(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 3 145 582 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
21.10.2020 Bulletin 2020/43

(21) Application number: **15795695.4**

(22) Date of filing: **12.05.2015**

(51) Int Cl.:
A61N 1/34 *(2006.01)* ***A61N 1/18*** *(2006.01)*

(86) International application number:
PCT/US2015/030402

(87) International publication number:
WO 2015/179177 (26.11.2015 Gazette 2015/47)

(54) **IMPLANTED PULSE GENERATORS WITH REDUCED POWER CONSUMPTION VIA SIGNAL STRENGTH/DURATION CHARACTERISTICS, AND ASSOCIATED SYSTEMS**

IMPLANTIERTE PULSGENERATOREN MIT REDUZIERTEM LEISTUNGSVERBRAUCH ÜBER SIGNALSTÄRKE-/SIGNALDAUEREIGENSCHAFTEN SOWIE ENTSPRECHENDE SYSTEME

GÉNÉRATEURS D'IMPULSION IMPLANTÉS AYANT UNE CONSOMMATION D'ÉNERGIE RÉDUITE PAR L'INTERMÉDIAIRE DE CARACTÉRISTIQUES DE FORCE/DURÉE DE SIGNAL, ET SYSTÈMES ASSOCIÉS

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **20.05.2014 US 201462000985 P**

(43) Date of publication of application:
29.03.2017 Bulletin 2017/13

(73) Proprietor: **Nevro Corporation**
Menlo Park, CA 94025 (US)

(72) Inventor: **PARKER, Jon**
San Jose, CA 95124 (US)

(74) Representative: **Murgitroyd & Company**
Murgitroyd House
165-169 Scotland Street
Glasgow G5 8PL (GB)

(56) References cited:
EP-A2- 2 243 510
JP-A- 2002 090 196
US-A1- 2009 018 607
US-A1- 2009 204 173
US-A1- 2013 035 740
US-A1- 2013 066 411
US-B2- 8 355 797

EP 3 145 582 B1

Description

TECHNICAL FIELD

[0001] The present technology is directed generally to implanted pulse generators with reduced power consumption, obtained via signal strength/duration characteristics, and associated systems and methods. Particular embodiments use a strength/duration characteristics to improve the delivery of electrical stimulation for patient therapy, as the voltage available from an implanted power source decreases.

BACKGROUND

[0002] Neurological stimulators have been developed to treat pain, movement disorders, functional disorders, spasticity, cancer, cardiac disorders, and various other medical conditions. Implantable neurological stimulation systems generally have an implantable signal generator and one or more leads that deliver electrical pulses to neurological tissue or muscle tissue. For example, several neurological stimulation systems for spinal cord stimulation (SCS) have cylindrical leads that include a lead body with a circular cross-sectional shape and one or more conductive rings (i.e., contacts) spaced apart from each other at the distal end of the lead body. The conductive rings operate as individual electrodes and, in many cases, the SCS leads are implanted percutaneously through a needle inserted into the epidural space, with or without the assistance of a stylet.

[0003] Once implanted, the signal generator applies electrical pulses to the electrodes, which in turn modify the function of the patient's nervous system, such as by altering the patient's responsiveness to sensory stimuli and/or altering the patient's motor-circuit output. In SCS therapy for the treatment of pain, the signal generator applies electrical pulses to the spinal cord via the electrodes. In conventional SCS therapy, electrical pulses are used to generate sensations (known as paresthesia) that mask or otherwise alter the patient's sensation of pain. For example, in many cases, patients report paresthesia as a tingling sensation that is perceived as less uncomfortable than the underlying pain sensation.

[0004] In contrast to traditional or conventional (i.e., paresthesia-based) SCS, a form of paresthesia-free SCS has been developed that uses therapy signal parameters that treat the patient's sensation of pain without generating paresthesia or otherwise using paresthesia to mask the patient's sensation of pain. One of several advantages of paresthesia-free SCS therapy systems is that they eliminate the need for uncomfortable paresthesias, which many patients find objectionable. However, a challenge with paresthesia-free SCS therapy systems is that the signal may be delivered at frequencies, amplitudes, and/or pulse widths that may use more power than conventional SCS systems. This in turn can deplete the battery of the implanted system at an accelerated rate. Accordingly, a follow-on challenge with providing spinal cord stimulation via an implanted pulse generator is that, in at least some cases, it may be difficult to maintain an effective signal as the charge available from the pulse generator battery decreases. One approach to the challenge in the context of conventional systems is to increase the frequency with which the pulse generator is charged, but this can be inconvenient for the patient. Another approach is to add signal conditioning hardware, for example, to boost the voltage provided by the battery as the battery discharges. A drawback with this approach is that it can be inefficient. Accordingly, there remains a need for effective and efficient therapy signal delivery, despite the decreasing voltage available from the battery or other power source of an implanted pulse generator during normal use.

[0005] US-A-2009/018607 discloses methods, devices, and systems for controlling an implantable pulse generator for activation of a nerve or receptor. The method, devices, and systems control the energy output of a battery in an implantable pulse generator for stimulation of the baroreflex system of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006]

Figure 1A is a partially schematic illustration of an implantable spinal cord modulation system positioned at the spine to deliver therapeutic signals in accordance with several embodiments of the present technology.

Figure 1B is a partially schematic, cross-sectional illustration of a patient's spine, illustrating representative locations for implanted lead bodies in accordance with embodiments of the present technology.

Figure 2 is a flow diagram illustrating a process for delivering a therapeutic electrical signal in accordance with a representative embodiment of the present technology.

Figure 3 is a graph illustrating a family of curves representing signal amplitude as a function of pulse width or duty cycle.

Figure 4 is a flow diagram illustrating a process for establishing a pulse width/amplitude correlation in accordance with an embodiment of the present technology.

Figure 5 is a flow diagram illustrating a process for delivering a therapy signal with a reduced available power source voltage in accordance with an embodiment of the present technology.

Figure 6 graphically illustrates a process for updating

signal amplitude and pulse width in accordance with an embodiment of the present technology.

DETAILED DESCRIPTION

[0007] The present technology is directed generally to delivering electrical signals (also referred to herein as "therapy signals") at reduced available voltage levels in implanted patient therapy systems, such as spinal cord stimulation (SCS) systems. For example, in one embodiment, the present technology includes reducing signal amplitude and increasing pulse width or duty cycle to maintain a target energy delivery rate. Because the technology can be employed in SCS systems that provide therapy (e.g., pain relief) without generating paresthesia, the patient can continue to receive effective therapy without sensing the amplitude change. Accordingly, the present technology can effectively increase the time between battery charging events, thus addressing potential instances in which paresthesia-free therapy might otherwise deplete the power available from an implanted battery faster than would a conventional, paresthesia-based device.

[0008] General aspects of the environments in which the disclosed technology operates are described below under heading 1.0 ("Overview") with reference to Figures 1A and 1B. Particular embodiments of the technology are described further under heading 2.0 ("Representative Embodiments") with reference to Figures 2-6. While the present technology is being described in the environment of SCS, one of skill in the art would recognize that one or more aspects of the present technology are applicable to other, non-SCS implantable and/or external devices; e.g., implantable or external neurostimulators for treatment of one or more patient indications.

1.0 Overview

[0009] One example of a paresthesia-free SCS therapy system is a "high frequency" SCS system. High frequency SCS systems can inhibit, reduce, and/or eliminate pain via waveforms with high frequency elements or components (e.g., portions having high fundamental frequencies), generally with reduced or eliminated side effects. Such side effects can include unwanted paresthesia, unwanted motor stimulation or blocking, unwanted pain or discomfort, and/or interference with sensory functions other than the targeted pain. In a representative embodiment, a patient may receive high frequency therapeutic signals with at least a portion of the therapy signal at a frequency of from about 1.5 kHz to about 100 kHz, or from about 1.5 kHz to about 50 kHz, or from about 3 kHz to about 20 kHz, or from about 5 kHz to about 15 kHz, or at frequencies of about 8 kHz, 9 kHz, or 10 kHz. These frequencies are significantly higher than the frequencies associated with conventional "low frequency" SCS, which are generally below 1,200 Hz, and more commonly below 100 Hz. Accordingly, modulation at these and other representative frequencies (e.g., from about 1.5 kHz to about 100 kHz) is occasionally referred to herein as "high frequency stimulation," "high frequency SCS," and/or "high frequency modulation." Further examples of paresthesia-free SCS systems are described in U.S. Patent Publication Nos. 2009/0204173 and 2010/0274314, as well as U.S. Provisional Application No. 61/901,255.

[0010] Figure 1A schematically illustrates a representative patient therapy system 100 for providing relief from chronic pain and/or other conditions, arranged relative to the general anatomy of a patient's spinal column 191. The system 100 can include a signal generator 101 (e.g., an implanted pulse generator or IPG), which may be implanted subcutaneously within a patient 190 and coupled to one or more signal delivery elements or devices 110. The signal delivery elements or devices 110 may be implanted within the patient 190, typically at or near the patient's spinal cord midline 189. The signal delivery elements 110 carry features for delivering therapy to the patient 190 after implantation. The signal generator 101 can be connected directly to the signal delivery devices 110, or it can be coupled to the signal delivery devices 110 via a signal link or lead extension 102. In a further representative embodiment, the signal delivery devices 110 can include one or more elongated lead(s) or lead body or bodies 111 (identified individually as a first lead 111a and a second lead 111b). As used herein, the terms signal delivery device, lead, and/or lead body include any of a number of suitable substrates and/or support members that carry electrodes/devices for providing therapy signals to the patient 190. For example, the lead or leads 111 can include one or more electrodes or electrical contacts that direct electrical signals into the patient's tissue, e.g., to provide for therapeutic relief. In other embodiments, the signal delivery elements 110 can include structures other than a lead body (e.g., a paddle) that also direct electrical signals and/or other types of signals to the patient 190.

[0011] In a representative embodiment, one signal delivery device may be implanted on one side of the spinal cord midline 189, and a second signal delivery device may be implanted on the other side of the spinal cord midline 189. For example, the first and second leads 111a, 111b shown in Figure 1A may be positioned just off the spinal cord midline 189 (e.g., about 1 mm offset) in opposing lateral directions so that the two leads 111a, 111b are spaced apart from each other by about 2 mm. In particular embodiments, the leads 111 may be implanted at a vertebral level ranging from, for example, about T8 to about T12. In other embodiments, one or more signal delivery devices can be implanted at other vertebral levels, e.g., as disclosed in U.S. Patent Application Publication No. 2013/0066411.

[0012] The signal generator 101 can transmit signals (e.g., electrical signals) to the signal delivery elements 110 that up-regulate (e.g., excite) and/or down-regulate (e.g., block or suppress) target nerves. As used herein,

and unless otherwise noted, the terms "modulate," "modulation," "stimulate," and "stimulation" refer generally to signals that have either type of the foregoing effects on the target nerves. The signal generator 101 can include a machine-readable (e.g., computer-readable) medium containing instructions for generating and transmitting suitable therapy signals. The signal generator 101 and/or other elements of the system 100 can include one or more processor(s) 107, memory unit(s) 108, and/or input/output device(s) 112. Accordingly, the process of providing modulation signals, providing guidance information for positioning the signal delivery devices 110, and/or executing other associated functions can be performed by computer-executable instructions contained by, on or in computer-readable media located at the pulse generator 101 and/or other system components. Further, the pulse generator 101 and/or other system components may include dedicated hardware, firmware, and/or software for executing computer-executable instructions that, when executed, perform any one or more methods, processes, and/or sub-processes described herein; e.g., the methods, processes, and/or sub-processes described with reference to Figures 2-6 below. Said dedicated hardware, firmware, and/or software also serve as "means for" performing the methods, processes, and/or sub-processes described herein. The signal generator 101 can also include multiple portions, elements, and/or subsystems (e.g., for directing signals in accordance with multiple signal delivery parameters), carried in a single housing, as shown in Figure 1A, or in multiple housings.

[0013] The signal generator 101 can also receive and respond to an input signal received from one or more sources. The input signals can direct or influence the manner in which the therapy and/or process instructions are selected, executed, updated, and/or otherwise performed. The input signals can be received from one or more sensors (e.g., an input device 112 shown schematically in Figure 1 for purposes of illustration) that are carried by the signal generator 101 and/or distributed outside the signal generator 101 (e.g., at other patient locations) while still communicating with the signal generator 101. The sensors and/or other input devices 112 can provide inputs that depend on or reflect patient state (e.g., patient position, patient posture, and/or patient activity level), and/or inputs that are patient-independent (e.g., time). Still further details are included in U.S. Patent No. 8,355,797.

[0014] In some embodiments, the signal generator 101 and/or signal delivery devices 110 can obtain power to generate the therapy signals from an external power source 103. In one embodiment, for example, the external power source 103 can bypass an implanted signal generator and generate a therapy signal directly at the signal delivery devices 110 (or via signal relay components). The external power source 103 can transmit power to the implanted signal generator 101 and/or directly to the signal delivery devices 110 using electromagnetic induction (e.g., RF signals). For example, the external power source 103 can include an external coil 104 that communicates with a corresponding internal coil (not shown) within the implantable signal generator 101, signal delivery devices 110, and/or a power relay component (not shown). The external power source 103 can be portable for ease of use.

[0015] In another embodiment, the signal generator 101 can obtain the power to generate therapy signals from an internal power source, in addition to or in lieu of the external power source 103. For example, the implanted signal generator 101 can include a non-rechargeable battery or a rechargeable battery to provide such power. When the internal power source includes a rechargeable battery, the external power source 103 can be used to recharge the battery. The external power source 103 can in turn be recharged from a suitable power source (e.g., conventional wall power).

[0016] During at least some procedures, an external stimulator or trial modulator 105 can be coupled to the signal delivery elements 110 during an initial procedure, prior to implanting the signal generator 101. For example, a practitioner (e.g., a physician and/or a company representative) can use the trial modulator 105 to vary the modulation parameters provided to the signal delivery elements 110 in real time, and select optimal or particularly efficacious parameters. These parameters can include the location from which the electrical signals are emitted, as well as the characteristics of the electrical signals provided to the signal delivery devices 110. In some embodiments, input is collected via the external stimulator or trial modulator and can be used by the clinician to help determine what parameters to vary. In a typical process, the practitioner uses a cable assembly 120 to temporarily connect the trial modulator 105 to the signal delivery device 110. The practitioner can test the efficacy of the signal delivery devices 110 in an initial position. The practitioner can then disconnect the cable assembly 120 (e.g., at a connector 122), reposition the signal delivery devices 110, and reapply the electrical signals. This process can be performed iteratively until the practitioner obtains the desired position for the signal delivery devices 110. Optionally, the practitioner may move the partially implanted signal delivery devices 110 without disconnecting the cable assembly 120. Furthermore, in some embodiments, the iterative process of repositioning the signal delivery devices 110 and/or varying the therapy parameters may not be performed.

[0017] The signal generator 101, the lead extension 102, the trial modulator 105 and/or the connector 122 can each include a receiving element 109. Accordingly, the receiving elements 109 can be patient implantable elements, or the receiving elements 109 can be integral with an external patient treatment element, device or component (e.g., the trial modulator 105 and/or the connector 122). The receiving elements 109 can be configured to facilitate a simple coupling and decoupling procedure between the signal delivery devices 110, the lead extension 102, the pulse generator 101, the trial modu-

lator 105 and/or the connector 122. The receiving elements 109 can be at least generally similar in structure and function to those described in U.S. Patent Application Publication No. 2011/0071593.

[0018] After the signal delivery elements 110 are implanted, the patient 190 can receive therapy via signals generated by the trial modulator 105, generally for a limited period of time. During this time, the patient wears the cable assembly 120 and the trial modulator 105 outside the body. Assuming the trial therapy is effective or shows the promise of being effective, the practitioner then replaces the trial modulator 105 with the implanted signal generator 101, and programs the signal generator 101 with therapy programs selected based on the experience gained during the trial period. Optionally, the practitioner can also replace the signal delivery elements 110. Once the implantable signal generator 101 has been positioned within the patient 190, the therapy programs provided by the signal generator 101 can still be updated remotely via a wireless physician's programmer (e.g., a physician's laptop, a physician's remote or remote device, etc.) 117 and/or a wireless patient programmer 106 (e.g., a patient's laptop, patient's remote or remote device, etc.). Generally, the patient 190 has control over fewer parameters than does the practitioner. For example, the capability of the patient programmer 106 may be limited to starting and/or stopping the signal generator 101, and/or adjusting the signal amplitude. The patient programmer 106 may be configured to accept pain relief input as well as other variables, such as medication use.

[0019] In any of the foregoing embodiments, the parameters in accordance with which the signal generator 101 provides signals can be adjusted during portions of the therapy regimen. For example, the frequency, amplitude, pulse width, and/or signal delivery location can be adjusted in accordance with a pre-set therapy program, patient and/or physician inputs, and/or in a random or pseudorandom manner. Such parameter variations can be used to address a number of potential clinical situations. Certain aspects of the foregoing systems and methods may be simplified or eliminated in particular embodiments of the present disclosure. Further aspects of these and other expected beneficial results are detailed in U.S. Patent Application Publication Nos. 2010/0274317; 2010/0274314; 2009/0204173; and 2013/0066411.

[0020] Figure 1B is a cross-sectional illustration of the spinal cord 191 and an adjacent vertebra 195 (based generally on information from Crossman and Neary, "Neuroanatomy," 1995 (published by Churchill Livingstone)), along with multiple leads 111 (shown as leads 111a-111e) implanted at representative locations. For purposes of illustration, multiple leads 111 are shown in Figure 1B implanted in a single patient. In actual use, any given patient will likely receive fewer than all the leads 111 shown in Figure 1B.

[0021] The spinal cord 191 is situated within a vertebral foramen 188, between a ventrally located ventral body 196 and a dorsally located transverse process 198 and spinous process 197. Arrows V and D identify the ventral and dorsal directions, respectively. The spinal cord 191 itself is located within the dura mater 199, which also surrounds portions of the nerves exiting the spinal cord 191, including the ventral roots 192, dorsal roots 193 and dorsal root ganglia 194. The dorsal roots 193 enter the spinal cord 191 at the dorsal root entry zone 187, and communicate with dorsal horn neurons located at the dorsal horn 186. In one embodiment, the first and second leads 111a, 111b are positioned just off the spinal cord midline 189 (e.g., about 1 mm. offset) in opposing lateral directions so that the two leads 111a, 111b are spaced apart from each other by about 2 mm, as discussed above. In other embodiments, a lead or pairs of leads can be positioned at other locations, e.g., toward the outer edge of the dorsal root entry zone 187 as shown by a third lead 111c, or at the dorsal root ganglia 194, as shown by a fourth lead 111d, or approximately at the spinal cord midline 189, as shown by a fifth lead 111e.

2.0 Representative Embodiments

[0022] As discussed above, systems of the type described with reference to Figures 1A-B can include implanted pulse generators having rechargeable batteries or other rechargeable power sources that are periodically recharged with an external recharger. As the battery discharges, the voltage put out by the battery typically also decreases. Conventional techniques for addressing this voltage reduction (and voltage variation generally) include "boost and buck" devices. However, a drawback with such devices is that they are inefficient. In particular, such devices can reduce the overall efficiency of delivering electrical signals to the patient by 20%-30%.

[0023] Figure 2 illustrates a process 200 for more efficiently providing power from an implanted battery (or other power source), as the battery discharges. The process can make use of the relationship between the pulse width and amplitude for therapy signals applied to a patient. Accordingly, the process 200 can include establishing a pulse width/amplitude correlation, e.g., on a patient-by-patient basis (block 202). The process 200 can further include receiving a request for a therapy amplitude (block 204). The request may come via a patient or practitioner selecting a particular therapy program, and/or requesting an amplitude adjustment once the particular program has been activated. The amplitude can be a current amplitude (e.g., in the context of a system that includes a current source between the power source and the electrodes), or a voltage amplitude. In block 206, the available voltage is measured or otherwise identified (e.g., at the battery, or downstream from the battery). The method further includes setting the pulse width to provide the requested therapy amplitude based on the available voltage and the pulse width/amplitude correlation (block 208). Accordingly, the pulse width can be adjusted to provide the same or approximately the same level of therapy to the

patient despite the fact that the available voltage (e.g., the battery output voltage) has decreased.

[0024] Figure 3 illustrates a graph 300 of signal amplitude as a function of pulse width or duty cycle. For much of the discussion that follows, the functions will be described in the context of amplitude as a function of pulse width, with the understanding that the function and the relationships associated with the function may apply to duty cycle as well.

[0025] Figure 3 illustrates a plurality of curves 302 (four are shown as first-fourth curves 302a-302d) that indicate the functional relationship between amplitude and pulse width for a variety of different patients, evaluation criteria, and/or other factors. These curves are often referred to as "strength-duration" curves. Each curve 302 represents amplitude as a function of pulse width for an effective or target level of electrical stimulation. For example, an effective level of stimulation can include a level of stimulation that provides pain relief without paresthesia. In another embodiment, a target level of stimulation can include stimulation sufficient to generate a sensory response (e.g., paresthesia or another sensation) in the patient. For a given patient, the curve may differ depending upon whether the target result is paresthesia-free therapy, or a sensory response. In addition, the curve for an effective or target stimulation level may be different for one patient than for another. Accordingly, there can exist multiple curves (as shown in Figure 3) that may be patient-specific and/or target level-specific.

[0026] As is also shown in Figure 3, the pulse width or duty cycle can vary as a function of the available voltage, in a manner similar to the manner in which these parameters vary with amplitude. In particular, each curve 302 can indicate the pulse width or duty cycle appropriate for a given available voltage, assuming a fixed impedance for the signal delivery circuit. Accordingly, Figure 3 indicates that a given therapy level or efficacy can be delivered with a relatively high voltage and short pulse width, or with a lower voltage and longer pulse width. The relationships between amplitude, available voltage, and pulse width or duty cycle shown in Figure 3 are used to implement the methods discussed further below with reference to Figures 4-6.

[0027] Figure 4 illustrates representative processes for establishing an amplitude/pulse width correlation, as described above with reference to block 202 in Figure 2. The process 202 can include establishing a "map" with a series of pulse width/amplitude curves (block 404). The map can have the format shown in Figure 3 in some embodiments, and in other embodiments, the map can have other formats. Such formats can include other graphical formats, a tabular format, a series of equations describing individual curves or functions, and/or other suitable techniques for establishing a correlation between amplitude and pulse width. The map can be based on clinical data obtained from multiple patients. In particular embodiments, different maps can be established for different parameters (e.g., different patient indications, patient physiologies and/or treatment parameters).

[0028] In block 406, the process includes identifying the values (e.g., numerical values) for one or more patient-specific pulse width/amplitude pairs or coordinates. For example, referring to Figure 3, the practitioner can identify a single point 310a based on data received from the patient, which is sufficient to indicate that the appropriate patient-specific curve is the first curve 302a. The data may indicate that the patient receives effective therapy at the amplitude and pulse width coordinates of the first point 310a. Another patient may be characterized by a second point 310b and accordingly have the second curve 302b as his/her patient-specific curve. Still another patient may be characterized by a third point 310c and accordingly have the third curve 302c as his/her patient-specific curve.

[0029] In another embodiment, an individual patient may have a plurality of points associated with him or her, e.g., first-sixth points 310a-310f. In this particular instance, four of the six points (points 310b, 310d, 310e, 310f) fall on the second curve 302b, which can be a sufficient indication that the particular patient's patient-specific curve is the second curve 302b.

[0030] In still further embodiments, different points can correspond to a different parameter for the same individual patient. For example, the first point 310a (and the associated first curve 302a) can correspond to a level of paresthesia-free therapy at a particular vertebral level. The second point 310b (and the associated second curve 302b) can correspond to a stimulation threshold, for example, the threshold at which the patient first feels paresthesia or another sensation. The third point 310c (and the associated third curve 302c) can correspond to the threshold at which a signal applied to the patient produces an evoked potential. The evoked potential can be physically measured, thus indicating at which amplitude and pulse width the patient's neurons generate an action potential in response to a stimulus at the amplitude/pulse width coordinates of the third point 310c. Methods for establishing which of the curves shown in Figure 3 is an appropriate patient-specific curve are further described below, with reference to the three thresholds described above: the paresthesia or sensory threshold, the therapeutic threshold, and the evoked potential threshold.

[0031] Returning to Figure 4, in block 408, the process includes identifying the patient-specific correlation using paresthesia. This process can include selecting an amplitude (block 414), selecting a pulse width (block 416), and administering a signal to the patient in accordance with the selected amplitude and pulse width (block 418). In at least some instances, the pulse width and/or amplitude used for this process may be deliberately selected to be different than the expected pulse width and/or amplitude used for therapy. In particular, the selected amplitude and/or pulse width can be more likely to produce paresthesia. Block 419 includes determining whether the patient reports paresthesia or another suitable sensory feedback. If not, the amplitude is increased at block 420

and the signal is re-administered. Once the patient reports paresthesia, block 422 includes determining whether another coordinate pair (e.g., another pair of amplitude and pulse width values) is to be obtained. If so, the process returns to block 414. If not, the process proceeds to block 424 where it is determined whether or not to apply a correction factor to the coordinate pair or pairs obtained in block 422.

[0032] The correction factor can be based on any of a number of suitable parameters. For example, a representative correction factor can include reducing the reported amplitude to account for the expected amplitude difference between a signal that produces paresthesia and a signal that can produce therapy (e.g., pain relief) without paresthesia. If the pulse width used to generate paresthesia is different than the expected therapeutic pulse width, the correction factor can also account for that difference. In any of these embodiments, the correction factor can be patient-specific, or it can be determined from a pool of patient data. The correction factor can be determined empirically through patient testing, or it can be estimated and/or calculated, depending upon the particular embodiment. If such a correction factor is to be applied, it is applied in block 428.

[0033] The process then proceeds to block 426 where the coordinate or coordinates, with or without a correction factor, are used to identify the patient-specific curve on the map established at block 404. For example, with reference again to Figure 3, the coordinates can be used to determine which of the multiple curves 302 best corresponds to or fits with the coordinate or coordinates obtained in block 422. Once the appropriate curve is identified, the curve can be used to select therapeutic amplitudes and pulse widths as a function of available voltage, in a manner described later with reference to Figures 5 and 6.

[0034] As noted above, block 408 includes identifying the patient-specific curve (or other correlation) in conjunction with a paresthesia threshold identified by the patient. Other techniques can be used to establish which correlation is best suited to an individual patient. For example, block 410 includes identifying the patient-specific correlation based on the threshold at which the patient receives or experiences paresthesia-free pain relief. In this process, the amplitude and pulse width are selected (blocks 430 and 432) and the signal is administered to the patient (block 434). Instead of identifying whether or not the patient has paresthesia, as discussed above with reference to block 419, block 436 can include determining whether the patient has received therapy (e.g., pain relief) without paresthesia. If not, the amplitude is increased in block 437 and the signal is re-administered to the patient. If therapy without paresthesia is obtained, block 438 includes determining whether to obtain an additional coordinate pair. If not, the process proceeds to block 424 to determine whether a correction factor is to be applied and, with or without the correction factor, block 426 includes identifying the patient-specific curve or correlation using the map established in block 404.

[0035] In at least some embodiments, it is expected that it may take some time for the patient to detect and report the paresthesia-free therapy (e.g., pain relief). In such instances, it may be more efficient to use the paresthesia threshold technique described above with reference to blocks 408-422 (e.g., with a correction factor applied), or to use other techniques that can more rapidly identify the amplitude/pulse width coordinates. One such technique includes identifying the patient-specific curve or correlation via an evoked potential (block 412). This process also includes selecting an amplitude (block 440), selecting a pulse width (block 442), and applying a therapy signal with the selected amplitude and pulse width (block 444). In block 446, the process includes checking for an evoked potential (e.g., a physiological electrical response to a stimulation signal at the selected amplitude and pulse width). If no evoked potential is measured, then in block 447 the amplitude is increased and the signal is re-administered to the patient in block 444. If an evoked potential is measured, then block 448 includes determining whether or not to obtain an additional amplitude/pulse width coordinate pair. The process then proceeds to block 424 (determining whether or not to apply a correction factor) and to block 426 to identify the patient-specific correlation or curve on the map established in block 404.

[0036] The result of any of the foregoing embodiments described above with reference Figure 4 is identifying a patient-specific curve or correlation between signal amplitude and pulse width (or duty cycle). Figure 5 illustrates a representative process 500 for using this information to identify a therapeutic amplitude and pulse width as a function of a variable available voltage (e.g., battery output voltage or a downstream correlate of battery output voltage). In block 502, the patient or practitioner selects a requested therapy amplitude, which is received by the system at block 504. In block 506, the system receives an initial pulse width and frequency. In at least some embodiments, the initial pulse width and frequency are established by default values stored in memory so that neither the patient nor the practitioner needs to separately input these values. In other embodiments, one or both of these values can be selected by the patient or practitioner. In any of these embodiments, block 508 includes temporarily setting the available voltage high enough to generate a signal at any selected amplitude (within a proscribed limit). This may include using a boost circuit if the battery voltage is insufficient. However, even if a boost circuit is used for this portion of the process, it need not be used to generate the therapy signal over a long period of time, which, as discussed above can produce system efficiencies.

[0037] In block 510, one or more pulses are delivered at the requested amplitude, with the initial pulse width and the initial frequency. As the pulses are delivered, the voltage across the therapy circuit is measured or otherwise determined (block 512). For example, if the signal

is delivered to a bipole (two electrodes), the voltage across the bipole is measured. In block 514, the voltage required to deliver a consistent therapy signal at the requested amplitude, and with the initial pulse width and frequency, is determined. This process can include adding a margin (e.g., a loss margin and/or an impedance variation margin) to the therapy circuit voltage measured at block 512. Typical margins range from 100mV to 1.5V. Accordingly, block 514 can account for one or more system losses, variations, and/or measurement inaccuracies. In block 516, the available voltage is measured. The available voltage can be determined (e.g., measured) at the battery or at any other suitable point (e.g., downstream point) at which the voltage is at least correlated with the available battery voltage. In block 518, the required voltage is compared to the available voltage. If the required voltage does not exceed the available voltage, then the requested therapy signal is delivered at block 520. If the required voltage exceeds the available voltage, then the process continues at block 522.

[0038] In block 522, the process includes determining the circuit impedance (e.g., the impedance of the circuit that provides therapy to the patient, including the signal delivery electrodes and the patient's own tissue). The impedance can be obtained using voltage/current/impedance relationships (e.g., V=IR) based on the requested current amplitude (from block 504) and the measured therapy circuit voltage (from block 512). In block 524, the process includes calculating an updated current amplitude based on the available voltage and circuit impedance. Blocks 522 and 524 are typically implemented for a current-based system, e.g., a system with a current source connected between the battery or other power source and the electrodes. Accordingly, these blocks may be skipped or deleted in a voltage-amplitude-based system.

[0039] Blocks 526 and 528 are discussed below with reference to Figure 6. Block 526 includes determining an updated pulse width from the identified patient-specific curve. Figure 6 illustrates a representative patient-specific curve 302b with the requested amplitude 610a and initial pulse width 610b identified as an initial therapy point 610. The updated amplitude 620a identified in block 524 is also indicated in Figure 6. By proceeding along the patient-specific curve 302b as indicated by arrow A1, the program can identify an updated coordinate pair 620 having the updated amplitude 620a and a corresponding updated pulse width 620b. The therapy signal to be applied to the patient will be applied with the updated amplitude 620a and the updated pulse width 620b.

[0040] Block 528 determines, if necessary, an updated frequency. For example, if the updated pulse width is significantly greater than the initial pulse width, then the frequency may need to be decreased to account for the change. Alternatively, if an interpulse interval (e.g., the time period between adjacent pulses) is long enough to allow for an increase in pulse width without requiring a decrease in frequency, then the frequency can remain the same. In either case, a therapy signal with the updated amplitude, the updated pulse width, and the initial (or updated) frequency is then delivered at block 520.

[0041] The foregoing processes can be invoked, as needed, during the normal course of therapy. For example, the process described above with reference to Figure 4 may be completed when the patient first begins receiving the therapy, and need not be repeated unless, for example, there is a basis for believing that the patient-specific correlation between pulse width and amplitude has shifted. The process described above with reference to Figure 5 can be invoked periodically throughout the normal course of therapy. In another embodiment, the process described above with reference to Figure 5 can first be invoked when the battery voltage (or other measure of available voltage) falls below a threshold level, and can then be invoked periodically until the battery is recharged. For current-based systems, it may be beneficial to determine the circuit impedance (block 522 in Figure 5) relatively frequently to account for factors such as scar tissue build-up that may affect impedance.

[0042] One feature of at least some of the foregoing embodiments is that they can include using an established relationship between amplitude and pulse width (or duty cycle) to produce therapeutic results even when the voltage of the battery providing power for the electrical signal is reduced. An advantage of this arrangement is that it can eliminate the need for a boost circuit to deliver therapy, except as may be needed to identify the therapy delivery parameters. A corresponding advantage of this feature is that, because boost circuits can be inefficient, the amount of power lost as a result of delivering a therapy signal with a reduced battery output voltage can be reduced. Accordingly, the battery can last longer and can increase the time between battery charging events.

[0043] Another feature of at least some of the foregoing embodiments described above is that they may have particular applicability to therapies that do not produce paresthesia or other sensations in the patient. In particular, therapies that produce (and more generally rely on) paresthesia or other sensations may have those paresthesias or sensations change in nature, strength, and/or duration if the amplitude is shifted in the manner described above. Because it is expected that the amplitude for paresthesia-free therapy may be shifted without being sensed or detected by the patient, the foregoing process may be particularly beneficial in the context of therapies that do not produce paresthesia.

[0044] From the foregoing, it will be appreciated that specific embodiments of the presently disclosed technology have been described herein for purposes of illustration, but that various modifications may be made without deviating from the disclosed technology. For example, embodiments described above in the context of pulse width as a function of amplitude can apply as well for duty cycle as a function of amplitude. While the foregoing embodiments were described in the context of battery voltage and an associated current amplitude produced by

an intermediate current source, in other embodiments, the technique can be applied in a voltage-amplitude-based system. In such embodiments, the amplitude axis of the curves shown in Figures 3 and 6 is voltage amplitude, and the pulse width can be determined directly from the curve (using the determined available voltage) without the intermediate step of calculating an updated amplitude based on the available voltage and circuit impedance.

[0045] In particular embodiments, representative current amplitudes for the therapy signal are from 0.1 mA to 20 mA, or 0.5 mA to 10 mA, or 0.5 mA to 7 mA, or 0.5 mA to 5 mA. Representative pulse widths range from about 10 microseconds to about 333 microseconds, about 10 microseconds to about 166 microseconds, 20 microseconds to about 100 microseconds, 30 microseconds to about 100 microseconds, and 30 microseconds to about 40 microseconds. Duty cycles can range from about 10% to about 100%, and in a particular duty cycle, signals are delivered for 20 seconds and interrupted for 2 minutes (an approximate 14% duty cycle). In other embodiments, these parameters can have other suitable values. For example, in at least some embodiments, the foregoing systems and methods may be applied to therapies that have frequencies outside the ranges discussed above (e.g., 1.5 kHz-100 kHz) but which also do not produce paresthesia. Representative therapies include therapies having relatively narrow pulse widths, as disclosed in co-pending U.S. Provisional Patent Application No. 61/901,255, filed November 7, 2013. Representative pulse widths (which can be delivered at frequencies above or below 1.5 kHz, depending upon the embodiment) include pulse widths from 10-50 microseconds, 20-40 microseconds, 25-35 microseconds, 30-35 microseconds, and 30 microseconds.

[0046] In still further embodiments, techniques generally similar to those described above may be applied to therapies that are directed to tissues other than the spinal cord. Representative tissues can include peripheral nerve tissue and/or brain tissue. In such contexts, the strength/duration relationships discussed above can be the same as or different than the relationships for spinal cord neurons, depending on the embodiment. The mechanism of action by which pain relief is obtained in any of the foregoing embodiments may include, but is not limited to, those described in co-pending U.S. Provisional Patent Application No. 61/833,392, filed June 10, 2013.

[0047] In other embodiments, other methodologies may be used to provide pain therapy to the patient, and in some instances, such methodologies may provide paresthesia-free pain relief. Representative methods asserted to provide paresthesia-free pain relief are disclosed in U.S. Patent No. 8,224,453 to De Ridder and U.S. Patent No. 8,380,318 to Kishawi et al. De Ridder discloses the use of "burst" stimulation (e.g., bursts of spikes at a frequency of up to 1,000 Hz, with a 0.1-1.0 millisecond interval between spikes, and a quiescent period of 1 millisecond to about 5 seconds between bursts) applied to the spinal cord. Kishawi et al. discloses applying a signal to the dorsal root ganglion at a frequency of less than 25 Hz, a pulse width of less than 120 microseconds and an amplitude of less than 500 microamps.

[0048] In several embodiments described above, a patient-specific relationship includes determining the amplitude and pulse width based on patient-specific testing. In other embodiments, where applicable, data from a pool of patients (e.g., patients with the same pain indication and/or other attributes) can be applied to a similarly situated patient without the need for a patient-specific test. Several embodiments were described above in the context of a battery (e.g., a lithium ion battery), and in other embodiments, the technology is applicable to other rechargeable power sources, e.g., capacitors.

[0049] Certain aspects of the technology described in the context of particular embodiments may be combined or eliminated in other embodiments. For example, selected process steps may be combined in some embodiments, and skipped in others. In particular embodiments, specific values described above (e.g., battery voltage, signal amplitude and the like) may be replaced by correlates of these values for data handling or other purposes. Certain of the processes described above may be carried out in an automated or semi-automated manner using the implanted signal generator 101 described above with reference to Figure 1A. In other embodiments, some of the foregoing steps may be carried out by an external device (e.g., the physician programmer 117).

3.0 Additional Embodiments

[0050] In one embodiment, there is provide a method for treating a patient, comprising: receiving an input corresponding to an available voltage for an implanted medical device; identifying a signal delivery parameter value of an electrical signal based on a correlation between values of the signal delivery parameter and signal delivery amplitudes, wherein the signal delivery parameter includes at least one of pulse width or duty cycle; and delivering an electrical therapy signal to the patient at the identified signal delivery parameter value using a voltage within a margin of the available voltage. The signal delivery parameter may be pulse width and/or duty cycle. The available voltage may be an output voltage of a battery that provides power for the electrical therapy signal. The method may further comprise: receiving at least one input corresponding to a target therapy amplitude and a target pulse width; determining that the available voltage is insufficient to supply a therapy signal at the target therapy amplitude and the target pulse width; identifying an updated therapy amplitude less than the target therapy amplitude; based at least in part on the updated therapy amplitude and the correlation, identifying an updated pulse width greater than the target pulse width; and delivering the electrical therapy signal to the patient at the updated therapy amplitude and the updated pulse width. The correlation may be patient-specific correlation, and

wherein the method may further comprise establishing the correlation. Establishing the correlation may include establishing the correlation by producing paresthesia in the patient, and wherein delivering the electrical therapy signal does not produce paresthesia in the patient.

[0051] In another embodiment, there is provided a method for treating pain in a patient, comprising: establishing a patient-specific correlation between amplitudes and pulse widths by identifying at least one pulse width/amplitude pair that produces a detectable result in the patient; receiving at least one input corresponding to a target therapy amplitude, pulse width and frequency; determining an available voltage of a battery-powered implanted medical device; determining whether the available voltage is sufficient to direct a therapy signal to the patient at the target therapy amplitude, pulse width and frequency; and if the available voltage is not sufficient: determining an updated therapy amplitude and, based on the patient-specific correlation, an updated pulse width; and delivering an electrical therapy signal to the patient at the updated therapy amplitude and the updated pulse width; and if the available voltage is sufficient: delivering an electrical therapy signal to the patient at the target amplitude and pulse width. The detectable result may be a non-therapeutic result, and wherein the method may further comprise applying a correction factor to the patient-specific correlation to account for an expected difference between the non-therapeutic result and a target therapeutic result. The non-therapeutic result may include producing paresthesia in the patient and wherein the target therapeutic result may include producing pain relief without paresthesia in the patient. The method may further comprise determining if the updated pulse width can be delivered at the target frequency; and if the updated pulse width cannot be delivered at the target frequency, updating the target frequency. Establishing the patient-specific correlation may include using the at least one pulse width/amplitude pair to determine which of a plurality of pulse width/amplitude correlations applies to the patient. At least one pulse width/amplitude pair may be one of multiple pulse width/amplitude pairs used to determine which of the plurality of pulse width/amplitude correlations applies to the patient. Establishing the patient-specific correlation may include using data from other patients. Identifying the at least one pulse width/ amplitude pair may be based at least in part on producing paresthesia in the patient with a signal having the pulse width and amplitude of the at least one pulse width/amplitude pair. Identifying the at least one pulse width/ amplitude pair may be based at least in part on producing pain relief without producing paresthesia in the patient, with a signal having the pulse width and amplitude of the at least one pulse width/amplitude pair. Identifying the at least one pulse width/ amplitude pair may be based at least in part on producing an evoked potential in the patient with a signal having the pulse width and amplitude of the at least one pulse width/amplitude pair. Determining the updated therapy amplitude may be based at least in part on the available voltage and on an impedance of a circuit via which the electrical therapy signal is delivered. The method may further comprise determining the impedance by: delivering an electrical therapy signal at the target amplitude and pulse width; determining a voltage across the circuit; and determining the impedance based on the target amplitude and the voltage across the circuit.

[0052] In another embodiment, there is provided a method of treating a patient by programming an implantable/external pulse generator to perform any one or more of the herein described methods, process, and/or sub-processes. In still another embodiment, there is provided a system for treating a patient comprising means for performing any one or more of the herein described methods, process, and/or sub-processes.

[0053] In another embodiment, there is provided a patient therapy system, comprising: (a) a pulse generator programmed with instructions for delivering an electrical therapy signal to a patient; (b) a processor operatively coupled to the pulse generator and programmed with instructions that, when executed: receive an input corresponding to an available voltage for the pulse generator; identify a signal delivery parameter value of an electrical signal based on a correlation between values of the signal delivery parameter and signal delivery amplitudes, wherein the signal delivery parameter includes at least one of pulse width or duty cycle; and direct the pulse generator to deliver an electrical therapy signal at the identified signal delivery parameter value using a voltage within a margin of the available voltage. The system may further comprise a signal delivery element coupled to the pulse generator to deliver the electrical therapy signal to a patient. The processor and the pulse generator may be housed in a patient-implantable device. The pulse generator may be housed in a patient-implantable device, and the processor may be housed in an external device. The system may further comprise a computer-readable medium coupled to the processor, and wherein the instructions are carried by the computer-readable medium. The pulse generator may be programmed with instructions for delivering the electrical therapy signal at a frequency of from 1.5 kHz to 100 kHz (or any range of the above-described frequencies). The pulse generator may be programmed with instructions for delivering the electrical therapy signal at a pulse width of from 10 microseconds to 333 microseconds (or any range of the above-described pulse widths). The processor may be programmed with instructions that, when executed: receive at least one input corresponding to a target therapy amplitude and a target pulse width; determine that the available voltage is insufficient to supply a therapy signal at the target therapy amplitude and the target pulse width; identify an updated therapy amplitude less than the target therapy amplitude; based at least in part on the updated therapy amplitude and the correlation, identify an updated pulse width greater than the target pulse width; and deliver the electrical therapy signal to the patient at the

updated therapy amplitude and the updated pulse width.

[0054] In yet another embodiment, there is provide a patient therapy system, comprising: (a) an implantable housing; (b) a pulse generator carried within the housing and programmed with instructions for delivering an electrical therapy signal to a patient; (c) an implantable signal delivery element coupled to the pulse generator; (d) a battery carried within the housing and coupled to the pulse generator to provide power for the electrical therapy signal; and (e) a processor carried within the housing and operatively coupled to the pulse generator, the processor being programmed with instructions that, when executed: receive an input corresponding to an available voltage from the battery; identify a pulse width of an electrical signal based on a correlation between pulse widths and signal delivery amplitudes; and direct the pulse generator to deliver an electrical therapy signal at the identified pulse width value using a voltage within a margin of the available voltage. The processor may be programmed with instructions that, when executed: receive at least one input corresponding to a target current amplitude and a target pulse width; determine that the available voltage is insufficient to supply a therapy signal at the target current amplitude and the target pulse width; determine an impedance of a circuit via which the electrical therapy signal is delivered, the circuit including the patient; based at least in part on the impedance and the available voltage, determine an updated current amplitude less than the target current amplitude; based on the updated current amplitude and the correlation, identify an updated pulse width greater than the target pulse width. The pulse generator may be programmed with instructions for delivering the electrical therapy signal at a frequency of from 1.5 kHz to 100 kHz (or any of the above-described frequencies). The pulse generator may be programmed with instructions for delivering the electrical therapy signal at a pulse width of from 10 microseconds to 333 microseconds (or any of the above-described pulse widths).

[0055] While advantages associated with certain embodiments of the disclosed technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the present technology. The following examples provide additional embodiments of the present technology.

[0056] The present invention is set out in the appended claims. The embodiments, aspects or examples according to the present description that do not fall within the scope of said claims are provided for illustrative purposes only and do not form part of the present invention.

Claims

1. A patient therapy system (100) for delivering spinal cord stimulation, comprising:

a pulse generator (101) configured to deliver an electrical therapy signal to a patient (190);

a power source (103);

a processor (107) operatively coupled to the pulse generator (101) and programmed with instructions for delivering the electrical therapy signal that, when executed:

receive an input corresponding to an available voltage, obtained from the power source (103), for the pulse generator (101);

identify a value of a signal delivery parameter of an electrical therapy signal based on a correlation between values of signal delivery amplitudes and values of pulse width or duty cycle, wherein the identified value of the signal delivery parameter is increased in response to a decrease in the available voltage; and

direct the pulse generator (101) to deliver the electrical therapy signal at the identified signal delivery parameter value using a voltage within a margin of the available voltage.

2. The system (100) of claim 1, further comprising a signal delivery element (110) coupled to the pulse generator (101) to deliver the electrical therapy signal to a patient (190).

3. The system (100) of claim 1 wherein the processor (107) and the pulse generator (101) are housed in a patient-implantable device.

4. The system (100) of claim 1 wherein the pulse generator (101) is housed in a patient-implantable device, and the processor (107) is housed in an external device.

5. The system (100) of claim 1, further comprising a computer-readable medium coupled to the processor (107), and wherein the instructions are carried by the computer-readable medium.

6. The system (100) of claim 1 wherein the pulse generator (101) is programmed with instructions for delivering the electrical therapy signal at a frequency of from 1.5 kHz to 100 kHz.

7. The system (100) of claim 1 wherein the pulse generator (101) is programmed with instructions for delivering the electrical therapy signal at a pulse width of from 10 microseconds to 333 microseconds.

8. The system (100) of claim 1 wherein the processor (107) is programmed with instructions that, when executed:

receive at least one input corresponding to a tar-

get therapy amplitude and a target pulse width;
determine that the available voltage is insufficient to deliver the electrical therapy signal at the target therapy amplitude and the target pulse width;
identify an updated therapy amplitude less than the target therapy amplitude;
based at least in part on the updated therapy amplitude and the correlation, identify an updated pulse width greater than the target pulse width; and
deliver the electrical therapy signal to the patient (190) at the updated therapy amplitude and the updated pulse width.

9. The system (100) of claim 1, comprising:

an implantable housing carrying the pulse generator (101) and the processor (107);
an implantable signal delivery element (110) coupled to the pulse generator (101);
a battery carried within the housing and coupled to the pulse generator (101) to provide power for the electrical therapy signal; and wherein:

the input corresponds to an available voltage from the battery; and
the signal delivery parameter is the pulse width of the electrical signal.

10. The system (100) of claim 9 wherein the processor (107) is programmed with instructions that, when executed:

receive at least one input corresponding to a target current amplitude and a target pulse width;
determine that the available voltage is insufficient to supply a therapy signal at the target current amplitude and the target pulse width;
determine an impedance of a circuit via which the electrical therapy signal is delivered, the circuit including the patient (190);
based at least in part on the impedance and the available voltage, determine an updated current amplitude less than the target current amplitude; and
based on the updated current amplitude and the correlation, identify an updated pulse width greater than the target pulse width.

11. The system (100) of claim 9 wherein the pulse generator (101) is programmed with instructions for delivering the electrical therapy signal at a frequency of from 1.5 kHz to 100 kHz.

12. The system (100) of claim 9 wherein the pulse generator (101) is programmed with instructions for delivering the electrical therapy signal at a pulse width of from 10 microseconds to 333 microseconds.

13. The system (100) of claim 1, wherein the correlation is a patient-specific correlation.

14. The system (100) of claim 13 wherein the patient-specific correlation includes data from other patients.

15. The system (100) of claim 8 wherein the updated therapy amplitude is identified based at least in part on the available voltage and on an impedance of a circuit via which the electrical therapy signal is delivered.

16. The system (100) of claim 15 wherein the instructions, when executed, determine the impedance by:

delivering an electrical therapy signal at the target amplitude and pulse width;
determining a voltage across the circuit; and
determining the impedance based on the target amplitude and the voltage across the circuit.

17. The system (100) of claim 1 wherein the identified signal delivery parameter value includes a duty cycle value.

18. The system (100) of claim 1 wherein the identified signal delivery parameter value includes a pulse width value.

Patentansprüche

1. Ein Patiententherapiesystem (100) zur Abgabe einer Rückenmarkstimulation, das Folgendes beinhaltet:

einen Pulsgenerator (101), der konfiguriert ist, um ein elektrisches Therapiesignal an einen Patienten (190) abzugeben;
eine Energiequelle (103);
einen Prozessor (107), der mit dem Pulsgenerator (101) betriebsfähig gekoppelt ist und mit Anweisungen zur Abgabe des elektrischen Therapiesignals programmiert ist, die bei Ausführung:

eine Eingabe erhalten, die einer verfügbaren Spannung entspricht, die von der Energiequelle (103) für den Pulsgenerator (101) bezogen wird;
einen Wert eines Signalabgabeparameters eines elektrischen Therapiesignals basierend auf einer Korrelation zwischen Werten von Signalabgabeamplituden und Werten einer Pulsbreite oder eines Tastgrads identifizieren, wobei der identifizierte Wert des Signalabgabeparameters als Reaktion auf

eine Abnahme der verfügbaren Spannung erhöht wird; und
den Pulsgenerator (101) anweisen, das elektrische Therapiesignal mit dem identifizierten Signalabgabeparameterwert unter Verwendung einer Spannung innerhalb einer Spanne der verfügbaren Spannung abzugeben.

2. System (100) gemäß Anspruch 1, das ferner ein Signalabgabeelement (110) beinhaltet, das mit dem Pulsgenerator (101) gekoppelt ist, um das elektrische Therapiesignal an einen Patienten (190) abzugeben.

3. System (100) gemäß Anspruch 1, wobei der Prozessor (107) und der Pulsgenerator (101) in einer in einen Patienten implantierbaren Vorrichtung untergebracht sind.

4. System (100) gemäß Anspruch 1, wobei der Pulsgenerator (101) in einer in einen Patienten implantierbaren Vorrichtung untergebracht ist und der Prozessor (107) in einer externen Vorrichtung untergebracht ist.

5. System (100) gemäß Anspruch 1, das ferner ein computerlesbares Medium beinhaltet, das mit dem Prozessor (107) gekoppelt ist, und wobei die Anweisungen durch das computerlesbare Medium aufgenommen sind.

6. System (100) gemäß Anspruch 1, wobei der Pulsgenerator (101) mit Anweisungen zur Abgabe des elektrischen Therapiesignals mit einer Frequenz von 1,5 kHz bis 100 kHz programmiert ist.

7. System (100) gemäß Anspruch 1, wobei der Pulsgenerator (101) mit Anweisungen zur Abgabe des elektrischen Therapiesignals mit einer Pulsbreite von 10 Mikrosekunden bis 333 Mikrosekunden programmiert ist.

8. System (100) gemäß Anspruch 1, wobei der Prozessor (107) mit Anweisungen programmiert ist, die bei Ausführung:

mindestens eine Eingabe erhalten, die einer Zieltherapieamplitude und einer Zielpulsbreite entspricht;
bestimmen, dass die verfügbare Spannung nicht ausreicht, um das elektrische Therapiesignal mit der Zieltherapieamplitude und der Zielpulsbreite abzugeben;
eine aktualisierte Therapieamplitude identifizieren, die kleiner als die Zieltherapieamplitude ist;
mindestens teilweise basierend auf der aktualisierten Therapieamplitude und der Korrelation eine aktualisierte Pulsbreite identifizieren, die größer als die Zielpulsbreite ist; und
das elektrische Therapiesignal mit der aktualisierten Therapieamplitude und der aktualisierten Pulsbreite an den Patienten (190) abgeben.

9. System (100) gemäß Anspruch 1, das Folgendes beinhaltet:

ein implantierbares Gehäuse, das den Pulsgenerator (101) und den Prozessor (107) aufnimmt;
ein implantierbares Signalabgabeelement (110), das mit dem Pulsgenerator (101) gekoppelt ist;
eine Batterie, die innerhalb des Gehäuses aufgenommen und mit dem Pulsgenerator (101) gekoppelt ist, um Energie für das elektrische Therapiesignal bereitzustellen; und wobei:

die Eingabe einer an der Batterie verfügbaren Spannung entspricht; und
der Signalabgabeparameter die Pulsbreite des elektrischen Signals ist.

10. System (100) gemäß Anspruch 9, wobei der Prozessor (107) mit Anweisungen programmiert ist, die bei Ausführung:

mindestens eine Eingabe erhalten, die einer Zielstromamplitude und einer Zielpulsbreite entspricht;
bestimmen, dass die verfügbare Spannung nicht ausreicht, um ein Therapiesignal mit der Zielstromamplitude und der Zielpulsbreite zu liefern;
eine Impedanz eines Kreises bestimmen, über den das elektrische Therapiesignal abgegeben wird, wobei der Kreis den Patienten (190) umfasst;
mindestens teilweise basierend auf der Impedanz und der verfügbaren Spannung eine aktualisierte Stromamplitude bestimmen, die kleiner als die Zielstromamplitude ist; und
basierend auf der aktualisierten Stromamplitude und der Korrelation eine aktualisierte Pulsbreite identifizieren, die größer als die Zielpulsbreite ist.

11. System (100) gemäß Anspruch 9, wobei der Pulsgenerator (101) mit Anweisungen zur Abgabe des elektrischen Therapiesignals mit einer Frequenz von 1,5 kHz bis 100 kHz programmiert ist.

12. System (100) gemäß Anspruch 9, wobei der Pulsgenerator (101) mit Anweisungen zur Abgabe des elektrischen Therapiesignals mit einer Pulsbreite von 10 Mikrosekunden bis 333 Mikrosekunden pro-

grammiert ist.

13. System (100) gemäß Anspruch 1, wobei die Korrelation eine patientenspezifische Korrelation ist.

14. System (100) gemäß Anspruch 13, wobei die patientenspezifische Korrelation Daten von anderen Patienten umfasst.

15. System (100) gemäß Anspruch 8, wobei die aktualisierte Therapieamplitude mindestens teilweise basierend auf der verfügbaren Spannung und einer Impedanz eines Kreises, über den das elektrische Therapiesignal abgegeben wird, identifiziert wird.

16. System (100) gemäß Anspruch 15, wobei die Anweisungen bei Ausführung die Impedanz durch Folgendes bestimmen:

Abgeben eines elektrischen Therapiesignals mit der Zielamplitude und -pulsbreite;
Bestimmen einer Spannung an dem Kreis; und
Bestimmen der Impedanz basierend auf der Zielamplitude und der Spannung an dem Kreis.

17. System (100) gemäß Anspruch 1, wobei der identifizierte Signalabgabeparameterwert einen Tastgradwert umfasst.

18. System (100) gemäß Anspruch 1, wobei der identifizierte Signalabgabeparameterwert einen Pulsbreitenwert umfasst.

Revendications

1. Un système de thérapie pour patient (100) pour délivrer une stimulation de moelle épinière, comprenant :

un générateur d'impulsions (101) configuré pour délivrer un signal de thérapie électrique à un patient (190) ;
une source de puissance (103) ;
un processeur (107) couplé de manière fonctionnelle au générateur d'impulsions (101) et programmé avec des instructions pour délivrer le signal de thérapie électrique qui,
lors de leur exécution :

reçoivent une entrée correspondant à une tension disponible, obtenue à partir de la source de puissance (103), pour le générateur d'impulsions (101) ;
identifient une valeur d'un paramètre de délivrance de signal d'un signal de thérapie électrique sur la base d'une corrélation entre des valeurs d'amplitudes de délivrance de signal et des valeurs de largeur d'impulsion ou de cycle de service, dans lequel la valeur identifiée du paramètre de délivrance de signal est accrue en réponse à une diminution dans la tension disponible ; et
ordonnent au générateur d'impulsions (101) de délivrer le signal de thérapie électrique à la valeur de paramètre de délivrance de signal identifiée en utilisant une tension au sein d'une marge de la tension disponible.

2. Le système (100) de la revendication 1, comprenant en outre un élément de délivrance de signal (110) couplé au générateur d'impulsions (101) afin de délivrer le signal de thérapie électrique à un patient (190).

3. Le système (100) de la revendication 1 dans lequel le processeur (107) et le générateur d'impulsions (101) sont logés dans un dispositif implantable dans un patient.

4. Le système (100) de la revendication 1 dans lequel le générateur d'impulsions (101) est logé dans un dispositif implantable dans un patient, et le processeur (107) est logé dans un dispositif externe.

5. Le système (100) de la revendication 1, comprenant en outre un support lisible par ordinateur couplé au processeur (107), et dans lequel les instructions sont portées par le support lisible par ordinateur.

6. Le système (100) de la revendication 1 dans lequel le générateur d'impulsions (101) est programmé avec des instructions pour délivrer le signal de thérapie électrique à une fréquence allant de 1,5 kHz à 100 kHz.

7. Le système (100) de la revendication 1 dans lequel le générateur d'impulsions (101) est programmé avec des instructions pour délivrer le signal de thérapie électrique à une largeur d'impulsion allant de 10 microsecondes à 333 microsecondes.

8. Le système (100) de la revendication 1 dans lequel le processeur (107) est programmé avec des instructions qui, lors de leur exécution :

reçoivent au moins une entrée correspondant à une amplitude de thérapie cible et une largeur d'impulsion cible ;
déterminent que la tension disponible est insuffisante pour délivrer le signal de thérapie électrique à l'amplitude de thérapie cible et à la largeur d'impulsion cible ;
identifient une amplitude de thérapie mise à jour inférieure à l'amplitude de thérapie cible ;

sur la base au moins en partie de l'amplitude de thérapie mise à jour et de la corrélation, identifient une largeur d'impulsion mise à jour plus grande que la largeur d'impulsion cible ; et
délivrent le signal de thérapie électrique au patient (190) à l'amplitude de thérapie mise à jour et à la largeur d'impulsion mise à jour.

9. Le système (100) de la revendication 1, comprenant :

un boîtier implantable portant le générateur d'impulsions (101) et le processeur (107) ;
un élément de délivrance de signal implantable (110) couplé au générateur d'impulsions (101) ;
une batterie portée au sein du boîtier et couplée au générateur d'impulsions (101) afin de fournir de la puissance pour le signal de thérapie électrique ; et dans lequel :

l'entrée correspond à une tension disponible en provenance de la batterie ; et
le paramètre de délivrance de signal est la largeur d'impulsion du signal électrique.

10. Le système (100) de la revendication 9 dans lequel le processeur (107) est programmé avec des instructions qui, lors de leur exécution :

reçoivent au moins une entrée correspondant à une amplitude de courant cible et une largeur d'impulsion cible ;
déterminent que la tension disponible est insuffisante pour fournir un signal de thérapie à l'amplitude de courant cible et à la largeur d'impulsion cible ;
déterminent une impédance d'un circuit par l'intermédiaire duquel le signal de thérapie électrique est délivré, le circuit incluant le patient (190) ;
sur la base au moins en partie de l'impédance et de la tension disponible, déterminent une amplitude de courant mise à jour inférieure à l'amplitude de courant cible ; et
sur la base de l'amplitude de courant mise à jour et de la corrélation, identifient une largeur d'impulsion mise à jour plus grande que la largeur d'impulsion cible.

11. Le système (100) de la revendication 9 dans lequel le générateur d'impulsions (101) est programmé avec des instructions pour délivrer le signal de thérapie électrique à une fréquence allant de 1,5 kHz à 100 kHz.

12. Le système (100) de la revendication 9 dans lequel le générateur d'impulsions (101) est programmé avec des instructions pour délivrer le signal de thérapie électrique à une largeur d'impulsion allant de 10 microsecondes à 333 microsecondes.

13. Le système (100) de la revendication 1, dans lequel la corrélation est une corrélation spécifique à un patient.

14. Le système (100) de la revendication 13 dans lequel la corrélation spécifique à un patient inclut des données en provenance d'autres patients.

15. Le système (100) de la revendication 8 dans lequel l'amplitude de thérapie mise à jour est identifiée sur la base au moins en partie de la tension disponible et d'une impédance d'un circuit par l'intermédiaire duquel le signal de thérapie électrique est délivré.

16. Le système (100) de la revendication 15 dans lequel les instructions, lors de leur exécution, déterminent l'impédance par :

la délivrance d'un signal de thérapie électrique à l'amplitude et à la largeur d'impulsion cibles ;
la détermination d'une tension dans l'ensemble du circuit ; et
la détermination de l'impédance sur la base de l'amplitude cible et de la tension dans l'ensemble du circuit.

17. Le système (100) de la revendication 1 dans lequel la valeur de paramètre de délivrance de signal identifiée inclut une valeur de cycle de service.

18. Le système (100) de la revendication 1 dans lequel la valeur de paramètre de délivrance de signal identifiée inclut une valeur de largeur d'impulsion.

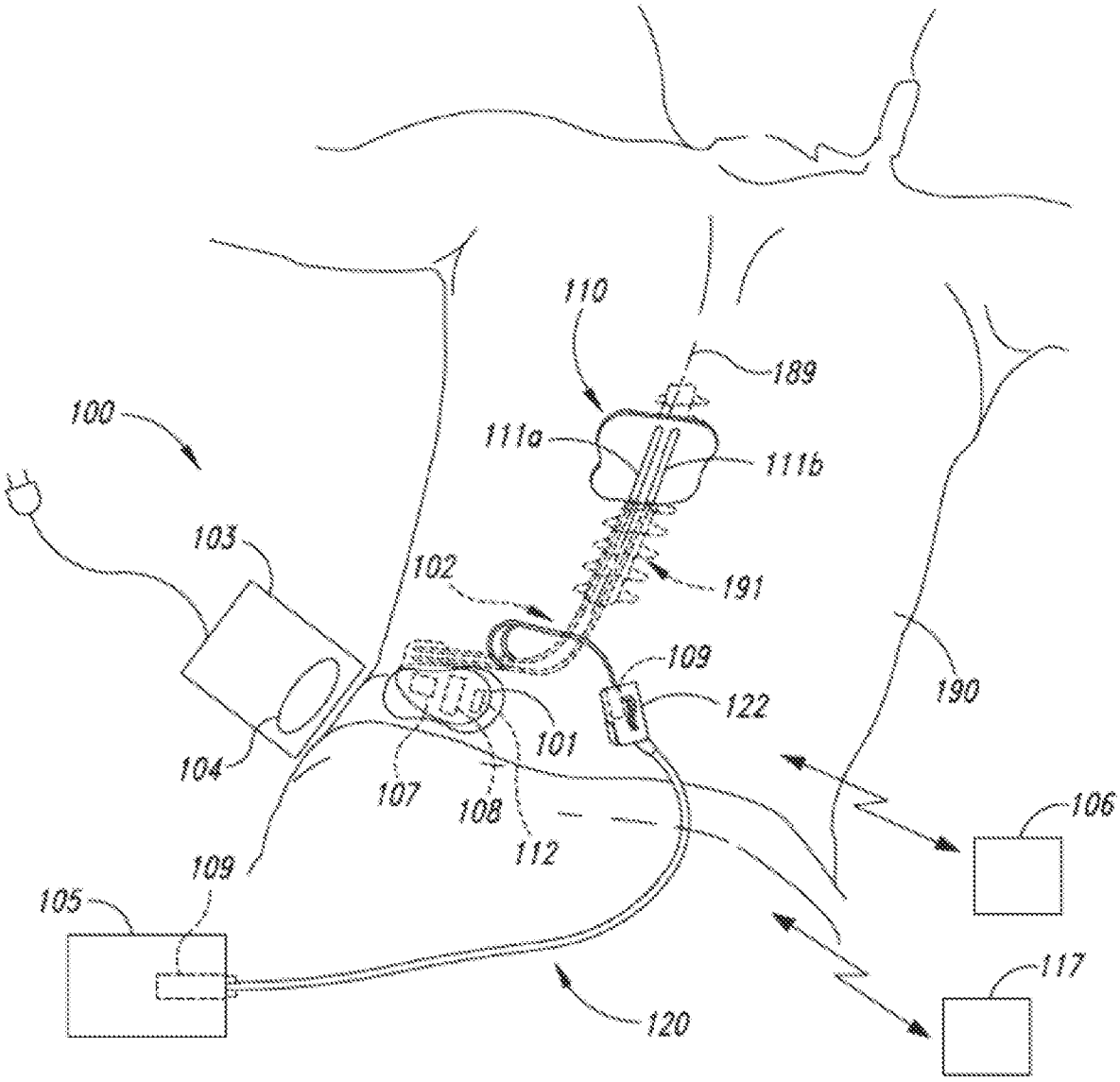
110
189
100
111a
111b
103
102
191
109
122
190
104
101
107
108
112
106
109
105
117
120

FIG. 1A

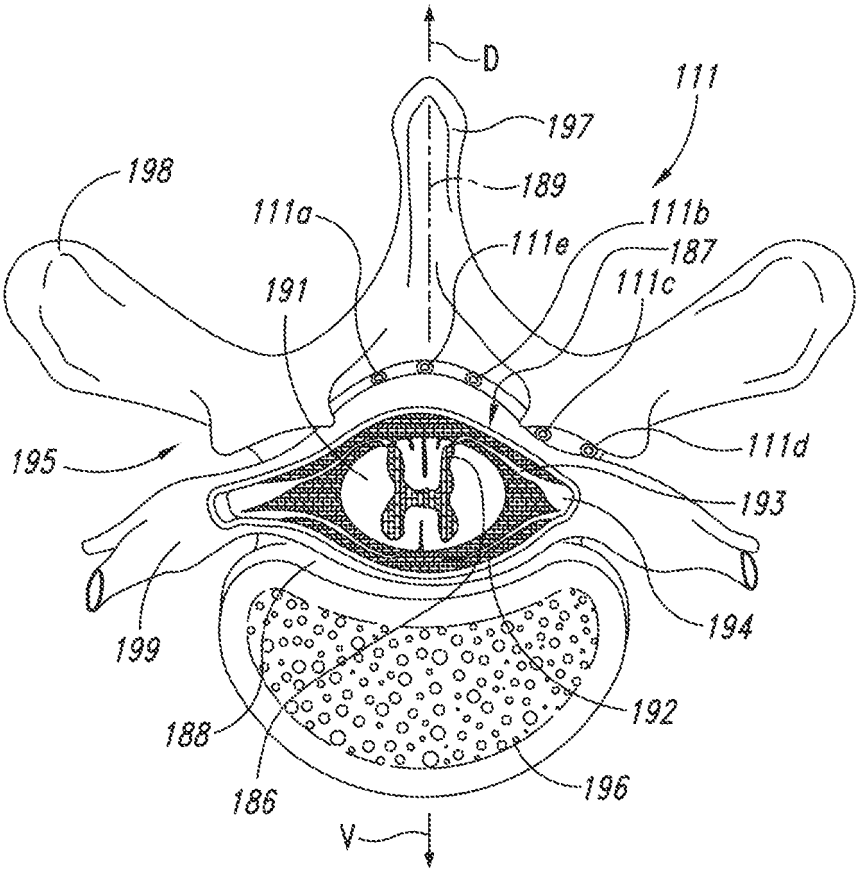
D
111
197
198
189
111a
111b
111e
187
191
111c
195
111d
193
194
199
192
188
196
186
V

FIG. 1B

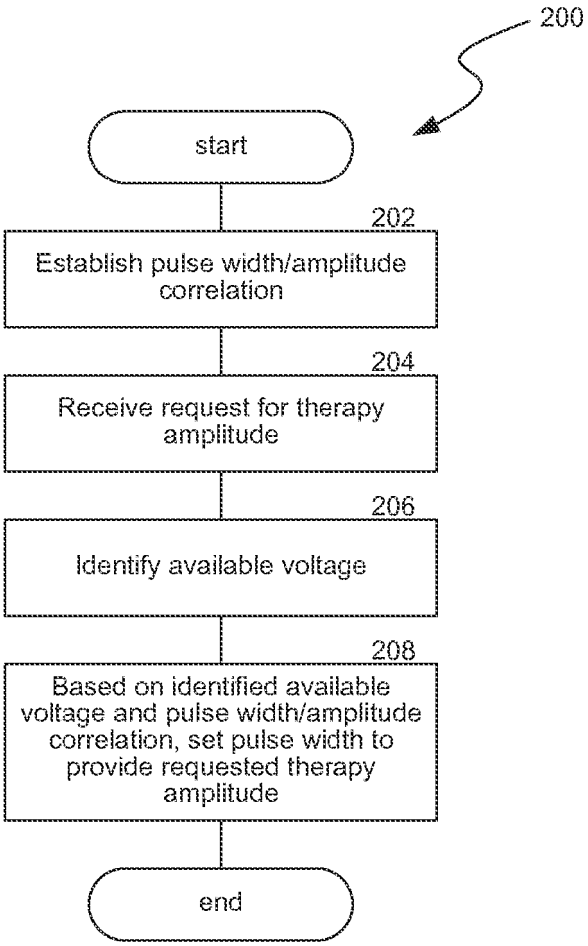
200
start
202
Establish pulse width/amplitude correlation
204
Receive request for therapy amplitude
206
Identify available voltage
208
Based on identified available voltage and pulse width/amplitude correlation, set pulse width to provide requested therapy amplitude
end

FIG. 2

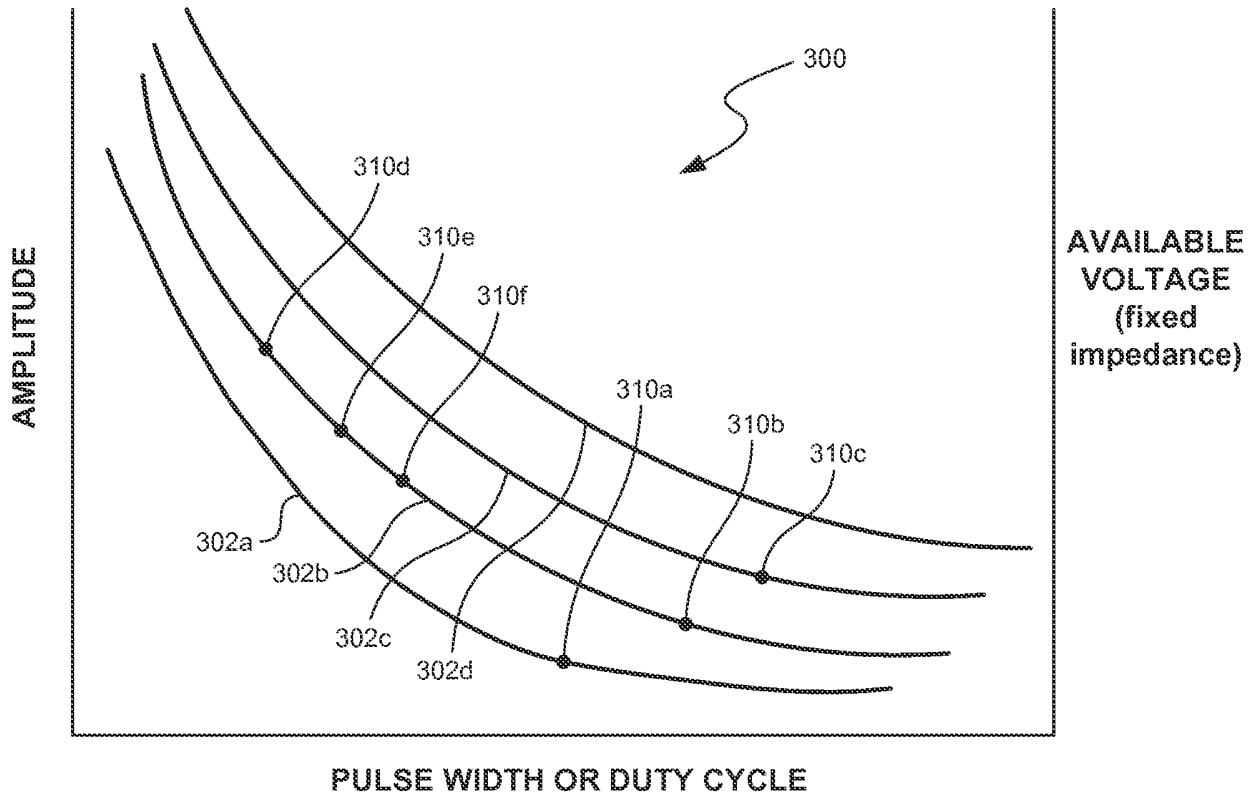
300
310d
310e
310f
310a
310b
310c
302a
302b
302c
302d
AMPLITUDE
AVAILABLE VOLTAGE (fixed impedance)
PULSE WIDTH OR DUTY CYCLE

FIG. 3

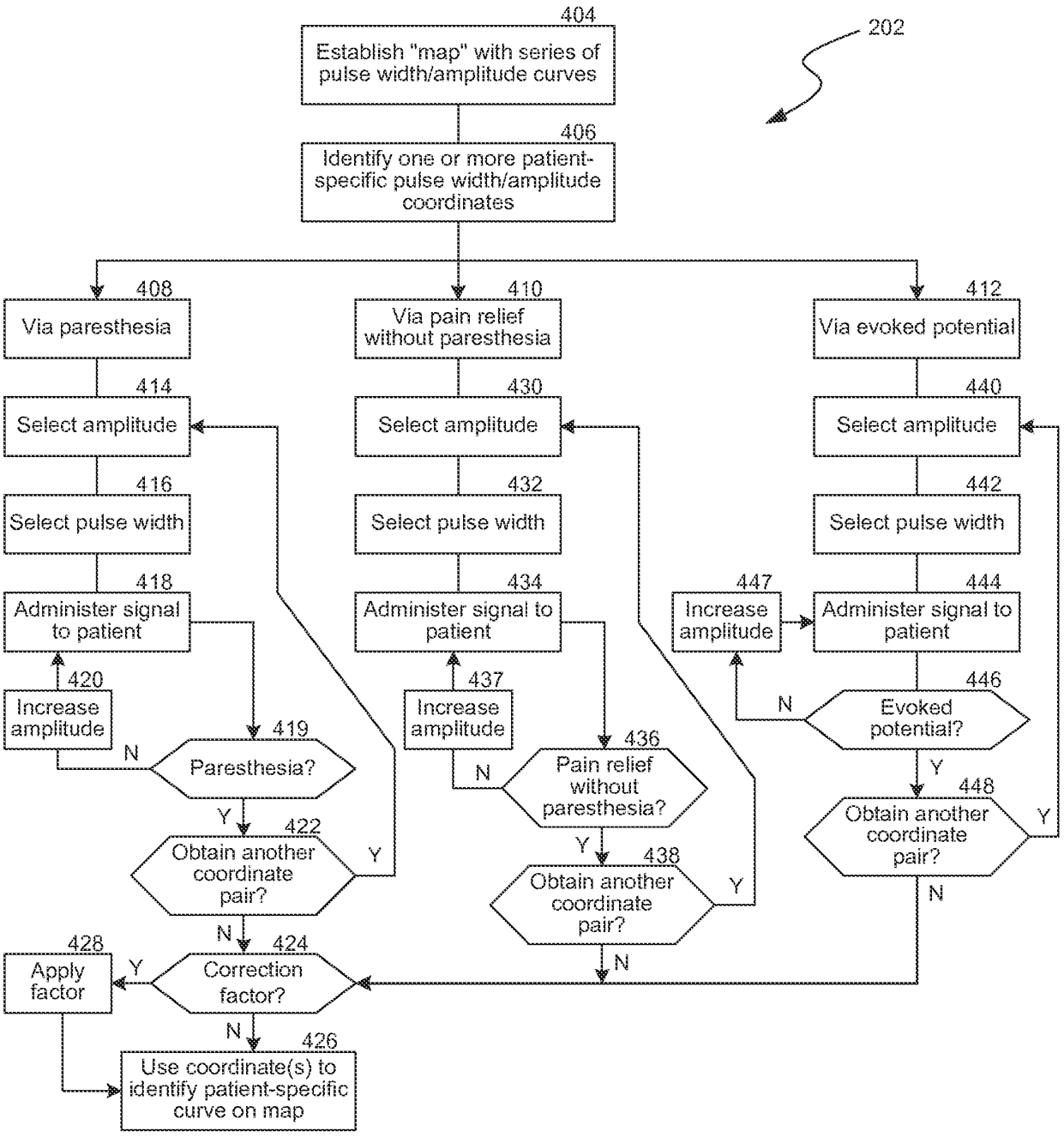
404
Establish "map" with series of pulse width/amplitude curves
202
406
Identify one or more patient-specific pulse width/amplitude coordinates
408
Via paresthesia
410
Via pain relief without paresthesia
412
Via evoked potential
414
Select amplitude
430
Select amplitude
440
Select amplitude
416
Select pulse width
432
Select pulse width
442
Select pulse width
418
Administer signal to patient
434
Administer signal to patient
447
Increase amplitude
444
Administer signal to patient
420
Increase amplitude
437
Increase amplitude
446
Evoked potential?
N
419
Paresthesia?
436
Pain relief without paresthesia?
Y
448
Obtain another coordinate pair?
Y
422
Obtain another coordinate pair?
Y
438
Obtain another coordinate pair?
Y
N
428
Apply factor
Y
424
Correction factor?
N
426
Use coordinate(s) to identify patient-specific curve on map

FIG. 4

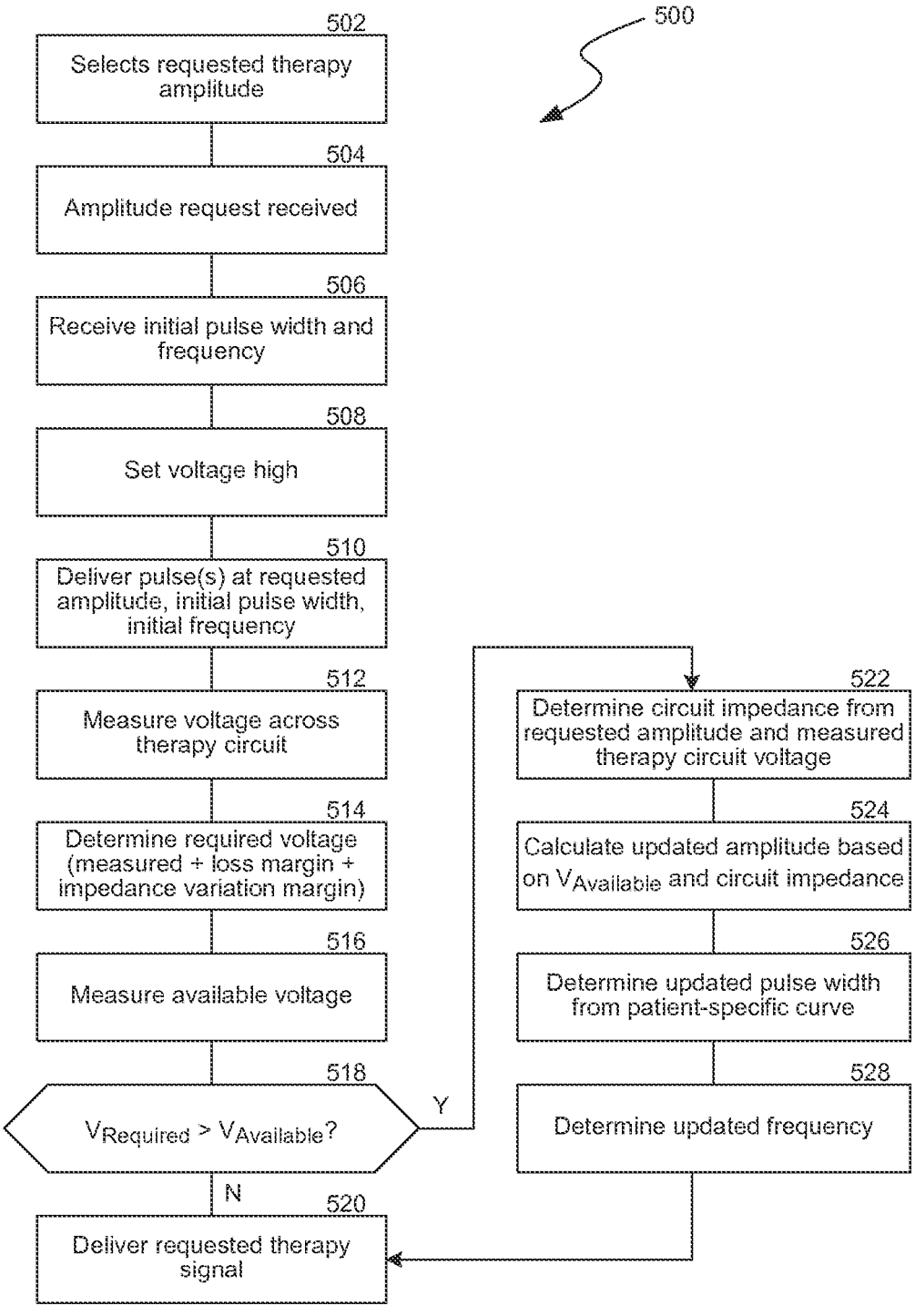
500
502
Selects requested therapy amplitude
504
Amplitude request received
506
Receive initial pulse width and frequency
508
Set voltage high
510
Deliver pulse(s) at requested amplitude, initial pulse width, initial frequency
512
Measure voltage across therapy circuit
514
Determine required voltage (measured + loss margin + impedance variation margin)
516
Measure available voltage
518
$V_{Required} > V_{Available}$?
Y
N
520
Deliver requested therapy signal
522
Determine circuit impedance from requested amplitude and measured therapy circuit voltage
524
Calculate updated amplitude based on $V_{Available}$ and circuit impedance
526
Determine updated pulse width from patient-specific curve
528
Determine updated frequency

FIG. 5

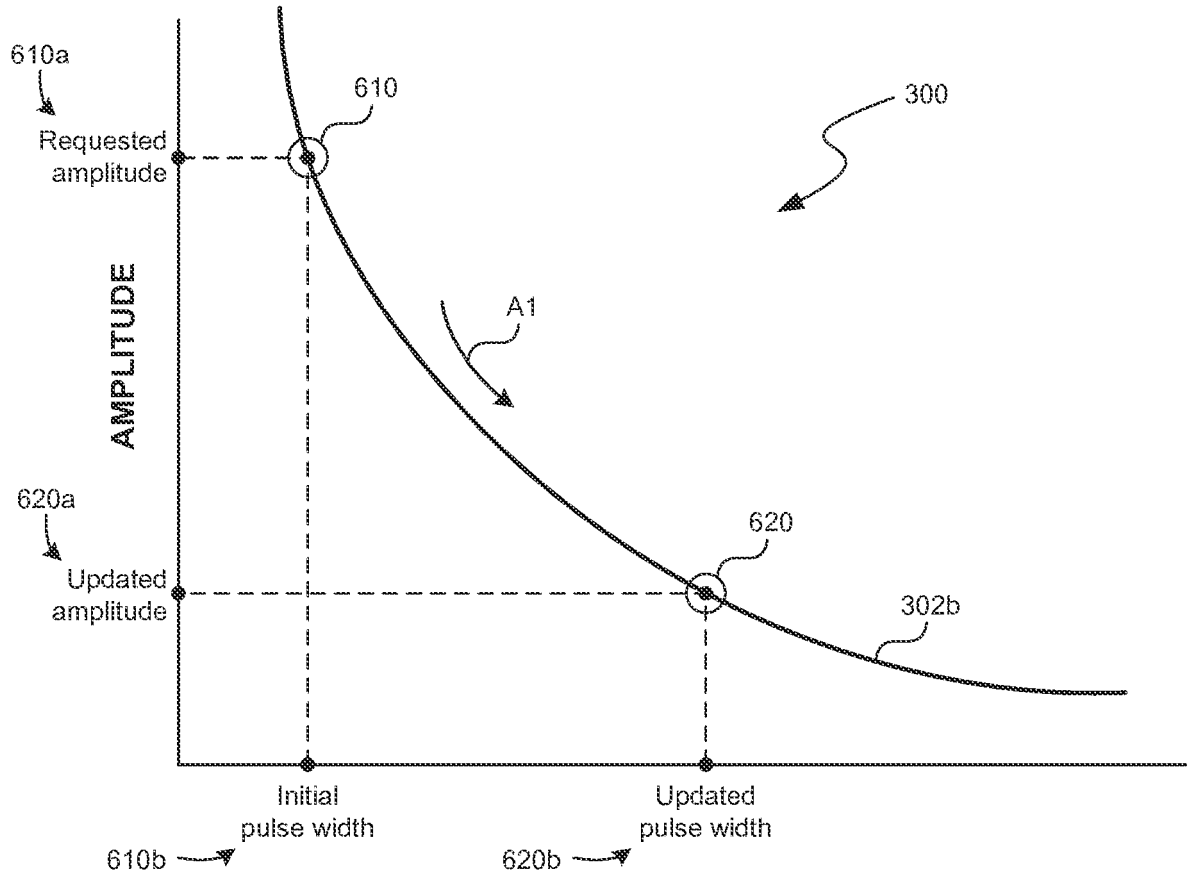
610a
Requested amplitude
610
300
AMPLITUDE
A1
620a
Updated amplitude
620
302b
Initial pulse width
610b
Updated pulse width
620b

FIG. 6

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 2009018607 A **[0005]**
- US 20090204173 A **[0009] [0019]**
- US 20100274314 A **[0009] [0019]**
- US 61901255 **[0009] [0045]**
- US 20130066411 **[0011]**
- US 8355797 B **[0013]**
- US 20110071593 **[0017]**
- US 20100274317 **[0019]**
- US 20130066411 A **[0019]**
- US 61833392 **[0046]**
- US 8224453 B, De Ridder **[0047]**
- US 8380318 B, Kishawi **[0047]**

Non-patent literature cited in the description

- **CROSSMAN ; NEARY.** Neuroanatomy. Churchill Livingstone, 1995 **[0020]**