(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 May 2020 (22.05.2020)

WIPO | PCT

(10) International Publication Number
WO 2020/102580 A1

(51) International Patent Classification:
A61M 25/00 (2006.01) *H01M 8/02* (2016.01)
H01M 8/00 (2016.01) *H01M 8/16* (2006.01)

(21) International Application Number: PCT/US2019/061537

(22) International Filing Date: 14 November 2019 (14.11.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/767,389 14 November 2018 (14.11.2018) US

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

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

(54) Title: IMPLANTABLE, BIOFUEL CELLS FOR SELF-CHARGING MEDICAL DEVICES

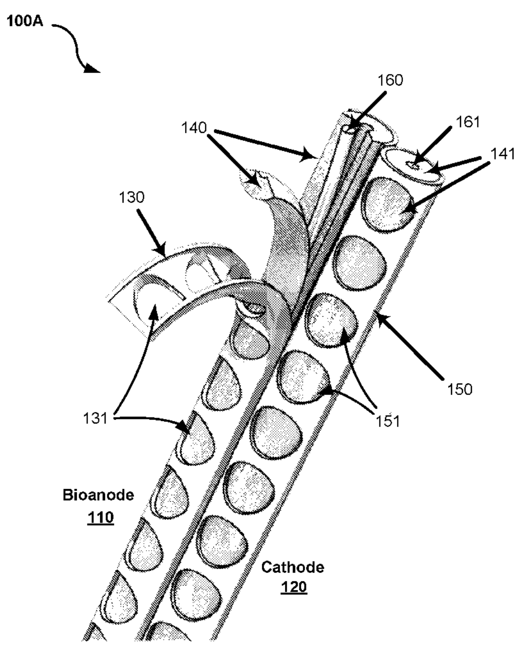

FIG. 1B

(57) Abstract: Disclosed are devices, systems and methods for implantable biofuel cells. In some aspects, a biofuel cell device for extracting energy from a biological fluid includes a substrate including two compartments each with one or more openings; an anode assembly disposed in the substrate and including an anode electrode and functionalization material to facilitate an oxidative process that releases electrons captured at the anode electrode; and a cathode assembly disposed in the substrate separated from the anode assembly and including a catalytic material facilitate a chemical reduction process such that the biofuel cell device extracts electrical energy from the substance in the biological fluid.

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

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

IMPLANTABLE, BIOFUEL CELLS FOR SELF-CHARGING MEDICAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent document claims priorities to and benefits of U.S. Provisional Patent Application No. 62/767,389 entitled "SELF-RECHARGING CATHETER-BASED BIOFUEL CELL DEVICES" filed on November 14, 2018. The entire content of the aforementioned patent application is incorporated by reference as part of the disclosure of this patent document

TECHNICAL FIELD

[0002] This patent document relates to biofuel cell technology.

BACKGROUND

[0003] A fuel cell is a device that converts chemical energy from a substance (e.g., referred to as a fuel) into electrical energy (e.g., electricity). Generally, the energy conversion includes a chemical reaction with oxygen or another oxidizing agent. For example, hydrogen is among a common fuel, and hydrocarbons such as natural gas and alcohols can also be used in fuel cells. For example, fuel cells differ from batteries in that they require a constant source of fuel and oxygen to operate. A fuel cell can produce electricity continuously provided the fuel and oxygen inputs are supplied to the fuel cell.

SUMMARY

[0004] Disclosed are devices, systems, and methods for implantable biofuel cells integrable in a medical device to extract energy from a substance in a biological environment providing a fuel to a fuel cell.

[0005] In some aspects, an implantable biofuel cell device for extracting energy from a biological fluid includes a substrate, including (i) a first compartment having a first hollow interior portion and (ii) a second compartment having a second hollow interior portion, the second hollow interior portion separated from the first hollow interior portion, wherein the substrate includes one or more openings into each of the first hollow interior portion and the second hollow interior portion; an anode assembly, including (i) a first electrode disposed in the first hollow interior portion of the substrate and (ii) a functionalization material disposed on or integrated with the first electrode proximate the one or more openings, wherein the functionalization material includes a catalyst to facilitate conversion of a substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first electrode; and a cathode assembly, including (i) a second electrode disposed in the second hollow interior portion of the substrate and (ii) a catalytic material to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons, wherein, when the biofuel cell device is inserted in a tissue exposing the biofuel cell device to the biological fluid, the biofuel cell device is operable to extract electrical energy from the substance in the biological fluid across the anode assembly and the cathode assembly.

[0006] In some aspects, a biofuel cell device for extracting energy from a biological fluid includes an anode assembly comprising: a first hollow elongated element, a first substance at least partially disposed inside the first hollow elongated element and that is at least partially electrically conductive, a first electrically conductive elongated element at least partially disposed inside the first hollow elongated element and coupled with the first substance, wherein the first hollow elongated element has at least one opening in its surface to expose at least a portion of the first substance; and a cathode assembly comprising: a second hollow elongated element, at second substance at least partially disposed inside the second hollow elongated element and that is at least partially electrically conductive, a second electrically conductive elongated element at least partially disposed inside the second hollow elongated element and coupled with the second substance, wherein the second hollow elongated element has at least one opening in its surface to expose at least a portion of the second substance, wherein the biofuel cell device to is operable to facilitate conversion of a substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first electrically conductive elongated element of the anode assembly and to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons, thereby extracting energy from the substance in the biological fluid across the anode and the cathode assemblies.

[0007] In some aspects, a self-charging medical device includes a catheter comprising a first elongated tube and a second elongated tube coupled to the first elongated tube at one or more coupling positions along a longitudinal side of the first and second elongated tubes, the first elongated tube including a first compartment having a first hollow interior portion and a plurality of openings from an outer surface of the first elongated tube into the first hollow interior portion, the second elongated tube including a second compartment having a second hollow interior portion and a plurality of openings from an outer surface of the second elongated tube into the second hollow interior portion, wherein the second hollow interior portion is separated from the first hollow interior portion, and wherein the first and second elongated tubes include a bendable material; and a biofuel cell integrated in the catheter and comprising an anode assembly disposed in the first elongated tube and a cathode assembly disposed in the second elongated tube, the biofuel cell operable to extract electrical energy from a substance in a biological fluid across the anode assembly and the cathode assembly to supply the extracted electrical energy for the catheter. The anode assembly includes a first wire and a first substance, the first wire and the first substance disposed within the first hollow interior portion, wherein the first substance is coupled to at least a portion of the first wire proximate the plurality of openings of the first elongated tube, and wherein the first substance includes a functionalization material comprising a catalyst to facilitate conversion of the substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first wire. The cathode assembly includes a second wire and a second substance, the second wire and the second substance disposed within the second hollow interior portion, wherein the second substance is coupled to at least a portion of the second wire proximate the plurality of openings of the second elongated tube, and wherein the second substance includes a catalytic material to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons.

[0008] In some embodiments, the biofuel cell is integrated with a catheter, such as a spinal cord catheter. In some implementations, a catheter-based fuel cell device uses cerebrospinal fluid (CSF) as a source of fuel, e.g., which enables the catheter-based fuel cell device to bypass an impulse pulse generator required for spinal cord stimulation by conventional spinal cord catheters. In some embodiments, the biofuel cell comprises an anode used to oxidize the biofuel (e.g., glucose or lactate in some implementations) and a cathode adapted to reduce a chemical substance, e.g. oxygen, generating electrical energy that can be used an electrical output for the integrated medical device. In some implementations of a spinal cord catheter-based biofuel cell device, for example, the device can direct current in the dorsal column or dorsal horn of the spinal cord to cause increased gamma-aminobutyric acid (GABA) neurotransmitter, e.g., resulting in decreased peripheral-to-central pain transmission. In this patent document, the terms "fuel cell" and "biofuel cell" may be used interchangeably. Example applications of the disclosed implantable biofuel cell-powered medical devices are envisioned to be used for treating refractory chronic pain through spinal cord neurostimulation, and in the treatment and management of conditions related to depression, acute pain, spinal cord paralysis, autonomic disorders, obesity, Tourette syndrome, and deafness, among others.

[0009] The subject matter described in this patent document can be implemented in specific ways that provide one or more of the following features.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1A shows a diagram of an example embodiment of an implantable biofuel cell device in accordance with the present technology.

[0011] FIG. 1B shows an illustration of an example embodiment of an implantable biofuel cell device in accordance with the present technology, depicting the electrode composition at the anode and cathode assemblies.

[0012] FIG. 1C shows an illustration the example embodiment of the implantable biofuel cell device shown in FIG. 1B, depicting various views of the anode and cathode contingents encased by a substrate.

[0013] FIG. 1D shows a diagram depicting example electrochemical reactions occurring at the anode and cathode of an example embodiment of the biofuel cell device in accordance with the disclosed technology.

[0014] FIG. 1E shows a schematic representation of the stages in functioning of a self-charging capacitor, occurring on the example biofuel cell device of FIG. 1D.

[0015] FIG. 1F shows an illustration of the voltage and current profiles created by an example biofuel cell device in accordance with the disclosed technology.

[0016] FIG. 2A shows scanning electron microscopy (SEM) images of hollow flexible tubes used for electrodes preparation for an example embodiment of the biofuel cell device.

[0017] FIG. 2B shows a scanning electron microscopy (SEM) image of the electrodes packed with the active electrode materials for the example biofuel cell device shown in FIG. 2A.

[0018] FIG. 3A shows an illustration of a catheter-based device being inserted into the epidural space.

[0019] FIG. 3B shows a schematic representation of a catheter-based device implanted along the spinal subdural space.

[0020] FIG. 3C shows an optical microscopy image of an implanted catheter-based fuel cell device in a spinal cord model.

[0021] FIGS. 3D-DF show images depicting in-vivo implantation procedures of an example catheter-based biofuel cell device in a human cadaver model.

[0022] FIG. 3G shows a posteroanterior X-ray view of an example implanted catheter-based biofuel cell device and a spinal needle.

[0023] FIG. 4A shows linear sweep voltammograms (LSV) for the anode of an example embodiment of the biofuel cell device in accordance with the disclosed technology.

[0024] FIG. 4B shows linear sweep voltammogram (LSV) for the cathode of an example embodiment of the biofuel cell device in accordance with the disclosed technology.

[0025] FIG. 4C shows polarization plots for an example embodiment of an implantable biofuel cell device in accordance with the disclosed technology.

[0026] FIG. 4D shows power density versus voltage plots for an example embodiment of an implantable biofuel cell device in accordance with the disclosed technology.

[0027] FIG. 4E shows apparent capacitance profiles at different scan rates for an example embodiment of an implantable biofuel cell device in accordance with the disclosed technology.

[0028] FIG. 4F shows the apparent capacitance versus scan rate for different concentrations of the fuel source for an example embodiment of an implantable biofuel cell device in accordance with the disclosed technology.

[0029] FIG. 4G shows voltage recordings while harvesting current pulses in the absence and presence of 2.8 mM lactate in an artificial CSF for an example embodiment of an implantable biofuel cell device in accordance with the disclosed technology.

[0030] FIG. 4H shows voltage recordings while harvesting different current pulses in the presence of 2.8 mM lactate in the artificial CSF for an example embodiment of an implantable biofuel cell device in accordance with the disclosed technology.

[0031] FIG. 4I shows a power curve profile for an example embodiment of an implantable biofuel cell device in accordance with the disclosed technology.

[0032] FIG. 5 shows a block diagram of an example embodiment of an electronic device that can interface with various embodiments of the biofuel cell device and/or integrated medical device for various implementations.

DETAILED DESCRIPTION

[0033] Implantable bioelectronics has opened fascinating opportunities for biomedical applications, including personalized diagnostic and therapeutic purposes, e.g., including pain management. Yet, in order to drive such systems, a significant amount of power is needed to stimulate the electronics. Special requirements are often needed for the power source due to the emerging technologies and techniques used, especially when optimizing a usable battery. These challenges have hindered widespread adoption of new technologies for therapeutic treatments, particularly in pain management.

[0034] Take for example, devices for spinal cord stimulation. Currently, approximately 140 spinal cord neuromodulation devices are implanted for pain therapy every day. Spinal cord stimulation (SCS) involves using an electrical generator that supplies current pulses to a targeted spinal cord location. Besides applications for pain management, SCS can also be used, for example, to study the effects of Parkinson's disease and angina pectoris in affected patients. The SCS electrodes can be inserted by laminectomy or percutaneously. Although SCS can efficiently attenuate chronic pain in a large portion of the population (e.g., 50–70%), implementation of devices for SCS remains a challenge as it mandates a viable energy source which depends on an implanted battery and is capable of driving the electrical circuits used for the SCS. Typical energy-storage devices rely on re-charging and operation under non-physiological conditions. In addition, flexible and implantable batteries are very challenging to miniaturize. Moreover, it is highly desirable to avoid additional surgeries to replace such implanted energy devices. These factors add to the difficulties in the implementation of devices for SCS.

[0035] Despite attractive advantages of energy-harvesting devices, very few reports exist on the utilization of bioenergy available in cerebrospinal fluids (CSF) from the brain or spinal cord. However, to date, there are no reports on any implantable medical devices that have the capabilities of energy-harvesting and actuation functionality of the medical device powered by the energy-harvesting, e.g., such as electrical pulse generation, which could be used for spinal cord stimulation.

[0036] Disclosed are devices, systems, and methods for implantable biofuel cells capable of being integrated in a medical device to extract energy from a substance in a biological environment for providing a self-charging medical device.

[0037] Some example embodiments of the implantable biofuel cells described herein include flexible and integrated bioenergy-harvesting and spinal cord stimulating implant devices. Biofuel cells (BFCs) such as enzymatic biofuel cells can convert biochemical energy contained in metabolites, such as glucose or lactate, into electrical energy via biologically safe catalytic reactions. BFCs can harvest bioenergy from a biofuel present in biological fluids, ranging from blood to sweat or tears. The disclosed BFCs are integrated with bioelectronic devices, which can seamlessly integrate the functions of energy conversion and energy storage for the bioelectronic device. In some example embodiments, an implantable biofuel cell-integrable self-charging medical device can include miniaturized electrode designs which provide suitable bioelectronics-to-spinal cord interfaces, as described in further detail below. The example bioelectronic devices disclosed herein can harvest energy from biofuels in various implementations, such as lactate and glucose present in the cerebrospinal fluid, for example, and deliver electrical pulses for spinal cord stimulation.

[0038] Also disclosed are results of experimental implementations of example embodiments of a biofuel cell-integrated self-charging catheter device, which can be used for spinal cord stimulation for pain treatment. As discussed below, the example results showed that the waveforms of electrical pulses, supplied by the example BFC energy harvester, can effectively lessen chronic neuropathic pain in animal models. Also, for example, the superior efficiency of energy harvesting can be observed in the high-energy mode, e.g., by combining dual platforms of the seamless synergy of an energy-conversion BFC and an energy-storage capacitor. For example, the bipole lead and engineered materials of the example bioelectronic device concurrently behave as a completely integrated hybrid energy device that can deliver high power output during the discharge for spinal cord electrical stimulation tasks. The capacitance of the implantable biodevices described herein can unceasingly recharge through the natural recirculating energy-harvesting process. This self-charging capability addresses the limitations of the local consumption and diffusion of biofuels. Self-powered devices in accordance with the disclosed technology can deliver useful waveforms for spinal cord stimulation. Example implementations described herein demonstrate that electrical pulses, supplied by the devices in accordance with the disclosed technology, can be used for spinal cord stimulation that may effectively lessen chronic neuropathic pain in subjects, as shown in the example animal models.

[0039] Various example embodiments of self-charging medical devices integrated with biofuel cell devices in accordance with the present technology are described.

[0040] FIG. 1A shows a diagram of an example embodiment of an implantable biofuel cell device for providing a self-powered, self-charging medical device in accordance with the present technology, labeled device **100**. The device **100** includes a substrate **101**, which includes a first compartment **102A** having a first hollow interior portion **103A** and a second compartment **102B** having a second hollow interior portion **103B**. The substrate includes a separation **101S** between the first hollow interior portion **103A** of the first compartment **102A** and the second hollow interior portion **103B** of the second compartment **102B**. In some embodiments, for example, the separation **101S** can include a wall structure that is part of one or both of the first compartment **102A** and the second compartment **102B**. In some embodiments, the separation **101S** can include a separate structure that connects at least a portion of the first compartment **102A** with the second compartment **102B**. The substrate **101** includes one or more openings **101H** into each of the first hollow interior portion **103A** and the second hollow interior portion **103B**.

[0041] The device **100** includes an anode assembly **104** that includes an anode electrode **105** disposed in the first hollow interior portion **103A** of the substrate **101**. The anode assembly **104** can be disposed in the first hollow interior portion **103** proximate the one or more openings **101H** of the first compartment **102A**. The device **100** includes a cathode assembly **107** that includes a cathode electrode **108** disposed in the second hollow interior portion **103B** of the second compartment **102B**. In various implementations of the device **100**, for example, the anode assembly **104** facilitates conversion of a biofuel substance in a surrounding biological fluid to a first product in an oxidative process that releases electrons captured at the anode electrode **105**, and the cathode assembly **107** provides a catalyst that reduces an oxygenated substance in the biological fluid in a chemical reduction process, which extracts or harvests energy from the biofuel substance in the biological fluid for the device **100**.

[0042] In some embodiments, for example, the anode assembly **104** includes a functionalization material **106** disposed on or integrated with at least a portion of the anode electrode **105**. In some implementations of the device **100**, for example, the functionalization material **106** can include a catalyst molecule to facilitate conversion of a substance in a biological fluid to a first product in an oxidative process that releases electrons captured at the anode electrode **105** of the anode assembly **104**, thereby extracting energy from the substance in the biological fluid. In some embodiments of the device **100**, for example, the functionalization material **106** can include a redox reaction mediator substance. FIG. 1A illustrates an example implementation where the functionalization material **106** is layer on the anode electrode **105**.

[0043] The cathode assembly **107** provides a catalyst that reduces an oxygenated substance in the biological fluid in a chemical reduction process. In some embodiments, the cathode assembly **107** includes a catalytic material **109** that is disposed on or integrated with at least a portion of cathode electrode **108**. FIG. 1A illustrates the catalytic material **109** as layer on the cathode electrode **108**.

[0044] In some embodiments, the biofuel cell device **100** is electrically coupled to an electrical circuit **90** in an electrical configuration where the circuit is electrically coupled between the anode electrode and the cathode electrode. For example, the biofuel cell device 100 can include electrically conductive elements **160** and **161** that are coupled to or extensions of the anode electrode **105** and the cathode electrode **108**. As shown in FIG. 1A, at least one of the electrically conductive elements **160** and **161** of the device **100**, electrically coupled to the anode electrode **105** and the cathode electrode **108**, respectively, which can be connected to the electric circuit **90** (e.g., which can be a switch, a control circuit, a sensor, or other circuit or can be included in a circuit-containing device) via electrical connection links **70** and/or **80**. In various implementations, for example, the electric circuit **90** can affect control, measurement, and monitoring functions, among other functions, which are related to operation of the biofuel cell device **100**. In some example implementations, the electrical circuit **90** can be included in an electronics unit of the integrated medical device, which can be used to regulate a switch to turn on or turn off to the biofuel cell device **100**, and/or to control the amount current to flow through the biofuel cell device **100**. In such implementations, the electronics unit can be used to control the electrical parameters of the medical device integrated to the biofuel cell device **100**, e.g., such as amplitude, frequency, current level, wave forms, etc.

[0045] In some embodiments, the biofuel cell device is integrated with or structured as a medical device, such as a catheter. In some embodiments, the substrate can include two hollow tubes, coupled to each other, with an array of the openings to expose the hollow interior of each of the two hollow tubes, within which the anode assembly and the cathode assembly are disposed.

[0046] FIG. 1B shows a diagram illustrating a perspective view of an example embodiment of the implantable biofuel cell device **100**, labeled as device **100A**. The device **100A** includes anode contingent **110** (also referred to as anode **110**, bioanode **110**, or electrode **110**) and cathode contingent **120** (also referred to as cathode **120** or electrode **120**). In this example, the bioanode **110** includes an elongated hollow element **130**, e.g., a tube, having at least one opening **131** located, e.g., on a side of the elongated hollow element **130**. The opening(s) **131** can have any shape (e.g., circular, rectangular, arbitrary), and any size. The cathode **120** includes an elongated hollow element **150**, e.g. a tube, having at least one opening **151** located, e.g., on a side of the elongated hollow element **150**. The opening(s) **151** can have any shape (e.g., circular, rectangular, arbitrary), and any size. The elongated hollow elements **130** and **150** are configured to separate their respective interior regions so as to separate an anode and cathode of the biofuel cell device **100A**. For example, in some embodiments, the elongated hollow elements **130** and **150** are configured to separate the anode contingent **110** and the cathode contingent **120** by at least 5 μm. Each of the elements **130** and **150** can have any cross-section shape including but not limited to the elliptical, circular, rectangular, polygonal, and or other shape capable of insertion in a desired region of tissue. For example, the cross-section shape and/or the size of each of the elements **130** and **150** can vary along the length of the elements **130** and **150**, respectively. Element **130** can have length which is different from the length of the element **150**. Element **130** can have variations of its cross-section shape and/or its size which are different from variations of the cross-section shape and/or the size of the element **150**. In various embodiments, for example, the element **130** and/or the element **150** can be formed, e.g., of a polymer material such as polytetrafluoroethylene (PTFE), polyurethane, or polyethylene, among other materials. For example, the element **130** and/or the element **150** can be made, for example, from a material suitable for a medical catheter. In some embodiments, for example, Material of the element **130** can be different from the material of the element **150**.

[0047] In the example embodiment shown in FIG. 1B, the elongated hollow element **130** of the bioanode **110** is at least partially filled with a material **140**, which can be at least partially electrically conductive. For example, in some embodiments, the material **140** includes a material with an electrical resistivity of less than 100 Ω cm or electrical conductivity above 0.01 S cm^{-1}. In some embodiments, the material **140** can include, e.g., multi-walled carbon nanotubes (e.g., purity 95%, diameter 9.5 nm, length 1.5 μm) or a conductive polymer material. In some embodiments, the material **140** also includes enzyme molecules which can oxidize a substance (e.g., glucose, lactate, among other biofuel substances) in a biological fluid such as, for example, the cerebrospinal fluid. In example implementations where lactate is a target biofuel for the device **100A**, the example enzyme contained in the material **140** can be, for example, lactate oxidase (LOx) enzyme that oxidizes lactate. In some embodiments, the material **140** also includes a redox mediator, e.g. 1,4-naphthoquinone (NQ), that improves electron conductivity within the material **140** (e.g., for electron or charge transfer to the anode electrode and/or the electrical wiring of the device **100A**), which can help to increase power density of the device **100A**. In some embodiments, material **140** can also have constituents that act as a binding material for the other constituents or components of the material **140**. In some embodiments, material **140** is characterized by having a porous structure such that to allow access of the constituents of a biofluid, e.g. the cerebrospinal fluid, to the portions of the material **140** beyond its surface visible from the outside of the material **140**. In implementations of the material **140** including the enzyme and/or redox mediator, the enzyme and/or redox mediator substances included in the material **140** are preferably spread over the volume of the material **140** beyond its surface visible from the outside of the material **140**. The bioanode **110** includes an electrically conductive element **160**, which can include a wire and/or be made of, e.g., platinum (Pt) or another metal or electrically conductive substance such as an electrically conductive polymer, which is at least partially in contact with the material **140**. Element **160** can have a form of, for example, a wire, a strip, a mesh, or a fiber.

[0048] In the example embodiment shown in FIG. 1B, the elongated hollow element **150** of the cathode **120** is at least partially filled with a material **141**, which can be at least partially electrically conductive. For example, in some embodiments, the material **141** includes a material with an electrical resistivity of less than 100 Ω cm or electrical conductivity above 0.01 S cm^{-1}. In some embodiments, material **141** can include, e.g., multi-walled carbon nanotubes (e.g., purity 95%, diameter 9.5 nm, length 1.5 μm) or a conductive polymer material, e.g., poly(3,4-ethylenedioxythiophene) (PEDOT). Material **141** also includes a catalyst which helps to reduce an oxygenated substance (e.g., oxygen). In some embodiments, the catalyst can be, e.g., platinum (Pt) or, e.g., bilirubin oxidase, among others. In some embodiments, material **141** can also include a redox mitigation compound, e.g., polychlorotrifluoroethylene (PCTFE), which is characterized by a relatively high oxygen solubility and helps mitigate effects of oxygen fluctuations in the environment of the device **100A**. Material **141** can also have components which act as binding materials for the other components of the material **141**. For example, PCTFE can play the role of such a binding component, where the binding component(s) can support structural integrity of the material **141**. In various example embodiments, the material **141** is characterized by having a porous structure such that to allow access of the constituents of a biofluid, e.g., the cerebrospinal fluid, to the portions of the material **141** beyond its surface visible from the outside of the material **141**. In implementations of the material **141** including the platinum catalyst and/or a redox mitigation compound such as PCTFE, the platinum and PCTFE compounds, for example, are preferably spread over the volume of the material **141** beyond its surface visible from the outside of the material **141**. The cathode **120** includes an electrically conductive element **161**, which can include a wire and/or made of, e.g., platinum or another metal or electrically conductive substance such as an electrically conductive polymer, which is at least partially in contact with the material **141**. Element **160** can have a form of, for example, a wire, a strip, a mesh, or a fiber.

[0049] In various example embodiments, the material **140** can fill different percentage of the volume inside the element **130** which is available for the material **140**. For example, material **140** can fill only the parts of the volume inside the element **130** which are adjacent to one or more of the openings **131** in the element **130**. For example, material **140** can fill substantially the whole volume available for the material **140** inside the element **130**.

[0050] Similarly, in various example embodiments, the material **141** can fill different percentage of the volume inside the element **150** which is available for the material **141**. For example, material **141** can fill only the parts of the volume inside the element **150** which are adjacent to one or more of the openings **151** in the element **150**. For example, material **141** can fill substantially the whole volume available for the material **141** inside the element **150**.

[0051] Moreover, in various embodiments of the biofuel cell device **100A**, the elongated hollow element **130** has a ratio of its length to its width measured at a point along the length of the element **130** which is at least 1.1. In some example embodiments of the biofuel cell device **100A**, the elongated hollow element **130** has a ratio of its length to its width measured at a point along the length of the element **130** which is at least 2. In some example embodiments of the biofuel cell device **100A**, the elongated hollow element **130** has a ratio of its length to its width measured at a point along the length of the element **130** which is at least 5. In some example embodiments of the biofuel cell device **100A**, the elongated hollow element **130** has a ratio of its length to its width measured at a point along the length of the element **130** which is at least 10. In some example embodiments of the biofuel cell device **100A**, the elongated hollow element **130** has a ratio of its length to its width measured at a point along the length of the element **130** which is at least 20. In some example embodiments of the biofuel cell device **100A**, the elongated hollow element **130** has a ratio of its length to its width measured at a point along the length of the element **130** which is at least 50. In some example embodiments of the biofuel cell device **100A**, the elongated hollow element **130** has a ratio of its length to its width measured at a point along the length of the element **130** which is at least 100. Notably, these example length-width ratios can be applied to the elongated hollow element **150** for various embodiments of the biofuel cell device **100A**.

[0052] FIG. 1C shows additional illustrations of the example implantable biofuel cell device **100A**, depicting various views of the anode and cathode contingents encased by a substrate. The left panel (Panel (a)) illustrates a cross-sectional view of the example tubing used to make the elements **130** and **150** of an embodiment of the implantable biofuel cell device **100A**. In some implementations, the diameter of the elements **130** and **150** includes 900 μm. The right panel (Panel (b)) illustrates the top view, side view, and longitudinal view of an embodiment of the implantable biofuel cell device **100A**.

[0053] FIG. 1D shows a diagram of an example embodiment of the material **140** and/or material **141** that illustrates an example implementation of processes **111** and **121** taking place at the bioanode **110** and cathode **120** of the implantable biofuel cell device **100A**, respectively. In the example implementation, the process **111** includes a reaction between lactate and lactate oxidase (LOx) that leads to oxidation of lactate to pyruvate and releases electrons which are captured at the anode **110**. The oxidation of lactate can be assisted by the functionalized correspond LOx enzyme. Such an enzyme-catalyzed oxidation at the bioanode **110** can operate under mild conditions (e.g., normal physiological conditions). For a glucose-based biofuel cell, for example, lactate, pyruvate, and lactate oxidase (LOx) can be replaced by glucose, gluconolactone, and glucose oxidase (GOx), respectively. For glucose oxidation via the GOx-catalyzed oxidation at the glucose bioanode, for example, the glucose can provide the electrons and gluconolactone as a byproduct. Processes **111** includes, for example, electron shuttling from LOx to the carbon nanotubes using redox mediator NQ. For example, the example redox mediator NQ can provide a key function of assisting the electron shuttle process between the enzyme redox center (e.g., in LOx or GOx) and the electrode material (e.g., carbon nanotubes). An example of the role of the mediator can be described as the following events. The redox mediator ($NQ_{(ox)}$, oxidized form) accepts the electrons (generated from lactate via the oxidation); simultaneously, the mediator is converted into the reduced form (e.g., $NQ_{(red)}$, containing more electrons). Subsequently, the reduced form of the NQ mediator is reoxidized at the electrode, giving electrons to the electrode. While the electrochemical oxidation (e.g., process **111**) occurs on the anode, the electrochemical reduction (e.g., process **121**) occurs on the cathode. Process **121** include, for example, an oxygen-reduction reaction (ORR). In general, the electrocatalyst in the cathode (such as Pt, presented in process **121**) can help the electroreduction of oxygen. The example of corresponding reaction is $O_2 + 4H^+ + 4e^- \rightarrow 2H_2O$.

[0054] FIG. 1E shows schematic diagrams representing stages in functioning of a self-charging capacitor, occurring on an example biofuel cell device in accordance with the disclosed technology. At stage **170**, while the circuit is opened, the device is self-charged due to the electrochemically catalyzed fuel conversion at both electrodes **110** and **120**. At stage **180**, closing the circuit using, e.g., a switch connected to the elements **160** and **161** of the device **100** allows the current to flow, and the device is discharged for neurostimulation. At stage **190**, the device performance is recovered through self-powered charging.

[0055] FIG. 1F shows an illustrative plot depicting an example of the voltage and current profiles created by an example biofuel cell device **110** in accordance with the disclosed technology during the stages **170**, **180**, and **190** illustrated in FIG. 1E. Profiles in the plot portion **175** correspond to the stage **170** where the example self-charging capacitor circuit is open (and at rest), profiles in the plot portion **185** correspond to the stage **180** where the example self-charging capacitor circuit is closed (and discharging), and profiles in the plot portion **195** correspond to the stage **190** where the example self-charging capacitor circuit is open again (and self re-charging).

[0056] During the "Rest" stage **170** (FIG. 1E), the open circuit voltage (OCV) of the biofuel cell device **100** is determined by the half reactions taking place at the electrodes **110** and **120**. At the anode **110**, the lactate oxidation reaction is equal to ~ –0.2 mV vs Ag/AgCl. Conversely at the cathode **120**, the oxygen reduction reaction is at ~ –0.5 mV vs Ag/AgCl. When the circuit is open, the LOx enzyme at the anode **110** is oxidizing lactate to generate electrons and the platinum catalyst at the cathode is helping to reduce the oxygen to remove electrons. After some elapsed time, both electrodes are fully and oppositely charged, behaving like a two-plate capacitor. The excess charge at both electrodes is balanced by the electrolyte ions found in the cerebrospinal fluid (e.g., Na^+, K^+, Ca^{2+}, Mg^{2+}, Cl^-, $H_2PO_4^-$, HPO_4^{2-}, and PO_4^{3-}). These electrolyte ions migrate to their respective electrode and form an electrochemical double layer (EDL) at each of the electrodes **110** and **120**. Similar to an electrical double layer capacitor (EDLC), the biofuel cell device **100** is electrostatically storing energy at an open circuit that can be used upon closure of the circuit.

[0057] During the "Discharge" stage **180 (**FIG. 1E**)**, upon closure of the circuit using, e.g., a switch connected to the elements **160** and **161** of the device **100**, current flows from the electron-rich anode **110** to the electron-poor cathode **120** discharging the biofuel cell. Surfaces previously carrying charge are gradually neutralized, and the electrochemical double layers found at the electrodes **110** and **120** are dissipated throughout the solution, e.g., CSF. Therefore, the energy that was electrostatically stored in the device **100** prior to the stage **180** can be delivered in galvanostatic discharge pulses. Those pulses can be powerful enough to perform the spinal cord stimulation. Note that during the stage **180** the enzymes are still continuously converting the fuel substrates thus adding current to the one flowing due to the discharging of the accumulated charges.

[0058] Stage **190** ("Self-powered charge", FIG. 1E**)** allows the biofuel cell device **100** to self-charge through enzymatic reactions at the electrodes **110** and **120**. During the stage **190** the device **100** is set to an open circuit mode by, e.g., opening the switch which was used to close the circuit during the stage **180**. Opening the switch allows for the continuously-operating enzymes to reestablish the opposite charges and recreate the electrochemical double layers at the electrodes **110** and **120**. This behavior allows the device **100** to operate as a self-rechargeable capacitor by simply opening and closing the circuit. The cycle of closing and opening the circuit can be frequently repeated with well-defined recharging periods (sub ms $pulse^{-1}$) to allow generation of high-current pulses.

[0059] Example uses of example embodiments of the implantable biofuel cell device **100** can include integration with a medical device and/or its implantation in a human body, such as in the spinal space, to, e.g., power a medical device electrically coupled to the device **100**. Device **100** provides a useful power source for low-power implantable medical devices. Device **100** can be used, for example, to generate electrical pulses for treating refractory chronic pain through the spinal cord stimulation. Device **100** can operate under physiologic conditions, such as intra-body pH and temperature and can be employed for harvesting energy from biochemical constituents of biofluids such as cerebrospinal fluid which is repeatedly produced by the choroid plexus.

[0060] FIG. 2A shows scanning electron microscopy (SEM) images of an implementation of an example implantable biofuel cell device, e.g. for providing a self-charging medical device such as a spinal cord catheter, which shows the dual hollow flexible tubes embodied as the elements **130** and **150** used for preparation of electrodes **110** and **120**. Panel **135** of FIG. 2A shows a SEM image of the example dual hollow flexible tubes taken at a certain resolution, and panel **138** shows a zoomed-in SEM image of a smaller portion of the tubes taken at a higher resolution. One of the openings in the side of one of the tubes is shown by the arrow **232**.

[0061] FIG. 2B shows a scanning electron microscopy (SEM) image of the example implantable biofuel cell device shown in FIG. 2A, where the electrodes of the biofuel cell, labeled **210** and **220**, packed with the active electrode materials **240** and **241**, which include multi-walled carbon nanotubes in this example.

[0062] FIG. 3A shows an illustration of a catheter-based biodevice **300** being inserted into the epidural space through a spinal needle with an introducer **301**. A catheter-based device is generally a device in which a catheter, e.g. a medical catheter, is used as one of its elements or is used to make one of its elements; generally, the term "catheter" refers to a flexible tube or a flexible lead. In the case of the example device **300**, a catheter, including a medical one, can be used, for example, to provide elements **130** and/or **150** to encase the bioanode **110** and cathode **120** of an example biofuel cell device **100A**.

[0063] FIG. 3B shows a schematic representation of an example embodiment of the biofuel cell device **100A** configured as a medical catheter implanted along the spinal subdural space. The schematic illustrates how the elements **130** and **150** that encases the bioanode **110** and cathode **120** of the example biofuel cell device **100A** can interface with the spinal cord tissue. The schematic also illustrates how the structure of the example embodiment of the biofuel cell device **100A** can provide a degree of bendability for the biofuel cell device **100A** sufficient for interfacing the biofuel cell device **100A** with the spinal cord tissue. The bendability of the device is provided, at least in part, through a sufficiently high ratio of the length to the diameter of the elements **130** and **150**, and/or a sufficiently high number of openings in the surfaces of the elements **130** and **150**, and/or a sufficiently high bendability of the elongated elements **160** and **161**, and/or a sufficient bendability and/or dispersion of the materials **140** and **141**, and/or through a sufficiently high bendability of elements **130** and **150**, or through a combination of one or more of the above features.

[0064] FIG. 3C shows an optical microscopy image of an example implanted catheter-based biodevice inserted in a physical model of a spinal cord.

[0065] FIGS. 3D-3F show images of in-vivo implantation procedures of an example catheter-based biofuel cell device in accordance with the present technology being implanted in a human cadaver model. As shown in FIG. 3D, the image depicts the cadaver model **310**. The image of FIG. 3E shows the example implanted catheter-based biodevice **320** being implanted by a spinal needle with an introducer **330**. The image of FIG. 3F shows human cadaver model 310 after the example implanted catheter-based biodevice **320** was inserted via the spinal needle with an introducer.

[0066] FIG. 3G shows a posteroanterior X-ray view of the example implanted catheter-based biofuel cell device **320** and spinal needle **330**.

[0067] Example implementations were performed where electrochemical properties of an example embodiment of the implantable biofuel cell device **100** in accordance with the disclosed technology were investigated. The example BFC device was investigated at room temperature in a single chamber without any separating membrane. Batch experiments were performed. Electrochemical experiments were carried out using a μAutolab Type II controlled by NOVA software (version 1.11). The power curves were obtained by scanning the voltage between the open circuit voltage (OCV) of the BFC to 0 V at a constant scan rate (e.g., such as 5 mV s^{-1}). A 0.5 M phosphate buffer solution was used as a supporting electrolyte. The total geometrical volume of both electrodes was used to normalize the volumetric density values. Electrochemical properties of the electrodes of the example BFC device used in the experiment were investigated by observing electrochemical voltage–current profiles.

[0068] FIG. 4A shows linear sweep voltammograms (LSV) for the anode of the example BFC device in the absence and presence (dotted line **410** and solid line **420**, respectively) of 2.8 mM lactate in 0.5 M phosphate-buffered saline containing potassium, PBS, (pH 7.4). The anode was scanned in 2.8 mM lactate with a linear sweep voltammogram (5 mV s^{-1}), revealing a catalytic onset around at –0.4 V (vs. Ag/AgCl) and the peak is near –0.2 V (FIG. 4A).

[0069] Pt was selected as the catalyst in the cathode for oxygen reduction because it can catalyze the reaction with a low overpotential. FIG. 4B shows LSV **430** at the Pt-containing cathode of the example BFC device for O_2 reduction in 0.5 M PBS (pH 7.4). As depicted in the data plot, the start of the reduction at the cathode appears at +0.50 V.

[0070] FIG. 4C shows a data plot depicting polarization plots for an example embodiment of the implantable biofuel cell device **100** in PBS at pH 7.0 corresponding to the concentrations of lactate of 0, 2.5, 5.0, 7.5, 10.0 mM (which correspond to data curves **441**, **442**, **443**, **444**, and **445**, respectively).

[0071] FIG. 4D shows a data plot depicting power density versus voltage plots for an embodiment of the implantable biofuel cell device **100** in PBS at pH 7.0 corresponding to the concentrations of lactate of 0, 2.5, 5.0, 7.5, 10.0 mM (curves **451**, **452**, **453**, **454**, and **455**, respectively).

[0072] In the example implementations, to examine the capacitance of the example biofuel cell device, cyclic voltammograms (CV) were performed at different scan rates. As the scan rate was increased, the current reading increased proportionally as well.

[0073] FIG. 4E shows apparent capacitance profiles at different scan rates for an example embodiment of the implantable biofuel cell device **100**. Profiles **461**, **462**, **463**, **464**, **465**, and **466** correspond to the scan rates of 10, 25, 50, 75, and 100 (mV s^{-1}), respectively. Drops at specific capacitances were observed at a faster scan rate. The voltammograms showed that a high capacitance in the example biofuel cell device can be achieved at a proper charge propagation within the potential window of 0 to ~0.6 V.

[0074] FIG. 4F shows the apparent capacitance versus scan rate for different concentrations of the lactate for an example embodiment of the implantable biofuel cell device **100**. Curves **467** and **468** correspond to the concentrations of lactate 0 mM and 2.8 mM, respectively.

[0075] FIG. 4G shows voltage recordings while harvesting current pulses in the absence (**471**) and presence (**472**) of 2.8 mM lactate in the artificial CSF. Current pulses had 10 Hz repetition rate, 100-μA amplitude, and 0.2 ms pulse width.

[0076] FIG. 4H shows voltage recordings while harvesting current pulses of different amplitudes in the presence of 2.8 mM lactate in the artificial CSF. Traces **480**, **481**, **482**, **483**, **484**, **485**, **486**, **487**, and **488** correspond to the current pulses amplitudes of 0.50, 1.00, 1.50, 1.75, 2.00, 2.25, 2.50, 2.75, and 3.00 mA, respectively. Pulse repetition rate was 40 Hz, and pulse width was 0.2 ms.

[0077] The voltage and current pulse profiles shown in FIG. 1E illustrate that capacitive ($\Delta V_{capacitive}$) and resistive (ΔV_{ohmic}) contributions cause a decrease in the open circuit voltage OCV (also referred to as V_{max}). For example, $\Delta V_{capacitive}$ and ΔV_{ohmic} can be seen in FIG. 1. For the example embodiment of the biofuel cell device used in the example implementations, the voltage loss due to resistive behaviors represented an equivalent series resistance (*ESR*) below 200 Ω. The values of capacitance C, estimated by analyzing the voltage slope, were in the range of 10-500 µF cm^{-3}, e.g., reflecting the charge-storing performance of the example biofuel cell device. Through the analysis of the example biofuel cell device behavior at different currents (FIG. 4H), a power curve for the example biofuel cell device was generated. The power curve could display a maximum power output above 15 µW cm^{-3} at a current of 60 mA cm^{-3} and an OCV above 0.4 mV. The BFC self-charging behavior was examined using charge/discharge cycling at 40 Hz. After each discharge pulse, the example biofuel cell device recovered itself to its starting OCV as a result of the continuous enzymatic and catalytic reactions of lactate and oxygen at the anode and cathode electrodes of the BFC device, respectively. Larger voltage drops occurred when higher currents were applied, resulting in a longer recovery time back to the initial OCV.

[0078] FIG. 4I shows a power curve profile **490** for an example embodiment of an implantable biofuel cell device **100**. The power curve profile was calculated from the minimum voltage, which can be defined as OCV - $\Delta V_{capacitive}$ - ΔV_{ohmic} (e.g., as illustrated in FIG 1F). The highest value of the minimum power density (P_{min}) could reach above 15 mW cm^{-3} was then obtained. A voltage drop, whose intensity is observed after a current pulse is applied, depends on the applied current. After a 0.2 ms pulse, the potential quickly resets to its initial value.

[0079] FIG. 5 shows a block diagram of an example embodiment of an electronic device **500** that can interface with various embodiments of the biofuel cell device **100** and/or integrated medical device for various implementations. For example, the electronic device **500** can connect an electrical circuit of the electronic device **500** with the elements **160** and **161** of the device **100**; whereas in some embodiments, the electronic device **500** is coupled to an electronic interface of the medical device contingent of the integrated medical device / biofuel cell device. In various implementations, the electronic device **500** operable to store and execute the software application and algorithms and implement various controls of the biofuel cell device **100** and/or functionalities of a medical device integrated with the biofuel cell device **100**. In various implementations, the electronic device **500** can be implemented as a portable computing device, such as a mobile communications device, such as a smartphone, tablet or wearable device, like a smartwatch, glasses, etc.; and/or the electronic device **500** can be implemented as a stationary computing device, such as a desktop computer. In some embodiments, the electronic device **500** includes a dongle that couples to the elements **160** and **161** of the device **100** and/or the medical device contingent to wirelessly connect to the computing components (e.g., a data processing unit) of the electronic device **500**.

[0080] In some embodiments, the electronic device **500** includes a data processing unit **510** includes a processor **511** to process data, a memory **512** in communication with the processor **511** to store data, and an input/output unit (I/O) **513** to interface the processor **511** and/or memory **512** to other modules, units or devices, including other external computing devices. For example, the processor **511** can include a central processing unit (CPU) or a microcontroller unit (MCU). For example, the memory **512** can include and store processor-executable code, which when executed by the processor, configures the data processing unit **510** to perform various operations, e.g., such as receiving information, commands, and/or data, processing information and data, and transmitting or providing information/data to another device. In some implementations, the data processing unit **510** can transmit raw or processed data to a computer system or communication network accessible via the Internet (referred to as 'the cloud') that includes one or more remote computational processing devices (e.g., servers in the cloud). To support various functions of the data processing unit **510**, the memory **512** can store information and data, such as instructions, software, values, images, and other data processed or referenced by the processor. For example, various types of Random Access Memory (RAM) devices, Read Only Memory (ROM) devices, Flash Memory devices, and other suitable storage media can be used to implement storage functions of the memory **512**. In some embodiments, the data processing unit **510** includes a wireless communication unit **520**, such as a wireless transmitter to transmit stored and/or processed data or a wireless transceiver (Tx/Rx) to transmit and receive data. The I/O **513** of the data processing unit **510** can interface the data processing unit **510** with the wireless communications unit **520** to utilize various types of wired or wireless interfaces compatible with typical data communication standards, for example, which can be used in communications of the data processing unit **510** with other devices, via a wireless transmitter/receiver (Tx/Rx) unit, e.g., including, but not limited to, Bluetooth, Bluetooth low energy, Zigbee, IEEE 802.11, Wireless Local Area Network (WLAN), Wireless Personal Area Network (WPAN), Wireless Wide Area Network (WWAN), WiMAX, IEEE 802.16 (Worldwide Interoperability for Microwave Access (WiMAX)), 3G/4G/LTE/5G cellular communication methods, NFC (Near Field Communication), and parallel interfaces. In some embodiments, the data processing unit **510** includes a display unit **530**, which can include a visual display such as a display screen, an audio display such as a speaker, or other type of display or combinations thereof. The I/O **513** of the data processing unit **510** can also interface with other external interfaces, sources of data storage, and/or visual or audio display devices, etc. to retrieve and transfer data and information that can be processed by the processor **511**, stored in the memory **512**, or exhibited on an output unit (e.g., display unit **530**) of the electronic device **500** or an external device. For example, the display unit **530** can be configured to be in data communication with the data processing unit **510**, e.g., via the I/O **513**, to provide a visual display, an audio display, and/or other sensory display that produces the user interface of the software application. In some examples, the display unit **530** can include various types of screen displays, speakers, or printing interfaces, e.g., including but not limited to, light emitting diode (LED), or liquid crystal display (LCD) monitor or screen, cathode ray tube (CRT) as a visual display; audio signal transducer apparatuses as an audio display; and/or toner, liquid inkjet, solid ink, dye sublimation, inkless (e.g., such as thermal or UV) printing apparatuses, etc.

[0081] In some example implementations, various example embodiments of the biofuel cell device **100** can be electrically interfaced to a medical device that includes the electronic device **500**, such that the biofuel cell device **100** harvests electrical energy from a biological fluid where the biofuel cell device **100** is implanted (e.g., converting bio/chemical energy into electrical energy), and the generated electrical energy will be managed by the electronic device **500** of the integrated medical device for various actuatable functions of the medical device. In examples where the medical device includes a catheter for electrical stimulation, the biofuel cell device **100** supplies the electrical energy used to actuate electrical stimulation output by the catheter to the target location for the stimulation application. In some implementations of the integrated biofuel cell device **100** integrated with a medical device as an implantable spinal cord catheter device, for example, the electronic device **500** can control the catheter functionality, such as direct current in the dorsal column or dorsal horn of the spinal cord to cause increased gamma-aminobutyric acid (GABA) neurotransmitter, e.g., resulting in decreased peripheral-to-central pain transmission. In some example implementations, the medical device can include sensors (e.g., biosensors), where the harvested electrical energy can be used by the self-charging medical device for sensing applications.

[0082] Examples

[0083] In some embodiments in accordance with the disclosed technology (example A1), a biofuel cell device for extracting energy from a biological fluid includes a substrate that includes a first compartment having a first hollow interior portion and a second compartment having a second hollow interior portion, wherein the first hollow interior portion of the first compartment and the second hollow interior portion of the second compartment are separated, the substrate including one or more openings into each of the first hollow interior portion and the second hollow interior portion; an anode assembly that includes an anode electrode disposed in the first hollow interior portion of the substrate and a functionalization material disposed on or integrated with the anode electrode proximate the one or more openings, in which the functionalization material includes a catalyst molecule to facilitate conversion of a substance in a biological fluid to a first product in an oxidative process that releases electrons captured at the anode electrode, thereby extracting energy from the substance in the biological fluid; and a cathode assembly that includes a cathode electrode disposed in the second hollow interior portion of the substrate separated from the anode electrode, the cathode assembly including a catalytic material operable to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons.

[0084] Example A2 includes the biofuel cell device as in example A1, in which the anode assembly includes a surface having a plurality of cavities in which the functionalization layer is disposed over the anode electrode.

[0085] Example A3 includes the biofuel cell device as in examples A1 or A2, further including a cover disposed over the anode assembly, the cover having a plurality of openings that expose at least some portions of the anode contingent.

[0086] Example A4 includes the biofuel cell device as in example A3, in which the cover is a polymer tubing that tightly surrounds the anode assembly.

[0087] Example A5 includes the biofuel cell device as in example A3, in which the cover includes a biocompatible material.

[0088] Example A6 includes the biofuel cell device as in example A5, in which the biocompatible material includes polydimethylsiloxane (PDMS), polytetrafluoroethylene (PTFE), or polyurethane (PU).

[0089] Example A7 includes the biofuel cell device as in any of the preceding examples, in which the functionalization layer includes a mediator layer disposed on the anode electrode and an enzymatic layer disposed on the mediator layer.

[0090] Example A8 includes the biofuel cell device as in any of the preceding examples, in which the device is operable to provide the extracted energy to an implantable medical device.

[0091] Example A9 includes the biofuel cell device as in any of the preceding examples, in which the device is operable to provide the extracted energy as a pulse generator for treating refractory chronic pain through stimulation in a spinal cord of a patient.

[0092] Example A10 includes the biofuel cell device as in any of the preceding examples, in which the substance in the biological fluid includes glucose, the catalyst includes glucose oxidase (GOx), and the first product includes gluconolactone, or in which the substance in the biological fluid includes lactate, the catalyst includes lactate oxidase (LOx), and the first product includes pyruvate.

[0093] Example A11 includes the biofuel cell device as in any of the preceding examples, in which the catalytic material includes platinum.

[0094] Example A12 includes the biofuel cell device as in any of the preceding examples, further including an amplifier circuit to supply electrical current from the extracted energy to another device that electrically couples to the biofuel cell device.

[0095] Example A13 includes the biofuel cell device as in example A12, in which the enzymatic biofuel cell and the amplifier circuit are coupled to a single substrate.

[0096] In some embodiments in accordance with the disclosed technology (example B1), an implantable biofuel cell device for extracting energy from a biological fluid includes a substrate, including (i) a first compartment having a first hollow interior portion and (ii) a second compartment having a second hollow interior portion, the second hollow interior portion separated from the first hollow interior portion, wherein the substrate includes one or more openings into each of the first hollow interior portion and the second hollow interior portion; an anode assembly, including (i) a first electrode disposed in the first hollow interior portion of the substrate and (ii) a functionalization material disposed on or integrated with the first electrode proximate the one or more openings, wherein the functionalization material includes a catalyst to facilitate conversion of a substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first electrode; and a cathode assembly, including (i) a second electrode disposed in the second hollow interior portion of the substrate and (ii) a catalytic material to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons, wherein, when the biofuel cell device is inserted in a tissue exposing the biofuel cell device to the biological fluid, the biofuel cell device is operable to extract electrical energy from the substance in the biological fluid across the anode assembly and the cathode assembly.

[0097] Example B2 includes the biofuel cell device as in any of examples B1-B17, wherein the first compartment of the substrate includes a first elongated tube includes a surface having a plurality of the openings on at least a portion of a longitudinal side that spans the length of the first elongated tube, and wherein the second compartment of the substrate includes a second elongated tube includes a surface having a plurality of the openings on at least a portion of a longitudinal side that spans the length of the second elongated tube.

[0098] Example B3 includes the biofuel cell device as in any of examples B1-B17, further comprising a cover disposed over the substrate, the cover having a plurality of apertures that expose at least some portions of the anode assembly and of the cathode assembly.

[0099] Example B4 includes the biofuel cell device as in any of examples B1-B17, wherein the first elongated tube and the second elongated tube include a biocompatible polymer material.

[00100] Example B5 includes the biofuel cell device as in any of examples B1-B17, wherein the biocompatible polymer material includes one or more of polydimethylsiloxane (PDMS), polytetrafluoroethylene (PTFE), or polyurethane (PU).

[00101] Example B6 includes the biofuel cell device as in any of examples B1-B17, wherein the functionalization material of the anode assembly includes a conductive polymer material.

[00102] Example B7 includes the biofuel cell device as in any of examples B1-B17, wherein the functionalization material of the anode assembly includes multi-walled carbon nanotubes.

[00103] Example B8 includes the biofuel cell device as in any of examples B1-B17, wherein the functionalization material of the anode assembly includes a redox mediator to increase electron conductivity within the functionalization material.

[00104] Example B9 includes the biofuel cell device as in any of examples B1-B17, wherein the redox mediator includes 1,4-naphthoquinone (NQ).

[00105] Example B10 includes the biofuel cell device as in any of examples B1-B17, wherein the catalytic material of the cathode assembly includes a conductive polymer material.

[00106] Example B11 includes the biofuel cell device as in any of examples B1-B17, wherein the catalytic material of the cathode assembly includes multi-walled carbon nanotubes.

[00107] Example B12 includes the biofuel cell device as in any of examples B1-B17, wherein the catalytic material of the cathode assembly includes polychlorotrifluoroethylene (PCTFE) to mitigate effects of oxygen fluctuations in the biological fluid during an operation of the biofuel cell device.

[00108] Example B13 includes the biofuel cell device as in any of examples B1-B17, wherein the one or both of the first electrode and second electrode includes platinum.

[00109] Example B14 includes the biofuel cell device as in any of examples B1-B17, wherein the biofuel cell device is integrated with an implantable medical device to provide the extracted electrical energy to the implantable medical device.

[00110] Example B15 includes the biofuel cell device as in any of examples B1-B17, wherein the implantable medical device and the biofuel cell device are integrated as a spinal catheter, and wherein the biofuel cell device is operable to provide the extracted electrical energy to the spinal catheter to enable the spinal catheter to generate electrical pulses.

[00111] Example B16 includes the biofuel cell device as in any of examples B1-B17, further comprising an electrical circuit to supply electrical current from the extracted electrical energy to an external device that electrically couples to the biofuel cell device.

[00112] Example B17 includes the biofuel cell device as in any of examples B1-B16, wherein the substance in the biological fluid includes glucose, the catalyst includes glucose oxidase (GOx), and the first product includes gluconolactone, and/or wherein the substance in the biological fluid includes lactate, the catalyst includes lactate oxidase (LOx), and the first product includes pyruvate.

[00113] In some embodiments in accordance with the disclosed technology (example B18), a self-charging medical device includes a catheter comprising a first elongated tube and a second elongated tube coupled to the first elongated tube at one or more coupling positions along a longitudinal side of the first and second elongated tubes, the first elongated tube including a first compartment having a first hollow interior portion and a plurality of openings from an outer surface of the first elongated tube into the first hollow interior portion, the second elongated tube including a second compartment having a second hollow interior portion and a plurality of openings from an outer surface of the second elongated tube into the second hollow interior portion, wherein the second hollow interior portion is separated from the first hollow interior portion, and wherein the first and second elongated tubes include a bendable material; and a biofuel cell integrated in the catheter and comprising an anode assembly disposed in the first elongated tube and a cathode assembly disposed in the second elongated tube, the biofuel cell operable to extract electrical energy from a substance in a biological fluid across the anode assembly and the cathode assembly to supply the extracted electrical energy for the catheter. The anode assembly includes a first wire and a first substance, the first wire and the first substance disposed within the first hollow interior portion, wherein the first substance is coupled to at least a portion of the first wire proximate the plurality of openings of the first elongated tube, and wherein the first substance includes a functionalization material comprising a catalyst to facilitate conversion of the substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first wire. The cathode assembly includes a second wire and a second substance, the second wire and the second substance disposed within the second hollow interior portion, wherein the second substance is coupled to at least a portion of the second wire proximate the plurality of openings of the second elongated tube, and wherein the second substance includes a catalytic material to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons.

[00114] Example B19 includes the medical device as in any of examples B18-B28, wherein the catheter is configured as a spinal catheter, such that the biofuel cell is operable to provide the extracted electrical energy to the spinal catheter to enable actuation of the spinal catheter to generate electrical pulses.

[00115] Example B20 includes the medical device as in any of examples B18-B28, further comprising a cover disposed over the at least a portion of the first elongated tube and the second elongated tube, the cover having a plurality of apertures that expose at least some portions of the anode assembly and of the cathode assembly through the plurality of openings of the first hollow interior portion and the second hollow interior portion, respectively.

[00116] Example B21 includes the medical device as in any of examples B18-B28, wherein the bendable material of the first elongated tube and the second elongated tube include a biocompatible polymer material comprising one or more of polydimethylsiloxane (PDMS), polytetrafluoroethylene (PTFE), or polyurethane (PU).

[00117] Example B22 includes the medical device as in any of examples B18-B28, wherein the functionalization material of the anode assembly includes one or both of a conductive polymer material and multi-walled carbon nanotubes.

[00118] Example B23 includes the medical device as in any of examples B18-B28, wherein the functionalization material of the anode assembly includes a redox mediator including 1,4-naphthoquinone (NQ) to increase electron conductivity within the functionalization material.

[00119] Example B24 includes the medical device as in any of examples B18-B28, wherein the second substance of the cathode assembly includes one or both of a conductive polymer material and multi-walled carbon nanotubes.

[00120] Example B25 includes the medical device as in any of examples B18-B28, wherein the catalytic material of the cathode assembly includes polychlorotrifluoroethylene (PCTFE) to mitigate effects of oxygen fluctuations in the biological fluid during an operation of the biofuel cell device.

[00121] Example B26 includes the medical device as in any of examples B18-B28, wherein the one or both of the first wire and second wire includes platinum.

[00122] Example B27 includes the medical device as in any of examples B18-B28, further comprising an electrical circuit coupled to the biofuel cell and operable to supply electrical current from the extracted electrical energy to an external device that electrically couples to the biofuel cell device.

[00123] Example B28 includes the medical device as in any of examples B18-B27, wherein the substance in the biological fluid includes glucose, the catalyst includes glucose oxidase (GOx), and the first product includes gluconolactone, and/or wherein the substance in the biological fluid includes lactate, the catalyst includes lactate oxidase (LOx), and the first product includes pyruvate.

[00124] In some embodiments in accordance with the disclosed technology (example B29), a biofuel cell device for extracting energy from a biological fluid includes an anode assembly comprising: a first hollow elongated element, a first substance at least partially disposed inside the first hollow elongated element and that is at least partially electrically conductive, a first electrically conductive elongated element at least partially disposed inside the first hollow elongated element and coupled with the first substance, wherein the first hollow elongated element has at least one opening in its surface to expose at least a portion of the first substance; and a cathode assembly comprising: a second hollow elongated element, at second substance at least partially disposed inside the second hollow elongated element and that is at least partially electrically conductive, a second electrically conductive elongated element at least partially disposed inside the second hollow elongated element and coupled with the second substance, wherein the second hollow elongated element has at least one opening in its surface to expose at least a portion of the second substance, wherein the biofuel cell device to is operable to facilitate conversion of a substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first electrically conductive elongated element of the anode assembly and to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons, thereby extracting energy from the substance in the biological fluid across the anode and the cathode assemblies.

[00125] Example B30 includes the fuel cell device as in any of examples B29-B34, wherein the first substance comprises an enzyme.

[00126] Example B31 includes the fuel cell device as in any of examples B29-B34, wherein the second substance comprises a chemical compound which can catalyze a reduction reaction.

[00127] Example B32 includes the fuel cell device as in any of examples B29-B34, wherein the first substance comprises a chemical compound which is a redox mediator.

[00128] Example B33 includes the fuel cell device as in any of examples B29-B34, wherein the second substance comprises a compound capable to absorb oxygen.

[00129] Example B34 includes the fuel cell device as in any of examples B29-B33, wherein the second substance comprises a compound capable to adsorb oxygen.

[00130] Implementations of the subject matter and the functional operations described in this patent document can be implemented in various systems, digital electronic circuitry, or in computer software, firmware, or hardware, including the structures disclosed in this specification and their structural equivalents, or in combinations of one or more of them. Implementations of the subject matter described in this specification can be implemented as one or more computer program products, i.e., one or more modules of computer program instructions encoded on a tangible and non-transitory computer readable medium for execution by, or to control the operation of, data processing apparatus. The computer readable medium can be a machine-readable storage device, a machine-readable storage substrate, a memory device, a composition of matter effecting a machine-readable propagated signal, or a combination of one or more of them. The term “data processing unit” or “data processing apparatus” encompasses all apparatus, devices, and machines for processing data, including by way of example a programmable processor, a computer, or multiple processors or computers. The apparatus can include, in addition to hardware, code that creates an execution environment for the computer program in question, e.g., code that constitutes processor firmware, a protocol stack, a database management system, an operating system, or a combination of one or more of them.

[00131] A computer program (also known as a program, software, software application, script, or code) can be written in any form of programming language, including compiled or interpreted languages, and it can be deployed in any form, including as a stand-alone program or as a module, component, subroutine, or other unit suitable for use in a computing environment. A computer program does not necessarily correspond to a file in a file system. A program can be stored in a portion of a file that holds other programs or data (e.g., one or more scripts stored in a markup language document), in a single file dedicated to the program in question, or in multiple coordinated files (e.g., files that store one or more modules, sub programs, or portions of code). A computer program can be deployed to be executed on one computer or on multiple computers that are located at one site or distributed across multiple sites and interconnected by a communication network.

[00132] The processes and logic flows described in this specification can be performed by one or more programmable processors executing one or more computer programs to perform functions by operating on input data and generating output. The processes and logic flows can also be performed by, and apparatus can also be implemented as, special purpose logic circuitry, e.g., an FPGA (field programmable gate array) or an ASIC (application specific integrated circuit).

[00133] Processors suitable for the execution of a computer program include, by way of example, both general and special purpose microprocessors, and any one or more processors of any kind of digital computer. Generally, a processor will receive instructions and data from a read only memory or a random access memory or both. The essential elements of a computer are a processor for performing instructions and one or more memory devices for storing instructions and data. Generally, a computer will also include, or be operatively coupled to receive data from or transfer data to, or both, one or more mass storage devices for storing data, e.g., magnetic, magneto optical disks, or optical disks. However, a computer need not have such devices. Computer readable media suitable for storing computer program instructions and data include all forms of nonvolatile memory, media and memory devices, including by way of example semiconductor memory devices, e.g., EPROM, EEPROM, and flash memory devices. The processor and the memory can be supplemented by, or incorporated in, special purpose logic circuitry.

[00134] It is intended that the specification, together with the drawings, be considered exemplary only, where exemplary means an example. As used herein, the singular forms “a”, “an” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. Additionally, the use of “or” is intended to include “and/or”, unless the context clearly indicates otherwise.

[00135] While this patent document contains many specifics, these should not be construed as limitations on the scope of any invention or of what may be claimed, but rather as descriptions of features that may be specific to particular embodiments of particular inventions. Certain features that are described in this patent document in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

[00136] Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. Moreover, the separation of various system components in the embodiments described in this patent document should not be understood as requiring such separation in all embodiments.

[00137] Only a few implementations and examples are described, and other implementations, enhancements and variations can be made based on what is described and illustrated in this patent document.

CLAIMS

What is claimed is:

1. An implantable biofuel cell device for extracting energy from a biological fluid, comprising:

a substrate, including (i) a first compartment having a first hollow interior portion and (ii) a second compartment having a second hollow interior portion, the second hollow interior portion separated from the first hollow interior portion, wherein the substrate includes one or more openings into each of the first hollow interior portion and the second hollow interior portion;

an anode assembly, including (i) a first electrode disposed in the first hollow interior portion of the substrate and (ii) a functionalization material disposed on or integrated with the first electrode proximate the one or more openings, wherein the functionalization material includes a catalyst to facilitate conversion of a substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first electrode; and

a cathode assembly, including (i) a second electrode disposed in the second hollow interior portion of the substrate and (ii) a catalytic material to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons,

wherein, when the biofuel cell device is inserted in a tissue exposing the biofuel cell device to the biological fluid, the biofuel cell device is operable to extract electrical energy from the substance in the biological fluid across the anode assembly and the cathode assembly.

2. The biofuel cell device as in claim 1, wherein the first compartment of the substrate includes a first elongated tube includes a surface having a plurality of the openings on at least a portion of a longitudinal side that spans the length of the first elongated tube, and wherein the second compartment of the substrate includes a second elongated tube includes a surface having a plurality of the openings on at least a portion of a longitudinal side that spans the length of the second elongated tube.

3. The biofuel cell device as in any of claims 1 or 2, further comprising a cover disposed over the substrate, the cover having a plurality of apertures that expose at least some portions of the anode assembly and of the cathode assembly.

4. The biofuel cell device as in any of claims 2 or 3, wherein the first elongated tube and the second elongated tube include a biocompatible polymer material.

5. The biofuel cell device as in claim 4, wherein the biocompatible polymer material includes one or more of polydimethylsiloxane (PDMS), polytetrafluoroethylene (PTFE), or polyurethane (PU).

6. The biofuel cell device as in any of claims 1-5, wherein the functionalization material of the anode assembly includes a conductive polymer material.

7. The biofuel cell device as in any of claims 1-6, wherein the functionalization material of the anode assembly includes multi-walled carbon nanotubes.

8. The biofuel cell device as in any of claims 1-7, wherein the functionalization material of the anode assembly includes a redox mediator to increase electron conductivity within the functionalization material.

9. The biofuel cell device as in claim 8, wherein the redox mediator includes 1,4-naphthoquinone (NQ).

10. The biofuel cell device as in any of claims 1-9, wherein the catalytic material of the cathode assembly includes a conductive polymer material.

11. The biofuel cell device as in any of claims 1-10, wherein the catalytic material of the cathode assembly includes multi-walled carbon nanotubes.

12. The biofuel cell device as in any of claims 1-11, wherein the catalytic material of the cathode assembly includes polychlorotrifluoroethylene (PCTFE) to mitigate effects of oxygen fluctuations in the biological fluid during an operation of the biofuel cell device.

13. The biofuel cell device as in any of claims 1-12, wherein the one or both of the first electrode and second electrode includes platinum.

14. The biofuel cell device as in any of claims 1-13, wherein the biofuel cell device is integrated with an implantable medical device to provide the extracted electrical energy to the implantable medical device.

15. The biofuel cell device as in claim 14, wherein the implantable medical device and the biofuel cell device are integrated as a spinal catheter, and wherein the biofuel cell device is operable to provide the extracted electrical energy to the spinal catheter to enable the spinal catheter to generate electrical pulses.

16. The biofuel cell device as in any of claims 1-15, further comprising an electrical circuit to supply electrical current from the extracted electrical energy to an external device that electrically couples to the biofuel cell device.

17. The biofuel cell device as in any of the preceding claims,

wherein the substance in the biological fluid includes glucose, the catalyst includes glucose oxidase (GOx), and the first product includes gluconolactone, and/or

wherein the substance in the biological fluid includes lactate, the catalyst includes lactate oxidase (LOx), and the first product includes pyruvate.

18. A self-charging medical device, comprising:

a catheter comprising a first elongated tube and a second elongated tube coupled to the first elongated tube at one or more coupling positions along a longitudinal side of the first and second elongated tubes, the first elongated tube including a first compartment having a first hollow interior portion and a plurality of openings from an outer surface of the first elongated tube into the first hollow interior portion, the second elongated tube including a second compartment having a second hollow interior portion and a plurality of openings from an outer surface of the second elongated tube into the second hollow interior portion, wherein the second hollow interior portion is separated from the first hollow interior portion, and wherein the first and second elongated tubes include a bendable material; and

a biofuel cell integrated in the catheter and comprising an anode assembly disposed in the first elongated tube and a cathode assembly disposed in the second elongated tube, the biofuel cell operable to extract electrical energy from a substance in a biological fluid across the anode assembly and the cathode assembly to supply the extracted electrical energy for the catheter,

the anode assembly comprising a first wire and a first substance, the first wire and the first substance disposed within the first hollow interior portion, wherein the first substance is coupled to at least a portion of the first wire proximate the plurality of openings of the first elongated tube, and wherein the first substance includes a functionalization material comprising a catalyst to facilitate conversion of the substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first wire,

the cathode assembly comprising a second wire and a second substance, the second wire and the second substance disposed within the second hollow interior portion, wherein the second substance is coupled to at least a portion of the second wire proximate the plurality of openings of the second elongated tube, and wherein the second substance includes a catalytic material to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons.

19. The medical device as in claim 18, wherein the catheter is configured as a spinal catheter, such that the biofuel cell is operable to provide the extracted electrical energy to the spinal catheter to enable actuation of the spinal catheter to generate electrical pulses.

20. The medical device as in any of claims 18 or 19, further comprising a cover disposed over the at least a portion of the first elongated tube and the second elongated tube, the cover having a plurality of apertures that expose at least some portions of the anode assembly and of the cathode assembly through the plurality of openings of the first hollow interior portion and the second hollow interior portion, respectively.

21. The medical device as in any of claims 18-20, wherein the bendable material of the first elongated tube and the second elongated tube include a biocompatible polymer material comprising one or more of polydimethylsiloxane (PDMS), polytetrafluoroethylene (PTFE), or polyurethane (PU).

22. The medical device as in any of claims 18-21, wherein the functionalization material of the anode assembly includes one or both of a conductive polymer material and multi-walled carbon nanotubes.

23. The medical device as in any of claims 18-22, wherein the functionalization material of the anode assembly includes a redox mediator including 1,4-naphthoquinone (NQ) to increase electron conductivity within the functionalization material.

24. The medical device as in any of claims 18-23, wherein the second substance of the cathode assembly includes one or both of a conductive polymer material and multi-walled carbon nanotubes.

25. The medical device as in any of claims 18-24, wherein the catalytic material of the cathode assembly includes polychlorotrifluoroethylene (PCTFE) to mitigate effects of oxygen fluctuations in the biological fluid during an operation of the biofuel cell device.

26. The medical device as in any of claims 18-25, wherein the one or both of the first wire and second wire includes platinum.

27. The medical device as in any of claims 18-26, further comprising an electrical circuit coupled to the biofuel cell and operable to supply electrical current from the extracted electrical energy to an external device that electrically couples to the biofuel cell device.

28. The medical device as in any of claims 18-27,

wherein the substance in the biological fluid includes glucose, the catalyst includes glucose oxidase (GOx), and the first product includes gluconolactone, and/or

wherein the substance in the biological fluid includes lactate, the catalyst includes lactate oxidase (LOx), and the first product includes pyruvate.

29. A biofuel cell device for extracting energy from a biological fluid, comprising:

an anode assembly comprising:

a first hollow elongated element, a first substance at least partially disposed inside the first hollow elongated element and that is at least partially electrically conductive, a first electrically conductive elongated element at least partially disposed inside the first hollow elongated element and coupled with the first substance, wherein the first hollow elongated element has at least one opening in its surface to expose at least a portion of the first substance; and

a cathode assembly comprising:

a second hollow elongated element, at second substance at least partially disposed inside the second hollow elongated element and that is at least partially electrically conductive, a second electrically conductive elongated element at least partially disposed inside the second hollow elongated element and coupled with the second substance, wherein the second hollow elongated element has at least one opening in its surface to expose at least a portion of the second substance,

wherein the biofuel cell device to is operable to facilitate conversion of a substance in the biological fluid to a first product in an oxidative process that releases electrons captured at the first electrically conductive elongated element of the anode assembly and to reduce an oxygenated substance in the biological fluid to a second product in a chemical reduction process in which the second product gains electrons, thereby extracting energy from the substance in the biological fluid across the anode assembly and the cathode assembly.

30. The fuel cell device as in claim 29, wherein the first substance comprises an enzyme.

31. The fuel cell device as in claim 29, wherein the second substance comprises a chemical compound which can catalyze a reduction reaction.

32. The fuel cell device as in claim 29, wherein the first substance comprises a chemical compound which is a redox mediator.

33. The fuel cell device as in claim 29, wherein the second substance comprises a compound capable to absorb oxygen.

34. The fuel cell device as in claim 29, wherein the second substance comprises a compound capable to adsorb oxygen.

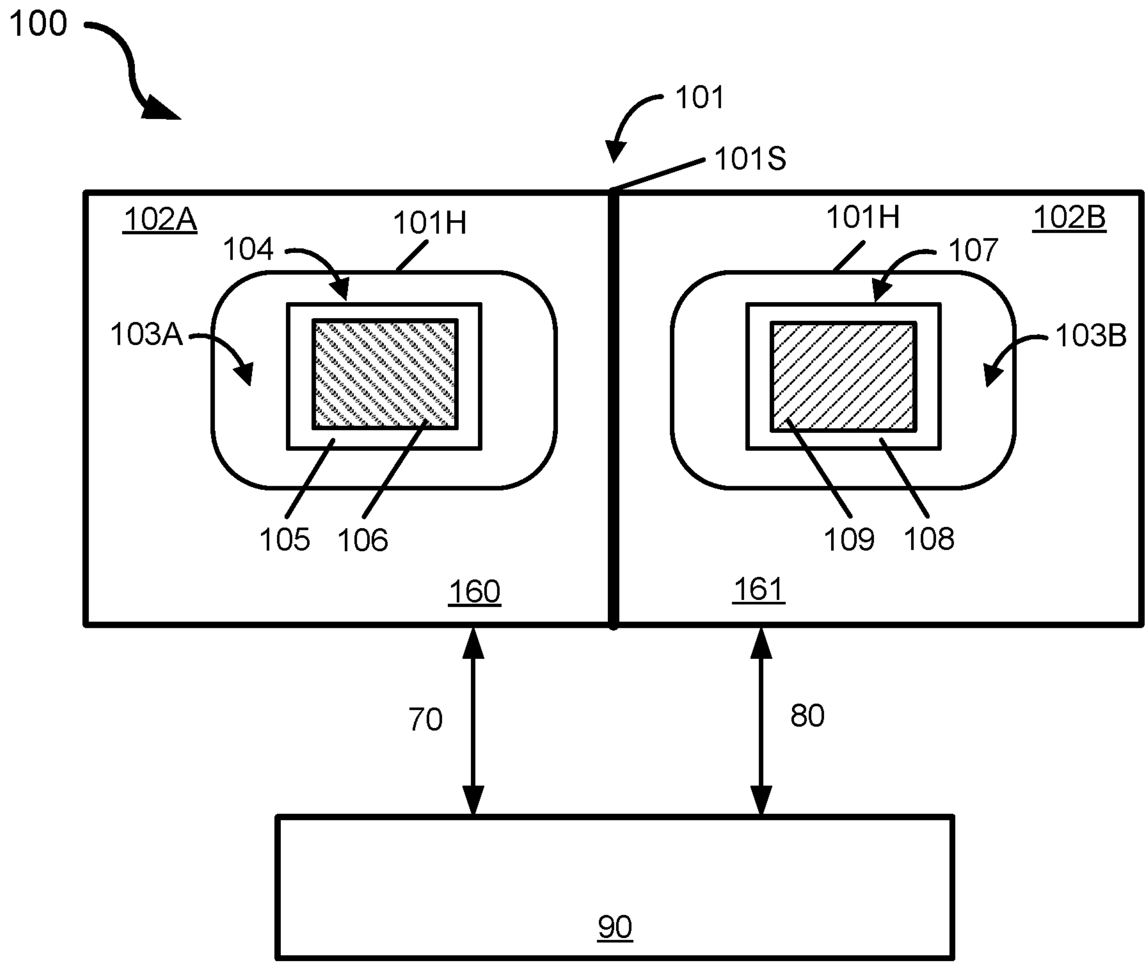
100
101
101S
102A
101H
104
103A
105
106
160
101H
107
102B
103B
109
108
161
70
80
90

FIG. 1A

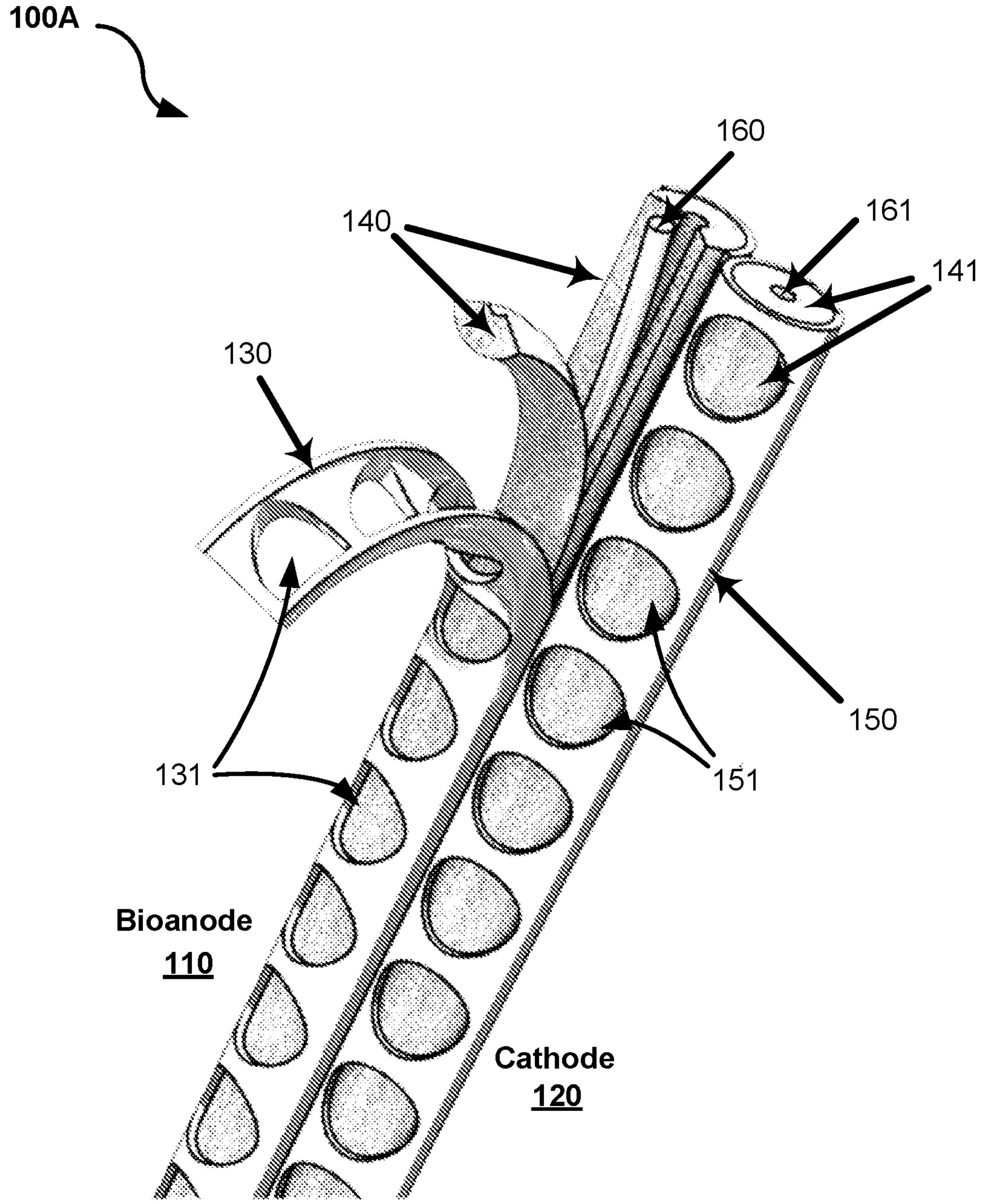

FIG. 1B

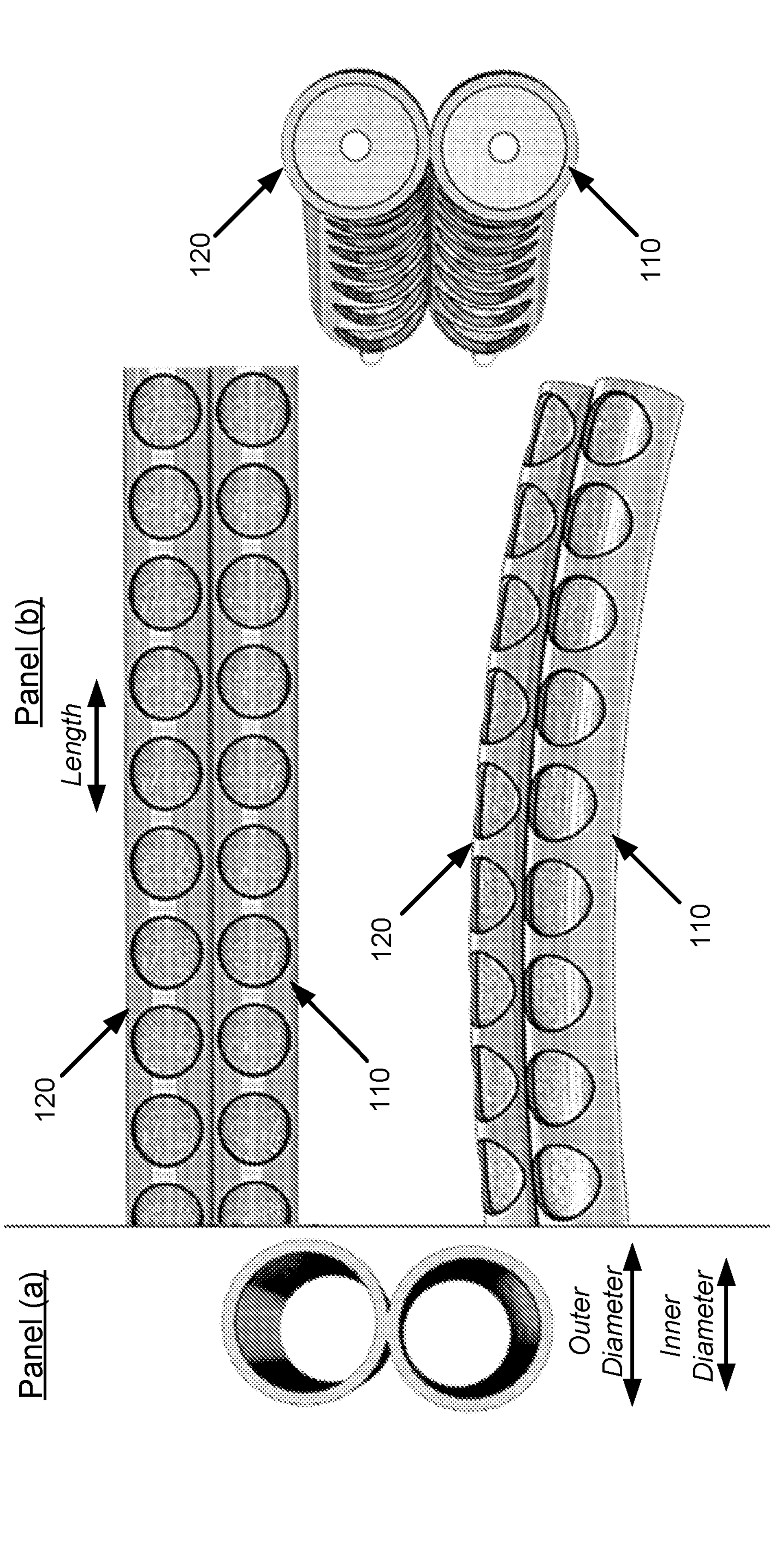
Panel (a)
Outer Diameter
Inner Diameter
Panel (b)
Length
120
110
120
110
120
110

FIG. 1C

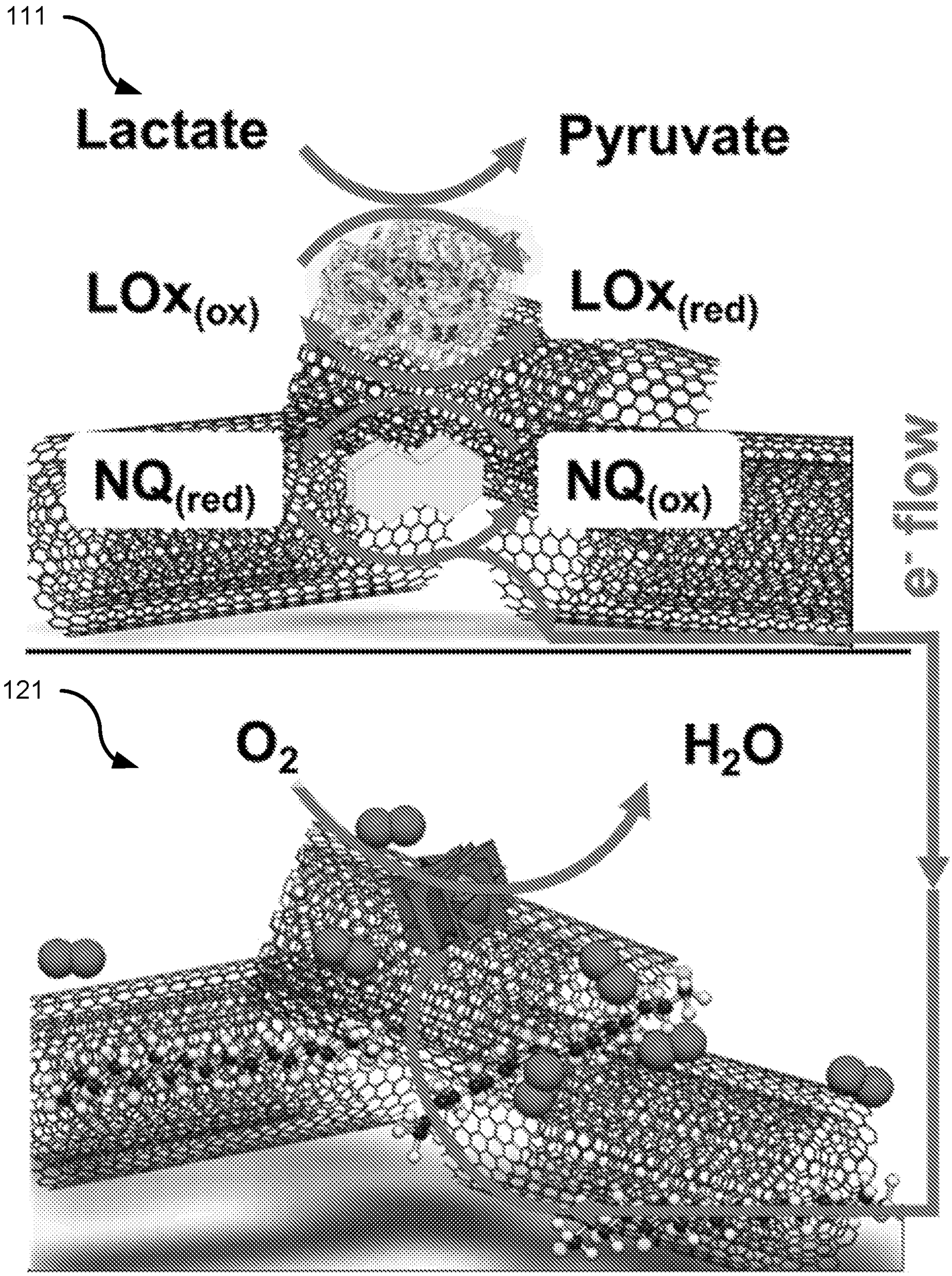
111
Lactate
Pyruvate
LOx(ox)
LOx(red)
NQ(red)
NQ(ox)
e- flow
121
O2
H2O

FIG. 1D

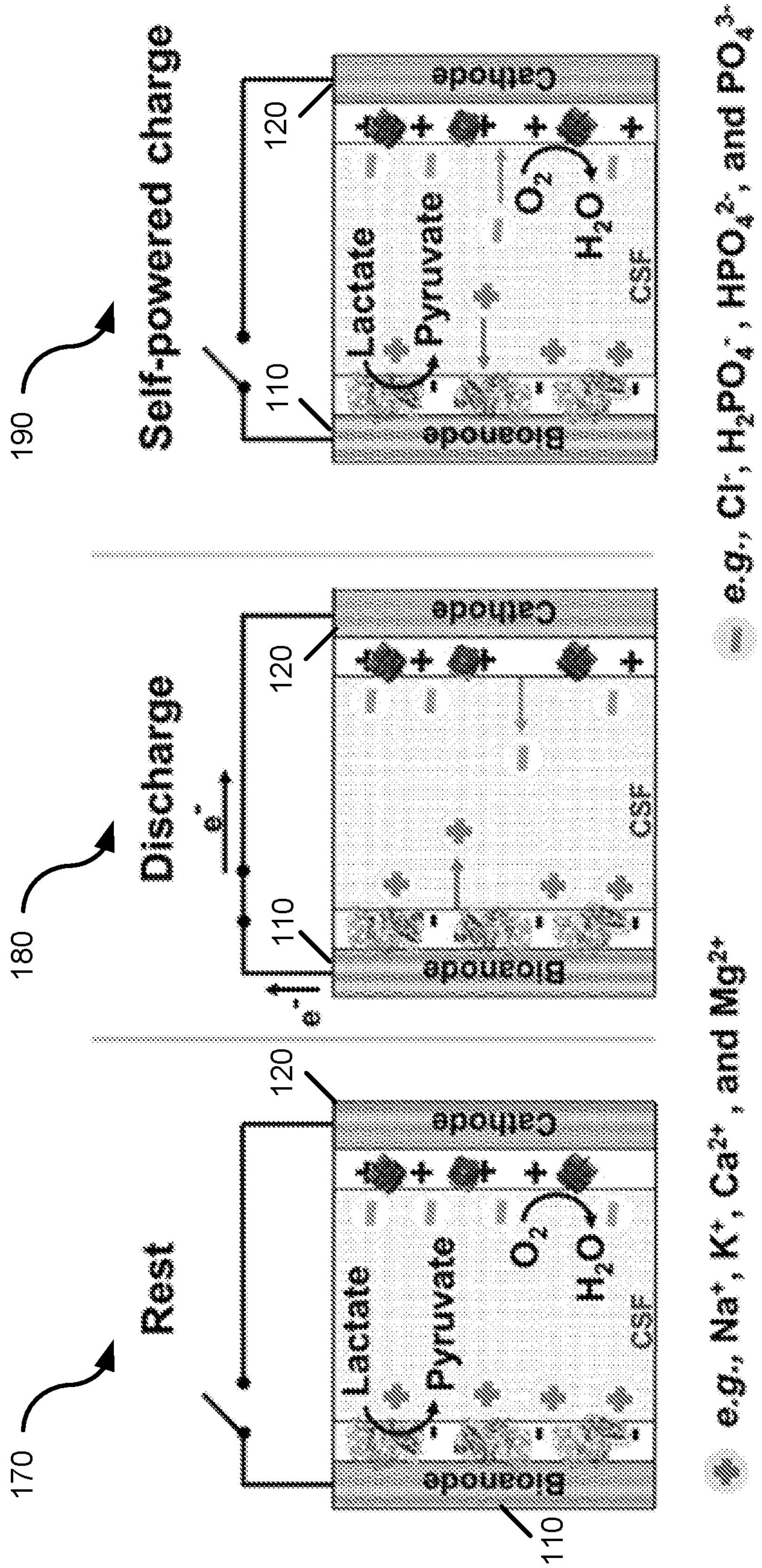
170
Rest
180
Discharge
190
Self-powered charge
110
120
Bioanode
Cathode
Lactate
Pyruvate
O_2
H_2O
CSF
e^-
e.g., Na^+, K^+, Ca^{2+}, and Mg^{2+}
e.g., Cl^-, $H_2PO_4^-$, HPO_4^{2-}, and PO_4^{3-}

FIG. 1E

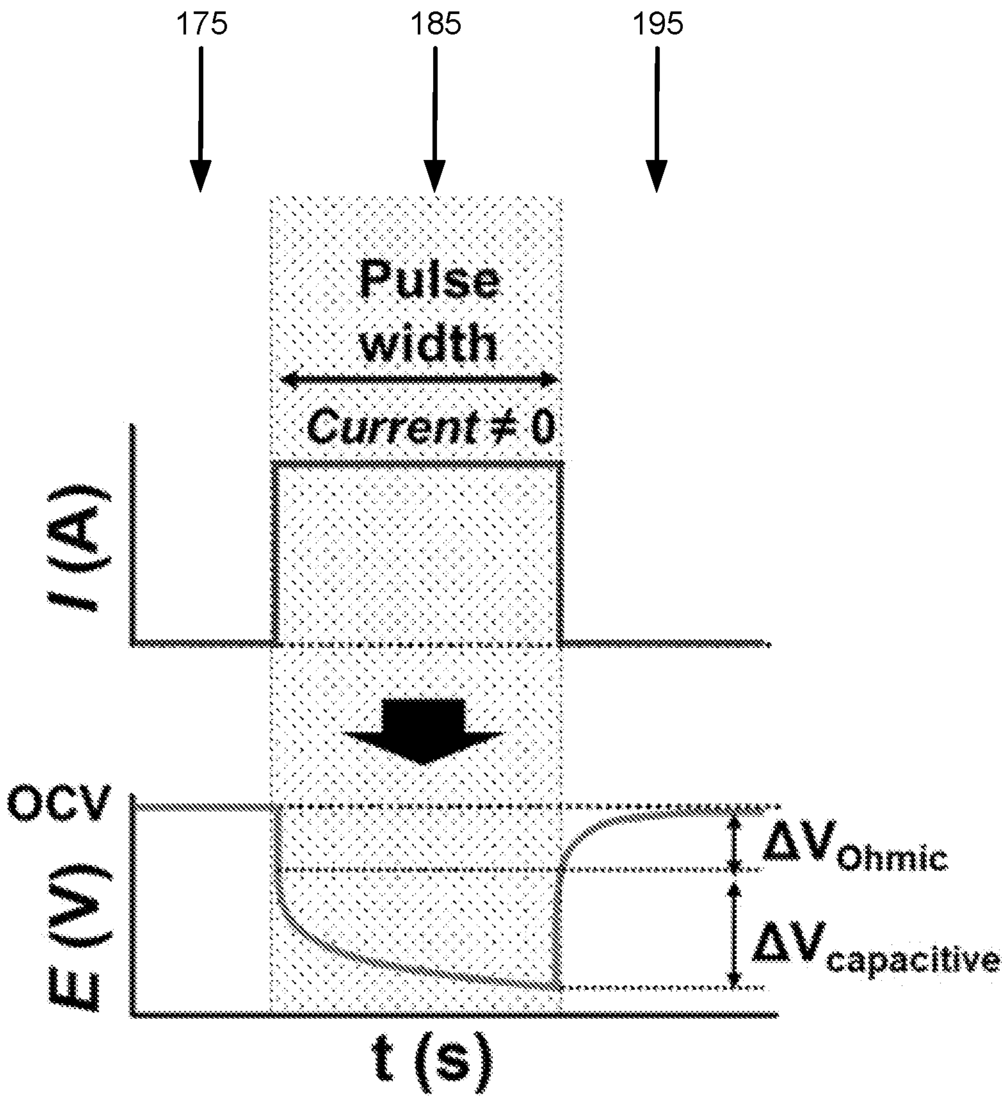
175
185
195
Pulse width
Current ≠ 0
I (A)
OCV
E (V)
ΔV Ohmic
ΔV capacitive
t (s)

FIG. 1F

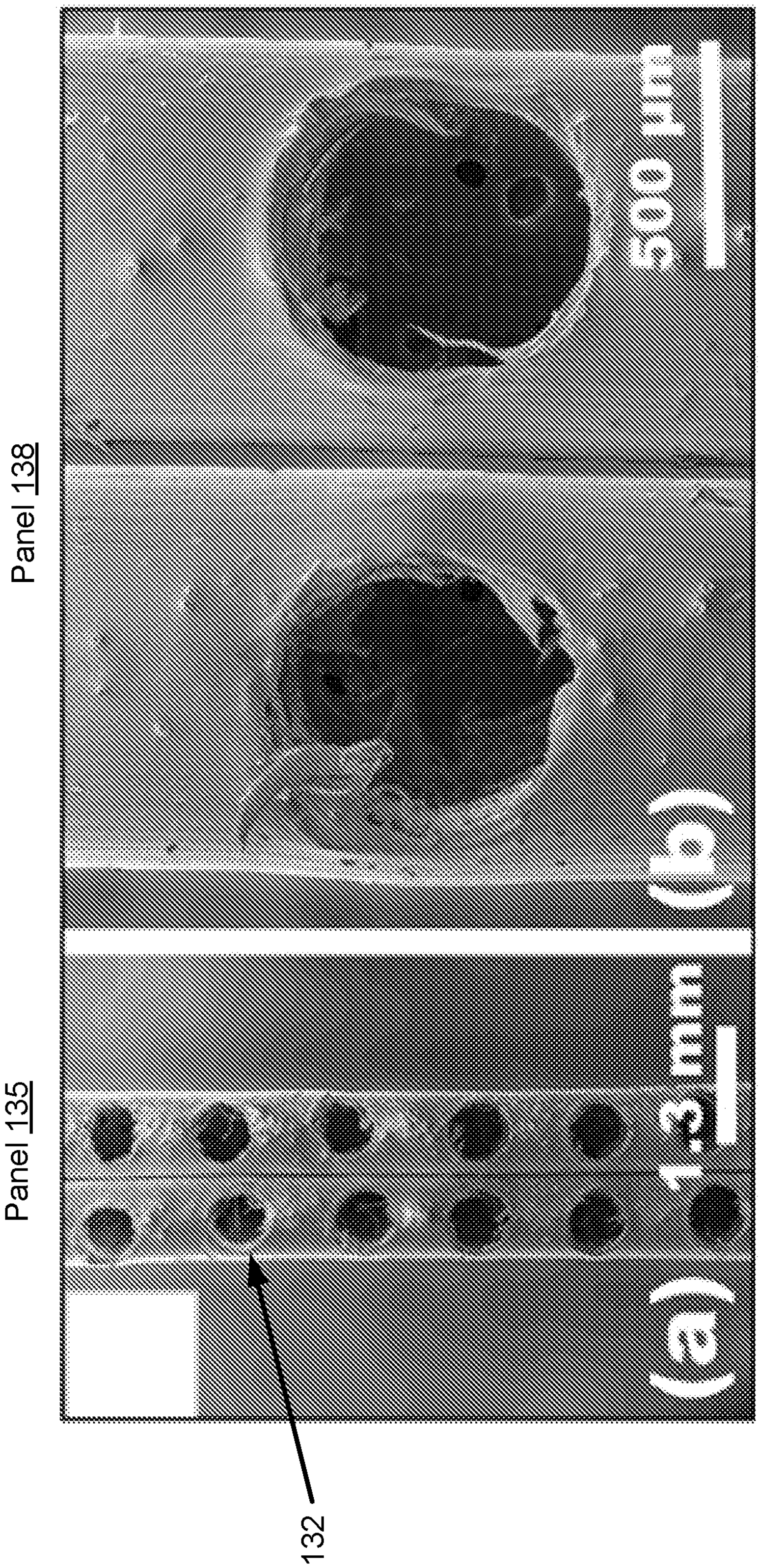

FIG. 2A

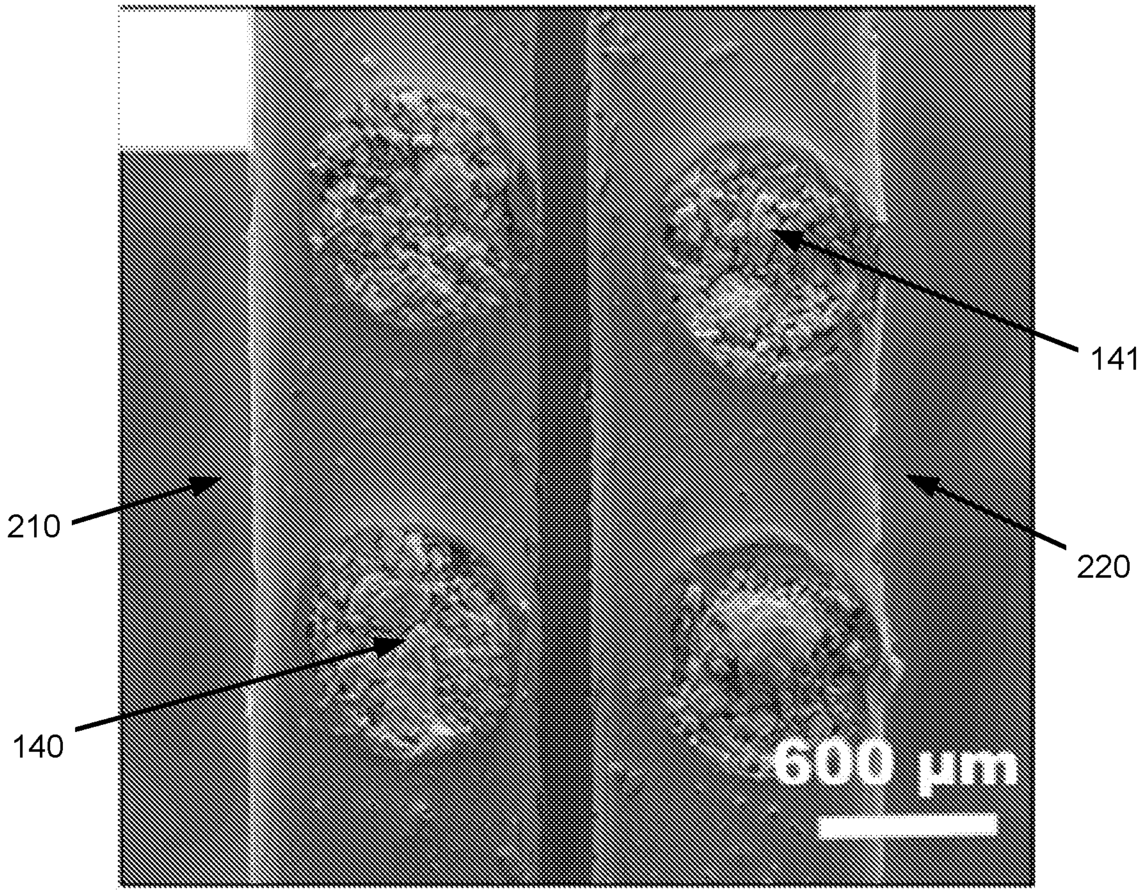

FIG. 2B

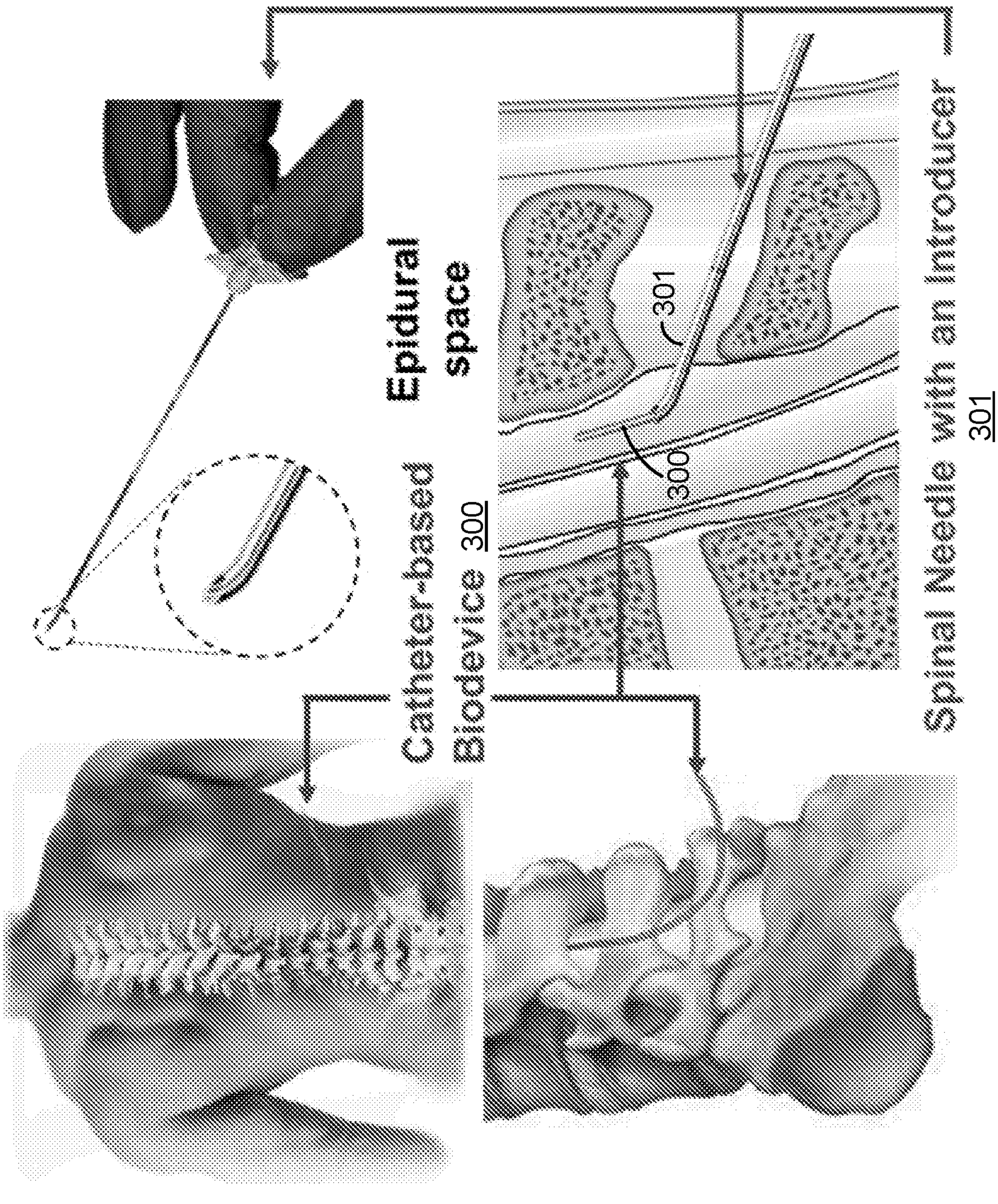
Epidural space
Catheter-based Biodevice 300
301
300
Spinal Needle with an Introducer 301

FIG. 3A

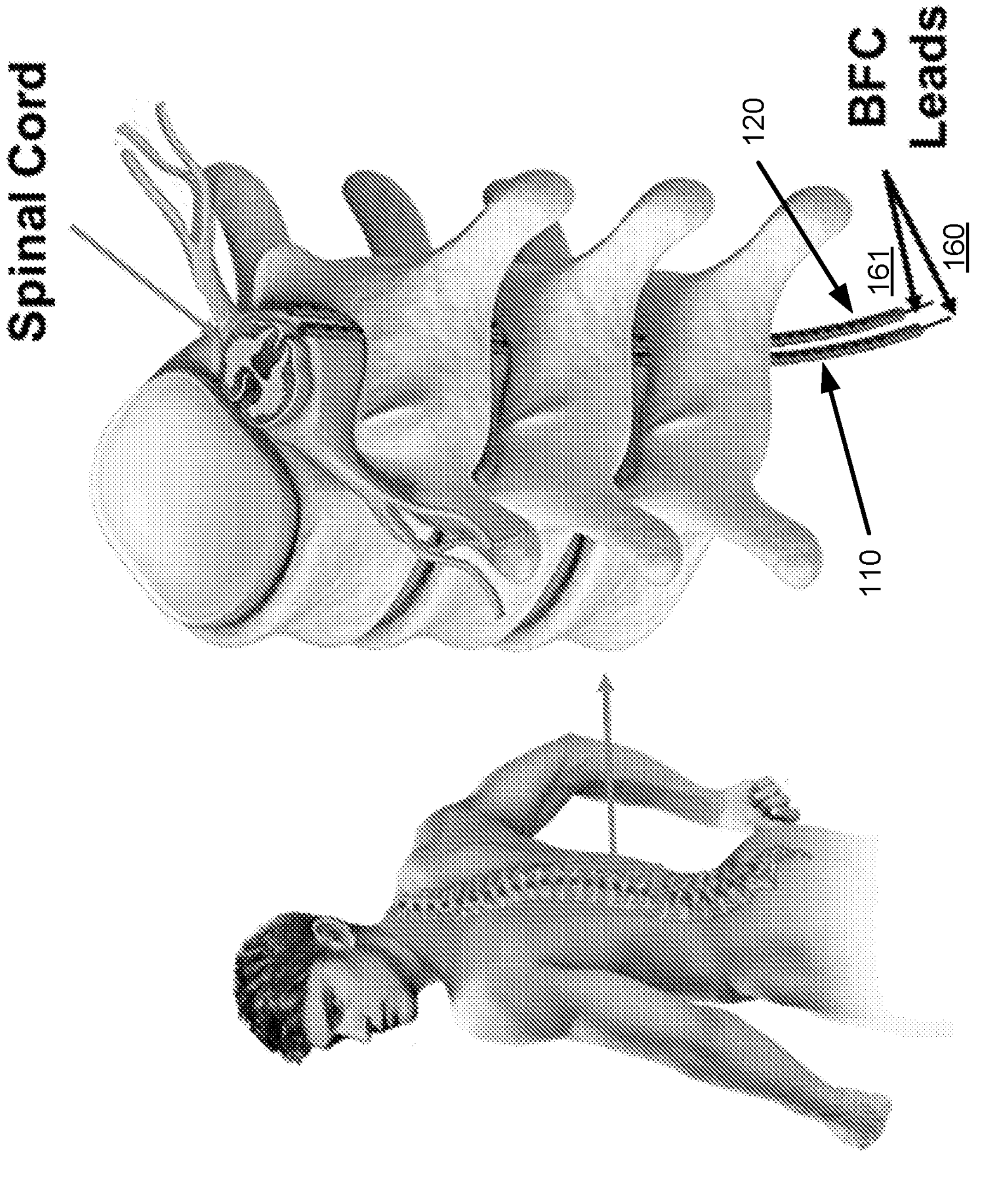

FIG. 3B

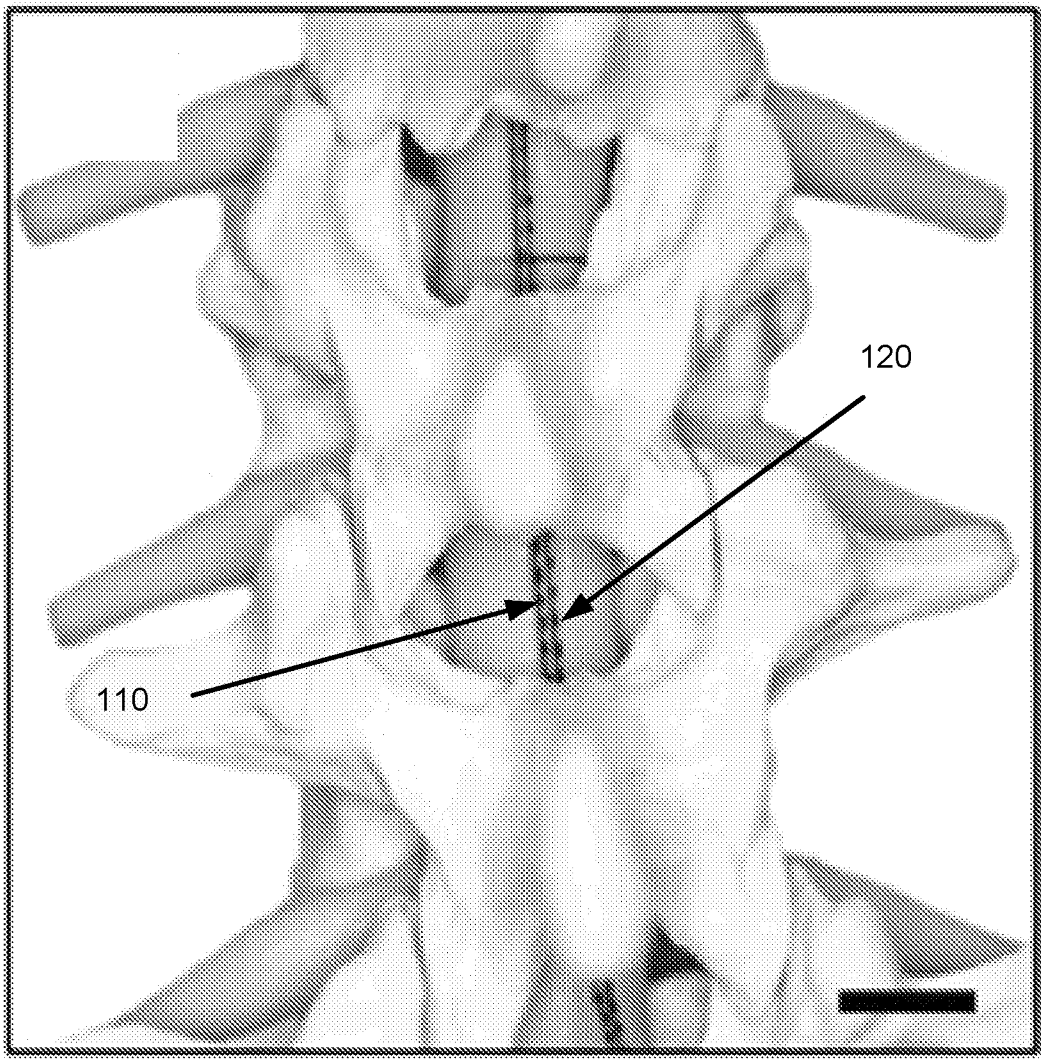

FIG. 3C

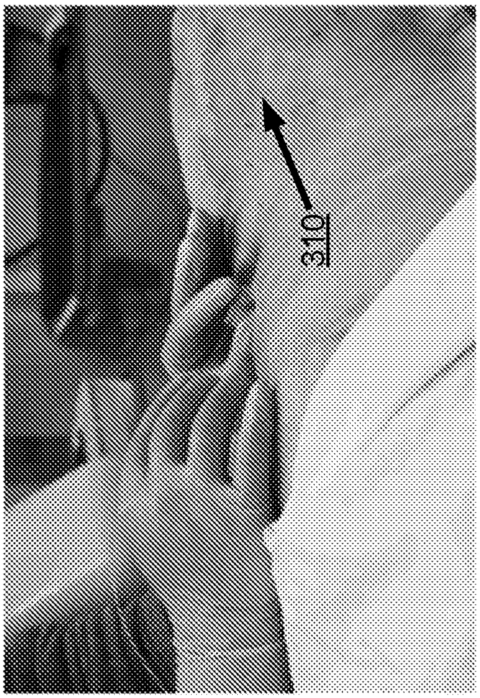

FIG. 3D

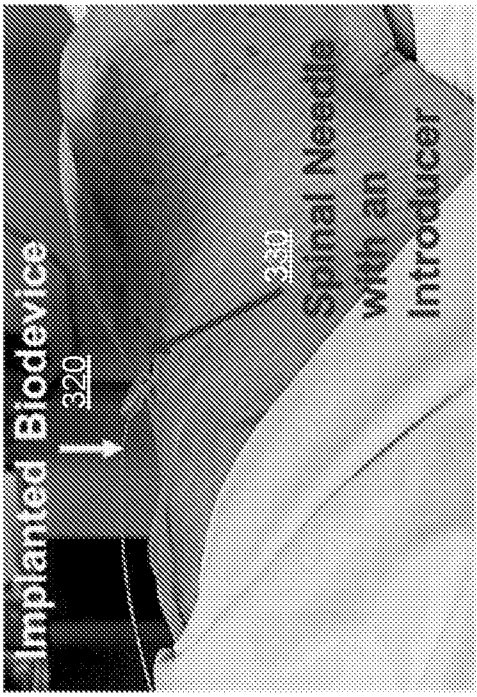

FIG. 3E

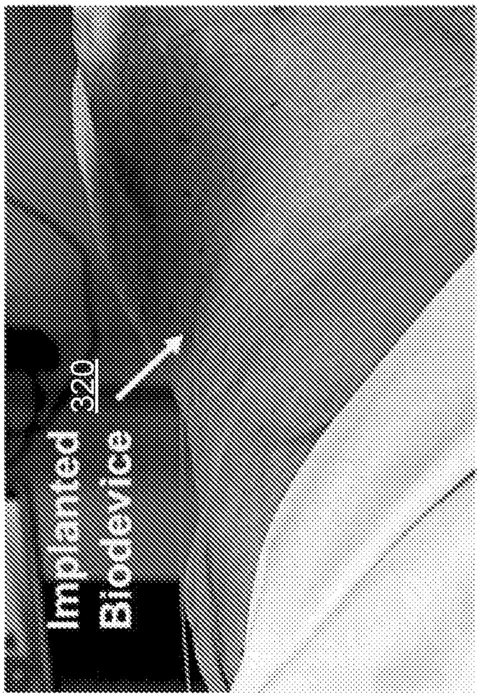

FIG. 3F

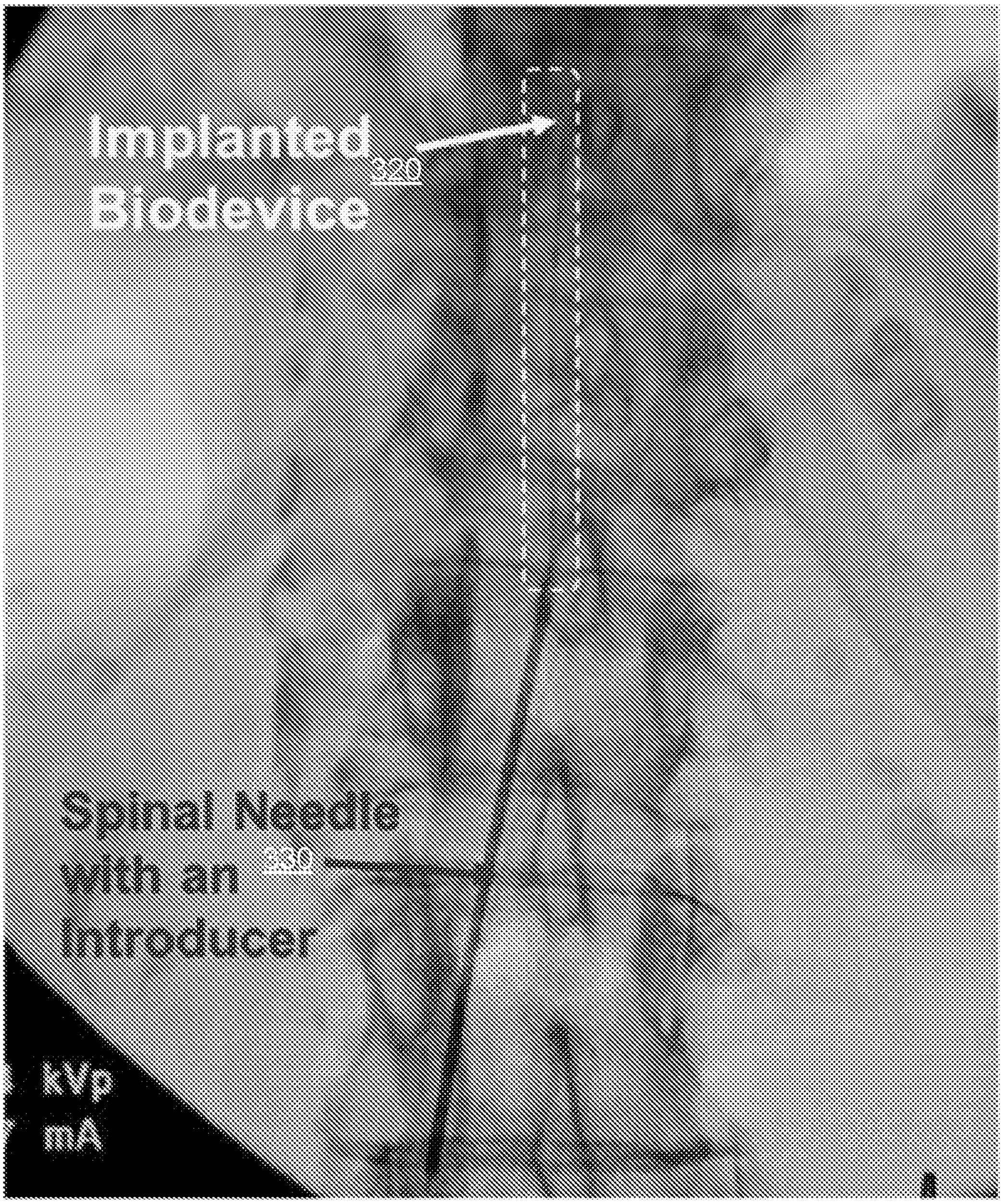
Implanted Biodevice
320
Spinal Needle with an Introducer
330
kVp
mA

FIG. 3G

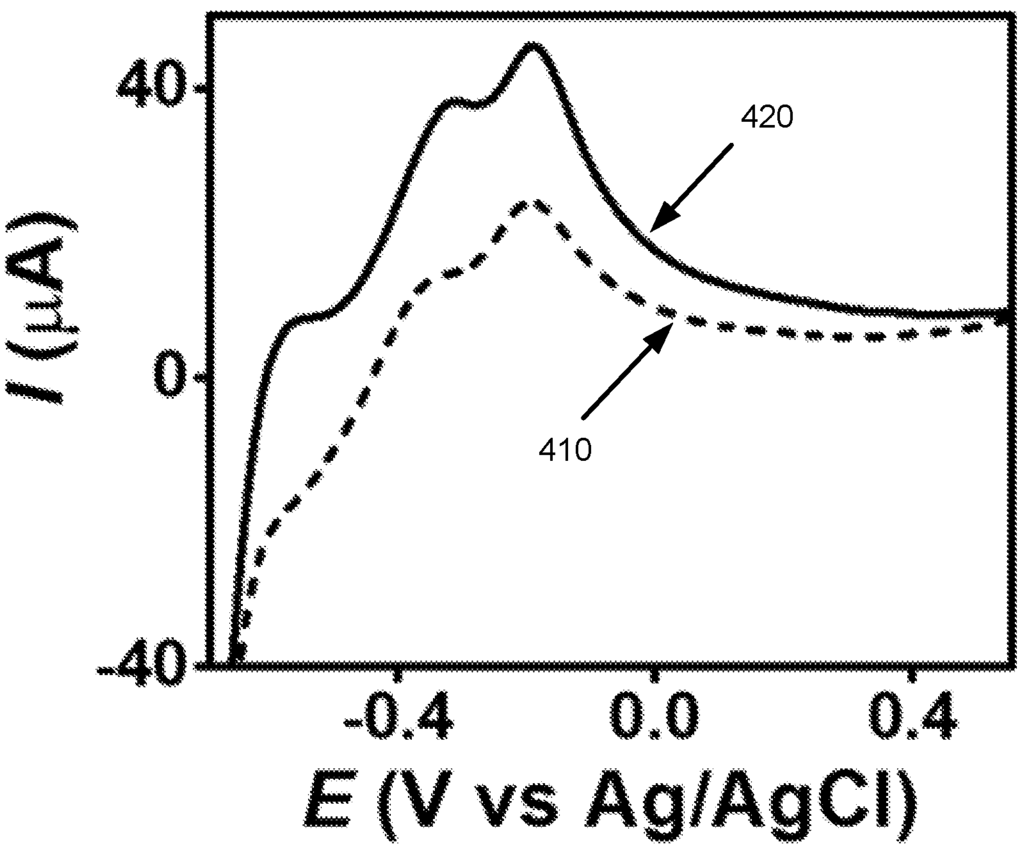

FIG. 4A

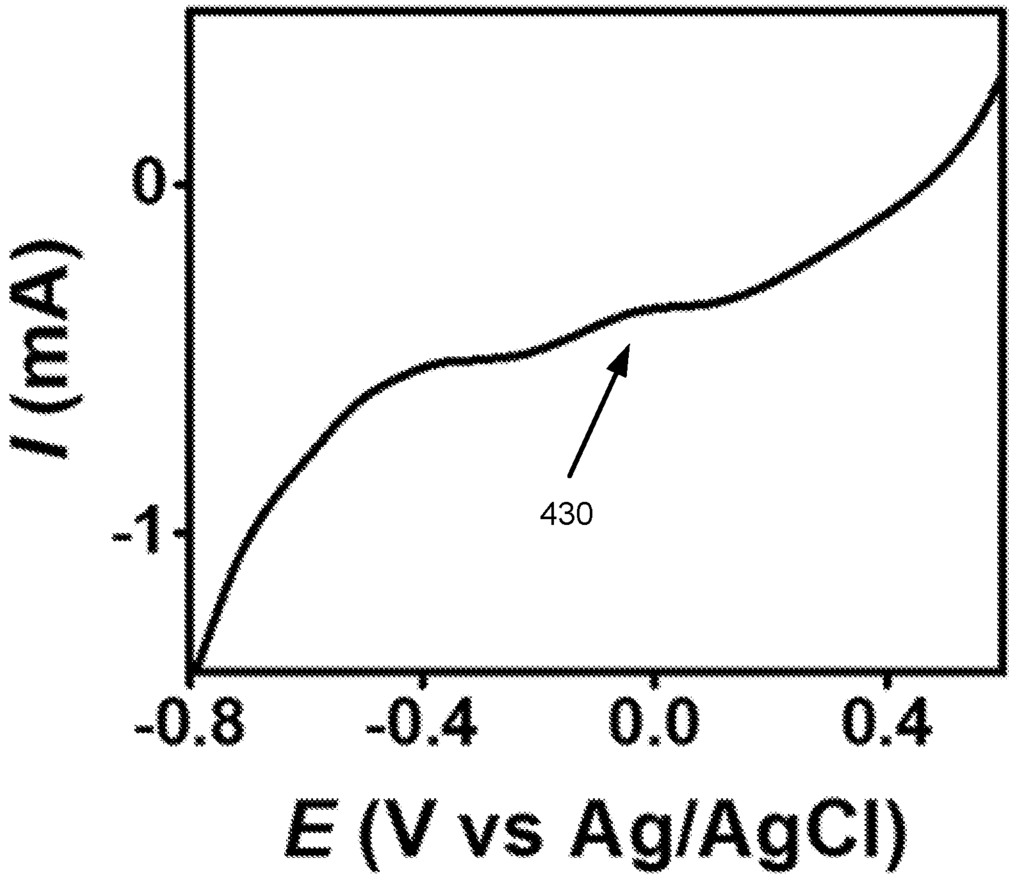

FIG. 4B

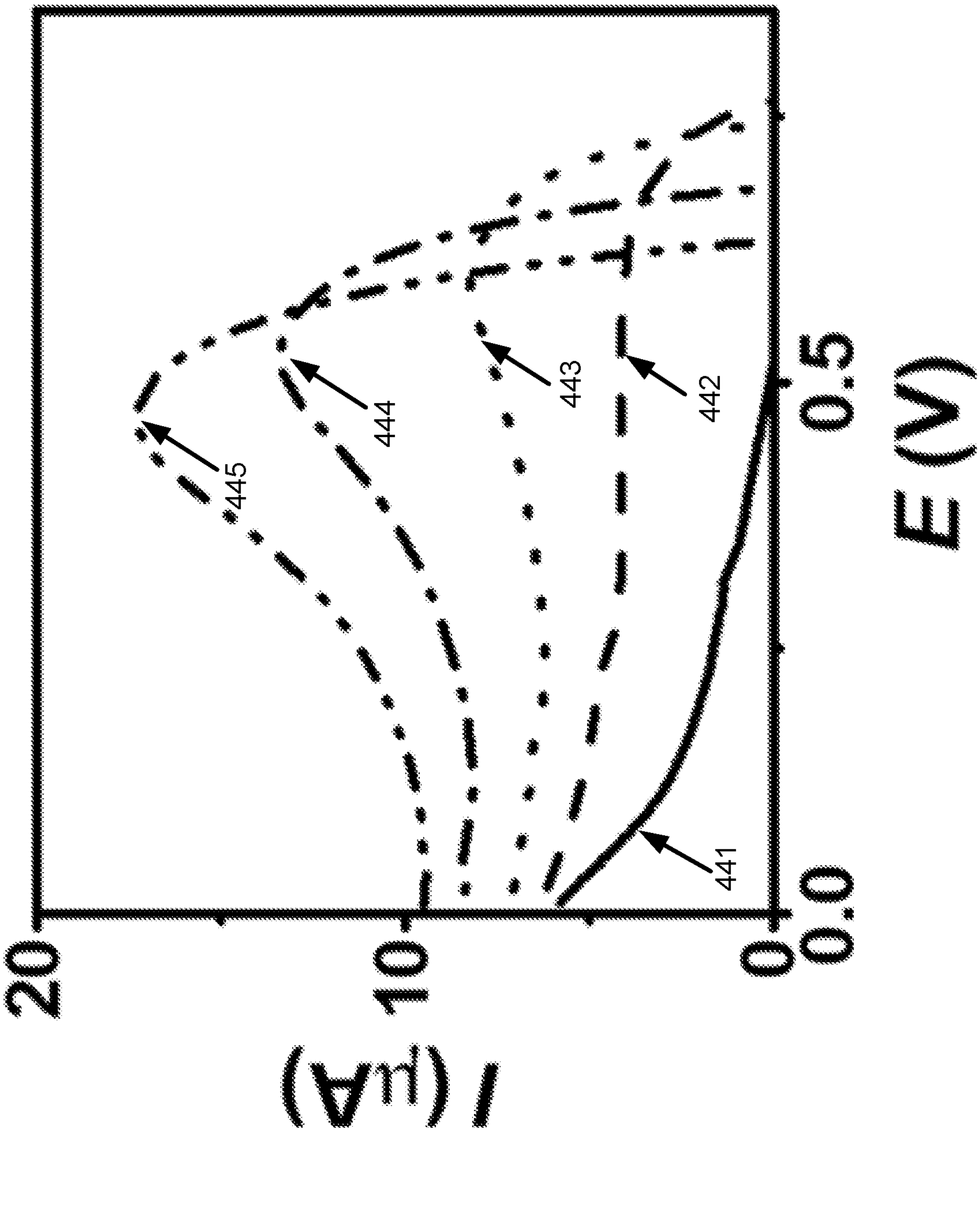

FIG. 4C

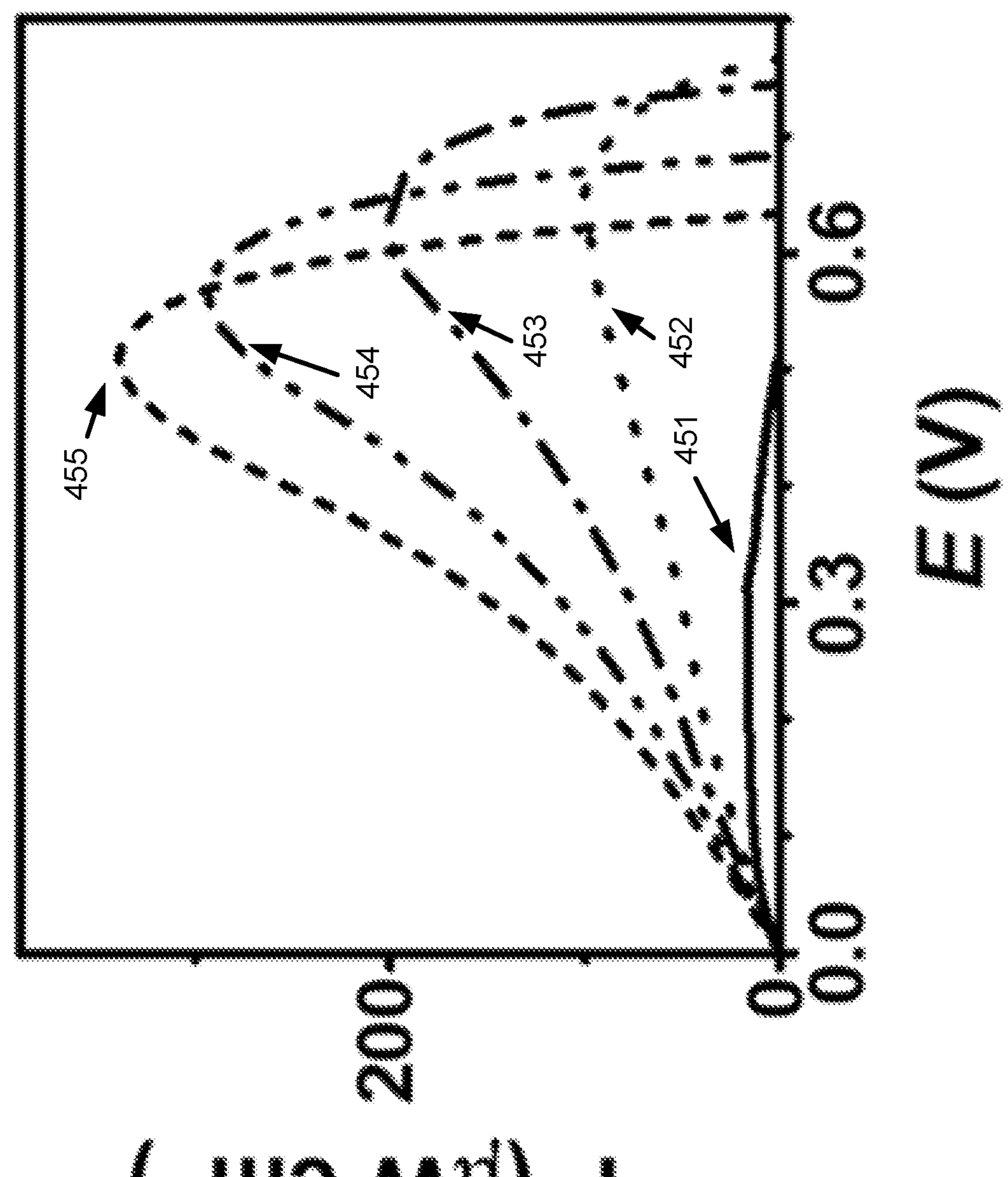

FIG. 4D

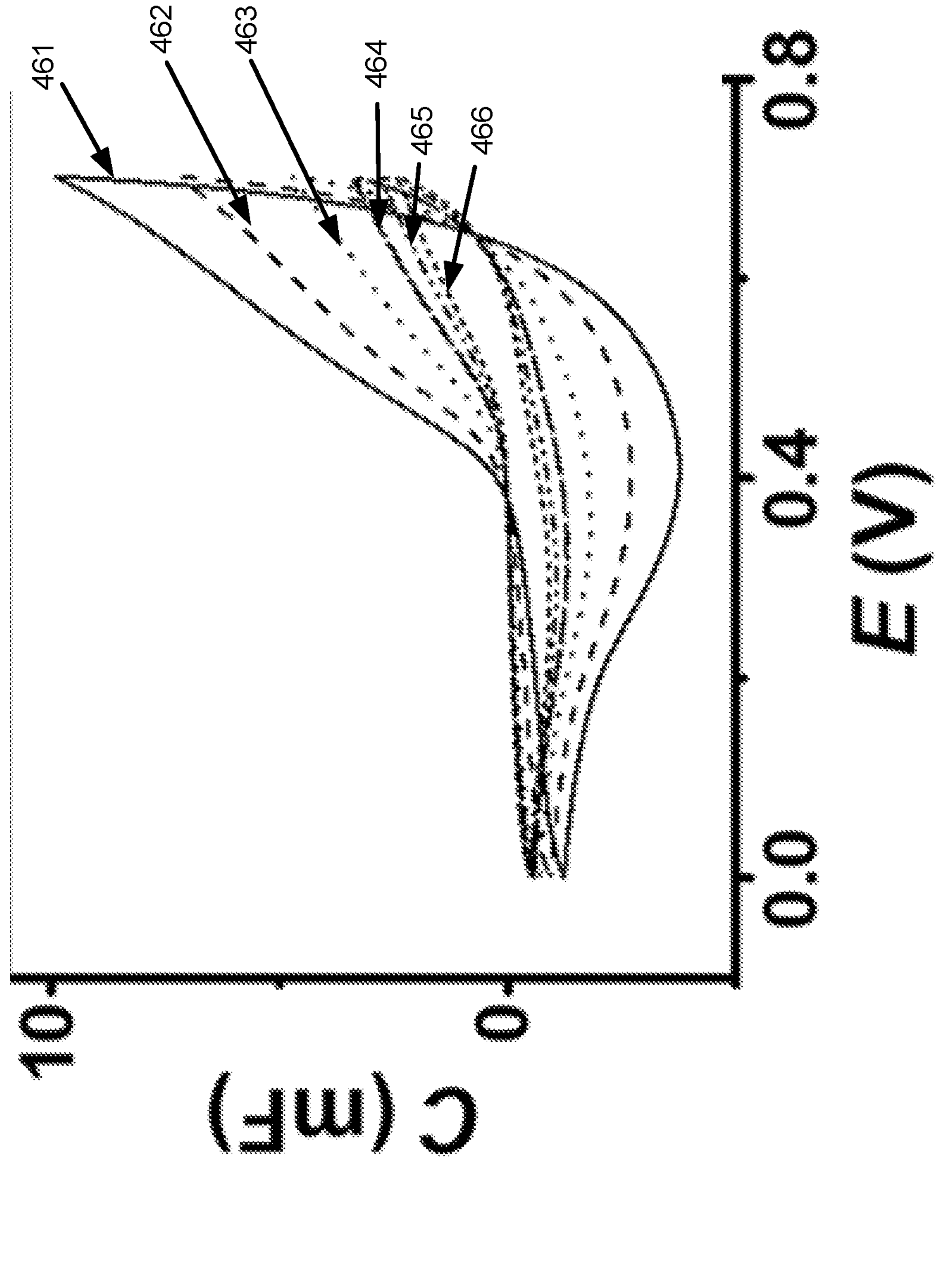

FIG. 4E

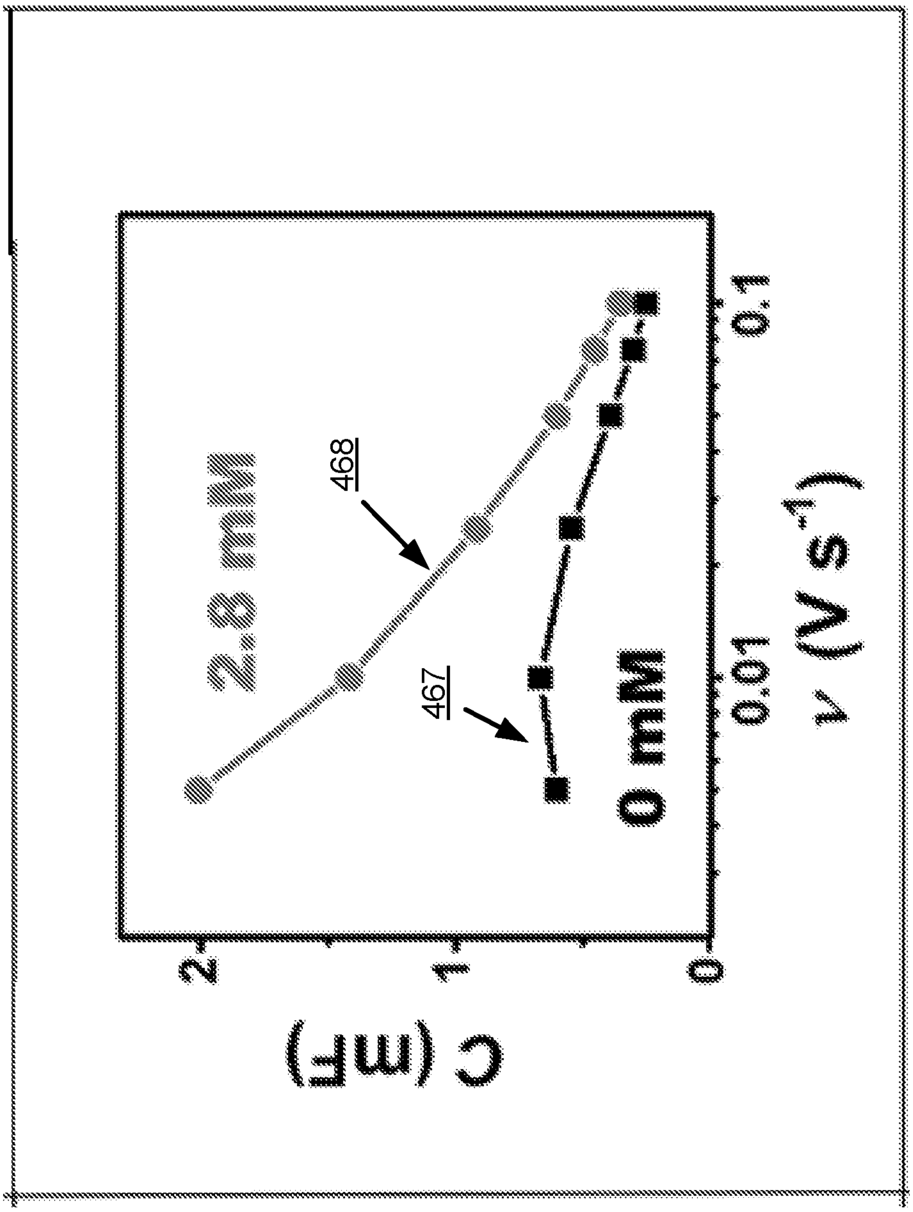

FIG. 4F

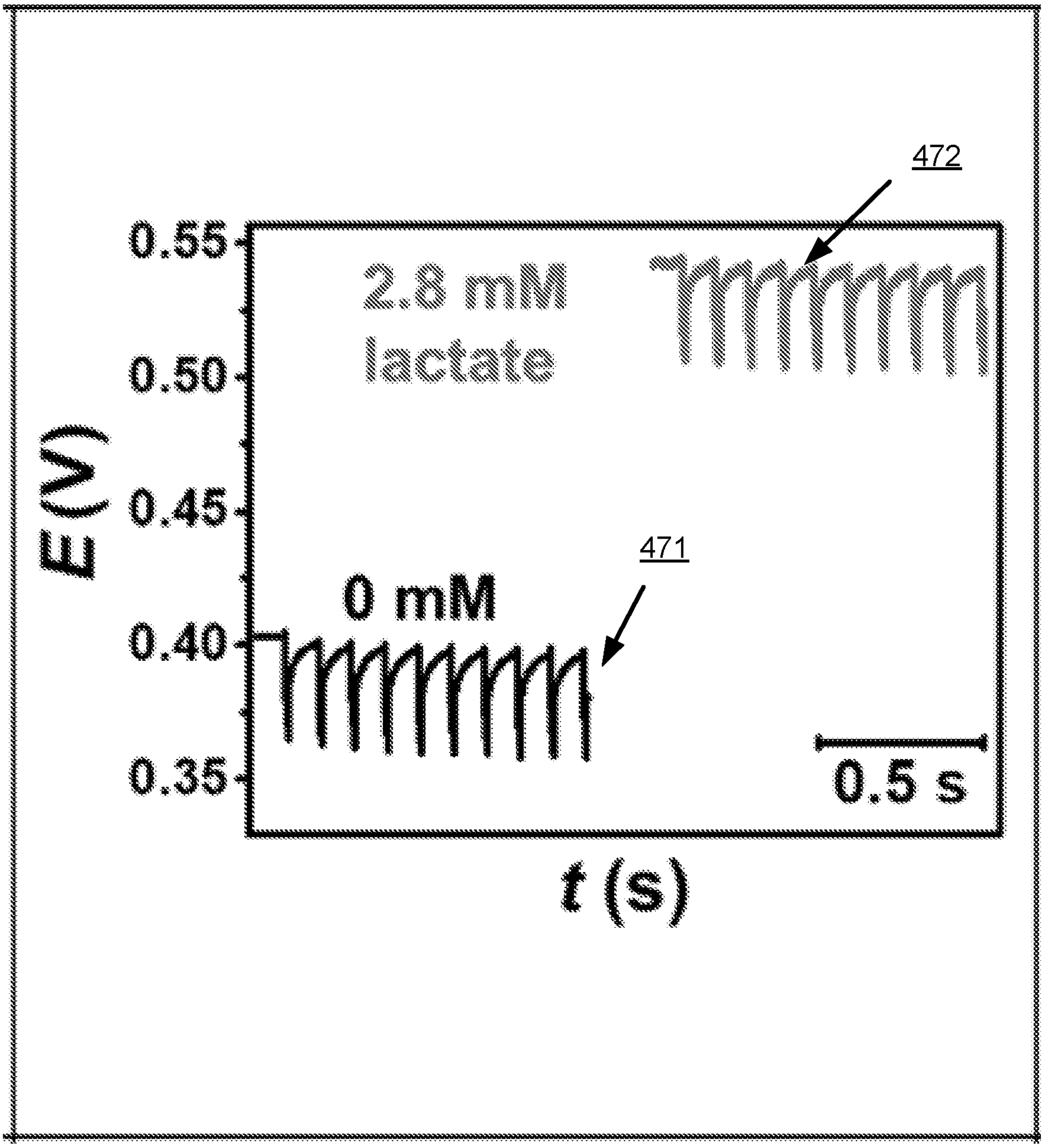

FIG. 4G

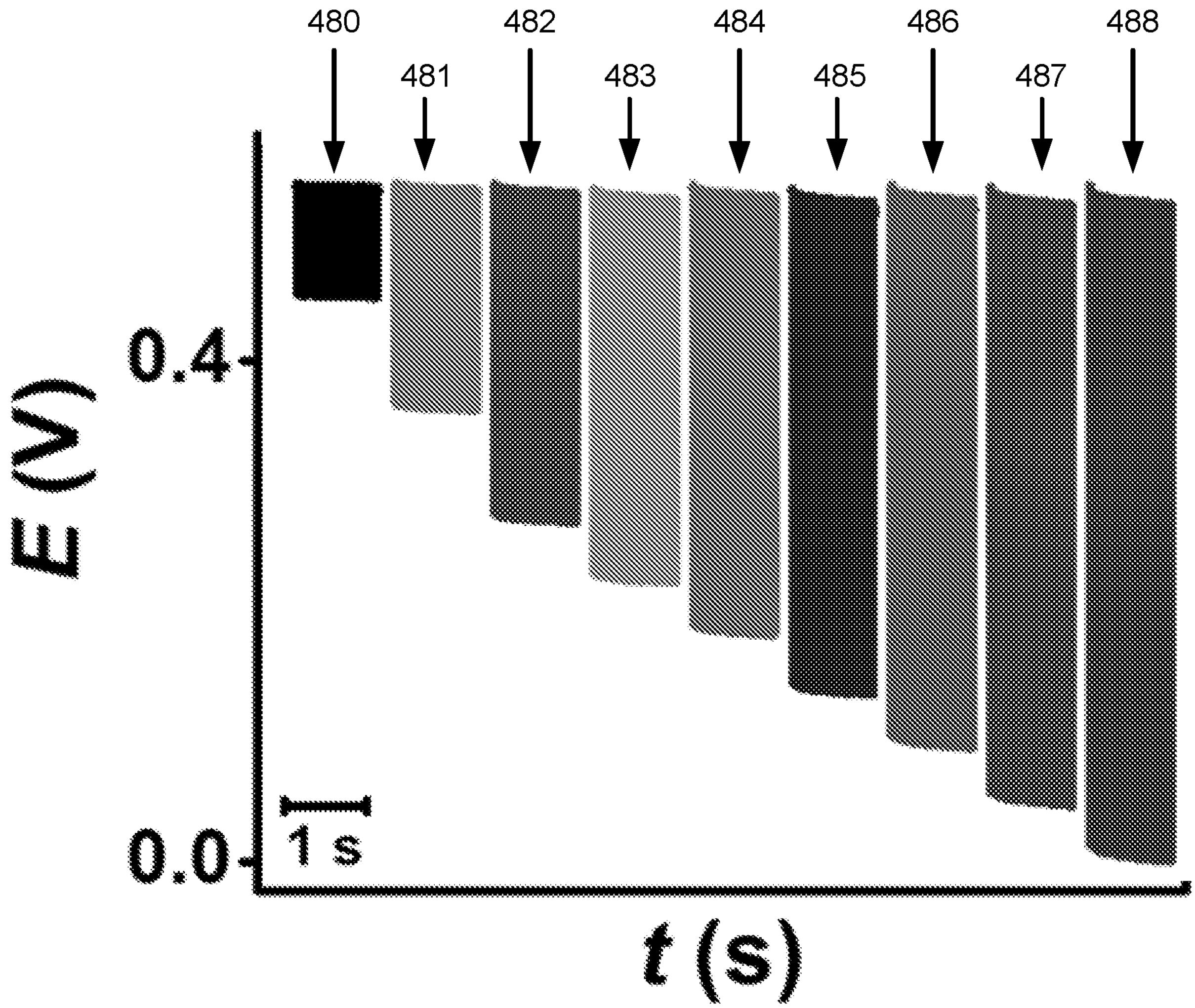

FIG. 4H

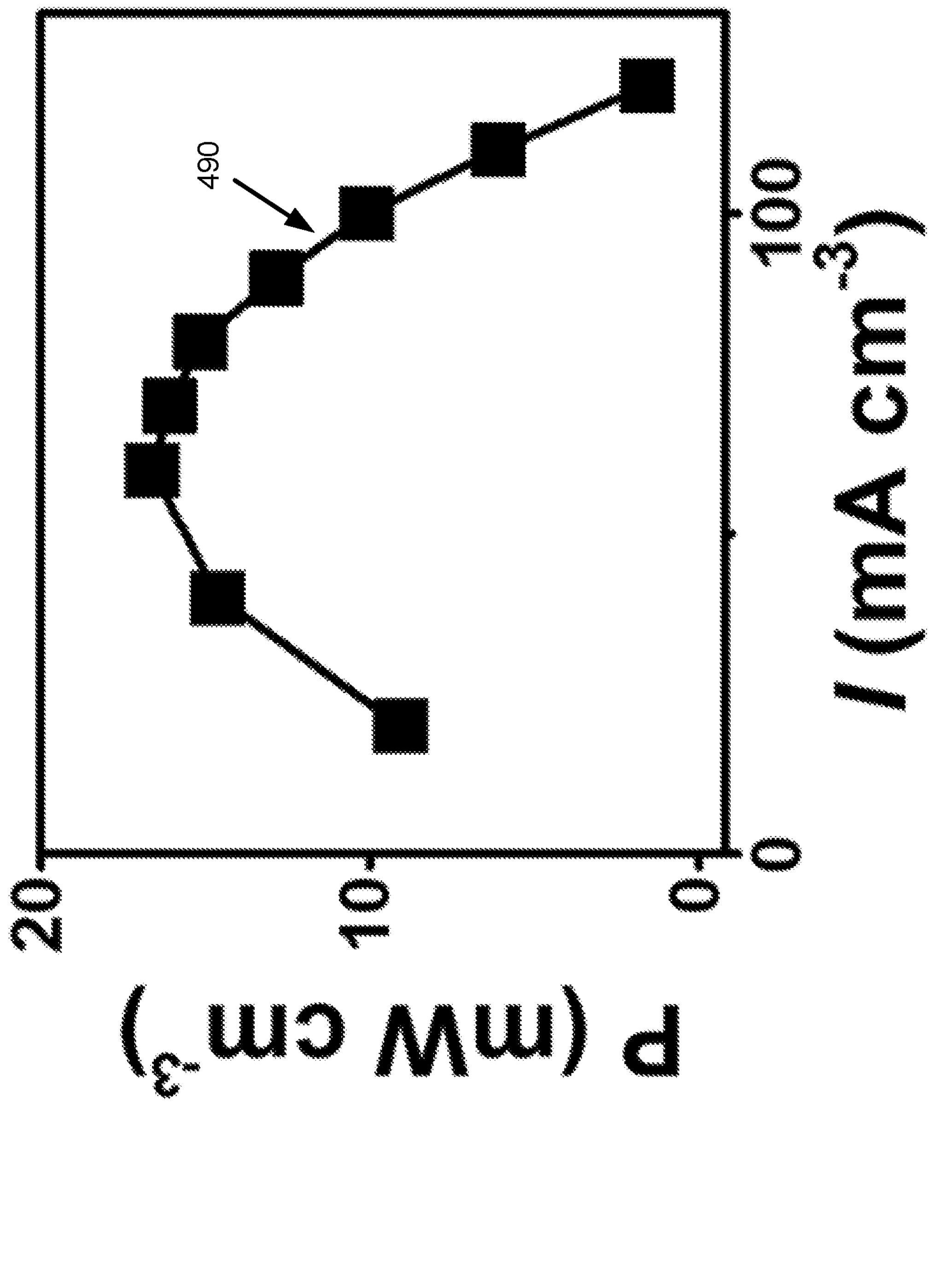

FIG. 4I

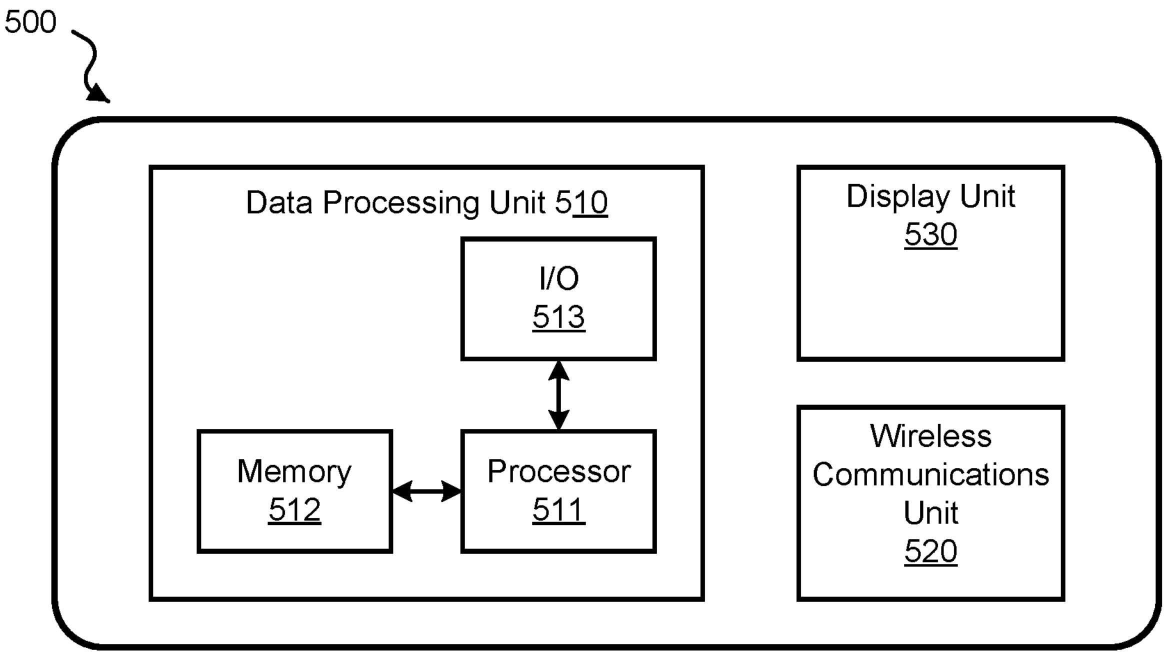
500
Data Processing Unit 510
I/O
513
Memory
512
Processor
511
Display Unit
530
Wireless
Communications
Unit
520

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/61537

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 25/00; H01M 8/00, 8/02, 8/16 (2020.01)

CPC - A61M 25/00; H01M 8/00, 8/02, 8/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y --- A	US 2009/0305089 A1 (MINTEER, S et al.) 10 December 2009; figures 18, 19b, paragraphs [0043], [0044], [0046], [0051], [0107], [0124], [0134], [0146]-[0149], [0154], [0159], [0166]	1 --- 2, 3, 18, 19, 29-34 --- 20
Y --- A	US 2005/0118494 A1 (CHOI, S) 02 June 2005; figure 1A, paragraphs [0052], [0054]	2, 3/2, 29-34 --- 20
Y --- A	WO 2008/035258 A2 (KONIN-KLUKE PHILIPS ELECTRONICS N.V.) 27 March 2008; page 10, lines 1-2, page 11, lines 5-6, 15-17	3 --- 20
Y	US 6,862,479 B1 (WHITEHURST, T et al.) 01 March 2005; abstract, column 8, lines 28-38, column 10, lines 62-65	18, 19
Y	US 2017/0242271 A1 (JOHNSON & JOHNSON VISION CARE, INC.) 24 August 2017; paragraph [0095]	33, 34

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

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 January 2020 (07.01.2020)	29 JAN 2020
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/61537

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

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

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

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

3. ☒ Claims Nos.: 4-17, 21-28
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.