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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 January 2021 (28.01.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/013654 A1

(51) International Patent Classification:
A61N 1/04 (2006.01) *A61N 1/36* (2006.01)

(21) International Application Number:
PCT/EP2020/070025

(22) International Filing Date:
15 July 2020 (15.07.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1910452.0 22 July 2019 (22.07.2019) GB

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

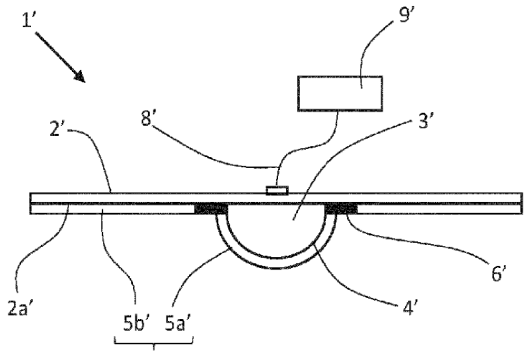

Fig. 3

(57) Abstract: The present disclosure relates to devices, systems and methods for the delivery of electrical stimulation for the treatment of acute or chronic pain and/or for the improvement of body function. There is described a neuromodulation electrode device comprising a substrate having a skin-facing surface and an electrode having at least one convex active surface projecting from the skin-facing surface of substrate for applying an electrical stimulation signal. A conductive gel layer having an electrode portion overlies the convex active surface(s) of the electrode. The substrate is formed of a conductive gel or the conductive gel layer further comprises a substrate portion overlying the skin-facing surface of the substrate. The device further comprises an isolating frame surrounding the perimeter of the electrode to provide electrical isolation between the electrode and the conductive gel substrate or from the substrate portion of the conductive gel layer.

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ELECTRODE

Field of the disclosure

This invention relates to devices, systems and methods for the delivery of electrical stimulation for the treatment of acute or chronic pain and/or for the improvement of body function.

Background

It is known that the application of a mild electrical current through a patient's skin can reduce pain and improve body function e.g. improve digestive function. Such nerve stimulation - or neuromodulation - has been used to help relieve a wide range of ailments including migraines, arthritic pain, muscular pain and neuropathic pain.

Devices used to apply such electrical stimulation include hand-held devices for at-home use by patients. The known devices include sticky electrode patches applied to the skin in the general vicinity of the pain and connected to a power supply. One problem with these known devices is that they are unfocussed and only apply the stimulation to the upper layers of the skin. They are thus unable to provide a focussed and suitably penetrative stimulation depth to target deeper nerves.

To try and provide for a more targeted and deeper penetration of the current, devices have been developed which incorporate electrodes having a domed or ball-like surface that can be pressed into the skin. Such domed/ball electrodes are typically provided only on hand-held probes.

Patients have reported discomfort caused by the pressure of the hard-rounded end of the domed/ball electrodes of the hand held probes. Skin irritation can also arise after prolonged use. To ameliorate these problems, probes having a softer coating e.g. formed of hydrogel have been developed. Such hand-held probes can be uncomfortable to maintain in position, especially if longer application times are required and/or if the body area requiring treatment is not easily accessible.

There is a desire to provide an improved device/system for neuromodulation for the treatment of acute or chronic pain and/or for the improvement of body function, which provides increased comfort and convenience for the user and which maximises the targeted penetration of the electrical stimulation.

Summary

Accordingly, in a first aspect, there is provided a neuromodulation electrode device comprising:

a substrate having a skin-facing surface;

an electrode having at least one convex active surface projecting from the skin-facing surface of substrate for applying an electrical stimulation signal; and

a conductive gel layer having an electrode portion overlying the convex active surface(s) of the electrode;

wherein the substrate is formed of a conductive gel or the conductive gel layer further comprises a substrate portion overlying the skin-facing surface of the substrate; and

wherein the device further comprises an isolating frame extending around the perimeter of the electrode to provide electrical isolation between the electrode and the conductive gel substrate or from the substrate portion of the conductive gel layer.

By providing a conductive gel layer to the active surface(s) of the electrode, and either a conductive gel substrate or a conductive gel layer substrate portion over the skin-facing surface of the substrate, the comfort of the device against the wearer's skin is significantly increased. Furthermore, the conductive gel layer may reduce any risk of burn injury to the patient. The gel or gel-coated substrate can be used to comfortably affix and maintain the position of the device without the user having to hold it in place – this makes longer application times and inaccessible treatment areas easier to manage for the user. The isolating frame concentrates/focusses and isolates the electrical stimulation through the electrode portion of the conductive gel layer. Without the isolating frame, the inventors found that the electrical stimulation was applied across the whole extent of the conductive gel substrate or conductive gel layer. This attenuation of the electrical stimulation was found to significantly decrease effectiveness in the treatment of pain and improvement of body function. Thus provision of the isolating frame has thus been shown to provide better penetration of the electrical stimulus to the body.

In some embodiments, the substrate is formed of a conductive gel. The conductive gel may be the same or different to the conductive gel of the conductive gel layer.

Where the substrate is formed of conductive gel, there may be a backing layer formed on the surface of the (conductive gel) substrate opposing the skin-facing surface. The backing layer is preferably non-conductive (an electrical insulator).

The backing layer may be a textile backing layer (e.g. a woven or knitted textile fabric layer). In other embodiments, the backing layer may be formed of plastics material. The backing layer may be a silicone rubber.

In other embodiments, the substrate may be formed of non-gel material e.g. a non-conductive plastics (e.g. silicone rubber) or textile material. In these embodiments, the conductive gel layer further comprises a substrate portion that overlies the substrate.

The skin-facing surface of the substrate or the substrate portion of the conductive gel layer may be adhesive. This facilitates attachment and position maintenance of the device on the skin of the patient. It also ensures a firm pressure of the active surface of the electrode into the patient's skin. The adhesive properties of the conductive gel used to form the substrate or to form the substrate portion of the conductive gel layer may be utilised to provide attachment to the patient.

Ideally a conductive gel having reusable adhesive properties is used to form the substrate/substrate portion of the conductive gel layer to allow the device to be reused.

The backing layer or the non-gel substrate may be a stiff and/or self-supporting layer/substrate but pliable to conform to the body part to which the device is applied. It may be pre-formed into a curved profile for application to a specific body part.

In other embodiments, the backing layer or the non-gel substrate may comprise a thermo-formable or curable (e.g. air or chemically curable) material so as to assume a shape that it will retain in use. It can thus be pre-shaped over the site to be treated, and then heated or otherwise treated in order to achieve the desired shape or form.

The backing layer/non-gel substrate may also be used with or be provided with an attachment element such as a strap or band to assist in attaching it firmly to the desired position on a patient. The strap/band may conveniently be secured by means

of a hook and loop connection (e.g. Velcro®) so that in use, the device can be held firmly against the skin of a patient.

The isolating frame electrically isolates the electrode (and the electrode portion of the conductive gel layer) from the conductive gel substrate or from the electrode portion of the conductive gel layer.

If the non-gel substrate is conductive, the isolating frame will also electrically isolate the electrode (and the electrode portion of the conductive gel layer) from the non-gel substrate.

The isolating frame may have a width of between 2 and 20 mm i.e. it will provide a non-conductive spacing from the electrode of between 2 and 20mm.

In some embodiments, the isolating frame is an isolating annulus. The isolating annulus has an inner radius (adjacent the electrode) and an outer radius (adjacent the substrate). The radial spacing between the inner radius and outer radius may be between 2 and 20mm.

In some embodiments, the isolating annulus is an isolating ring formed of a non-conductive material, e.g. a non-conductive plastics material.

In other embodiments, the isolating frame/annulus is an isolating gap e.g. an isolating gap between the electrode portion and substrate portion of the conductive gel layer.

The electrode is generally formed of a conductive material such as a conductive metal material. It may be formed of a plastic material with a conductive e.g. metallic coating.

The electrode has as least one convex stimulating surface. The electrode may have at least one domed, hemispherical or parabolic stimulating surface.

It may have a circular, triangular, polygonal or square cross section in a plane parallel to the substrate.

In preferred embodiments, the electrode has a single hemispherical stimulating surface with a circular cross-section i.e. the electrode is a domed stud.

Where the electrode has a circular cross-section (e.g. is a domed stud), the effective diameter of the stimulating surface (e.g. at the base of the stimulating surface proximal the substrate) that is in contact with the skin of a patient is typically between 2mm and 12mm, though more generally between 6mm to 10mm. For use on normal skin (as opposed to mucosal linings) it has been found that an electrode where the diameter of the stimulating surface is between 5 and 10mm produces best results.

The convex stimulating surface of the electrode typically projects between 3 to 6mm beyond the skin-facing surface of the substrate.

In some embodiments, the device comprises a plurality of electrodes. In some embodiments, the device comprises an even number of electrodes wherein pairs of electrodes are arranged to receive opposite electrical polarities.

The plurality of electrodes may be mounted in an array or matrix on the substrate. Each of the plurality of electrodes will have a respective isolating frame/annulus.

In some embodiments, the conductive gel layer or the conductive gel substrate is formed of a deformable, electrically-conducting polymeric gel material e.g. a conductive silicone gel polymer.

The conductive gel layer or the conductive gel substrate may be formed of a conductive hydrogel.

A hydrogel is a three-dimensional (3D) network of hydrophilic polymers that can swell in water and hold a large amount of water while maintaining the structure due to chemical or physical cross-linking of individual polymer chains. By definition, water must constitute at least 10% of the total weight (or volume) for a material to be a hydrogel. The conductive hydrogel may contain up to 90wt% water.

Hydrogels possess a degree of flexibility very similar to natural tissue due to their significant water content. The hydrogel layer is soft and flexible (providing improved comfort to the user) as well as being a good electrical conductor that can also provide a low electrical resistance in contact with skin. Hydrogels are non-irritant to skin and hypoallergenic making them suitable for prolonger contact with skin.

The hydrophilicity of the network is due to the presence of hydrophilic groups such as $-NH_2$, -COOH, -OH, $-CONH_2$, - CONH -, and $-SO_3H$.

Such hydrogels may also adhere lightly to the skin, thus allowing for easy removal and re-use (e.g. up to 10 times). In this specification the term 'hydrogel' refers to any similar gel or substance that may possess such properties.

The conductive gel layer (e.g. the electrode portion) may be between 0.5 to 2.5mm thick, e.g. between 0.75 to 1mm thick. Where the conductive gel layer further comprises a substrate portion, the thickness of the substrate portion may match the thickness of the electrode portion.

The conductive gel layer may be provided as a removable and replaceable layer thus allowing the device to be reused indefinitely.

The device may further comprise a protective covering to protect it the conductive gel layer/conductive substrate prior to use and application to a patient's skin and between applications.

In a second aspect, there is provided a neuromodulation system comprising one or more neuromodulation electrode devices according to the first aspect.

Each electrode will have or will be connectable to an electrically-conducting lead for connection to an external electric power supply.

The substrate (where conductive or where further comprising a conductive layer) may additionally, if desired, be connectable (by an electrically conducting lead) to the external power supply permitting it to be used as a grounding electrode or an electrode of the opposite polarity from that of the electrode.

Suitable electric power supplies generate a stimulating signal which may have a frequency from 1Hz to 10kHz or higher, and a current of up to 40mA or higher. Most such generators offer a choice of various wave forms or bursts that will be selected by a professional practitioner.

In a third aspect, there is provided a method for treating chronic or acute pain and/or improving body function comprising application of one or more neuromodulation electrode devices according to the first aspect to an area affected by the pain, and applying a stimulating signal in the range 1 to 10,000Hz.

The neuromodulation electrode devices should be applied using a firm pressure sufficient to cause indentation of the skin.

The stimulating current is generally chosen within the range 1 to 40mA, according to the sensitivity of the area to be treated. In some specific instances a higher current may need to be applied.

Various wave forms and wave patterns may be used to stimulate through the electrodes.

The skilled person will appreciate that except where mutually exclusive, a feature or parameter described in relation to any one of the above aspects may be applied to any other aspect. Furthermore, except where mutually exclusive, any feature or parameter described herein may be applied to any aspect and/or combined with any other feature or parameter described herein.

Brief description of the drawings

Embodiments will now be described by way of example only, with reference to the Figures, in which:

Figure 1 is a cross-sectional view of a device according to a first embodiment;

Figure 2 is a top view of the Figure 1 embodiment;

Figure 3 is a cross-sectional view of a device according to a second embodiment;

Figure 4 shows a cross-sectional view of a device according to a third embodiment; and

Figure 5 shows a top view of the Figure 4 embodiment.

Detailed description

Aspects and embodiments of the present disclosure will now be discussed with reference to the accompanying figures. Further aspects and embodiments will be apparent to those skilled in the art.

Figures 1 and 2 show a device 1 comprising a substrate 2 having a skin-facing surface 2a formed of a conductive hydrogel having a thickness of 2mm. Although not

shown, the conductive hydrogel substrate 2 may comprise a backing layer formed of a thermo-formable or curable material that can be moulded to and retained in the shape a body portion to be treated.

The skin-facing surface 2a of the conductive hydrogel substrate 2 is adhesive. Prior to use, the adhesive surface 2a is protected with a protective cover layer 10 (shown in Figure 2).

The substrate 2 surrounds an electrode 3 having a circular cross-section with a maximum diameter of 17mm and a depth of 6mm. The electrode has a domed/hemispherical stimulating surface 4 which is coated with an electrode portion of a conductive hydrogel layer 5 having a thickness of 1mm.

An isolating annulus comprising an isolating ring 6 of non-conductive material encircles the base of the electrode and electrically isolates the electrode 3 and conductive hydrogel layer 5.

The electrode comprises an electrically conducting lead 8 for connection to a power supply 9.

In use, the device 1 is applied to the patient's skin with the adhesive skin-facing surface 2a of the substrate 2 affixed to the skin such that the active surface 4 of the electrode 3 in indented into the skin. The hydrogel layer 5 helps cushion the skin and increases comfort. The power supply 9 and electrically conducting lead 8 are used to apply a stimulating signal in the range 1 to 10,000Hz (with a stimulating current within the range 1 to 40mA) according to the sensitivity of the area to be treated. The signal is focussed through the electrode 3 and conductive gel layer 5 and is not attenuated through the hydrogel substrate 2. This has been found to increase the effectiveness of pain reduction and/or body function improvement.

Figure 3 shows an alternative embodiment of a device 1' where the substrate 2' comprises a non-woven textile material and the conductive hydrogel layer 5' comprises an electrode portion 5a' (covering the active surface 4' of the electrode 3') and a substrate portion 5b' (covering the skin-facing surface 2a' of the substrate 2').

The isolating ring 6' electrically isolates the electrode portion 5a' and the substrate portion 5b' from one another. The electrode portion 5a' of the conductive hydrogel layer 5' is also isolated from the substrate 2'.

The device 1' is used as described above for the first embodiment but with the adhesive substrate portion 5b' of the conductive hydrogel layer 5' affixed to the skin such that the active surface 4' of the electrode 3' in indented into the skin. The signal is focussed through the electrode 3' and the electrode portion 5a' of the conductive hydrogel layer 5' and is not attenuated through the substrate portion 5b' of the conductive hydrogel layer 5'.

Figures 4 and 5 show a third embodiment of the device 1'' comprising a plurality of electrodes 3'' mounted on a non-conductive substrate 2'' and surrounded by a substrate portion 5b'' of a conductive hydrogel layer 5''. The active surface 4'' of each electrode 3'' is covered by a respective electrode portion 5a'' of the conductive hydrogel layer 5''.

It will be understood that the invention is not limited to the embodiments above-described and various modifications and improvements can be made without departing from the concepts described herein. Except where mutually exclusive, any of the features may be employed separately or in combination with any other features and the disclosure extends to and includes all combinations and sub-combinations of one or more features described herein.

CLAIMS

1. A neuromodulation electrode device comprising:

a substrate having a skin-facing surface;

an electrode having at least one convex active surface projecting from the skin-facing surface of substrate for applying an electrical stimulation signal; and

a conductive gel layer having an electrode portion overlying the convex active surface(s) of the electrode;

wherein the substrate is formed of a conductive gel or the conductive gel layer further comprises a substrate portion overlying the skin-facing surface of the substrate; and

wherein the device further comprises an isolating frame extending around the perimeter of the electrode to provide electrical isolation between the electrode and the conductive gel substrate or from the substrate portion of the conductive gel layer.

2. The device according to claim 1 wherein the substrate is formed of conductive gel and further comprises a backing layer formed on the surface of the conductive gel substrate opposing the skin-facing surface.

3. The device of claim 1 wherein the substrate is formed of a non-gel material and the conductive gel layer further comprises a substrate portion that overlies the substrate.

4. The device of claims 3 wherein the electrode portion and substrate portion of the conductive gel layer are of uniform thickness.

5. The device of any one claims 2 to 4 wherein the backing layer or the non-gel substrate is formed of a stiff, pliable material.

6. The device of any one claims 2 to 4 wherein the backing layer or the non-gel substrate is formed of a thermos-formable or curable material.

7. The device of any one of the preceding claims wherein the skin-facing surface of the substrate or the substrate portion of the conductive gel layer is adhesive.

8. The device of any one of the preceding claims wherein the isolating frame has a width of between 2 and 20mm.

9. The device according to any one of the preceding claims wherein the isolating frame is an isolating annulus comprising an isolating ring formed of a non-conductive material or an isolating gap.

10. The device according to any one of the preceding claims wherein the electrode has a single hemispherical stimulating surface with a circular cross-section.

11. The device according to claim 10 wherein the diameter of the electrode is between 2 and 12 mm.

12. The device according to any one of the preceding claims wherein the convex stimulating surface of the electrode projects between 3 to 6mm beyond the skin-facing surface of the substrate.

13. The device according to any one of the preceding claims wherein the device comprises a plurality of electrodes mounted in an array or matrix on the substrate, each of the plurality of electrodes having a respective isolating frame.

14. The device according to any one of the preceding claims wherein the conductive gel layer or the conductive gel substrate is formed of a conductive hydrogel.

15. A device according to any one of the preceding claims wherein each of the electrodes and the conductive gel substrate/substrate portion of the conductive gel layer comprises a respective electrically conducting leads for connection to a power source so as to impart a first polarity to the electrode(s) and a second opposite polarity to the conductive gel substrate/substrate portion of the conductive gel layer.

16. A neuromodulation system comprising one or more neuromodulation electrode devices according to any one of the preceding claims and an external electric power supply.

17. The system according to claim 16 wherein the electric power supply is adapted to generate a stimulating signal having a frequency or from 1Hz to 10kH and a current of up to 40mA.

18. A method for treating chronic or acute pain and/or improving body function comprising application of one or more neuromodulation electrode devices according

to any one of claims 1 to 15 to an area affected by the pain, and applying a stimulating signal in the range 1 to 10,000Hz.

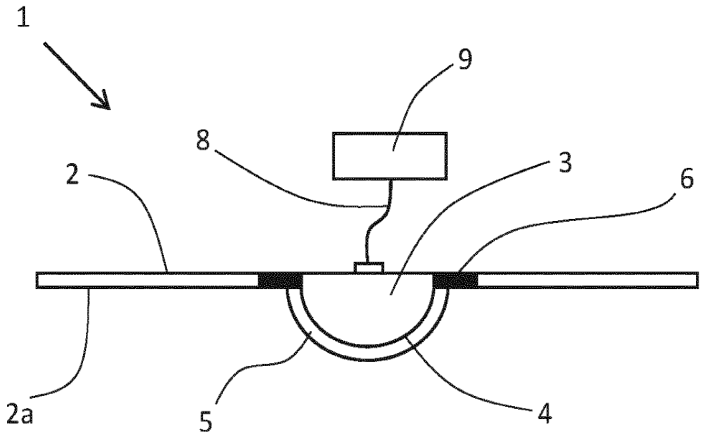

Fig. 1

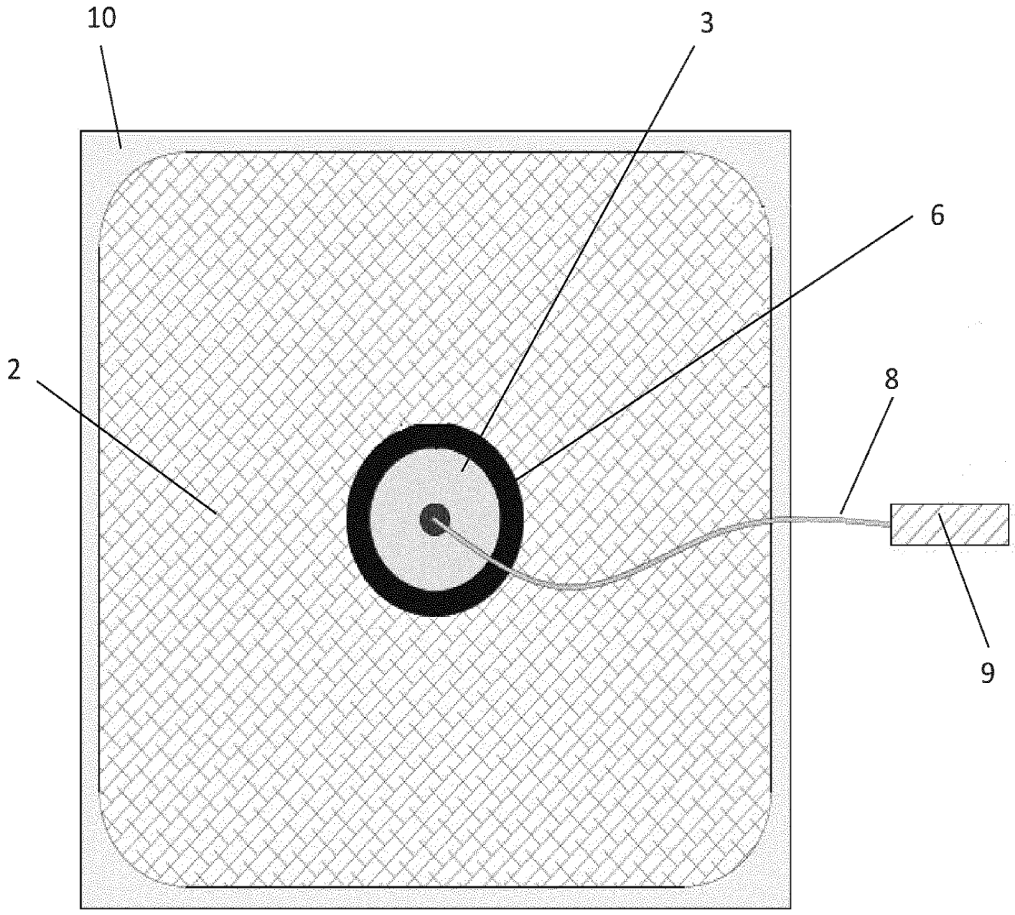

Fig. 2

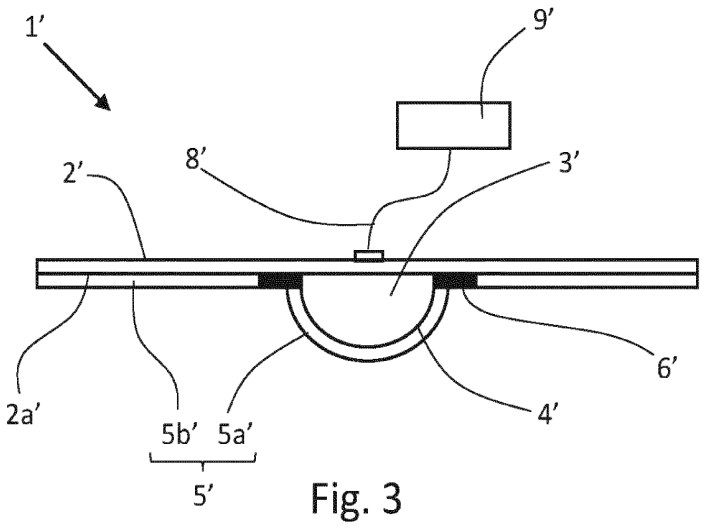

Fig. 3

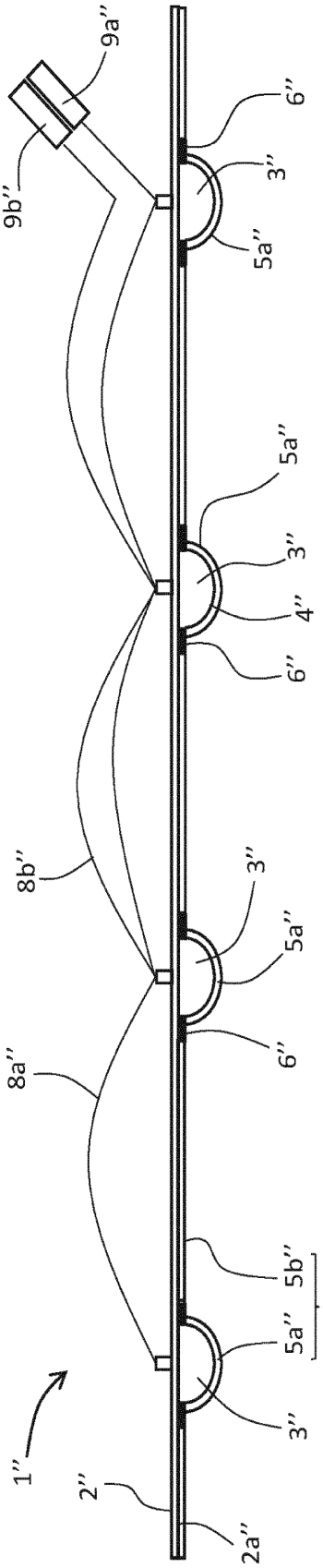

Fig. 4

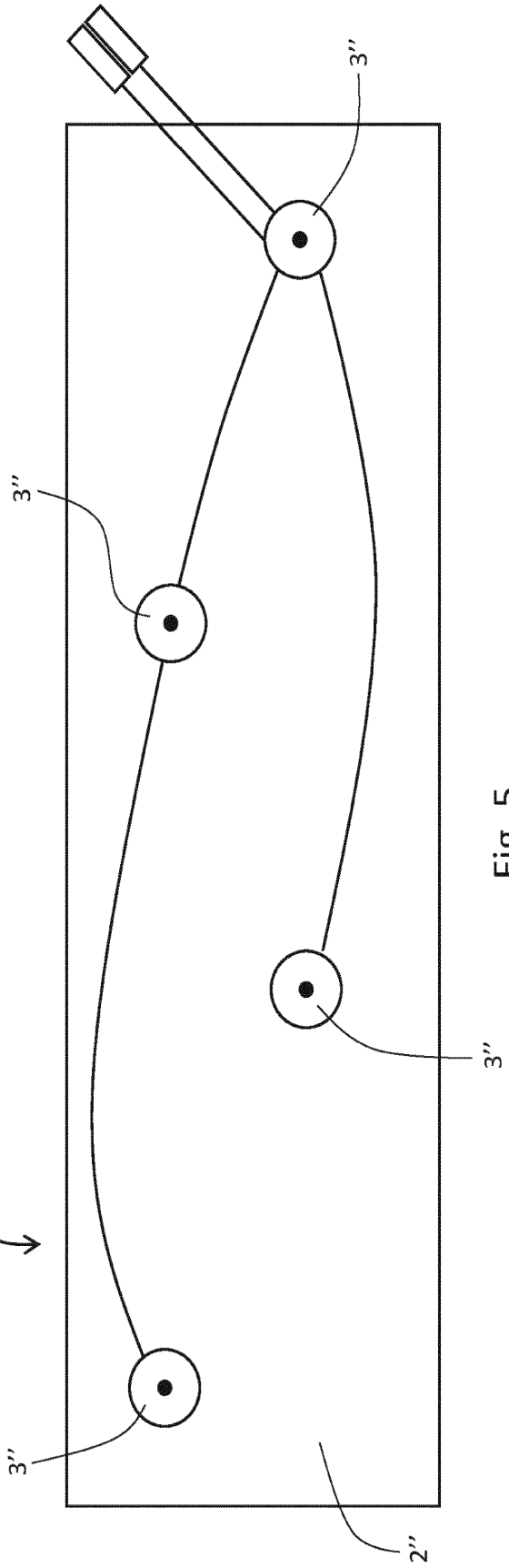

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/070025

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/04 A61N1/36
ADD.

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)
A61N

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 9 308 363 B2 (GOROSZENIUK TEODOR [GB]) 12 April 2016 (2016-04-12) abstract; figures 6-9 column 1, line 1 - column 15, line 49 -----	1-3,5-8, 10-17 4,9
Y	WO 2007/083275 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; SOLOSKO THOMAS [US] ET AL.) 26 July 2007 (2007-07-26) abstract; figure 1 -----	4
Y	US 5 395 398 A (ROGOZINSKI WALLACE J [US]) 7 March 1995 (1995-03-07) abstract; figures 1-3 -----	9
A	US 6 907 294 B2 (BIOFISICA LLC [US]) 14 June 2005 (2005-06-14) the whole document -----	1-17

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 October 2020	14/10/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Wetzig, Thomas

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2020/070025

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. [X] Claims Nos.: 18
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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:

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 an 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/EP2020/070025

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		ZA 200309399 B	22-02-2006

ABSTRACT

The present disclosure relates to devices, systems and methods for the delivery of electrical stimulation for the treatment of acute or chronic pain and/or for the improvement of body function. There is described a neuromodulation electrode device comprising a substrate having a skin-facing surface and an electrode having at least one convex active surface projecting from the skin-facing surface of substrate for applying an electrical stimulation signal. A conductive gel layer having an electrode portion overlies the convex active surface(s) of the electrode. The substrate is formed of a conductive gel or the conductive gel layer further comprises a substrate portion overlying the skin-facing surface of the substrate. The device further comprises an isolating frame surrounding the perimeter of the electrode to provide electrical isolation between the electrode and the conductive gel substrate or from the substrate portion of the conductive gel layer.

摘要

本公开涉及用于递送电刺激以治疗急性或慢性疼痛和/或用于改善身体功能的装置、系统和方法。描述了一种神经调节电极装置，其包括具有面向皮肤的表面的基底和具有从基底的面向皮肤的表面突出的用于施加电刺激信号的至少一个凸形活性表面的电极。具有电极部分的导电凝胶层覆盖在电极的凸形活性表面上。 基底由导电凝胶形成，或者所述导电凝胶层还包括覆盖所述基底的面向皮肤的表面的基底部分。该装置还包括围绕电极周边的隔离框架，以在所述电极和所述导电凝胶基底之间或与导电凝胶层的基板部分之间提供电隔离。