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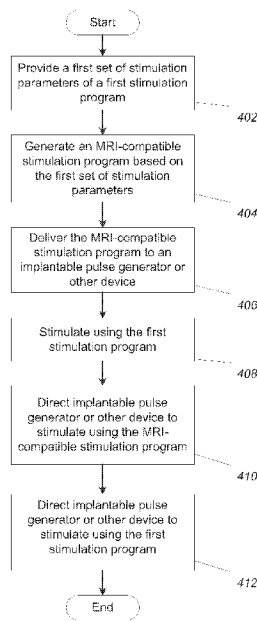


Fig. 4

(57) Abstract: Methods and systems for generating an MRI-compatible stimulation program based at least in part on a first set of stimulation parameters of a first stimulation program are presented. For example, a method or system (via a processor) can include receiving the first set of stimulation parameters, wherein the first set of stimulation parameters indicates a first set of stimulation electrodes; modifying the first set of stimulation parameters to generate a second set of stimulation parameters of the MRI-compatible stimulation program by at least one of 1) reducing a value of at least one stimulation parameter of the first set of stimulation parameters or 2) replacing, in the first set of electrodes, a case electrode with at least one electrode of the lead; and initiating a signal that provides the IPG with the MRI-compatible stimulation program.



SYSTEMS AND METHODS FOR SELECTING MRI-COMPATIBLE STIMULATION PARAMETERS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional
5 Patent Application Serial No. 62/441,944, filed January 3, 2017, which is incorporated
herein by reference.

FIELD

The present invention is directed to the area of implantable electrical stimulation
systems and methods of making and using the systems. The present invention is also
10 directed to systems and methods for selecting magnetic resonance imaging (MRI)-
compatible stimulation parameters.

BACKGROUND

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

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

BRIEF SUMMARY

One embodiment is a system for creating a magnetic resonance imaging (MRI)-
compatible stimulation program for electrical stimulation of a patient using an
30 implantable electrical stimulation system including an implantable pulse generator and a
lead having a plurality of electrodes. The system for creating the MRI-compatible

stimulation program includes a processor configured and arranged to: receive a first set of stimulation parameters of a first stimulation program, wherein the first set of stimulation parameters indicates a first set of electrodes for delivery of electrical stimulation; generate an MRI-compatible stimulation program based at least in part on the received first set of stimulation parameters, wherein the MRI-compatible stimulation program includes a second set of stimulation parameters that indicates a second set of electrodes from the plurality of electrodes for delivery of electrical stimulation, wherein generating the MRI-compatible stimulation program comprises modifying the first set of stimulation parameters by the processor to generate the second set of stimulation parameters by at least one of 1) reducing a value of at least one stimulation parameter of the first set of stimulation parameters or 2) replacing, in the first set of electrodes, a case electrode of the electrical stimulation system with at least one of the electrodes of the lead; and initiate a signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient.

In at least some embodiments, the processor is further configured to determine a value that indicates energy consumption for the first stimulation program, wherein generating the MRI-compatible stimulation program further includes reducing the value of the at least one stimulation parameter of the first set of stimulation parameters in response to the value that indicates energy consumption.

In at least some embodiments, generating the MRI-compatible stimulation program further includes reducing the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters includes at least one of stimulation current, stimulation voltage, pulse width, or pulse frequency.

In at least some embodiments, generating the MRI-compatible stimulation program further includes reducing the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters includes a stimulation current.

In at least some embodiments, the first set of electrodes includes the case electrode and wherein generating the MRI-compatible stimulation program includes

replacing, in the first set of electrodes, the case electrode of the electrical stimulation system with at least one of the electrodes of the lead.

In at least some embodiments, generating the MRI-compatible stimulation program further includes reducing the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of
5 the first set of stimulation parameters includes the pulse width.

In at least some embodiments, generating the MRI-compatible stimulation program further includes replacing the case electrode of the electrical stimulation system with at least one of the electrodes of the lead by distributing stimulation via the case
10 electrode for the first stimulation program over a plurality of electrodes of the lead that are unused in the first stimulation program.

In at least some embodiments, the system further includes a user interface communicably coupled to the computer processor, wherein the processor is further configured to receive, via the user interface, user input indicative of user-modification of
15 the MRI-compatible stimulation program; and, responsive to the user input, modify the MRI-compatible stimulation program in accordance with the user-modification to generate a user-modified MRI-compatible stimulation program, wherein initiating the signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the
20 patient includes initiating a signal that provides the implantable pulse generator of the electrical stimulation system with the user-modified MRI-compatible stimulation program for producing electrical stimulation to the patient.

In at least some embodiments, the processor is further configured to initiate a signal that initiates electrical stimulation to the patient by the electrical stimulation system
25 in accordance with the MRI-compatible program.

Another embodiment is a non-transitory computer-readable medium having computer executable instructions stored thereon that, when executed by a processor, cause the processor to perform a method for creating a magnetic resonance imaging (MRI)-compatible stimulation program for electrical stimulation of a patient using an
30 implantable electrical stimulation system including an implantable pulse generator and a

lead having a plurality of electrodes. The method includes receiving a first set of stimulation parameters of a first stimulation program, wherein the first set of stimulation parameters indicates a first set of electrodes for delivery of electrical stimulation; generating an MRI-compatible stimulation program based at least in part on the received first set of stimulation parameters, wherein the MRI-compatible stimulation program includes a second set of stimulation parameters that indicates a second set of electrodes from the plurality of electrodes for delivery of electrical stimulation, wherein generating the MRI-compatible stimulation program comprises modifying the first set of stimulation parameters by the processor to generate the second set of stimulation parameters by at least one of 1) reducing a value of at least one stimulation parameter of the first set of stimulation parameters or 2) replacing, in the first set of electrodes, a case electrode of the electrical stimulation system with at least one of the electrodes of the lead; and initiating a signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient.

In at least some embodiments, the method further includes determining a value that indicates energy consumption for the first stimulation program, wherein generating the MRI-compatible stimulation program further includes reducing the value of the at least one stimulation parameter of the first set of stimulation parameters in response to the value that indicates energy consumption.

In at least some embodiments, generating the MRI-compatible stimulation program further includes reducing the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters includes at least one of stimulation current, stimulation voltage, pulse width, or pulse frequency.

In at least some embodiments, generating the MRI-compatible stimulation program further includes reducing the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters includes at least one of stimulation current or pulse.

In at least some embodiments, generating the MRI-compatible stimulation program further includes replacing the case electrode of the electrical stimulation system

with at least one of the electrodes of the lead by distributing stimulation via the case electrode for the first stimulation program over a plurality of electrodes of the lead that are unused for the first stimulation program.

In at least some embodiments, the method further includes receiving, via a user interface, a user input indicative of one or more electrodes to exclude from the second set of electrodes; and responsive to the user input, excluding the one or more electrodes from the second set of electrodes.

Yet another embodiment is a method for creating a magnetic resonance imaging (MRI)-compatible stimulation program for electrical stimulation of a patient using an implantable electrical stimulation system including an implantable pulse generator and a lead having a plurality of electrodes. The method includes receiving, by a processor, a first set of stimulation parameters of a first stimulation program, wherein the first set of stimulation parameters indicates a first set of electrodes for delivery of electrical stimulation; generating, by the processor, an MRI-compatible stimulation program based at least in part on the received first set of stimulation parameters, wherein the MRI-compatible stimulation program includes a second set of stimulation parameters that indicates a second set of electrodes from the plurality of electrodes for delivery of electrical stimulation, wherein generating the MRI-compatible stimulation program comprises modifying the first set of stimulation parameters by the processor to generate the second set of stimulation parameters by at least one of 1) reducing a value of at least one stimulation parameter of the first set of stimulation parameters or 2) replacing, in the first set of electrodes, a case electrode of the electrical stimulation system with at least one of the electrodes of the lead; and initiating, by the processor, a signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient.

In at least some embodiments, the method further includes determining, by the processor, a value that indicates energy consumption for the first stimulation program, wherein generating the MRI-compatible stimulation program further includes reducing, by the processor, the value of the at least one stimulation parameter of the first set of stimulation parameters in response to the value that indicates energy consumption.

In at least some embodiments, generating the MRI-compatible stimulation program further includes reducing, by the processor, the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters includes at least one of
5 stimulation current, stimulation voltage, pulse width, or pulse frequency.

In at least some embodiments, generating the MRI-compatible stimulation program further includes replacing, by the processor, the case electrode of the electrical stimulation system with at least one of the electrodes of the lead by distributing
10 stimulation via the case electrode for the first stimulation program over a plurality of electrodes of the lead that are unused for the first stimulation program.

In at least some embodiments, initiating the signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient includes displaying, via a user interface communicatively coupled to the processor, one or more of 1) the second set of
15 stimulation parameters or 2) an estimated stimulation region based on the second set of stimulation parameters; receiving, by the processor via the user interface, a user input indicative of acceptance of the MRI-compatible stimulation program; responsive at least in part to the user input, initiating, by the processor, the signal that provides the
implantable pulse generator of the electrical stimulation system with the MRI-compatible
20 stimulation program for producing electrical stimulation to the patient ; responsive at least in part to the patient undergoing an MRI scan, initiating a signal that controls the implantable pulse generator of the electrical stimulation system to implement the MRI-compatible stimulation program; and responsive at least in part to conclusion of the MRI scan, initiating a signal that controls the implantable pulse generator of the electrical
25 stimulation system to implement the first stimulation program.

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

FIG. 1 is a schematic view of one embodiment of an electrical stimulation system,
5 according to the invention;

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

FIG. 3 is a schematic block diagram of one embodiment of a system for determining stimulation parameters, according to the invention;

10 FIG. 4 is a flowchart of one embodiment of a method of determining MRI-compatible stimulation parameters, according to the invention;

FIG. 5 is a flowchart of a second embodiment of a method of determining MRI-compatible stimulation parameters, according to the invention; and

15 FIG. 6 is a diagrammatic illustration of one embodiment of a method of determining MRI-compatible stimulation parameters, according to the invention.

DETAILED DESCRIPTION

The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to systems and methods for selecting MRI-compatible stimulation parameters.

20 Suitable implantable electrical stimulation systems include, but are not limited to, a least one lead with one or more electrodes disposed on a distal end of the lead and one or more terminals disposed on one or more proximal ends of the lead. Leads include, for example, percutaneous leads, paddle leads, cuff leads, or any other arrangement of electrodes on a lead. Examples of electrical stimulation systems with leads are found in,
25 for example, U.S. Patents Nos. 6,181,969; 6,516,227; 6,609,029; 6,609,032; 6,741,892; 7,244,150; 7,450,997; 7,672,734; 7,761,165; 7,783,359; 7,792,590; 7,809,446; 7,949,395; 7,974,706; 8,175,710; 8,224,450; 8,271,094; 8,295,944; 8,364,278; 8,391,985; and 8,688,235; and U.S. Patent Applications Publication Nos. 2007/0150036; 2009/0187222; 2009/0276021; 2010/0076535; 2010/0268298; 2011/0005069; 2011/0004267;

2011/0078900; 2011/0130817; 2011/0130818; 2011/0238129; 2011/0313500;
2012/0016378; 2012/0046710; 2012/0071949; 2012/0165911; 2012/0197375;
2012/0203316; 2012/0203320; 2012/0203321; 2012/0316615; 2013/0105071; and
2013/0197602, all of which are incorporated by reference. In the discussion below, a
5 percutaneous lead will be exemplified, but it will be understood that the methods and
systems described herein are also applicable to paddle leads and other leads.

A percutaneous lead for electrical stimulation (for example, deep brain or spinal
cord stimulation) includes stimulation electrodes that can be ring electrodes, segmented
electrodes that extend only partially around the circumference of the lead, or any other
10 type of electrode, or any combination thereof. The segmented electrodes can be provided
in sets of electrodes, with each set having electrodes circumferentially distributed about
the lead at a particular longitudinal position. 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
15 spinal cord stimulation, peripheral nerve stimulation, or stimulation of other nerves,
muscles, and tissues. In particular, stimulation may stimulate specific targets. Examples
of such targets include, but are not limited to, the subthalamic nucleus (STN), internal
segment of the globus pallidus (GPi), external segment of the globus pallidus (GPe), and
the like. In at least some embodiments, an anatomical structure is defined by its physical
20 structure and a physiological target is defined by its functional attributes. In at least one
of the various embodiments, the lead may be positioned at least partially within the target,
but in other embodiments, the lead may be near, but not inside, the target.

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

The IPG 14 is physically connected, optionally via one or more lead extensions
24, to the stimulation lead(s) 12. Each lead carries multiple electrodes 26 arranged in an
30 array. The IPG 14 includes pulse generation circuitry that delivers electrical stimulation
energy in the form of, for example, a pulsed electrical waveform (i.e., a temporal series of
electrical pulses) to the electrode array 26 in accordance with a set of stimulation

parameters. The IPG 14 can be implanted into a patient's body, for example, below the patient's clavicle area or within the patient's buttocks or abdominal cavity. The IPG 14 can have eight stimulation channels which may be independently programmable to control the magnitude of the current stimulus from each channel. In at least some
5 embodiments, the IPG 14 can have more or fewer than eight stimulation channels (for example, 4-, 6-, 16-, 32-, or more stimulation channels). The IPG 14 can have one, two, three, four, or more connector ports, for receiving the terminals of the leads.

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

The RC 16 may be used to telemetrically communicate with or control the IPG 14 or ETS 20 via a uni- or bi-directional wireless communications link 32. Once the IPG 14
20 and neurostimulation leads 12 are implanted, the RC 16 may be used to telemetrically communicate with or control the IPG 14 via a uni- or bi-directional communications link 34. Such communication or control allows the IPG 14 to be turned on or off and to be programmed with different stimulation parameter sets. The IPG 14 may also be operated to modify the programmed stimulation parameters to actively control the characteristics
25 of the electrical stimulation energy output by the IPG 14. The CP 18 allows a user, such as a clinician, the ability to program stimulation parameters for the IPG 14 and ETS 20 in the operating room and in follow-up sessions.

The CP 18 may perform this function by indirectly communicating with the IPG
30 14 or ETS 20, through the RC 16, via a wireless communications link 36. Alternatively, the CP 18 may directly communicate with the IPG 14 or ETS 20 via a wireless communications link (not shown). The stimulation parameters provided by the CP 18 are also used to program the RC 16, so that the stimulation parameters can be subsequently

modified by operation of the RC 16 in a stand-alone mode (i.e., without the assistance of the CP 18).

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

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

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

observe the muscle and indicate changes in, for example, tremor frequency or amplitude in response to stimulation of neurons. Alternatively, the patient or clinician can observe the muscle and provide feedback.

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

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

The lead 100 includes a lead body 110, terminals 135, one or more ring electrodes 120, and one or more sets of segmented electrodes 130 (or any other combination of electrodes). The lead body 110 can be formed of a biocompatible, non-conducting material such as, for example, a polymeric material. Suitable polymeric materials include, but are not limited to, silicone, polyurethane, polyurea, polyurethane-urea, polyethylene, or the like. Once implanted in the body, the lead 100 may be in contact with body tissue for extended periods of time. In at least some embodiments, the lead 100 has a cross-sectional diameter of no more than 1.5 mm and may be in the range of 0.5 to 1.5 mm. In at least some embodiments, the lead 100 has a length of at least 10 cm and the length of the lead 100 may be in the range of 10 to 70 cm.

The electrodes 125 can be made using a metal, alloy, conductive oxide, or any other suitable conductive biocompatible material. Examples of suitable materials include,

but are not limited to, platinum, platinum iridium alloy, iridium, titanium, tungsten, palladium, palladium rhodium, or the like. Preferably, the electrodes 125 are made of a material that is biocompatible and does not substantially corrode under expected operating conditions in the operating environment for the expected duration of use.

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

Deep brain stimulation leads may include one or more sets of segmented
10 electrodes. Segmented electrodes may provide for superior current steering than ring electrodes because target structures in deep brain stimulation are not typically symmetric about the axis of the distal electrode array. Instead, a target may be located on one side of a plane running through the axis of the lead. Through the use of a radially segmented electrode array (“RSEA”), current steering can be performed not only along a length of
15 the lead but also around a circumference of the lead. This provides precise three-dimensional targeting and delivery of the current stimulus to neural target tissue, while potentially avoiding stimulation of other tissue. Examples of leads with segmented electrodes include U.S. Patents Nos. 8,473,061; 8,571,665; and 8,792,993; U.S. Patent Application Publications Nos. 2010/0268298; 2011/0005069; 2011/0130803;
20 2011/0130816; 2011/0130817; 2011/0130818; 2011/0078900; 2011/0238129; 2012/0016378; 2012/0046710; 2012/0071949; 2012/0165911; 2012/197375; 2012/0203316; 2012/0203320; 2012/0203321; 2013/0197424; 2013/0197602; 2014/0039587; 2014/0353001; 2014/0358208; 2014/0358209; 2014/0358210; 2015/0045864; 2015/0066120; 2015/0018915; 2015/0051681; U.S. Patent Applications
25 Serial Nos. 14/557,211 and 14/286,797; and U.S. Provisional Patent Application Serial No. 62/113,291, all of which are incorporated herein by reference.

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

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

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

Any suitable memory 304 can be used for the computing device 302. The memory 304 illustrates a type of computer-readable media, namely computer-readable storage media. Computer-readable storage media may include, but is not limited to, nonvolatile, non-transitory, removable, and non-removable media implemented in any
15 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
20 medium which can be used to store the desired information and which can be accessed by a computing device.

Communication methods provide another type of computer readable media; namely communication media. Communication media typically embodies computer-readable instructions, data structures, program modules, or other data in a modulated data
25 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
30 cable, fiber optics, wave guides, and other wired media and wireless media such as acoustic, RF, infrared, and other wireless media.

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

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

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

The methods and systems described herein may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein.

20 Accordingly, the methods and systems described herein may take the form of an entirely hardware embodiment, an entirely software embodiment or an embodiment combining software and hardware aspects. Systems referenced herein typically include memory and typically include methods for communication with other devices including mobile devices. Methods of communication can include both wired and wireless (for example,
25 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.

30 Under normal operating conditions, a stimulation system that implements a stimulation program will stimulate a desired portion of patient tissue. It has been found,

however, that during an MRI scan a power source of the stimulation system may drain at a dramatically higher rate for the same stimulation program. Accordingly, the stimulation system may fail to sufficiently stimulate or may completely fail to stimulate the desired patient tissue.

5 To address this issued, the present systems or methods can generate an MRI-compatible stimulation program that will, at least partially, alleviate the battery drain while still providing useful stimulation to the patient tissue. In at least some embodiments, the stimulation may be less effective than stimulation using the original stimulation program, but the objective is to provide at least some effective stimulation
10 during the MRI procedure.

Figure 4 illustrates a flowchart of one embodiment of a method of creating the MRI-compatible stimulation program. In step 402, a first set of stimulation parameters of a first stimulation program is received. A stimulation program can be described by a set of stimulation parameters that produce the stimulation of the stimulation program.
15 Stimulation parameters can include, but are not limited to, selection of electrode or electrodes to produce the stimulation, stimulation amplitude (total amplitude or individual amplitude for each electrode when multiple electrodes are used to produce the stimulation), pulse width, pulse frequency, and the like. In at least some embodiments, at least one stimulation parameter may indicate a minimum permissible parameter value (for
20 example, a minimum stimulation current that represents an estimated minimum amount of current that stimulates the tissue), a maximum permissible parameter value (for example, a maximum pulse width that represents an upper limit of a range of pulse widths that the system may employ), or the like. Some stimulation programs may also be more complex where the selection of electrodes may change during the program (for example,
25 alternating between a first selection of electrodes and second selection of electrodes) or changes in amplitude, pulse width, pulse frequency, or the like. Also, some stimulation programs may also include bursts of stimulation pulses with at least one stimulation parameter indicating a burst frequency, burst width, duty cycle, burst pattern, or the like.

Examples of different stimulation programs and methods and systems for
30 choosing stimulation programs can be found at, for example, U.S. Patents Nos. 8,326,433; 8,675,945; 8,831,731; 8,849,632; and 8,958,615; U.S. Patent Application

Publications Nos. 2009/0287272; 2009/0287273; 2012/0314924; 2013/0116744; 2014/0122379; and 2015/0066111; and U.S. Provisional Patent Application Serial No. 62/030,655; U.S. Provisional Patent Application Serial No. 62/186,184, all of which are incorporated herein by reference.

5 The first set of stimulation parameters can be received in any suitable manner. For example, the first set of stimulation parameters may be retrieved from an internal or external memory. As another example, the clinician or user can input or otherwise generate the first stimulation program via any manner explained herein. The first set of stimulation parameters may be obtained from the IPG or other device. Combinations of
10 these methods, or any other suitable arrangement for providing the set of stimulation parameters, may also be used to obtain the first set of stimulation parameters.

 In step 404, a MRI-compatible stimulation program is generated based on the first stimulation program. In at least some embodiments, the MRI-compatible stimulation program is generated based at least in part on the first set of stimulation parameters of the
15 first stimulation program by modifying one or more of those stimulation parameters. The MRI-compatible stimulation program includes a second set of stimulation parameters. At least some of stimulation parameters of the second set of stimulation parameters are related to, or the same as, the corresponding stimulation parameters in the first set of stimulation parameters. In at least some embodiments, the MRI-compatible stimulation
20 program is generated by modifying one or more of the stimulation parameters of the first set to generate the second set of stimulation parameters.

 The MRI-compatible stimulation program is generated to increase likelihood that the stimulation system provides suitable stimulates the patient during an MRI scan while ameliorating one or more deleterious effects on the system or patient during the MRI
25 scan. In at least some embodiments, the first stimulation program can be used to stimulate the patient under normal or non-MRI conditions (for example, before or after an MRI scan of the patient) and the MRI-compatible stimulation program can be used for stimulating the patient under MRI scan conditions (for example, during the MRI scan of the patient).

30 In at least some embodiments, generating the MRI-compatible stimulation program may involve reducing, or otherwise altering, a value of at least one stimulation

parameter of the first set of stimulation parameters. For example, the value may be reduced or altered so that it does not exceed a predefined threshold, a maximum value, or an upper limit. In at least some embodiments that define the amount of stimulation using current, the total current (or the current associated with any specific electrode) delivered during stimulation may be limited to a predefined threshold (for example, no more than 1, 0.75, 0.5, or 0.25 mA) in the MRI-compatible program. If the current delivered during the first stimulation program exceeds this threshold, then current in the MRI-compatible stimulation program is reduced to the threshold amount (or lower). Other examples of stimulation parameters that may be altered in a similar manner to that described above for stimulation current include, but are not limited to, stimulation voltage, pulse width, pulse frequency, burst width, and burst frequency. Reducing one or more of these parameters may be beneficial during a MRI scan.

In at least some embodiments, generating the MRI-compatible stimulation program may involve altering a selection of electrodes for providing the stimulation. For example, the MRI-compatible stimulation program may only permit monophasic stimulation (i.e., only one anode and one cathode). In this instance, if the first stimulation program provides biphasic or multiphasic stimulation (using two or more anodes or two or more cathodes), then the selection of electrodes is altered in the MRI-compatible stimulation program to select only one of those anodes/cathodes for stimulation delivery.

As another example, the case of the IPG 14 is often used as an anode or cathode during stimulation, but the MRI-compatible stimulation program may not allow this usage and may require altering the placement of the cathode or anode on the case of the IPG 14 to one or more electrodes on the lead 12.

In step 406, the computing device 300 delivers the MRI-compatible stimulation program to the IPG 14, ETS 20, or other device. For example, the computing device 300 can initiate the signal that provides the IPG 14, ETS 20, or other device with the MRI-compatible stimulation program.

In step 408, the IPG 14, ETS 20, or other device stimulates the patient using the first stimulation program. This stimulation is provided except for periods of an MRI scan.

In step 410, the IPG 14, ETS 20, or other device is directed to stimulate the patient using the MRI-compatible stimulation program. In at least some embodiments, the IPG 14, ETS 20, or other device is coupled to a sensor or other device that can detect that an MRI scan is occurring or soon to occur (for example, detecting a large static magnetic field of the MRI device or changing magnetic field gradients or RF fields associated with MRI scans) and, responsive to this detection, automatically direct the IPG 14, ETS 20, or other device to switch to the MRI-compatible stimulation program. In at least some embodiments, a user (clinician, patient, or other person) using an external device, such as CP 18, RC 16, or another device, can communicate with the IPG 14, ETS 20, or other device to manually direct the IPG 14, ETS 20, or other device to switch to the MRI-compatible stimulation program. In at least some embodiments, a system may provide for both the automatic or manual direction of the IPG 14, ETS 20, or other device to switch to the MRI-compatible stimulation program.

In step 412, the IPG 14, ETS 20, or other device is directed to return to the first stimulation program to stimulate the patient. In at least some embodiments, the IPG 14, ETS 20, or other device may automatically switch to the first stimulation program after a predetermined period of time. In at least some embodiments, the IPG 14, ETS 20, or other device is coupled to a sensor or other device that can detect when an MRI scan is complete and, responsive to this detection, automatically direct the IPG 14, ETS 20, or other device to switch back to the first stimulation program. In at least some embodiments, a user (clinician, patient, or other person) using an external device, such as CP 18, RC 16, or another device, can communicate with the IPG 14, ETS 20, or other device to manually direct the IPG 14, ETS 20, or other device to switch back to the first stimulation program. In some systems, a combination of two or three of these mechanisms can be available to direct the IPG 14, ETS 20, or other device to switch back to the first stimulation program.

Figure 5 illustrates another embodiment of a method for creating the MRI-compatible stimulation program. In step 502, a first set of stimulation parameters of a first stimulation program is received just as in step 402.

In step 504, a value indicative of energy consumption is determined. This determination may be performed by the IPG 14, ETS 20, CP 18, RC 16, or other device.

In at least some embodiments, this value may be known or previously calculated or estimated. In at least some embodiments, the value may be indicative of energy consumption under normal conditions or energy consumption while the stimulation system implements the first stimulation program under MRI scan conditions. In at least
5 some embodiments, the value may be determined using a predefined formula or information in a database (for example, empirical data obtained from observing differences in energy consumption of various stimulation systems under normal conditions versus energy consumption of the various stimulation systems under MRI scan conditions).

10 One example of a value indicative of energy consumption is the pulse width multiplied by a square of the stimulation current or the pulse width multiplied by a square of the minimum stimulation current. Other values and calculations for the values may be used. Additionally or alternatively to calculating a value, at least one parameter value may be used in the calculation or as a representation of the energy consumption (for
15 example, pulse width, stimulation current, minimum stimulation current threshold, or another one of those discussed above). In addition, it will be understood that multiple values may be taken into account to describe energy consumption. In at least some embodiments, the value indicative of energy consumption may be a measured value (for example, a change in battery charge over time).

20 In step 506, a MRI-compatible stimulation program is generated based on the first stimulation program and the value indicative of energy consumption determined in the step 504. In determining the MRI-compatible stimulation program, the system may determine how to modify the first set of stimulation parameters to reduce the energy consumption to a threshold or target value (or lower). In at least some embodiments,
25 generating the MRI-compatible stimulation program may involve reducing, or otherwise altering, a value of at least one stimulation parameter of the first set of stimulation parameters or altering the selection of electrodes, or any combination thereof. Examples of such alterations are provided above with respect to step 404 in Figure 4. In at least some embodiments, the system may iteratively alter stimulation parameters until a value
30 of the energy consumption for the new stimulation program is equal to or less than a threshold or target value.

Steps 508 to 514 are the same as steps 406 to 412, respectively.

Figure 6 is a flowchart of one method of creating the MRI-compatible stimulation program. In step 602, the system provides a graphical user interface (GUI). The user interface may be on, for example, CP 18 or RC 16. In step 604, the first set of stimulation parameters of the first stimulation program are received and an MRI-compatible stimulation program is generated. For example, step 604 can be performed as described above in steps 402-404 of Figure 4 or steps 502-506 of Figure 5. Optionally, the user interface may allow the user to set user-defined limitations to the MRI-compatible stimulation program prior to generating the MRI-compatible stimulation program. For example, the user may be permitted to set limits on stimulation parameters or may be able to designate electrodes that cannot be used for stimulation or designate electrodes that must be used for stimulation.

In step 606, the MRI-compatible stimulation program (for example, the stimulation parameters of the MRI-compatible stimulation program) is displayed in the user interface. This permits a user, such as a clinician or patient, to review the MRI-compatible program.

In other embodiments, the system may display an estimated stimulation region based on the stimulation parameters of the MRI-compatible program. Optionally, the user interface may also display an estimated stimulation region for the first stimulation program.

In step 608, the user interface allows the user to modify the MRI-compatible stimulation program. For example, the user may be allowed to modify values of one or more of the stimulation parameters or modify electrode selection (either adding or deleting electrodes to be used for stimulation), or any combination thereof. The modified MRI-compatible stimulation program may then be displayed in the user interface.

In at least some embodiments, the system may provide at least one warning if an adjustment is outside of previously set thresholds or rules for the MRI-compatible stimulation program. For example, a warning may be issued if an adjusted stimulation parameter exceeds a predefined value or if the resulting value indicative of energy consumption, for that set of stimulation parameters, exceeds a threshold value. As other

example, a warning may be issued if the modified electrode selection is biphasic or multiphasic when the MRI-compatible stimulation program is intended to be monophasic or when the case electrode is modified to be used as an anode or cathode when the MRI-compatible stimulation program is intended not to use the case electrode. Any suitable
5 warning can be used including, but not limited to, a visual, audible, or haptic warning or any combination thereof. Alternatively, the system may simply prevent an adjustment that is outside of previously set thresholds or limits or that violates rules for the MRI-compatible stimulation program. In at least some embodiments, some adjustments may be prevented while other adjustments may be allowed with a warning to the user.

10 In embodiments that display an estimated stimulation region based on the stimulation parameters of the MRI-compatible program, that estimated stimulation region may be altered with alteration of the stimulation parameters. In at least some embodiments, the user interface may also display the estimated stimulation region based on the stimulation parameters of the unmodified MRI-compatible program. Each of the
15 estimated stimulation regions may be displayed with a visual or graphical difference (such as different coloring, shaping, or the like).

Steps 610 to 616 are the same as steps 406 to 412, respectively.

In at least some embodiments, the system may require the clinician or user to approve the MRI-compatible stimulation program prior to delivery or use of the MRI-
20 compatible stimulation program. In at least some embodiments, the system may require testing via the ETS 20 before approval.

It will be understood that the system can include one or more of the methods described hereinabove with respect to Figures 4-6 in any combination. The methods, systems, and units described herein may be embodied in many different forms and should
25 not be construed as limited to the embodiments set forth herein. Accordingly, the methods, systems, and units described herein may take the form of an entirely hardware embodiment, an entirely software embodiment or an embodiment combining software and hardware aspects. The methods described herein can be performed using any type of processor or any combination of processors where each processor performs at least part of
30 the process.

It will be understood that each block of the flowchart illustrations, and combinations of blocks in the flowchart illustrations and methods disclosed herein, can be implemented by computer program instructions. These program instructions may be provided to a processor to produce a machine, such that the instructions, which execute
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 computing device.

20

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

CLAIMS

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

1. A system for creating a magnetic resonance imaging (MRI)-compatible stimulation program for electrical stimulation of a patient using an implantable electrical stimulation system comprising an implantable pulse generator and a lead having a plurality of electrodes, the system for creating the MRI-compatible stimulation program comprising:

a processor configured to:

receive a first set of stimulation parameters of a first stimulation program, wherein the first set of stimulation parameters indicates a first set of electrodes for delivery of electrical stimulation;

generate an MRI-compatible stimulation program based at least in part on the received first set of stimulation parameters, wherein the MRI-compatible stimulation program comprises a second set of stimulation parameters that indicates a second set of electrodes from the plurality of electrodes for delivery of electrical stimulation, wherein generating the MRI-compatible stimulation program comprises modifying the first set of stimulation parameters by the processor to generate the second set of stimulation parameters by at least one of 1) reducing a value of at least one stimulation parameter of the first set of stimulation parameters or 2) replacing, in the first set of electrodes, a case electrode of the electrical stimulation system with at least one of the electrodes of the lead; and

initiate a signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient.

2. The system of claim 1, wherein the processor is further configured to determine a value that indicates energy consumption for the first stimulation program, wherein generating the MRI-compatible stimulation program further comprises reducing

the value of the at least one stimulation parameter of the first set of stimulation parameters in response to the value that indicates energy consumption.

3. The system of any one of claims 1 or 2, wherein generating the MRI-compatible stimulation program further comprises reducing the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters comprises at least one of stimulation current, stimulation voltage, pulse width, or pulse frequency.

4. The system of any one of claims 1-3, wherein the first set of electrodes comprises the case electrode and wherein generating the MRI-compatible stimulation program comprises replacing, in the first set of electrodes, the case electrode of the electrical stimulation system with at least one of the electrodes of the lead, wherein, optionally, the at least one of the electrodes of the lead is a plurality of electrodes of the lead that are unused in the first stimulation program.

5. The system of any one of claims 1-4, further comprising a user interface communicably coupled to the computer processor, wherein the processor is further configured to:

receive, via the user interface, user input indicative of user-modification of the MRI-compatible stimulation program; and

responsive to the user input, modify the MRI-compatible stimulation program in accordance with the user-modification to generate a user-modified MRI-compatible stimulation program, wherein initiating the signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient comprises initiating a signal that provides the implantable pulse generator of the electrical stimulation system with the user-modified MRI-compatible stimulation program for producing electrical stimulation to the patient.

6. A non-transitory computer-readable medium having computer executable instructions stored thereon that, when executed by a processor, cause the processor to perform a method for creating a magnetic resonance imaging (MRI)-compatible stimulation program for electrical stimulation of a patient using an implantable electrical stimulation system comprising an implantable pulse generator and a lead having a plurality of electrodes, the method comprising:

receiving a first set of stimulation parameters of a first stimulation program, wherein the first set of stimulation parameters indicates a first set of electrodes for delivery of electrical stimulation;

generating an MRI-compatible stimulation program based at least in part on the received first set of stimulation parameters, wherein the MRI-compatible stimulation program comprises a second set of stimulation parameters that indicates a second set of electrodes from the plurality of electrodes for delivery of electrical stimulation, wherein generating the MRI-compatible stimulation program comprises modifying the first set of stimulation parameters by the processor to generate the second set of stimulation parameters by at least one of 1) reducing a value of at least one stimulation parameter of the first set of stimulation parameters or 2) replacing, in the first set of electrodes, a case electrode of the electrical stimulation system with at least one of the electrodes of the lead; and

initiating a signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient.

7. The non-transitory computer-readable medium of claim 6, wherein the method further comprises determining a value that indicates energy consumption for the first stimulation program, wherein generating the MRI-compatible stimulation program further comprises reducing the value of the at least one stimulation parameter of the first set of stimulation parameters in response to the value that indicates energy consumption.

8. The non-transitory computer-readable medium of any one of claims 6 or 7, wherein generating the MRI-compatible stimulation program further comprises reducing

the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters comprises at least one of stimulation current, stimulation voltage, pulse width, or pulse frequency.

9. The non-transitory computer-readable medium of any one of claims 6-8, wherein generating the MRI-compatible stimulation program further comprises replacing the case electrode of the electrical stimulation system with at least one of the electrodes of the lead by distributing stimulation via the case electrode for the first stimulation program over a plurality of electrodes of the lead that are unused for the first stimulation program.

10. The non-transitory computer-readable medium of any one of claims 6-9, wherein the method further comprises:

receiving, via a user interface, a user input indicative of one or more electrodes to exclude from the second set of electrodes; and

responsive to the user input, excluding the one or more electrodes from the second set of electrodes.

11. A method for creating a magnetic resonance imaging (MRI)-compatible stimulation program for electrical stimulation of a patient using an implantable electrical stimulation system comprising an implantable pulse generator and a lead having a plurality of electrodes, the method comprising:

receiving, by a processor, a first set of stimulation parameters of a first stimulation program, wherein the first set of stimulation parameters indicates a first set of electrodes for delivery of electrical stimulation;

generating, by the processor, an MRI-compatible stimulation program based at least in part on the received first set of stimulation parameters, wherein the MRI-compatible stimulation program comprises a second set of stimulation parameters that indicates a second set of electrodes from the plurality of electrodes for delivery of electrical stimulation, wherein generating the MRI-compatible stimulation program comprises modifying the first set of stimulation parameters by the processor to generate

the second set of stimulation parameters by at least one of 1) reducing a value of at least one stimulation parameter of the first set of stimulation parameters or 2) replacing, in the first set of electrodes, a case electrode of the electrical stimulation system with at least one of the electrodes of the lead; and

initiating, by the processor, a signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient.

12. The method of claim 11, further comprising determining, by the processor, a value that indicates energy consumption for the first stimulation program, wherein generating the MRI-compatible stimulation program further comprises reducing, by the processor, the value of the at least one stimulation parameter of the first set of stimulation parameters in response to the value that indicates energy consumption.

13. The method of any one of claims 11 or 12, wherein generating the MRI-compatible stimulation program further comprises reducing, by the processor, the value of the at least one stimulation parameter of the first set of stimulation parameters, wherein the at least one stimulation parameter of the first set of stimulation parameters comprises at least one of stimulation current, stimulation voltage, pulse width, or pulse frequency.

14. The method of any one of claims 11-13, wherein generating the MRI-compatible stimulation program further comprises replacing, by the processor, the case electrode of the electrical stimulation system with at least one of the electrodes of the lead by distributing stimulation via the case electrode for the first stimulation program over a plurality of electrodes of the lead that are unused for the first stimulation program.

15. The method of any one of claims 11-14, wherein initiating the signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient comprises:

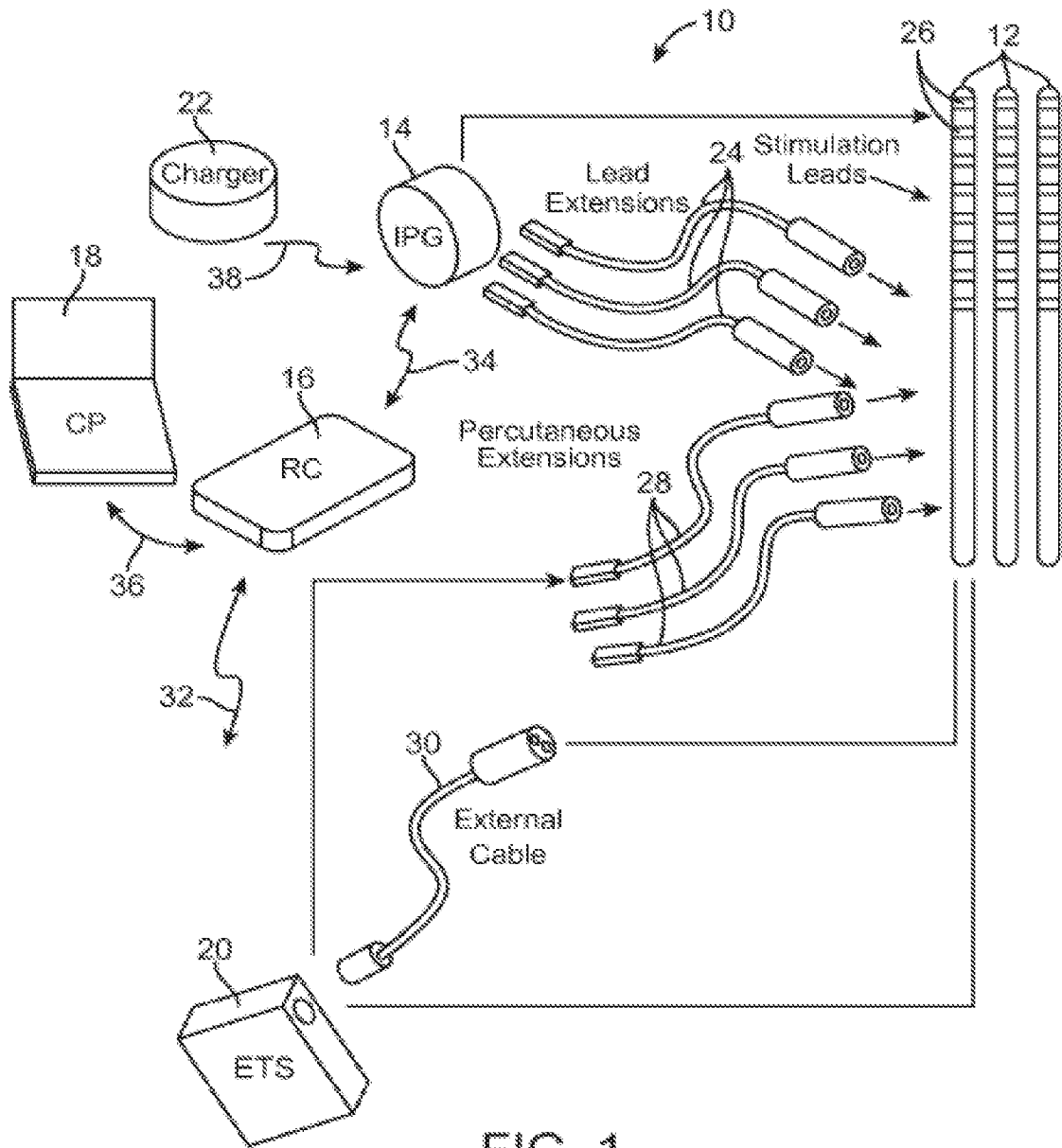
displaying, via a user interface communicatively coupled to the processor, one or more of 1) the second set of stimulation parameters or 2) an estimated stimulation region based on the second set of stimulation parameters;

receiving, by the processor via the user interface, a user input indicative of acceptance of the MRI-compatible stimulation program;

responsive at least in part to the user input, initiating, by the processor, the signal that provides the implantable pulse generator of the electrical stimulation system with the MRI-compatible stimulation program for producing electrical stimulation to the patient;

responsive at least in part to the patient undergoing an MRI scan, initiating a signal that controls the implantable pulse generator of the electrical stimulation system to implement the MRI-compatible stimulation program; and

responsive at least in part to conclusion of the MRI scan, initiating a signal that controls the implantable pulse generator of the electrical stimulation system to implement the first stimulation program.



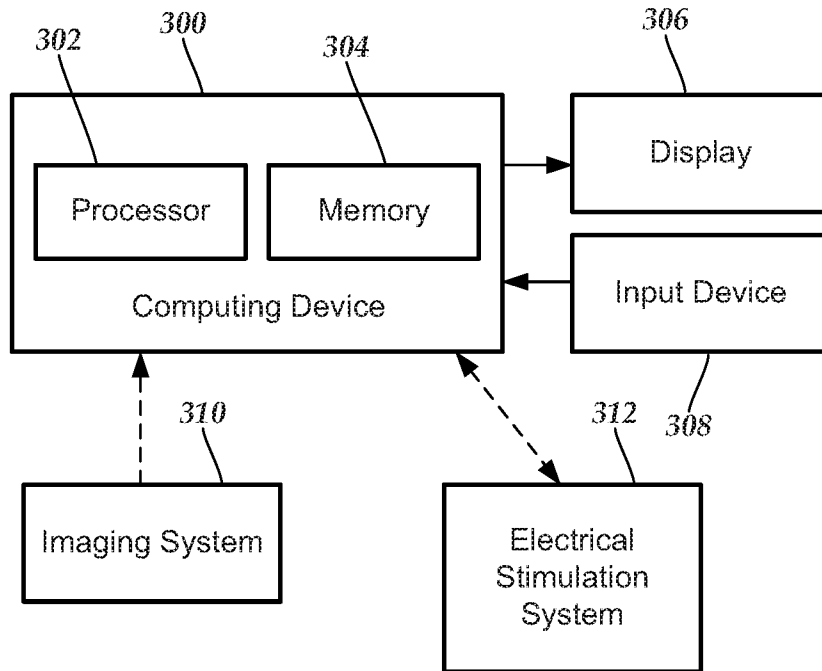
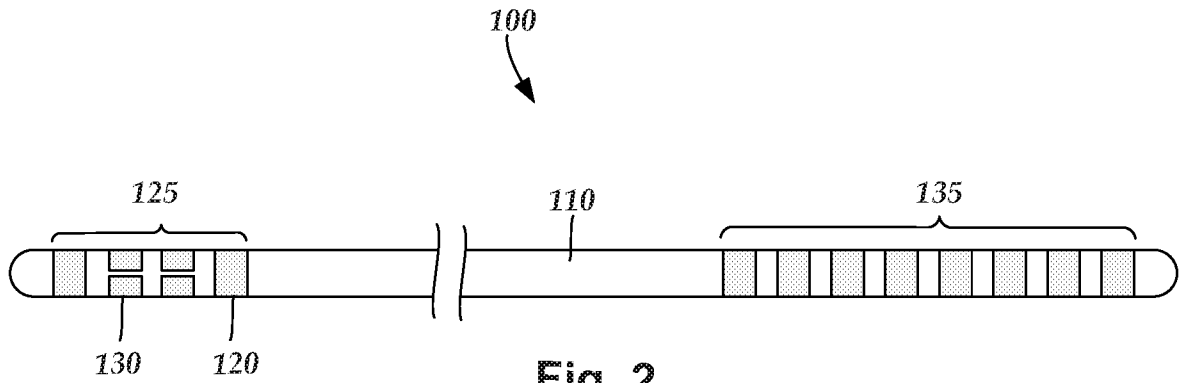


Fig. 3

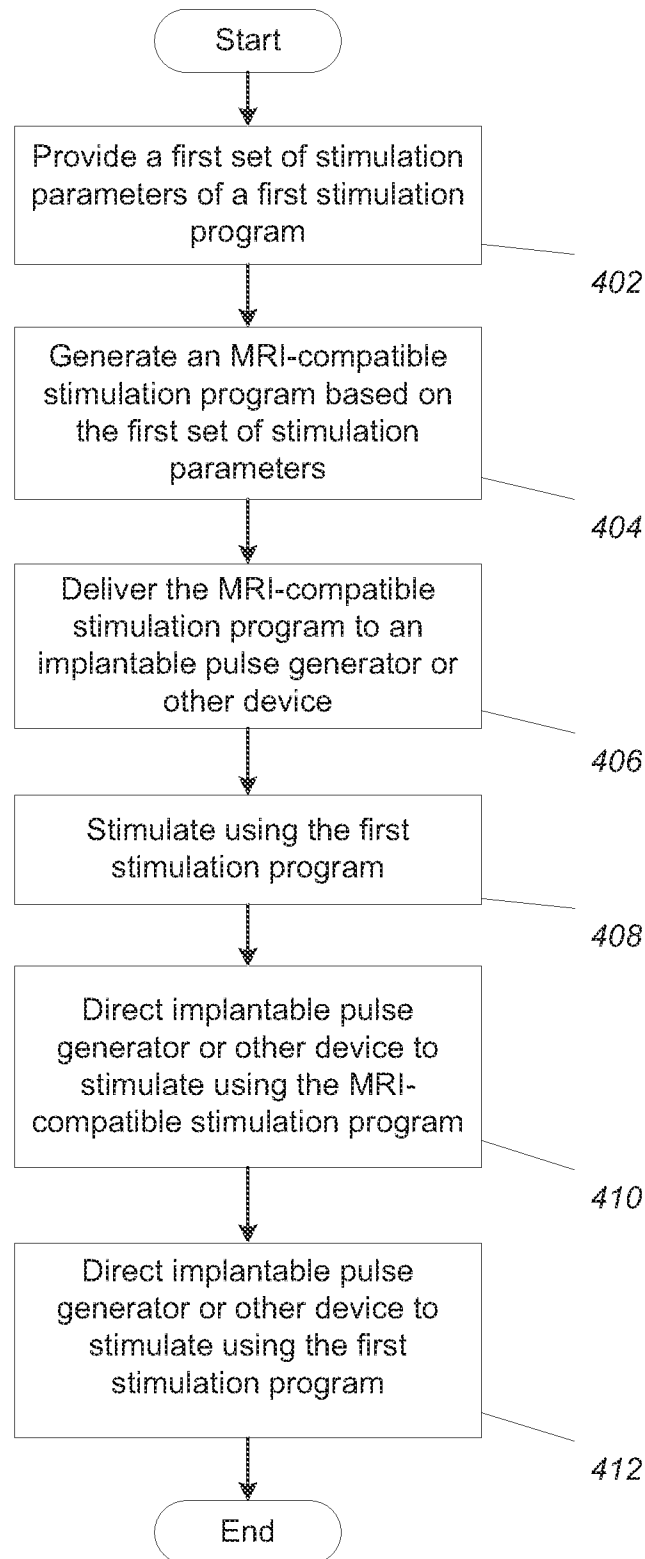


Fig. 4
3/5

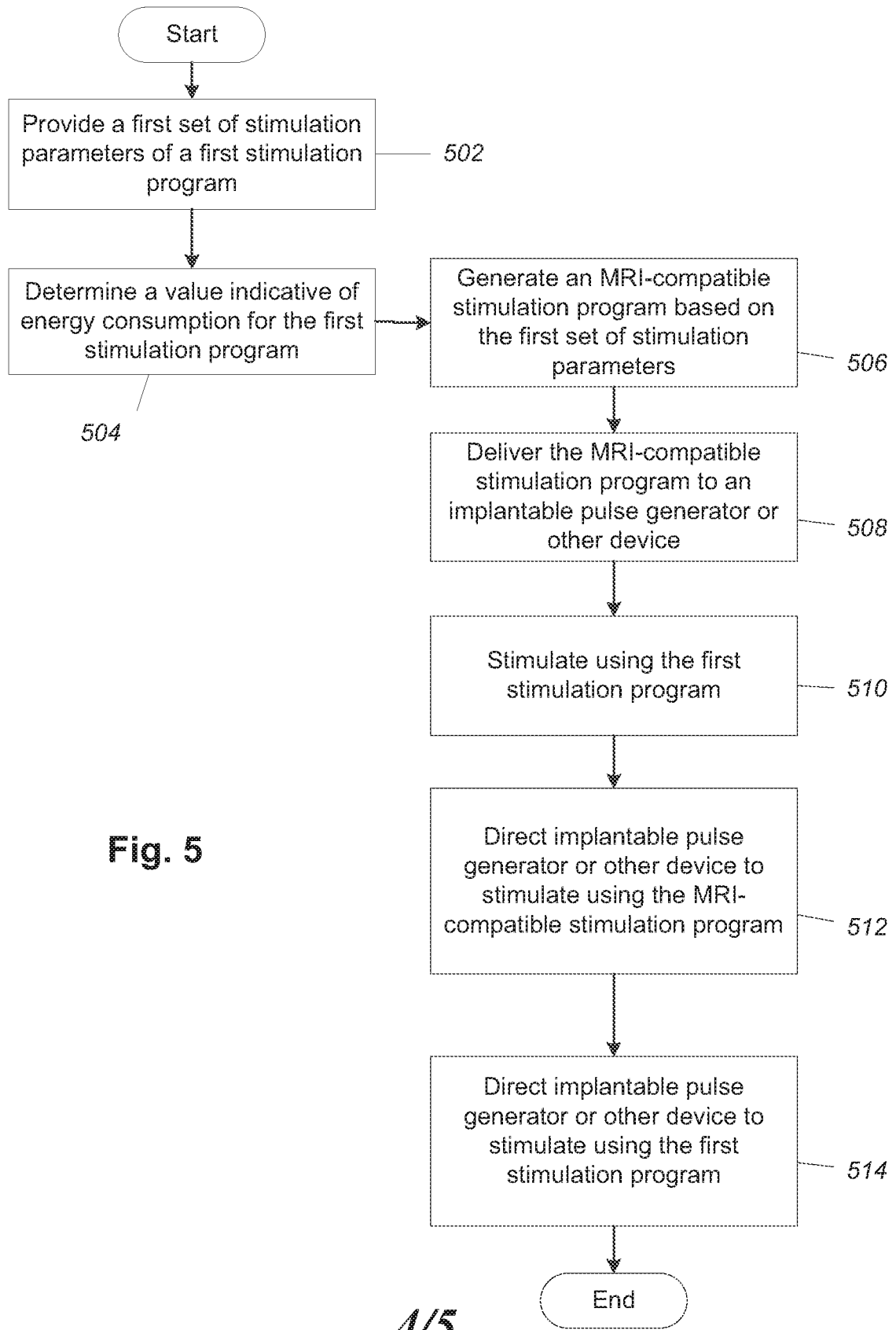


Fig. 5

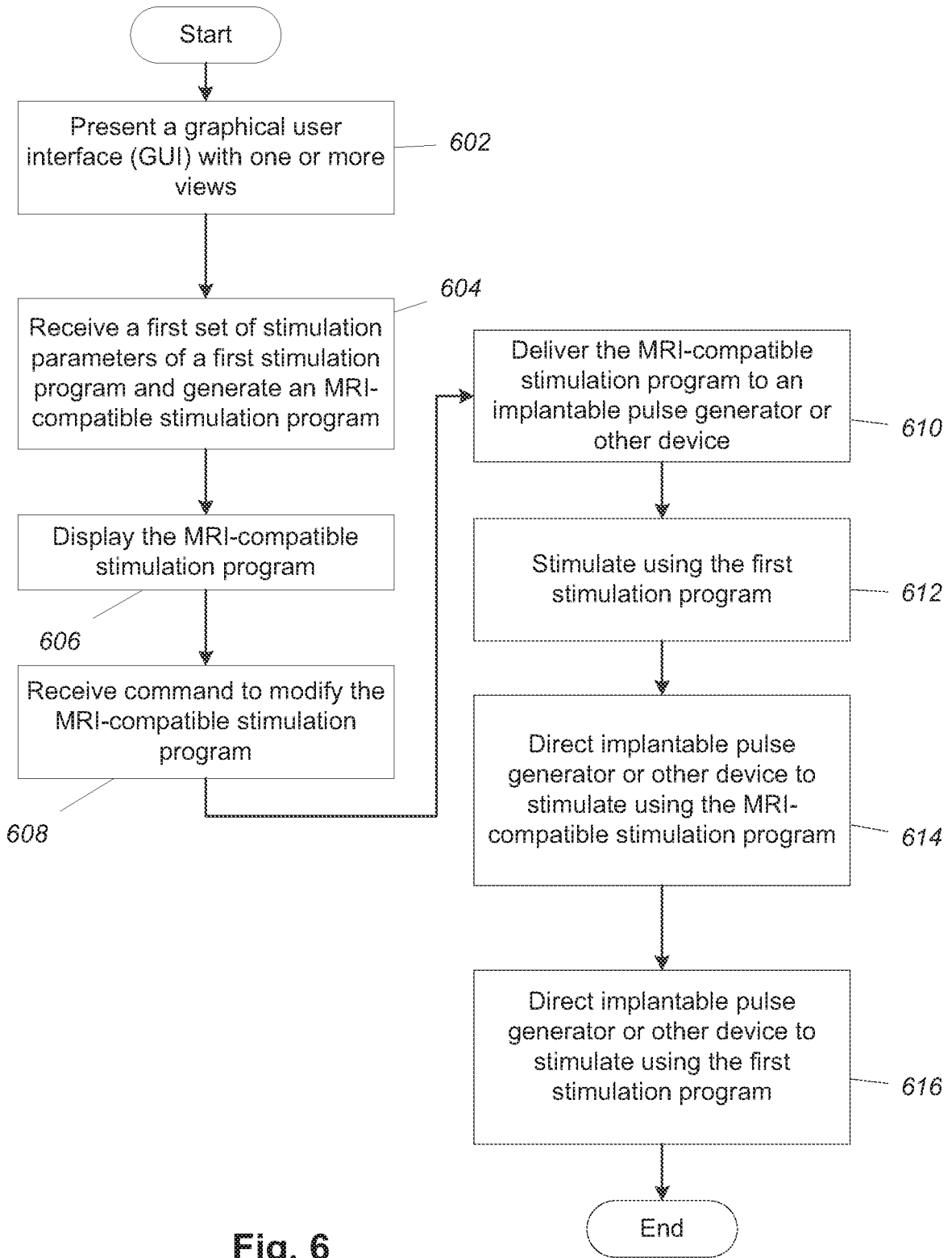


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/069118

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 11-15
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/069118

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/08
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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/137945 A1 (GADAGKAR HRISHIKESH [US] ET AL) 3 June 2010 (2010-06-03) abstract; claim *; figure * paragraphs [0054] - [0072] paragraphs [0201] - [0205] -----	1-10
A	US 2012/053652 A1 (DIANATY ALI [US] ET AL) 1 March 2012 (2012-03-01) the whole document -----	1-10
A	WO 2011/053378 A1 (MEDTRONIC INC [US]; YOON HYUN J [US]; ELLINGSON MICHAEL L [US]; PRZYBY) 5 May 2011 (2011-05-05) the whole document -----	1-10
A	US 2011/160808 A1 (LYDEN MICHAEL J [US] ET AL) 30 June 2011 (2011-06-30) the whole document -----	1-10

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search 13 March 2018	Date of mailing of the international search report 21/03/2018
--------------------------------------------------------------------------------	----------------------------------------------------------------------

Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Scheffler, Arnaud
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/069118

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010137945	A1	03-06-2010	EP 2384220 A2
			EP 2384480 A2
			EP 2384481 A2
			US 2010137945 A1
			US 2010137946 A1
			US 2010137947 A1
			US 2014222108 A1
			US 2017348537 A1
			WO 2010062978 A2
			WO 2010062984 A2
			WO 2010062988 A2

US 2012053652	A1	01-03-2012	NONE

WO 2011053378	A1	05-05-2011	US 2011106204 A1
			WO 2011053378 A1

US 2011160808	A1	30-06-2011	NONE

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 11-15

The method of producing electrical stimulation as defined in claims 11-15 is regarded to be a method for treatment of the human or animal body by therapy/surgery. Therefore, the subject-matter of claims 11-15 has not been searched (Art.17(2)(a)(i) and Rule 39.1). Moreover, according to Article 34(4)(a)(i) PCT and Rule 67.1(iv) PCT, no international preliminary examination is required to be carried out on the subject-matter of these claims.