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(54) **NEUROMODULATION SYSTEMS AND METHODS OF USING SAME**

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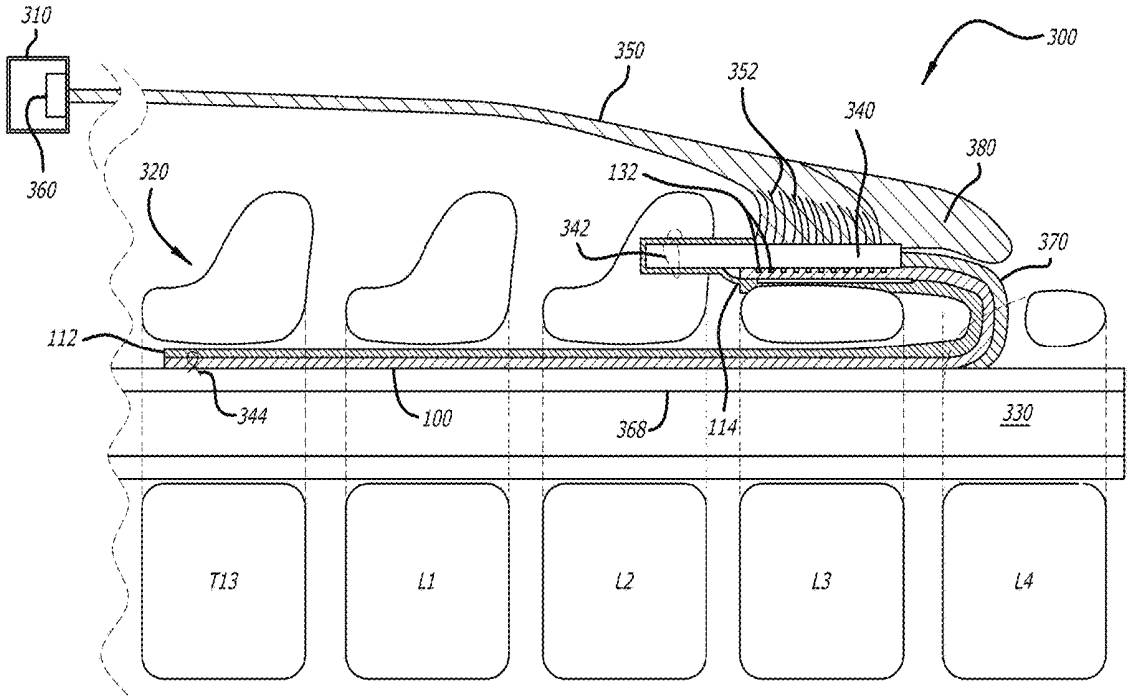
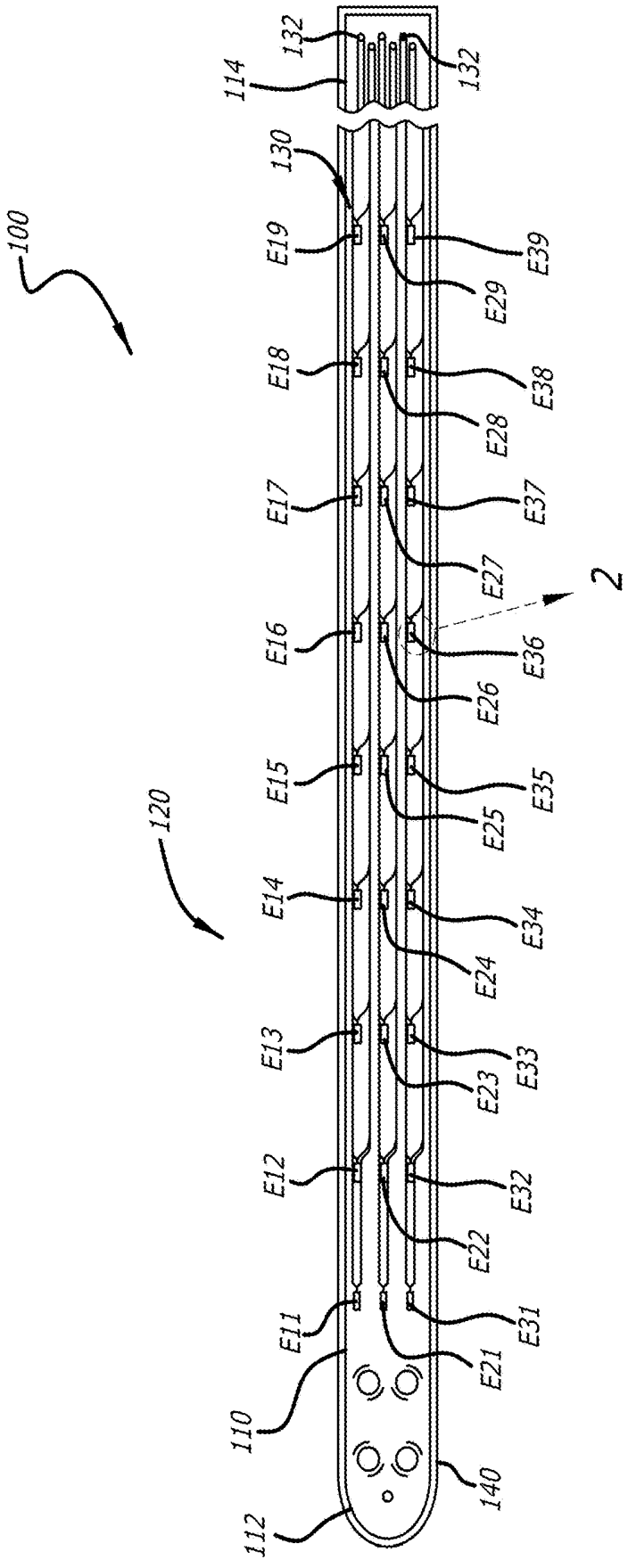
(57) **ABSTRACT**

Neuromodulation systems are described. An example neuromodulation system includes a controller wirelessly communicatively coupled to a host computer, a signal generator communicatively coupled to the controller, and a plurality of electrodes communicatively coupled to the signal generator. The controller, in conjunction with the signal generator and the at least one electrode are configured to deliver a stimulation to a mammal based on an instruction received from the host computer. The stimulation is configured to induce voluntary movement or restore function in the mammal.




100
120
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114
130
132
132
140
E11
E12
E13
E14
E15
E16
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E18
E19
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E26
E27
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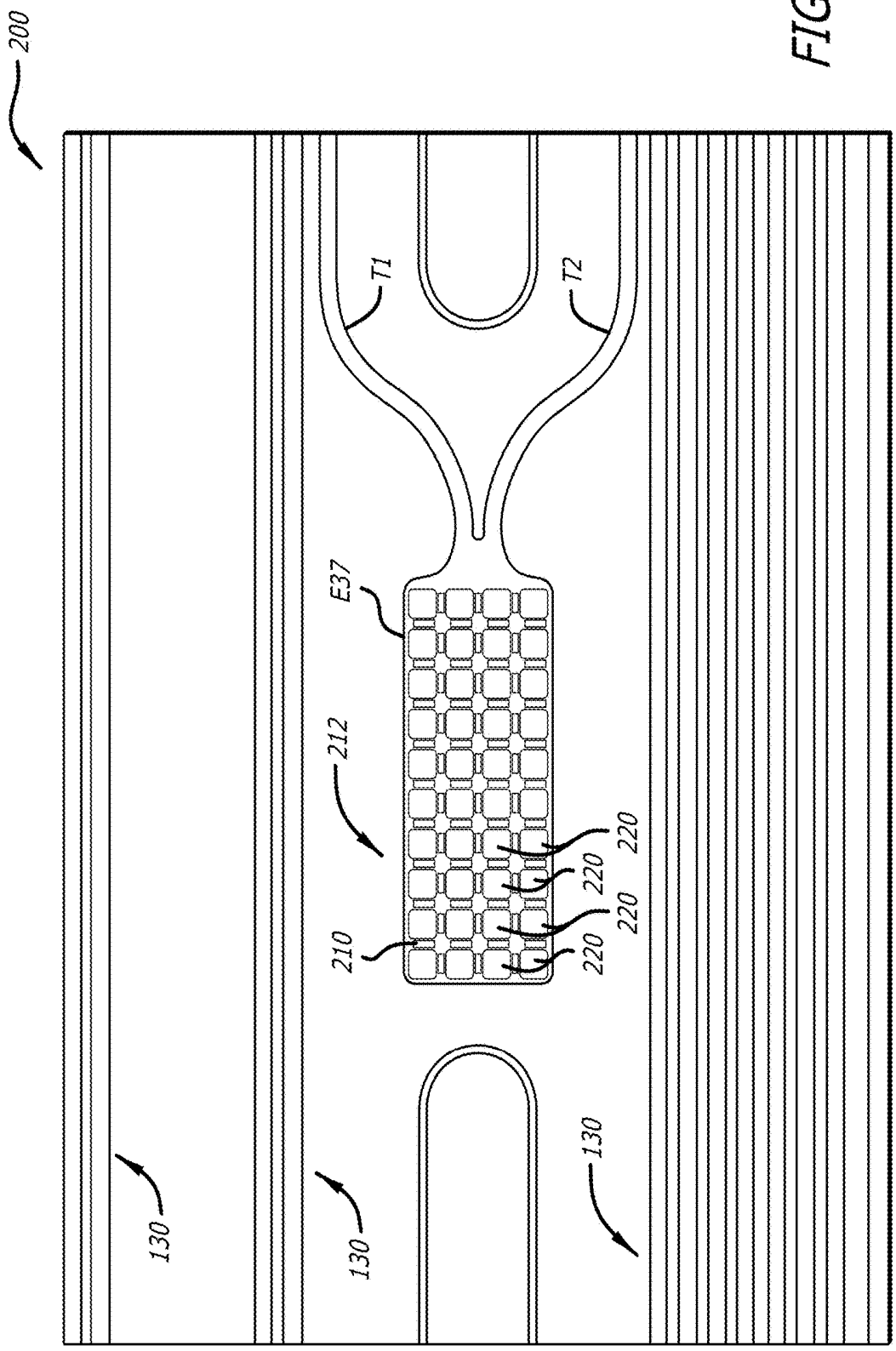
E38
E39
2

FIG. 1

FIG. 2



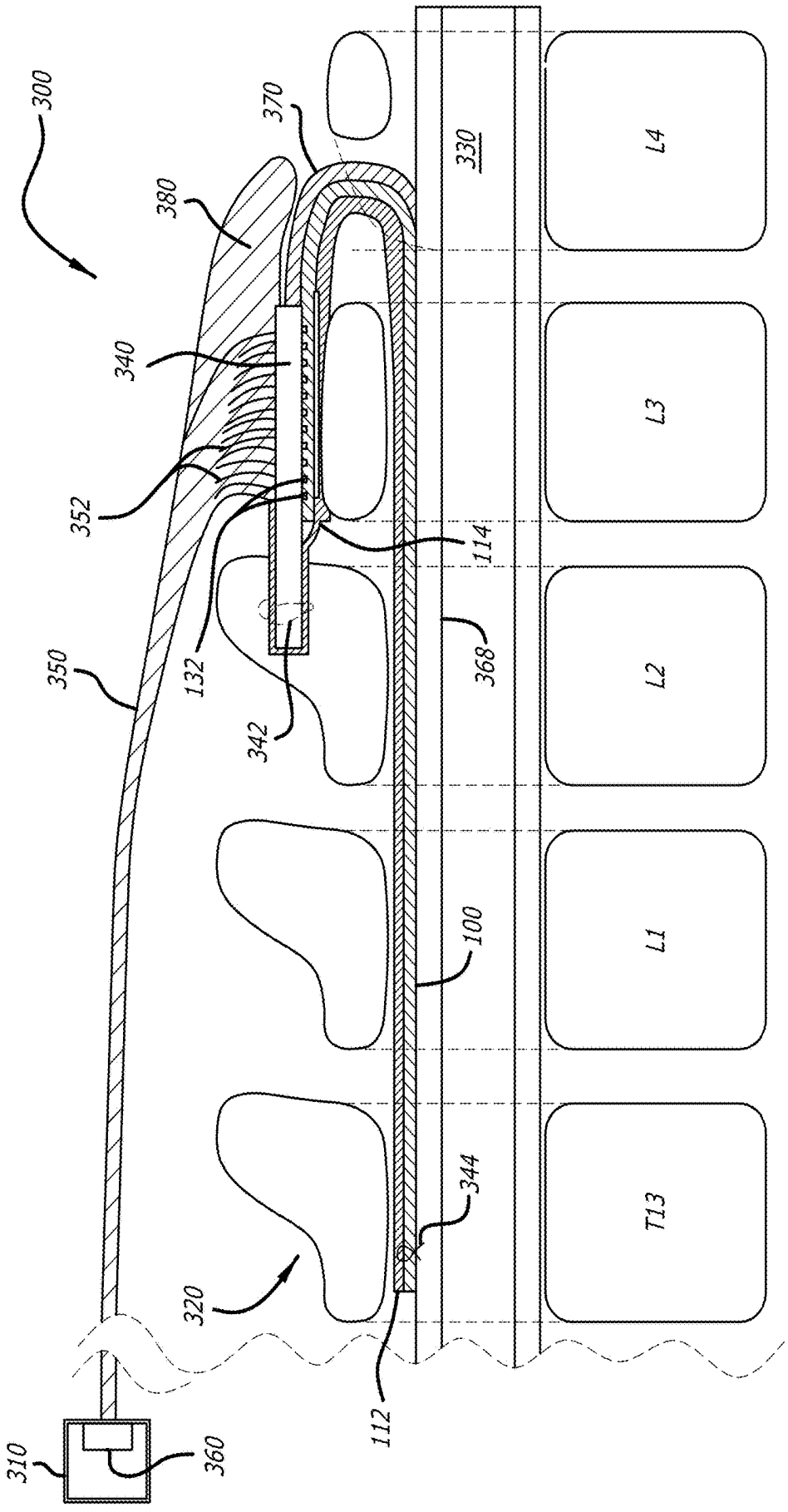

300
370
380
330
L4
340
L3
352
114
132
350
368
L2
342
100
L1
T13
344
320
112
310
360

FIG. 3

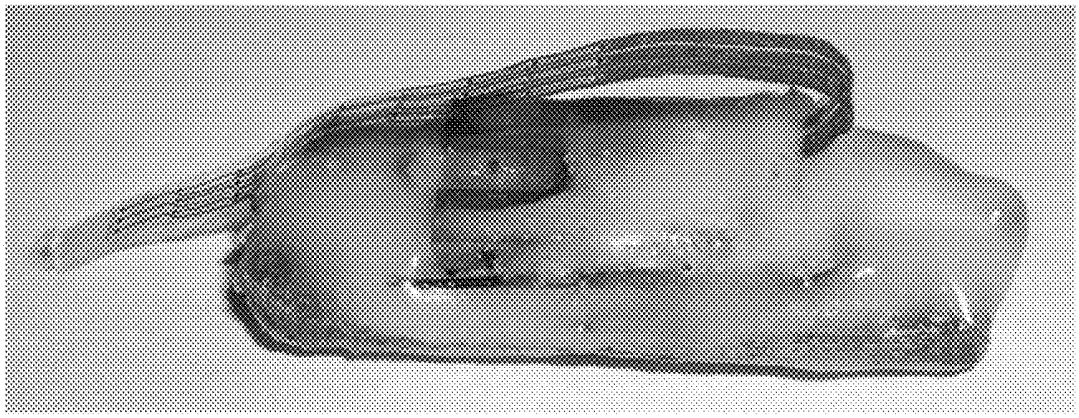


FIG. 4

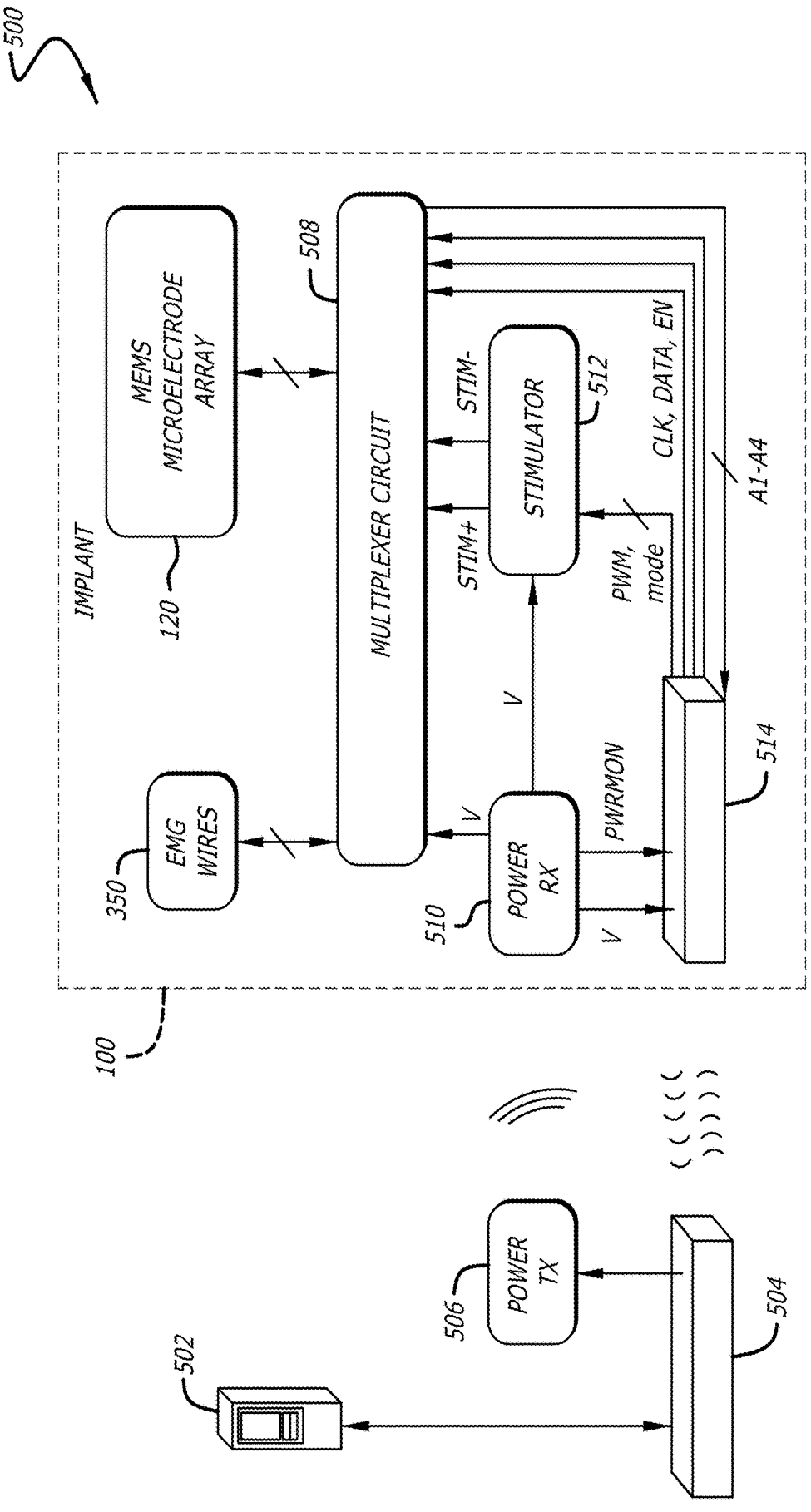

500
IMPLANT
MEMS MICROELECTRODE ARRAY
120
508
MULTIPLEXER CIRCUIT
STIM-
STIM+
STIMULATOR
512
CLK, DATA, EN
A1-A4
PWM, mode
V
EMG WIRES
350
V
POWER RX
510
PWRMON
V
514
100
POWER TX
506
504
502

FIG. 5

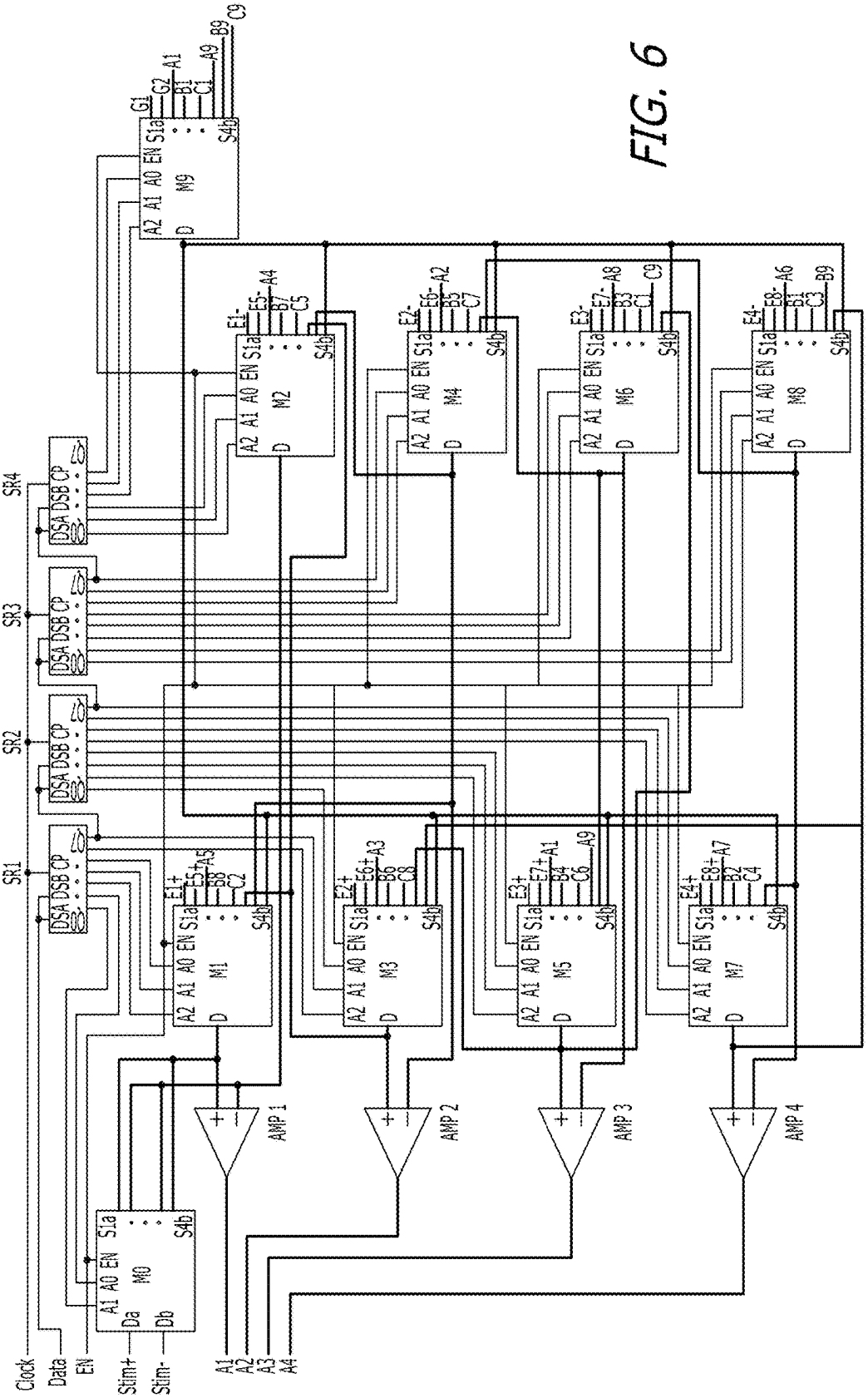

SR4
SR3
SR2
SR1
DSA DSB CP
M0
M1
M2
M3
M4
M5
M6
M7
M8
M9
AMP 1
AMP 2
AMP 3
AMP 4
Clock
Data
EN
Stim+
Stim-
A1
A2
A3
A4

FIG. 6

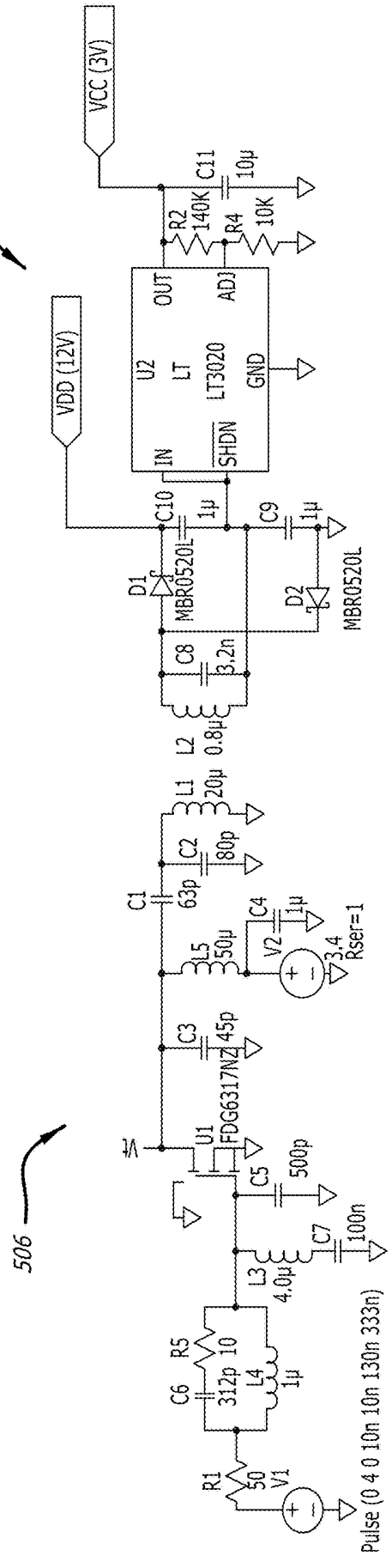

510
VCC (3V)
VDD (12V)
U2
LT
LT3020
IN
SHDN
OUT
ADJ
GND
R2 140K
R4 10K
C11 10µ
C10 1µ
C9 1µ
D1 MBR0520L
D2 MBR0520L
C8 3.2n
L2 0.8µ
L1 20µ
C2 80p
C1 63p
L5 50µ
C4 1µ
V2 3.4
Rser=1
C3 45p
U1 FDG6317NZ
C5 500p
C7 100n
L3 4.0µ
R5 10
C6 312p
L4 1µ
R1 50
V1
Pulse (0 4 0 10n 10n 130n 333n)
506

FIG. 7

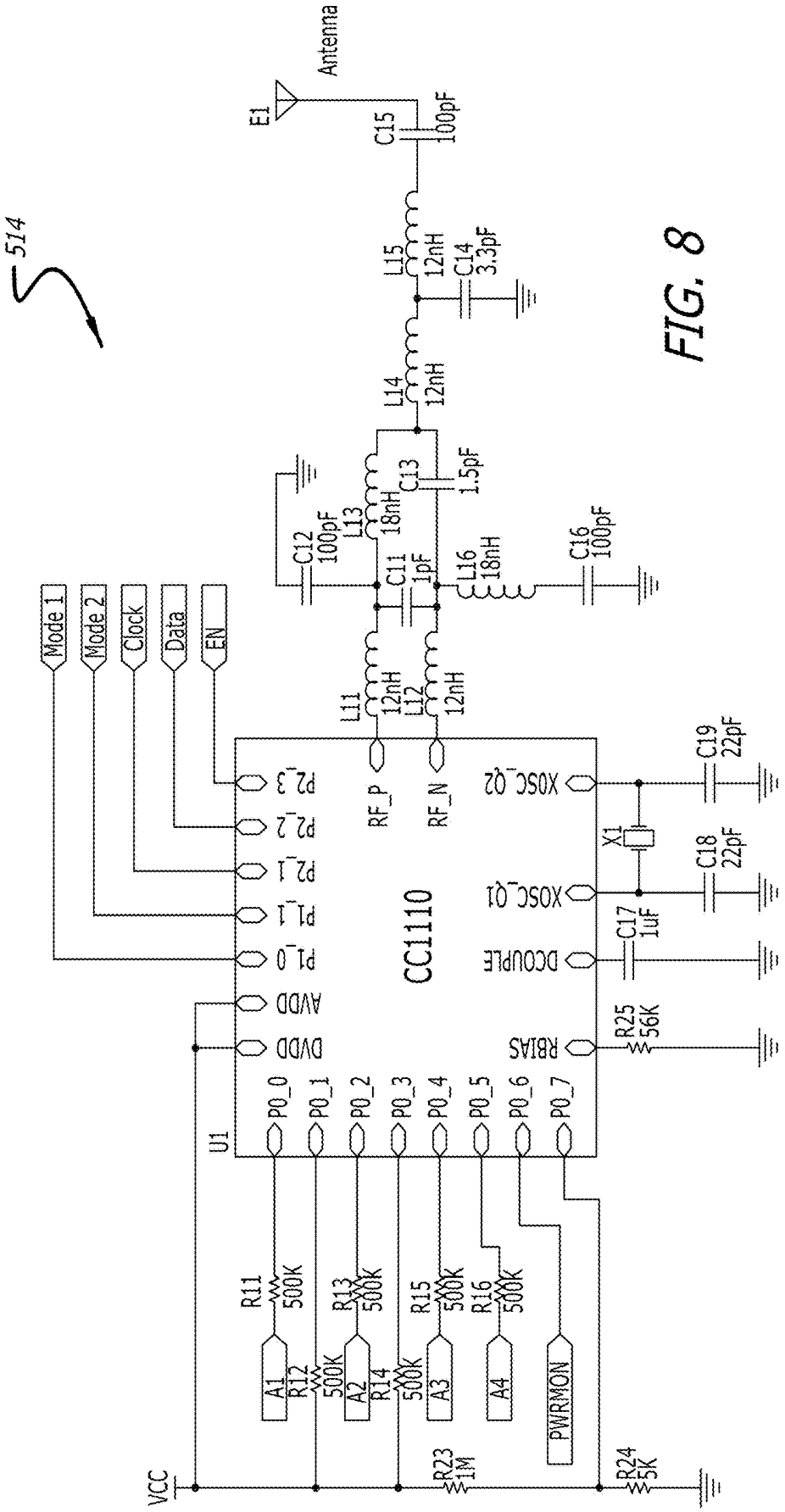

514
E1
Antenna
C15
100pF
L15
12nH
C14
3.3pF
L14
12nH
C13
1.5pF
L13
18nH
C12
100pF
C11
1pF
L16
18nH
C16
100pF
L11
12nH
L12
12nH
Mode 1
Mode 2
Clock
Data
EN
RF_P
RF_N
CC1110
U1
P2_3
P2_2
P2_1
P1_1
P1_0
AVDD
DVDD
P0_0
P0_1
P0_2
P0_3
P0_4
P0_5
P0_6
P0_7
XOSC_Q2
XOSC_Q1
DCOUPLE
RBIAS
X1
C19
22pF
C18
22pF
C17
1uF
R25
56K
R11
500K
R13
500K
R15
500K
R16
500K
R12
500K
R14
500K
A1
A2
A3
A4
PWRMON
R23
1M
R24
5K
VCC

FIG. 8

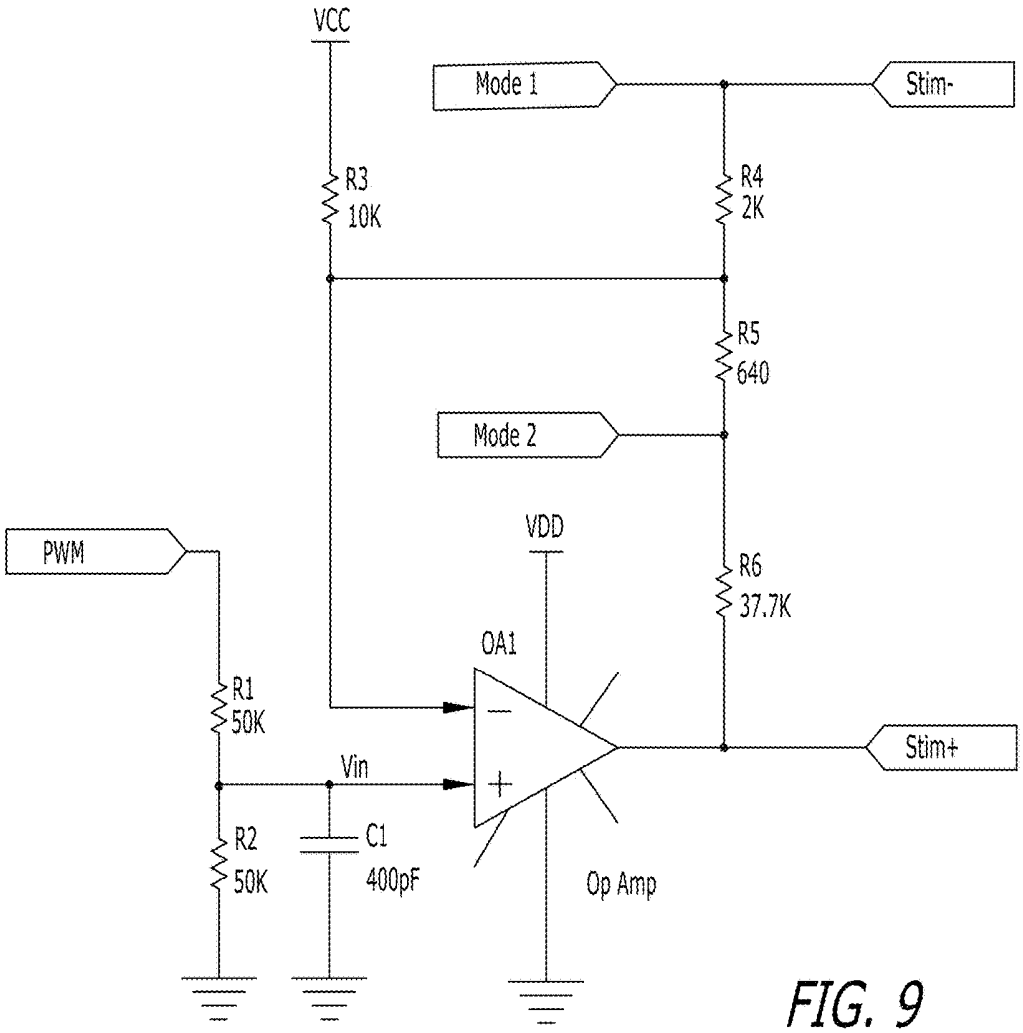

VCC
Mode 1
Stim-
R3
10K
R4
2K
R5
640
Mode 2
VDD
PWM
R6
37.7K
OA1
R1
50K
Vin
Stim+
R2
50K
C1
400pF
Op Amp

FIG. 9

NEUROMODULATION SYSTEMS AND METHODS OF USING SAME

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional patent application No. 61/926,457, filed Jan. 13, 2014, the entire disclosure of which is incorporated herein by reference.

GOVERNMENT LICENSE RIGHTS

[0002] This invention was made with government support under EB0076151 awarded by the National Institutes of Health. The government has certain rights in the invention.

SUMMARY

[0003] Described herein generally are neuromodulation systems. The systems can include a programmable controller wirelessly communicatively coupled to a host computer, a signal generator communicatively coupled to the controller, and a plurality of electrodes and/or sensors communicatively coupled to the signal generator. In some embodiments, the controller, in cooperation with the signal generator and the at least one electrode can be configured to deliver a stimulation to a mammal based on an instruction received from the host computer, the stimulation thereby inducing voluntary movement and/or enabling restoration of function.

[0004] In other embodiments, the neuromodulation systems can include a multiplexer circuit configured to enable the processor to select a first pair of the electrodes to deliver the stimulation. The multiplexer circuit can be configured to enable the processor to select a second pair of electrodes to sense an electrical signal within the mammal.

[0005] In some embodiments, the stimulator system can receive a signal or signals from one or more electrodes or pairs of electrodes (or other communicatively coupled sensors/devices/systems)

[0006] In some embodiments, the neuromodulation systems can further comprise a wireless power receiver. The wireless power receiver can be configured to: receive power wirelessly from a wireless power supply; and rectify the received power into at least one DC voltage for the controller and the signal generator.

[0007] The neurostimulation systems can induce voluntary movements of a foot, a toe, an ankle, a knee, a leg, a hip, a shoulder, an arm, a wrist, a hand, a finger, a waist, a trunk, a neck, a head, or a combination thereof. The voluntary movement can include at least one of standing, stepping, a walking motor pattern, sitting down, sitting up, laying down, reaching, grasping, pulling and pushing, swallowing and chewing, breathing, and coughing. In some embodiments the neurostimulation system can induce or enable the restoration of function of a targeted organ, organ system, or a cell or cell body making up an organ or organ system.

[0008] The neurostimulation systems can be used to apply stimulation over a cervical portion of the spinal cord or the brainstem. The delivered signal can be applied epidurally over at least one of a thoracic, a thoraco-lumbar, a lumbar portion, a lumbosacral portion, and a sacral portion of the spinal cord.

[0009] Methods of inducing movement, e.g., voluntary movement using the herein described neurostimulation systems are also described. Methods of inducing a voluntary movement in a mammal with a spinal injury can comprise: receiving in a programmable controller from a wirelessly communicatively coupled host computer an instruction to apply a stimulation to a mammal; instructing a signal generator via the controller to apply the stimulation; and applying via the signal generator to at least one electrode the stimulation including a monophasic or biphasic signal and/or a mono-polar or bi-polar stimulus.

[0010] The methods can further include transmitting a control instruction from the programmable controller to a multiplexer circuit to select the at least one electrode for applying the stimulation.

[0011] In some embodiments, selecting the electrode can include selecting a pair or pairs of electrodes within a MEMS microelectrode array, electromyography ("EMG") wires, or EMG electrodes.

[0012] The methods can further include transmitting a control instruction from the controller to a multiplexer circuit to select the at least one electrode to sense an electrical signal within the mammal. The at least one electrode selected may be from within the same microelectrode array, another microelectrode array and/or a sensor. The sensor may include a pressure sensor, a temperature sensor, a chemical sensor, a flow sensor, a flex sensor, a gyroscope, or an accelerometer.

[0013] In some embodiments, the methods can further include receiving power wirelessly in a wireless power receiver from a wireless power supply; and rectifying the received power in a DC voltage for the controller and the signal generator.

[0014] In still other embodiments, the methods can further include determining in the controller that received power is insufficient for the stimulation; and transmitting a message to the wireless power receiver for additional power.

[0015] Neuromodulation systems are also described including: a controller configured to wirelessly receive operating instructions from a host computer; a signal generator communicatively coupled to the controller; a multiplexer circuit communicatively coupled to the controller and the signal generator; a wireless power receiver electrically coupled to a wireless power supply and configured to power the controller, the signal generator, the multiplexer circuit; a plurality of EMG wires electrically coupled to the multiplexer circuit; and a microelectrode array including (but not limited to) a 9×3 array of electrodes electrically coupled to the multiplexer circuit. In some embodiments, the controller, in cooperation with the signal generator, the multiplexer circuit, and at least one of an EMG wire and an electrode within the microelectrode array are configured to deliver a stimulation (e.g., an epidural stimulation) to a mammal, the stimulation being configured to induce voluntary movement or enable restoration of a function in the mammal.

[0016] In some embodiments, the multiplexer circuit can be configured to enable a pair of the EMG wires or a pair or pairs of the electrodes within the microelectrode array to receive the stimulation from the signal generator.

[0017] Additional features and advantages are described herein, and will be apparent from the following Detailed Description and figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] FIG. **1** shows a diagram of a view of an underside of an implantable electrode array assembly, according to an example embodiment of the present disclosure.

[0019] FIG. **2** shows a diagram of an enlarged view of a portion of the assembly of FIG. **1**, according to an example embodiment of the present disclosure.

[0020] FIG. **3** shows a diagram of a cross-sectional view of a cable system incorporating the assembly of FIG. **1**, according to an example embodiment of the present disclosure.

[0021] FIG. **4** shows a diagram of the cable system of FIG. **3** coated with a coating, according to an example embodiment of the present disclosure.

[0022] FIG. **5** shows a diagram of an example implant system including the implantable electrode array assembly and cable system of FIGS. **1** to **3**, according to an example embodiment of the present disclosure.

[0023] FIG. **6** shows a diagram of a multiplexer circuit, according to an example embodiment of the present disclosure.

[0024] FIG. **7** shows a diagram of a wireless power supply and a wireless power receiver, according to an example embodiment of the present disclosure.

[0025] FIG. **8** shows a diagram of a controller, according to an example embodiment of the present disclosure.

[0026] FIG. **9** shows a diagram of a stimulator, according to an example embodiment of the present disclosure.

DETAILED DESCRIPTION

[0027] The present disclosure relates in general to the field of neurological treatment and rehabilitation for injury and disease including traumatic spinal cord injury, non-traumatic spinal cord injury, stroke, movement disorders, brain injury, and other diseases or injuries that result in paralysis and/or nervous system disorder. Neuromodulation systems, devices, and methods are provided to facilitate recovery of posture, locomotion, and voluntary movements such as those of the fingers, hands, arms, trunk, legs, and feet and recovery of autonomic, sexual, vasomotor, speech, swallowing, chewing, respiratory and cognitive function, in a human subject having spinal cord injury, brain injury, or any other neurological disorder or impairment. In some embodiments, the systems can include wireless communications.

[0028] The neuromodulation systems can include: a controller wirelessly communicatively coupled to a host computer; a signal generator communicatively coupled to the controller; and a plurality of electrodes communicatively coupled to the signal generator. In some embodiments, the controller, in cooperation with the signal generator and the at least one electrode can be configured to deliver a stimulation to a mammal based on an instruction received from the host computer, the stimulation including being configured to induce voluntary movement or enable restoration of function.

[0029] The use of conventional wire electrodes for spinal cord stimulation can be effective in facilitating locomotor recovery in rats that have lower body paralysis. The use of a MEMS high-density microelectrode array may offer greater selectivity and flexibility in stimulation patterns, allowing for optimization of hindlimb stepping motion and better study of electrophysiological changes following the spinal cord injury. However, in some circumstances, **37** wires are needed for this passive implant and can often cause health complications.

[0030] Although active electronics have been implemented to reduce the number of wires, the present devices, e.g., implants, and systems present a fully wireless spinal cord implant. In some embodiments, this wireless implant can be for mammals. In other embodiments, the implant can be for humans.

[0031] This wireless spinal cord implant can include an epidural microelectrode array and optional electrodes for evoked potentials and/or sensors.

[0032] The herein described implant is capable or can be configured to both stimulate and record spinal cord, EMG responses, evoked potentials, sensory evoked potentials, or a type of physiological signal (i.e. electrical, chemical, photonic, mechanical, acoustic, etc.) from a subjects body or body parts (i.e. organ or organ system or the cells that make up the organ or organ system). Additionally, the implant (by way of non-limiting example) may be part of a closed loop system. In other embodiments the implant may communicate with other systems and devices either implanted or external to the body such as, for example, a pharmaceutical pump or a robotic system.

[0033] In one example embodiment, the wireless implant can include a 9×3 MEMS microelectrode array, a PCB with wireless microprocessor/transceiver, EMG wires, a power coil configured to receive power wirelessly, and sealing materials.

[0034] The microelectrode, by way of a non-limiting example, can be fabricated with a parylene-metal-parylene sandwich structure. The microelectrode can incorporate an improved microelectrode design and other additions to improve mechanical reliability and minimize delamination while retaining flexibility. The PCB can fit 22 IC chips and about 100 passive components into a compact having a 10 mm×32 mm footprint.

[0035] In some embodiments, the microelectrode array can include a plurality of electrodes. Each individual electrode within the plurality of electrodes can be pulsed or stimulated individually. In some embodiments, electrodes can be pulsed in pairs. A pair can include two or more individual electrodes group together. In some embodiments, an electrode or groups of electrodes can also be configured to record electrical signals.

[0036] The stimulator associated with the wireless implant can be configured to send a stimulating pulse to any pair of electrodes in the electrode array. In some embodiments, the stimulator system can receive a signal or signals from one or more electrodes or pairs of electrodes (or other communicatively coupled sensors/devices/systems). In other embodiments, the electrode array can include more than 2 electrodes, more than 5 electrodes, more than 10 electrodes, more than 15 electrodes, more than 20 electrodes, more than 25 electrodes, more than 30 electrodes, more than 50 electrodes, more than 100 electrodes, more than 500 electrodes, more than 1,000 electrodes, more than 5,000 electrodes, more than 10,000 electrodes, between about 2 electrodes and about 10,000 electrodes, between about 25 electrodes and about 35 electrodes, or between about 25 electrodes and about 100 electrodes. In some embodiments, the electrode array can include 27 electrodes, 54 electrodes, 108 electrodes, 216 electrodes, or more.

[0037] In some embodiments, the circuitry encased in the wireless electrode can switch between different electrode pairs very rapidly, this circuitry can be configured to effectively send an arbitrary pattern of pulses to a multi-electrode array or other electrode array as described herein.

[0038] In one embodiment, the systems described can address 27 electrodes, two reference wires, and 16 EMG wires.

[0039] In some embodiments, the systems can include a maximum stimulating voltage. This maximum stimulating voltage can be achieved in a constant voltage mode. Example stimulating voltages can be about ±5 V, about ±6 V, about ±7 V, about ±8 V, about ±9 V, about ±10 V, about ±11 V, about ±12 V, about ±13 V, about ±14 V, about ±15 V, about ±20 V, at least about ±5 V, at least about ±10 V, at least about ±12 V, between about ±5 V and about ±20 V, or between about ±10 V and about ±15 V. In one embodiment, the maximum stimulating voltage can be ±12V.

[0040] In some embodiments, the systems can include a maximum stimulating current. This maximum stimulating current can be achieved in a constant current mode. Maximum stimulating currents can be about ±1 mA, about ±2 mA, about ±3 mA, about ±4 mA, about ±5 mA, about ±6 mA, about ±7 mA, about ±8 mA, about ±9 mA, about ±10 mA, at least about ±1 mA, at least about ±2 mA, at least about ±4 mA, between about ±1 mA and about ±10 mA, or between about ±4 mA and about ±6 mA. In one embodiment, the maximum stimulating current can be ±5 mA.

[0041] In embodiments, the systems can provide an arbitrary waveform stimulation. Arbitrary waveform stimulation can be about 10 kHz, about 20 kHz, about 30 kHz, about 40 kHz, about 50 kHz, about 60 kHz, about 70 kHz, about 80 kHz, about 90 kHz, about 100 kHz, about 110 kHz, about 120 kHz, about 130 kHz, about 140 kHz, about 150 kHz, about 160 kHz, about 170 kHz, about 180 kHz, about 190 kHz, about 200 kHz, at least about 50 kHz, at least about 80 kHz, at least about 90 kHz, between about 10 kHz and about 200 kHz, or between about 90 kHz and about 110 kHz. In one embodiment, the arbitrary waveform stimulation can be 100 kHz.

[0042] The systems can provide virtually any pulsed waveform. The pulsed waveform can be as low as about 0.1 ms pulse width, as high as 50 kHz frequency with a recording bandwidth up to about 60 kHz (−3 dB).

[0043] The herein described systems can provide a digital-to-analog (DAC) resolution between about 5 bits and about 15 bits, between about 6 bits and about 13 bits, or between about 7 bits and about 12 bits.

[0044] The systems can have a characteristic configuration switch time. Characteristic switch times can be about 1 μs, about 2 μs, about 3 μs, about 4 μs, about 5 μs, about 6 μs, about 7 μs, about 8 μs, about 9 μs, about 10 μs, less than about 10 μs, less than about 8 μs, less than about 4 μs, between about 1 μs and about 10 μs, or between about 2 μs and about 4 μs. In one embodiment, the maximum stimulating current can be 3 μs.

[0045] The systems can configure and pulse a number of times per given time period. In some embodiments, the systems can configure and pulse about 10 times/millisecond (ms), about 20 times/ms, about 30 times/ms, about 40 times/ms, about 50 times/ms, about 60 times/ms, about 70 times/ms, about 80 times/ms, about 90 times/ms, about 100 times/ms, about 110 times/ms, about 120 times/ms, about 130 times/ms, about 140 times/ms, about 150 times/ms, about 160 times/ms, about 170 times/ms, about 180 times/ms, about 190 times/ms, about 200 times/ms, at least about 10 times/ms, at least about 20 times/ms, at least about 40 times/ms, at least about 60 times/ms, at least about 80 times/ms, at least about 100 times/ms, between about 10 times/ms and about 200 times/ms, or between about 90 times/ms and about 110 times/ms. In one embodiment, the systems can configure and pulse 100 times/ms.

[0046] The systems can be configured to simultaneously address a given number of electrodes. In some embodiments, the electrodes can be arbitrary. In one embodiment, the systems can simultaneously address 2 electrodes, 4 electrodes, 6 electrodes, 8 electrodes, 10 electrodes, 12 electrodes, 14 electrodes, 16 electrodes, 18 electrodes, 20 electrodes, or any group of electrodes. Further, the system can simultaneously address 2 arbitrary electrodes, 4 arbitrary electrodes, 6 arbitrary electrodes, 8 arbitrary electrodes, 10 arbitrary electrodes, 12 arbitrary electrodes, 14 arbitrary electrodes, 16 arbitrary electrodes, 18 arbitrary electrodes, 20 arbitrary electrodes, or more arbitrary electrodes. In some embodiments, the systems can simultaneously address up to 8 arbitrary electrodes with limited configuration flexibility.

[0047] Further, the systems can be configured such that any two electrodes, if not used for stimulating, can be chosen as the differential pair for recording. Thus, any two electrodes not being used for stimulation can be used for recording. However, the recording electrodes are not limited to two at a time. The systems can be configured to allow 4 electrodes, 6 electrodes, 8 electrodes, 10 electrodes, 12 electrodes, 14 electrodes, 16 electrodes, 18 electrodes, 20 electrodes, or more electrodes to be used for recording.

[0048] The systems can communicate wirelessly and possess characteristic data transfer rates. For example, the systems can have wireless data transfer rates of about 250 kBps, 500 kBps, 750 kBps, 1,000 kBps, at least 250 kBps, at least 500 kBps, between about 250 kBps and about 500 kBps, between about 250 kBps and about 1,000 kBps, or between about 250 kBps and about 750 kBps. These data rates can be on ISM band 915 MHz. In one example embodiment, the systems can have wireless data transfer rates of about 250 kBps.

[0049] The systems can also be configured as low power drawing systems. The max power consumption of the systems can be less than about 100 mW, less than about 90 mW, less than about 80 mW, less than about 70 mW, less than about 60 mW, less than about 50 mW, less than about 40 mW, less than about 30 mW, or less than about 20 mW. In one embodiment, the systems use less than about 100 mW of power when active.

[0050] FIG. **1** illustrates an implantable electrode array assembly **100**, according to an example embodiment of the present disclosure. While the embodiment of the assembly **100** illustrated is configured for implantation in a rat, embodiments may be constructed for use in other subjects, such as other mammals, including humans, and such embodiments are within the scope of the present teachings. The assembly **100** is for use with a subject that has a spinal cord **330** (see FIG. **3**) with at least one selected spinal circuit (not shown) and a neurologically derived paralysis in a portion of the subject's body. By way of a non-limiting example, the assembly **100** may be implanted epidurally along the spinal cord **330**. The assembly **100** may be positioned at one or more of a sacral region, lumbosacral

region, a lumbar region, a thoraco-lumbar region, a thoracic region, and/or a cervical region of the spinal cord **330** or a brainstem.

[0051] By way of non-limiting examples, when activated, the selected spinal circuit may (a) enable voluntary movement of muscles involved in at least one of standing, stepping, reaching, grasping, chewing, swallowing, breathing, voluntarily changing positions of one or both legs, voiding the subject's bladder, voiding the subject's bowel, postural activity, sitting, and locomotor activity; (b) enable or improve autonomic control of at least one of cardiovascular function, body temperature, and metabolic processes; and/or (c) help facilitate recovery of at least one of an autonomic function, sexual function, vasomotor function, and cognitive function. Without being limited by theory, it is believed that the selected spinal circuit has a first stimulation threshold representing a minimum amount of stimulation required to activate the selected spinal circuit, and a second stimulation threshold representing an amount of stimulation above which the selected spinal circuit is fully activated and adding the induced neurological signals has no additional effect on the at least one selected spinal circuit.

[0052] The paralysis may be a motor complete paralysis or a motor incomplete paralysis. The paralysis may have been caused by a spinal cord injury classified as motor complete or motor incomplete. The paralysis may have been caused by an ischemic or traumatic brain injury. The paralysis may have been caused by an ischemic brain injury that resulted from a stroke or acute trauma. By way of another example, the paralysis may have been caused by a neurodegenerative brain injury. The neurodegenerative brain injury may be associated with at least one of Parkinson's disease, Huntington's disease, Alzheimer's, ischemia, stroke, amyotrophic lateral sclerosis (ALS), primary lateral sclerosis (PLS), and cerebral palsy.

[0053] If the paralysis was caused by a spinal cord injury at a first location along the spinal cord **330**, the assembly **100** may be implanted (e.g., epidurally) at a second location below the first location along the spinal cord relative to the subject's brain (not shown).

[0054] The example assembly **100** is configured to apply electrical stimulation to a portion of a spinal cord **330** of a subject. The electrical stimulation may include at least one of tonic stimulation and intermittent stimulation. The stimulation applied may be pulsed. The electrical stimulation may include simultaneous or sequential stimulation of different regions of the spinal cord. The electrical stimulation applied by the assembly **100** may be below the second stimulation threshold such that the at least one selected spinal circuit is at least partially activatable by the addition of signals generated by the subject. By way of a non-limiting example, such subject generated signals may be induced by subjecting the subject to physical activity or training (such as stepping on a treadmill). These signals may be induced in a paralyzed portion of the subject. By way of another non-limiting example, the subject generated signals may include supraspinal signals.

[0055] In one embodiment, the assembly **100** illustrated in FIGS. **1** to **3** can be configured for implantation in a rat. Thus, in some embodiments of the assembly **100** illustrated, the implant can be sized (e.g., about 59 mm by about 3 mm) and shaped for implantation into the rat. However, embodiments may be constructed for use with other subjects, such as other mammals, including humans.

[0056] FIG. **2** illustrates an enlarged portion **200** of the assembly **100** depicted in FIG. **1**, according to an example embodiment of the present disclosure. The assembly **100** may be characterized as being a microelectromechanical systems ("MEMS") device. As mentioned above, the assembly **100** is configured for implantation along the spinal cord **330** (see FIG. **3**) and to provide electrical stimulation thereto. For example, the assembly **100** may provide epidural stimulation to the spinal cord **330**. The assembly **100** enables a high degree of freedom and specificity in selecting the site of stimulation compared to prior art wire-based implants, and triggers varied biological responses that can lead to an increased understanding of the spinal cord **330** and locomotive, movement, autonomic and functional recovery for victims of spinal cord injury.

[0057] Turning to FIG. **1**, the assembly **100** includes a body portion **110**, an electrode array **120**, and a plurality of electrically conductive traces **130**. The body portion **110** includes a distal end portion **112**, a proximal end portion **114** (opposite the distal end portion), a frame **140**, and a grid structure **210** (see FIG. **2**) for each electrode E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** of the electrode array **120**. Each of the grid structures **210** defines a plurality of cells **212**. By way of a non-limiting example, the grid structures **210** may each be constructed from parylene (e.g., parylene-C). In the embodiment illustrated, the grid structure **210** includes **40** cells.

[0058] As mentioned above, the electrode array **120** includes the plurality of electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** (e.g., 9×3 electrodes). The electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** are arranged in a two-dimensional array. Each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** includes a plurality of electrically conductive contacts **220**. The contacts **220** are sites at which the electrode (e.g., the electrode E**37** illustrated in FIG. **2**) will contact the spinal cord (e.g., the dura). The contacts **220** are in electrically communication with one another. The embodiment of the electrode E**37** illustrated includes **40** contacts **220**. However, this is not a requirement. As mentioned above, each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** corresponds to a unique one of the grid structures **210**. In the embodiment illustrated, for each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39**, each of the contacts **220** is positioned within a different one of the cells **212** of the corresponding grid structure **210**. The grid structure **210** may help prevent delamination of the layers of the assembly **100** (see FIG. **1**). The grid structure **210** and contacts **220** may be formed by selectively etching a layer of substantially electrically non-conductive material (e.g., parylene) adjacent a pad of electrically conductive material (e.g., metal such as platinum or gold) to define the grid structure **210** and expose portions of the electrically conductive material within the cells **212** of the grid structure to define the contacts **220**.

[0059] While the electrode array **120** illustrated includes **27** electrodes, in other embodiments, the number of electrodes may range from one electrode to about 1000 electrodes or more. As discussed above, the electrode array **120** includes at least 10, at least 15, at least 20, at least 25, at least 50, at least 100, at least 250, at least 500, or at least 1000 electrodes. In various embodiments, the inter-electrode spacing of adjacent electrodes in the electrode array **120** varies from about 100 μm or about 500 μm, or about 1000 μm or about 1500 μm to about 2000 μm, or about 3000 μm, or about 4000 μm, or about 4500 μm, or about 5000 μm. In

various embodiments, inter-electrode spacing ranges from about 100 μm, about 150 μm, about 200 μm, or about 250 μm up to about 1,000 μm, about 2000 μm, about 3000 μm, or about 4,000 μm. In some embodiments, the diameter (or width) of each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** ranges from about 50 μm, 100 μm, 150 μm, 200 μm, or 250 μm up to about 500 μm, about 1000 μm, about 1500 μm, or about 2000 μm.

[0060] The electrode array **120** can be formed in any geometric shape such as a square shape, rectangular shape, circular shape, tubular shape, fan shape, or fusiform shape. Typically the size of the electrode array **120** will be on the order of about 0.1 mm to about 2 cm, wide or in diameter, depending in part on the number of electrodes in the electrode array **120**. In various embodiments, the length of the electrode array **120** ranges from about 0.01 mm, or 0.1 mm up to about 10 cm or greater.

[0061] One or more of the traces **130** is connected to each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39**. Referring to FIG. **2**, in the embodiment illustrated, two traces "T**1**" and "T**2**" are connected to each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39**. In alternate embodiments, more than two traces **130** may be connected to each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39**. Connecting more than one of the traces **130** to each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** helps ensure signals reach each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39**. In other words, redundancy may be used to improve reliability. For each of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39**, the traces **130** are connected to each of the contacts **220** of the electrode and carry or receive signals thereto. Openings **132** (see FIG. **3**) formed (e.g., etched) in the body portion **110** expose portions of the traces **130**.

[0062] The traces **130** may be used to selectively deliver electrical signals (e.g., pulsed signals) to (or record signals from) the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39**. In this manner, only a selected one or more of the electrodes (or pair of electrodes) E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** may deliver stimulation to the spinal cord **330** (see FIG. **3**). The electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** are operably linked by the traces **130** to control circuitry, as discussed in further detail below. The control circuitry is configured to select one or more of the electrodes E**11**-E**19**, E**21**-E**29**, and E**31**-E**39** to activate/stimulate/record and/or to control the parameters (e.g., frequency, pulse width, amplitude, etc.) of the electrical stimulation. In various embodiments, the electrode selection, frequency, amplitude, and pulse width are independently selectable. For example, at different times, different electrodes can be selected. At any time, different electrodes can provide stimulation having different parameter values (e.g., frequencies, amplitudes, and the like). In various embodiments, at least a portion of the electrodes may be operated in a monopolar mode and/or a bipolar mode. In such embodiments, constant current or constant voltage may be used to deliver the stimulation.

[0063] In some embodiments, the traces **130** may receive signals from implantable control circuitry and/or an implantable power source (not shown). The implantable control circuitry may be programmed and/or reprogrammed by an external device (e.g., using a handheld device that communicates with the control circuitry through the skin). The programming may be repeated as often as necessary.

[0064] FIG. **3** illustrates a cable system **300** incorporating the assembly **100** of FIG. **1**, according to an example embodiment of the present disclosure. The example cable system **300** is illustrated implanted along the spine **320** and spinal cord **330** of a rat. The cable system **300** is composed of a spinal baseplate **340**, EMG wires **350**, and/or EMG electrodes **310**. The baseplate **340** may be constructed from a FR-4 PCB substrate. The baseplate **340** is attached (e.g., by a suture **342**) to a selected vertebrae (e.g., vertebrae "L2"). In the embodiment illustrated, the baseplate **340** is attached to the "L2" vertebrae. The assembly **100** is attached (e.g., by a suture **344**) to the spinal cord **300**. In the embodiment illustrated, the distal end portion **112** of the assembly **100** is attached to the spinal cord **300** at a location adjacent vertebrae "T13." The proximal end portion **114** of the assembly **100** is attached to the baseplate **340** using a conductive material (e.g., conductive epoxy) to bridge electrical connections. By way of a non-limiting example, the proximal end portion **114** of the assembly **100** may be secured to the baseplate **340** using Loctite M-121HP Medical device epoxy.

[0065] The example EMG wires **350** may be connected to hind limbs or other structure of a subject for inducing electrical stimulation or recording one or more signals. The EMG wires **350** may be connected to or include one or more EMG electrodes **310**. In some embodiments, the EMG wires **350** may be replaced with connections to other types of electrodes, sensors, and/or systems/devices either wired or wireless, or may also be omitted.

[0066] The EMG wires **350** include a plurality of wires **352**. By way of a non-limiting example, the wires **352** may each be connected to a separate electrode **310**. Each of the wires **352** may be constructed from gold and include a Teflon coating. For example, 75 μm gold wires (e.g., Teflon coated gold wire manufactured by AM Systems) may be used. The wires **352** may be soldered to the baseplate **340** and connected by high density connectors **360** to the respective electrodes **310**. The traces **130** are connected to the baseplate **340** via the openings **132** formed in the body portion **110** of the assembly **100**. By way of a non-limiting example, silver epoxy (not shown) may be used to connect the traces **130** to the baseplate **340**.

[0067] As shown in FIG. **4**, the entire cable system **300** (except a portion **368** of the assembly **100**) may be coated with a coating **370** configured to insulate electrical connections and provide mechanical strength while retaining the flexibility wherever necessary. The implants described herein can be covered and/or sealed to prevent exposure of the implant or portions of the implant to tissues. In some embodiments, the entire implant can be covered or sealed. In other embodiments, substantially all of the implant is coated or sealed.

[0068] In one embodiment, the implant can be sealed using a combination of parylene, an epoxy and a silicone. In some embodiments, the implant can be sealed by coating it in silicone. In other embodiments, an epoxy can be used to seal the implant, in still other embodiments, parylene can be used to seal the implant. Parylene is used to describe a variety of chemical vapor deposited polyp-xylylene) polymers used as moisture and dielectric barriers. In one example embodiment, parylene-C is used to seal the implant. Combinations of epoxy, parylene and silicone can be used to seal the implant.

[0069] By way of a non-limiting example, the coating **370** may include a biomedical grade epoxy and a silicone elastomer (e.g., MDX 4-4210 Biomedical grade silicone).

[0070] Further, commercially available, hermetic metal packaging cannot satisfy size and feed-through requirements for the presently described wireless implants. New metal packaging and feed-through assemblies can be mechanically designed, manufactured and incorporated. However, in some embodiments, a new sealing technique can be used to encase the wireless implants. The technique used to seal the wireless implants can use parylene-C, epoxy, and/or silicone.

[0071] In some embodiments, components of the implant can be attached using an epoxy and then completely coated with silicone. In other embodiments, components of the implant can be attached using an epoxy and then completely coated with parylene. The implant can be coated by methods such as dipping, brushing, spray coating, rolling, vapor deposition, and the like. In one example embodiment, the implant can be sealed by dipping the implant in a coating solution. The coating solution can include epoxy, silicone, and/or parylene. In some embodiments, the implant can be covered in an epoxy, for example, by dipping and then coated with parylene, silicone or a combination thereof.

[0072] The sealed wireless implant can remain sealed in vivo for a useful lifetime of the implant. In some embodiments, the wireless implant can remain sealed for at least one month, at least two months, at least three months, at least four months, at least five months, at least six months, at least one year, at least two years, at least five years, between about two months and about 5 years, between about 1 year and about 5 years, or between about 6 months and about 5 years. In one embodiment, the technique of sealing the wireless implant can provide sufficient sealing for at least two months of in vivo functionality.

[0073] A silicone cap **380** (or overhanging portion) is formed on the end of the baseplate **340** to protect the assembly **100** from external moving tissue. The cap **380** may be formed from the same material as the coating **370**. Along portions of the assembly **100**, the coating **370** may be implemented as a thin layer of silicone (e.g., about 100 μm thick) to reduce stress concentration as the assembly **100** bends with the subject's spine **320** during movement. A thicker layer of silicone applied to the assembly **100** may be detrimental to the health of the spinal cord **330** because of increased pressure that is applied by a more rigid assembly to the spinal cord. In other words, flexibility may be an important feature of a successful chronic implantable electrode array assembly.

[0074] FIG. **5** shows a diagram of an example implant system **500**, according to an example embodiment of the present disclosure. The example implant system **500** includes the example implantable electrode array assembly **100** discussed above in conjunction with FIGS. **1** to **4**. The system **500** also includes a host computer **502** that is configured to be communicatively coupled to the implantable electrode array assembly **100**. The example host computer **502** may include any computer, laptop computer, server, workstation, processor, tablet computer, smartphone, smart-eyewear, smart-watch, lab instrument, etc. The host computer **502** may be centralized or distributed via a network or cloud computing environment. In some embodiments, the host computer **502** may include an interface, which enables remote devices (e.g., smartphones) to remotely specify data (or instructions) to be transmitted to the implantable electrode array assembly **100** and view data received from the implantable electrode array assembly **100**.

[0075] The example host computer **502** is configured to determine and/or control data streams for transmission to the implantable electrode array assembly **100**. In some instances, a user may specify the data streams (or instructions) to be transmitted. In other instances, the host computer **502** may include machine-readable instructions, which when executed, cause the host computer **502** to operate one or more algorithms for determining data streams to be transmitted to the implantable electrode array assembly **100**. The host computer **502** is also configured to receive, process, and/or analyze data streams from the implantable electrode array assembly **100**. In some instances, the host computer **502** may include machine-readable instructions, which when executed, cause the host computer **502** to operate one or more algorithms that analyze received data streams from the implantable electrode array assembly **100**. The host computer **502** may also be configured to provide a graphical representation indicative of the data streams transmitted to the implantable electrode array assembly **100** and/or a graphical representation indicative of the data streams received from the implantable electrode array assembly **100**.

[0076] To facilitate communication between the host computer **502** and the assembly **100**, the example implant system **500** includes a controller **504**. In other embodiments, to facilitate communication between the host computer **502** and the assembly **100**, the example implant system **500** may include a controller **504** The example controller **504** includes a transceiver configured to convert communications from the host computer **502** into a wireless format (e.g., a low power RF format, Bluetooth®, Zigbee®, etc.) for transmission to the assembly **100**. The example controller **504** is also configured to receive wireless signals (e.g., wireless streams of data) from the assembly **100** and convert the wireless signals into a format compatible for the host computer **502**. In some instances, the controller **504** is communicatively coupled to the host computer **502** via a Universal Serial Bus ("USB"). In other embodiments, the controller **504** is communicatively coupled wirelessly to the host computer **502**. The controller **504** may also include memory to buffer or queue data streams for transmission. In an embodiment, the controller **504** (by way of a non-limiting example) may include the Texas Instruments® CC1111 Sub-1 GHz RF System-on-Chip.

[0077] The example system **500** also includes a wireless power supply **506** configured to provide wireless power to the assembly **100**. The power supply **506** is communicatively coupled to at least one of the host computer **502** and/or the controller **504** to receive power control instructions. The example wireless power supply **506** may include a Class E amplifier and inductive coupling components to enable wireless transmission of power to the assembly **100** (as discussed further in conjunction with FIG. **7**). The example wireless power supply **506** may also include a variable output to enable the amount of power provided to the assembly **100** to be adjusted based on, for example, application of the assembly **100**, power requirements of the assembly **100**, and/or operations being performed by the assembly **100**. For example, the host computer **502** may instruct the wireless power supply **506** to output relatively more wireless power when relatively more stimulation signals are to be provided by the assembly **100**.

[0078] As discussed above, the example implantable electrode array assembly **100** includes EMG wires **350**, a MEMS

microelectrode array **120**, and implantable control circuitry. In the example embodiment of FIG. **5**, the implantable control circuitry includes a multiplexer circuit **508**, a wireless power receiver **510**, a stimulator **512** (e.g., a signal generator/receiver), and a controller **514**. It should be appreciated that the implantable control circuitry of the assembly **100** may include additional or fewer components. For example, the implantable control circuitry may also include a battery for long term storage of power from the wireless power supply **506**, a memory to store instructions for operation of the implantable control circuitry, a memory to store data streams transmitted from the host computer **502** and/or detected by the assembly **100**, etc. Further, the implantable control circuitry of FIG. **5** may be combined and/or partitioned differently based on hardware used, application, etc.

[0079] The example wireless power receiver **510** (discussed further in conjunction with FIG. **7**) is configured to receive wireless power from the wireless power supply **506** and convert the wireless power into a DC voltage. In some embodiments, the wireless power receiver **510** is configured to output 3 V DC and 12 V DC. In other embodiments, the wireless power receiver **510** may output 5 V DC. It should be appreciated that the wireless power receiver **510** may be configured to output one or more different DC voltages having any magnitude based, for example, on power requirements of the other implantable control circuitry, electromagnetic considerations of the assembly, etc. The wireless power receiver **510** may also output an AC signal and/or a power monitor signal (e.g., PWRMON) based on requirements of the implantable control circuitry. For instance, the wireless power receiver **510** is configured to output a power monitor signal to the controller **514** to enable the controller **514** to monitor power received from the wireless power supply **506**.

[0080] The example controller **514** (discussed further in conjunction with FIG. **8**) is configured to operate instructions that control the multiplexer circuit **508** and/or the stimulator **512**. The controller **514** includes a transceiver configured to receive a data stream wirelessly from the controller **504** and convert the wireless data stream for processing. The example controller **514** may also include instructions that instruct the controller **514** how to control the multiplexer circuit **508** and/or the stimulator **512** based on the data stream generated by the host computer **502**. For example, after receiving a data stream that indicates that electrode pair E**13** and E**33** are to be stimulated with a waveform having a specified amplitude, shape, frequency, etc., the controller **514** transmits the appropriate signal (e.g., appropriate digital word) via Clock, Data, and EN (enable) lines to the multiplexer circuit **508** to cause the specified waveform (e.g., stimulation signal) to be provided by the E**13** and E**33** electrode pair of the MEMS microelectrode array **120**.

[0081] In other instances, the example controller **514** is configured to be programmed with operating instructions from the host computer **502** via the controller **504**. The operating instructions may specify the stimulation signal(s) and timing that is to be controlled and/or managed by the controller **514**. Such a configuration enables the controller **514** to provide stimulation signals as specified without having the controller **504** and/or host computer **502** in constant contact or proximity of the subject.

[0082] The example controller **514** can also be configured to record amplified signals (e.g., signals A**1**-A**4**) received from the EMG wires **350**, EMG electrodes **310**, the MEMS microelectrode array **120**, or other electrodes, sensors, or systems. In some embodiments, a senor or system may wirelessly provide an indication of a recoded signal. For instance, the host computer **502** may specify within a data stream that electrodes E**18** and E**39** are to sense or otherwise detect an electrical signal after stimulation by another electrode pair. The controller **514** is configured to transmit the appropriate signal (e.g., appropriate digital word) via Clock, Data, and EN (enable) lines to the multiplexer circuit **508** to cause voltages detected by the E**18** and E**39** electrodes of the MEMS microelectrode array **120** to be amplified and recorded. In other embodiments, the host computer **502** may specify within a data stream that electrodes and/or sensors **350** are to record signal(s). The controller **514** is configured to transmit the appropriate signal (e.g., appropriate digital word) via Clock, Data, and EN (enable) lines to the multiplexer circuit **508** to cause voltages detected by the electrodes and/or sensors to be amplified and recorded. The controller **514** may then transmit the recorded data via a data stream to the transceiver **504**.

[0083] The example controller **514** can also be configured to monitor the wireless power received at the wireless power receiver **510**. For instance, the controller **514** is configured to enable that enough power is provided to enable the multiplexer circuit **508** to output the specified stimulating pulses to the subject. In one example, the controller **514** may receive within a data stream a sequence of pulses to be applied to the subject and determine that the power being received at the wireless power receiver **510** is insufficient. In response, the controller **514** may transmit a message to the transceiver **504** for additional power (or an amount of additional power needed), which causes the controller **504** to increase the amount of power output by the wireless power supply **506**. In an embodiment, the controller **514** may include the Texas Instruments® CC1111 Sub-1 GHz RF System-on-Chip.

[0084] The example stimulator **512** (discussed further in conjunction with FIG. **9**) is configured to provide a constant voltage and/or current to the multiplexer circuit **508**. The constant voltage and/or current is provided via a Stim+ and a Stim− signal lines to the multiplexer circuit **508**. The amount of voltage and/or current provided by the stimulator **512** may be set via a pulse width modulation ("PWM") signal from the controller **514**. The amount of voltage provided may be based on a stimulation signal specified by the host computer **502**. A mode between voltage and current output may be set via a mode signal from the controller **514**.

[0085] The example multiplexer circuit **508** is configured to route connections between the stimulator **512** and/or amplifiers and the EMG wires **350**, the EMG electrodes **310**, the MEMS microelectrode array **120**, or other types of electrodes, sensors, systems, devices, etc. FIG. **6** shows a diagram of the multiplexer circuit **508**, according to an example embodiment of the present disclosure. The example multiplexer circuit **508** includes multiplexers M**0**, M**1**, M**2**, M**3**, M**4**, M**5**, M**6**, M**7**, M**8**, and M**9**, which may include Analog Devices® ADG1209 or ADG1208 multiplexers. The multiplexer circuit **508** also includes shift registers SR**1**, SR**2**, SR**3**, and SR**4**, which may include NXP Semiconductors® 74HC164 shift registers. The multiplexer circuit **508** further includes amplifiers AMP**1**, AMP**2**, AMP**3**, and

AMP4, which may include Analog Devices AD8224 amplifiers. The multiplexer circuit **508** receives as control inputs from the controller **514** Clock, Data, and EN, which specify which of the EMG wires **350**, the EMG electrodes **310**, the electrode pair within MEMS microelectrode array **120**, or other types of electrodes, sensors, systems, devices, etc. are to be configured to output a stimulation signal (e.g., Stim+ or Stim−) and/or configured to receive an electrical signal. The multiplexer circuit **508** receives the stimulation signals Stim+ and Stim− from the stimulator **512**.

[0086] The desired configuration can be achieved by sending, for example, a 30-bit serial data stream through the Clock and Data inputs into the shift registers SR1 to SR4. The example shift registers SR1 to SR4 in turn control or select which output of the multiplexers M1 to M9 are to receive and output the Stim+ and Stim− signals. The EN signal is used by the controller **514** to enable the multiplexers M0 to M9. The example multiplexer M0 is configured to disconnect the stimulation wires to the multiplexers M1 to M9 in instances where the controller **514** instructs the multiplexer circuit **508** to configure the EMG wires **350** and/or the MEMS microelectrode array **120** to record. The multiplexer MO is also configured to select a polarity of the stimulation signal to be provided to any one of the multiplexers M1 to M9 in instances where the controller **514** instructs that a stimulation signal is to be output to a subject.

[0087] The example multiplexers M1 to M9 are configured to receive control signals from the shift registers SR1 to SR4 to determine which output is to receive a stimulation signal. As shown in FIG. **6**, the multiplexers M1 to M9 are interconnected to enable almost any two of the electrodes within the MEMS microelectrode array **120**, the EMG wires **350**, the EMG electrodes **310**, or other types of electrodes, sensors, systems, devices, etc. to be selected for outputting a stimulation signal or detecting an electrical signal within the subject. The illustrated embodiment shows the multiplexers M1 to M9 connected to an electrodes designated by an alpha-numeric identifier. The letter "E" refers to an EMG wire **350** where "E#+" and "E#" are EMG wire pairs. The letters "A", "B", and "C" refer to spinal cord electrode columns shown in FIG. **1**, where the letter "A" corresponds to column **1**, the letter "B' corresponds to column **2**, and the letter "C" corresponds to the column **3**. Thus, A3 refers to the electrode E13 of the MEMS microelectrode array **120** of FIG. **1**. Outputs G1 and G2 refer to reference wires placed, for example, near the shoulder and the lower back respectively on a subject. The multiplexer M1 is configured to be selectively connected to E1+, E5+, A5, B8, and C2. The multiplexer M2 is configured to be selectively connected to El−, E55, A4, B7, and C5. The multiplexer M3 is configured to be selectively connected to E2+, E6+, A3, B6, and C8. The multiplexer M4 is configured to be selectively connected to E2−, E6−, A2, B5, and C7. The multiplexer M5 is configured to be selectively connected to E3+, E7+, A1, B4, C6, and A9. The multiplexer M6 is configured to be selectively connected to E3−, E7−, A8, B3, C1, and C9. The multiplexer M7 is configured to be selectively connected to E4+, E8+, A7, B2, and C4. The multiplexer M8 is configured to be selectively connected to E4−, E8−, A6, B1, C3, and B9. Finally, the multiplexer M9 is configured to be selectively connected to G1, G2, A1, B1, C1, A9, B9, and C9. It should be appreciated that some key electrodes (e.g., the electrodes corresponding to A9, B9, and C9) have two connections or outputs within the multiplexer circuit **508** to further increase electrode pairing configurations. It should be appreciated that the number of multiplexers and/or multiplexer outputs may change based on the number of EMG wires **350** and/or electrodes within the MEMS microelectrode array **120**.

[0088] The example amplifiers AMP **1** to AMP **4** are configured to amplify a differential signal received from selected ones of the EMG wires **350**, the EMG electrodes **310**, electrodes within the MEMS microelectrode array **120**, and/or other types of electrodes, sensors, systems, devices, etc. Each of the amplifiers AMP1 to AMP4 may be configured to have a gain of 200 and output respective signals A1 to A4 representative of detected electrical pulses within a subject. For example, the controller **514** may instruct the multiplexer circuit **508** to enter a 'listen mode' where the E1+ and E1− EMG wires **350** and/or EMG electrodes **310** (or other types of electrodes, sensors, systems, devices, etc.) are set to record or otherwise sense an electrical signal and convey this signal via multiplexers M1 and M2 to one or more of the amplifiers AMP1 to AMP4, for transmission to the controller **514**.

[0089] The example multiplexer circuit **508** of FIG. **6** may be configured to operate in four different modes to meet experimental requirements. A first mode enables a simulation signal to be applied by any two electrodes within the MEMS microelectrode array **120**, the EMG wires **350**, and/or the EMG electrodes **310**. A second mode enables the multiplexer circuit **508** to record from any four EMG wire pairs, EMG electrodes, or other types of electrodes, sensors, systems, devices, etc. A third mode enables the multiplexer circuit **508** to record from any two electrodes within the array **120**. A fourth mode enables the multiplexer circuit **508** to record from four electrodes of the same column within the array **120** with respect to a fifth electrode. The example multiplexer circuit **508** is configured to switch between the different modes and configurations of selected electrodes of the array **120** and/or EMG wires **350** or EMG electrodes **310** within 1 microsecond, thereby enabling the Stim+ and Stim− stimulation signals to delivery relatively short pulses to many electrodes and/or EMG wires or EMG electrodes in a one millisecond timeframe. Such a configuration also enables the amplifiers AMP1 to AMP4 to rapidly switch input signals to effectively record from eight or sixteen signals instead of four within a specified timeframe.

[0090] FIG. **7** shows a diagram of the example wireless power supply **506** and the wireless power receiver **510** of FIG. **5**, according to an example embodiment of the present disclosure. As illustrated, the example wireless power supply **506** uses inductor L1 to convert power provided by supply V1 for transmission via a wireless medium. The wireless power supply **506** also includes circuitry to convert the voltage from supply V1 into an AC signal. The example wireless power supply **510** uses indictor L2 to receive the power and convert the power into an AC signal. The wireless power supply **510** also includes a voltage regulator U2 and circuitry D1, D2, C9, and C10 configured to convert or rectify the AC signal into one or more DC voltages (e.g., 3 V and 12 V).

[0091] FIG. **8** shows a diagram of the example controller **514** of FIG. **5**, according to an example embodiment of the present disclosure. The example controller **514** is wirelessly communicatively coupled to the controller **504** via antenna E1 and corresponding circuitry. As described above in conjunction with FIGS. **5** and **6**, the example controller **514** is configured to instruct the stimulator **512** to operate in a

voltage or current mode via the Mode1 and Mode2 outputs and instruct the multiplexer circuit **508** via the Clock, Data, and EN outputs. The example controller **514** receives one or more detected signals via inputs A1 to A4.

[0092] The example controller **514** may include memory to enable instructions to be stored from the host computer **502** specifying how and types of stimulation pulses are to be applied to a subject. The example controller **514** may include memory to enable instructions to be stored from the host computer **502** specifying which electrodes and/or EMG wires/electrodes (or other types of electrodes, sensors, systems, devices, etc.) are to be used for recording electrical signals. The example controller **514** may include memory to store a data structure of operations including when pulses were applied and data representative of data received via inputs A1 to A4.

[0093] FIG. **9** shows a diagram of the example stimulator **512** of FIG. **5**, according to an example embodiment of the present disclosure. As discussed above, the example stimulator **512** is configured to receive a Mode1 signal and a Mode2 signal from the controller **514** and accordingly output a constant voltage or constant current via Stim+ and Stim− signal lines. For instance, if the Mode1 signal is set to ground and Mode2 is set to a high impedance, then the stimulator **512** is configured to operate in a constant voltage mode. Alternatively, if the Mode1 signal is set to a high impedance and Mode2 is set to ground, then the stimulator **512** is configured to operate in a constant current mode. The magnitude of the voltage and/or current may be set via a PWM signal from the controller **514**.

[0094] Unless otherwise indicated, all numbers expressing quantities of ingredients, properties such as molecular weight, reaction conditions, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless indicated to the contrary, the numerical parameters set forth in the following specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present invention. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

[0095] The terms "a" and "an" and "the" and similar referents used in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g. "such as") provided herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0096] The use of the term "or" in the claims is used to mean "and/or" unless explicitly indicated to refer to alternatives only or the alternatives are mutually exclusive, although the disclosure supports a definition that refers to only alternatives and "and/or."

[0097] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other members of the group or other elements found herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is herein deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0098] Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on those preferred embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects those of ordinary skill in the art to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0099] Specific embodiments disclosed herein may be further limited in the claims using consisting of or consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the invention so claimed are inherently or expressly described and enabled herein.

[0100] Further, it is to be understood that the embodiments of the invention disclosed herein are illustrative of the principles of the present invention. Other modifications that may be employed are within the scope of the invention. Thus, by way of example, but not of limitation, alternative configurations of the present invention may be utilized in accordance with the teachings herein. Accordingly, the present invention is not limited to that precisely as shown and described.

We claim:

1. A neuromodulation system comprising:

a controller wirelessly communicatively coupled to a host computer;

a signal generator communicatively coupled to the controller; and

a plurality of electrodes communicatively coupled to the signal generator;

wherein the controller, in conjunction with the signal generator and the at least one electrode are configured to deliver a stimulation to a mammal based on an instruction received from the host computer, the stimulation being configured to induce voluntary movement or restore function of the mammal.

2. The neuromodulation system of claim **1**, further comprising a multiplexer circuit configured to enable the processor to select a first pair of the electrodes to deliver the stimulation.

3. The neuromodulation system of claim **2**, wherein the multiplexer circuit is configured to enable the processor to select a second pair of electrodes to sense an electrical signal within the mammal.

4. The neuromodulation system of claim **1**, wherein the mammal is a human.

5. The neuromodulation system of claim **1**, further comprising a wireless power receiver configured to:

receive power wirelessly from a wireless power supply; and

rectify the received power into at least one DC voltage for the controller and the signal generator.

6. The neuromodulation system of claim **1**, wherein the voluntary movement is of a foot, a toe, an ankle, a knee, a leg, a hip, a shoulder, an arm, a hand, a wrist, a finger, a waist, a trunk, a neck, a head or a combination thereof and the voluntary movement comprises at least one of standing, stepping, a walking motor pattern, sitting down, sitting up, laying down, reaching, grasping, pulling and pushing, swallowing and chewing, breathing, and coughing.

7. The neuromodulation system of claim **1**, wherein the stimulation is applied over a cervical portion of the spinal cord or the brainstem.

8. The neuromodulation system of claim **1**, wherein the delivered signal is applied epidurally over at least one of a lumbar portion, a lumbosacral portion, and a sacral portion of the spinal cord.

9. The neuromodulation system of claim **1**, wherein the delivered signal is applied to a thoracic or thoracic-lumbar portion of the spinal cord.

10. A method of inducing a voluntary movement in a mammal with a spinal injury, the method comprising:

receiving in a controller from a wirelessly communicatively coupled host computer an instruction to apply a stimulation to a mammal;

instructing a signal generator via the controller to apply the stimulation; and

applying via the signal generator to at least one electrode the stimulation.

11. The method of claim **10**, further comprising transmitting a control instruction from the controller to a multiplexer circuit to select the at least one electrode for applying the stimulation.

12. The method of claim **11**, wherein selecting the electrode includes selecting a pair of electrodes within a MEMS microelectrode array and electromyography ("EMG") wires or electrodes.

13. The method of claim **12**, further comprising transmitting a control instruction from the controller to a multiplexer circuit to select the at least one electrode within the microelectrode array, the EMG wires, or a sensor to sense an electrical signal within the mammal.

14. The method of claim **13**, wherein the sensor includes at least one of a pressure sensor, a temperature sensor, a chemical sensor, a light sensor, a photonic sensor, an acoustic sensor, a flow sensor, a flex sensor, a gyroscope, and an accelerometer.

15. The method of claim **10**, further comprising:

receiving power wirelessly in a wireless power receiver from a wireless power supply; and

rectifying the received power in a DC voltage for the controller and the signal generator.

16. The method of claim **15**, further comprising:

determining in the controller that received power is insufficient for the stimulation; and

transmitting a message to the wireless power receiver for additional power.

17. A neuromodulation system comprising:

a controller configured to wirelessly receive operating instructions from a host computer;

a signal generator communicatively coupled to the controller;

a multiplexer circuit communicatively coupled to the controller and the signal generator;

a wireless power receiver electrically coupled to a wireless power supply and configured to power the controller, the signal generator, and the multiplexer circuit;

a plurality of EMG wires or electrodes electrically coupled to the multiplexer circuit; and

a microelectrode array including a 9×3 array of electrodes electrically coupled to the multiplexer circuit,

wherein the controller, in conjunction with the signal generator, the multiplexer circuit, and at least one of an EMG wire or electrode and an electrode within the microelectrode array are configured to deliver a stimulation to a mammal, the stimulation being configured to induce voluntary movement or enable restoration of function in the mammal.

18. The neuromodulation system of claim **17**, wherein the stimulation includes an epidural stimulation.

19. The neuromodulation system of claim **17**, wherein the multiplexer circuit is configured to enable a pair of the EMG wires or a pair of the electrodes within the microelectrode array to receive the stimulation from the signal generator.

20. The neuromodulation system of claim **17**, wherein the controller is configured to transmit a control instruction to a multiplexer circuit to select the at least one electrode within the microelectrode array, the EMG wires or electrodes, or a sensor to sense an electrical signal within the mammal.

* * * * *

专利名称(译)	神经调节系统及其使用方法		
公开(公告)号	US20180185648A1	公开(公告)日	2018-07-05
申请号	US15/713456	申请日	2017-09-22
[标]申请(专利权)人(译)	Nandra先生MANDHEEREJ TAI鱼虫		
申请(专利权)人(译)	Nandra先生，MANDHEEREJ TAI，YU-CHONG		
当前申请(专利权)人(译)	Nandra先生，MANDHEEREJ TAI，YU-CHONG		
[标]发明人	NANDRA MANDHEEREJ TAI YU CHONG		
发明人	NANDRA, MANDHEEREJ TAI, YU-CHONG		
IPC分类号	A61N1/36 A61N1/05 A61B5/0488 A61B5/00 A61N1/378		
CPC分类号	A61N1/36003 A61N1/36103 A61B2562/0271 A61B2562/0247 A61B2562/0219 A61N1/36185 A61B5/0488 A61N1/36067 A61N1/0558 A61N1/0553 A61B5/4836 A61B5/0031 A61N1/3787 A61N1/36139		
优先权	61/926457 2014-01-13 US		
外部链接	Espacenet USPTO		

摘要(译)

描述了神经调节系统。示例性神经调节系统包括无线通信地耦合到主计算机的控制器，通信地耦合到控制器的信号发生器，以及通信地耦合到信号发生器的多个电极。控制器结合信号发生器和至少一个电极配置成基于从主计算机接收的指令向哺乳动物传递刺激。刺激被配置为在哺乳动物中诱导自主运动或恢复功能。