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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 November 2015 (26.11.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/179571 A1

(51) International Patent Classification:
A61N 1/36 (2006.01)

(21) International Application Number:
PCT/US2015/031847

(22) International Filing Date:
20 May 2015 (20.05.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/001,004	20 May 2014 (20.05.2014)	US
14/292,491	30 May 2014 (30.05.2014)	US
14/335,726	18 July 2014 (18.07.2014)	US
14/335,784	18 July 2014 (18.07.2014)	US

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

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

Published:

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

(54) **Title:** NON-INVASIVE NERVE STIMULATION VIA MOBILE DEVICES

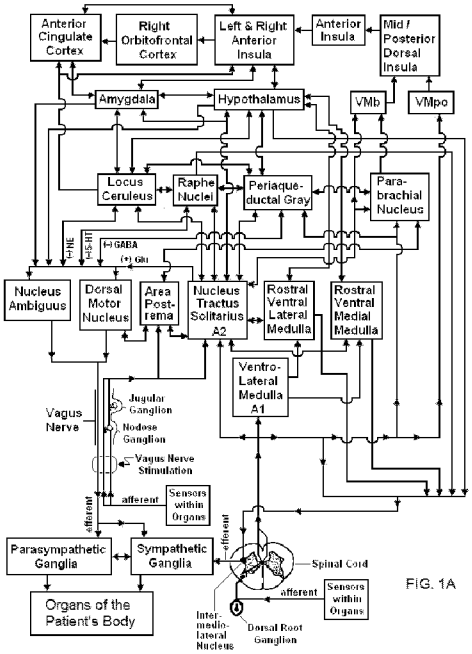

FIG. 1A

(57) **Abstract:** Devices, systems, and methods are disclosed that allow a patient to self-treat a medical condition, such as a migraine headache,an epileptic seizure, a neurodegenerative disease, such as dementia, Alzheimer's disease, ischemic stroke, post-concussion syndrome, chronic traumatic encephalopathy or the like, by electrical non-invasive stimulation of a vagus nerve. The system can comprise a hand-held stimulator which is applied to a surface of the patient's neck, wherein the stimulator comprises or is joined to a mobile device. A camera of the mobile device may be used to position and reposition the stimulator to a particular location on the patient's neck. The system may also comprise a base station that is used to meter the charging of a rechargeable battery within the stimulator. The base station and stimulator transmit data to one another regarding the status of a stimulation session.

TITLE OF INVENTION

NON-INVASIVE NERVE STIMULATION VIA MOBILE DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of priority to U.S. Provisional Application Serial No. 62/001,004 filed 20 May 2014; U.S. Nonprovisional Application Serial No. 14/292,491 filed 30 May 2014; U.S. Nonprovisional Application Serial No. 14/335,726 filed 18 July 2014; and U.S. Nonprovisional Application Serial No. 14/335,784 filed 18 July 2014; each of which is incorporated herein by reference in its entirety for all purposes.

BACKGROUND

[0002] The field of the present disclosure relates to the delivery of energy impulses (and/or fields) to bodily tissues for therapeutic purposes. The present disclosure relates more specifically to devices and methods for treating medical conditions, such as migraine headaches, epilepsy, or others, wherein the patient uses the devices and methods as self-treatment, without the direct assistance of a healthcare professional. The energy impulses (and/or fields) that are used to treat those conditions comprise electrical and/or electromagnetic energy, delivered non-invasively to the patient, particularly to a vagus nerve of the patient.

[0003] The use of electrical stimulation for treatment of medical conditions is well known. One of the most successful applications of modern understanding of the electrophysiological relationship between muscle and nerves is the cardiac pacemaker. Although origins of the cardiac pacemaker extend back into the 1800's, it was not until 1950 that the first practical, albeit external and bulky, pacemaker was developed. The first truly functional, wearable pacemaker appeared in 1957, and in 1960, the first fully implantable pacemaker was developed.

[0004] Around this time, it was also found that electrical leads could be connected to the heart through veins, which eliminated the need to open the chest cavity and attach the lead to the heart wall. In 1975, the introduction of the lithium-iodide battery prolonged the battery life of a pacemaker from a few months to more than a decade. The modern pacemaker can treat a variety of different signaling pathologies in the cardiac muscle, and can serve as a defibrillator as well (see U.S. Patent Number 6,738,667 to DENO, et al., the disclosure of which is fully incorporated herein by reference for all purposes). Because the leads are implanted within the patient, the pacemaker is an example of an implantable medical device.

[0005] Another such example is electrical stimulation of the brain with implanted electrodes (deep brain stimulation), which has been approved for use in the treatment of various conditions, including pain and movement disorders such as essential tremor and Parkinson's disease [Joel S. PERLMUTTER and Jonathan W. Mink. Deep brain stimulation. Annu. Rev. Neurosci 29 (2006):229-257].

[0006] Another application of electrical stimulation of nerves is the treatment of radiating pain in the lower extremities by stimulating the sacral nerve roots at the bottom of the spinal cord [Paul F. WHITE, Shitong Li and Jen W. Chiu. Electroanalgesia: Its Role in Acute and Chronic Pain Management. Anesth Analg 92(2001):505-513; patent US6871099, entitled Fully implantable microstimulator for spinal cord stimulation as a therapy for chronic pain, to WHITEHURST, et al].

[0007] Vagus nerve stimulation (VNS, also known as vagal nerve stimulation) is a form of electrical stimulation. It was developed initially for the treatment of partial onset epilepsy and was subsequently developed for the treatment of depression and other disorders. The left vagus nerve is ordinarily stimulated at a location within the neck by first surgically implanting an electrode there and then connecting the electrode to an electrical stimulator [Patent numbers US4702254 entitled Neurocybernetic prosthesis, to ZABARA; US6341236 entitled Vagal nerve stimulation techniques for treatment of epileptic seizures, to OSORIO

et al; US5299569 entitled Treatment of neuropsychiatric disorders by nerve stimulation, to WERNICKE et al; G.C. ALBERT, CM. Cook, F.S. Prato, A.W. Thomas. Deep brain stimulation, vagal nerve stimulation and transcranial stimulation: An overview of stimulation parameters and neurotransmitter release. Neuroscience and Biobehavioral Reviews 33 (2009):1 042-1 060; GROVES DA, Brown VJ. Vagal nerve stimulation: a review of its applications and potential mechanisms that mediate its clinical effects. Neurosci Biobehav Rev 29(2005):493-500; Reese TERRY, Jr. Vagus nerve stimulation: a proven therapy for treatment of epilepsy strives to improve efficacy and expand applications. Conf Proc IEEE Eng Med Biol Soc. 2009; 2009:4631 -4634; Timothy B. MAPSTONE. Vagus nerve stimulation: current concepts. Neurosurg Focus 25 (3,2008):E9, pp. 1-4; ANDREWS, R.J. Neuromodulation. I. Techniques-deep brain stimulation, vagus nerve stimulation, and transcranial magnetic stimulation. Ann. N. Y. Acad. Sci. 993(2003):1-1 3; LABINER, D.M., Ahern, G.L. Vagus nerve stimulation therapy in depression and epilepsy: therapeutic parameter settings. Acta. Neurol. Scand. 115(2007):23-33].

[0008] Chronic daily headache by definition occurs with a frequency of at least 15 headache days per month for greater than 3 months duration. Chronic migraine sufferers comprise a subset of the population of chronic headache sufferers, as do those who suffer other primary headache disorders such as chronic tension-type headache [Bert B.VARGAS, David W. Dodick. The Face of Chronic Migraine: Epidemiology, Demographics, and Treatment Strategies. Neurol Clin 27 (2009) 467-479; Peter J. GOADSBY, Richard B. Lipton, Michel D. Ferrari. Migraine - Current understanding and treatment. N Engl J Med 346 (4,2002): 257- 270; Stephen D SILBERSTEIN. Migraine. LANCET 363 (2004):381 -391].

[0009] A migraine headache typically passes through the following stages: prodrome, aura, headache pain, and postdrome. All these phases do not necessarily occur, and there is not necessarily a distinct onset or end of each stage,

with the possible exception of the aura. An interictal period follows the postdrome, unless the postrome of one migraine attack overlaps the prodrome of the next migraine attack.

[0010] The prodrome stage comprises triggering events followed by premonitory symptoms. The prodrome is often characterized by fatigue, sleepiness, elation, food cravings, depression, and irritability, among other symptoms. Triggers (also called precipitating factors) such as excessive stress or sensory barrage usually precede the attack by less than 48 h. The average duration of the prodrome is 6 to 10 hours, but in half of migraine attacks, the prodrome is less than two hours (or absent), and in approximately 15% of migraine attacks, the prodrome lasts for 12 hours to 2 days.

[001 1] The aura is due to cortical spreading depression within the brain. Approximately 20-30% of migraine sufferers experience an aura, ordinarily a visual aura, which is perceived as a scintillating scotoma (zig-zag line) that moves within the visual field. However, aura symptoms, regardless of their form, vary to a great extent in duration and severity from patient to patient, and also within the same individual.

[0012] Although the headache phase can begin at any hour, it most commonly begins as mild pain when the patient awakens in the morning. It then gradually builds at variable rates to reach a peak at which the pain is usually described as moderate to severe. Migraine headaches often occur on both sides of the head in children, but an adult pattern of unilateral pain often emerges in adolescence. The pain is often reported as starting in the occipital/neck regions, later becoming frontotemporal. It is throbbing and aggravated by physical effort, with all stimuli tending to accentuate the headache. The pain phase lasts 4-72 h in adults and 1-72 h in children, with a mean duration generally of less than 1 day. The pain intensity usually follows a smooth curve with a crescendo with a diminuendo. After the headache has resolved, many patients are left with a

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