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(54) Title: APPARATUS FOR DELIVERING CUSTOMIZED STIMULATION WAVEFORMS

(57) Abstract: Provided is a stimulation apparatus for a patient, the stimulation system comprising: an implantable system and an external system. The implantable system comprises: an implantable device for delivery stimulation energy to the patient. The implantable device comprises multiple stimulation delivery elements configured to deliver the stimulation energy to the patient. The external system comprises an external device comprising a user interface.

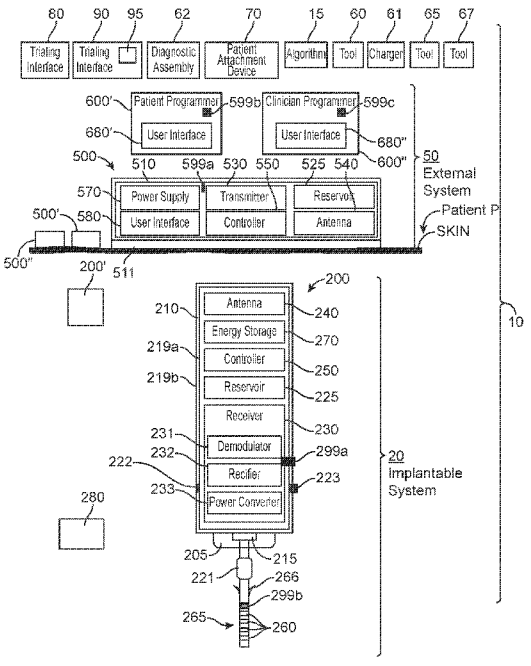

FIG. 1

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APPARATUS FOR DELIVERING CUSTOMIZED STIMULATION WAVEFORMS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present PCT application claims priority to United States Provisional Application Serial Number 63/071,925, titled "Apparatus for Delivering Customized Stimulation Waveforms", filed August 28, 2020 [Docket nos. 47476-718.101; NAL-024-PR1], the content of which is incorporated herein by reference in its entirety for all purposes.

[0002] The subject matter of this application is related to that in: United States Patent Application Serial Number 15/664,231, titled "Medical Apparatus Including an Implantable System and an External System ", filed July 31, 2017 [Docket nos. 47476-706.301; NAL-011-US]; United States Patent Application Serial Number 16/111,868, titled "Devices and Methods for Positioning External Devices in Relation to Implanted Devices ", filed August 24, 2018 [Docket nos. 47476-709.301; NAL-016-US]; United States Patent Application Serial Number 16/222,959, titled "Methods and Systems for Treating Pelvic Disorders and Pain Conditions ", filed December 17, 2018 [Docket nos. 47476-711.301; NAL-017-US]; United States Patent Application Serial Number 16/266,822, titled "Method and Apparatus for Versatile Minimally Invasive Neuromodulators ", filed February 4, 2019 [Docket nos. 47476-704.302; NAL-007-US-CON1]; United States Patent Application Serial Number 16/453,917, titled "Stimulation Apparatus", filed June 26, 2019 [Docket nos. 47476-712.301; NAL-015-US]; United States Patent Application Serial Number 16/505,425, titled "Wireless Implantable Sensing Devices ", filed July 8, 2019 [Docket nos. 10220-728.300; NAL-006-US-CON1]; United States Patent Application Serial Number 16/539,977, titled "Apparatus with Sequentially Implanted Stimulators", filed August 13, 2019 [Docket nos. 47476-713.301; NAL-019-US]; United States Patent Application Serial Number 16/993,999, titled "Apparatus for Peripheral or Spinal Stimulation ", filed August 14, 2020 [Docket nos. 47476-707.302; NAL-012-US-CON1]; United States Patent Application Serial Number 17/081,351, titled "Methods and Systems for Insertion and Fixation of Implantable Devices ", filed October 27, 2020 [Docket nos. 47476-710.302; NAL-013-US-CON1]; United States Provisional Patent Application Serial Number 63/112,055, titled "Apparatus for Delivering Enhanced Stimulation Waveforms", filed November 10, 2020 [Docket nos. 47476-723.101; NAL-026-PR1]; United States Patent Application Serial Number 17/187,654, titled "Method and Apparatus for Neuromodulation Treatments of Pain and Other Conditions ", filed February 26, 2021 [Docket nos. 47476-705.303; NAL-008-US-CON2]; United States Provisional Patent Application Serial Number 63/161,757, titled "Apparatus for

Delivering Enhanced Stimulation Waveforms", filed March 16, 2021 [Docket nos. 47476-724.101; NAL-027-PR1]; United States Patent Application Serial Number 17/240,629, titled "Method and Apparatus for Minimally Invasive Implantable Modulators", filed April 26, 2021 [Docket nos. 47476-703.302; NAL-005-US-CON1]; United States Provisional Patent Application Serial Number 63/218,159, titled "Apparatus for Delivering Enhanced Stimulation Waveforms", filed July 2, 2021 [Docket nos. 47476-723.102; NAL-026-PR2]; United States Patent Application Serial Number 17/372,095, titled "Apparatus with Enhanced Stimulation Waveforms", filed July 9, 2021 [Docket nos. 47476-708.302; NAL-014-US-CON1]; United States Patent Application Serial Number 17/379,928, titled "Stimulation Apparatus", filed July 19, 2021 [Docket nos. 47476-714.302; NAL-020-US-CON1]; United States Patent Application Serial Number 17/383,915, titled "Stimulation Apparatus", filed July 23, 2021 [Docket nos. 47476-715.301; NAL-021-US]; United States Patent Application Serial Number 17/383,972, titled "Systems with Implanted Conduit Tracking", filed July 23, 2021 [Docket nos. 47476-716.301; NAL-022-US]; United States Patent Application Serial Number 17/383,985, titled "Stimulation Energy Systems with Current Steering", filed July 23, 2021 [Docket nos. 47476-717.301; NAL-023-US]; United States Patent Application Serial Number 17/384,020, titled "Stimulation Apparatus", filed July 23, 2021 [Docket Nos. 47476-719.301; NAL-025-US]; the contents of each of which is incorporated herein by reference in its entirety for all purposes.

TECHNICAL FIELD

[0003] The present invention relates generally to medical apparatus for a patient, and in particular, apparatus that deliver enhanced stimulation to effectively deliver a therapy while avoiding undesired effects.

BACKGROUND OF THE INVENTION

[0004] Implantable devices that treat a patient and/or record patient data are known. For example, implants that deliver energy such as electrical energy, or deliver agents such as pharmaceutical agents are commercially available. Implantable electrical stimulators can be used to pace or defibrillate the heart, as well as modulate nerve tissue (e.g. to treat pain). Most implants are relatively large devices with batteries and long conduits, such as implantable leads configured to deliver electrical energy or implantable tubes (i.e. catheters) to deliver an agent. These implants require a fairly invasive implantation procedure, and periodic battery replacement, which requires additional surgery. The large sizes of these devices and their high costs have prevented their use in a variety of applications.

[0005] Nerve stimulation treatments have shown increasing promise recently, showing potential in the treatment of many chronic diseases including drug-resistant hypertension, motility disorders in the intestinal system, metabolic disorders arising from diabetes and obesity, and both chronic and acute pain conditions among others. Many of these implantable device configurations have not been developed effectively because of the lack of miniaturization and power efficiency, in addition to other limitations.

[0006] There is a need for apparatus, systems, devices and methods that provide one or more implantable devices and are designed to provide enhanced treatment of pain and other enhanced benefits.

SUMMARY

[0007] According to an aspect of the present inventive concepts, a stimulation apparatus for a patient comprises an implantable system including an implantable device for delivering stimulation energy to the patient. The implantable device comprises multiple stimulation delivery elements configured to deliver the stimulation energy to the patient. The stimulation apparatus further comprises an external system including an external device comprising a user interface.

[0008] In some embodiments, the apparatus is configured to perform a combination of active charge recovery and passive charge recovery. The stimulation energy can be delivered to multiple tissue locations, and the combination of active charge recovery and passive charge recovery can be performed over the multiple tissue locations. A net zero charge can be achieved collectively over the multiple tissue locations. The apparatus can be configured to optimize the combination of active charge recovery and passive charge recovery. The apparatus can optimize based on expanding a viable range of charge delivery.

[0009] In some embodiments, the stimulation energy is delivered as stimulation pulses, and the apparatus is configured to perform a charge recovery between at least 50% of the stimulation pulses. The apparatus can be configured to not perform charge recovery between at least one pair of pulses.

[0010] In some embodiments, the apparatus is configured to normalize charge delivery based on defined time periods.

[0011] In some embodiments, the apparatus can further comprise a user interface configured to allow an operator to modify one or more stimulation parameter settings. The apparatus can be configured to automatically adjust an operator entered value to a predetermined incremental value proximate the operator entered value. The user interface can comprise one or more icons configured to allow an operator to enter one or more stimulation parameter settings. The one or

more stimulation parameter settings can comprise settings for one or more stimulation parameters selected from the group consisting of: number of areas of stimulation; pulse width of stimulation; amplitude of stimulation; rate of stimulation; form of charge recovery; dosage on time; dosage off time; and combinations of these. The one or more stimulation parameter settings can comprise settings for two or more stimulation parameters selected from the group consisting of: number of areas of stimulation; pulse width of stimulation; amplitude of stimulation; rate of stimulation; form of charge recovery; dosage on time; dosage off time; and combinations of these. The one or more stimulation parameter settings can comprise settings for three or more stimulation parameters selected from the group consisting of: number of areas of stimulation; pulse width of stimulation; amplitude of stimulation; rate of stimulation; form of charge recovery; dosage on time; dosage off time; and combinations of these. The one or more icons can include one or more sets of data input icons configured to receive user input to set a dosage on time and/or a dosage off time for one or more anatomical locations to receive the stimulation energy. Two locations receiving stimulation energy can be limited to having the same dosage on and/or same dosage off times.

[0012] In some embodiments, the apparatus is configured to deliver the stimulation energy using an N of M scheme.

[0013] In some embodiments, the apparatus further comprises a controller and a memory coupled to the controller, and the memory stores instructions for the controller to perform an algorithm. The algorithm can be configured to provide feedback to a user regarding changing a desired passive charge recovery to active charge recovery. The stimulation energy can be delivered as stimulation pulses, and the algorithm can be configured to provide the feedback when there is insufficient time between stimulation pulses to provide a desired charge recovery.

[0014] In some embodiments, the stimulation energy is delivered as waveforms that comprise complex and/or arbitrary rate combinations using a greatest common divisor (GCD) scheme.

[0015] In some embodiments, the stimulation energy is delivered as dosed envelopes that are time-shifted to be non-overlapping in time. The apparatus can be configured to maximize the time separation between envelopes.

[0016] In some embodiments, the stimulation energy is delivered as stimulation pulses, and the apparatus is configured to avoid and/or minimize an overlapping of stimulation pulses. The apparatus can avoid overlapping of stimulation pulses in order to achieve: reduced power requirements of the implantable device; reduced transfer of energy between the external device and the implantable device; and/or a relatively constant average load condition for the implantable device.

[0017] In some embodiments, the apparatus is configured to receive a stimulation parameter setting from a user and to adjust the received setting to a closest incremental step value.

[0018] In some embodiments, the stimulation energy delivered comprises a pre-pulse delivered prior to a stimulation pulse that is configured to prime and/or hyperpolarize neurons and/or other cells receiving the stimulation energy.

[0019] In some embodiments, the apparatus is configured to deliver the stimulation energy via a chirp stimulation waveform that includes a chirp signal comprising a frequency that continuously varies with time. The chirp signal frequency can increase over time. The chirp signal frequency can decrease over time. The chirp stimulation waveform can comprise a sawtooth and/or triangle wave. The chirp stimulation waveform can comprise a ramp. The ramp can have a sinusoidal, sigmoidal, and/or rectangular shape. The ramp can have an adjustable slope.

[0020] In some embodiments, the stimulation energy delivered comprises a stimulation waveform that is delivered at a sub-threshold level in its entirety.

[0021] In some embodiments, the stimulation energy delivered comprises a stimulation waveform that is delivered at both a sub-threshold level and a supra threshold level.

[0022] In some embodiments, the apparatus further comprises a user interface configured to receive stimulation parameter settings from a user, and the stimulation energy is delivered based on the stimulation parameter settings. The stimulation parameter settings can comprise energy delivery parameters to be delivered per a time schedule. The time schedule can be configured to be adjusted by a user via the user interface. The apparatus can be configured to deliver the stimulation energy per the time schedule, manually, or both. The stimulation parameter settings can comprise a setting selected from the group consisting of: duration of stimulation; a name or other identifier for a particular set of stimulation parameter settings; the location to which stimulation energy can be to be delivered; and combinations thereof. The apparatus can be configured to record a satisfaction level associated with the stimulation parameter settings. The apparatus can be further configured to adjust future stimulation energy delivery based on the recorded satisfaction level.

[0023] In some embodiments, the implantable device comprises at least one lead comprising the multiple stimulation elements and a connecting assembly configured to operably attach to the at least one lead. The lead can comprise a marker positioned to enable a user to partially insert the at least one lead into the connecting assembly. The connecting assembly can comprise an elongate component for insertion into the connecting assembly to limit travel of the at least one lead into the connecting assembly.

[0024] In some embodiments, the apparatus further comprises a charging assembly configured to provide power to the external device and to upload data from the external device. The charging assembly can be further configured to transmit the uploaded data to a remote computer and/or memory storage location.

[0025] The technology described herein, along with the attributes and attendant advantages thereof, will best be appreciated and understood in view of the following detailed description taken in conjunction with the accompanying drawings in which representative embodiments are described by way of example.

INCORPORATION BY REFERENCE

[0026] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference. The content of all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference in their entirety for all purposes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The foregoing and other objects, features and advantages of embodiments of the present inventive concepts will be apparent from the more particular description of preferred embodiments, as illustrated in the accompanying drawings in which like reference characters refer to the same or like elements. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the preferred embodiments.

[0028] **Fig. 1** is a schematic anatomical view of a medical apparatus comprising an external system and an implantable system, consistent with the present inventive concepts.

[0029] **Figs. 2A-B** illustrate a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0030] **Fig. 3** illustrates a user's view of a user interface for providing stimulation parameter settings, consistent with the present inventive concepts.

[0031] **Figs. 4A-B** illustrate a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0032] **Fig. 5** is a graphical view of a stimulation waveform, consistent with the present inventive concepts.

[0033] **Figs. 6A-B** illustrate a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0034] **Figs. 7A-B** are graphical views of two stimulation waveforms, consistent with the present inventive concepts.

[0035] **Figs. 8A-C** are a set of stimulation waveforms in which a dosing envelope is applied, consistent with the present inventive concepts.

[0036] **Figs. 9A-D** illustrate a user's view of a user interface for providing stimulation parameter settings and three graphical views of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0037] **Figs. 10A-D** illustrate a user's view of a user interface for providing stimulation parameter settings and three graphical views of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0038] **Figs. 11A-B** are graphs of stimulation waveforms, consistent with the present inventive concepts.

[0039] **Figs. 12A-B** are graphs of stimulation waveforms, consistent with the present inventive concepts.

[0040] **Figs. 13A-C** illustrate a user's view of a user interface for providing stimulation parameter settings and two graphical views of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0041] **Figs. 14A-C** illustrate a user's view of a user interface for providing stimulation parameter settings and two graphical views of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0042] **Figs. 15A-C** illustrate two user's views of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown in Fig. 15B, respectively, consistent with the present inventive concepts.

[0043] **Figs. 16A-C** illustrate a user's view of a user interface for providing stimulation parameter settings and two graphical views of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0044] **Figs. 17A-B** illustrate a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, consistent with the present inventive concepts.

[0045] **Figs. 18A-B** are two stimulation waveforms, consistent with the present inventive concepts.

[0046] **Figs. 19A-B** illustrate schematic views of a trialing interface device with two different connecting assemblies, consistent with the present inventive concepts.

[0047] **Fig. 20** illustrates a user's view of a user interface, consistent with the present inventive concepts.

[0048] **Figs. 21A-E** illustrate a series of side sectional views of connection arrangements between an implantable device connector and an implantable lead, consistent with the present inventive concepts.

[0049] **Figs. 22A-C** illustrate perspective views of various assemblies for connecting a trialing stimulator to an implanted lead, consistent with the present inventive concepts.

[0050] **Fig. 23** illustrates a schematic view of a charging assembly for an external device, consistent with the present inventive concepts.

[0051] **Figs. 24A-K** illustrate views of various stimulation waveforms, consistent with the present inventive concepts.

DETAILED DESCRIPTION OF THE DRAWINGS

[0052] The terminology used herein is for the purpose of describing particular embodiments and is not intended to be limiting of the inventive concepts. Furthermore, embodiments of the present inventive concepts may include several novel features, no single one of which is solely responsible for its desirable attributes or which is essential to practicing an inventive concept described herein. As used herein, the singular forms "a," "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise.

[0053] It will be further understood that the words "comprising" (and any form of comprising, such as "comprise" and "comprises"), "having" (and any form of having, such as "have" and "has"), "including" (and any form of including, such as "includes" and "include") or "containing" (and any form of containing, such as "contains" and "contain") when used herein, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

[0054] It will be understood that, although the terms first, second, third etc. may be used herein to describe various limitations, elements, components, regions, layers, and/or sections, these limitations, elements, components, regions, layers, and/or sections should not be limited by these terms. These terms are only used to distinguish one limitation, element, component, region, layer or section from another limitation, element, component, region, layer or section. Thus, a first limitation, element, component, region, layer or section discussed below could be termed a

second limitation, element, component, region, layer or section without departing from the teachings of the present application.

[0055] It will be further understood that when an element is referred to as being "on", "attached", "connected" or "coupled" to another element, it can be directly on or above, or connected or coupled to, the other element, or one or more intervening elements can be present. In contrast, when an element is referred to as being "directly on", "directly attached", "directly connected" or "directly coupled" to another element, there are no intervening elements present. Other words used to describe the relationship between elements should be interpreted in a like fashion (e.g. "between" versus "directly between," "adjacent" versus "directly adjacent," etc.). A first component (e.g. a device, assembly, housing or other component) can be "attached", "connected" or "coupled" to another component via a connecting filament (as defined below). In some embodiments, an assembly comprising multiple components connected by one or more connecting filaments is created during a manufacturing process (e.g. pre-connected at the time of an implantation procedure of the apparatus of the present inventive concepts). Alternatively or additionally, a connecting filament can comprise one or more connectors (e.g. a connectorized filament comprising a connector on one or both ends), and a similar assembly can be created by a user (e.g. a clinician) operably attaching the one or more connectors of the connecting filament to one or more mating connectors of one or more components of the assembly.

[0056] It will be further understood that when a first element is referred to as being "in", "on" and/or "within" a second element, the first element can be positioned: within an internal space of the second element, within a portion of the second element (e.g. within a wall of the second element); positioned on an external and/or internal surface of the second element; and combinations of one or more of these.

[0057] Spatially relative terms, such as "beneath," "below," "lower," "above," "upper" and the like may be used to describe an element and/or feature's relationship to another element(s) and/or feature(s) as, for example, illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use and/or operation in addition to the orientation depicted in the figures. For example, if the device in a figure is turned over, elements described as "below" and/or "beneath" other elements or features would then be oriented "above" the other elements or features. The device can be otherwise oriented (e.g. rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly.

[0058] As used herein, the term "proximate" shall include locations relatively close to, on, in, and/or within a referenced component or other location.

[0059] The term "and/or" where used herein is to be taken as specific disclosure of each of the two specified features or components with or without the other. For example, "A and/or B" is to be taken as specific disclosure of each of (i) A, (ii) B and (iii) A and B, just as if each is set out individually herein.

[0060] The term "diameter" where used herein to describe a non-circular geometry is to be taken as the diameter of a hypothetical circle approximating the geometry being described. For example, when describing a cross section, such as the cross section of a component, the term "diameter" shall be taken to represent the diameter of a hypothetical circle with the same cross-sectional area as the cross section of the component being described.

[0061] The terms "major axis" and "minor axis" of a component where used herein are the length and diameter, respectively, of the smallest volume hypothetical cylinder which can completely surround the component.

[0062] The term "functional element" where used herein, is the be taken to include a component comprising one, two or more of: a sensor; a transducer; an electrode; an energy delivery element; an agent delivery element; a magnetic field generating transducer; and combinations of one or more of these. In some embodiments, a functional element comprises a transducer selected from the group consisting of: light delivery element; light emitting diode; wireless transmitter; Bluetooth device; mechanical transducer; piezoelectric transducer; pressure transducer; temperature transducer; humidity transducer; vibrational transducer; audio transducer; speaker; and combinations of one or more of these. In some embodiments, a functional element comprises a needle, a catheter (e.g. a distal portion of a catheter), an iontophoretic element or a porous membrane, such as an agent delivery element configured to deliver one or more agents. In some embodiments, a functional element comprises one or more sensors selected from the group consisting of: electrode; sensor configured to record electrical activity of tissue; blood glucose sensor such as an optical blood glucose sensor; pressure sensor; blood pressure sensor; heart rate sensor; inflammation sensor; neural activity sensor; muscular activity sensor; pH sensor; strain gauge; accelerometer; gyroscope; GPS; respiration sensor; respiration rate sensor; temperature sensor; magnetic sensor; optical sensor; MEMs sensor; chemical sensor; hormone sensor; impedance sensor; tissue impedance sensor; body position sensor; body motion sensor; physical activity level sensor; perspiration sensor; patient hydration sensor; breath monitoring sensor; sleep monitoring sensor; food intake monitoring sensor; urine movement sensor; bowel movement sensor; tremor sensor; pain level sensor; orientation sensor; motion sensor; and combinations of one or more of these.

[0063] The term "transducer" where used herein is to be taken to include any component or combination of components that receives energy or any input, and produces an output. For example, a transducer can include an electrode that receives electrical energy, and distributes the electrical energy to tissue (e.g. based on the size of the electrode). In some configurations, a transducer converts an electrical signal into any output, such as light (e.g. a transducer comprising a light emitting diode or light bulb), sound (e.g. a transducer comprising a piezo crystal configured to deliver ultrasound energy), pressure, heat energy, cryogenic energy, chemical energy, mechanical energy (e.g. a transducer comprising a motor or a solenoid), magnetic energy, and/or a different electrical signal (e.g. a Bluetooth or other wireless communication element). Alternatively or additionally, a transducer can convert a physical quantity (e.g. variations in a physical quantity) into an electrical signal. A transducer can include any component that delivers energy and/or an agent to tissue, such as a transducer configured to deliver one or more of: electrical energy to tissue (e.g. a transducer comprising one or more electrodes); light energy to tissue (e.g. a transducer comprising a laser, light emitting diode and/or optical component such as a lens or prism); mechanical energy to tissue (e.g. a transducer comprising a tissue manipulating element); sound energy to tissue (e.g. a transducer comprising a piezo crystal); thermal energy to tissue (e.g. heat energy and/or cryogenic energy); chemical energy; electromagnetic energy; magnetic energy; and combinations of one or more of these.

[0064] The term "transmission signal" where used herein is to be taken to include any signal transmitted between two components, such as via a wired or wireless communication pathway. For example, a transmission signal can comprise a power and/or data signal wirelessly transmitted between a component external to the patient and one or more components implanted in the patient. A transmission signal can include one or more signals transmitted using body conduction. Alternatively or additionally, a transmission signal can comprise reflected energy, such as energy reflected from any power and/or data signal.

[0065] The term "data signal" where used herein is to be taken to include a transmission signal including at least data. For example, a data signal can comprise a transmission signal including data and sent between a component external to the patient and one or more components implanted in the patient. Alternatively, a data signal can comprise a transmission signal including data sent from an implanted component to one or more components external to the patient. A data signal can comprise a radiofrequency signal including data (e.g. a radiofrequency signal including both power and data) and/or a data signal sent using body conduction.

[0066] The term "implantable" where used herein is to be taken to define a component which is constructed and arranged to be fully or partially implanted in a patient's body and/or a

component that has been fully or partially implanted in a patient. The term "external" where used herein is to be taken to define a component which is constructed and arranged to be positioned outside of the patient's body.

[0067] The terms "attachment", "attached", "attaching", "connection", "connected", "connecting" and the like, where used herein, are to be taken to include any type of connection between two or more components. The connection can include an "operable connection" or "operable attachment" which allows multiple connected components to operate together such as to transfer information, power, and/or material (e.g. an agent to be delivered) between the components. An operable connection can include a physical connection, such as a physical connection including a connection between two or more: wires or other conductors (e.g. an "electrical connection"), optical fibers, wave guides, tubes such as fluid transport tubes, and/or linkages such as translatable rods or other mechanical linkages. Alternatively or additionally, an operable connection can include a non-physical or "wireless" connection, such as a wireless connection in which information and/or power is transmitted between components using electromagnetic energy. A connection can include a connection selected from the group consisting of: a wired connection; a wireless connection; an electrical connection; a mechanical connection; an optical connection; a sound propagating connection; a fluid connection; and combinations of one or more of these.

[0068] The term "connecting filament" where used herein is to be taken to define a filament connecting a first component to a second component. The connecting filament can include a connector on one or both ends, such as to allow a user to operably attach at least one end of the filament to a component. A connecting filament can comprise one or more elements selected from the group consisting of: wires; optical fibers; fluid transport tubes; mechanical linkages; wave guides; flexible circuits; and combinations of one or more of these. A connecting filament can comprise rigid filament, a flexible filament or it can comprise one or more flexible portions and one or more rigid portions.

[0069] The term "connectorized" where used herein is to be taken to refer to a filament, housing or other component that includes one or more connectors (e.g. clinician or other user-attachable connectors) for operably connecting that component to a mating connector (e.g. of the same or different component).

[0070] The terms "**stimulation parameter**", "**stimulation signal parameter**" or "**stimulation waveform parameter**" where used herein can be taken to refer to one or more parameters of a stimulation waveform (also referred to as a stimulation signal). Applicable stimulation parameters of the present inventive concepts shall include but are not limited to: amplitude (e.g.

amplitude of voltage and/or current); average amplitude; peak amplitude; frequency; average frequency; pulse width (also referred to as "pulse pattern on time"); period; phase; polarity; pulse shape; a duty cycle parameter (e.g. frequency, pulse width, and/or off time); inter-pulse gap (also referred to as "pulse pattern off time", or "inter-pulse interval"); polarity; burst-on (also referred to as "dosage on") period; burst-off (also referred to as "dosage off") period; inter-burst period; pulse train; train-on period; train-off period; inter-train period; drive impedance; duration of pulse and/or amplitude level; duration of stimulation waveform; repetition of stimulation waveform; an amplitude modulation parameter; a frequency modulation parameter; a burst parameter; a power spectral density parameter; an anode/cathode configuration parameter; amount of energy and/or power to be delivered; rate of energy and/or power delivery; time of energy delivery initiation; method of charge recovery; and combinations of one or more of these. A "stimulation parameter" can refer to a level and/or other "setting" of a stimulation parameter, such as: a quantitative level (e.g. an amplitude of X volts, or a frequency of Y hertz), a configuration (e.g. use of passive and/or active charge recovery) and/or other setting of a parameter (e.g. as entered by a user and or determined by apparatus 10). A stimulation parameter can refer to a single stimulation pulse, multiple stimulation pulses, or a portion of a stimulation pulse. The term "**amplitude**" where used herein can refer to an instantaneous or continuous amplitude of one or more stimulation pulses (e.g. the instantaneous voltage level or current level of a pulse). The term "**pulse**" where used herein can refer to a period of time during which stimulation energy is relatively continuously being delivered. In some embodiments, stimulation energy delivered during a pulse comprises energy selected from the group consisting of: electrical energy; magnetic energy; electromagnetic energy; light energy; sound energy such as ultrasound energy; mechanical energy such as vibrational energy; thermal energy such as heat energy or cryogenic energy; chemical energy; and combinations of one or more of these. In some embodiments, stimulation energy comprises electrical energy and a pulse comprises a phase change in current and/or voltage. In these embodiments, an "**inter-phase gap**" can be present within a single pulse. The term inter-phase gap where used herein can refer to a period of time between two portions of a pulse comprising a phase change during which zero energy or minimal energy is delivered. The term "**quiescent period**" where used herein can refer to a period of time during which zero energy or minimal energy is delivered (e.g. insufficient energy to elicit an action potential and/or other neuronal response). The term "**inter-pulse gap**" where used herein can refer to a quiescent period between the end of one pulse to the onset of the next (sequential) pulse. The terms "**pulse train**" or "**train**" where used herein can refer to a series of pulses. The terms "**burst**", "**burst of pulses**" or "**burst stimulation**" where

used herein can refer to a series of pulse trains, each separated by a quiescent period. The term "**train-on period**" where used herein can refer to a period of time from the beginning of the first pulse to the end of the last pulse of a single train. The term "**train-off period**" where used herein can refer to a quiescent period between the end of one train and the beginning of the next train. The term "**burst-on period**" where used herein can refer to a period of time from the beginning of the first pulse of the first train to the end of the last pulse of the last train of a single burst. The term "**burst-off period**" where used herein can refer to a quiescent period between the end of one burst and the beginning of the next burst. The term "**inter-train period**" where used herein can refer to a quiescent period between the end of one train and the beginning of the next train. The term "**inter-burst period**" where used herein can refer to a quiescent period between the end of one burst and the beginning of the next burst. The term "**train envelope**" where used herein can refer to a curve outlining the amplitude extremes of a series of pulses in a train. The term "**burst envelope**" where used herein can refer to a curve outlining the amplitude extremes of a series of pulses in a burst. The term "**train ramp duration**" where used herein can refer to the time from the onset of a train until its train envelope reaches a desired target magnitude. The term "**burst ramp duration**" where used herein can refer to the time from the onset of a burst until its burst envelope reaches a desired target magnitude.

[0071] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable sub-combination. For example, it will be appreciated that all features set out in any of the claims (whether independent or dependent) can be combined in any given way.

[0072] The present inventive concepts include a medical apparatus and clinical methods for treating a patient, such as to treat pain. The patient can comprise a human or other mammalian patient. The medical apparatus can comprise a stimulation apparatus. The medical apparatus can comprise an implantable system and an external system. The implantable system can comprise one or more similar and/or dissimilar implantable devices. Each implantable device comprises a housing surrounding one or more stimulation producing components. A lead comprising one or more stimulation elements can be pre-attached to the housing, or attachable to the housing (e.g. attached in a clinical procedure in which the implantable device is implanted in a patient).

[0073] The apparatus can include a trialing interface which provides energy to the stimulation elements during the implantation procedure, such as to confirm proper placement of the

stimulation elements and/or to titrate the stimulation delivered. In embodiments in which the lead is pre-attached to the housing of the implantable device, the trialing interface can be configured to provide power (e.g. wireless power) to the implantable device, the implantable device providing stimulation energy to the stimulation elements derived from the power provided by the trialing interface. In embodiments in which the lead is attachable to the housing of the implantable device, the trialing interface can attach to the lead (prior to its attachment to the housing of the implantable device), and the trialing interface can then provide the stimulation energy directly to the stimulation elements.

[0074] In some embodiments, the implantable system comprises a first implantable device that delivers stimulation energy via energy received wirelessly from one or more external devices, and a second implantable device that delivers stimulation energy via an integral (e.g. also implanted) battery. In these embodiments, the first implantable device can be configured to deliver stimulation energy during a limited period of time (e.g. a trial period in which stimulation parameter settings are determined and/or acceptability of the apparatus is determined), and the second implantable device can be configured to deliver stimulation energy for a prolonged period of time in which long-term stimulation therapy is provided to a patient. In these embodiments, a single implantable lead comprising one or more stimulation energy delivery elements (e.g. electrodes) can be connected to the first implantable device and then the second implantable device. In some embodiments, a first implantable device can be configured to remain implanted in the patient for a limited period of time, such as to reduce cost of manufacture, and a second implantable device is configured for a longer implant life. The first implantable device can be used in a trialing procedure in which the stimulation apparatus is assessed for acceptable use (e.g. by the patient and/or clinician) and/or one or more stimulation parameter settings are optimized or otherwise determined.

[0075] Each implantable device can comprise one or more implantable antennas configured to receive power and/or data. Each implantable device can comprise an implantable receiver configured to receive the power and/or data from the one or more implantable antennas. Each implantable device can comprise one or more implantable functional elements (e.g. an implantable stimulation element). An implantable functional element can be configured to interface with the patient (e.g. interface with tissue of the patient or interface with any patient location). Alternatively or additionally, an implantable functional element can interface with a portion of an implantable device (e.g. to measure an implantable device parameter). In some embodiments, the one or more implantable functional elements can comprise one or more transducers, electrodes, and/or other elements configured to deliver energy to tissue.

Alternatively or additionally, the one or more implantable functional elements can comprise one or more sensors, such as a sensor configured to record a physiologic parameter of the patient. In some embodiments, one or more implantable functional elements are configured to record device information and/or patient information (e.g. patient physiologic or patient environment information).

[0076] Each implantable device can comprise an implantable controller configured to control (e.g. modulate power to, send a signal to, and/or receive a signal from) the one or more implantable functional elements. In some embodiments, an implantable controller of a first implantable device is configured to control one or more other implantable devices. Each implantable device can comprise an implantable energy storage assembly (e.g. a battery and/or a capacitor) configured to provide power to the implantable controller (e.g. a controller comprising a stimulation waveform generator), the implantable receiver and/or the one or more implantable functional elements. In some embodiments, an implantable energy storage assembly is further configured to provide power to an assembly that transmits signals via the implantable antenna (e.g. when the implantable device is further configured to transmit data to one or more external devices). Each implantable device can comprise an implantable housing surrounding the implantable controller and the implantable receiver. In some embodiments, one or more implantable antennas are positioned within the implantable housing. Alternatively or additionally, one or more implantable antennas and/or implantable functional elements can be positioned outside the implantable housing, and tethered (e.g. electrically tethered) to one or more electrical components of the implantable device positioned within the implantable housing. In some embodiments, one or more implantable functional elements are positioned on an implantable lead, such as a flexible lead mechanically fixed or attachable to the implantable housing and operably connected (e.g. electrically, fluidly, optically and/or mechanically) to one or more components internal to the implantable housing. The implantable lead can be inserted (e.g. tunneled) through tissue of the patient, such that its one or more functional elements are positioned proximate tissue to be treated and/or positioned at an area in which data is to be recorded. In some embodiments, the implantable lead is configured to operably attach to and/or detach from, multiple implantable devices.

[0077] The external system of the medical apparatus of the present inventive concepts can comprise one or more similar and/or dissimilar external devices. Each external device can comprise one or more external antennas configured to transmit power and/or data to one or more implanted components of the implantable system. Each external device can comprise an external transmitter configured to drive the one or more external antennas. Each external device can

comprise an external power supply configured to provide power to at least the external transmitter. Each external device can comprise an external programmer configured to control the external transmitter and/or an implantable device (e.g. when an external power transmitter is not included in the apparatus or otherwise not present during use). Each external device can comprise an external housing that surrounds at least the external transmitter. In some embodiments, the external housing surrounds the one or more external antennas, the external power supply and/or the external programmer.

[0078] The external programmer can comprise a discrete controller separate from the one or more external devices, and/or a controller integrated into one or more external devices. The external programmer can comprise a user interface, such as a user interface configured to set, adjust, and/or otherwise modify one or more treatment and/or data recording settings of the medical apparatus of the present inventive concepts. In some embodiments, the external programmer is configured to collect and/or diagnose recorded patient information, such as to provide the information and/or diagnosis to a clinician of the patient, to a patient family member and/or to the patient themselves. The collected information and/or diagnosis can be used to modify treatment or other operating parameters of the medical apparatus. In some embodiments, at least two external programmers are included, such as a first external programmer configured for use by the patient, and a second external programmer configured for use by a clinician of the patient.

[0079] In some embodiments, a medical apparatus comprises a stimulation apparatus for activating, blocking, affecting or otherwise stimulating (hereinafter "stimulate" or "stimulating") tissue of a patient, such as nerve tissue or nerve root tissue (hereinafter "nerve", "nerves", "nerve tissue" or "nervous system tissue"). The stimulation apparatus comprises an external system configured to transmit power, and an implanted system configured to receive the power from the external system and to deliver stimulation energy to tissue. The delivered stimulation energy can comprise one or more stimulation waveforms, such as a stimulation waveform configured to enhance treatment of pain while minimizing undesired effects. The stimulation signal (also referred to as "stimulation energy" herein) delivered by the implanted system can be independent of the power received from the external system, such as to be independent of one or more of: the position of one or more components of the external system; the changing position of one or more components of the external system; the frequency of the power received from the external system; the amplitude of the power received from the external system; changes in amplitude of the power received from the external system; duty cycle of the power received from the external

system; envelope of the power received from the external system; and combinations of one or more of these.

[0080] **Referring now to Fig. 1**, a schematic anatomical view of a stimulation apparatus for providing a therapy to a patient is illustrated, consistent with the present inventive concepts. **Apparatus 10** comprises **implantable system 20** and **external system 50**. External system 50 transmits transmission signals to one or more components of implantable system 20. These transmission signals can comprise power and/or data. Implantable system 20 comprises **implantable device 200** shown implanted beneath the skin of patient P.

[0081] In some embodiments, implantable system 20 comprises multiple similar or dissimilar implantable devices 200 (singly or collectively implantable device 200), such as is described in applicant's co-pending United States Patent Application Serial Number 17/372,095, titled "Apparatus with Enhanced Stimulation Waveforms", filed July 9, 2021 [Docket nos. 47476-708.302; NAL-014-US-CON1]. Each implantable device 200 can be configured to receive power and data from a transmission signal transmitted by external system 50, such as when stimulation energy delivered to the patient (e.g. to nerve or other tissue of the patient) by implantable device 200 is provided via wireless transmissions signals from external system 50. In some embodiments, implantable system 20 comprises at least two implantable devices, such as implantable device 200 and **implantable device 200'** shown in Fig. 1. Implantable device 200' can be of similar construction and arrangement to implantable device 200, and it can include components of a different configuration. Each implantable device 200 comprises one or more housings, **housing 210** shown, which surrounds various other components of device 200. Each implantable device 200 comprises one or more stimulation and/or other functional elements, such as **stimulation element 260** shown, where stimulation elements 260 are configured to deliver stimulation energy, a stimulating drug or other agent, and/or another form of stimulation (e.g. another form of tissue stimulation) to the patient. In some embodiments, one or more stimulation elements 260 are further configured as a sensor (e.g. when comprising an electrode configured to both deliver electrical energy and record electrical signals). Each implantable device 200 can include one or more leads, **lead 265** shown, and each lead 265 can include one or more stimulation elements 260. Alternatively or additionally, one or more stimulation elements 260 can be positioned on housing 210 or one or more other components of implantable device 200. Each lead can include one or more elements configured to anchor lead 265 to tissue, such as anchor element 221 shown. Anchor element 221 can be configured to slidingly receive the shaft of lead 265 (e.g. to position anchor element 221 about lead 265 in manufacturing and/or in an implantation procedure). Anchor element 221 can include one or

more fixation points, such as one or more circumferential recesses. Surgical clips or sutures can be placed around a recess and into tissue, such as to fixate anchor element 221 and an inserted lead 265 to tissue.

[0082] Each implantable device 200 can comprise one or more other types of functional elements, such as **functional element 299a** shown positioned proximate housing 210 (e.g. within and/or on the external surface of housing 210) and/or **functional element 299b** shown positioned on lead 265. Functional element 299a and/or 299b (singly or collectively **functional element 299**) can comprise a transducer, a sensor, and/or other functional element as described herein. In some embodiments, a functional element 299 comprises a visualizable marker, such as a radiopaque marker, an ultrasonically visible marker, and/or a magnetic marker.

[0083] External system 50 can comprise an **external device 500**, which includes one or more housings, **housing 510** shown, which surrounds various other components of device 500. In some embodiments, external system 50 comprises multiple external devices 500 (singly or collectively external device 500), such as an external device as is described in applicant's co-pending United States Patent Application Serial Number 17/372,095, titled "Apparatus with Enhanced Stimulation Waveforms", filed July 9, 2021 [Docket nos. 47476-708.302; NAL-014-US-CON1]. In some embodiments, external system 50 comprises at least two, or at least three external devices (e.g. at least two external devices configured to deliver power and/or data to one or more implantable devices 200), such as external device 500, **external device 500'**, and **external device 500''** shown in Fig. 1. External device 500' and/or 500'' can be of similar construction and arrangement to external device 500, and these devices can include components of a different configuration.

[0084] External system 50 can comprise one or more programming devices, **programmer 600**, such as **patient programmer 600'** and **clinician programmer 600''** shown. Patient programmer 600' and clinician programmer 600'' (singly or collectively programmer 600) each comprise a user interface, such as **user interfaces 680' and 680''** shown (singly or collectively user interface 680). Programmer 600 can be configured to control one or more external devices 500. Alternatively or additionally, programmer 600 can be configured to control one or more implantable devices 200 (e.g. when no external device 500 is included in apparatus 10 or at least no external device 500 is available to communicate with an implantable device 200). Patient programmer 600' can be configured to be used by the patient, patient caregiver (e.g. clinician of the patient), and/or a family member of the patient.

[0085] Clinician programmer 600'' can be of similar construction and arrangement to patient programmer 600'. In some embodiments, clinician programmer 600'' provides additional

functions not available using patient programmer 600'. In some embodiments, clinician programmer 600'' can modify the programming of patient programmer 600' (e.g. modify the programming options available to the patient or family member of the patient).

[0086] Patient programmer 600' can be further configured as a smart phone and/or a music playing device (e.g. an mp3 player). For example, patient programmer 600' can comprise a smart phone or other commercial device onto which a software program of apparatus 10 is embedded to cause the commercial device to function as patient programmer 600'. Clinician programmer 600'' can comprise a tablet-like device. For example, clinician programmer 600'' can comprise a commercial tablet device onto which a software program of apparatus 10 is embedded to cause the commercial tablet to function as clinician programmer 600''.

[0087] Clinician programmer 600'' can configure multiple (e.g. all) external devices 500 used by a patient, as well as patient programmer 600', so that the set of devices are configured as a **"trusted"** network. After this configuration, patient programmer 600' can safely and effectively communicate with the one or more external devices 500 of the patient. The patient programmer 600' can upload (e.g. automatically upload) configuration information from an external device 500 (e.g. stimulation parameter settings and the like). In some embodiments, patient programmer 600' and/or clinician programmer 600'' uploads configuration information from an external device 500 any time certain information (e.g. stimulation information) on that external device 500 has changed (e.g. a change is detected by the programmer 600 or otherwise).

[0088] External system 50 can comprise one, two, three, or more functional elements, such as functional elements **599a, 599b, and/or 599c** (singly or collectively functional element 599), shown positioned in external device 500, patient programmer 600', and clinician programmer 600'', respectively.

[0089] Apparatus 10 can be configured to stimulate tissue (e.g. stimulate nerve tissue such as tissue of the central nervous system or tissue of the peripheral nervous system, such as to neuromodulate nerve tissue), such as by having one or more implantable devices 200 deliver and/or otherwise provide energy (hereinafter **"deliver energy"**) and/or deliver an agent (e.g. a pharmaceutical compound or other agent) to one or more tissue locations, such as via one or more stimulation elements 260. In some embodiments, one or more implantable devices 200 deliver energy and/or an agent while receiving power and/or data from one or more external devices 500. In some embodiments, one or more implantable devices 200 deliver energy and/or an agent (e.g. continuously or intermittently) using energy provided by an internal power source (e.g. a battery and/or capacitor) without receiving externally supplied power, such as for periods

of at least 1 hour, at least 1 day, at least 1 month or at least 1 year. In some embodiments, one or more stimulation parameters are varied (e.g. systematically and/or randomly), during that period.

[0090] In some embodiments, apparatus 10 is further configured as a patient diagnostic apparatus, such as by having one or more implantable devices 200 record a patient parameter (e.g. a patient physiologic parameter) from one or more tissue locations, such as while receiving power and/or data from one or more external devices 500. In some embodiments, during its use, one or more implantable devices 200 at least receives power from one or more external devices 500 (e.g. with or without also receiving data). Alternatively or additionally, one or more patient parameters can be recorded by an external device of apparatus 10, such as via a programmer 600 and/or an external device 500.

[0091] Apparatus 10 can be configured as a patient information recording apparatus, such as by having one or more implantable devices 200 and/or one or more external devices 500 record patient information (e.g. patient physiologic information and/or patient environment information). In some embodiments, one or more implantable devices 200 and/or one or more external devices 500 further collect information (e.g. status information or configuration settings) of one or more of the components of apparatus 10.

[0092] In some embodiments, apparatus 10 is configured to deliver stimulation energy to tissue to treat pain. In particular, apparatus 10 can be configured to deliver stimulation energy to tissue of the spinal cord and/or tissue associated with the spinal cord (**"tissue of the spinal cord"**, **"spinal cord tissue"** or **"spinal cord"** herein), the tissue including roots, dorsal root, dorsal root ganglia, spinal nerves, ganglia, and/or other nerve tissue. The delivered energy can comprise energy selected from the group consisting of: electrical energy; magnetic energy; electromagnetic energy; light energy such as infrared light energy, visible light energy and/or ultraviolet light energy; mechanical energy; thermal energy such as heat energy and/or cryogenic energy; sound energy such as ultrasonic sound energy (e.g. high intensity focused ultrasound and/or low intensity focused ultrasound) and/or subsonic sound energy; chemical energy; and combinations of one or more of these. In some embodiments, apparatus 10 is configured to deliver to tissue energy in a form selected from the group consisting of: electrical energy such as by providing a controlled (e.g. constant or otherwise controlled) electrical current and/or voltage to tissue; magnetic energy (e.g. magnetic field energy) such as by applying controlled current or voltage to a coil or other magnetic field generating element positioned proximate tissue; and/or electromagnetic energy such as by providing both current to tissue and a magnetic field to tissue. A coil or other magnetic field generating element can surround (e.g. at least partially surround) the target nerve. Alternatively, or additionally, the magnetic energy can be applied externally

and focused to specific target tissue via an implant comprising a coil and/or ferromagnetic materials. In some embodiments, the magnetic energy is configured to induce the application of mechanical energy. Delivered energy can be supplied in one or more stimulation waveforms, each waveform comprising one or more pulses of energy, as described in detail herebelow.

[0093] In some embodiments, apparatus 10 is configured as a stimulation apparatus in which external system 50 transmits a power signal to one or more implantable devices 200, and the one or more implantable devices 200 deliver stimulation energy to tissue with a stimulation signal (also referred to as a stimulation waveform), with the power signal and the stimulation signal having one or more different characteristics (e.g. as described herebelow). The power signal can be modulated with data (e.g. configuration or other data to be sent to one or more implantable devices 200). In these embodiments, the characteristics of the stimulation signal delivered (e.g. amplitude, frequency, duty cycle and/or pulse width), can be independent (e.g. partially or completely independent) of the characteristics of the power signal transmission (e.g. amplitude, frequency, phase, envelope, duty cycle and/or modulation). For example, the frequency and modulation of the power signal can change without affecting those or other parameters of the stimulation signal, and/or the parameters of the stimulation signal can be changed (e.g. via programmer 600), without requiring similar or any changes to the power signal. In some embodiments, implantable system 20 is configured to rectify the received power signal, and to produce a stimulation waveform with entirely different characteristics (e.g. amplitude, frequency and/or duty cycle) from the rectified power signal. Each implantable device 200 can comprise an oscillator and/or controller configured to produce the stimulation signal. In some embodiments, one or more implantable devices 200 is configured to perform frequency multiplication, in which multiple signals are multiplexed, mixed, added, and/or combined in other ways to produce a broadband stimulation signal.

[0094] In some embodiments, apparatus 10 is configured such that external system 50 transmits data (e.g. data and power) to implantable system 20, and implantable system 20 recovers (e.g. decodes, demodulates or otherwise recovers) the transmitted data without synchronizing to the carrier and/or data symbol rate of the transmitted signal from external system 50. In some embodiments, the transmitted signal comprises a power signal, and a clock and/or data is recovered without synchronizing to the power signal. In some embodiments, the transmitted signal comprises a clock and/or data signal, and a clock and/or data is recovered without synchronizing to the transmitted clock and/or data signal. In some embodiments, the recovered signal comprises a clock and/or data and a clock and/or data is recovered from the transmission signal without synchronizing to the recovered clock and/or data. Avoiding synchronization

reduces power consumption of each implantable device 200, such as by obviating the need for (and avoiding the power consumed by) a frequency locked loop (FLL); phase locked loop (PLL); high frequency clock; and/or crystal oscillator needed to perform the synchronization. Avoiding these components can also be correlated to reduced package size of each implantable device 200 (e.g. avoidance of a relatively large sized crystal oscillator). Asynchronous data transfer between external system 50 and implantable system 20 is also advantageous as it relates to: increased communication data rate; power transfer efficiency; operation with more than one implantable device 200; and combinations of one or more of these. In some embodiments, one or more components of apparatus 10 are of similar construction and arrangement as similar components described in United States Patent Application Serial Number 13/591,188, titled "Method of Making and Using an Apparatus for a Locomotive Micro-Implant using Active Electromagnetic Propulsion", filed August 21, 2012. In some embodiments, external system 50 and implantable system 20 provide asynchronous data transfer or are otherwise configured as described in United States Patent Application Serial Number 13/734,772, titled "Method and Apparatus for Efficient Communication with Implantable Devices", filed January 4, 2013.

[0095] Apparatus 10 can be configured to treat pain, such as back pain and/or limb pain treated by stimulating dorsal root ganglia and/or other nerves or locations of the spinal cord or other nervous system locations. In some embodiments, apparatus 10 is configured to treat a type of pain selected from the group consisting of: back pain; joint pain; neuropathic pain; tennis elbow; muscle pain; shoulder pain; chronic, intractable pain of the back and/or limbs including unilateral or bilateral pain; neuropathic groin pain; perineal pain; phantom limb pain; complex regional pain syndrome; failed back surgery syndrome; cluster headaches; migraines; inflammatory pain; arthritis; abdominal pain; pelvic pain; and combinations of one or more of these.

[0096] In some embodiments, apparatus 10 is configured to treat a patient disease or disorder selected from the group consisting of: chronic pain; acute pain; migraine; cluster headaches; urge incontinence; pelvic dysfunction such as overactive bladder; fecal incontinence; bowel disorders; tremor; obsessive compulsive disorder; depression; epilepsy; inflammation; tinnitus; hypertension; heart failure; carpal tunnel syndrome; sleep apnea; obstructive sleep apnea; dystonia; interstitial cystitis; gastroparesis; obesity; mobility issues; arrhythmia; rheumatoid arthritis; dementia; Alzheimer's disease; eating disorder; addiction; traumatic brain injury; chronic angina; congestive heart failure; muscle atrophy; inadequate bone growth; post-laminectomy pain; liver disease; Crohn's disease; irritable bowel syndrome; erectile dysfunction; kidney disease; and combinations of one or more of these.

[0097] In some embodiments, apparatus 10 is configured to treat one or more diseases or disorders by delivering stimulation to perform renal modulation. In some embodiments, apparatus 10 is configured to treat hypertension, such as when apparatus 10 is configured to deliver stimulation to perform renal neuromodulation.

[0098] Apparatus 10 can be configured to treat heart disease, such as heart failure of a patient. In these embodiments, stimulation of the spinal cord can be performed. In canine and porcine animals with failing hearts, spinal cord stimulation has been shown to reverse left ventricular dilation and improve cardiac function, while suppressing the prevalence of cardiac arrhythmias. In canines, coronary artery occlusion has been associated with increased intracardiac nerve firing, and stimulation at spinal segment T1 has been shown to suppress that nerve firing. Stimulation via apparatus 10 at one or more spinal cord locations can be used to suppress undesired cardiac nerve firing in humans and other mammalian patients. In some embodiments, stimulation via apparatus 10 at multiple spinal cord locations is used to enhance a cardiac treatment. For example, one or more stimulation elements 260 of one or more implantable devices 200 can be implanted at one or more spinal cord locations, such as to deliver stimulation to tissue proximate those locations. In some embodiments, stimulation elements 260 comprise two or more stimulation elements (e.g. electrodes) that span multiple vertebra of the spinal column (e.g. multiple stimulation elements that span at least T-8 to T-9 and/or T-9 to T-10). Power and/or data can be transmitted to the one or more implantable devices 200 via one or more external devices 500 of external system 50. One or more stimulation signals can be delivered to spinal cord tissue, such as to treat heart failure or other cardiac disease or disorder. In some embodiments, one or more stimulation elements 260 are configured to deliver energy (e.g. electrical energy) to tissue to treat heart failure, such as tissue selected from the group consisting of: spinal canal; nerves in the spinal canal; nerves in the epidural space; peripheral nerves; posterior spinal nerve root; dorsal root; dorsal root ganglion; pre-ganglionic tissue on posterior spinal nerve root; post-ganglionic tissue on posterior nerve root; dorsal ramus; grey ramus communicans; white ramus communicans; ventral ramus; and combinations of one or more of these. In some embodiments, one or more functional elements of apparatus 10 (e.g. one or more stimulation elements 260, functional elements 299, functional elements 599 and/or other functional elements of implantable system 20) are configured (e.g. further configured) to record a patient parameter (e.g. stimulation element 260, functional element 299, functional element 599, and/or another functional element of apparatus 10 are configured as a sensor), such as a patient heart or spine parameter, and the information recorded is used to modify the delivered stimulation signals. The at least one heart parameter can comprise a parameter selected from the

group consisting of: EKG; blood oxygen; blood pressure; heart rate; ejection fraction; wedge pressure; cardiac output; and combinations of one or more of these.

[0099] Apparatus 10 can be configured to pace and/or defibrillate the heart of a patient. One or more stimulation elements 260 can be positioned proximate cardiac tissue and deliver a stimulation signal as described herein (e.g. based on power and/or data received by implantable system 20 from external system 50). The stimulation signal can be used to pace, defibrillate and/or otherwise stimulate the heart. Alternatively or additionally, apparatus 10 can be configured to record cardiac activity (e.g. by recording EKG, blood oxygen, blood pressure, heart rate, ejection fraction, wedge pressure, cardiac output, lung impedance and/or other properties or functions of the cardiovascular system via a sensor-based element 260, and/or other sensor of apparatus 10), such as to determine an onset of cardiac activity dysfunction or other undesired cardiac state. In some embodiments, apparatus 10 is configured to both record cardiac or other information and deliver a stimulation signal to cardiac tissue (e.g. stimulation varied or otherwise based on the recorded information). For example, apparatus 10 can be configured such that external system 50 transmits power and/or data to implantable system 20, and implantable system 20 can monitor cardiac activity, and upon detection of an undesired cardiovascular state, implantable system 20 delivers a pacing and/or defibrillation signal to the tissue that is adjacent to one or more stimulation elements 260 configured to deliver a cardiac stimulation signal.

[0100] Apparatus 10 can be configured to perform a diagnostic procedure including measuring one or more patient parameters (e.g. patient physiologic or other patient parameters), such as are described in detail herebelow. In some embodiments, apparatus 10 is configured to measure a physiologic parameter that can be sensed from one or more sensor-based stimulation elements 260, functional elements 299, and/or functional elements 599 positioned in subcutaneous tissue. In these embodiments, external system 50 can comprise an external device 500 configured for placement proximate an implantable device 200 implanted in a position to record data from subcutaneous tissue (e.g. blood glucose data). External device 500 can comprise a wrist band, a wristwatch, and/or an arm band configuration such as when the implantable device 200 is positioned in subcutaneous tissue proximate the patient's wrist or upper arm. The external device 500 can comprise a leg, knee or ankle band configuration, such as when one or more implantable devices 200 are positioned in subcutaneous tissue proximate the patient's ankle, knee, and/or thigh. In some embodiments, external device 500 comprises a band or other attachment device for positioning about the thorax, neck, groin, and/or head of the patient. Power and/or data can be sent to the implantable device 200 from the external device 500, and

data (e.g. blood glucose data) can be sent to external device 500 (or another component of external system 50) by implantable device 200, such as using a wireless communication configuration known to those of skill in the art. In some embodiments, external system 50 comprises a functional element 599 (e.g. functional element 599a, 599b, and/or 599c) configured to deliver an agent (e.g. insulin or glucose delivered by a needle-based functional element 599), based on the information received from implantable device 200. Alternatively, or additionally, implantable device 200 comprises a stimulation element 260 configured to deliver an agent (e.g. insulin or glucose delivered by a needle-based stimulation element 260), based on the information recorded by implantable device 200. Various closed loop sensing and agent delivery combinations and configurations should be considered within the spirit and scope of the present inventive concepts, including but not limited to: sensing a blood parameter such as white blood cell count and delivering a chemotherapeutic or other agent based on the blood parameter; sensing a hormone level and delivering a hormone or a hormone affecting agent; sensing blood pressure and delivering stimulation energy and/or a blood pressure affecting agent; sensing neural activity and delivering stimulation energy and/or a neural affecting agent or other agent based on the neural activity, such as for treating epilepsy; and combinations of one or more of these.

[0101] As described hereabove, external system 50 can be configured to transmit power and/or data (e.g. implantable system 20 configuration data) to one or more implantable devices 200 of implantable system 20. Implantable system 20 configuration data provided by external system 50 (e.g. via one or more antennas, **antenna 540** shown, of one or more external devices 500) can include when to initiate stimulation delivery (e.g. energy delivery), and/or when to stop stimulation delivery, and/or it can include data related to the value or change to a value of one or more stimulation parameters as described hereabove. The configuration data can include a stimulation parameter such as an agent (e.g. a pharmaceutical agent) delivery stimulation parameter selected from the group consisting of: initiation of agent delivery; cessation of agent delivery; amount of agent to be delivered; volume of agent to be delivered; rate of agent delivery; duration of agent delivery; time of agent delivery initiation; and combinations of one or more of these. The configuration data can include a sensing parameter, such as a sensing parameter selected from the group consisting of: initiation of sensor recording; cessation of sensor recording; frequency of sensor recording; resolution of sensor recording; thresholds of sensor recording; sampling frequency of sensor recording; dynamic range of sensor recording; initiation of calibration of sensor recording; and combinations of one or more of these.

[0102] As described hereabove, external system 50 can comprise one or more external devices 500. External system 50 can comprise one or more antennas 540, such as when a single external device 500 comprises one or more antennas 540, and/or when multiple external devices 500 each comprise one or more antennas 540. The one or more antennas 540 can transmit power and/or data to one or more **antennas 240** of implantable system 20, such as when a single implantable device 200 comprises one or more antennas 240, and/or when multiple implantable devices 200 each comprise one or more antennas 240. In some embodiments, one or more antennas 540 define a radiation footprint (e.g. a footprint defining a volume, such as a volume of tissue, in which electromagnetic transmissions radiated by antennas 540 can be properly received by antennas 240), such as is described in applicant's co-pending United States Patent Application Serial Number 15/664,231, titled "Medical Apparatus Including an Implantable System and an External System", filed July 31, 2017 [Docket nos. 47476-706.301; NAL-011-US].

[0103] External system 50 transmits power and/or data with a transmission signal comprising at least one wavelength, λ. External system 50 and/or implantable system 20 can be configured such that the distance between an external antenna 540 transmitting the power and/or data and one or more implantable antennas 240 receiving the power and/or data transmission signal is equal to between 0.1λ and 10.0λ, such as between 0.2λ and 2.0λ. In some embodiments, one or more transmission signals are delivered by a transmitter, **transmitter 530**, at a frequency range between 10MHz and 10.6GHz, such as between 0.1GHz and 10.6GHz, between 10MHz and 3.0GHz, between 40MHz and 1.5GHz, between 10MHz and 100MHz, between 0.902GHz and 0.928GHz, in a frequency range proximate to 40.68MHz, in a frequency range proximate to 866MHz, or approximately between 863MHz and 870MHz. Transmitter 530 can comprise a transmitter that produces a transmission signal with a power level between 0.01W and 4.0W, such as a transmission signal with a power level between 0.01W and 2.0W or between 0.2W and 1.0W.

[0104] In addition to transmitting power and/or data to implantable system 20, external system 50 can be further configured to provide information (e.g. patient information and/or apparatus 10 performance information) to one or more other components of apparatus 10, such as **tool 60** shown in Fig. 1 and described in detail herebelow.

[0105] One or more external devices 500 (singly or collectively external device 500) can be configured to transmit power and/or data (e.g. implantable system 20 configuration data) to one or more implantable devices 200 (singly or collectively implantable device 200). In some embodiments, one or more external devices 500 are configured to transmit both power and data (e.g. simultaneously and/or sequentially) to one or more implantable devices 200. In some

embodiments, one or more external devices 500 are further configured to receive data from one or more implantable devices 200 (e.g. via data transmitted by one or more antennas 240 of one or more implantable devices 200). Each external device 500 can comprise housing 510, **power supply 570**, a transmitter 530, a **controller 550**, and/or one or more antennas 540, each shown in Fig. 1 and described in detail herebelow. Each external device 500 can further comprise one or more functional elements 599a, such as a functional element comprising a sensor, electrode, energy delivery element, a magnetic-field-generating transducer, and/or any transducer, also described in detail herebelow. In some embodiments, a functional element 599a comprises one or more sensors configured to monitor performance of external device 500 (e.g. to monitor voltage of power supply 570, quality of transmission of power and/or data to implantable system 20, temperature of a portion of an external device 500, and the like).

[0106] One or more housings 510 (singly or collectively housing 510) of each external device 500 can comprise one or more rigid and/or flexible materials which surround various components of external device 500 such as antenna 540, transmitter 530, controller 550, and/or power supply 570 shown in Fig. 1. In some embodiments, a single external device 500 comprises multiple discrete (i.e. separate) housings 510, two or more of which can each transfer data and/or other signals via a wired or wireless connection to the other, to an implantable device 200, and/or to another component of apparatus 10. In some embodiments, a housing 510 further surrounds a programmer 600 (e.g. programmer 600' or 600'') and/or a power supply 570. In some embodiments, housing 510 comprises both a rigid material and a flexible material. In some embodiments, housing 510 comprises a material selected from the group consisting of: plastic; injection-molded plastic; an elastomer; metal; and combinations of one or more of these. In some embodiments, housing 510 comprises a shielded portion (e.g. shielded to prevent transmission of electromagnetic waves), and an unshielded portion, such as an unshielded portion surrounding antenna 540.

[0107] Housing 510 can comprise an adhesive element (e.g. a spacer 511 configured as an adhesive element), such as an adhesive element configured to temporarily attach an external device 500 to the patient's skin. Alternatively or additionally, housing 510 can be constructed and arranged to engage (e.g. fit in the pocket of) a patient attachment device, such as **patient attachment device 70** described herebelow.

[0108] One or more antennas 540 (singly or collectively antenna 540) can each comprise one, two, three, or more external antennas. Antenna 540 can comprise one or more polarizable antennas, such as one or more antennas with adjustable polarization. Antenna 540 can comprise an array of antennas, such as an array of antennas configured to: support beam shaping and/or

focusing; allow adjustment of the amplitude and/or phase of the transmission signal; increase the radiation footprint; and combinations of one or more of these. An array of antennas 540 can be configured to be selectively activated, such as to improve coupling with one or more implanted antennas 240, such as to adjust for movement of the array of the antennas 540 relative to the implanted antennas 240. Antenna 540 can comprise an array of selectable conductors configured to adjust a radiation pattern and/or an electromagnetic field of a resultant antenna. Antenna 540 can comprise a surface and shield material positioned on the surface, such as when the shield material is positioned on the side facing away from the patient's skin. The shield material can comprise radio-absorptive shield material and/or radio-reflective shield material. For antenna 540 to operate effectively at higher frequencies, the shield material can comprise a ferrite material that has a low conductivity and low magnetic loss tangent at a frequency of interest, and whereby a higher permeability is achieved. By placing a material with a high magnetic permeability (μ'), low magnetic loss tangent (μ''/μ'), and low conductivity at the operating frequency (such as a high frequency ferrite) between the antenna and other elements of the transmitter, the losses or loading effects due to these elements can be dramatically reduced. In some cases, the magnetic field magnification of this shielding layer will enhance the overall performance. Additionally, this layer shields the outside environment from unwanted radiation from the antenna, and it protects the antenna from radiation originating in the environment.

[0109] In some embodiments, a spacing layer is positioned between antenna 540 and the shield material. The spacing layer can comprise a thickness of between 0mm and 5mm, such as between 0. 25mm and 1mm. The spacing layer can comprise non-conductive dielectric materials, air, or other materials that have minimal impact on antenna performance. The spacing layer can also be incorporated into a board thickness, with the antenna being constructed on the opposite side of the board in relation to the shielding layer. The shielding layer can comprise a ferrite material as described hereabove, or any material with the desired permeability, magnetic loss, and conductivity at the frequency of interest. The thickness of the shielding layer can be dependent on its specific material properties and the application. In some embodiments, a conductive layer on the side of the shielding layer is positioned opposite the antenna to further shield unwanted radiation. To reduce weight, the shielding layer material can be porous or incorporate holes or slots spaced in a way to minimize the reduction in performance. The holes and spacings can be sized smaller than a wavelength of the RF signal. If no spacing layer is used, the shielding layer can extend inside the antenna. Additionally or alternatively, the shielding layer can be positioned on the other side or both sides of the antenna because of the

field magnification effect. In some embodiments, the shielding layer is constructed to increase the directivity of the antenna or focus the electromagnetic energy.

[0110] One or more antennas 540 can be positioned in a housing 510 that is otherwise void of other components (e.g. void of power supply 570, controller 550 and/or transmitter 530), such as when an antenna 540 is positioned within a first housing 510 and communicates with components positioned in a second housing 510.

[0111] In some embodiments, one or more spacers, **spacer 511** shown, is positioned between antenna 540 and the patient's skin, such as a spacer comprising a thickened portion of housing 510 or a discrete spacer 511 placed on a side of housing 510 (as shown) or on a side of antenna 540. Spacer 511 can comprise one or more materials that match the impedance of antenna 540 to the impedance of the patient's tissue. Spacer 511 can comprise a thickness of between 0.1cm to 3cm, such as a thickness between 0.2cm and 1.5cm. Spacer 511 can comprise materials which isolate heat (e.g. a spacer 511 comprising thermally insulating material). Alternatively, or additionally, housing 510 can comprise a heat insulating and/or dissipating material. Spacer 511 can comprise a soft or otherwise compressible material (e.g. foam) for patient comfort. Spacer 511 can be inflatable, such as to control the separation distance of an external antenna 540 from the patient's skin. An inflatable spacer 511 can be compartmentalized into several sections with independently controlled air pressure or volume to adjust the separation distance of an external antenna 540 and the patient's skin and/or its angle (e.g. tilt) with respect to the tissue surface.

[0112] In some embodiments, antenna 540 comprises a multi-feed point antenna, such as a multi-feed point antenna configured to: support beam shaping and/or focusing; allow modification of amplitude and/or phase of a transmission signal; increase the radiation footprint; and combinations of one or more of these.

[0113] In some embodiments, antenna 540 comprises one or more antennas selected from the group consisting of: patch antenna; slot antenna; array of antennas; a loop antenna (e.g. a concentric loop antenna); antenna loaded with reactive elements; dipole antenna; polarizable antenna; selectable conductors that form an antenna; and combinations of one or more of these.

[0114] Antenna 540 can comprise a major axis between 1cm and 10cm, such as a major axis between 2cm and 5cm, and/or a major axis of approximately 4cm. Antenna 540 can be further configured to receive a signal, such as when an antenna 240 is configured to transmit data to an external device 500. Antenna 540 can be positioned on (e.g. fabricated onto) a substrate, such as a flexible printed circuit board or other printed circuit board (e.g. a single or multiple layer printed circuit board comprising electrical traces connecting components).

[0115] A single external antenna 540 can be configured to transmit power and/or data to multiple implantable devices 200 (e.g. each containing one or more antennas 240). In some embodiments, a single external device 500, comprising one or more antennas 540 can be configured to transmit power and/or data to multiple implantable devices 200.

[0116] One or more antennas 540 can comprise a multi-turn spiral loop antenna, such as a multi-turn spiral loop antenna configured to desensitize coupling sensitivity and/or boost input voltage. In some embodiments, one or more antennas 540 comprise multiple concentric loops with varied dimensions, such as concentric loops configured to desensitize coupling sensitivity. In these embodiments, the multiple concentric loops can be: connected in parallel and driven from the same feed point; driven from the same feed point and connected using one or more of a capacitor, inductor, varactor, and combinations of one or more of these; and/or driven from multiple feed points.

[0117] In some embodiments, one or more external devices 500 comprise a first antenna 540 and a second antenna 540. In these embodiments, the first antenna 540 can be similar or dissimilar to the second antenna 540. In some embodiments, a first antenna 540 and a dissimilar second antenna 540 are positioned within a single external device 500 (e.g. within housing 510). In other embodiments, a first antenna 540 is positioned in a first external device 500, and a dissimilar second antenna 540 is positioned in a second external device 500. The similarity or dissimilarity of the antennas can be configured to enhance one or more design and/or performance parameters selected from the group consisting of: implantable device 200 operation depth; polarization; power efficiency; a radiation footprint; directional gain; beam shaping and/or focusing; sensitivity to implantable device 200 placement; patient comfort; patient usability; data transfer; and combinations of one or more of these. In some embodiments, the first antenna 540 is optimized for a different design parameter than the second antenna 540, and each antenna 540 can be activated independently or simultaneously to realize both benefits. In some embodiments, the first antenna 540 is similar to the second antenna 540 and placed in an array to increase the radiation footprint or placed in different external locations to operate with multiple implantable devices 200 implanted at different sites.

[0118] In some embodiments, a first external antenna 540 and a second external antenna 540 transmit power and/or data to a single implantable antenna 240. In some embodiments, a first antenna 540 and a second antenna 540 transmit power and/or data to one or more antennas 240, the transmissions performed simultaneously or sequentially. In sequential power and/or data transfers, a first external device 500 comprising a first one or more antennas 540 can be replaced (e.g. swapped) with a second external device 500 comprising a second one or more antennas

540. Alternatively or additionally, sequential power and/or data transfer can be initiated by one or more of the following conditions: when a first external antenna 540 moves (e.g. moves relative to an implanted antenna 240); when a second external device 500 comprising a second antenna 540 is turned on or otherwise activated; when a second antenna 540 provides improved power and/or data transfer to antenna 240 than that which is provided by a first antenna 540; and/or when power received from a first antenna 540 decreases (e.g. decreases below a threshold). In some embodiments, an antenna 240 receives power from a first antenna 540 and a second antenna 540, but only receives data from the first antenna 540. In some embodiments, a first antenna (e.g. an antenna 240 or an antenna 540) is driven with a different carrier signal than a second antenna (e.g. an antenna 240 or an antenna 540). The two carrier signals can comprise differences in amplitudes and/or relative phases as compared to each other. Each carrier signal can include a data transmission signal (e.g. data to be transmitted to an implantable device 200 from an external device 500 or to an external device 500 from an implantable device 200).

[0119] External device 500 can comprise an electronics module, controller 550 shown, configured to control one or more other components of external device 500. Controller 550 can comprise one or more electronic elements, electronic assemblies, and/or other electronic components, such as components selected from the group consisting of: memory storage components; analog-to-digital converters; rectification circuitry; state machines; microprocessors; microcontrollers; filters and other signal conditioners; sensor interface circuitry; transducer interface circuitry; and combinations thereof. In some embodiments, controller 550 comprises a memory storage component that includes instructions, such as instructions used by controller 550 to produce a stimulation waveform and/or perform an algorithm, each as described herein.

[0120] One or more transmitters 530 (singly or collectively external transmitter 530) can each comprise one or more external transmitters that drive one or more antennas 540 (e.g. one or more antennas 540 positioned in a single external device 500 or multiple external devices 500). Transmitter 530 is operably attached to antenna 540 and is configured to provide one or more drive signals to antenna 540, such as one or more power signals and/or data signals transmitted to one or more implantable devices 200 of implantable system 20. Transmitter 530 can be configured to perform multi-level amplitude shift keying. The amplitude shift-keying can be configured to provide adjustable-depth modulation between 0-100% depth, such as between 5-75% depth, or such as between 10-50% depth.

[0121] As described herein, one or more external devices 500 can be configured to transmit data (e.g. configuration data) to one or more implantable devices 200, such as via a data

transmission produced by transmitter 530 and sent to one or more antennas 540. In some embodiments, a transmitter 530 is configured to perform data modulation comprising amplitude shift keying with pulse width modulation. In these embodiments, the transmitter can be configured to perform multi-level amplitude shift keying. The amplitude shift-keying can be configured to provide adjustable-depth modulation between 0-100% depth, such as between 5-75% depth, or such as between 10-50% depth. In some embodiments, one or more external devices 500 transmit data to one or more implantable devices 200 using time division multiple access (TDMA). In some embodiments, one or implantable devices 200 are independently addressable through unique identification (ID) codes. Alternatively or additionally, transmitter 530 can be configured to transmit one or more data signals with a bandwidth between 1kHz and 100MHz, between 0.1MHz and 100MHz, or between 1MHz and 26MHz.

[0122] As described herein, one or more external devices 500 can be configured to transmit power to one or more implantable devices 200, such as via a power transmission produced by transmitter 530 and set to one or more antennas 540. One or more transmitters 530 can deliver power to one or more implantable devices 200 simultaneously or sequentially. In some embodiments, one or more transmitters 530 are configured to modify the level of power transmitted to one or more implantable devices 200, such as by modifying one or more duty cycling parameters. In these embodiments, power transmitted can be modified to: set a power transfer based on a stimulation level produced by implantable system 20; prevent oversaturation; to reduce interference with implantable system 20 data transmissions (e.g. when one or more implantable devices 200 are further configured to transmit data to external system 50); set a power transfer based on charge information and/or discharge information related to an implantable device 200 (e.g. charge rate and/or discharge rate of implantable **energy storage assembly 270** described herebelow); and combinations of one or more of these. In some embodiments, implantable system 20 comprises a first **receiver 230** (e.g. of a first implantable device 200) and a second receiver 230 (e.g. of a second implantable device 200'). One or more transmitters 530 can be configured to transmit a first power transmission to the first receiver 230, and a second power transmission to the second receiver 230. The first power transmission and the second power transmission can be modified or otherwise be different, such as to prevent oversaturation.

[0123] In some embodiments, transmitter 530 (and/or another component of external system 50) is further configured as a receiver (e.g. can further include a receiver, in addition to a transmitter or include a transmitter that further functions as a receiver), such as to receive data from implantable system 20. For example, a transmitter 530 can be configured to receive data

via one or more antennas 240 of one or more implantable devices 200. Data received can include patient information (e.g. patient physiologic information, patient environment information or other patient information) and/or information related to an implantable system 20 parameter (e.g. an implantable device 200 stimulation parameter and/or another configuration parameter as described herein).

[0124] In some embodiments, transmitter 530 comprises a first transmitter to transmit power and/or data to one or more implantable devices 200, and a second transmitter to transmit data to a different device, as described herein. In these embodiments, a second transmitter of transmitter 530 can be configured to transmit data to tool 60 or another device such as a programmer 600; cell phone; computer; tablet; computer network such as the internet or a LAN; and combinations of one or more of these. In some embodiments, the second transmitter of transmitter 530 comprises a wireless transmitter; a Bluetooth transmitter; a cellular transmitter; and combinations of one or more of these. In some embodiments, a functional element 599 comprises a transmitter such as a Bluetooth transmitter.

[0125] Each power supply 570 (singly or collectively power supply 570) can be operably attached to a transmitter 530, and one or more other electrical components of each external device 500. Power supply 570 can comprise a power supplying and/or energy storage element selected from the group consisting of: battery; replaceable battery (e.g. via a battery door of housing 510); rechargeable battery; AC power converter; capacitor; and combinations of one or more of these. In some embodiments, power supply 570 comprises two or more batteries, such as two or more rechargeable batteries, such as to allow the first battery to be replaced (e.g. serially replaced) by the second battery (e.g. external device 500 can function with a single battery). In some embodiments, power supply 570 is configured to provide a voltage of at least 3V. In some embodiments, power supply 570 is configured to provide a capacity between 1Watt-hour and 75Watt-hours, such as a battery or capacitor with a capacity of approximately 5Watt-hours. In some embodiments, power supply 570 comprises an AC power source. Power supply 570 can include voltage and/or current control circuitry. Alternatively or additionally, power supply 570 can include charging circuitry, such as circuitry configured to interface a rechargeable battery with an external charging device. In some embodiments, apparatus 10 includes one or more charging devices, **charger 61 shown**, which can be configured to recharge a component of apparatus 10, such as to recharge power supply 570 of one or more external devices 500.

[0126] Each external device 500 can include one or more user interface components, **user interface 580** shown, such as to allow the patient or other user to enter, adjust and/or otherwise

modify ("enter", "adjust", and/or "modify" herein) one or more parameters of apparatus 10 (e.g. one or more variable stimulation parameters of apparatus 10). User interface 580 can include one or more user input components (e.g. buttons, slides, knobs, and the like) and/or one or more user output components (e.g. lights, displays and the like). In some embodiments, user interface 580 includes one or more controls configured to provide a water-ingress-resistant barrier.

[0127] Each patient programmer 600' or clinician programmer 600'' (singly or collectively programmer 600) comprises a programming device configured to control one or more components of apparatus 10. Programmer 600 can comprise a user interface 680. Programmer 600 can send and/or receive commands to and/or from one or more external devices 500 via a wireless or wired connection (wired connection not shown but such as one or more insulated conductive wires). In some embodiments, one or more external devices 500 comprise all or a portion of programmer 600, such as when all or a portion of user interface 680 is integrated into housing 510 of external device 500. In some embodiments, apparatus 10 comprises multiple programmers 600, such as one or more patient programmers 600' and/or one or more clinician programmers 600''.

[0128] Programmer 600 can be configured to modify one or more parameters of apparatus 10, such as a stimulation parameter (e.g. a stimulation waveform parameter as described herein); a sensing parameter; a therapy parameter; a data recording parameter (e.g. a patient data recording parameter and/or an implantable device 200 data recording parameter); power transfer; data rate; activity of one or more external transmitters 530; activity of one or more external antennas 540; a stimulation element 260 parameter; a functional element 299 and/or 599 parameter; and combinations of one or more of these, such as is described hereabove. Programmer 600 can be further configured to provide information, such as patient physiologic information recorded by apparatus 10 (e.g. by one or more implantable devices 200 and/or one or more external devices 500), or apparatus 10 information, such as performance and/or configuration information (singly or collectively **"status information"**) of one or more components of apparatus 10 (e.g. one or more external devices 500 and/or implantable devices 200). In some embodiments, programmer 600 uses information recorded by one or more implantable devices 200, apparatus 10 information, and/or information from external devices 500 to adapt configuration parameters of one or more components of apparatus 10.

[0129] In some embodiments, programmer 600 is configured to confirm that an adequate power transmission and/or an adequate data transmission has occurred between one or more external devices 500 and one or more implantable devices 200. In these embodiments, programmer 600 can comprise **diagnostic assembly 62** described herebelow, or otherwise be

configured to detect one or more of: power transmission to the implantable system 20 (e.g. to detect power transmission to implantable system 20 below a threshold); power transmission to the implantable system 20 trending in an undesired direction; improper and/or inadequate data transfer to the implantable system 20; and combinations of one or more of these. In some embodiments, programmer 600 monitors power transfer in real time and modifies power transmission accordingly to optimize the rectifier efficiency (e.g. efficiency of rectifier 232 described herebelow) of one or more implantable devices 200. In some embodiments, apparatus 10 can be configured to modify (e.g. in real time) the power transmission from one or more external devices 500 of external system 50 to one or more implantable devices 200 of implantable system 20, such as to optimize or otherwise improve an efficiency of apparatus 10, such as to improve the efficiency of transmissions between an external device 500 and an implantable device 200. These modifications can include modification of one or more of: power transmission amplitude, duty cycle, frequency, phase, and periodicity.

[0130] In some embodiments, programmer 600 and/or another component of apparatus 10 comprises a matching network configured to match the impedance of one or more antennas 540 to one or more transmitters 530. The matching network can comprise an adjustable matching network. The matching network can comprise a directional coupler configured to measure a reflection coefficient. A transmitter 530 can comprise an output, and a programmer 600 can be configured to monitor a standing wave pattern at the output of the transmitter 530.

[0131] In some embodiments, programmer 600 comprises a lookup table of stimulation signal waveform patterns, such as to allow a clinician, patient and/or other operator (**"user"** or **"operator"** herein) of apparatus 10 to view and/or select a predetermined stimulation pattern (e.g. using user interface 680). In some embodiments, programmer 600 comprises a set of adjustable stimulation signal parameters configured to be varied to allow an operator to construct customized waveforms, such as to vary one or more stimulation parameters described hereabove. In some embodiments, programmer 600 is configured to allow an operator to create a customized waveform by specifying an amplitude of one or more discrete pulses or steps of a stimulation signal. In some embodiments, a clinician programmer 600'' can include stimulation waveform customization options not provided by a patient programmer 600'.

[0132] In some embodiments, programmer 600 comprises a transmitter configured to transmit data to tool 60 or another device such as a cell phone; computer; tablet; computer network such as the internet or a LAN; and combinations of one or more of these. In these embodiments, programmer 600 can comprise a wireless transmitter; a Bluetooth transmitter; a cellular transmitter; and combinations of one or more of these. In some embodiments, programmer 600

comprises a receiver configured to receive data, or a transceiver configured to both transmit and receive data.

[0133] User interface 680 of programmer 600 can comprise one or more user input components and/or user output components, such as a component selected from the group consisting of: keyboard; mouse; keypad; switch; membrane switch; touchscreen; display; audio transducer such as a speaker or buzzer; vibrational transducer; light such as an LED; and combinations of one or more of these.

[0134] In some embodiments, one or more components of external system 50 and/or other external component of apparatus 10, comprises one or more functional elements 599, such as functional elements 599a, 599b, and/or 599c, shown positioned in external device 500, programmer 600', and in programmer 600'', respectively. Each functional element 599 can comprise a functional element as defined hereabove (e.g. a sensor, a transducer, and/or other functional element as described herein). In some embodiments, a functional element 599 comprises a needle, a catheter (e.g. a distal portion of a catheter), an iontophoretic element or a porous membrane, such as an agent delivery element configured to deliver one or more agents contained (e.g. one or more agents in a reservoir, such as **reservoir 525** described herebelow) within an external device 500 and delivered into the patient (e.g. into subcutaneous tissue, into muscle tissue and/or into a blood vessel such as a vein).

[0135] In some embodiments, the functional element 599 comprises an electrode for sensing electrical activity and/or delivering electrical energy. In some embodiments, apparatus 10 is configured to cause stochastic resonance, and the addition of white noise can enhance the sensitivity of nerves to be stimulated and/or boost weak signals to be recorded by the one or more stimulation elements 260.

[0136] In some embodiments, one or more functional elements 599 comprise a sensor, such as a sensor configured to record data related to a patient parameter (e.g. a patient physiologic parameter), an external system 50 parameter and/or an implantable system 20 parameter. In some embodiments, operation of one or more implantable devices 200 (e.g. stimulation energy delivered by one or more implantable devices 200) is configured to be delivered based on the data recorded by one or more sensor-based functional elements 599, such as in a closed-loop energy delivery mode.

[0137] Functional element 599 can comprise one or more sensors configured to record data regarding a patient parameter selected from the group consisting of: blood glucose; blood pressure; EKG; heart rate; cardiac output; oxygen level; pH level; pH of blood; pH of a bodily fluid; tissue temperature; inflammation level; bacteria level; type of bacteria present; gas level;

blood gas level; neural activity; neural spikes; neural spike shape; action potential; local field potential (LFP); EEG; muscular activity (e.g. as measured using electromyography, EMG); electrical activity produced by skeletal muscles (e.g. as measured using EMG); gastric volume; peristalsis rate; impedance; tissue impedance; electrode-tissue interface impedance; physical activity level; pain level; body position; body motion; organ motion; respiration rate; respiration level; perspiration rate; sleep level; sleep cycle; digestion state; digestion level; urine production; urine flow; bowel movement; tremor; ion concentration; chemical concentration; hormone level; viscosity of a bodily fluid; patient hydration level; and combinations of one or more of these.

[0138] Functional element 599 can comprise one or more sensors configured to record data representing a parameter of external system 50 or any component of apparatus 10. Functional element 599 can comprise one or more sensors selected from the group consisting of: an energy sensor; a voltage sensor; a current sensor; a temperature sensor (e.g. a temperature of one or more components of external device 500 or programmer 600); an antenna matching and/or mismatching assessment sensor; power transfer sensor; link gain sensor; power use sensor; energy level sensor; energy charge rate sensor; energy discharge rate sensor; impedance sensor; load impedance sensor; instantaneous power usage sensor; average power usage sensor; bit error rate sensor; signal integrity sensor; and combinations of one or more of these. Apparatus 10 can be configured to analyze (e.g. via **controller 250** described herebelow) the data recorded by functional element 599 to assess one or more of: power transfer; link gain; power use; energy within power supply 570; performance of power supply 570; expected life of power supply 570; discharge rate of power supply 570; ripple or other variations of power supply 570; matching of antennas 240 and 540; communication error rate between implantable device 200 and external device 500; integrity of transmission between implantable device 200 and external device 500; and combinations of one or more of these.

[0139] In some embodiments, one or more functional elements 599 are positioned on a housing 510. A functional element 599 can comprise a body conduction sensor, such as a body conduction sensor configured to record and/or receive data via skin conduction. A functional element 599 can be configured to record data associated with stimulation delivered by one or more implantable devices 200 (e.g. record data associated with stimulation energy delivered by one or more stimulation elements 260), such as to provide closed loop or semi-closed loop stimulation. A functional element 599 can be configured to record temperature, such as when apparatus 10 is configured to deactivate or otherwise modify the performance of an external device 500 when the recorded temperature (e.g. patient temperature and/or external device 500 temperature) exceeds a threshold.

[0140] In some embodiments, an external device 500, programmer 600', and/or programmer 600'' comprises a temperature sensor, such as when functional elements 599a, 599b, and/or 599c, respectively, comprise a temperature sensor. The temperature-based functional element 599 can be positioned proximate a portion of programmer 600, housing 510 and/or one or more antennas 540 (e.g. to measure the temperature of one or more portions of a programmer 600 and/or external device 500). In these embodiments, the temperature data recorded by the functional element 599 is used to modify one or more of: matching network; stimulation level (e.g. stimulation energy delivered by one or more implantable devices 200); power transmission level (e.g. level of power transmitted between one or more external devices 500 and one or more implantable devices 200); and combinations of one or more of these. In some embodiments, the temperature sensor-based functional element 599 is a part of a safety mechanism that deactivates programmer 600 and/or an external device 500 if the recorded temperature exceeds a threshold. Alternatively or additionally, a temperature sensor-based functional element 599 can be configured to measure temperature of the patient, such as when placed on housing 510, such as to modify energy and/or agent delivery performed by implantable device 200 based on the recorded patient temperature.

[0141] In some embodiments, an external device 500, programmer 600', and/or programmer 600'' comprise an accelerometer, vibration sensor, and/or other motion or shock sensor, such when functional elements 599a, 599b, and/or 599c comprise this type of sensor. In these embodiments, the functional elements 599 can comprise a sensor configured to produce a signal used to detect when an external device 500, programmer 600', and/or programmer 600'' is dropped, as well as assess the forces generated during the drop. Alternatively or additionally, this sensor can be configured to produce a signal configured to detect a tap (e.g. on a housing) of the device, such that a tap gesture can be used in place of a control (e.g. a discrete switch) on the device.

[0142] As described hereabove, implantable system 20 comprises one or more implantable devices 200, such as one or more implantable devices 200 provided sterile or configured to be sterilized for implantation into the patient. A first implantable device 200 can be of similar or dissimilar construction and arrangement to a second implantable device 200'. Each implantable device 200 can be configured to treat a patient (e.g. treat pain of the patient) and/or record patient information, such as by delivering energy and/or an agent to tissue and/or by recording one or more physiologic parameters of the patient (e.g. parameters of tissue of the patient).

[0143] One or more portions of an implantable device 200 or other component of implantable system 20 can be configured to be visualized or contain a visualizable portion or other

visualizable element, such as **visualizable element 222** shown. Visualizable element 222 can comprise a material selected from the group consisting of: radiopaque material; ultrasonically reflective material; magnetic material; and combinations of one or more of these. In these embodiments, each implantable device 200 can be visualized (e.g. during and/or after implantation) via an imaging device such as a CT, X-ray, fluoroscope, ultrasound imager and/or MRI.

[0144] In some embodiments, implantable system 20 comprises multiple implantable devices 200 (e.g. implantable device 200 and implantable device 200' shown in Fig. 1) and implantable system 20 comprises a "**multi-point ready**" system, in which the operation (e.g. energy delivery, agent deliver, data recording and/or other function) of the multiple implantable devices 200 is performed simultaneously, asynchronously, and/or sequentially. The implantable devices 200 can be part of a network including one or more external devices 500 (e.g. external device 500 and external device 500' shown in Fig. 1) in which the treating of a patient and/or the recording of patient information relies on operation of the implantable devices 200 at one or more implantation sites in a synchronized, asynchronized, and/or otherwise coordinated way. The synchronization or otherwise coordination can be controlled by a single external device 500 and/or by multiple external devices 500, which can further be synchronized (e.g. to a single clock). Each implantable device 200 of implantable system 20 can receive a power signal and/or a data signal from one or more external devices 500. In some embodiments of the multi-point ready implantable system 20, each implantable device 200 comprises a unique ID, such that each implantable device 200 is individually addressed (e.g. receive unique signals from external system 50). In some embodiments, external system 50 transmits high-bandwidth signals to implantable system 20, such that time-domain multiple access communication is performed while operating in near real time. In some embodiments, implantable system 20 is configured as a multi-point ready system such that stimulation energy delivered by implantable system 20 is independent of power received by implantable system 20 from external system 50.

[0145] Two implantable devices 200, or two discrete components of a single implantable device 200 (e.g. two components comprising or positioned in different housings), can be attached to each other by a connecting filament as defined hereabove. In some embodiments, a connecting filament comprises a user-attachable (e.g. clinician-attachable) connector on at least one end. The filament connector is configured to operably attach to a mating connector on a component (e.g. a housing 210) of an implantable device 200.

[0146] Each implantable device 200 is configured to receive power and/or data (e.g. implantable system 20 configuration data) from one or more external devices 500. In some

embodiments, one or more implantable devices 200 are configured to receive both power and data (e.g. simultaneously and/or sequentially) from one or more external devices 500. In some embodiments, a single external device 500 sends power and/or data to multiple implantable devices 200. Alternatively or additionally, a single implantable device 200 can receive power and/or data from multiple external devices 500. In some embodiments, a first external device 500 is positioned on or near the patient's skin at a location proximate an implanted first implantable device 200, and a second external device 500 is positioned on or near the patient's skin (generally "on" the patient's skin) at a location proximate an implanted second implantable device 200. In these embodiments, the first external device 500 transmits data and/or power to at least the first implantable device 200 and the second external device 500 transmits data and/or power to at least the second implantable device 200.

[0147] Each implantable device 200 can comprise one or more stimulation elements 260, configured to stimulate, deliver energy to, deliver an agent to, record information from and/or otherwise interface with the patient. Alternatively or additionally, the one or more stimulation elements 260 can be configured as a sensor, such as to record patient information. Each implantable device 200 can comprise housing 210, receiver 230, **controller 250**, **energy storage assembly 270** and/or one or more antennas 240, each described in detail herein. Each stimulation element 260 can comprise a sensor and/or any transducer, as described in detail herein. One or more stimulation elements 260 can be positioned on a lead, **lead 265** shown (e.g. a flexible filament including wires or other conductors that connect each stimulation element 260 to electronics within housing 210). Each implantable device 200 can comprise one or more leads 265, such as two leads attached to a single housing 210, or a first lead 265 attached to a first housing 210 and a second lead 265 attached to a second housing 210. Each implantable device 200 can comprise one or more other functional elements, such as functional elements 299a and 299b described herein. Each implantable device 200 can further comprise one or more anchoring or other fixation elements, **anchor element 223** shown., as described in detail herebelow.

[0148] In some embodiments, one or more implantable devices 200 are further configured to transmit data to one or more external devices 500, such as via one or more antennas 240 transmitting a signal to one or more antennas 540, or otherwise. Data transmitted by an implantable device 200 can comprise patient information (e.g. patient physiologic information recorded by one or more stimulation elements 260 configured as a physiologic sensor), or implantable device 200 information (e.g. data recorded by one or more stimulation elements 260

configured as a sensor and positioned in implantable device 200, or other implantable device 200 configuration and/or performance data).

[0149] Housing 210 of each implantable device 200 can comprise one or more rigid and/or flexible materials which surround various components, such as antenna 240, energy storage assembly 270, controller 250 and/or receiver 230 as shown in Fig. 1. In some embodiments, one or more stimulation elements 260 are positioned in, on and/or within housing 210. In some embodiments, housing 210 surrounds a substrate, such as a flexible and/or foldable printed circuit board, such as multiple discrete or continuous printed circuit boards positioned in different planes (e.g. a flexible or foldable printed circuit board). In some embodiments, one or more antennas 240 and/or other components (e.g. a functional element 299) are positioned outside of housing 210, such as when at least one antenna 240 or other components is operably connected to one or more components (e.g. electrical components) positioned within housing 210 via a tether comprising one or more electrical conduits.

[0150] Housing 210 can comprise one or more shapes or combination of shapes, such as one or more shapes selected from the group consisting of: disc; pill; cylinder; sphere; oblate spheroid; dish-like shape; bowl-like shape; cone; rectangular prism; trapezoidal prism; a portion of a toroid; and combinations of one or more of these.

[0151] Housing 210 can comprise a major axis and a minor axis, defined hereabove. In some embodiments, housing 210 comprises a major axis less than or equal to 20mm, such as a major axis less than or equal to 15mm, 12mm or 10mm. In some embodiments, housing 210 comprises a minor axis less than or equal to 8mm, such as a minor axis less than or equal to 6mm, or less than or equal to 5mm. Housing 210 can comprise a wall thickness between 0.1mm and 1.0mm, such as a wall thickness between 0.2mm and 0.5mm, such as a wall thickness of approximately 0.3mm. Housing 210 can comprise a displacement volume less than or equal to 2000mm^3, such as less than or equal to 600mm^3.

[0152] Housing 210 can comprise one or more portions that are transmissive to radiofrequency (RF) signals. In some embodiments, housing 210 comprises glass. In some embodiments, housing 210 comprises a material selected from the group consisting of: glass; ceramic; stainless steel; titanium; polyurethane; an organic compound; liquid crystal polymer (LCP); gold; platinum; platinum iridium; tungsten; epoxy; a thermoplastic; a thermoset plastic; and combinations of one or more of these. In some embodiments, one or more portions of housing 210 comprises one or more coatings, such as one or more coatings configured to cause or prevent a physiologic reaction and/or a coating configured to block (e.g. shield) an electromagnetic transmission.

[0153] Housing 210 can comprise one or more passageways or other feedthroughs, such as for the passage of a lead, wire, optical fiber, fluid delivery tube, mechanical linkage and/or other conduit through a wall of housing 210, such as is described in applicant's co-pending United States Patent Application Serial Number 15/664,231, titled "Medical Apparatus Including an Implantable System and an External System", filed July 31, 2017 [Docket nos. 47476-706.301; NAL-011-US].

[0154] In some embodiments, one or more inner or outer surfaces (or portions of surfaces) of housing 210 includes an insulating and/or shielding layer (e.g. a conductive electromagnetic shielding layer), such as inner coating 219a and/or outer coating 219b shown (singly or collectively coating 219). Coating 219 can comprise an electrically insulating and/or a thermally insulating layer or other coating. In some embodiments, one or more portions of housing 210 comprise an electrically shielding coating, coating 219, while other portions are transmissive to electromagnetic signals such as radiofrequency signals.

[0155] In some embodiments, housing 210 comprises an array of feedthroughs, not shown. In some embodiments, housing 210 is surrounded (e.g. partially or fully surrounded) by a covering, such as a flexible and/or non-conductive covering, such as a covering made of an elastomer.

[0156] In some embodiments, implantable device 200 and/or another component of apparatus 10 can include one or more features to prevent or at least reduce migration of implant 200 within the patient's body. In some embodiments, one or more implantable devices 200 comprises one or more anchor elements configured to secure one or more portions of implantable device 200 to tissue (e.g. anchor element 223 described hereabove and/or an anchor element in an overmold positioned about a portion of housing 210). Anchor element 223 can comprise one or more anchoring elements selected from the group consisting of: a sleeve such as a silicone sleeve; suture tab; suture eyelet; bone anchor, wire loops; porous mesh; penetrable wing; penetrable tab; bone screw eyelet; tine; pincers; suture slits; and combinations of one or more of these. While anchor element 223 is shown proximate housing 210 (e.g. to fixedly attach housing 210 to tissue), in some embodiments anchor element 223 surrounds or is otherwise proximate lead 265 (e.g. to fixedly attach lead 265 to tissue). In some embodiments, anchor element 223 comprises a porous mesh that surrounds all or a portion of housing 210. The porous mesh can be configured to promote tissue ingrowth, such as to prevent or at least limit (**"prevent"** herein) migration of housing 210 when implantable device 200 is implanted in the patient. In some embodiments, anchor element 223 comprises a mesh that is attached to the top side of implantable device 200 (side in closest proximity to the patient's skin), such as to prevent

housing 210 from migrating away from the patient's skin (e.g. prevent from migrating deeper into the patient).

[0157] One or more antennas 240 (singly or collectively antenna 240) can be configured to receive power and/or data, and receiver 230 can receive the power and/or data from the one or more antennas 240. Each antenna 240 can comprise one or more implantable antennas, such as one or more antennas positioned within housing 210, and/or one or more antennas electrically attached to a connecting filament. In some embodiments, one or more implantable devices 200 comprise at least two antennas 240, or at least three antennas 240. Antenna 240 can be configured to receive power and/or data from one or more external devices 500, such that an attached receiver 230 receives the power and/or data. In some embodiments, implantable system 20 comprises at least two implantable devices 200, each of which comprise one or more (e.g. two or three) antennas 240 which are positioned within a housing 210 and/or electrically tethered to a housing 210. In some embodiments, an implantable device 200 comprises a first antenna 240 positioned in a first plane and a second antenna 240 positioned in a second plane. The first plane and second plane can be relatively orthogonal planes, or planes oriented between 30° and 90° relative to each other, such as between 40° and 90°, approximately 30°, approximately 45° and/or approximately 60° relative to each other. In some embodiments, an implantable device 200 comprises a first antenna 240 positioned in a first plane, a second antenna 240 positioned in a second plane, and a third antenna 240 positioned in a third plane.

[0158] In some embodiments, implantable device 200 comprises one or more antennas 240 positioned on a substrate, such as a printed circuit board (PCB), a flexible printed circuit board and/or a foldable substrate (e.g. a substrate comprising rigid portions and hinged portions). In some embodiments, the substrate is folded or otherwise pivoted to position the various antennas 240 on differently oriented planes, such as multiple planes oriented between 5° and 90° relative to each other, such as two antennas 240 positioned on two planes oriented between 30° and 90° or between 40° and 90° relative to each other, or three antennas 240 positioned on three planes oriented between 5° and 60° relative to each other. Two or more antennas 240 can be positioned on two or more different planes that are approximately 45° relative to each other, or approximately 60° or approximately 90° relative to each other.

[0159] Implantable device 200 can comprise three antennas 240. In some embodiments, a first antenna 240 comprises an electrical dipole antenna, and the second and third antennas 240 can be positioned in different planes than the first antenna 240. In some embodiments, the three antennas 240 each comprise a loop antenna, such as when each loop antenna is positioned on a different plane. In some embodiments, a first antenna 240 comprises an electrical dipole

antenna, and a second antenna 240 and a third antenna 240 each comprise a loop antenna. In these embodiments, the second antenna 240 and the third antenna 240 can be positioned relatively orthogonal to each other (e.g. positioned on two relatively orthogonal planes). In some embodiments, a first antenna (e.g. an electrical dipole antenna) is positioned outside of housing 210, while a second antenna (e.g. a loop antenna) and a third antenna (e.g. a loop antenna) are each positioned on, in and/or within housing 210. In some embodiments, implantable device 200 comprises one or more antennas 240 in which any combination of antenna types (as described herein) are used in combination.

[0160] One or more antennas 240 can comprise an antenna selected from the group consisting of: loop antenna; multiple-turn loop antenna; planar loop antenna; coil antenna; dipole antenna; electric dipole antenna; magnetic dipole antenna; patch antenna; loaded dipole antenna; concentric loop antenna; loop antenna with ferrite core; and combinations of one or more of these. One or more antennas 240 can comprise a loop antenna, such as an elongated loop antenna or a multiple-turn loop antenna.

[0161] One or more antennas 240 can comprise a multi-turn spiral loop antenna, such as a multi-turn spiral loop antenna configured to desensitize coupling sensitivity and/or boost input voltage. In some embodiments, one or more antennas 240 comprise multiple concentric loops with varied dimensions, such as concentric loops configured to desensitize coupling sensitivity. In these embodiments, the multiple concentric loops can be arranged as follows: connected in parallel and driven from the same feed point; driven from the same feed point and connected using one or more of a capacitor, inductor, varactor, and combinations of one or more of these; and/or driven from multiple feed points.

[0162] One or more antennas 240 can comprise a minor axis and a major axis. In some embodiments, one or more antennas 240 comprise a minor axis between 1mm and 8mm, such as between 2mm and 5mm. In some embodiments, one or more antennas 240 comprise a major axis between 3mm and 15mm, such as between 4mm and 8mm. In some embodiments, one or more antennas 240 comprise a major axis above 3mm, such as between 3mm and 15mm, such as when the antenna 240 is positioned outside of housing 210.

One or more antennas 240 can comprise a foldable and/or unfoldable antenna, such as is described in applicant's co-pending United States Patent Application Serial Number 17/240,629, titled "Method and Apparatus for Minimally Invasive Implantable Modulators", filed April 26, 2021 [Docket nos. 47476-703.302; NAL-005-US-CON1].

[0163] One or more antennas 240 can be positioned inside of housing 210. Alternatively or additionally, one or more antennas 240 can be positioned outside of housing 210.

[0164] Implantable system 20, one or more implantable devices 200 and/or one or more antennas 240 can be configured to be positioned at a desired depth beneath the patient's skin, such as at a depth between 0.5cm and 7.0cm, such as a depth of between 1.0cm and 3.0cm.

[0165] One or more energy storage assemblies 270 (singly or collectively energy storage assembly 270) can comprise one or more implantable energy storage components, such as one or more batteries (e.g. rechargeable batteries) and/or capacitors (e.g. a supercapacitor). Energy storage assembly 270 can be configured to provide power to one or more of: one or more stimulation elements 260; controller 250; receiver 230; and combinations of one or more of these. In some embodiments, energy storage assembly 270 further provides power to one or more antennas 240 and/or circuitry configured to transmit data via antenna 240. In some embodiments, energy storage assembly 270 includes digital control for charge/discharge rates, voltage outputs, current outputs, and/or system power distribution and/or management.

[0166] Energy storage assembly 270 can comprise one or more capacitors with a single or collective capacitance between 0.01μF and 10F, such as a capacitance between 1μF and 1.0mF, or between 1μF and 10μF. The energy storage assembly 270 can comprise one or more capacitors with capacitance between 1mF and 10F, such as when energy storage assembly 270 comprises a super-capacitor and/or an ultra-capacitor. Such large capacitance can be used to store sufficient charge to maintain operation (e.g. maintain delivery of stimulation energy and/or delivery of an agent) without the use (e.g. sufficient proximity) of an associated external device 500. A capacitor or other energy storage element (e.g. a battery) can be chosen to provide sufficient energy to maintain operation for at least 30 seconds, at least 2 minutes, at least 5 minutes, at least 30 minutes, and up to several hours or more (e.g. during showering, swimming or other physical activity). In some embodiments, energy storage assembly 270 is configured to provide continuous and/or intermittent stimulation energy for at least one charge-balanced pulse (e.g. for the duration of at least one charge-balanced pulse). In some embodiments, a capacitor, battery or other energy storage element is configured to provide stimulation energy without receiving externally supplied power for periods of at least 1 hour, at least 1 day, at least 1 month or at least 1 year. Energy storage assembly 270 can comprise one or more capacitors with a breakdown voltage above 1.0V, such as a breakdown voltage above 1.5V, 4.0V, 10V, or 15V. In some embodiments, energy storage assembly 270 can comprise capacitors distributed outside of housing 210, such as when one or more capacitors are distributed along lead 265. Energy storage assembly 270 can comprise one or more capacitors with low self-leakage, such as to maintain stored energy for longer periods of time.

[0167] In some embodiments, energy storage assembly 270 comprises a temporary energy storage component, such as a super-capacitor, configured to store a sufficient quantity of energy to provide uninterrupted stimulation, such as during time periods in which the link gain may be of poor quality or it may be temporarily unavailable (e.g. an external device 500 not being in place such as during a shower, swimming, and the like). An energy storage assembly 270 comprising an ultra-capacitor, super-capacitor or flexible battery can be charged via the wireless power transmission of the present inventive concepts, such as to store a sufficient amount of energy for one or more stimulation elements 260 to deliver stimulation energy during subsequent (intended or unintended) unavailability of one or more external devices 500 (e.g. an external device 500 is intentionally removed or unintentionally falls off or otherwise loses its position sufficiently proximate one or more implantable devices 200). An energy storage assembly 270 comprising one or more high capacity energy storage components can be beneficial in applications where therapy interruption provides a significant risk or is otherwise relatively unacceptable, such as for life support therapies, cardiac resynchronization therapies, and the like. The high capacity energy storage components of energy storage assembly 270 can be positioned in an assembly positioned within housing 210, on an inner or outer surface of housing 210, within a separate housing, and/or within lead 265.

[0168] In some embodiments, during use (e.g. during period of providing stimulation or other function) implantable device 200 receives power regularly from external system 50 (e.g. relatively continuously while implantable device 200 delivers stimulation energy), and energy storage assembly 270 comprises a relatively small battery or capacitor, such as a battery or capacitor that has an energy storage capacity of less than or equal to 0.6 Joules, 7 Joules or 40 Joules.

[0169] One or more controllers 250 (singly or collectively controller 250) can be configured to control one or more stimulation elements 260, such as a stimulation element 260 comprising a stimulation-based transducer (e.g. an electrode or other energy delivery element) and/or a sensor (e.g. a physiologic sensor and/or a sensor configured to monitor an implantable device 200 parameter). In some embodiments, controller 250 is configured to transmit a stimulation signal (e.g. transmit stimulation energy configured in one or more stimulation waveforms) to one or more stimulation elements 260 (e.g. one or more stimulation elements 260 comprising an electrode and/or other energy delivery element), independent of the power signal received by one or more antennas 240 (e.g. independent of power transmitted by external system 50), such as by using energy stored in energy storage assembly 270. In these embodiments, the power signal and/or the RF path for the power signal can be modified to optimize power efficiency (e.g. by

tuning matching network on transmitter 530 and/or receiver 230; configuring antennas 540 and/or 240 in an array; tuning operating frequency; duty cycling the power signal; adjusting antenna 540 and/or 240 position; and the like), and a stimulation signal can be precisely delivered (e.g. by using energy stored on energy storage assembly 270 and generating stimulation signal locally on the implantable device 200) to ensure clinical efficacy. Also, if the power signal transmission (also referred to as **"power link"**) is perturbed unexpectedly, the stimulation signal can be configured so that it is not significantly affected (e.g. unaffected). In some configurations, the stimulation signal being delivered by one or more implantable devices 200 is insensitive to interference that may be present. In these embodiments, a power transmission signal and stimulation signal can vary in one or more of: amplitude; changes in amplitude; average amplitude; frequency; changes in frequency; average frequency; phase; changes in phase; average phase; waveform shape; pulse shape; duty cycle; polarity; and combinations of one or more of these.

[0170] Controller 250 can receive commands from receiver 230, such as one or more commands related to one or more implantable device 200 configuration parameters selected from the group consisting of: stimulation parameter; data rate of receiver; data rate of data transmitted by the first implantable device 200 at least one implantable antenna 240; stimulation element 260 configuration; state of controller 250; antenna 240 impedance; clock frequency; sensor configuration; electrode configuration; power management parameter; energy storage assembly parameter; agent delivery parameter; sensor configuration parameter; and combinations of one or more of these.

[0171] In some embodiments, one or more stimulation elements 260 comprise a stimulation element configured to deliver energy (e.g. one or more electrodes configured to deliver monopolar or bipolar electrical energy) to tissue, and controller 250 is configured to control the energy delivery, such as to control (e.g. provide, determine, and/or adjust) one or more stimulation parameters. Each of these stimulation parameters can be held relatively constant, and/or varied, such as a variation performed in a continuous or intermittent manner. In some embodiments, one or more stimulation parameters are varied in a random or pseudo-random (hereinafter **"random"**) manner, such as a variation performed by apparatus 10 using a probability distribution as described in applicant's co-pending United States Patent Application Serial Number 17/372,095, titled "Apparatus with Enhanced Stimulation Waveforms", filed July 9, 2021 [Docket nos. 47476-708.302; NAL-014-US-CON1]. In some embodiments, stimulation (e.g. stimulation comprising high frequency and/or low frequency signal components) is varied randomly to eliminate or at least reduce synchrony of neuronal firing with the stimulation signal

(e.g. to reduce paresthesia or other patient discomfort). In some embodiments, one or more stimulation elements 260 comprise a stimulation element configured to stimulate a target (e.g. nerve tissue such as spinal nerve tissue and/or peripheral nerve tissue). The amount of stimulation delivered to the target can be controlled by varying a parameter selected from the group consisting of: stimulation element 260 size and/or configuration (e.g. electrode size and/or configuration); stimulation element 260 shape (e.g. electrode shape, magnetic field generating transducer shape or agent delivering element shape); shape of a generated electric field; shape of a generated magnetic field; stimulation signal parameters; and combinations of one or more of these.

[0172] In some embodiments, one or more stimulation elements 260 comprise an element configured to deliver electrical energy to tissue (e.g. one or more electrodes configured to deliver monopolar or bipolar electrical energy), and controller 250 is configured to control charge balance, such as to actively and/or passively control charge balance, as described herebelow. Charge balance can be essential for patient safety in electrical stimulation of nerves or other tissue. Imbalanced stimulation waveforms can cause electrode corrosion and/or dissolution which can lead to deposition of toxic materials in tissue, implant rejection, and nerve damage. The stimulation waveform can be balanced such that net outflow charge approximately equals net inflow charge. With stimulation waveform amplitudes that can vary between 0.01mA to 15mA (such as between 0.1mA and 15ma, between 0.1mA and 12mA, or between 0.1mA and 10mA), depending on the treatment, the error in charge balance can be on the order of 0.001% to 0.01%. Alternatively or additionally, controller 250 can comprise AC coupling capacitors that are configured to balance stimulation waveforms passively. The AC coupling capacitance can be fairly large (e.g. greater than 10μF), in order to pass the stimulation waveform with minimal filtering. In some embodiments, apparatus 10 is configured to perform active charge balancing. In some embodiments, an implantable device 200 comprises a precise resistor in series with a stimulation electrode-based stimulation element 260. The precise resistor can be used to measure outflow and inflow currents, such as when controller 250 comprises an analog to digital converter (ADC). Controller 250 can integrate current over time during a first phase in which stimulation energy is delivered, and during a second phase in which a reverse current is applied (e.g. a reverse current used to balance charge). Controller 250 can be configured to balance the total charge in the two phases, to ensure that the net DC current is approximately zero. The integration can be achieved using an analog integrator and/or a digital summer of controller 250, with controller 250 keeping track of one or more parameters of the pulses delivered (e.g. pulses delivered within a train or a burst). Implantable device 200 can comprise a precise series

resistance comprising an **"on-chip"** trimmed resistor or an **"off-chip"** resistor. In some embodiments, implantable device 200 comprises a bank of trimmed resistors that are used to control the net series resistance, such as to adjust resistance based on stimulation amplitude requirements (e.g. to take advantage of the full dynamic range of an ADC of controller 250). In some embodiments, controller 250 comprises a shunt path with an RC-based low pass filter used for both outflow and inflow of current. RC elements of controller 250 can be chosen such that the shunt current is only a fraction of the stimulation current. Since the same RC elements can be used for both outflow and inflow current, the precision required for the RC components can be lower. An ADC can be used to sense the voltage on the capacitor at the end of a stimulation pulse. After the stimulation pulse, the capacitor can be discharged and the polarity of the stimulation current can be reversed and set to any amplitude, until the capacitor is charged to approximately the same voltage (according to the ADC precision) as it was charged during the stimulation pulse. The ADC resolution can be high enough to ensure the residual error is less than what would cause an undesired charge accumulation. ADC resolution requirements can be further reduced by reducing the net capacitance in a shunt RC circuit, to cause accelerated charging of the capacitor. The capacitor can be discharged every time the voltage exceeds a certain predefined threshold, while controller 250 keeps track of the number of times the capacitor has been charged and reset. By resetting the capacitor through a low resistance path, the discharge time can be insignificant compared to the charge time, reducing the error due to the discharge period. Since the net charge equivalent to full scale voltage on the ADC can be divided into multiple cycles, the required resolution of the ADC to achieve the same residual error can be divided by the number of cycles.

[0173] In some embodiments, controller 250 is configured to produce a stimulation signal comprising a waveform or a waveform pattern (hereinafter stimulation waveform), for one or more stimulation elements 260 configured as a stimulation element (e.g. such that one or more stimulation elements 260 deliver stimulation energy comprising or at least resembling that stimulation waveform). Controller 250 can produce a stimulation signal comprising a waveform selected from the group consisting of: square wave; rectangle wave; sine wave; sawtooth; triangle wave (e.g. symmetric or asymmetric); trapezoidal; ramp; waveform with exponential increase; waveform with exponential decrease; pulse shape which minimizes power consumption; Gaussian pulse shape; pulse train; root-raised cosine; bipolar pulses; and combinations of one or more of these. In some embodiments, controller 250 is configured to produce a stimulation signal comprising a waveform including a combination of two or more waveforms selected from the group consisting of: square wave; rectangle wave; sine wave;

triangle wave (symmetric or asymmetric); ramp; waveform with exponential increase; waveform with exponential decrease; pulse shape which minimizes power consumption; Gaussian pulse shape; pulse train; root-raised cosine; bipolar pulses; and combinations of one or more of these. In some embodiments, controller 250 is configured to construct a custom waveform (e.g. an operator customized waveform), such as by adjusting amplitude at specified time steps (e.g. for one or more pulses). In some embodiments, controller 250 is configured to generate a waveform including one or more random parameters (e.g. random timing of pulses or random changes in frequency, rate of change or amplitude).

[0174] In some embodiments, controller 250 is configured to provide a stimulation signal comprising waveforms and/or pulses repeated at a frequency (e.g. includes a frequency component) between 1.0Hz and 50KHz, such as between 10Hz and 500Hz, between 40Hz and 160Hz and/or between 5KHz and 15KHz. In some embodiments, controller 250 is configured to produce a stimulation signal comprising a frequency between 1Hz and 1000Hz, such as a stimulation signal with a frequency between 10Hz and 500Hz. In some embodiments, controller 250 is configured to produce a stimulation signal comprising a duty cycle between 0.1% and 99%, such as a duty cycle between 1% and 10% or between 1% and 25%. In some embodiments, controller 250 is configured to produce a stimulation signal comprising a frequency modulated stimulation waveform, such as a stimulation waveform comprising a frequency component (e.g. signal) between 1kHz and 20kHz. In some embodiments, controller 250 is configured to produce a stimulation signal comprising a mix and/or modulation of low frequency and high frequency signals, which comprise any of the waveform types, shapes and other configurations. In these embodiments, the stimulation signal can comprise low frequency signals between 1Hz and 1000Hz, and high frequency signals between 600Hz and 50kHz, or between 1kHz and 20kHz. Alternatively or additionally, the stimulation signal can comprise a train of high frequency signals and bursts of low frequency signals, and/or a train of low frequency signals and bursts of high frequency signals. Alternatively or additionally, the stimulation signal can comprise one or more high frequency signals modulated with one or more low frequency signals, such as one or more high frequency signals frequency modulated (FM), amplitude modulated (AM), phase modulated (PM) and/or pulse width modulated (PWM) with one or more low frequency signals. The stimulation signal can cycle among different waveforms shapes at specified time intervals. The stimulation signal can comprise a pseudo random binary sequence (PRBS) non-return-to-zero or return-to-zero waveform, such as with a fixed and/or time-varying pulse width and/or frequency of the pulses.

[0175] Controller 250 can comprise a clamping circuit configured to allow fast charging and/or discharging of the energy storage assembly 270, stimulation element 260 drivers (e.g. electrode drivers) of controller 250, and/or other components of implantable device 200. The clamping circuit can improve pulse shape by offering additional control and/or configuration of rise and fall times in the shape of the waveform (e.g. to create rapid rise or fall times). In some embodiments, the clamping circuit can be configured to limit the rise and/or fall time to be less than or equal to one-tenth (10%) of the pulse width of an applied stimulation pulse (e.g. less than or equal to 1μsec rise and/or fall time for a 10μsec stimulation pulse).

[0176] In some embodiments, controller 250 comprises a matching network configured to match the impedance of a first antenna 240 with the impedance of the receiver 230. In these embodiments, controller 250's matching network can be adjustable. Alternatively or additionally, controller 250 can comprise an adjustable loading impedance to stabilize the load seen at an antenna 240 under different operating conditions. In some embodiments, the adjustable loading impedance is controlled according to the charge rate of the energy storage assembly 270.

[0177] Controller 250 and/or any other component of each implantable device 200 can comprise an integrated circuit comprising one or more components selected from the group consisting of: matching network; rectifier; DC-DC converter; regulator; bandgap reference; overvoltage protection; overcurrent protection; active charge balance circuit; analog to digital converter (ADC); digital to analog converter (DAC); current driver; voltage driver; digital controller; clock generator; data receiver; data demodulator; data modulator; data transmitter; electrode drivers; sensing interface analog front end; power management circuit; energy storage interface; memory register; timing circuit; and combinations of one or more of these.

[0178] One or more receivers 230 (singly or collectively receiver 230) can comprise one or more components, such as **demodulator 231**, **rectifier 232,** and/or **power converter 233** shown in Fig. 1. In some embodiments, receiver 230 can comprise a DC-DC converter such as a boost converter. Receiver 230 can comprise a data receiver, such as a data receiver including an envelope detector and demodulator and/or an envelope averaging circuit. In some embodiments, one more antennas 240 separately connect to one or more receivers 230. In some embodiments, one or more antennas 240 connect to a single receiver 230, such as via a series connection or a parallel connection.

[0179] One or more implantable devices 200 can be configured to transmit a data signal to external system 50. In some embodiments, receiver 230 is configured to drive one or more antennas 240 to transmit data to external system 50 (e.g. to an antenna 540 of an external device

500). Alternatively or additionally, implantable device 200 can be configured to transmit a data signal by having receiver 230 adjust a load impedance to backscatter energy, such as a backscattering of energy which can be detected by external system 50. In some embodiments, data transmission is accomplished by receiver 230 manipulating a signal at a tissue interface, such as to transmit a data signal using body conduction.

[0180] In some embodiments, receiver 230 comprises a matching network, such as a matching network configured to detune to prevent oversaturation. For example, implantable system 20 can comprise two or more implantable devices 200 each of which includes a receiver 230 comprising a matching network. A first implantable device 200's receiver 230's matching network can be configured to detune based on power received by the second implantable device 200's receiver 230.

[0181] Demodulator 231 can comprise circuitry that asynchronously recovers signals modulated on the power signal provided by external system 50, and that converts the modulated signals into digital signals. In some embodiments, demodulator 231 asynchronously recovers the modulated signal by comparing a dynamically generated moving average with the envelope, outputting a high voltage when the envelope is greater than the moving average and a low voltage when the envelope is less than the moving average. Data can then be extracted from this resulting digital signal from the width and/or amplitude of the pulses in the signal, according to the encoding method used by external system 50. In some embodiments, demodulator 231 recovers a digital signal that is used as timing information for an implantable device 200, similar to an on-chip clock. The recovered clock signal can also be used to synchronize an on-chip clock generator of controller 250, such as through the use of a frequency and/or phase locked loop (FLL or PLL).

[0182] Rectifier 232 can comprise a power signal rectifier, such as to provide power to the energy storage assembly 270 and/or controller 250. In some embodiments, rectifier 232 comprises one or more self-driven synchronous rectifier (SDSR) stages connected in charge-pump configuration, to boost the voltage from input RF amplitude to the rectifier to a higher voltage. The boosted voltage can directly charge energy storage assembly 270, or it can be further boosted by a DC-DC converter or boost converter. In some embodiments, rectifier 232 comprises diode-capacitor ladder stages instead of, or in addition to, SDSR stages. On-chip diodes, such as Schottky diodes, or off-chip diodes can be used in one or more rectifier 232 stages. For maximum efficiency, the rectification elements, such as diodes, can be optimized to minimize forward conduction and/or reverse conduction losses by properly sizing the

components and selecting appropriate number of stages based on the input RF voltage and load current.

[0183] Power converter 233 can comprise one or more voltage conversion elements such as DC-DC converters that boost or otherwise change the voltage to a desired level. In some embodiments, voltage conversion is achieved with a buck-boost converter, a boost converter, a switched capacitor, and/or charge pumps. One or more power converters 233 can interface with energy storage assembly 270 and charge up associated energy storage components to desired voltages. In some embodiments, power converter 233 receives control signals from controller 250, such as to configure voltages, currents, charge/discharge rates, switching frequencies, and/or other operating parameters of power converter 233.

[0184] One or more implantable leads 265 (singly or collectively lead 265) can be attached to one or more housings 210, such as a lead 265 comprising one or more stimulation elements 260. Lead 265 can comprise one or more stimulation elements 260 configured as a stimulation element (e.g. an electrode configured to deliver electrical energy in monopolar or bipolar mode or an agent delivery element such as an output port fluidly connected to a reservoir within housing 210). Alternatively or additionally, lead 265 can comprise one or more stimulation elements 260 and/or functional elements 299b that is configured as a physiologic sensor (e.g. an electrode configured to record electrical activity of tissue or another physiologic sensor as described herein). Alternatively or additionally, lead 265 can comprise one or more stimulation elements 260 and/or functional elements 299b that is configured to transmit signals through tissue to external system 50, such as through body conduction.

[0185] In some embodiments, implantable device 200 comprises a connector, **connector 215**, that operably attaches (e.g. electrically attaches) one or more stimulation elements 260 to one or more components (e.g. electronic components) internal to housing 210 (e.g. to transfer power and/or data therebetween). In some embodiments, connector 215 is operably attached (e.g. in a manufacturing process) or attachable (e.g. in a clinical procedure) to lead 265 as shown in Fig. 1. Alternatively, connector 215 can be operably attached and/or attachable to a lead connection assembly, **assembly 280**, which in turn can be attached to a lead 265. In some embodiments, connector 215 passes through an opening in housing 210, in a feed-through arrangement. In some embodiments, an overmold or other sealing element, **sealing element 205** shown, provides a seal about connector 215, the opening in housing 210 and/or the interface between connector 215 and housing 210.

[0186] In some embodiments, lead 265 comprises a removable stylet configured to aid in the implantation of lead 265, such as is described in applicant's co-pending United States Patent

Application Serial Number 15/664,231, titled "Medical Apparatus Including an Implantable System and an External System", filed July 31, 2017 [Docket nos. 47476-706.301; NAL-011-US]. In some embodiments, implantable system 20 comprises more than one lead 265, comprising one or more stimulation elements 260 and attached to one or more housings 210 of one or more implantable devices 200. In some embodiments, one or more leads 265 can be attached to a single housing 210.

[0187] In some embodiments, lead 265 comprises a diameter between 1mm and 4mm, such as a diameter between 1mm and 2mm, such as a lead with a diameter of approximately 1.35mm. In some embodiments, lead 265 comprises a length between 3cm and 60cm, such as a length between 6cm and 30cm. One or more leads 265 can include between 2-64 stimulation elements 260, such as when a lead 265 comprises between 2 and 64 electrodes, such as between 4 and 32 electrodes. In some embodiments, lead 265 comprises a paddle lead. In some embodiments, lead 265 comprises a single or multi-lumen catheter, such as when an attached implantable device 200 is configured as an agent delivery apparatus as described herein (e.g. a stimulation element 260 configured as a catheter comprises at least a portion of lead 265).

[0188] In some embodiments, lead 265 comprises one or more tines, such as **tines 266** shown. Tines 266 can be configured to anchor or otherwise stabilize (**"anchor"** or **"stabilize"** herein) lead 265 relative to patient tissue, such as to prevent undesired movement during and/or after an implantation procedure for lead 265. One or more tines 266 can be configured to biodegrade after implantation in the patient, such that the stabilization provided is temporary. Tines 266 can be configured to biodegrade over a time period of approximately 4 to 12 weeks. In some embodiments, biodegradable tines 266 are configured to be incorporated when lead stimulation elements 260 are positioned to stimulate a peripheral nerve (e.g. lead 265 is implanted such that one or more stimulation elements 260 are positioned proximate one or more peripheral nerves).

[0189] In some embodiments, one or more tines 266 are configured to be deployed, such as via an operator-accessible control.

[0190] One or more stimulation elements 260 (singly or collectively stimulation element 260) and/or functional element 299 (e.g. functional element 299a and/or 299b) can comprise one or more sensors, transducers and/or other functional elements. In some embodiments, one or more stimulation elements 260 and/or functional elements 299 comprise at least one sensor and/or at least one transducer (e.g. a single stimulation element 260 or multiple stimulation elements 260). In some embodiments, stimulation element 260 and/or functional element 299 comprises a functional element configured to provide a therapy, such as one or more stimulation elements 260 configured to deliver an agent to tissue (e.g. a needle or catheter), to deliver energy to tissue

and/or to otherwise therapeutically affect tissue. In some embodiments, stimulation element 260 and/or functional element 299 comprises one or more functional elements configured to record patient information, such as when stimulation element 260 and/or functional element 299 comprises one or more sensors configured to measure a patient physiologic parameter, as described herein. In some embodiments, stimulation element 260 and/or functional element 299 comprises one or more sensors configured to record an implantable device 200 parameter, also as described herein.

[0191] One or more stimulation elements 260 can be positioned on lead 265 as shown in Fig. 1. Alternatively or additionally, one or more stimulation elements 260 can be positioned on housing 210. One or more functional elements 299 can be positioned on lead 265 (e.g. functional element 299b shown) and/or positioned on and/or within housing 210 (e.g. functional element 299a shown).

[0192] Stimulation element 260 can comprise one or more stimulation elements positioned at one or more internal body locations. Stimulation element 260 can comprise one or more stimulation elements positioned to interface with (e.g. deliver energy to and/or record a physiologic parameter from) spinal cord tissue, spinal canal tissue, epidural space tissue, spinal root tissue (dorsal or ventral), dorsal root ganglion, nerve tissue (e.g. peripheral nerve tissue, spinal nerve tissue or cranial nerve tissue), brain tissue, ganglia (e.g. sympathetic or parasympathetic) and/or a plexus. In some embodiments, stimulation element 260 comprises one or more elements positioned proximate and/or within one or more tissue types and/or locations selected from the group consisting of: one or more nerves; one or more locations along, in and/or proximate to the spinal cord; peripheral nerves of the spinal cord including locations around the back; the knee; the tibial nerve (and/or sensory fibers that lead to the tibial nerve); the occipital nerve; the sphenopalatine ganglion; the sacral and/or pudendal nerve; brain tissue, such as the thalamus; baroreceptors in a blood vessel wall, such as in the carotid artery; one or more muscles; the medial nerve; the hypoglossal nerve and/or one or more muscles of the tongue; cardiac tissue; the anal sphincter; the dorsal root ganglion; motor nerves; muscle tissue; the spine; the vagus nerve; the renal nerve; an organ; the heart; the liver; the kidney; an artery; a vein; bone; and combinations of one or more of these, such as to stimulate and/or record data from the tissue and/or location in which the stimulation element 260 is positioned proximate to and/or within. In some embodiments, apparatus 10, implantable device 200 and/or stimulation element 260 are configured to stimulate spinal nerves, peripheral nerves and/or other tissue as described in applicant's co-pending United States Patent Application Serial Number 16/993,999,

titled "Apparatus for Peripheral or Spinal Stimulation ", filed August 14, 2020 [Docket nos. 47476-707.302; NAL-012-US-CON1].

[0193] In some embodiments, stimulation element 260 and/or functional element 299 comprises one or more sensors configured to record data representing a physiologic parameter of the patient. Stimulation element 260 and/or functional element 299 can comprise one or more sensors selected from the group consisting of: electrode; sensor configured to record electrical activity of tissue; blood glucose sensor; gas sensor; blood gas sensor; ion concentration sensor; oxygen sensor; pressure sensor; blood pressure sensor; heart rate sensor; cardiac output sensor; inflammation sensor; neural activity sensor; neural spike sensor; muscular activity sensor; EMG sensor, bladder volume sensor, bladder pressure sensor, gastric volume sensor; peristalsis rate sensor; pH sensor; strain gauge; accelerometer; gyroscope; GPS; respiration sensor; respiration rate sensor; flow sensor; viscosity sensor; temperature sensor; magnetic sensor; optical sensor; MEMs sensor; chemical sensor; hormone sensor; impedance sensor; tissue impedance sensor; electrode-tissue interface impedance sensor; body position sensor; body motion sensor; organ motion sensor; physical activity level sensor; perspiration sensor; patient hydration sensor; breath monitoring sensor; sleep monitoring sensor; food intake monitoring sensor; digestion monitoring sensor; urine movement sensor; bowel movement sensor; tremor sensor; pain level sensor; and combinations of one or more of these.

[0194] Apparatus 10 (e.g. via stimulation element 260, functional element 299, and/or functional element 599) can be configured to record a patient parameter (e.g. patient physiologic and/or patient environment parameter) selected from the group consisting of: blood glucose; blood pressure; EKG; heart rate; cardiac output; oxygen level; pH level; pH of blood; pH of a bodily fluids; tissue temperature; inflammation level; bacteria level; type of bacteria present; gas level; blood gas level; neural activity; neural spikes; neural spike shape; action potential; local field potential (LFP); EEG; muscular activity (e.g. as measured using EMG); skeletal muscle activity; bladder volume; bladder pressure; gastric volume; peristalsis rate; impedance; tissue impedance; electrode-tissue interface impedance; physical activity level; pain level; body position; body motion; organ motion; respiration rate; respiration level; perspiration rate; sleep level; sleep cycle; digestion state; digestion level; urine production; urine flow; bowel movement; tremor; ion concentration; chemical concentration; hormone level; viscosity of a bodily fluid; patient hydration level; and combinations of one or more of these.

[0195] In some embodiments, stimulation element 260 and/or functional element 299 comprises one or more sensors configured to record data representing a parameter of implantable device 200. In these embodiments, stimulation element 260 and/or functional element 299 can

comprise one or more sensors selected from the group consisting of: an energy sensor; a voltage sensor; a current sensor; a temperature sensor (e.g. a temperature of one or more components of implantable device 200); a contamination detector (e.g. to detect undesired material that has passed through housing 210); an antenna matching and/or mismatching assessment sensor; power transfer sensor; link gain sensor; power use sensor; energy level sensor; energy charge rate sensor; energy discharge rate sensor; impedance sensor; load impedance sensor; instantaneous power usage sensor; average power usage sensor; bit error rate sensor; signal integrity sensor; and combinations of one or more of these. Apparatus 10 can be configured to analyze (e.g. via implantable controller 250, programmer 600 and/or diagnostic assembly 62 described herebelow) the data recorded by stimulation element 260 and/or functional element 299 to assess one or more of: power transfer; link gain; power use; energy within energy storage assembly 270; performance of energy storage assembly 270; expected life of energy storage assembly 270; discharge rate of energy storage assembly 270; ripple or other variations of energy storage assembly 270; matching of antenna 240 and 540; communication error rate between implantable device 200 and external device 500; integrity of transmission between implantable device 200 and external device 500; and combinations of one or more of these. A stimulation element 260 can be configured to record temperature, such as when apparatus 10 is configured to deactivate or otherwise modify the performance of an implantable device 200 when the recorded temperature exceeds a threshold.

[0196] In some embodiments, one or more stimulation elements 260 comprise a transducer configured to deliver energy to tissue, such as to treat pain and/or to otherwise stimulate or affect tissue. In some embodiments, stimulation element 260 comprises a stimulation element, such as one or more transducers selected from the group consisting of: an electrode; an energy delivery element such as an electrical energy delivery element, a light energy delivery element, a laser light energy delivery element, a sound energy delivery element, a subsonic sound energy delivery element and/or an ultrasonic sound delivery element; an electromagnetic field generating element; a magnetic field generating element; a mechanical transducer (e.g. delivering mechanical energy to tissue); a tissue manipulating element; a heat generating element; a cooling (e.g. cryogenic or otherwise heat extracting energy) element; an agent delivery element such as a pharmaceutical drug delivery element; and combinations of one or more of these.

[0197] In some embodiments, one or more stimulation elements 260 comprises a drug or other agent delivery element, such as a needle, port, iontophoretic element, catheter, or other agent delivering element that is connected to a reservoir of agent positioned within housing 210 (e.g.

reservoir 225 described herebelow). In some embodiments, one or more stimulation elements 260 comprise a drug eluting element configured to improve biocompatibility of implantable system 20.

[0198] In some embodiments, one or more stimulation elements 260 comprise one or more electrodes configured to deliver energy to tissue and/or to sense a patient parameter (e.g. electrical activity of tissue or other patient physiologic parameter). In these embodiments, one or more stimulation elements 260 can comprise one or more electrodes selected from the group consisting of: microelectrode; cuff electrode; array of electrodes; linear array of electrodes; circular array of electrodes; paddle-shaped array of electrodes; bifurcated electrodes; and combinations of one or more of these.

[0199] In some embodiments, apparatus 10 (e.g. via stimulation element 260, functional element 299, and/or functional element 599) is configured to both record one or more patient parameters, and also to perform a medical therapy (e.g. stimulation of tissue with energy and/or an agent). In these embodiments, the medical therapy can be performed in a closed-loop fashion, such as when energy and/or agent delivery is modified based on the measured one or more patient physiologic parameters.

[0200] In some embodiments, one or more stimulation elements 260 comprise an agent delivery element, such as a fluid delivery element (e.g. a catheter, a porous membrane, an iontophoretic element or a needle) in fluid communication with a reservoir of the agent positioned within housing 210, such as reservoir 225 described herebelow.

[0201] In some embodiments, apparatus 10 comprises one or more tools, **tool 60** shown. Tool 60 can comprise a data logging and/or analysis tool configured to receive data from external system 50 or implantable system 20, such as data comprising: diagnostic information recorded by external system 50 and/or implantable system 20; therapeutic information recorded by external system 50 and/or implantable system 20; patient information (e.g. patient physiologic information) recorded by implantable system 20; patient environment information recorded by implantable system 20; and combinations of one or more of these. Tool 60 can be configured to receive data from wired or wireless (e.g. Bluetooth) means. Tool 60 can comprise a tool selected from the group consisting of: a data logging and/or storage tool; a data analysis tool; a network such as a LAN or the Internet; a cell phone; and combinations of one or more of these.

[0202] In some embodiments, tool 60 comprises a battery charging assembly, such as an assembly configured to recharge one or more power supplies 570 comprising a rechargeable battery or capacitor.

[0203] In some embodiments, tool 60 comprises a user interface of apparatus 10, such as a user interface configured to allow the patient, clinician, or other user to create a set of stimulation parameter settings based on various user input.

[0204] Apparatus 10 can include one or more placement tools, positioning **tool 67** shown, which can be configured to aid in the positioning and/or maintenance of one or more external devices 500 on the patient's skin (e.g. at a location proximate an implanted implantable device 200).

[0205] Apparatus 10 can include one or more implantation tools, **tool 65** shown. Implantation tool 65 can comprise an introducer, tunneller, and/or other implantation tool constructed and arranged to aid in the implantation of housing 210, implantable antenna 240, lead 265 and/or one or more stimulation elements 260. In some embodiments, tool 65 comprises a component configured to anchor implantable device 200 to tissue, such as a mesh or wrap that slides around at least a portion of implantable device 200 and is configured to engage tissue (e.g. via tissue ingrowth) or be engaged with tissue (e.g. via suture or clips).

[0206] In some embodiments, one or more components (and/or portions of components) of tool 65 comprises a lubricious coating and/or a lubricous material (**"lubricious coating"** herein), such as to reduce tissue trauma and/or reduce pain to the patient. For example, tool 65 can comprise an introducer, tunneller, pocket formation tool, needle, and/or other insertion tool with at least a portion comprising a lubricious coating configured to ease insertion of the tool. Typical coatings and materials include but are not limited to: a polytetrafluoroethylene coating or material; a hydrophilic coating or material; and combinations of these.

[0207] In some embodiments, one or more components (and/or portions of components) of tool 65 comprises one or more **"visualizable portions"**, such as a radiopaque portion that is visible in X-ray imaging (e.g. fluoroscopy) and/or ultrasonically visible portion that is visible in ultrasound imaging. For example, tool 65 can comprise an introducer including an ultrasonically visible or otherwise visible portion that is used to position the introducer, such as during the implantation of lead 265 or another portion of implantable device 200.

[0208] In some embodiments, lead 265 comprises a paddle lead or other stimulating lead and tool 65 comprises an introducer (e.g. a needle or an extended-width introducer) configured to deliver at least a distal portion of lead 265 into an epidural space of a patient. Tool 65 can comprise an introducer comprising a Tuohy needle, such as a Tuohy needle of 12 gauge or smaller. Tool 65 can comprise a handle for manipulating lead 265. Tool 65 can be configured to place lead 265 at an entry point above the lumbar spinal column (e.g. between L1 and L2 vertebrae). Tool 65 can include extension tubing used to insert lead 265. Tool 65 can further

comprise a tool configured to anchor lead 265, such as when tool 65 comprises sutures, clips, other anchoring elements and/or an anchor securing tool (e.g. a needle or a stapling device), such as to secure lead 265 in subcutaneous tissue. Lead 265 and/or tool 65 can comprise extension tubing used to place lead 265, such as extension tubing that remains in place after removal of an introducer of tool 65. Tool 65 can be configured to place lead 265 against the dura of the spinal cord of the patient.

[0209] In some embodiments, tool 65 and/or lead 265 are constructed and arranged to implant lead 265 to stimulate one or more multifidus (MF) muscle fascicles, such as at least three sets of multifidus muscle fascicles. Lead 265 can be secured to a vertebra (e.g. on the transverse process, lamina or vertebral body). Lead 265 can be placed via tool 65 such that one or more stimulation elements 260 (e.g. electrodes) are positioned within the multifidus muscle structures. One or more stimulation elements 260 can be positioned to deliver electrical energy and/or to otherwise stimulate tissue selected from the group consisting of: muscle motor point(s) or the deep fibers of lumbar multifidus; quadratus lumborum; the erector spinae; psoas major; transverse abdominis; connective tissue such as the annulus or facet capsule; ligaments coupling bony structures of the spine; and combinations of one or more of these. Stimulation elements 260 can be positioned to: depolarize, hyperpolarize and/or block innervated sections of the muscle that will then propagate an activating and/or inhibiting stimulus along the nerve fibers recruiting muscle tissue remote from the site of stimulation and/or modulate nerve activity (including inhibiting nerve conduction, improving nerve conduction and/or improving muscle activity). In some embodiments, stimulation elements 260 are positioned to cause transvascular stimulation (e.g. transvascular stimulation from arteries and/or veins in a leg or arm). In some embodiments, stimulation elements 260 are positioned to stimulate nerve tissue selected from the group consisting of: dorsal ramus nerve; medial branch of dorsal ramus nerve; nervous tissue associated with multifidus muscle; and combinations of one or more of these. In some embodiments, stimulation elements 260 are configured to deliver stimulation energy to contract the multifidus muscle. In some embodiments, stimulation elements 260 are configured to stimulate tissue by providing episodic electrical stimulation. In some embodiments, apparatus 10 comprises a tool 60 configured to diagnose a defect in spinal muscle or the motor control system. In some embodiments, apparatus 10 comprises a tool 60 configured to test function of the multifidus muscle, such as when tool 60 comprises an MRI; ultrasound imager; electromyogram; tissue biopsy device; and/or a device configured to test displacement as a function of load for a spine.

[0210] In some embodiments, two or more external system 50 components are connected by a connecting filament, such as is described hereabove. Alternatively or additionally, two or more implantable system 20 components are connected by a conduit, such as a connecting filament as described herein. Alternatively or additionally, two more external system 50 components and/or two or more implantable system 20 components transmit information and/or power via a wireless transmitter (e.g. an RF transmitter), magnetic coupling, inductive coupling; capacitive coupling and/or other wireless transmission means.

[0211] Apparatus 10 can include one or more positioning devices, such as **patient attachment device 70** shown in Fig. 1, that is used to attach one or more components of external system 50 to a location on or at least proximate the patient. In some embodiments, patient attachment device 70 is constructed and arranged as described in applicant's co-pending United States Patent Application Serial Number 17/187,654, titled "Method and Apparatus for Neuromodulation Treatments of Pain and Other Conditions ", filed February 26, 2021 [Docket nos. 47476-705.303; NAL-008-US-CON2].

[0212] Patient attachment device 70 can comprise one or more elements configured to attach one or more external devices 500 and/or programmer 600 at one or more locations on or proximate the patient's skin, that are relatively close to one or more implantable devices 200 that have been implanted in the patient. Patient attachment device 70 can comprise a component selected from the group consisting of: belt; belt with pockets; belt with adhesive; adhesive; strap; strap with pockets; strap with adhesive shoulder strap; shoulder band; shirt; shirt with pockets; clothing; clothing with pockets; epidural electronics packaging; clip; bracelet; wrist band; wrist watch; anklet; ankle bracelet; knee strap; knee band; thigh strap; thigh band; necklace; hat; headband; collar; glasses; goggles; earpiece; behind-the-earpiece; and combinations of one or more of these. In some embodiments, patient attachment device 70 comprises a belt configured to surround at least one antenna 540 (e.g. at least one antenna 540 mounted to or otherwise positioned on a printed circuit board such as a flexible printed circuit board). Patient attachment device 70 can include one or more pockets, such as one or more pockets configured to collectively surround one or more of: external device 500; one or more antennas 540; power supply 570; programmer 600; and combinations of one or more of these. In some embodiments, patient attachment device 70 comprises multiple pockets, such as to allow repositioning of an external antenna 540, programmer 600, external transmitter 530 and/or external power supply 570 to various different locations, such as to improve transmission of power and/or data to one or more implantable devices 200 and/or improve patient comfort. In some embodiments, one or more antennas 540, power supplies 570, and/or transmitters 530 are connected through flexible

cables positioned in patient attachment device 70. In some embodiments, the flexible cables are small coax cables that accommodate the power levels and frequencies of the carried signals. In some embodiments, the one or more antennas 540 are connected to one or more additional components of external device 500 through a single cable with a local power splitting component and/or active matching element that adjusts signal power to each of the one or more antennas 540.

[0213] In some embodiments, patient attachment device 70 and/or external device 500 can be configured to prevent adversely affecting portions of the skin contacted by either device. Alternatively or additionally, patient attachment device 70 and/or external device 500 can be configured to clean and/or to promote healing of one or more skin-contacting portions. For example, patient attachment device 70 can include an agent (e.g. a coating or other included agent) selected from the group consisting of: a bactericidal agent; an anti-fungal agent; and combinations thereof.

[0214] In some embodiments, an anchoring-based tool, patient attachment device 70, is used on a patient-by-patient basis, such as when used on overweight patients and/or to otherwise avoid migration of implantable device 200 sideways and/or downward (e.g. into fat tissue).

[0215] Apparatus 10 can comprise a device configured to operate (e.g. temporarily operate) one or more implantable devices 200, such as **trialing interface 80** shown in Fig. 1. Trialing interface 80 can be configured to wirelessly deliver power to an implantable device 200, wirelessly deliver data to an implantable device 200, and/or wirelessly receive data from an implantable device 200. Trialing interface 80 can be configured to interface with one or more implantable devices 200 during an implantation procedure in which one or more implantable devices 200 are implanted in a patient (e.g. a sterile clinical procedure in which an implantable device 200 comprising a pre-attached lead 265 is implanted in a patient). Trialing interface 80 can be configured to be sterilized one or more times. Trialing interface 80 can comprise one or more antennas, such as an antenna similar to antenna 540 of an external device 500. Trialing interface 80 can comprise a transmitter, such as a transmitter similar to transmitter 530 of external device 500, and a power supply, such as a power supply similar to power supply 570 of external device 500. In some embodiments, trialing interface 80 is of similar construction and arrangement to the trialing interface described in applicant's co-pending United States Patent Application Serial Number 17/187,654, titled "Method and Apparatus for Neuromodulation Treatments of Pain and Other Conditions ", filed February 26, 2021 [Docket nos. 47476-705.303; NAL-008-US-CON2]. In some embodiments, trialing interface 80 includes a housing to be positioned proximate at least a portion of implantable device 200, such as a housing 210

that surrounds an antenna and a transmitter that is configured to operatively couple to (e.g. transmit power and/or data to) one or more antennas 240 of one or more implantable devices 200.

[0216] In some embodiments, trialing interface 80 is constructed and arranged as described an applicant's co-pending United States Patent Application Serial Number 17/379,928, titled "Stimulation Apparatus", filed July 19, 2021 [Docket nos. 47476-714.302; NAL-020-US-CON1]. In some embodiments, trialing interface 80 is of similar construction and arrangement as trialing interface 80 described herein in reference to Figs. 19A-B and/or 21A-E.

[0217] As described hereabove, trialing interface 80 can be used in clinical procedures in which an implantable device 200 including a pre-attached lead 265 is implanted. In some embodiments, implantable device 200 includes an attachable lead 265, and apparatus 10 includes trialing interface 90. Trialing interface 90 can be configured to operably (e.g. electrically) attach to lead 265, such as to deliver stimulation energy via a wired connection during a trialing procedure, as described herein. For example, trialing interface 90 can deliver stimulation energy to one or more stimulation elements 260 of lead 265 during a trialing procedure in which proper position of stimulation element 260 is confirmed and/or modified, and/or one or more stimulation waveforms are tested. Trialing interface 90 can include an interface connector 95 configured to operably attach (e.g. electrically attach) trialing interface 90 to lead 265 (e.g. after lead 265 has been implanted in tissue of the patient). Connector 95 can be configured to be used in a single trialing procedure (e.g. on a single patient), while the remainder of trialing interface 90 can be reused (e.g. in multiple trialing procedures for multiple patients). Trialing interface 90 can comprise a device that is sterilized, and it can be a device that can be re-sterilized (e.g. to be used in multiple sterile clinical procedures). In some embodiments, trialing interface 80 and trialing interface 90 include similar components, (e.g. similar components used to create similar stimulation waveforms to be used in a trialing procedure). In some embodiments, trialing interface 90 is of similar construction and arrangement as trialing interface 80 described herein in reference to Figs. 19A-B and/or 21A-E.

[0218] In some embodiments, one or more implantable devices 200 of implantable system 20 comprises an implantable transmitter configured to transmit data, such as to transmit data (e.g. stimulation information, patient physiologic information, patient environment information, implantable device 200 performance and/or configuration information, and the like) to one or more external devices 500. In these embodiments, receiver 230 can be configured as both a receiver and a transmitter. One or more implantable devices 200 can be configured to transmit data by sending a signal to (i.e. **"driving"**) one or more antennas 240 or another antenna of

implantable device 200. An implantable device 200 can be configured to transmit data using one or more of: load modulation; a signal carrier; and/or body conduction. An implantable device 200 can be configured to adjust the transmission, such as to adjust a data transmission parameter selected from the group consisting of: data rate; pulse width; duration of carrier signal; amplitude of carrier signal; frequency of carrier signal; configurable load; and combinations of one or more of these.

[0219] In some embodiments, apparatus 10 comprises a diagnostic assembly, **diagnostic assembly 62** shown in Fig. 1. In some embodiments, programmer 600 and/or implantable controller 250 comprise all or a portion of diagnostic assembly 62. Diagnostic assembly 62 can be configured to assess, monitor, determine and/or otherwise analyze patient information and/or implantable device 200 information, such as when one or more stimulation elements 260, functional elements 299, and/or functional elements 599 are configured as a sensor configured to record patient information (e.g. patient physiologic information and/or patient environment information) and/or apparatus 10 information (e.g. implantable device 200 information) as described herein. Diagnostic assembly 62 can be configured to analyze communication and/or the power link between an implantable device 200 and an external device 500. In some embodiments, such a communication link analysis can be performed by measuring bit error rate (BER) of a known data stream during communication signal transmission (also referred to as **"communication link"**) measurement phase (e.g. such as during a calibration procedure). The BER can be tracked by the implant controller 250 or programmer 600, such as to monitor and keep track of any trends in the link. This trend can be used to adjust the link and/or provide feedback to an operator of apparatus 10 (e.g. the patient), in case the link cannot be automatically adjusted to compensate for a negative trend (e.g. such that the operator can perform physical re-adjustment of the external system 50). Alternatively or additionally, a power link analysis can be performed by monitoring charge/discharge rate of the implanted energy storage assembly 270. Similar to the communication link, the power link status and/or trending can be monitored and recorded for link adjustment and/or feedback purposes. Diagnostic assembly 62 can be configured to analyze a result of stimulation energy delivered by implantable device 200, such as when a stimulation element 260 comprises an electrode to record electrical activity of tissue (e.g. in addition to delivering electrical energy to stimulate tissue). A stimulation element 260, a functional element 299, and/or a functional element 599 can comprise a sensor configured to record neural activity and/or muscular activity, and the diagnostic assembly configured to analyze the recorded sensor data. In some embodiments, diagnostic assembly 62 is configured to analyze impedance, such as when a stimulation element 260, a functional element 299, and/or

functional element 599 comprises a sensor configured to record data related to impedance, such as when implantable device 200 performs a frequency sweep, performs an impulse response and/or compares voltage and current of a stimulation waveform. In some embodiments, diagnostic assembly 62 is configured to assess the impedance of one or more implantable antennas 240 and/or one or more external antennas 540. In these embodiments, impedance can be assessed by performing a function selected from the group consisting of: performing a frequency sweep; performing an impulse response; comparing voltage and current of a waveform; and combinations of one or more of these.

[0220] In some embodiments, diagnostic assembly 62 is configured to test or otherwise assess the link between one or more implantable antennas 240 and one or more external antennas 540 (e.g. during a procedure in which one or more implantable devices 200 are implanted in a patient). In these embodiments, diagnostic assembly 62 can be configured to perform a test prior to anchoring housing 210 to tissue (e.g. prior to initial or final suturing into tissue such as the fascia layer). For example, lead 265 can be implanted at a location to stimulate target tissue (e.g. one or more nerves identified to treat pain or another patient condition). Prior to suturing housing 210 in its implant location, diagnostic assembly 62 can be configured to confirm that one or more external antenna 540 transmission links to one or more implantable antennas 240 are above an efficiency threshold, for example such that sufficient power will be received by the one or more implantable devices 200. Additionally, the procedure can be performed to optimize or otherwise improve the position of the one or more implantable devices 200 to be implanted and subsequently secured to tissue.

[0221] In these link testing embodiments, diagnostic assembly 62 can comprise a handheld assembly (e.g. a sterile assembly comprising a wand or other handheld housing). Diagnostic assembly 62 can be configured to send a simple signal to one or more implantable devices 200 (e.g. a diagnostic assembly 62 with similar power and/or data transmission capabilities as an external device 500). Each implantable device 200 can respond (e.g. via data sent via an implantable antenna 240 or other transmitter) with information related to the quality of the transmission link (e.g. information about the power received by the one or more implantable devices 200). Diagnostic assembly 62 could provide a user interface (e.g. a speaker, a text screen and/or a video display) that provides quality or other information (go/no go information, digital or other discrete level information, and/or analog information). Diagnostic assembly 62 could be further configured to provide information confirming detection of one or more implantable devices 200, status of one or more implantable devices 200 (e.g. parameter level and/or fault detection status), and/or self-diagnostic status (i.e. diagnostic assembly 62 status).

[0222] Each implantable device 200 can be configured to specifically identify and/or specifically reply to diagnostic assembly 62 (e.g. in a different form than communications with an external device 500). Each implantable device 200 can be configured to provide information related to one or more of: the charge and/or discharge rate of energy storage assembly 270 (e.g. the charge and/or discharge rate of a capacitor or battery of energy storage assembly 270); or the frequency of a voltage-controlled oscillator that is driven by an unregulated voltage of power converter 233. Diagnostic assembly 62 can be configured to perform numerous performance tests (e.g. of one or more implantable devices 200 or implantation locations for one or more implantable devices 200), prior to completion of the implantation procedure (e.g. prior to closing one or more incisions).

[0223] In some embodiments, apparatus 10 is configured to provide a therapy by delivering stimulation energy to tissue, such as electrical energy delivered to tissue by one or more stimulation elements 260 comprising one or more electrodes. Alternatively or additionally, apparatus 10 can be configured as an agent-delivery apparatus (e.g. a pharmaceutical or other agent delivery apparatus). In some embodiments, apparatus 10 comprises one or more reservoirs for storing the agent, such as **reservoir 525** of external device 500 and/or **reservoir 225** of implantable device 200, each shown in Fig. 1. Reservoirs 525 and/or 225 can be fluidly connected to one or more functional elements 599 and/or functional elements 299, respectively (e.g. via one or more tubes). Reservoirs 525 and/or 225 can comprise one or more chambers (e.g. independent chambers configured to separately contain incompatible drugs or otherwise prevent undesired multiple drug interactions). Reservoirs 525 and/or 225 can comprise a volume (e.g. a volume to store one or more agents) between 0.1ml and 50ml, such as between 0.1 ml and 3.0ml, or between 0.1ml and 1.0ml. Reservoirs 525 and/or 225 can comprise pressurized reservoirs or otherwise comprise a fluid pumping mechanism (e.g. a peristaltic mechanism, syringe pump or other fluid pump). Reservoirs 525 and/or 225 and can comprise refillable reservoirs (e.g. when reservoir 225 of an implantable device 200 comprises a valved opening such as a silicone septum or a mechanical valve, either accessible via a needle for refilling). The fluidly attached functional elements 599 and/or functional elements 299 can comprise a fluid delivery element selected from the group consisting of: a catheter; a porous membrane; an iontophoretic element; a needle; and combinations of one or more of these. Delivered and/or stored (e.g. in a reservoir) agents can comprise an agent selected from the group consisting of: an analgesic agent such as morphine, fentanyl, lidocaine or other agent delivered to treat pain; a chemotherapeutic agent such as a chemotherapeutic agent delivered systemically (e.g. throughout the blood system of the patient) and/or to a location in or proximate an organ such as

the liver or brain to treat cancer; an antibiotic configured to treat or prevent an infection; a hormone such as a hormone delivered intravenously in hormonal therapy; heart medications such as nitroglycerin, a beta blocker or a blood pressure lowering medication; a carbohydrate such as glucose or dextrose delivered to treat a low blood sugar condition; insulin such as to treat a high blood sugar condition; a diabetic medication; a neurological medication; an epilepsy medication; and combinations of one or more of these. In some embodiments, apparatus 10 comprises the one or more agents stored in reservoir 225 and/or 525. In some embodiments, apparatus 10 is constructed and arranged to deliver the agent (e.g. via a catheter-based functional element 599, functional element 299, and/or stimulation element 260) to a patient location selected from the group consisting of: a vessel; a blood vessel; a vein; an artery; heart; brain; liver; spine; epidural space; intrathecal space; subcutaneous tissue; bone; intraperitoneal space, intraventricular space, and combinations of one or more of these.

[0224] In some embodiments, an external device 500 is attached to the patient via a patient attachment device 70 comprising a wrist band, wrist watch, leg band, ankle band or other band configured to position an external device 500 about a limb of the patient (i.e. arm or leg of the patient). In these embodiments, one or more implantable devices 200 are implanted under the skin proximate the intended (limb) location of external device 500 and patient attachment device 70. Apparatus 10 can be configured such that external device 500 comprises one or more antennas 540; one or more implantable devices 200 each comprise one or more antennas 240; and each implantable device 200 one or more antennas 240 receive power and/or data from the one or more antennas 540 of the limb-attached external device 500. The limb-attached external device 500 can comprise one or more reservoirs 525 described hereabove and/or one or more functional elements 599 configured as agent delivery elements and/or sensors. The one or more implantable devices 200 can comprise one or more reservoirs 225 described hereabove and/or one or more stimulation elements 260 configured as agent delivery elements and/or sensors.

[0225] In some embodiments, apparatus 10 comprises an agent delivery apparatus and agent is delivered into the patient (e.g. into a blood vessel, muscle or subcutaneous tissue) by an external device 500 functional element 599 (e.g. a needle) based on signals recorded by an implantable device 200 functional element 299 and/or stimulation element 260 (e.g. a sensor). Alternatively or additionally, agent can be delivered into the patient (e.g. into a blood vessel, muscle or subcutaneous tissue) by an implantable device 200 stimulation element 260 (e.g. a needle, catheter, porous membrane or iontophoretic delivery element). The amount of agent delivered by stimulation element 260 can be based on signals recorded by an implantable device 200 stimulation element 260 (e.g. a sensor) and/or an external device 500 functional element 599a

(e.g. a sensor). External device 500 can provide power to one or more implantable devices 200 and/or it can send data (e.g. sensor data from a functional element 599) to implantable device 200, such as to control agent delivery by implantable device 200.

[0226] Apparatus 10 can be configured to prevent an electromagnetic field (e.g. an electromagnetic field produced by one or more devices not included in apparatus 10 and/or other present in the patient environment) from adversely affecting and/or otherwise affecting the patient treatment and/or patient information recording (e.g. patient tissue stimulation and/or patient physiologic information gathering) performed by apparatus 10. Electromagnetic fields from one or more apparatus 10 devices and/or otherwise present in the patient environment can potentially interfere with apparatus 10. The architecture of the wireless signal transmissions of apparatus 10 can be configured to include certain unique and/or identifiable patterns in the signals transmitted by apparatus 10 to confirm (upon receipt) that the signal originated from a component of apparatus 10. Alternatively or additionally, the stimulation signal produced by an implantable device 200 can be created independent from a power signal received from an external device 500, so that any electromagnetic interference in the wireless link does not affect generation and delivery of the stimulation signal. In some embodiments, each implantable device 200 and/or external device 500 includes unique identification codes that are required to be transmitted prior to any changes in stimulation or other implantable device 200 configuration, ensuring correct operation in the presence of interference. Alternatively or additionally, the communication link can incorporate handshaking protocols, confirmation protocols, data encryption and/or scrambling, coding and other security measures to ensure that interfering signals do not adversely affect the implantable system 20 performance (e.g. stimulation). In some embodiments, external system 50 and/or implantable system 20 incorporate electromagnetic absorptive and/or reflective materials to minimize external interference from other sources and/or minimize the probability of apparatus 10 interfering with other systems. Alternatively or additionally, apparatus 10 can incorporate error detection and protocols for entering an alarm state (e.g. and shutting down normal operation) and/or otherwise ensuring safe operation.

[0227] In some embodiments, implantable system 20 of apparatus 10 is configured to perform magnetic field modulation, such as targeted magnetic field neuromodulation (TMFN), electro-magnetic field neuromodulation, such as targeted electro-magnetic field neuromodulation (TEMFN), transcutaneous magnetic field stimulation (TMS), or any combination of these. Each implantable device 200, via one or more of its stimulation elements 260 (e.g. electrodes) can be configured to provide localized (e.g. targeted) magnetic and/or electrical stimulation. Combined

electrical field stimulation and magnetic field stimulation can be applied by using superposition, and this combination can reduce the overall energy requirement. In some embodiments, implantable apparatus 10 comprises one or more stimulation elements 260 comprising a magnetic field generating transducer (e.g. microcoils or cuff electrodes positioned to partially surround or otherwise be proximate to one or more target nerves). Stimulation elements 260 comprising microcoils can be aligned with nerves to minimize affecting non-targeted tissue (e.g. to avoid one or more undesired effects to non-target tissue surrounding or otherwise proximate the target tissue). In some embodiments, the target tissue comprises dorsal root ganglia (DRG) tissue, and the non-target tissue comprises ventral root tissue (e.g. when the stimulation energy is below a threshold that would result in ventral root tissue stimulation).

[0228] In some embodiments, external system 50 of apparatus 10 is configured to provide mechanically adjustable alignment of one or more external antennas 540 alignment. Link gain between one or more external antennas 540 and one or more implantable antennas 240 can degrade over time due to physical misalignment of the antennas, relative orientation changes between antennas and/or relative angular misalignment between antennas. In order to compensate for misaligned antennas, electrical beam steering can be included in apparatus 10. Antennas comprising a multi-feed antenna structure and/or those comprising an array of antennas can be incorporated (e.g. into external antenna 540, implantable antenna 240 or both) for electrical beam steering. Alternatively or additionally, mechanical antenna steering can be implemented to physically realign one or more external antennas 540 with one or more implanted antennas 240 (or vice versa). A substrate of an implantable antenna 240 and/or an external antenna 540 can be flexible and/or rigid (e.g. a substrate comprising polyamide, polyimide, liquid crystal polymer (LCP), Rogers, FR4, or a similar material). One or more antennas 540 can be connected to electronics (e.g. a transmitter, receiver or transceiver) using a flexible waveguide or cable (e.g. 50 ohm 0.047inch coaxial cable designed to provide patient comfort) and/or a flexible PCB substrate transmission line. Mechanical or physical realignment of antennas 240 and/or 540 can be accomplished using one or more of: use of motorized positioners, such as a mechanism including one or more small pulleys and/or tensioners used to translate one or more antennas 240 and/or 540 about one or more axes; an actuator (e.g. a piezoelectric actuator) with directional gears configured to translate one or more antennas 240 and/or 540 about one or more axes; a micro-pump with fluid reservoir (e.g. liquid or gas reservoir) configured to hydraulically and/or pneumatically translate one or more antennas 240 and/or 540 about one or more axes, such as by creating a local pressure difference. In some embodiments, a micro-pump with fluid reservoir is used to move one or more antennas 240

and/or 540, such as to move an external antenna 540 away from tissue to reduce specific absorption rate (SAR). In these embodiments, external antenna 540 can be positioned in mechanical contact with an expandable reservoir (e.g. a balloon) positioned between external antenna 540 and tissue. The reservoir can be inflated or deflated to control separation distance of the external antenna 540 from the patient's skin surface.

[0229] In some embodiments, implantable system 20 of apparatus 10 is configured to provide paresthesia-reduced (e.g. paresthesia-free) high frequency pain management and rehabilitation therapy (e.g. via delivery of a stimulation signal above 600Hz or 1kHz, or other stimulation signal resulting in minimal paresthesia). Apparatus 10 can be configured to provide both low frequency (e.g. <1kHz) stimulation and high frequency stimulation, such as when providing low frequency stimulation to elicit feedback from a patient during intraoperative or other (e.g. post-implantation) stimulation configuration. For example, trialing interface 80 and/or 90 can be used during an intra-operative titration of stimulation configuration using low frequency stimulation (e.g. to position and/or confirm position of one or more stimulation elements 260, such as to confirm sufficient proximity to target tissue to be stimulated and/or sufficient distance from non-target tissue not to be stimulated). In some embodiments, high frequency stimulation is delivered to reduce pain over extended periods of time, and low frequency stimulation is used in these intraoperative and/or post-implantation titration or other stimulation configuration procedures. Intentional elicitation of paresthesia (e.g. via low frequency stimulation and/or high frequency stimulation) is beneficial during stimulation element 260 (e.g. electrode) implantation because a patient can provide feedback to the implanting clinician to ensure that the stimulation elements 260 are positioned close to the target neuromodulation or energy delivery site. This implantation position-optimizing procedure can advantageously reduce the required stimulation energy due to stimulation elements 260 being closer to target tissue, since a minimum threshold for efficacious stimulation amplitude is proportional to the proximity of stimulation elements 260 to target tissue (e.g. target nerves). The patient can inform the clinician of the sensation of paresthesia coverage, and the clinician can adjust stimulation element 260 position to optimize stimulation element 260 location for efficacious treatment while minimizing unintentional stimulation of non-target tissue (e.g. motor nerves or other nerves which are not causing the patient's pain). These paresthesia-inducing techniques (e.g. using low frequency stimulation and/or high frequency stimulation) can be used during or after implantation of one or more implantable devices 200.

[0230] In some embodiments, apparatus 10 is configured to deliver low frequency stimulation energy (e.g. electrical energy comprising a low frequency signal) to stimulate motor nerves, such

as to improve tone and structural support (e.g. physical therapy). In these embodiments, apparatus 10 can be further configured to provide high frequency stimulation, such as to treat pain (e.g. suppress and/or control pain). The combined effect can be used not only for pain management but also muscle strengthening and gradual healing of supportive structures. Alternatively or additionally, as described herein, apparatus 10 can be configured to deliver low frequency stimulation energy (e.g. electrical energy) to induce paresthesia, which can also be accompanied by the delivery of high frequency stimulation (e.g. to suppress and/or control pain). In some embodiments, apparatus 10 is configured to deliver low frequency stimulation (e.g. electrical energy comprising a low frequency signal) and burst stimulation, delivered simultaneously or sequentially. The low frequency stimulation and the burst stimulation can be delivered on similar and/or dissimilar stimulation elements 260 (e.g. similar or dissimilar electrode-based stimulation elements 260).

[0231] As described herein, apparatus 10 can be configured for treating numerous disease and disorders, such as when apparatus 10 is configured to deliver electrical or other stimulation energy to treat pain (e.g. by delivering electrical or other energy to the spine or other neural location). Apparatus 10 can be configured to stimulate tissue with various stimulation waveforms, such as those described in applicant's co-pending United States Patent Application Serial Number 17/372,095, titled "Apparatus with Enhanced Stimulation Waveforms", filed July 9, 2021 [Docket nos. 47476-708.302; NAL-014-US-CON1].

[0232] Apparatus 10 can be configured to treat neuropathy, neuralgia and/or other nerve pain that is related to: surgery; trauma; infection (e.g. a herpetic infection); and/or diabetes (e.g. diabetic neuropathy). One or more stimulation elements 260 can be configured to deliver stimulation energy (e.g. electrical energy, magnetic energy, light energy, thermal energy, sound energy, and/or chemical energy (e.g. energy from a drug or reagent) to nerve tissue such as tissue of the central nervous system and/or peripheral nervous system. One or more leads 265 (each comprising one or more stimulation elements 260) can be implanted in and/or proximate the spinal cord, the groin and/or a joint such as the hip. For example, apparatus 10 can be configured to treat one or more of: post-surgical neuralgia (e.g. following hernia repair such as a hernia repair including an implanted mesh); headache (e.g. due to occipital neuralgia); post-herpetic neuralgia; chronic pelvic and/or hip pain; knee pain; and combinations of one or more of these.

[0233] To treat pain related to hernia or hernia repair, one or more stimulation elements 260 (e.g. on a lead 265 and/or on a housing 210) can be positioned to stimulate tissue of the peripheral nervous system and/or the central nervous system. In some embodiments, one or

more stimulation elements 260 are positioned to stimulate the cutaneous branch of the ilioinguinal, inguinal and/or genital branch of the genitofemoral nerves. In some embodiments, one or more stimulation elements 260 are positioned to stimulate corresponding branches of spinal nerves correlating to one or more dermatomes related to pain associated with at least one of hernia or hernia repair.

[0234] Hernia or hernia repair can lead to: inguinal pain; ilioinguinal neuralgia; post-traumatic neuropathic pain; ilioinguinal nerve entrapment; neuropathic pain of ilioinguinal origin; post-surgical inguinal pain; genitofemoral pain; genitofemoral neuralgia; genitofemoral nerve entrapment; neuropathic pain of genitofemoral origin; post-surgical genitofemoral pain; iliohypogastric pain; iliohypogastric neuralgia; iliohypogastric nerve entrapment; neuropathic pain of iliohypogastric origin; post-surgical iliohypogastric pain; testicular pain; scrotal pain; penis pain; groin pain; thigh pain; anal pain; rectal pain; perineal pain; abdominal adhesions; pelvic adhesions; scar pain; diffuse polyneuropathy; and combinations of one or more of these. In some embodiments, apparatus 10 is configured to treat hernia pain by delivering a low frequency stimulation signal (e.g. an electrical signal less than or equal to 1kHz delivered by one or more electrode-based stimulation elements 260). Alternatively or additionally, apparatus 10 can treat hernia pain with a high frequency stimulation signal, such as a signal comprising a frequency greater than 1kHz. Stimulation can be accomplished either via subcutaneous field stimulation and/or by stimulation elements 260 positioned adjacent or at least near the nerves and/or their branches. In some embodiments, stimulation is accomplished transvascularly (e.g. stimulation including low and/or high frequencies).

[0235] The apparatus of the present inventive concepts can be configured to stimulate the ilioinguinal nerve, genitofemoral nerve and/or iliohypogastric nerves, such as to ameliorate pain following hernia repair. One or more leads 265 (e.g. one or more leads 265 comprising one or more electrode-based or otherwise stimulation-based stimulation elements 260) can be inserted over the inguinal region (which may include the inguinal ring) to stimulate any or all three of these nerves (e.g. in a unilateral or bilateral fashion). Both the ilioinguinal and genital branch of the genitofemoral nerves pass through the inguinal ring. The anterior cutaneous iliohypogastric and femoral branch of the genitofemoral nerve can be stimulated at one or more locations proximate but rostral (iliohypogastric) or lateral (genitofemoral) to the inguinal ring. Leads 265 can comprise one or more stimulation elements 260 comprising cylindrical, paddle, cuff and/or hemi-cuff electrodes (electrodes placed surgically near and/or around these nerves). The nerves can be localized via ultrasound or other imaging modalities. Contrast can be used to image the vessels nearby (e.g. the testicular and/or ovarian vein and/or artery). The genital branch of the

genitofemoral nerve can be stimulated in a transvascular manner through the testicular vein and/or artery. The genitofemoral and/or the ilioinguinal nerves can also be stimulated (e.g. transvascularly stimulated) through the femoral vein and/or artery, or via the superficial or deep external pudendal vein and/or artery, and/or via the superficial epigastric vein and/or artery.

[0236] The painful areas innervated by the ilioinguinal nerve, genitofemoral nerve and/or iliohypogastric nerves, can also be treated via spinal cord stimulation provided by apparatus 10 in the L1-L5 region of the spinal cord. In some embodiments, direct stimulation of the L1-L2 dorsal root ganglia is provided in a similar treatment. Leads 265 (e.g. percutaneous or paddle) including stimulation-based stimulation elements 260 can be placed over the dorsal columns, over the dorsal roots and/or in the dorsal root entry zone, in a unilateral, bilateral and/or midline fashion.

[0237] To treat occipital neuralgia, also known as C2 neuralgia, one or more stimulation elements 260 can be positioned to stimulate peripheral nerve tissue to reduce pain. Occipital neuralgia is a medical condition characterized by chronic pain in the upper neck, back of the head and/or behind the eyes (areas corresponding to the locations of the lesser and greater occipital nerves). In some embodiments, one or more leads 265, each comprising one or more stimulation elements 260, are implanted transversely, either unilaterally or bilaterally, at the level of the appropriate target cervical nerve (C1, C2, etc.). The C1, 2, 3 cervical roots include the greater occipital nerve which originates primarily from C2, and the lesser occipital nerves. Relevant trigeminal branches include both the supraorbital and supratrochlear nerves from V1, the infraorbital branches from V2, and the superficial temporal nerves from V3. A partial convergence of these two systems occurs at the Trigemino-Cervical Complex (TCC). In some embodiments, one or more stimulation elements 260 are positioned to stimulate the trigeminal and/or occipital nerves. One or more leads 265 can be anchored to the fascia proximate the tissue to be stimulated.

[0238] To treat post-herpetic neuralgia (e.g. neuralgia associated with shingles), one or more stimulation elements 260 can be positioned to stimulate corresponding branches of the spinal nerves and/or peripheral nerves correlating to one or more dermatomes related to the patient's shingles.

[0239] In some embodiments, apparatus 10 is configured to treat pelvic, bladder and/or bowel disorders, such as by stimulating sacral, pudendal and/or tibial nerves. In some embodiments, apparatus 10 is configured to treat pelvic pain by stimulating the tibial nerve.

[0240] Apparatus 10 can be configured to treat a bladder, bowel or other dysfunction selected from the group consisting of: overactive bladder; urinary urgency; urinary frequency; urinary

urgency frequency; urinary urge incontinence; urinary stress incontinence; urge incontinence; stress incontinence; non-obstructive urinary retention; female sexual dysfunction; fecal incontinence; accidental bowel leakage; constipation; diarrhea; irritable bowel syndrome; colitis; detrusor instability; detrusor dysfunction; spastic bladder; neurogenic bladder; detrusor sphincter dyssynergia; detrusor hyperreflexia; detrusor areflexia; and combinations of one or more of these.

[0241] Apparatus 10 can be configured to treat a pelvic disorder selected from the group consisting of: pelvic pain; painful bladder syndrome; Hunner's ulcers or lesions; interstitial cystitis; pelvic floor dysfunction; endometriosis; vulvodynia; dyspareunia; pelvic adhesions; abdominal adhesions; irritable bowel syndrome; pelvic girdle pain; pudendal nerve entrapment; pudendal neuralgia; dysmenorrhea; Müllerian abnormalities; pelvic inflammatory disease; ovarian cysts; ovarian torsion; Loin pain hematuria syndrome; proctitis; prostatitis; prostadynia; post-abdominal surgical pain; post-pelvic surgical pain; hernia pain; post-hernia surgical pain; anal pain; rectal pain; perineal pain; groin pain; vulvar pain; vaginal pain; clitoral pain; colitis; and combinations of one or more of these.

[0242] Apparatus 10 can be configured to treat one or more of the pelvic disorders, bladder dysfunctions and/or and bowel dysfunctions listed above, by stimulating (e.g. using bilateral and/or unilateral stimulation) one or more of the targets listed below.

[0243] In some embodiments, the stimulated targets include the sacral nerves (roots) S2, S3 and/or S4. One or more leads 265 (e.g. each including one or more stimulation-delivering stimulation elements 260) can be positioned to stimulate any or all of the three roots, on a single side or both sides, in any bilateral or unilateral combination. The roots can be accessed, with the patient lying in the prone position, by positioning one or more leads 265 (e.g. percutaneously), with or without the use of fluoroscopy, ultrasound or any other imaging modality, into one/any of the sacral foramen(a) from the posterior aspect of the sacrum. One or more leads 265 can be passed through the foramen to the anterior side of the sacrum, and/or one or more leads 265 can remain inside the foramen(a).

[0244] In some embodiments, the sacral roots are approached rostrally, via the sacral canal in a retrograde manner. In these embodiments, one or more leads 265 can be passed through the ligamentum flavum, just caudal to L5 or via any of the intervertebral spaces from L5 to T12, into the spinal canal. One or more leads 265 are then threaded, with or without the aid of visualization (fluoroscopy, ultrasound or other imaging modality), in a caudal (retrograde) manner to enter the sacral canal. One or more leads 265 can be placed along the sacral canal, and each root can be stimulated individually and/or each root can be stimulated in concert, via

one or more leads 265 positioned along the internal surface of the sacral canal, and spanning one or more foramina.

[0245] In some embodiments, one or more leads 265 are threaded from the spinal canal into each and/or all sacral foramen(a), in an anterior direction. The sacral canal can also be accessed caudally by one or more leads 265, via the sacral hiatus in an anterograde manner.

[0246] In some embodiments, the sacral roots (S2, S3 and/or S4) are accessed as they enter the spinal cord at the cauda equina. This access can be achieved by inserting the one or more leads 265 through the ligamentum flavum, at a location just caudal to L5, or via any of the intervertebral spaces from L5 to T12, into the spinal canal. The one or more leads 265 can then be threaded, with or without the aid of visualization (fluoroscopy, ultrasound or other imaging modality), up to the cauda equina, where the S2, S3 and/or S4 roots can be stimulated where they enter the spinal cord, and/or the conus medullaris can be stimulated directly (e.g. in the same location).

[0247] In some embodiments, the pudendal nerve is stimulated through one or more different approaches. The pudendal nerve contains both afferent and efferent fibers carried by S2, S3 and S4 roots. The pudendal fibers exit Alcock's canal near the ischial spine, where they spread out to innervate to the bladder wall, perineum, anus, genitals and urethra. Pelvic and voiding disorders can be treated by stimulating pudendal nerve fibers. The fibers can be accessed at the Alcock's canal via various approaches. In one embodiment, a transperineal approach is achieved by positioning the patient in the lithotomy position and inserting the lead 265 midpoint between the ischial tuberosity and the anus. A lead 265 is inserted toward the ischial spine, which can be palpated transvaginally or transrectally. The ischial spine can also be visualized through a number of imaging modalities (e.g. fluoroscopy, x-ray, ultrasound, and the like). In another embodiment, a transvaginal approach is achieved by positioning the patient in the lithotomy position and inserting a lead 265 through the vaginal wall, adjacent to the ischial spine (e.g. through the vaginal wall toward the ischial spine). In another embodiment, a posterior approach is achieved by laying the patient in the prone position and inserting a lead 265 just medial to the ischial tuberosity toward the ischial spine. This insertion can be facilitated by rectal palpation of the ischial spine and through visualization via a number of imaging modalities (e.g. fluoroscopy, x-ray, ultrasound, and the like).

[0248] In some embodiments, apparatus 10 is configured to stimulate pudendal afferents, such as by stimulating the dorsal genital nerve. These fibers are located just below the skin on the dorsum of the penis or just rostral to the clitoris. In some embodiments, pudendal afferents are

stimulated periurethrally. One or more leads 265 can be inserted alongside the urethra to stimulate the pudendal fibers.

[0249] In some embodiments, apparatus 10 is configured to stimulate tibial nerve fibers, such as to treat one or more pelvic disorders (e.g. voiding dysfunction). In order to provide stimulation of the tibial nerve, lead 265 can be inserted at a location close to the knee and/or at a location near the ankle. For example, the tibial nerve can be accessed a few mm below the skin surface in the ankle immediately posterior to the medial malleolus. Lead 265 can comprise a cylindrical SCS-type lead, which can be inserted percutaneously in this location. Alternatively or additionally, a direct (surgical) cut-down procedure can be used to insert a cylindrical lead or to apply a cuff electrode directly to the nerve. The tibial nerve can also be accessed approximately half way up the lower leg adjacent to the tibia. One or more leads 265 can be inserted percutaneously in this location. Alternatively or additionally, a direct cut-down can be used to insert lead 265 (e.g. a cylindrical lead or a cuff electrode and/or hemi-cuff electrode applied directly to the nerve in the mid-shin location). Tibial nerve fibers can be accessed in the popliteal fossa behind the knee, for example percutaneously with a lead 265 comprising a cylindrical lead, and/or via a direct cut-down, for example with a lead 265 comprising either a cylindrical or cuff electrode.

[0250] In some embodiments, apparatus 10 and one or more leads 265 are constructed and arranged to stimulate the tibial and/or pudendal nerves via a transvascular approach (i.e. stimulation energy delivered from inside a blood vessel to nerve tissue proximate the blood vessel), such as via the femoral vein and/or artery, each of which provide intraluminal access to many other blood vessels (e.g. using standard interventional techniques). The tibial nerve can be transvascularly stimulated by the popliteal vein and/or artery (e.g. by placing one or more stimulation elements 260 in the popliteal vein and/or artery), at a location behind the knee. The popliteal vein and/or artery can be intraluminally accessed from the femoral artery and vein. The tibial nerve also passes near the small saphenous vein, where it branches off of the popliteal vein. The posterior tibial vein and/or artery are positioned adjacent to the tibial nerve, from the knee to the foot. One or more leads 265 can utilize one or more of these above locations to stimulate the tibial nerve.

[0251] In some embodiments, apparatus 10 and one or more leads 265 are constructed and arranged to stimulate the pudendal nerve and/or sacral roots, such as using a lead 265 placed via the femoral vein and/or artery, which in turn provides intraluminal access to many vessels. One or more leads 265 can be configured to utilize any of the following arteries and veins to stimulate the pudendal nerve and/or the sacral roots. One or more leads 265 can be constructed and

arranged to stimulate a target site via a blood vessel selected from the group consisting of: the internal pudendal artery or vein (which branch off of common iliac artery or vein, respectively); the inferior and superior gluteal vein and/or artery; middle rectal, pudendal plexus and internal iliac vein and/or artery; medial and lateral sacral vein and/or artery; uterine and obturator vein and/or artery; and combinations of one or more of these.

[0252] In some embodiments, apparatus 10 is configured to treat pelvic dysfunction, overactive bladder, and/or urinary incontinence (singly or collectively **"overactive bladder"** herein). In some embodiments, apparatus 10 is configured to treat overactive bladder such as to reduce the effects of overactive bladder and/or to decrease use of one or more medications taken by the patient to treat overactive bladder. In some embodiments, one or more stimulation elements 260 are positioned to stimulate tissue of the central nervous system or tissue and/or tissue of the peripheral nervous system to treat overactive bladder, such as to stimulate one or more nerves that control and/or are otherwise related to bladder function (e.g. to increase bladder capacity, improve bladder emptying, reduce urge incontinence and/or reduce stress incontinence). For example, one or more stimulation elements 260 are be positioned to stimulate tibial nerve tissue and/or sacral nerve tissue (e.g. at least the S3 nerve root) to treat overactive bladder. In some embodiments, one or more stimulation elements 260 can be positioned to stimulate sacral nerve tissue to treat urinary urgency, urinary frequency (e.g. urinary urgency frequency), and/or painful bladder syndrome. In some embodiments, lead 265 is constructed and arranged to be positioned along one or more locations of the tibial nerve, such as a positioning performed using percutaneous technique (e.g. when lead 265 comprises a cylindrical SCS-type lead) and/or surgical (cut-down) techniques (e.g. when lead 265 comprise a cuff electrode and/or hemi-cuff electrode applied directly to the nerve). The tibial nerve branches off of the sciatic nerve just above the knee, and runs along the length of the tibia, medial and lateral to the tibia. The tibial nerve then passes posterior to the medial malleolus prior to innervating the plantar surface of the foot. Lead 265 can be constructed and arranged to access sites proximate the tibial nerve percutaneously and/or through an incision at the back of the knee in the popliteal fossa, along the tibia or behind the medial malleolus. The housing 210 can be placed anywhere in the leg when stimulating the tibial nerve. Lead 265 can be constructed and arranged to stimulate the tibial nerve through a transvascular approach, via the femoral vein and/or artery, each of which provide intraluminal access to many vessels. The tibial nerve can be accessed by the popliteal artery and vein behind the knee, which are intraluminally accessible from the femoral artery and vein, respectively. The tibial nerve also passes near the small saphenous vein, where it branches off of the popliteal vein. The posterior tibial vein and artery travel adjacent to the tibial nerve

from the knee to the foot. One or more leads 265 can be constructed and arranged to utilize any of these locations to transvascularly stimulate the tibial nerve (e.g. transvascularly stimulate the tibial nerve via the popliteal artery, popliteal vein, saphenous vein, posterior tibial artery and/or posterior tibial vein via a lead 265 advanced via the femoral vein and/or artery). In these transvascular embodiments, the housing 210 can be placed near the femoral or popliteal access point at locations in the groin, perineum, scrotum, pelvis, hip, thigh, leg, behind the knee, buttocks, abdomen and/or low back. In the case of sacral nerve stimulation, one or more leads 265 can be inserted through an incision(s) made in the lower back, such that one or more stimulation elements 260 are positioned proximate (e.g. in contact) with the sacral nerve root(s). The housing 210 can be placed anywhere in the groin, perineum, scrotum, pelvis, hip, thigh, leg, behind the knee, buttocks, abdomen and/or low back. Lead 265 (e.g. a lead 265 comprising a lead extension) can be extended underneath the skin (e.g. tunneled) to a second incision (e.g. across the flank to the lower abdomen, across the midline to the buttocks, or low back), and a third incision can be made (e.g. in the abdomen, back or buttocks) where housing 210 can be inserted and connected to lead 265. Alternatively, housing 210 can be inserted at another internal location. If lead 265 is already connected (e.g. attached in manufacturing) to housing 210, lead 265 can be advanced in the opposite direction, such as from the third incision, to the second incision, to the first incision (if three incisions are made), or housing 210 can be advanced under the tissue from incision 1 to incision 2 or from incision 2 to incision 3. In some embodiments, only 1 or 2 incisions are performed. In some embodiments, such as when lead 265 is already connected (e.g. attached in manufacturing) to housing 210, lead 265 and housing 210 are implanted. In some embodiments, a first lead 265 and a first housing 210 (pre-attached or attachable) are utilized in a dose titration or other **"trialing procedure"**, and a second lead 265 and housing 210 (pre-attached or attachable) are implanted in the patient for subsequent treatment of the patient.

[0253] In some embodiments, one or more stimulation elements 260 are positioned to perform posterior tibial nerve stimulation (PTNS), such as to perform an indirect form of neuromodulation to treat bladder voiding dysfunction. The posterior tibial nerve is derived from the lumbar-sacral nerves (L4-S3), which innervate the bladder detrusor and pelvic floor. In some embodiments, one or more stimulation elements 260 are positioned to perform retrograde stimulation of the sacral nerve plexus and restore the balance between bladder inhibitory and excitatory control systems of the bladder. One or more stimulation elements 260 can be positioned above the ankle, proximate and/or into the tibial nerve. Implantable device 200 can deliver stimulation energy to the stimulation elements 260 comprising low-voltage electrical

stimulation configured to produce sensor and/or motor responses. Apparatus 10 can be configured to provide continuous and/or intermittent stimulation to tissue, such as to modulate transmission of excitatory nerve signals to the bladder muscles. In some embodiments, implantable system 20 is configured to deliver a series of repeated stimulation periods, such as a regimen of approximately: weekly thirty-minute sessions of stimulation for twelve weeks. In some embodiments, implantable system 20 is configured to provide weekly, daily and/or hourly sessions that deliver stimulation for between 10 minutes and 60 minutes. Implantable system 20 can deliver stimulation for any number of minutes per day. In some embodiments, apparatus 10 is configured to achieve an approximate 50% reduction in urinary urge incontinence and/or urinary urgency/frequency episodes.

[0254] In some embodiments, apparatus 10 is configured to provide temporary stimulation of tissue to treat overactive bladder, such as by using trialing interface 80 and/or 90 described hereabove, such as to provide power and/or data to one or more implantable devices 200 to confirm acceptable improvement of the patient's overactive bladder (e.g. successful stimulation of one or more sacral nerves, tibial nerves or other tissue), before closing an incision or otherwise fully implanting one or more implantable devices 200. In some embodiments, a temporary stimulation (for overactive bladder or in a trialing procedure for any therapy) is provided for up to one week, up to one month, more than 1 month, more than 2 months, or more than 3 months. In some embodiments, one or more implantable devices 200 are left in place if the temporary stimulation period is successful or unsuccessful (e.g. left implanted due to its small size or otherwise minimal impact on the patient).

[0255] In some embodiments, apparatus 10 is configured to stimulate a region of the pelvic floor, such as to: change the reflex thresholds of the bladder muscles responsible for bladder emptying, strengthen and/or otherwise improve the condition of the muscles that maintain closure on the bladder outlet; change the state of the neural pathways, musculature and/or bladder during and beyond the period stimulation; and/or otherwise decrease the severity of urinary incontinence. In some embodiments, one or more stimulation elements 260 are positioned to stimulate periurethral muscles. In some embodiments, one or more stimulation elements 260 are positioned to stimulate tissue of the vagina or anus. In some embodiments, one or more stimulation elements 260 are positioned to stimulate sphincter muscles for controlling the bladder, such as two stimulation elements 260 positioned on either side of the urethral orifice. In these embodiments, housing 210 can be implanted in suprapubic region or in the perineum. In some embodiments, lead 265 comprises (e.g. on a distal portion) a pessary ring

comprising two stimulation elements 260. In some embodiments, stimulation elements 260 comprise periurethral electrodes configured to stimulate pudendal afferents.

[0256] As described above, apparatus 10 can be configured for treating numerous diseases, disorders or other undesirable patient conditions, such as fecal incontinence. Injury of nerves that sense stool in the rectum can lead to fecal incontinence. In some embodiments, one or more stimulation elements 260 (e.g. one or more electrical, magnetic, light or other energy delivery elements) of one or more leads 265 and/or one or more implantable devices 200 are configured to stimulate tissue to treat fecal incontinence, such as to treat tissue selected from the group consisting of: sacral nerve tissue; tissue whose stimulation strengthens muscles of the bowel and/or rectum; and combinations of one or more of these. In these fecal incontinence applications, leads 265 can be implanted in a location selected from the group consisting of: the pelvic girdle; the sacral foramina; the lower back; the upper buttock; and combinations of one or more of these, such as to stimulate sacral nerve tissue. Leads 265 can be anchored via lead anchors (silicone or other materials), suture, staples, clips, adhesive and the like, such as an attachment to the underlying fascia of target tissue to be stimulated. In some embodiments, apparatus 10 is configured to treat both fecal incontinence and a bladder disorder such as overactive bladder, such as when one or more stimulation elements 260 are configured to deliver energy to sacral nerve or other tissue.

[0257] In some embodiments, apparatus 10 is configured to treat fecal incontinence, overactive bladder (i.e. overactive bladder and/or urinary incontinence), and/or pelvic disorders, and implantable device 200: comprises between 1 and 16 stimulation elements 260, such as four or more electrodes; delivers electrical stimulation energy at a range of approximately between 10Hz and 15Hz (or a range of between 5Hz and 25Hz); delivers electrical stimulation energy with a pulse width of approximately between 180μsec and 240μsec (or between 1μsec and 200μsec); provides electrical stimulation energy with an amplitude of approximately 0.1V to 8.5V (e.g. providing a current between 0.1mA to 10mA, which can be adjusted in increments between 0.01mA and 0.1mA), such as an amplitude between 0.4V and 2.0V; delivers continuous electrical stimulation energy; delivers intermittent electrical stimulation energy, such as with a period between 8 seconds and 24 seconds and/or an on time between 8 seconds and 16 seconds; or an on time of several hours followed by an off time of several hours (such as 8 hours of stimulation ON and 16 hours of stimulation OFF or 16 hours on and 8 hours off, and 12 hour on and 12 hours off; delivers monopolar electrical energy; delivers bipolar electrical energy; and combinations of one or more of these.

[0258] In some embodiments, apparatus 10 is configured to treat an occipital neuralgia, such as migraine headache, headache and/or cluster headache, and one or more stimulation elements 260 (e.g. small column paddle electrodes, standard paddle electrodes or other electrodes) are positioned to stimulate nerve tissue selected from the group consisting of: occipital; supraorbital; infraorbital; greater occipital nerve (GON); lesser occipital nerve (LON); both supraorbital and GON; supratroclear; sphenopalantine (SPG); and combinations of one or more of these.

[0259] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a neuralgia resulting from surgery (e.g. groin, shoulder, lung and/or amputation), trauma and/or phantom pain, and one or more stimulation elements 260 are positioned to stimulate nerve tissue.

[0260] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a neuralgia resulting from groin surgery (e.g. hernia or other groin surgery), and one or more stimulation elements 260 are positioned to stimulate nerve tissue selected from the group consisting of: ilioinguinal; genitofemoral; iliohypogastric; and combinations of one or more of these.

[0261] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a neuralgia resulting from shoulder surgery, and one or more stimulation elements 260 are positioned to stimulate axial nerve tissue (e.g. one or more stimulation elements 260 positioned on a lead 265 implanted in a suprascapular location).

[0262] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a neuralgia resulting from lung surgery, and one or more stimulation elements 260 are positioned to stimulate intercostal nerve tissue.

[0263] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a neuralgia associated with carpal tunnel syndrome, and one or more stimulation elements 260 are positioned to stimulate median nerve tissue.

[0264] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a neuralgia associated with temporomandibular joint disorder (TMJ), and one or more stimulation elements 260 are positioned to stimulate V2 of trigeminal nerve tissue.

[0265] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a facial neuralgia, and one or more stimulation elements 260 are positioned to stimulate trigeminal nerve tissue.

[0266] In some embodiments, apparatus 10 is configured to treat neuralgia, such as a leg (sciatic) neuralgia, and one or more stimulation elements 260 are positioned to stimulate nerve tissue proximal a contributing lesion.

[0267] In some embodiments, apparatus 10 is configured to treat pelvic pain, such as interstitial cystitis and/or bladder pain, and one or more stimulation elements 260 are positioned to

stimulate peripheral nervous system tissue (e.g. pudendal tissue and/or S-2, S-3 and/or S-4 roots) and/or central nervous system tissue (e.g. lower spinal cord and/or S3 neural foramen).

[0268] In some embodiments, apparatus 10 is configured to treat pelvic pain, such as anal pain, and one or more stimulation elements 260 are positioned to stimulate peripheral nerve tissue such as pudendal tissue and/or S-2, S-3 and/or S-4 roots.

[0269] In some embodiments, apparatus 10 is configured to treat subcutaneous pain, and one or more stimulation elements 260 (e.g. paddle electrodes) are positioned to stimulate nerve tissue.

[0270] In some embodiments, apparatus 10 is configured to treat diabetic neuropathy, such as painful diabetic neuropathy, and one or more stimulation elements 260 are positioned proximate the lower spinal cord (e.g. to stimulate S3 nerves) or other body location to stimulate nerve tissue.

[0271] In some embodiments, apparatus 10 is configured to treat visceral pain, angina and/or other pain, and one or more stimulation elements 260 are positioned to stimulate the vagus nerve.

[0272] In some embodiments, apparatus 10 is configured to treat peripheral vascular disease, diabetic neuropathy and/or other conditions associated with diabetes, such as to treat a disease or disorder selected from the group consisting of: peripheral diabetic neuropathic pain; painful diabetic peripheral neuropathy; peripheral vascular disease; peripheral arterial disease; peripheral artery disease; cardiac autonomic neuropathy; diabetic autonomic neuropathy; diabetic sensory neuropathy; diabetic motor neuropathy; diabetic sensorimotor neuropathy; diabetic muscular atrophy; diabetic neurovascular disease; and combinations of one or more of these. In these embodiments, lead 265 can be positioned proximate a nerve in the foot, leg, arm and/or sacrum (e.g. such that one or more stimulation elements 260 are positioned proximate the nerve to be stimulated). In some embodiments, lead 265 is positioned to stimulate the dorsal root ganglia to treat diabetic neuropathy (e.g. diabetic neuropathy of the hand and/or foot). Lead 265 can be implanted percutaneously and/or surgically as described herein. Lead 265 and/or one or more stimulation elements 260 can comprise a paddle electrode, such as one or more paddle electrodes implanted in the foot, leg and/or arm. Lead 265 and/or one or more stimulation elements 260 can comprise a cuff or hemi-cuff electrode surgically implanted around a nerve in the foot, leg and/or arm. Apparatus 10 can be configured to provide spinal cord stimulation, either through percutaneous insertion of one or more leads 265 in the epidural space or surgical implantation of a lead 265 comprising a paddle lead positioned in the epidural space. Apparatus 10 can be configured to provide transvascular stimulation of nerves in the foot, leg and/or arm, (e.g. to treat diabetic neuropathy) such as when one or more leads 265 are interventionally advanced into the venous or arterial system. Leads 265 can be positioned using percutaneous transforaminal

placement in the sacral foramina, such as for treatment of foot or leg disorders. Leads 265 can be constructed and arranged for cephalocaudal insertion (retrograde) into the epidural space or sacral canal, such as for treatment of foot or leg disorders. Leads 265 can be constructed and arranged to provide dorsal root ganglion stimulation, such as for treatment of trunk, neck, head, back, foot, leg, arm and/or hand disorders.

[0273] One or more leads 265 (e.g. each including one or more stimulation elements 260) can be constructed and arranged to stimulate tibial nerve fibers, such as to treat diabetic neuropathy and/or diabetic related maladies of the foot. The tibial nerve can be accessed as described herein.

[0274] One or more leads 265 can be configured to stimulate the peroneal nerve or saphenous nerve, such as at one or more locations described herebelow. The peroneal nerve can be accessed percutaneously or surgically behind the knee in the popliteal fossa where it branches off the sciatic nerve. It can also be accessed as it wraps around the lateral aspect of the knee just prior to diving under the fibularis longus and extensor digitorum longus muscles. The deep fibular nerve (a branch of the peroneal nerve) innervates top medial foot, whereas the superficial fibular (peroneal) innervates top of both medial and lateral foot. In some embodiments, stimulation element 260 comprises one or more electrodes positioned in the anterior tibial vein and/or artery to transvascularly stimulate the deep fibular nerve. The saphenous nerve comes off the femoral nerve deep in the thigh. It passes around the medial aspect of the knee medial to the patella. It then runs down the medial shin adjacent to the tibia, gastrocnemius and soleus muscles where it can be accessed surgically or percutaneously. It then surfaces just as it warps around the anterior aspect of the medial malleolus where it supplies the medial posterior foot in front of heel. The medial sural cutaneous nerve comes off the tibial at the popliteal fossa, then runs down the back of the calf (over the gastrocnemius) and wraps around the posterior aspect of the lateral malleolus before innervating the lateral aspect of the sole and heel. In some embodiments, the saphenous nerve is transvascularly stimulated by positioning one or more stimulation elements 260 in a blood vessel selected from the group consisting of: femoral vein; femoral artery; great saphenous vein; great saphenous artery; and combinations of one or more of these. In some embodiments, the sural nerve is stimulated. In these embodiments, the sural nerve can be transvascularly stimulated by positioning one or more stimulation elements 260 in the saphenous vein.

[0275] One or more leads 265 can be configured to stimulate the median nerve, ulnar nerve and/or radial nerve. The median nerve can be accessed percutaneously in the upper arm lateral to the brachial vein and/or artery, but medial to the biceps muscle, whereas the ulnar nerve runs

medial to the brachial artery in the upper arm. The median nerve passes through the anterior aspect of the elbow under the bicipital aponeurosis. The ulnar nerve runs medial and posterior to the medial epicondyle of the humerus. The median nerve can also be accessed in the wrist just proximal to the palm and the palmar carpal ligament. The ulnar nerve can be accessed just proximal to the palmar carpal ligament adjacent to the pisiform. The radial nerve can be accessed percutaneously just as it passes anterior to the lateral epicondyle. In some embodiments, apparatus 10 is configured to transvascularly stimulate at least one of a median nerve, an ulnar nerve or a radial nerve, and stimulation element 260 comprises one or more electrodes positioned in a vessel selected from the group consisting of: brachial vein; brachial artery; basilic vein; basilic artery; deep vein of the arm; deep artery of the arm; and combinations of one or more of these. In some embodiments, apparatus 10 is configured to transvascularly stimulate at least one of a median nerve or an ulnar nerve, and stimulation element 260 can comprise one or more electrodes positioned in a vessel selected from the group consisting of: brachial vein; brachial artery; and combinations of one or more of these. In some embodiments, apparatus 10 is configured to transvascularly stimulate the radial nerve, and stimulation element 260 comprises one or more electrodes positioned in a vessel selected from the group consisting of: deep vein of arm; deep artery of arm; basilic vein; radial collateral vein; radial collateral artery; medial collateral vein; medial collateral artery; radial vein; radial artery; and combinations of one or more of these. In some embodiments, apparatus 10 can be configured to transvascularly stimulate the medial cutaneous nerve, and stimulation element 260 comprises one or more electrodes positioned in the basilic vein. In some embodiments, apparatus 10 is configured to transvascularly stimulate the ulnar nerve, and stimulation element 260 comprises one or more electrodes positioned in a vessel selected from the group consisting of: ulnar collateral vein; ulnar collateral artery; ulnar vein; ulnar artery; and combinations of one or more of these. In some embodiments, apparatus 10 is configured to transvascularly stimulate the median nerve, and stimulation element 260 can comprise one or more electrodes positioned in a vessel selected from the group consisting of: brachial vein; brachial artery; ulnar vein; ulnar artery; and combinations of one or more of these.

[0276] As described herein, one or more leads 265 can be positioned to stimulate the spinal cord, such as via percutaneous insertion of a lead 265 in the epidural space or surgical implantation of the lead 265 (e.g. a paddle lead) in the epidural space. A lead 265 can be placed such that one or more stimulation elements 260 (e.g. one or more electrodes) are positioned from T5-S5, such as to capture the area of pain or reduced circulation of the leg or foot. One or more stimulation elements 260 of one or more leads 265 can be positioned from C2 to T8, such as to

capture the area of pain or reduced circulation of the arm or hand. One or more leads 265 can be placed along the midline, unilaterally and/or bilaterally over the dorsal columns, in the gutter (over dorsal roots) and/or in the dorsal root entry zone. Leads 265 can span several vertebral levels or they can be positioned to span a single level.

[0277] One or more stimulation elements 260 (e.g. one or more electrodes attached to one or more leads 265) can be positioned to transvascularly stimulate one or more nerves, such as one or more nerves in the foot, leg and/or arm, such as when the one or more stimulation elements 260 are implanted within one or more blood vessels of the venous and/or arterial system.

[0278] In the leg, the tibial nerve, sacral roots and/or deep fibular nerve can be stimulated, such as when a lead 265 accesses the tissue to be stimulated through a transvascular approach, such as via the femoral vein and/or artery, as described herein. The deep fibular nerve can be stimulated by one or more stimulation elements 260 positioned in the anterior tibial vein and/or the anterior tibial artery. In the arm, the median nerve, ulnar nerve, superior ulnar nerve, medial cutaneous nerve and/or radial nerve can be stimulated, such as when lead 265 accesses the tissue to be stimulated through a transvascular approach, such as via the brachial vein and/or artery, the basilic vein and/or artery, and/or the deep vein and/or artery.

[0279] One or more stimulation elements 260 (e.g. one or more electrodes attached to one or more leads 265) can be positioned to stimulate dorsal root ganglia that supply the following nerves (e.g. to treat the leg and/or foot): common peroneal (L4-S2); tibial (L4-S3); femoral (L2-L4); and combinations of one or more of these. One or more stimulation elements 260 (e.g. one or more electrodes attached to one or more leads 265) can be positioned to stimulate dorsal root ganglia that supply the following nerves (e.g. to treat the hand and/or arm): radial (C5-T1); median (C5-T1); ulnar (C7-T1); and combinations of one or more of these. In these embodiments, one or more leads 265 can be passed through the intervertebral foramina, either unilaterally or bilaterally, at a single vertebral level or at multiple vertebral levels.

[0280] In some embodiments, apparatus 10 is configured to treat post-amputation pain, such as to treat a disease or disorder selected from the group consisting of: phantom limb pain; phantom stump pain; acute and persistent stump pain; limb pain; neuroma; Morton's neuroma; neurilemoma; neurolemoma; Schwann cell tumor; phantom limb itch; phantom limb sensations; and combinations of one or more of these. Apparatus 10 can be configured to treat the conditions associated with post-amputation pain (i.e., stump pain), such as by using a high frequency alternating current (HFAC) block approaches. In these embodiments, one or more leads 265 can be implanted such that one or more stimulation elements 260 stimulate one or more nerves in the leg, arm and/or sacrum. One or more leads 265 can be surgically implanted,

such as when lead 265 comprises a paddle electrode positioned near a nerve in the foot, leg or arm and/or a cuff electrode or hemi-cuff electrode positioned to at least partially surround a nerve in the foot, leg or arm. One or more leads 265 can be positioned to stimulate the spinal cord, such as via a percutaneous insertion of the leads 265 in the epidural space or surgical implantation of the lead 265 (e.g. a paddle lead) in the epidural space. One or more leads 265 can be positioned to provide transvascular stimulation of nerves in the leg or arm, such as when one or more stimulation elements 260 are implanted within a vein or artery. One or more leads 265 can be implanted using percutaneous transforaminal placement in the sacral foramina, such as for treatment of leg stump pain. One or more leads 265 can be implanted using cephalocaudal insertion (retrograde) into the epidural space or sacral canal, such as for treatment of leg stump pain. One or more leads 265 can be positioned to perform dorsal root ganglion stimulation and/or block, such as for treatment of leg and/or arm stump pain.

[0281] In some embodiments, apparatus 10 is configured to treat occipital and/or headache (HA) pain, such as when apparatus 10 is configured to treat a disease or disorder selected from the group consisting of: occipital neuralgia; cervicogenic headache; tension headache; chronic and episodic migraine headache; tension headache; hemicrania continua; trigeminal autonomic cephalalgias (TACs); chronic and episodic cluster headache; chronic and episodic paroxysmal hemicranias; short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT); short-lasting unilateral neuralgiform headache attacks with cranial autonomic symptoms (SUNA); long-lasting autonomic symptoms with hemicrania (LASH); post-traumatic headache; and combinations of one or more of these.

[0282] Apparatus 10 can be configured to treat the conditions associated with headache pain and/or occipital neuralgia by stimulating one or more nerves in the head, such as one or more nerves selected from the group consisting of: greater and/or lesser occipital nerve (e.g. which arise from C2 and C3); the greater and/or lesser auricular nerves (e.g. which also arise from C2/C3); the third (least) occipital nerve (e.g. which arises from C3); and combinations of one or more of these. The infraorbital or supraorbital nerves can be access subcutaneously below and above the eye, respectively. Apparatus 10 can be configured to stimulate auriculotemporal, supratrochlear and/or sub-occipital nerves. To stimulate any of these nerves, lead 265 (e.g. a cylindrical SCS-type lead) can be inserted percutaneously either subcutaneously or under the muscle. Alternatively, surgery (e.g. direct cut-down) can be performed to insert lead 265 (e.g. a cylindrical lead, a paddle lead, a cuff or hemi-cuff electrode) proximate, one and/or around these nerves. Alternatively or additionally, the nerves can be accessed transvascularly as described herein (e.g. when one or more stimulation elements 260 are implanted in a blood vessel).

Housing 210 can be implanted anywhere in the head under the skin, including: behind the ear, back of the head, the neck, in the face, and the like, where one or more external devices 500 can be positioned in, on and/or within a hat, headband, glasses, goggles, earpiece, necklace, patch, and the like. Apparatus 10 can be configured to treat headache pain and/or occipital neuralgia by stimulating tissue in the cervical spinal cord (C2-C3), for example proximate the location the nerve enters the cord from the foramen. One or more leads 265 can be placed over the dorsal columns, in the gutter, over the dorsal root entry zone and/or out in the foramen at the dorsal root ganglion. In some embodiments, the trigeminal and pterygopalatine ganglia are accessed by inserting one or more leads 265 through the face or the roof of the mouth. In these embodiments, housing 210 can be placed anywhere in the head under the skin, as described herein.

[0283] In some embodiments, apparatus 10 is configured to treat post-herpetic neuralgia, such as to treat a disease or disorder selected from the group consisting of: shingles; herpes zoster; zoster; zona; varicella zoster virus infection; zoster sine herpete; fever blisters; herpes zoster blisters; herpes zoster rash; and combinations of one or more of these. In some embodiments, apparatus 10 is configured to treat post-herpetic neuralgia using high frequency alternating current (HFAC) block approaches. In these embodiments, one or more leads 265 can be implanted such that one or more stimulation elements 260 stimulate one or more nerves in the leg, arm, torso and/or sacrum. One or more leads 265 can be surgically implanted, such as when lead 265 comprises a paddle electrode positioned near a nerve in the foot, leg, torso and/or arm and/or a cuff electrode or hemi-cuff electrode positioned to at least partially surround a nerve in the foot, leg, torso or arm. One or more leads 265 can be positioned to stimulate the spinal cord, such as via a percutaneous insertion of the leads 265 in the epidural space or surgical implantation of the lead 265 (e.g. a paddle lead) in the epidural space. One or more leads 265 can be positioned to provide transvascular stimulation of nerves in the leg, torso and/or arm, such as when one or more stimulation elements 260 are implanted within a vein or artery. One or more leads 265 can be implanted using percutaneous transforaminal placement in the sacral foramina, such as for treatment of leg or foot pain. One or more leads 265 can be implanted using cephalocaudal insertion (retrograde) into the epidural space or sacral canal, such as for treatment of leg or foot pain. One or more leads 265 can be positioned to perform dorsal root ganglion stimulation and/or block, such as for treatment of leg, torso and/or arm pain.

[0284] In some embodiments, apparatus 10 is configured to treat angina, such as to treat a disease or disorder selected from the group consisting of: angina; chest pain caused by reduced blood flow to the heart muscle; chest pain associated with coronary artery disease such as

squeezing, pressure, heaviness, tightness or pain in the chest; recurring angina pectoris; acute angina pectoris; chronic angina pectoris; acute coronary syndrome; chest pain; coronary artery spasms; microvascular angina; Prinzmetal's angina; angina inversa; stable or common angina; unstable angina; variant angina; and combinations of one or more of these.

[0285] In some embodiments, apparatus 10 is configured to treat carpal tunnel syndrome, such as to treat a disease or disorder selected from the group consisting of: median nerve entrapment; tingling and/or numbness in fingers or hand; median nerve irritation or compression; narrowing of the carpal tunnel; and combinations of one or more of these. In these embodiments, apparatus 10 can be configured to deliver stimulation to median nerve tissue; ulnar nerve tissue and/or radial nerve tissue.

[0286] In some embodiments, apparatus 10 is configured to treat erectile dysfunction (ED), such as to treat a disease or disorder selected from the group consisting of: impotence; male sexual dysfunction; inability to develop or maintain an erect penis; cardiogenic ED; vasculogenic ED; diabetic ED; neurogenic ED; traumatic ED; post-prostatectomy ED; hormonal ED; hyopogonadism; pharmacological ED; and combinations of one or more of these.

[0287] In some embodiments, apparatus 10 is configured to treat complex regional pain syndrome (CRPS), such as to treat a disease or disorder selected from the group consisting of: CRPS type 1; CRPS type 2; reflex sympathetic dystrophy; causalgia; reflex neurovascular dystrophy; amplified musculoskeletal pain syndrome; systemic autonomic dysregulation; neurogenic edema; musculoskeletal pain; and combinations of one or more of these.

[0288] In some embodiments, apparatus 10 is configured to treat knee pain. Knee pain from joint degeneration or join replacement surgery can be treated via stimulation of the nerves innervating the knee and/or via stimulation of the tissue surrounding the knee (sometimes referred to as peripheral field stimulation). Apparatus 10 can comprise between one and eight leads 265 whose stimulation elements 260 are placed near and around the knee. In some embodiments, four leads 265 are placed, in locations medial, lateral, superior and inferior to the knee. The leads 265 can be placed subcutaneously for field stimulation, or they can be placed directly adjacent to specific nerve targets. Applicable nerve targets are as follows: medial knee can include medial femoral cutaneous and infrapatellar cutaneous branches of saphenous nerve; lateral knee can include constant articular branches of common peroneal, lateral retinacular nerve; anterior knee can include lateral, medial, and anterior cutaneous femoral nerve, infrapatellar branch of saphenous nerve, medial and lateral retinacular nerve and articular branches of peroneal nerve; posterior knee can include obturator, posterior tibial and sciatic nerves. In addition, the following nerves can be stimulated via stimulation elements 260 to treat

knee pain: nerves arising from the tibial nerve such as the superior, middle and inferior genicular nerves; nerves arising from the common peroneal such as the superior lateral, inferior lateral, and recurrent genicular nerves; and nerves arising from the obturator nerve such as the genicular branch of obturator; and nerves arising from the femoral nerve such as the saphenous nerve. Each of these targets can be stimulated transvascularly by one or more stimulation elements 260.

[0289] In some embodiments, implantable device 200 has an internal battery or other power supply such that stimulation (e.g. stimulation energy and/or a stimulation agent) is delivered to one or more locations within a patient for an extended time period (e.g. at least 1 hour, at least 1 day, at least 1 month or at least 1 year), without receiving a power transmission (e.g. as described herein from an external device such as external device 500) during that time period. In some embodiments, at least a portion of a single pulse of energy (e.g. at least a single phase) is delivered by implantable device 200 using energy provided by an internal power supply 570 such as a battery or a capacitor. In these embodiments, data can be transmitted by one or more of an external device 500 and/or a programmer 600, such as to activate or modify stimulation being delivered, with or without also transmitting power.

[0290] In some embodiments, implantable device 200 comprises one or more components configured to receive transmitted power (e.g. via an external device 500), receive transmitted data (e.g. via an external device 500 and/or programmer 600) and/or deliver stimulation (e.g. deliver stimulation energy and/or a stimulation agent).

[0291] In some embodiments, one or more implantable devices 200 are configured to deliver stimulation energy (e.g. via one or more stimulation elements 260 comprising an electrode) with a stimulation waveform comprising one or more high frequency signals (e.g. a signal comprising one or more high frequency components). For example, one or more implantable devices 200 can deliver one or more stimulation waveforms comprising one or more signals above 600Hz, such as one or more signals above 1.0kHz, 1.2kHz, 5kHz, 10kHz or 25kHz.

[0292] In these embodiments, the delivered stimulation waveform can be configured to be void of (i.e. not include) one or more lower frequency signals, such as by not including any signals at a frequency below 100Hz, below 500Hz, below 1000Hz, below 1200Hz or below 1500Hz.

[0293] One or more implantable devices 200 can be configured to deliver stimulation energy with a stimulation waveform that varies over time. In some embodiments, one or more stimulation parameters of the stimulation waveform are randomly varied over time, such as by using a probability distribution as described in applicant's co-pending United States Patent Application Serial Number 17/372,095, titled "Apparatus with Enhanced Stimulation Waveforms", filed July 9, 2021 [Docket nos. 47476-708.302; NAL-014-US-CON1]. Each

stimulation waveform can comprise one or more pulses, such as a group of pulses that are repeated at regular and/or irregular intervals. In some embodiments, a pulse can comprise delivery of electrical energy, such as electrical energy delivered in one or more phases (e.g. a pulse comprising at least a cathodic or anodic portion followed by passive capacitive recovery with an optional open circuit time between the first portion and recovery). In some embodiments, a group of pulses is delivered, each pulse comprising an anodic or cathodic portion that can include charge recovery after each pulse, such as charge recovery comprising active (opposite polarity pulse) recovery, and/or passive (capacitive) recovery. In some embodiments, there is no recovery between pulses, but instead active or passive recovery is included at the end of the set of the first (anodic or cathodic) portions. In some embodiments, single or groups of pulses are provided at time-varying modes of repetition (e.g. regular intervals for a period, then a period of irregular intervals) or at regular intervals with occasional (random) spurious pulses inserted (creating a single irregular event in an otherwise regular series). Non-limiting examples of waveform variations include: a variation in frequency (e.g. frequency of one or more signals of the waveform); variation of a signal amplitude; variation of interval time period (e.g. at time period between pulses or a time period between pulse trains); variation of a pulse width; multiple piecewise or continuous variations of one of more stimulation parameters in a single pulse (e.g. multi-step, multi-amplitude in one **"super-pulse"**); variation of pulse symmetry (e.g. via active drive, passive recovery and/or active-assisted passive recovery); variation of stimulation energy over a time window and/or overlapping time windows; variation of the power in the frequency spectrum of the stimulation waveform; and combinations of one or more of these. In some embodiments, apparatus 10 and/or implantable device 200 can be configured to vary a stimulation waveform **"systematically"** (e.g. automatically and/or at least semi-automatically by apparatus 10) such as a variation performed temporally (e.g. on predetermined similar or dissimilar time intervals) and/or a variation performed based on a parameter, such as a measured parameter that can be based on a signal produced by a sensor of implantable device 200 or another component of apparatus 10. Alternatively or additionally, apparatus 10 and/or implantable device 200 can be configured to vary a stimulation waveform randomly. Random variation shall include discrete or continuous variations that can be selected from a distribution, such as a probability distribution selected from the group consisting of: a uniform distribution; an arbitrary distribution; a gamma distribution; a normal distribution; a log-normal distribution; a Pareto distribution; a Gaussian distribution; a Poisson distribution; a Rayleigh distribution; a triangular distribution; a statistic distribution; and combinations of one or more of these. Random pulses or groups of pulses can be generated based on randomly

varying one or more stimulation signal parameters. One or more stimulation parameters can be varied randomly through the use of one or more probability distributions, as described herebelow.

[0294] In some embodiments, the amplitude of a signal delivered by one or more implantable devices 200 is adjusted to prevent discomfort to the patient (e.g. paresthesia or other undesired condition) from the stimulation signal. In some embodiments, the amplitude of the stimulation signal can be ramped (e.g. up and/or down), a single time or multiple times (e.g. continuously or intermittently). In some embodiments, a titration procedure is performed to set (e.g. define) one or more stimulation parameters based on avoiding patient discomfort.

[0295] In some embodiments, one or more implantable devices 200 are configured to deliver stimulation energy (e.g. via one or more stimulation elements 260 comprising an electrode) with a stimulation waveform comprising one or more waveform patterns. The stimulation waveforms delivered can be configured to treat various conditions of a patient. Each stimulation waveform can comprise a series of continuous pulses, intermittent pulses, and/or spurious pulses (e.g. occasional events in an otherwise continuous stream). Each pulse can comprise a pulse train that is repeatedly delivered by implantable device 200, the train comprising one or more cathodic pulses and/or one or more anodic pulses. In some embodiments, implantable device 200 delivers a multiphasic pulse comprising at least two cathodic pulses and/or anodic pulses, with or without any time between each pulse. For example, implantable device 200 can deliver a biphasic pulse comprising a cathodic pulse followed by an anodic pulse, a triphasic pulse comprising a cathodic pulse followed by an anodic pulse followed by a second cathodic pulse, or any series of two or more cathodic and/or anodic pulses. In some embodiments, delivered pulses are exponential in nature (e.g. comprise an exponential portion), such as dynamic return pulses that exceed a minimum current (e.g. at least 1mA, 10mA or 50mA) for a short duration (e.g. for approximately 1μsec), and then decay to lower current levels (e.g. a level of approximately 100nA), with a time constant on the order of 1μsec to 100μsec.

[0296] The stimulation waveforms delivered by implantable device 200 can comprise one or more high frequencies. The stimulation waveform frequency or other stimulation parameter can be set, adjusted, and/or modified (**"set", "adjusted", and/or "modified" herein**) to optimize therapeutic benefit to the patient and minimize undesired effects (e.g. paresthesia or other patient discomfort). In some embodiments, a stimulation waveform is adjusted based on a signal produced by a sensor of apparatus 10 (e.g. a sensor of implantable device 200, such as a stimulation element 260 configured as a sensor or other sensor of implantable device 200 as described hereabove). Adjustment of a stimulation waveform parameter can be performed

automatically by the implantable device 200 and/or via an external device 500 and/or programmer 600).

[0297] In some embodiments, a pulse shape of a stimulation waveform can be varied, such as a pulse shape comprising: a sinusoidal geometry; a square geometry (e.g. a waveform comprising a square wave); a rectangular geometry; a triangular geometry; (e.g. symmetric or asymmetric); a trapezoidal geometry; a sawtooth geometry; a ramped geometry; an exponential geometry; a piece-wise step function geometry; a root-raised cosine geometry; and combinations of one or more of these.

[0298] In some embodiments, a charge recovery phase (e.g. anodal phase) of a stimulation waveform is varied by implantable device 200.

[0299] Inter-pulse gap, the time between one or more pulses (e.g. a biphasic or other multiphasic pulse that is repeated continuously), can be varied systematically and/or randomly by implantable device 200. In some embodiments, inter-pulse gap between one or more pulses comprises zero time (i.e. a first pulse is immediately followed by a similar or dissimilar second pulse). In some embodiments, inter-pulse gap is varied systematically, such as on a routine basis (i.e. temporally) and/or varied based on a signal produced by a sensor of apparatus 10. Alternatively or additionally, inter-pulse gap can be varied randomly, such as a random variation based on a distribution (e.g. a probability distribution with a pre-determined shape) as described herebelow.

[0300] In some embodiments, implantable device 200 delivers a stimulation waveform comprising a series of frequency modulated (FM) pulses, such that the frequency of stimulation varies. Implantable device 200 can be configured to deliver a frequency modulated stimulation waveform comprising a carrier signal, at a carrier frequency, that is modulated continuously between a first frequency and a second frequency. For example, implantable device 200 can deliver a stimulation waveform that modulates between 2.0kHz and 3.0kHz every second (e.g. comprising a carrier signal at 2.5kHz that is modulated at 1Hz) with a modulation range (the excursion from the carrier signal) of +/-500Hz. In some embodiments, implantable device 200 can deliver a stimulation waveform that comprises: a carrier frequency between 1kHz and 50kHz, a modulation frequency between 0.1Hz and 10kHz and/or a modulation range between 1Hz and the carrier frequency.

[0301] In some embodiments, implantable device 200 delivers a stimulation waveform comprising a series of amplitude modulated (AM) pulses, such that the amplitude of stimulation varies (e.g. varying the amplitude of the voltage and/or current of the stimulation signal). The amplitude of delivered current can be varied in a single amplitude modulated sweep, such as a

sweep from 2mA to 3mA. In some embodiments, amplitude of a signal can be varied continuously, such as when current is varied between 2mA and 3mA every second (e.g. a signal comprising a modulation frequency of 1Hz). In these embodiments, the depth of modulation would be 33%, where depth of modulation is equal to 1- [lower range/upper range]. In some embodiments, amplitude of delivered current fluctuates between 1mA and 3mA (i.e. a depth of modulation of 66%), while in other embodiments, current fluctuates between 0mA and 10mA (e.g. a depth of modulation of 100%). In some embodiments, implantable device 200 is configured to deliver an amplitude modulated signal comprising: a carrier frequency between 1Khz and 50kHz; a modulation frequency between 0.1Hz and the carrier frequency and/or a depth of modulation between 0.1% and 100%.

[0302] In some embodiments, implantable device 200 delivers a stimulation waveform comprising delivery of continuously balanced analog current waveforms, for example from a differential Howland current source. In these embodiments, there are not independent pulses, but rather there is true analog frequency and amplitude modulation. Periods of delivering stimulation (or presence of balanced differential analog stimulation) and periods of no stimulation (e.g. a quiescent period) can be included. In some embodiments, controller 250 comprises one or more reconfigurable stimulation blocks including one or more Howland or other current sources. The one or more current sources (e.g. two or more current sources) can each be attached to a stimulation element 260 (e.g. in a monopolar configuration when the current source is also connected to housing 210 or in a bipolar configuration when the current source is connected to a pair of stimulation elements 260). Alternatively, controller 250 can comprise one or more current sources that are attached to a matrix of switches that selectively connect the one or more current sources to multiple stimulation elements 260 (e.g. connect a single current source to 2, 4, 8, 12 or 16 electrodes). In some embodiments, controller 250 is configured such that a stimulation waveform signal provided to the current source passes through a capacitor (e.g. capacitor C1 shown), the capacitor providing DC balance.

[0303] In some embodiments, implantable device 200 delivers a stimulation waveform comprising delivery of multiple trains of pulses that are delivered intermittently, a **"burst stimulation"** waveform as defined hereabove. For example, implantable device 200 can be configured to deliver a series or train of five pulses, each with a 1msec pulse width. The each of the five pulses can be separated by an inter-pulse gap of 4msec, creating a train-on period of 16msec. These five pulses can be repeated every 25msec (the **"inter-train period"**). In some embodiments, implantable device 200 can be configured to deliver a burst stimulation waveform comprising a pulse width between 5µsec and 1msec. Implantable device 200 can deliver a train

or burst stimulation waveform comprising pulses with constant pulse widths and/or varying pulse widths, such as when the pulse widths (and/or other stimulation parameters) are varied randomly and/or systematically. Implantable device 200 can deliver a train or burst stimulation waveform with a varied or constant pulse shape selected from the group consisting of: sinusoid; square, rectangle; triangle (symmetric or asymmetric); trapezoid; sawtooth; ramp (e.g. a linear ramp); exponential curve; piece-wise step function; and combinations of one or more of these. Implantable device 200 can deliver a train or burst stimulation waveform with an inter-pulse gap less than inter-train period. The inter-pulse gap can be relatively constant, and/or it can be varied, such as when implantable device 200 randomly varies the inter-pulse gap or varies the inter-pulse gap systematically. In some embodiments, the inter-pulse gap between any two pulses within a pulse train (or burst) can be varied between 0.1μsec and the inter-train period (or inter-burst period). Implantable device 200 can deliver a train stimulation waveform with an inter-pulse gap between 1μsec and 1 second. Implantable device 200 can deliver a burst stimulation waveform with an inter-train period between 1μsec and 1 second. Implantable device 200 can deliver a burst stimulation waveform with an inter-burst period between 20μsec and 24 hours. The inter-burst period can be relatively constant, and/or it can be varied, such as when implantable device 200 randomly varies the inter-burst period or varies the inter-burst period systematically. In some embodiments, inter-burst period is varied by the user, such as via a user using programmer 600. In these embodiments, user activation can be regulated with one or more safeguards or other limits such as those incorporated into patient-controlled analgesia devices. The inter-train period can be varied between 1μsec and 24 hours. Implantable device 200 can deliver a train or burst stimulation waveform with a train-on period (the time between the onset of a first pulse in a pulse train to the end of the last pulse in a pulse train) between 10μsec and 24 hours. The train-on and/or burst-on period can be relatively constant, and/or it can be varied, such as when implantable device 200 randomly varies the train-on and/or burst-on period or varies the train-on and/or burst-on period systematically. Implantable device 200 can deliver a train or burst stimulation waveform with a train or burst envelope selected from the group consisting of: cosine; cosine-squared; sine; square; rectangle; triangle (symmetric or asymmetric); trapezoid: sawtooth; ramp (e.g. linear ramp); and combinations of one or more of these. Implantable device 200 can deliver a train and/or burst stimulation waveform with a train ramp duration or burst ramp duration between 1μsec to 10 minutes. Implantable device 200 can deliver a train and/or burst stimulation waveform with a depth of modulation between train and/or bursts of between 1% and 99%. For example, between some or all of the trains and/or bursts (burst-off or train-off periods), a signal may be present and may contain the same or

different elements contained in the train-on and/or burst-on period. These burst-off or train-off periods may comprise a quiescent period. The amplitude of the signal contained in these quiescent periods can be from 0% to 99% of the signal amplitude during the train-on and/or burst-on period, such as a signal with an amplitude less than 50% of the signal amplitude during the train-on and/or burst-on period or another amplitude below a neuronal excitation threshold.

[0304] In some embodiments, apparatus 10 is configured to deliver stimulation energy to dorsal root ganglion and/or spinal cord tissue to treat a condition such as pain. In these and other embodiments, apparatus 10 can be configured to provide a stimulation waveform comprising: a combination of low frequency stimulation (e.g. electrical energy comprising a low frequency signal) and burst stimulation; burst stimulation (e.g. burst stimulation alone); a combination of low frequency stimulation and high frequency stimulation; a combination of low frequency stimulation, high frequency stimulation and burst stimulation; and combinations of one or more of these. The stimulation energy provided by apparatus 10 can be delivered to tissue via one or more stimulation elements 260, such as two or more electrodes which deliver similar or dissimilar stimulation waveforms simultaneously and/or sequentially. Each of the stimulation waveforms can comprise one or more pulses comprising an entire phase or at least a portion of a phase at a superthreshold level. Alternatively or additionally, each of the stimulation waveforms can comprise one or more pulses comprising an entire phase or at least a portion of a phase at a subthreshold level.

[0305] In some embodiments, apparatus 10 is configured to vary one or more stimulation parameters. The stimulation parameters can be varied to optimize (e.g. balance the benefits of) therapeutic benefit, system efficiency, stimulation efficiency, avoidance and/or reduction of paresthesia, and/or reduction of charge.

[0306] Apparatus 10 can comprise one or more memory storage components (e.g. of an implantable device 200, external device 500, and/or other component of apparatus 10) that can store instructions for performing one or more algorithms, **algorithm 15** shown. Algorithm 15 can comprise one or more algorithms that are configured to analyze data (e.g. data produced by a sensor-based functional element of apparatus 10) and produce a result. Algorithm 15 can comprise an algorithm (e.g. one or more algorithms) that are configured to steer current delivered by one or more stimulation elements 260, such as is described in applicant's co-pending United States Patent Application Serial Number 17/383,972, titled "Systems with Implanted Conduit Tracking", filed July 23, 2021 [Docket nos. 47476-716.301; NAL-022-US]. Algorithm 15 can comprise one or more algorithms configured to analyze data input by a user of apparatus 10 (e.g. a patient and/or a clinician of the patient), such as data entered via a user

interface 680, and determine a stimulation paradigm SP, where paradigm SP comprises a set of stimulation parameter settings (e.g. stimulation energy settings as described herein) used to provide a therapy and/or otherwise treat a patient.

[0307] Each implantable device 200 of the present inventive concepts can be configured to deliver stimulation energy to one, two, three, four, or more anatomical locations of a patient, such as via sets of one or more stimulation elements 260 (e.g. electrodes) that can be positioned on one or more leads 265. The stimulation energy delivered by the elements 260 can comprise tonic stimulation (e.g. a stimulation paradigm comprising a repeating pattern of pulses that are defined by pulse width, rate, and amplitude, where at the specified rate a pulse is delivered comprising a specified pulse width and a specified amplitude) and/or more complex stimulation waveforms. A first set of stimulation elements 260 can be positioned (e.g. implanted) and deliver and/or receive electrical current to deliver therapy (e.g. treat pain) in a first anatomical location, while a second set of stimulation elements 260 can be positioned and deliver and/or receive electrical current to deliver therapy (e.g. treat pain) in a second anatomical location. The first and second anatomical locations can include overlapping portions (e.g. the same tissue is included in each location) or they can be completely different volumes of tissue. The stimulation energy delivered to the two locations can be delivered sequentially, and/or simultaneously. In some embodiments, three, four or more anatomical locations receive therapy from corresponding sets of stimulation elements 260.

[0308] In some embodiments, one or more sets of stimulation elements 260 are configured to provide **"combination waveform therapy"**, where the stimulation waveform delivered comprises a combination of two or more waveforms. For example, a first waveform can be delivered to a first anatomical location in which pain is present, and a second waveform can be delivered to a second anatomical location. The first waveform can comprise stimulation energy delivered at a frequency up to 100Hz (e.g. to treat pain). The second waveform can comprise stimulation energy delivered at a higher frequency than the first waveform, such as a frequency of 1KHz or more (e.g. for sub-threshold stimulation).

[0309] In some embodiments, one or more sets of stimulation elements 260 are configured to provide **"microburst waveform therapy"**, where the stimulation waveform delivered comprises delivery of stimulation energy that is repeatedly turned on and off, such as to provide a therapy based on the repeated enhancement of onset of stimulation energy delivery (e.g. versus continuous stimulation energy delivery).

[0310] In some embodiments, one or more stimulation elements 260 are configured to provide **"paired stimulation therapy"**, wherein the stimulation waveform delivered comprises at least

two different types of waveforms that are delivered simultaneously, such as when the stimulation waveform comprises two or more of: a tonic stimulation waveform; a microburst stimulation waveform; and/or a waveform comprising a combination of pulses, trains, and/or bursts.

[0311] Each implantable device 200 can be configured to perform charge recovery in an "active" and/or a "passive" manner. For example, device 200 can perform active recovery by including a pulse of opposite polarity to the stimulating pulse(s) such that the net charge at the stimulation element 260 is zero (e.g. stimulating charge = recovery charge). Device 200 can perform passive charge recovery by electrically connecting the stimulation elements 260 for a period of time after delivery of stimulation energy to allow charge to dissipate (e.g. to allow the charge on included blocking capacitors to dissipate), thereby resulting in net zero charge at the stimulation elements 260. In some embodiments, implantable device 200 can perform charge recovery as described in applicant's co-pending United States Patent Application Serial Number 17/383,915, titled "Stimulation Apparatus", filed July 23, 2021 [Docket nos. 47476-715.301; NAL-021-US].

[0312] In some embodiments, apparatus 10 (e.g. algorithm 15) is configured to apply a "**pulse width constraint**" when assessing the compatibility of a set of stimulation parameters, and/or when determining an acceptable range of values for a stimulation parameter to be used with a set of other stimulation parameters. For example, when a delivered stimulation includes delivery of stimulation at a relatively high rate (e.g. above 1kHz, such as approximately 1.5kHz), there may be parameter limitations applied due to the shorter pulse widths of stimulation pulses. Implantable device 200 can include a "**minimum switching time**" to account for in determining stimulation parameter setting compatibility, such as a switching time of approximately 180μsecs. In some embodiments, apparatus 10 is configured to deliver the pulses for each area before a subsequent stimulation cycle begins. For example, the minimum amount of time available to deliver all the pulses is determined by the highest programmed stimulation rate (i.e. the waveform including the shortest interval), while considering any associated other requirements, "**overhead**" herein, such as the switching time requirements (e.g. switching requirements of the current sources, such as a time requirement of approximately 180μsecs). In other words, the minimum stimulation interval is determined (e.g. via algorithm 15) to be at least the time of the sum of all the pulse widths plus the overhead. In some embodiments, the stimulation delivered includes a high rate stimulation waveform of 1.5kHz, and algorithm 15 limits passive recovery pulse width to a maximum of 110μsecs, and active recovery pulse width to a maximum of 55μsecs.

[0313] In some embodiments, apparatus 10 (e.g. algorithm 15) is configured to apply an envelope for stimulation based on: dosage on and dosage off times (D_{ON} and D_{OFF} times, respectively, each as described herein). Apparatus 10 can provide up to two dosing periods, which can be associated with the rate of stimulation. In some embodiments, apparatus 10 constrains D_{ON} and/or D_{OFF}. D_{ON} can be limited to a maximum time period, such as a maximum of 1 second. D_{OFF} can be limited to a maximum time period, such as a maximum of 2 seconds, such as when the dosage period (D_{ON} plus D_{OFF}) is limited to a time period of 2 seconds. Apparatus 10 can be configured to deliver stimulation energy at multiple rates, where a first rate (e.g. a relatively high rate) is delivered at a prescribed rate (e.g. a rate entered via user interface 680), while a second rate (e.g. a relatively low rate or otherwise lower than the first rate) is generated using a "N of M scheme" where a subset N of M pulses of the higher rate are delivered to effectively achieve the lower rate, such as is described herein in reference to Figs 7-8.

[0314] Figs. 2 thru 24 described herebelow below include views of a user interface for providing (e.g. setting) stimulation parameter settings, such as stimulation parameter settings representing a stimulation paradigm SP which includes identification of a set of multiple stimulation elements 260 to source and/or sink stimulation current, and the parameters (e.g. amplitudes, pulse widths, dosage amount (e.g. as defined by dosage on and off times), form of charge recovery, waveform shapes, and the like) of the stimulation energy to be provided, collectively, by the set of stimulation elements 260 that are identified. These user interfaces shown herein represent one or more user interfaces of apparatus 10, such as user interface 680' of patient programmer 600', user interface 680'' of clinician programmer 600'', and/or another user interface of apparatus 10 (singly or collectively user interface 680). In some embodiments, a user interface 680 is included in a tool of apparatus 10 (e.g. tool 60 of Fig. 1), such as a manufacturing tool used in the production of one or more components of apparatus 10, such as to enter pre-programmed stimulation waveforms to later be accessed by the patient and/or clinician (e.g. provided as a pre-programmed set of particular stimulation parameters). Each user interface 680 can comprise a touchscreen or other combination of user input and output components that provide one or more **"input icons"** that allow a user to enter data, such as icons 6801, 6802, 6803, 6804, 6805, and/or 6806 as shown in the figures.

[0315] Input icons 6801 thru 6806 allow a user (e.g. the patient or clinician) to enter various input information to create a desired stimulation waveform for delivery of stimulation energy in multiple anatomical areas, such as multiple anatomical locations as determined by the surgical

placement and component configuration of multiple implanted stimulation elements 260 (e.g. as included on one or more implanted leads 265).

[0316] Icon 6801 can include a single data input icon that allows a user to select the number of anatomical locations to receive stimulation energy (e.g. between 1 and 4 locations). Icons 6802 thru 6806 can each include multiple data input icons, the number included based on the number of anatomical locations selected via icon 6801 (e.g. each of icons 6802 thru 6806 displaying four input icons correlating to the number of anatomical areas selected via icon 6801).

[0317] Icon 6802 can include one or more data input icons (e.g. as determined by data provided via icon 6801), where each icon is configured to receive user input to set a pulse width of stimulation energy to be delivered for the associated anatomical location (e.g. independently set a pulse width for each of the anatomical locations selected).

[0318] Icon 6803 can include one or more data input icons (e.g. as determined by data provided via icon 6801), where each icon is configured to receive user input to set an amplitude of stimulation energy to be delivered for the associated anatomical location (e.g. independently set an amplitude for each of the anatomical locations selected).

[0319] Icon 6804 can include one or more data input icons (e.g. as determined by data provided via icon 6801), where each icon is configured to receive user input to set a rate of stimulation energy to be delivered for the associated anatomical location (e.g. independently set a rate of stimulation for each of the anatomical locations selected). In some embodiments, icon 6804 is configured to provide at least 2 rates. In some embodiments, icon 6804 is configured to provide rates in increments of 5Hz.

[0320] Icon 6805 can include one or more data input icons (e.g. as determined by data provided via icon 6801), where each icon is configured to receive user input to set the form of charge recovery (e.g. active or passive) to be used in the delivery of stimulation energy for the associated anatomical location (e.g. independently set the form of charge recovery for each of the anatomical locations selected).

[0321] Icon 6806 can include one or more sets (e.g. pairs) of data input icons (e.g. as determined by data provided via icon 6801), where each set of icons is configured to receive user input to set the dosage (e.g. period of time in which dosing is on and/or off) to be used in the delivery of stimulation energy for the associated anatomical location (e.g. independently set the D_{ON}, D_{OFF}, and/or other dosage parameters for each of the anatomical locations selected). In some embodiments, all anatomical locations with the same rate (e.g. as entered via icon 6804) are limited to having (e.g. required to have) the same dosage on (D_{ON}) and dosage off (D_{OFF}) values.

[0322] User interface 680 can be configured to allow a user (e.g. the patient or their clinician) to enter (e.g. initially enter and/or modify) a set of stimulation parameters (e.g. via any or all of icons 6801 thru 6806), after which apparatus 10 performs (e.g. algorithm 15 performs) a diagnostic procedure confirming the compatibility of signal parameter settings selected. For example, algorithm 15 can determine that an incompatibility exists in a particular set of selected stimulation parameters, and algorithm 15 can alert the user via user interface 680 (e.g. a visual alert notice) and/or via another alert component of apparatus 10 (e.g. an audible alert delivered through a functional element comprising a speaker, buzzer, or other audio transducer). In some embodiments, algorithm 15 can "suggest" or otherwise provide changes (e.g. minor changes) to one or more of the stimulation parameter settings in order to resolve the incompatibility issue. For example, algorithm 15 can suggest changing (e.g. provide feedback via user interface 680) a passive charge recovery to an active charge recovery (e.g. when there is not enough time between pulses for passive recovery to provide a desired charge recovery). Algorithm 15 can define a set of stimulation parameter settings that includes pulse widths that are of a short enough duration that all the intended pulses fit within a stimulation interval. Algorithm 15 can be configured such that dosage on (D_{ON}) times include at least two pulses in order to avoid changing the effective rate of the stimulation waveform.

[0323] Apparatus 10 can be configured such that the one or more stimulation parameters, such as those which can be entered and/or viewed via icons 6801 thru 6808, have (e.g. are provided by apparatus 10 with) a minimum level, a maximum level, and/or an "**incremental step size**" comprising the minimum value of a change of a variable from one level to another level (e.g. a variable with an incremental step size of 0.1 change can be increased from 2.0 to 2.1 and greater in 0.1 increments, or decreased from 2.0 to 1.9 and lower in 0.1 increments). In some embodiments, the incremental step size of a stimulation parameter setting is determined by algorithm 15, such as when the incremental step size for a stimulation parameter setting is calculated based on an analysis of one or more other stimulation parameter settings (e.g. as entered by a user). In some embodiments, the incremental step size of a stimulation parameter setting is pre-determined (e.g. stored in memory of a component of apparatus 10). In some embodiments, apparatus 10 comprises a pre-determined incremental step size for one or more stimulation parameter settings, and a calculated (e.g. by algorithm 15 as described herein) incremental step size for one or more stimulation parameter settings.

[0324] In some embodiments, apparatus 10 is configured to provide a "**rounding function**" when an entered value is mathematically rounded to the next level of a pre-determined increment (e.g. when 1.05 is rounded to 1.10 when an increment of 0.1 is in place). Apparatus 10 can be

configured to provide (e.g. allow) a particular number of areas to receive stimulation energy (e.g. as set, changed, and/or viewed by icon 6801), such as to have a minimum of 1 area and a maximum of 16 areas (e.g. while also providing an increment step size of 1). Apparatus 10 can be configured to provide (e.g. allow) a pulse width of stimulation energy delivery (e.g. as set, changed, and/or viewed by icon 6802) that is constrained to a minimum duration and/or a maximum duration, such as a minimum of 1μsec and a maximum of 2msec (e.g. while also providing an increment step size of 1μsec). Apparatus 10 can be configured to provide (e.g. allow) an amplitude of stimulation energy delivery (e.g. as set, changed, and/or viewed by icon 6803) that is constrained to a minimum and/or a maximum level, such as a minimum of 1μA and a maximum of 24mA (e.g. while also providing an increment step size of 10μA). Apparatus 10 can be configured to provide (e.g. allow) a rate of stimulation energy delivery (e.g. as set, changed, and/or viewed by icon 6804) that is constrained to a minimum and/or a maximum rate, such as a minimum of 1Hz and a maximum of 100kHz (e.g. while also providing an increment step size of 1Hz). Apparatus 10 can be configured to provide (e.g. allow) the D_{ON} and/or D_{OFF} periods (e.g. as set, changed, and/or viewed by icon 6806) that is constrained to a minimum and/or a maximum time period, such as a minimum of 100μsec and a maximum of 2sec (e.g. while also providing an increment step size of 10μsec).

[0325] In some embodiments, apparatus 10 (e.g. algorithm 15) is configured to provide one or more stimulation waveforms that include a combination of active and passive charge recovery, such as to provide the stimulation energy defined by user interface 680 in a safe, effective, reliable, and/or efficient manner. A stimulation waveform that includes a combination of both active and passive charge recovery can provide numerous advantages, such as when a stimulation waveform utilizes passive recovery for energy efficiency, and active recovery when passive recovery is not possible or otherwise is not practical (e.g. when the time available is not practical for passive charge recovery). In some embodiments, at least a portion of the overall charge recovery includes active charge recovery that is implemented when multiple areas of stimulation are provided. For example, active charge recovery can be utilized on some of the stimulated areas (e.g. one or more tissue locations receiving stimulation energy without enough time to complete passive recovery), while other stimulation areas utilize passive charge recovery. Each stimulated area can independently receive active recovery, passive recovery, or both, such as to achieve zero net charge in each area independently. A mix (i.e. a combination) of active and passive charge recovery can be performed over multiple tissue locations (e.g. multiple neighboring tissue locations) such that the overall cumulative charge over the multiple locations

is balanced (e.g. zero net charge is achieved over the collective areas without necessarily achieving zero charge in each area independently).

[0326] **Referring now to Figs. 2A-B**, a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 2A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 400μsec for each of Areas 0 thru 3 as selected via input icon 6802 as shown; an amplitude of 2000μA for each of Areas 0 thru 3 as selected via input icon 6803 as shown; a rate of 40Hz for each of Areas 0 thru 3 as selected via input icon 6804 as shown; and a form of charge recovery equating to be "Passive" (e.g. charge is recovered for each of Areas 0 thru 3 as selected via input icon 6805 as shown). Note that the set of stimulation parameter settings selected in Fig. 2A did not include a "dosing" configuration, such as that described herebelow in reference to Fig. 3.

[0327] Fig. 2B is a graph of the basic tonic stimulation waveform that results from the particular stimulation parameter settings selected via icons 6801 thru 6805 of Fig. 2A.

[0328] **Referring now to Fig. 3**, a user's view of a user interface for providing stimulation parameter settings is illustrated, consistent with the present inventive concepts. In Fig. 3, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 400μsec for each of Areas 0 thru 3 as selected via input icon 6802 as shown; an amplitude of 2000μA for each of Areas 0 thru 3 as selected via input icon 6803 as shown; a rate of 40Hz for each of Areas 0 thru 3 as selected via input icon 6804 as shown; a form of charge recovery equating to be "Passive" as selected for each of Areas 0 thru 3 as selected via input icon 6805 as shown; and a D_{ON} of 25msec and a D_{OFF} of 0msec for each of Areas 0 thru 3 as selected via input icon 6806 as shown.

[0329] **Referring now to Figs. 4A-B**, a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 4A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 1000μsec for each of Areas 0 thru 3 as selected via input icon 6802 as shown; an amplitude of 1000μA, 2000μA, 250μA, and 500μA for Areas 0 thru 3, respectively, as selected via input icon 6803 as shown; a rate of 40Hz

for each of Areas 0 thru 3 as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active" as selected for each of Areas 0 thru 3 as selected via input icon 6805 as shown; and a D_{ON} of 25msec and a D_{OFF} of 0msec for each of Areas 0 thru 3 as selected via input icon 6806 as shown.

[0330] Fig. 4B is a graph of a stimulation waveform including active charge recovery that results from the particular stimulation parameter settings selected via icons 6801 thru 6806 of Fig. 4A.

[0331] **Referring now to Fig. 5**, a graphical view of a stimulation waveform is illustrated, consistent with the present inventive concepts. In some embodiments, implantable device 200 comprises multiple current sources, such as four current sources comprising digital-to-analog converters (DACs). Implantable device 200 can further comprise multiple reconfigurable stimulation blocks (RSBs), each of which includes a DAC. The RSBs can be configured to be turned on and off at different times. Implantable device 200 can be configured (e.g. via algorithm 15) to perform passive charge recovery in a way that reduces the memory requirements of implantable device 200 (e.g. by performing selective charge recovery). In some embodiments, apparatus 10 is configured to perform charge recovery between all or at least a majority (e.g. at least 50%, 60%, or 70%) of the delivered stimulation pulses. In these configurations, algorithm 15 can included an additional statement (e.g. in memory) to implement the charge recovery. Depending on the amount of charge delivered on each pulse, apparatus 10 may not (e.g. it may not be necessary to) perform charge recovery on each stimulation element 260 in all the intervals between pulses (e.g. there may be sufficient time between groups of two or more pulses, or only some of the intervals will need to be used for charge recovery). In these configurations, memory requirements of apparatus 10 (e.g. memory requirements of implantable device 200) are reduced, without adversely affecting charge recovery. In the embodiment shown in Fig. 5, four RSBs, RSB0, RSB1, RSB2, and RSB3 are utilized to deliver stimulation current and perform charge recovery for an implantable device 200. In a first time interval, a drive pulse is delivered from RSB3, and charge recovery for only RSB3 is performed. In a second time interval, a drive pulse is delivered from RSB2, and charge recovery for only RSB2 is performed. In a third time interval, a drive pulse is delivered from RSB1, and charge recovery for all RSBs is performed. In a fourth time period, a drive pulse is delivered from RSB0, and charge recovery for all RSBs is performed. The various configurations of which RSBs deliver current, and from which RSB charge recovery is performed, can be determined in order to reduce memory requirements of implantable device 200.

[0332] **Referring now to Figs. 6A-B**, a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 6A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 30μsec for each of Areas 0 thru 3 as selected via input icon 6802 as shown; an amplitude of 2000μA for each of Areas 0 thru 3 as selected via input icon 6803 as shown; a rate of 1000Hz, 1000Hz, 40Hz, and 40Hz, for Areas 0 thru 3, respectively, as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active" as selected for each of Areas 0 thru 3 as selected via input icon 6805 as shown; and a D_{ON} of 1msec and a D_{OFF} of 0msec, a D_{ON} on of 1msec and a D_{OFF} of 0msec, a D_{ON} of 25msec and a D_{OFF} of 0msec, and a D_{ON} of 25msec and D_{OFF} of 0msec, for Areas 0 thru 3, respectively, as selected via input icon 6806 as shown.

[0333] Fig. 6B is a graph of a stimulation waveform including active charge recovery that results from the particular stimulation parameter settings selected via icons 6801 thru 6806 of Fig. 6A. The stimulation waveform defined by user interface 680 and shown in Fig. 6B is limited to two rates (e.g. 40Hz and 1000Hz as shown via icon 6804). In some embodiments, more than two rates are used. In some embodiments, each area has a unique rate.

[0334] **Referring now to Figs. 7A-B**, graphical views of two stimulation waveforms are illustrated, consistent with the present inventive concepts. These waveforms include complex and/or arbitrary rate combinations using a greatest common divisor (GCD) scheme (e.g. as implemented in an "N of M" scheme). For example, apparatus 10 can be configured to deliver multiple rate stimulation where the high rate is accurately generated (e.g. as per the programming) while the low rate is generated using an "N of M" scheme in which the lower rate is effectively achieved over a period of time equating to M high rate intervals (i.e. the average rate of pulses over M high rate intervals approximates the desired lower rate). Referring additionally to Fig. 8A, a stimulation waveform delivered by apparatus 10 comprises a first pulse rate of 1000Hz (represented by thick line segments) in area 0, and a lower pulse rate of 750Hz (also represented by thick line segments) in area 1. Using an N of M scheme, the lower rate of area 1 can be effectively generated by delivering 3 out of 4 pulses (N = 3, M = 4) of the higher rate. When dosing is applied to such a waveform, the D_{ON} time made available (e.g. provided by apparatus 10 via user interface 680) is constrained such that the dosed output effectively retains the desired (e.g. underlying) pulse rate. For example, for the higher rate of area 0, this constraint correlates to a minimum of 2 pulses occurring during the D_{ON} duration. For the lower rate of

area 1, this constraint correlates to a minimum of two "average intervals" (i.e. wherein an average interval equates to M high rate intervals) occurring during the D_{ON} duration. In Fig. 8B, the pulse pattern prior to dosing is illustrated by the thick line segments, while the dosing envelope (minimum D_{ON} durations) is illustrated by the thin line segments. Fig. 8C illustrates the pulse pattern (thick line segments) that results after the dosing illustrated in Fig. 8B is applied. Note that for this example, in the lower rate of area 1, the 3-1-3 pattern is preserved after dosing. The D_{OFF} duration, similarly, is restricted to be 1 pulse duration for the high rate area, and 1 "average interval" (i.e. equal to M) for the lower rate area. In some embodiments, dosed envelopes are time-shifted (per area receiving stimulation) such that they are non-overlapping in time, as shown and described herein in reference to Figs. 10A-D. In some embodiments, the time-separation between envelopes is maximized, also as shown and described herein in reference to Figs. 10A-D.

[0335] **Referring now to Figs. 9A-D**, a user's view of a user interface for providing stimulation parameter settings and three graphical views of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 9A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 100μsec, 100μsec, 50μsec, and 50μsec, for Areas 0 thru 3, respectively, as selected via input icon 6802 as shown; an amplitude of 1000μA, 2000μA, 250μA, and 500μA, respectively, for Areas 0 thru 3, respectively, as selected via input icon 6803 as shown; a rate of 1000Hz, 1000Hz, 40Hz, and 40Hz, for Areas 0 thru 3, respectively, as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active", "Active", "Passive", and "Passive", for Areas 0 thru 3, respectively, as selected via input icon 6805 as shown; and a D_{ON} of 20msec and a D_{OFF} of 80msec, a D_{ON} of 20msec and a D_{OFF} of 80msec, a D_{ON} of 100msec and a D_{OFF} of 100msec, and a D_{ON} of 100msec and D_{OFF} of 100msec, for Areas 0 thru 3, respectively, as selected via input icon 6806 as shown.

[0336] Fig. 9B is a graph of the stimulation waveform that results from the settings shown in Fig. 9A. Figs. 9C-D illustrate magnified portions of the waveform of Fig. 9B. Fig. 9D illustrates the organization of pulses within a stimulation interval, and the advantages (e.g. flexibility) provided by combining active and passive charge recovery.

[0337] **Referring now to Figs. 10A-D**, a user's view of a user interface for providing stimulation parameter settings and three graphical views of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In some

embodiments, apparatus 10 (e.g. algorithm 15) is configured to tend to avoid (e.g. includes a bias to avoid) overlapping of stimulation pulses, such as to reduce power requirements (e.g. reduce peak power requirements by temporally spreading the stimulation load) of implantable device 200 and/or the transfer of energy between external device 500 and implantable device 200. In some embodiments, algorithm 15 is configured to provide stimulation waveforms that avoid overlapping of stimulation pulses to create an average load condition for the stimulation circuitry of implantable device 200 that remains relatively constant. In Fig. 10A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 30μsec for each of Areas 0 thru 3 as selected via input icon 6802 as shown; an amplitude of 2000μA for each of Areas 0 thru 3 as selected via input icon 6803 as shown; a rate of 1000Hz, 1000Hz, 500Hz, and 500Hz, for Areas 0 thru 3, respectively, as selected via input icon 6804 as shown; a form of charge recovery equating to be "Passive" as selected for each of Areas 0 thru 3 as selected via input icon 6805 as shown; and a D_{ON} of 20msec and a D_{OFF} off of 80msec, a D_{ON} of 20msec and a D_{OFF} of 80msec, a D_{ON} of 40msec and a D_{OFF} of 60msec, and a D_{ON} of 40msec and D_{OFF} of 60msec, for Areas 0 thru 3, respectively, as selected via input icon 6806 as shown.

[0338] Fig. 10B is a graph of the stimulation waveform that results from the settings shown in Fig. 10A. Figs. 10C-D illustrate magnified portions of the waveform of Fig. 10B, including the non-overlapping nature of the stimulation waveform (e.g. non-overlapping "**ensemble**" of pulses). In some embodiments (e.g. for certain sets of stimulation parameter settings), avoiding overlapping stimulation is not possible, or at least non-practical. In these embodiments, apparatus 10 (e.g. algorithm 15) can be configured to minimize the amount of overlap encountered in the delivery of the stimulation energy to the patient.

[0339] **Referring now to Figs. 11A-B**, graphs of stimulation waveforms are illustrated, consistent with the present inventive concepts. The stimulation waveforms of Fig. 11A-B include no dosing requirement, in other words, apparatus 10 is providing a therapy in which stimulation is always on (e.g. stimulation energy is continuously delivered). Four areas are stimulated as follows: a first area receives stimulation at 1454Hz and undergoes "Active" recovery, and three separate areas receive stimulation at 95Hz and each undergo "Passive" recovery. Apparatus 10 can implement a combination of active and passive recovery to achieve numerous advantages, such as a reduced power consumption.

[0340] **Referring now to Figs. 12A-B**, graphs of stimulation waveforms are illustrated, consistent with the present inventive concepts. The stimulation waveforms of Figs. 12A-B include no dosing requirement, in other words, apparatus 10 is providing a therapy in which stimulation is always on (e.g. stimulation energy is continuously delivered). Four areas are stimulated as follows: a first area receives stimulation at 1500Hz and undergoes "Active" recovery, and three separate areas receive stimulation at 2Hz and each undergo "Passive" recovery.

[0341] **Referring now to Figs. 13A-C**, a user's view of a user interface for providing stimulation parameter settings and two graphical views of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 13A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 30μsec for each of Areas 0 thru 3 as selected via input icon 6802 as shown; an amplitude of 2000μA for each of Areas 0 thru 3 as selected via input icon 6803 as shown; a rate of 1500Hz, 2Hz, 2Hz, and 2Hz, for Areas 0 thru 3, respectively, as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active", "Passive", "Passive", and "Passive", for Areas 0 thru 3, respectively, as selected via input icon 6805 as shown; and a D_{ON} of 5.33msec and a D_{OFF} of 994.67msec, a D_{ON} of 500msec and a D_{OFF} of 0msec, a D_{ON} of 500msec and a D_{OFF} of 0msec, and a D_{ON} of 500msec and D_{OFF} of 0msec, for Areas 0 thru 3, respectively, as selected via input icon 6806 as shown. In some embodiments, apparatus 10 can be configured to "snap" one or more settings (e.g. round to a pre-determined interval), such as is described in reference to Figs. 15A-C herein. For example, the D_{ON} and/or D_{OFF} settings of user interface 680 of Fig. 13A can comprise values that resulted from a slightly different entry by a user, after a rounding algorithm (e.g. as described herein) has been performed by apparatus 10 (e.g. via algorithm 15).

[0342] Figs. 13B-C are graphs of the stimulation waveform generated by the stimulation parameter settings shown in Fig. 13A.

[0343] **Referring now to Figs. 14A-C**, a user's view of a user interface for providing stimulation parameter settings and two graphical views of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 14A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 400μsec, 400μsec, 1000μsec, and 1000μsec, for Areas 0 thru 3, respectively, as selected via input icon 6802 as

shown; an amplitude of 500μA, 500μA, 2000μA, and 2000μA for Areas 0 thru 3, respectively, as selected via input icon 6803 as shown; a rate of 100Hz, 100Hz, 30Hz, and 30Hz, for Areas 0 thru 3, respectively, as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active", "Active", "Passive", and "Passive", for Areas 0 thru 3, respectively, as selected via input icon 6805 as shown; and a D_{ON} of 50msec and a D_{OFF} of 50msec, a D_{ON} of 50msec and a D_{OFF} of 50msec, a D_{ON} of 300msec and a D_{OFF} of 300msec, and a D_{ON} of 300msec and D_{OFF} of 300msec, for Areas 0 thru 3, respectively, as selected via input icon 6806 as shown.

[0344] Figs. 14B-C are graphs of the stimulation waveform generated by the stimulation parameter settings shown in Fig. 14A

[0345] **Referring now to Figs. 15A-C**, two user's views of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown in Fig. 15B, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 15A, a user has selected a set of stimulation parameters via user interface 680 to create a stimulation paradigm SP, the set of selected parameters comprising: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 400μsec, 400μsec, 1000μsec, and 1000μsec, for Areas 0 thru 3, respectively, as selected via input icon 6802 as shown; an amplitude of 500μA, 500μA, 2000μA, and 2000μA for Areas 0 thru 3, respectively, as selected via input icon 6803 as shown; a rate of 84Hz, 84Hz, 31Hz, and 31Hz, for Areas 0 thru 3, respectively, as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active", "Active", "Passive", and "Passive", for Areas 0 thru 3, respectively, as selected via input icon 6805 as shown; and a D_{ON} of 50msec and a D_{OFF} of 50msec, a D_{ON} of 50msec and a D_{OFF} of 50msec, a D_{ON} of 300msec and a D_{OFF} of 300msec, and a D_{ON} of 300msec and D_{OFF} of 300msec, for Areas 0 thru 3, respectively, as selected via input icon 6806 as shown. Apparatus 10 can be configured to cause one or more entered stimulation parameter settings to be automatically modified (e.g. adjusted by algorithm 15 using a rounding function as described herein), such as an adjustment in which settings are "**snapped**" to a closest incremental amount (e.g. to an incremental step value that is calculated by algorithm 15 and/or pre-determined, each as described herein). For example, the settings selected as shown in Fig. 15A, can be automatically adjusted to the settings shown in Fig. 15B as follows: The stimulation rates selected via icon 6804 are changed, respectively, from 84Hz, 84Hz, 31Hz, and 31Hz (for Areas 0 thru 3, respectively), to 85Hz, 85Hz, 30Hz, and 30Hz (for Areas 0 thru 3, respectively). Also, the D_{ON} and D_{OFF} variables are changed, respectively, from D_{ON} of 50msec and a D_{OFF} of 50msec, a D_{ON} of 50msec and a D_{OFF} of 50msec, a D_{ON} of 300msec and a D_{OFF} of 300msec, and a D_{ON} of 300msec and D_{OFF} of 300msec (for Areas 0 thru

3, respectively), to D_{ON} of 105.88msec and a D_{OFF} of 94.12msec, a D_{ON} of 105.88msec and a D_{OFF} of 94.12msec, a D_{ON} of 400msec and a D_{OFF} of 200msec, and a D_{ON} of 400msec and D_{OFF} of 200msec (for Areas 0 thru 3, respectively). For example, the change to D_{ON} ensures that at least 2 pulses are provided in each area, and ensures that the dosing is applied in all areas in a manner that approximates the original settings entered by the user, prior to the adjustment performed by apparatus 10.

[0346] Fig. 15C is a graph of the stimulation waveform that results from the settings shown in Fig. 15B (after the automatic changes to the settings selected and shown in Fig. 15A that are made by algorithm 15).

[0347] **Referring now to Figs. 16A-C**, a user's view of a user interface for providing stimulation parameter settings and two graphical views of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 16A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: four stimulation areas (Area0, Area1, Area2, and Area3) to receive stimulation energy, as selected via input icon 6801 as shown; a pulse width of 55µsec, 55µsec, 110µsec, and 110µsec, for Areas 0 thru 3, respectively, as selected via input icon 6802 as shown; an amplitude of 500µA, 500µA, 2000µA, and 2000µA for Areas 0 thru 3, respectively, as selected via input icon 6803 as shown; a rate of 1500Hz for each of Areas 0 thru 3 as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active", "Active", "Passive", and "Passive", for Areas 0 thru 3, respectively, as selected via input icon 6805 as shown; and a D_{ON} of 0.67msec and a D_{OFF} of 0msec for each of Areas 0 thru 3 as selected via input icon 6806 as shown.

[0348] Figs. 16B-C are graphs of the stimulation waveform generated by the stimulation parameter settings shown in Fig. 16A. The waveform utilizes "**distributed charge recovery**" (e.g. a complex mixture of active and passive charge recovery to optimize performance). Algorithm 15 can include one or more optimization algorithms configured to "opportunistically" perform charge recovery (e.g. passive and/or active charge recovery) between stimulation pulses. This distributed charge recovery configuration provides an optimized charge recovery that expands the viable range of charge delivery (e.g. by having a larger total recovery time).

[0349] **Referring now to Figs. 17A-B**, a user's view of a user interface for providing stimulation parameter settings and a graphical view of a waveform created by the settings shown, respectively, are illustrated, consistent with the present inventive concepts. In Fig. 17A, a set of stimulation parameters has been selected via user interface 680 to create a stimulation paradigm SP representing: two stimulation areas (Area0 and Area1) to receive stimulation energy, as

selected via input icon 6801 as shown; a pulse width of 110msec for each of Areas 0 thru 1 as selected via input icon 6802 as shown; an amplitude of 500μA for each of Areas 0 thru 1 as selected via input icon 6803 as shown; a rate of 1500Hz for each of Areas 0 thru 1 as selected via input icon 6804 as shown; a form of charge recovery equating to be "Active" as selected for each of Areas 0 thru 1 as selected via input icon 6805 as shown; and a D_{ON} of 0.67msec and a D_{OFF} of 0msec for each of Areas 0 thru 1 as selected via input icon 6806 as shown.

[0350] Fig. 17B is a graph of the stimulation waveform that results from the settings shown in Fig. 17A, including two 1500Hz waveforms utilizing active recovery.

[0351] **Referring now to Fig. 18A**, a graph of a stimulation waveform is illustrated, consistent with the present inventive concepts. Fig. 18B illustrates a stimulation waveform, as well as a magnified view of a portion of that waveform, as shown. In some embodiments, apparatus 10 is configured, via stimulation elements 260 of one or more leads 265 to provide one or more of the stimulation waveforms illustrated in Figs. 18A-B, each waveform comprising an extended pulse width configured to cause priming and hyper-polarizing effects. A background **"pre-pulse"** (a low amplitude pulse that precedes a stimulation pulse) can be used to prime and/or hyperpolarize neurons or other types of cells (e.g. glial cells). Neurons have their own spontaneous firing patterns that when observed appear to be a stochastic phenomenon. The waveforms of Figs. 18A-B induce such effects by providing a continuous "**background stimulation**" comprising low level stimulation (e.g. one or more background pre-pulses as shown).

[0352] The waveform shown in Fig. 18A includes a train comprising a first pulse and a second pulse. The second pulse of the train is **"extended"**, thereby effectively making the pulse width significantly larger. The pulse is shown to extend for a certain limited duration, but it can also **"extend"** all the way to the next pulse. In some embodiments, a zero level is present between the first pulse and the second pulse, or it is at a non-zero, but background level. In some embodiments, a zero level (or a background level) is present during a train off period. A limit on the pulse width can be included (e.g. required via algorithm 15) such as to cause the resultant stimulation to remain within one or more safe stimulation charge limits (e.g. charge per phase, charge density, current density, and the like). Apparatus 10 can be configured in a **"persistent pre-pulse connected"** mode, in which every pulse in a train is connected via a background stimulation pulse in this manner, effectively generating an ultra-long pulse width signal. Alternatively or additionally, one or more trains can be similarly provided as being persistent pre-pulse-connected to a subsequent train. For example, a stimulation waveform comprising a combination of one or more persistent pre-pulse-connected pulses and one or more persistent pre-pulse-connected trains can be provided by apparatus 10.

[0353] In Fig. 18B, an alternative (more complex) waveform is illustrated, including implementation of background stimulation. Apparatus 10 can be configured to include background pulses that are delivered between pulses of a train, between trains, and/or between bursts.

[0354] In some embodiments, one or more bursts can be persistent pre-pulse-connected to a subsequent burst (e.g. all or some of the bursts). In these embodiments, the charge balancing can occur between pulses, between trains, or in some combination of both of these.

[0355] The amplitude of these background pulses can be set to a fraction of the main pulse amplitude, and/or to a pre-determined amplitude, such as an amplitude that is based on physiological consideration (e.g. based on a strength-duration curve) and/or an amplitude that is determined using patient feedback (paresthesia).

[0356] **Referring now to Figs. 19A-B**, schematic views of a trialing interface device with two different connecting assemblies is illustrated, consistent with the present inventive concepts. Apparatus 10 can include trialing interface 80 and/or trialing interface 90, as described herein in reference to Fig. 1, and each of these can be connected to one or more leads 265 via a connecting assembly, such as connecting assemblies 800 and 800' shown in Figs. 19A and 19B, respectively. Connecting assemblies 800 and/or 800' can comprise an assembly that is provided in a sterile condition. In some embodiments, connecting assembly 800 and/or 800' can be configured to be sterilized (e.g. re-sterilized), such as to be used in a second trialing procedure (e.g. on the same or a different patient). Connecting assemblies 800 and 800' comprise one or more connectors, as described herebelow, for allowing attachment and/or detachment of one portion to another, such as male-female connectors, HDMI-type mating connecting components, and the like. In Fig. 19A, connecting assembly 800 comprises a housing, housing 810 shown, which can include an attachment element, receptacle 811, for electrically attaching to trialing interface 80 via a mating connector, plug 802, and a conduit (e.g. a flexible conduit) including one or more wires or other conductors, conduit 801 (e.g. when interface 80 includes conduit 801 with attached plug 802 in an attachable or pre-attached arrangement). Conduit 801 can comprise a length of at least 5cm, such as length of between 5cm and 100cm. Housing 810 can further comprise one, two, three, or more additional attachment elements, such as connectors 812a and 812b shown (singly or collectively connector 812). Each connector 812 is configured to operably (e.g. at least electrically) attach to one or more leads 265 (not shown, but each lead 265 comprising one or more stimulation elements 260 as described herein), such that trialing interface 80 can deliver stimulation energy through connecting assembly 800 and to the patient during a trialing procedure, as described herein. Housing 810 and/or another component of

connecting assembly 800 can include one or more elements that are configured to reduce the likelihood of infection, such as an element selected from the group consisting of: anti-infective coating; anti-infective agent delivery assembly; and combinations thereof, such as is described herein in reference to Figs. 22A-C.

[0357] Referring now to Fig. 19B, connecting assembly 800' can include all the components of connecting assembly 800 of Fig. 19A (as shown), and it can also include an extension assembly, assembly 820, which is configured to allow additional physical separation between trialing interface 80 and leads 265 during a trialing procedure. Extension assembly 820 can comprise a length of at least 10cm, such as a length of between 10cm and 200cm. Extension assembly 820 can comprise a conduit, conduit 822, which includes an attachment element on each end, receptacle 821 and plug 823, each as shown. Receptacle 821 is configured to operably attach to plug 802, and plug 823 is configured to operably attach to receptacle 811, such that trialing interface 80 can deliver stimulation energy through connecting assembly 800 (including extension 820) and to the patient during a trialing procedure, as described herein.

[0358] **Referring now to Fig. 20**, a user's view of a user interface is illustrated, consistent with the present inventive concepts. A user interface 680 of apparatus 10 can be configured to allow a user (e.g. a clinician of the patient) to schedule apparatus 10 to perform certain procedures (e.g. the delivery of stimulation energy via one or more stimulation paradigms SP) per a time schedule. Alternatively or additionally, the user interface 680 can be configured to simply provide the schedule to a user (e.g. to provide the schedule to a first user such as the patient, while allowing entry and/or adjustment of the schedule by a second user such as the patient's clinician). In Fig. 20, user interface 680 is displaying scheduling information of stimulation therapy to be provided by apparatus 10. The displayed information (e.g. information that can be simply displayed or also adjusted) can include stimulation mode information; duration of stimulation (e.g. seconds, minutes, hours, or days); a name or other identifier for a particular stimulation paradigm ID; the location (e.g. tissue location) to which stimulation energy is to be delivered; and the like. In some embodiments, a list of multiple sets of stimulation parameter settings can be delivered in a fixed order and/or a random order. In some embodiments, user interface 680 is configured to provide information (e.g. adjustable information) related to periods of time in which no stimulation energy is provided.

[0359] In some embodiments, user interface 680 is configured to provide sets of stimulation parameter settings (e.g. sets of stimulation paradigms SP) that are included (e.g. provided) in a current time schedule, as well as other sets of stimulation parameter settings that are available to be activated manually (e.g. stimulation energy per those parameters that otherwise will not be

delivered). The sets of stimulation parameter settings in the current schedule can also be activated manually (e.g. used at a different time than in the current schedule).

[0360] In some embodiments, apparatus 10 (e.g. via user interface 680) is configured to record a satisfaction level to be associated with a particular stimulation paradigm SP (e.g. a stimulation paradigm SP currently being delivered to the patient). For example, the patient can record that a particular stimulation paradigm is providing a desired level of therapy (e.g. pain relief), in other words is "liked", while another stimulation paradigm SP is not sufficiently efficacious, in other words is "disliked". Apparatus 10 can be configured to automatically adjust the schedule of future therapy based on this patient satisfaction feedback provided (e.g. include in the upcoming schedule a stimulation paradigm SP not previously included and/or increase the duration of a stimulation paradigm SP already in the schedule).

[0361] **Referring now to Figs. 21A-E**, a series of side sectional views of connection arrangements between an implantable device connector and an implantable lead is illustrated, consistent with the present inventive concepts. Apparatus 10 can include one or more connecting assemblies, such as for connecting a lead 265 comprising four or eight stimulation elements 260 (e.g. electrodes), to another component, such as for connecting a lead 265 to a trialing interface 80 to be used in a trialing procedure (e.g. a procedure in which lead 265 is connected to an external stimulator for a limited period of time, typically less than or equal to four weeks, two weeks, and/or 1 week). Figs. 21A-E show different configurations of connecting assembly 800, assemblies 8001, 8002, 8003, 8004, and 8005 shown, respectively. In some embodiments, assembly 800 of Figs. 21A-E is of similar construction and arrangement to connecting assembly 800 of Figs. 19A-B described herein.

[0362] Each connecting assembly 800 of Figs. 21A-E can comprise an assembly that is provided in a sterile condition. In some embodiments, connecting assembly 800 can be configured to be sterilized (e.g. re-sterilized), such as to be used in a second trialing procedure (e.g. on the same or a different patient). Connecting assembly 800 can comprise one or more connectors, as described herebelow, for allowing attachment and/or detachment of one portion to another, such as male-female connectors, HDMI-type mating connecting components, and the like. Each connecting assembly 800 can comprise a housing, housing 810 shown, which can include an attachment element, receptacle 811, for electrically attaching to trialing interface 80 via a mating connector, plug 802, and a conduit (e.g. a flexible conduit) including one or more wires or other conductors, conduit 801 (e.g. when interface 80 includes conduit 801 with attached plug 802 in an attachable or pre-attached arrangement). Conduit 801 can comprise a length of at least 5cm, such as length of between 5cm and 100cm. Housing 810 can further

comprise one, two, three, or more additional attachment elements, such as connectors 812a and 812b shown (singly or collectively connector 812). Each connector 812 is configured to operably (e.g. at least electrically) attach to one or more leads 265 as shown, such that trialing interface 80 can deliver stimulation energy through connecting assembly 800 and to the patient (via stimulation elements 260) during a trialing procedure, as described herein. Housing 810 and/or another component of connecting assembly 800 can include one or more elements that are configured to reduce the likelihood of infection, such as an element selected from the group consisting of: anti-infective coating; anti-infective agent delivery assembly; and combinations thereof, such as is described herein in reference to Figs. 22A-C.

[0363] Each lead 265 of Figs. 21A-E includes four stimulation elements 260 on the distal portion of the lead 265. Each lead 265 includes a corresponding four contacts, contacts 267, which are positioned on the proximal portion of lead 265. Each contact 267 is operably connected (e.g. electrically connected) to a separate stimulation element 260 (e.g. via a wire, not shown). Each lead 265 can comprise one or more rigid portions, such as a rigid circumferential band, band 268 (e.g. bands 268a and/or 268b shown, such as a band configured to withstand a clamping force without adverse effect upon lead 265).

[0364] **In Fig. 21A**, connecting assembly 8001 shown is configured to attach to two or more leads 265, such as leads 265a and 265b shown, such as to electrically connect the stimulation elements 260 of each lead 265 to associated stimulation circuitry of trialing interface 80. Leads 265a and 265b shown contain four stimulation elements 260a, and four stimulation elements 260b, respectively. Leads 265a and 265b further include four contacts 267a and four contacts 267b, respectively, that independently connect to the associated stimulation elements 260 of each lead 265 (e.g. via wires not shown). Connecting assembly 8001 of Fig. 21A comprises two connectors 812, where connector 812a comprises four contacts 813a, and connector 812b comprises four contacts 813b. Contacts 813 are positioned in housing 810 at a similar spacing as contacts 267 of lead 265, as shown, such that when the proximal portion of each lead 265 is inserted into the associated connector 812, the four contacts 813 are aligned with and independently connect (e.g. electrically connect) to the four inserted contacts 267.

[0365] Connecting assembly 8001 includes a set screw for each connector 812, such as set screws 814a and 814b shown, where each screw 814 includes threads that are each rotatingly engaged with a threaded hole of housing 810. Each lead 265 comprises band 268 such that when a lead 265 is inserted into a connector 812 (such as lead 265b shown in Fig. 21A), rotation of a set screw 814 causes the set screw 814 to frictionally engage band 268 of the inserted lead 265, fixedly securing the lead 265 in the connector 812 and providing an electrical connection

between the four contacts 813 of assembly 8001 with the four contacts 267 of lead 265 (e.g. such as to provide an independent electrical connection between the stimulation circuitry of trialing interface 80 with each stimulation element 260 of each inserted lead 265).

[0366] **In Fig. 21B**, connecting assembly 8002 shown is configured to attach to two or more leads 265, such as leads 265a and 265b shown, such as to electrically connect the stimulation elements 260 of each lead 265 to associated stimulation circuitry of trialing interface 80. Leads 265a and 265b shown contain four stimulation elements 260a, and four stimulation elements 260b, respectively. Leads 265a and 265b further include four contacts 267a and four contacts 267b, respectively, that independently connect to the associated stimulation elements 260 of each lead 265 (e.g. via wires not shown). Connecting assembly 8002 of Fig. 21B comprises two connectors 812, where connector 812a comprises more than four contacts 813a (e.g. eight contacts 813a as shown), and connector 812b comprises more than four contacts 813b (e.g. eight contacts 813b as shown). Connecting assembly 8002 is configured such that an operator (e.g. a clinician trained in the insertion technique) partially inserts each lead 265 into the associated connector 812, such as an insertion that is determined by positioning a marker, marker 2691 (e.g. markers 2691a and 2691b shown on leads 265a and 265b, respectively). The four contacts 813 closest to the opening of each connector 812 (e.g. the right-most contacts on the page, the "first four" contacts 813) are positioned in housing 810 at a similar spacing as contacts 267 of lead 265, as shown. When each lead 265 is partially inserted into a connector 812, such as by positioning marker 2691 up against or otherwise relative to housing 810, the first four contacts 813 are aligned with and independently connect (e.g. electrically connect) to the four inserted contacts 267. Connecting assembly 8002 is configured to attach to one or more leads 265 comprising four or more stimulation elements, such as a lead 265 including more than four stimulation elements 260 (e.g. eight stimulation elements 260), where the lead 265 is fully inserted into the connector 812, or a lead 265 including four stimulation elements 260, where the lead 265 is partially inserted into the connector 812.

[0367] Similar to connecting assembly 8001, connecting assembly 8002 includes a set screw 814 for each connector 812, for securing the lead 265 within the connector 812 by (e.g. when rotated) frictionally engaging the associated band 268.

[0368] **In Fig. 21C**, connecting assembly 8003 shown is configured to attach to two or more leads 265, such as leads 265a and 265b shown, such as to electrically connect the stimulation elements 260 of each lead 265 to associated stimulation circuitry of trialing interface 80. Leads 265a and 265b shown contain four stimulation elements 260a, and four stimulation elements 260b, respectively. Leads 265a and 265b further include four contacts 267a and four contacts

267b, respectively, that independently connect to the associated stimulation elements 260 of each lead 265 (e.g. via wires not shown). Connecting assembly 8003 of Fig. 21C comprises two connectors 812, where connector 812a comprises more than four contacts 813a (e.g. eight contacts 813a as shown), and connector 812b comprises more than four contacts 813b (e.g. eight contacts 813b as shown). Connecting assembly 8003 is configured such that an operator (e.g. a clinician trained in the insertion technique) fully inserts each lead 265 into the associated connector 812, such as an insertion that is determined by tactile feedback received upon full insertion. The four contacts 813 further from the opening of each connector 812 (e.g. the left-most contacts on the page, the "final four" contacts 813) are positioned in housing 810 at a similar spacing as contacts 267 of lead 265, as shown. When each lead 265 is fully inserted into a connector 812, the final four contacts 813 are aligned with and independently connect (e.g. electrically connect) to the four inserted contacts 267. Connecting assembly 8003 is configured to attach to one or more leads 265 comprising four or more stimulation elements, such as a lead 265 including more than four stimulation elements 260 (e.g. eight stimulation elements 260), where the lead 265 is fully inserted into the connector 812, or a lead 265 including four stimulation elements 260, where the lead 265 is also fully inserted into the connector 812.

[0369] Similar to connecting assembly 8001 and 8002, connecting assembly 8003 includes a set screw 814 for each connector 812, for securing the lead 265 within the connector 812 by (e.g. when rotated) frictionally engaging a band 268. In Fig. 21C, each lead 265 includes one or more bands 268 for engaging a set screw 814. For example, lead 265a includes band 268a' and lead 265b includes band 268b' which are positioned on each lead 265 such as to engage the associated set screw 814 when each lead 265 is fully inserted into a connector 812 (e.g. lead 265b shown fully inserted into connector 812b in Fig. 21C). In some embodiments, a lead 265 can include a second band 268 (e.g. bands 268a'' and 268b'' shown on leads 265a and 265b, respectively), such as to engage a set screw 814 when the lead 265 is partially inserted into a connector 812 (e.g. the partial insertion described hereabove in reference to Fig. 21B).

[0370] **In Fig. 21D**, connecting assembly 8004 shown is configured to attach to two or more leads 265, such as leads 265a and 265b shown, such as to electrically connect the stimulation elements 260 of each lead 265 to associated stimulation circuitry of trialing interface 80. Leads 265a and 265b shown contain four stimulation elements 260a, and four stimulation elements 260b, respectively. Leads 265a and 265b further include four contacts 267a and four contacts 267b, respectively, that independently connect to the associated stimulation elements 260 of each lead 265 (e.g. via wires not shown). Connecting assembly 8004 of Fig. 21D comprises two connectors 812, where connector 812a comprises more than four contacts 813a (e.g. eight

contacts 813a as shown), and connector 812b comprises more than four contacts 813b (e.g. eight contacts 813b as shown). Connecting assembly 8004 is configured such that an operator partially inserts each lead 265 into the associated connector 812, such as an insertion that is determined by an elongate filament or other insertable component that limits the insertion distance of lead 265, filler 2692 (e.g. filler 2692a and 2692b shown within connectors 812a and 812b, respectively). The four contacts 813 closest to the opening of each connector 812 (e.g. the right-most contacts on the page, the "first four" contacts 813) are positioned in housing 810 at a similar spacing as contacts 267 of lead 265, as shown. When each lead 265 is inserted into a connector 812 such that the inserted end of lead 265 makes contact with filler 2692 (e.g. preventing further advancement), filler 2692 comprises a length such that the first four contacts 813 are aligned with and independently connect (e.g. electrically connect) to the four inserted contacts 267. Connecting assembly 8004 can be configured to attach to one or more leads 265 comprising four or more stimulation elements, such as a lead 265 including more than four stimulation elements 260 (e.g. eight stimulation elements 260), where the filler 2692 is removed (e.g. by an operator), and a lead 265 is fully inserted into the connector 812.

[0371] Similar to connecting assembly 8001, 8002, and 8003, connecting assembly 8004 includes a set screw 814 for each connector 812, for securing the lead 265 within the connector 812 by (e.g. when rotated) frictionally engaging a band 268, such as is shown for lead 265b in Fig. 21D.

[0372] **In Fig. 21E**, connecting assembly 8005 shown is configured to attach to two or more leads 265, such as leads 265a and 265b shown, such as to electrically connect the stimulation elements 260 of each lead 265 to associated stimulation circuitry of trialing interface 80. Leads 265a and 265b shown contain four stimulation elements 260a, and four stimulation elements 260b, respectively. Leads 265a and 265b further include four contacts 267a and four contacts 267b, respectively, that independently connect to the associated stimulation elements 260 of each lead 265 (e.g. via wires not shown). Connecting assembly 8005 of Fig. 21E is similar to connecting assembly 8004 of Fig. 21D, where connectors 812 include one or more fillers 2692 as shown. In the embodiment of Fig. 21E, one or more fillers 2692 are provided separately, not inserted into a connector 812, and are configured to be inserted by an operator if desired such as if a lead 265 comprising four contacts 267 (e.g. four stimulation elements 260) is to be inserted into a connector 812 comprising more than four contacts 813.

[0373] **Referring now to Figs. 22A-C**, perspective views of various assemblies for connecting a trialing stimulator to an implanted lead are illustrated, consistent with the present inventive concepts. Apparatus 10 can include one or more connecting assemblies 800, such as for

connecting a lead 265 comprising four or eight stimulation elements, to another component, such as for connecting a lead 265 to a trialing interface 80 to be used in a trialing procedure (e.g. a procedure in which lead 265 is connected to an external stimulator for a limited period of time, typically less than or equal to four weeks, or two weeks). Connecting assemblies 800 include one or more connectors, each for attaching to a lead 265, such as connectors 812a and 812b shown, as well as a connector, receptacle 811 shown, for operably attaching to trialing interface 80, each as described herein. Connecting assemblies 800 of Figs. 22A-C are each configured to reduce likelihood of infection during the use of trialing interface 80 (e.g. reduce the likelihood of infection pathways developing). These connecting assemblies 800 elevate lead 265 above the patient's skin, and/or have an increased surface area (e.g. increased surface area of housing 810) that is in contact with the patient's skin, each of which simplify and improve the ability of an operator (e.g. a nurse or clinician of the patient) to apply sterile tape in an infection-reducing manner.

[0374] **In Fig. 22A**, connecting assembly 800 includes a housing 810 that includes a flange 8101 with a width sufficient to use sterile tape to adhere assembly 800 to the patient's skin, such as sterile tape used to provide a sterile barrier to reduce likelihood of infection. Flange 8101 can extend at least 0.5cm from housing 810, such as an extension of up to 3cm from housing 810.

[0375] **In Fig. 22B**, connecting assembly 800 includes a housing 810 that includes an undercut flange 8102 with a width sufficient to easily use sterile tape to adhere assembly 800 to the patient's skin. Housing 810 comprises a taller height than housing 810 of Fig. 22A, further elevating an attached lead 265.

[0376] **In Fig. 22C**, connecting assembly 800 includes a housing 810 that includes a collapsible envelope, bag 8103, where bag 8103 is configured to be sterile and to surround the other portions 8104 of housing 810 as shown. Bag 8103 includes one or more cutouts 811a, that are sized to closely surround (e.g. elastically surround) receptacle 811, avoiding the need of an operator to carefully tape around receptacle 811.

[0377] **Referring now to Fig. 23**, a schematic view of a charging assembly for an external device 500 is illustrated, consistent with the present inventive concepts. Charging assembly 61 can be configured to upload data from an attached (e.g. attached via a wired or wireless connection) external device 500, such as to allow analysis of the uploaded data (e.g. usage statistics, patient interaction information, and the like). At least a portion of the data that charging assembly 61 uploads from an external device 500 can comprise data that the external device 500 has uploaded from one or more implantable devices 200.

[0378] Charging assembly 61 can be configured to automatically upload data from an external device 500 once the external device is attached to assembly 61 (e.g. attached to charge the external device 500). Charging assembly 61 can be configured to transmit the uploaded data to a remote computer and/or memory storage location, such as a secure cloud (e.g. using an included WiFi module 613 as shown).

[0379] Charging assembly 61 of Fig. 23 can comprise power module 611, BLE module 612, WiFi module 613 (e.g. a WiFi, Cellular, or other communication module), LED drive 614, flash memory 615, real time clock 616, and/or Qi/WPC transmitter 617, each as shown. Qi/WPC TX 617 is configured to wirelessly charge an external device 500. BLE module 612 is configured to establish communication with the external device 500 and extract data from it (e.g. usage information, logging information, error information, and the like), such as information that is stored in flash memory 615. The extracted data can be uploaded to a network storage device (e.g. a secure cloud), such as via WiFi module 613. RTC 616 can include a battery, and it can provide a clock (e.g. a real time clock). In some embodiments, time information is obtained from a network (e.g. the Internet or other network via WiFi module 613). Time information can be used by apparatus 10 in analysis of the data extracted from an external device 500 by charging assembly 61 and/or an analysis of other data collected by apparatus 10.

[0380] **Referring now to Figs. 24A-K**, views of various stimulation waveforms are illustrated, consistent with the present inventive concepts. In some embodiments, apparatus 10 is configured to produce a stimulation paradigm SP that provides a stimulation waveform that includes a **"chirp signal"** whose frequency continuously varies with time, such as the chirp frequency stimulation (**CFS**) waveform shown in Fig. 24A in which the frequency increases over the time window shown. Apparatus 10 can be configured to provide "**chirp stimulation**" in which one or more CFS waveforms (e.g. simultaneously and/or sequentially) are delivered to provide stimulation therapy (e.g. pain relief), such as when delivered as spinal cord stimulation and/or peripheral nerve stimulation. These configurations of waveforms can provide numerous advantages, such as: causing random firing of neurons due to the irregular stimulation pattern, such as to prevent accommodation and/or habituation; varying paresthesia sensation (e.g. if used in a supra-threshold configuration), such as to fine tune the sensation to a patient preference; and/or providing a therapeutic benefit that results from delivering multiple frequencies within the same waveform.

[0381] Referring to Fig. 24B, another CFS waveform of apparatus 10 is illustrated, in which a stimulation pattern repeats (e.g. continuously repeats) after a period of time, T_{CHIRP} as shown. T_{CHIRP} can comprise a time period between 100μsec and 60min, such as a time period between

1msec and100msec, between 500μsec and 5msec, between 100msec and 10sec, between 1sec and 1min, between 1min and 10min; and/or between 10min and 60 min. T_{MAX} and T_{MIN} represent the maximum and minimum, respectively, pulse separations within the chirp. These time durations can represent a range between 1μsec and 1sec, such as a range between 1μsec and 10μsec, between 5μsec and 100μsec, between 50μsec and 500μsec, between 100μsec and 1msec, between 500μsec and 5msec, between 1msec and 100msec, and/or between 10msec and 1sec. The number of pulses within the CFS waveform can be an independent parameter (e.g. a parameter that can be independently configured by apparatus 10 and/or a user of system 10). Apparatus 10 can constrain the number of pulses of the CFS waveform based on other stimulation parameters, such as pulse width, T_{MAX}, T_{MIN}, and/or T_{CHIRP}. In Fig. 24B, the CFS waveform comprises a chirp that increases in frequency over time, in other words the T_{CHIRP} duration decreases over time. Alternatively, apparatus 10 can provide a CFS waveform where the T_{CHIRP} duration increases over time (the chirp frequency decreases over time), as shown in Fig. 24C.

[0382] Apparatus 10 can provide a CFS waveform with various profiles of signal ramping, as shown in the two CFS waveforms of Fig. 24D. The duration and slope of the ramps can be determined by apparatus 10 and/or an operator of apparatus 10. The ramps of the provided CFS waveforms can comprise a sawtooth (as shown on the left) and/or a triangle wave (as shown on the right). Alternatively or additionally, apparatus 10 can provide ramps with sinusoidal, sigmoidal, rectangle, and/or other shape (e.g. an arbitrary and/or random shape). In some embodiments, the slope (e.g. rate) of the ramp is adjustable, as shown in Fig. 24E.

[0383] As apparatus 10 provides a CFS waveform, as described hereabove, the relative intensity of the sensation perceived by the patient over the course of the CFS waveform delivery can be assessed. The sensation of the stimulus depends on the charge delivered in a given period of time. In some embodiments, apparatus 10 can monitor (e.g. limit or otherwise control) the charge delivered in a time period between 10msec and 100msec, such as when apparatus 10 normalizes the charge delivered in sequential time periods between 10msec and 100msec (e.g. to provide similar sensation to the patient in each time period). The associated time period can be greater than 100msec (e.g. depending on T_{CHIRP}). In some embodiments, apparatus 10 (e.g. algorithm 15) takes into account (e.g. automatically adjusts for) pulse width and the paresthesia level experienced by the patient.

[0384] In some embodiments, apparatus 10 does not provide equal sensation throughout the delivery of a CFS waveform, such as when sensation is varied intentionally (e.g. in a low frequency region of the stimulus perhaps a strong sensation is preferred but in a high frequency

region a weaker sensation is preferred). In some embodiments, apparatus 10 provides a stimulation waveform in which the entire waveform is delivered at a sub-threshold level in which sensation may be moot. In other embodiments, a part of the delivered waveform comprises a supra threshold level of stimulation, while other parts comprise a sub-threshold level of stimulation.

[0385] Apparatus 10 can be configured to normalize charge delivery, such as when the time periods shown in Fig. 24F are defined to achieve the normalization. Referring now to Fig. 24G, apparatus 10 can provide normalization via a linear charge approach or one relying on a relationship such as the strength-duration curve. When using the strength-duration relationship, apparatus 10 can sum the pulse widths of all the pulses within a time epoch to determine the corresponding stimulus amplitude. The final stimulus amplitude can then be determined by ratiometrically apportioning the amplitude to each of the constituent pulses. The result of the charge normalization provided by apparatus 10 can result in a stimulation waveform as shown in Fig. 24H. The intensity within the CFS waveform can be set (e.g. automatically by apparatus 10 and/or manually by the patient or other user) in the manner shown in Fig. 24I, where the intensity is ramped up and/or down linearly, parabolically, and/or via a step function (e.g. as previously described, including incorporation of subthreshold and/or suprathreshold stimulation levels).

[0386] Apparatus 10 can provide chirp stimulation with pulses with a common pulse width (e.g. a constant, similar duration pulse width) and/or with pulses with varying pulse width as shown in Fig. 24J.

[0387] The stimulation waveforms shown in Figs. 24I-J do not illustrate charge recovery for illustrative clarity, however apparatus 10 can be configured to provide charge recovery portions of those stimulation waveforms. In some embodiments, apparatus 10 provides a CFS waveform that includes charge recovery, as shown in Fig. 24K. Apparatus 10 can provide charge recovery after each pulse of the chirp, between some pulses of the chirp, and/or at the end of the chirp. Apparatus 10 can provide this charge recovery in an active configuration (as shown in Fig. 24K) and/or in a passive configuration, each as is described herein.

[0388] While the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the present inventive concepts. Modification or combinations of the above-described assemblies, other embodiments, configurations, and methods for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims. In addition, where this application has listed

the steps of a method or procedure in a specific order, it may be possible, or even expedient in certain circumstances, to change the order in which some steps are performed, and it is intended that the particular steps of the method or procedure claim set forth herebelow not be construed as being order-specific unless such order specificity is expressly stated in the claim.

CLAIMS

WHAT IS CLAIMED IS:

1. A stimulation apparatus for a patient, comprising:
an implantable system comprising:
an implantable device for delivering stimulation energy to the patient, comprising:
multiple stimulation delivery elements configured to deliver the stimulation energy to the patient; and
an external system comprising:
an external device comprising a user interface.

2. The apparatus as claimed in at least one of the preceding claims, wherein the apparatus is configured to perform a combination of active charge recovery and passive charge recovery.

3. The apparatus according to claim 2, wherein the stimulation energy is delivered to multiple tissue locations, and the combination of active charge recovery and passive charge recovery is performed over the multiple tissue locations.

4. The apparatus according to claim 3, wherein a net zero charge is achieved collectively over the multiple tissue locations.

5. The apparatus according to claim 2, wherein the apparatus is configured to optimize the combination of active charge recovery and passive charge recovery.

6. The apparatus according to claim 5, wherein the apparatus optimizes based on expanding a viable range of charge delivery.

7. The apparatus as claimed in at least one of the preceding claims, wherein the stimulation energy is delivered as stimulation pulses, and wherein the apparatus is configured to perform a charge recovery between at least 50% of the stimulation pulses.

8. The apparatus according to claim 7, wherein the apparatus is configured to not perform charge recovery between at least one pair of pulses.

9. The apparatus as claimed in at least one of the preceding claims, wherein the apparatus is configured to normalize charge delivery based on defined time periods.

10. The apparatus as claimed in at least one of the preceding claims, further comprising a user interface configured to allow an operator to modify one or more stimulation parameter settings.

11. The apparatus according to claim 10, wherein the apparatus is configured to automatically adjust an operator entered value to a predetermined incremental value proximate the operator entered value.

12. The apparatus according to claim 10, wherein the user interface comprises one or more icons configured to allow an operator to enter one or more stimulation parameter settings.

13. The apparatus according to claim 12, wherein one or more stimulation parameter settings comprise settings for one or more stimulation parameters selected from the group consisting of: number of areas of stimulation; pulse width of stimulation; amplitude of stimulation; rate of stimulation; form of charge recovery; dosage on time; dosage off time; and combinations of these.

14. The apparatus according to claim 12, wherein one or more stimulation parameter settings comprise settings for two or more stimulation parameters selected from the group consisting of: number of areas of stimulation; pulse width of stimulation; amplitude of stimulation; rate of stimulation; form of charge recovery; dosage on time; dosage off time; and combinations of these.

15. The apparatus according to claim 12, wherein one or more stimulation parameter settings comprise settings for three or more stimulation parameters selected from the group consisting of: number of areas of stimulation; pulse width of stimulation; amplitude of stimulation; rate of stimulation; form of charge recovery; dosage on time; dosage off time; and combinations of these.

16. The apparatus according to claim 12, wherein the one or more icons include one or more sets of data input icons configured to receive user input to set a dosage on time and/or a dosage off time for one or more anatomical locations to receive the stimulation energy.

17. The apparatus according to claim 16, wherein two locations receiving stimulation energy are limited to having the same dosage on and/or same dosage off times.

18. The apparatus as claimed in at least one of the preceding claims, wherein the apparatus is configured to deliver the stimulation energy using an N of M scheme.

19. The apparatus as claimed in at least one of the preceding claims, further comprising a controller and a memory coupled to the controller, wherein the memory stores instructions for the controller to perform an algorithm.

20. The apparatus according to claim 19, wherein the algorithm is configured to provide feedback to a user regarding changing a desired passive charge recovery to active charge recovery.

21. The apparatus according to claim 20, wherein the stimulation energy is delivered as stimulation pulses, and wherein the algorithm is configured to provide the feedback when there is insufficient time between stimulation pulses to provide a desired charge recovery.

22. The apparatus as claimed in at least one of the preceding claims, wherein the stimulation energy is delivered as waveforms that comprise complex and/or arbitrary rate combinations using a greatest common divisor (GCD) scheme.

23. The apparatus as claimed in at least one of the preceding claims, wherein the stimulation energy is delivered as dosed envelopes that are time-shifted to be non-overlapping in time.

24. The apparatus according to claim 23, wherein the apparatus is configured to maximize the time separation between envelopes.

25. The apparatus as claimed in at least one of the preceding claims, wherein the stimulation energy is delivered as stimulation pulses, and wherein the apparatus is configured to avoid and/or minimize an overlapping of stimulation pulses.

26. The apparatus according to claim 25, wherein the apparatus avoids overlapping of stimulation pulses in order to achieve: reduced power requirements of the implantable device; reduced transfer of energy between the external device and the implantable device; and/or a relatively constant average load condition for the implantable device.

27. The apparatus as claimed in at least one of the preceding claims, wherein the apparatus is configured to receive a stimulation parameter setting from a user and to adjust the received setting to a closest incremental step value.

28. The apparatus as claimed in at least one of the preceding claims, wherein the stimulation energy delivered comprises a pre-pulse delivered prior to a stimulation pulse that is configured to prime and/or hyperpolarize neurons and/or other cells receiving the stimulation energy.

29. The apparatus as claimed in at least one of the preceding claims, wherein the apparatus is configured to deliver the stimulation energy via a chirp stimulation waveform that includes a chirp signal comprising a frequency that continuously varies with time.

30. The apparatus according to claim 29, wherein the chirp signal frequency increases over time.

31. The apparatus according to claim 29, wherein the chirp signal frequency decreases over time.

32. The apparatus according to claim 29, wherein the chirp stimulation waveform comprises a sawtooth and/or triangle wave.

33. The apparatus according to claim 29, wherein the chirp stimulation waveform comprises a ramp.

34. The apparatus according to claim 33, wherein the ramp has a sinusoidal, sigmoidal, and/or rectangular shape.

35. The apparatus according to claim 33, wherein the ramp has an adjustable slope.

36. The apparatus as claimed in at least one of the preceding claims, wherein the stimulation energy delivered comprises a stimulation waveform that is delivered at a sub-threshold level in its entirety.

37. The apparatus as claimed in at least one of the preceding claims, wherein the stimulation energy delivered comprises a stimulation waveform that is delivered at both a sub-threshold level and a supra threshold level.

38. The apparatus as claimed in at least one of the preceding claims, further comprising a user interface configured to receive stimulation parameter settings from a user, and wherein the stimulation energy is delivered based on the stimulation parameter settings.

39. The apparatus according to claim 38, wherein the stimulation parameter settings comprise energy delivery parameters to be delivered per a time schedule.

40. The apparatus according to claim 39, wherein the time schedule is configured to be adjusted by a user via the user interface.

41. The apparatus according to claim 39, wherein the apparatus is configured to deliver the stimulation energy per the time schedule, manually, or both.

42. The apparatus according to claim 38, wherein the stimulation parameter settings comprise a setting selected from the group consisting of: duration of stimulation; a name or other identifier for a particular set of stimulation parameter settings; the location to which stimulation energy is to be delivered; and combinations thereof.

43. The apparatus according to claim 38, wherein the apparatus is configured to record a satisfaction level associated with the stimulation parameter settings.

44. The apparatus according to claim 43, wherein the apparatus is further configured to adjust future stimulation energy delivery based on the recorded satisfaction level.

45. The apparatus as claimed in at least one of the preceding claims, wherein the implantable device comprises at least one lead comprising the multiple stimulation elements and a connecting assembly configured to operably attach to the at least one lead.

46. The apparatus according to claim 45, wherein the lead comprises a marker positioned to enable a user to partially insert the at least one lead into the connecting assembly.

47. The apparatus according to claim 45, wherein the connecting assembly comprises an elongate component for insertion into the connecting assembly to limit travel of the at least one lead into the connecting assembly.

48. The apparatus as claimed in at least one of the preceding claims, further comprising a charging assembly configured to provide power to the external device and to upload data from the external device.

49. The apparatus according to claim 48, wherein the charging assembly is further configured to transmit the uploaded data to a remote computer and/or memory storage location.

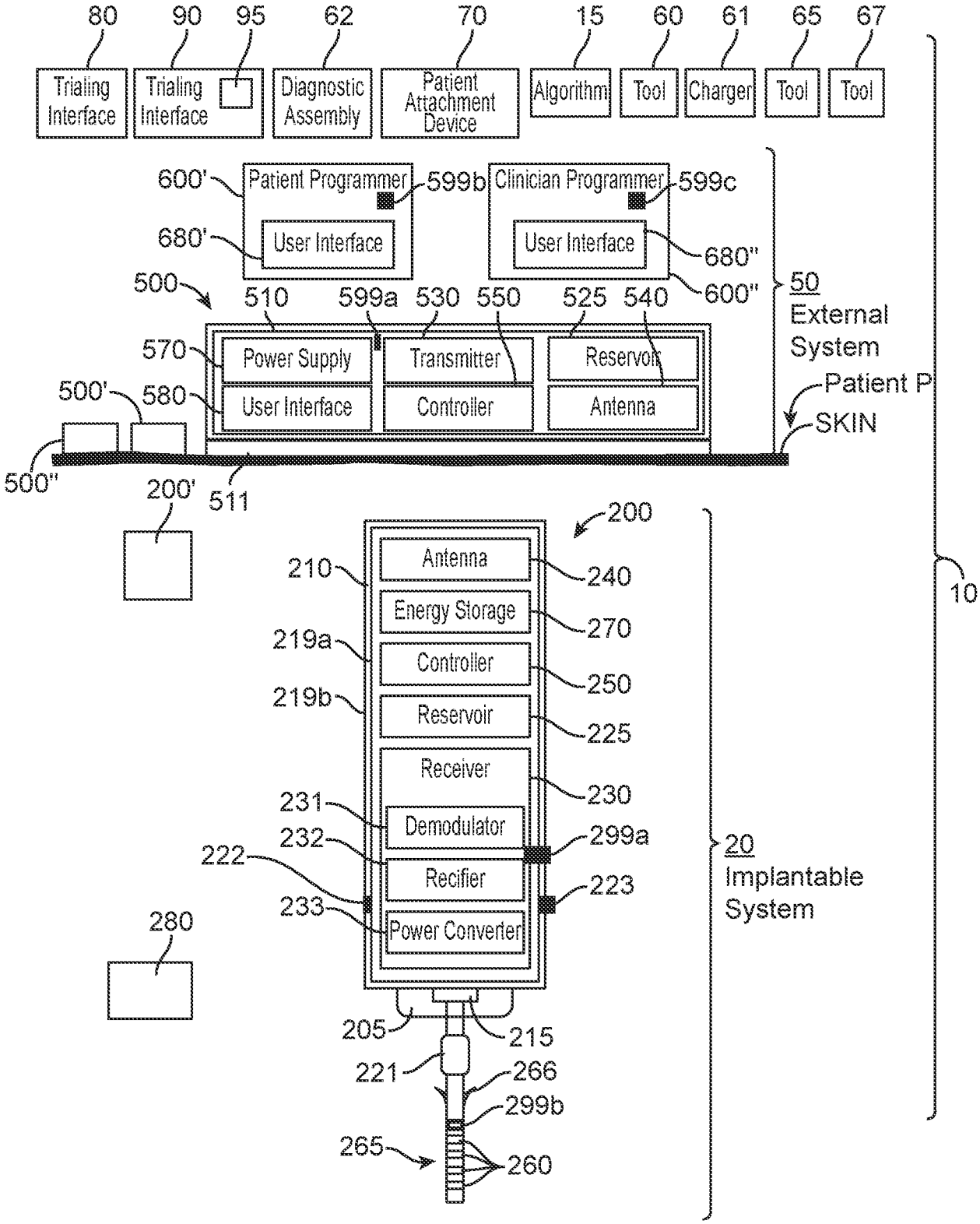

80
90
95
62
70
15
60
61
65
67
Trialing Interface
Trialing Interface
Diagnostic Assembly
Patient Attachment Device
Algorithm
Tool
Charger
Tool
Tool
600'
Patient Programmer
599b
Clinician Programmer
599c
680'
User Interface
User Interface
680"
600"
500
510
599a
530
550
525
540
50
External System
570
Power Supply
Transmitter
Reservoir
Patient P
500'
580
User Interface
Controller
Antenna
SKIN
500"
200'
511
200
210
Antenna
240
Energy Storage
270
219a
Controller
250
219b
Reservoir
225
Receiver
230
231
Demodulator
299a
232
222
Recifier
223
233
Power Converter
280
205
215
221
266
299b
265
260
20
Implantable System
10

FIG. 1

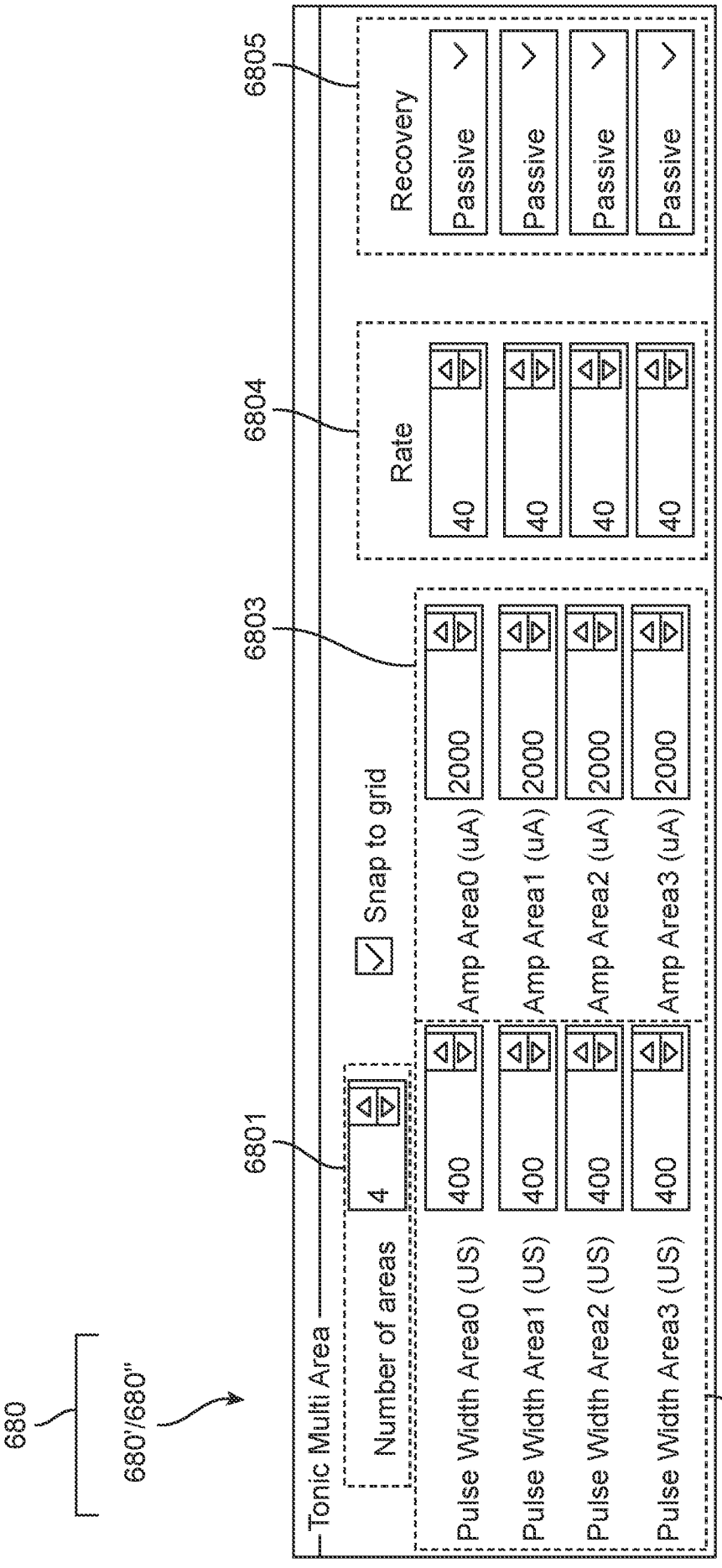

680
680'/680"
Tonic Multi Area
Number of areas
4
6801
Snap to grid
6803
Pulse Width Area0 (US)
400
Amp Area0 (uA)
2000
Pulse Width Area1 (US)
400
Amp Area1 (uA)
2000
Pulse Width Area2 (US)
400
Amp Area2 (uA)
2000
Pulse Width Area3 (US)
400
Amp Area3 (uA)
2000
6802
6804
Rate
40
40
40
40
6805
Recovery
Passive
Passive
Passive
Passive

FIG. 2A

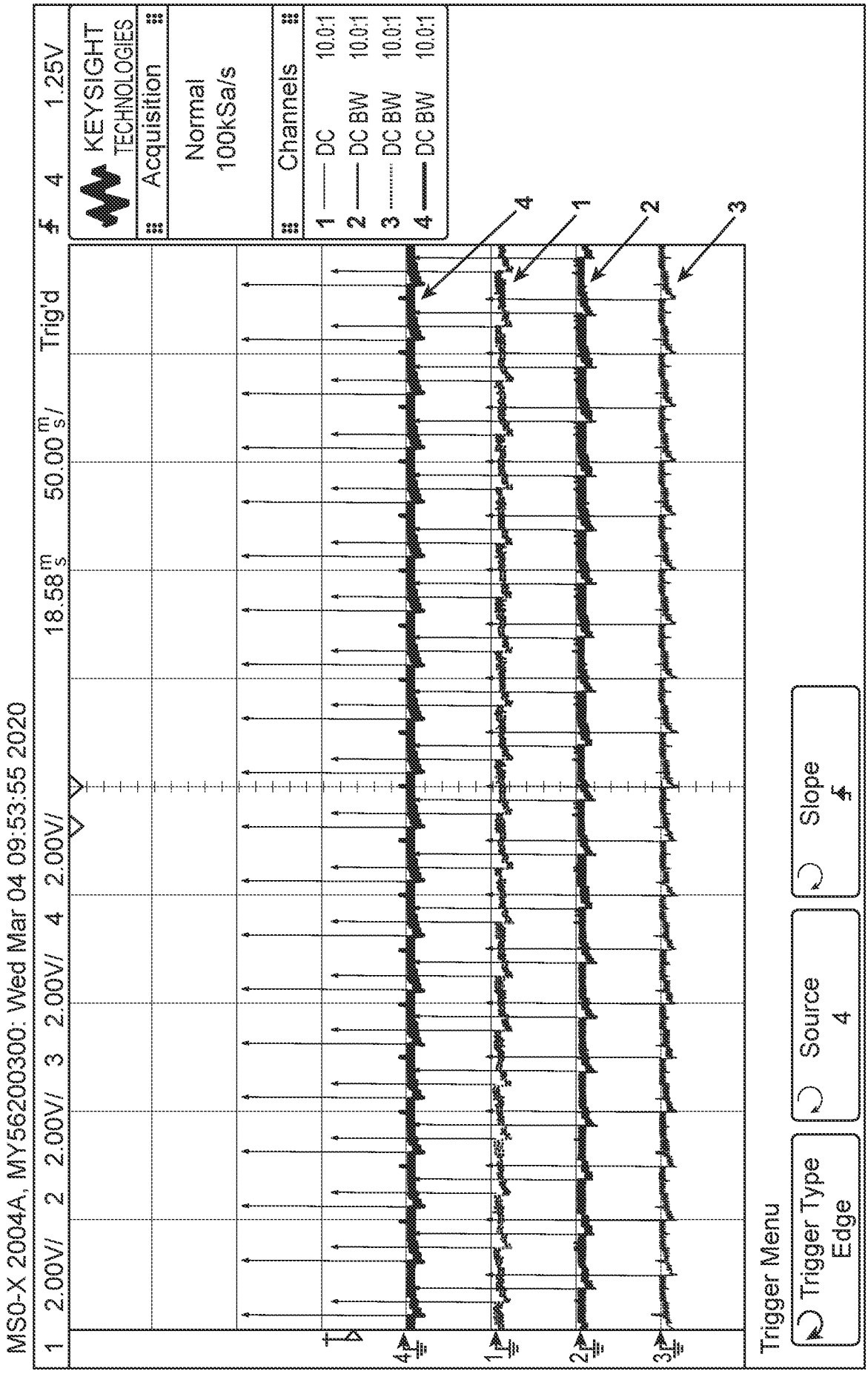

MSO-X 2004A, MY56200300: Wed Mar 04 09:53:55 2020
1 2.00V/ 2 2.00V/ 3 2.00V/ 4 2.00V/
18.58 ms
50.00 ms/
Trig'd
4 1.25V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
100kSa/s
Channels
1 DC 10:1
2 DC BW 10:1
3 DC BW 10:1
4 DC BW 10:1
4
1
2
3
Trigger Menu
Trigger Type Edge
Source 4
Slope

FIG. 2B

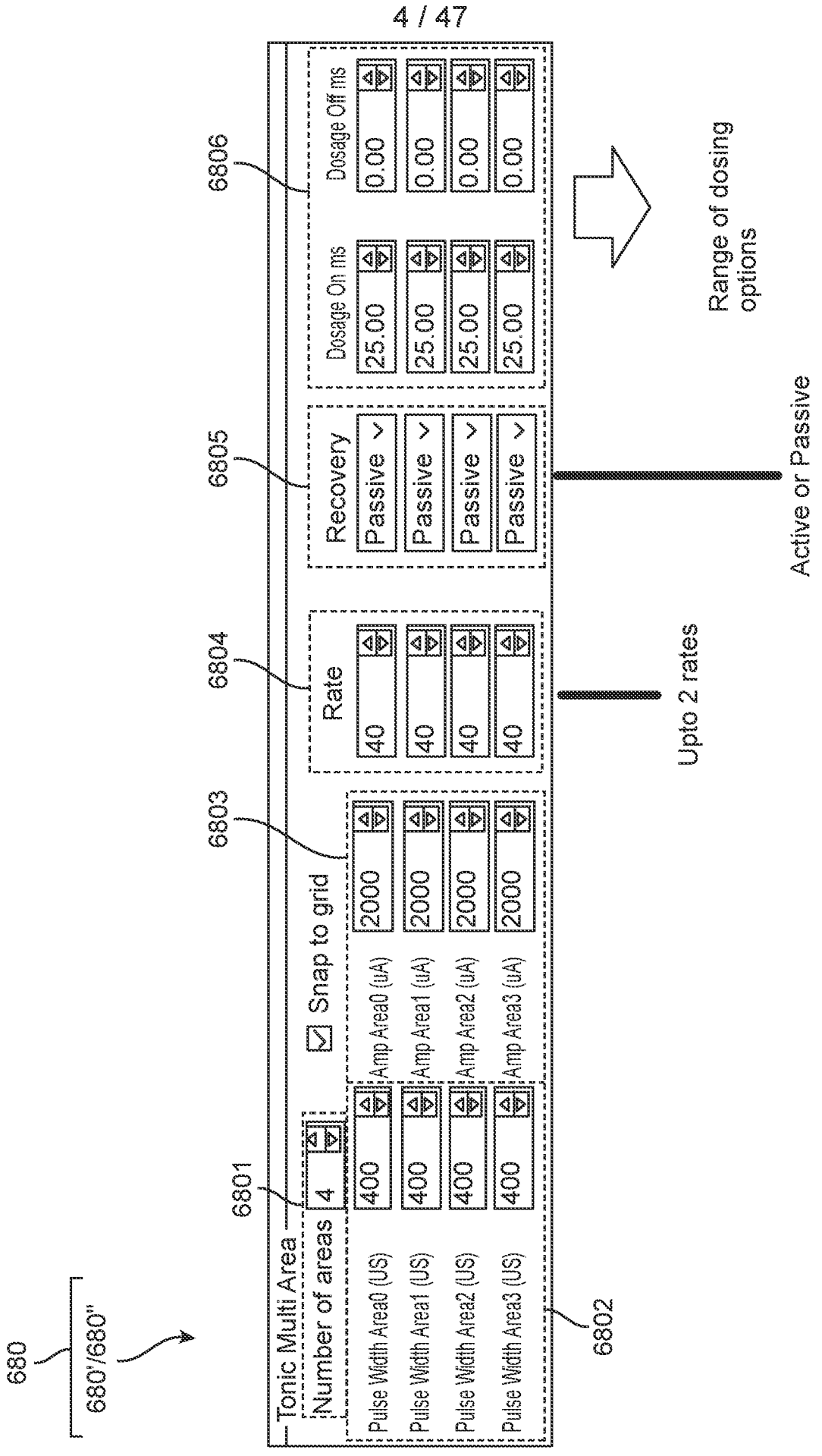

680
680'/680"
Tonic Multi Area
Number of areas
4
Snap to grid
Pulse Width Area0 (US)
Pulse Width Area1 (US)
Pulse Width Area2 (US)
Pulse Width Area3 (US)
400
Amp Area0 (uA)
Amp Area1 (uA)
Amp Area2 (uA)
Amp Area3 (uA)
2000
Rate
40
Recovery
Passive
Dosage On ms
25.00
Dosage Off ms
0.00
6801
6802
6803
6804
6805
6806
Upto 2 rates
Active or Passive
Range of dosing options

FIG. 3

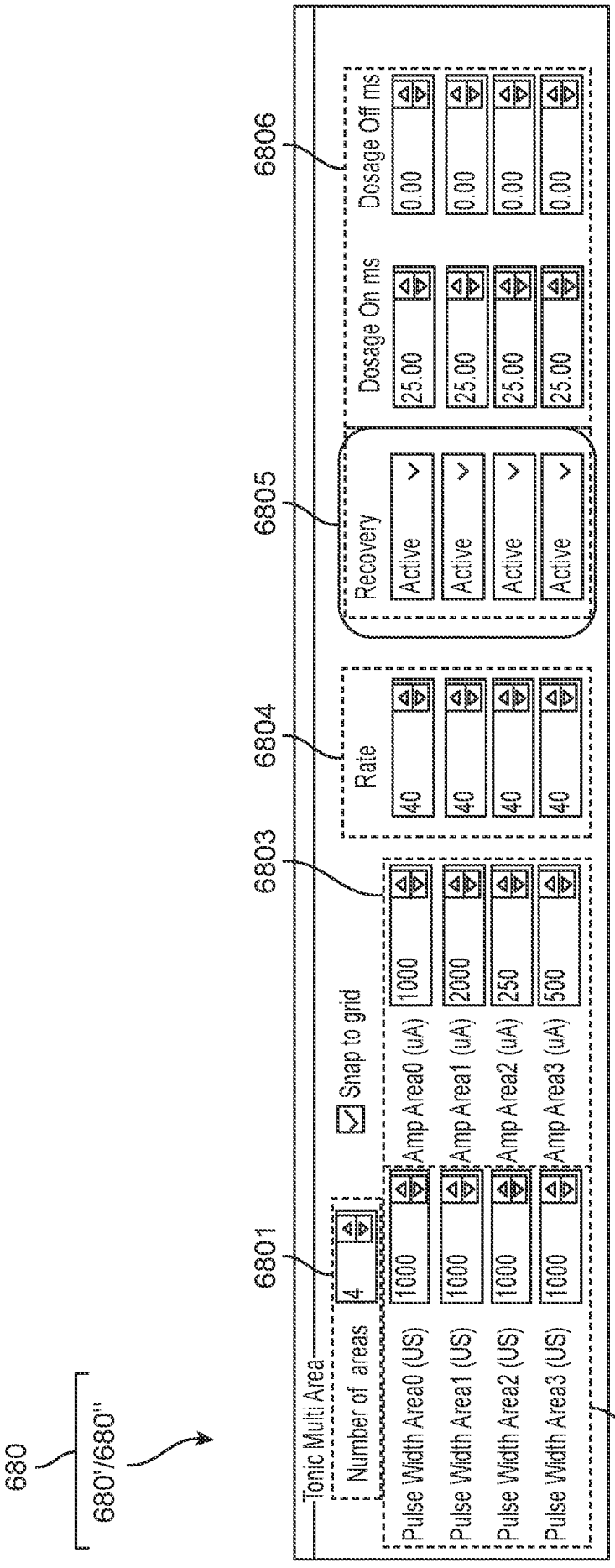
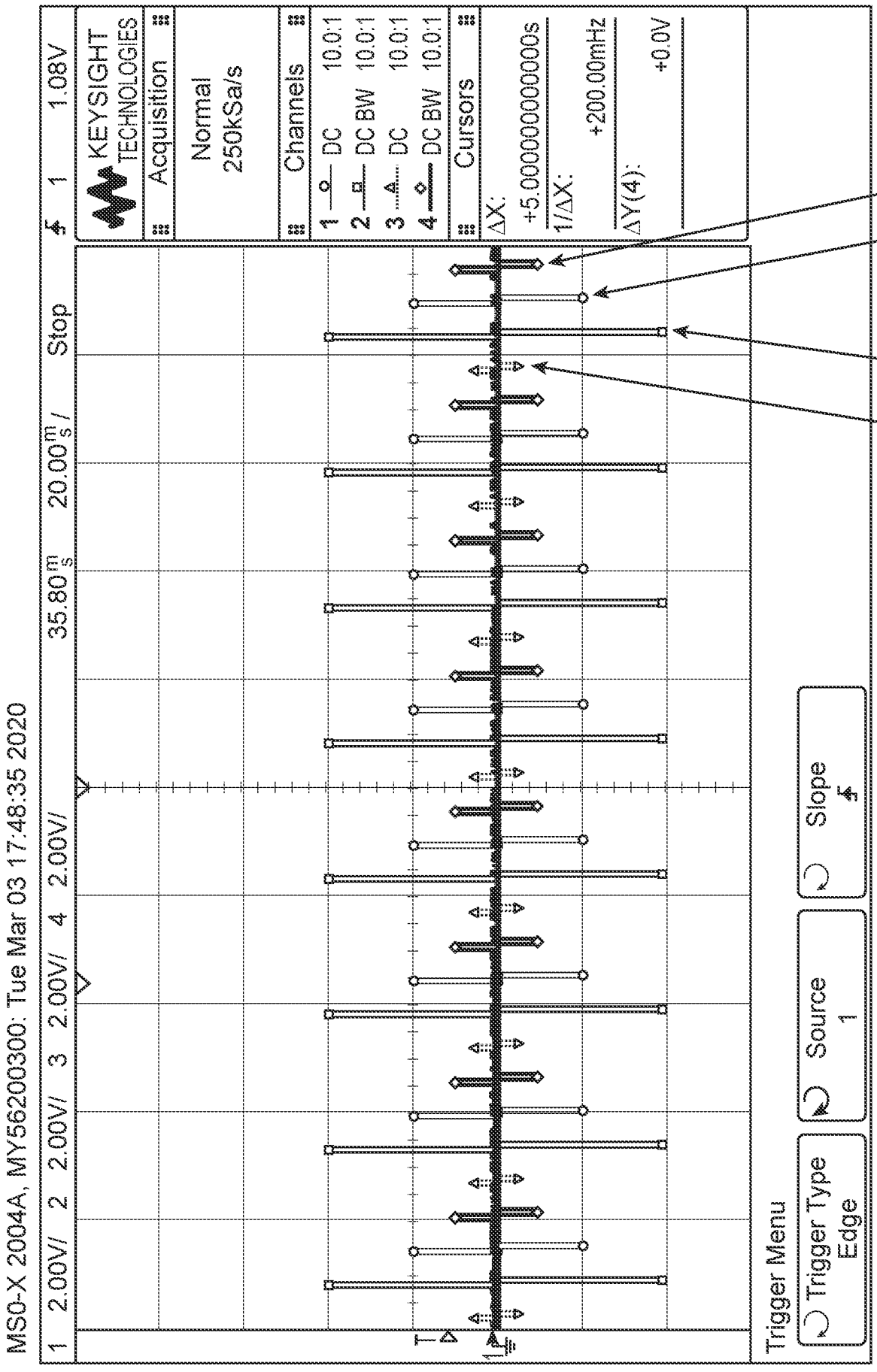

680
680'/680''
Tonic Multi Area
Number of areas
4
Snap to grid
Rate
Recovery
Dosage On ms
Dosage Off ms
Pulse Width Area0 (US)
1000
Amp Area0 (uA)
40
Active
25.00
0.00
Pulse Width Area1 (US)
1000
Amp Area1 (uA)
2000
40
Active
25.00
0.00
Pulse Width Area2 (US)
1000
Amp Area2 (uA)
250
40
Active
25.00
0.00
Pulse Width Area3 (US)
1000
Amp Area3 (uA)
500
40
Active
25.00
0.00
6801
6802
6803
6804
6805
6806

FIG. 4A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35.80 ms
20.00 ms/
Stop
1 1.08V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
250kSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC 10.0:1
4 DC BW 10.0:1
Cursors
ΔX:
+5.000000000000s
1/ΔX:
+200.00mHz
ΔY(4):
+0.0V
Trigger Menu
Trigger Type Edge
Source 1
Slope
1
2
3
4

FIG. 4B

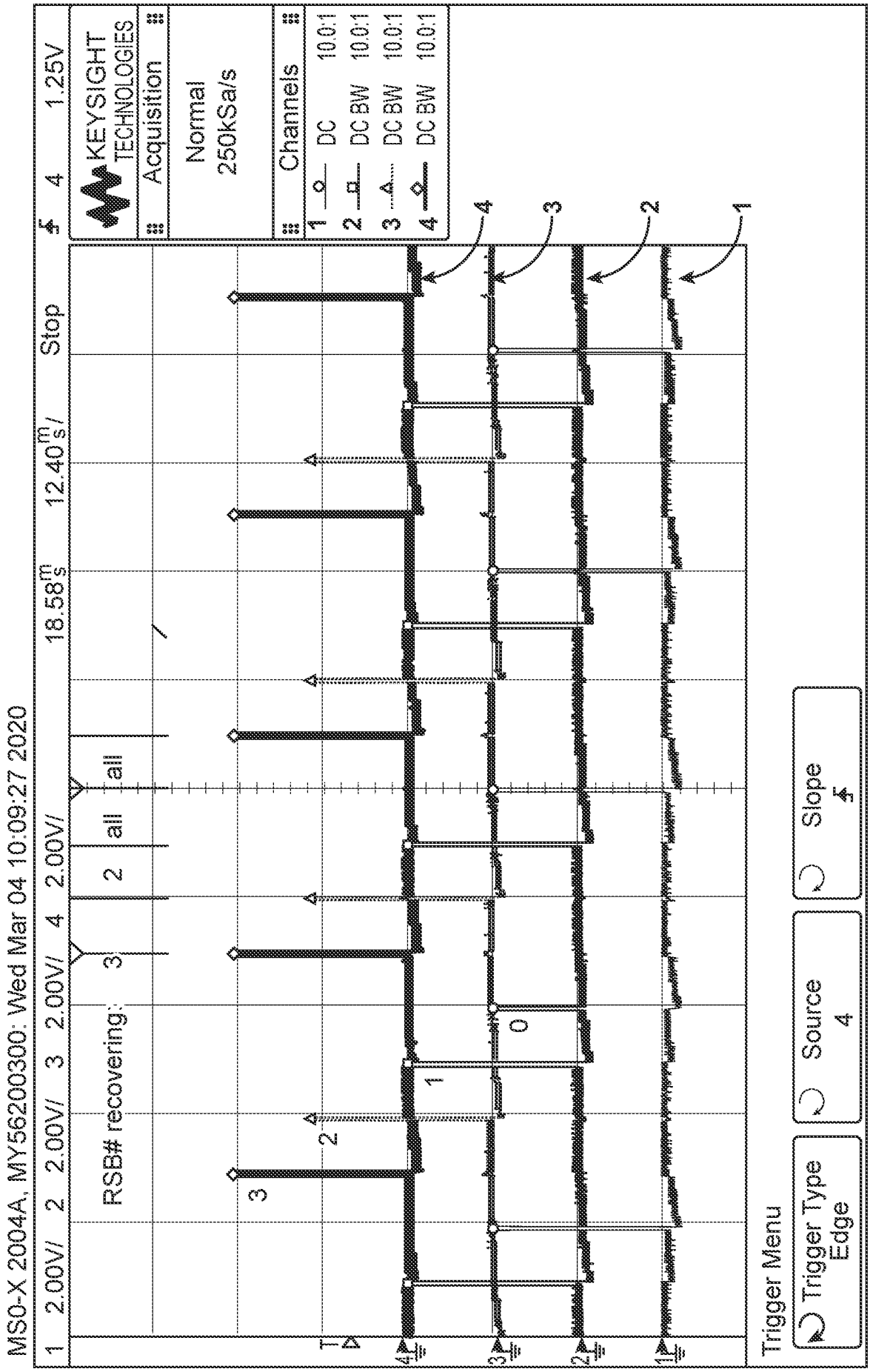

MSO-X 2004A, MY56200300: Wed Mar 04 10:09:27 2020
1 2.00V/ 2 2.00V/ 3 2.00V/ 4 2.00V/
18.58ms
12.40ms/
Stop
4 1.25V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
250kSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
RSB# recovering: 3 2 all all
Trigger Menu
Trigger Type Edge
Source 4
Slope

FIG. 5

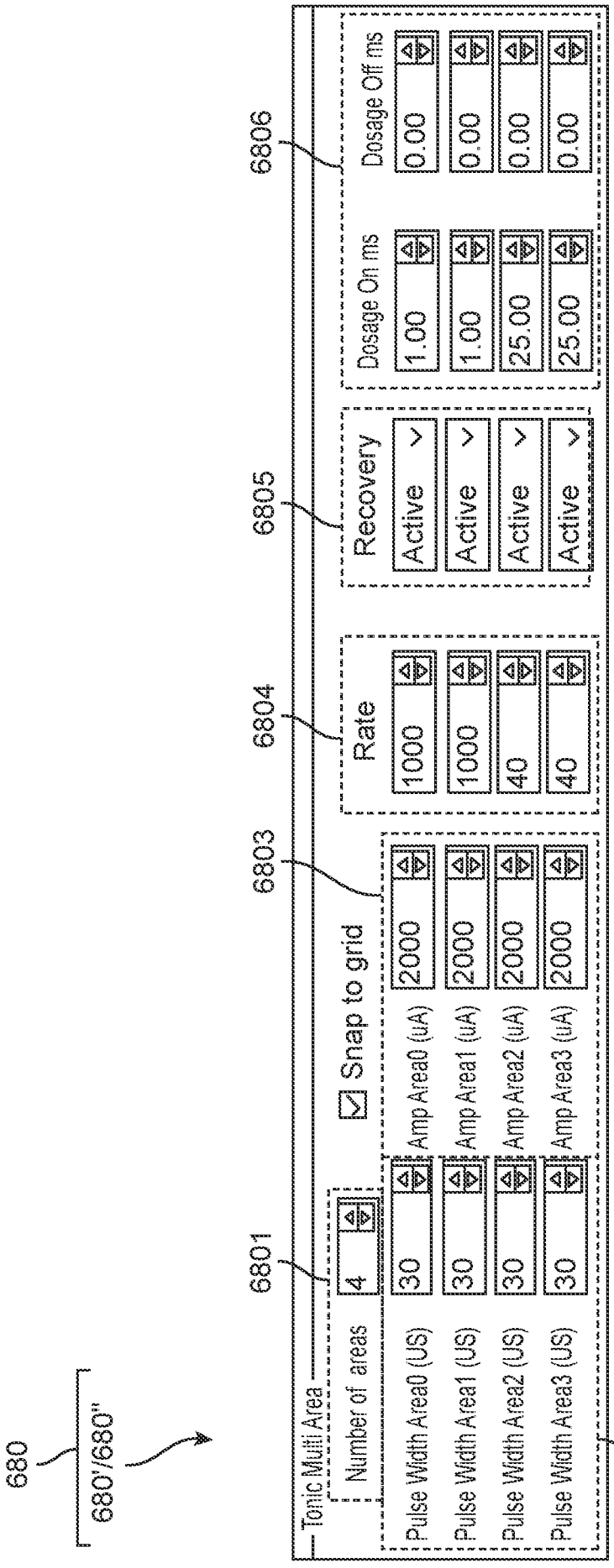

680
680'/680''
Tonic Multi Area
Number of areas
4
Snap to grid
Pulse Width Area0 (US)
Pulse Width Area1 (US)
Pulse Width Area2 (US)
Pulse Width Area3 (US)
30
Amp Area0 (uA)
Amp Area1 (uA)
Amp Area2 (uA)
Amp Area3 (uA)
2000
Rate
1000
40
Recovery
Active
Dosage On ms
1.00
25.00
Dosage Off ms
0.00
6801
6802
6803
6804
6805
6806

FIG. 6A

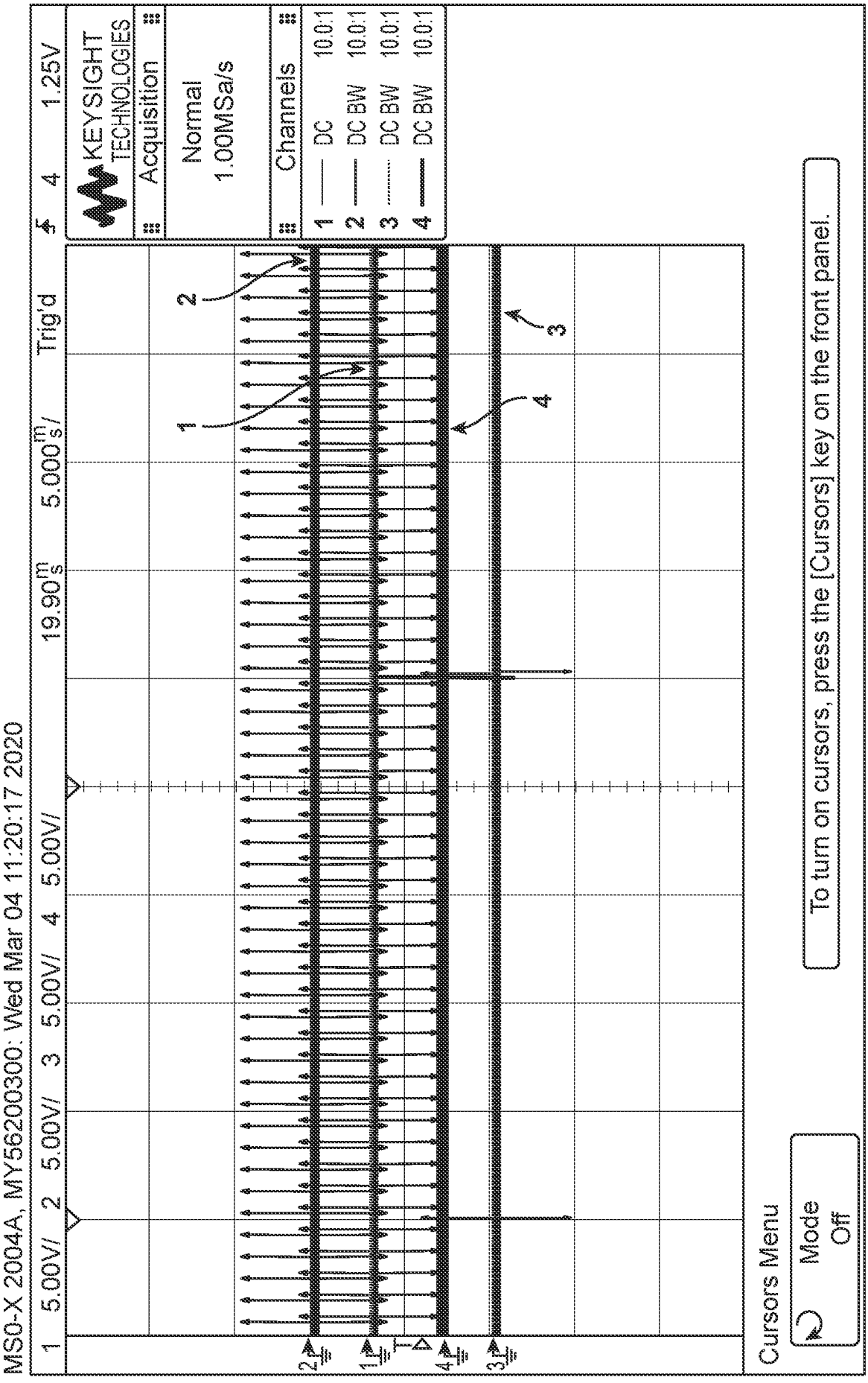

MSO-X 2004A, MY56200300: Wed Mar 04 11:20:17 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
19.90ms 5.000ms/ Trig'd 4 1.25V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
1.00MSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
1
2
3
4
Cursors Menu
Mode Off
To turn on cursors, press the [Cursors] key on the front panel.

FIG. 6B

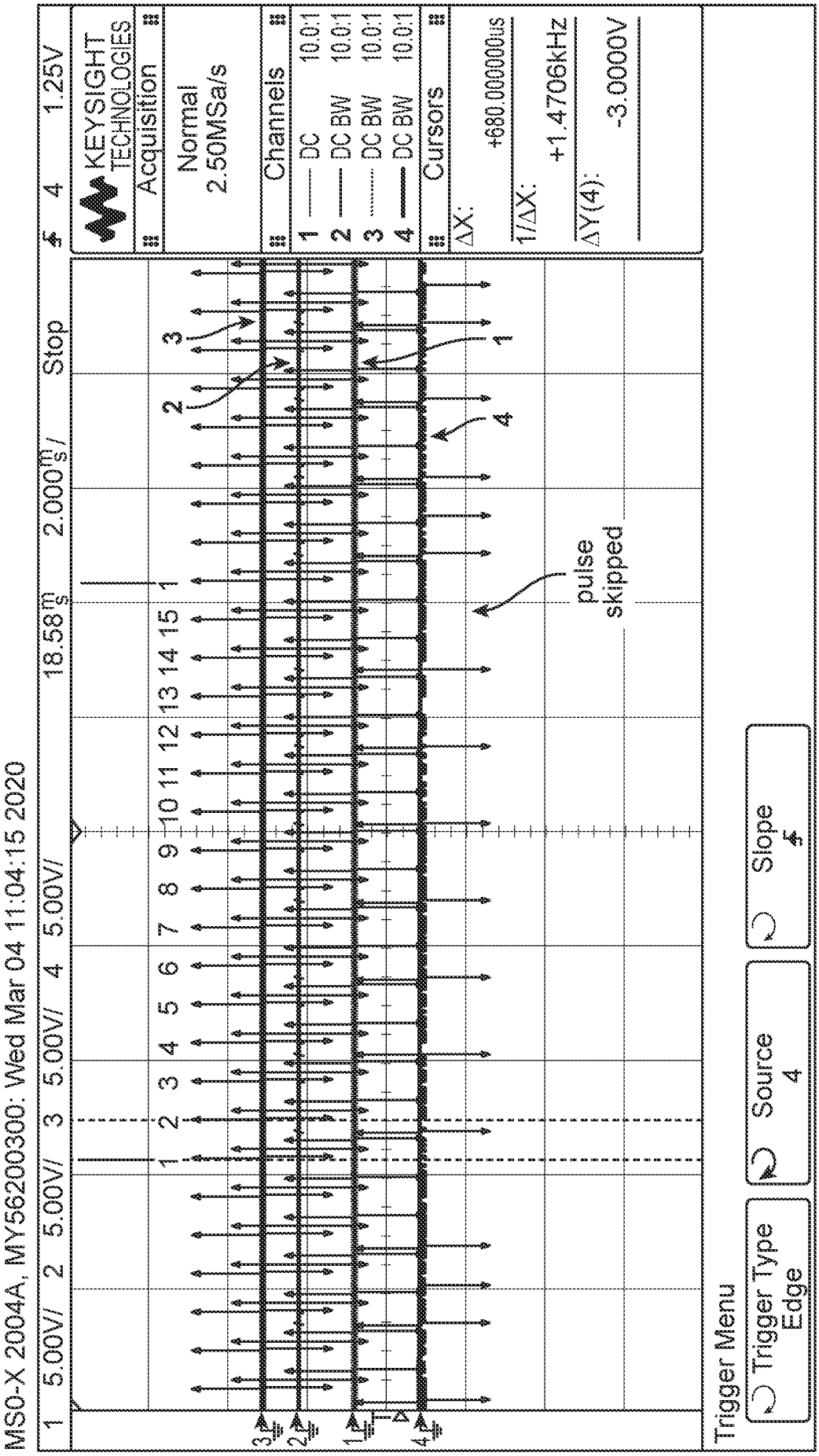
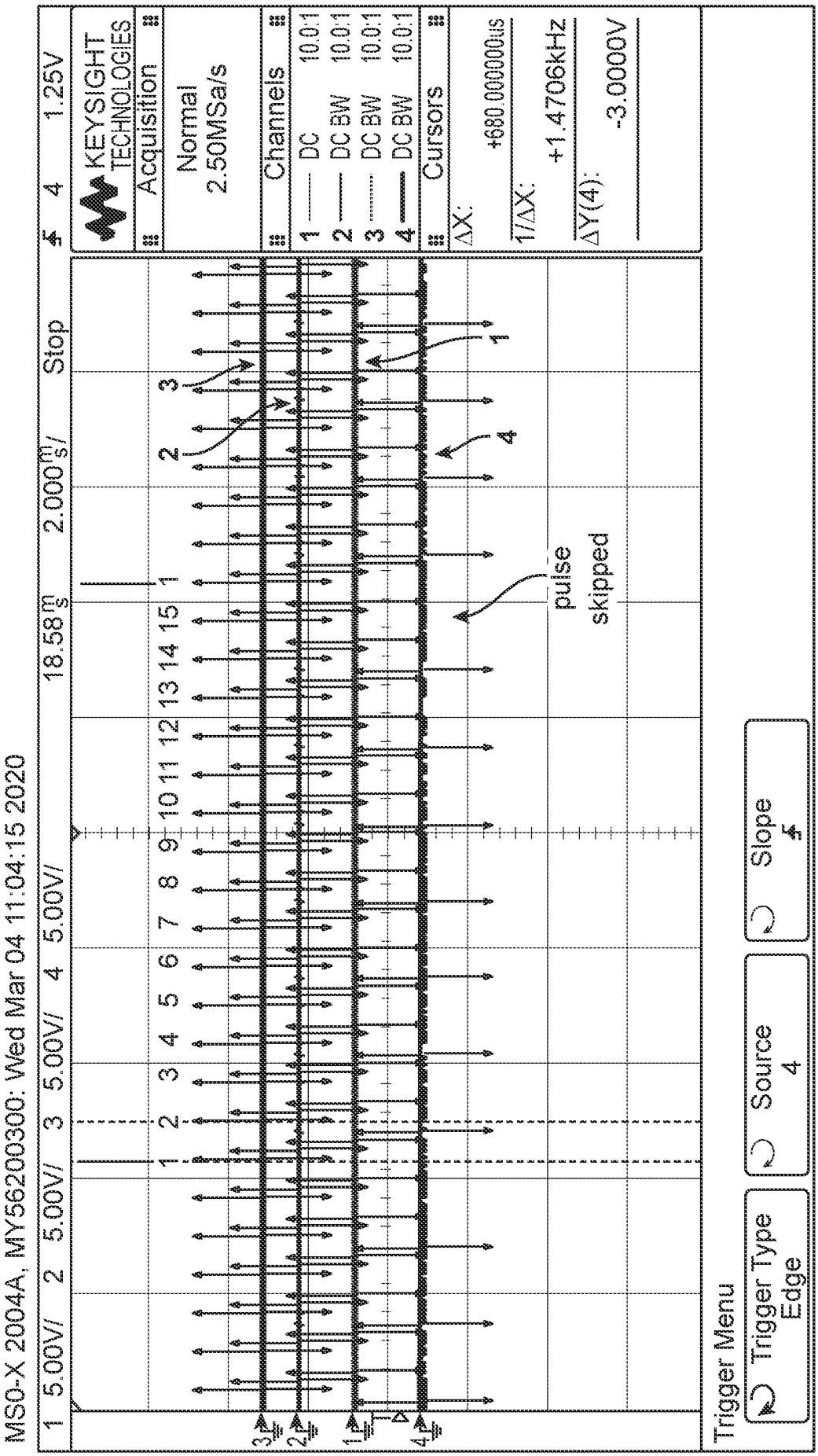

MSO-X 2004A, MY56200300: Wed Mar 04 11:04:15 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
18.58ms 2.000ms/ Stop
1.25V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
2.50MSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Cursors
ΔX: +680.000000µs
1/ΔX: +1.4706kHz
ΔY(4): -3.0000V
pulse skipped
Trigger Menu
Trigger Type Edge
Source 4
Slope

FIG. 7A


MSO-X 2004A, MY56200300: Wed Mar 04 11:04:15 2020
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18.58ms 2.000ms/ Stop
4 1.25V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
2.50MSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Cursors
ΔX: +680.000000µs
1/ΔX: +1.4706kHz
ΔY(4): -3.0000V
pulse skipped
Trigger Menu
Trigger Type Edge
Source 4
Slope

FIG. 7B

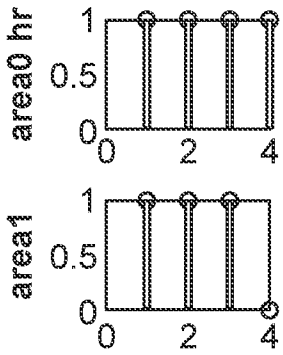

FIG. 8A

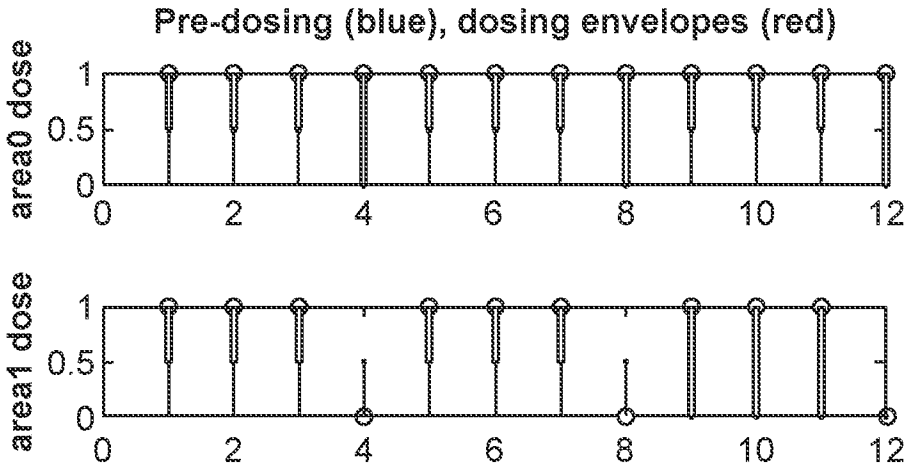

FIG. 8B

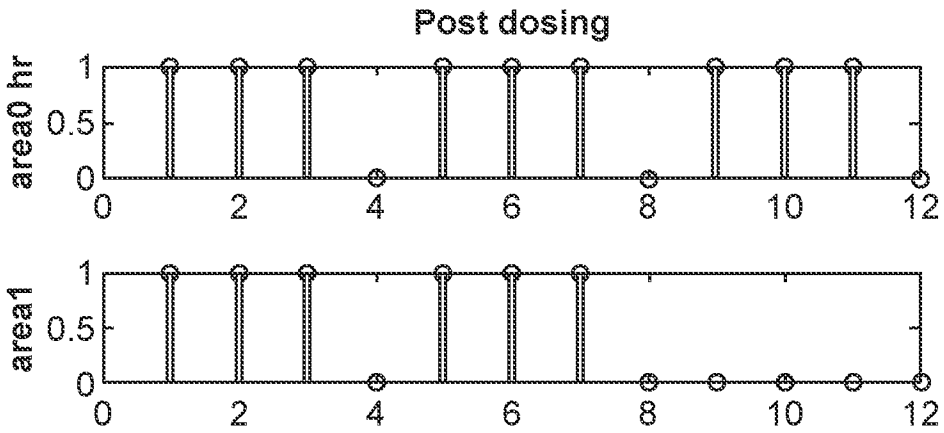

FIG. 8C

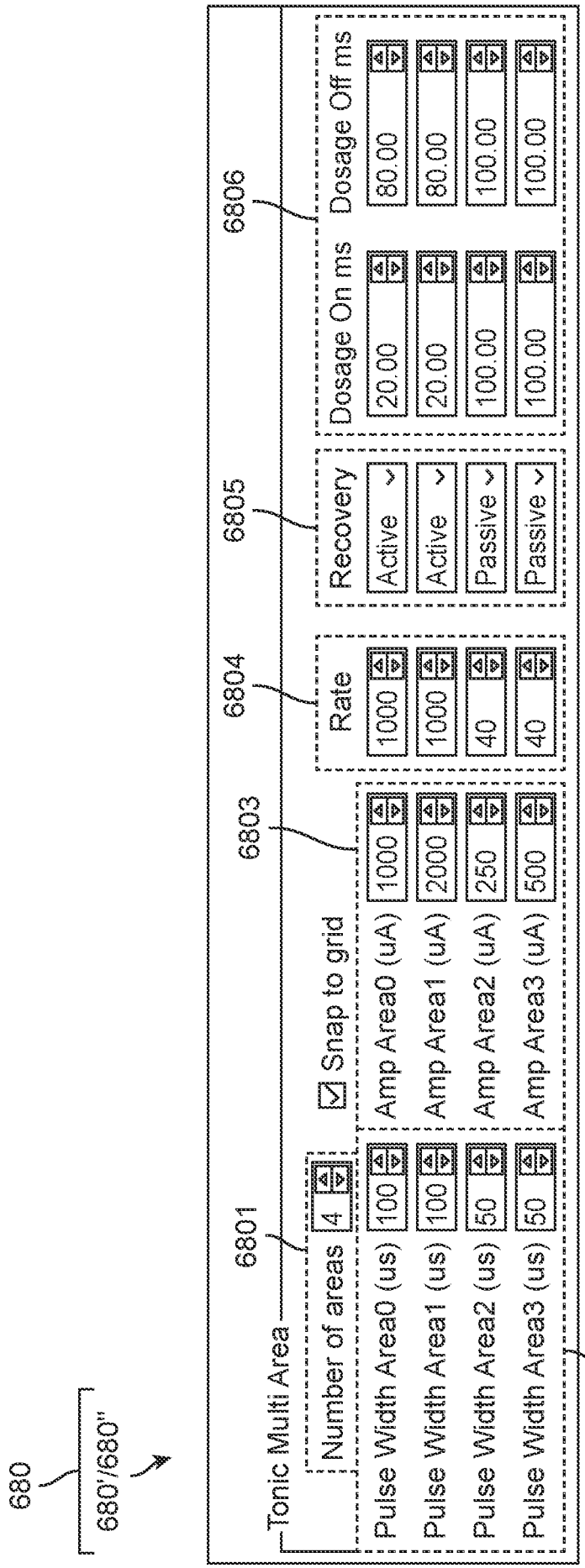
680
680'/680''
Tonic Multi Area
6801
Number of areas
4
Snap to grid
6803
6804
6805
6806
Rate
Recovery
Dosage On ms
Dosage Off ms
Pulse Width Area0 (us)
100
Amp Area0 (uA)
1000
1000
Active
20.00
80.00
Pulse Width Area1 (us)
100
Amp Area1 (uA)
2000
1000
Active
20.00
80.00
Pulse Width Area2 (us)
50
Amp Area2 (uA)
250
40
Passive
100.00
100.00
Pulse Width Area3 (us)
50
Amp Area3 (uA)
500
40
Passive
100.00
100.00
6802

FIG. 9A

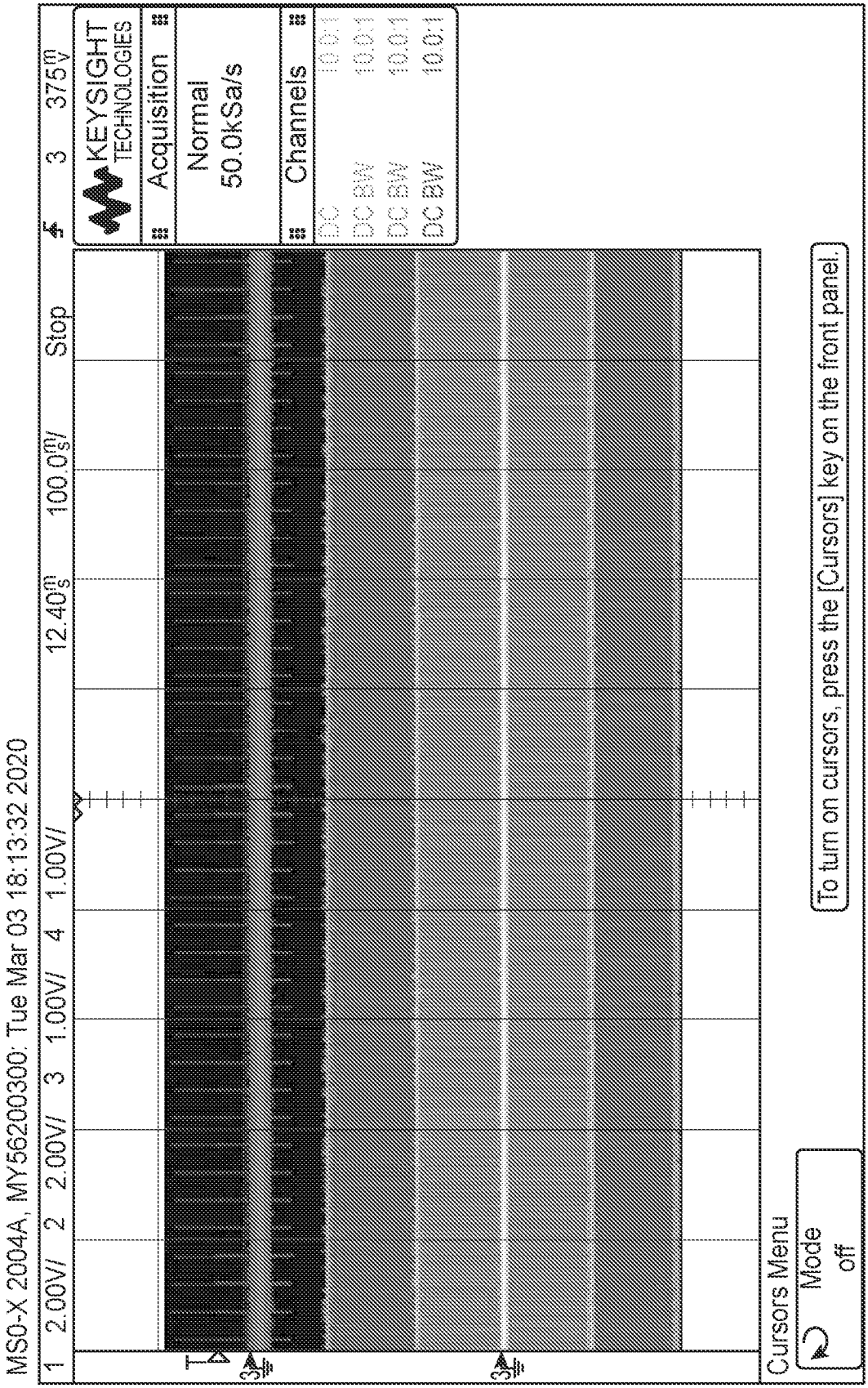
MSO-X 2004A, MY56200300: Tue Mar 03 18:13:32 2020
1 2.00V/ 2 2.00V/ 3 1.00V/ 4 1.00V/
12.40ns 100.0ns/ Stop
3 375mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
50.0kSa/s
Channels
DC 10:1
DC BW 10:1
DC BW 10:1
DC BW 10:1
To turn on cursors, press the [Cursors] key on the front panel.
Cursors Menu
Mode
off

FIG. 9B

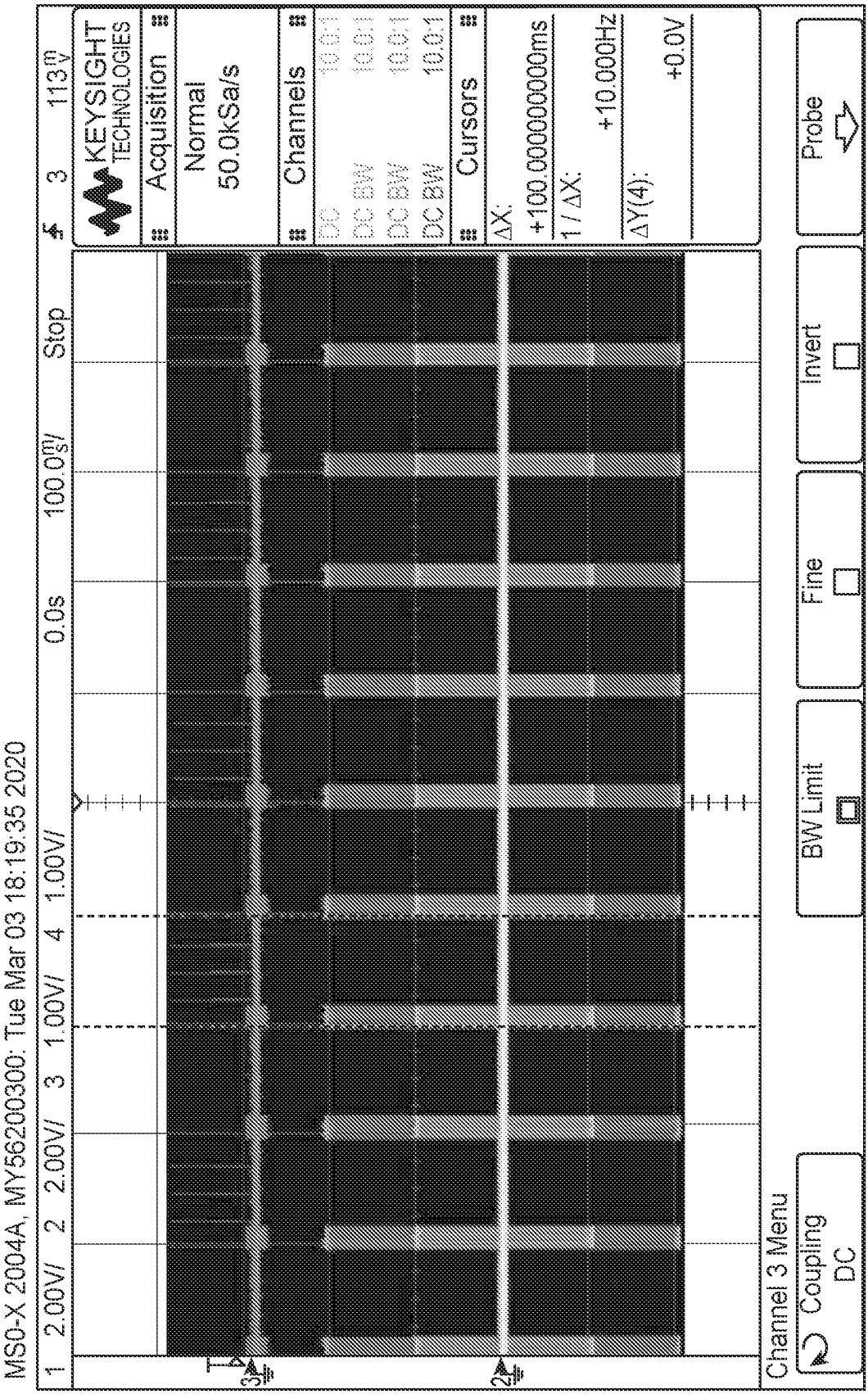
MSO-X 2004A, MY56200300: Tue Mar 03 18:19:35 2020
1 2.00V/ 2 2.00V/ 3 1.00V/ 4 1.00V/
0.0s
100.0ms/
Stop
3
113
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
50.0kSa/s
Channels
DC 10:1
DC BW 10:1
DC BW 10:1
DC BW 10:1
Cursors
ΔX:
+100.000000000ms
1 / ΔX:
+10.000Hz
ΔY(4):
+0.0V
Channel 3 Menu
Coupling
DC
BW Limit
Fine
Invert
Probe

FIG. 9C

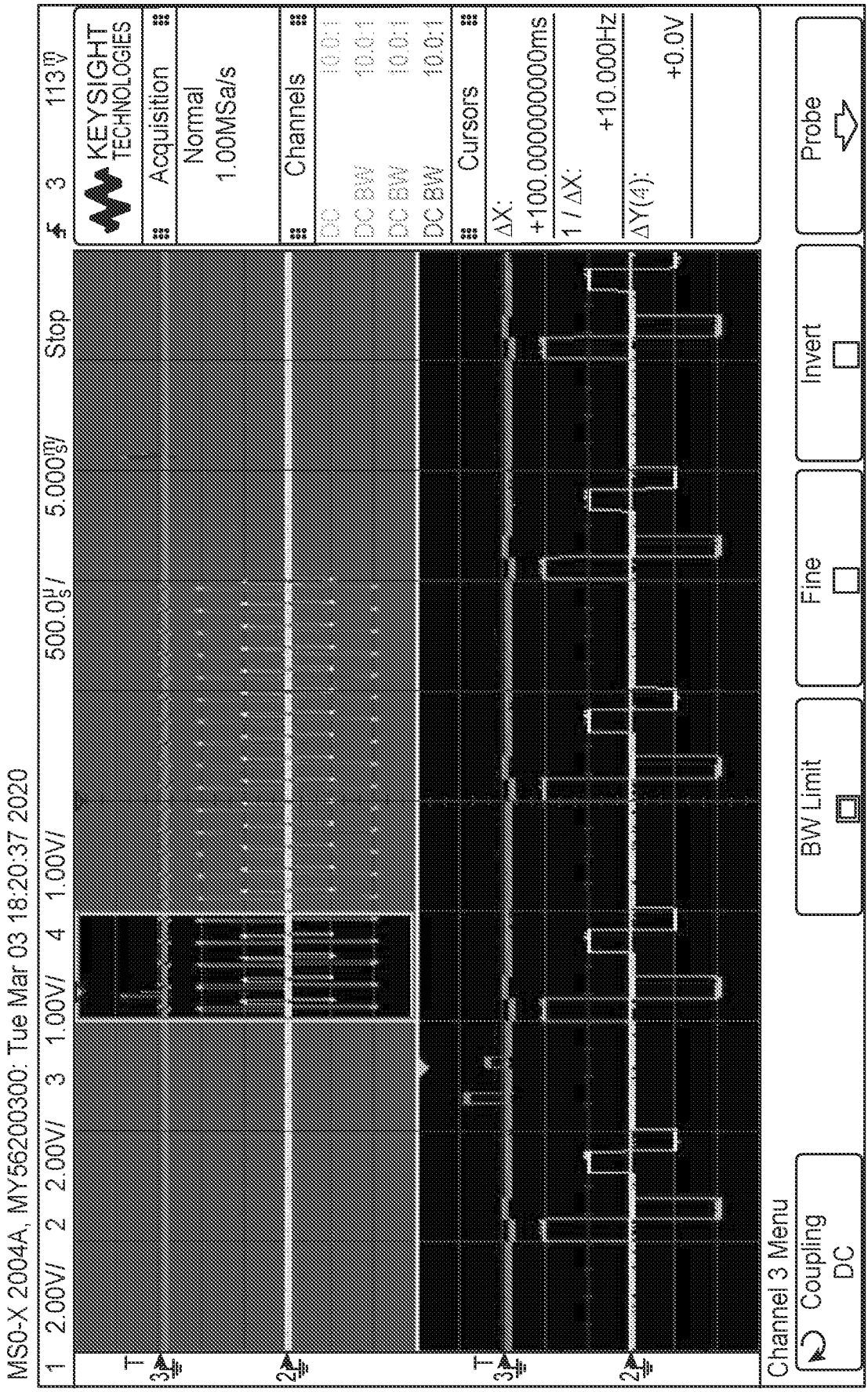
MSO-X 2004A, MY56200300: Tue Mar 03 18:20:37 2020
1 2.00V/ 2 2.00V/ 3 1.00V/ 4 1.00V/
500.0µs/ 5.000ms/ Stop
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
1.00MSa/s
Channels
DC 10:1
DC BW 10:1
DC BW 10:1
DC BW 10:1
Cursors
ΔX:
+100.000000000ms
1 / ΔX:
+10.000Hz
ΔY(4):
+0.0V
Channel 3 Menu
Coupling
DC
BW Limit
Fine
Invert
Probe

FIG. 9D

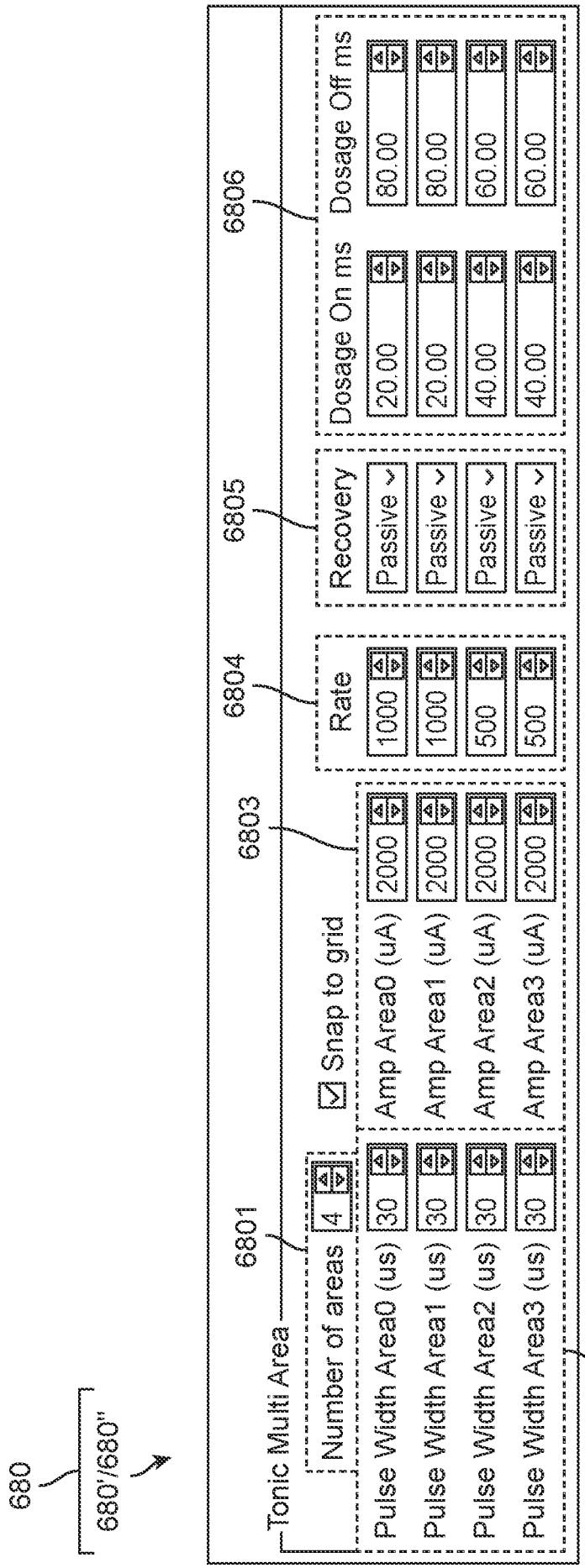
680
680'/680"
6801
6802
6803
6804
6805
6806
Tonic Multi Area
Number of areas
4
Snap to grid
Rate
Recovery
Dosage On ms
Dosage Off ms
Pulse Width Area0 (us)
30
Amp Area0 (uA)
2000
1000
Passive
20.00
80.00
Pulse Width Area1 (us)
30
Amp Area1 (uA)
2000
1000
Passive
20.00
80.00
Pulse Width Area2 (us)
30
Amp Area2 (uA)
2000
500
Passive
40.00
60.00
Pulse Width Area3 (us)
30
Amp Area3 (uA)
2000
500
Passive
40.00
60.00

FIG. 10A

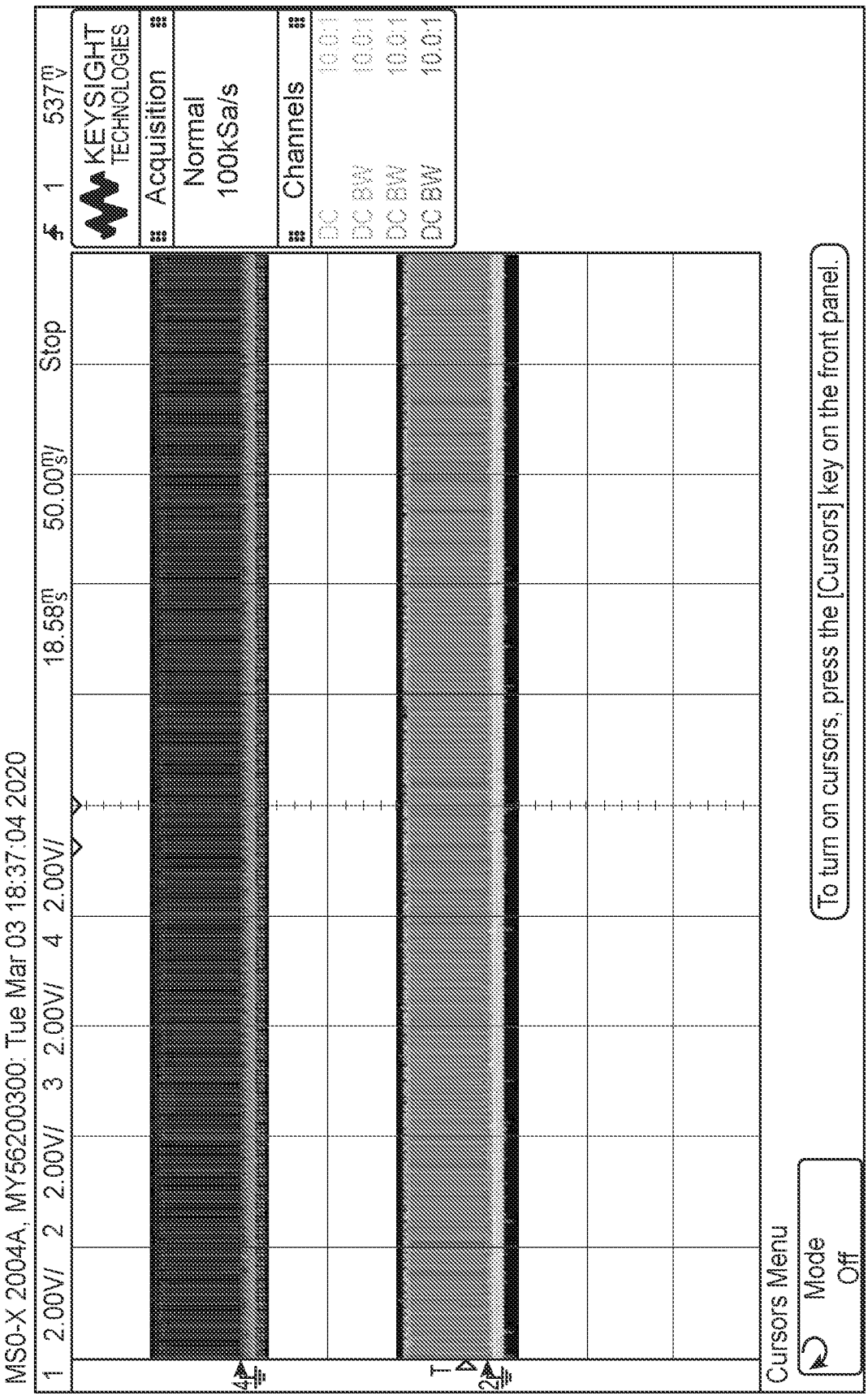
MSO-X 2004A, MY56200300: Tue Mar 03 18:37:04 2020
1 2.00V/ 2 2.00V/ 3 2.00V/ 4 2.00V/
18.58ms 50.00mV/ Stop
1 537mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
100kSa/s
Channels
DC 10.0:1
DC BW 10.0:1
DC BW 10.0:1
DC BW 10.0:1
Cursors Menu
Mode
Off
To turn on cursors, press the [Cursors] key on the front panel.

FIG. 10B

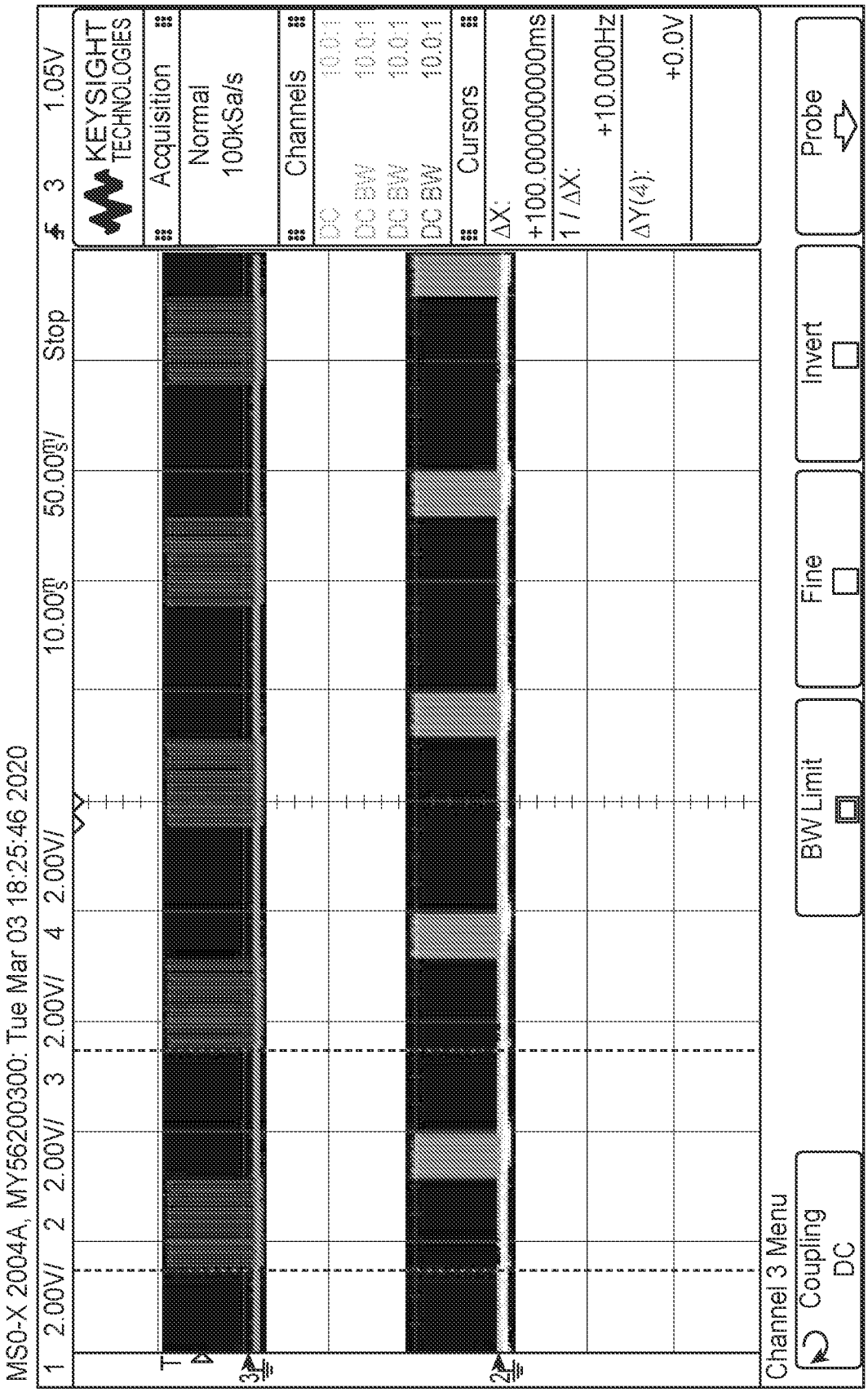
MSO-X 2004A, MY56200300: Tue Mar 03 18:25:46 2020
1 2.00V/ 2 2.00V/ 3 2.00V/ 4 2.00V/
10.00ns/ 50.00GS/ Stop
3 1.05V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
100kSa/s
Channels
DC 10.01
DC BW 10.01
DC BW 10.01
DC BW 10.01
Cursors
ΔX:
+100.000000000ms
1 / ΔX:
+10.000Hz
ΔY(4):
+0.0V
Channel 3 Menu
Coupling
DC
BW Limit
Fine
Invert
Probe

FIG. 10C

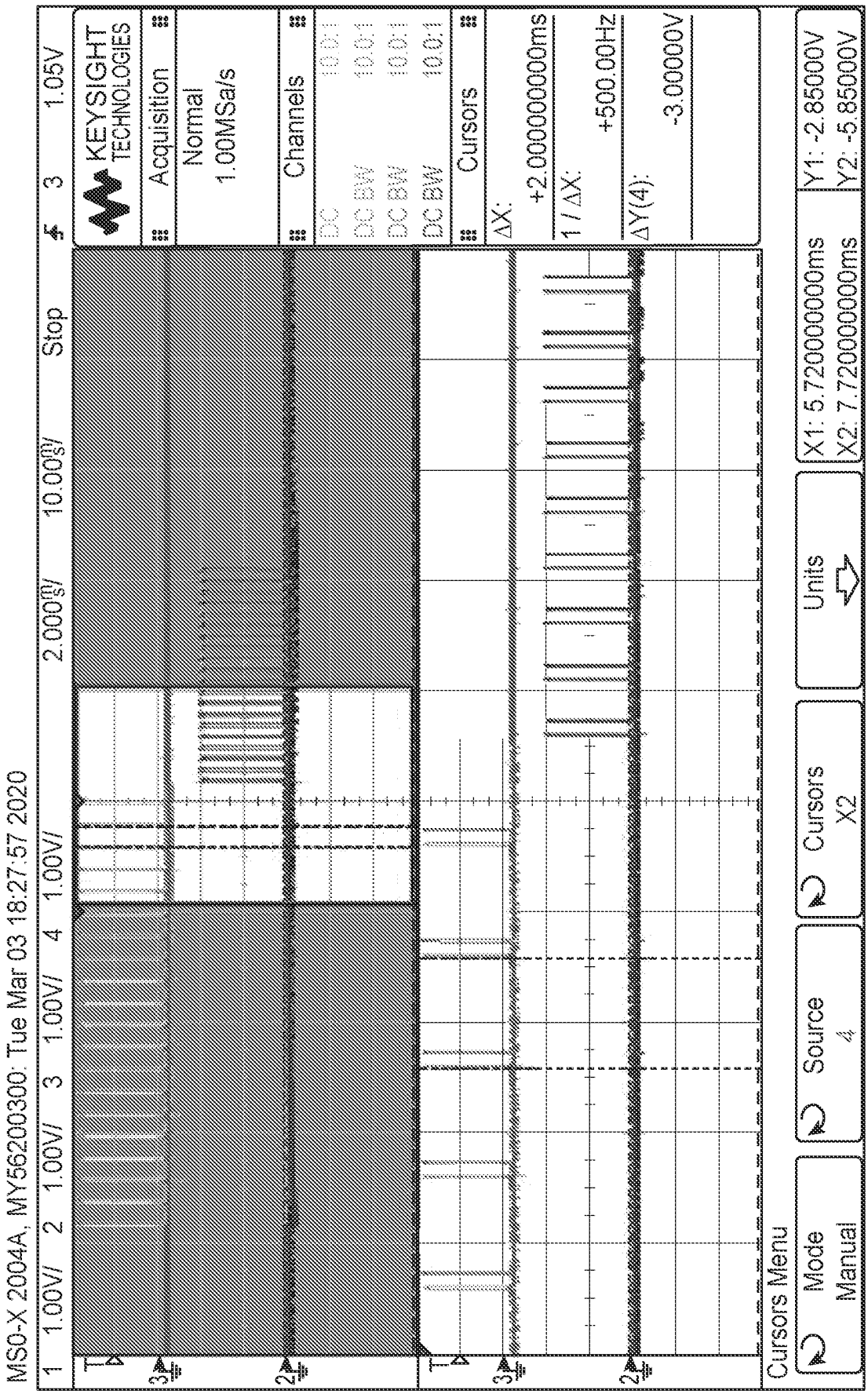
MSO-X 2004A, MY56200300: Tue Mar 03 18:27:57 2020
1 1.00V/ 2 1.00V/ 3 1.00V/ 4 1.00V/
2.000ns/ 10.00ns/ Stop
1.05V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
1.00MSa/s
Channels
DC 10.0:1
DC BW 10.0:1
DC BW 10.0:1
DC BW 10.0:1
Cursors
ΔX:
+2.000000000ms
1 / ΔX:
+500.00Hz
ΔY(4):
-3.00000V
Cursors Menu
Mode
Manual
Source
4
Cursors
X2
Units
X1: 5.720000000ms
X2: 7.720000000ms
Y1: -2.85000V
Y2: -5.85000V

FIG. 10D

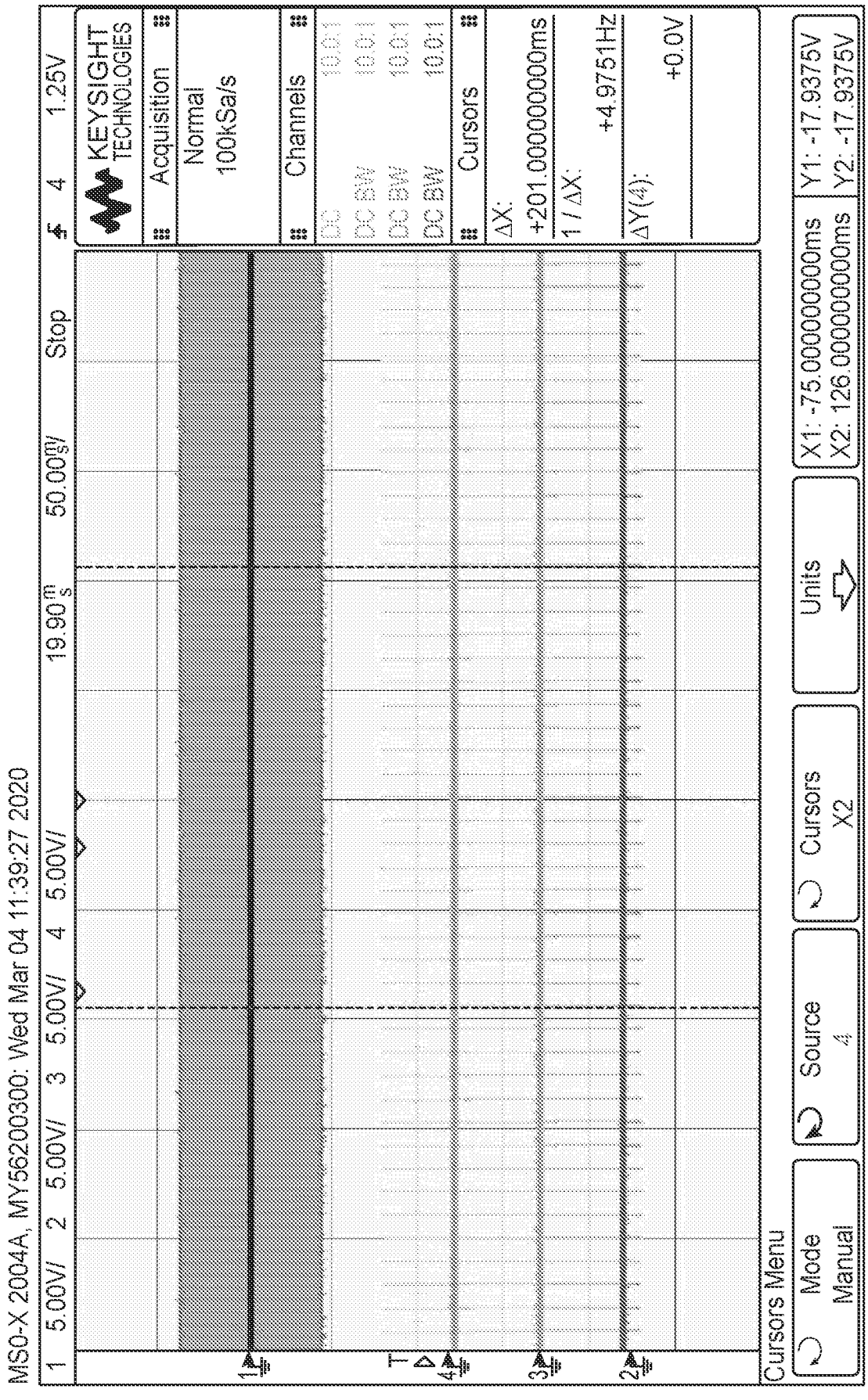
MSO-X 2004A, MY56200300: Wed Mar 04 11:39:27 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
19.90ms
50.00mV/
Stop
4 1.25V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
100kSa/s
Channels
DC 10:1
DC BW 10:1
DC BW 10:1
DC BW 10:1
Cursors
ΔX:
+201.000000000ms
1 / ΔX:
+4.97751Hz
ΔY(4):
+0.0V
Cursors Menu
Mode
Manual
Source
4
Cursors
X2
Units
X1: -75.000000000ms
X2: 126.000000000ms
Y1: -17.9375V
Y2: -17.9375V

FIG. 11A

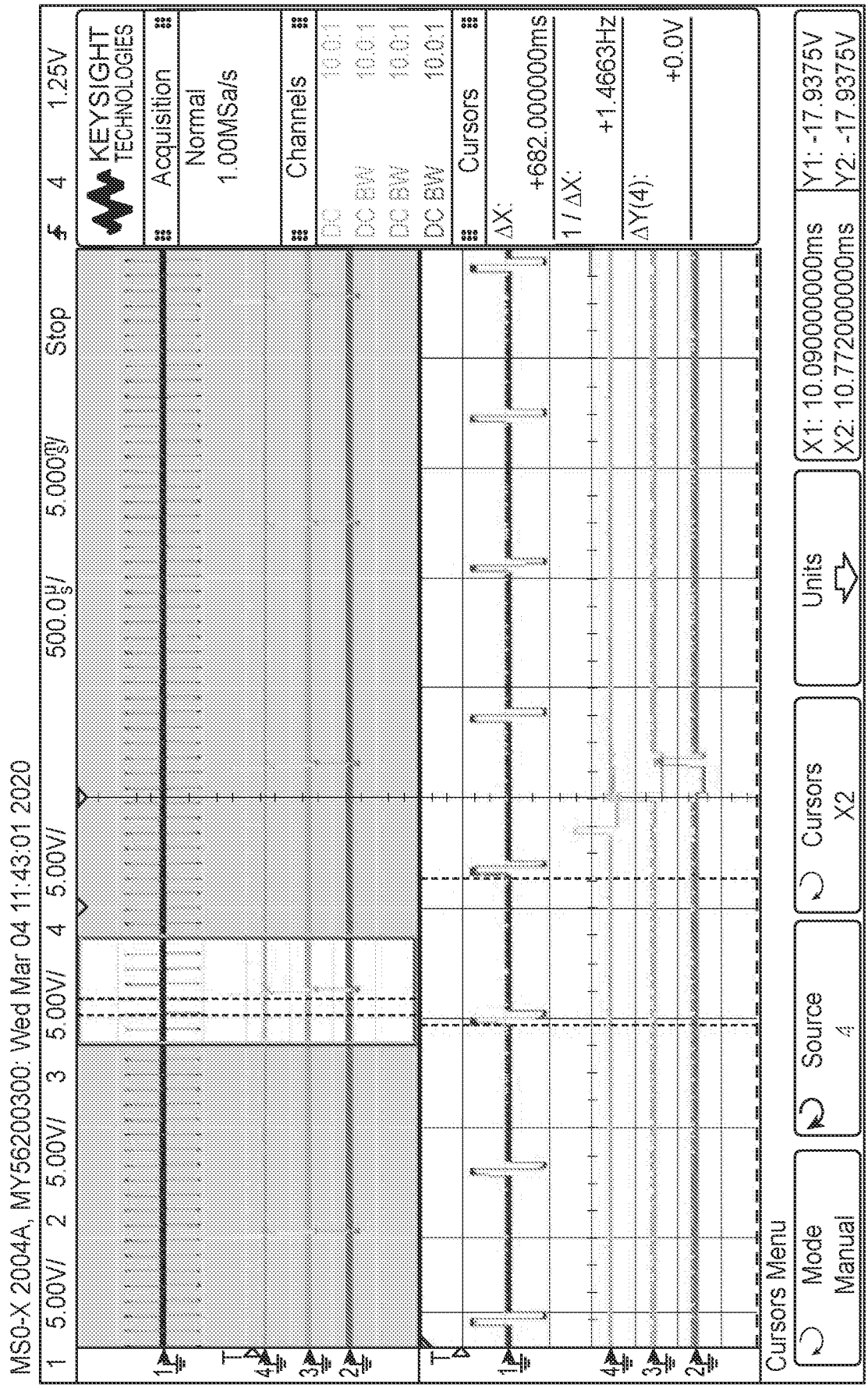
MSO-X 2004A, MY56200300: Wed Mar 04 11:43:01 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
500.0µs/
5.000gV/
Stop
4 1.25V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
1.00MSa/s
Channels
DC 10.0:1
DC BW 10.0:1
DC BW 10.0:1
DC BW 10.0:1
Cursors
ΔX:
+682.000000ms
1 / ΔX:
+1.4663Hz
ΔY(4):
+0.0V
Cursors Menu
Mode
Manual
Source
4
Cursors
X2
Units
X1: 10.090000000ms
X2: 10.772000000ms
Y1: -17.9375V
Y2: -17.9375V

FIG. 11B

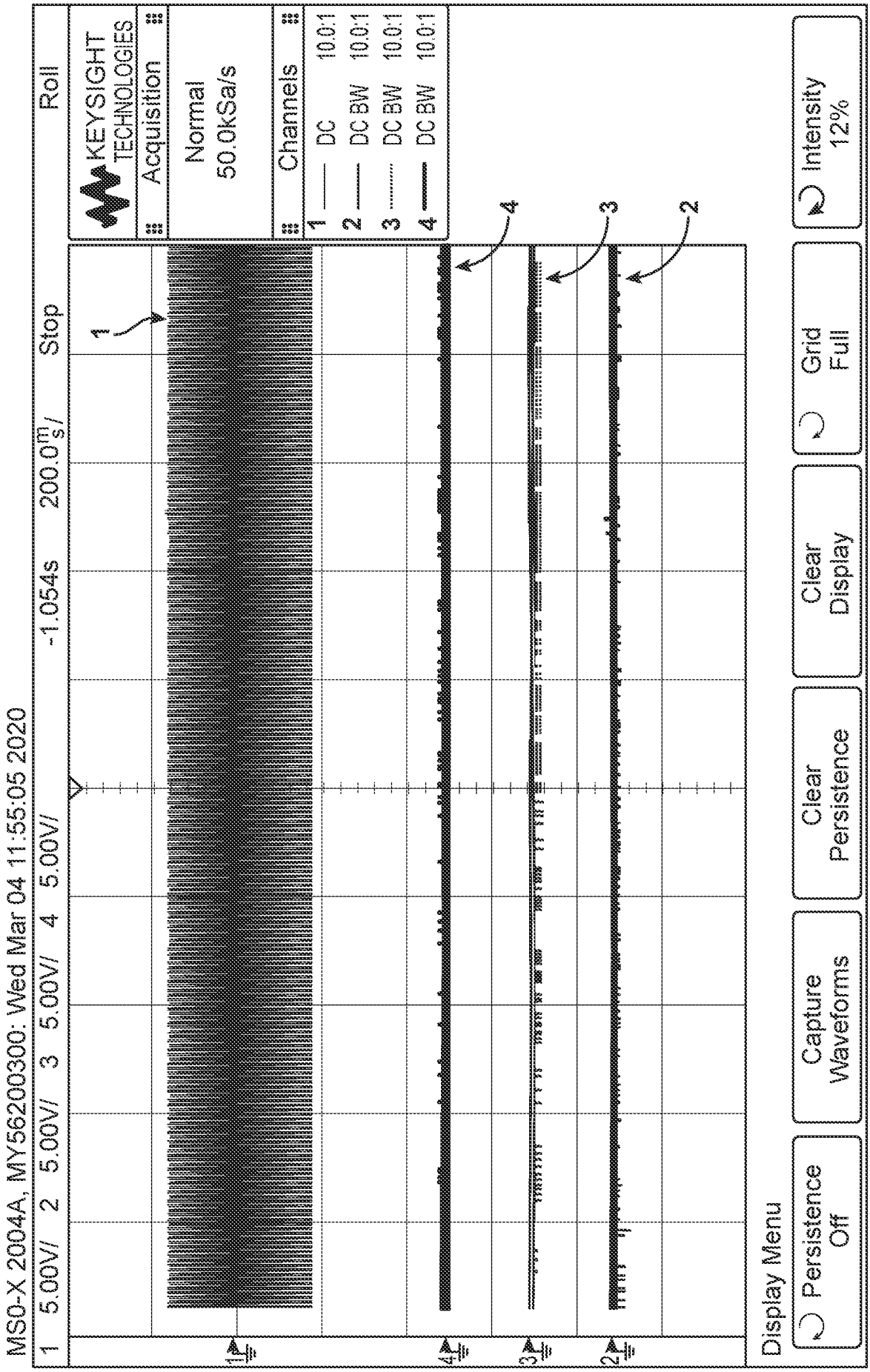
MSO-X 2004A, MY56200300: Wed Mar 04 11:55:05 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
-1.054s
200.0ns/
Stop
Roll
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
50.0kSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Intensity 12%
Grid Full
Clear Display
Clear Persistence
Capture Waveforms
Persistence Off
Display Menu

FIG. 12A

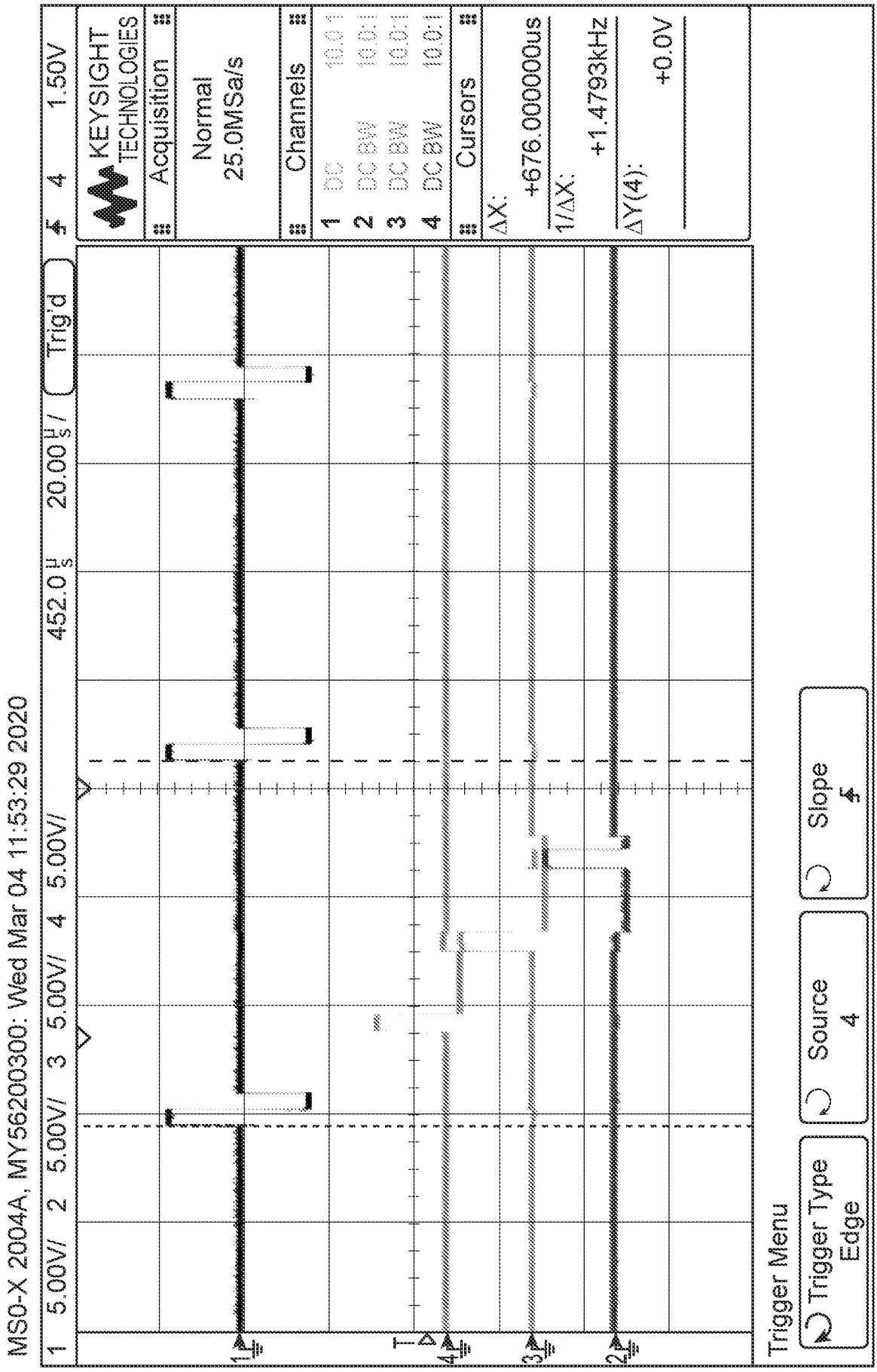
MSO-X 2004A, MY56200300: Wed Mar 04 11:53:29 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
452.0 µs
20.00 µs/
Trig'd
4 1.50V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
25.0MSa/s
Channels
1 DC 10:1
2 DC BW 10:1
3 DC BW 10:1
4 DC BW 10:1
Cursors
ΔX:
+676.000000us
1/ΔX:
+1.4793kHz
ΔY(4):
+0.0V
Trigger Menu
Trigger Type
Edge
Source
4
Slope

FIG. 12B

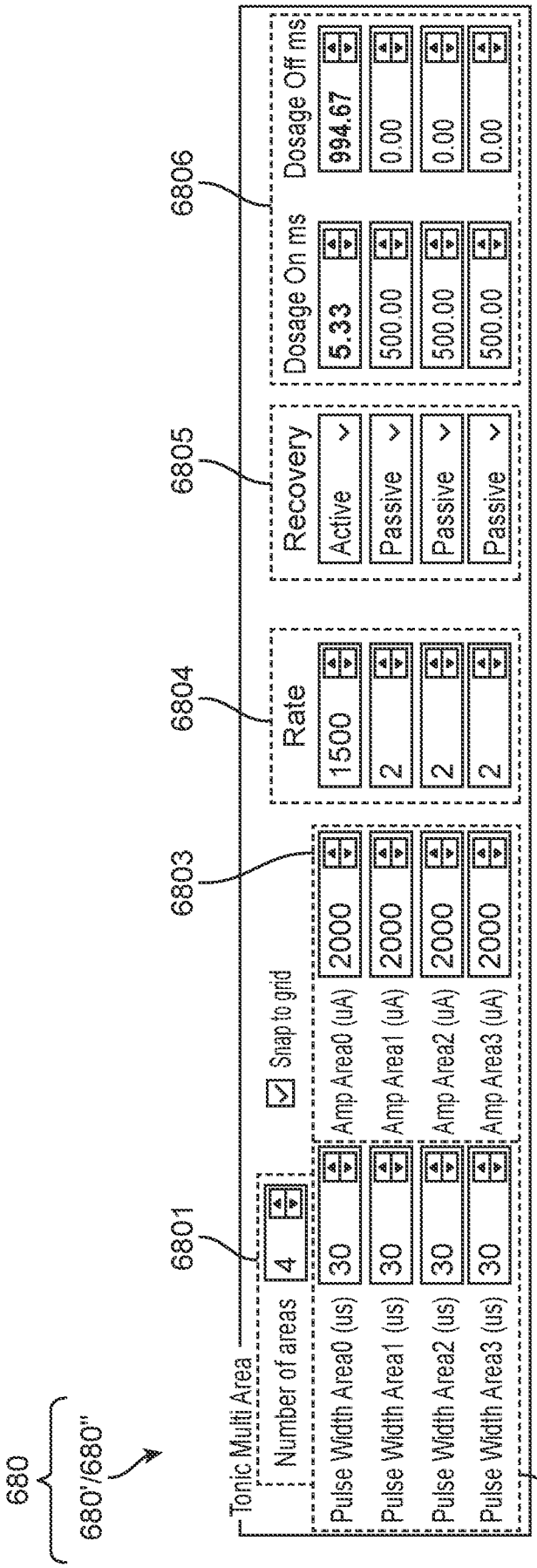
680
680'/680"
Tonic Multi Area
Number of areas
4
Snap to grid
Pulse Width Area0 (us)
30
Amp Area0 (uA)
2000
Pulse Width Area1 (us)
30
Amp Area1 (uA)
2000
Pulse Width Area2 (us)
30
Amp Area2 (uA)
2000
Pulse Width Area3 (us)
30
Amp Area3 (uA)
2000
Rate
1500
2
2
2
Recovery
Active
Passive
Passive
Passive
Dosage On ms
5.33
500.00
500.00
500.00
Dosage Off ms
994.67
0.00
0.00
0.00
6801
6802
6803
6804
6805
6806

FIG. 13A

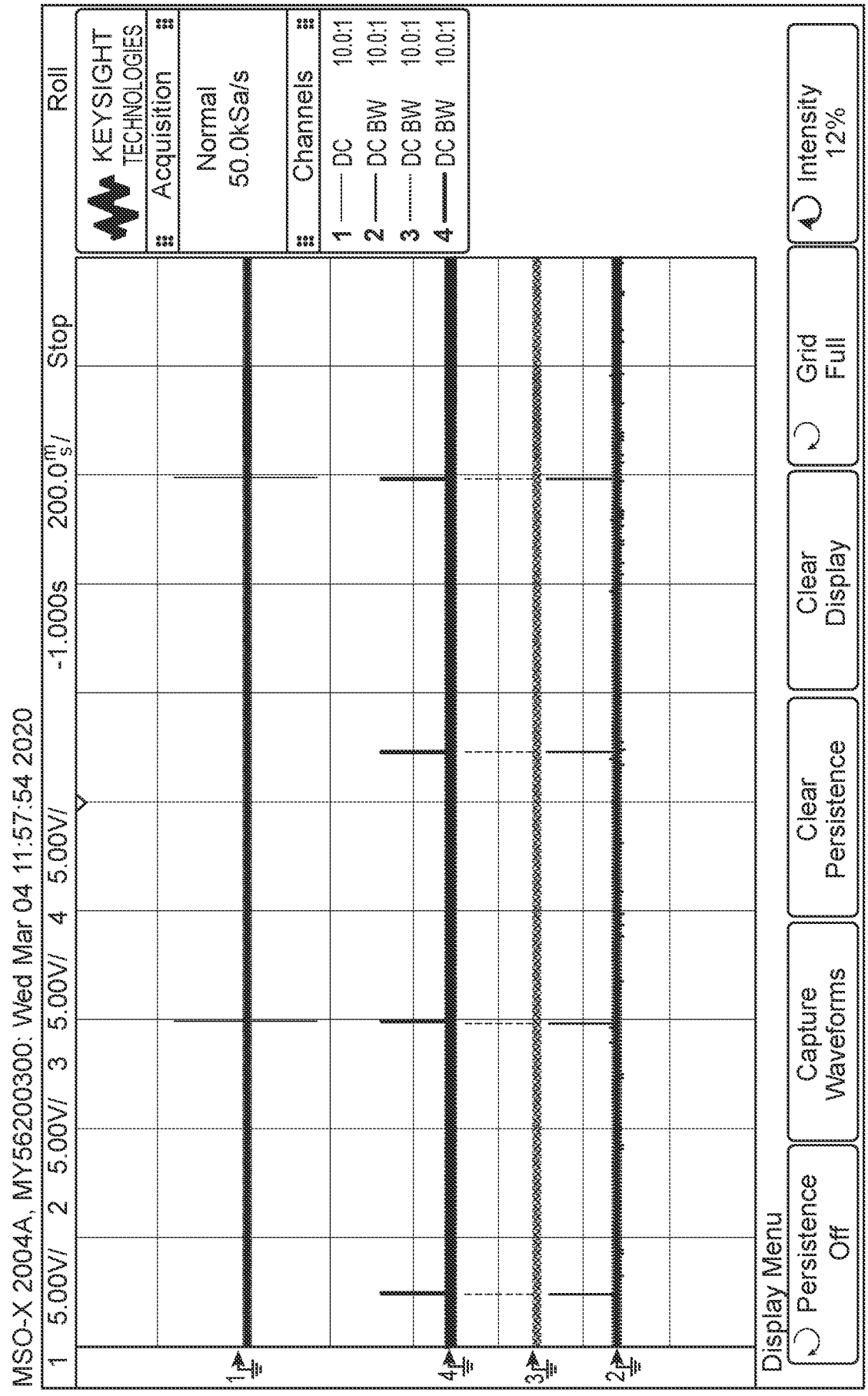
MSO-X 2004A, MY56200300: Wed Mar 04 11:57:54 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
-1.000s
200.0ms/
Stop
Roll
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
50.0kSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Intensity 12%
Grid Full
Clear Display
Clear Persistence
Capture Waveforms
Persistence Off
Display Menu

FIG. 13B

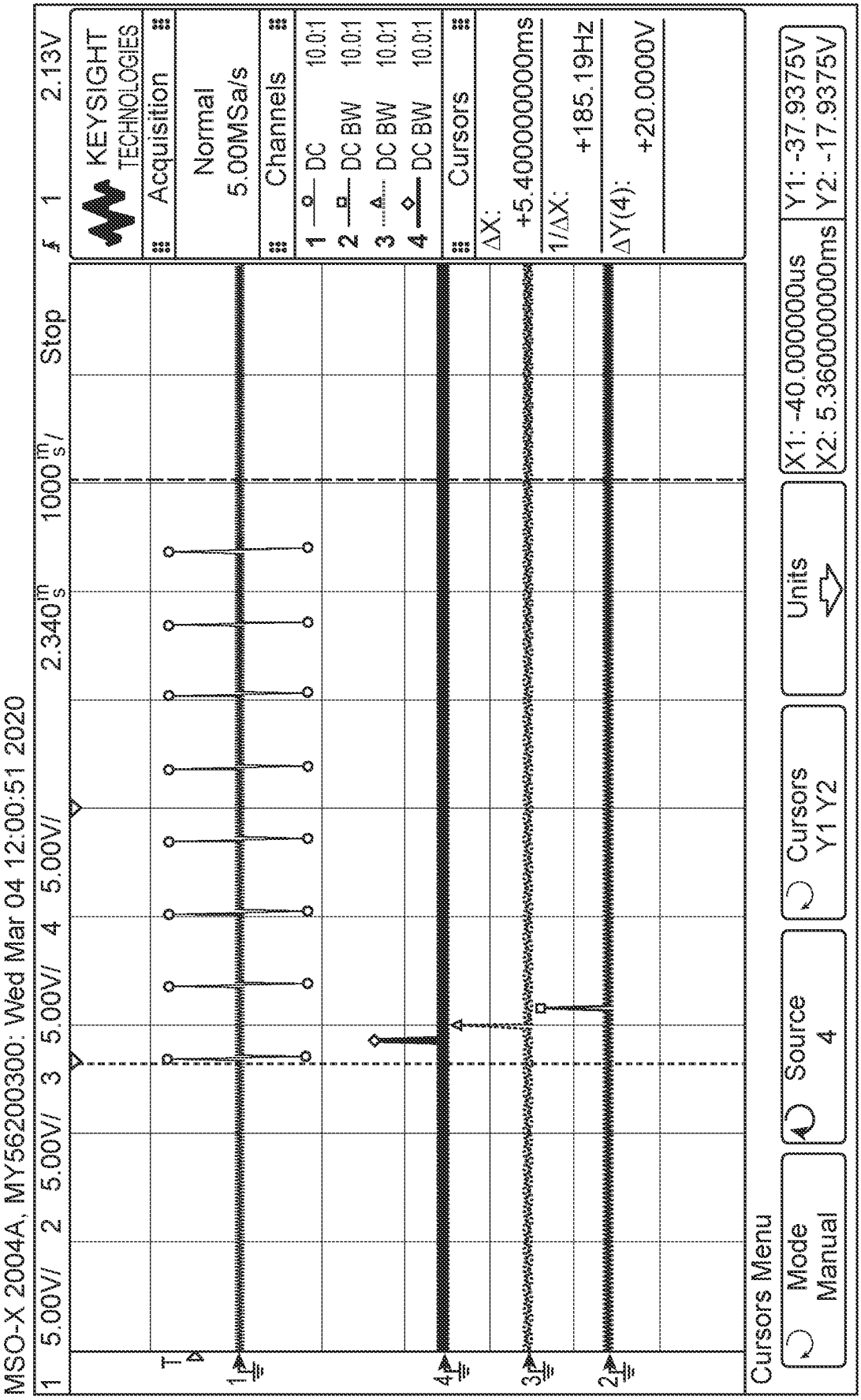
MSO-X 2004A, MY56200300: Wed Mar 04 12:00:51 2020
1 5.00V/ 2 5.00V/ 3 5.00V/ 4 5.00V/
2.340 ns
1000 ns/
Stop
1 2.13V
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
5.00MSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Cursors
ΔX:
+5.400000000ms
1/ΔX:
+185.19Hz
ΔY(4):
+20.0000V
Cursors Menu
Mode Manual
Source 4
Cursors Y1 Y2
Units
X1: -40.000000us
X2: 5.360000000ms
Y1: -37.9375V
Y2: -17.9375V

FIG. 13C

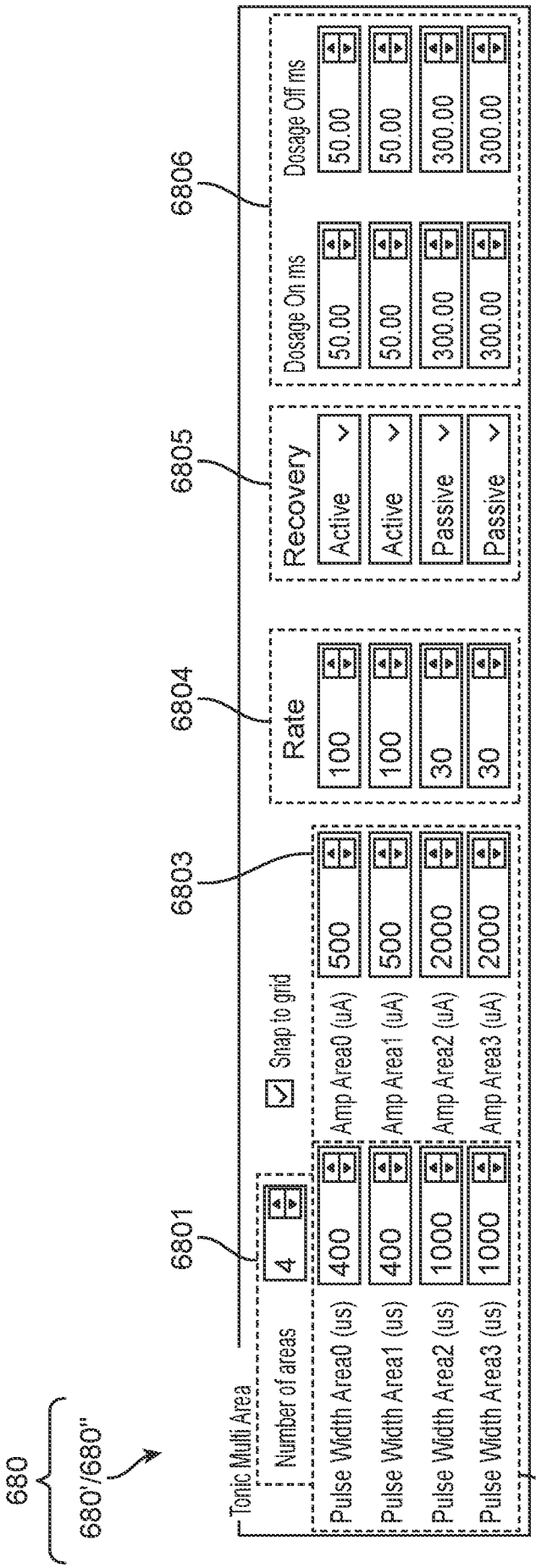
680
680'/680"
Tonic Multi Area
Number of areas
4
Snap to grid
Pulse Width Area0 (us)
400
Amp Area0 (uA)
500
Rate
100
Recovery
Active
Dosage On ms
50.00
Dosage Off ms
50.00
Pulse Width Area1 (us)
400
Amp Area1 (uA)
500
100
Active
50.00
50.00
Pulse Width Area2 (us)
1000
Amp Area2 (uA)
2000
30
Passive
300.00
300.00
Pulse Width Area3 (us)
1000
Amp Area3 (uA)
2000
30
Passive
300.00
300.00
6801
6802
6803
6804
6805
6806

FIG. 14A

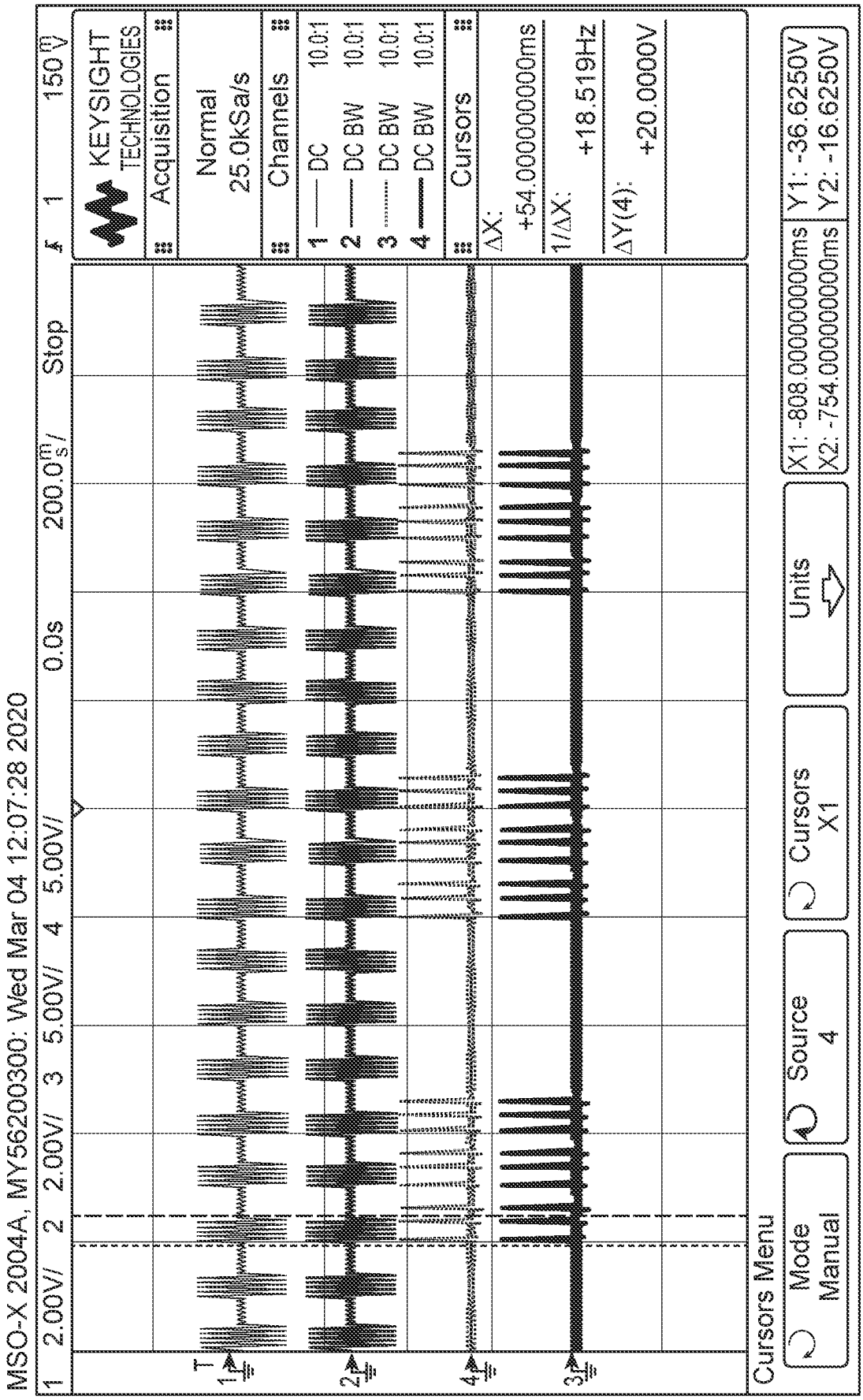
MSO-X 2004A, MY56200300: Wed Mar 04 12:07:28 2020
1 2.00V/ 2 2.00V/ 3 5.00V/ 4 5.00V/
0.0s
200.0ms/
Stop
1 150mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
25.0kSa/s
Channels
1 DC 10:1
2 DC BW 10:1
3 DC BW 10:1
4 DC BW 10:1
Cursors
ΔX:
+54.000000000ms
1/ΔX:
+18.519Hz
ΔY(4):
+20.0000V
Cursors Menu
Mode
Manual
Source
4
Cursors
X1
Units
X1: -808.000000000ms
X2: -754.000000000ms
Y1: -36.6250V
Y2: -16.6250V

FIG. 14B

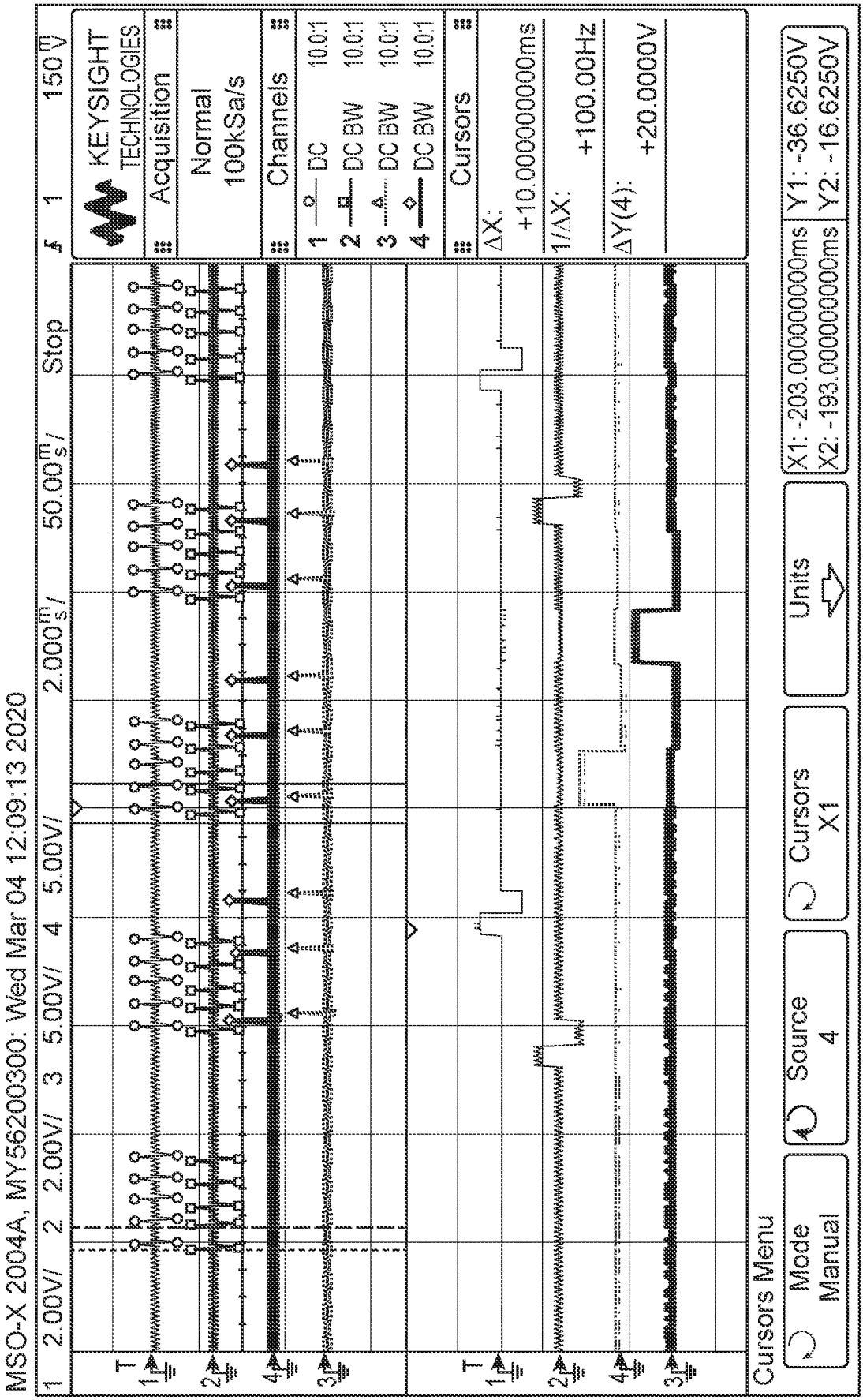
MSO-X 2004A, MY56200300: Wed Mar 04 12:09:13 2020
1 2.00V/ 2 2.00V/ 3 5.00V/ 4 5.00V/
2.000ms/
50.00ms/
Stop
1 150mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
100kSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Cursors
ΔX:
+10.000000000ms
1/ΔX:
+100.00Hz
ΔY(4):
+20.0000V
Cursors Menu
Mode Manual
Source 4
Cursors X1
Units
X1: -203.000000000ms
X2: -193.000000000ms
Y1: -36.6250V
Y2: -16.6250V

FIG. 14C

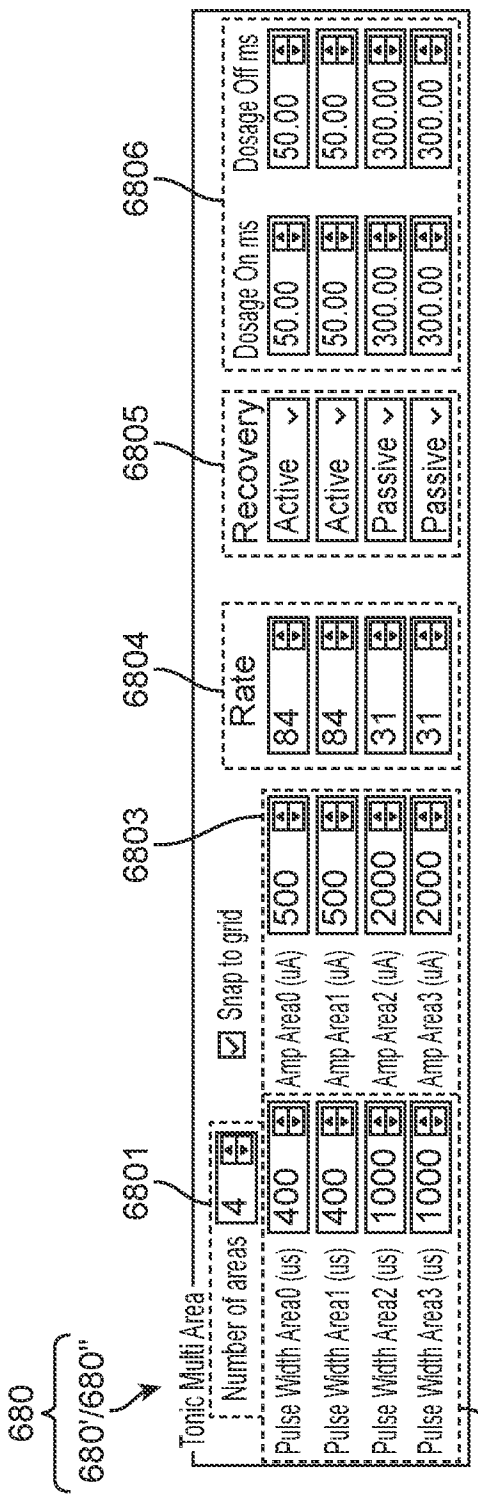

FIG. 15A

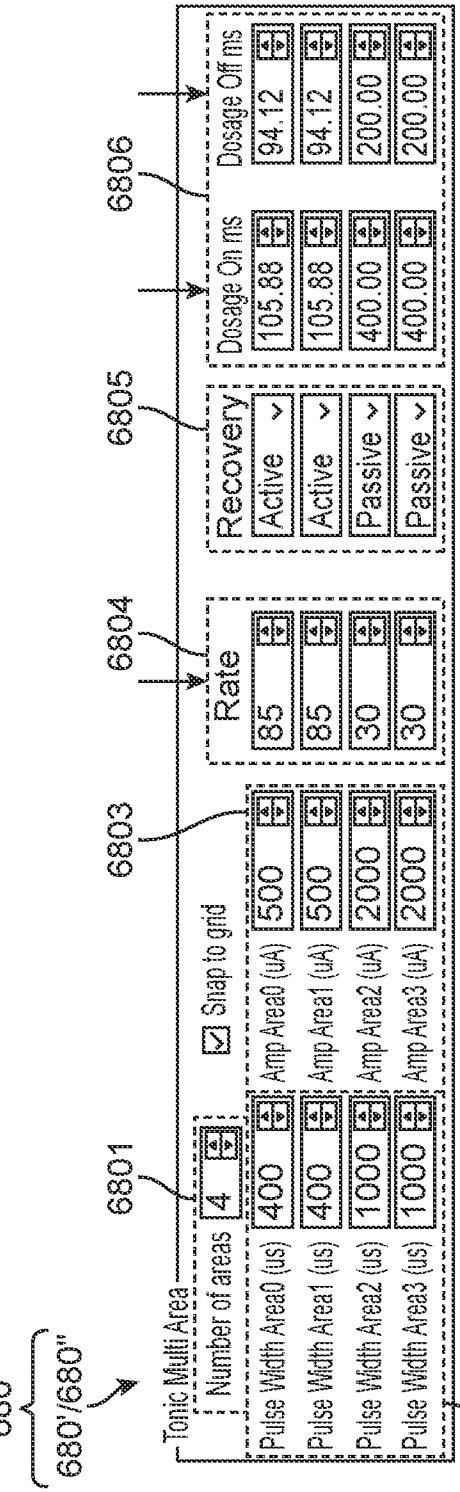

FIG. 15B

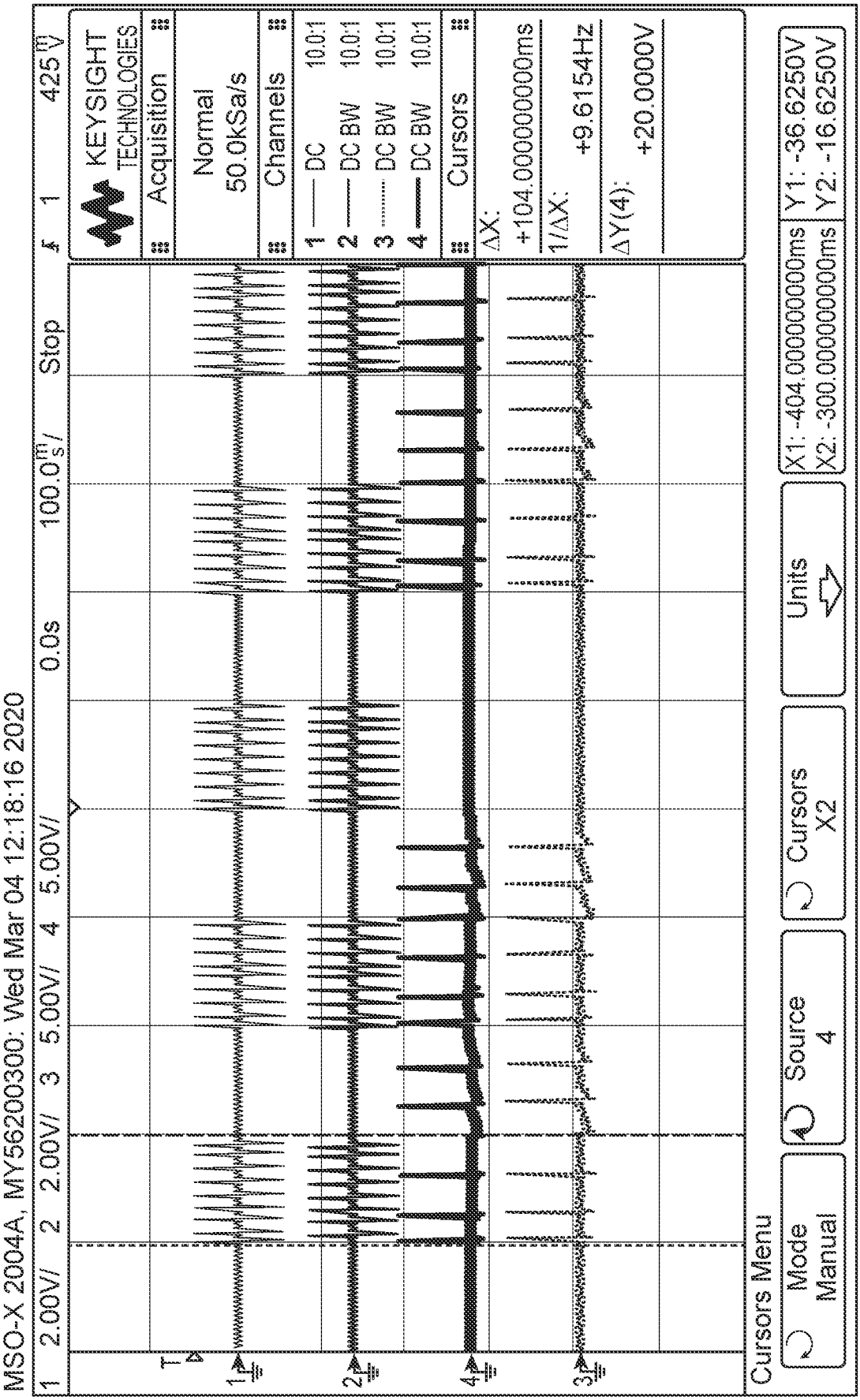
MSO-X 2004A, MY56200300: Wed Mar 04 12:18:16 2020
1 2.00V/ 2 2.00V/ 3 5.00V/ 4 5.00V/ 0.0s 100.0ms/ Stop 425mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
50.0kSa/s
Channels
1 DC 10:1
2 DC BW 10:1
3 DC BW 10:1
4 DC BW 10:1
Cursors
ΔX:
+104.000000000ms
1/ΔX:
+9.6154Hz
ΔY(4):
+20.0000V
Cursors Menu
Mode Manual
Source 4
Cursors X2
Units
X1: -404.000000000ms
X2: -300.000000000ms
Y1: -36.6250V
Y2: -16.6250V

FIG. 15C

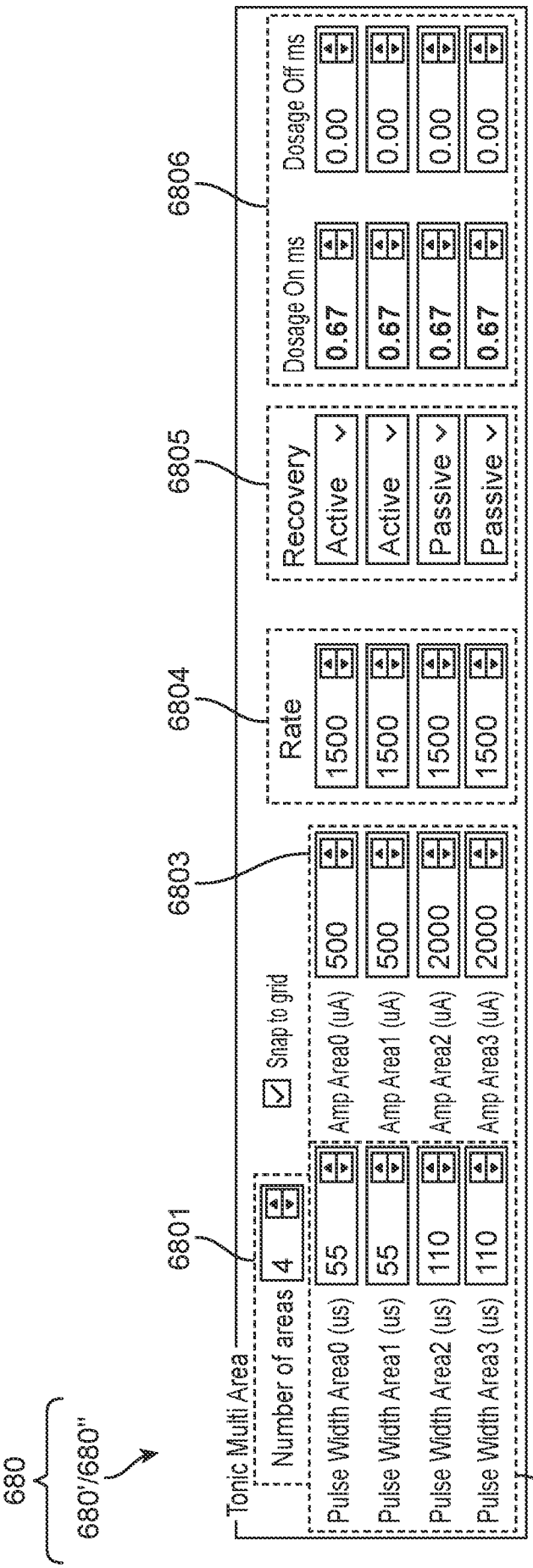
680
680'/680''
Tonic Multi Area
Number of areas
4
Snap to grid
Pulse Width Area0 (us)
55
Amp Area0 (uA)
500
Rate
1500
Recovery
Active
Dosage On ms
0.67
Dosage Off ms
0.00
Pulse Width Area1 (us)
55
Amp Area1 (uA)
500
1500
Active
0.67
0.00
Pulse Width Area2 (us)
110
Amp Area2 (uA)
2000
1500
Passive
0.67
0.00
Pulse Width Area3 (us)
110
Amp Area3 (uA)
2000
1500
Passive
0.67
0.00
6801
6802
6803
6804
6805
6806

FIG. 16A

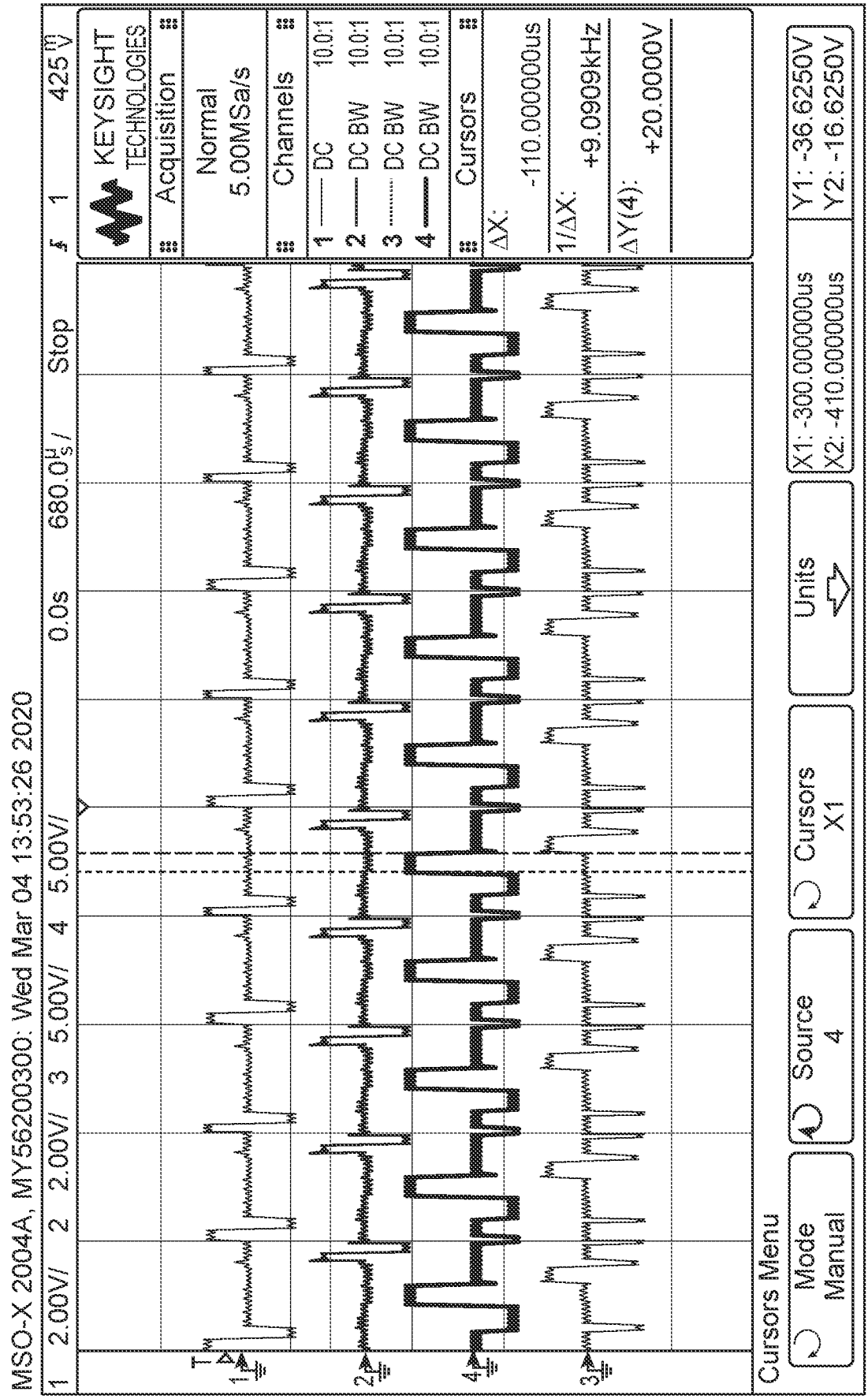
MSO-X 2004A, MY56200300: Wed Mar 04 13:53:26 2020
1 2.00V/ 2 2.00V/ 3 5.00V/ 4 5.00V/ 0.0s 680.0µs/ Stop 1 425 mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
5.00MSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Cursors
ΔX:
-110.000000us
1/ΔX:
+9.0909kHz
ΔY(4):
+20.0000V
Cursors Menu
Mode Manual
Source 4
Cursors X1
Units
X1: -300.000000us
X2: -410.000000us
Y1: -36.6250V
Y2: -16.6250V

FIG. 16B

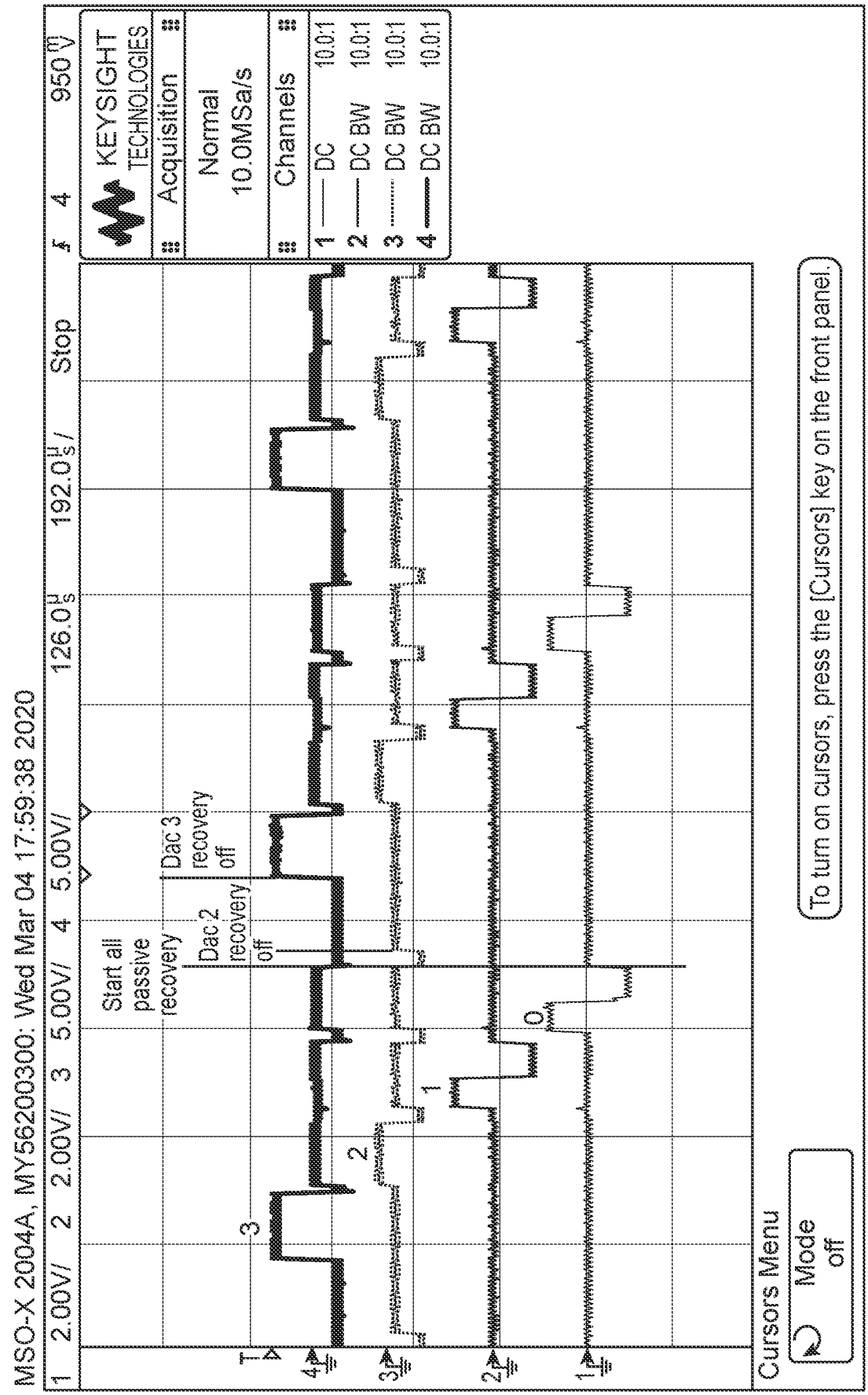
MSO-X 2004A, MY56200300: Wed Mar 04 17:59:38 2020
1 2.00V/ 2 2.00V/ 3 5.00V/ 4 5.00V/ 126.0µs 192.0µs/ Stop 4 950 mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
10.0MSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Start all passive recovery
Dac 2 recovery off
Dac 3 recovery off
Cursors Menu
Mode off
To turn on cursors, press the [Cursors] key on the front panel.

FIG. 16C

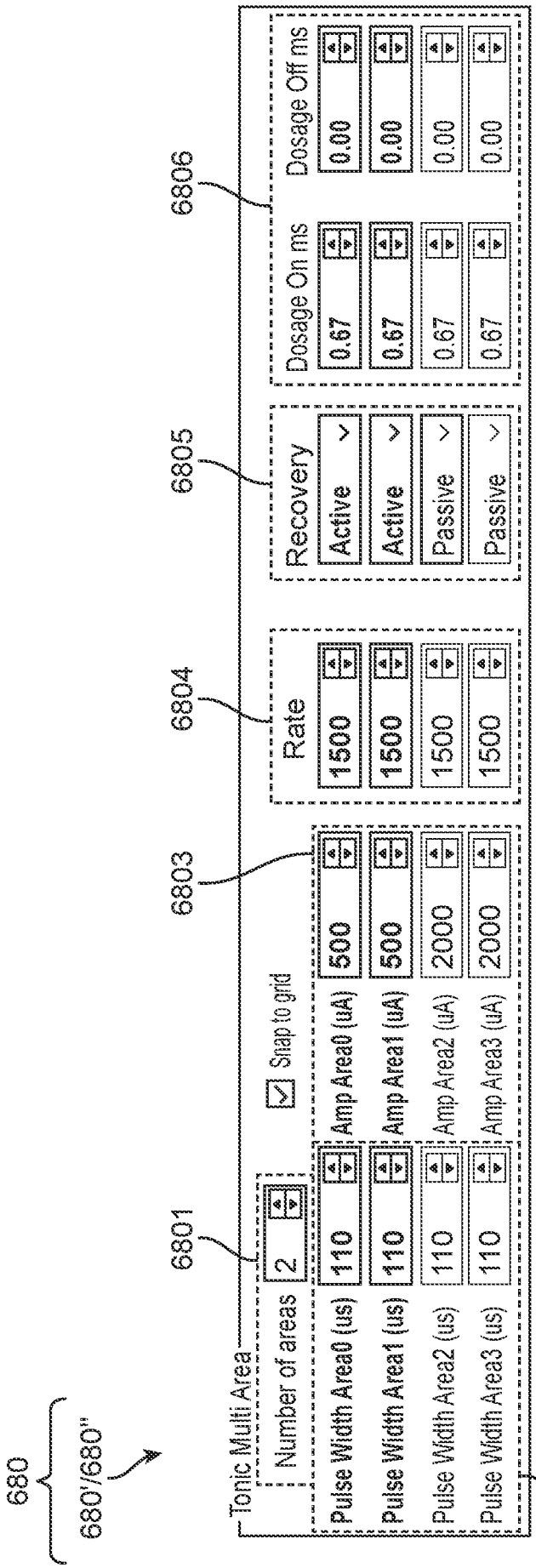
680
680'/680"
6802
Tonic Multi Area
Number of areas
2
Snap to grid
6801
6803
6804
6805
6806
Rate
Recovery
Dosage On ms
Dosage Off ms
Pulse Width Area0 (us)
110
Amp Area0 (uA)
500
1500
Active
0.67
0.00
Pulse Width Area1 (us)
110
Amp Area1 (uA)
500
1500
Active
0.67
0.00
Pulse Width Area2 (us)
110
Amp Area2 (uA)
2000
1500
Passive
0.67
0.00
Pulse Width Area3 (us)
110
Amp Area3 (uA)
2000
1500
Passive
0.67
0.00

FIG. 17A

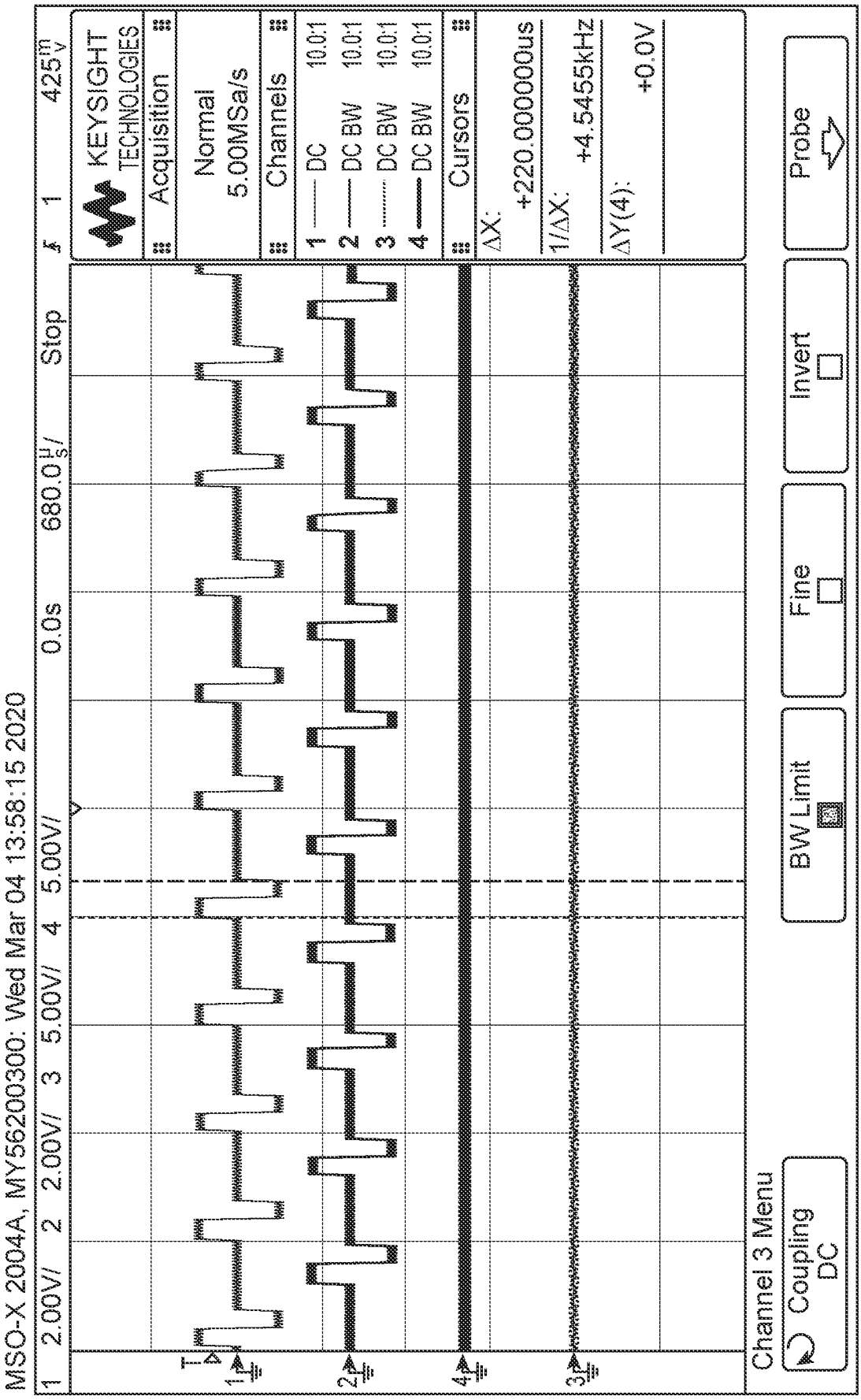
MSO-X 2004A, MY56200300: Wed Mar 04 13:58:15 2020
1 2.00V/ 2 2.00V/ 3 5.00V/ 4 5.00V/
0.0s
680.0µs/
Stop
1 425mV
KEYSIGHT TECHNOLOGIES
Acquisition
Normal
5.00MSa/s
Channels
1 DC 10.0:1
2 DC BW 10.0:1
3 DC BW 10.0:1
4 DC BW 10.0:1
Cursors
ΔX:
+220.000000us
1/ΔX:
+4.5455kHz
ΔY(4):
+0.0V
Channel 3 Menu
Coupling
DC
BW Limit
Fine
Invert
Probe

FIG. 17B

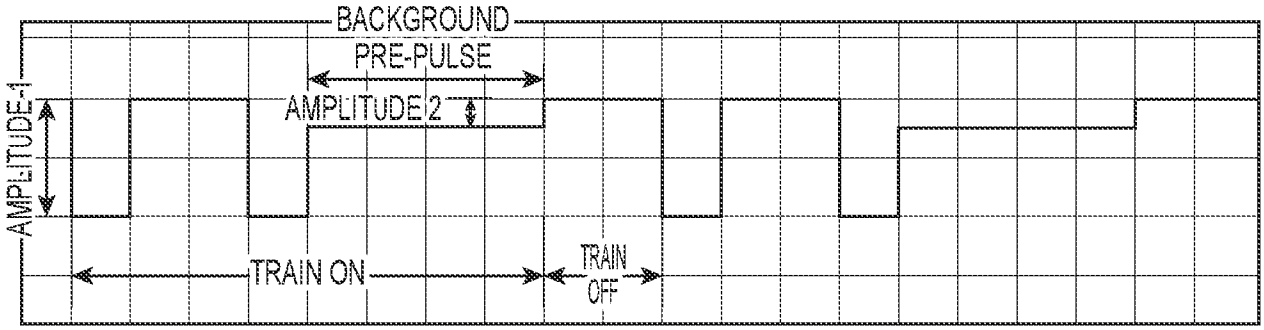

FIG. 18A

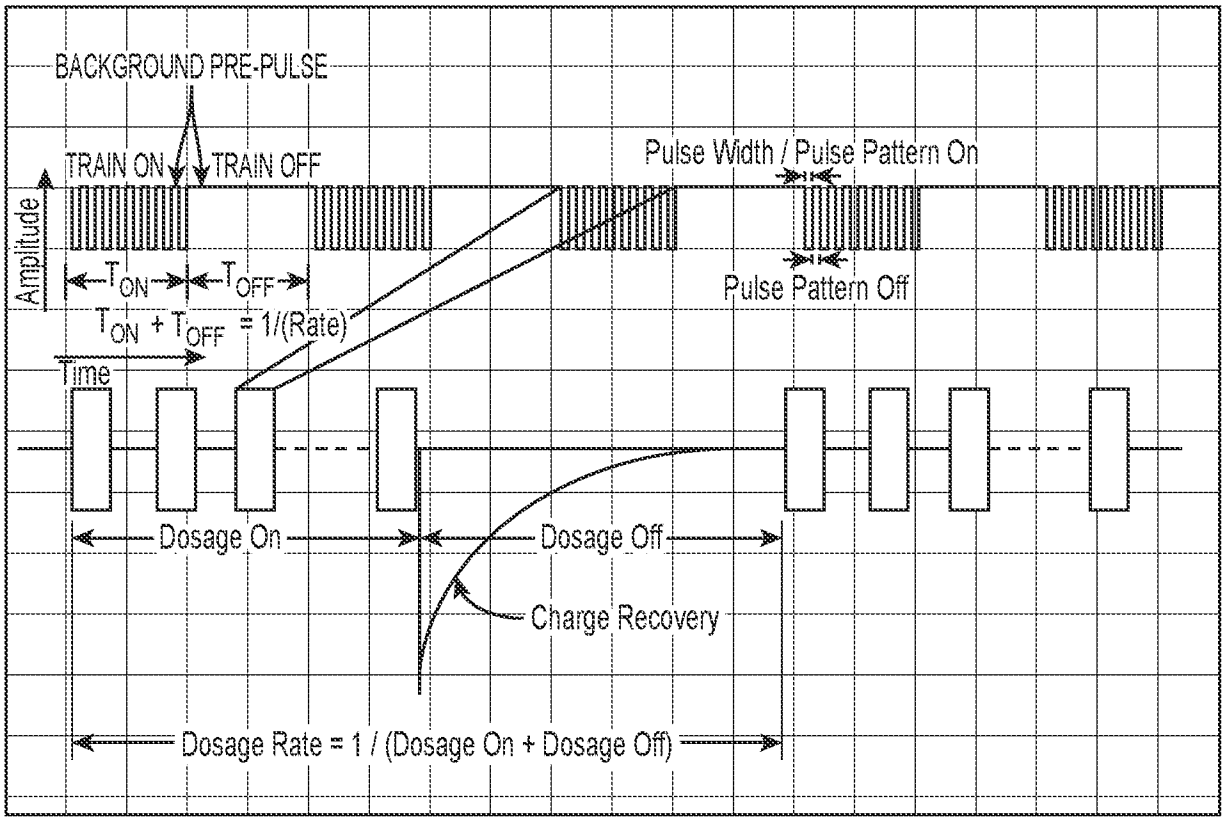

FIG. 18B

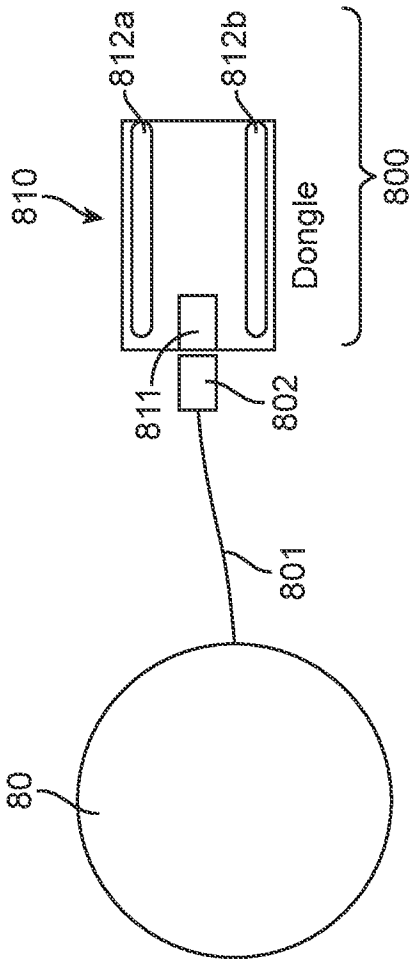

FIG. 19A

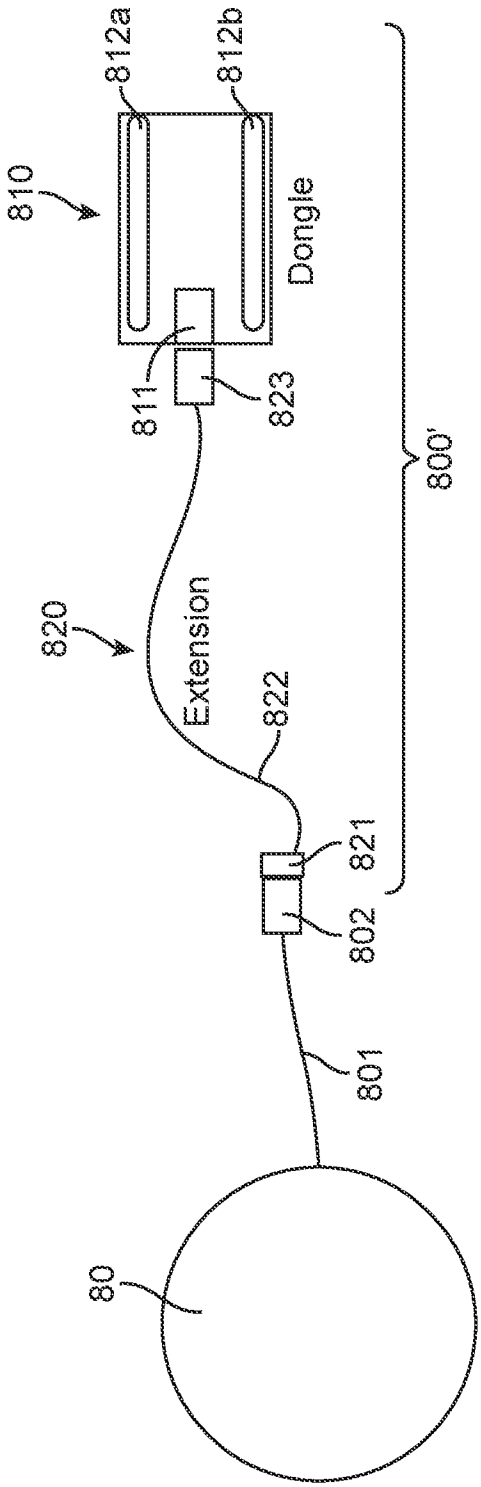

FIG. 19B

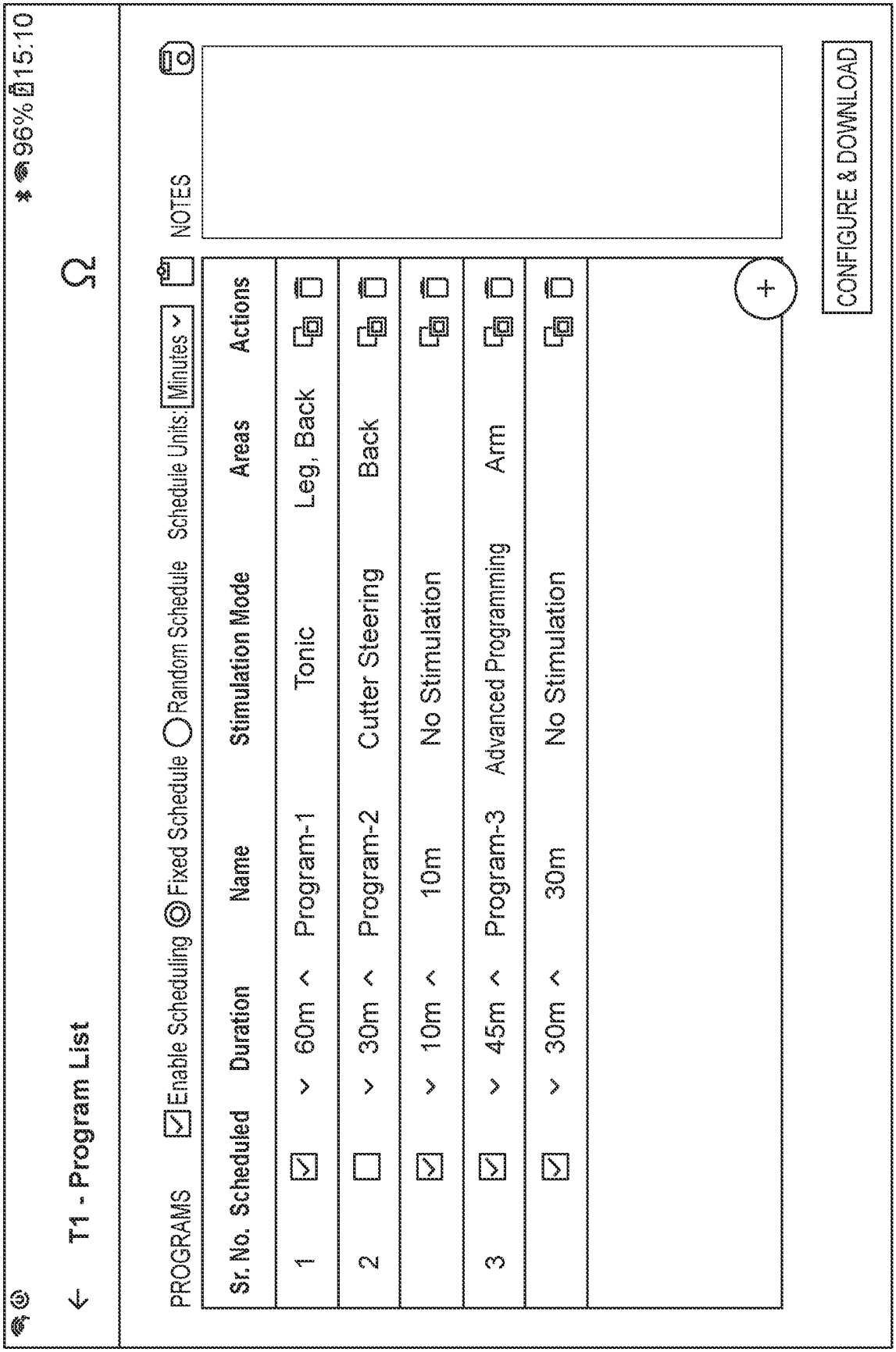
96% 15:10
T1 - Program List
PROGRAMS
Enable Scheduling
Fixed Schedule
Random Schedule
Schedule Units:
Minutes
NOTES
Sr. No.
Scheduled
Duration
Name
Stimulation Mode
Areas
Actions
1
60m
Program-1
Tonic
Leg, Back
2
30m
Program-2
Cutter Steering
Back
10m
10m
No Stimulation
3
45m
Program-3
Advanced Programming
Arm
30m
30m
No Stimulation
CONFIGURE & DOWNLOAD

FIG. 20

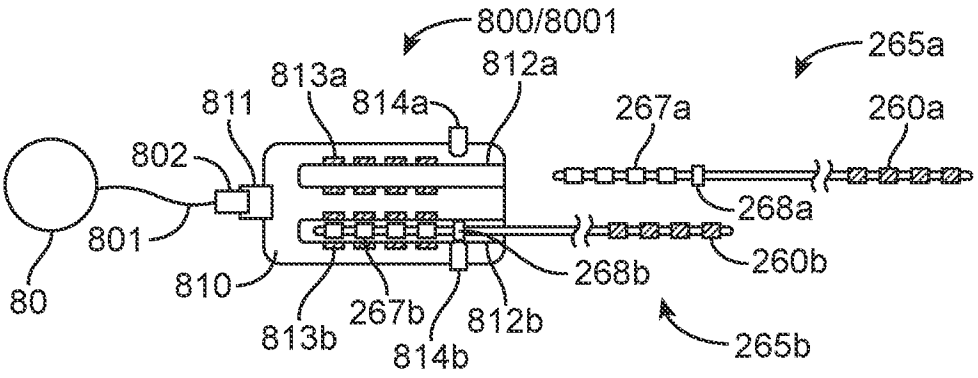

FIG. 21A

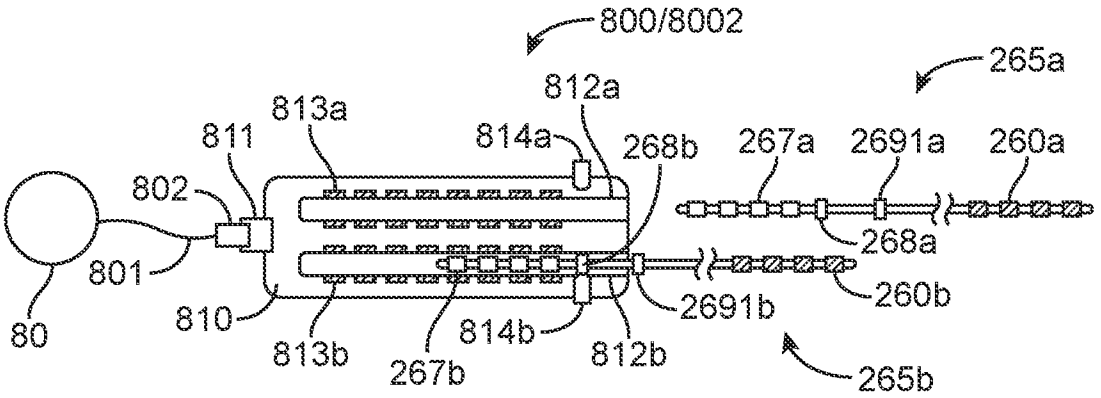

FIG. 21B

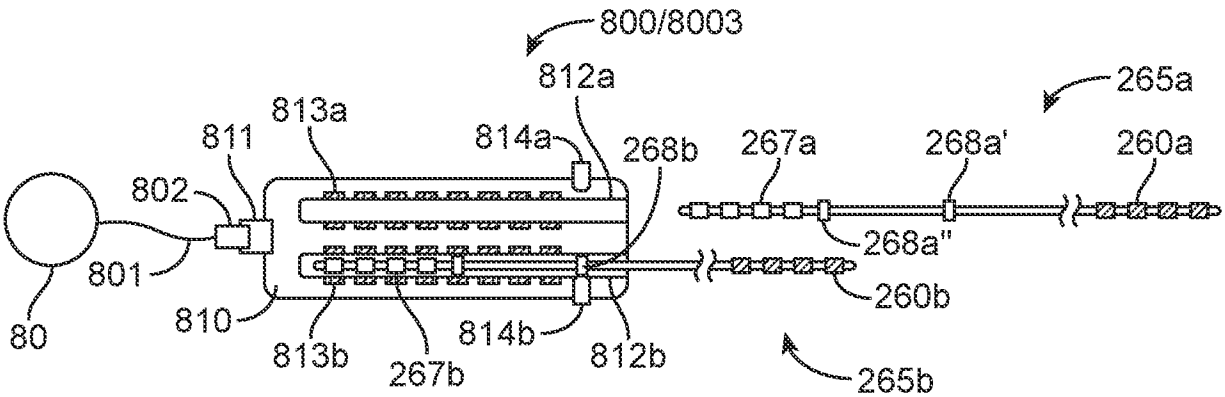

FIG. 21C

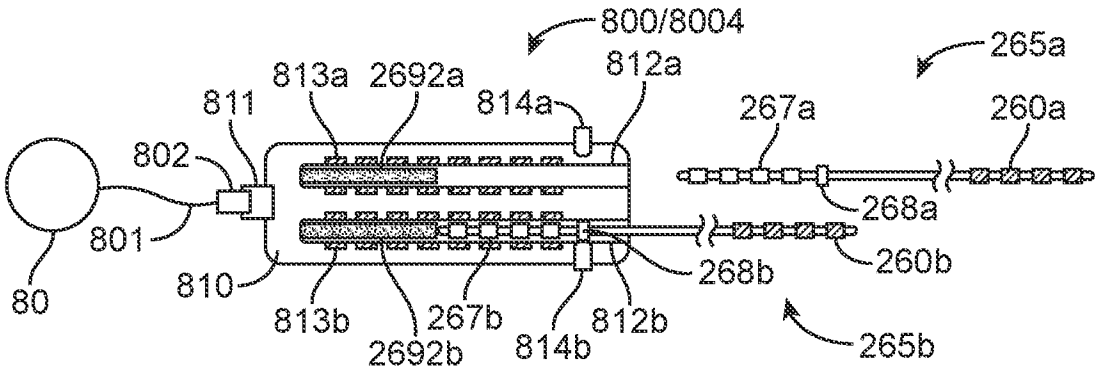

FIG. 21D

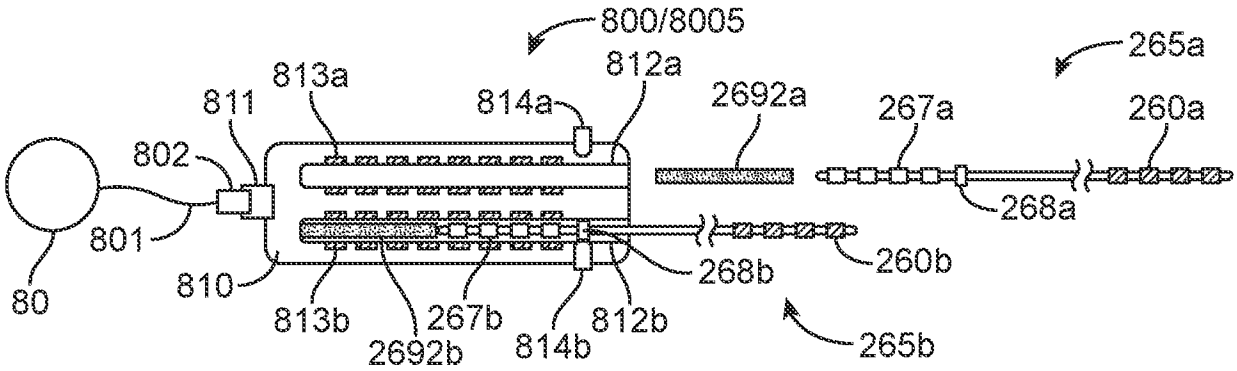

FIG. 21E

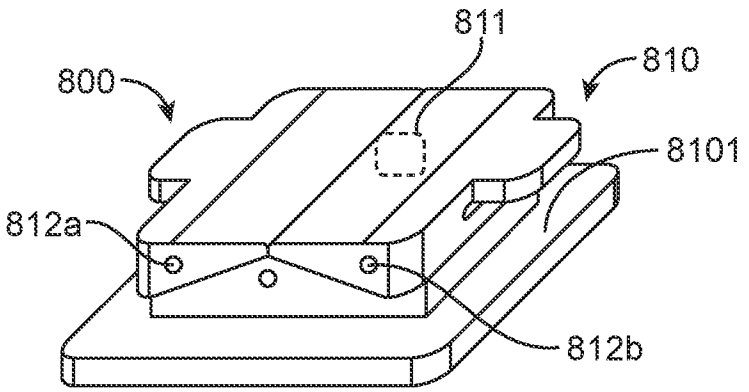

FIG. 22A

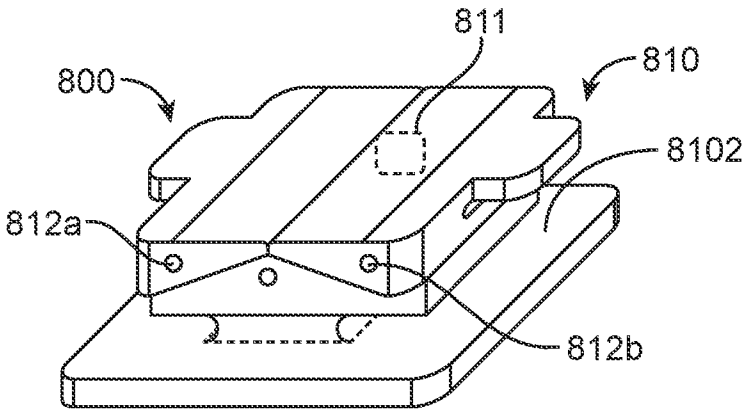

FIG. 22B

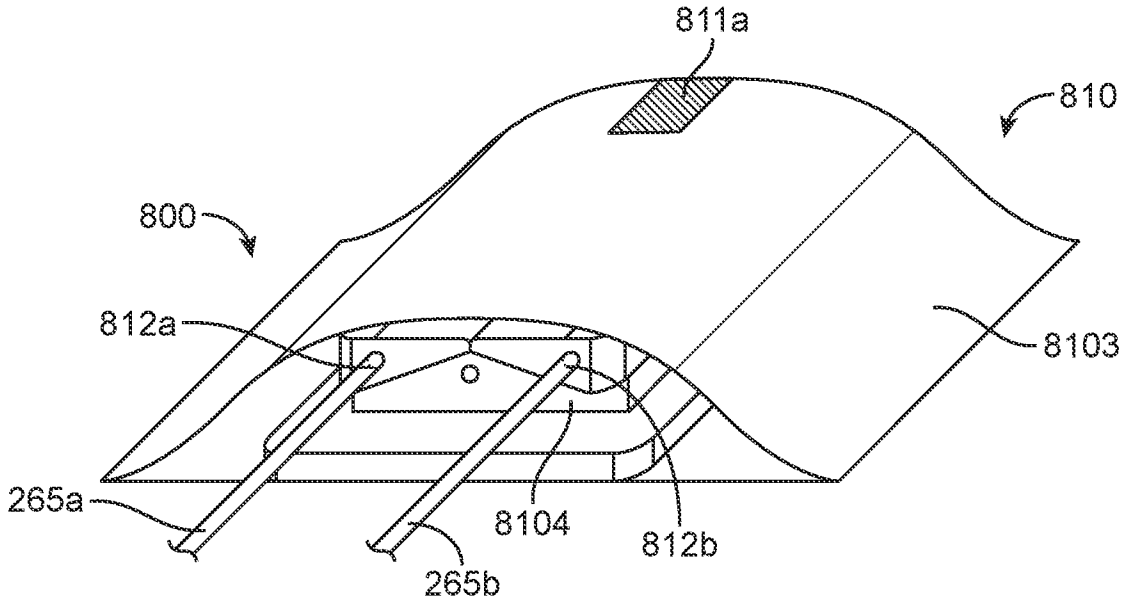

FIG. 22C

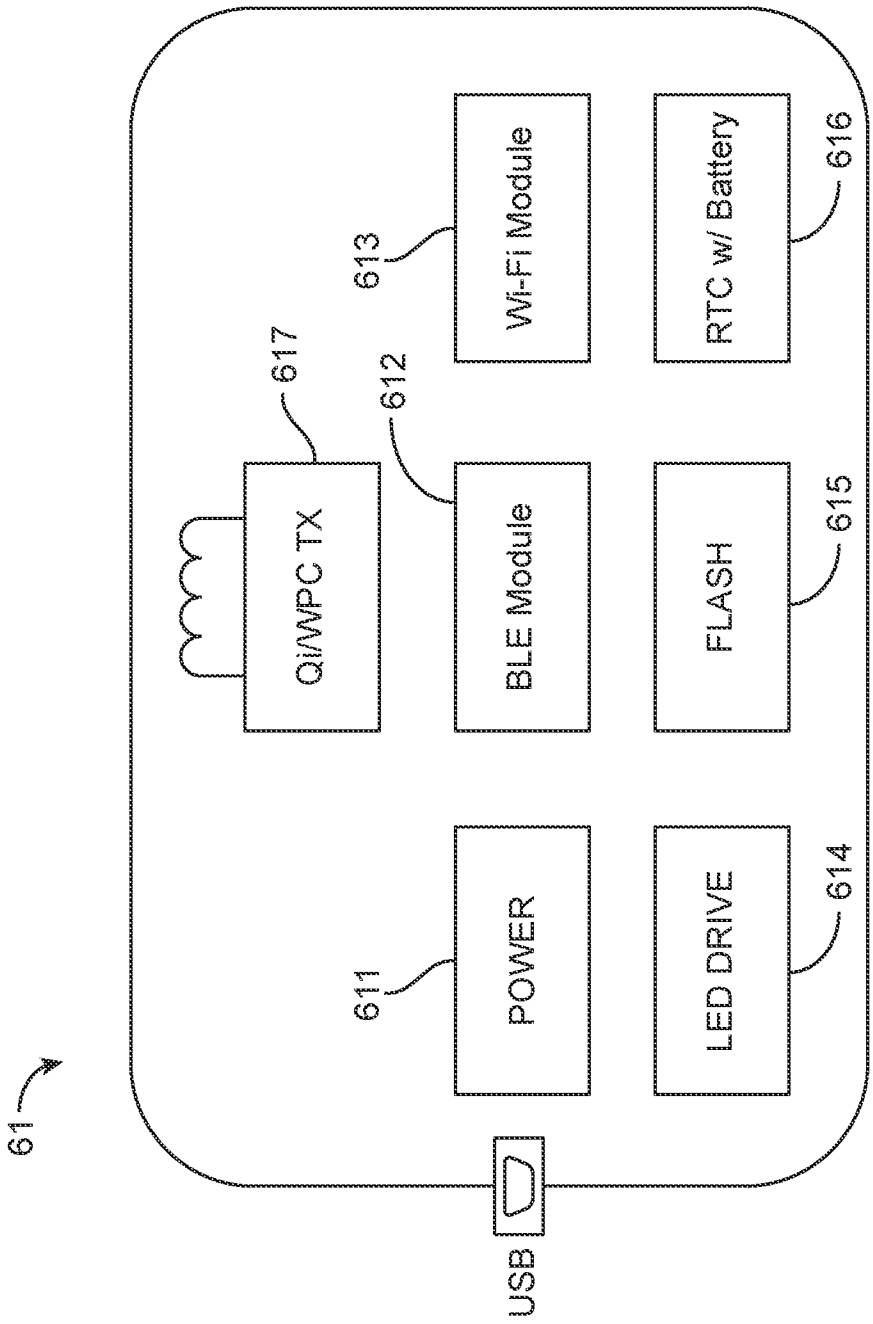
61
USB
611
POWER
LED DRIVE
614
612
BLE Module
FLASH
615
617
Qi/WPC TX
613
Wi-Fi Module
RTC w/ Battery
616

FIG. 23

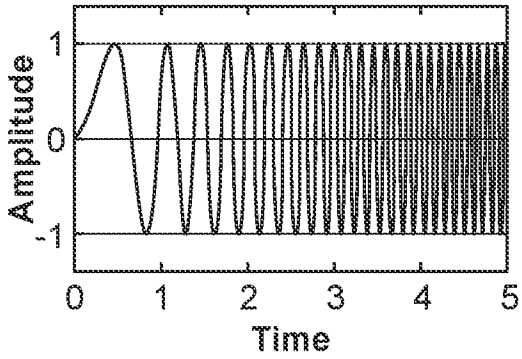

FIG. 24A

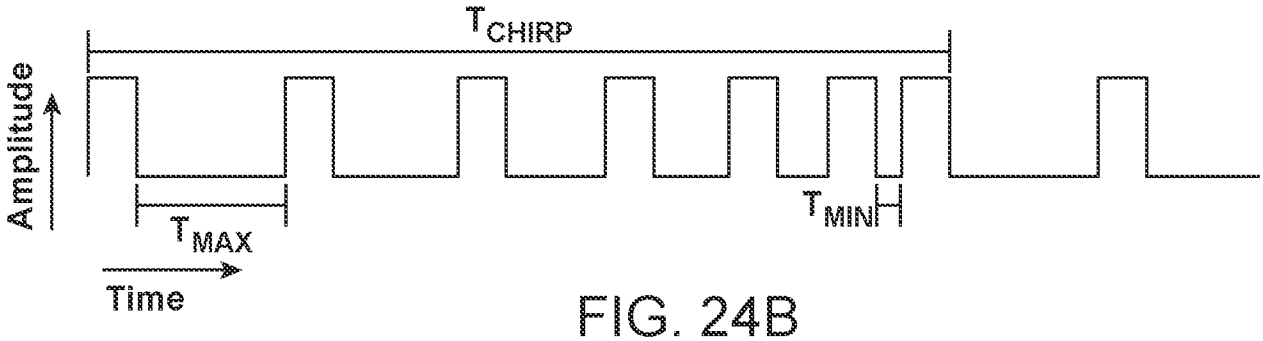

FIG. 24B

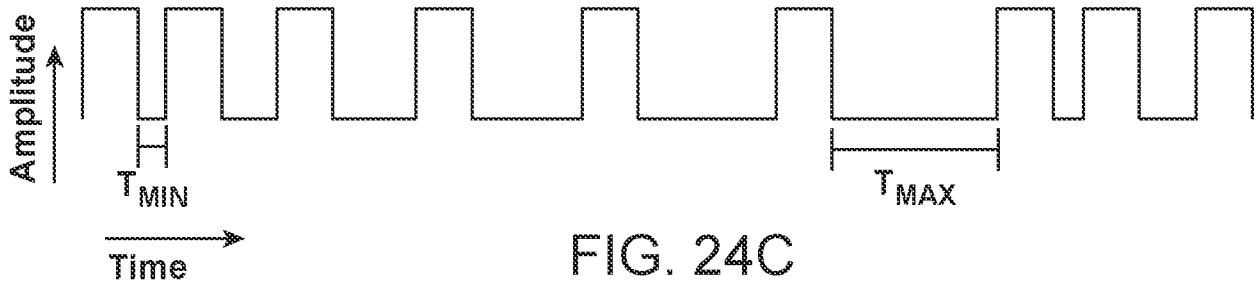

FIG. 24C

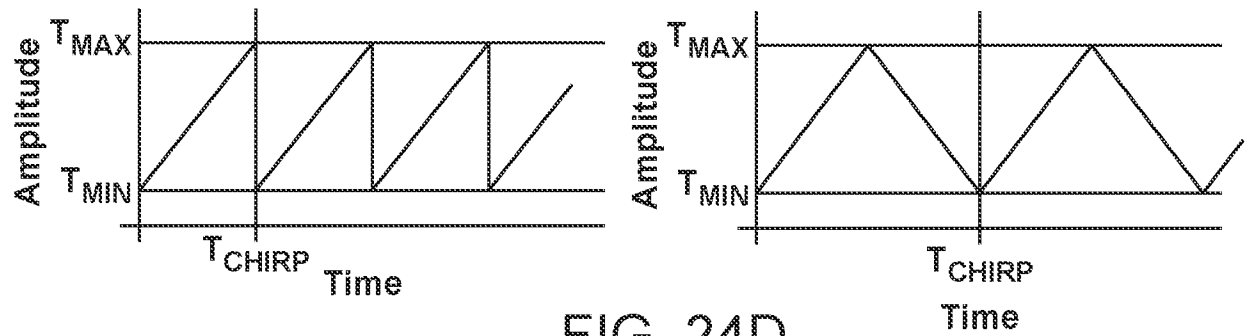

FIG. 24D

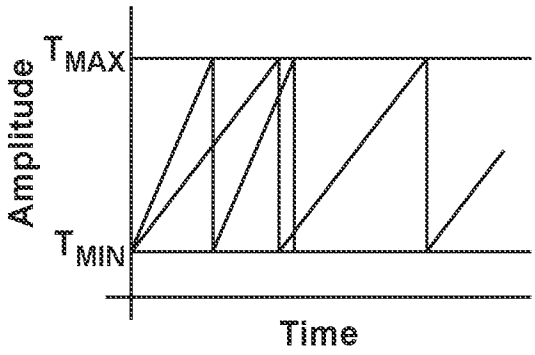

FIG. 24E

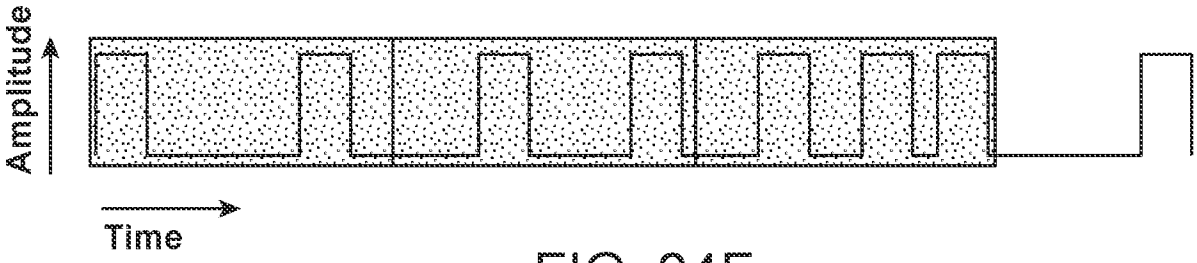

FIG. 24F

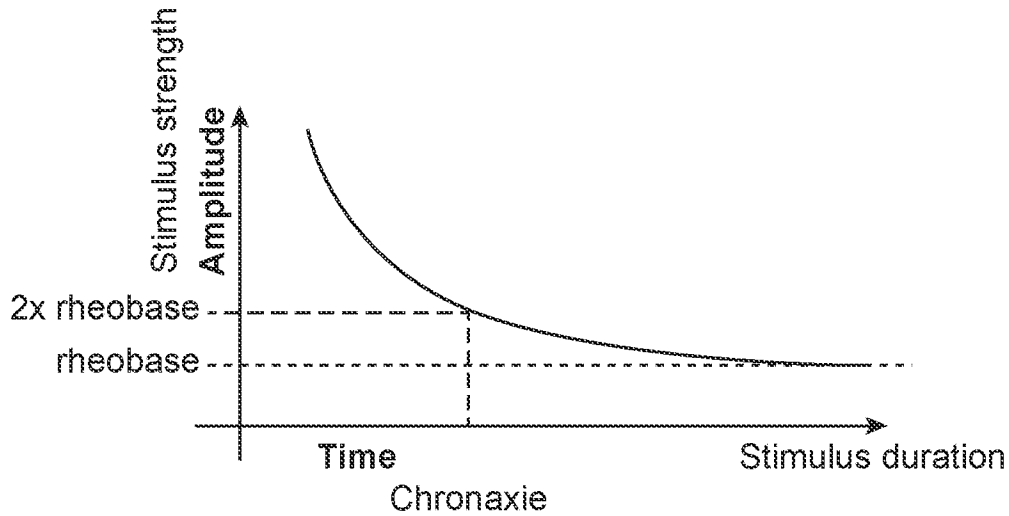

FIG. 24G

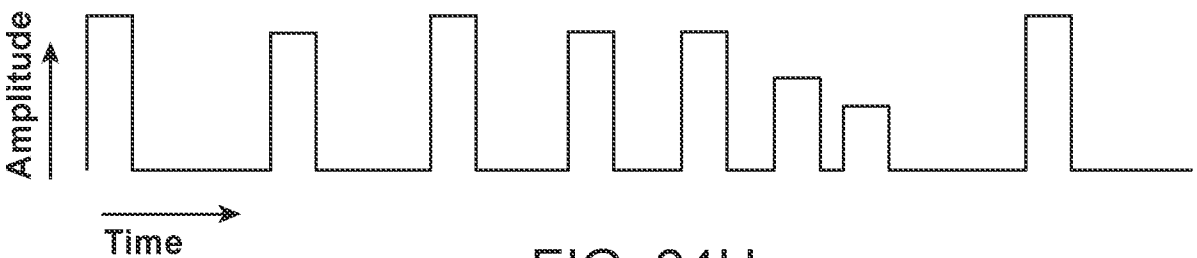

FIG. 24H

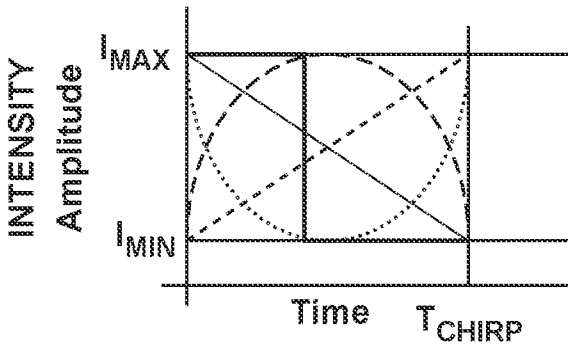

FIG. 24I

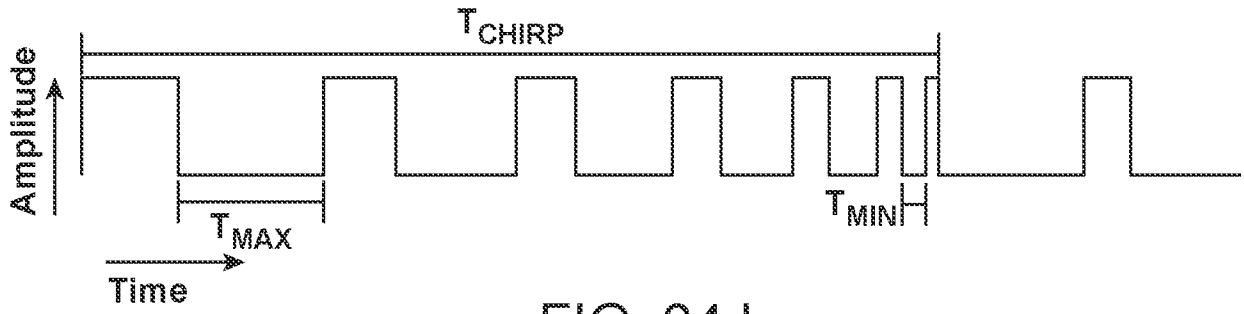

FIG. 24J

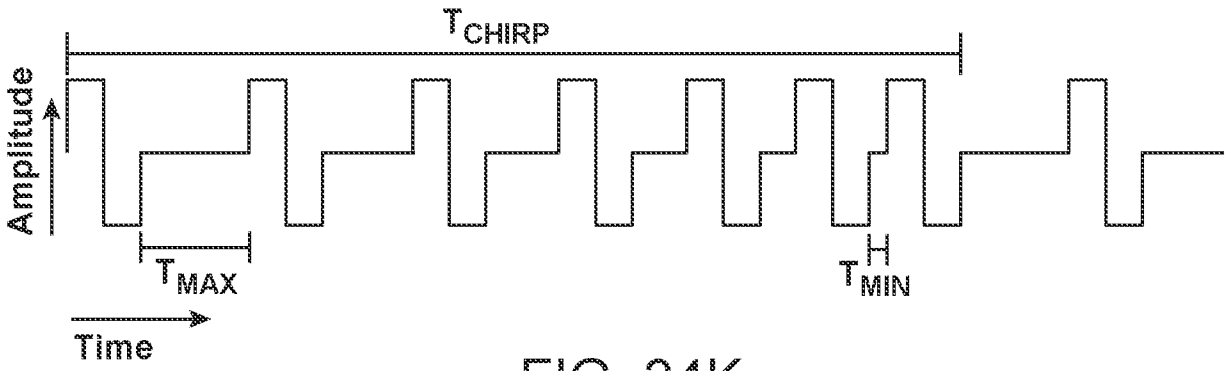

FIG. 24K

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/47815

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61N 1/36 (2021.01)

CPC - A61N 1/36146, A61N 1/36125, A61N 1/36

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)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/0144184 A1 (BOSTON SCIENTIFIC NEUROMODULATION CORPORATION) 26 May 2016 (26.05.2016) Entire document.	1-7
A	US 2015/0080982 A1 (BOSTON SCIENTIFIC NEUROMODULATION CORPORATION) 19 March 2015 (19.03.2015) Entire document.	1-7
A	US 2018/0071512 A1 (BOSTON SCIENTIFIC NEUROMODULATION CORPORATION) 15 May 2018 (15.05.2018) Entire document.	1-7

☐ 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
"D" document cited by the applicant in the international application
"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	Date of mailing of the international search report
07 November 2011 (07.11.2021)	DEC 14 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/47815

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 8-49
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.