



(51) International Patent Classification:
A61N 1/372 (2006.01)

(21) International Application Number:
PCT/US2018/064079

(22) International Filing Date:
05 December 2018 (05.12.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/599,546 15 December 2017 (15.12.2017) US

(71) Applicant: **BOSTON SCIENTIFIC NEUROMODULATION CORPORATION** [US/US]; 25155 Rye Canyon Loop, Valencia, CA 91355 (US).

(72) Inventors: **ZHANG, Tianhe**; 10900 Bluffside Dr, Apt. 316, Studio City, CA 91604 (US). **STEINKE, G., Karl**; 28160 McBean Parkway, #22306, Valencia, CA 91354 (US). **MCDONALD, Matthew, L.**; 808 Vallombrosa Drive, Pasadena, CA 91107 (US).

(74) Agent: **LEWIS, Terril**; Lewis & Reese, PLLC, 11625 Spring Cypress Rd., Suite A, Tomball, TX 77377 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,

(54) Title: USE OF CHARGE IMBALANCED PULSES IN AN IMPLANTABLE STIMULATOR TO EFFECT A PSEUDO-CONSTANT DC CURRENT BIAS

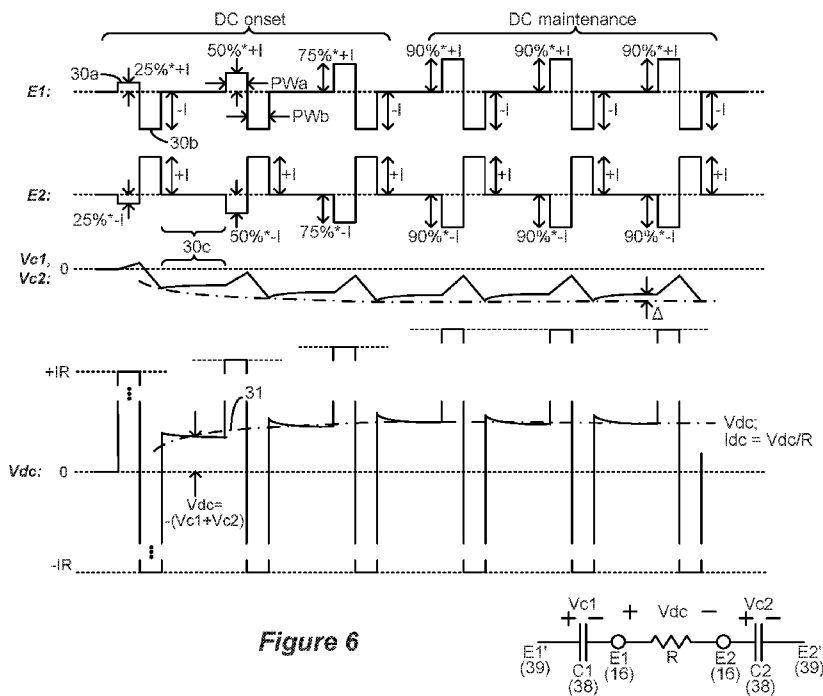


Figure 6

(57) Abstract: Techniques are described for providing a therapeutic pseudo-constant DC current in an implantable stimulator using pulses whose positive and negative phases are not charge balanced. Such charge imbalanced pulses act to charge any capacitance in the current path between selected electrode nodes, such as the DC-blocking capacitors and/or any inherent capacitance such as those present at the electrode/tissue interface. These charged capacitances act during quiet periods between the pulses to induce a pseudo-constant DC current. Beneficially, these DC currents can be small enough to stay within charge density limits and hence not corrode the electrode or cause tissue damage, and further can be controlled to stay within such limits or for other reasons. Graphical user interface (GUI) aspects for generating the charge imbalanced pulses and for determining and/or controlling the pseudo-constant DC current are also provided.



SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Declarations under Rule 4.17:

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

Published:

- *with international search report (Art. 21(3))*

Use of Charge Imbalanced Pulses in an Implantable Stimulator to Effect a Pseudo-Constant DC Current Bias

FIELD OF THE INVENTION

[001] This application relates to Implantable Medical Devices (IMDs), and more specifically to techniques for creating a DC current in implantable neurostimulation systems.

INTRODUCTION

[002] 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. Patent 6,516,227. However, the present invention may find applicability with any implantable neurostimulator device system.

[003] An SCS system typically includes an Implantable Pulse Generator (IPG) 10 shown in Figure 1. The IPG 10 includes a biocompatible device case 12 that holds the IPG's circuitry and a battery 14 for providing power for the IPG to function. The IPG 10 is coupled to tissue-stimulating electrodes 16 via one or more electrode leads that form an electrode array 17. For example, one or more percutaneous leads 15 can be used having ring-shaped or split-ring electrodes 16 carried on a flexible body 18. In another example, a paddle lead 19 provides electrodes 16 positioned on one of its generally flat surfaces. Lead wires 20 within the leads are coupled to proximal contacts 21, which are insertable into lead connectors 22 fixed in a header 23 on the IPG 10, which header can comprise an epoxy for example. Once inserted, the proximal contacts 21 connect to header contacts 24 within the lead connectors 22, which are in turn coupled by feedthrough pins 25 through a case feedthrough 26 to stimulation circuitry 28 within the case 12, which stimulation circuitry 28 is described below.

[004] In the illustrated IPG 10, there are thirty-two electrodes (E1-E32), split between four percutaneous leads 15, or contained on a single paddle lead 19, and thus the

header 23 may include a 2x2 array of eight-electrode lead connectors 22. However, the type and number of leads, and the number of 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 lead(s) are typically implanted in the spinal column proximate to the dura in a patient's spinal cord, preferably spanning left and right of the patient's spinal column. The proximal contacts 21 are then tunneled through the patient's tissue to a distant location such as the buttocks where the IPG case 12 is implanted, where they are coupled to the lead connectors 22. 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 10 for contacting the patient's tissue. The IPG lead(s) can be integrated with and permanently connected to the IPG 10 in other solutions. The goal of SCS therapy is to provide electrical stimulation from the electrodes 16 to alleviate a patient's symptoms, such as chronic back pain.

[005] IPG 10 can include an antenna 27a allowing it to communicate bi-directionally with a number of external devices discussed subsequently. Antenna 27a as shown comprises a conductive coil within the case 12, although the coil antenna 27a can also appear in the header 23. When antenna 27a is configured as a coil, communication with external devices preferably occurs using near-field magnetic induction. IPG 10 may also include a Radio-Frequency (RF) antenna 27b. RF antenna 27b is shown within the header 23, but it may also be within the case 12. RF antenna 27b may comprise a patch, slot, or wire, and may operate as a monopole or dipole. RF antenna 27b preferably communicates using far-field electromagnetic waves, and may operate in accordance with any number of known RF communication standards, such as Bluetooth, Zigbee, WiFi, MICS, and the like.

[006] Stimulation in IPG 10 is typically provided by a sequence of pulses (or waveforms more generally) each of which may include a number of phases such as 30a and 30b, as shown in the example of Figure 2A. Stimulation parameters typically include amplitude (current I, although a voltage amplitude V can also be used); frequency (F); pulse width (PW) of the pulses or of its individual phases such as 30a and 30b; the electrodes 16 selected to provide the stimulation; and the polarity of such selected electrodes, i.e., whether they act as anodes that source current to the tissue or cathodes that sink current from the tissue. These and possibly other stimulation parameters taken together comprise a stimulation program that the stimulation circuitry 28 in the IPG 10 can execute to provide therapeutic stimulation to a patient.

[007] In the example of Figure 2A, electrode E1 has been selected as an anode

(during first pulse phases 30a), and thus provides pulses which source a positive current of amplitude $+I$ to the tissue. Electrode E2 has been selected as a cathode (again during first phases 30a), and thus provides pulses which sink a corresponding negative current of amplitude $-I$ from the tissue. This is an example of bipolar stimulation, in which only lead-based electrodes are used to provide stimulation to the tissue (one anode, one cathode). However, more than one electrode may be selected to act as an anode at a given time, and more than one electrode may be selected to act as a cathode at a given time.

[008] IPG 10 as mentioned includes stimulation circuitry 28 to form prescribed stimulation at a patient's tissue. Figure 3 shows an example of stimulation circuitry 28, which includes one or more current sources 40 and one or more current sinks 42. The sources and sinks 40 and 42 can comprise Digital-to-Analog converters (DACs), and may be referred to as PDACs 40 and NDACs 42 in accordance with the Positive (anodic) and Negative (cathodic) currents they respectively issue. The sourced and sunk current from one or more selected PDACs 40 or NDACs 42 are respectively directed in this example by switch matrices 44 and 46 to selected electrode nodes E_i' 39 coupled to the electrodes E_i 16. Although not shown, the DACs 40 and 42 and switch matrices 44 and 46 receive digital information regarding the stimulation parameters to form the stimulation at selected electrodes with the correct amplitude and timing. The stimulation circuitry 28 in this example also supports selection of the conductive case 12 as an electrode (E_c 12), which case electrode is typically selected for monopolar stimulation. DACs 40 and 42 can also comprise voltage sources.

[009] Proper control of the DACs 40 and 42 and the switching matrices 44 and 46 allows any of the electrodes 16 to act as anodes or cathodes to create a current through a patient's tissue, R, hopefully with beneficial therapeutic effect. In the example shown, PDAC 40₂ is selected to source a current of amplitude I to electrode node E_1' and to anode electrode E_1 via switch matrix 44, while NDAC 42₁ is selected to sink a current of amplitude I from electrode node E_2' and cathode electrode E_2 via switching matrix 46. Other PDACs 40 and NDACs 42, or one of more of each, could also have been selected to produce $+I$ at E_1 and $-I$ at E_2 . Power for the stimulation circuitry 28 is provided by a compliance voltage V_H , as described in further detail in U.S. Patent Application Publication 2013/0289665. More than one anode electrode and more than one cathode electrode may be selected at one time, and thus current can flow through the tissue R between two or more of the electrodes 16.

[0010] Other stimulation circuitries 28 can also be used in the IPG 10. For example, in an example not using switching matrices, each electrode node E_i' 39 can be hardwired to a

dedicated PDAC 40i and a dedicated NDAC 42i, such as is disclosed in USP 6,181,969 for example. In another example, the PDACs 40 and NDACs 42 may provide currents of fixed amplitudes, with multiple of these DACs being selected by the switching matrices 44 and 46 to provide a sum of their currents at a selected electrode node, such as described in U.S. Patent Application Publications 2007/0038250 and 2007/0100399.

[0011] Much of the stimulation circuitry 28 of Figure 3, including the DACs 40 and 42, the switch matrices 44 and 46, and the electrode nodes E_i 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 telemetry antennas 27a and/or 27b), circuitry for generating the compliance voltage V_H , various measurement circuits, etc.

[0012] Also shown in Figure 3 are DC-blocking capacitors C_i 38, which are placed in series in the current paths between each of the electrode nodes E_i 39 and the electrodes E_i 16/case electrode E_c 12. The DC-blocking capacitors 38 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. The DC-blocking capacitors 38 are typically provided off-chip (off of the ASIC(s)), and instead may be provided in or on a circuit board in the IPG 10 used to integrate its various components, as explained in U.S. Patent Application Publication 2015/0157861.

[0013] Referring again to Figure 2A, the stimulation pulses as shown are biphasic, with each pulse comprising a first phase 30a followed thereafter by a second phase 30b of opposite polarity. (Although not shown, an interphase period during which no active current is driven may intervene between the phases 30a and 30b). Biphasic pulses are useful to actively recover any charge that might be stored on capacitive elements in the current path, such as on the DC-blocking capacitors 38. Charge recovery is shown with reference to both Figures 2A and 2B. During the first pulse phases 30a, charge will build up across the DC-blocking capacitors C_1 and C_2 associated with the electrodes E_1 and E_2 selected to produce the current, giving rise to voltages V_{c1} and V_{c2} . Given the definition of these voltages in Figure 2B, they are of the same polarity as shown in Figure 2A. During the second pulse phases 30b, when the polarity of the current I is reversed at the selected electrodes E_1 and E_2 , the stored charge on capacitors C_1 and C_2 is recovered, and thus voltages V_{c1} and V_{c2} return to 0V at the end the second pulse phase 30b.

[0014] To recover all charge by the end of the second pulse phase 30b of each pulse

($V_{c1} = V_{c2} = 0V$), the first and second phases 30a and 30b are charged balanced. In the example shown, such charge balancing is achieved by using the same pulse width ($PW_a = PW_b$) and the same amplitude ($|+I| = |-I|$) for each of the pulse phases 30a and 30b. However, the pulse phases 30a and 30b may also be charged balance if the product of the amplitude and pulse width of each phase is equal, as is known.

[0015] Figure 4 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 electrode arrays 17' (e.g., one or more trial percutaneous leads 15 or trial paddle leads 19) are implanted in the patient's tissue at a target location 52, such as within the spinal column as explained earlier. The proximal ends of the trial electrode array(s) 17' exit an incision 54 and are connected to an External Trial Stimulator (ETS) 50. The ETS 50 generally mimics operation of the IPG 10, and thus can provide stimulation to the patient's tissue as explained above. See, e.g., 9,259,574, disclosing a design for an ETS. The ETS 50 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 hopefully find a stimulation program that alleviates the patient's symptoms (e.g., pain). If external trial stimulation proves successful, the trial electrode array(s) 17' are explanted, and a full IPG 10 and a permanent electrode array 17 (e.g., one or more percutaneous 15 or paddle 19 leads) are implanted as described above; if unsuccessful, the trial electrode array(s) 17' are simply explanted.

[0016] Like the IPG 10, the ETS 50 can include one or more antennas to enable bi-directional communications with external devices such as those shown in Figure 5. Such antennas can include a near-field magnetic-induction coil antenna 56a, and/or a far-field RF antenna 56b, as described earlier. ETS 50 may also include stimulation circuitry 58 (Fig. 4) able to form stimulation 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 50 may also include a battery (not shown) for operational power.

[0017] Figure 5 shows various external devices that can wirelessly communicate data with the IPG 10 and the ETS 50, including a patient hand-held external controller 60, and a clinician programmer 70. Both of devices 60 and 70 can be used to wirelessly transmit a stimulation program to the IPG 10 or ETS 50—that is, to program their stimulation circuitries 28 and 58 to produce stimulation with a desired amplitude and timing described earlier. Both devices 60 and 70 may also be used to adjust one or more stimulation parameters of a

stimulation program that the IPG 10 or ETS 50 is currently executing. Devices 60 and 70 may also wirelessly receive information from the IPG 10 or ETS 50, such as various status information, etc.

[0018] External controller 60 can be as described in U.S. Patent Application Publication 2015/0080982 for example, and may comprise a controller dedicated to work with the IPG 10 or ETS 50. External controller 60 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 50, as described in U.S. Patent Application Publication 2015/0231402. External controller 60 includes a Graphical User Interface (GUI), preferably including means for entering commands (e.g., buttons or selectable graphical icons) and a display 62. The external controller 60's GUI enables a patient to adjust stimulation parameters, although it may have limited functionality when compared to the more-powerful clinician programmer 70, described shortly.

[0019] The external controller 60 can have one or more antennas capable of communicating with the IPG 10 and ETS 50. For example, the external controller 60 can have a near-field magnetic-induction coil antenna 64a capable of wirelessly communicating with the coil antenna 27a or 56a in the IPG 10 or ETS 50. The external controller 60 can also have a far-field RF antenna 64b capable of wirelessly communicating with the RF antenna 27b or 56b in the IPG 10 or ETS 50.

[0020] Clinician programmer 70 is described further in U.S. Patent Application Publication 2015/0360038, and can comprise a computing device 72, 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 Figure 5, computing device 72 is shown as a laptop computer that includes typical computer user interface means such as a screen 74, a mouse, a keyboard, speakers, a stylus, a printer, etc., not all of which are shown for convenience. Also shown in Figure 5 are accessory devices for the clinician programmer 70 that are usually specific to its operation as a stimulation controller, such as a communication "wand" 76 coupleable to suitable ports on the computing device 72, such as USB ports 79 for example.

[0021] The antenna used in the clinician programmer 70 to communicate with the IPG 10 or ETS 50 can depend on the type of antennas included in those devices. If the patient's IPG 10 or ETS 50 includes a coil antenna 27a or 56a, wand 76 can likewise include a coil antenna 80a to establish near-field magnetic-induction communications at small

distances. In this instance, the wand 76 may be affixed in close proximity to the patient, such as by placing the wand 76 in a belt or holster wearable by the patient and proximate to the patient's IPG 10 or ETS 50. If the IPG 10 or ETS 50 includes an RF antenna 27b or 56b, the wand 76, the computing device 72, or both, can likewise include an RF antenna 80b to establish communication with the IPG 10 or ETS 50 at larger distances. The clinician programmer 70 can also communicate with other devices and networks, such as the Internet, either wirelessly or via a wired link provided at an Ethernet or network port.

[0022] To program stimulation programs or parameters for the IPG 10 or ETS 50, the clinician interfaces with a clinician programmer GUI 82 provided on the display 74 of the computing device 72. As one skilled in the art understands, the GUI 82 can be rendered by execution of clinician programmer software 84 stored in the computing device 72, which software may be stored in the device's non-volatile memory 86. Execution of the clinician programmer software 84 in the computing device 72 can be facilitated by control circuitry 88 such as one or more microprocessors, microcomputers, FPGAs, DSPs, other digital logic structures, etc., which are capable of executing programs in a computing device, and which may comprise their own memories. In one example, control circuitry 88 may comprise an i5 processor manufactured by Intel Corp., as described at <https://www.intel.com/content/www/us/en/products/processors/core/i5-processors.html>. Such control circuitry 88, in addition to executing the clinician programmer software 84 and rendering the GUI 82, can also enable communications via antennas 80a or 80b to communicate stimulation parameters chosen through the GUI 82 to the patient's IPG 10 or ETS 50.

[0023] The GUI of the external controller 60 may provide similar functionality because the external controller 60 can include the same hardware and software programming as the clinician programmer. For example, the external controller 60 includes control circuitry 66 similar to the control circuitry 88 in the clinician programmer 70, and may similarly be programmed with external controller software stored in device memory.

SUMMARY

[0024] In a first example, a system is disclosed, which may comprise: an external device configured to program an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, wherein the external device comprises control circuitry configured to: generate a graphical user interface (GUI) at the external device; receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises

a positive phase and a negative phase, wherein one of the parameters comprises a charge imbalance parameter that sets a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms; and transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms.

[0025] The plurality of parameters may comprise at least one of: an amplitude of at least one waveform in the sequence of waveforms, a pulse width of at least one waveform in the sequence of waveforms, a pulse width of the positive phase or the negative phase of at least one waveform in the sequence of sequence of waveforms, or a frequency at which waveforms are provided in the sequence of waveforms. The control circuitry may be further configured to receive, via the GUI, selection of the at least two electrodes. In the defined sequence of waveforms, a total anodic current sourced to at least one of the at least two electrodes may equal a total cathodic current sunk to at least one of the at least two electrodes.

[0026] The charge imbalance parameter may comprise a difference between the positive phase and the negative phase of the at least one waveform. The difference may comprise a difference in amplitude, a difference in pulse width, or a difference in charge. The difference may be expressed as a ratio, a percentage, or a differential. The charge imbalance parameter may set a charge imbalance between the positive phase and the negative phase of each waveform in the sequence of waveforms.

[0027] The control circuitry may be further configured to use the plurality of parameters to determine a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence of waveforms. The GUI may be configured to display the determined pseudo-constant DC current, DC voltage or DC current density. The control circuitry may also be further configured to receive, via the GUI, an input specifying a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence of waveforms. The control circuitry may be further configured to determine the charge imbalance parameter based on the specified pseudo-constant DC current, DC voltage or DC current density.

[0028] In a second example, a non-transitory computer readable media is disclosed which may comprise instructions executable on an external device for programming an implantable stimulator device, wherein the implantable stimulator device comprises a

plurality of electrodes configured to contact a patient's tissue, wherein the instructions when executed are configured to enable control circuitry in the external device to: generate a graphical user interface (GUI) at the external device; and receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase, wherein one of the parameters comprises a charge imbalance parameter that sets a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms.

[0029] The instructions when executed may be further configured to enable control circuitry in the external device to: transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms. The non-transitory computer readable media may further comprise instructions for any of the concepts mentioned in the first example.

[0030] In a third example, a method is disclosed for programming an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, which method may comprise: using a graphical user interface (GUI) of an external device to define a sequence of waveforms to be provided at at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase; using the GUI to further set a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms; and transmitting information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms.

[0031] The GUI may be used to set the charge imbalance by selecting a charge imbalance parameter provided by the GUI. The charge imbalance parameter may comprise a difference between the positive phase and the negative phase of the at least one waveform. The difference may comprise a difference in amplitude, a difference in pulse width, or a difference in charge. The difference may be expressed as a ratio, a percentage, or a differential. The GUI may be used to set a charge imbalance between the positive phase and the negative phase of each waveform in the sequence of waveforms.

[0032] In the defined sequence of waveforms, a total anodic current sourced to at least one of the at least two electrodes may equal a total cathodic current sunk to at least one of the at least two electrodes at any point in time.

[0033] The method may further comprise determining in the external device a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence using at least the charge imbalance. The determined pseudo-constant DC current, DC voltage or DC current density may be displayed using the GUI.

[0034] In a fourth example, a system is disclosed, which may comprise: an external device configured to program an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, wherein the external device comprises control circuitry configured to: generate a graphical user interface (GUI) at the external device; receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase, wherein one of the parameters comprises of a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence; determine a charge imbalance parameter that adjusts a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms using the plurality of parameters; and transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms as adjusted by the charge imbalance parameter.

[0035] In the defined sequence of waveforms as adjusted by the charge imbalance parameter, a total anodic current sourced to at least one of the at least two electrodes may equal a total cathodic current sunk to at least one of the at least two electrodes at any point in time.

[0036] The plurality of parameters may comprise at least one of: an amplitude of at least one waveform in the sequence of waveforms, a pulse width of at least one waveform in the sequence of waveforms, a pulse width of the positive phase or the negative phase of at least one waveform in the sequence of sequence of waveforms, or a frequency at which waveforms are provided in the sequence of waveforms.

[0037] The control circuitry may be configured to determine the charge imbalance parameter that adjusts the charge imbalance of each waveform in the sequence of waveforms. The control circuitry may be further configured to display the determined charge imbalance parameter in the GUI.

[0038] In a fifth example, a non-transitory computer readable media is disclosed

which may comprise instructions executable on an external device for programming an implantable stimulator device, wherein the implantable stimulator device comprises a plurality of electrodes configured to contact a patient's tissue, wherein the instructions when executed are configured to enable control circuitry in the external device to: generate a graphical user interface (GUI) at the external device; receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase, wherein one of the parameters comprises of a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence; and determine a charge imbalance parameter that adjusts a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms using the plurality of parameters.

[0039] The instructions when executed may be further configured to enable control circuitry in the external device to: transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms as adjusted by the charge imbalance parameter. The non-transitory computer readable media may further comprise instructions for any of the concepts mentioned in the fourth example.

[0040] In a sixth example, a method is disclosed for programming an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, which method may comprise: using an graphical user interface (GUI) of an external device to define a sequence of waveforms to be provided at at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase; using the GUI to further specify a pseudo-constant DC current, DC voltage or DC current density that will form between the at least two electrodes during quiet periods between waveforms in the sequence; determine at the external device a charge imbalance parameter that adjusts a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms using at least the pseudo-constant DC current, DC voltage or DC current density; and transmitting information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms as adjusted by the charge imbalance parameter.

[0041] The charge imbalance parameter may comprise a difference between the

positive phase and the negative phase of the at least one waveform. The difference may comprise a difference in amplitude, a difference in pulse width, or a difference in charge. The difference may be expressed as a ratio, a percentage, or a differential.

[0042] In the defined sequence of waveforms as adjusted by the charge imbalance parameter, a total anodic current sourced to at least one of the at least two electrodes may equal a total cathodic current sunk to at least one of the at least two electrodes at any point in time.

[0043] The method may further comprise displaying the determined charge imbalance parameter using the GUI. The charge imbalance parameter may be determined using at least one other parameter comprising an amplitude of at least one waveform in the sequence of waveforms, a pulse width of at least one waveform in the sequence of waveforms, a pulse width of the positive phase or the negative phase of at least one waveform in the sequence of waveforms, or a frequency at which waveforms are provided in the sequence of waveforms.

[0044] In all of these examples, the implantable stimulator device may comprise a fully-implantable stimulator device. The implantable stimulator device may also comprise a conductive case, wherein one of the at least two electrodes comprises the conductive case. The implantable stimulator device may also comprise at least one lead that comprises the plurality of electrodes. The implantable stimulator device may also comprise an external stimulator, wherein the plurality of electrodes are implantable in a patient. The implantable stimulator device may also further comprise decoupling capacitors in series with the at least two electrodes. All of these examples may further include the implantable stimulator device itself.

BRIEF DESCRIPTION OF THE DRAWINGS

[0045] Figure 1 shows an Implantable Pulse Generator (IPG), in accordance with the prior art.

[0046] Figures 2A and 2B show an example of stimulation pulses (waveforms) producible by the IPG or in an External Trial Stimulator (ETS), in accordance with the prior art.

[0047] Figure 3 shows stimulation circuitry useable in the IPG or ETS, in accordance with the prior art.

[0048] Figure 4 shows an ETS environment useable to provide stimulation before implantation of an IPG, in accordance with the prior art.

[0049] Figure 5 shows various external devices capable of communicating with and programming stimulation in an IPG and ETS, in accordance with the prior art.

[0050] Figure 6 shows an example of using charge imbalanced pulses to create a pseudo-constant DC current (I_{dc}) in a patient's tissue during quiet periods between the pulses, in which the pulses are amplitude imbalanced.

[0051] Figure 7 shows an example of using charge imbalanced pulses to create I_{dc} in a patient's tissue during quiet periods between the pulses, in which the pulses are pulse width imbalanced.

[0052] Figures 8A-8E show different examples of charge imbalanced pulses.

[0053] Figure 9 shows an example of using charge imbalanced pulses to create I_{dc} in a patient's tissue during quiet periods between the pulses, in which only some but not all pulses are charge imbalanced.

[0054] Figure 10 shows how the charge imbalanced pulses can be manipulated to cause I_{dc} to flow in different directions between selected electrodes.

[0055] Figure 11 shows passive charge recovery circuitry that has the potential to interfere with I_{dc} generation, and which can be at least partially disabled.

[0056] Figure 12 shows monophasic charge imbalanced pulses useable to generate I_{dc} in a patient's tissue.

[0057] Figure 13 shows the use of inherent capacitance in the current path between active electrodes useful in generating I_{dc} .

[0058] Figure 14 shows a Graphical User Interface (GUI) operable in an external device and useable to define charge imbalanced pulses to create and control I_{dc} in a patient's tissue during quiet periods between the pulses.

[0059] Figures 15A-15D show charge imbalanced pulses formed using various options provided by the GUI of Figure 14.

[0060] Figure 16 shows further aspect of the GUI of Figure 14, and shows a DC algorithm useful to determine or control I_{dc} and related parameters.

DETAILED DESCRIPTION

[0061] As discussed in the Introduction, DC-blocking capacitors 38 (Fig. 3) are preferably located in current paths between the electrode nodes 39 and the actual electrodes 16 that contact a patient's tissue. These capacitors 38 provide safety by blocking the flow of DC currents to the tissue, and instead only allow the AC current to pass, such as are provided by time-varying pulses.

[0062] Nonetheless, there can be therapeutic benefits to providing a DC current to a patient's tissue. Direct current (DC) current stimulation has emerged as a neuromodulation paradigm having the capability to produce neurologically favorable effects such as symptom relief from neuropsychiatric disorders and neural enhancement. DC current stimulation is also hypothesized to cause specific neurological effects, including but not limited to neuron polarization, changes in synaptic efficacy, or even DC conduction block. See, e.g., M. Bikson et al., "Effects of Uniform Extracellular DC Electric Fields on Excitability in Rat Hippocampal Slices In Vitro," *J. Physiology* 557.1, pp. 175-190 (2004); A. Rahman et al., "Cellular Effects of Acute Direct Current Stimulation: Somatic and Synaptic Terminal Effects," *J. Physiology*, 591.10, pp. 2563-2578 (2013); and K.L. Kilgore et al., "Nerve Conduction Block Utilising High-Frequency Alternating Current," *Medical & Biological Eng'g & Computing*, Vol. 42, pp. 394-406 (2004).

[0063] However, the inventors notice problems to implementing DC current stimulation in an IPG or ETS. First, DC current stimulation alone over long periods of time without any AC variation has the potential to erode and corrode the electrodes 16 (typically platinum and/or iridium) used to deliver the stimulation, and can cause tissue damage, especially if current densities exceed about $50 \mu\text{C}/\text{cm}^2$ at the surface of the electrode. See, e.g., D.R. Merrill et al., "Electrical Stimulation of Excitable Tissue: Design of Efficacious and Safe Protocols," *J. Neuroscience Methods*, 141:171-98 (2005); and R.V. Shannon, "A Model of Safe Levels for Electrical Stimulation.," *IEEE Trans. on Biomedical Eng'g*, Vol. 39, pp. 424-26 (1992).

[0064] Second, and as just discussed, DC-blocking capacitors 38 (Fig. 3) are often provided in the current paths of an IPG or ETS. While use of DC-blocking capacitors 38 promotes safety, DC-blocking capacitors inhibit using stimulation circuitry such as 38 to actively drive a DC current because they would block any DC current, or any DC current offset, that the stimulation circuitry 38 might seek to provide.

[0065] This is addressed in the present disclosure by providing pulses whose positive and negative phases are not charge balanced. Such charge imbalanced pulses act to charge any capacitances in the current path between electrode nodes selected for stimulation, including the DC-blocking capacitors and/or any inherent capacitances such as those present at the electrode/tissue interface or in the tissue itself. These charged capacitance(s) act during quiet periods between the actively-driven charge imbalanced pulses to induce a pseudo-constant DC current, I_{dc} . Beneficially, these DC currents can be small enough to stay within charge density limits and hence not corrode electrodes or cause tissue damage, and further

can be controlled to stay within such limits or for other therapeutic reasons. Graphical user interface (GUI) aspects for generating the charge imbalanced pulses and for determining and/or controlling the pseudo-constant DC current are also disclosed.

[0066] A first example of the use of charge imbalanced pulses to create a pseudo-constant therapeutic DC current in a patient's tissue is shown in Figure 6. As will be shown below, this pseudo-constant therapeutic DC current, I_{dc} , will flow from electrode E1 to electrode E2, i.e., the two electrodes selected to provide the stimulation.

[0067] In this example, biphasic pulses are used with first and second phases 30a and 30b of opposite polarities at each of the electrodes. Each pulse is charge imbalanced: for example, the first phase 30a of the first pulse at electrode E1 has an amplitude of $25\% * +I$ while its second phase 30b has an amplitude of $-I$. Because the pulse widths of the two phases are equal in this example ($PW_a = PW_b$), the total charge of the first pulse phase 30a ($25\% * |+I| * PW_a$) is 25% of the total charge of the second pulse phase 30b ($|-I| * PW_a$). E2 provides the same amplitude of current as does E1 at any point in time, but with opposite polarity so that the total anodic current actively sourced to the tissue equals the total cathodic current sunk from the tissue. Any two or more of the IPG's or ETS's electrodes 16 could be selected to receive charge imbalanced pulses, including case electrode E_c (12). However, E1 and E2 are selected in illustrated examples for simplicity.

[0068] In Figure 6, the amount of charge imbalance of subsequent pulses initially changes over time. The first pulses at E1 and E2 are charge imbalanced at a ratio of 0.25:1 (comparing the first 30a and second phases 30b), the next at 0.5:1, the next at 0.75:1, then followed by a few pulses with a charge imbalance ratio of 0.9:1. As will be explained further below, the ending pulses (0.9:1) are used to maintain a particular I_{dc} in the tissue R, and are shown as "DC maintenance" pulses. The preceding pulses during which the charge imbalance ramps (from 0.25:1 to 0.9:1) are shown as "DC onset" pulses. It is not necessary to use both DC onset and DC maintenance charge imbalanced pulses, as either could be solely used in the disclosed technique. However, in this example, the DC onset pulses are helpful to more quickly establish I_{dc} , as explained below.

[0069] Figure 6 shows voltages V_{c1} and V_{c2} that are generated across capacitances present in the current path between electrode nodes E1' to E2' and through the tissue R. These voltages may most significantly comprise the voltages formed across the DC-blocking capacitors 38 that are associated with E1 and E2. However, V_{c1} and V_{c2} may also include or comprise voltages formed by inherent capacitances in the current path, as explained further below.

[0070] Given the manner in which the polarity of V_{c1} and V_{c2} are defined in Figure 6, it is seen that both increase slightly during the first phase 30a of the first pulse, but then are pulled more strongly negative during the second phase 30b. This occurs because the amplitude of the current from E1 to E2 during the first phase 30a is smaller than the amplitude of the current in the opposite direction from E2 to E1 during the second phase 30b. The rate of increase of V_{c1} and V_{c2} during the first phase 30a is therefore smaller than the rate of decrease of the voltage during the second phase ($dV/dt = I / C$). The net effect is that at the end of the second phase 30b, the capacitances C1 and C2 (assuming they are equal, which isn't necessarily true) are each charged with the same negative voltage V_{c1} and V_{c2} .

[0071] During a quiet period 30c between the pulses, no active current is being driven by the stimulation circuitry 28/58, i.e., electrode nodes E1' and E2' 39 are disconnected from the stimulation circuitry, as shown at the bottom of Figure 6. Nonetheless, the previously-charged capacitances will cause a voltage V_{dc} to be formed across the tissue R from E1 and E2, which given its definition will be opposite the sum of V_{c1} and V_{c2} , i.e., $V_{dc} = -(V_{c1} + V_{c2})$. Voltages V_{c1} and V_{c2} will start to exponentially decay towards 0V in accordance with an RC time constant dictated by the capacitances and the resistance R of the tissue, and thus so too will V_{dc} across the tissue decay. In any event, the creation of V_{dc} will cause a current I_{dc} to flow from E1 and E2 through the tissue R, where $I_{dc} = V_{dc}/R$. I_{dc} , like V_{c1} , V_{c2} , and V_{dc} , will exponentially decay. The extent to which I_{dc} is constant over a quiet period 30c will depend on how quickly V_{dc} is expected to decay based on the RC time constant.

[0072] The first DC onset pulse during the DC onset period was significantly imbalanced (0.25:1), which acts to lower V_{c1} and V_{c2} and raise V_{dc}/I_{dc} significantly during the subsequent quiet period 30c. Subsequent pulses may ramp V_{dc}/I_{dc} more slowly. Thus, the second pulse in Figure 6 is not as imbalanced (0.5:1). This charge imbalance continues to pull V_{c1} and V_{c2} more negative during a next quiet period 30c, but not by as much as the first pulse. The result is that V_{dc}/I_{dc} increases but at a slower rate, as shown by dotted line 31.

[0073] Eventually, less-imbalanced DC maintenance pulses (0.9:1) are issued during the DC maintenance period. At this point, the decay Δ in V_{c1} and V_{c2} during the quiet periods 30c equals the variation in V_{c1} and V_{c2} during the first and second pulse phases 30a and 30b. Therefore, although V_{dc}/I_{dc} continues to decay in each quiet period 30c, the relative or average value of V_{dc}/I_{dc} doesn't increase or decrease in the quiet periods 30c, and dotted line 31 flatens.

[0074] To summarize, through the use of charge imbalanced pulses, capacitances in the current path such as the DC-blocking capacitors 38 and/or capacitances at the electrode/tissue interface or in the tissue become charged, which then produces a current I_{dc} during quiet periods 30c between active phases of the pulses such as 30a and 30b. This is true despite the IPG 10 or ETS 50 having DC-blocking capacitors 38 that would otherwise prevent the stimulation circuitry 28/58 from actively providing a DC current. Therefore, therapeutic benefits of a DC current can be had while still retaining the safety that DC-blocking capacitors 38 provide. Again, the DC current I_{dc} may not perfectly constant during each quiet period 30c, and may vary slightly between different quiet periods 30c. Nonetheless, I_{dc} is still pseudo-constant, enough so to provide therapeutic benefits such as those described earlier. Further, the magnitude of I_{dc} can be controlled, as explained further below.

[0075] Figure 7 shows another example of charge imbalanced pulses that would have the same effect as the charge imbalanced pulses of Figure 6 to produce a pseudo-constant current I_{dc} in the tissue. In Figure 7, charge imbalance is achieved not through amplitude variation but through pulse width variation. Thus, in Figure 7, all pulse phases 30a and 30b have the same amplitude—+I or -I depending on the polarity of the phase. However, the pulse widths in phases 30a and 30b differ. In this example, the pulse width of each second phase 30b is set (PW_b), but the pulse width of each first phase 30a (PW_a) comprises a fraction of PW_b. Because the charge of each phase comprises its amplitude time its pulse width, this affects the same charge imbalance as occurred in Figure 6: 0.25:1 for the first pulse, 0.5:1 for the second pulse, and so on. This would similarly charge the capacitances causing V_{c1} and V_{c2} to decrease during the quiet periods 30c, V_{dc} and I_{dc} to increase, etc. Again, I_{dc} is established in the patient's tissue during the quiet periods 30c.

[0076] Figures 8A-8E show various ways charge imbalanced pulses can be formed to affect the generation of I_{dc} during quiet periods 30c as just described. Figures 8A and 8B are similar to the pulses shown in Figure 6 and Figure 7: Figure 8A effects charge imbalance by differing the amplitudes of the first and second pulse phases 30a and 30b while keeping the pulse widths constant; Figure 8B affects charge imbalance by differing the pulse widths of the first and second pulse phases 30a and 30b while keeping the amplitudes constant.

[0077] Figure 8C shows that first and second pulse phases 30a and 30b can be charged imbalanced while being formed of random shapes that are not necessarily square wave current pulses. Charge comprises the integration of current over time ($Q = \int (I) dt$),

effectively defining charge as the area under the curve of each phase 30a and 30b. If these areas are different, charge imbalance is achieved.

[0078] Figures 8D and 8E show that the first and second phases 30a and 30b of each pulse can each comprise one or more non-contiguous portions 33a and 33b. In Figure 8D, second pulse phase 30b comprises different portions 33b. Nonetheless, because the charge of pulse portion 30a does not equal the sum of the charge provided by portions 33b in second pulse phase 30b, the pulse is charge imbalanced.

[0079] Figure 8E shows that all portions 33a of pulse phase 30a need not precede all pulse portions 33b of pulse phase 30b. In the example shown, the portions 33a of positive pulse phase 30a are interwoven with the portions 33b of negative pulse phase 30b. Nonetheless, the sum of the portions 33a does not equal the sum of the portions 33b, and thus the pulse in total is charge imbalanced.

[0080] Figure 9 shows that not every pulse need be imbalanced to create I_{dc} in the tissue. In this example, only every third pulse is charge imbalanced: for example, the first two pulses have first and second pulses phases 30a and 30b each of the same pulse width and amplitude I , which are charge balanced. The third pulse however is charge imbalanced at a ratio of 0.8:1. This would likewise charge any capacitances in the current path, again drawing V_{c1} and V_{c2} negative during the quiet periods 30c after this third pulse. V_{c1} and V_{c2} are essentially not affected by the next two pulses that are not charge imbalanced, because each of these pulses will increase them during phase 30a and decrease them during phase 30b by equal amounts. Notice though that V_{c1} and V_{c2} will still decay during quiet periods 30c, until a next charge imbalanced pulse forces V_{c1} and V_{c2} further negative. The cumulative effect is that V_{c1} and V_{c2} will decrease over time until the decay of V_{c1} and V_{c2} equals the amount of charge imbalance provided by the charge imbalanced pulses as explained earlier. At this point V_{c1} and V_{c2} are essentially constant, and thus so are V_{dc} and I_{dc} in the tissue R.

[0081] I_{dc} in the examples shown thus far are made to flow from E1 to E2, because the net charge of the pulses at E1 are negative while the net charge of the pulses at E2 are positive. In this regard, it doesn't matter whether the larger negative pulse phases (or portions) at E1 come before or after the smaller positive pulse phases (or portions), or whether the smaller negative pulse phases (or portions) at E2 come before or after the larger positive pulse phases (or portions), as shown to the left in in Figure 10. In either case, V_{c1} and V_{c2} will be drawn negative, thus causing V_{dc} and I_{dc} to be positive during the quiet periods 30c. To reverse the polarity of V_{dc}/I_{dc} so that it flows from E2 to E1, the polarity of

these pulses can be flipped, so that the net charge of the pulses at E1 are positive while the net charge of the pulses at E2 are negative. Again, it doesn't matter whether the larger positive pulse phases (or portions) at E1 come before or after the smaller negative pulse phases (or portions), or whether the smaller positive pulse phases (or portions) at E2 come before or after the larger negative pulse phases (or portions), as shown to the right in Figure 10. In this circumstance, V_{c1} and V_{c2} will be drawn positive, thus causing V_{dc} and I_{dc} to be negative during the quiet periods 30c.

[0082] Figure 11 illustrates a practical consideration when using charge imbalanced pulses to generate a pseudo-constant DC current I_{dc} in the tissue. Shown are passive recovery switches 90_i , which may generally comprise part of the IPG's or ETS's stimulation circuitry 28/58 (Figs. 3 and 4), and which are described further in U.S. Patent Application Publications 2018/0071527 and 2018/0140831. Passive recovery switches 90_i may be attached to each of the electrode nodes E_i 39, and are conventionally used to recover any charge remaining on the DC-blocking capacitors C_i 38 after issuance of the active charge recovery pulse 30b. Passive charge recovery can be prudent, because active charge recovery using intentionally charge balanced pulse phases 30a and 30b may not be perfect given non-idealities in the stimulation circuitry. Therefore, passive charge recovery typically occurs after the issuance of second pulse phases 30b, for example during the quiet periods 30c and more specifically during passive recovery periods 91, by closing passive recovery switches 90_i . As explained in the above-cited references, such passive charge recovery tends to equilibrate the charge on the DC-blocking capacitors 38.

[0083] However, when intentionally using charge imbalanced pulses to generate a pseudo-constant DC current I_{dc} in the tissue in accordance with the disclose technique, it may be desirable to disable passive charge recovery, i.e., to disable closing of the passive recovery switches 90_i entirely or for at least a portion of the passive recovery periods 91. This is because the disclosed technique intentionally charges the DC-blocking capacitors 38 (or other charging path capacitances) as a means to generate I_{dc} , whereas passive charge recovery seeks to remove such charged capacitances. However, as passive charge recovery may also promote the flow of current through the tissue in some circumstances, it is not strictly necessary that passive charge recovery be disabled when generating I_{dc} .

[0084] Figure 12 shows that the disclosed technique need not involve the use of biphasic pulses with positive and negative pulse phases. Instead, as shown, monophasic pulses can be used having only a single pulse phase 30. Such monophasic pulses have a net charge and are therefore inherently charge imbalanced, and so will charge the DC-blocking

capacitors 38, causing V_{c1} and V_{c2} to drop as shown. The charged capacitances will again decay during quiet periods 30c, and if they don't decay back to $V_{c1} = V_{c2} = 0$, then a subsequent pulse phase 30 will drive V_{c1} and V_{c2} even further negative. As before, this would continue (if not controlled, as discussed shortly) until the decay equals the total charge of the pulses, at which point V_{dc} and I_{dc} would stop rising during each subsequent quiet period 30c.

[0085] Traditionally, monophasic pulses 30 such as those shown in Figure 12 are followed by a passive recovery period 91, as explained with reference to Figure 11, to passively recover any charge stored on capacitances in the current path. Thus, it may again be desirable to disable closing of the passive recovery switches 90_i for all or a portion of the passive recovery periods 91 so as not to defeat the mechanism by which I_{dc} is generated.

[0086] The disclosed technique is particularly well suited to use in IPG or ETS having DC-blocking capacitors 38 because, as discussed above, it provides a means of providing a pseudo-constant DC current even though the DC-blocking capacitors 38 act to prevent DC current from being driven by the stimulation circuitry 28/58 into the tissue. However, the disclosed technique is not limited to use in IPGs or ETSs having DC-blocking capacitors 38, as shown in Figure 13. In Figure 13, DC-blocking capacitors 38 are not present in the current path. However, inherent capacitances C_{1i} and C_{2i} 92 are shown, which comprise any inherent capacitance in the current path. In particular, inherent capacitances 92 may comprise the capacitances naturally present at the electrode 16/tissue R interfaces. Inherent capacitances 92 could also comprise capacitances naturally present in the tissue R itself, which can be modeled as a single capacitance. In any event, the inherent capacitance(s) 92 can also be charged by the charge imbalanced pulses and used to provide I_{dc} as described.

[0087] A portion of a Graphical User Interface (GUI) 100 useable to define charge imbalanced pulses and to control the generation of I_{dc} in patent tissue is shown in Figure 14. GUI 100 preferably runs in an external device as described earlier and can telemeter stimulation parameters to the IPG 10 or ETS 50 for execution. In the description that follows it is assumed for simplicity that GUI 100 is executed on a clinician programmer 70 (Fig. 5) as part of its clinician programmer software 84 and as executable in its control circuitry 88, as described earlier. However, GUI 100 can also similarly be executed on an external controller 60 (Fig. 5). GUI 100 may comprise a portion of module of a more general GUI running of the clinician programmer 70, such as GUI 82 (Fig. 5). GUI 100 may be presented to the user based on where the clinician programmer software 84 is in its execution, which may depend

on GUI selections the clinician has previously made. GUI 100 need not comprise just a single displayed screen, but can include multiple screens that are presented based on user selections.

[0088] GUI 100 can provide options to set stimulation parameters for the patient. For example, values for stimulation parameters such as amplitude (I), pulse width (PW), and frequency (F) can be displayed and set in a waveform parameter interface 102, including buttons the clinician can use to increase or decrease these values. Amplitude I sets the value of the total anodic current +I one or more selected anode electrodes will source to the patient, and the value of the total cathodic current -I one or more selected anode electrodes will sink from the patient. Pulse width PW can allow a total duration of pulses to be set, or may set the pulse widths of the pulse phases (such as PWa and PWb) individually, although this isn't shown for simplicity. Option 103 allows the user to choose whether the pulses are to be applied as biphasic pulses or not. If biphasic pulses are selected, the information entered in waveform parameter interface 102 can be automatically applied to both the first 30a and second 30b phases of the pulse. In the description that follows, it is assumed that biphasic pulses have been selected.

[0089] Stimulation parameters relating to the electrodes 16 are made adjustable in an electrode parameter interface 104. Electrodes are manually selectable in a leads interface 106 that displays a graphical representation of the electrode array 17 or 17' that has been implanted in a particular patient (a paddle lead 19 is shown as one example). A cursor 108 or other selection means such as a mouse pointer can be used to select a particular electrode in the leads interface 106. Buttons in the electrode parameter interface 104 allow the selected electrode (including the case electrode, Ec) to be designated as an anode or cathode (during first pulse phases 30a), or off. The electrode parameter interface 104 further allows the relative amount of total anodic or cathodic current +I or -I 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. In the example shown, two electrodes have been selected, one as an anode (+) which will receive 100% of the total anodic current +I, and another as a cathode (-) which will receive 100% of the total cathodic current -I.

[0090] More automated means can be used to choose electrodes for stimulation. In USP 8,412,345 for example, target poles can be chosen in a GUI and may not correspond to the locations of physical electrodes 16. Target poles are then processed by the clinician programmer software 84 to determine which physical electrodes 16 should be selected, and with what relative amplitudes and polarities, to best approximate the desired electric field in

the tissue as defined by the target poles.

[0091] An advanced menu 110 can be used (among other things) to define more complicated pulses or waveforms more generically. For example, advanced menu 110 can be used to set specific amplitudes (I) and pulse widths (PW) of individual phases of a pulse, to set pulse phases with random shapes (Fig. 8C), or to set pulses whose phases comprise portions 33a and 33b if applicable (Fig. 8D and 8E), although these details aren't shown. Advanced menu 110 can also allow for the selection of more advanced modifications to the waveforms, such as setting of a duty cycle (on/off time) for the waveforms, a ramp-up time over which the waveforms reach the programmed amplitude (I), various parameters relating to the issuance of a burst of waveforms, parameters relevant to defining waveforms of random (e.g., non-constant pulse) shapes, etc.

[0092] GUI 100 also includes a charge imbalance interface 120 which allows a user to select one or more charge imbalance parameters to modify the pulses as otherwise prescribed (e.g., using interfaces 102 and 104), and hence generate I_{dc} in the tissue.

[0093] For example, option 122 allows a charge imbalance parameter I_{IM} to be set for the first and second pulses phases 30a and 30b (or their portions 33a and 33b; see Figs. 8D and 8E), which describes a difference in the amplitude of the current that will be applied during each phase. This amplitude imbalance parameter I_{IM} can be specified in different manners. In Figure 14, I_{IM} is shown as a ratio (X:Y), with X specifying the amplitude of the first phase 30a, and Y specifying the amplitude of the second phase 30b. Thus, 1:0.8 would mean that the first phase 30a would receive an amplitude of I, while the second phase 30b would receive an amplitude of $0.8 * I$, with their polarities being set at the selected electrodes in accordance with their status as anodes or cathodes. Amplitude imbalance parameter I_{IM} can also be specified as a percentage; for example, 125% would equal 1/0.8. A differential percentage could also be used; for example 1/0.8 could be represented as -20%. Amplitude imbalance parameter I_{IM} can also be specified by a charge differential between the two phases (e.g., in nC), which is computable by multiplying the amplitude of each phase times its pulse width (or the sum of the widths of its portions). If the first phase 30a is to have a smaller charge than the second phase 30b, the ratio can be smaller than 1 (e.g., 0.8:1), the percentage can be less than 100% (e.g., 80%), the differential percentage can be positive (+20%) or the charge differential can be negative (e.g., -10 nC). Amplitude imbalance parameter can also comprise the strength of the weaker phase relative to the stronger phase or vice versa using any of these metrics.

[0094] Use of amplitude imbalance parameter I_{IM} to set a desired charge imbalance may be most useful if the first and second pulses phases 30a and 30b have constant amplitudes and equal pulse widths PW_a and PW_b (see, e.g., Fig. 8A), although I_{IM} is not so limited.

[0095] Other charge imbalance parameters can also be used. Option 124 allows a charge imbalance parameter PW_{IM} to be set for the first and second pulses phases 30a and 30b (or their portions 33a and 33b), which describes a difference in the pulse width that will be applied during each phase. In Figure 14, a percentage is shown, but again a ratio, charge differential, or other metric could be specified. Use of pulse width imbalance parameter PW_{IM} to set a desired charge imbalance may be most useful if the first and second pulses phases 30a and 30b have equal constant amplitudes (see, e.g., Fig. 8B), although again PW_{IM} is not so limited.

[0096] Option 126 allows a charge imbalance parameter Q_{IM} to be set for the first and second pulses phases 30a and 30b (or their portions 33a and 33b; see Figs. 8D and 8E), which describes a difference in the total charge that will be applied during each phase. Again, a ratio, percentage, or other metric could also be specified for Q_{IM} . Use of charge imbalance parameter Q_{IM} to set a desired charge imbalance may be most useful if the first and second pulses phases 30a and 30b have unusual or randomized shapes (see, e.g., Fig. 8C), but again Q_{IM} is not so limited.

[0097] Note that charge imbalance parameter options 122-126 used to select a charge imbalance parameter may be made on a per electrode basis, for example, the electrode currently selected by cursor 108. This can be important to control the direction that I_{dc} will flow. For example, if electrode E1 is an anode (during its first phase 30a), and it is desired that I_{dc} flow from E1 to E2 (see Fig. 10), then options 122-126 should reflect that first phase 30a will have a smaller amount of charge than second phase 30b.

[0098] Other options in the charge imbalance interface 120 specify manners in which the charge imbalance parameter (e.g., I_{IM} , PW_{IM} , Q_{IM}) can be applied to a sequence of pulses or waveforms more generally. For example, option 128 in the charge imbalance interface 120 can be used to set a period over which the charge imbalanced pulses are issued, as shown in Figure 15A for electrode E1 only, although electrode E2 would be of opposite polarity as before. The charge imbalance period can be specified as a time period, or as a number of pulses, or in other manners. This can be useful for example if it is desired to test charge imbalanced pulses and generate I_{dc} in a patient for just a set period of time. Alternatively,

option 128 may also include an option to allow the charge imbalanced pulses to issue continuously (“cont.”) for an indefinite time period.

[0099] Option 130 allows imbalanced pulses to be cycled on and off for different time periods, as shown in Figure 15B. This can include options to specify an “on” time or number of pulses that charge imbalanced pulses will issue, and an “off” time or number of pulses that non-charge imbalanced pulses will issue. These on and off periods are then cycled so that I_{dc} is formed in the tissue during the on periods, but not during the off periods.

[00100] Option 132 in the charge imbalance interface 120 can be used to set the DC onset during which the charge imbalance in the pulses is ramped to a desired amount, as explained earlier with reference to Figure 6, but shown again in Figure 15C. The DC onset can be specified as a time period, or as a number of pulses over which the charge imbalance is ramped (just two ramped pulses with ratios of 0.3:1 and 0.6:1 are shown in Fig. 15C). The clinician programmer software 84 can automatically compute the amount of charge imbalance during specified ramping periods, such as by scaling the charge imbalance during the ramp, which scaling can be linear, exponential, or generally non-linearly. The DC onset period can be followed by non-ramped charge imbalanced pulses (e.g., 0.9:1), such as the DC maintenance period described earlier (Fig. 6), or the “imbalance on” time periods of Figures 15A and 15B.

[00101] Note also that option 132 can comprise a DC offset time during which charge imbalance is ramped downward. This is helpful to ramp I_{dc} back to zero as explained in Figure 15C. Notice that two ramp down pulses are used, which mirror the two ramp up pulses, but have their polarities changed. For example, whereas the first ramp up pulse has a ratio (plus to minus) of 0.3:1 to accelerate pulling V_{c1} and V_{c2} negative (and thus V_{dc} and I_{dc} positive), the last ramp down pulse has a ratio of 1:0.3 to accelerate pulling V_{c1} and V_{c2} (and thus V_{dc} and I_{dc}) positive and back to zero. Again, the clinician programmer software 84 can automatically define the magnitudes and phases of the DC offset pulses over the specified time period. Although not shown in Figure 14, option 132 can include the ability to separately control the DC onset and DC offset times, as they don’t need to be equal.

[00102] Option 133 allows I_{dc} to be generated by specifying how frequently charge imbalanced pulses are issued. For example, and similar to what was shown earlier in Figure 9, option 133 can be used to specify that every third pulse can be charge imbalanced, with remaining pulses being charge balanced. More complicated manners for specifying how to intersperse charge imbalanced and charge balanced pulses can also be specified at option 133, allowing more complicated patterns to be defined.

[00103] Option 134 allows the I_{dc} to be controlled so that it oscillates between positive and negative. In other words, I_{dc} will flow from E1 to electrode E2 during some periods, and will flow in the opposite direction from E2 to E1 during other periods. This is shown in Figure 15D, which shows charge imbalanced pulses being formed in alternating periods 135a and 135b. During periods 135a, the pulse at E1 have a net negative charge, which as explained earlier with reference to Figure 10, causes I_{dc} to flow from E1 to E2. During periods 135b, the pulses at E1 have a net positive charge, which can occur for example by reversing the charge imbalance ratio of the pulses. For example, while the charge imbalance ratio of the pulses at E1 in periods 135a is 0.5:1, the ratio is 1:0.5 in periods 135b. Using such net positive pulses in periods 135b causes I_{dc} to flow in the opposite direction from E2 to E1. Thus, I_{dc} will oscillate over a period t , or with a frequency f , as shown in Figure 15D. Option 134 can provide options to allow this period or frequency to be set as shown in Figure 14, or I_{dc} oscillation can be specified by other means, such as by defining the duration of periods 135a and 135b. Note that the transition in the polarity of I_{dc} may not be sharp at the boundary between the periods 135a and 135b, as it may take some time for net positive charge pulses to offset V_{c1} and V_{c2} charging caused by preceding net negative charge pulses, and vice versa. Nonetheless, I_{dc} 's polarity can generally be made to oscillate.

[00104] The charge imbalance interface 120 in Figure 14 can also include an option 136 to control passive charge recovery during periods when charge imbalanced pulses are issued. As explained earlier with reference to Figure 11, passive charge recovery during the quiet periods 30c—i.e., turning on passive recovery switches 90_i during recovery periods 91—can interfere with building charge on the capacitances, which can interfere with I_{dc} generation. Thus, option 136 provides the ability to disable passive charge recovery when charge imbalanced pulses are issued. Although not shown, further control could allow passive recovery to be limited to some degree rather than being completely disabled.

[00105] Changes to therapy made within GUI 100, including changes pertaining to prescribing charge imbalanced pulses as just described, can be compiled as a stimulation program by the control circuitry 88 and wirelessly transmitted by the clinician programmer 70's antenna 80a and/or 80b (Fig. 5) and its telemetry circuitry to the IPG 10 or ETS 50 for execution by their stimulation circuitries 28 and 58, as explained earlier.

[00106] Figure 16 shows further options in the charge balance interface 120 that can be used to estimate or control V_{dc} , I_{dc} , or J_{dc} in accordance with a DC algorithm 150 operable as part of clinician programmer software 84 and executable in control circuitry 88 (Fig. 5). Instructions for DC algorithm 150 and for GUI 100 more generally can be stored on a non-

transitory computer readable media, such as a solid state, optical, or magnetic memory residing in or associated with the control circuitry 88. The algorithms can also be stored on similar media outside the external device, such as on an (Internet) server or an external memory stick or disk, and loaded into the relevant external device.

[00107] Jdc comprises the current density of Idc at the selected electrodes, which generally varies as a function of the area A of the electrodes 16 and Idc. For example, Jdc may generally comprise Idc/A, and is written as such in Figure 16 for simplicity. However, Jdc may also comprise a maximum value as determined from Idc and A, but also based upon modelling that takes into account the shape of the electrodes. In this regard, the current density may not be uniform across the entire area of the electrodes 16. For example, the current density may be maximized at the edges of the electrodes, and therefore Jdc may comprise this maximum current density. The electrode area A and any modelling useful for calculating a maximum current density can be programmed into the DC algorithm 150, although this isn't shown.

[00108] As explained earlier $V_{dc} = I_{dc} / R$, where R is the resistance of the patient's tissue between the selected electrodes. Techniques for measuring R in an IPG or ETS are well known. See, e.g., USP 9,061,140 (describing a technique for measuring R). Thus, R can be measured by the IPG or ETS, transmitted to the clinician programmer 70, and programmed into or stored in the control circuitry for use by the DC algorithm 150.

[00109] The Idc algorithm 150 can preferably both (i) determine a pseudo-constant Vdc, Idc, and/or Jdc using set stimulation parameters and one or more charge imbalance parameters, and/or (ii) determine one or more charge imbalance parameters using a set Vdc, Idc, and/or Jdc and stimulation parameters.

[00110] Indicators 140 show estimations of Vdc, Idc, and/or Jdc for a specified waveform having charge imbalanced pulses. To provide these estimations to the user of GUI 100, the DC algorithm 150 can receive and process various pieces of information at a modeling logic block 152. For example, modeling block 152 can receive one or more of the parameters specified in the GUI 100 of Figure 14. Such parameters can comprise stimulation parameters that do not promote charge imbalance, such as the amplitude I, pulse width(s) PW, and frequency F as specified in waveform parameter interface 102. Modeling block 152 also preferably receives one or more parameters relevant to how the waveform is charge imbalanced, such as the amplitude imbalance, pulse width imbalance, or charge imbalance 122-126 (I_{IM} , PW_{IM} , Q_{IM}). Although not shown in Figure 16, modeling block 152 may further receive other parameters relevant to charge imbalancing such as the imbalance time

128, imbalance cycling 130, onset/offset time 132, imbalance pulse frequency, Idc oscillation parameters 134, and whether passive recovery is disabled 136.

[00111] Modeling block 152 may also receive the resistance of the tissue R between the selected electrodes, which as pointed out earlier can be measured at the IPG 10 or ETS 50 and stored in a manner accessible by the control circuitry 88 in the clinician programmer 70. Modeling block 152 may also receive information regarding one or more capacitances in the current path between the selected electrodes C , such as the capacitance of the DC-blocking capacitors 38 $C1$ and $C2$, and any other inherent capacitances. The values of such capacitances if already known can be stored, or may be determined by a telemetered measurement in the IPG 10 or ETS 50. For example, a measurement voltage V_m across the electrodes nodes 39 $E1'$ and $E2'$ may be measured, which spans across capacitances in the current path. The capacitance can be determined by monitoring the rate at which V_m changes in response to a known constant current (i.e., $I = C \, dV_m/dt$). Finally, modeling block 152 may include information regarding the electrode areas A , which again may be stored.

[00112] From one or more of these pieces of information, the modeling block 152 can determine V_{dc} , I_{dc} (V_{dc}/R), and J_{dc} (a function of I_{dc} , A , and perhaps electrode geometry modelling as explained above). This can occur by using a look up table 154 which correlates the various parameters to one or more of V_{dc} , I_{dc} , or J_{dc} . For example, look up table 154 may reveal that for 30 specified biphasic pulses with stimulation parameters such as an amplitude $I = 2$ mA, a pulse width of $PW = 30$ microseconds, and a frequency of $F = 100$ Hz, and with a charge imbalance parameter such as an amplitude imbalance ratio I_{IM} of 0.8:1, and assuming a capacitance of values $C1$ and $C2$, V_{dc} will equal 100 mV, or may be within a range of 50 to 200 mV, either of which may then be indicated at 140. I_{dc} and J_{dc} may then also be indicated at 140 using R and A as explained above. The data in look up table 154 may be established using mathematical relationships or based on actual empirical or experimental data.

[00113] Option 144 in charge imbalance interface 120 may be used to set limits for V_{dc} ($V_{dc_{MAX}}$), I_{dc} ($I_{dc_{MAX}}$), and/or J_{dc} ($J_{dc_{MAX}}$). Such maximum limits can be adjustable by the user, or may comprise non-adjustable limits set in the clinician programmer software 84. This can be important particularly as concerns $J_{dc_{MAX}}$, because, as pointed out earlier, exceeding DC current density limits for extended periods of time can corrode electrodes or cause tissue damage. If the determined V_{dc} , I_{dc} , or J_{dc} exceeds the maximum limit specified at option 144, the DC algorithm 150 can issue an alarm. In one example not shown, GUI 100

can display a message on the screen 74 of the clinician programmer 70 alerting the user to the fact that the parameters entered will exceed one or more of $V_{dc_{MAX}}$, $I_{dc_{MAX}}$, or $J_{dc_{MAX}}$. The user of GUI 100 may decide to override these maximum limits, or alternatively the clinician programmer software 84 may (for safety) reject the charge imbalance parameters that lead to these limits being exceeded. For example, the GUI 100 may either automatically adjust relevant charge imbalance parameters (such as I_{IM}) so that no maximum limit is exceeded, or may prevent transmission of these charge imbalance parameters to the IPG 10 or ETS 50. An alarm may be implemented in other manners.

[00114] The DC algorithm 150 may also allow a user to set a particular value or range for V_{dc} , I_{dc} , or J_{dc} using option 142. When one of these values is set using option 142, the DC algorithm 150 will preferably automatically set one or more charge imbalance parameters appropriately in the GUI 100 to achieve the set value. (Stimulation parameters could also be automatically adjusted or set, but this is less preferred). Such adjustment can essentially work the reverse of the process just described. For example, if the user inputs at option 142 specify that I_{dc} should equal $30 \mu A$, DC algorithm 150 can equate this value (using R) to $V_{dc} = 100 \text{ mV}$ ($V_{dc} = I_{dc} * R$). Using the look up table 154 in the modeling block 152, the DC algorithm 150 can determine the relevant charge imbalance parameter (e.g., 122-126, perhaps as modified by 128-136) necessary to achieve the desired $V_{dc} = 100 \text{ mV}$. This may depend on the stimulation parameters (e.g., I , PW , F) otherwise chosen. Given such stimulation parameters, the DC algorithm 150 may for example conclude that amplitude imbalance I_{IM} should be set to 0.85:1, and thus may automatically populate option 122 accordingly. Options 124 (pulse width imbalance PW_{IM}) or 126 (charge differential Q_{IM}) could likewise or additionally be so populated. DC algorithm 150 may additionally recognize that other charge imbalance parameters would be useful to automatically select. For example, DC algorithm 150 might determine that to create the desired V_{dc} , I_{dc} , or J_{dc} set at option 142, imbalance may need to be cycled (option 130), and may automatically populate this option.

WHAT IS CLAIMED IS:

1. A system, comprising:
 - an external device configured to program an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, wherein the external device comprises control circuitry configured to:
 - generate a graphical user interface (GUI) at the external device;
 - receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase, wherein one of the parameters comprises a charge imbalance parameter that sets a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms; and
 - transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms.
2. The system of claim 1, wherein the plurality of parameters comprise at least one of: an amplitude of at least one waveform in the sequence of waveforms, a pulse width of at least one waveform in the sequence of waveforms, a pulse width of the positive phase or the negative phase of at least one waveform in the sequence of sequence of waveforms, or a frequency at which waveforms are provided in the sequence of waveforms.
3. The system of claims 1 or 2, wherein the control circuitry is further configured to receive, via the GUI, selection of the at least two electrodes.
4. The system of any of claims 1-3, wherein in the defined sequence of waveforms, a total anodic current sourced to at least one of the at least two electrodes equals a total cathodic current sunk to at least one of the at least two electrodes.
5. The system of any of claims 1-4, wherein the charge imbalance parameter comprises a difference between the positive phase and the negative phase of the at least one waveform.

6. The system of claim 5, wherein the difference comprises a difference in amplitude, a difference in pulse width, or a difference in charge.
7. The system of any of claims 1-6, wherein the charge imbalance parameter sets a charge imbalance between the positive phase and the negative phase of each waveform in the sequence of waveforms.
8. The system of any of claims 1-7, wherein the control circuitry is further configured to use the plurality of parameters to determine a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence of waveforms.
9. The system of claim 8, wherein the GUI is configured to display the determined pseudo-constant DC current, DC voltage or DC current density.
10. The system of any of claims 1-7, wherein the control circuitry is further configured to receive, via the GUI, an input specifying a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence of waveforms.
11. The system of claim 10, wherein the control circuitry is further configured to determine the charge imbalance parameter based on the specified pseudo-constant DC current, DC voltage or DC current density.
12. The system of any of claims 1-11, further comprising the implantable stimulator device, wherein the implantable stimulator device comprises a fully-implantable stimulator device, or an external stimulator wherein the plurality of electrodes are implantable in a patient.
13. The system of claim 12, wherein the implantable stimulator device further comprises decoupling capacitors in series with the at least two electrodes.

14. A non-transitory computer readable media comprising instructions executable on an external device for programming an implantable stimulator device, wherein the implantable stimulator device comprises a plurality of electrodes configured to contact a patient's tissue, wherein the instructions when executed are configured to enable control circuitry in the external device to:

generate a graphical user interface (GUI) at the external device; and
receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase, wherein one of the parameters comprises a charge imbalance parameter that sets a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms.

15. The non-transitory computer readable media of claim 14, wherein the instructions when executed are further configured to enable control circuitry in the external device to:

transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms.

16. A method for programming an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, the method comprising:

using a graphical user interface (GUI) of an external device to define a sequence of waveforms to be provided at at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase;

using the GUI to further set a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms;

and

transmitting information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms.

17. A system, comprising:
an external device configured to program an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, wherein the external device comprises control circuitry configured to:
generate a graphical user interface (GUI) at the external device;
receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase, wherein one of the parameters comprises of a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence;
determine a charge imbalance parameter that adjusts a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms using the plurality of parameters; and
transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms as adjusted by the charge imbalance parameter.
18. The system of claim 17, wherein in the defined sequence of waveforms as adjusted by the charge imbalance parameter, a total anodic current sourced to at least one of the at least two electrodes equals a total cathodic current sunk to at least one of the at least two electrodes at any point in time.
19. The system of claims 17 or 18, wherein the plurality of parameters comprise at least one of: an amplitude of at least one waveform in the sequence of waveforms, a pulse width of at least one waveform in the sequence of waveforms, a pulse width of the positive phase or the negative phase of at least one waveform in the sequence of sequence of waveforms, or a frequency at which waveforms are provided in the sequence of waveforms.

20. The system of any of claims 17-19, wherein the control circuitry is configured to determine the charge imbalance parameter that adjusts the charge imbalance of each waveform in the sequence of waveforms.
21. The system of any of claims 17-20, wherein the control circuitry is further configured to display the determined charge imbalance parameter in the GUI.
22. The system of any of claims 17-21, further comprising the implantable stimulator device, wherein the implantable stimulator device comprises a fully-implantable stimulator device, or an external stimulator wherein the plurality of electrodes are implantable in a patient.
23. The system of claim 22, wherein the implantable stimulator device comprises a conductive case, wherein one of the at least two electrodes comprises the conductive case.
24. The system of claims 22 or 23, wherein the implantable stimulator device comprises at least one lead that comprises the plurality of electrodes.
25. The system of any of claims 22-24, wherein the implantable stimulator device further comprises decoupling capacitors in series with the at least two electrodes.
26. A non-transitory computer readable media comprising instructions executable on an external device for programming an implantable stimulator device, wherein the implantable stimulator device comprises a plurality of electrodes configured to contact a patient's tissue, wherein the instructions when executed are configured to enable control circuitry in the external device to:
- generate a graphical user interface (GUI) at the external device;
 - receive, via the GUI, selection of a plurality of parameters defining a sequence of waveforms to be provided to at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase, wherein one of the parameters comprises of a pseudo-constant DC current, DC voltage or DC current density to be formed between the at least two electrodes during quiet periods between waveforms in the sequence; and

determine a charge imbalance parameter that adjusts a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms using the plurality of parameters.

27. The non-transitory computer readable media of claim 26, wherein the instructions when executed are further configured to enable control circuitry in the external device to:

transmit information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms as adjusted by the charge imbalance parameter.

28. A method for programming an implantable stimulator device comprising a plurality of electrodes configured to contact a patient's tissue, the method comprising:

using an graphical user interface (GUI) of an external device to define a sequence of waveforms to be provided at at least two of the electrodes, wherein each waveform comprises a positive phase and a negative phase;

using the GUI to further specify a pseudo-constant DC current, DC voltage or DC current density that will form between the at least two electrodes during quiet periods between waveforms in the sequence;

determine at the external device a charge imbalance parameter that adjusts a charge imbalance between the positive phase and the negative phase of at least one waveform in the sequence of waveforms using at least the pseudo-constant DC current, DC voltage or DC current density; and

transmitting information to the implantable stimulator device, wherein the information is configured to program the implantable stimulator device to provide electrical stimulation at the at least two electrodes in accordance with the defined sequence of waveforms as adjusted by the charge imbalance parameter.

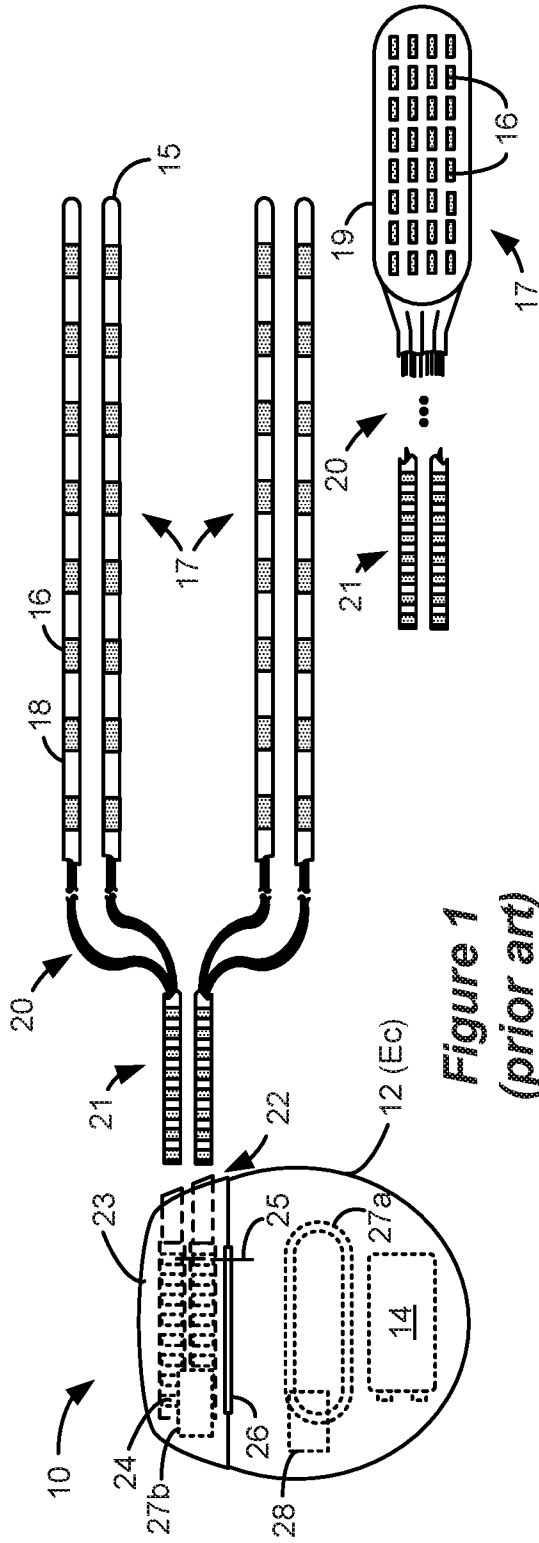


Figure 1 (prior art)

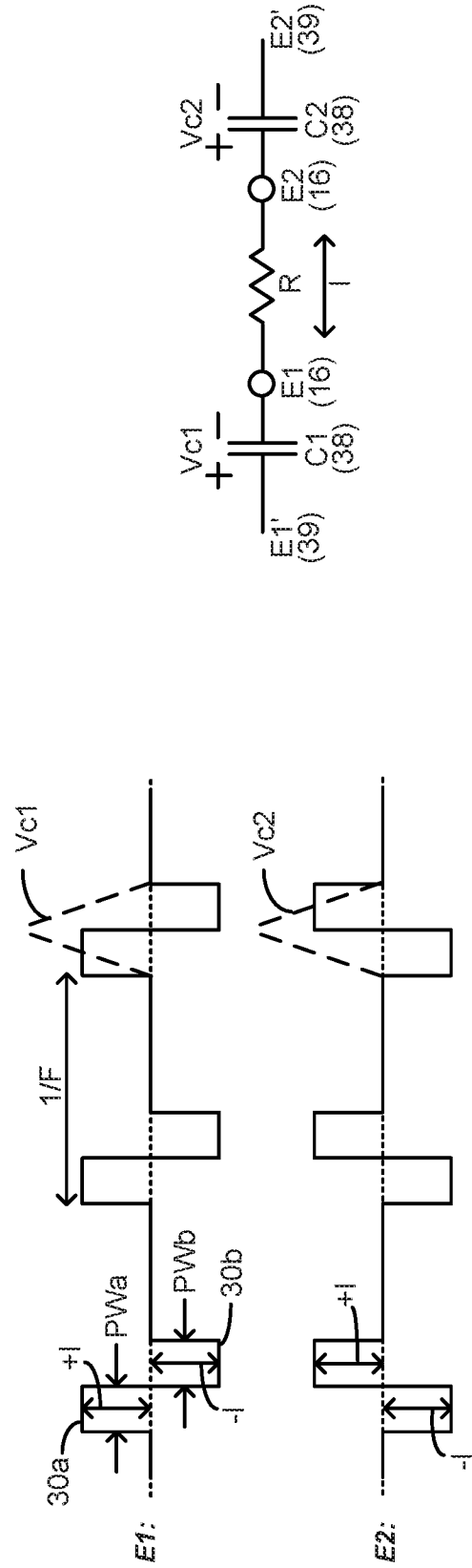


Figure 2A (prior art)

Figure 2B (prior art)

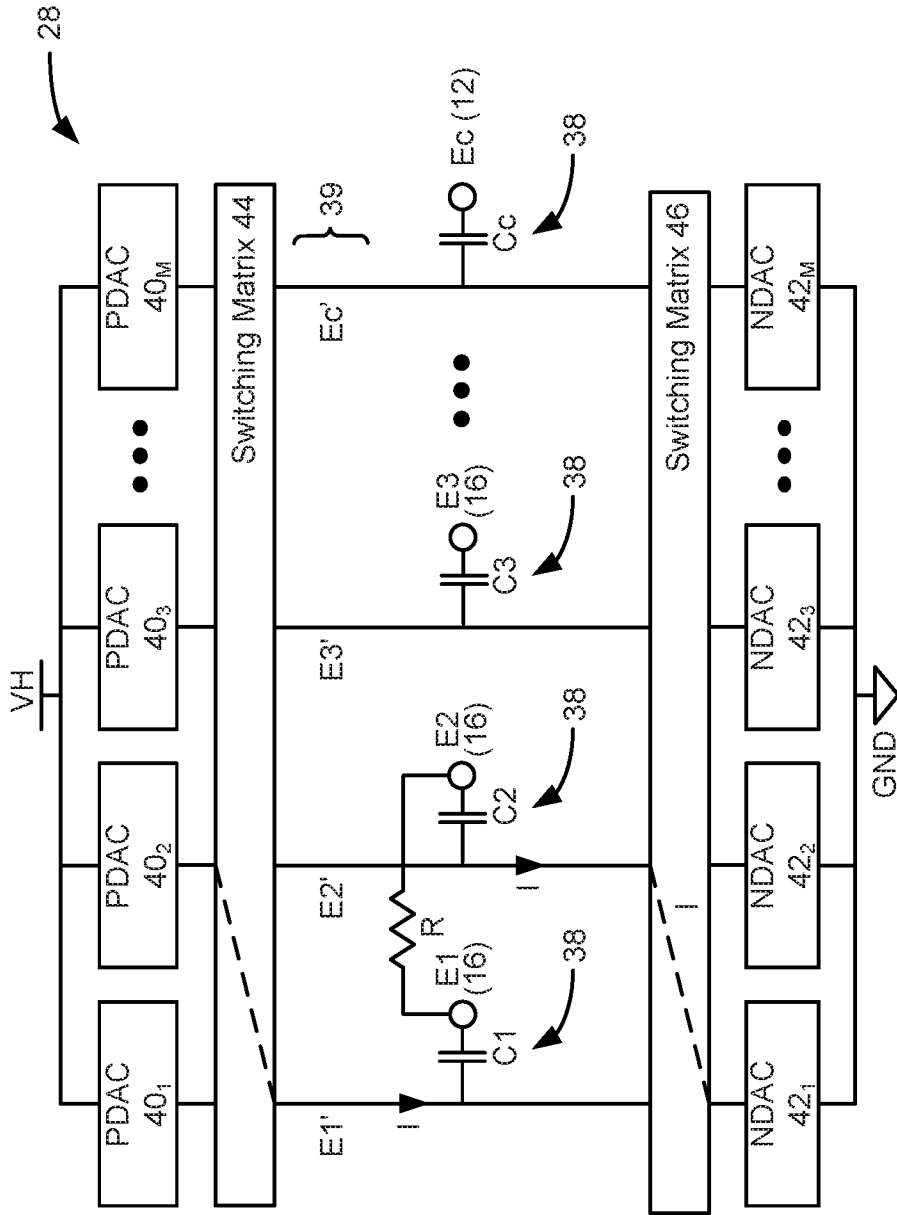


Figure 3
(prior art)

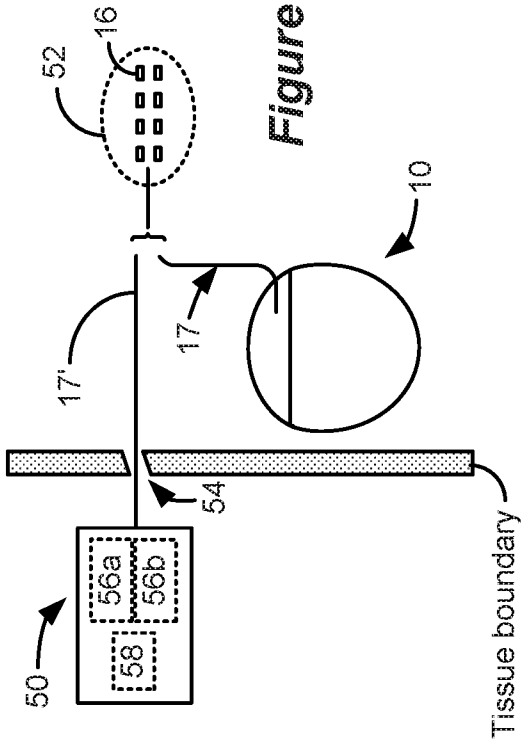


Figure 4 (prior art)

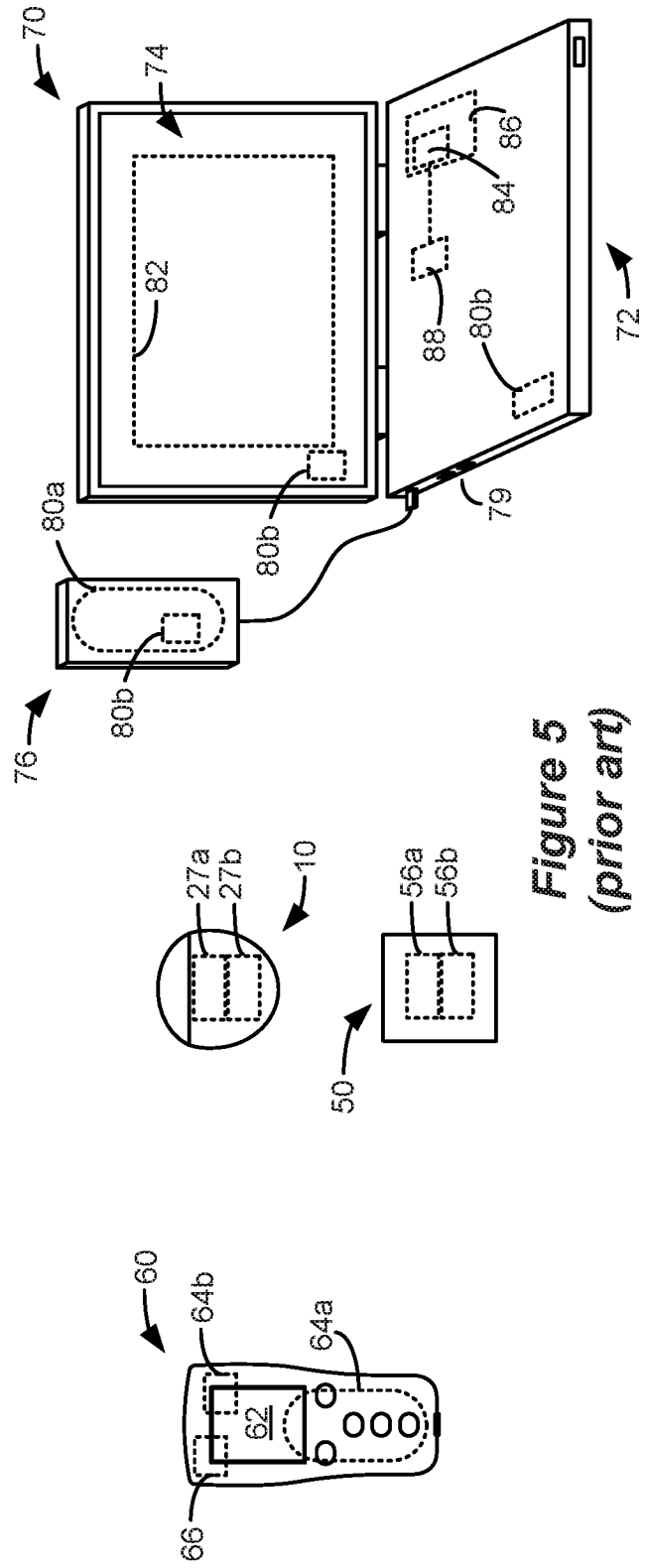


Figure 5 (prior art)

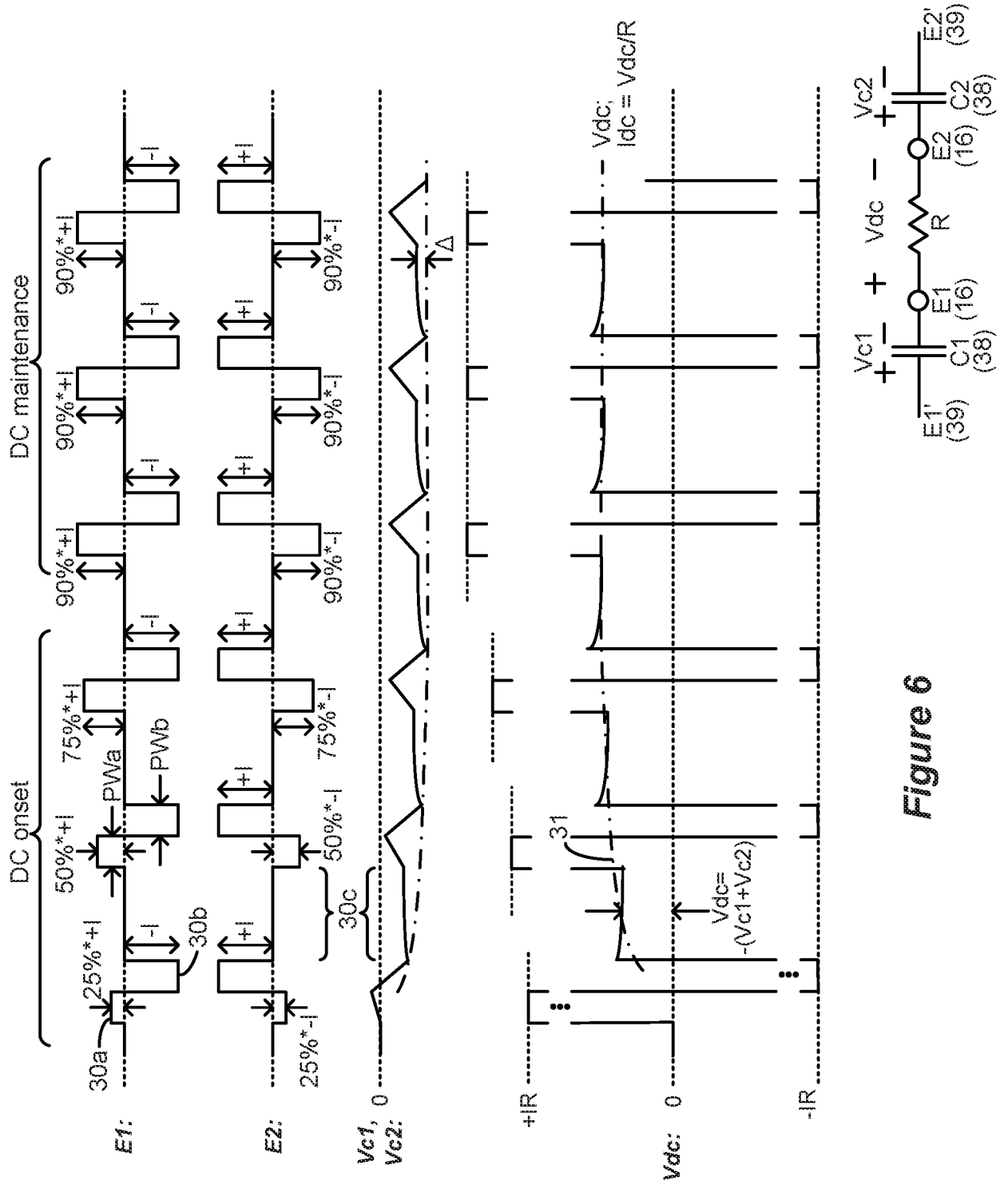


Figure 6

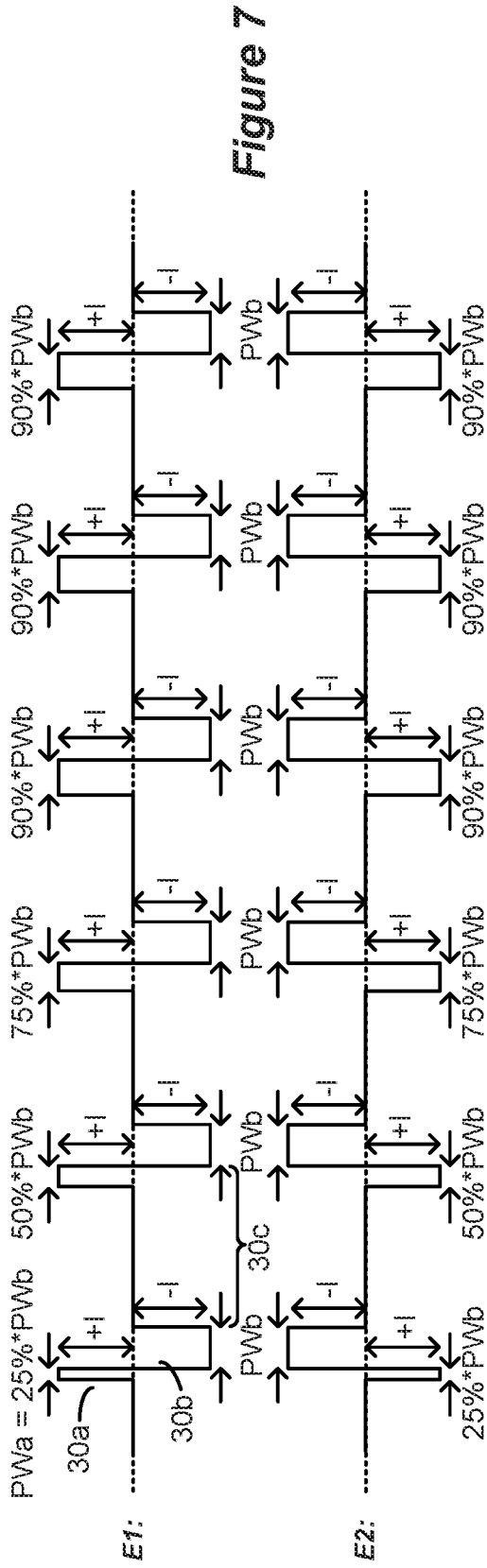


Figure 7

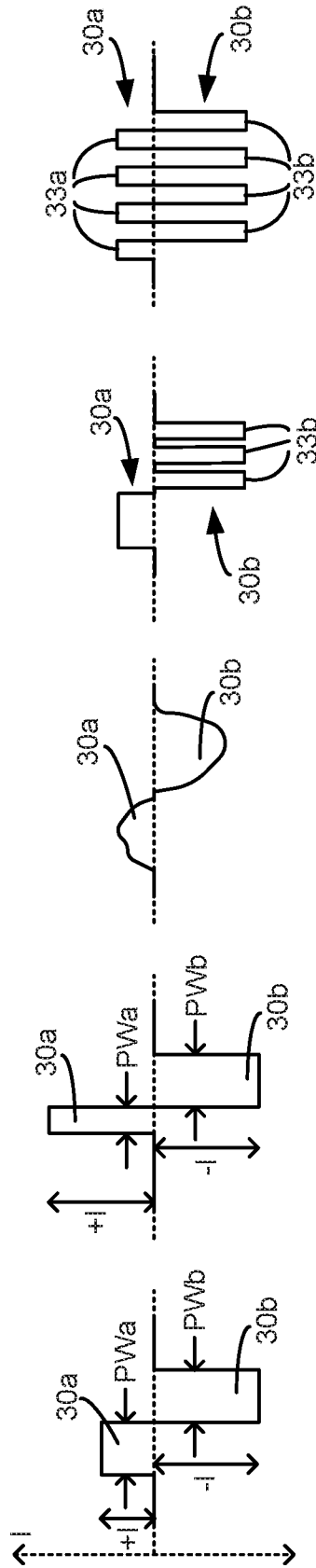


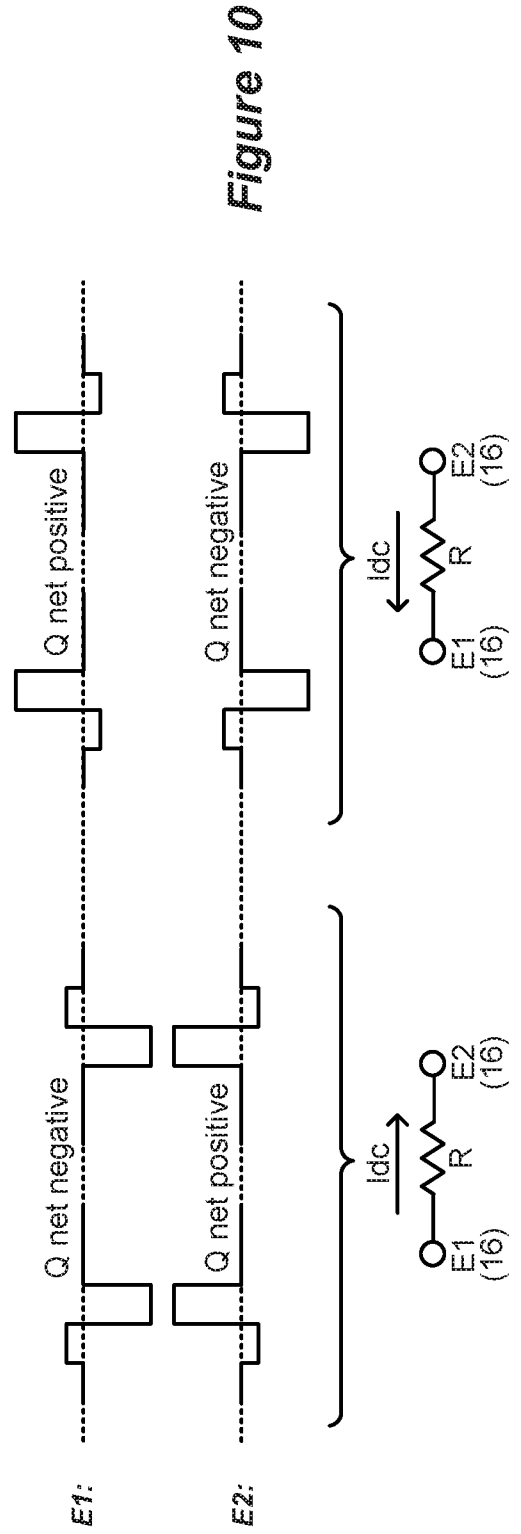
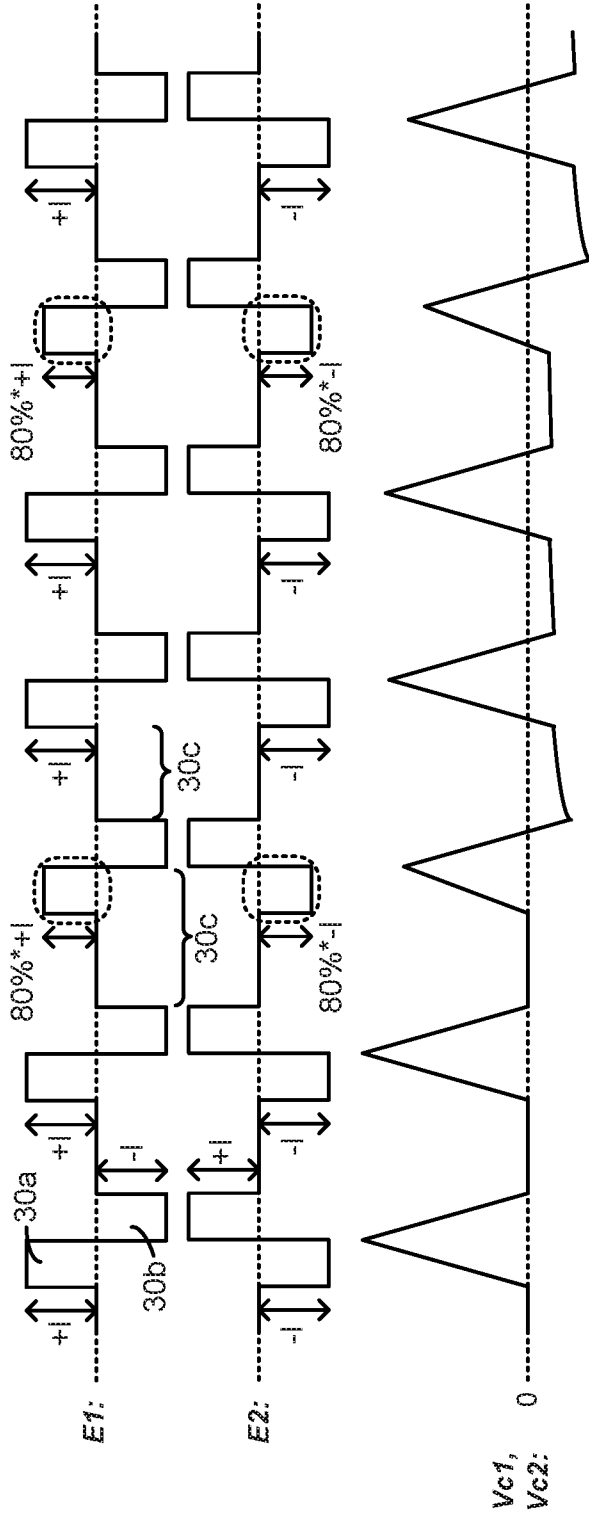
Figure 8E

Figure 8D

Figure 8C

Figure 8B

Figure 8A



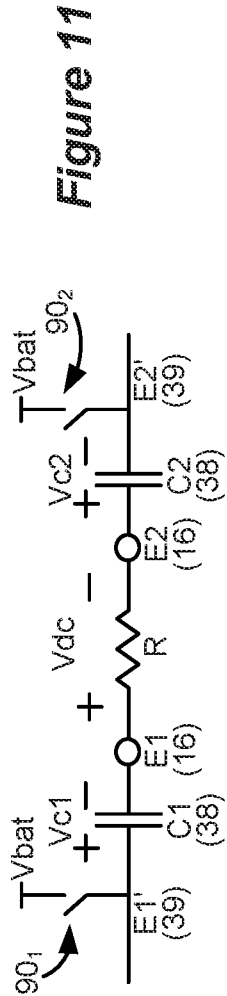
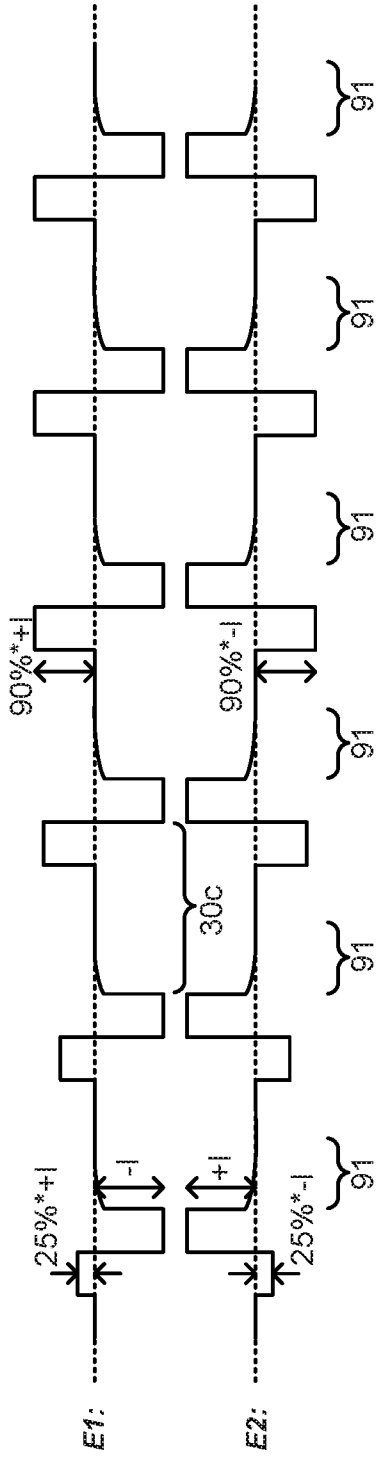


Figure 11

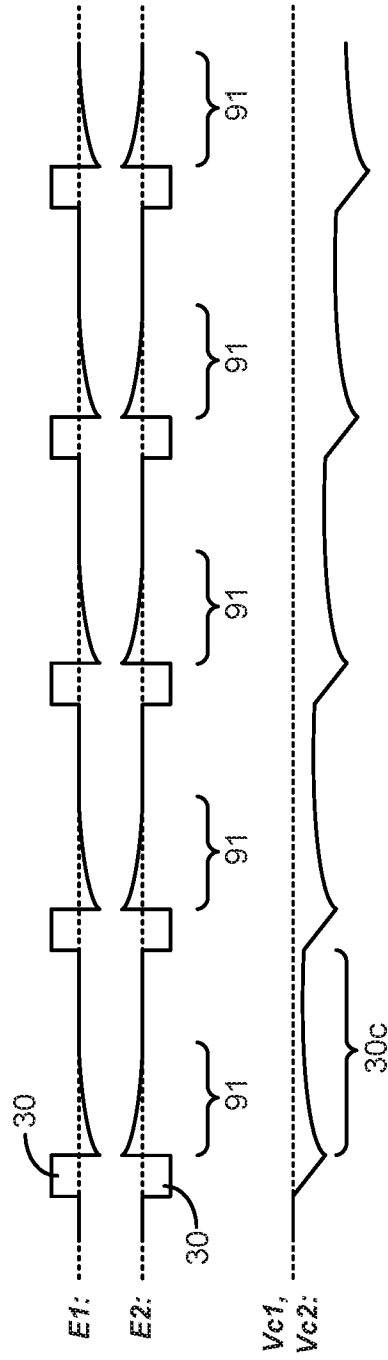


Figure 12

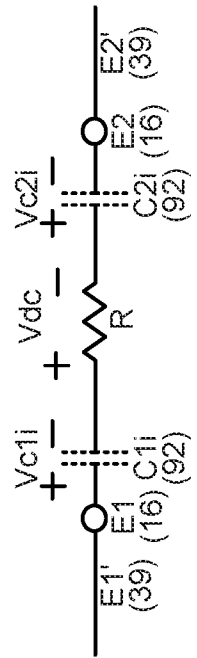


Figure 13

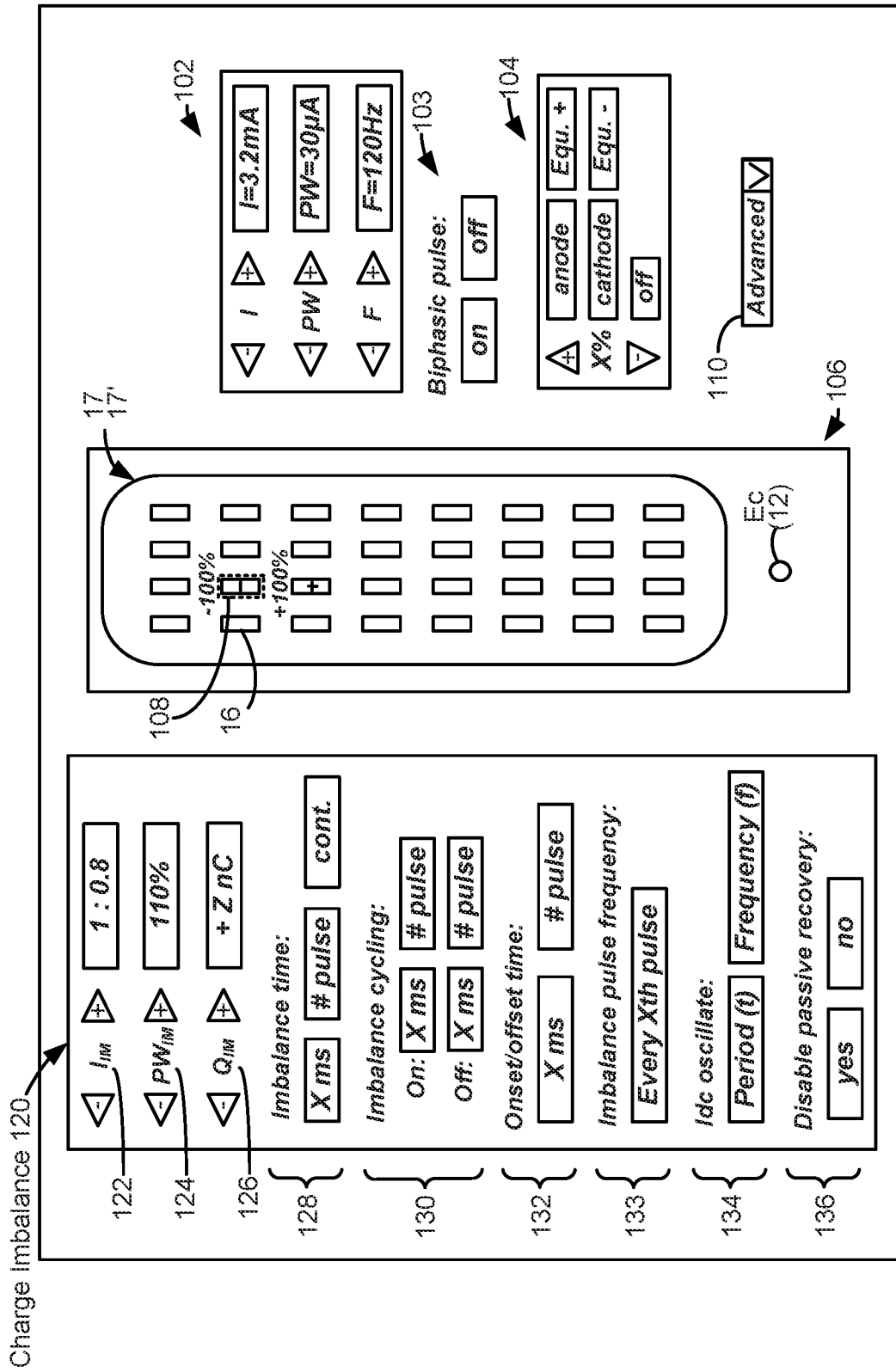


Figure 14

GUI 100

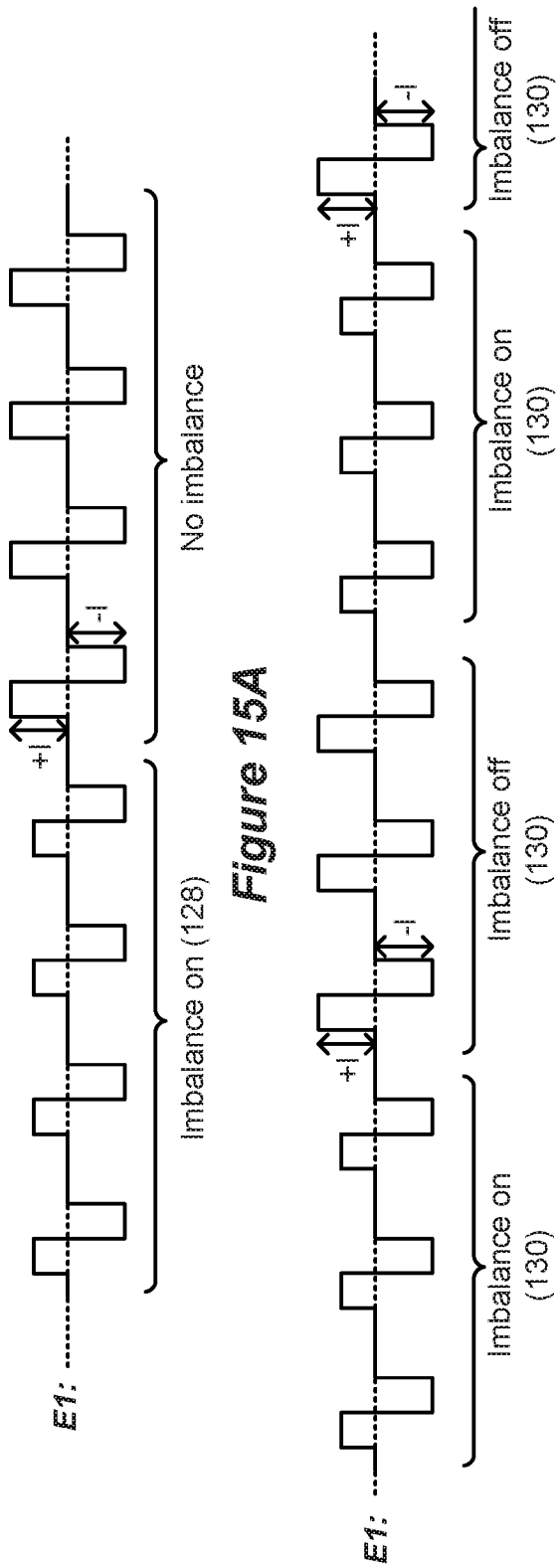


Figure 15A

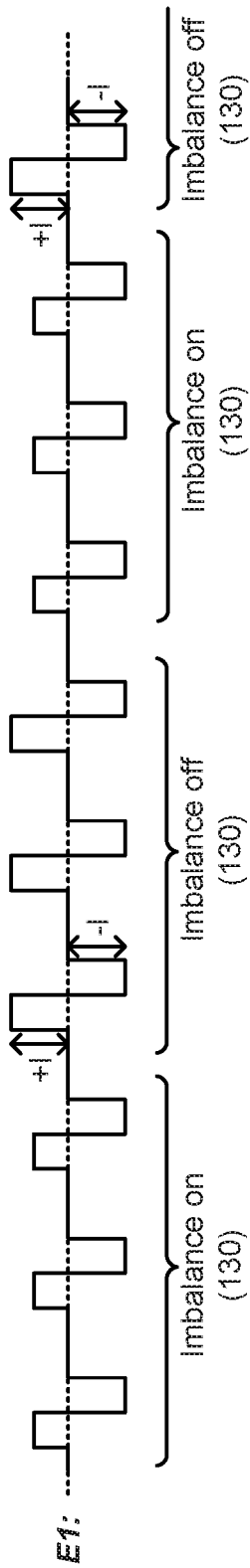


Figure 15B

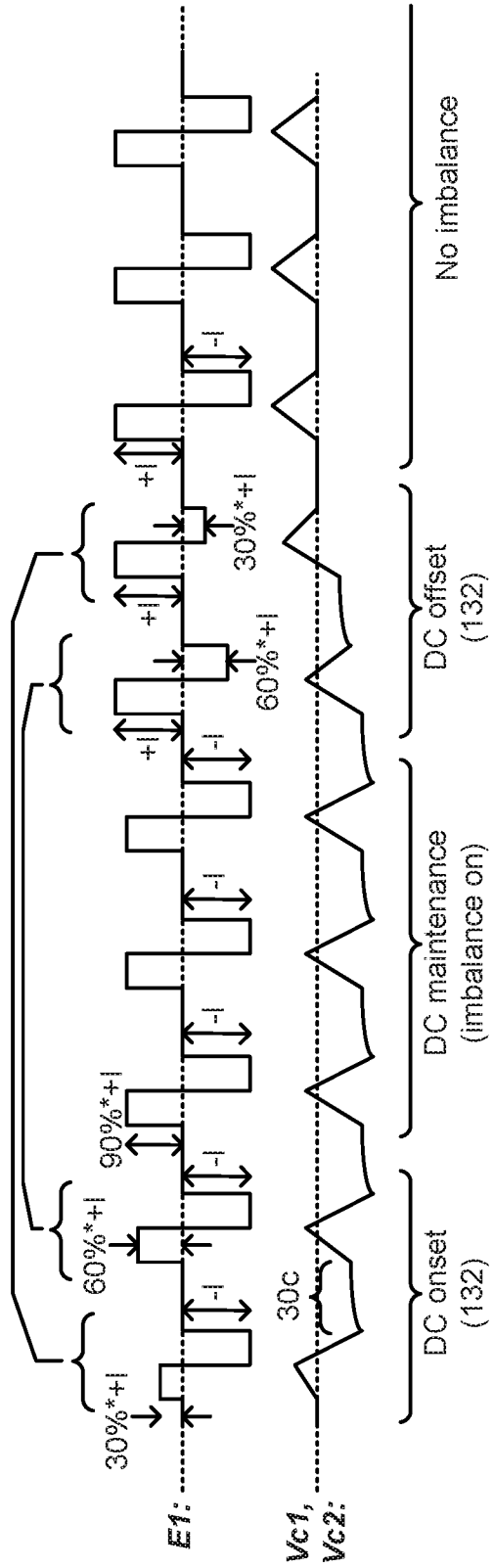


Figure 15C

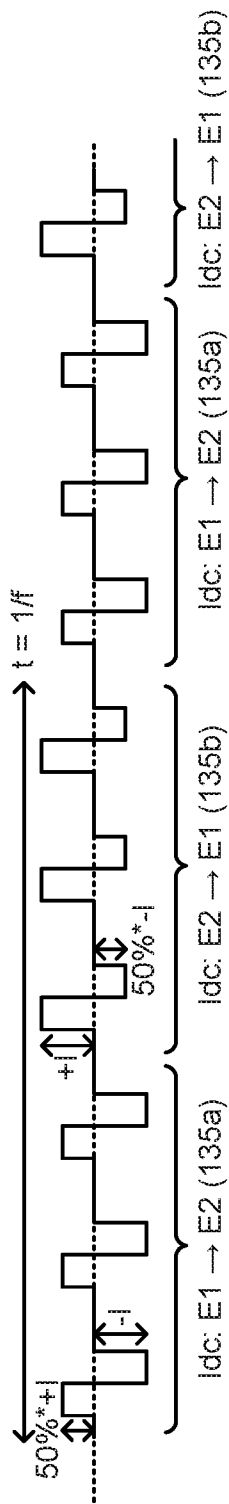


Figure 15D

Waveform parameters:
 - Stimulation parameters (e.g., I, PW, F);
 - Charge imbalance parameters (e.g., I_{lim}, PW_{lim}, Q_{lim}, etc.)

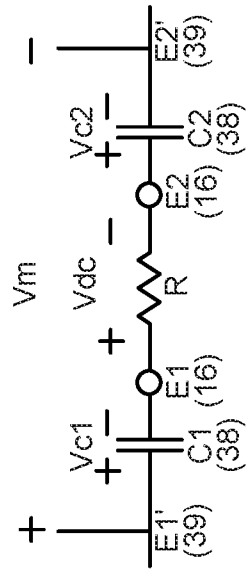
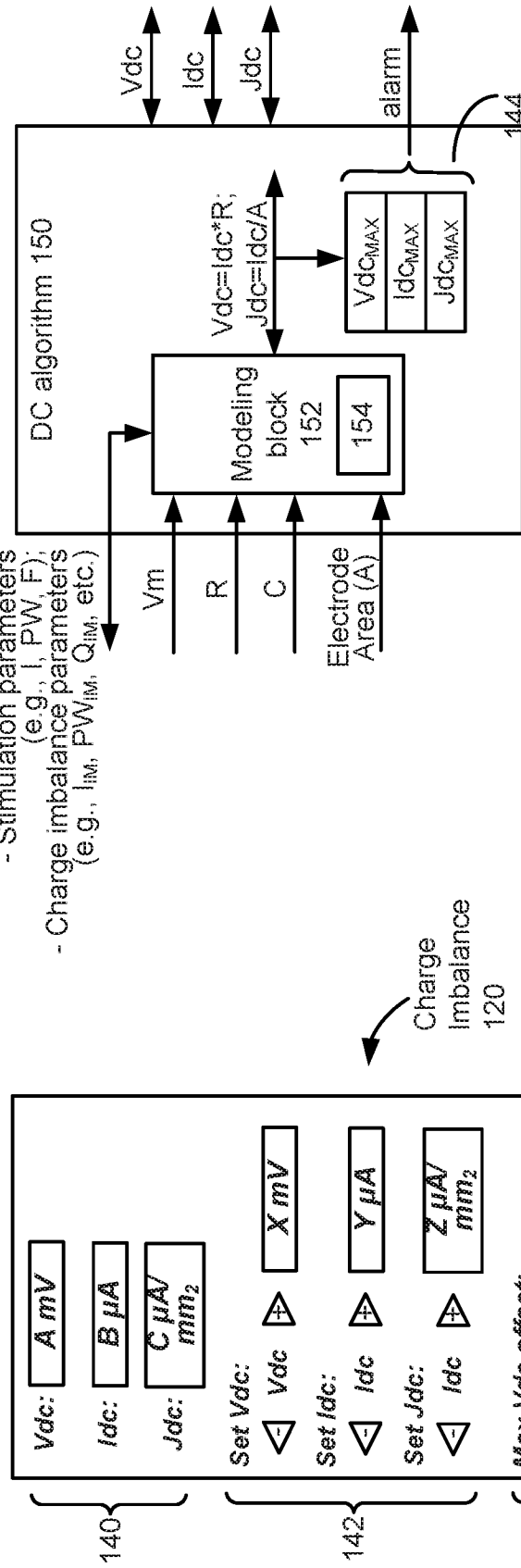
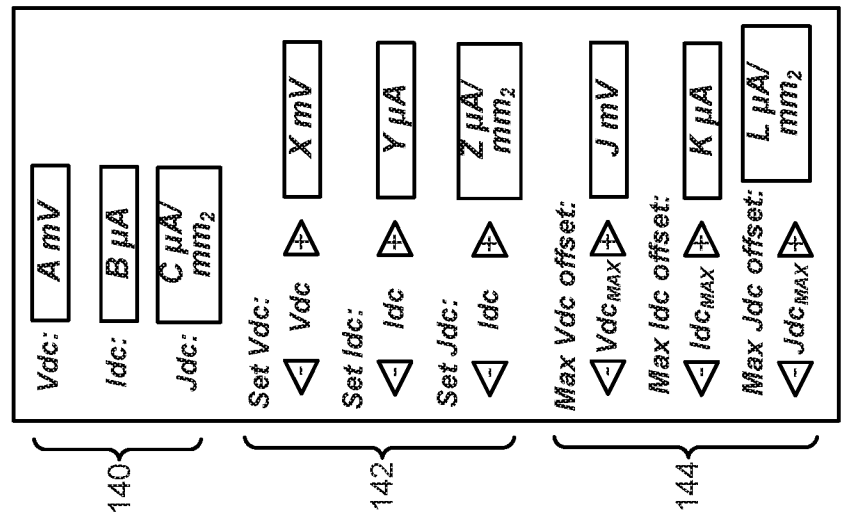


Figure 16



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/064079

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/372
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61N

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/121126 A1 (MARNFELDT GORAN N [US]) 5 May 2016 (2016-05-05) abstract; figures 4-8 paragraph [0002] paragraph [0038] - paragraph [0042] paragraph [0046] - paragraph [0048] paragraph [0057] - paragraph [0085]	1-28
A	US 2016/220820 A1 (ZOTTOLA DENNIS [US]) 4 August 2016 (2016-08-04) the whole document	1-28
A	US 2013/289661 A1 (GRIFFITH PAUL J [US] ET AL) 31 October 2013 (2013-10-31) the whole document	1-28
	----- -/--	

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 11 March 2019	Date of mailing of the international search report 20/03/2019
--	--

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/064079

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2014/035731 A1 (BOSTON SCIENT NEUROMODULATION [US]) 6 March 2014 (2014-03-06) the whole document -----	1-28

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/064079

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
US 2016121126	A1	05-05-2016	AU 2015343483 A1	18-05-2017
			CN 107073269 A	18-08-2017
			EP 3215217 A1	13-09-2017
			JP 6452836 B2	16-01-2019
			JP 2017533072 A	09-11-2017
			US 2016121126 A1	05-05-2016
			WO 2016073271 A1	12-05-2016

US 2016220820	A1	04-08-2016	AU 2016215425 A1	10-08-2017
			CN 107249681 A	13-10-2017
			EP 3253444 A1	13-12-2017
			JP 6452833 B2	16-01-2019
			JP 2018504237 A	15-02-2018
			US 2016220820 A1	04-08-2016
			US 2017333717 A1	23-11-2017
			WO 2016126718 A1	11-08-2016

US 2013289661	A1	31-10-2013	AU 2013252839 A1	13-11-2014
			EP 2841152 A1	04-03-2015
			JP 6070828 B2	01-02-2017
			JP 2015514550 A	21-05-2015
			US 2013289661 A1	31-10-2013
			US 2015174419 A1	25-06-2015
			US 2016008611 A1	14-01-2016
			US 2017021181 A1	26-01-2017
			US 2018169424 A1	21-06-2018
			WO 2013162793 A1	31-10-2013

WO 2014035731	A1	06-03-2014	AU 2013309216 A1	02-04-2015
			EP 2890452 A1	08-07-2015
			US 2014067015 A1	06-03-2014
			WO 2014035731 A1	06-03-2014
