of activation around an implanted electrical stimulation lead for a set of stimulation parameters, the system comprising:
a processor configured to:

receive a plurality of planar distributions of stimulation threshold values for multiple sets of stimulation parameters comprising a stimulation amplitude and a selection of one of more electrodes of the implanted electrical stimulation lead for delivery of the stimulation amplitude;

compress the plurality of planar distributions of stimulation threshold values into a compressed database comprising a plurality of unique planar distributions of stimulation threshold values; and

generate a map relating the unique planar distributions of stimulation threshold values to the planar distributions of stimulation threshold values for the multiple sets of stimulation parameters.

14. The system of claim 13, wherein the compressing comprises compress the plurality of planar distributions of stimulation threshold values into a compressed database using a lossless compression technique.

15. The system of claim 13, wherein the compressing comprises compress the plurality of planar distributions of stimulation threshold values into a compressed database using a lossy compression technique.

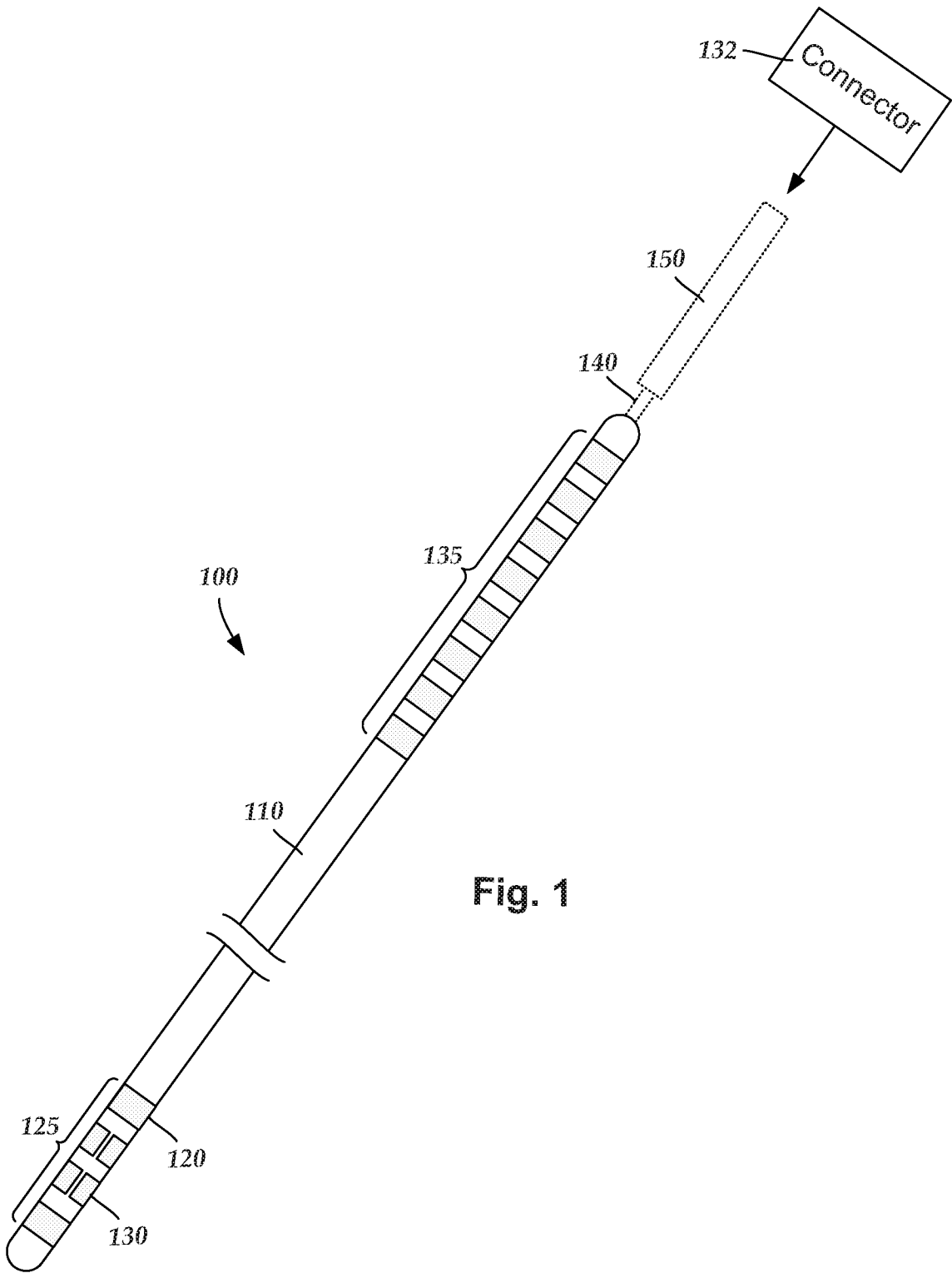


Fig. 1

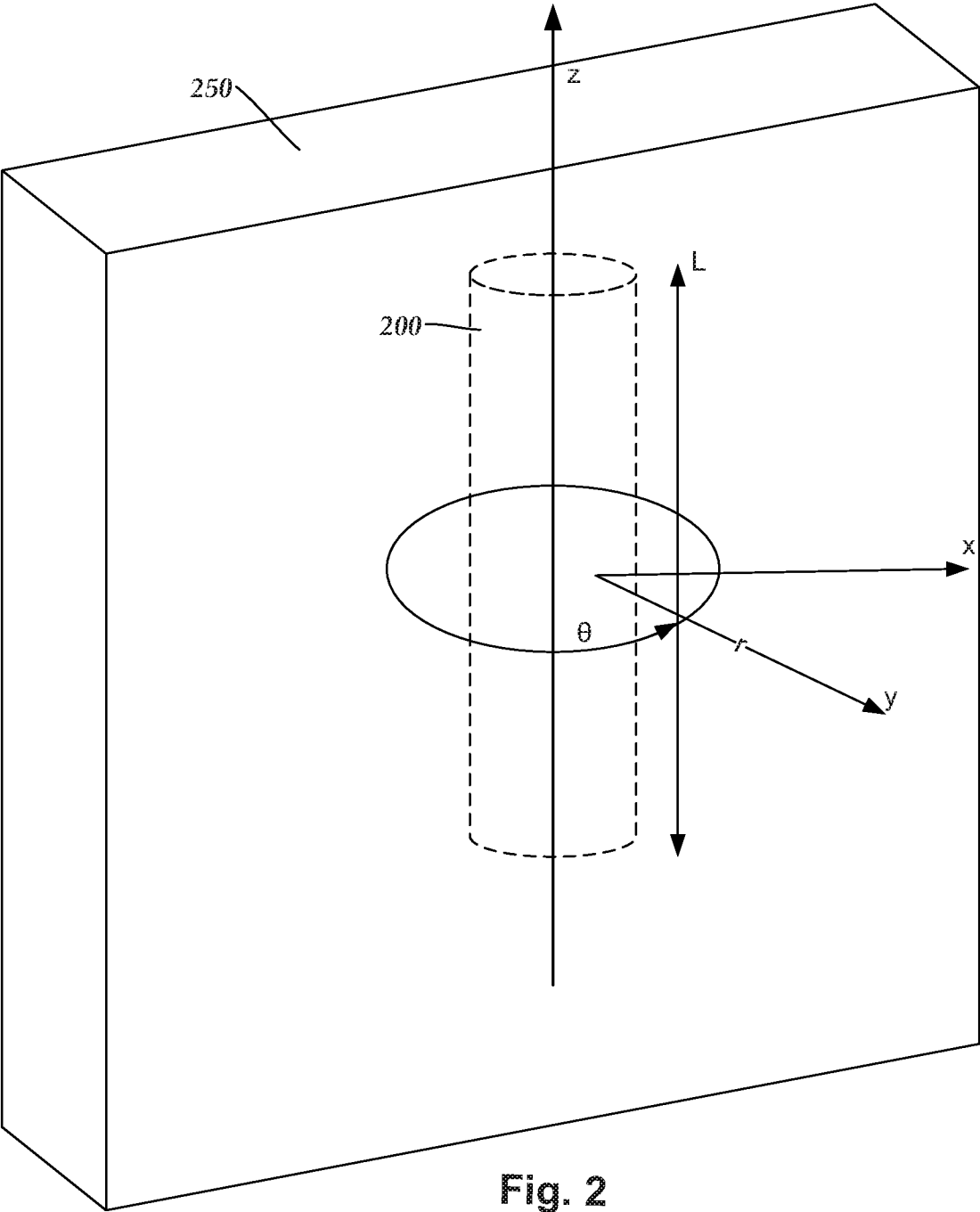
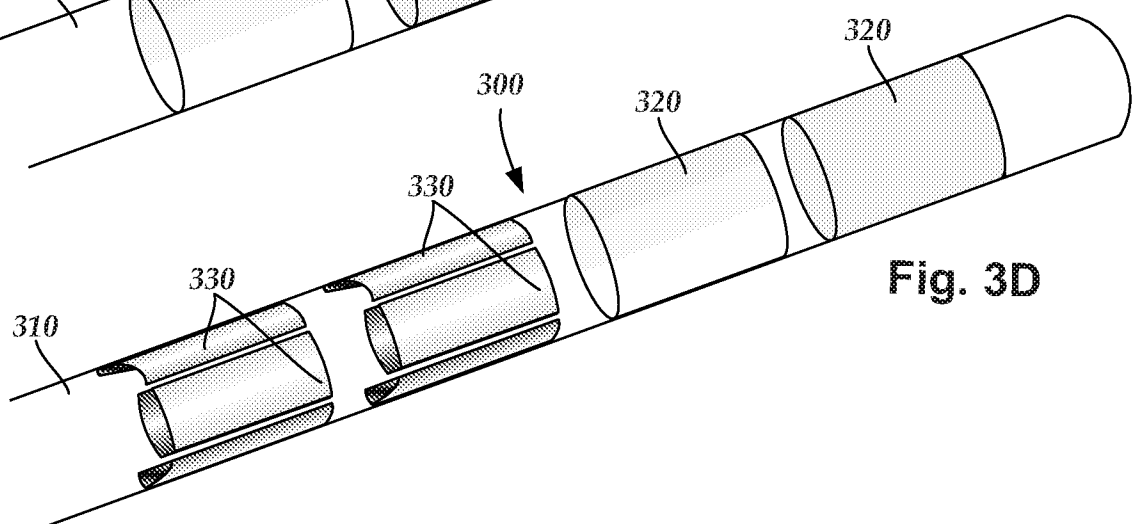
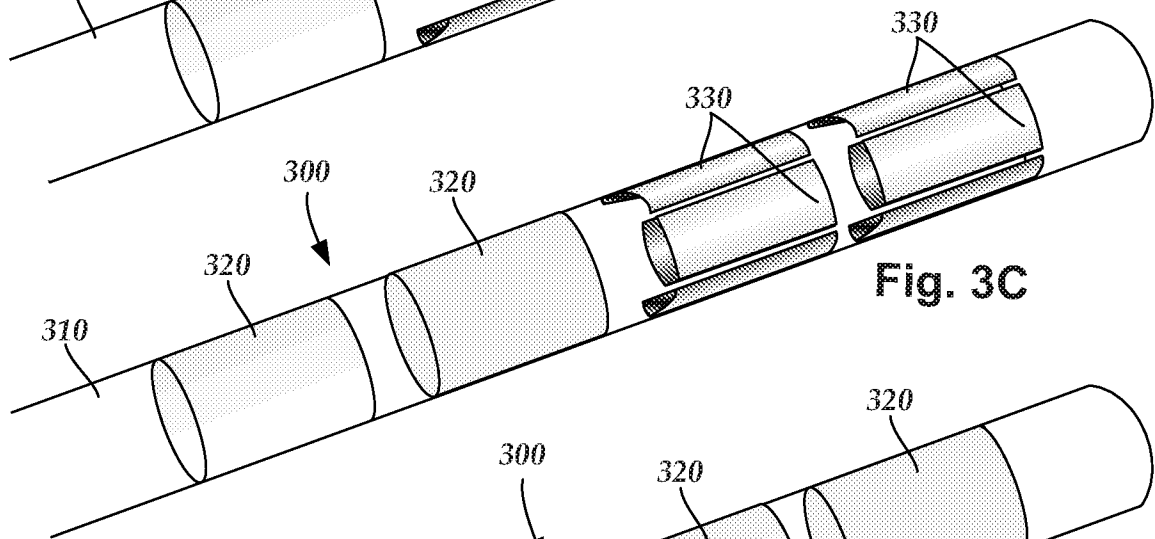
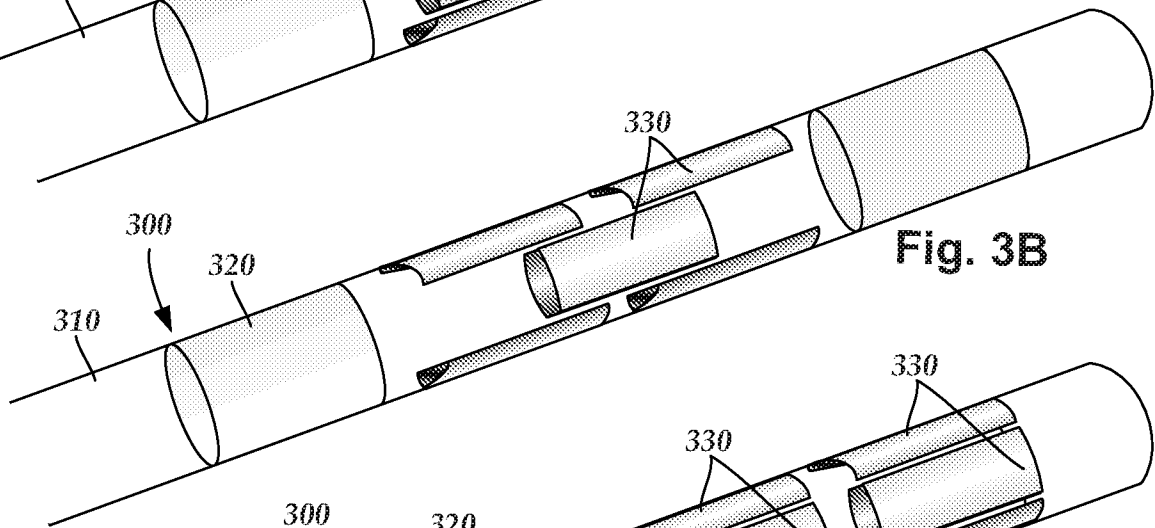
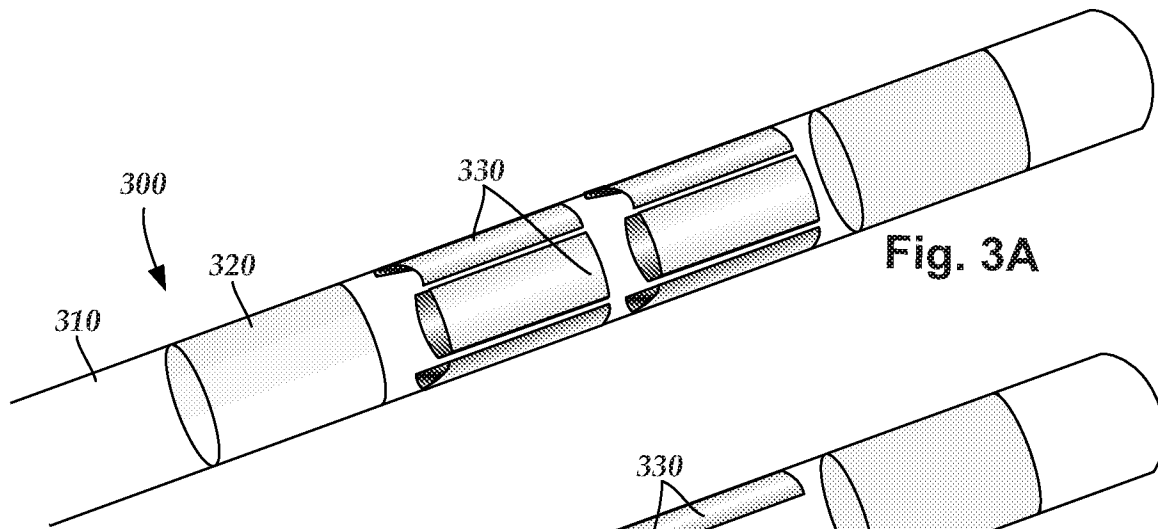
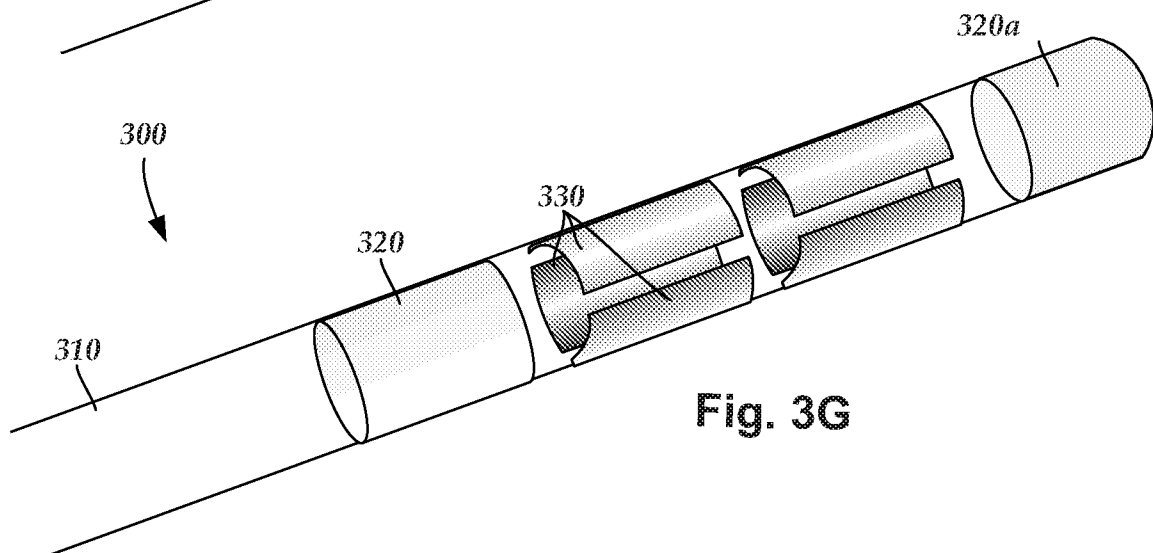
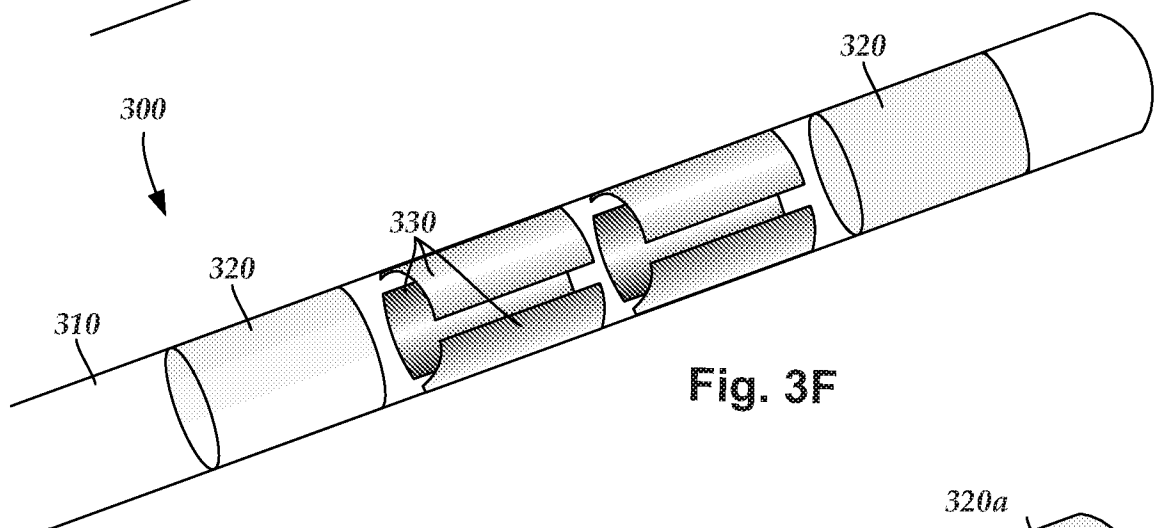
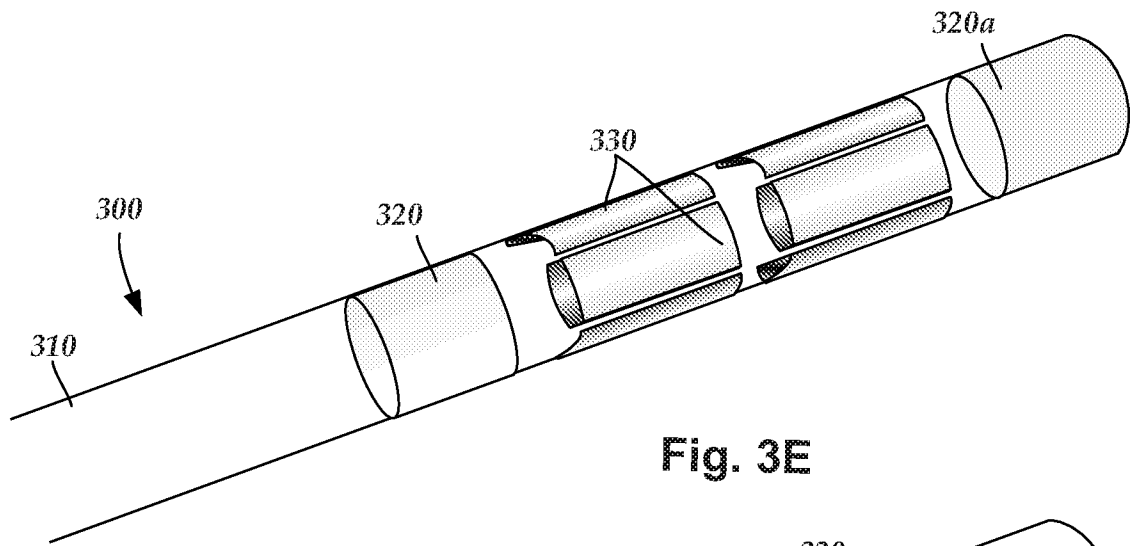
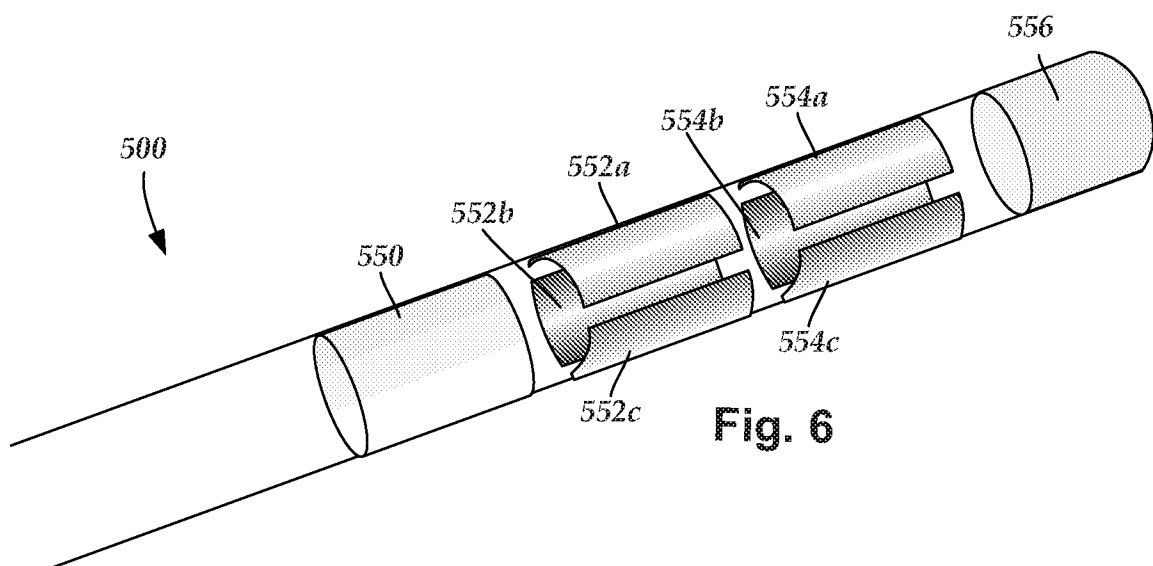
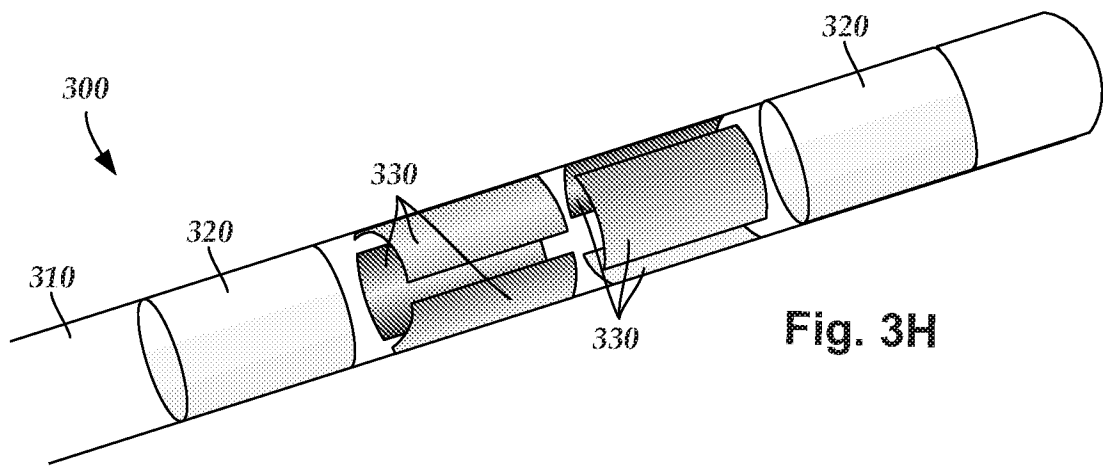


Fig. 2







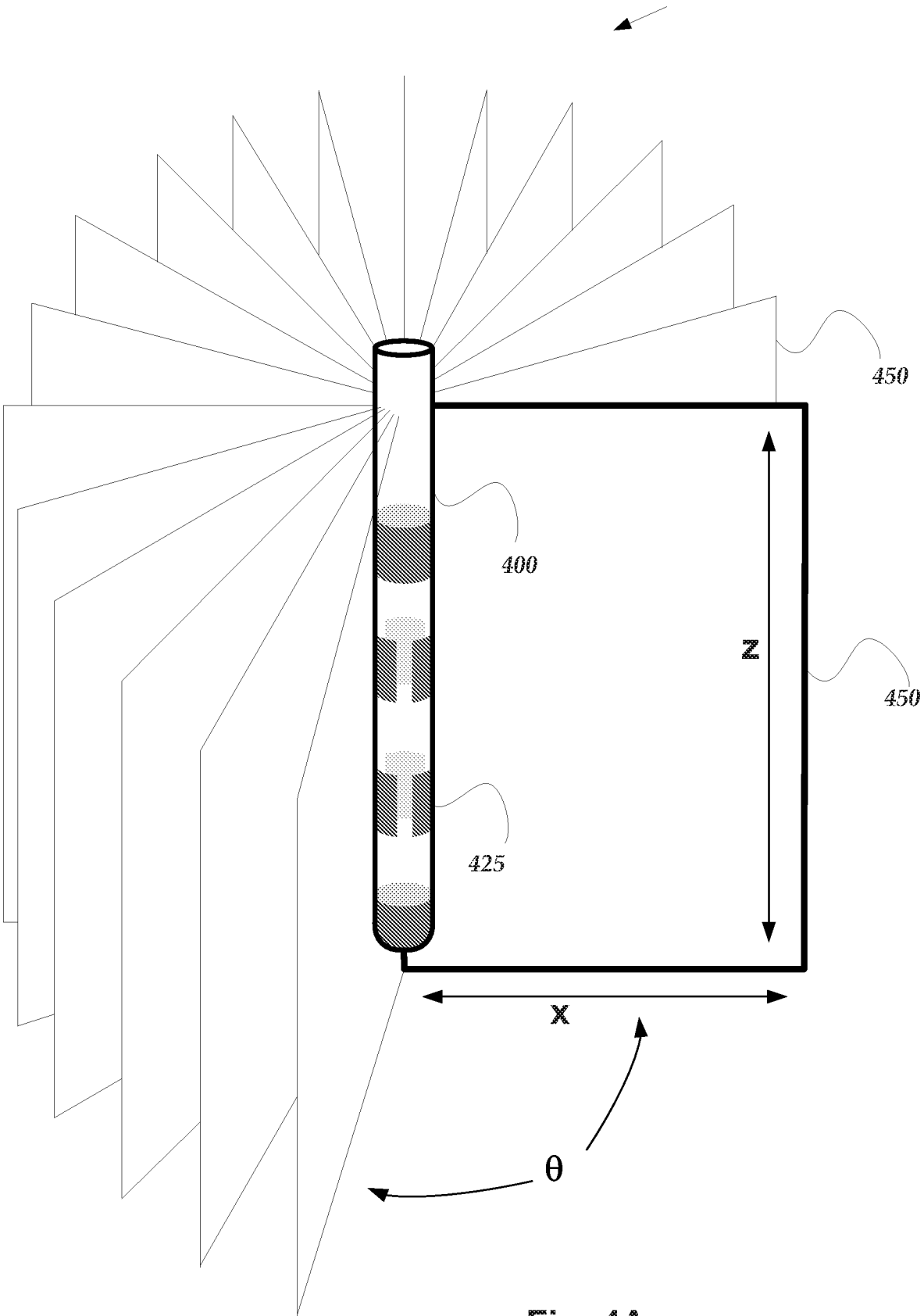


Fig. 4A

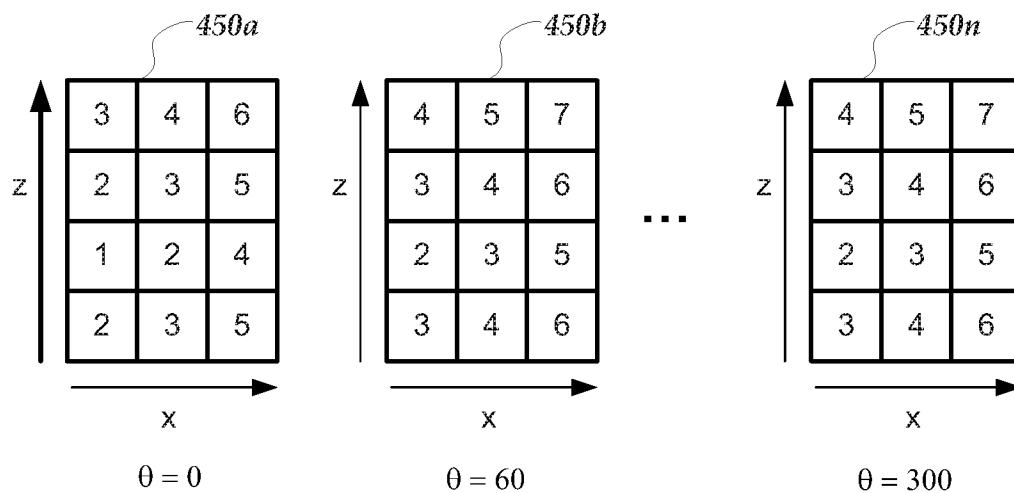


Fig. 4B

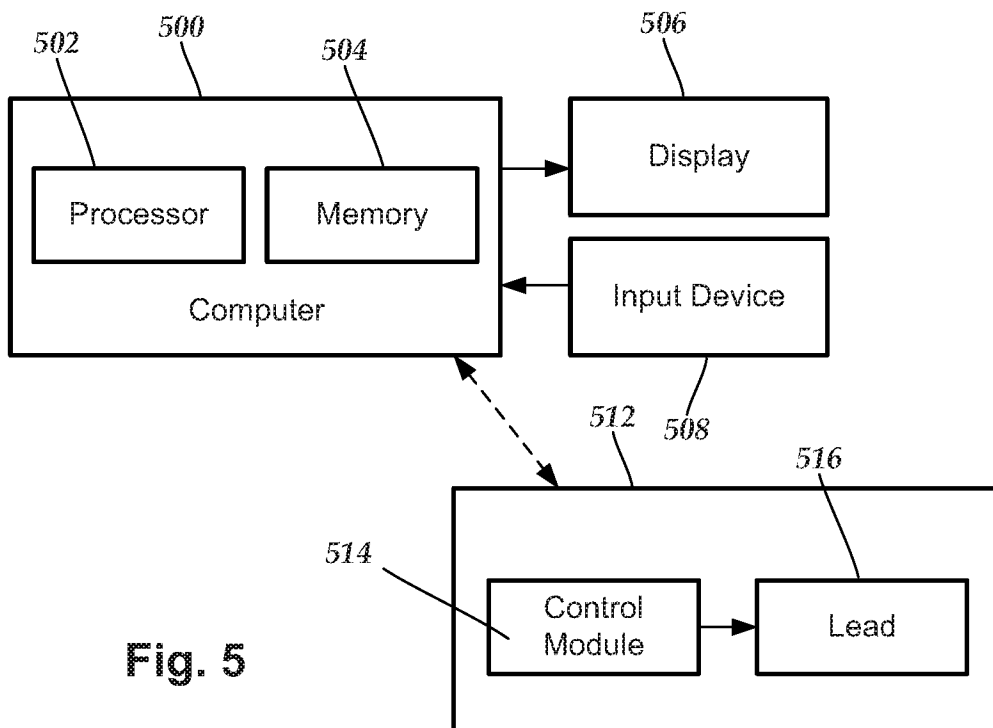
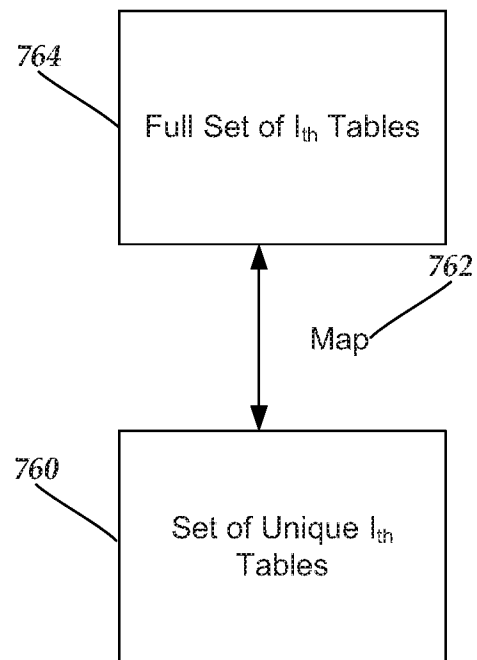
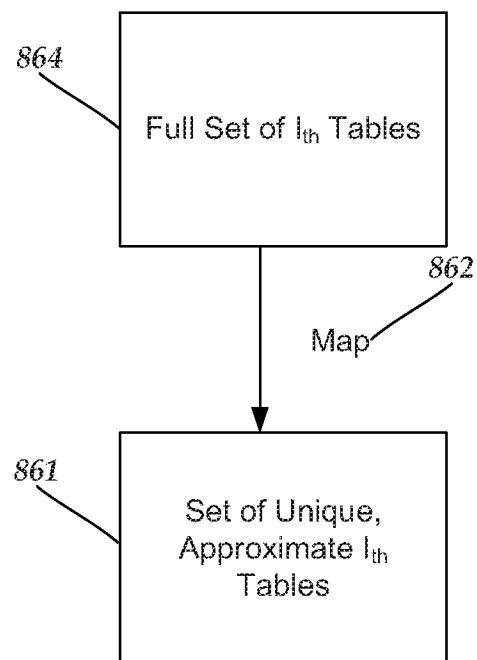
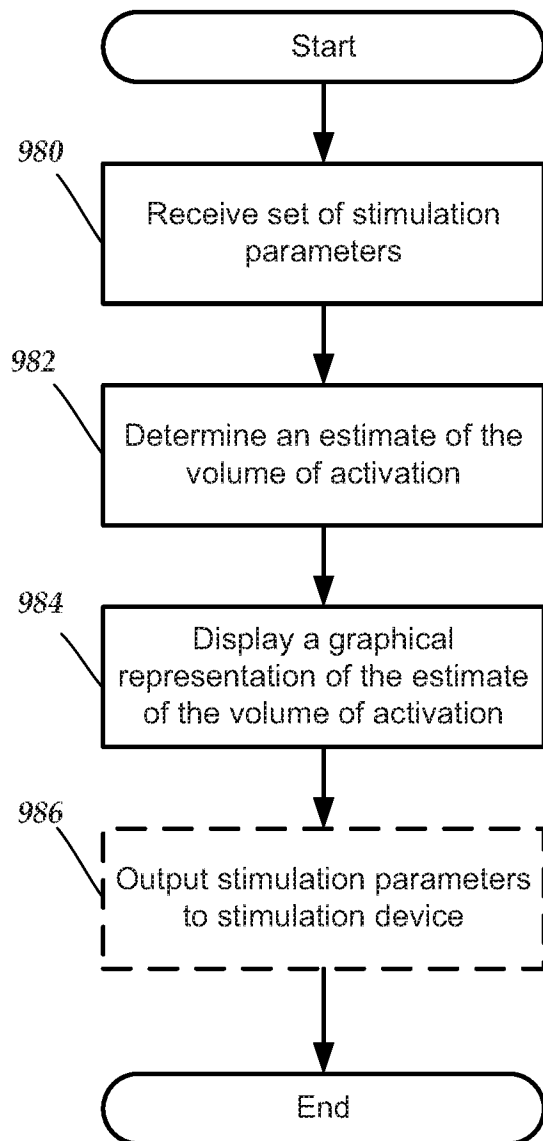
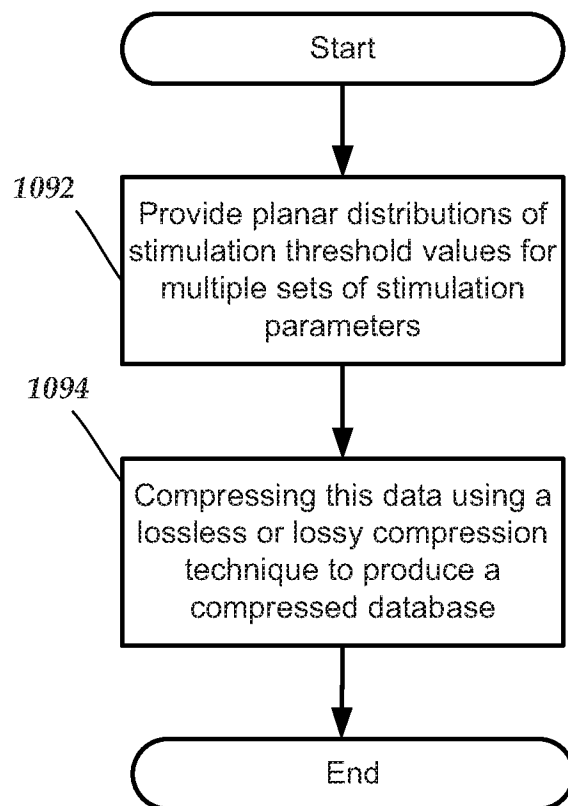
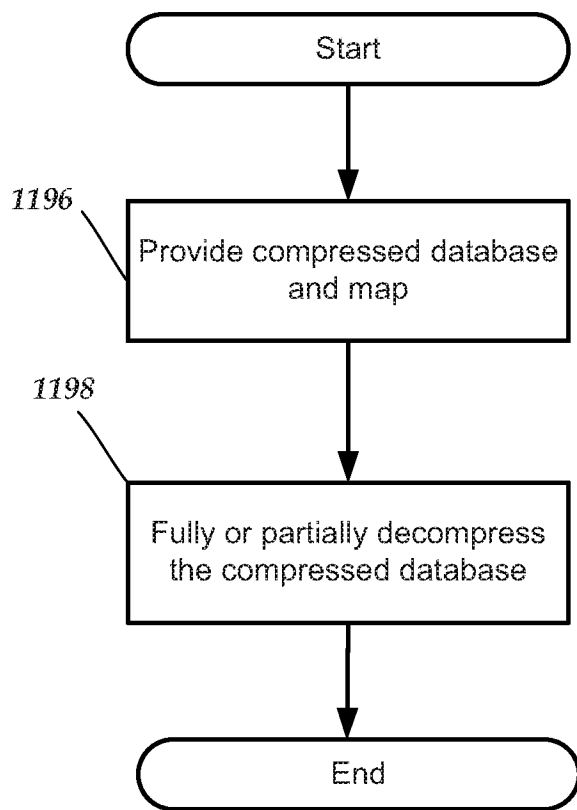


Fig. 5

**Fig. 7****Fig. 8**

**Fig. 9****Fig. 10**

**Fig. 11**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/024568

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/36 A61N1/372
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N G16H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

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Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

24 May 2018

Date of mailing of the international search report

04/06/2018

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Authorized officer

Hübner, Jens

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2018/024568

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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International application No

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