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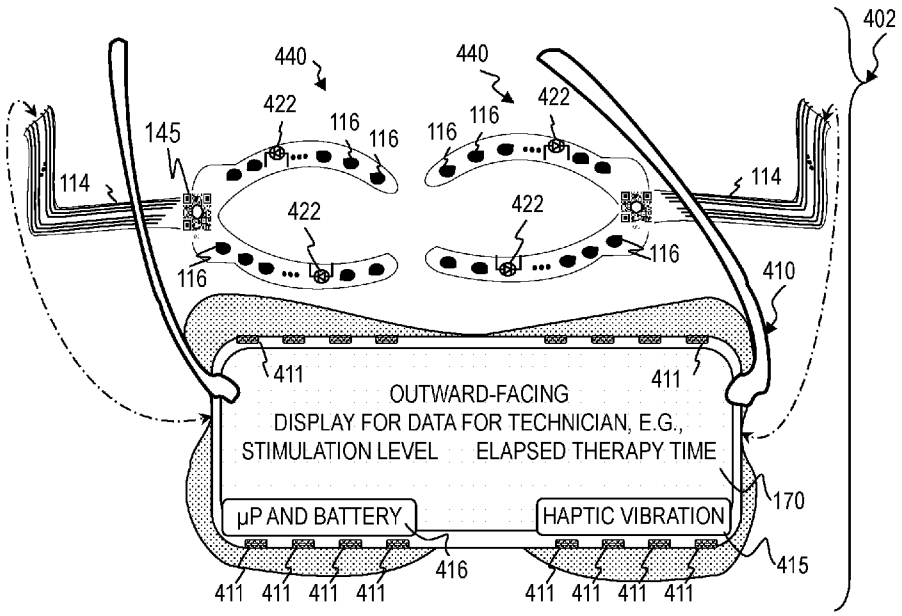

FIG. 4B

(57) Abstract: Apparatus and method for treatment of a human condition and more particularly for applying bio-electric microcurrent stimulation therapy to the human body, via an apparatus which connects to a micro-stimulation current generating device, and application of microcurrent stimulation therapy, that includes a headset device encircling the head, and connected to electrode strips (such as a one-use disposable chip-electrode array having a unique serial number or crypto code and other functionality that is used by the system to look up and deliver customized therapy to a particular patient having their own particular symptoms and medical history), which deliver the stimulation.

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TITLE OF THE INVENTION:

APPARATUS AND METHOD FOR MICROCURRENT STIMULATION THERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority benefit, including under 35 U.S.C. §119(e), of U.S. Provisional Patent Application No. 62/783,116 filed December 20, 2018 by Marshall T. Masko, et al., titled "Apparatus and Method for Microcurrent Stimulation Therapy," which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to treatment of a human condition and more particularly to an apparatus and a method for applying bio-electric microcurrent stimulation therapy to the human body, via an apparatus which connects to a micro-stimulation current generating device, and application of microcurrent stimulation therapy, that includes a headset device encircling the head, and connected to electrode strips (such as a one-use disposable chip-electrode array having a unique serial number or crypto code and other functionality that is used by the system to look up and deliver customized therapy to a particular patient having their own particular symptoms and medical history), which deliver the stimulation. In some embodiments, the apparatus also either contains a stimulation controller device or is connected to a separate control device, via either wired or wireless communications. Some embodiments include applying bio-electric microcurrent stimulation therapy for macular degeneration, retinitis pigmentosa, glaucoma, optic neuritis, Bell's Palsy and other eye diseases to key points around the eye, as well as other diseases requiring localized and precision stimulation on other body parts.

BACKGROUND OF THE INVENTION

[0003] Chronic pain is a problem for millions of individuals throughout the world. One method of treating such pain is to provide microcurrent stimulation around or near the areas where the pain is occurring. Microcurrent, which typically is defined as current below 1 milliamp, can provide rapid and long-lasting pain relief for a wide variety of pain syndromes.

Generally, microcurrent stimulation therapy typically includes applying a current in the range of about 20 to about 300 microamps to the affected area. The current blocks neuronal transmission of pain signals and stimulates the release of endorphins to help relieve the pain in chronic and acute pain patients. Within certain levels of this range, the microcurrent mimics the body's own electrical current level and is what we term "bio-electric current."

[0004] In addition to chronic pain relief, microcurrent therapy is being used to treat a number of visual diseases, including macular degeneration, retinitis pigmentosa, and glaucoma, among other eye diseases. It is believed through secondary literature that this microcurrent treatment stimulates blood flow, increases ATP (adenosine triphosphate) at the cellular level, and enhances cellular permeability. Further, it is believed such stimulation can re-establish functional neural pathways for muscle and brain, as well as for blood vessel and brain.

[0005] 1. PRIMARY DISEASE FOR TREATMENT (AMD)

[0006] Age-related Macular degeneration (AMD) is a very common eye disease, affecting more people than glaucoma. Macular degeneration is the most frequent cause of blindness for patients aged 60 and above in the United States, and is estimated to affect over 10 million Americans. (Source: National Health Institute). Macular degeneration results in the deterioration of various retinal tissues in the region of the macula, the central, most sensitive light-sensing area of the retina responsible for detailed central vision. Impaired blood circulation in the central retina, with partial to full corresponding vision loss, is a typical consequence of macular degeneration.

[0007] COSTS OF HEALTHCARE AND EYE CARE

[0008] The U.S. spends $2.7 trillion in healthcare each year, of which eye care represents roughly three percent or $60-$70 billion of the total. According to Eurostat, the European Union (EU) spends 45.7% of that amount or about $1.23 trillion. Expenditures for eye care are growing at six percent annually. According to the National Institutes of Health (NIH), it is expected to continue to grow at least six percent over the next several decades, driven by the aging population.

[0009] Macular degeneration causes about $184 billion in lost productivity each year and approximately $51 billion is spent treating macular degeneration each year in the United States. 90% of macular degeneration cases are the "Dry" or non-bleeding form, termed "Atrophic AMD," and about 10% of cases are the "Wet" or bleeding form, termed "Exudative AMD."

[0010] DISEASE PREVALENCE

[0011] Because there is currently no approved treatment for dry AMD, little research has been done on the market potential. There is, however, significant data on the large numbers of people affected by AMD and is estimated to cause about 8.7% of blindness and low vision globally. According to a report from the World Health Organization, "AMD is the primary cause of blindness in the developed countries and the third leading cause worldwide." The prevalence of AMD in Europe is estimated to be: 16.3 million people (excluding southeastern and Eastern Europe), and in the United States 10.2 million people. (Source: www.wrongdiagnosis.com).

[0012] Further, this increases to a combined total of 41 million when adding in Canada, Australia/New Zealand, Russia, and Japan. Ninety percent (90%) of these cases are dry AMD for which there is no currently approved treatment to restore vision.

[0013] Approximately 25% of the population (in the target markets, aged 65 to 75 years old) has AMD, and this increases to 35% for ages 75 and older. Within the next 10 to 20 years, as baby boomers reach their mid-sixties and older, the prevalence of the disease is projected to dramatically increase. In a study funded by the U.S. Centers for Disease Control and Prevention, researchers reported that as many as 9.1 million people in the U.S. had AMD in 2010 and 17.8 million would have it by 2020.

[0014] CAUSES OF AMD

[0015] Normal retinal cell function is a photochemical reaction converting light energy to an electrical impulse which travels to the brain and vision occurs. With AMD and other visual system diseases, diseased, inflamed retinal cells eventually lose cell function. Adenosine triphosphate (ATP) levels drop, protein synthesis drops, the electrical resistance goes up, and cell membrane electrical potential goes down. Basically, the cells would appear to go dormant for a time before they die.

[0016] It is believed that, when electrical stimulation is provided to the cells before they die, blood vessel permeability is increased, normal cellular electrical potential is achieved, the ATP levels increase, protein synthesis will occur again, and normal cell metabolism is restored thereby improving or restoring vision loss. In addition, in vitro studies have demonstrated that electrical stimulation appears to have a healing effect on the small blood vessels in the retina, promoting a more efficient delivery of nutrients to the retinal cells and a more efficient elimination of metabolic by-products.

[0017] The retinal pigment epithelium (RPE) is the support-cell complex for the photosensitive rod and cone cells which make up the light-sensing retina. The RPE is the first to be affected by circulation impairment. Once affected by poor circulation, the RPE cannot efficiently assist the rods and cones in removing the metabolic and photochemical response by-products, which are common during cellular function. Yellowish-colored sub-retinal deposits called "drusen" form when extracellular by-products are not carried away by blood circulating through the eye. As a result, the photoreceptor cells in the macula enter a dormant, toxic state and do not respond to light. If normal retinal cellular metabolism is not restored, the cells die and visual acuity is permanently lost. Thus, it is believed that microcurrent stimulation will help rejuvenate the cells in the retina to slow or stop degeneration of the eye due to AMD.

[0018] 5. POTENTIAL TREATMENT/SOLUTION

[0019] Clinical studies have demonstrated that with the proper bio-electric microcurrent stimulation waveform and therapy procedure, AMD may be slowed or stopped in a large number of people suffering from the disease. But, the efficacy of these therapies can be affected by the manual techniques medical professionals use to administer said therapy. Where patients have significant skin impedance, or there is a poor conductivity, uptake of the stimulation level is limited and will limit the treatment efficacy. This invention, consisting of a headset appliance of electrodes in a circular, or semi-circular fashion around the eye addresses that problem by communicating, via sensors, with an apparatus that generates bio-electric microcurrent stimulation.

[0020] U.S. Patent No. 10,391,312, issued August 27, 2019 to Blair P. Mowery et al. and titled "APPARATUS AND METHOD FOR OCULAR MICROCURRENT STIMULATION THERAPY," is a U.S national phase of

PCT Application Serial Number PCT/US16/51550 filed on September 13, 2016 with the title "APPARATUS AND METHOD FOR OCULAR MICROCURRENT STIMULATION THERAPY," which claims priority to

U.S. Provisional Patent Application No. 62/283,870 filed on September 15, 2015 by Blair Phillip Mowery et al., titled "Appliance for microstimulation therapy using a disposable material afixed to the upper and lower eye lid & other body parts,"

U.S. Provisional Patent Application No. 62/283,871 filed on September 15, 2015 by Marshall T. Masko et al., titled "Apparatus for a method of application of microcurrent stimulation therapy, consisting of a goggle device affixed to and encircling the upper and/or lower eyelids,

as well as other body parts," and

U.S. Provisional Patent Application No. 62/365,838, filed July 22, 2016 by Tapp et al., titled "Appliance for micro-current stimulation," each of which is incorporated herein by reference in its entirety.

[0021] U.S. Patent No. 10,391,312 describes devices and methods to deliver microcurrent stimulation therapy to the human body, when connected to a micro-stimulation current-generating apparatus. The method of applying microcurrent stimulation therapy to key points around the eye for treatment of problems such as macular degeneration, retinitis pigmentosa, glaucoma, optic neuritis and other eye-related or nerve-related conditions, as well as other diseases, such as Bell's Palsy, requiring localized stimulation to the eyes and/or on other body parts.

[0022] United States Patent 6,035,236 issued to Jarding, et al. on March 7, 2000 with the title "Methods and apparatus for electrical microcurrent stimulation therapy" and is incorporated herein by reference in its entirety. Patent 6,035,236 describes an apparatus for supplying an electrical signal to a body part in order to provide microcurrent stimulation therapy to the body part. The apparatus preferably includes a first sweep wave or sweep frequency signal generator configured to generate a first sweep wave signal, a buffer amplifier circuit configured to receive the first sweep wave signal from the first sweep signal generator and amplify and buffer the sweep wave signal creating a buffered sweep wave signal. In addition, the apparatus preferably includes a current limiting circuit configured to receive the buffered sweep wave signal from the buffer amplifier circuit and limit the amount of current supplied to the body part. Finally, the apparatus preferably comprises a probe for applying the sweep wave signal to the body part. The apparatus may further comprise a second signal generator for generating a second signal which may comprise either a sweep wave signal or a non-sweep wave signal. The apparatus also will include a signal combining circuit configured to receive the first and second signals from the first and second signal generators and combine the first and second signals into a composite sweep wave signal.

[0023] United States Patent 6,275,735 issued to Jarding et al. on August 14, 2001 with the title "Methods and apparatus for electrical microcurrent stimulation therapy" and is incorporated herein by reference in its entirety. Patent 6, 275,735 describes a method and apparatus for providing microcurrent stimulation therapy to a body part. In one embodiment, a method allows digital control of the modulation frequency of the microcurrent signal. The method includes

receiving a first digital data word which is used to produce a first frequency related to the first digital data word, whereupon, a first microcurrent signal at the first frequency is applied to the body part. A second digital data word is received and used to produce a second frequency related to the second digital data word. A second microcurrent signal at the second frequency is applied to the body part. In another embodiment, a method allows direct digital synthesis of the microcurrent stimulation signal. A first digital data word is used to produce a first analog voltage which is applied to the body part. A second digital data word is used to produce a second analog voltage which is also applied to the body part, where the first analog voltage is different from the second analog voltage. In yet another embodiment, an apparatus for providing microcurrent stimulation therapy includes a digital-to-analog converter, a controller and a plurality of data words. The controller is coupled to the digital-to-analog converter and supplies the digital-to-analog converter with digital data words in order to generate an electrical signal for the microcurrent stimulation therapy.

[0024] United States Patent Application Publication 2014/0081369 by Sosa, Victor Manuel Valencia et al. published on March 20, 2014 with the title "HEADACHE-TREATMENT DEVICE WITH GEL DISPENSING KIT AND METHOD" and is incorporated herein by reference in its entirety. Patent Application Publication 2014/0081369 describes an electrical-stimulation device with gel-dispensing kit, and a method of making and using the parts of the kit. A convenient and easy-to-use system to provide an electrically conductive path from a transcutaneous electrical nerve stimulation (TENS) device to the skin surface of a patient to supply transcutaneous stimulation, even through hair. The invention provides improved prevention and treatment for headache, depression, alertness, attention deficit hyperactivity disorder (ADHD), epilepsy, anxiety, post-traumatic stress disorder (PTSD), and behavioral and/or other disorders. Some embodiments provide a headache-treatment system that includes an electrode base shaped to conform to a back of a human head; a TENS having projecting spring electrodes each connected to the electrode base; means for holding an electrically conductive gel in a plurality of sealed pockets; and means for unsealing the means for holding the gel and applying the gel substantially simultaneously to the projecting spring electrodes.

[0025] United States Patent Application Publication 2017/0300098 by Sen et al. published on October 19, 2017 with the title "SUPPLYING POWER TO A COMPUTER ACCESSORY FROM A CAPTURED WIFI SIGNAL" and is incorporated herein by reference in its entirety. Patent Application Publication 2017/0300098 describes examples of capturing a Wi-Fi signal from a computing device corresponding to a computing accessory and harvesting energy from

the captured Wi-Fi signal. The examples power the computing accessory based on the harvested energy.

[0026] United States Patent Application Publication 2008/0028214 by Tafoya et al. published on January 31, 2008 with the title "Secure flash media for medical records" and is incorporated herein by reference in its entirety. Patent Application Publication 2008/0028214 describes a secure mobile device for storing data in a secure manner. The secure mobile device has a microarchitecture connected via an interface to flash memory on the device. The microarchitecture is able to authenticate the access of information stored on the secure mobile device using a private key. Upon authentication of the access of information, a record owner of the device may provide the stored information to third party trusted entities using an associated public key. The secure mobile device allows for secure transaction of confidential data on a variety of systems at a number of locations.

[0027] United States Patent 6,385,727 issued to Cassagnol et al. on May 7, 2002 with the title "Apparatus for providing a secure processing" and is incorporated herein by reference in its entirety. Patent 6,385,727 describes a secure processing environment. In one embodiment, the apparatus includes a read/write memory for storing encrypted information. It also includes a processor, a cipherer and an authenticator. The cipherer is in communication with the read/write memory for receiving encrypted information therefrom and is configured to decrypt the encrypted information into decrypted information to be returned to the memory for subsequent use by the processor. The authenticator authenticates the decrypted information prior to use by the processor and re-authenticates the information prior to re-encryption by the cipherer

[0028] There is a long-felt need for an improved method and apparatus for micro-stimulation electrical therapy.

SUMMARY OF THE INVENTION

[0029] The bio-electric micro-stimulation apparatus is comprised of a headset, similar to a crown, which connects to electrodes for each eye to provide stimulation, when in contact with the skin around the outer closed eye, encircling and/or overlapping the outer orbital cavity. The electrodes' contact points deliver the bio-electric microcurrent therapy, when the headset is connected to a bio-electric micro-stimulation device (i.e., a "controller") that generates and conveys such current.

[0030] In some embodiments, the treatment electrodes contain a micro-chip (i.e., a "chip") to authenticate itself and connect with the headset to control therapy, payment, and usage. In addition, there is a grounding electrode component as well, consisting of one or two grounding electrodes. The headset connects to the bio-electric micro-stimulation device ("controller") in one of three ways: (i) the controller is built into the headset; (ii) the controller is connected via wires to the headset and/or to the electrodes; or (iii) the controller connects to the headset via WIFI or Bluetooth®. The Wikipedia entry for "Wi-Fi" indicates: "Wi-Fi is technology for radio wireless local area networking of devices based on the IEEE 802.11 standards." The Wikipedia entry for "Bluetooth" indicates: "Bluetooth is a wireless technology standard for exchanging data over short distances (using short-wavelength UHF radio waves in the ISM band from 2.400 to 2.485 GHz) from fixed and mobile devices, and building personal area networks (PANs)." The headset may be adjustable to fit various sized heads, or it may have an open-ended back which does not completely encircle the head (similar to eyeglass temples), so as to fit any sized head.

[0031] In some embodiments, the headset also connects via WIFI or Bluetooth® to server or computer, which recognizes the individual headset via algorithmic codes built into the headset's control unit. Once the server or computer is connected to the headset and recognizes the headset's unique algorithmic code, it can enable the headset, when initiated by a clinician or physician to conduct a treatment session and it can simultaneously bill or charge the provider for payment of such treatment session. The headset is rechargeable and is recharged via a base station.

[0032] This description of the invention uses the term "bio-electric microcurrent" because the microcurrent level selected for the applied therapy mirrors the body's own biological electrical current. Hence the term: "bio-electric current."

[0033] In some embodiments, this headset device is not a disposable unit. Further, since it does not directly touch the treated eye area, (in contrast, the electrodes, which are disposable, do touch the treated area), there is no need for repeated sterilization or sanitization to avoid cross-patient eye contamination. The headset device will be maintained at a sanitary standard.

[0034] In some embodiments, the electrodes, which connect to the headset, have a conductive gel (or the like) applied on the inner perimeter at the electrode points for proper conductivity for stimulation therapy, which generates the prescribed bio-electric microcurrent at an appropriate amplitude, duty cycle, and/or repetition rate or frequency to the appropriate area

of the eye, in a timed and dosed sequence to the multiple electrode points on the electrodes affixed near or to the eye lids. In some embodiments, the electrode points also connect to a sensor (such as an electrical preamplifier and/or analog-to-digital converters, or sensors embedded in the headset or in the outside stimulation device, which will provide feedback to the device to measure for any impedance, and contain the ability to automatically adjust the current level to maintain the initially selected prescribed treatment bio-electric current level.

[0035] Microcurrent stimulation therapy has begun to be used to treat age-related muscular degeneration (AMD) and other visual system diseases; however, the methods and apparatus used in the prior art do not maximize the therapeutic effect and do not provide a way to monitor the therapeutic delivery and encourage patient compliance with the prescribed treatment regimen. Current devices may not deliver properly concentrated stimulation signals at the point where it is appropriately needed. In addition, stimulation levels can encounter impedance, which blocks or reduces the stimulation level chosen, thereby failing to deliver the appropriate level of stimulation required for proper treatment.

[0036] This new invention contains a method to carry and apply an electrical signal, termed "bio-electric microcurrent," which is a form of electrical stimulation, or "e-stim," to a specific body part, in this case the eye, or other selected body parts for treatable diseases, to promote or enable healing of the selected and treated tissue areas. Bio-electric microcurrent is that microcurrent ramie (100 IA to 350 LA) pulsed into the body, which mimics the body's own electric current. Said apparatus can deliver the appropriate stimulation to specifically targeted selected areas, as well as maintain the appropriate pressure required to eliminate or minimize patient impedance, while also continuously monitoring the stimulation level delivered to the patient, via a proprietary sensor to ensure it stays consistent with the level selected by the clinician, regardless of impedance or other issues. The invention, which is placed on the upper and lower eye lids, via the sensor, can automatically adjust such stimulation to the initial prescribed dosage when impedance is detected. The present invention provides this and other solutions to ensure optimum therapy is delivered, during the administration of treatments for macular degeneration and other eye disease problems.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] A more complete understanding of the present invention may be derived by referring to the detailed description and claims when considered in connection with the figures, wherein like reference numbers refer to similar items throughout the figures.

[0038] FIG. 1A is a block diagram of a system 101 for delivering stimulation signals to at least some of a plurality 116 of electrodes connected to the skin of a patient and for optionally sensing signals from at least some of the plurality 116 of electrodes, according to some embodiments of the present invention.

[0039] FIG. 1B is a block diagram of a system 102 for delivering stimulation signals to at least some of a plurality 116 of electrodes connected to the skin of a patient and for optionally sensing signals from at least some of the plurality 116 of electrodes, according to some embodiments of the present invention.

[0040] FIG. 1C is a diagram of a system 103, according to some embodiments of the present invention.

[0041] FIG. 1D is a cross-section diagram of and electrode-and-gel system 104, according to some embodiments of the present invention.

[0042] FIG. 1E is a cross-section diagram of an electrode-and-gel system 105, according to some embodiments of the present invention.

[0043] FIG. 2 is a diagram of a goggle-type device 201, according to some embodiments of the present invention.

[0044] FIG. 3 is a diagram of a goggle-type device 301, according to some embodiments of the present invention.

[0045] FIG. 4A is a diagram of a goggle-type device 401, according to some embodiments of the present invention.

[0046] FIG. 4B is a diagram of a system 402, according to some embodiments of the present invention.

[0047] FIG. 5 is a diagram of a goggle-type device 501, according to some embodiments of the present invention.

[0048] FIG. 6 is a diagram of goggle-type device 601, according to some embodiments of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0049] Although the following detailed description contains many specifics for the purpose of illustration, a person of ordinary skill in the art will appreciate that many variations and alterations to the following details are within the scope of the invention. Specific examples are used to illustrate particular embodiments; however, the invention described in the claims is not intended to be limited to only these examples, but rather includes the full scope of the attached claims. Accordingly, the following preferred embodiments of the invention are set forth without any loss of generality to, and without imposing limitations upon the claimed invention. Further, in the following detailed description of the preferred embodiments, reference is made to the accompanying drawings that form a part hereof, and in which are shown by way of illustration specific embodiments in which the invention may be practiced. It is understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

[0050] It is specifically contemplated that the present invention includes embodiments having combinations and subcombinations of the various embodiments and features that are individually described herein (i.e., rather than listing every combinatorial of the elements, this specification includes descriptions of representative embodiments and contemplates embodiments that include some of the features from one embodiment combined with some of the features of another embodiment, including embodiments that include some of the features from one embodiment combined with some of the features of embodiments described in the patents and application publications incorporated by reference in the present application). Further, some embodiments include fewer than all the components described as part of any one of the embodiments described herein.

[0051] The leading digit(s) of reference numbers appearing in the Figures generally corresponds to the Figure number in which that component is first introduced, such that the same reference number is used throughout to refer to an identical component which appears in multiple Figures. Signals and connections may be referred to by the same reference number or label, and the actual meaning will be clear from its use in the context of the description.

[0052] Certain marks referenced herein may be common-law or registered trademarks of third parties affiliated or unaffiliated with the applicant or the assignee. Use of these marks is for providing an enabling disclosure by way of example and shall not be construed to limit the scope of the claimed subject matter to material associated with such marks.

[0053] OVERVIEW OF THE NEW TECHNOLOGY

[0054] Embodiments of the present invention replace the need for manual application of the therapy currently used by a clinical professional. The appliance comprises a headset, connecting to a gel-strip or gel-strips containing electrodes and sensors for applying the bio-electric microcurrent therapy to the body part, in this case the eye. The headset's circular inner frame is positioned on the patient's head for both comfort and ease of treatment application. The headset is wired to either a self-contained controller or wired to connect to a separate bio-electric microcurrent stimulation device that generates the prescribed bio-electric microcurrent in sequence to the multiple electrode points on the material strips placed over to totality of the eye, or above and under the eye. The control device to which the headset invention is connected also contains a software system that is programmed to not only sequence the therapy to the various points on the material but also to detect impendence and adjust the level of bio-electric microcurrent to achieve optimum therapy.

[0055] In some embodiments, the present invention could be useful to include in a therapy for treating cancer or other maladies, for example by activating (or suppressing) chemicals of a chemotherapy or antibodies of an immunotherapy directed to a particular volume of tissue such as a tumor.

[0056] In some embodiments, the present invention includes an apparatus that replaces the need for long manual applications of the microcurrent /electrostimulation therapy currently used or being envisioned as used by a clinical professional. And, it also enables the clinician or physician to deliver stimulation to a particular designated point on the body, as opposed to a broader coverage or blanketed area of the body. Current technologies have two major drawbacks. First, stimulation delivered with a probe or pointer, is applied manually and takes a large amount of clinician time to administer it and properly deliver it. Secondly, when gel pads are used in any kind of electrostimulation or microcurrent therapy, the gel pads cover and deliver stimulation affecting a broad part of the human body, usually well in excess of 20 millimeters. This shortcoming of conventional systems prevents the delivery of stimulation to a "pinpointed" area of 2-15 millimeters, which present invention does allow for, and can in certain treatment therapies, be more efficacious with a greater stimulation level delivered on a smaller surface area that penetrates more deeply and improves treatment performance.

[0057] Figure 1A is a block diagram of a system 101 for delivering stimulation signals to at least some of a plurality 116 of electrodes connected to the skin of a patient and for optionally

sensing signals from at least some of the plurality 116 of electrodes, according to some embodiments of the present invention. In some embodiments, system 101 includes a one-use disposable chip-electrode array 110 (which may include one or more integrated-circuit chips 111 and/or other circuitry along with an array of electrodes 116 on a flexible and/or elastic substrate 119 such as described in U.S. Patent No. 10,391,312 issued on August 27, 2019 to Blair P. Mowery et al., titled "APPARATUS AND METHOD FOR OCULAR MICROCURRENT STIMULATION THERAPY," which is incorporated herein by reference), a local microprocessor system 120, and a central server 130, wherein chip-electrode array 110 is communicatively coupled to local microprocessor system 120, and local microprocessor system 120 is communicatively coupled to central server 130. In some embodiments, chip-electrode array 110 communicates with local microprocessor system 120 via a wired connection, and/or by a wireless connection such as Bluetooth®, Wi-Fi, infrared light, or the like. In some embodiments, chip-electrode array 110 is powered by a local power source 113 such as a battery, while in other embodiments, power 114 is supplied by a wired connection or, for example, from power captured from the Wi-Fi signal such as described in United States Patent Application Publication 20170300098 by Sen et al. which published on October 19, 2017 with the title "SUPPLYING POWER TO A COMPUTER ACCESSORY FROM A CAPTURED WIFI SIGNAL," and which is incorporated herein by reference. In some embodiments, chip-electrode array 110 includes circuitry such as a microprocessor and signal processor 111 (in some embodiments, microprocessor and signal processor 111 is implemented as a single chip that is integral; in some other embodiments, the circuitry for microprocessor and signal processor 111 is implemented by a plurality of integrated circuit chips).

[0058] In some embodiments, microprocessor and signal processor 111 has an embedded unique serial number (USN) information 118 that uniquely identifies each one of the chip-electrode arrays 110 of a plurality of identical or similar devices in order that quality control is maintained (e.g., by tracking the manufacturing date, batch, version, and the like by the serial number (e.g., in some embodiments, in a device database 133) to help ensure that the device is fresh (not expired) and has up-to-date functionality and features suitable for each particular patient).

[0059] In some embodiments, embedded serial number information 118 further includes public-key encryption information that is used by server 130 to encrypt data being sent back to chip-electrode array 110, where private-key information needed to decrypt the returned encrypted data 124 from server 130 remains hidden inside microprocessor and signal processor

111 (e.g., in some embodiments, the decryptor is part of data and software in decryptor/pulse-enable-and-control module 112). In some embodiments, the present invention uses public-key encryption private-key decryption methods and systems such as described in United States Patent Application Publication 2008/0028214 by Tafoya et al. or United States Patent 6,385,727 to Cassagnol et al.. Such systems allow the destination system (in this case, the microprocessor and signal processor 111) send out a public key that any source (in this case, server 130) can use to encrypt data that requires the corresponding private key (which is not publicly available) to correctly descript the date returned from the source.

[0060] In some embodiments, the returned data 128 contains medically relevant stimulation-control parameters that are customized (potentially differently) for each particular patient or population of patients having a given set of diagnoses and physiological data. In some embodiments, results of each therapy are collected in database 134 and are collectively analyzed to obtain improved future therapy sessions.

[0061] By using public-key/private-key communications between the microprocessor and signal processor 111 and server 130, the returned data 124 can be checked for validity or modifications after decryption using the private key data in microprocessor and signal processor chip 111, and the risk of third parties accessing the information, including patient's data, is reduced. In some embodiments, local microprocessor system 120 also receives a unique patient identifier (UPID) 121 associated with the particular patient who is to receive therapy. In some embodiments, the UPID is associated with the patient but in a sense relatively anonymous until used by the server 130 to associate that UPID to the patient PII and medical history 122 in server 130. In some embodiments, local microprocessor system 120 appends (or otherwise combines) the USN 118 and UPID 121, and in some embodiments, encrypts the result via encryptor-encapsulator-transmission circuit 125 and then transmits this information to server 130 (e.g., via a cell phone connection and/or the internet or the like).

[0062] In some embodiments, a separate process 122 is used to input more complete patient personal identifying information (PII) and the patient's medical history that, in some embodiments, is encrypted and stored in patient database (PAT DB) 132. In some embodiments, server 130 includes a decryptor/encryptor function 131 that decrypts data from transmitted data 129 to locate and retrieve data associated with the particular patient from patient database 132. In some embodiments, the patient information itself as stored on PAT DB 132 is encrypted, and so when retrieved, the data needs to be decrypted (at least in part) by

decryptor 136.

[0063] In various embodiments of the present invention, the functions shown in Figure 1A and Figure 1B are implemented as a combination of hardware circuitry and software, wherein the some of the various parts of the combination of hardware circuitry and software are implemented in the one-use disposable chip-electrode array 110, in a stand-alone local microprocessor 120 and/or in one or more mobile communications device(s) such as a cell phone, laptop, iPad® or the like. In some embodiments, some or all of local microprocessor system 120 and/or its function described above is located in a head-worn (goggle-type) apparatus worn by the patient during the procedure. In some embodiments, some or all of local microprocessor system 120 and/or its function described above is located in a bed-side device located near the patient during the procedure. In some embodiments, some or all of local microprocessor system 120 and/or its function described above is located in a cell phone located near the patient during the procedure.

[0064] When the USN and UPID information 129 from transmission circuit 125 is received by server 130, the PPID information is correlated to the particular patient to locate and retrieve patient information, history and treatment parameters from PAT DB 132, which together with USN and UPID information 129 are decrypted by decrypt function 136 and the device USN is sent to device and billing database 133.

[0065] In some embodiments, device and billing database 133 tracks each device serial number and the associated data regarding the particular chip-electrode array 110, such that system 101 can warn if the particular chip-electrode array 110 has been recalled, is out-of-date (expired due to age), has previously been used (such that re-use of the single-use device is contraindicated), is inappropriate for the particular patient or therapy procedure being requested by the medical professional, or other such problems.

[0066] In addition, in some embodiments, device and billing database 133 is used to generate a bill to the patient or their insurance carrier for the use of that device, wherein the bill can thereby reflect the cost of the device as well as the cost of the procedure and other deliverables. The patient information 137 and the device information 139 (e.g., which includes, in some embodiments, the number and configuration of electrodes 116, the circuitry and software version, and the like) are used to access the proper therapy parameters 138 from the medical results and indication database 134. In some embodiments, those therapy parameters 138 are encrypted (e.g., in some embodiments, using the public key information 118 sent from

the particular chip-electrode array 110) by encryption function 135 and transmitted back to local microprocessor system 120, wherein in some embodiments, optional decryption function 123 decrypts at least some of the information for visual and/or audio presentation on display output unit 170 (such as displaying patient name, medical history and the like for review by the attending medical professional supervising the therapy session so that, for example, that medical professional and/or the patient can verify the correct therapy is being applied to the correct patient).

[0067] In some embodiments, optional decryption function 123 supplies some or all of the private key information and/or control information 124 needed by circuit 111 to decrypt the control parameters needed for the therapy session. In other embodiments, optional decryption function 123 decrypts only the patient PII and history information displayed on display 170, and for the control information, leaves that portion of the payload of data encrypted for the circuit 111 to decrypt and use to control the therapy session. In some embodiments, circuit 111 includes a plurality of transmitter/receivers (that each transmit pulsed or otherwise varying micro-current stimulation to an individual one of electrodes 116 (wherein a common ground connection is used for the return path of the current) or to a selected pair (or other plurality) of the electrodes that are chosen/determined in order to apply the current along a chosen path from selected source electrode(s) (one or more of the plurality of electrodes 116) to selected destination electrode(s) (another one or more of the plurality of electrodes 116). In this way, the selected set paths and the selected sequence of those paths are chosen to target the desired shape and size of the volume of tissue to be receiving the therapy.

[0068] Once the integrity of the decrypted version of the returned encrypted data 124 is validated, the payload of the returned data is used to control the transmit portion of transmit/receive (TX/RX) circuitry 115 to deliver micro-stimulation signals that are customized for the particular patient. In some embodiments, the medical indication database provides the initial values for the amplitude, frequency, duty cycle, DC balance, and/or other parameters for the transmit signal sent from transmit/receive (TX/RX) circuitry 115.

[0069] In some embodiments, sensed signals 117 from the electrodes 116 are obtained from the receive portion of transmit/receive (TX/RX) circuitry 115 and are processed by process (e.g., feedback-determining) function 127 and the pulse-adjust results 118 are used to adjust (e.g., change the amplitude, frequency, duty cycle, DC balance, and/or other parameters) the transmit signal sent from transmit/receive (TX/RX) circuitry 115. In some embodiments, the sensed

signal is indicative of the impedance/resistance seen by a particular electrode or electrode pair. In some embodiments, the sensed signals are from other electrodes (one or more of the plurality of electrodes 116) not involved in the transmitted pulse and are indicative of nerve signals or other physiological processes.

[0070] In some embodiments, information reflecting the sensed signals and the corresponding stimulation (transmitted) signals on electrodes 116 is processed and encrypted by function 125 and transmitted to server 130 to be stored in PAT DB 132 to be associated with this patient and this therapy session. In some embodiments, reported results information 126 reflecting information from the patient as to their feeling about the therapy session and the results obtained from the therapy is processed and encrypted by function 125 and transmitted to server 130 to be stored in PAT DB 132 to be associated with this patient and this therapy session.

[0071] In some embodiments, results information and therapy session information from a large plurality of patients is processed and aggregated by software in server 130 or operating on data supplied by server 130 to modify the medical indications in database 138 such that over time the therapy for each patient or each type of patient provide improved parameters for future therapy sessions.

[0072] Figure 1B is a block diagram of a system 102 for delivering stimulation signals to at least some of a plurality 116 of electrodes connected to the skin of a patient and for optionally sensing signals from at least some of the plurality 116 of electrodes, according to some embodiments of the present invention. In some embodiments, much of the functionality of circuit 111 of system 101 has been moved into a local microprocessor system 150, leaving only the electrodes 116 and their conductor traces on a flexible substrate of one-use disposable electrode array 140. In some embodiments, a unique serial number (USN) is printed on one-use disposable electrode array 140 or its wrapper, which in some embodiments, is machine readable in the form of a bar code or quick-response (QR)-type symbol 145 or the like. In some embodiments, symbol 145 includes the USN as well as a website identifier that is used to retrieve a public-key encryption key from an internet site. In some embodiments, the data and software in decryptor/pulse-enable-and-control module 112 functionality that is on chip-electrode array110 is replaced by data and software in decryptor/pulse-enable-and-control module 152 in local microprocessor system 150. In some embodiments, encryptor-encapsulator-transmission circuit 155 includes the functionality of encryptor-encapsulator-transmission circuit

125 in addition to an imager used to capture the image of QR symbol 145 (e.g., in some embodiments, the camera in a cell phone is used to obtain the data from symbol 145, and the cell phone provides the functionality, or at least part of the functionality of reference numbers 155, 123, 124, 127 and 152). In some embodiments, some of the functionality of local microprocessor system 150 (such as decryptor/pulse-enable-and-control module 152, TX/RX 155, and/or display 170) is located on a head-mounted goggle-type device 201 (such as shown in the diagram in Figure 1C and Figure 2), and communicates wirelessly to a cell phone that implements the remainder of functions of local microprocessor system 150. The remainder of the functions shown in Figure 1B are as shown by like reference numbers in Figure 1A.

[0073] Figure 1C is a diagram of system 103, according to some embodiments of the present invention. In some embodiments, system 103 includes the goggle-type device 201, which, in some embodiments, is configured to be placed on the head and connected to the electrodes of one-use disposable chip-electrode array 210 (e.g., an array such as array 110 or array 140) that is placed over both upper and lower eyelids, or on another body part, along with some of its componentry (e.g., chip 111). In some embodiments, array 210 includes unique serial number information 118 that is embedded in one or more integrated circuit chips 111; in other embodiments, array 210 and/or its wrapper is machine readable in the form of a bar code/UPC code such as quick-response (QR)-type symbol 145 or the like. In some embodiments, system 103 further includes headset frame 211, contact points 212 between the electrode(s) and the headset frame 211, and electrode skin-contact points 213, numbered from as few as two (2) per electrode to as many as ten (10) or more (in some embodiments, as shown in Figure 1C, there are six skin-contact points 213). In some embodiments, system 103 further includes side temple piece 214 that goes around the side of the head, optional extended lens cover "arm" 215, which, in some embodiments, is used to adjust the contact pressure over the electrodes of the various contact points 213 around the eye socket, and grounding electrode(s) 216 that, in some embodiments, provides a ground connection between headset frame 211 and the patient's body. Section line 1D-1D of Figure 1C shows the location of the cross-section of Figure 1D. In some embodiments, not shown in Figure 1C, system 103 includes a lens cover arm 215, an array 210, and a contact point 212 on both sides of headset frame 211.

[0074] Figure 1D is a cross-section diagram (along section line 1D-1D of Figure 1C) of an electrode-and-gel system 104, according to some embodiments of the present invention. In some embodiments, electrode-and-gel system 104 includes one-use disposable electrode array 140 having a skin-facing adhesive 161 on flexible and/or elastic substrate 119, wherein the

adhesive 161 and electrically conductive gel 163 are covered by a removable cover 162. In some embodiments, each of the plurality of conductive electrodes 116 is formed (e.g., by printing, plating and/or etching) on a pocket 165 formed in substrate 119, wherein each pocket 165 contains a selected amount of electrically conductive gel 163 held in place by adhesive 161 and cover 162, until the cover 162 is removed so that one-use disposable electrode array 140 can be applied to the skin of the patient with each portion of gel 163 and its electrode being electrically isolated from the other electrodes and their gel. In some embodiments, each electrode 116 is connected to a corresponding one of a plurality of electrical connectors 164 to send and receive signals to and from local microprocessor system 150 (see Figure 1B).

[0075] Figure 1E is a cross-section diagram of an electrode-and-gel system 105, according to some embodiments of the present invention. In some embodiments, electrode-and-gel system 105 includes one-use disposable chip-electrode array 110 having a skin-facing adhesive 161 on flexible and/or elastic substrate 119, wherein the adhesive 161 and electrically conductive gel 163 are covered by a removable cover 162. In some embodiments, each of the plurality of conductive electrodes 116 is formed (e.g., by printing, plating and/or etching) on a pocket 165 formed in substrate 119, wherein each pocket 165 contains a selected amount of electrically conductive gel 163 held in place by adhesive 161 and cover 162, until the cover 162 is removed so that one-use disposable chip-electrode array 110 can be applied to the skin of the patient with each portion of gel 163 and its electrode being electrically isolated from the other electrodes and their gel. In some embodiments, each electrode 116 is connected to a corresponding TX/RX 115 of chip 111, and chip 111 communicates information signals 117, 118, 119 and 124 via a plurality of electrical connectors 165 or, in other embodiments, wirelessly by Bluetooth® or WiFi, to local microprocessor system 120 (see Figure 1A).

[0076] Figure 2 is a diagram of goggle-type device 201, according to some embodiments of the present invention. In some embodiments, device 201 includes a visual screen 220, incorporated into headset frame 211, indicating a display of the various elements of information visible on screen at any one time. In some embodiments, device 201 further includes a display-screen frame 221 that includes, for example, two (2) to ten (10) lights 222 on the display screen frame 221 (upper plus lower). In some embodiments, lights 222 includes light(s) 223 that indicate which electrode contact point 213 is currently in session, light(s) 224 that indicate the level of stimulation, and light(s) 225 that indicate the stimulation time that has elapsed. In some embodiments, lights 222 are also configured to provide a confirmation or indication that the contact points of the electrode are functioning properly and delivering the appropriate level of

current chosen to stimulate the eye.

[0077] Figure 3 is a diagram of a goggle-type device 301, according to some embodiments of the present invention. In some embodiments, device 301 includes lights on the headset frame (e.g., headset frame 211) to help the clinician know the status of treatment. In some embodiments, light 322 indicates if there is stimulation impedance, and if the stimulation level chosen is being properly delivered; in addition, some embodiments include ON/OFF lights. In some embodiments, the OFF light 325 activates to indicate that the treatment session has finished. In some embodiments, the ON light 326 illuminates when the treatment session is in process. There may also be individual treatment "session" lights (one per each electrode stimulation point; e.g., light(s) 223). In some embodiments, the session lights illuminate according to the specific treatment point being stimulated at that particular moment of the therapy, enabling the clinician to know exactly where in the treatment process the patient was.

[0078] Figure 4A is a diagram of a goggle-type device 401, according to some embodiments of the present invention. In some embodiments, device 401 includes a light filament 422 that is used to provide indicating light to the patient. In some embodiments, light filament 422 is located on the interior side of the headset frame (e.g., headset frame 211) such that light is projected toward the patient from light filament 422. A single or a double filament line may be used for filament 422. In some embodiments, device 401 further includes a vibration filament 430 that is embedded in the headset frame (e.g., headset frame 211).

[0079] Figure 4B is a diagram of a system 402, according to some embodiments of the present invention. In some embodiments, the present invention uses one, two or more electrode strips 440 such as one-use disposable chip-electrode array 110 (as described above for Figure 1A) or one-use disposable electrode array 140 (as described above for Figure 1B) that are electrically connected to headset 410. In some embodiments, headset 410 is worn by the patient during the therapy session, and includes the functionality as described above for local microprocessor system 120 (as described above for Figure 1A) and/or local microprocessor system 150 (as described above for Figure 1B). In addition, in some embodiments, headset 410 includes one or more LEDs 411 that provide flashes or other light signals (for the patient to perceive even when their eyes are closed, and/or the medical professional who is administering the micro-current electrical stimulation therapy) to indicate that the therapy is working and/or to provide other feedback or information to the patient or medical professional. Also, in some embodiments, headset 410 includes one or more haptic vibration devices 415 that provide

vibration through the frame of headset 410 or by direct contact to the patient's skin (for the patient to perceive even when their eyes are closed, and/or via wireless transmission to a wrist-worn fitness monitor, Apple Watch®, Fitbit® or the like such that the medical professional who is administering the micro-current electrical stimulation therapy is notified to look at information displayed on display 170 or other notification) to indicate that the therapy is working and/or to provide other feedback or information to the patient or medical professional. In some embodiments, headset 410 includes an on-board microprocessor and battery 416 to support the functionality for local microprocessor system 120 (as described above for Figure 1A) and/or local microprocessor system 150 (as described above for Figure 1B). In some embodiments, one-use disposable chip-electrode array 110 (as described above for Figure 1A) or one-use disposable electrode array 140 (as described above for Figure 1B) further include one or more LEDs 422 to provide an indication of functionality (e.g., that the electrode array 110 or 140 is properly electrically connected to headset 410) and/or an indication that therapy is underway. In some embodiments, power for electrode array 440 is supplied by a wired connection 114 on a flexible substrate along with the connector that lead to electrodes 116. In some embodiments, electrode array 110 or 140 has an adhesive layer 161 (see Figure 1D) to hold the electrode array 110 or 140 to the patient's skin. In some embodiments, electrode array 110 or 140 is first adhered to the patient in the desired location, then the patient puts on headset 410 and the electrode arrays 110 or 140 are connected to a corresponding jack or other electrical connection.

[0080] Figure 5 is a diagram of a goggle-type device 501, according to some embodiments of the present invention. In some embodiments, device 501 includes a connecting wire 541 that runs from the headset frame (e.g., headset frame 211) to a bio-electric microcurrent controller device 545. In some embodiments, device 501 includes a bio-electric microcurrent controller device 550 that is built into the headset frame (e.g., headset frame 211). In some embodiments, device 501 includes a sensor 560 on the headset frame (e.g., headset frame 211) that provides feedback to the controller device (e.g., controller device 545 and/or controller device 550) for stimulation level being delivered, etc.

[0081] Figure 6 is a diagram of a goggle-type device 601, according to some embodiments of the present invention. In some embodiments, device 601 includes a WiFi connection 670 that allows device 601 to connect, via WiFi, to a separate device such as controller device 545, a server, a computer, or the like, in order to provide remote access to device 601.

[0082] The headset apparatus may contain an LED, LCD, or some other type of screen, like a small i-Phone touch screen to show the treatment sequencing, the status of such treatment, and/or to engage or halt such treatment. This screen may show graphics, pictures, or even video footage related to such treatment process, with the purpose of making it easier for a clinician to readily assess where the patient is within the treatment cycle, or to enable the clinician to start, change, or stop such treatment cycle. The screen can be a touch screen that enables the clinician to modify the treatment parameters, such as stimulation level or duration under treatment.

[0083] The headset connects via WIFI to server or computer, which recognizes the individual headset via a unique set of algorithmic codes built into the headset's control unit. Once the server or computer is connected to the headset and it recognizes the headset's unique algorithmic code, it can then enable the headset, when initiated by a clinician or physician, to conduct a treatment session. It can also simultaneously bill or charge the provider for payment of such treatment session. The headset can also send the treatment parameters used to the server or computer for record of how the device was used. The headset is rechargeable for repeated use, and it connects to a base station. The base station can plug into the wall to maintain the charge to recharge the headset. The headset does not plug into the wall directly for safety purposes.

[0084] The apparatus may contain a "light" filament or filaments threaded through the headset to convey a low level of light through the patient's closed eyes, indicating to the patient, that the appliance/strip is functioning as intended. This low level of light will penetrate the patient's closed eyelid and be received by those photoreceptor cells functioning in the back of the retina. It will resemble a dull flash, and may be either a white light or a specially colored light (such as red or green, like a laser light).

[0085] The apparatus may also contain a vibrating filament threaded through the headset, to convey a light level of vibration as the stimulation is being applied. Again, this is for the function of conveying to the patient that the stimulation is being delivered for those instances where the bio-electric microcurrent, itself, may be simply unfelt by the patient. The benefit of this is that the patient can feel it working, and will then be more willing to sit and complete the full treatment session, versus a session where they have no marker to indicate that anything is happening.

[0086] The application of the apparatus will be performed by the attending physician or clinician in the clinic. The patient's eye lids will be cleaned with sterile solution contained in a

wipe or similar material. The clinician, using sterile surgical gloves, will then open the packet containing the headset; the headset will then be mounted on the patient's head by the clinician. The clinician will then connect the headset (or goggle) – both forms to be used interchangeably in the following descriptions – to the bio-electric microcurrent strips, and the entire headset will be configured to the patient in the following manner:

- The headset will be sized to properly fit the patient in terms of the size of their head.
- The headset will be connected to the individual bio-electric microcurrent strip(s), (electrode)(s) whose contact points will be placed on the patient's closed eyelids, just below the eyebrows, across the bone of the upper eye orbit cavity, and also applied under the eye, along the bone of the lower orbit.
- The treatment electrode(s) contain an embedded chip to regulate the performance during treatment, including one-time usage, identification purposes, and purchase confirmation by clinic or user.
- The headset is also connected to one or two grounding electrodes placed at another point on the body to complete the closed circuit of the individual bio-electric microcurrent strips.
- The headset would be connected to the bio-electric microcurrent device (i.e. controller), built into the headset, or connected via wire when it is a separate device, or connected via WIFI when it is a separate device, to initiate therapy.

[0087] In some embodiments, when the therapy is finished, a beeper will sound. The clinician will then disconnect the headset from the electrodes, and in the case of a separate control device, from the separate control device if it is attached via wires generating the bio-electric microcurrent. Next, the clinician will gently remove the headset from the patient. The headset will be cleaned in accordance with company instructions as guided by any government directives, or in the case of a disposable headset, disposed of in accordance with any government directives. The patient's eye(s) will be re-cleansed with a sterile wipe/pad.

[0088] **ADVANTAGES OF THE NEW TECHNOLOGY**

[0089] (MICROSTIMULATION HEADSET FRAME)

a. It is an advantage of the present invention to provide a novel electrode apparatus for providing bio-electric microcurrent stimulation therapy to a body part to combat chronic pain, injury, or disease in that body part, or to assess or monitor internal organ function within the body.
b. Another advantage of the present invention is to provide a novel electrode apparatus for treating various diseases, including macular degeneration and retinitis pigmentosa.
c. Yet another advantage of the present invention is to provide an electrode apparatus that delivers bio-electric microcurrent stimulation therapy via a headset frame attached to electrodes that are wired to (or connected via WIFI to) the control apparatus and are positioned on the upper or lower eye lid with an adhesive material.
d. Yet another advantage of the headset is that the clinician can begin treatment and leave the patient during the treatment cycle for multi-tasking efficiency and reducing clinician labor.
e. Yet another advantage is that the clinician can be away from the patient, but periodically check on the patient's progress with the headset's screen.
f. Yet another advantage of the headset/goggle device, with the connected electrodes, is the automation of the treatment process and its ability to deliver a consistent treatment, thereby minimizing variability of such treatment that otherwise would be present if it were delivered manually by a clinician in terms of: time, pressure of the electrode at the point of stimulation, consistency of application, contact of the electrode, and consistency of the stimulation level being delivered as initially selected for treatment setup.
g. Yet another advantage is that both eyes are set up simultaneously for treatment, saving time since there is just one set up. (The patient may have one eye treated at a time and then the other, during the treatment cycle, OR the headset could be configured to simultaneously treat both eyes at once, one electrode point at a time per each eye until the cycle is completed.)
h. Yet another advantage of the headset's inner circular frame is that it will comfortably and easily fit most patients' heads and make for easy connection of the electrodes around the eye.
i. This headset contains or will be connected to various numbers of electrodes or sensors, which are wired and sensed individually by a controller device, which gives the ability of the apparatus to monitor the current supplied to the various contact points in the electrodes, and to adjust the current based upon the degree of impedance.

j. The invention will be packaged as sanitary, depending upon the requirements in a barrier-proof package.

k. Yet another advantage is this headset apparatus will be connected to a software program that can administer the treatment therapy, and can also collect patient information regarding the application of the treatment applied to the patient, for improved patient outcomes.

l. Yet another advantage is that the invention contains one or a number of light filaments in the headset frame, that can signal the patient that the proper level of therapy is being delivered to the patient and that they are not experiencing undue impedance.

m. Yet another advantage is in the field of safety, as the device cannot be randomly used since it needs to be pre-authorized by the server or computer, via the unique algorithm, to conduct the treatment session.

n. Yet another advantage is that the payment for each treatment is monitored on an individual basis by the server or computer, with each session used being specifically enabled by the server/computer, tracked, and accounted for, so it can be paid for by the clinic.

o. Yet another advantage is that the clinician can see the status of the therapy in session and or modify it at any time, with the use of the headset's touch screen.

p. Yet another advantage is the headset plugs into a base station device that recharges the headset, so that the headset can be recharged and used repeatedly, and so that the headset does not directly plug into the wall, which is a usage safety guard for the patient per regulatory codes.

q. Yet another advantage is that the treatment electrodes contain a chip, similar to a security chip in a credit card but optionally with additional functionality such as a controller and current drivers and receiving preamplifiers and the like, which enables a one-time use and can be tracked via the headset controller. This prevents the reuse of electrodes for a safety and hygiene basis, as well as insures proper accounting for the electrodes from a purchase and billing standpoint. This chip technology will enable confirmation of: electrode identity and authenticity, purchase, and one-time usage.

r. Accordingly, it is an advantage of the present invention to incorporate a safety element by individually wiring each electrode sensor point connected to the treatment device, which provides the bio-electric stimulation. Such design prevents more than one electrode point delivering the therapy simultaneously, unless so specifically programmed, and potentially injuring the patient.

s. The advantage of this apparatus is that the bio-electric stimulation is not carried simultaneously over the entire surface of the treated area, and that an individually targeted area of the eye can be treated with stimulation therapy, while not stimulating other areas of the eye or surrounding tissues. Stimulation is delivered at differing specific individual points in a programmed manner, versus the current standard of a general stimulation delivery over the affected area in the many other medical fields where electrode stimulation is used.

t. The advantage of highly targeted bio-electric stimulation is that this ensures that a more concentrated delivery is made to the targeted area, with a greater chance of deeper inner penetration of the stimulation, to the back of the retinal tissues, where it can do the most good to reactivate cellular activity, and avoiding higher levels of stimulation, which might otherwise be required without such targeting, which can incidentally cause damage to the more sensitive tissues.

u. Another advantage is that specific areas of bio-electric stimulation can be chosen by the physician, as determined by the program used in the bio-electric microcurrent device connected to the headset/ apparatus. It has specifically sequenced points within the electrodes that can deliver timed specific stimulation to different points along the frame itself, in a pre-set sequence, for a varied or pre-set time, at an individual point of contact, or at two or more points of individual contact, with preset stimulation levels, as opposed to a single Gel Pad which offers blanket stimulation over the entire surface area of the pad.

v. Another advantage of this appliance and its treatment methodology is that it enables the physician to target bio-electric stimulation to a particular treatment point (as small as 1-2 millimeters, or as large as 5-10 millimeters), which improves treatment efficacy since a higher current dose cannot be tolerated by the body at a small pinpoint of delivery, or be effective if delivered over a larger surface area, such as by a standard gel pad. Further, this bio-electric stimulation can be delivered to a specifically designed and tolerated treatment point within a timed sequence and then on to another in a pre-set pattern designed to optimize treatment results for patients.

[0090] **ELEMENTS OF APPARATUS DESIGN ACCORDING TO SOME EMBODIMENTS:**

a) Method for Application to upper, and/or lower eye, as well as other body parts.

b) Bio-electric Microcurrent Headset Frame.

c) Headset Frame connects to electrodes, which stimulate the upper and lower eyelid, or other body part(s) as applied, using an electrode with a gel coating.

a. Such electrodes contain a chip and this technology serves to identify the electrode using this chip to the controller as authentic, to allow a one-time use for safety and hygiene purposes, and to ensure payment regulation.

d) Headset frame connects to electrodes which:

1. Have between 1-10 (or more) contact points on the top of the strip for the top closed eye lid or skin covering the upper orbit.
2. Have between 1-10 (or more) contact points on the bottom of the strip for the bottom closed eye lid or skin covering the lower orbit.
3. Do not stimulate entire eye, only under those specific points selected within the stimulation program determined by physician and programmed into device.
4. Contact points can be individual or multiple, meaning that ONE contact point can stimulate at a time per eye, or body part; OR two to several contact points may stimulate simultaneously, determined by the program selected on the device. (In addition, the entirety of the strip(s), and all of the contact points may also be active with stimulation at any one given point during the treatment in addition to the individual points stimulated.)
5. Contact points may stimulate individually or in multiple points, in a pre-programmed sequence, with a pattern that is pre-set in terms of specific stimulation level(s), individual stimulation point duration time(s), total program run time, number of times of stimulation per eye point, etc., all of which is determined by the program in the device, selected by the attending clinician delivering the stimulation.
6. Contact points are capable of receiving varied stimulation levels as determined by device. (Meaning that the stimulation level delivered through the various contact points can vary and be increased or decreased throughout the course of the treatment program selected.)

e) This invention makes it is less labor intensive to conduct the treatment (since the clinician can turn the headset on, start the programmed treatment, and go off to do another task while the program runs its course); less time consuming (since the clinician is freed up during the programs duration to attend to other tasks), and less fatiguing (since the clinician does not need to stand over the patient and hold the stimulation probe.)

f) Safety Element: The headset and its controller (whether built in or attached via wires) rely on a safety governor built in to the controller device, so one point cannot deliver more than 350 microamps of current. Sensors: Headset, controller, and strips have a built-in sensor to monitor stimulation level delivered to improve treatment performance:

1. Sensor also gauges impedance of skin:
2. Sensor to give feedback to device to actual stimulation delivered to skin. (Feedback loop)
3. Sensor to automatically adjust bio-electric current level deliver to patient, to achieve the selected/programmed stimulation level, regardless of impedance. (Up to 350 microamps, and no more.)

g) Headset may contain an internal light filament built in to frame to indicate stimulation delivery to patient. Filament would flash lightly in conjunction with the delivery of the stimulation. This feature can be manually turned off for no flash.

h) Headset may contain an external visible light for the clinician to monitor treatment. Light will go from constant (when selected stimulation is appropriately delivered); to flash if stimulation being delivered has impedance and is under-delivered; or, to rapid flash if impedance is high and stimulation being delivered is significantly under-delivered.

i) Headset may contain a vibration element built into frame, designed to indicate stimulation delivery.

j) Headset either has a built-in controller or contains a connection element to primary controller device, via either wires or via WIFI.

1. The controller has a unique algorithm ensuring its identification and connection to the server or computer.
2. Each controller can be identified as to location and modified by the company as to its operational capabilities, permitting the company to upgrade the controller software and operating system at any time.
3. The controller requires the connection to the server or computer for activation of the therapy to ensure control over the therapy sessions being delivered and to ensure proper payment for such sessions.

k) Headset has a built-in touch screen (in some embodiments, smaller, but similar to an Apple iPhone®). This touch screen enables the clinician to start the program; to stop the program; and to adjust any of the treatment variables. It also features a display with a

read-out of the treatment status in progress.

l) Headset may have two moveable or "flip-oriented" lens covers, (one around each eye), that are lens-less, but designed to come in moderately tight contact, (1/4# {one-quarter pound} to 15# {fifteen pounds} pressure per square inch), with the closed upper and lower eye lid, to ensure proper contact with the electrode. This could be done via a spring mounted to the lens cover arm, as it is flipped down to cover the electrode strip(s), or some other form of applying pressure to the lens cover arm.

m) The headset design can be adjusted to accommodate different sized anatomical head configurations.

n) Headset may contain a sensor for feedback to device to register stimulation level being delivered.

o) Headset may contain a timing sensor (buzzer/chime) to notify when session is completed.

p) Headset may contain an LED or LCD type of screen, in some embodiments, similar to a small iPod® screen, showing the status of the treatment session, including which eye is being stimulated, which eye point is being stimulated, where in the cycle of stimulation the treatment session is, and when the session has ended. This visual screen will also show product name, program time elapsed, and stimulation level being delivered to patient.

[0091] In some embodiments, the present invention provides an apparatus for applying bio-electric microcurrent stimulation therapy to the human body, via a disposable chip-electrode array that connects to a micro-stimulation current generating device, for application of the microcurrent stimulation therapy. In some embodiments, the apparatus includes a headset device for mounting to the patient's head; and one or more electrode strips such as a one-use disposable chip-electrode array having a unique serial number or crypto code and other functionality that is used by the system to look up and deliver customized therapy to a particular patient having their own particular symptoms and medical history, which deliver the stimulation to the patient's skin.

[0092] In some embodiments, the present invention provides a method for applying bio-electric microcurrent stimulation therapy to the human body of a particular patient, via a disposable chip-electrode array strips such as a one-use disposable chip-electrode array having a unique serial number or crypto code that connects to a micro-stimulation current generating headset, for application of the microcurrent stimulation therapy. This method includes mounting the headset to the patient's head; applying one or more electrode strips to the patient's skin;

connecting the one or more electrode strips to the headset; communicating the unique serial number or crypto code to a computer server; using the unique serial number or crypto code in the computer server to look up and return a customized therapy regimen specification to the headset for the a particular patient having their own particular symptoms and medical history; and using the customized therapy regimen specification, deliver the microcurrent stimulation to the patient's skin.

[0093] In some embodiments, the present invention provides a non-transitory computer-readable medium having instructions stored thereon for causing a suitably programmed information processor to execute a method for applying bio-electric microcurrent stimulation therapy to the human body of a particular patient, via a disposable chip-electrode array strips such as a one-use disposable chip-electrode array having a unique serial number or crypto code that connects to a micro-stimulation current generating headset, for application of the microcurrent stimulation therapy. This method includes mounting the headset to the patient's head; applying one or more electrode strips to the patient's skin; connecting the one or more electrode strips to the headset. The instructions cause the suitably programmed information processor to execute a method that includes: communicating the unique serial number or crypto code to a computer server; using the unique serial number or crypto code in the computer server to look up and return a customized therapy regimen specification to the headset for the a particular patient having their own particular symptoms and medical history; and using the customized therapy regimen specification, deliver the microcurrent stimulation to the patient's skin.

[0094] It is to be understood that the above description is intended to be illustrative, and not restrictive. Although numerous characteristics and advantages of various embodiments as described herein have been set forth in the foregoing description, together with details of the structure and function of various embodiments, many other embodiments and changes to details will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should be, therefore, determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein," respectively. Moreover, the terms "first," "second," and "third," etc., are used merely as labels, and are not intended to impose numerical requirements on their objects.

What is claimed is:

1. A system for applying bio-electric microcurrent stimulation therapy to a patient, the system comprising:

a head-mounted device configured to be mounted to the patient's head;

a chip-electrode-array circuit operatively coupled to the head-mounted device, wherein the chip-electrode-array circuit includes at least one integrated-circuit chip and at least one electrode-array strip configured to deliver the bio-electric microcurrent stimulation therapy to the patient, wherein the chip-electrode-array circuit includes a unique identification number; and

a computer server operatively coupled to the chip-electrode-array circuit, wherein the chip-electrode-array circuit is configured to communicate with the computer server in order to have the computer server look up parameters based at least in part on the unique identification number and communicate the looked-up parameters to the chip-electrode-array circuit for the bio-electric microcurrent stimulation therapy.

2. The system of claim 1, wherein the parameters are further based on particular symptoms and medical history associated with the patient.

3. The system of claim 1, wherein the unique identification number is a serial number stored in the at least one integrated-circuit chip and communicated from the at least one integrated-circuit chip to the computer server.

4. The system of claim 1, wherein the unique identification number is a serial number printed on the at least one electrode-array strip and read by a camera to obtain image data that is communicated to the computer server.

5. The system of claim 1, wherein the chip-electrode-array circuit is a one-use disposable chip-electrode-array circuit.

6. The system of claim 1, wherein the unique identification number includes public-key encryption information that is used by the computer server to encrypt data sent to the chip-electrode-array circuit.

7. The system of claim 1, wherein the computer server includes a medical-results-and-indication database, and wherein results of the bio-electric microcurrent stimulation therapy are

transmitted to the medical-results-and-indication database to be analyzed in order to improve future therapy sessions.

8. The system of claim 1, wherein the chip-electrode-array circuit includes a microprocessor integrated with the chip-electrode-array circuit.

9. The system of claim 1, further comprising:

a local microprocessor system operatively coupled to the chip-electrode-array circuit.

10. The system of claim 1, further comprising:

a local microprocessor system operatively coupled to the chip-electrode-array circuit, wherein the local microprocessor system includes a first portion located on the head-mounted device and a second portion located remotely from the head-mounted device.

11. A method for applying bio-electric microcurrent stimulation therapy to a patient via a chip-electrode-array circuit that includes at least one integrated-circuit chip, at least one electrode-array strip, and a unique identification number, the method comprising:

providing a head-mounted device;

connecting the at least one electrode-array strip to the head-mounted device;

mounting the head-mounted device to the patient's head such that the head-mounted device applies the at least one electrode-array strip to the patient's skin;

transmitting information from the chip-electrode-array circuit to a computer server, wherein the transmitted information includes the unique identification number;

receiving into the chip-electrode-array circuit, from the computer server, parameters for the bio-electric microcurrent stimulation therapy, wherein the received parameters are based at least in part on the unique identification number; and

delivering, via the at least one electrode-array strip, the bio-electric microcurrent stimulation therapy to the patient based on the received parameters.

12. The method of claim 11, wherein the received parameters are further based on particular symptoms and medical history associated with the patient.

13. The method of claim 11, wherein the unique identification number is a serial number stored in the at least one integrated-circuit chip, and wherein the transmitting of the information

includes communicating the serial number from the at least one integrated-circuit chip to the computer server.

14. The method of claim 11, wherein the unique identification number is a serial number printed on the at least one electrode-array strip, and wherein the transmitting of the information includes reading, using a camera, the printed serial number to obtain image data and communicating the obtained image data to the computer server.

15. The method of claim 11, wherein the chip-electrode-array circuit is a one-use disposable chip-electrode-array circuit.

16. The method of claim 11, wherein the unique identification number includes public-key encryption information, the method further comprising encrypting data sent to the chip-electrode-array circuit from the computer server using the public-key encryption information.

17. The method of claim 11, further comprising

transmitting results of the bio-electric microcurrent stimulation therapy to a database located on the computer server; and

analyzing the results in order to improve future therapy sessions.

18. The method of claim 11, further comprising integrating a microprocessor with the chip-electrode-array circuit.

19. The method of claim 11, further comprising:

providing a local microprocessor system; and

coupling the local microprocessor system to the chip-electrode-array circuit.

20. The method of claim 11, further comprising:

providing a local microprocessor system, wherein the local microprocessor system includes a first portion and a second portion; and

coupling the first portion of the local microprocessor system to the head-mounted device, wherein the second portion of the local microprocessor system is located remotely from the head-mounted device.

21. A non-transitory computer-readable medium having instructions stored thereon for causing a suitably programmed information processor to execute a method for applying bio-electric microcurrent stimulation therapy to a patient via a chip-electrode-array circuit that includes at least one integrated-circuit chip, at least one electrode-array strip, and a unique identification number, wherein the chip-electrode-array circuit is coupled to a head-mounted device, the method comprising:

transmitting information from the chip-electrode-array circuit to a computer server, wherein the transmitted information includes the unique identification number;

receiving into the chip-electrode-array circuit, from the computer server, parameters for the bio-electric microcurrent stimulation therapy, wherein the received parameters are based at least in part on the unique identification number; and

delivering, via the at least one electrode-array strip, the bio-electric microcurrent stimulation therapy to the patient based on the received parameters.

22. The non-transitory computer-readable medium of claim 21, further comprising instructions such that the received parameters are further based on particular symptoms and medical history associated with the patient.

23. The non-transitory computer-readable medium of claim 21, further comprising instructions such that the unique identification number is a serial number stored in the at least one integrated-circuit chip, and wherein the transmitting of the information includes communicating the serial number from the at least one integrated-circuit chip to the computer server.

24. The non-transitory computer-readable medium of claim 21, wherein the unique identification number is a serial number printed on the at least one electrode-array strip, and wherein the transmitting of the information includes reading, using a camera, the printed serial number to obtain image data and communicating the obtained image data to the computer server.

25. The non-transitory computer-readable medium of claim 21, further comprising instructions such that the unique identification number includes public-key encryption information, the non-transitory computer-readable medium further comprising instructions such that the method further comprises:

encrypting data sent to the chip-electrode-array circuit from the computer server using the public-key encryption information.

26. The non-transitory computer-readable medium of claim 21, further comprising instructions such that the method further comprises:

transmitting results of the bio-electric microcurrent stimulation therapy to a database located on the computer server; and

analyzing the results in order to improve future therapy sessions.

27. An apparatus for applying bio-electric microcurrent stimulation therapy to a patient, the apparatus comprising:

a head-mounted device configured to mount to a head of the patient;

a plurality of electrodes coupled to the head-mounted device such that the plurality of electrodes contact the patient at a plurality of contact points when the head-mounted device is worn by the patient, wherein the plurality of electrodes is configured to deliver the bio-electric microcurrent stimulation therapy to the patient via the plurality of contact points;

a controller operatively coupled to the plurality of electrodes and configured to control electrical current that passes through the plurality of electrodes during delivery of the bio-electric microcurrent stimulation therapy; and

a pressure device configured to control a contact pressure of the plurality of electrodes at the plurality of contact points.

28. The apparatus of claim 27, further comprising at least a first ground electrode coupled to the head-mounted device and configured to be placed at a ground location on the patient.

29. The apparatus of claim 27, wherein the head-mounted device includes a display configured to present information related to the bio-electric microcurrent stimulation therapy.

30. The apparatus of claim 27, wherein the head-mounted device includes a plurality of light-emitting-diodes (LEDs) configured to provide light signals that provide information related to the bio-electric microcurrent stimulation therapy.

31. The apparatus of claim 27, wherein the head-mounted device includes at least a first haptic vibration device configured to provide vibration that provides information related to the

bio-electric microcurrent stimulation therapy.

32. The apparatus of claim 27, wherein the plurality of electrodes is part of at least a first disposable chip-electrode-array circuit.

33. The apparatus of claim 27, wherein the plurality of electrodes is part of at least a first disposable chip-electrode-array circuit on a flexible substrate, and wherein the flexible substrate further includes an adhesive layer and electrically conductive gel.

34. The apparatus of claim 27, wherein the controller is built into the head-mounted device.

35. The apparatus of claim 27, wherein the controller is located separately from the head-mounted device and is wirelessly coupled to the head-mounted device.

36. The apparatus of claim 27, wherein the plurality of electrodes is part of at least a first disposable chip-electrode-array circuit that includes a unique serial number (USN) that identifies the at least first disposable chip-electrode-array circuit and allows encrypted communications between the controller and a remote server that contains medical and therapy information associated with the patient.

37. The apparatus of claim 27, further comprising sensors operatively coupled to the controller and configured to provide feedback related to the bio-electric microcurrent stimulation therapy.

38. The apparatus of claim 27, wherein the pressure device includes a lens cover coupled to the head-mounted device and configured to contact the plurality of electrodes to apply pressure between the plurality of electrodes and the plurality of contact points.

39. The apparatus of claim 27, wherein the pressure device includes a lens cover coupled to the head-mounted device and configured to contact the plurality of electrodes to apply pressure between the plurality of electrodes and the plurality of contact points, wherein the lens cover is spring-mounted such that the lens cover is configured to flip between a first position that contacts the plurality of electrodes and a second position that is not in contact with the plurality of electrodes.

40. The apparatus of claim 27, wherein the pressure device includes a lens cover coupled to the head-mounted device and configured to contact the plurality of electrodes to apply pressure between the plurality of electrodes and the plurality of contact points, the apparatus further comprising:

sensors operatively coupled to the controller and configured to provide feedback related to the bio-electric microcurrent stimulation therapy.

41. A method for applying bio-electric microcurrent stimulation therapy to a patient via a disposable chip-electrode-array circuit that connects to a micro-stimulation current generating head-mounted device, the method comprising:

mounting the head-mounted device to the patient's head;

applying one or more electrode strips of the disposable chip-electrode-array circuit to a plurality of contact points on the patient's skin;

connecting the one or more electrode strips to the head-mounted device;

controlling electrical current that passes through the one or more electrode strips during delivery of the bio-electric microcurrent stimulation therapy; and

controlling a contact pressure of the one or more electrode strips at the plurality of contact points.

42. The method of claim 41, further comprising:

providing a first ground electrode;

coupling the first ground electrode to the head-mounted device; and

placing the first ground electrode at a ground location on the patient.

43. The method of claim 41, further comprising:

displaying information related to the bio-electric microcurrent stimulation therapy.

44. The method of claim 41, wherein the head-mounted device includes a plurality of light-emitting-diodes (LEDs), the method further comprising:

generating light signals using the plurality of LEDs in order to provide information related to the bio-electric microcurrent stimulation therapy.

45. The method of claim 41, wherein the head-mounted device includes at least a first haptic

vibration device, the method further comprising:

generating vibration signals using the at least first haptic vibration device in order to provide information related to the bio-electric microcurrent stimulation therapy.

46. The method of claim 41, further comprising:

providing a flexible substrate that includes an adhesive layer and electrically conductive gel; and

mounting the at least a first disposable chip-electrode-array circuit on the flexible substrate.

47. The method of claim 41, wherein the controlling of the electrical current occurs within the head-mounted device.

48. The method of claim 41, wherein the controlling of the electrical current occurs remote from the head-mounted device.

49. The method of claim 41, wherein the disposable chip-electrode-array circuit includes a unique serial number (USN) that identifies the disposable chip-electrode-array circuit for a remote server that contains medical and therapy information associated with the patient, wherein the controlling of the electrical current includes transmitting and receiving encrypted communications between the chip-electrode-array circuit and the remote server.

50. The method of claim 41, further comprising:

providing one or more sensors operatively coupled to the head-mounted device, wherein the controlling of the electrical current includes receiving feedback from the one or more sensors during the applying of the bio-electric microcurrent stimulation therapy.

51. The method of claim 41, further comprising:

providing a lens cover coupled to the head-mounted device, wherein the controlling of the contact pressure of the one or more electrode strips includes pushing the lens cover into the one or more electrode strips to apply pressure between the plurality of electrodes and the plurality of contact points.

52. The method of claim 41, further comprising:

providing a lens cover coupled to the head-mounted device, wherein the controlling of the contact pressure of the one or more electrode strips includes flipping the lens cover between a first position that contacts the one or more electrode strips and a second position that is not in contact with the one or more electrode strips.

53. The method of claim 41, further comprising:

providing a lens cover coupled to the head-mounted device, wherein the controlling of the contact pressure of the one or more electrode strips includes flipping the lens cover between a first position that contacts the one or more electrode strips and a second position that is not in contact with the one or more electrode strips; and

providing one or more sensors operatively coupled to the head-mounted device, wherein the controlling of the electrical current includes receiving feedback from the one or more sensors during the applying of the bio-electric microcurrent stimulation therapy.

FIG. 1A

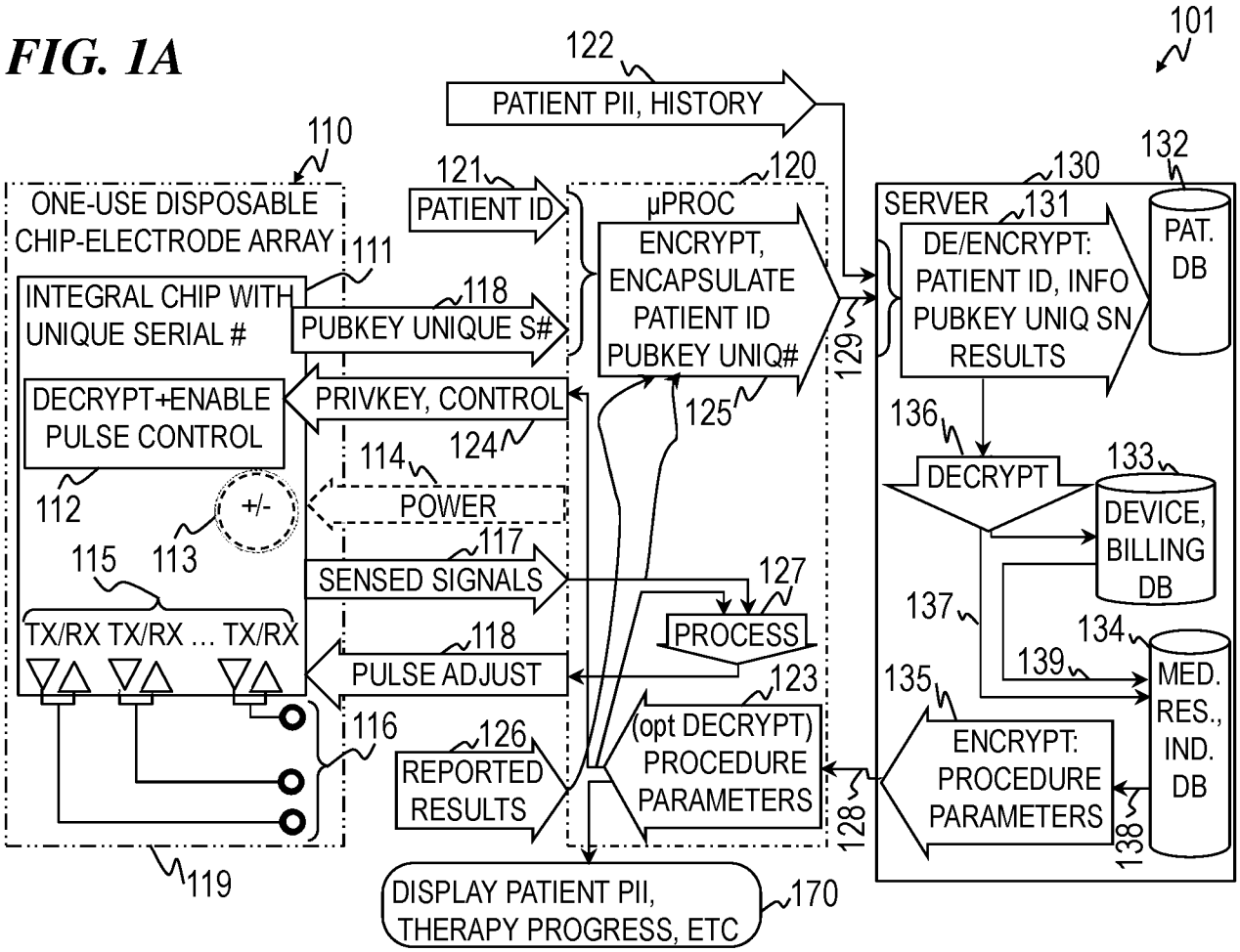
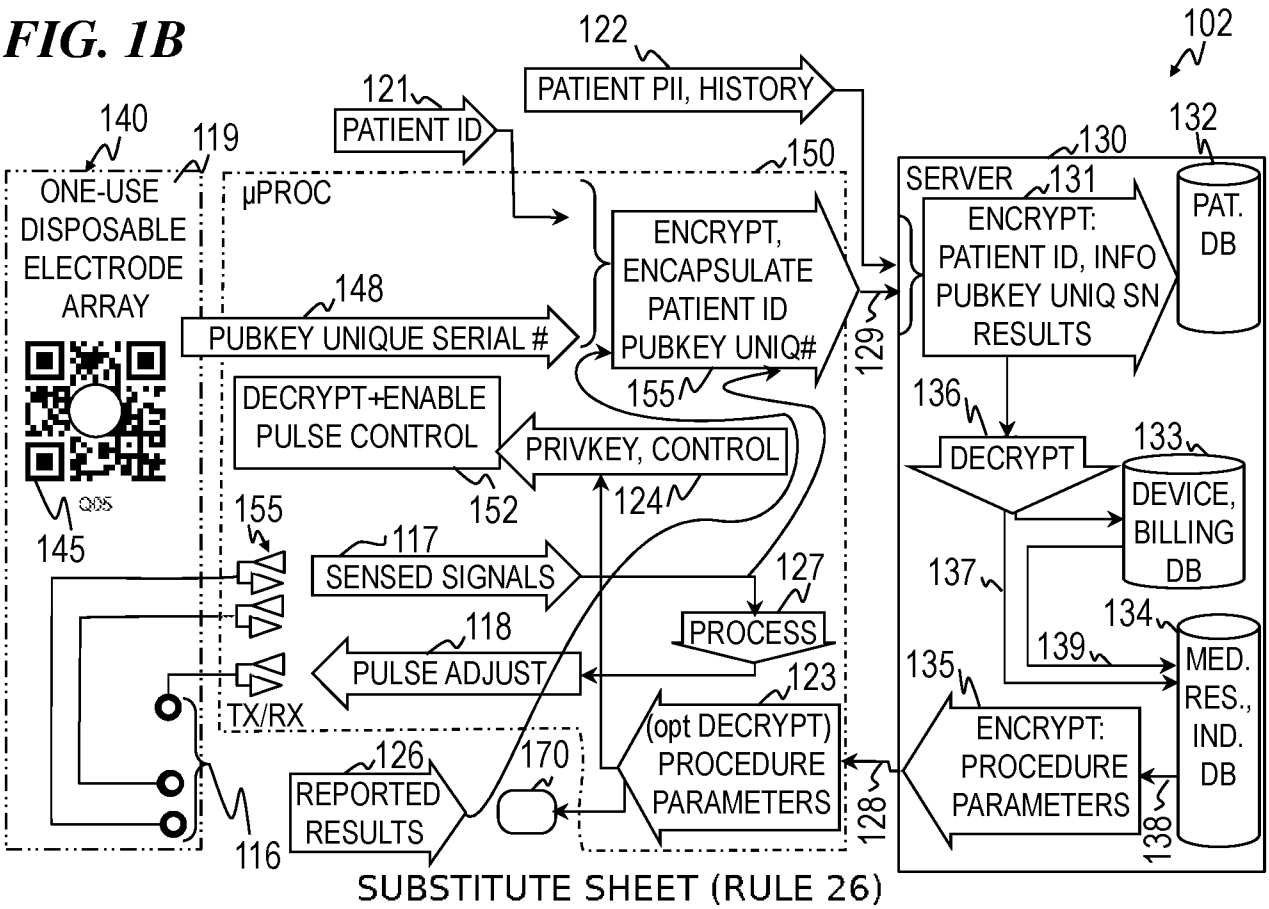
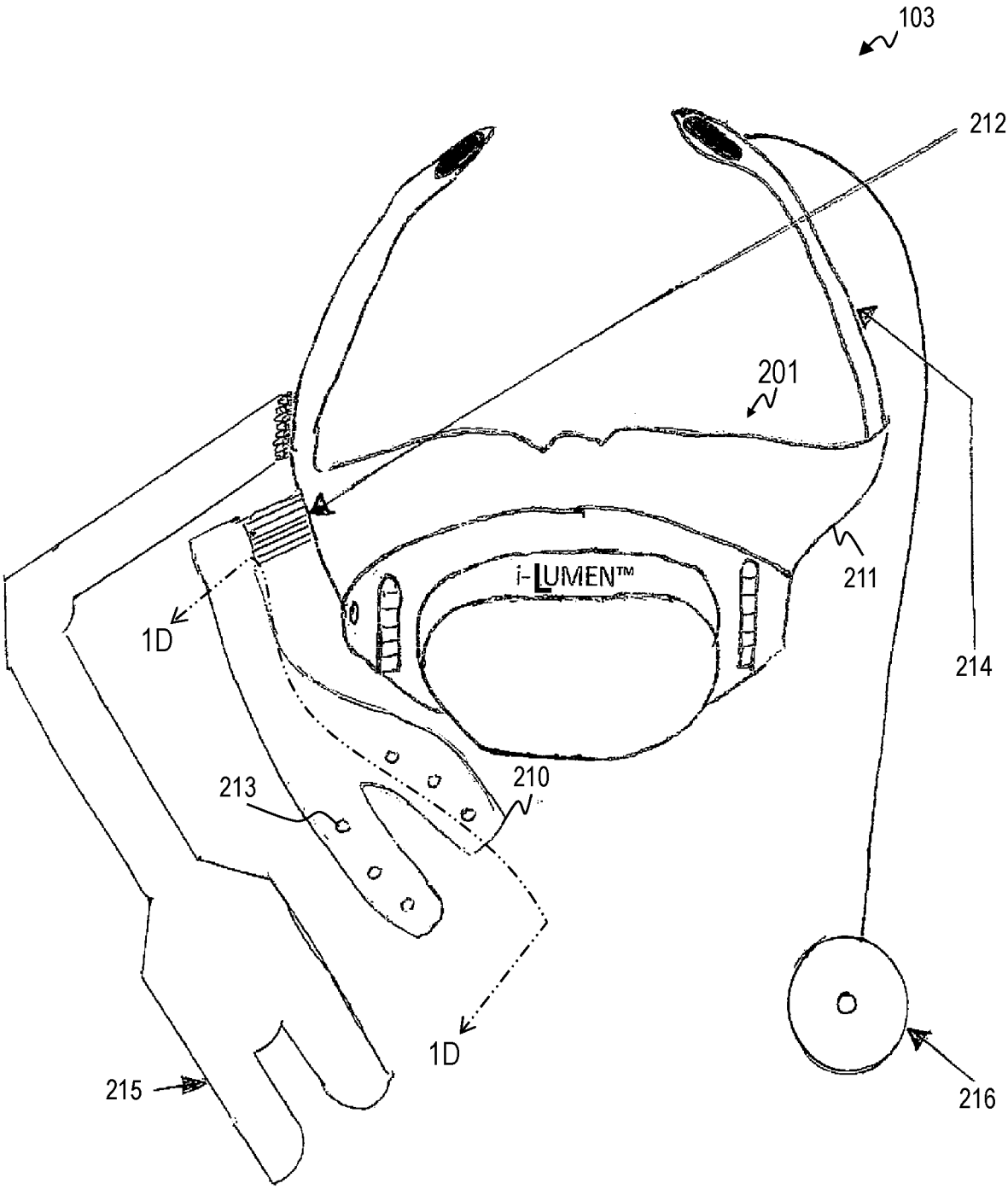


FIG. 1B



SUBSTITUTE SHEET (RULE 26)

FIG. 1C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1D
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FIG. 1D

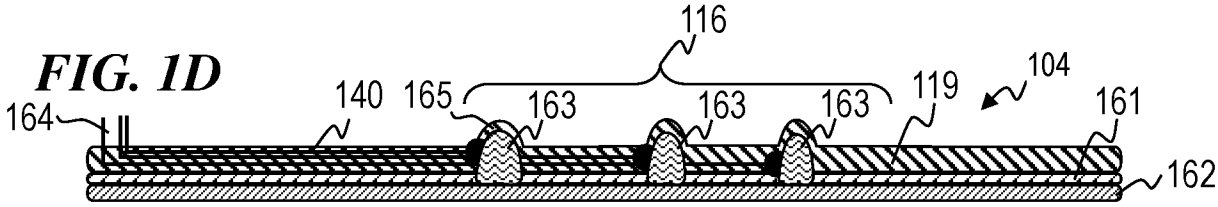
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FIG. 1E

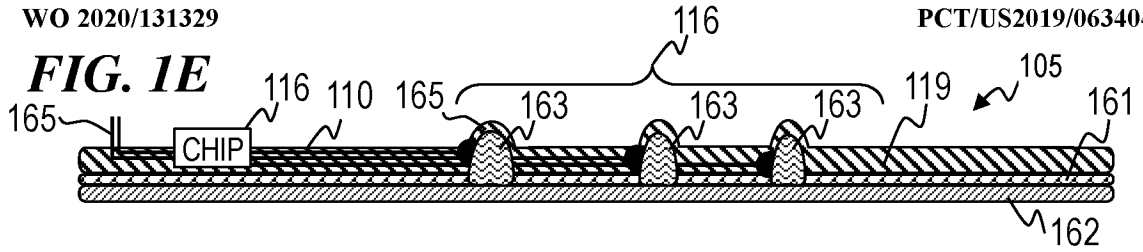
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FIG. 2

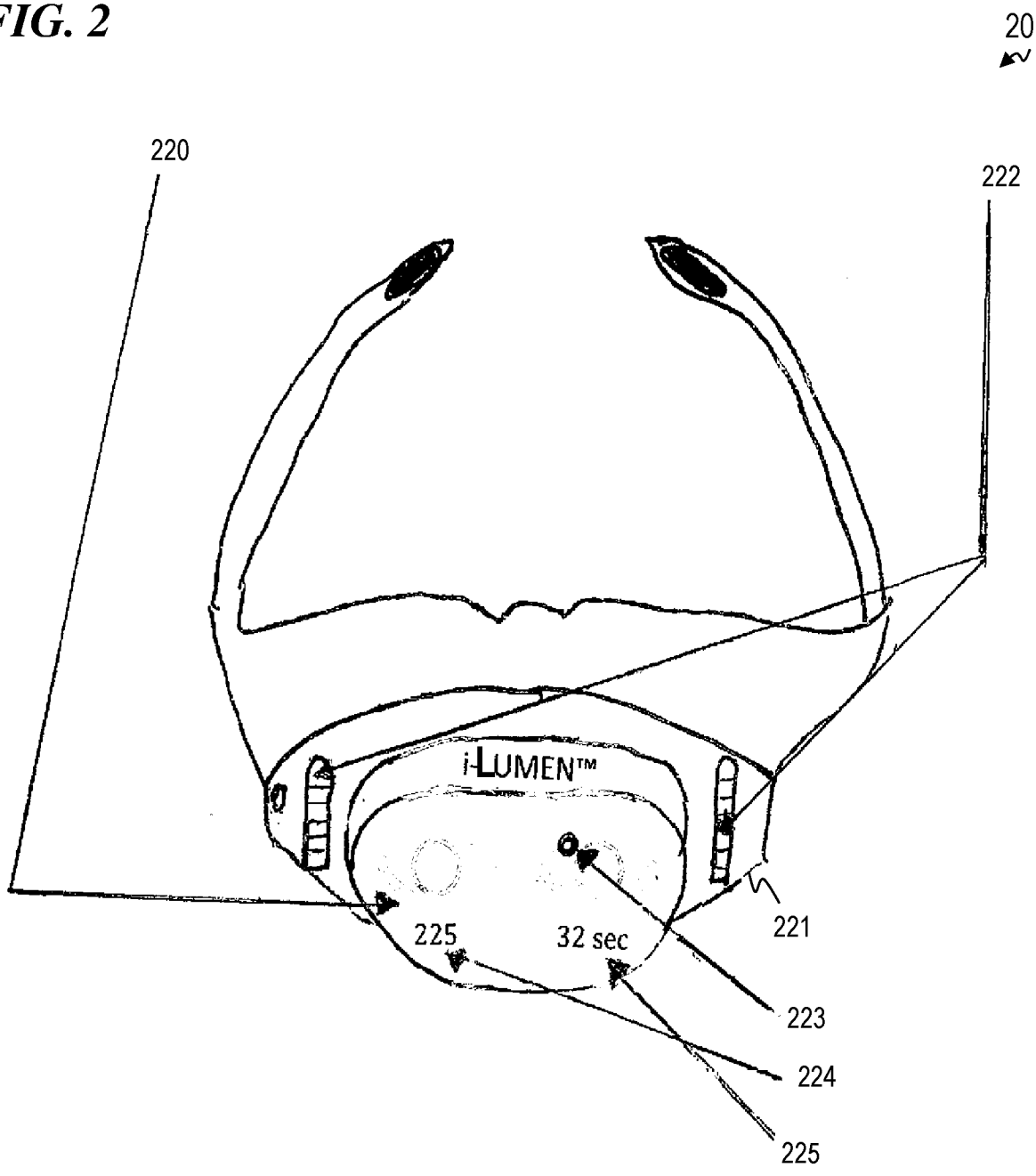
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FIG. 3

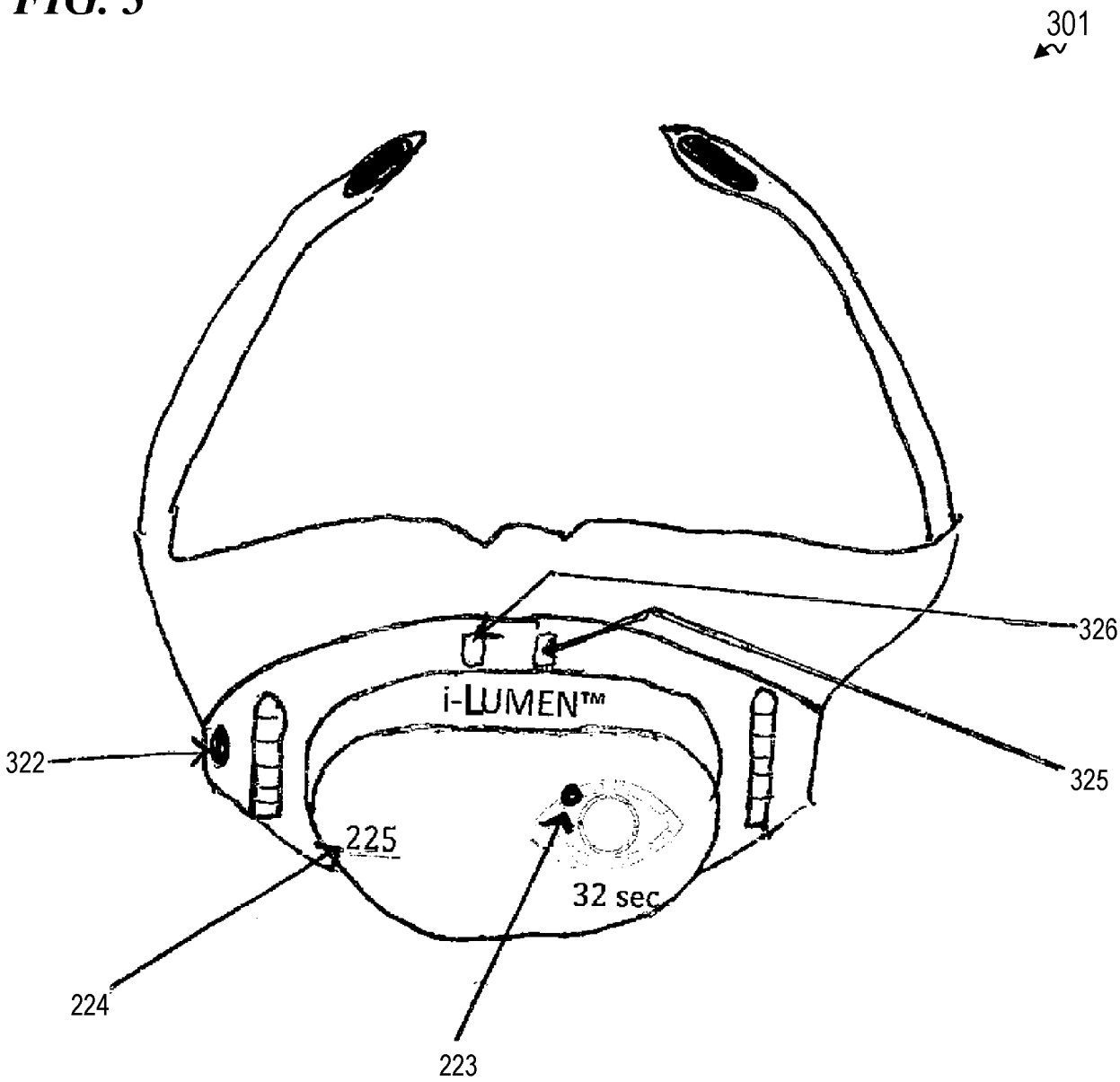

FIG. 4A

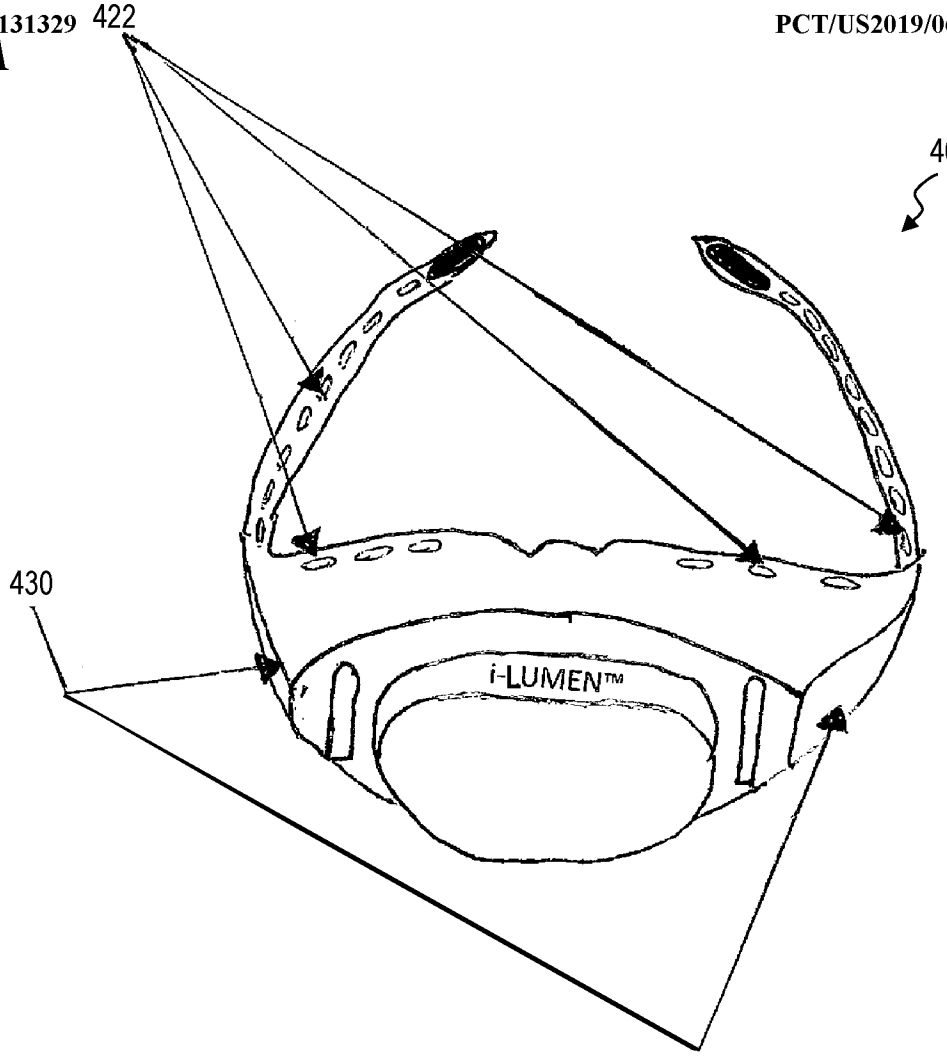
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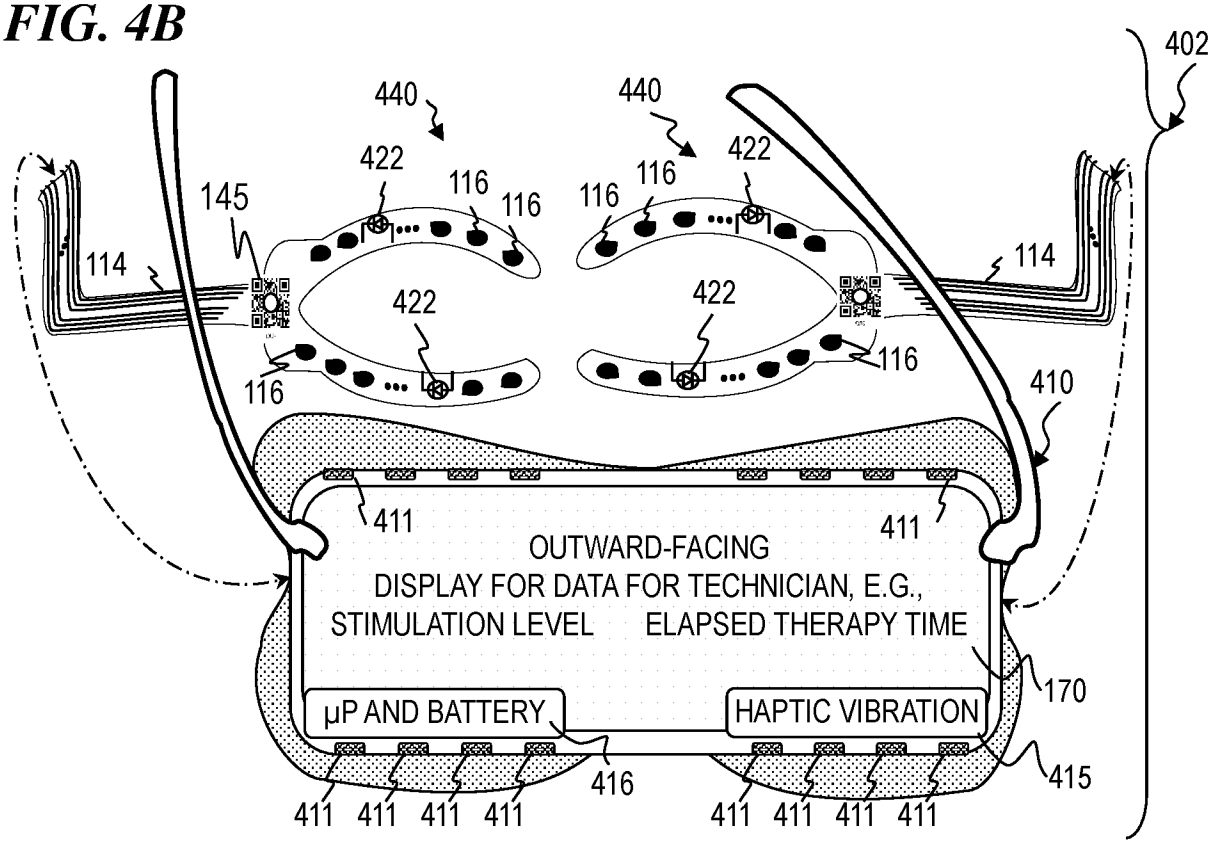
FIG. 4B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OUTWARD-FACING
DISPLAY FOR DATA FOR TECHNICIAN, E.G.,
STIMULATION LEVEL
ELAPSED THERAPY TIME
170
μP AND BATTERY
HAPTIC VIBRATION
415
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411 411 411 411

FIG. 5

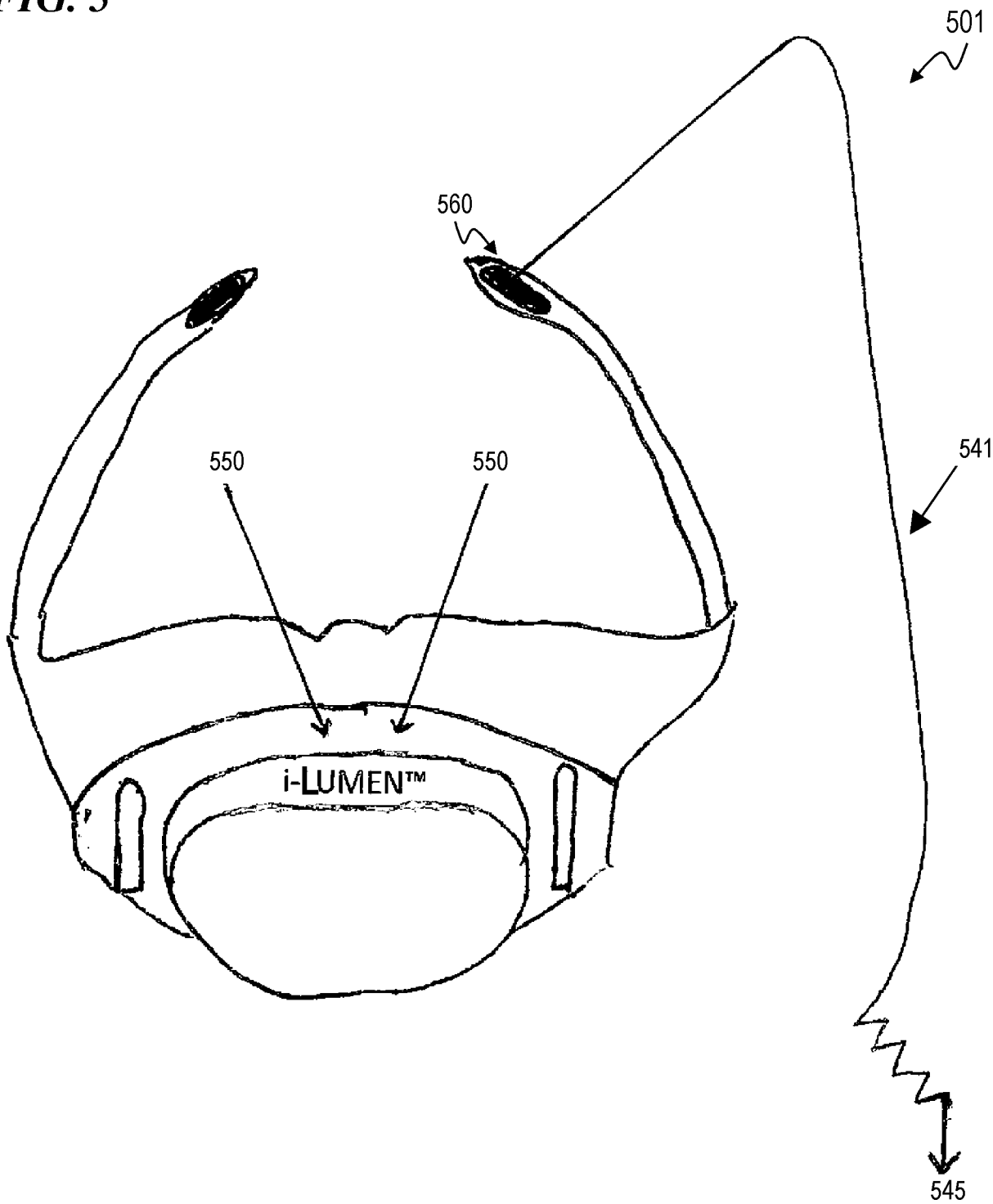
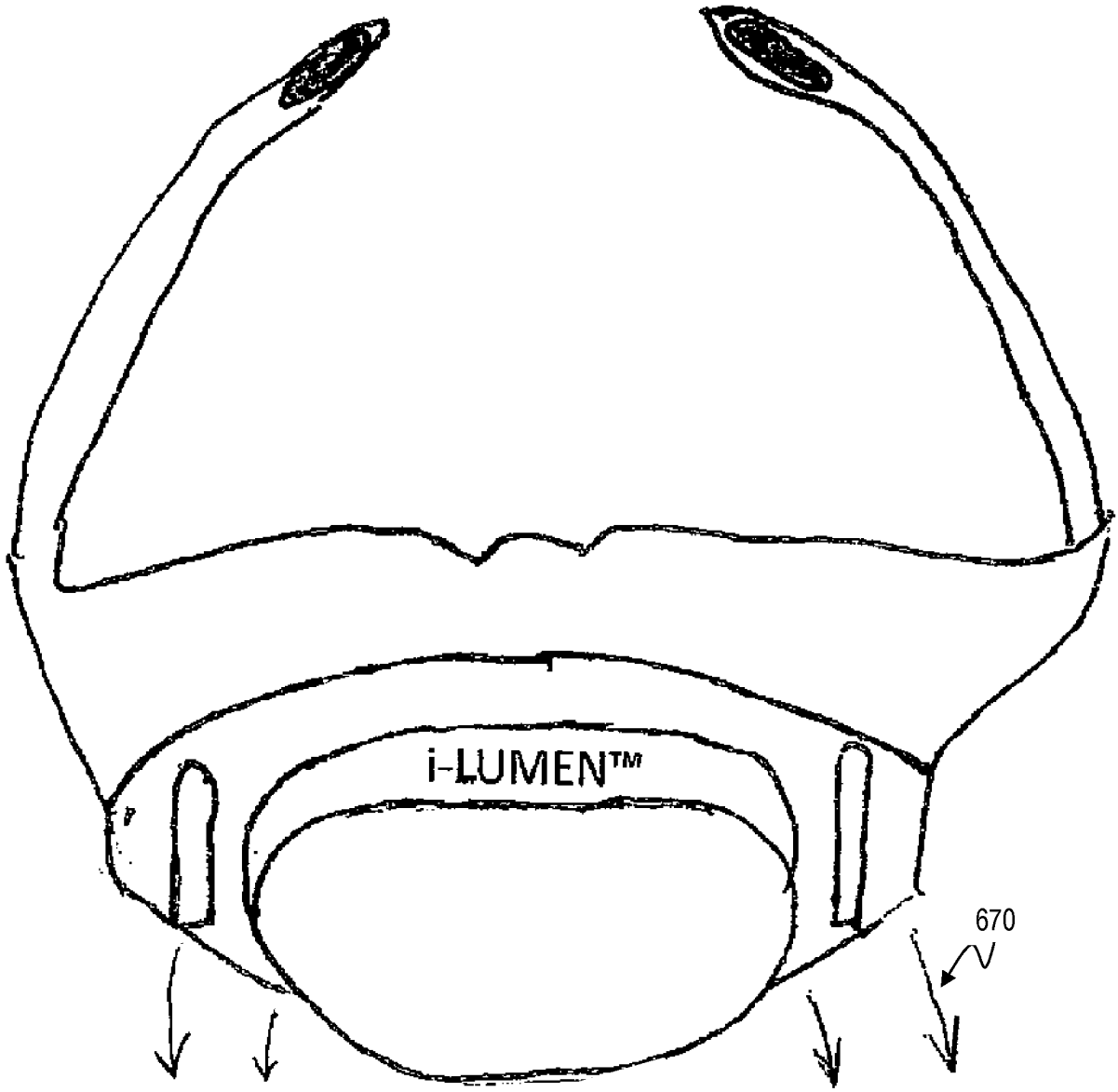


FIG. 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 19/63404

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61N 1/32; A61N 1/36 (2020.01)

CPC - A61N 1/36046; A61N 1/38; A61N 1/36014; A61N 1/36

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y --- A	WO 2017/048731 A1 (AMERIVISION INT INC) 23 March 2017 (23.03.2017), entire document, especially para [0068], [0074], [0078], [0082], [0086]	1, 2, 5, 7-12, 15, 17-22, 26 --- 27-30, 32-37, 41-44, 46-48, 50 --- 3, 4, 6, 13, 14, 16, 23-25, 31, 36, 38-40, 45, 49, 51-53
Y --- A	US 2018/0318586 A1 (NOVA OCULUS CANADA MANUFACTURING ULC) 08 November 2018 (08.11.2018), entire document, especially para [0041], [0117]	27-30, 32-37, 41-44, 46-48, 50 --- 3, 4, 6, 13, 14, 16, 23-25, 31, 36, 38-40, 45, 49, 51-53

☐ 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
26 April 2020	14 MAY 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 Lee Young Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 19/63404

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.:
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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-26 drawn to applying bio- electric microcurrent stimulation therapy to a patient including a chip-electrode-array circuit includes a unique identification number.

Group II: Claims 27-53 drawn to applying bio-electric microcurrent stimulation therapy to a patient including a pressure device configured to control a contact pressure of the plurality of electrodes at the plurality of contact points.

---see extra sheet---

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.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US 19/63404

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

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

Special technical features

Group I requires wherein the chip-electrode-array circuit includes a unique identification number, not required by Group II.

Group II requires a pressure device configured to control a contact pressure of the plurality of electrodes at the plurality of contact points, not required by Group I.

Shared technical features:

The only technical features shared by Groups I and II that would otherwise unify the groups are applying bio-electric microcurrent therpy to a patient; a head mounted device configured to be mounted to the patient's head; electrodes configured to deliver the bio-electric microcurrent stimulation to the patient.

However, these shared technical features do no represent a contribution over prior art, because the shared technical features are disclose by US 2004/0176820 A1 to Paul, JR. (hereinafter 'Paul') published on 09 September 2004 (09.09.2004). Paul discloses applying bio-electric microcurrent therpy to a patient (para [0002] "The present invention relates to a method and apparatus for performing microcurrent simulation (MSC) therapy."); a head mounted device configured to be mounted to the patient's head (where eyes are located on the head, para [0032] "FIGS. 3A-3C illustrate various views of the MCS apparatus of the present invention in accordance with another embodiment. In accordance with this embodiment, the microcurrent is provided to the user's ocular tissues by goggles to which the electrodes are connected. FIG. 3A shows the MCS components, which include plastic goggles (40), an elastic band (41) for providing a force that holds the goggles in place when worn by the user, a casing (42) that houses the MCS electrical components, and a cable (43) that supplies the current generated by the electrical components in casing (42) to the electrodes in the goggles (40). ");
electrodes configured to deliver the bio-electric microcurrent stimulation to the patient (para [0032] "FIGS. 3A-3C illustrate various views of the MCS apparatus of the present invention in accordance with another embodiment. In accordance with this embodiment, the microcurrent is provided to the user's ocular tissues by goggles to which the electrodes are connected. FIG. 3A shows the MCS components, which include plastic goggles (40), an elastic band (41) for providing a force that holds the goggles in place when worn by the user, a casing (42) that houses the MCS electrical components, and a cable (43) that supplies the current generated by the electrical components in casing (42) to the electrodes in the goggles (40). ").

As the shared technical features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Groups I and II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.