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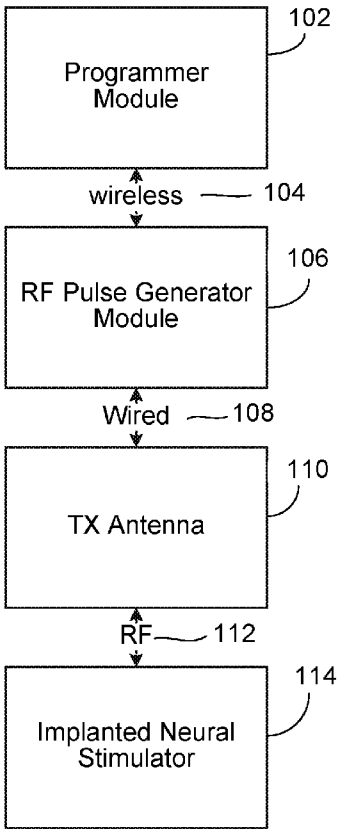

FIG 1

(57) Abstract: A flexible circuit includes a substrate; one or more radio-frequency (RF) ports on the substrate, the ports configured to couple to RF antennas configured to receive RF pulses from an external controller device; one or more banks of components on the substrate, the one or more banks of components configured to extract RF energy from the received RF pulses and to deliver electrical pulses suitable to stimulate neural tissue; an integrated circuit (IC) component on the substrate, the IC component configured to generate the electrical pulses suitable to stimulate neural tissue solely based on the extracted RF energy; and wherein the substrate, the one or more banks of components, and the integrated circuit component are sized and positioned on the substrate such that the flexible circuit flexes during implantation in a patient without becoming inoperable.

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FLEXIBLE CIRCUIT FOR AN IMPANTABLE DEVICE

TECHNICAL FIELD

This application relates generally to implantable stimulators.

BACKGROUND

Modulation of excitable tissue in the body by electrical stimulation has become an important type of therapy for patients with chronic disabling conditions, including chronic pain, problems of movement initiation and control, involuntary movements, vascular insufficiency, heart arrhythmias and more. A variety of therapeutic intra-body electrical stimulation techniques can treat these conditions. For instance, devices may be used to deliver stimulatory signals to excitable tissue, record vital signs, perform pacing or defibrillation operations, record action potential activity from targeted tissue, control drug release from time-release capsules or drug pump units, or interface with the auditory system to assist with hearing. Typically, such devices utilize a subcutaneous battery operated implantable pulse generator (IPG) to provide power or other charge storage mechanisms.

SUMMARY

In one aspect, some implementations provide a flexible circuit that includes a substrate; one or more radio-frequency (RF) ports on the substrate, the ports configured to couple to RF antennas configured to receive RF pulses from an external controller device; one or more banks of components on the substrate, the one or more banks of components configured to extract RF energy from the received RF pulses and to deliver electrical pulses suitable to stimulate neural tissue; an integrated circuit (IC) component on the substrate, the IC component configured to generate the electrical pulses suitable to stimulate neural tissue solely based on the extracted RF energy; and wherein the substrate, the one or more banks of components, and the integrated circuit component are sized and positioned on the substrate such that the flexible circuit flexes during implantation in a patient without becoming inoperable.

Implementations may include one or more of the following features.

The substrate may be sized to fit through a needle that is no larger than gauge 13. The substrate may have an aspect ratio of no less than 50.

Each bank of components may include components no more than 3mm wide, and the components may be spaced no more than 0.75mm apart. The components may be between 0.6 mm to 0.8 mm in height. Each bank of component is spaced 1.25 mm or more away from the IC component.

At least one component may include a capacitor no less than 1 μF. The one or more banks of components may include more than one capacitor. The banks of component bank may be configured to extract RF energy from a first portion of the received RF pulses and extract stimulation waveform parameters and polarity settings from a second portion of the received RF pulses, and wherein the first portion may precede the second portion.

The IC component is configured to: configure electrode settings according the extracted polarity settings.

The flexible circuit may further include one or more electrode interfaces attachable to electrodes to be placed around neural tissue.

The one or more banks of components may be configured to deliver the electrical pulses suitable to stimulate neural tissue to the one or more electrode interfaces such that neural tissue is stimulated by the electrical pulses according to the stimulation waveform parameter as extracted from the first portion of the received RF pulses.

The one or more electrode interfaces may be configured to adjust polarity settings on the electrodes according to the polarity settings as extracted from the second portion of the received RF pulses. No component on the flexible circuit breaks off from the substrate when a first end of the flexible circuit is bent towards a second end of the flexible circuit such that the first end and the second end form an angle as sharp as 45 degrees.

The flexible circuit may further include: one or more solder pond pad, the solder pond pad configured to localize tension during soldering such that surface mount components on the flexible circuit will not be displaced due to soldering heat.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts a high-level diagram of an example of a wireless stimulation system.

FIG. 2 depicts a detailed diagram of an example of the wireless stimulation system.

FIG. 3 is a circuit diagram showing an example of a wireless implantable stimulator device.

FIG. 4 is a circuit diagram of another example of a wireless implantable stimulator device.

FIG. 5 is a diagram of an example application-specific integrated circuit (ASIC) chip for implantable use.

FIG. 6 shows an example sequence during operation of the ASIC chip shown in FIG. 5.

FIG. 7A shows an example ASIC chip model for the ASIC chip shown in FIG. 5.

FIG. 7B shows example waveforms simulated based on the chip model of FIG. 7A.

FIG. 8A shows an example current steering feature for the ASIC chip shown in FIG. 5.

FIG. 8B shows example waveforms at various points in an ASIC chip with the current steering feature.

FIGS. 9A-9B show an example of a flexible circuit for an implantable neural stimulator device.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

In various implementations, systems and methods are disclosed for applying one or more electrical impulses to targeted excitable tissue, such as nerves, for treating chronic pain, inflammation, arthritis, sleep apnea, seizures, incontinence, pain associated with cancer, incontinence, problems of movement initiation and control, involuntary movements, vascular insufficiency, heart arrhythmias, obesity, diabetes, craniofacial pain, such as migraines or cluster headaches, and other disorders. In certain embodiments, a device may be used to send electrical energy to targeted nerve tissue by using remote radio frequency (RF) energy without cables or inductive coupling to power a passive implanted wireless stimulator device. The targeted nerves can include, but are not limited to, the spinal cord and surrounding areas, including the dorsal horn, dorsal root ganglion, the exiting nerve roots, nerve ganglions, the dorsal column fibers and the peripheral nerve bundles leaving the dorsal column and brain, such as the vagus, occipital, trigeminal, hypoglossal, sacral, coccygeal nerves and the like.

A wireless stimulation system can include an implantable stimulator device with one or more electrodes and one or more conductive antennas (for example, dipole or patch antennas), and internal circuitry for frequency waveform and electrical energy rectification. The system may further comprise an external controller and antenna for transmitting radio

frequency or microwave energy from an external source to the implantable stimulator device with neither cables nor inductive coupling to provide power.

In various implementations, the wireless implantable stimulator device is powered wirelessly (and therefore does not require a wired connection, or a power source such as a battery) and contains the circuitry necessary to receive the pulse instructions from a source external to the body. For example, various embodiments employ internal dipole (or other) antenna configuration(s) to receive RF power through electrical radiative coupling. This allows such devices to produce electrical currents capable of stimulating nerve bundles without a physical connection to an implantable pulse generator (IPG) or use of an inductive coil.

According to some implementations, the wireless implantable stimulator device includes an application-specific integrated circuit (ASIC) chip for interacting with an external controller and the electrodes contained within the device. The ASIC chip may harvest RF power from the received input signal sent from the external controller to power the wireless implantable stimulator device, including the ASIC chip. The ASIC chip may also extract waveform parameters from the received input signal and use such information to create electrical impulses for stimulating excitable tissues through the electrodes. In particular, the ASIC chip contains a current steering feature to mirror currents to each electrode with evenness while maintaining a compact chip size. Moreover, the ASIC chip may extract polarity setting information from the received input signal and use such information to set the polarity for electrode interfaces.

Implementations include a flexible circuit on which various components are included, such as rectifying circuits, waveform conditioning circuits, voltage regulators, shunt resistors, as well as the ASIC chip. The flexible circuit and various components thereon are shaped and sized such that the flexible circuit, as integrated into a neural stimulator device, can be delivered through the inner lumen of a needle of gauge 13 or smaller. In particular, various components are each kept no more than 3mm wide and more than 0.75mm apart to maintain an overall flexibility of the circuit.

FIG. **1** depicts a high-level diagram of an example of a wireless stimulation system. The wireless stimulation system may include four major components, namely, a programmer module **102**, an RF pulse generator module **106**, a transmit (TX) antenna **110** (for example, a patch antenna, slot antenna, or a dipole antenna), and an implanted wireless stimulator device **114**. The programmer module **102** may be a computer device, such as a smart phone, running a software application that supports a wireless connection **104**, such

as Bluetooth®. The application can enable the user to view the system status and diagnostics, change various parameters, increase/decrease the desired stimulus amplitude of the electrode pulses, and adjust feedback sensitivity of the RF pulse generator module **106**, among other functions.

The RF pulse generator module **106** may include communication electronics that support the wireless connection **104**, the stimulation circuitry, and the battery to power the generator electronics. In some implementations, the RF pulse generator module **106** includes the TX antenna embedded into its packaging form factor while, in other implementations, the TX antenna is connected to the RF pulse generator module **106** through a wired connection **108** or a wireless connection (not shown). The TX antenna **110** may be coupled directly to tissue to create an electric field that powers the implanted wireless stimulator device **114**. The TX antenna **110** communicates with the implanted wireless stimulator device **114** through an RF interface. For instance, the TX antenna **110** radiates an RF transmission signal that is modulated and encoded by the RF pulse generator module **110**. The implanted wireless stimulator device of module 114 contains one or more antennas, such as dipole antenna(s), to receive and transmit through RF interface **112**. In particular, the coupling mechanism between antenna **110** and the one or more antennas on the implanted wireless stimulation device of module **114** utilizes electrical radiative coupling and not inductive coupling. In other words, the coupling is through an electric field rather than a magnetic field.

Through this electrical radiative coupling, the TX antenna **110** can provide an input signal to the implanted wireless stimulator device **114**. This input signal contains energy and may contain information encoding stimulus waveforms to be applied at the electrodes of the implanted wireless stimulator device **114**. In some implementations, the power level of this input signal directly determines an applied amplitude (for example, power, current, or voltage) of the one or more electrical pulses created using the electrical energy contained in the input signal. Within the implanted wireless stimulator device **114** are components for demodulating the RF transmission signal, and electrodes to deliver the stimulation to surrounding neuronal tissue.

The RF pulse generator module **106** can be implanted subcutaneously, or it can be worn external to the body. When external to the body, the RF generator module **106** can be incorporated into a belt or harness design to allow for electric radiative coupling through the skin and underlying tissue to transfer power and/or control parameters to the implanted wireless stimulator device **114**. In either event, receiver circuit(s) internal to the wireless

stimulator device **114** (or wireless implantable stimulator device 500 shown in FIG. 5) can capture the energy radiated by the TX antenna **110** and convert this energy to an electrical waveform. The receiver circuit(s) may further modify the waveform to create an electrical pulse suitable for the stimulation of neural tissue.

In some implementations, the RF pulse generator module **106** can remotely control the stimulus parameters (that is, the parameters of the electrical pulses applied to the neural tissue) and monitor feedback from the wireless stimulator device **114** based on RF signals received from the implanted wireless stimulator device **114**. A feedback detection algorithm implemented by the RF pulse generator module **106** can monitor data sent wirelessly from the implanted wireless stimulator device **114**, including information about the energy that the implanted wireless stimulator device **114** is receiving from the RF pulse generator and information about the stimulus waveform being delivered to the electrode pads. In order to provide an effective therapy for a given medical condition, the system can be tuned to provide the optimal amount of excitation or inhibition to the nerve fibers by electrical stimulation. A closed loop feedback control method can be used in which the output signals from the implanted wireless stimulator device **114** are monitored and used to determine the appropriate level of neural stimulation current for maintaining effective neuronal activation, or, in some cases, the patient can manually adjust the output signals in an open loop control method.

FIG. **2** depicts a detailed diagram of an example of the wireless stimulation system. As depicted, the programming module **102** may comprise user input system **202** and communication subsystem **208**. The user input system **221** may allow various parameter settings to be adjusted (in some cases, in an open loop fashion) by the user in the form of instruction sets. The communication subsystem **208** may transmit these instruction sets (and other information) via the wireless connection **104**, such as Bluetooth or Wi-Fi, to the RF pulse generator module **106**, as well as receive data from module **106**.

For instance, the programmer module **102**, which can be utilized for multiple users, such as a patient's control unit or clinician's programmer unit, can be used to send stimulation parameters to the RF pulse generator module **106**. The stimulation parameters that can be controlled may include pulse amplitude, pulse frequency, and pulse width in the ranges shown in Table **1**. In this context the term pulse refers to the phase of the waveform that directly produces stimulation of the tissue; the parameters of the charge-balancing phase (described below) can similarly be controlled. The patient and/or the clinician can also optionally control overall duration and pattern of treatment.

Stimulation Parameter Table 1

Pulse Amplitude:	0 to 20 mA
Pulse Frequency:	0 to 10000 Hz
Pulse Width:	0 to 2 ms

The RF pulse generator module **106** may be initially programmed to meet the specific parameter settings for each individual patient during the initial implantation procedure. Because medical conditions or the body itself can change over time, the ability to re-adjust the parameter settings may be beneficial to ensure ongoing efficacy of the neural modulation therapy.

The programmer module **102** may be functionally a smart device and associated application. The smart device hardware may include a CPU **206** and be used as a vehicle to handle touchscreen input on a graphical user interface (GUI) **204**, for processing and storing data.

The RF pulse generator module **106** may be connected via wired connection **108** to an external TX antenna **110**. Alternatively, both the antenna and the RF pulse generator are located subcutaneously (not shown).

The signals sent by RF pulse generator module **106** to the implanted wireless stimulator device **114** may include both power and parameter-setting attributes in regards to stimulus waveform, amplitude, pulse width, and frequency. The RF pulse generator module **106** can also function as a wireless receiving unit that receives feedback signals from the implanted wireless stimulator device **114**. To that end, the RF pulse generator module **106** may contain microelectronics or other circuitry to handle the generation of the signals transmitted to the device **114** as well as handle feedback signals, such as those from the stimulator device **114**. For example, the RF pulse generator module **106** may comprise controller subsystem **214**, high-frequency oscillator **218**, RF amplifier **216**, a RF switch, and a feedback subsystem **212**.

The controller subsystem **214** may include a CPU **230** to handle data processing, a memory subsystem **228** such as a local memory, communication subsystem **234** to communicate with programmer module **102** (including receiving stimulation parameters from programmer module), pulse generator circuitry **236**, and digital/analog (D/A) converters **232**.

The controller subsystem **214** may be used by the patient and/or the clinician to control the stimulation parameter settings (for example, by controlling the parameters of the signal sent from RF pulse generator module **106** to the stimulator device **114**). These parameter settings can affect, for example, the power, current level, or shape of the one or more electrical pulses. The programming of the stimulation parameters can be performed using the programming module **102**, as described above, to set the repetition rate, pulse width, amplitude, and waveform that will be transmitted by RF energy to the receiving (RX) antenna **238**, typically a dipole antenna (although other types may be used), in the implanted wireless stimulation device **214**. The clinician may have the option of locking and/or hiding certain settings within the programmer interface, thus limiting the patient's ability to view or adjust certain parameters because adjustment of certain parameters may require detailed medical knowledge of neurophysiology, neuroanatomy, protocols for neural modulation, and safety limits of electrical stimulation.

The controller subsystem **214** may store received parameter settings in the local memory subsystem **228**, until the parameter settings are modified by new input data received from the programming module **102**. The CPU **206** may use the parameters stored in the local memory to control the pulse generator circuitry **236** to generate a stimulus waveform that is modulated by a high frequency oscillator **218** in the range from **300** MHz to **8** GHz (preferably between about 700 MHz and 5.8 GHz and more preferably between about 800 MHz and 1.3 GHz). The resulting RF signal may then be amplified by RF amplifier **226** and then sent through an RF switch **223** to the TX antenna **110** to reach through depths of tissue to the RX antenna **238**.

In some implementations, the RF signal sent by TX antenna **110** may simply be a power transmission signal used by the wireless stimulation device module **114** to generate electric pulses. In other implementations, a telemetry signal may also be transmitted to the wireless stimulator device **114** to send instructions about the various operations of the wireless stimulator device **114**. The telemetry signal may be sent by the modulation of the carrier signal (through the skin if external, or through other body tissues if the pulse generator module **106** is implanted subcutaneously). The telemetry signal is used to modulate the carrier signal (a high frequency signal) that is coupled onto the implanted antenna(s) **238** and does not interfere with the input received on the same stimulator device to power the device. In one embodiment the telemetry signal and powering signal are combined into one signal, where the RF telemetry signal is used to modulate the RF powering signal, and thus the wireless stimulation device is powered directly by the

received telemetry signal; separate subsystems in the wireless stimulation device harness the power contained in the signal and interpret the data content of the signal.

The RF switch **223** may be a multipurpose device such as a dual directional coupler, which passes the relatively high amplitude, extremely short duration RF pulse to the TX antenna **110** with minimal insertion loss while simultaneously providing two low-level outputs to feedback subsystem **212**; one output delivers a forward power signal to the feedback subsystem **212**, where the forward power signal is an attenuated version of the RF pulse sent to the TX antenna **110**, and the other output delivers a reverse power signal to a different port of the feedback subsystem **212**, where reverse power is an attenuated version of the reflected RF energy from the TX Antenna **110**.

During the on-cycle time (when an RF signal is being transmitted to wireless stimulator device **114**), the RF switch **223** is set to send the forward power signal to feedback subsystem. During the off-cycle time (when an RF signal is not being transmitted to the wireless stimulator device **114**), the RF switch **223** can change to a receiving mode in which the reflected RF energy and/or RF signals from the wireless stimulator device **114** are received to be analyzed in the feedback subsystem **212**.

The feedback subsystem **212** of the RF pulse generator module **106** may include reception circuitry to receive and extract telemetry or other feedback signals from the wireless stimulator device **114** and/or reflected RF energy from the signal sent by TX antenna **110**. The feedback subsystem may include an amplifier **226**, a filter **224**, a demodulator **222**, and an A/D converter **220**.

The feedback subsystem **212** receives the forward power signal and converts this high-frequency AC signal to a DC level that can be sampled and sent to the controller subsystem **214**. In this way the characteristics of the generated RF pulse can be compared to a reference signal within the controller subsystem **214**. If a disparity (error) exists in any parameter, the controller subsystem **214** can adjust the output to the RF pulse generator **106**. The nature of the adjustment can be, for example, proportional to the computed error. The controller subsystem **214** can incorporate additional inputs and limits on its adjustment scheme such as the signal amplitude of the reverse power and any predetermined maximum or minimum values for various pulse parameters.

The reverse power signal can be used to detect fault conditions in the RF-power delivery system. In an ideal condition, when TX antenna **110** has perfectly matched impedance to the tissue that it contacts, the electromagnetic waves generated from the RF pulse generator **106** pass unimpeded from the TX antenna **110** into the body tissue.

However, in real-world applications a large degree of variability may exist in the body types of users, types of clothing worn, and positioning of the antenna **110** relative to the body surface. Since the impedance of the antenna **110** depends on the relative permittivity of the underlying tissue and any intervening materials, and also depends on the overall separation distance of the antenna from the skin, in any given application there can be an impedance mismatch at the interface of the TX antenna **110** with the body surface. When such a mismatch occurs, the electromagnetic waves sent from the RF pulse generator **106** are partially reflected at this interface, and this reflected energy propagates backward through the antenna feed.

The dual directional coupler RF switch **223** may prevent the reflected RF energy propagating back into the amplifier **226**, and may attenuate this reflected RF signal and send the attenuated signal as the reverse power signal to the feedback subsystem **212**. The feedback subsystem **212** can convert this high-frequency AC signal to a DC level that can be sampled and sent to the controller subsystem **214**. The controller subsystem **214** can then calculate the ratio of the amplitude of the reverse power signal to the amplitude of the forward power signal. The ratio of the amplitude of reverse power signal to the amplitude level of forward power may indicate severity of the impedance mismatch.

In order to sense impedance mismatch conditions, the controller subsystem **214** can measure the reflected-power ratio in real time, and according to preset thresholds for this measurement, the controller subsystem **214** can modify the level of RF power generated by the RF pulse generator **106**. For example, for a moderate degree of reflected power the course of action can be for the controller subsystem **214** to increase the amplitude of RF power sent to the TX antenna **110**, as would be needed to compensate for slightly non-optimum but acceptable TX antenna coupling to the body. For higher ratios of reflected power, the course of action can be to prevent operation of the RF pulse generator **106** and set a fault code to indicate that the TX antenna **110** has little or no coupling with the body. This type of reflected-power fault condition can also be generated by a poor or broken connection to the TX antenna. In either case, it may be desirable to stop RF transmission when the reflected-power ratio is above a defined threshold, because internally reflected power can lead to unwanted heating of internal components, and this fault condition means the system cannot deliver sufficient power to the implanted wireless stimulation device and thus cannot deliver therapy to the user.

The controller **242** of the wireless stimulator device **114** may transmit informational signals, such as a telemetry signal, through the antenna **238** to communicate with the RF

pulse generator module **106** during its receive cycle. For example, the telemetry signal from the wireless stimulator device **114** may be coupled to the modulated signal on the dipole antenna(s) **238**, during the on and off state of the transistor circuit to enable or disable a waveform that produces the corresponding RF bursts necessary to transmit to the external (or remotely implanted) pulse generator module **106**. The antenna(s) **238** may be connected to electrodes **254** in contact with tissue to provide a return path for the transmitted signal. An A/D (not shown) converter can be used to transfer stored data to a serialized pattern that can be transmitted on the pulse-modulated signal from the internal antenna(s) **238** of the wireless stimulator device **114**. The telemetry signal can also use backscattering technique, where the uplink signal from the stimulator to the external module can overlap in time, while downlink and uplink signals occur at the same time, and external device demodulates the signal via reflected power level reading.

A telemetry signal from the implanted wireless stimulator device **114** may include stimulus parameters such as the power or the amplitude of the current that is delivered to the tissue from the electrodes. The feedback signal can be transmitted to the RF pulse generator module **116** to indicate the strength of the stimulus at the nerve bundle by means of coupling the signal to the implanted RX antenna **238**, which radiates the telemetry signal to the external (or remotely implanted) RF pulse generator module **106**. The feedback signal can include either or both an analog and digital telemetry pulse modulated carrier signal. Data such as stimulation pulse parameters and measured characteristics of stimulator performance can be stored in an internal memory device within the implanted stimulator device **114**, and sent on the telemetry signal. The frequency of the carrier signal may be in the range of at **300** MHz to **8** GHz (preferably between about 700 MHz and 5.8 GHz and more preferably between about 800 MHz and 1.3 GHz).

In the feedback subsystem **212**, the telemetry signal can be down modulated using demodulator **222** and digitized by being processed through an analog to digital (A/D) converter **220**. The digital telemetry signal may then be routed to a CPU **230** with embedded code, with the option to reprogram, to translate the signal into a corresponding current measurement in the tissue based on the amplitude of the received signal. The CPU **230** of the controller subsystem **214** can compare the reported stimulus parameters to those held in local memory **228** to verify the wireless stimulator device **114** delivered the specified stimuli to tissue. For example, if the wireless stimulation device reports a lower current than was specified, the power level from the RF pulse generator module **106** can be increased so that the implanted wireless stimulator device **114** will have more available

power for stimulation. The implanted wireless stimulator device **114** can generate telemetry data in real time, for example, at a rate of **8** Kbits per second. All feedback data received from the implanted stimulator device **114** can be logged against time and sampled to be stored for retrieval to a remote monitoring system accessible by the health care professional for trending and statistical correlations.

The sequence of remotely programmable RF signals received by the internal antenna(s) **238** may be conditioned into waveforms that are controlled within the implantable wireless stimulator device **114** by the control subsystem **242** and routed to the appropriate electrodes **254** that are placed in proximity to the tissue to be stimulated. For instance, the RF signal transmitted from the RF pulse generator module **106** may be received by RX antenna **238** and processed by circuitry, such as waveform conditioning circuitry **240**, within the implanted wireless stimulator device **114** to be converted into electrical pulses applied to the electrodes **254** through electrode interface **252**. In some implementations, the implanted wireless stimulator device **114** contains between two to sixteen electrodes **254**.

The waveform conditioning circuitry **240** may include a rectifier **244**, which rectifies the signal received by the RX antenna **238**. The rectified signal may be fed to the controller **242** for receiving encoded instructions from the RF pulse generator module **106**. The rectifier signal may also be fed to a charge balance component **246** that is configured to create one or more electrical pulses based such that the one or more electrical pulses result in a substantially zero net charge at the one or more electrodes (that is, the pulses are charge balanced). The charge-balanced pulses are passed through the current limiter **248** to the electrode interface **252**, which applies the pulses to the electrodes **254** as appropriate.

The current limiter **248** insures the current level of the pulses applied to the electrodes **254** is not above a threshold current level. In some implementations, an amplitude (for example, current level, voltage level, or power level) of the received RF pulse directly determines the amplitude of the stimulus. In this case, it may be particularly beneficial to include current limiter **248** to prevent excessive current or charge being delivered through the electrodes, although current limiter **248** may be used in other implementations where this is not the case. Generally, for a given electrode having several square millimeters surface area, it is the charge per phase that should be limited for safety (where the charge delivered by a stimulus phase is the integral of the current). But, in some cases, the limit can instead be placed on the current, where the maximum current multiplied by the maximum possible pulse duration is less than or equal to the maximum safe charge.

More generally, the limiter **248** acts as a charge limiter that limits a characteristic (for example, current or duration) of the electrical pulses so that the charge per phase remains below a threshold level (typically, a safe-charge limit).

In the event the implanted wireless stimulator device **114** receives a "strong" pulse of RF power sufficient to generate a stimulus that would exceed the predetermined safe-charge limit, the current limiter **248** can automatically limit or "clip" the stimulus phase to maintain the total charge of the phase within the safety limit. The current limiter **248** may be a passive current limiting component that cuts the signal to the electrodes **254** once the safe current limit (the threshold current level) is reached. Alternatively, or additionally, the current limiter **248** may communicate with the electrode interface **252** to turn off all electrodes **254** to prevent tissue damaging current levels.

A clipping event may trigger a current limiter feedback control mode. The action of clipping may cause the controller to send a threshold power data signal to the pulse generator **106**. The feedback subsystem **212** detects the threshold power signal and demodulates the signal into data that is communicated to the controller subsystem **214**. The controller subsystem **214** algorithms may act on this current-limiting condition by specifically reducing the RF power generated by the RF pulse generator, or cutting the power completely. In this way, the pulse generator **106** can reduce the RF power delivered to the body if the implanted wireless stimulator device **114** reports it is receiving excess RF power.

The controller **250** of the stimulator **205** may communicate with the electrode interface **252** to control various aspects of the electrode setup and pulses applied to the electrodes **254**. The electrode interface **252** may act as a multiplex and control the polarity and switching of each of the electrodes **254**. For instance, in some implementations, the wireless stimulator **106** has multiple electrodes **254** in contact with tissue, and for a given stimulus the RF pulse generator module **106** can arbitrarily assign one or more electrodes to **1)** act as a stimulating electrode, **2)** act as a return electrode, or **3)** be inactive by communication of assignment sent wirelessly with the parameter instructions, which the controller **250** uses to set electrode interface **252** as appropriate. It may be physiologically advantageous to assign, for example, one or two electrodes as stimulating electrodes and to assign all remaining electrodes as return electrodes.

Also, in some implementations, for a given stimulus pulse, the controller **250** may control the electrode interface **252** to divide the current arbitrarily (or according to instructions from pulse generator module **106)** among the designated stimulating

electrodes. This control over electrode assignment and current control can be advantageous because in practice the electrodes **254** may be spatially distributed along various neural structures, and through strategic selection of the stimulating electrode location and the proportion of current specified for each location, the aggregate current distribution in tissue can be modified to selectively activate specific neural targets. This strategy of current steering can improve the therapeutic effect for the patient.

In another implementation, the time course of stimuli may be arbitrarily manipulated. A given stimulus waveform may be initiated at a time T_start and terminated at a time T_final, and this time course may be synchronized across all stimulating and return electrodes; further, the frequency of repetition of this stimulus cycle may be synchronous for all the electrodes. However, controller **250**, on its own or in response to instructions from pulse generator **106**, can control electrode interface **252** to designate one or more subsets of electrodes to deliver stimulus waveforms with non-synchronous start and stop times, and the frequency of repetition of each stimulus cycle can be arbitrarily and independently specified.

For example, a stimulator having eight electrodes may be configured to have a subset of five electrodes, called set A, and a subset of three electrodes, called set B. Set A might be configured to use two of its electrodes as stimulating electrodes, with the remainder being return electrodes. Set B might be configured to have just one stimulating electrode. The controller **250** could then specify that set A deliver a stimulus phase with **3** mA current for a duration of **200** us followed by a **400** us charge-balancing phase. This stimulus cycle could be specified to repeat at a rate of **60** cycles per second. Then, for set B, the controller **250** could specify a stimulus phase with 1 mA current for duration of 500 us followed by a 800 us charge-balancing phase. The repetition rate for the set-B stimulus cycle can be set independently of set A, say for example it could be specified at **25** cycles per second. Or, if the controller **250** was configured to match the repetition rate for set B to that of set A, for such a case the controller **250** can specify the relative start times of the stimulus cycles to be coincident in time or to be arbitrarily offset from one another by some delay interval.

In some implementations, the controller **250** can arbitrarily shape the stimulus waveform amplitude, and may do so in response to instructions from pulse generator **106**. The stimulus phase may be delivered by a constant-current source or a constant-voltage source, and this type of control may generate characteristic waveforms that are static, e.g. a constant-current source generates a characteristic rectangular pulse in which the current

waveform has a very steep rise, a constant amplitude for the duration of the stimulus, and then a very steep return to baseline. Alternatively, or additionally, the controller **250** can increase or decrease the level of current at any time during the stimulus phase and/or during the charge-balancing phase. Thus, in some implementations, the controller **250** can deliver arbitrarily shaped stimulus waveforms such as a triangular pulse, sinusoidal pulse, or Gaussian pulse for example. Similarly, the charge-balancing phase can be arbitrarily amplitude-shaped, and similarly a leading anodic pulse (prior to the stimulus phase) may also be amplitude-shaped.

As described above, the wireless stimulator device **114** may include a charge-balancing component **246**. Generally, for constant current stimulation pulses, pulses should be charge balanced by having the amount of cathodic current should equal the amount of anodic current, which is typically called biphasic stimulation. Charge density is the amount of current times the duration it is applied, and is typically expressed in the units uC/cm^2. In order to avoid the irreversible electrochemical reactions such as pH change, electrode dissolution as well as tissue destruction, no net charge should appear at the electrode-electrolyte interface, and it is generally acceptable to have a charge density less than **30** uC/cm^2. Biphasic stimulating current pulses ensure that no net charge appears at the electrode after each stimulation cycle and the electrochemical processes are balanced to prevent net dc currents. The wireless stimulator device **114** may be designed to ensure that the resulting stimulus waveform has a net zero charge. Charge balanced stimuli are thought to have minimal damaging effects on tissue by reducing or eliminating electrochemical reaction products created at the electrode-tissue interface.

A stimulus pulse may have a negative- voltage or current, called the cathodic phase of the waveform. Stimulating electrodes may have both cathodic and anodic phases at different times during the stimulus cycle. An electrode that delivers a negative current with sufficient amplitude to stimulate adjacent neural tissue is called a "stimulating electrode." During the stimulus phase the stimulating electrode acts as a current sink. One or more additional electrodes act as a current source and these electrodes are called "return electrodes." Return electrodes are placed elsewhere in the tissue at some distance from the stimulating electrodes. When a typical negative stimulus phase is delivered to tissue at the stimulating electrode, the return electrode has a positive stimulus phase. During the subsequent charge-balancing phase, the polarities of each electrode are reversed.

In some implementations, the charge balance component **246** uses a blocking capacitor(s) placed electrically in series with the stimulating electrodes and body tissue,

between the point of stimulus generation within the stimulator circuitry and the point of stimulus delivery to tissue. In this manner, a resistor-capacitor (RC) network may be formed. In a multi-electrode stimulator, one charge-balance capacitor(s) may be used for each electrode or a centralized capacitor(s) may be used within the stimulator circuitry prior to the point of electrode selection. The RC network can block direct current (DC), however it can also prevent low-frequency alternating current (AC) from passing to the tissue. The frequency below which the series RC network essentially blocks signals is commonly referred to as the cutoff frequency, and in one embodiment the design of the stimulator system may ensure the cutoff frequency is not above the fundamental frequency of the stimulus waveform. In this embodiment as disclosed herein, the wireless stimulator may have a charge-balance capacitor with a value chosen according to the measured series resistance of the electrodes and the tissue environment in which the stimulator is implanted. By selecting a specific capacitance value the cutoff frequency of the RC network in this embodiment is at or below the fundamental frequency of the stimulus pulse.

In other implementations, the cutoff frequency may be chosen to be at or above the fundamental frequency of the stimulus, and in this scenario the stimulus waveform created prior to the charge-balance capacitor, called the drive waveform, may be designed to be non-stationary, where the envelope of the drive waveform is varied during the duration of the drive pulse. For example, in one embodiment, the initial amplitude of the drive waveform is set at an initial amplitude Vi, and the amplitude is increased during the duration of the pulse until it reaches a final value k*Vi. By changing the amplitude of the drive waveform over time, the shape of the stimulus waveform passed through the charge-balance capacitor is also modified. The shape of the stimulus waveform may be modified in this fashion to create a physiologically advantageous stimulus.

In some implementations, the wireless stimulator device **114** may create a drive-waveform envelope that follows the envelope of the RF pulse received by the receiving dipole antenna(s) **238**. In this case, the RF pulse generator module **106** can directly control the envelope of the drive waveform within the wireless stimulator device **114**, and thus no energy storage may be required inside the stimulator itself. In this implementation, the stimulator circuitry may modify the envelope of the drive waveform or may pass it directly to the charge-balance capacitor and/or electrode-selection stage.

In some implementations, the implanted wireless stimulator device **114** may deliver a single-phase drive waveform to the charge balance capacitor or it may deliver multiphase drive waveforms. In the case of a single-phase drive waveform, for example, a negative-

going rectangular pulse, this pulse comprises the physiological stimulus phase, and the charge-balance capacitor is polarized (charged) during this phase. After the drive pulse is completed, the charge balancing function is performed solely by the passive discharge of the charge-balance capacitor, where is dissipates its charge through the tissue in an opposite polarity relative to the preceding stimulus. In one implementation, a resistor within the stimulator facilitates the discharge of the charge-balance capacitor. In some implementations, using a passive discharge phase, the capacitor may allow virtually complete discharge prior to the onset of the subsequent stimulus pulse.

In the case of multiphase drive waveforms the wireless stimulator may perform internal switching to pass negative-going or positive-going pulses (phases) to the charge-balance capacitor. These pulses may be delivered in any sequence and with varying amplitudes and waveform shapes to achieve a desired physiological effect. For example, the stimulus phase may be followed by an actively driven charge-balancing phase, and/or the stimulus phase may be preceded by an opposite phase. Preceding the stimulus with an opposite-polarity phase, for example, can have the advantage of reducing the amplitude of the stimulus phase required to excite tissue.

In some implementations, the amplitude and timing of stimulus and charge-balancing phases is controlled by the amplitude and timing of RF pulses from the RF pulse generator module **106**, and in others this control may be administered internally by circuitry onboard the wireless stimulator device **114**, such as controller **250**. In the case of onboard control, the amplitude and timing may be specified or modified by data commands delivered from the pulse generator module **106**.

FIG. 3 is a circuit diagram showing an example of a wireless stimulator device **114**. This example contains paired electrodes, comprising cathode electrode(s) **308** and anode electrode(s) **310**, as shown. When energized, the charged electrodes create a volume conduction field of current density within the tissue. In this implementation, the wireless energy is received through a dipole antenna(s) **238**. At least four diodes are connected together to form a full wave bridge rectifier **302** attached to the dipole antenna(s) **238**. Each diode, up to **100** micrometers in length, uses a junction potential to prevent the flow of negative electrical current, from cathode to anode, from passing through the device when said current does not exceed the reverse threshold. For neural stimulation via wireless power, transmitted through tissue, the natural inefficiency of the lossy material may lead to a low threshold voltage. In this implementation, a zero biased diode rectifier results in a low output impedance for the device. A resistor **304** and a smoothing capacitor **306** are

placed across the output nodes of the bridge rectifier to discharge the electrodes to the ground of the bridge anode. The rectification bridge **302** includes two branches of diode pairs connecting an anode-to-anode and then cathode to cathode. The electrodes **308** and **310** are connected to the output of the charge balancing circuit **246**.

FIG. **4** is a circuit diagram of another example of a wireless stimulator device **114**. The example shown in FIG. **4** includes multiple electrode control and may employ full closed loop control. The wireless stimulation device includes an electrode array **254** in which the polarity of the electrodes can be assigned as cathodic or anodic, and for which the electrodes can be alternatively not powered with any energy. When energized, the charged electrodes create a volume conduction field of current density within the tissue. In this implementation, the wireless energy is received by the device through the dipole antenna(s) **238**. The electrode array **254** is controlled through an on-board controller circuit **242** that sends the appropriate bit information to the electrode interface **252** in order to set the polarity of each electrode in the array, as well as power to each individual electrode. The lack of power to a specific electrode would set that electrode in a functional OFF position. In another implementation (not shown), the amount of current sent to each electrode is also controlled through the controller **242**. The controller current, polarity and power state parameter data, shown as the controller output, is be sent back to the antenna(s) **238** for telemetry transmission back to the pulse generator module **106**. The controller **242** also includes the functionality of current monitoring and sets a bit register counter so that the status of total current drawn can be sent back to the pulse generator module **106**.

At least four diodes can be connected together to form a full wave bridge rectifier **302** attached to the dipole antenna(s) **238**. Each diode, up to **100** micrometers in length, uses a junction potential to prevent the flow of negative electrical current, from cathode to anode, from passing through the device when said current does not exceed the reverse threshold. For neural stimulation via wireless power, transmitted through tissue, the natural inefficiency of the lossy material may lead to a low threshold voltage. In this implementation, a zero biased diode rectifier results in a low output impedance for the device. A resistor **304** and a smoothing capacitor **306** are placed across the output nodes of the bridge rectifier to discharge the electrodes to the ground of the bridge anode. The rectification bridge **302** may include two branches of diode pairs connecting an anode-to-anode and then cathode to cathode. The electrode polarity outputs, both cathode **308** and anode **310** are connected to the outputs formed by the bridge connection. Charge balancing circuitry **246** and current limiting circuitry **248** are placed in series with the outputs.

FIG. 5 is a diagram of an example of ASIC chip 500 for implantable use. Chip 500 may be fabricated based on a 0.6um, double poly process utilizing High Value resistors, Schottky diodes and High Voltage Transistors. In some implementations, chip 500 can be fabricated at a width of 0.5 mm for fitting into, for example, an 18 Gauge needle. In these implementations, chip 500 can have a length-width ratio of up to 10 to 1. Chip 500 can be coupled to, for example, either four (4) or eight (8) platinum-iridium electrodes that deliver electrical impulses to tissue.

Chip 500 includes rectifying circuit 502, a logic control circuit 504, and a driving circuit 506. Rectifying circuit 502 is coupled to differential antennas 512A and 512B. An RF input signal can be received at the differential antennas and then rectified to have the amplitude detected. The rectified signal may provide power for the chip 500. Thereafter, logic control circuit 504 may extract waveform parameters from the amplitude detected signal. Subsequently, logic control circuit 504 may generate electrical impulses according to the extracted waveform parameters and solely based on the extracted electric power. The generated electrical impulses may then be provided to the driving circuit 506, which includes charge balancing and current mirroring circuits. Driving circuit 506 is coupled to electrode interfaces 508A to 508H, each coupled to a respective electrical load 509A through 509H. The electrical impulses are subsequently delivered to each electrode, namely 510A through 510H.

In this diagram, a diode bridge circuit 514 is included to provide full-wave rectification to the input signal received in differential form from differential antennas 512A and 512B. Full-wave rectification may utilize both the positive and negative portions of the RF input signal as received at differential antennas 512A and 512B.

In some implementations, a dipole antenna in a differential configuration may be embedded into a wireless implantable stimulator device. The dipole antenna receives power, serial communication, and stimulus waveforms from an external transmitter placed outside the patient's body. The dipole antenna is connected directly to a flexible circuit board embedded within the implantable stimulator device that contains discrete components and chip 500. Chip 500 can include wireless serial command receiver with up to eight channel multiplexing functionality.

The rectification may provide power to remaining portions of chip 500. In some instances, VDD circuit 518 and ground circuit 519 are coupled to capacitor C1 520 to provide stored charges. The stored charges may generally power chip 500. In some implementations, a diode may be used to supply the VDD logic supply from Vrect. If chip

500 is active and the voltage VDD dips below 1.8V, chip 500 may enter into a "VDD low voltage recovery" mode. In this state any/all high side drivers will be temporarily over ridden to Hi-Z and all low side drivers will be Hi-Z. Once VDD returns to above 3.0V state and in the running mode the drivers would return to their previously programmed state.

Output from rectifying circuit 502 is coupled to the logic control circuit 504. As depicted, logic control circuit 504 may include logic control/state machine 522 and timer/oscillator 524. Logic control/state machine 522 may be coupled to channel selector 526.

The received RF input signal may contain waveform parameters for electrical impulses to stimulate tissues. The received RF input signal may contain polarity setting information for setting the interface for each electrode.

Referring to FIG. 6, a sequence diagram during operation of the chip 500 is shown. Specifically, the pulse sequence 600 includes segments of pulses. Each segment may last an epoch time (depicted as Tepoch). Each segment may include two portions, namely an initial portion and a subsequent stimulation portion. In more detail, the initial portion refers to the portion in which electrical power contained in the RF input signal is harvested and electrical charges are pumped into capacitor C1 520. The initial portion may last a period marked as Thigh. The initial portion may be referred to as the communication initialization pulses 602A and 602B. The stimulation portion corresponds to portion 604 and may contain a serial message encoding waveform parameters for electrical impulses and polarity setting information for the electrode interfaces. In some instances, portion 604 may be present in the first segment of sequence 600 to configure electrical impulses and polarity setting. Absent a power-on reset event, the configuration information of waveform parameters and polarity setting may be fixed once the initialization is completed.

Chip 500 may tolerate serial messages embedded between power bursts. For example, the transmitter may initiate a serial communication message by sending a 2 ms "communication Initialization Pulse" (Thigh) followed by a 2ms period of no power transmission (T msg - Thigh). In this example, data transmission may immediately follow this 2ms delay and starts at time T msg. Bit timing calibration may be performed by measuring the length of the header byte in the transmitted data stream.

In some implementations, serial data may use a format based on the IrDA SIR format. This coding format sends a pulse where the bit to be sent is a '0'. During bit times where the bit is set to “1," no pulse may be sent. Each pulse may be 3/16ths of a bit time

however this width can be adjusted if necessary. This format may require less power and therefore can allow serial data transmission to operate at lower baud rates.

In an example serial data communication, data can be transmitted asynchronously as bytes with 1start and 1 stop bit (e.g. 8-n-l format carries the same overhead to RS-232 with 10 bits transmitted but only 8 of the 10 bits carry data while the other 2 bits are protocol overhead). The LSB may be the first data bit transmitted. This adds up to 70 bits total transmitted for 7 bytes of data. Ten of these bits are protocol overhead and 60 of these bits are available to carry data. In this example, there is no additional delay between bytes, the data stream is continuous.

In the example, the serial baud rate is 19200. Serial messages can be of a fixed length of 7 bytes, including a header byte, five payload bytes, and a checksum byte. Payload bytes may generally encode the polarity setting for each electrode interface, the electrode drivers to use for each electrode, the amplitude level for each electrode driver, etc. The checksum byte generally helps ensuring message integrity.

The header byte is used to identify the start of a data message. In some implementations, it can be preset to the value OxAA. In these implementations, the header byte can be discarded until a correct header byte is received. The header may also be used to calibrate the internal oscillator, which is powered by wireless energy stored on VDD. Some implementations may provide a unique structure of on-off-on-off-on-off-on-off-on-off for the 10-bit sequence as timing markers at regular (104 μs between transmissions) intervals.

In some implementations, the header may include the address of an electrode array. For example, Bit 7 of Byte 1 can be the Lead Address to distinguish between one of two possible electrode arrays is the message intended. An electrode array may only implement messages that match its lead address assigned. If a lead of channel A receives a message that is intended for channel B, the state machine may reject the new message and maintain the previously stored register contents. In this example, each electrode array can have an address of 0 or 1 that can be determined by pin strapping during manufacture of the lead.

Returning to FIG. 5, in some implementations, AM detector 516 may output logic zero when RF power is received. In some implementations, pre-amplification of low voltage data signals or limiting of high voltage data signals may extend the operational range of the AM detector 516. As such, signals 100 mV or greater will be detected. AM detector 516 may decode serial streams that are transmitted at 19200 Baud. The AM

detector 516 input may be internal to chip 500 and characterized for use at high frequencies (869 - 915 MHz).

AM detector 516 may generally process rectified signals within a nominal range from between 50mVpp to 15 Vpp power supply levels (peak to peak). AM detector 516 may include a preamp to clamp higher swing signals without output collapsing or folding down. The preamp should have sufficient gain and low offset to resolve 100m Vpp data signals.

AM detector 516 may detect serial data encoded using IrDA (SIR) formatting. The serial data receiver may be included in AM detector 516 and may convert the data from a serial format into a parallel format. Operations of the serial data receiver hardware may be controlled by a clock signal, which runs at a multiple of the data rate. In some implementations, the receiver can test the state of the incoming signal on each clock pulse to search the start bit. If the apparent start bit is valid, then the bit signals the start of a new character. If not, the bit is considered a spurious pulse or power pulse and is ignored. After waiting a further bit time, the state of the line is again sampled and the resulting level clocked into a shift register.

After the required number of bit periods for the character length to have elapsed, the contents of the shift register are made available to the receiving system. The serial data receiver has no shared timing system with the transmitter apart from the communication signal.

Serial data receiver on chip 500 may receive and buffer seven (7) eight-bit words. The data contained in the words shall be used to program the control registers in the LMI927 if a checksum match is successful. The data will be ignored if a checksum match is unsuccessful and the receiver will continue to listen for valid data. The serial data receiver will reset and prepare to receive a new word if a received byte does not meet IrDA (SIR) framing parameters. This will allow the serial receiver to quickly reset after being falsely activated by reception of a spurious signal or a stim power pulse. The serial data receiver will not have to wait to fully receive all words if any individual byte does not meet timing parameters.

Chip 500 may remain in an unconfigured state (all high-side outputs are high-Z, low-side outputs are in triode mode) until a valid set of serial data is received. Notably, in some implementations, the serial receiver may be not be operational if the Device Lock bit is set.

Logic control/state machine 522 may be synchronized by timer/oscillator 524. The synchronization may enable logic control/state machine 522 to extract and decode waveform parameters as well as polarity setting information from portion 604. Logic control/state machine 522 may then create one or more electrical impulses according to the waveform parameters. The Logic control/state machine 522 may also set polarities of electrode interfaces 508A to 508H according to the extracted polarity setting information.

The output of Logic Control/State Machine 522 may be coupled to driving circuit 506 which includes features of charge balancing, shunt resistors, and current mirroring. In particular, driving circuit 506 includes shunt resistor controller 530 constructed to couple a shunt resistor to switch network 532. The coupling can enhance default resistor 531 through delay controller 533. The delay controller may insert a corresponding shunt resistor to the circuit including the stimulating electrode at the end of an electrical impulse to reduce the amount of leakage current.

Some implementations may incorporate a variable shunt resistor to control the discharge of the stimulus pulse from the DC-Blocking capacitors. In these implementations, the initial serial commands contain instructions for the set value for the shunt resistor. For example, the operator may select between four (4) different settings. The internal shunts are configured so that during a stimulus pulse they are off, and after a pulse they are engaged.

The engagement of the resistors can be delayed following application of the electrical impulse. The timer is to delay the onset of the discharge of the DC Blocking capacitors. The timer may be initialized during the stimulus pulse and it starts its delay at the end of the stimulus phase. The delay has a fixed duration and may be independent of the stimulus amplitude, repetition rate, and pulse width.

In some implementations, the stimulating electrical impulse is delivered to a particular electrode through switch network 532. To deliver electrical impulses at both polarities, the switch network is coupled to current source DAC 534A and current sink DAC 534B. As depicted, current source DAC 534A includes a 7-bit dynamic range and is coupled to the rectifying voltage Vrect 517. Current source DAC 534A is invoked with the polarity of the connected electrode is set as positive. Similarly, current source DAC 534A includes a 7-bit dynamic range. Current source DAC 534A is invoked with the polarity of the connected electrode is set as negative.

In the context of simulating the effect of the driving circuit with the shunt resistors and switch network, FIG. 7A shows an example chip model 700 highlighting the modeled

components. In this arrangement, a H-bridge models a particular electrode along with the corresponding electrode interface and the capacitor. This arrangement investigates a direct coupling of the H-bridge supply. As depicted, each the H-bridge includes a pair of coupling capacitors 709A and 709C as well as a tissue load 709B. Each gate on the H-Bridge includes a full transmission gate switch 710. An example full transmission gate switch 710 includes mirrored transistor gates 710A and 710B.

Buffer 507 models the effect of driving transistor for current source DAC 534A and current sink DAC 534B as coupled to the particular electrode interface. Logic gates 506 models representative logic gates for memory and H-bridge control, for example, for configuring polarity setting for each electrode. Shunt regulator 530 models the effect of the shunt resistor controller 530. Resistor 704 and capacitor 703 model the effective load of storage capacitor C1 520 as well as VDD 518. In particular, resistor 704 represents a typical DC current drawing load of an Application Specific Integrated Circuit (ASIC). Diode Bridge 514 models the effect of the rectifying diode bridge.

Based on this model, a variety of electrical signal parameters can be modeled before an ASIC chip is fabricated. In one example, denoting stimulating waveform after rectification as Vstim, FIG. 7B shows the expected Vstim waveform (on channel 1) and RF input signal (on channel 2). As demonstrated, a great deal of detailed performance can be simulated during the design stage. In other examples, the H-bridge transmission gate on/off leakage between different approaches can be compared (for example, with varying application of shunt resistors).

Chip 500 may include a supervisory Power On Reset (POR) circuit designed to keep the device in reset until the system voltage has reached the proper level and stabilized. The POR circuit also operates as protection from brownout conditions when the supply voltage drops below a minimum operating level. The POR circuit design is such that it incorporates appropriate hysteresis between reset and enable levels to prevent start up inrush currents from causing the device to reset during normal operating power-up conditions. The POR circuit performs as needed to maintain proper chip functionality under all power fluctuation conditions including high-speed transients and slow rate of change voltage conditions. If required, the POR circuit can incorporate a watchdog timer tick event to ensure proper operation of the chip 500.

As depicted in FIG. 5, each electrode interface is coupled to a respective capacitor 509A through 1909H. These capacitors are placed in series for the purpose of DC blocking. The capacitors are last in the signal chain before the stimulation electrical impulses are

delivered to the electrodes. In some implementations, the nominal series capacitance may be 3.0 /μF at each electrode. Each capacitor in turn couples to a respective electrode 510A through 510H on an 8-electrode stimulator device. As noted, chip 500 may be coupled to 8 electrode outputs. Each electrode output can be set to either sourcing, sinking or Hi-Z.

Referring to FIG. 8A, an example digital-to-analog mirror is shown for chip 500. The example highlights a current mirroring feature. Generally, multiple DACs with individually addressable and controllable current codes would increase ASIC's register space and design complexity and die area. On the other hand, having fewer DACs than available channels may require coulomb counting to limit the current through individual channels. With few DAC channels than the electrodes, the current through individual electrodes may increase for lower impedance channels.

In some implementations, a single current-steering DAC with a scaled-down least significant bit (LSB) current value is used to generate a master bias current. In these implementations, no current may be wasted in the current mirrors. After the master bias current is generated, the DAC current is then mirrored to individual electrodes with a current mirror ratio of 1:N. N can be selected based on current-steering DAC matching requirements. For example, N can be in the range of 10. The LSB size of the individual electrodes may be 100uA. With 7-bits, full dynamic range of the driving current can be up to 12.7mA.

The implementation depicted in FIG. 8A shows a dual-DAC approach with mirrored current sources across eight (8) electrodes. Transistor gate 803A is a replicate of transistor gate 803B in the 1:1 transistor mirror. Digital to Analog Conversion (DAC) circuit 802A represents a push DAC and may correspond to a current sink. Meanwhile, DAC 802B represents a pull DAC and may correspond to a current source. Logically, DAC 802A and DAC 802B may respectively correspond to DAC 534A and DAC 534B as depicted in FIG. 5. To minimize current mirror mismatches and wasted current, an N-side, current-sink DAC is used for this application. In this configuration, individual channels are enabled with complementary signals. Specifically, channel 0 is enabled by complementary transistors 804A (for CH0 positive) and 804B (for CH0 negative). Transistor gate 804A is coupled to Vrect 517 while transistor gate 804B is coupled to VDD 518. Circuit 805 represents the tissue load on channel 0 as well as DC blocking capacitors, similar to circuits 709A to 709C depicted in FIG. 7A In some implementations, the tissue load of channel 0 may include a capacitive component in addition to the resistance component. Likewise, complementary transistors 806A and 806B respectively represent

the positive and negative polarity arrangements for driving tissue load 807 for channel 1. This implementation depicts an 8-side, current-sink DAC configuration in which the current mirroring is replicated for each channel of the 8-channel electrode lead coupled to. For example, channel 7 driving arrangements are represented by complementary transistors 808A and 808B as well as tissue load 808, as shown in FIG. 8A. Notably, in this N-side implementation, three states can be configured for each of the current sinks, namely, controlled (mirrored) current sink mode, a cutoff device (off mode), and turned-on device as a triode mode switch. As depicted, each channel further includes an ON switch. For example channel 0 includes a CH0_ON switch, while channel 1 and channel 7 respectively include CH1_ON and CH7_ON switches.

FIG. 8B provides an example timing of waveforms in the above implementation. Trace 812 shows the stimulation portion of a rectified RF input signal as seen on switch $CH0_N$, while trace 814A shows the waveform seen on switch $\overline{CHO}_N$ and trace 814B shows the waveform seen on switch CH0_ON. The ON resistance of the triode mode may not be critical, since it is on during reverse discharge, and not during stimulus mode.

Current steering as implemented (one current source and eight mirrors) may limit the charge per phase such that electrical impulses are applied for stimulation within safety ranges. In some implementations, the external transmitter may prescribe a limit on pulse width and the serial-written current level of the amplitude. With these parameters prescribed (or capped), a patient user is prevented from requesting an unsafe charge per phase because the patient user has limited parameter selection choices. In these implementations, when the stimulus portion is not present in the rectified RF input signal, the current DACs may be inactive.

To prevent a single electrode from sourcing or sinking more than the acceptable charge per phase, a current control approach can be used for both high and low sides. In the current steering stimulus approach, high side is a single current source DAC connected to Vrect voltage with current mirrors for each electrode. The low side is a current sink DAC. Each current steering DAC may include a 7-bit converter. Because a LSB corresponds to 100 μA, the maximum current can be limited to 12.7 mA per electrode. The master current reference for the DAC can be derived from Vrect. Following-current mirrors can be taken from Vrect. A similar approach on the low side can be used to prevent a single electrode from sinking too much charge.

A passive implantable neural stimulator having no on-board power supply or inductive loops can be miniaturized into a compact form factor suitable for minimally

invasive implantation. In some implementations, the wirelessly powered neural stimulator can fit in the inner lumen of a needle device 13G or smaller. To facilitate delivery through the inner lumen, the passive implantable neural stimulator may be made in a string form (with a large aspect ratio of length over height/width), for example, with a height/width under 2mm and length of tens of millimeters.

FIGS. 9A-9B show an example of a flexible circuit 900 for an implantable neural stimulator device. In this example, flexible circuit 900 has four sides, namely 901A to 901D. Proximal tip 901A and distal tip 901C are measured at 1.1 mm in height. The thickness of both tips can be smaller than 1.1mm. Lateral sides 901B and 901D are measured at 52.975 mm long. Circuit 900 is shaped and configured in this form with aspect ratios greater than 50 such that circuit 900 is flexible to accommodate bending and twisting during an implantation procedure.

Flexible circuit 900 includes RF ports 902A and 902B, each configured to be attached to an antenna. In implementations discussed above in association with FIGS. 3-4, the antennas (such as antennas 238) may be configured as differential antennas. In one example, components banks 904A, 906A, 904B, and 906B are mounted between RF ports 902A and 902B. In this example, components banks 904A and 906A are coupled to RF port 902A by signal traces that are thin enough to preserve flexibility in the context of in-vivo implantation through the inner lumen of a needle device. Notably, copper used in the signal traces causes rigidity and a reduction of copper usage (through a reduction of the size of the signal traces) can improve flexibility of the circuit 900. In some implementations, the copper traces can be systematically tested to determine a dimension suitable for conducting electrical current while preserving flexibility, for example copper trace width can be from 3 mm to 1 mm. For instances, copper traces of various thickness were subjected to rigidity tests to determine the abilities to bend and maintain integrity after flexible cycling which mimic the environmental stress that an implantable neural stimulator may experience. Meanwhile, the resistance of these traces were determined suitable (e.g., with acceptable impedances) for conducting current. Components banks 904A and 906A include rectifying circuit components and waveform conditioning components as discussed above in association with FIGS, 2, 3, 4, and 5. As illustrated, RF port 902A is 1 mm apart from the proximal end of components bank 904A. Likewise, components banks 904B and 906B are coupled to RF port 902B via thin signal traces to achieve mechanical flexibility while preserving electrical conductivity. Components banks 904B and 906B include similar components (such as diodes, resistors, and capacitors). The distal end of

components bank 904B is spaced 1 mm apart from RF port 902B. As illustrated, the gap between components banks 906A and 906B is about 0.75mm or under. Further, each components bank has a lateral length that is short enough to preserve flexibility of circuit 900. For example, the length of a components bank is determined to be generally under 3mm. The determination was made by gradually increasing the length of a particular components bank until flexible circuit 900 is found to be no longer flexible for the implantation procedure, for example, whether one can still navigate the flexible circuit at a bend angle as the implantable stimulator device travels through the mouth of the introduction needle into the epidural space. That threshold length was thus determined to be under 3mm or so. Additionally, the height of these components is generally between 0.6 mm and 0.8 mm to preserve functionality as well as flexibility of the overall circuit.

Flexible circuit 900 further includes components banks 908, 910, and 912 placed in series from the proximal direction to the distal direction. Components bank 908 is spaced 1 mm apart from RF port 902B in the distal direction. Generally, component banks 908, 910, and 912 are spaced no more than 0.75 mm apart. As discussed above in association with FIGS. 5 and 7A, component banks 908, 910, and 912 generally include voltage regulators, current shunt resistors, and waveform conditioning components. Each bank of components may also include a capacitor with a capacitance no less than 1 μF. This capacitance range generally renders it less feasible to integrate the capacitor into ASIC chip 914. A capacitor implemented on ASIC chip 914 would be constructed with two conductor plates with a dielectric layer between them, which can require more surface area in comparison to a discrete capacitor. In some cases, the capacitance generated on an ASIC chip may be on the order of 10E-15 Farad per-square-micron area. In these cases, a capacitor of 1μF on an ASIC chip may lead to thousands of square mm of chip footprint, an unrealistic size for the application.

ASIC chip 914 is mounted on flexible circuit 900 approximately 1.25 mm distal from component bank 912. In some implementations, ASIC chip 914 is no longer than 3 mm to allow for sufficient flexibility of the circuit 900. ASIC chip 914 can be smaller than 0.5 mm in width. Example configurations of ASIC chip 914 can be found in association with FIGS. 5 and 7A, as discussed above. ASIC chip 914 generally leverages RF power extracted from a first portion of a received RF pulse as well as waveforms parameters and polarity information extracted from a second portion of the received RF pulses. ASIC chip 914 can provide stimulation waveforms using the extracted RF energy and according to the extracted waveform parameters, and configure electrode interfaces according to the

extracted polarity information. These electrode interfaces are coupled to component banks 916A to 916H, as discussed below.

Flexible circuit 900 further includes eight components banks 916A to 916H (from proximal to distal). These components banks are spaced 1.25 mm distally away from ASIC chip 914 and may generally include capacitors. The capacitors in each components bank block DC component in a stimulation waveform to maintain a zero net charge in neural tissue under stimulation. Generally, an increase in capacitance leads to improved DC blockage. Size and flexibility limitations of flexible circuit 900 may render large capacitors unfeasible. In one configuration, multiple capacitors can be stacked to boost the capacitance of the components bank. As noted earlier, as the number of components increases, the rigidity of the components bank increases which may render circuit 900 too rigid for implantation purposes. Some implementations can include increasing the number of capacitors in each components bank and then determining whether the rigidity of circuit 900 can preclude implantation procedures meant to accommodate subcutaneous implantation and spinal cord implantation through epidural space. In some instances, rigidity is determined qualitatively as the flexible circuit undergoes cyclic flex testing in which the flexible circuit are subjected to bending and twisting that the implantable neurostimulator device may experience during implantation procedure. Components will either break off or snap. In other instances, rigidity is determined by the maneuverability of the device entering and accessing the physiological locations, for example, at the bend out of the spoonbill mouth of the needle. If too rigid, the device will not make the angle or break in the process. The spinal cord stimulation (SCS) application may entail a standard approach of a 45 degree angle of bending, which can be a demanding application. In this application, proximal tip 901A may be bent towards distal tip 901C (or vice versa) such that the proximal tip 901A and the distal tip 901C form an angle as sharp as 45 degrees. In an unbent state, as shown in Figs. 9A to 9B, the proximal tip 901A and the distal tip 901C form an angle of 180 degrees. Even in this demanding SCS application, no component breaks off the flexible circuit when the proximal tip 901A is bent towards the distal tip 901C to form an angle as sharp as 45 degrees. The length of each components bank is thus determined to be under about 3mm and the gap between the components bank is determined to be at least 0.75mm. If the gap is longer, the flexibility will increase but the design could be much too long for feasible use in the human body.

Flexible circuit 900 supports eight (8) electrode-interface pads. As illustrated electrode interfaces 918A to 918H are respectively coupled to an electrode capable of

releasing electrical impulses to stimulate neural tissue. As illustrated, each electrode is thus connected to a components bank of capacitors. Flexible circuit 900 also include solder pond pads (not shown) located at the distal tip 901c to localize tensions during soldering such that surface mount components on flexible circuit 900 will not be displaced due to heating of solder.

A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made. Accordingly, other implementations are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A flexible circuit comprising:

a substrate;

one or more radio-frequency (RF) ports on the substrate, the ports configured to couple to RF antennas configured to receive RF pulses from an external controller device;

one or more banks of components on the substrate, the one or more banks of components configured to extract RF energy from the received RF pulses and to deliver electrical pulses suitable to stimulate neural tissue;

an integrated circuit (IC) component on the substrate, the IC component configured to generate the electrical pulses suitable to stimulate neural tissue solely based on the extracted RF energy; and

wherein the substrate, the one or more banks of components, and the integrated circuit component are sized and positioned on the substrate such that the flexible circuit flexes during implantation in a patient without becoming inoperable.

2. The flexible circuit of claim **1** wherein the substrate is sized to fit through a needle that is no larger than gauge 13.

3. The flexible circuit of claim **1** wherein the substrate has an aspect ratio of no less than 50.

4. The flexible circuit of claim 1, wherein each bank of components include components no more than 3mm wide, and wherein the components are spaced no more than 0.75mm apart.

5. The flexible circuit of claim 4, wherein the components are between 0.6 mm to 0.8 mm in height.

6. The flexible circuit of claim 4, wherein each bank of component is spaced 1.25 mm or more away from the IC component.

7. The flexible circuit of claim 1, wherein at least one component includes a capacitor no less than 1 μF.

8. The flexible circuit of claim 1, wherein the one or more banks of components include more than one capacitor.

9. The flexible circuit of claim 1, wherein the banks of component bank are configured to extract RF energy from a first portion of the received RF pulses and extract stimulation waveform parameters and polarity settings from a second portion of the received RF pulses, and wherein the first portion precedes the second portion.

10. The flexible circuit of claim 9, wherein the IC component is configured to:
configure electrode settings according the extracted polarity settings.

11. The flexible circuit of claim 9, further comprising:
one or more electrode interfaces attachable to electrodes to be placed around neural tissue.

12. The flexible circuit of claim 11, wherein the one or more banks of components are configured to deliver the electrical pulses suitable to stimulate neural tissue to the one or more electrode interfaces such that neural tissue is stimulated by the electrical pulses according to the stimulation waveform parameter as extracted from the first portion of the received RF pulses.

13. The flexible circuit of claim 11, wherein the one or more electrode interfaces are configured to adjust polarity settings on the electrodes according to the polarity settings as extracted from the second portion of the received RF pulses.

14. The flexible circuit of claim 1, wherein no component on the flexible circuit breaks off from the substrate when a first end of the flexible circuit is bent towards a second end of the flexible circuit such that the first end and the second end form an angle as sharp as 45 degrees.

15. The flexible circuit of claim 1, further comprising: one or more solder pond pad, the solder pond pad configured to localize tension during soldering such that surface mount components on the flexible circuit will not be displaced due to soldering heat.

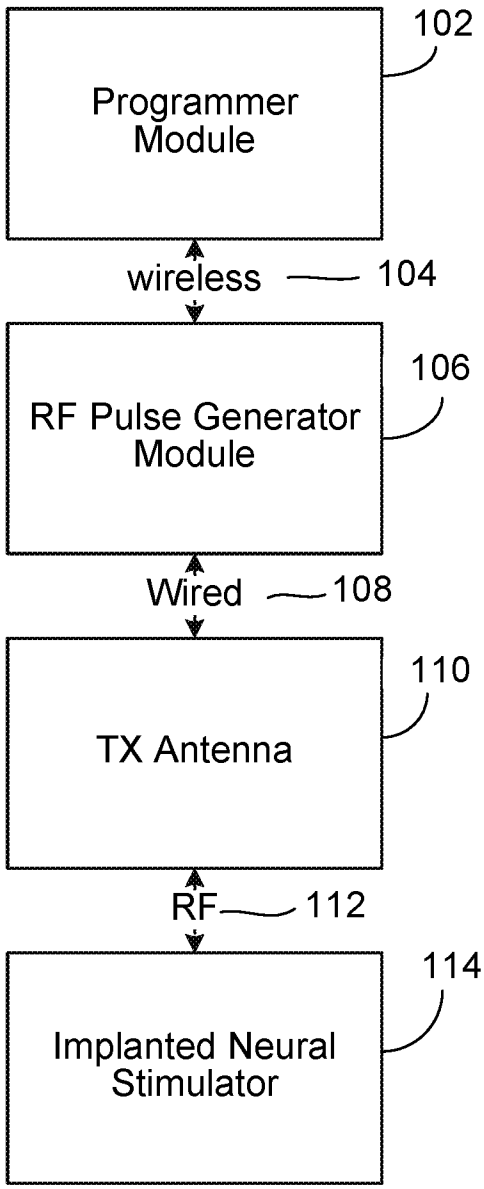
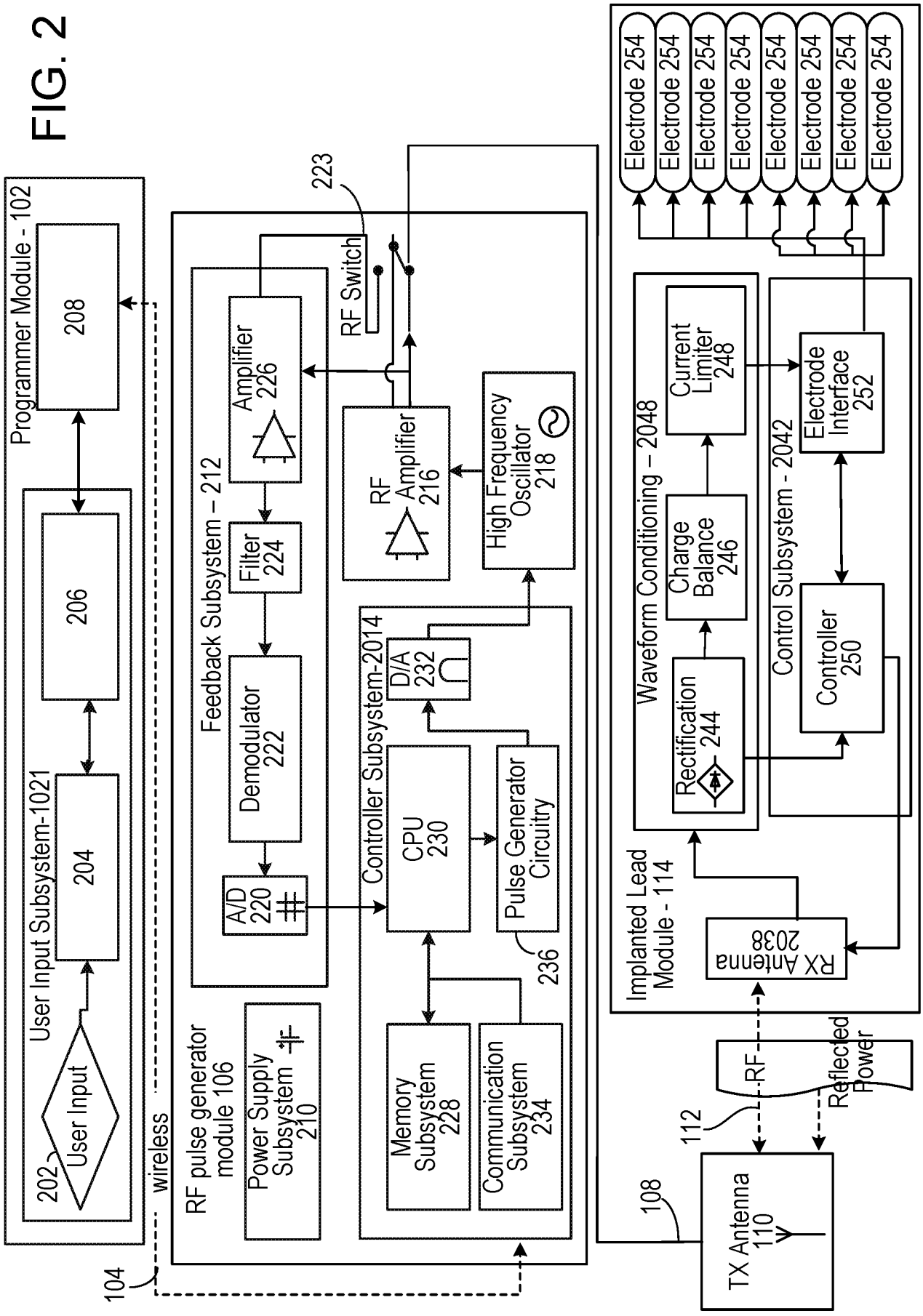

Programmer Module
102
wireless
104
RF Pulse Generator Module
106
Wired
108
TX Antenna
110
RF
112
Implanted Neural Stimulator
114

FIG 1

FIG. 2


Programmer Module - 102
208
User Input Subsystem-1021
206
204
User Input
202
wireless
104
RF pulse generator module 106
Power Supply Subsystem 210
Feedback Subsystem – 212
Amplifier 226
Filter 224
Demodulator 222
A/D 220
223
RF Switch
RF Amplifier 216
High Frequency Oscillator 218
Controller Subsystem-2014
D/A 232
CPU 230
Pulse Generator Circuitry
236
Memory Subsystem 228
Communication Subsystem 234
Electrode 254
Electrode 254
Electrode 254
Electrode 254
Electrode 254
Electrode 254
Electrode 254
Electrode 254
Waveform Conditioning – 2048
Current Limiter 248
Charge Balance 246
Rectification 244
Control Subsystem - 2042
Electrode Interface 252
Controller 250
Implanted Lead Module - 114
RX Antenna 2038
112
RF
Reflected Power
108
TX Antenna 110

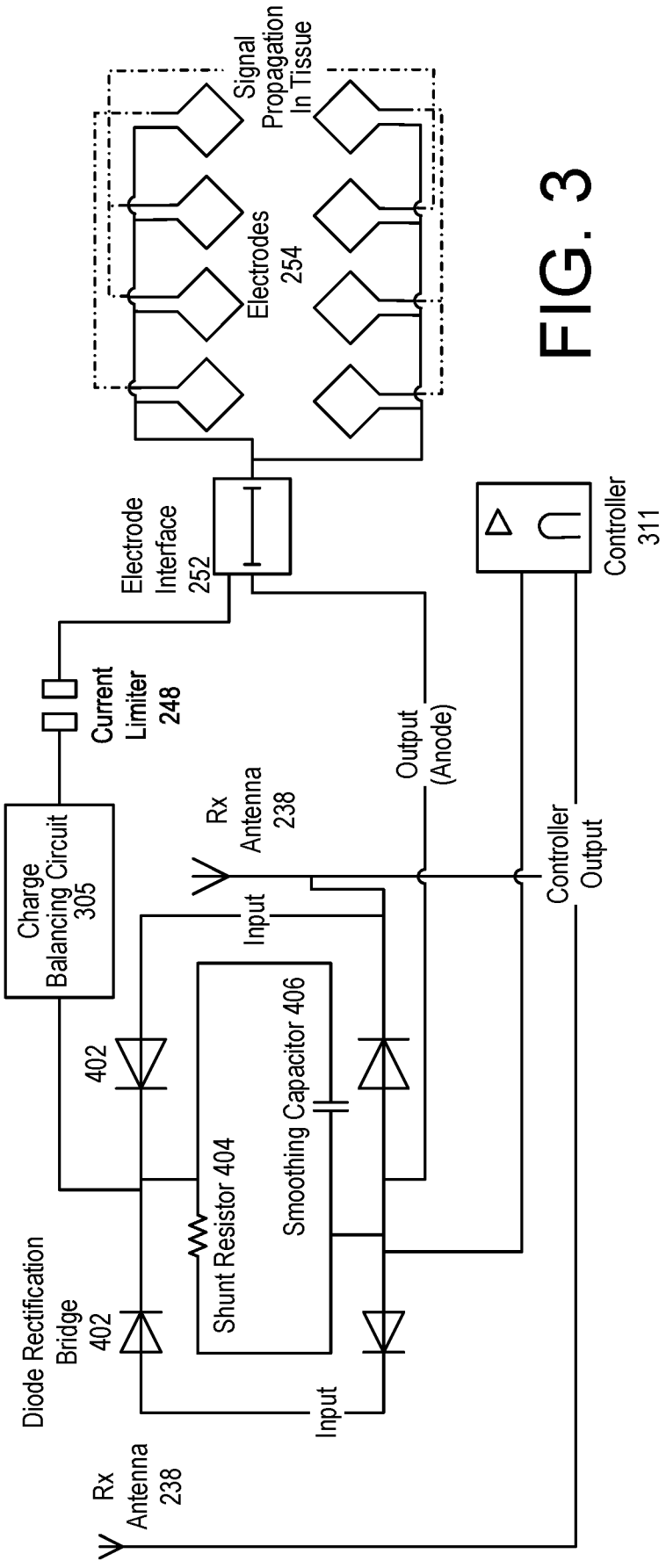

Signal Propagation In Tissue
Electrodes 254
Electrode Interface 252
Controller 311
Current Limiter 248
Output (Anode)
Rx Antenna 238
Charge Balancing Circuit 305
Input
Controller Output
402
Smoothing Capacitor 406
Shunt Resistor 404
Diode Rectification Bridge 402
Input
Rx Antenna 238

FIG. 3

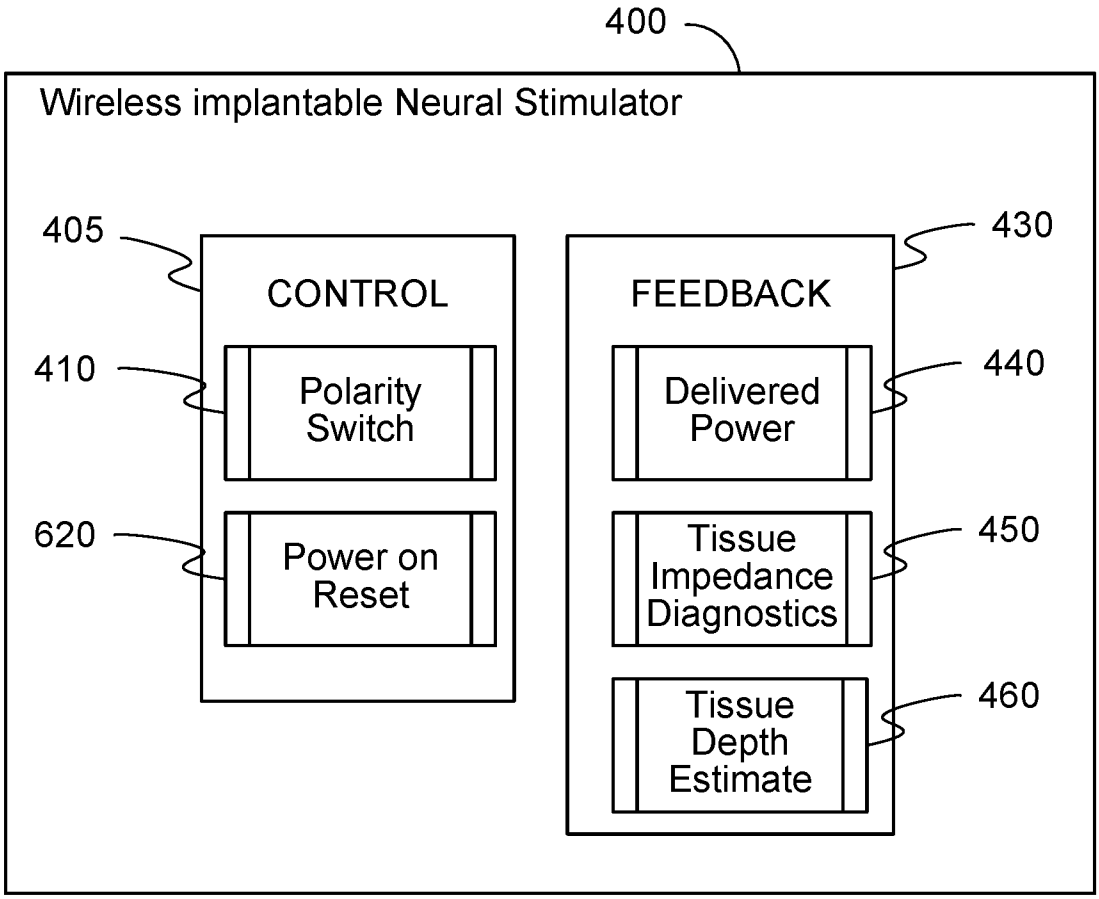

400
Wireless implantable Neural Stimulator
405
CONTROL
410
Polarity Switch
620
Power on Reset
430
FEEDBACK
440
Delivered Power
450
Tissue Impedance Diagnostics
460
Tissue Depth Estimate

FIG. 4

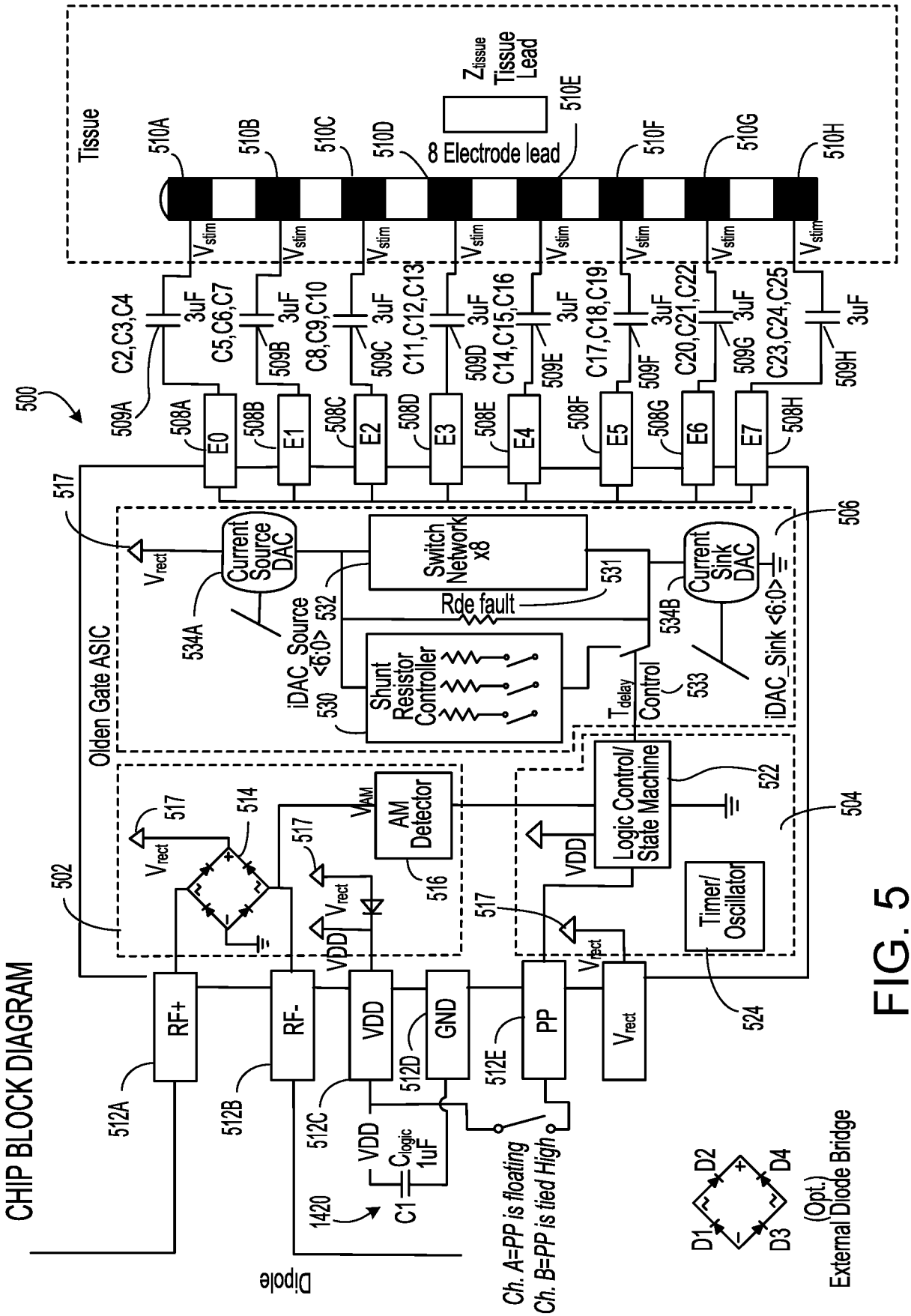

CHIP BLOCK DIAGRAM
Tissue
8 Electrode lead
Tissue Lead
Olden Gate ASIC
Current Source DAC
Switch Network x8
Current Sink DAC
Shunt Resistor Controller
Logic Control/ State Machine
AM Detector
Timer/ Oscillator
RF+
RF-
VDD
GND
PP
Vrect
Rde fault
iDAC_Source <6:0>
iDAC_Sink <6:0>
Tdelay
Control
Ch. A=PP is floating
Ch. B=PP is tied High
Dipole
External Diode Bridge
(Opt.)

FIG. 5

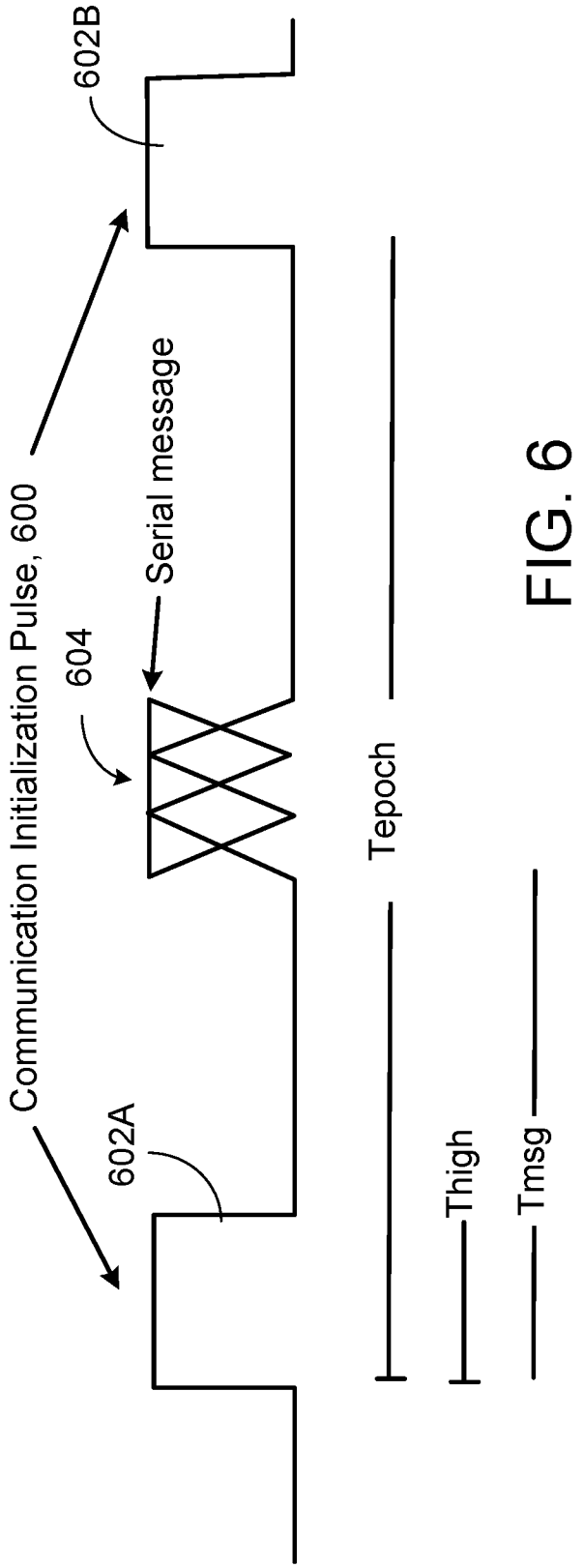

602B
Serial message
604
Communication Initialization Pulse, 600
602A
Tepoch
Thigh
Tmsg

FIG. 6

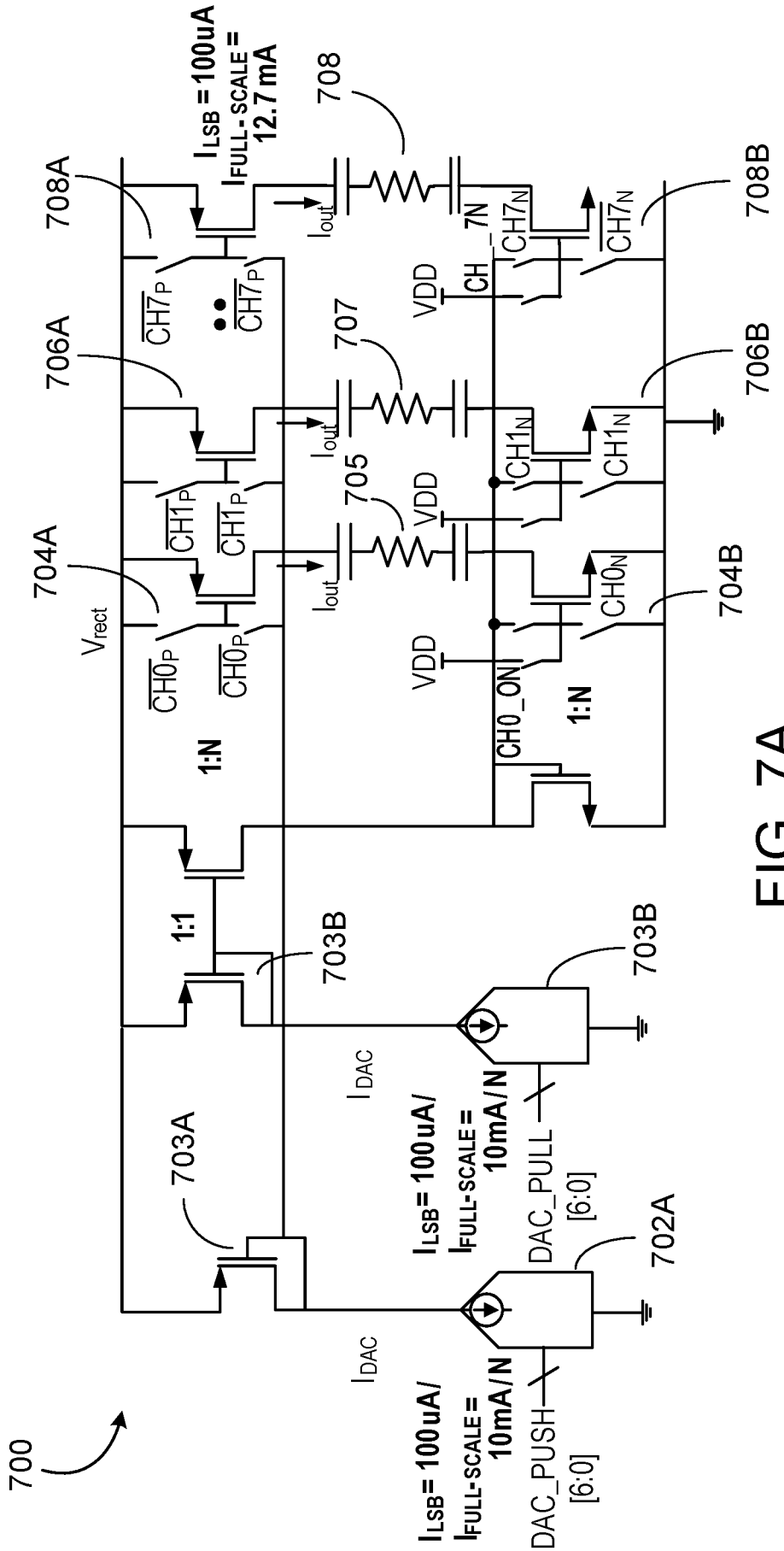

700
708
708A
708B
707
706A
706B
705
704A
704B
703A
703B
702A
I_{LSB} = 100uA
$I_{FULL-SCALE}$ = 12.7 mA
I_{out}
V_{rect}
VDD
1:N
1:1
I_{DAC}
I_{LSB}= 100 uA/
$I_{FULL-SCALE}$ = 10mA/N
DAC_PULL [6:0]
DAC_PUSH [6:0]
CH0_ON
$\overline{CH7_P}$
$CH7_N$
$\overline{CH1_P}$
$CH1_N$
$\overline{CH0_P}$
$CH0_N$

FIG. 7A

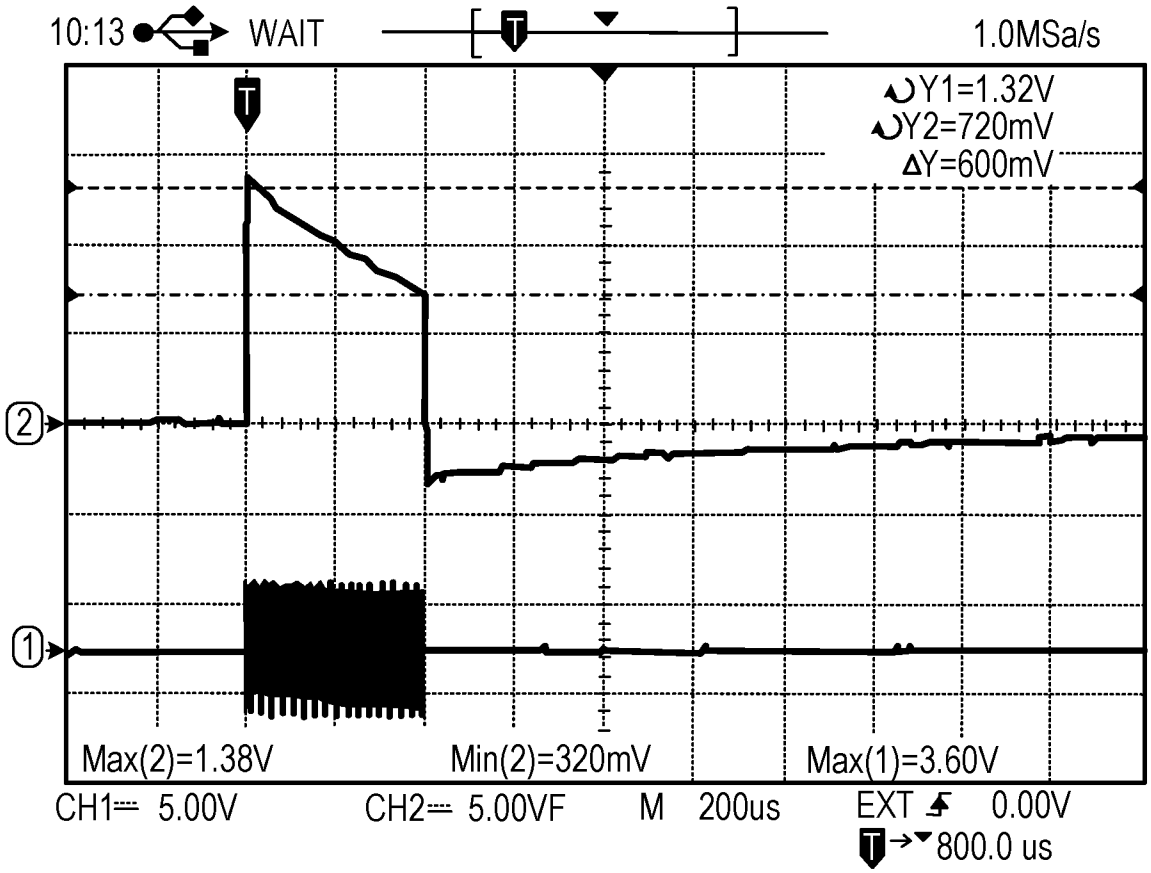

10:13
WAIT
1.0MSa/s
Y1=1.32V
Y2=720mV
ΔY=600mV
2
1
Max(2)=1.38V
Min(2)=320mV
Max(1)=3.60V
CH1 5.00V
CH2 5.00VF
M 200us
EXT 0.00V
800.0 us

FIG. 7B

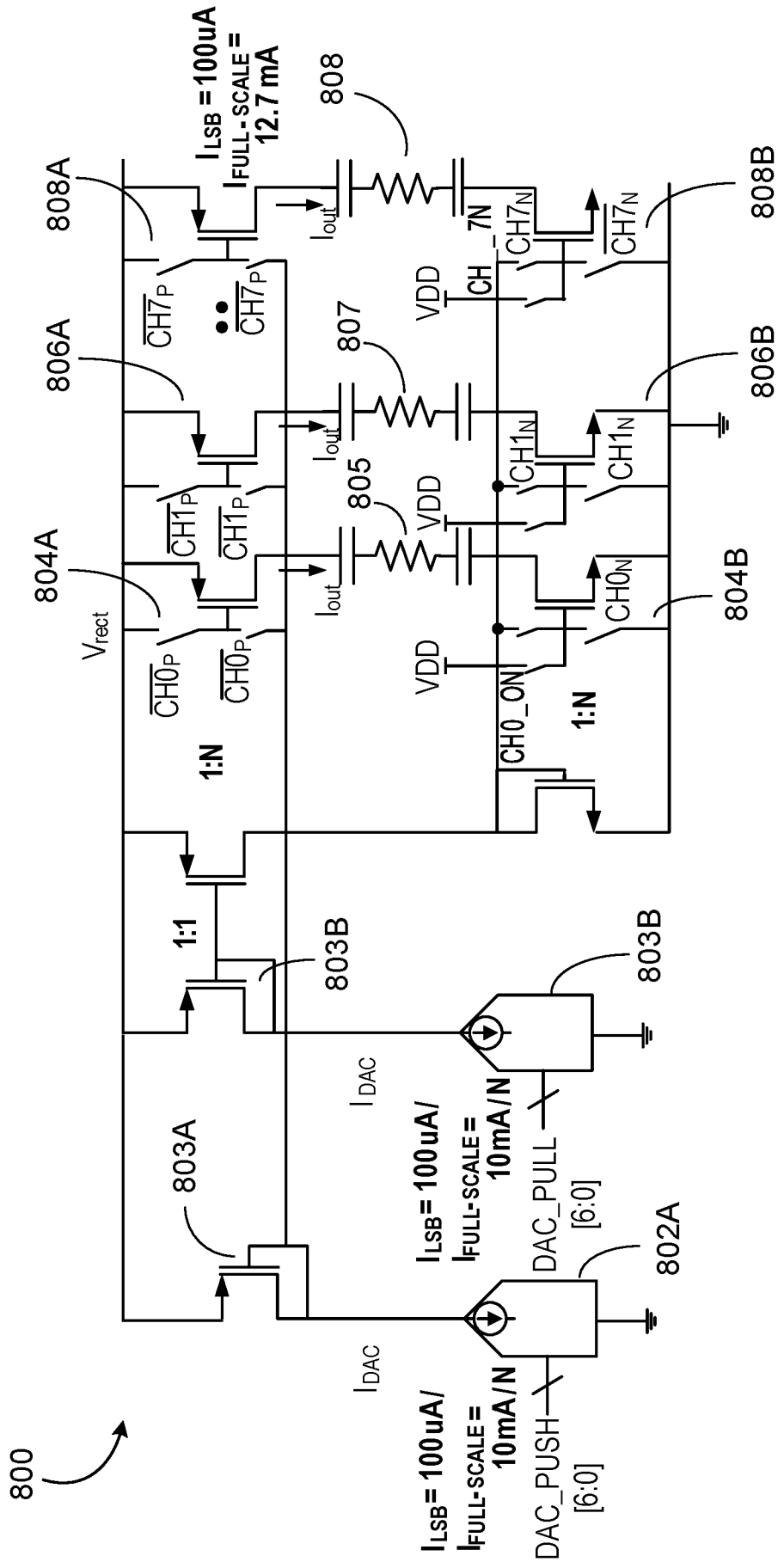

800
808
808A
808B
806A
806B
804A
804B
807
805
803A
803B
802A
1:1
1:N
1:N
I_{LSB} = 100uA
$I_{FULL-SCALE}$ = 12.7 mA
I_{LSB}= 100uA/
$I_{FULL-SCALE}$ = 10mA/N
I_{LSB}= 100uA/
$I_{FULL-SCALE}$ = 10mA/N
I_{DAC}
I_{DAC}
I_{out}
V_{rect}
VDD
CH_7N
CH0_ON
DAC_PULL [6:0]
DAC_PUSH [6:0]

FIG. 8A

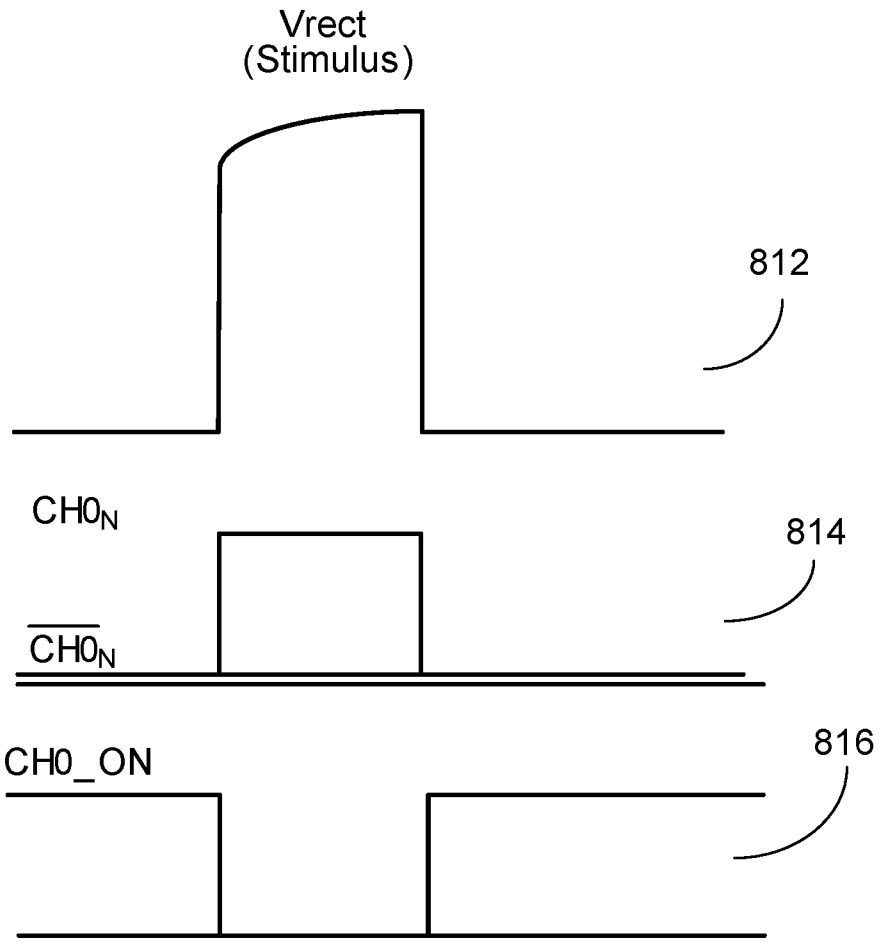


FIG. 8B

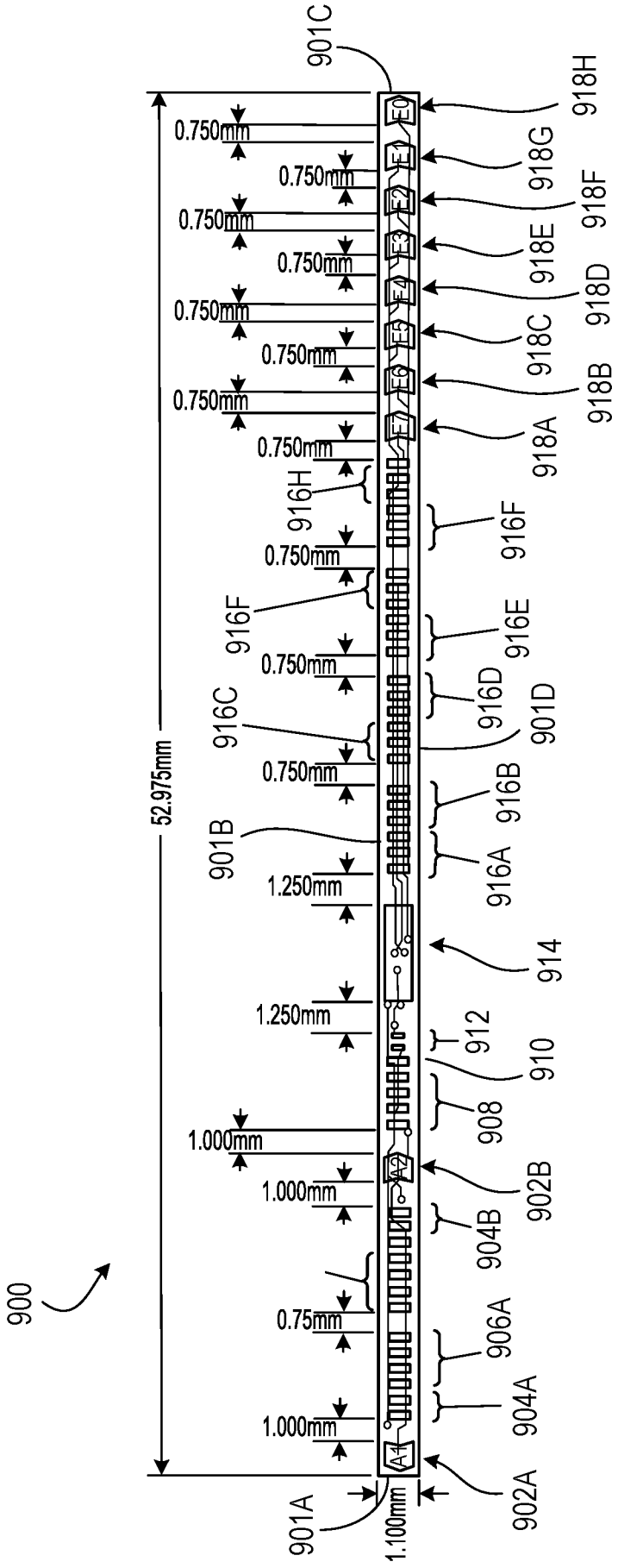

900
901C
901B
901A
52.975mm
1.100mm
0.750mm
1.250mm
1.000mm
0.75mm
E0
E1
E2
E3
E4
E5
E6
E7
A1
A2
918H
918G
918F
918E
918D
918C
918B
918A
916H
916F
916E
916D
916C
916B
916A
901D
914
912
910
908
902B
904B
906A
904A
902A

FIG. 9A

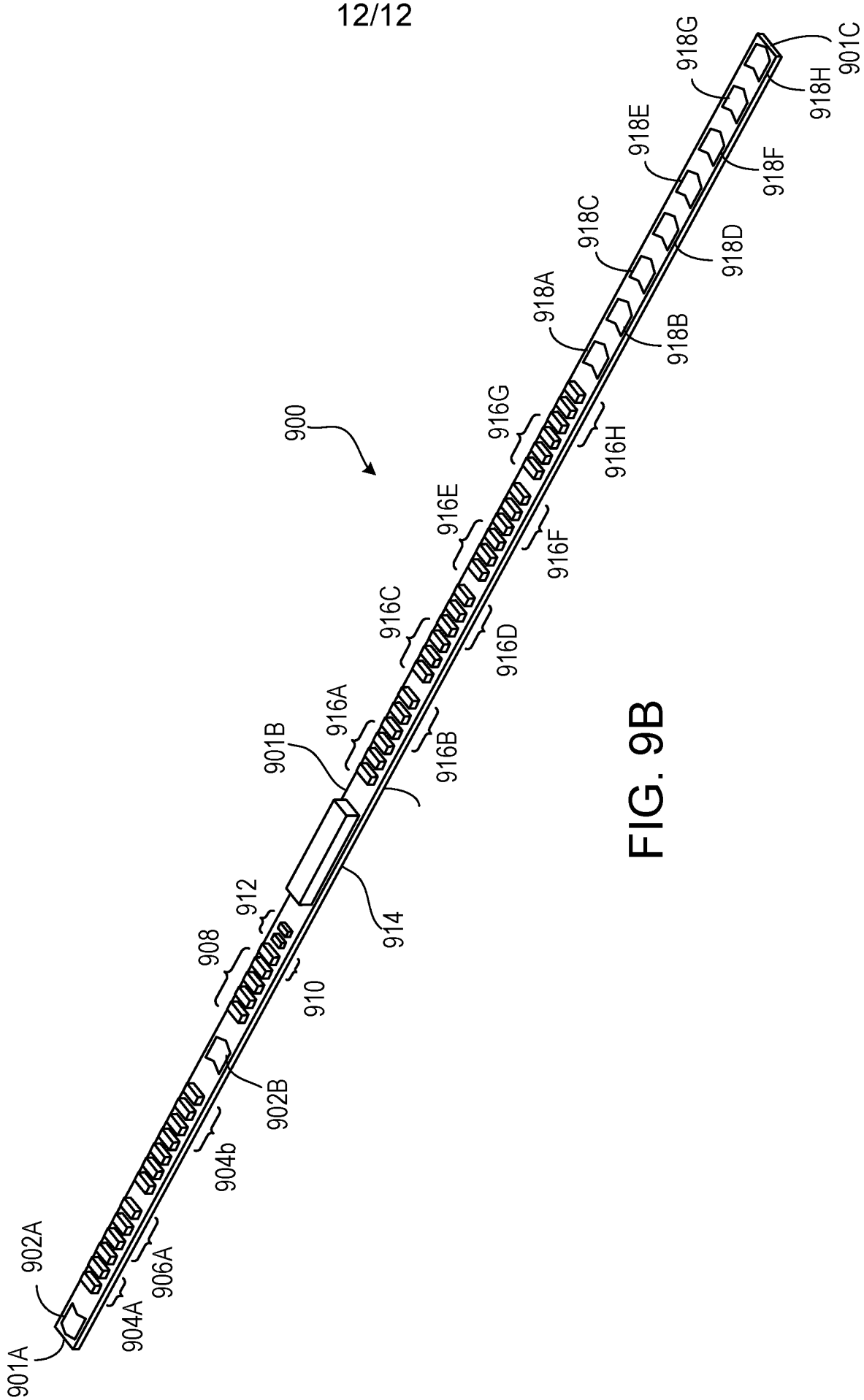

900
901A
902A
904A
906A
904b
902B
910
908
912
914
901B
916A
916B
916C
916D
916E
916F
916G
916H
918A
918B
918C
918D
918E
918F
918G
918H
901C

FIG. 9B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/028041

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61N 1/372; A61N 1/05; A61N 1/36 (2016.01)
CPC - A61N 1/36125; A61N 1/0553; A61N 1/37223 (2016.05)
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)
IPC(8) - A61N 1/372; A61N 1/05; A61N 1/36 (2016.01)
CPC - A61N 1/36125; A61N 1/0553; A61N 1/37223 (2016.05)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 607/2, 6, 60, 62, 70, 72 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, ProQuest
Search terms used: flexible circuit, substrate, rf, antenna, neural tissue, implant, diodes, banks, spaced, series

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO 2014/089299 A2 (PERRYMAN LAURA TYLER et al) 12 June 2014 (12.06.2014) entire document	1-3, 7-14 --- 4-6, 15
Y	US 2014/0031915 A1 (MASHIACH et al) 30 January 2014 (30.01.2014) entire document	4-6
Y	US 5,951,594 A (KERVER) 14 September 1999 (14.09.1999) entire document	15
A	US 2014/0031837 A1 (PERRYMAN et al) 30 January 2014 (30.01.2014) entire document	1-15
A	US 2014/0081154 A1 (TOTH) 20 March 2014 (20.03.2014) entire document	1-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 June 2016	15 JUL 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774