

US Patent & Trademark Office

Patent Public Search | Text View

United States Patent Application Publication

20250256112

Kind Code

A1

Publication Date

August 14, 2025

Inventor(s)

Auten; Kacey et al.

Paresthesia-Free Spinal Cord Stimulation Occurring at Lower Frequencies Involving Perception Threshold Determinations

Abstract

Methods and systems for testing and treating spinal cord stimulation (SCS) patients are disclosed. Patients are eventually treated with sub-perception (paresthesia free) therapy. However, supra-perception stimulation is used during “sweet spot searching” during which a stimulation location in an electrode array is determined. Preferably, the supra-perception stimulation comprises a bipole formed using actively-driven symmetric biphasic waveforms at active ones of the electrodes in the array. After determining the location, a perception threshold for the bipole at the location is determined and stored, and an amplitude of the stimulation is reduced below the perception threshold to provide a sub-perception stimulation bipole. The determined perception threshold may be used to compose one or more programs using stimulation amplitudes that are a percentage of the determined perception threshold. The one or more programs may run according to schedule. For example, the programs may be interleaved.

Inventors: Auten; Kacey (Williamston, MI), Pehler; Nina (Edina, MN), Huertas Fernandez; Ismael (Seville, ES)

Applicant: Boston Scientific Neuromodulation Corporation (Valencia, CA)

Family ID: 94869634

Appl. No.: 19/044098

Filed: February 03, 2025

Related U.S. Application Data

us-provisional-application US 63551944 20240209

Publication Classification

Int. Cl.: A61N1/372 (20060101); A61N1/36 (20060101)

Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application is a non-provisional of U.S. Provisional Patent Application Ser. No. 63/551,944, filed Feb. 9, 2024, which is incorporated herein by reference in its entirety, and to which priority is claimed.

FIELD OF THE INVENTION

[0002] This application relates to Implantable Medical Devices (IMDs), generally, Spinal Cord Stimulators, more specifically, and to methods of control of such devices.

INTRODUCTION

[0003] Implantable neurostimulator devices are devices that generate and deliver electrical stimuli to body nerves and tissues for the therapy of various biological disorders, such as pacemakers to treat cardiac arrhythmia, defibrillators to treat cardiac fibrillation, cochlear stimulators to treat deafness, retinal stimulators to treat blindness, muscle stimulators to produce coordinated limb movement, spinal cord stimulators to treat chronic pain, cortical and deep brain stimulators to treat motor and psychological disorders, and other neural stimulators to treat urinary incontinence, sleep apnea, shoulder subluxation, etc. The description that follows will generally focus on the use of the invention within a Spinal Cord Stimulation (SCS) system, such as that disclosed in U.S. Pat. No. 6,516,227. However, the present invention may find applicability with any implantable neurostimulator device system.

[0004] An SCS system typically includes an Implantable Pulse Generator (IPG) **10** shown in FIG. **1**. The IPG **10** includes a biocompatible device case **12** that holds the circuitry and battery **14** necessary for the IPG to function. The IPG **10** is coupled to electrodes **16** via one or more electrode leads **15** that form an electrode array **17**. The electrodes **16** are configured to contact a patient's tissue and are carried on a flexible body **18**, which also houses the individual lead wires **20** coupled to each electrode **16**. The lead wires **20** are also coupled to proximal contacts **22**, which are insertable into lead connectors **24** fixed in a header **23** on the IPG **10**, which header can comprise an epoxy for example. Once inserted, the proximal contacts **22** connect to header contacts within the lead connectors **24**, which are in turn coupled by feedthrough pins through a case feedthrough to circuitry within the case **12**, although these details aren't shown.

[0005] In the illustrated IPG **10**, there are sixteen lead electrodes (E1-E16) split between two leads **15**, with the header **23** containing a 2×1 array of lead connectors **24**. However, the number of leads and electrodes in an IPG is application specific and therefore can vary. The conductive case **12** can also comprise an electrode (Ec). In a SCS application, the electrode leads **15** are typically implanted proximate to the dura in a patient's spinal column on the right and left sides of the spinal cord midline. The proximal electrodes **22** are tunneled through the patient's tissue to a distant location such as the buttocks where the IPG case **12** is implanted, at which point they are coupled to the lead connectors **24**. In other IPG examples designed for implantation directly at a site requiring stimulation, the IPG can be lead-less, having electrodes **16** instead appearing on the body of the IPG for contacting the patient's tissue. The IPG leads **15** can be integrated with and permanently connected the case **12** in other IPG solutions. The goal of SCS therapy is to provide electrical stimulation from the electrodes **16** to alleviate a patient's symptoms, most notably chronic back pain.

[0006] IPG **10** can include an antenna **26a** allowing it to communicate bi-directionally with a number of external devices, as shown in FIG. **4**. The antenna **26a** as depicted in FIG. **1** is shown as

a conductive coil within the case **12**, although the coil antenna **26a** can also appear in the header **23**. When antenna **26a** is configured as a coil, communication with external devices preferably occurs using near-field magnetic induction. IPG may also include a Radio-Frequency (RF) antenna **26b**. In FIG. **1**, RF antenna **26b** is shown within the header **23**, but it may also be within the case **12**. RF antenna **26b** may comprise a patch, slot, or wire, and may operate as a monopole or dipole. RF antenna **26b** preferably communicates using far-field electromagnetic waves. RF antenna **26b** may operate in accordance with any number of known RF communication standards, such as Bluetooth, Zigbee, WiFi, MICS, and the like.

[0007] Stimulation in IPG **10** is typically provided by pulses, as shown in FIG. **2**. Stimulation parameters typically include the amplitude of the pulses (A; whether current or voltage); the frequency (F) and pulse width (PW) of the pulses; the electrodes **16** (E) activated to provide such stimulation; and the polarity (P) of such active electrodes, i.e., whether active electrodes are to act as anodes (that source current to the tissue) or cathodes (that sink current from the tissue). These stimulation parameters taken together comprise a stimulation program that the IPG **10** can execute to provide therapeutic stimulation to a patient.

[0008] In the example of FIG. **2**, electrode E5 has been selected as an anode, and thus provides pulses which source a positive current of amplitude +A to the tissue. Electrode E4 has been selected as a cathode, and thus provides pulses which sink a corresponding negative current of amplitude -A from the tissue. This is an example of bipolar stimulation, in which only two lead-based electrodes are used to provide stimulation to the tissue (one anode, one cathode). However, more than one electrode may act as an anode at a given time, and more than one electrode may act as a cathode at a given time (e.g., tripole stimulation, quadripole stimulation, etc.).

[0009] The pulses as shown in FIG. **2** are biphasic, comprising a first phase **30a**, followed quickly thereafter by a second phase **30b** of opposite polarity. As is known, use of a biphasic pulse is useful in active charge recovery. For example, each electrodes' current path to the tissue may include a serially-connected DC-blocking capacitor, see, e.g., U.S. Patent Application Publication 2016/0144183, which will charge during the first phase **30a** and discharged (be recovered) during the second phase **30b**. In the example shown, the first and second phases **30a** and **30b** have the same duration and amplitude (although opposite polarities), which ensures the same amount of charge during both phases. However, the second phase **30b** may also be charged balance with the first phase **30a** if the integral of the amplitude and durations of the two phases are equal in magnitude, as is well known. The width of each pulse, PW, is defined here as the duration of first pulse phase **30a**, although pulse width could also refer to the total duration of the first and second pulse phases **30a** and **30b** as well. Note that an interphase period (IP) during which no stimulation is provided may be provided between the two phases **30a** and **30b**.

[0010] IPG **10** includes stimulation circuitry **28** that can be programmed to produce the stimulation pulses at the electrodes as defined by the stimulation program. Stimulation circuitry **28** can for example comprise the circuitry described in U.S. Patent Application Publications 2018/0071513 and 2018/0071520, or in U.S. Pat. Nos. 8,606,362 and 8,620,436. These references are incorporated herein by reference.

[0011] FIG. **3** shows an external trial stimulation environment that may precede implantation of an IPG **10** in a patient. During external trial stimulation, stimulation can be tried on a prospective implant patient without going so far as to implant the IPG **10**. Instead, one or more trial leads **15'** are implanted in the patient's tissue **32** at a target location **34**, such as within the spinal column as explained earlier. The proximal ends of the trial lead(s) **15'** exit an incision **36** and are connected to an External Trial Stimulator (ETS) **40**. The ETS **40** generally mimics operation of the IPG **10**, and thus can provide stimulation pulses to the patient's tissue as explained above. See, e.g., U.S. Pat. No. 9,259,574, disclosing a design for an ETS. The ETS **40** is generally worn externally by the patient for a short while (e.g., two weeks), which allows the patient and his clinician to experiment with different stimulation parameters to try and find a stimulation program that alleviates the

patient's symptoms (e.g., pain). If external trial stimulation proves successful, trial lead(s) **15'** are explanted, and a full IPG **10** and lead(s) **15** are implanted as described above; if unsuccessful, the trial lead(s) **15'** are simply explanted.

[0012] Like the IPG **10**, the ETS **40** can include one or more antennas to enable bi-directional communications with external devices, explained further with respect to FIG. **4**. Such antennas can include a near-field magnetic-induction coil antenna **42a**, and/or a far-field RF antenna **42b**, as described earlier. ETS **40** may also include stimulation circuitry **44** able to form the stimulation pulses in accordance with a stimulation program, which circuitry may be similar to or comprise the same stimulation circuitry **28** present in the IPG **10**. ETS **40** may also include a battery (not shown) for operational power.

[0013] FIG. **4** shows various external devices that can wirelessly communicate data with the IPG **10** and the ETS **40**, including a patient, hand-held external controller **45**, and a clinician programmer (CP) **50**. Both of devices **45** and **50** can be used to send a stimulation program to the IPG **10** or ETS **40**—that is, to program their stimulation circuitries **28** and **44** to produce pulses with a desired shape and timing described earlier. Both devices **45** and **50** may also be used to adjust one or more stimulation parameters of a stimulation program that the IPG **10** or ETS **40** is currently executing. Devices **45** and **50** may also receive information from the IPG **10** or ETS **40**, such as various status information, etc.

[0014] External controller **45** can be as described in U.S. Patent Application Publication 2015/0080982 for example, and may comprise either a dedicated controller configured to work with the IPG **10**. External controller **45** may also comprise a general purpose mobile electronics device such as a mobile phone which has been programmed with a Medical Device Application (MDA) allowing it to work as a wireless controller for the IPG **10** or ETS **40**, as described in U.S. Patent Application Publication 2015/0231402. External controller **45** includes a user interface, including means for entering commands (e.g., buttons or icons) and a display **46**. The external controller **45**'s user interface enables a patient to adjust stimulation parameters, although it may have limited functionality when compared to the more-powerful clinician programmer **50**, described shortly.

[0015] The external controller **45** can have one or more antennas capable of communicating with the IPG **10** and ETS **40**. For example, the external controller **45** can have a near-field magnetic-induction coil antenna **47a** capable of wirelessly communicating with the coil antenna **26a** or **42a** in the IPG **10** or ETS **40**. The external controller **45** can also have a far-field RF antenna **47b** capable of wirelessly communicating with the RF antenna **26b** or **42b** in the IPG **10** or ETS **40**.

[0016] The external controller **45** can also have control circuitry **48** such as a microprocessor, microcomputer, an FPGA, other digital logic structures, etc., which is capable of executing instructions an electronic device. Control circuitry **48** can for example receive patient adjustments to stimulation parameters, and create a stimulation program to be wirelessly transmitted to the IPG **10** or ETS **40**.

[0017] Clinician programmer **50** is described further in U.S. Patent Application Publication 2015/0360038, and is only briefly explained here. The clinician programmer **50** can comprise a computing device **51**, such as a desktop, laptop, or notebook computer, a tablet, a mobile smart phone, a Personal Data Assistant (PDA)-type mobile computing device, etc. In FIG. **4**, computing device **51** is shown as a laptop computer that includes typical computer user interface means such as a screen **52**, a mouse, a keyboard, speakers, a stylus, a printer, etc., not all of which are shown for convenience. Also shown in FIG. **4** are accessory devices for the clinician programmer **50** that are usually specific to its operation as a stimulation controller, such as a communication “wand” **54**, and a joystick **58**, which are coupleable to suitable ports on the computing device **51**, such as USB ports **59** for example.

[0018] The antenna used in the clinician programmer **50** to communicate with the IPG **10** or ETS **40** can depend on the type of antennas included in those devices. If the patient's IPG **10** or ETS **40**

includes a coil antenna **26a** or **42a**, wand **54** can likewise include a coil antenna **56a** to establish near-filed magnetic-induction communications at small distances. In this instance, the wand **54** may be affixed in close proximity to the patient, such as by placing the wand **54** in a belt or holster wearable by the patient and proximate to the patient's IPG **10** or ETS **40**.

[0019] If the IPG **10** or ETS **40** includes an RF antenna **26b** or **42b**, the wand **54**, the computing device **51**, or both, can likewise include an RF antenna **56b** to establish communication with the IPG **10** or ETS **40** at larger distances. (Wand **54** may not be necessary in this circumstance). The clinician programmer **50** can also establish communication with other devices and networks, such as the Internet, either wirelessly or via a wired link provided at an Ethernet or network port.

[0020] To program stimulation programs or parameters for the IPG **10** or ETS **40**, the clinician interfaces with a clinician programmer graphical user interface (GUI) **64** provided on the display **52** of the computing device **51**. As one skilled in the art understands, the GUI **64** can be rendered by execution of clinician programmer software **66** on the computing device **51**, which software may be stored in the device's non-volatile memory **68**. One skilled in the art will additionally recognize that execution of the clinician programmer software **66** in the computing device **51** can be facilitated by control circuitry **70** such as a microprocessor, microcomputer, an FPGA, other digital logic structures, etc., which is capable of executing programs in a computing device. Such control circuitry **70**, in addition to executing the clinician programmer software **66** and rendering the GUI **64**, can also enable communications via antennas **56a** or **56b** to communicate stimulation parameters chosen through the GUI **64** to the patient's IPG **10**.

[0021] A portion of the GUI **64** is shown in one example in FIG. 5. One skilled in the art will understand that the particulars of the GUI **64** will depend on where clinician programmer software **66** is in its execution, which will depend on the GUI selections the clinician has made. FIG. 5 shows the GUI **64** at a point allowing for the setting of stimulation parameters for the patient and for their storage as a stimulation program. To the left a program interface **72** is shown, which as explained further in the '038 Publication allows for naming, loading and saving of stimulation programs for the patient. Shown to the right is a stimulation parameters interface **82**, in which specific stimulation parameters (A, D, F, E, P) can be defined for a stimulation program. Values for stimulation parameters relating to the shape of the waveform (A; in this example, current), pulse width (PW), and frequency (F) are shown in a waveform parameter interface **84**, including buttons the clinician can use to increase or decrease these values.

[0022] Stimulation parameters relating to the electrodes **16** (the electrodes E activated and their polarities P), are made adjustable in an electrode parameter interface **86**. Electrode stimulation parameters are also visible and can be manipulated in a leads interface **92** that displays the leads **15** (or **15'**) in generally their proper position with respect to each other, for example, on the left and right sides of the spinal column. A cursor **94** (or other selection means such as a mouse pointer) can be used to select a particular electrode in the leads interface **92**. Buttons in the electrode parameter interface **86** allow the selected electrode (including the case electrode, Ec) to be designated as an anode, a cathode, or off. The electrode parameter interface **86** further allows the relative strength of anodic or cathodic current of the selected electrode to be specified in terms of a percentage, X. This is particularly useful if more than one electrode is to act as an anode or cathode at a given time, as explained in the '038 Publication. In accordance with the example waveforms shown in FIG. 2, as shown in the leads interface **92**, electrode E5 has been selected as the only anode to source current, and this electrode receives X=100% of the specified anodic current, +A. Likewise, electrode E4 has been selected as the only cathode to sink current, and this electrode receives X=100% of that cathodic current, -A.

[0023] The GUI **64** as shown specifies only a pulse width PW of the first pulse phase **30a**. The clinician programmer software **66** that runs and receives input from the GUI **64** will nonetheless ensure that the IPG **10** and ETS **40** are programmed to render the stimulation program as biphasic pulses if biphasic pulses are to be used. For example, the clinician programming software **66** can

automatically determine durations and amplitudes for both of the pulse phases **30a** and **30b** (e.g., each having a duration of PW, and with opposite polarities +A and -A). An advanced menu **88** can also be used (among other things) to define the relative durations and amplitudes of the pulse phases **30a** and **30b**, and to allow for other more advance modifications, such as setting of a duty cycle (on/off time) for the stimulation pulses, and a ramp-up time over which stimulation reaches its programmed amplitude (A), etc. A mode menu **90** allows the clinician to choose different modes for determining stimulation parameters. For example, as described in the '038 Publication, mode menu **90** can be used to enable electronic trolling, which comprises an automated programming mode that performs current steering along the electrode array by moving the cathode in a bipolar fashion.

[0024] While GUI **64** is shown as operating in the clinician programmer **50**, the user interface of the external controller **45** may provide similar functionality.

SUMMARY

[0025] Disclosed herein is a method for programming a spinal cord stimulator for providing spinal cord stimulation (SCS) for a patient, the spinal cord stimulator having a plurality of electrodes comprising an array, the method comprising: (a) using a first external device to provide a supra-perception stimulation field to the spinal cord stimulator, wherein the supra-perception stimulation field comprises a pole configuration formed in the electrode array; (b) using the first external device to provide stimulation to the patient while move the pole configuration in the electrode array to a location that best treats a symptom of the patient; (c) determining, using the first external device, a perception threshold (pth) of the pole configuration at the location by varying an amplitude of the supra-perception stimulation field; (d) using the pth to determine at least a first sub-perception stimulation program having an amplitude that is a first fraction of the pth and a second sub-perception stimulation program having an amplitude that is a second fraction of pth, wherein the second fraction of pth is greater than the first fraction of the pth; and (e) using the first external device to program a second external device usable by the patient with the determined first and second sub-perception stimulation programs. According to some embodiments, the first fraction is about 10% to about 50% of the pth and the second fraction is about 50% to about 80% of the pth. According to some embodiments, the method further comprises using the first external device to compose a schedule comprising a first duration during which the first sub-perception stimulation program is active to provide stimulation to the patient and a second duration during which the second sub-perception stimulation program is active to provide stimulation to the patient; and using the first external device to program the second external device with the schedule.

According to some embodiments, the first duration is about 2 to about 6 hours and the second duration is about 1 to about 20 minutes. According to some embodiments, determining the first and second sub-perception stimulation programs and composing the schedule comprises executing a script, wherein the script: receives an indication of the pth; uses the pth to automatically determine the first and second fractions; and automatically composes the schedule. According to some embodiments, the script is a patient indication-specific script and wherein the method further comprises: receiving an input indicative of a patient indication; selecting the patient indication-specific script corresponding to the received input, and executing the selected patient indication-specific script to provide determine first and second fractions and compose a schedule that is specific for the patient indication. According to some embodiments, the pole configuration comprises a bipole comprising an anode pole and a cathode pole. According to some embodiments, when the bipole is at the location, the anode pole is formed at two or more electrodes, and wherein the cathode pole is formed at two or more different of the electrodes. According to some embodiments, the bipole comprises an anode pole and a cathode pole, wherein more than one electrode is active to form the anode pole, and wherein more than one electrode is active to form the cathode pole. According to some embodiments, the first external device is used to move the pole configuration linearly along a length of the electrode array. According to some embodiments,

the pole configuration comprises actively-driven symmetric biphasic pulses at active ones of the electrodes. According to some embodiments, the pulses are formed at a frequency of 130 Hz or less. According to some embodiments, the pulses have a pulse width within a range from 50 to 500 microseconds. According to some embodiments, the pulses have a pulse width within a range from 160 to 260 microseconds.

[0026] Also disclosed herein is a system configured to program a spinal cord stimulator for providing spinal cord stimulation (SCS) for a patient, the spinal cord stimulator having a plurality of electrodes comprising an array, the system comprising: a first external device comprising control circuitry configured to render a user interface, wherein the user interface enables a user to: (a) provide a supra-perception stimulation field to the spinal cord stimulator, wherein the supra-perception stimulation field comprises a pole configuration formed in the electrode array; (b) move the pole configuration in the electrode array to a location that best treats a symptom of the patient; (c) determine a perception threshold (pth) of the pole configuration at the location by varying an amplitude of the supra-perception stimulation field; (d) use the pth to determine at least a first sub-perception stimulation program having an amplitude that is a first fraction of the pth and a second sub-perception stimulation program having an amplitude that is a second fraction of pth, wherein the second fraction of pth is greater than the first fraction of the pth; and (e) use the first external device to program a second external device usable by the patient with the determined first and second sub-perception stimulation programs. According to some embodiments, the first fraction is about 10% to about 50% of the pth and the second fraction is about 50% to about 80% of the pth. According to some embodiments, the control circuitry is further configured to: compose a schedule comprising a first duration during which the first sub-perception stimulation program is active to provide stimulation to the patient and a second duration during which the second sub-perception stimulation program is active to provide stimulation to the patient; and program the second external device with the schedule. According to some embodiments, the first duration is about 2 to about 6 hours and the second duration is about 1 to about 10 minutes. According to some embodiments, determining the first and second sub-perception stimulation programs and composing the schedule comprises executing a script, wherein the script: receives an indication of the pth; uses the pth to automatically determine the first and second fractions; and automatically composes the schedule. According to some embodiments, the script is a patient indication-specific script. According to some embodiments, the user interface allows the user to: select a patient indication-specific script corresponding to an indication for their patient from a plurality of patient indication-specific scripts; and execute the selected patient indication-specific script. According to some embodiments, the patient indication is selected from the group of indications consisting of failed back surgery syndrome (FBSS), nociceptive pain, and diabetic peripheral neuropathy (DPN). According to some embodiments, the pole configuration comprises a bipole comprising an anode pole and a cathode pole. According to some embodiments, the bipole is at the location, the anode pole is formed at two or more electrodes, and wherein the cathode pole is formed at two or more different of the electrodes. According to some embodiments, the bipole comprises an anode pole and a cathode pole, wherein more than one electrode is active to form the anode pole, and wherein more than one electrode is active to form the cathode pole. According to some embodiments, the first external device is used to move the pole configuration linearly along a length of the electrode array. According to some embodiments, the pole configuration comprises actively-driven symmetric biphasic pulses at active ones of the electrodes. According to some embodiments, the pulses are formed at a frequency of 130 Hz or less. According to some embodiments, the pulses have a pulse width within a range from 50 to 500 microseconds. According to some embodiments, the pulses have a pulse width within a range from 160 to 260 microseconds. According to some embodiments, the system further comprises the second device.

[0027] Also disclosed herein is a non-transitory computer readable medium containing instructions executable on a first external device configured to program a stimulator having a plurality of

electrodes comprising an array, wherein the instructions when executed, enable a user to perform a method comprising: (a) use the first external device to provide a supra-perception stimulation field to the spinal cord stimulator, wherein the supra-perception stimulation field comprises a pole configuration formed in the electrode array; (b) use the first external device to provide stimulation to the patient while move the pole configuration in the electrode array to a location that best treats a symptom of the patient; (c) determine, using the first external device, a perception threshold (pth) of the pole configuration at the location by varying an amplitude of the supra-perception stimulation field; (d) use the pth to determine at least a first sub-perception stimulation program having an amplitude that is a first fraction of the pth and a second sub-perception stimulation program having an amplitude that is a second fraction of pth, wherein the second fraction of pth is greater than the first fraction of the pth; and (e) use the first external device to program a second external device usable by the patient with the determined first and second sub-perception stimulation programs. According to some embodiments, the first fraction is about 10% to about 50% of the pth and the second fraction is about 50% to about 80% of the pth. According to some embodiments, the method further comprises: using the first external device to compose a schedule comprising a first duration during which the first sub-perception stimulation program is active to provide stimulation to the patient and a second duration during which the second sub-perception stimulation program is active to provide stimulation to the patient; and using the first external device to program the second external device with the schedule. According to some embodiments, the first duration is about 2 to about 6 hours and the second duration is about 1 to about 20 minutes. According to some embodiments, determining the first and second sub-perception stimulation programs and composing the schedule comprises executing a script, wherein the script: receives an indication of the pth; uses the pth to automatically determine the first and second fractions; and automatically composes the schedule. According to some embodiments, the script is a patient indication-specific script and wherein the method further comprises: receiving an input indicative of a patient indication; selecting the patient indication-specific script corresponding to the received input, and executing the selected patient indication-specific script to provide determine first and second fractions and compose a schedule that is specific for the patient indication. According to some embodiments, the pole configuration comprises a bipole comprising an anode pole and a cathode pole. According to some embodiments, when the bipole is at the location, the anode pole is formed at two or more electrodes, and wherein the cathode pole is formed at two or more different of the electrodes. According to some embodiments, the bipole comprises an anode pole and a cathode pole, wherein more than one electrode is active to form the anode pole, and wherein more than one electrode is active to form the cathode pole. According to some embodiments, the first external device is used to move the pole configuration linearly along a length of the electrode array. According to some embodiments, the pole configuration comprises actively-driven symmetric biphasic pulses at active ones of the electrodes. According to some embodiments, the pulses are formed at a frequency of 130 Hz or less. According to some embodiments, the pulses have a pulse width within a range from 50 to 500 microseconds. According to some embodiments, the pulses have a pulse width within a range from 160 to 260 microseconds.

[0028] The invention may also reside in the form of a programed external device (via its control circuitry) for carrying out the above methods, a programmed implantable pulse generator (IPG) or external trial stimulator (ETS) (via its control circuitry) for carrying out the above methods, a system including a programed external device and IPG or ETS for carrying out the above methods, or as a computer-readable media for carrying out the above methods stored in an external device or IPG or ETS. The invention may also reside in one or more non-transitory computer-readable media comprising instructions, which when executed by a processor of a machine configure the machine to perform any of the above methods.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. 1 shows an Implantable Pulse Generator (IPG) useable for Spinal Cord Stimulation (SCS), in accordance with the prior art.

[0030] FIG. 2 shows an example of stimulation pulses producible by the IPG, in accordance with the prior art.

[0031] FIG. 3 shows use of an External Trial Stimulator (ETS) useable to provide stimulation before implantation of an IPG, in accordance with the prior art.

[0032] FIG. 4 shows various external devices capable of communicating with and programming stimulation in an IPG and ETS, in accordance with the prior art.

[0033] FIG. 5 shows a Graphical User Interface (GUI) of a clinician programmer external device for setting or adjusting stimulation parameters, in accordance with the prior art.

[0034] FIG. 6 shows sweet spot searching to determine effective electrodes for a patient using a movable sub-perception bipole.

[0035] FIGS. 7A-7D show sweet spot searching to determine effective electrodes for a patient using a movable supra-perception bipole.

[0036] FIG. 8 shows stimulation circuitry useable in the IPG or ETS capable of providing Multiple Independent Current Control to independently set the current at each of the electrodes.

[0037] FIG. 9 shows a sub-perception stimulation algorithm used to optimize sub-perception stimulation for the patient.

[0038] FIG. 10 shows aspects of the graphical user interfaces at both a clinician programmer and a patient remote control that are implicated during use of the sub-perception algorithm.

[0039] FIG. 11 shows an embodiment of a program list having multiple sub-perception stimulation programs.

[0040] FIG. 12 shows an embodiment of a schedule interface for scheduling multiple sub-perception stimulation programs.

[0041] FIG. 13 shows an embodiment of a workflow for automating and scheduling dosing of sub-perception stimulation and transmitting the stimulation programs and schedule to a patient's remote control.

[0042] FIG. 14 shows an embodiment of a GUI element for selecting a script based on a particular patient indication.

DETAILED DESCRIPTION

[0043] While Spinal Cord Stimulation (SCS) therapy can be an effective means of alleviating a patient's pain, such stimulation can also cause paresthesia. Paresthesia—sometimes referred to a “supra-perception” therapy—is a sensation such as tingling, prickling, heat, cold, etc. that can accompany SCS therapy. Generally, the effects of paresthesia are mild, or at least are not overly concerning to a patient. Moreover, paresthesia is generally a reasonable tradeoff for a patient whose chronic pain has now been brought under control by SCS therapy. Some patients even find paresthesia comfortable and soothing.

[0044] Nonetheless, at least for some patients, SCS therapy would ideally provide complete pain relief without paresthesia—what is often referred to as “sub-perception” or sub-threshold therapy that a patient cannot feel. Effective sub-perception therapy may provide pain relief without paresthesia by issuing stimulation pulses at higher frequencies. Unfortunately, such higher-frequency stimulation may require more power, which tends to drain the battery 14 of the IPG 10. See, e.g., U.S. Patent Application Publication 2016/0367822. If an IPG's battery 14 is a primary cell and not rechargeable, high-frequency stimulation means that the IPG 10 will need to be replaced more quickly. Alternatively, if an IPG battery 14 is rechargeable, the IPG 10 will need to be charged more frequently, or for longer periods of time. Either way, the patient is

inconvenienced.

[0045] In an SCS application, it is desirable to determine a stimulation program that will be effective for each patient. A significant part of determining an effective stimulation program is to determine a “sweet spot” for stimulation in each patient, i.e., to select which electrodes should be active (E) and with what polarities (P) and relative amplitudes (X %) to recruit and thus treat a neural site at which pain originates in a patient. Selecting electrodes proximate to this neural site of pain can be difficult to determine, and experimentation is typically undertaken to select the best combination of electrodes to provide a patient's therapy.

[0046] As described in U.S. Patent Application Publication 2019/0366104, which is hereby expressly incorporated by reference, selecting electrodes for a given patient can be even more difficult when sub-perception therapy is used, because the patient does not feel the stimulation, and therefore it can be difficult for the patient to feel whether the stimulation is “covering” or masking his pain and therefore whether selected electrodes are effective. Further, sub-perception stimulation therapy may require a “wash in” period before it can become effective. A wash in period can take up to a day or more, and therefore sub-perception stimulation may not be immediately effective, making electrode selection more difficult.

[0047] FIG. 6 briefly explains the '104 Publication's technique for a sweet spot search, i.e., how electrodes can be selected that are proximate to a site of pain in a patient, when sub-perception stimulation is used. The technique of FIG. 6 is particularly useful in a trial setting after a patient is first implanted with an electrode array, i.e., after receiving their IPG or ETS.

[0048] In the example shown, it is assumed that a site **298** where stimulation will be effective at treating the patient's pain (i.e., a “sweet spot” for stimulation) is likely within a tissue region **299**. Such region **299** may be deduced by a clinician based on the patient symptoms, e.g., by understanding which electrodes are proximate to certain vertebrae (not shown), such as within the T9-T10 interspace. In the example shown, region **299** is bounded by electrodes **E2**, **E7**, **E15**, and **E10**, meaning that electrodes outside of this region (e.g., **E1**, **E8**, **E9**, **E16**) are unlikely to have an effect on the patient's symptoms. Therefore, these electrodes may not be selected during the sweet spot search depicted in FIG. 6, as explained further below.

[0049] In FIG. 6, a sub-perception bipole **297a** is selected, in which one electrode (e.g., **E2**) is selected as an anode that will source a positive current (+A) to the patient's tissue, while another electrode (e.g., **E3**) is selected as a cathode that will sink a negative current (−A) from the tissue. This is similar to what was illustrated earlier with respect to FIG. 2, and biphasic stimulation pulses can be used employing active charge recovery. Because the bipole **297a** provides sub-perception stimulation, the amplitude A used during the sweet spot search is titrated down until the patient no longer feels paresthesia. This sub-perception bipole **297a** is provided to the patient for a duration, such as a few days, which allows the sub-perception bipole's potential effectiveness to “wash in,” and allows the patient to provide feedback concerning how well the bipole **297a** is helping their symptoms. Such patient feedback can comprise a pain scale ranking. For example, the patient can rank their pain on a scale from 1-10 using a Numerical Rating Scale (NRS) or the Visual Analogue Scale (VAS), with 1 denoting no or little pain and 10 denoting the worst pain imaginable. As discussed in the '104 Publication, such pain scale ranking can be entered into the patient's external controller **45**.

[0050] After the bipole **297a** is tested at this first location, a different combination of electrodes is chosen (e.g., anode electrode **E3**, cathode electrode **E4**), which moves the location of the bipole **297** in the patient's tissue. Again, the amplitude of the current A may need to be titrated to an appropriate sub-perception level. In the example shown, the bipole **297a** is moved down one electrode lead, and up the other, as shown by path **296** in the hope of finding a combination of electrodes that covers the sweet spot **298**. In the example of FIG. 6, given the sweet spot's **298**'s proximity to electrodes **E13** and **E14**, it might be expected that a bipole **297a** at those electrodes will provide the best relief for the patient, as reflected by the patient's pain score rankings. The

particular stimulation parameters chosen when forming bipole **297a** can be selected at the GUI **64** of the clinician programmer **50** or other external device (such as a patient external controller **45**) and wirelessly telemetered to the patient's IPG or ETS for execution. Note that the bipole **297a** can be moved up, down, left, or right using directional arrows **99** provided in the GUI **64** of the CP **50**. Alternatively, the bipole can be moved using a peripheral device connected to the CP **50**, such as a mouse or joystick.

[0051] While the sweet spot search of FIG. **6** can be effective, it can also take a significantly long time when sub-perception stimulation is used. As noted, sub-perception stimulation is provided at each bipole **297** location for a number of days, and because a large number of bipole locations are chosen, the entire sweep spot search can take up to a month to complete.

[0052] The inventors have determined via testing of SCS patients that even if it is desired to eventually use sub-perception therapy for a patient going forward after the sweet spot search, it is beneficial to use supra-perception stimulation during the sweet spot search to select active electrodes for the patient. Use of supra-perception stimulation during the sweet spot search greatly accelerates determination of effective electrodes for the patient compared to the use of sub-perception stimulation, which requires a wash in period at each set of electrodes tested. After determining electrodes for use with the patient using supra-perception therapy, therapy may be titrated to sub-perception levels keeping the same electrodes determined for the patient during the sweet spot search. Because the selected electrodes are known to be recruiting the neural site of the patient's pain, the application of sub-perception therapy to those electrodes is more likely to have immediate effect, reducing or potentially eliminating the need to wash in the sub-perception therapy that follows. In short, effective sub-perception therapy can be achieved more quickly for the patient when supra-perception sweet spot searching is utilized. Preferably, supra-perception sweet spot searching occurs using symmetric biphasic pulses occurring at low frequencies—such as between 40 and 200 Hz in one example.

[0053] In accordance with one aspect of the disclosed technique, a patient will be provided sub-perception therapy. Sweet spot searching to determine electrodes that may be used during sub-perception therapy may precede such sub-perception therapy. In some aspects, when sub-perception therapy is used for the patient, sweet spot searching may use a bipole **297a** that is sub-perception (FIG. **6**), as just described. This may be relevant because the sub-perception sweet spot search may match the eventual sub-perception therapy the patient will receive.

[0054] However, the inventors have determined that even if sub-perception therapy is eventually to be used for the patient, it can be beneficial to use supra-perception stimulation—that is, stimulation with accompanying paresthesia—during the sweet spot search. This is shown in FIG. **7A**, where the movable bipole **301a** provides supra-perception stimulation that can be felt by the patient. Providing bipole **301a** as supra-perception stimulation can merely involve increasing its amplitude (e.g., current **A**) when compared to the sub-perception bipole **297a** of FIG. **6**, although other stimulation parameters might be adjusted as well, such as by providing longer pulse widths.

[0055] The inventors have determined that there are benefits to employing supra-perception stimulation during the sweet spot search even though sub-perception therapy will eventually be used for the patient.

[0056] First, as mentioned above, the use of supra-perception therapy by definition allows the patient to feel the stimulation, which enables the patient to provide essentially immediate feedback to the clinician whether the paresthesia seems to be well covering his pain site. In other words, it is not necessary to take the time to wash in bipole **301a** at each location as it is moved along path **296**. Thus, a suitable bipole **301a** proximate to the sweet spot **298** can be established much more quickly, such as within a single clinician's visit, rather than over a period of days or weeks. In one example, when sub-perception therapy is preceded with supra-perception sweet spot searching, the time needed to wash in the sub-perception therapy can be one hour or less, ten minutes or less, or even a matter of seconds. This allows wash-in to occur during a single programming session during

which the patient's IPG or ETS is programmed, and without the need for the patient to leave the clinician's office.

[0057] Second, use of supra-perception stimulation during the sweet spot search ensures that electrodes are determined that well recruit the sweet spot **298**. As a result, after the sweet spot search is complete and eventual sub-perception therapy is titrated for the patient, wash in of that sub-perception therapy may not take as long because the electrodes needed for good recruitment have already been confidently determined.

[0058] FIGS. **7B-7D** show other supra-perception bipoles **301b-301d** that may be used, and in particular show how the virtual bipoles may be formed using virtual poles by activating three or more of the electrodes **16**. Virtual poles are discussed further in U.S. Pat. No. 10,881,859, which is incorporated herein by reference in its entirety, and thus virtual poles are only briefly explained here. Forming virtual poles is assisted if the stimulation circuitry **28** or **44** used in the IPG or ETS is capable of independently setting the current at any of the electrodes—what is sometimes known as a Multiple Independent Current Control (MICC), which is explained further below with reference to FIG. **8**.

[0059] When a virtual bipole is used, the GUI **64** (FIG. **5**) of the clinician programmer **50** (FIG. **4**) can be used to define an anode pole (+) and a cathode pole (−) at positions **291** (FIG. **7B**) that may not necessarily correspond to the position of the physical electrodes **16**. The control circuitry **70** in the clinician programmer **50** can compute from these positions **291** and from other tissue modeling information which physical electrodes **16** will need to be selected and with what amplitudes to form the virtual anode and virtual cathode at the designated positions **291**. As described earlier, amplitudes at selected electrodes may be expressed as a percentage X % of the total current amplitude A specified at the GUI **64** of the clinician programmer **50**.

[0060] For example, in FIG. **7B**, the virtual anode pole is located at a position **291** between electrodes **E2**, **E3** and **E10**. The clinician programmer **50** may then calculate based on this position that each of these electrodes (during first pulse phase **30a**) will receive an appropriate share (X %) of the total anodic current +A to locate the virtual anode at this position. Since the virtual anode's position is closest to electrode **E2**, this electrode **E2** may receive the largest share of the specified anodic current +A (e.g., $75\% \cdot +A$). Electrodes **E3** and **E10** which are proximate to the virtual anode pole's position but farther away receive lesser shares of the anodic current (e.g., $15\% \cdot +A$ and $10\% \cdot +A$ respectively). Likewise, it can be seen that from the designated position **291** of the virtual cathode pole, which is proximate to electrodes **E4**, **E11**, and **E12**, that these electrodes will receive an appropriate share of the specified cathodic current −A (e.g., $20\% \cdot -A$, $20\% \cdot -A$, and $60\% \cdot -A$ respectively, again during the first pulse phase **30a**). These polarities would then be flipped during the second phases **30b** of the pulses, as shown in the waveforms of FIG. **7B**. In any event, the use of virtual poles in the formation of bipole **301b** allows the field in the tissue to be shaped, and many different combinations of electrodes can be tried during the sweet spot search. In this regard, it is not strictly necessary that the (virtual) bipole be moved along an orderly path **296** with respect to the electrodes, and the path may be randomized, perhaps as guided by feedback from the patient.

[0061] FIG. **7C** shows a useful virtual bipole **301c** configuration that can be used during the sweet spot search. This virtual bipole **301c** again defines a target anode and cathode whose positions do not correspond to the position of the physical electrodes. The virtual bipole **301c** is formed along a lead—essentially spanning the length of four electrodes from **E1** to **E5**. This creates a larger field in the tissue better able to recruit the patient's pain site **298**. Note that in this bipole more than one electrode is active to form the anode (e.g., **E1** and **E2**), and more than one anode is active to form the cathode (e.g., **E4** and **E5**). With reference to the center of the bipole (e.g., **E3**), notice that anode electrodes farther from the center carry a larger percentage of the anodic current (e.g., with **E1/E2** carrying 67%/33% respectively), and that that cathode electrodes farther from the center carry a larger percentage of the cathodic current (e.g., with **E5/E4** carrying 67%/33% respectively). This could be varied: for example, **E1** may carry $33\% \cdot +A$, **E2** $67\% \cdot +A$, **E4** $33\% \cdot -A$, and **E5** $67\% \cdot -A$.

This bipole configuration **301c** may need to be moved to a smaller number of locations than would a smaller bipole configuration compared **301a** of FIG. 7A) as it moves along path **296**, thus accelerating pain site **298** detection. FIG. 7D expands upon the bipole configuration of FIG. 7C to create a virtual bipole **301d** using electrodes formed on both leads, e.g., from electrodes **E1** to **E5** and from electrodes **E9** to **E13**. Again, the fractionalization of the current can be varied, as shown using the arrows in FIG. 7D, where the amount of currents is flipped at **E1** and **E2**, and at **E9** and **E10**. This bipole **301d** configuration need only be moved along a single linear path **296** along the electrode array that is parallel to the leads, as its field is large enough to recruit neural tissue proximate to both leads. This can further accelerate pain site detection.

[0062] In some aspects, the supra-perception bipoles **301a-301d** used during the sweet spot search comprise symmetric biphasic waveforms having actively-driven (e.g., by the stimulation circuitry **28** or **44**) pulse phases **30a** and **30b** of the same pulse width PW and the same amplitude (with the polarity flipped during the phases) (e.g., $A_{sub.30a}=A_{sub.30b}$, and $PW_{sub.30a}=PW_{sub.30b}$). This is beneficial because the second pulse phase **30b** provides active charge recovery, with in this case the charge provided during the first pulse phase **30a** ($Q_{sub.30a}$) equaling the charge of the second pulse phase **30b** ($Q_{sub.30b}$), such that the pulses are charge balanced. Use of biphasic waveforms are also believed beneficial because, as is known, the cathode is largely involved in neural tissue recruitment. When a biphasic pulse is used, the positions of the (virtual) anode and cathode will flip during the pulse's two phases. This effectively doubles the neural tissue that is recruited for stimulation, and thus increases the possibility that the pain site **298** will be covered by a bipole at the correct location. In effect, the symmetric biphasic pulse provides two center points of stimulation to the tissue.

[0063] The supra-perception bipoles **301a-301d** do not, however, need to comprise symmetric biphasic pulses as just described. For example, the amplitude and pulse width of the two phases **30a** and **30b** can be different, while keeping the charge (Q) of the two phases balanced (e.g., $Q_{sub.30a}=A_{sub.30a}*PW_{sub.30a}=A_{sub.30b}*PW_{sub.30b}=Q_{sub.30b}$). Alternatively, the two phases **30a** and **30b** may be charge imbalanced (e.g., $Q_{sub.30a}=A_{sub.30a}*PW_{sub.30a}>A_{sub.30b}*PW_{sub.30b}=Q_{sub.30b}$, or $Q_{sub.30a}=A_{sub.30a}*PW_{sub.30a}<A_{sub.30b}*PW_{sub.30b}=Q_{sub.30b}$). In short, the pulses in bipoles **301-301d** can be biphasic symmetric (and thus inherently charge balanced), biphasic asymmetric but still charge balanced, or biphasic asymmetric and charge imbalanced.

[0064] In a preferred example, the frequency F of the supra-perception pulses **301a-301d** used during the supra-perception sweet spot search may be 10 kHz or less, 1 kHz or less, 500 Hz or less, 300 Hz or less, 200 Hz or less, 130 Hz or less, or 100 Hz or less, or ranges bounded by two of these frequencies (e.g., 100-130 Hz, or 100-200 Hz). In particular examples, frequencies of 90 Hz, 40 Hz, or 10 Hz can be used, with pulses comprising biphasic pulses which are preferably symmetric. However, a single actively-driven pulse phase followed by a passive recovery phase could also be used. The pulse width PW may also comprise a value in the range of hundreds of microseconds, such as 150 to 400 microseconds. Because the goal of supra-perception sweet spot searching is merely to determine electrodes that appropriately cover a patient's pain, frequency and pulse width may be of less importance at this stage, or the frequency and pulse width used during the sweet spot searching can also be used for the eventual sub-perception. Once electrodes have been chosen for sub-perception stimulation, frequency and pulse width can be optimized, as discussed further below.

[0065] It is preferable that the same electrodes selected to position the supra-perception bipole **301a-d** at an optimal location during the sweet spot are also selected during the sub-perception therapy that follows, although this isn't necessarily required. Instead, the best location of the bipole noticed during the search can be used as the basis to modify the selected electrodes. Suppose for example that a bipole **301a** (FIG. 7A) is used during sweep spot searching, and it is determined that bipole provides the best pain relief when located at electrodes **E13** and **E14**. At that point, sub-

perception therapy using those electrodes E13 and E14 can be tried for the patient going forward. Alternatively, it may be sensible to modify the selected electrodes to see if the patient's symptoms can be further improved before sub-perception therapy is tried. For example, the distance (focus) between the cathode and anode can be varied, using virtual poles as already described. Or, a tripole (anode/cathode/anode) consisting of electrodes E12/E13/E14 or E13/E14/E15 could be tried, see U.S. Pat. No. 10,881,859 (discussing tripoles), and still other multipole configurations could be used as well. Or electrodes on a different lead could also be tried in combination with E13 and E14. For example, because electrodes E5 and E6 are generally proximate to electrodes E13 and E14, it may be useful to add E5 or E6 as sources of anodic or cathodic current (again creating virtual poles). All of these types of adjustments should be understood as comprising "steering" or an adjustment to the "location" at which therapy is applied, even if a central point of stimulation doesn't change (as can occur for example when the distance or focus between the cathode and anode is varied).

[0066] Multiple Independent Current Control (MICC) is explained in one example with reference to FIG. 8, which shows the stimulation circuitry 28 (FIG. 1) or 44 (FIG. 3) in the IPG or ETS used to form prescribed stimulation at a patient's tissue. The stimulation circuitry 28 or 44 can control the current or charge at each electrode independently, and using GUI 64 (FIG. 5) allows the current or charge to be steered to different electrodes, which is useful for example when moving the bipole 301i along path 296 during the sweet spot search (FIG. 7A-7D). The stimulation circuitry 28 or 44 includes one or more current sources 440; and one or more current sinks 442.sub.i. The sources and sinks 440.sub.i and 442.sub.i can comprise Digital-to-Analog converters (DACs), and may be referred to as PDACs 440.sub.i and NDACs 442.sub.i in accordance with the Positive (sourced, anodic) and Negative (sunk, cathodic) currents they respectively issue. In the example shown, a NDAC/PDAC 440.sub.i/442.sub.i pair is dedicated (hardwired) to a particular electrode node ei 39. Each electrode node ei 39 is preferably connected to an electrode Ei 16 via a DC-blocking capacitor Ci 38, which act as a safety measure to prevent DC current injection into the patient, as could occur for example if there is a circuit fault in the stimulation circuitry 28 or 44. PDACs 440.sub.i and NDACs 442.sub.i can also comprise voltage sources.

[0067] Proper control of the PDACs 440.sub.i and NDACs 442.sub.i via GUI 64 allows any of the electrodes 16 and the case electrode Ec 12 to act as anodes or cathodes to create a current through a patient's tissue. Such control preferably comes in the form of digital signals lip and lin that set the anodic and cathodic current at each electrode Ei. If for example it is desired to set electrode E1 as an anode with a current of +3 mA, and to set electrodes E2 and E3 as cathodes with a current of -1.5 mA each, control signal I1p would be set to the digital equivalent of 3 mA to cause PDAC 440.sub.1 to produce +3 mA, and control signals I2n and I3n would be set to the digital equivalent of 1.5 mA to cause NDACs 442.sub.2 and 442.sub.3 to each produce -1.5 mA. Note that definition of these control signals can also occur using the programmed amplitude A and percentage X % set in the GUI 64. For example, A may be set to 3 mA, with E1 designated as an anode with X=100%, and with E2 and E3 designated at cathodes with X=50%. Alternatively, the control signals may not be set with a percentage, and instead the GUI 64 can simply prescribe the current that will appear at each electrode at any point in time.

[0068] In short, the GUI 64 may be used to independently set the current at each electrode, or to steer the current between different electrodes. This is particularly useful in forming virtual bipoles, which as explained earlier involve activation of more than two electrodes. MICC also allows more sophisticated electric fields to be formed in the patient's tissue.

[0069] Other stimulation circuitries 28 can also be used to implement MICC. In an example not shown, a switching matrix can intervene between the one or more PDACs 440.sub.i and the electrode nodes ei 39, and between the one or more NDACs 442.sub.i and the electrode nodes. Switching matrices allows one or more of the PDACs or one or more of the NDACs to be connected to one or more electrode nodes at a given time. Various examples of stimulation

circuitries can be found in U.S. Pat. Nos. 6,181,969, 8,606,362, 8,620,436, U.S. Patent Application Publication 2018/0071513, 2018/0071520, and U.S. Provisional Patent Application Ser. No. 62/559,247, filed Sep. 15, 2017.

[0070] Much of the stimulation circuitry **28** or **44**, including the PDACs **440.sub.i** and NDACs **442.sub.i**, the switch matrices (if present), and the electrode nodes **ei 39** can be integrated on one or more Application Specific Integrated Circuits (ASICs), as described in U.S. Patent Application Publications 2012/0095529, 2012/0092031, and 2012/0095519. As explained in these references, ASIC(s) may also contain other circuitry useful in the IPG **10**, such as telemetry circuitry (for interfacing off chip with the IPG's or ETS's telemetry antennas), circuitry for generating the compliance voltage **VH** that powers the stimulation circuitry, various measurement circuits, etc.

[0071] While it is preferred to use sweet spot searching, and in particular supra-perception sweet spot searching, to determine the electrodes to be used during subsequent sub-perception therapy, it should be noted that this is not strictly necessary. Sub-perception therapy can be preceded by sub-perception sweet spot searching, or may not be preceded by sweet spot searching at all. In short, sub-perception therapy may not be reliant on the use of any sweet spot search.

[0072] FIG. **9** discloses a sub-perception algorithm **350** that details steps that can be used to provide fast-acting sub-perception stimulation therapy for a patient. Some of the steps in algorithm **350** are automated in the clinician programmer (CP) **50** described earlier, although aspects of the algorithm can also be implemented in or affect the patient's external remote controller (RC) **45** (FIG. **4**). FIG. **10** shows aspects of the GUI's of the CP **50** and RC **45** as implicated by the algorithm **350**. Note that sub-perception algorithm **350** does not need to occur in the exact order shown. Further, steps can be removed from or added to the algorithm as depicted.

[0073] Steps **360-364** show steps implicated during the sweet spot search described above. In step **360**, the CP **50**'s GUI **64** is used to provide a stimulation field to the patient. Preferably, and as discussed earlier (FIGS. **7A-7D**), the stimulation field comprises supra-perception stimulation formed as bipole **301** (e.g., any of bipoles **301a-301d** described earlier) in the electrode array, which can comprise leads **15** or **15'** depending whether the implant the patient has received in an IPG **10** or ETS **40**. Because the bipole **301** is supra-perception, note that the amplitude **A** for the bipole **301** at step **360** may be adjusted in the CP **50** to ensure that the stimulation can be comfortably felt by the patient as paresthesia. While use of a bipole **360** is preferred to provide the stimulation field, other pole configurations could be used as well. For example, a tripole could be used comprising two poles of a given polarity (e.g., anode poles) surrounding a third pole of the opposite polarity (a cathode pole). Still other multipole configurations could be used as well. For simplicity, the following example assume the use of a bipole for the pole configuration. Furthermore, while it is preferred that the stimulation field comprise supra-perception stimulation, this is not strictly required, and sub-perception stimulation could be used in other examples. Again, the following example assumes the use of supra-perception stimulation for simplicity.

[0074] Step **360** can be initiated using mode menu **90** in the GUI **64**, as shown in FIG. **10**, which essentially allows steps in the sub-perception algorithm **350** to run. As shown in FIG. **10**, the relevant mode is called FAST™, because it allows sub-perception stimulation to be established quickly for the patient. An indicator **91** can be provided in the GUI **64** to make clear to the clinician that this mode has been selected. Certain default stimulation parameters for the bipole **301** can be used which have been noticed to be effective, as shown in step **362**, and these default parameters can either be manually entered in the GUI **64** or automatically populated upon selection of the FAST mode. For example, the stimulation field (e.g., supra-perception bipole **301**) can be formed using actively-driven symmetric biphasic waveforms. As discussed earlier, symmetric biphasic waveforms are beneficial because they promote active charge recovery at the relevant electrodes, and because the flipping of the polarity at those electrodes (from phase **30a** to **30b**) effectively doubles the neural tissue that is recruited for stimulation to increases the possibility that the pain site **298** will be covered by the bipole when it is set at the correct location. However, active charge

recovery, while preferred, is not strictly required, and the stimulation field can be provided using other types of waveforms.

[0075] Step **362** also sets other default parameters for the supra-perception bipole **301**, such as its pulse width $PW=210$ microseconds (of pulse phase **30a**), the frequency of the pulses $F=90$ Hz. Generally speaking, the frequency may be 130 Hz or less, and the pulse width may range from 160 to 260 microseconds. A default focus (distance) between the poles (e.g., 12 mm) may also be set, as shown at GUI element **85**. Still further, a default resolution (e.g., fine) may also be used, as also shown at GUI element **85**. A fine resolution allows the bipole to be moved in the electrode array at fine increments (e.g., 0.1 mm), which is useful in subsequent steps. Although not shown, the position of the bipole **301** in the electrode array can also be set as a default starting point, or a present or previously-determined location of the bipole can be used as well. While these parameters may be used as defaults, they may also be made adjustable in the CP, as shown in FIG. **10**.

[0076] At step **364**, and using the CP **50**, the stimulation field (e.g., supra-perception bipole **301**) is moved in the electrode array to a location that best covers the patient's symptoms, such as pain. In this step **364**, the optimal goal is to have the patient feel only the paresthesia of the stimulation field (assuming it is supra-perception) and little or no pain. As discussed above, the use of supra-perception stimulation enables the patient to provide essentially immediate feedback to the clinician regarding pain coverage. Pain coverage at step **364** may be assessed using patient pain scores as described earlier or other rating scales. If the stimulation field provides sub-perception stimulation, the goal is to have the patient feel little or no pain. As described earlier, the position of the bipole **301** can be moved in the electrode array in small increments (preferably with a fine resolution), and may be established as virtual poles as it is moved along a path **296**. Although not shown in FIG. **10** for simplicity, directional arrows **99** (FIG. **5**) or other peripheral devices connected to the CP **50**, can be used to move the bipole **301**.

[0077] When moving the stimulation field (e.g., supra-perception bipole **301**) to new locations during step **364**, it may be beneficial to wait for a wash out period before stimulation is provided at a new location. A “wash out” period comprises a period of time after the cessation of stimulation therapy during which the benefits of stimulation therapy (e.g., pain reduction) are still present. Typically, when a supra-perception bipole **301** is used, such wash out may be a number of minutes, and therefore it may be preferred to wait this duration of time after providing stimulation at a first location before providing stimulation at a next location. This is preferred to ensure that previous stimulation does not affect results when assessing coverage and effectiveness at a new location. Note that a wash out period may need to be longer if the preceding stimulation had been established for a longer period of time. Sub-perception stimulation if used for bipole **301** may also require waiting for longer wash out periods as well.

[0078] Furthermore, it may be necessary to adjust the supra-perception amplitude of the stimulation field each time it is moved, so that the patient generally feels a constant level of paresthesia (e.g., a low-to-medium sense of paresthesia). In this regard, note that different electrodes in the array may be closer to or farther from the spinal cord. Thus, as the stimulation field is moved to new electrodes, the stimulation may be more strongly felt or less strongly felt by the patient, meaning that the amplitude should be adjusted down or up to compensate and to achieve a generally uniform intensity of paresthesia at all tested locations. Failing to normalize the intensity of perceived paresthesia may confuse the patient's ability to assess pain coverage (e.g., by assuming very intense stimulation well covers pain when in fact it does not).

[0079] It may also be useful to test each location—and in particular the last “best” location—at a very low level of paresthesia to ensure or double check pain coverage. If pain overlap is not 100%, other stimulation parameters of the stimulation field such as focus and pulse width can be adjusted to see if even better coverage can be achieved.

[0080] It may be useful once the best location is found to test other locations very close to this location to see if the best location can be finely tuned. For example, if a number of very close

locations are tested, all showing the good (or best) results, the best location may be determined to be at the center of those locations. This is preferred to ensure that therapy will still be effective to treat the patient's symptoms even if the electrodes move or migrate slightly in the patient's spinal column.

[0081] It may also be useful to have the patient use the resulting simulation field at the best location for a short period of time to verify effectiveness of therapy. Effectiveness can be determined using patient feedback, which again can occur by having the patient score or rank their symptoms. Although not shown, the clinician may have the patient engage in certain activities (e.g., walking), or to position themselves in different postures (e.g., sitting, standing, etc.) to ensure that therapy is effective at the best location. In a sense, the clinician may have the patient give the stimulation field a “test drive” at step **364** before proceeding to next steps.

[0082] At step **366**, a perception threshold pth is determined for the stimulation field (e.g., bipole **301**) provided at the location determined in step **364**. Perception threshold pth can be expressed using a stimulation parameter such as amplitude A, and generally denotes a threshold between sub-perception stimulation and supra-perception stimulation. As such, pth can comprise a maximum amplitude at which the patient cannot feel the stimulation, and/or as a minimum amplitude at which the patient can still feel the stimulation. Determining pth can be assisted using the GUI **64** of the CP **50** as shown in FIG. **10**, and in particular can be determined by adjusting the amplitude A of the bipole **301** up or down in waveform parameter interface **84**. For example, the amplitude A can be gradually increased the amplitude A to a point where the patient reports feeling the stimulation (paresthesia), or the amplitude can be gradually decreased to a point where the patient reports no longer feels the stimulation. Once determined, the perception threshold pth can be marked or otherwise entered into the GUI **64** of the CP. This can occur in different ways, but in the example of FIG. **10**, the determined pth can be typed into a field in a perception threshold interface **96**. The perception threshold pth can also be stored in the CP **50**, although it may also be useful to do this later after verifying that sub-perception stimulation works well for the patient, as discussed in next steps **368** and **370**. In the example of FIG. **10**, it is assumed that $pth=5\text{ mA}$.

[0083] At step **368**, the stimulation field (e.g., bipole **301**) at the location is adjusted to a sub-perception level by adjusting the amplitude to a fraction of pth. This can involve the clinician adjusting the amplitude to a value below pth, for example using waveform parameter interface **84**. Alternatively, the GUI **64** may include a selectable option to apply a default fraction to pth, such as 50%, as shown in perception threshold interface **96**. Still alternatively, once pth has been entered and stored, a different means for adjusting the amplitude may be provided in the GUI **64**. For example, and as shown in FIG. **10**, the waveform parameters interface **84** can include an adjustment mechanism such as a slider **98** to allow the amplitude to be adjusted to sub-perception levels between 0 mA (or some other minimum value) and $100\%*pth$. Regardless of how this occurs, application of the 50% fraction sets the amplitude to 2.5 mA (e.g., $50\%*5\text{ mA}$), and the IPG is programmed accordingly.

[0084] At step **370**, the effectiveness of providing sub-perception stimulation with the bipole **301** at the location is verified. As discussed above, having initially used a fast-acting supra-perception bipole **301** during sweet spot searching to determine an optimal stimulation location (**364**), it is expected that the sub-perception stimulation provided at step **368** will wash in quickly.

Effectiveness can be determined at step **370** using patient feedback, which again can occur by having the patient score or rank their symptoms. Although not shown, the clinician at step **370** may have the patient engage in certain activities (e.g., walking), or to position themselves in different postures (e.g., sitting, standing, etc.) to ensure that the sub-perception therapy is effective in reducing symptoms under a variety of conditions. If the efficacy of the sub-perception stimulation is not optimal at step **370**, the sub-perception algorithm **350** can return to earlier steps to try to improve the situation. For example, as shown in FIG. **9**, the algorithm **350** can return to step **364** to repeat the supra-perception sweet spot search in the hopes of finding a better location for the bipole

in the electrode array **301** that better covers the patient's symptoms.

[0085] Once suitable sub-perception therapy has been verified (step **370**), the now-vetted perception threshold pth can be stored in the CP **50** (step **372**) as a maximum amplitude, as shown in perception threshold interface **96**. This may have also occurred earlier in the process, such as at step **366** when the perception threshold was first entered in the GUI **64**. Although not shown, note that pth may be stored with information regarding the location of the bipole, as defined by the active electrodes, their polarities, and their currents, as described above. This is beneficial because pth may change depending on where in the electrode array the bipole **301** is positioned, and in this regard, the CP **50** may store numerous pth values each associated with different bipole positions. Note that pth may also be stored with the stimulation program (Program **1**) used to form the bipole **301**, and as such may be stored with all relevant stimulation parameters (such as A, F, PW, etc.).

[0086] Once pth has been verified as effective and stored in the CP **50**, the algorithm **350** can undertake steps to allow the patient to control the sub-perception therapy, which can be affected by programming the patient RC **45** at step **374**. Programming the patient's RC **45** can occur in different ways, but in FIG. **10**, a selectable option is provided in the perception threshold interface **96**. This input may also allow the clinician to set a default fraction of pth as the amplitude for the patient (step **376**). This default fraction may be different from the fraction of pth that was used earlier to verify the efficacy of sub-perception stimulation (at steps **368**, **370**). For example, in the depicted example, the default fraction is set to $30\% \cdot \text{pth}$, although this may also be adjustable by the clinician using the GUI **64**. Setting the default fraction to be relatively low may be preferable, because it will allow the patient RC **45** to both increase and decrease the amplitude throughout a sub-perception range of amplitudes, as explained subsequently.

[0087] Upon selection of the programming option, the CP **50** can transmit the pth, the default fraction (30%), as well as other stimulation parameters to the patient's RC **45**. Preferably the stimulation parameters include those necessary to form the bipole at the determined location (**364**), and so such stimulation parameters will include an indication of which electrodes are active, and with what polarities and relative strengths, as discussed above. The stimulation parameters will also include information necessary to form the stimulation as symmetric biphasic waveforms with the proper frequency (F) and pulse width (PW), which may be those used earlier as defaults (**362**). In effect, the CP **50** transmits a stimulation program to the RC **45**, including pth variables that will be used to limit the amplitude to sub-perception levels at the RC **45**, as explained next.

[0088] At step **378**, the now-programmed RC **45** can be used by the patient to control the IPG to produce the stimulation program defining the symmetric biphasic bipole. In one example, the patient may only be able to adjust the amplitude of the stimulation, as explained further below. However, in other examples, other stimulation parameters, such as pulse width (PW) and frequency (F) may be adjustable by the patient using the RC **45**, although perhaps only slight adjustments from default values may be allowed. Experience teaches that an effective amplitude for typical activities will be about 40% to 60% of pth. Because sub-perception therapy achieved using algorithm **350** has been noted to have a possible curative effect, it is possible that a patient may be able to gradually reduce the amplitude of the sub-perception stimulation over time. Also, if a patient experiences side effects such as headache, cramps, pressure, heavy limbs, or general discomfort, the patient should be advised to decrease the sub-perception amplitude even if pain symptoms are under control. On the other hand, if a patient starts to experiencing pain symptoms, the patient should be advised to increase the sub-perception amplitude to bring their pain symptoms back under control.

[0089] Although not shown, the patient may also provide sub-perception therapy at step **378** in boluses—e.g., by providing sub-perception stimulation at $80\% \cdot \text{pth}$ for 30-60 minutes every 2-4 hours. Preferably, a patient would not exceed use of six bolus of stimulation in a 24 hours period. Providing boluses of stimulation is described further in PCT (Int'l) Patent Application Serial No. PCT/US2021/016867, filed Feb. 21, 2021, which is incorporated herein by reference in its entirety.

[0090] FIG. **10** shows the graphical user interface of the RC **45** once it has been programmed as just described. Significantly, the previously-determined perception threshold pth preferably comprises a maximum amplitude that the patient can select ($100\% \cdot \text{pth}$), and so limits control to only sub-perception amplitudes. In FIG. **10**, the default fraction of 30% has been applied, and thus an amplitude of $30\% \cdot \text{pth}$ (e.g., 1.5 mA) is being produced, although the patient can increase or decrease this amplitude using the GUI of the RC **45**. In this regard, the patient RC **45** may include user interface elements similar to those described earlier for the CP **50**. For example, the GUI include a slider **98** which limits the amplitude A to from 0 mA (or some minimum value) to $100\% \cdot \text{pth}$. In one example, the RC **45** may not display an actual current amplitude (in mA), as this value may be too technical and not understandable to the patient. Instead, the RC **45** may only display a relative sub-perception amplitude from 0 to 100%, which may be more intuitive for the patient. Still other amplitude indicators (e.g., a number of bars, or various other numbers) can be used to indicate sub-perception amplitude as well.

[0091] In the embodiment illustrated in FIGS. **9** and **10**, the patient's RC **45** is programmed with the determined pth and a default stimulation amplitude that is a fraction of the determined pth (e.g., 30% pth). The patient may use their RC to adjust the amplitude of their stimulation up to any amplitude not exceeding pth. The inventors have recognized that it can be beneficial to program the patient's RC with one or more predetermined stimulation programs having predetermined stimulation amplitudes. According to some embodiments, the clinician may use the CP **50** to configure one or more stimulation programs wherein the stimulation amplitude is fixed or varies with time in a predetermined way. Such stimulation programs can then be provided to the patient's RC **45**. For example, the patient's RC may be programmed to run one or more stimulation programs, whereby stimulation is provided at one stimulation amplitude for a first duration and another stimulation amplitude for a second duration.

[0092] FIG. **11** illustrates a program list **1102**, that may be included within the GUI **64** of the CP **50**. The program list may be used to store one or more stimulation programs, which will be used to program to the patient's RC. Each of the stimulation programs may define stimulation parameters, such as pulse width, frequency, and amplitude. The stimulation amplitude(s) may be based on percentages of the pth for the patient, which may be determined as described above. In the illustrated embodiment, assume that the determined pth is 5.0 mA. In the illustration Program A uses an amplitude that is 30% (i.e., 1.5 mA) of the determined pth and Program B uses an amplitude that is 70% (i.e., 3.5 mA) of the determined pth. The various programming controls, such as those included in the programming interface **72**, the waveform parameter interface **84**, and the perception threshold interface **96** described above with respect to FIG. **10** may be used to configure the stimulation programs. Once the stimulation programs are configured, they may be transmitted to the patient's RC **45**.

[0093] The inventors have recognized that some clinical indications respond well to stimulation protocols that comprise a first duration having a first stimulation amplitude and a second duration having a second stimulation amplitude. According to some embodiments, both the first and second stimulation amplitudes are below the patient's pth. According to some embodiments, the first stimulation amplitude is lower than the second one. For example, the first stimulation amplitude may be about 20%-30% of the patient's pth and the second stimulation amplitude may be about 60%-70% of pth. According to some embodiments, the first stimulation duration is longer than the second stimulation duration. For example, the first stimulation duration may be on the order of hours and the second stimulation duration may be on the order of minutes. Such a stimulation protocol may be viewed as a duration of relatively low amplitude stimulation interleaved with "boluses" of higher amplitude stimulation.

[0094] According to some embodiments, one or more programs may be configured for execution according to a predetermined schedule, for example, to provide a stimulation protocol having two or more interleaved amplitude durations. FIG. **12** illustrates a schedule interface **1202**, which may

be included within the GUI **64** of the CP **50**. The schedule interface allows the user to schedule given stimulation programs for a given duration. The schedule interface may comprise drop down menus or other GUI elements to select the desired programs and durations. For example, in the illustrated schedule interface **1202**, Program A (i.e., the “FAST 30” program of FIG. **11**) is scheduled to run for 4 hours and Program B (i.e., the “FAST 70” program of FIG. **11**) is scheduled to run for 10 minutes. The schedule of programs can be provided to the patient's RC **45** for execution. The patient's RC can be configured to run the schedule, cycling between the programs A and B according to the prescribed durations. As a result, the patient will receive four hours of stimulation at 30% pth, interleaved with ten minute boluses of stimulation at 70% pth.

[0095] It will be appreciated that the programming and scheduling capabilities of the disclosed CP **50** may be used to configure multiple schedules. For example, a first schedule may be configured for daytime use and a second schedule may be configured for nighttime/rest use. For example, the daytime schedule may interleave stimulation programs of higher stimulation intensity and the nighttime/rest schedule may interleave stimulation programs of lower intensity. For example, the daytime schedule may cycle between 30% and 70% pth and the nighttime/rest schedule may cycle between 20% and 60% pth. According to some embodiments, the patient may be able to cycle between schedules using their RC. According to some embodiments, the patient may be able to use their RC to adjust parameters of the various stimulation programs. According to other embodiments, the patient may be “locked out,” that is, they may not be able to adjust stimulation parameters of the various programs. It should be noted that the example programs described here differ from each other with respect to the stimulation amplitude. But it will be appreciated that the various stimulation programs may differ from each other with respect to other stimulation parameters, such as pulse width, frequency, and the like.

[0096] According to some embodiments, the CP **50** may feature one or more algorithms and/or scripts configured to automate aspects of composing the programs and/or schedules of programs described above. FIG. **13** illustrates an example of a workflow **1300** for using such an algorithm and/or script. The illustrated workflow **1300** begins at step **1372**, which is analogous to step **372** of the sub-perception stimulation algorithm **350** (FIG. **9**) and comprises storing a determined pth in the GUI of the CP **50**. Thus, the workflow **1300** assumes that the clinician has performed the earlier steps of the sub-perception stimulation algorithm **350** (FIG. **9**) to determine the sweet spot and the pth. Step **1304** involves selecting an appropriate algorithm/script to compose the programs and/or schedules of programs that will be used to program the patient's RC. FIG. **14** illustrates an embodiment of a program list **1102** that may be included as an element of the GUI **64** of the CP **50**. Aspects of the program list **1102** were discussed above. The embodiment of the program list **1102** illustrated in FIG. **14** includes an automation GUI element **1402** (a drop-down menu, in the illustrated embodiment) whereby the user can select and launch the automation aspects described here.

[0097] The embodiment of the automation GUI element **1402** provides a menu **1404** of automation algorithms/scripts that may be selected. In the illustrated embodiment, the various algorithms/scripts may be selected based on the patient's particular indication(s). The programs and schedules appropriate for treating various patient indications may differ from each other. For example, a patient suffering from diabetic peripheral neuropathy (DPN) may be more sensitive to stimulation than a patient suffering from failed back surgery syndrome (FBSS). Thus, a suitable schedule for treating DPN may comprise interleaving programs with amplitudes of 20% and 60% pth, whereas a schedule for treating FBSS may interleave programs with amplitudes of 30% and 70% pth. Likewise, programs may differ from each other depending on whether they are intended for use while the patient is sleeping, active, resting, etc.

[0098] Referring again to FIG. **13**, aspects of the algorithm/scripts are shown in box **1306**. To execute an algorithm/script, the control circuitry receives a command to automate the composition of the programs and/or schedules. The command may be responsive to the user selecting the

appropriate algorithm/script using the automation GUI element **1402**. As described above, the appropriate algorithm/script may be selected based on the patient indication. The algorithm/script may be configured to provide the appropriate number of programs. In the illustrated embodiment, each program will provide stimulation having an amplitude that is a prescribed percentage of pth. Thus, the script receives the determined pth (determined as described above) and calculates the appropriate amplitudes based on the prescribed percentages of pth. The script may then populate the program list **1102** with the appropriate programs. The script also may populate the schedule interface **1202** (FIG. **12**) with the appropriate programs and durations.

[0099] At step **1308** of the workflow **1300**, the programs/schedule(s) may be used to program the patient's RC. Scripts/algorithms, such as used in the workflow **1300**, save the user from having to manually configure the programs and schedules that are needed to treat a given patient indication. This saves time and also increases reliability and consistency of the programming.

[0100] Various aspects of the disclosed techniques, including processes implementable in the IPG or ETS, or in external devices such as the clinician programmer or patient external controller to render and operate the GUI, can be formulated and stored as instructions in a computer-readable media associated with such devices, such as in a magnetic, optical, or solid state memory. The computer-readable media with such stored instructions may also comprise a device readable by the clinician programmer or external controller, such as in a memory stick or a removable disk, and may reside elsewhere. For example, the computer-readable media may be associated with a server or any other computer device, thus allowing instructions to be downloaded to the clinician programmer system or external controller or to the IPG or ETS, via the Internet for example.

[0101] Although particular embodiments of the present invention have been shown and described, it should be understood that the above discussion is not intended to limit the present invention to these embodiments. It will be obvious to those skilled in the art that various changes and modifications may be made without departing from the spirit and scope of the present invention. Thus, the present invention is intended to cover alternatives, modifications, and equivalents that may fall within the spirit and scope of the present invention as defined by the claims.

Claims

1. A method for programming a spinal cord stimulator for providing spinal cord stimulation (SCS) for a patient, the spinal cord stimulator having a plurality of electrodes comprising an array, the method comprising: (a) using a first external device to provide a supra-perception stimulation field to the spinal cord stimulator, wherein the supra-perception stimulation field comprises a pole configuration formed in the electrode array; (b) using the first external device to provide stimulation to the patient while move the pole configuration in the electrode array to a location that best treats a symptom of the patient; (c) determining, using the first external device, a perception threshold (pth) of the pole configuration at the location by varying an amplitude of the supra-perception stimulation field; (d) using the pth to determine at least a first sub-perception stimulation program having an amplitude that is a first fraction of the pth and a second sub-perception stimulation program having an amplitude that is a second fraction of pth, wherein the second fraction of pth is greater than the first fraction of the pth; and (e) using the first external device to program a second external device usable by the patient with the determined first and second sub-perception stimulation programs.

2. The method of claim 1, wherein the first fraction is about 10% to about 50% of the pth and the second fraction is about 50% to about 80% of the pth.

3. The method of claim 1, further comprising: using the first external device to compose a schedule comprising a first duration during which the first sub-perception stimulation program is active to provide stimulation to the patient and a second duration during which the second sub-perception stimulation program is active to provide stimulation to the patient; and using the first external

device to program the second external device with the schedule.

4. The method of claim 3, wherein the first duration is about 2 to about 6 hours and the second duration is about 1 to about 20 minutes.

5. The method of claim 3, wherein determining the first and second sub-perception stimulation programs and composing the schedule comprises executing a script, wherein the script: receives an indication of the pth; uses the pth to automatically determine the first and second fractions; and automatically composes the schedule.

6. The method of claim 5, wherein the script is a patient indication-specific script and wherein the method further comprises: receiving an input indicative of a patient indication; selecting the patient indication-specific script corresponding to the received input, and executing the selected patient indication-specific script to provide determine first and second fractions and compose a schedule that is specific for the patient indication.

7. The method of claim 1, wherein the pole configuration comprises a bipole comprising an anode pole and a cathode pole.

8. The method of claim 7, wherein when the bipole is at the location, the anode pole is formed at two or more electrodes, and wherein the cathode pole is formed at two or more different of the electrodes.

9. The method of claim 7, wherein the bipole comprises an anode pole and a cathode pole, wherein more than one electrode is active to form the anode pole, and wherein more than one electrode is active to form the cathode pole.

10. The method of claim 1, wherein the first external device is used to move the pole configuration linearly along a length of the electrode array.

11. A system configured to program a spinal cord stimulator for providing spinal cord stimulation (SCS) for a patient, the spinal cord stimulator having a plurality of electrodes comprising an array, the system comprising: a first external device comprising control circuitry configured to render a user interface, wherein the user interface enables a user to: (a) provide a supra-perception stimulation field to the spinal cord stimulator, wherein the supra-perception stimulation field comprises a pole configuration formed in the electrode array; (b) move the pole configuration in the electrode array to a location that best treats a symptom of the patient; (c) determine a perception threshold (pth) of the pole configuration at the location by varying an amplitude of the supra-perception stimulation field; (d) use the pth to determine at least a first sub-perception stimulation program having an amplitude that is a first fraction of the pth and a second sub-perception stimulation program having an amplitude that is a second fraction of pth, wherein the second fraction of pth is greater than the first fraction of the pth; and (e) use the first external device to program a second external device usable by the patient with the determined first and second sub-perception stimulation programs.

12. The system of claim 11, wherein the first fraction is about 10% to about 50% of the pth and the second fraction is about 50% to about 80% of the pth.

13. The system of claim 11, wherein the control circuitry is further configured to: compose a schedule comprising a first duration during which the first sub-perception stimulation program is active to provide stimulation to the patient and a second duration during which the second sub-perception stimulation program is active to provide stimulation to the patient; and program the second external device with the schedule.

14. The system of claim 13, wherein the first duration is about 2 to about 6 hours and the second duration is about 1 to about 10 minutes.

15. The system of claim 13, wherein determining the first and second sub-perception stimulation programs and composing the schedule comprises executing a script, wherein the script: receives an indication of the pth; uses the pth to automatically determine the first and second fractions; and automatically composes the schedule.

16. The system of claim 15, wherein the script is a patient indication-specific script and wherein the

method further comprises: receiving an input indicative of a patient indication; selecting the patient indication-specific script corresponding to the received input; executing the selected patient indication-specific script.

17. The system of claim 16, wherein the user interface enables a user to select the patient indication.

18. The system of claim 17, wherein the patient indication is selected from the group of indications consisting of failed back surgery syndrome (FBSS), nociceptive pain, and diabetic peripheral neuropathy (DPN).

19. The system of claim 11, wherein the pole configuration comprises a bipole comprising an anode pole and a cathode pole.

20. The system of claim 19, wherein when the bipole is at the location, the anode pole is formed at two or more electrodes, and wherein the cathode pole is formed at two or more different of the electrodes.
