



- (51) **International Patent Classification:**
A61N 1/36 (2006.01) *A61N 1/37* (2006.01)
- (21) **International Application Number:**
PCT/US2016/066935
- (22) **International Filing Date:**
15 December 2016 (15.12.2016)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
62/269,768 18 December 2015 (18.12.2015) US
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- (81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA,

MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

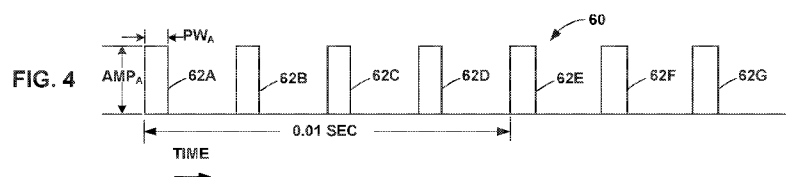
Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) **Title:** HIGH DUTY CYCLE ELECTRICAL STIMULATION THERAPY



(57) **Abstract:** In some examples, a medical device is configured to deliver high dose electrical stimulation therapy to a patient by at least generating and delivering an electrical stimulation signal having a relatively high duty cycle, and a stimulation intensity less than a perception or paresthesia threshold intensity level for the patient. The pulses of the electrical stimulation signal may each have a relatively low amplitude, but due at least in part to a relatively high number of pulses per unit of time, a dose of the electrical stimulation may be high enough to elicit a therapeutic response from the patient.



HIGH DUTY CYCLE ELECTRICAL STIMULATION THERAPY

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/269,768, which was filed on December 18, 2015 and is entitled, “HIGH DUTY CYCLE ELECTRICAL STIMULATION THERAPY.”

BACKGROUND

[0002] The disclosure relates to electrical stimulation therapy.

BACKGROUND

[0003] Medical devices may be external or implanted, and may be used to deliver electrical stimulation therapy to patients to various tissue sites to treat a variety of symptoms or conditions such as chronic pain, tremor, Parkinson’s disease, epilepsy, urinary or fecal incontinence, sexual dysfunction, obesity, or gastroparesis. A medical device may deliver electrical stimulation therapy via one or more leads that include electrodes located proximate to target locations associated with the brain, the spinal cord, pelvic nerves, peripheral nerves, or the gastrointestinal tract of a patient. Hence, electrical stimulation may be used in different therapeutic applications, such as deep brain stimulation (DBS), spinal cord stimulation (SCS), pelvic stimulation, gastric stimulation, or peripheral nerve field stimulation (PNFS).

[0004] A clinician may select values for a number of programmable parameters in order to define the electrical stimulation therapy to be delivered by the implantable stimulator to a patient. For example, the clinician may select one or more electrodes, a polarity of each selected electrode, a voltage or current amplitude, a pulse width, and a pulse frequency as stimulation parameters. A set of parameters, such as a set including electrode combination, electrode polarity, amplitude, pulse width and pulse rate, may be referred to as a program in the sense that they define the electrical stimulation therapy to be delivered to the patient.

SUMMARY

[0005] This disclosure describes example medical devices, systems, and techniques for delivering a relatively high dose of electrical stimulation therapy to a patient per unit of time

to treat one or more patient conditions. In some examples, a medical device is configured to deliver the high dose of electrical stimulation therapy by at least generating and delivering an electrical stimulation signal having a relatively high duty cycle, and stimulation intensity less than a perception or paresthesia threshold intensity level of the patient. The electrical stimulation therapy may comprise stimulation pulses that may each have relatively low amplitude. Due at least in part to a relatively high number of pulses per unit of time (e.g., per second) and the resulting relatively high energy delivery per unit of time, the dose of the electrical stimulation delivered to the patient may be high enough to elicit a therapeutic response from the patient.

[0006] In some examples, the electrical stimulation may have a duty cycle in a range of about 5% to about 50% and a frequency in a range about 1 Hertz (Hz) to about 1400 Hz, such as less than about 1000 Hz, and each of the pulses may have a pulse width less than or equal to about 5 milliseconds (ms), such as in a range of about 0.1 ms to about 5 ms, or in a range of about 0.1 ms to about 1 ms. In these examples, the frequency and pulse width may be selected such that the electrical stimulation may have a duty cycle in a range of about 5% to about 50%. In addition, the frequency, amplitude, and pulse width may be selected such that the stimulation intensity less than at least one of a perception threshold intensity level or a paresthesia threshold intensity level of the patient.

[0007] In some examples, the medical device may deliver a recharge signal (e.g., one or more pulses or other waveforms) to the patient after delivering the electrical stimulation signal having the relatively high duty cycle. Each electrical stimulation pulse has a first polarity and the recharge signal has a second polarity that is opposite to the first polarity. For example, in some examples, the medical device may deliver one or more recharge pulses to the patient after delivering a plurality of pulses of the electrical stimulation signal having the relatively high duty cycle. In this case, a plurality of stimulation pulses may be delivered without delivery of a recharge pulses between the stimulation pulses, but then the plurality of stimulation pulses may be followed by one or more recharge pulses.

[0008] In one example, a method includes generating, by a medical device, an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5

milliseconds, the electrical stimulation signal having a stimulation intensity less than of at least one of a perception threshold or a paresthesia threshold of a patient; and delivering, by the medical device, the electrical stimulation signal to the patient.

[0009] In another example, a method comprises generating, by a medical device, a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses; generating, by the medical device, a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds; delivering, by the medical device, the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields; and delivering, by the medical device, a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals. Delivering the first and second electrical stimulation signals comprises interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz. The first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

[0010] In another example, a method comprises determining a paresthesia or perception threshold for a patient; determining, for a selected frequency, a strength-duration curve based on the paresthesia or perception threshold; and determining, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating an electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 5% to about 50%, a frequency in a range of about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.

[0011] In another example, a system a stimulation generator configured to generate and deliver electrical stimulation therapy to a patient; and a processor configured to control the stimulation generator to generate and deliver an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a

frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of the patient.

[0012] In another example, a system comprises a plurality of electrodes; a stimulation generator configured to generate and deliver electrical stimulation therapy to a patient via one or more subset of the electrodes; and a processor configured to control the stimulation generator to generate a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses, generate a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, deliver the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields, wherein the processor is configured to control the stimulation generator to deliver the first and second electrical stimulation signals by at least interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz, and deliver a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals. The first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

[0013] In another example, a system comprises a processor configured to determine a paresthesia or perception threshold stimulation intensity level of a patient, determine, for a selected frequency, a strength-duration curve based on the paresthesia or perception threshold stimulation intensity level, and determine, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating an electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 5% to about 50%, a frequency in a range of about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.

[0014] In another example, a system includes means for generating an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of a patient; and means for delivering the electrical stimulation signal to the patient.

[0015] In another example, a system includes means for generating a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses, and a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds; means for delivering the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields, wherein the means for delivering delivers the first and second electrical stimulation signals by at least interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz; and means for delivering a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals. The first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

[0016] In another example, a system includes means for determining a paresthesia or perception threshold for a patient; means for determining, for a selected frequency, a strength-duration curve based on the paresthesia or perception threshold; and means for determining, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating an electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 20% to about 50%, a frequency in a range of

about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.

[0017] In another example, a computer-readable storage medium comprises instructions that, when executed by a processor, cause the processor to: control a stimulation generator to generate an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of a patient; and control the stimulation generator to deliver the electrical stimulation signal to the patient.

[0018] In another example, a computer-readable storage medium comprises instructions that, when executed by a processor, cause the processor to control a stimulation generator of a medical device to generate a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses; control the stimulation generator of the medical device to generate a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds; control the stimulation generator to deliver the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields by at least interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz; and control the stimulation generator to deliver a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals. The first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

[0019] In another example, a computer-readable storage medium comprises instructions that, when executed by a processor, cause the processor to: determine a paresthesia or perception threshold for a patient; determine, for a selected frequency, a strength-duration curve based

on the paresthesia or perception threshold; and determine, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating an electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 5% to about 50%, a frequency in a range of about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.

[0020] In another aspect, the disclosure is directed to a computer-readable storage medium, which may be an article of manufacture. The computer-readable storage medium includes computer-readable instructions for execution by one or more processors. The instructions cause one or more processors to perform any part of the techniques described herein. The instructions may be, for example, software instructions, such as those used to define a software or computer program.

[0021] The details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of examples according to this disclosure will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0022] FIG. 1 is a conceptual diagram illustrating an example system that includes a medical device programmer and an implantable medical device (IMD) configured to deliver high dose electrical stimulation therapy to a patient.

[0023] FIG. 2 is a block diagram of the example IMD of FIG. 1.

[0024] FIG. 3 is a block diagram of the example external programmer of FIG. 1.

[0025] FIGS. 4 and 5 illustrate an example of high duty cycle electrical stimulation waveforms.

[0026] FIG. 6 illustrates an example burst electrical stimulation waveform.

[0027] FIG. 7 illustrates an example high frequency electrical stimulation waveform.

[0028] FIG. 8 is a flow diagram of an example method of programming high dose electrical stimulation therapy having a stimulation intensity level that is less than a perception or paresthesia threshold intensity level for a patient.

[0029] FIG. 9 is a flow diagram of an example method of determining a perception or paresthesia threshold intensity level for a patient.

DETAILED DESCRIPTION

[0030] This disclosure describes example medical devices, systems, and techniques for delivering electrical stimulation therapy to treat one or more patient conditions, the electrical stimulation therapy providing a relatively high amount of electrical stimulation per unit of time (referred to herein as a “high dose”) and a stimulation intensity less than a perception or paresthesia threshold intensity level of the patient. The dose of electrical stimulation may be a function of a frequency and pulse width of the pulses. The perception threshold intensity level may be the lowest determined stimulation intensity level at which a patient perception of the electrical stimulation occurs, and the paresthesia threshold intensity level may be the lowest determined stimulation intensity level at which the electrical stimulation causes paresthesia, for example, within a predetermined time range (e.g., 30 seconds) of the patient receiving the electrical stimulation.

[0031] The high dose of electrical stimulation therapy described herein delivers a relatively high amount of energy (e.g., electrical charge) to tissue of the patient per unit of time (e.g., one second). For example, the high dose of electrical stimulation therapy may have a charge delivery of about 100 microCoulombs to about 2,000 microCoulombs per second. The sufficiency of electrical stimulation in producing a desired therapeutic effect may be based on the amount of charge delivered to the tissue of the patient per unit of time. In the case of electrical stimulation pulses, the amount of charge delivered to the tissue of the patient per unit of time may be calculated by multiplying the electrical current delivered during an electrical pulse by the pulse width, which yields the amount of electrical charge delivered during a single pulse, and multiplying the amount of electrical charge delivered to the patient for one pulse by the frequency of the electrical stimulation signal.

[0032] The high energy dose electrical stimulation described herein may be provided by an electrical stimulation signal having a relatively high duty cycle. The duty cycle may be, for example, the percentage of active electrical stimulation per unit of time (e.g., one second), and may, for example, be a product of a frequency of the pulses and a pulse width of the pulses. Thus, the duty cycle may, in some examples, be defined by a plurality of pulses per unit of time, rather than a single pulse. However, other waveforms may be used in other examples.

[0033] In some examples, a medical device is configured to generate and deliver, via one or more electrodes, an electrical stimulation signal having a high duty cycle and a frequency less than or equal to about 1400 Hertz (Hz), such as less than or equal to about 1000 Hz. The frequency may, for example, be in a range of about 1 Hz to about 1400 Hz, such as about 1000 Hz. The pulses may each have a relatively low amplitude (e.g., about 1 milliamp (mA) to about 25 mA, such as about 1 mA to about 5 mA), which can be the same or may vary between the pulses. In some examples, the duty cycle may be greater than 5% such as in a range of about 5% to about 50%, or about 20% to about 50%, or about 10% to about 40%, or about 20% to about 30%. Thus, in some examples, the frequency and pulse width of the pulses may be selected such that the electrical stimulation may have a duty cycle in a range of about 5% to about 50%, where the frequency is selected to be in a range of about 1 Hz to about 1400 Hz (e.g., less than or equal to about 1000 Hz) and the pulse width is selected to be in a range of about 0.1 ms to about 5 ms (e.g., about 0.1 ms to about 1 ms). In some examples, the amplitude of the pulses may be selected to provide therapeutic efficacy and so that the intensity of the delivered electrical stimulation is less than or equal to one or both of a paresthesia threshold or perception threshold of the patient.

[0034] Due at least in part to a relatively high number of pulses per unit of time and the selected pulse width, the dose (e.g., charge per second delivered) of the electrical stimulation signal may be high enough to elicit a therapeutic response from the patient, even though each individual pulse may have a relatively low amplitude. The relatively low amplitude of the pulses may also help keep the stimulation intensity level less than a perception or paresthesia threshold intensity level for the patient. In some examples, the plurality of pulses may have a duty cycle in a range of about 5% to about 50% and a frequency less than or equal to about 1000 Hz, and each of the pulses may have a pulse width in a range of about 0.1 ms to about 5 ms, such as about 0.1 ms to about 1 ms, or about 500 μ s to about 1 ms. For example, the plurality of pulses may have a duty cycle in a range of about 5% to about 50% and a frequency less equal to about 1000 Hz, and each of the pulses may have a pulse width less than or equal to about 0.5 ms.

[0035] In some examples in which the high duty cycle, relatively low stimulation intensity electrical stimulation is delivered to a tissue site in a patient proximate to the spinal cord, the electrical stimulation may modulate nerve fibers and produce pain relief via mechanisms that

do not rely on the activation of dorsal column fibers. Although the electrical stimulation may or may not also activate dorsal column fibers, the electrical stimulation may not rely on activation of dorsal column fibers, which may cause paresthesia, to provide therapeutic efficacy for pain or another patient condition. For example, the high duty cycle electrical stimulation may block endogenous action potentials in A-beta fibers at their branch points. A-beta fibers may be involved in some forms of chronic pain modulation, and the high duty cycle electrical stimulation may prevent A-fiber information from reaching the dorsal horn. Activation of dorsal column axons may cause paresthesia. Thus, the pain relief from the high duty cycle electrical stimulation described herein using relatively low amplitude pulses may be substantially paresthesia-free in some examples and with some patients. The paresthesia free electrical stimulation may be referred to as subliminal stimulation in some examples.

[0036] In some cases, the high duty cycle electrical stimulation described herein may modulate dorsal fibers, which may also be responsible for some aspects of pain (e.g., back pain) without causing activation of dorsal column fibers.

[0037] The mechanisms by which the high duty cycle, relatively low stimulation intensity electrical stimulation described herein may cause pain relief may include inhibition of spinal neurons, modulation of the activity of the central nervous system (CNS) and/or brainstem, or descending inhibition (e.g., suppression of pain messages to the brain).

[0038] The high duty cycle electrical stimulation techniques described herein may activate neurons in a different way than burst electrical stimulation techniques. In contrast to burst electrical stimulation techniques, the high duty cycle electrical stimulation described herein may provide better targeting of target tissue sites. For a given electrical stimulation dose (e.g., energy per second), burst electrical stimulation techniques may result in activation of more neural tissue (e.g., a larger volume of tissue) than the electrical stimulation described herein, which provides electrical stimulation with a higher frequency to achieve a dose sufficient to elicit a therapeutic response from a patient.

[0039] For example, the high duty cycle electrical stimulation described herein may deliver pulses having higher amplitudes, shorter pulse widths, or both higher amplitudes and shorter pulse widths than the burst electrical stimulation techniques. Compared to burst electrical stimulation techniques, the higher duty cycle described herein may allow for a larger therapeutic window for the amplitude of electrical stimulation (e.g., a range of values of the

stimulation signal amplitude that provides efficacious electrical stimulation therapy), which may result in more freedom to titrate the amplitude of the pulses. The larger therapeutic window may help a clinician tailor the electrical stimulation to a particular patient to allow for different neural mechanisms to be activated in order to elicit a therapeutic response from the patient, e.g., while maintaining the intensity of the electrical stimulation below a threshold stimulation intensity level. In addition, the larger therapeutic window for the amplitude may provide a clinician with more freedom to select therapy parameter values that balance power efficiency (power consumed by the IMD when generating the electrical stimulation) with the therapeutic effect.

[0040] In some examples, a therapeutic window is defined as the values of an electrical stimulation parameter between an efficacy threshold, which may be the lowest electrical stimulation parameter value (or highest, depending on the parameter) at which efficacious effects of the electrical stimulation were first observed for a particular patient, and an adverse-effects threshold, which may be the lowest electrical stimulation parameter value (or highest, depending on the parameter) at which adverse effects of the electrical stimulation were first observed for the patient.

[0041] The high duty cycle electrical stimulation described herein may also provide better targeting of target tissue sites compared to high frequency electrical stimulation techniques, in which a plurality of pulses are delivered at frequencies greater than or equal to 1.5 kilohertz (kHz). For a given dose, the high frequency electrical stimulation techniques may result in activation of more neural tissue than the high duty cycle electrical stimulation described herein, which provides electrical stimulation with wider pulse widths, but at lower frequencies than the high frequency electrical stimulation techniques to achieve a dose sufficient to elicit a therapeutic response from a patient. Compared to high frequency electrical stimulation techniques, the lower frequency of the high duty cycle electrical stimulation described herein may allow for a larger therapeutic window for the amplitude of electrical stimulation. As discussed above, a larger therapeutic window may help a clinician tailor the electrical stimulation to a particular patient and may provide the clinician with more freedom to select therapy parameter values that balance power efficiency with the therapeutic effect.

[0042] FIG. 1 is a conceptual diagram illustrating example system 10 that includes an implantable medical device (IMD) 14 configured to deliver electrical stimulation therapy to patient 12. In the example shown in FIG. 1, IMD 14 is configured to deliver SCS therapy. Although the techniques described in this disclosure are generally applicable to a variety of medical devices including external and implantable medical devices (IMDs), application of such techniques to IMDs and, more particularly, implantable electrical stimulators (e.g., neurostimulators) will be described for purposes of illustration. More particularly, the disclosure will refer to an implantable spinal cord stimulation (SCS) system for purposes of illustration, but without limitation as to other types of medical devices or other therapeutic applications of medical devices.

[0043] As shown in FIG. 1, system 10 includes an IMD 14, leads 16A, 16B, and external programmer 18 shown in conjunction with a patient 12, who is ordinarily a human patient. In the example of FIG. 1, IMD 14 is an implantable electrical stimulator that is configured to generate and deliver electrical stimulation therapy to patient 12 via electrodes of leads 16A, 16B, e.g., for relief of chronic pain or other symptoms. IMD 14 may be a chronic electrical stimulator that remains implanted within patient 12 for weeks, months, or even years. In other examples, IMD 14 may be a temporary, or trial, stimulator used to screen or evaluate the efficacy of electrical stimulation for chronic therapy.

[0044] IMD 14 may be constructed of any polymer, metal, or composite material sufficient to house the components of IMD 14 (e.g., components illustrated in FIG. 2) within patient 12. In this example, IMD 14 may be constructed with a biocompatible housing, such as titanium or stainless steel, or a polymeric material such as silicone, polyurethane, or a liquid crystal polymer, and surgically implanted at a site in patient 12 near the pelvis, abdomen, or buttocks. In other examples, IMD 14 may be implanted within other suitable sites within patient 12, which may depend, for example, on the target site within patient 12 for the delivery of electrical stimulation therapy. The outer housing of IMD 14 may be configured to provide a hermetic seal for components, such as a rechargeable power source. In addition, in some examples, the outer housing of IMD 14 may be selected of a material that facilitates receiving energy to charge the rechargeable power source.

[0045] Electrical stimulation energy, which may be constant current or constant voltage based pulses, for example, is delivered from IMD 14 to one or more target tissue sites of

patient 12 via one or more electrodes (not shown) of implantable leads 16A and 16B (collectively “leads 16”). In the example of FIG 1, leads 16 carry electrodes that are placed adjacent to the target tissue of spinal cord 20. One or more of the electrodes may be disposed at a distal tip of a lead 16 and/or at other positions at intermediate points along the lead. Leads 16 may be implanted and coupled to IMD 14. The electrodes may transfer electrical stimulation generated by an electrical stimulation generator in IMD 14 to tissue of patient 12. Although leads 16 may each be a single lead, each lead 16 may include a lead extension or other segments that may aid in implantation or positioning of the respective lead 16. In some other examples, IMD 14 may be a leadless stimulator with one or more arrays of electrodes arranged on a housing of the stimulator rather than leads that extend from the housing. In addition, in some other examples, system 10 may include one lead or more than two leads, each coupled to IMD 14 and directed to similar or different target tissue sites.

[0046] The electrodes of leads 16 may be electrode pads on a paddle lead, circular (e.g., ring) electrodes surrounding the body of the lead, conformable electrodes, cuff electrodes, segmented electrodes (e.g., electrodes disposed at different circumferential positions around the lead instead of a continuous ring electrode), or any other type of electrodes capable of forming unipolar, bipolar or multipolar electrode combinations for therapy. Ring electrodes arranged at different axial positions at the distal ends of lead 16 will be described for purposes of illustration.

[0047] The deployment of electrodes via leads 16 is described for purposes of illustration, but arrays of electrodes may be deployed in different ways. For example, a housing associated with a leadless stimulator may carry arrays of electrodes, e.g., rows and/or columns (or other patterns), to which shifting operations may be applied. Such electrodes may be arranged as surface electrodes, ring electrodes, or protrusions. As a further alternative, electrode arrays may be formed by rows and/or columns of electrodes on one or more paddle leads. In some examples, electrode arrays may include electrode segments, which may be arranged at respective positions around a periphery of a lead, e.g., arranged in the form of one or more segmented rings around a circumference of a cylindrical lead.

[0048] The therapy parameters for a therapy program (also referred to herein as a set of electrical stimulation parameter values) that controls delivery of stimulation therapy by IMD 14 through the electrodes of leads 16 may include information identifying which electrodes

have been selected for delivery of stimulation according to the therapy program, the polarities of the selected electrodes, i.e., the electrode configuration for the program, and voltage or current amplitude, pulse rate, and pulse width of stimulation delivered by the electrodes. Delivery of stimulation pulses will be described for purposes of illustration. However, electrical stimulation may be delivered in other forms such as continuous waveforms. Programs that control delivery of other therapies by IMD 14 may include other parameters, e.g., such as rate or the like in the case IMD 14 is also configured for drug delivery.

[0049] Although FIG. 1 is directed to SCS therapy, e.g., used to treat pain, in other examples system 10 may be configured to treat any other condition that may benefit from electrical stimulation therapy. For example, system 10 may be used to treat tremor, Parkinson's disease, epilepsy, a pelvic floor disorder (e.g., urinary incontinence or other bladder dysfunction, fecal incontinence, pelvic pain, bowel dysfunction, or sexual dysfunction), obesity, gastroparesis, or psychiatric disorders (e.g., depression, mania, obsessive compulsive disorder, anxiety disorders, and the like). In this manner, system 10 may be configured to provide therapy taking the form of deep brain stimulation (DBS), peripheral nerve stimulation (PNS), peripheral nerve field stimulation (PNFS), cortical stimulation (CS), pelvic floor stimulation, gastrointestinal stimulation, or any other stimulation therapy capable of treating a condition of patient 12.

[0050] In some examples, lead 16 may include one or more sensors configured to allow IMD 14 to monitor one or more parameters of patient 12. The one or more sensors may be provided in addition to, or in place of, therapy delivery by lead 16.

[0051] IMD 14 is configured to deliver high dose electrical stimulation therapy to patient 12 via selected combinations of electrodes carried by one or both of leads 16, alone or in combination with an electrode carried by or defined by an outer housing of IMD 14. The target tissue for the high dose electrical stimulation therapy may be any tissue affected by electrical stimulation, which may be in the form of electrical stimulation pulses or continuous waveforms. In some examples, the target tissue includes nerves, smooth muscle or skeletal muscle. In the example illustrated by FIG. 1, the target tissue is tissue proximate spinal cord 20, such as within an intrathecal space or epidural space of spinal cord 20, or, in some examples, adjacent nerves that branch off of spinal cord 20. Leads 16 may be introduced into

spinal cord 18 in via any suitable region, such as the thoracic, cervical or lumbar regions. Stimulation of spinal cord 18 may, for example, prevent pain signals from traveling through spinal cord 20 and to the brain of patient 12. Patient 12 may perceive the interruption of pain signals as a reduction in pain and, therefore, efficacious therapy results.

[0052] IMD 14 generates and delivers electrical stimulation therapy to a target stimulation site within patient 12 via the electrodes of leads 16 to patient 12 according to one or more therapy programs. A therapy program defines values for one or more parameters that define an aspect of the therapy delivered by IMD 14 according to that program. For example, a therapy program that controls delivery of stimulation by IMD 14 in the form of pulses may define values for voltage or current pulse amplitude, pulse width, and pulse rate for stimulation pulses delivered by IMD 14 according to that program.

[0053] Moreover, in some examples, IMD 14 delivers electrical stimulation therapy to patient 12 according to multiple therapy programs, which may be stored as a therapy program group. For example, as described below, in some examples, IMD 14 may deliver different pulses of a high duty cycle electrical stimulation signal via respective electrode combinations, and each of the electrode combinations may be associated with a respective therapy program. The therapy programs may be stored as a group, such that when IMD 14 generates and delivers electrical stimulation therapy via a selected group, IMD 14 delivers high duty cycle electrical stimulation signal via two or more therapy programs.

[0054] IMD 14 is configured to deliver a recharge signal (e.g., one or more recharge pulses or other waveforms), which may help balance a charge accumulation that may occur within tissue proximate the electrodes used to deliver the electrical stimulation. The recharge signal may also be referred to as a “recovery signal” or a “charge balancing signal” and may have a polarity opposite to that of the electrical stimulation signal generated and delivered by IMD 14. While recharge pulses are primarily referred to herein, in other examples, a recharge signal can have any suitable waveform.

[0055] In some examples, IMD 14 may deliver a recharge signal after delivery of multiple pulses of a high duty electrical stimulation signal, which may be defined by one therapy program or by multiple therapy programs. Thus, rather than charge balancing on a pulse-by-pulse basis (e.g., delivering one recharge pulse after each electrical stimulation pulse), in some examples, IMD 14 delivers one or more recharge pulses after delivery of two or more

electrical stimulation pulses. In some examples, IMD 14 delivers a high duty electrical stimulation signal to patient 12 according to multiple therapy programs by at least interleaving pulses of two or more therapy programs, the pulses having a first polarity. In some of these examples, IMD 14 may wait to deliver one or more recharge pulses until after one or more pulses of each of the therapy programs are delivered, each recharge pulse having a second polarity opposite to the first polarity. Thus, in some examples, IMD 14 may not deliver any recharge signals between therapy programs, but, rather, may withhold the delivery of one or more recharge signals until after IMD 14 delivers a plurality of pulses according to two or more therapy programs.

[0056] In some examples, IMD 14 is configured to generate and deliver high duty cycle electrical stimulation therapy to patient 12 via two or more electrodes, e.g., of leads 16 and/or a housing of IMD 14. In some examples, the high duty cycle electrical stimulation signal may have a duty cycle in a range of about 5% to about 50%, a frequency in a range of about 1 Hz to about 1400 Hz (e.g., less than about 1000 Hz in some examples), and a pulse width less than or equal to about 5 ms, such as about 0.1 ms to about 5 ms, or about 0.1 ms to about 1 ms. The amplitude and pulse width of the electrical stimulation signal are selected such that a stimulation intensity level of the electrical stimulation signal is less than a perception or paresthesia threshold intensity level for patient 12. For example, the amplitude may be selected to be in a range of about 1 mA to about 25 mA, such as in a range of about 1 mA to about 5 mA.

[0057] In some examples, IMD 14 delivers the pulses of the high duty cycle electrical stimulation signal via different electrode combinations. For example, IMD 14 may alternate delivery of pulses between two different electrode combinations, or may otherwise interleave the pulses using two or more electrode combinations in any suitable order. Regardless of the number of electrode combinations with which IMD 14 delivers the pulses, however, the combination of pulses delivered over time define an electrical stimulation signal that may have a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hz to about 1400 Hz.

[0058] A user, such as a clinician or patient 12, may interact with a user interface of an external programmer 18 to program IMD 14. Programming of IMD 14 may refer generally to the generation and transfer of commands, programs, or other information to control the

operation of IMD 14. In this manner, IMD 14 may receive the transferred commands and programs from programmer 18 to control stimulation therapy. For example, external programmer 18 may transmit therapy programs, stimulation parameter adjustments, therapy program selections, therapy program group selections, user input, or other information to control the operation of IMD 14, e.g., by wireless telemetry or wired connection.

[0059] In some cases, external programmer 18 may be characterized as a physician or clinician programmer if it is primarily intended for use by a physician or clinician. In other cases, external programmer 18 may be characterized as a patient programmer if it is primarily intended for use by a patient. A patient programmer may be generally accessible to patient 12 and, in many cases, may be a portable device that may accompany patient 12 throughout the patient's daily routine. For example, a patient programmer may receive input from patient 12 when the patient wishes to terminate or change stimulation therapy. In general, a physician or clinician programmer may support selection and generation of programs by a clinician for use by IMD 14, whereas a patient programmer may support adjustment and selection of such programs by a patient during ordinary use. In other examples, external programmer 18 may be included, or part of, an external charging device that recharges a power source of IMD 14. In this manner, a user may program and charge IMD 14 using one device, or multiple devices.

[0060] As described herein, information may be transmitted between external programmer 18 and IMD 14. Therefore, IMD 14 and programmer 18 may communicate via wireless communication using any techniques known in the art. Examples of communication techniques may include, for example, radiofrequency (RF) telemetry and inductive coupling, but other techniques are also contemplated. In some examples, programmer 18 may include a communication head that may be placed proximate to the patient's body near the IMD 14 implant site in order to improve the quality or security of communication between IMD 14 and programmer 18. Communication between programmer 18 and IMD 14 may occur during power transmission or separate from power transmission.

[0061] Although IMD 14 is generally described herein, techniques of this disclosure may also be applicable to external or partially external medical device in other examples. For example, IMD 14 may instead be configured as an external medical device coupled to one or more percutaneous medical leads. The external medical device may be a chronic, temporary,

or trial electrical stimulator. In addition, an external electrical stimulator may be used in addition to one or more IMDs 14 to deliver electrical stimulation described herein.

[0062] FIG 2 is a functional block diagram illustrating various components of an example IMD 14. In the example shown in FIG 2, IMD 14 includes processor 30, memory 32, stimulation generator 34, telemetry module 36, and power source 38. In other examples, IMD 14 may include a greater or fewer number of components. For example, IMD 14 may also include any one or more of a sensing module configured to sense one or more patient parameters, an inductive coil to receive power from an external charging device, and a recharge module that manages recharging of power source 38.

[0063] Processor 30 is operably connected to and configured to access information from memory 32 and to control stimulation generator 34 and telemetry circuit 36. Components described as processor 30 and other processors within IMD 14, external programmer 20 or any other device described in this disclosure may each comprise one or more processors, such as one or more microprocessors, digital signal processors (DSPs), application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), programmable logic circuitry, or the like, either alone or in any suitable combination. In general, IMD 14 may comprise any suitable arrangement of hardware (e.g., circuitry), alone or in combination with software and/or firmware, to perform the various techniques described herein attributed to IMD 14 and processor 30. In various examples, IMD 14 may include one or more processors 30, such as one or more DSPs, ASICs, FPGAs, programmable logic circuitry, or the like, either alone or in any suitable combination.

[0064] Memory 32 may store therapy programs 40 (or other instructions that specify therapy parameter values for the therapy provided by stimulation generator 34 and IMD 14), operating instructions 42 for execution by processor 30, and any other information regarding therapy of patient 12. In some examples, memory 32 may also store instructions for communication between IMD 14 and programmer 18, or any other instructions required to perform tasks attributed to IMD 14. Memory 32 may include separate memories for storing therapy programs, operating instructions, and any other data that may benefit from separate physical memory modules.

[0065] Memory 32 may comprise any suitable , such as random access memory (RAM), read only memory (ROM), programmable read only memory (PROM), erasable programmable

read only memory (EPROM), electronically erasable programmable read only memory (EEPROM), flash memory, comprising executable instructions for causing the one or more processors to perform the actions attributed to them. Although processor 30, therapy module 34, and telemetry module 36 are described as separate modules, in some examples, processor 30, therapy module 34, and telemetry module 36 may be functionally integrated. In some examples, processor 30, therapy module 34, and telemetry module 36 may correspond to individual hardware units, such as ASICs, DSPs, FPGAs, or other hardware units.

[0066] Stimulation generator 34 forms a therapy delivery module of IMD 14. Processor 30 controls stimulation generator 34 to generate and deliver electrical stimulation via electrode combinations formed by a selected subset of electrodes 24A–24D, 26A–26D (collectively, “electrodes 24, 26”) of leads 16. Stimulation generator 34 may deliver electrical stimulation therapy via electrodes on one or more of leads 16, e.g., as stimulation pulses. Stimulation generator 34 may include stimulation generation circuitry to generate stimulation pulses and, in some examples, switching circuitry to switch the stimulation across different electrode combinations, e.g., in response to control by processor 30. In other examples, stimulation generator 34 may include multiple current sources to drive more than one electrode combination at one time.

[0067] In some examples, processor 30 controls stimulation generator 34 by accessing memory 32 to selectively access and load at least one of the therapy programs 40 to stimulation generator 34. The stimulation parameter values of the stored therapy programs 40 may include, for example, a voltage amplitude, a current amplitude, a pulse frequency, a pulse width, a duty cycle, and a subset of electrodes 24, 26 of leads 16 for delivering the electrical stimulation signal. An electrode configuration may include the one or more electrodes 24, 26 with which stimulation generator 34 delivers the electrical stimulation to tissue of a patient, and the associated electrode polarities.

[0068] In some examples, IMD 14 may deliver a high duty cycle electrical stimulation signal to a target tissue site within patient 12 via one electrode combination, such that all pulses are delivered via the same electrode combination. In other examples, IMD 14 may deliver a high duty cycle electrical stimulation signal to a target tissue site within patient 12 via two or more electrode combinations, such that IMD 14 delivers at least two different pulses of a high duty cycle electrical stimulation signal via respective electrode combinations. The delivery of

different pulses via respective electrode combinations may help target the electrical stimulation to a target tissue site (e.g., in the case of pain relief, the target may be towards a midline of spinal cord 20, for example, near the T9–T10 vertebrae). The electrical stimulation delivered by each electrode combination, which may be referred to as a sub-signal, may be interleaved (e.g., delivered at different times) to define the high duty cycle electrical stimulation signal. In some of these examples, each sub-signal is associated with a respective therapy program. Thus, processor 30 may control stimulation generator 34 to generate and deliver a high duty cycle electrical stimulation signal by at least accessing memory 32 to selectively access and load multiple therapy programs 40 to stimulation generator 34.

[0069] IMD 14 also includes components to receive power from programmer 18 or a separate charging device to recharge a battery of power source 38. Power source 38 may include one or more capacitors, batteries, or other energy storage devices. IMD 14 may thus also include an inductive coil and a recharge module (both not shown) configured to manage the recharging session for power source 38. Although inductive coupling may be used to recharge power source 38, other wireless energy transfer techniques may alternatively be used. Alternatively, power source 38 may not be rechargeable.

[0070] Processor 30 may also control the exchange of information with programmer 18 and/or an external programmer using telemetry module 36. Telemetry module 36 may be configured for wireless communication using RF protocols, inductive communication protocols, or any other suitable technique. To support the wireless communication, telemetry circuit 36 may include appropriate electronic components, such as amplifiers, filters, mixers, encoders, decoders, and the like. Processor 30 may transmit operational information and receive therapy programs or therapy parameter adjustments via telemetry module 36. Also, in some examples, IMD 14 may communicate with other implanted devices, such as stimulators, control devices, or sensors, via telemetry module 36.

[0071] FIG 3 is a block diagram of an example external programmer 18. While programmer 18 may generally be described as a hand-held device, programmer 18 may be a larger portable device or a more stationary device in some examples. In addition, in other examples, programmer 18 may be included as part of an external charging device or include the functionality of an external charging device. As illustrated in FIG 3, programmer 18 may

include a processor 50, memory 52, user interface 54, telemetry module 56, and power source 58. Memory 52 may store instructions that, when executed by processor 50, cause processor 50 and external programmer 18 to provide the functionality ascribed to external programmer 18 throughout this disclosure.

[0072] Programmer 18 comprises any suitable arrangement of hardware, alone or in combination with software and/or firmware, to perform the techniques attributed to programmer 18, and processor 50, user interface 54, and telemetry module 56 of programmer 18. In various examples, processor 50 may include one or more processors, such as one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic circuitry, as well as any combinations of such components. Programmer 18 also, in various examples, may include a memory 52, such as RAM, ROM, PROM, EPROM, EEPROM, flash memory, a hard disk, a CD-ROM, comprising executable instructions for causing the one or more processors to perform the actions attributed to them. Moreover, although processor 50 and telemetry module 56 are described as separate modules, in some examples, processor 50 and telemetry module 56 are functionally integrated. In some examples, processor 50 and telemetry module 56 correspond to individual hardware units, such as ASICs, DSPs, FPGAs, or other hardware units.

[0073] Memory 52 may store instructions that, when executed by processor 50, cause processor 50 and programmer 18 to provide the functionality ascribed to programmer 18 throughout this disclosure. In addition, in some examples, memory 52 stores one or more therapy programs for execution by IMD 14 to deliver high dose electrical stimulation therapy.

[0074] User interface 54 may include a button or keypad, lights, a speaker for voice commands, a display, such as a liquid crystal (LCD), light-emitting diode (LED), or organic light-emitting diode (OLED). In some examples the display may be a touch screen. User interface 54 may be configured to display any information related to the delivery of stimulation therapy, such as currently selected parameter values, intensity thresholds, or any other therapy information. User interface 54 may also receive user input via user interface 54. The input may be, for example, in the form of pressing a button on a keypad or selecting an icon from a touch screen. The input may, for example, request starting or stopping

electrical stimulation, or requesting some other change to the delivery of electrical stimulation.

[0075] Telemetry module 56 may support wireless communication between IMD 14 and programmer 18 under the control of processor 50. Telemetry module 56 may also be configured to communicate with another computing device via wireless communication techniques, or direct communication through a wired connection. In some examples, telemetry module 56 may be substantially similar to telemetry module 36 of IMD 14 described herein, providing wireless communication via an RF or proximal inductive medium. In some examples, telemetry module 56 may include an antenna, which may take on a variety of forms, such as an internal or external antenna.

[0076] Examples of local wireless communication techniques that may be employed to facilitate communication between programmer 18 and IMD 14 include RF communication according to the 802.11 or Bluetooth specification sets or other standard or proprietary telemetry protocols. In this manner, other external devices may be capable of communicating with programmer 18 without needing to establish a secure wireless connection.

[0077] FIG 4 is a timing diagram of an example high density electrical stimulation signal 60 that IMD 14 may generate and deliver to patient 12. Electrical stimulation signal 60 includes a plurality of pulses 62A–62G (collectively, “pulses 62”). Although seven pulses are shown in FIG 4, stimulation signal 60 may include any number of pulses, which may depend on the time period over which IMD 14 delivers stimulation signal 60 to patient 12. Each pulse 62 has an amplitude AMP_A and a pulse width PW_A . In some examples, each pulse 62 of electrical stimulation signal 60 can have the same amplitude AMP_A and pulse width PW_A . In other examples, at least one pulse 62 of signal 60 may have a different amplitude AMP_A and/or pulse width PW_A than another pulse 62. However, in either example, electrical stimulation signal 60 has a duty cycle of about 5% to about 50% and a frequency in a range of about 1 Hz to about 1400 Hz or less (e.g., less than or equal to about 1000 Hz). In addition, in some examples, each pulse 62 may have a pulse width PW_A in a range of about 0.1 ms to about 5 ms (e.g., less than or equal to about 1 ms, such as in a range of about 0.5 ms to about 1 ms).

[0078] The duty cycle of electrical stimulation signal 60, which may be the on-time of electrical stimulation signal 60 per unit of time (e.g., one second), can be characterized by a product of a frequency and a pulse width PW_A of pulses 62. For example, for a stimulation signal 60 having a frequency of about 800 Hz and a pulse width of about 300 microseconds (μs) (0.0003 seconds), stimulation signal 60 may have a duty cycle of about 24%, calculated as follows:

$$\text{Duty Cycle} = \frac{800 \text{ pulses}}{1 \text{ sec}} * \frac{0.0003 \text{ sec}}{1 \text{ pulse}} = \frac{0.24 \text{ sec therapy "on time"}}{1 \text{ sec total time}} = 24\%$$

(Equation 1)

[0079] As another example, for a stimulation signal having a frequency of about 300 Hz and a pulse width of about 700 μs , stimulation signal 60 may have a duty cycle of about 21%, calculated as follows:

$$\text{Duty Cycle} = \frac{300 \text{ pulses}}{1 \text{ sec}} * \frac{0.0007 \text{ sec}}{1 \text{ pulse}} = \frac{0.21 \text{ sec therapy "on time"}}{1 \text{ sec total time}} = 21\%$$

(Equation 2)

[0080] In some examples, for a frequency of less than or equal to about 1000 Hz, the pulse width PW_A of pulses 62 can be selected such that stimulation signal 60 has a duty cycle of about 20% to about 50%. In addition, the amplitude AMP_A of stimulation signal 60 can be selected such that the dose of electrical stimulation signal 60 (having the desired duty cycle) is sufficient to elicit a therapeutic response from patient 12 when IMD 14 delivers electrical stimulation signal 60 to a target tissue site in patient 12 (e.g., proximate spinal cord 20, a peripheral nerve, a muscle, or another suitable tissue site, which may be selected based on the patient condition being treated). For example, in examples in which pulses 62 are substantially similar (e.g., identical or nearly identical amplitudes AMP_A and pulse widths PW_A), the dose of electrical stimulation signal 60 can be determined to be a product of the amplitude AMP_A and pulse width PW_A of the pulses 62A–62D, which are the pulses 62 delivered over a 0.01 second period of time. In some examples in which IMD 14 delivers stimulation signal 60 to patient 12 to spinal cord 20 to treat pain, stimulation signal 60 may have a duty cycle of about 20% to about 50%, a frequency in a range of about 1 Hz to about 1400 Hz, and pulses 62 may each have a pulse width PW_A less in a range of about 0.1 ms to about 5 ms and an amplitude AMP_A below a paresthesia threshold of patient 12.

[0081] Stimulation generator 34 of IMD 14 may generate and deliver high duty cycle electrical stimulation signal 60 using any suitable technique. In some examples, stimulation generator 34 may deliver each of the pulses 62 with the same electrode combination. In some examples, stimulation generator 34 may deliver one or more recharge pulses (also referred to as a “recovery pulse” or a “charge balancing pulse”) after a predetermined number of pulses 62 are delivered, the predetermined number being greater than one. Thus, rather than charge balancing on a pulse-by-pulse basis (e.g., delivering one recharge pulse after each pulse 62), in some examples, processor 30 may control stimulation generator 34 to deliver one or more recharge pulses after delivery of two or more pulses 62. In other examples, processor 30 may control stimulation generator 34 to deliver pulses to promote charge balance on a pulse-by-pulse basis.

[0082] In other examples, stimulation generator 34 may deliver different pulses 62 via respective electrode combinations, such that the high pulse density electrical stimulation signal is delivered via multiple therapy programs. For example, under the control of processor 30, stimulation generator 34 may deliver pulses 62A, 62C, 62E, 62G with a first electrode combination, and deliver pulses 62B, 62D, 62F with a second, different electrode combination. In this example, pulses 62A, 62C, 62E, 62G can be part of a first sub-signal delivered via the first electrode combination, and pulses 62B, 62D, 62F can be part of a second sub-signal delivered via the second electrode combination. The first and second sub-signals, when delivered together over time such that the pulses of the sub-signals interleaved together as shown in FIG 4, combine to define high duty cycle electrical stimulation signal 60. Although two sub-signals are used here as an example, in other examples, stimulation generator 34 of IMD 14 may generate and deliver high duty cycle electrical stimulation signal 60 using any suitable number of sub-signals. In some examples, stimulation generator 34 may generate each sub-signal using a respective therapy program, which may be stored as a group in memory 32 of IMD 14 (FIG 2).

[0083] In some examples in which stimulation generator 34 may deliver different pulses 62 via different electrode combinations, processor 30 may control stimulation generator 34 may deliver one or more recharge pulses after a predetermined number of pulses 62 are delivered, the predetermined number being greater than one. The predetermined number of pulses 62 may include pulses generated according to different therapy programs. Thus, in some

examples, stimulation generator 34 may deliver one or more recharge pulses after pulses of different sub-signals are delivered. For example, under the control of processor 30, stimulation generator 34 may deliver one or more recharge pulses after stimulation generator delivers pulses 62A and 62B, rather than delivering one or more recharge pulses between pulses 62A, 62B, and then again after pulse 62B. In this example, stimulation generator 34 may wait to deliver one or more recharge pulses until after stimulation generator delivers pulses 62C and 62D, rather than delivering one or more recharge pulses between pulses 62C, 62D, and then again after pulse 62B. In other examples, processor 30 may control stimulation generator 34 to deliver recharge pulses to balance charge on a pulse-by-pulse basis.

[0084] Stimulation generator 34 can deliver the sub-signals using electrodes from a single lead 16A or from two or more leads 16B. For example, under the control of processor 30, stimulation generator 34 may deliver a first pulse 62A with electrode 24A of lead 16A together with a housing electrode of outer housing 34 of IMD 14 and deliver pulse 62B with electrode 24B of lead 16A together with a housing electrode of outer housing 34. As another example, under the control of processor 30, stimulation generator 34 may deliver a first pulse 62A with electrodes 24A, 24B of lead 16A and deliver pulse 62B with electrodes 24B, 24C of the same lead 16A. In another example, stimulation generator 34 may deliver different pulses 62 with electrodes of different leads. Processor 30 may, for example, control stimulation generator 34 to alternate delivery of pulses 62 between leads 16A, 16B, or control stimulation generator 34 to otherwise deliver pulses 62 with electrodes of each lead 16A, 16B at different times. For example, under the control of processor 30, stimulation generator 34 may deliver a first pulse 62A with electrodes 24A, 24B of lead 16A and deliver pulse 62B with electrodes 26A, 26B of lead 16B.

[0085] Regardless of the number of electrode combinations with which stimulation generator 34 delivers pulses 62, the combination of pulses 62 may combine to define electrical stimulation signal 60 having a duty cycle in a range of about 20% to about 50% and a frequency in a range of about 1 Hz to about 1400 Hz.

[0086] Delivery of each sub-signal by stimulation generator 34 may generate a stimulation field within tissue of the patient, where the stimulation field may be a volume of tissue through which the electrical current from the delivered sub-signal propagates. The electrode

combinations with which pulses 62 are delivered and the frequency of high duty cycle electrical stimulation signal 60 can be selected such that the combination of pulses 62A, 62B (or any other number of pulses 62 delivered from any suitable number of different electrode combinations) results in stimulation fields that overlap. The region of overlap of the stimulation fields may be configured to target neural areas responsive to the high duty cycle mechanisms described herein, e.g., to provide the desired therapeutic effect. In some examples, the regions of the stimulation fields that do not overlap may not provide any therapeutic effect.

[0087] In some examples, processor 30 controls stimulation generator 34 to generate and deliver pulses 62 via two or more therapy programs, each defining a respective electrode combination. For example, some pulses 62 may be part of a first sub-signal defined by a first therapy program and delivered by stimulation generator 34 via a first electrode combination, and other pulses 62 may be part of a second sub-signal defined by a second therapy program and delivered by stimulation generator 34 via a second electrode combination. Stimulation generator 34 may interleave delivery of pulses of the first and second sub-signals, such that the pulses only partially overlap in time or do not overlap in time. Delivery of the first and second sub-signals may generate respective stimulation fields within tissue. In some examples, the stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of a perception threshold or a paresthesia threshold of the patient. In addition, in some examples, each pulse of the first and second sub-signals has a pulse width less than or equal to about 5 milliseconds, and stimulation generator 34 may interleave delivery of pulses of the first and second sub-signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hz to about 1400 Hz. In some examples, processor 30 controls stimulation generator 34 to deliver a recharge signal following the delivery of at least one pulse of each of the first and second electrical sub-signals.

[0088] Delivering stimulation signal 60 as multiple sub-signals delivered via respective electrode combinations may help reduce the charge density at the electrode-tissue interface of particular electrodes. In addition, delivering stimulation signal 60 via multiple sub-signals may provide more flexibility in programming the electrical stimulation therapy that has an intensity below the perception or paresthesia threshold intensity level of patient 12 because

the sub-signals may each have relatively low stimulation intensities, but due to the overlap in the stimulation fields that may result from the interleaving of the delivery of the sub-signals, the sub-signals may be combined to provide efficacious electrical stimulation therapy to patient 12.

[0089] In some examples in which stimulation generator 34 generates and delivers a plurality of sub-signals in order to deliver the electrical stimulation signal having the high duty cycle and frequency less than or equal to about 1400 Hz described herein, stimulation generator 34 may recharge at the end of the pulse train, e.g., after the pulses of the plurality of sub-signals are delivered. In other examples, stimulation generator 34 may recharge after each delivered pulse.

[0090] FIG 5 is a timing diagram of another example high duty cycle electrical stimulation signal 64 that IMD 14 may generate and deliver to patient 12. Electrical stimulation signal 64 includes a plurality of pulses 66. Stimulation signal 64 may include any number of pulses 66, which may depend on the duration that IMD 14 delivers stimulation signal 64 to patient 12. As with stimulation signal 60 (FIG 4), stimulation signal 64 may have duty cycle of about 5% to about 50%, a frequency in a range of about 1 Hz to about 1400 Hz. However, in contrast to stimulation signal 60, each pulse 66 of stimulation signal 64 has a smaller pulse width PW_B and a higher amplitude AMP_B than each of the pulses 62 of stimulation signal 60. The charge density of stimulation signal 64 may be similar to (e.g., identical or nearly identical) to stimulation signal 60, e.g., because the higher amplitude AMP_B may compensate for the decrease in energy delivery resulting from the decrease in pulse width PW_B relative to pulses 62 of signal 60. As with amplitude AMP_A , amplitude AMP_B may be less than or equal to a paresthesia or perception threshold of patient 12. In addition, the duty cycle of signal 64 can be substantially the same as the duty cycle of signal 60 (FIG 4), despite the smaller pulse width PW_B , due at least in part to the greater number of pulses 66 per second than signal 60.

[0091] Stimulation generator 34 of IMD 14 may generate and deliver high duty cycle electrical stimulation signal 64 using any suitable technique, such as those described with respect to signal 60.

[0092] As discussed above, due to potentially different mechanisms of action, a patient may respond differently to the high duty cycle electrical stimulation described herein, which may

have a duty cycle of about 5% to about 50% and a frequency in a range of about 1 Hz to about 1400 Hz, compared to burst electrical stimulation techniques and high frequency electrical stimulation techniques.

[0093] FIG 6 is a timing diagram of an example burst electrical stimulation signal 68, which includes a plurality of pulses 70A–70H (collectively, “pulses 70”). Burst electrical stimulation signal 68 has fewer pulses 70 per unit of time (e.g., one second) than high duty cycle electrical stimulation signals 60, 64 (FIG 4 and 5). During a particular period of time, e.g., one second as shown in FIG 6, an IMD delivers a burst of pulses 70A–70D of electrical stimulation signal 68 for a first time period 72, which is immediately followed by a second period of time 74 during which the IMD does not deliver any electrical stimulation, but, rather, delivers one or more recovery pulses. Second time period 74 may be referred to as a “recovery period.” After second time period 74, the IMD 14 may deliver another burst of pulses 70E–70H, which may be followed by another recovery period. First and second time periods 72, 74 may be substantially equal (e.g., equal or nearly equal) in some examples, and different in other examples.

[0094] In contrast to burst electrical stimulation signal 68, delivery of high duty cycle electrical stimulation signals 60, 64 by IMD 14 may provide better targeting of target tissue sites. For a given dose, burst electrical stimulation signal 68 may result in activation of more neural tissue (e.g., a larger volume of tissue) than high duty cycle electrical stimulation signals 60, 64, which may each provide electrical stimulation with a higher duty cycle than burst electrical stimulation signal 68 and with smaller pulse widths.

[0095] FIG. 7 is a timing diagram of an example high frequency electrical stimulation signal 76, which includes a plurality of pulses 78. High frequency electrical stimulation signal 76 has a higher frequency than high duty cycle electrical stimulation signals 60, 64 (FIG 4 and 5, such that signal 76 has a greater number of pulses 78 per unit of time than high duty cycle electrical stimulation signals 60, 64). For example, high frequency electrical stimulation signal 76 may have a frequency of 1500 Hz to about 100 kHz, or greater, whereas high duty cycle electrical stimulation signals 60, 64 may each have a frequency less than or equal to about 1400 Hz.

[0096] For a given duty cycle, high frequency electrical stimulation signal 76 may result in activation of more neural tissue than high duty cycle electrical stimulation signals 60, 64,

which have pulses 62, 66, respectively, with higher pulse widths than pulses 78 of high frequency electrical stimulation signal 76. The lower frequency of high duty cycle electrical stimulation signals 60, 64 may allow for a larger therapeutic window for the pulse amplitudes AMP_A and AMP_B , which may help a clinician tailor the electrical stimulation to a particular patient to allow for different neural mechanisms to be activated in order to elicit a therapeutic response from the patient. The therapeutic window for the pulse amplitudes AMP_A and AMP_B can be, for example, the range of amplitude values that provide efficacious therapy to patient 12 without resulting in undesired side effects.

[0097] The electrical stimulation parameter values with which IMD 14 may generate and deliver the high density electrical stimulation described herein, having a duty cycle of about 5% and about 50%, a frequency less in a range of about 1 Hz to about 1400 Hz (e.g., less than or equal to about 1000 Hz), and a pulse width of about 5 ms or less, may be selected using any suitable technique. FIG 8 is a flow diagram of an example technique for selecting the electrical stimulation parameter values. While FIG. 8 is described with respect to processor 30 of IMD 14, in other examples, processor 50 of programmer 18 may perform any part of the technique described with respect to FIG. 8, alone or in combination with processor 30 of IMD 14.

[0098] In the technique shown in FIG. 8, processor 30 determines a paresthesia or perception threshold intensity level for patient 12 (80), e.g., using the technique described below with respect to FIG. 9, by retrieving a stored paresthesia or perception threshold intensity level from memory 32 (FIG. 2), or by receiving a paresthesia or perception threshold intensity level from another device, e.g., programmer 18. Processor 30 may, for example, determine the paresthesia threshold (80), determine the perception threshold (80), determine the lower of the paresthesia threshold intensity level or the perception threshold intensity level for patient 12 (80), or determine the higher of the paresthesia threshold intensity level or the perception threshold intensity level for patient 12.

[0099] A paresthesia threshold intensity level may be a lowest determined electrical stimulation intensity level at which patient 12 first perceives paresthesia from the electrical stimulation delivered by IMD 14. A perception threshold intensity level may be a lowest determined electrical stimulation intensity level at which patient 12 first perceives the electrical stimulation delivered by IMD 14. In some cases, depending on the patient and/or

the target electrical stimulation site within the patient, the patient may first perceive the electrical stimulation delivered by IMD 14 as paresthesia. Thus, in some cases, the perception threshold intensity level may be substantially the same (e.g., identical or nearly identical) as the paresthesia threshold intensity level. In other cases, however, a patient may first perceive the electrical stimulation as a sensation different than paresthesia. Thus, some cases, the perception threshold intensity level may be different than the paresthesia threshold intensity level. In these examples, a clinician may program IMD 14 and/or programmer 18 to use either the perception or paresthesia threshold intensity levels to select the electrical stimulation parameter with the technique shown in FIG. 8.

[0100] After determining one or both of the paresthesia threshold intensity level or the perception threshold intensity level, processor 30 may determine a strength-duration curve based on the determined one or both of the paresthesia or perception threshold intensity level and one or more selected electrical stimulation signal frequencies (82). A strength-duration curve may describe the relationship between a strength of electrical stimulation and duration, e.g., for a particular physiological response, such as a response below the paresthesia or perception threshold of patient 12. The strength of electrical stimulation may be a function of, for example, any one or more of the voltage or current amplitude value of the stimulation signal, frequency of stimulation signals, signal duration (e.g., pulse width in the case of stimulation pulses), duty cycle, and the like.

[0101] An example of a strength duration curve is an amplitude-pulse width curve. The amplitude-pulse width curve may reflect, for a selected stimulation frequency, different combinations of amplitude and pulse width values that contribute to a stimulation field in a substantially similar manner. For example, the amplitude-pulse width curve may indicate that a first electrical stimulation signal with a first amplitude and a first pulse width, and a second electrical stimulation signal having a higher amplitude pulse with a shorter pulse width (i.e., shorter than the first pulse width) may both provide electrical stimulation therapy below the paresthesia or perception threshold of patient 12. Each position on the amplitude-pulse width curve, or each position within a particular range of positions along the amplitude-pulse width curve, may result in a substantially similar stimulation energy when the other therapy parameter values, such as a frequency, remain substantially constant (e.g., the other therapy parameter values may remain within a particular range of therapy parameter

values, such as within a 10% window or less from the values defined by the therapy program). Thus, for a given stimulation frequency, the amplitude-pulse width curve may define, e.g., via the amplitude-pulse width combinations associated with the area under the curve and/or along the curve, the amplitude and pulse width combinations that provide electrical stimulation therapy having an intensity level below the paresthesia or perception threshold intensity level of patient 12.

[0102] For a given frequency (e.g., in a range of about 1 Hz to about 1000 Hz), based on the strength-duration curve, processor 30 may determine the pulse width and amplitude combination that provides efficacious electrical stimulation therapy to patient 12 and also has a stimulation intensity below the paresthesia or perception threshold of patient 12 (84).

Processor 30 may, automatically or in response to user input provided via programmer 18, control stimulation generator 34 to generate and deliver electrical stimulation therapy to patient 12 with the frequency associated with the strength-duration curve, a selected combination of electrodes 24, 26, and a plurality of pulse width and amplitude combinations along the strength-duration curve or below the amplitude-pulse width curve. Processor 30 may determine whether any of the selected pulse width and amplitude combinations provides efficacious electrical stimulation therapy for patient 12, e.g., based on patient 12 input or input from another entity received via programmer 18, based on input from a sensing module of IMD 14 or a separate sensing module, or any combination thereof. Processor 30 may generate one or more therapy programs based on the one or more pulse width and amplitude combinations that provide efficacious electrical stimulation therapy to patient 12, together with the selected frequency and electrode combination (86).

[0103] In some examples in which stimulation generator 34 generates and delivers the high duty cycle electrical stimulation therapy via a plurality of sub-signals delivered via respective electrode combinations, processor 30 may determine a strength-duration curve for each electrode combination. Thus, for each electrode combination, the respective strength-duration curve may indicate a plurality of combinations of electrical stimulation parameters (e.g., amplitude and pulse width for a given frequency) that provide a charge per pulse below the paresthesia or perception threshold of patient 12. Based on the strength-duration curves, processor 30, alone or based on input from a clinician, may determine, for each of the electrode combinations, one or more therapy programs that provide a relatively high charge

per pulse (e.g., the relatively highest charge per pulse that remains at or below the paresthesia or perception threshold of patient 12). Each therapy program may define a sub-signal. Processor 30, alone or based on input from a clinician, may then determine a frequency to interleave the two or more sub-signals.

[0104] In some examples, to determine the therapy programs, processor 30 may determine one or more test therapy programs that define relatively wide pulse widths and relatively low frequencies of the sub-signals, control stimulation generator 34 to generate and deliver electrical stimulation to patient 12 according to the test therapy programs, and, if the delivered electrical stimulation therapy is not sufficiently efficacious, processor 30 may modify one or more of the test therapy programs until the electrical stimulation provides efficacious stimulation therapy for patient 12. The efficacy of the electrical stimulation therapy can be based on input from patient 12, from one or more sensed physiological parameters, or any combination thereof. Processor 30 may modify one or more of the test therapy programs by, for example, incrementally narrowing the pulse width (e.g., by a predetermined increment) and/or incrementally increasing the frequency (e.g., by a predetermined increment).

[0105] Processor 30 may store the one or more therapy programs 40 in memory 32 of IMD 12 or a memory of another device for later delivery of electrical stimulation therapy to patient 12 (86). Processor 30 may control stimulation generator 34 to generate and deliver electrical stimulation therapy to patient 12 in accordance with the one or more therapy programs 40.

[0106] In some cases, therapeutic efficacy of electrical stimulation therapy delivered by IMD 14 may change as the patient posture state (e.g., a particular patient posture or a combination of posture and activity) changes. Efficacy may refer to a combination of complete or partial alleviation of symptoms alone, or in combination with no side effects or an acceptable or tolerable degree of undesirable side effects. In some examples, processor 30 of IMD 14 may be configured to adjust one or more therapy parameter values based on different postures and/or activities engaged by patient 12 to maintain effective therapy, e.g., by selecting select different therapy programs based on a posture state of patient 12. In these examples, processor 30 may determine the paresthesia or perception threshold of patient 12 for each of a plurality of different posture states and determine one or more therapy programs 40 for

each of the posture states using the technique shown in FIG. 8 based on the respective paresthesia or perception threshold.

[0107] FIG. 9 is a flow diagram of an example technique by which processor 30 of IMD 14 can determine at least one of the perception or paresthesia threshold intensity level for patient 12. In some examples, processor 30 is configured to determine the perception threshold intensity level, while in other examples, processor 30 is configured to determine the paresthesia threshold intensity level or both the perception and paresthesia threshold intensity level.

[0108] The perception or paresthesia threshold intensity level can be patient-specific, as well as specific to a target tissue site within patient 12. Thus, a perception or paresthesia threshold intensity level can be determined for each target tissue site to which IMD 14 delivers stimulation therapy. In some examples, processor 30 of programmer 18 may implement the technique illustrated in FIG. 9 automatically, e.g., without user intervention or control after initiating the technique. In other examples, processor 30 may implement the technique illustrated in FIG. 9 under control of a user, such as a clinician, who controls processor 30 via programmer 18. While FIG. 9 is described with respect to processor 30 of IMD 14, in other examples, processor 50 of programmer 18 may perform any part of the technique described with respect to FIG. 9, alone or in combination with processor 30 of IMD 14.

[0109] In accordance with the technique shown in FIG. 9, processor 30 sets stimulation parameter values such that the stimulation parameter values define a relatively low stimulation intensity, e.g., an intensity below an expected perception or paresthesia threshold intensity (90). The initial stimulation parameter values may be selected by a clinician in some examples. In some examples in which processor 30 controls stimulation generator 34 to generate and deliver stimulation to patient 12 in the form of electrical pulses, the stimulation parameters include at least one of a voltage or current amplitude, a pulse width, a pulse rate, or a duty cycle. In examples in which processor 30 controls stimulation generator 34 to deliver stimulation to patient 12 in the form of a continuous waveform, the stimulation parameters include at least one of a voltage amplitude, a current amplitude, a frequency, a waveform shape, or a duty cycle.

[0110] In either case, processor 30 sets the stimulation parameters to respective values to define a stimulation intensity, and controls stimulation generator 34 to deliver stimulation to patient 12 at the set stimulation intensity (defined by the selected stimulation parameter values) (92). During therapy delivery or after stimulation generator 34 delivers stimulation to patient 12, processor 30 determines whether patient 12, a clinician, or patient caretaker has provided input indicating patient 12 has perceived the electrical stimulation or indicating paresthesia resulted from the electrical stimulation (94). Patient 12, the clinician, or patient caretaker can provide the input, e.g., via user interface 54 of programmer 18 or directly via IMD 14. For example, a motion sensor can be integrated into or on a housing of IMD 14, and the motion sensor can be configured to generate a signal that is indicative of patient 12 tapping IMD 14 through the skin. The number, rate, or pattern of taps may be associated with the input indicative of stimulation perception or paresthesia, and processor 30 may identify the tapping by patient 12 to determine when patient input is received. When the input is received via user interface 54 of programmer 18, processor 50 of programmer 18 may transmit a signal indicative of the input to IMD 14 via the respective telemetry modules 56, 36.

[0111] When processor 30 has not received an indication of the input indicative of the stimulation perception or paresthesia within a predetermined time period during or immediately after delivery of the stimulation according to the selected stimulation intensity ("NO" branch of block 94), processor 30 again sets the stimulation intensity, e.g., by adjusting at least one stimulation parameter value to increase a stimulation intensity of the stimulation signal (90). For example, processor 30 may increase a voltage amplitude or a current amplitude to increase the stimulation intensity. In some examples, processor 30 changes a value of only one of the stimulation parameters while the remaining parameters are kept approximately constant. The stimulation parameter that is selected may be known to affect stimulation intensity. In other examples, processor 30 may adjust a combination of two or more stimulation parameters to increase stimulation intensity.

[0112] After modifying the one or more stimulation parameter values, processor 30 controls stimulation generator 34 to deliver stimulation to patient 12 using the newly defined stimulation parameter values (92). In this way, processor 30 can implement an iterative

procedure to determine the perception or paresthesia threshold intensity for patient 12, and, in some examples, for a specific target tissue site within patient 12.

[0113] In response to not receiving input indicative of patient perception or paresthesia is received within a predetermined time period during or immediately after delivery of the stimulation according to the selected stimulation intensity (“NO” branch of block 94), processor 30 may again adjust at least one stimulation parameter value to increase a stimulation intensity of the stimulation signal (90). This process may repeat until processor 30 receives input indicative of patient perception or paresthesia within a predetermined time period during or immediately after delivery of the stimulation according to the selected stimulation intensity. In response to receiving the input (“YES” branch of block 94), processor 30 may store the stimulation intensity level as the patient perception threshold intensity level and/or paresthesia threshold intensity level (depending on whether the response indicates patient perception of the electrical stimulation or resulting paresthesia, respectively) in memory 32 of IMD 14 (FIG 2) or in another memory (e.g., memory 52 of programmer 18) (96).

[0114] In addition, processor 30 may define stimulation parameter values for the therapy programs 40 (FIG 2) for providing the high duty cycle electrical stimulation techniques described herein based on the determined patient perception threshold intensity level and/or paresthesia threshold intensity level, e.g., using the technique described with respect to FIG 8. For example, processor may define stimulation parameter values for the therapy programs 40 (FIG 2) that result in a stimulation intensity level less than or equal to one or both of the patient perception threshold intensity level or paresthesia threshold intensity level.

[0115] While the techniques described above are primarily described as being performed by processor 30 of IMD 14 or processor 50 of programmer 18, in other examples, one or more other processors may perform any part of the techniques described herein alone or in addition to processor 30 or processor 50. Thus, reference to “a processor” may refer to “one or more processors.” Likewise, “one or more processors” may refer to a single processor or multiple processors in different examples.

[0116] The techniques described in this disclosure, including those attributed to IMD 14, programmer 18, or various constituent components, may be implemented, at least in part, in hardware, software, firmware or any combination thereof. For example, various aspects of

the techniques may be implemented within one or more processors, including one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic circuitry, as well as any combinations of such components, embodied in programmers, such as clinician or patient programmers, medical devices, or other devices.

[0117] In one or more examples, the functions described in this disclosure may be implemented in hardware, software, firmware, or any combination thereof. If implemented in software, the functions may be stored on, as one or more instructions or code, a computer-readable medium and executed by a hardware-based processing unit. Computer-readable media may include computer-readable storage media forming a tangible, non-transitory medium. Instructions may be executed by one or more processors, such as one or more DSPs, ASICs, FPGAs, general purpose microprocessors, or other equivalent integrated or discrete logic circuitry. Accordingly, the term “processor,” as used herein may refer to one or more of any of the foregoing structure or any other structure suitable for implementation of the techniques described herein.

[0118] In addition, in some aspects, the functionality described herein may be provided within dedicated hardware and/or software modules. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components, or integrated within common or separate hardware or software components. Also, the techniques could be fully implemented in one or more circuits or logic elements. The techniques of this disclosure may be implemented in a wide variety of devices or apparatuses, including an IMD, an external programmer, a combination of an IMD and external programmer, an integrated circuit (IC) or a set of ICs, and/or discrete electrical circuitry, residing in an IMD and/or external programmer.

[0119] Various aspects of the disclosure have been described. These and other aspects are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A method comprising:
generating, by a medical device, an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of a patient; and
delivering, by the medical device, the electrical stimulation signal to the patient.
2. The method of claim 1, wherein the frequency is less than or equal to about 1000 Hertz.
3. The method of claim 1 or claim 2, wherein the pulse width is less than or equal to about 1 millisecond.
4. The method of any of claims 1–3, wherein the duty cycle is in a range about 10% to about 40%.
5. The method of any of claims 1–3, wherein the duty cycle is in a range of about 20% to about 30%.
6. The method of any of claims 1–5, wherein the duty cycle is an on-time of the pulses per second.
7. The method of any of claims 1–6, wherein generating the electrical stimulation signal comprises generating a plurality of sub-signals, wherein, when interleaved, the plurality of sub-signals define the electrical stimulation signal, and wherein delivering the electrical stimulation signal comprises interleaving delivery of the sub-signals.

8. The method of claim 7, wherein interleaving delivery of the sub-signals comprises delivering the sub-signals via respective electrode combinations.
9. The method of claim 7, the plurality of sub-signals comprising a first sub-signal and a second sub-signal, wherein interleaving delivery of the sub-signals comprises alternating delivery of the first sub-signal and the second sub-signal.
10. The method of any of claims 1–9, wherein the pulses have substantially the same pulse width.
11. The method of any of claims 1–9, wherein at least two of the pulses have different pulse widths.
12. A method comprising:
 - generating, by a medical device, a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses;
 - generating, by the medical device, a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds;
 - delivering, by the medical device, the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields; and
 - delivering, by the medical device, a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals,
 - wherein delivering the first and second electrical stimulation signals comprises interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz, and

wherein the first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

13. The method of claim 12, wherein the frequency is less than or equal to about 1000 Hertz.

14. The method of claim 12 or claim 13, wherein the pulse width is less than or equal to about 1 millisecond.

15. The method of any of claims 12–14, wherein the first and second electrical stimulation signals, when interleaved over time, define a combined electrical stimulation signal having a duty cycle in a range of about 5% to about 50%.

16. The method of claim 15, wherein the duty cycle is in a range of about 10% to about 40%, or in a range of about 20% to about 30%.

17. The method of any of claims 12–16, wherein interleaving delivery of the first and second electrical stimulation signals comprises alternating delivery of pulses of the first electrical stimulation signal with delivery of pulses of the second electrical stimulation signal.

18. A method comprising:
determining a paresthesia or perception threshold for a patient;
determining, for a selected frequency of an electrical stimulation signal, a strength-duration curve based on the paresthesia or perception threshold; and
determining, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating the electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 5% to about 50%, a frequency in a range of about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.
19. The method of claim 18, wherein the frequency is less than or equal to about 1000 Hertz.
20. The method of claim 18 or claim 19, wherein the pulse width is less than or equal to about 1 millisecond.
21. The method of any of claims 18–20, wherein the duty cycle is in a range of about 10% to about 40%, or in a range of about 20% to about 30%.
22. The method of any of claims 18–21, wherein determining the set of one or more electrical stimulation parameter values comprises determining a plurality of therapy programs each including a respective electrode combination, the method further comprising delivering the electrical stimulation signal to the patient by at least interleaving delivery of electrical stimulation according to the plurality of therapy programs.

23. A system comprising:
a stimulation generator configured to generate and deliver electrical stimulation therapy to a patient; and
a processor configured to control the stimulation generator to generate and deliver an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of the patient.
24. The system of claim 23, wherein the frequency is less than or equal to about 1000 Hertz.
25. The system of claim 23 or claim 24, wherein the pulse width is less than or equal to about 1 millisecond.
26. The system of any of claims 23–25, wherein the duty cycle is in a range of about 10% to about 40%.
27. The system of any of claims 23–25, wherein the duty cycle is in a range of about 20% to about 30%.
28. The system of any of claims 23–27, wherein the duty cycle is an on-time of the pulses per second.
29. The system of any of claims 23–28, wherein the processor is configured to control the stimulation generator to generate the electrical stimulation signal comprises by at least generating a plurality of sub-signals, wherein, when interleaved, the plurality of sub-signals define the electrical stimulation signal.

30. The system of claim 29, wherein the processor is configured to control the stimulation generator to interleave delivery of the sub-signals by at least delivering the sub-signals via respective electrode combinations.

31. The system of claim 29, the plurality of sub-signals comprising a first sub-signal and a second sub-signal, wherein the processor is configured to control the stimulation generator to interleave delivery of the sub-signals by at least alternating delivery of pulses of the first sub-signal with pulses of the second sub-signal.

32. The system of any of claims 23–31, wherein the pulses have substantially the same pulse width.

33. The system of any of claims 23–31, wherein at least two of the pulses have different pulse widths.

34. A system comprising:
a plurality of electrodes;
a stimulation generator configured to generate and deliver electrical stimulation therapy to a patient via one or more subset of the electrodes; and
a processor configured to control the stimulation generator to:
generate a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses,
generate a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds,

deliver the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields, wherein the processor is configured to control the stimulation generator to deliver the first and second electrical stimulation signals by at least interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz, and deliver a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals, wherein the first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

35. The system of claim 34, wherein the frequency is less than or equal to about 1000 Hertz.

36. The system of claim 34 or claim 35, wherein the pulse width is less than or equal to about 1 millisecond.

37. The system of any of claims 34–36, wherein the first and second electrical stimulation signals, when interleaved over time, define a combined electrical stimulation signal having a duty cycle in a range of about 5% to about 50%.

38. The system of claim 37, wherein the duty cycle is in a range of about 10% to about 40%, or in a range of about 20% to about 30%.

39. The system of any of claims 34–38, wherein the processor is configured to control the stimulation generator to interleave delivery of the first and second electrical stimulation signals by at least alternating delivery of pulses of the first electrical stimulation signal with delivery of pulses of the second electrical stimulation signal.

40. A system comprising:
a processor configured to:
determine a paresthesia or perception threshold stimulation intensity level of a patient,
determine, for a selected frequency, a strength-duration curve based on the paresthesia or perception threshold stimulation intensity level, and
determine, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating an electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 5% to about 50%, a frequency in a range of about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.
41. The system of claim 40, wherein the frequency is less than or equal to about 1000 Hertz.
42. The system of claim 40 or claim 41, wherein the pulse width is less than or equal to about 1 millisecond.
43. The system of any of claims 40–42, wherein the duty cycle is in a range of about 10% to about 40%, or in range of about 20% to about 30%.
44. The system of any of claims 40–43, wherein the processor is configured to determine the set of one or more electrical stimulation parameter values by at least determining a plurality of therapy programs each including a respective electrode combination, wherein when a medical device interleaves delivery of pulses of the plurality of therapy programs with each other, the medical device delivers the electrical stimulation signal.

45. A system comprising:

means for generating an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of a patient; and

means for delivering the electrical stimulation signal to the patient.

46. The system of claim 45, wherein the means for generating the electrical stimulation signal generates a plurality of sub-signals, wherein, the means for delivering delivers the electrical stimulation signal to the patient by at least interleaving pulses of the plurality of sub-signals.

47. A system comprising:

means for generating a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses, and a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds;

means for delivering the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields, wherein the means for delivering delivers the first and second electrical stimulation signals by at least interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz; and

means for delivering a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals,

wherein the first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

48. The system of claim 47, wherein the means for delivering interleaves delivery of the first and second electrical stimulation signals by at least alternating delivery of pulses of the first electrical stimulation signal and delivery of pulses of the second electrical stimulation signal.

49. A system comprising:

- means for determining a paresthesia or perception threshold for a patient;
- means for determining, for a selected frequency, a strength-duration curve based on the paresthesia or perception threshold; and
- means for determining, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating an electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 20% to about 50%, a frequency in a range of about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.

50. The system of claim 49, further comprising means for delivering electrical stimulation therapy to the patient, wherein the means for determining the set of one or more electrical stimulation parameter values determines a plurality of therapy programs each including a respective electrode combination, wherein when the means for delivering electrical stimulation interleaves delivery of pulses of the plurality of therapy programs with each other, the medical device delivers the electrical stimulation signal.

51. A computer-readable medium comprising instructions that, when executed by a processor, cause the processor to:

control a stimulation generator to generate an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of a patient; and

control the stimulation generator to deliver the electrical stimulation signal to the patient.

52. The computer-readable medium of claim 51, wherein the electrical stimulation signal comprises a plurality of sub-signals, and the instructions cause the processor to control the stimulation generator to deliver the electrical stimulation signal by at least interleaving pulses of the plurality of sub-signals.

53. A computer-readable medium comprising instructions that, when executed by a processor, cause the processor to:

control a stimulation generator of a medical device to generate a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses;

control the stimulation generator of the medical device to generate a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds;

control the stimulation generator to deliver the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields by at least interleaving delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz; and

control the stimulation generator to deliver a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals,

wherein the first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

54. The computer-readable medium of claim 53, wherein the instructions cause the processor to control the stimulation generator to interleave delivery of the first and second electrical stimulation signals by at least alternating delivery of pulses of the first electrical stimulation signal and delivery of pulses of the second electrical stimulation signal.

55. A computer-readable medium comprising instructions that, when executed by a processor, cause the processor to:

determine a paresthesia or perception threshold for a patient;

determine, for a selected frequency, a strength-duration curve based on the paresthesia or perception threshold; and

determine, based on the strength-duration curve, a set of one or more electrical stimulation parameter values for generating an electrical stimulation signal having stimulation intensity less than at least one of the perception threshold or the paresthesia threshold of the patient, and having a duty cycle in a range of about 5% to about 50%, a frequency in a range of about 1 Hertz to about 1400 Hertz, and a pulse width in a range of about 0.1 millisecond to about 5 milliseconds.

56. The computer-readable medium of claim 55, wherein the instructions cause the processor to determine the set of one or more electrical stimulation parameter values by at least determining a plurality of therapy programs each including a respective electrode combination, and to control a stimulation generator to deliver the electrical stimulation signal to the patient by at least interleaving of pulses of the plurality of therapy programs with each other.

57. A method comprising:

controlling, by a processor, a medical device, to generate an electrical stimulation signal comprising a plurality of pulses and having a duty cycle in a range of about 5% to about 50% and a frequency in a range of about 1 Hertz to about 1400 Hertz, wherein each of the pulses has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds, the electrical stimulation signal having a stimulation intensity less than at least one of a perception threshold or a paresthesia threshold of a patient; and

controlling, by the processor, the medical device to deliver the medical device, the electrical stimulation signal to the patient.

58. The method of claim 57, wherein the frequency is less than or equal to about 1000 Hertz.

59. The method of claim 57 or claim 58, wherein the pulse width is less than or equal to about 1 millisecond.

60. The method of any of claims 57–59, wherein controlling the medical device to generate the electrical stimulation signal comprises controlling the medical device to generate a plurality of sub-signals, wherein, when interleaved, the plurality of sub-signals define the electrical stimulation signal, and wherein controlling the medical device to deliver the electrical stimulation signal comprises controlling the medical device to interleave delivery of the sub-signals.

61. A method comprising:

controlling, by a processor, a medical device, to generate a first electrical stimulation signal according to a first therapy program, the first electrical stimulation signal comprising a first plurality of electrical stimulation pulses;

controlling, by the processor, the medical device, to generate a second electrical stimulation signal according to a second therapy program, the second electrical stimulation signal comprising a second plurality of electrical stimulation pulses, wherein each pulse of the first and second electrical stimulation signals has a pulse width in a range of about 0.1 millisecond to about 5 milliseconds;

controlling, by the processor, the medical device to deliver the first and second electrical stimulation signals to a patient via respective subsets of electrodes to generate first and second stimulation fields; and

controlling, by the processor, the medical device to deliver a recharge signal following the delivery of at least one pulse of each of the first and second electrical stimulation signals,

wherein controlling the medical device to deliver the first and second electrical stimulation signals controlling the medical device to interleave delivery of the first and second electrical stimulation signals to deliver electrical stimulation pulses at a frequency in a range of about 1 Hertz to about 1400 Hertz, and

wherein the first and second stimulation fields, individually and when overlapping, have stimulation intensities less than at least one of: a perception threshold or a paresthesia threshold of the patient.

62. The method of claim 61, wherein the frequency is less than or equal to about 1000 Hertz.

63. The method of claim 61 or claim 62, wherein the pulse width is less than or equal to about 1 millisecond.

64. The method of any of claims 61–63, wherein the first and second electrical stimulation signals, when interleaved over time, define a combined electrical stimulation signal having a duty cycle in a range of about 5% to about 50%.

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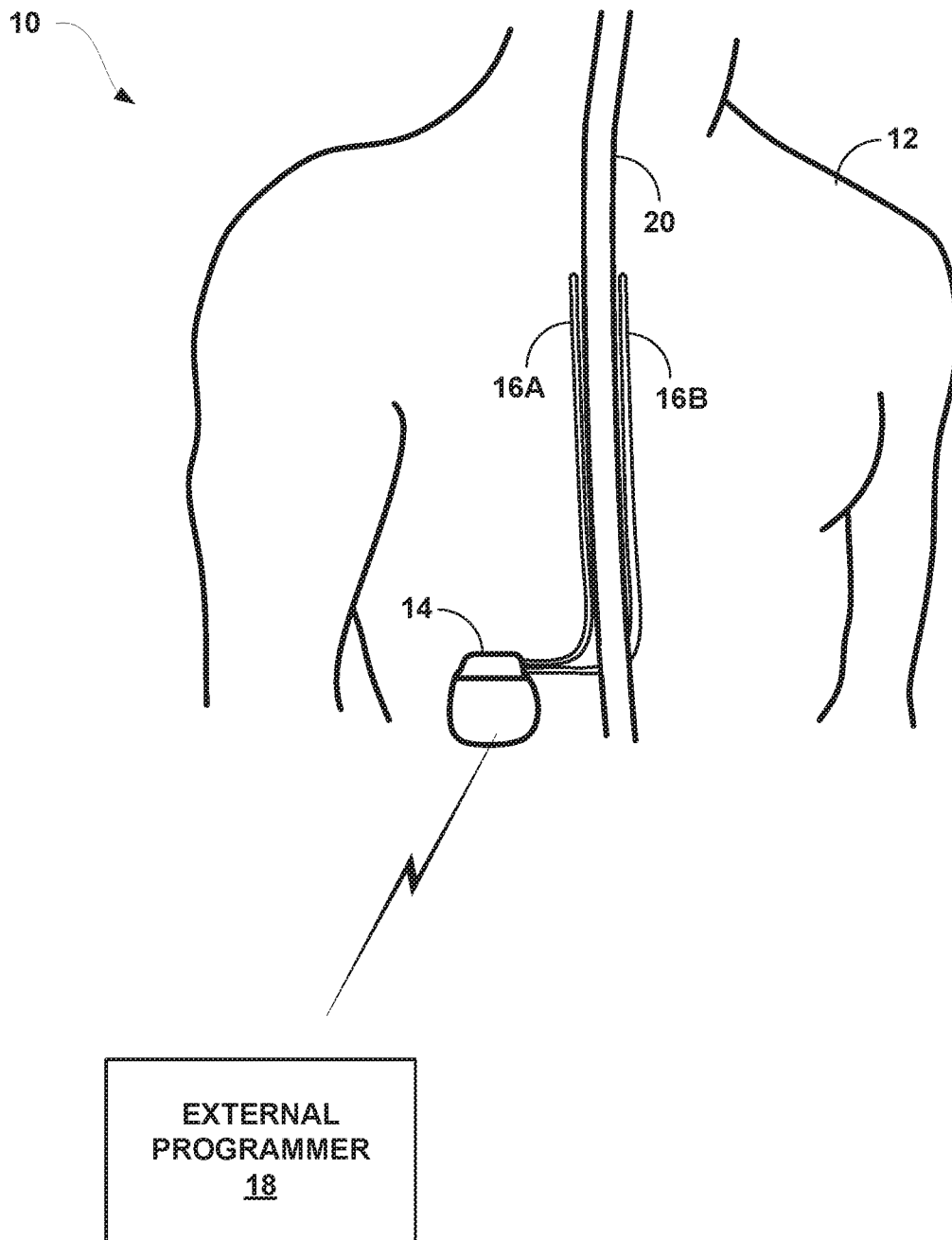


FIG. 1

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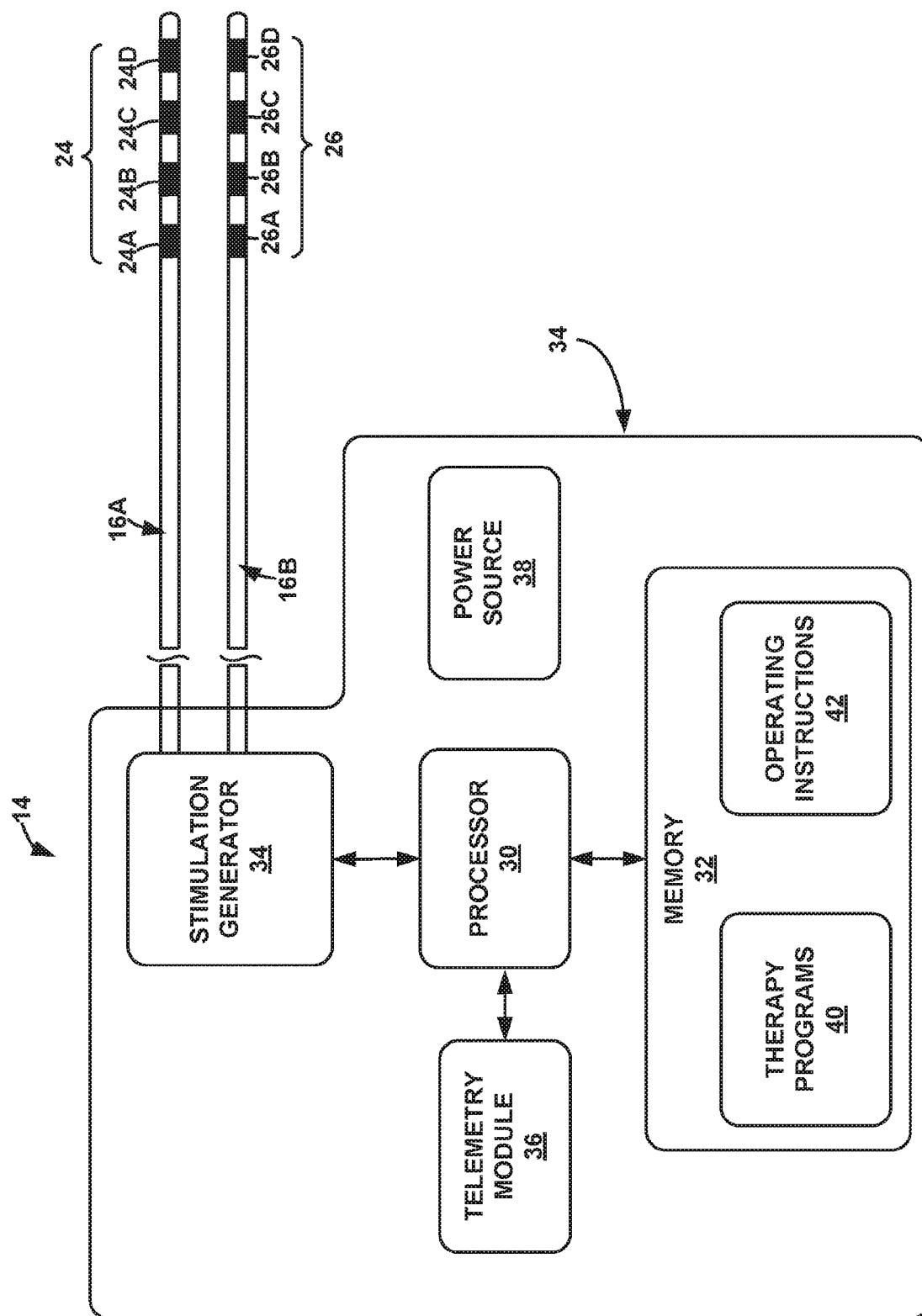


FIG. 2

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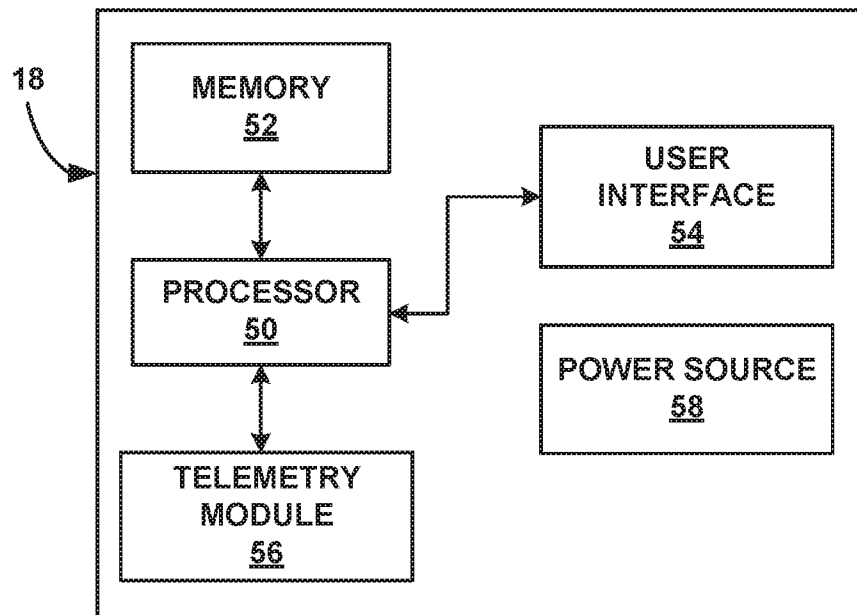
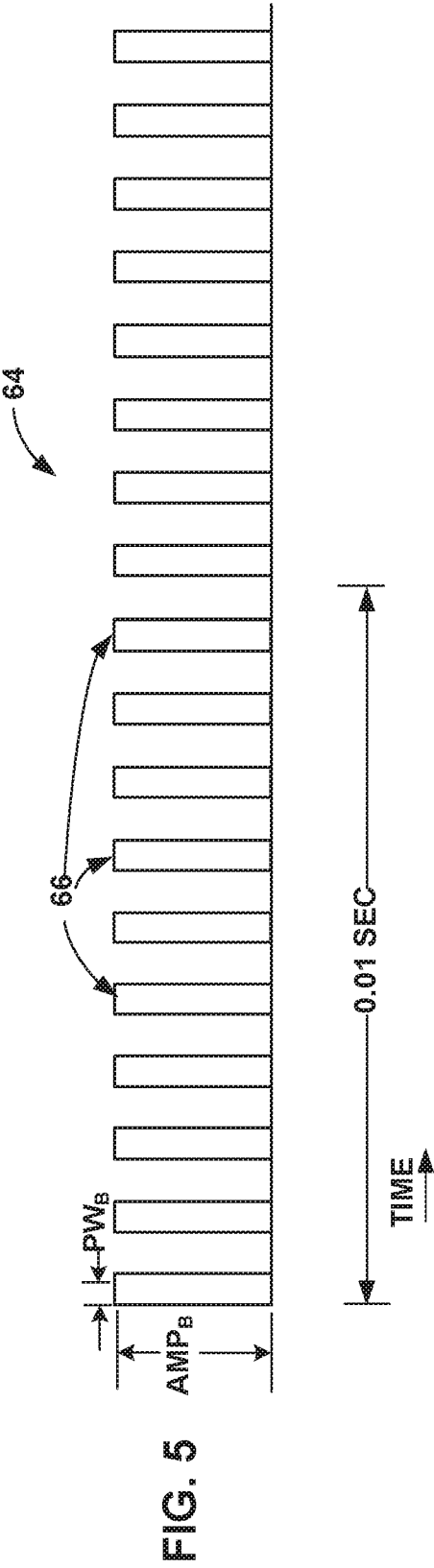
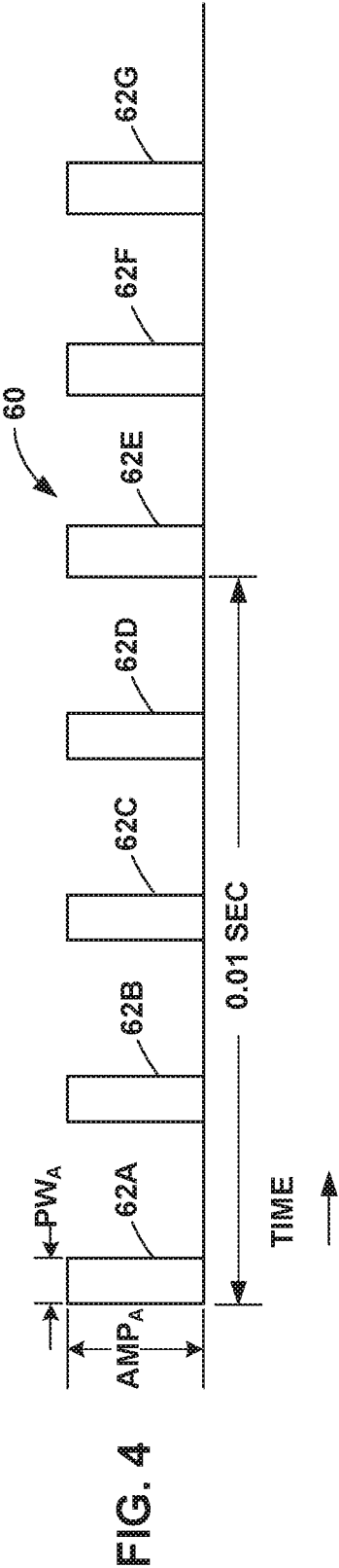


FIG. 3



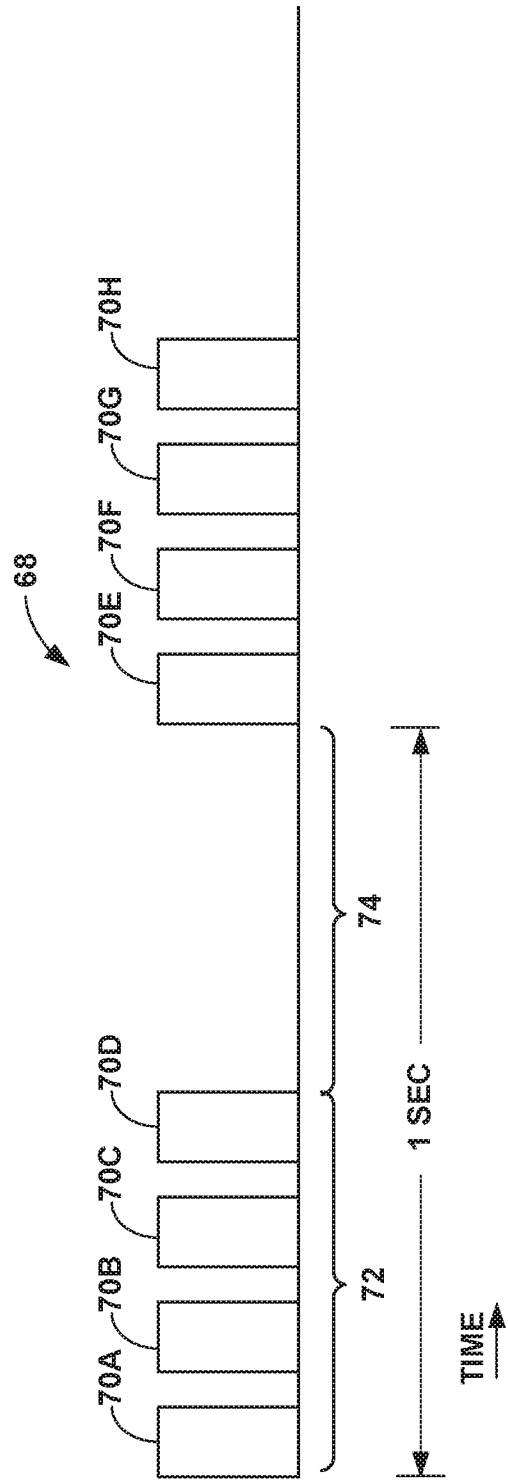


FIG. 6

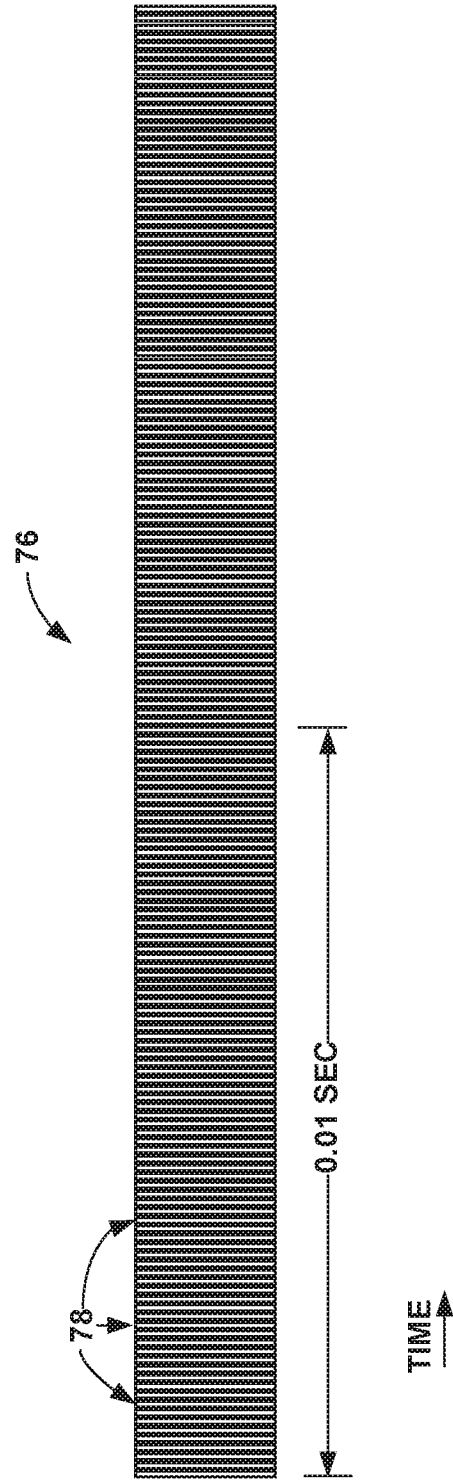


FIG. 7

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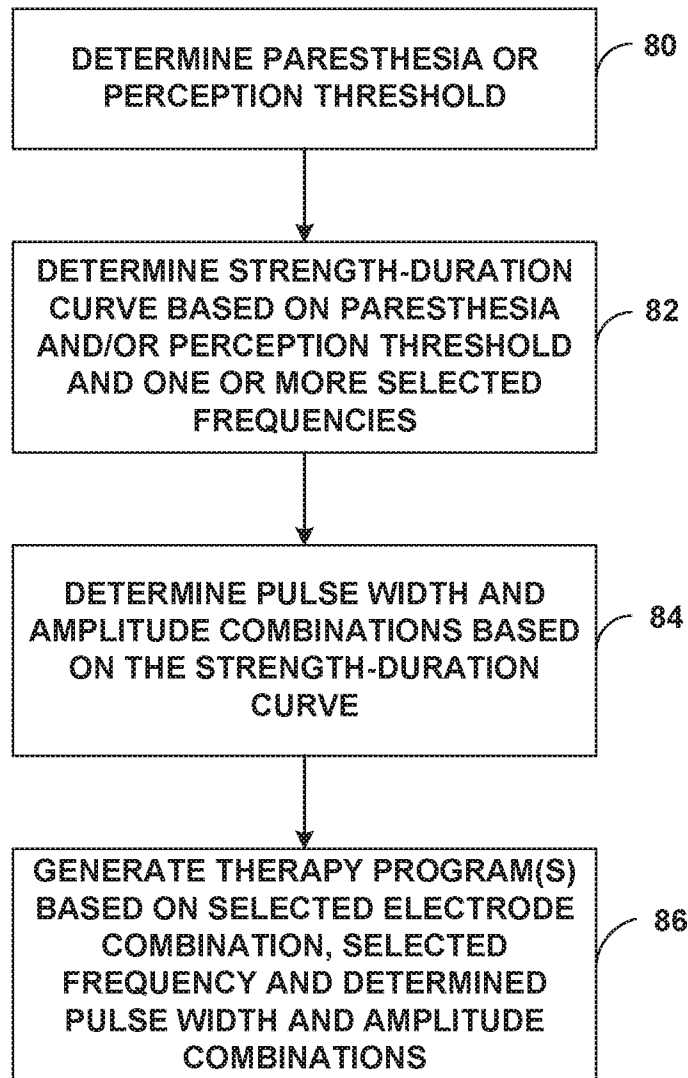


FIG. 8

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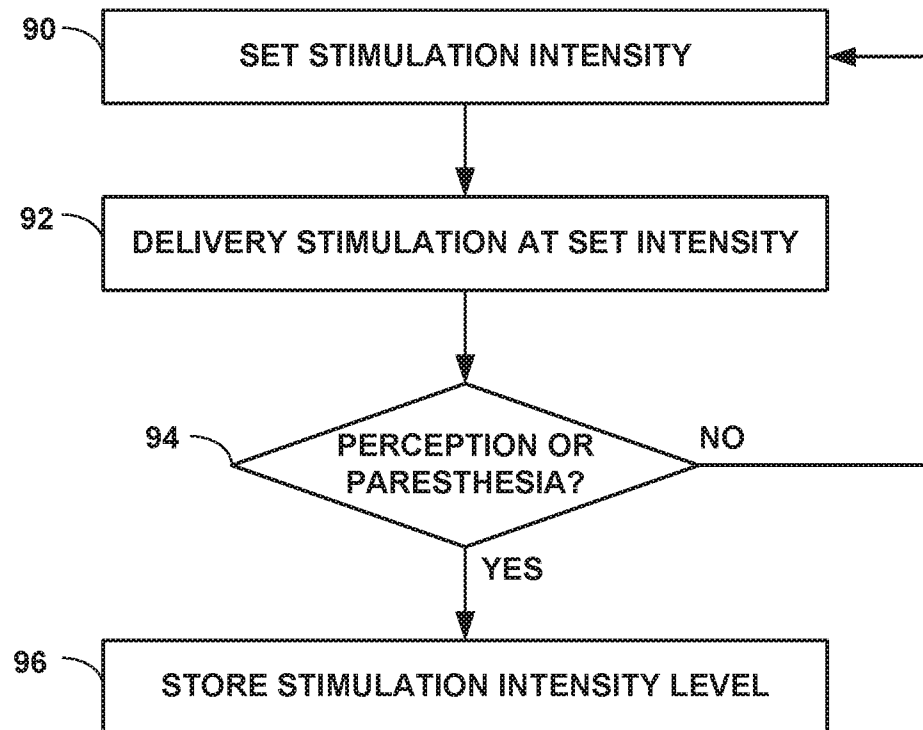


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/066935

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.: 1-22
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:

see additional sheet

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.:
23-39

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/US2016/066935

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61N1/36 A61N1/37
 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	WO 2015/179177 A1 (NEVRO CORP [US]) 26 November 2015 (2015-11-26)	23-33
A	abstract; claim *; figure * paragraphs [0018], [0049] - [0059] -----	34-39
A	US 2013/208390 A1 (SINGH VINIT [US] ET AL) 15 August 2013 (2013-08-15) the whole document -----	23-39
A	US 2013/289664 A1 (JOHANEK LISA M [US]) 31 October 2013 (2013-10-31) the whole document -----	23-39
A	US 2011/071589 A1 (STARKEBAUM WARREN L [US] ET AL) 24 March 2011 (2011-03-24) the whole document -----	23-39



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

27 January 2017

Date of mailing of the international search report

07/04/2017

Name and mailing address of the ISA/

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Authorized officer

Scheffler, Arnaud

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/066935

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2015179177 A1	26-11-2015	AU 2015264561 A1 EP 3145582 A1 US 2015335893 A1 US 2017036023 A1 WO 2015179177 A1	03-11-2016 29-03-2017 26-11-2015 09-02-2017 26-11-2015
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US 2011071589 A1	24-03-2011	AU 2010295275 A1 CN 102725021 A EP 2480283 A1 JP 2013505080 A US 2011071589 A1 UY 32901 A WO 2011035311 A1	16-02-2012 10-10-2012 01-08-2012 14-02-2013 24-03-2011 31-03-2011 24-03-2011

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 23-39

A system for applying electrical stimulation and having a stimulation generator

1.1. claims: 34-39

A system for applying electrical stimulation and having two different stimulation signals

2. claims: 40-44

A system comprising a processor configured to determine paresthesia

3. claims: 45-50

A system comprising means for delivering electrical stimulation

4. claims: 51-56

A computer-readable medium comprising instructions for the electrical stimulation

5. claims: 57-64

A method for controlling a medical device

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-22

Claims 1-22 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims. Claims 1-22 have not been searched, because they deal with methods of electrical stimulation (Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy).