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(54) Title: SYSTEM AND METHOD TO PERCUTANEOUSLY BLOCK PAINFUL SENSATIONS

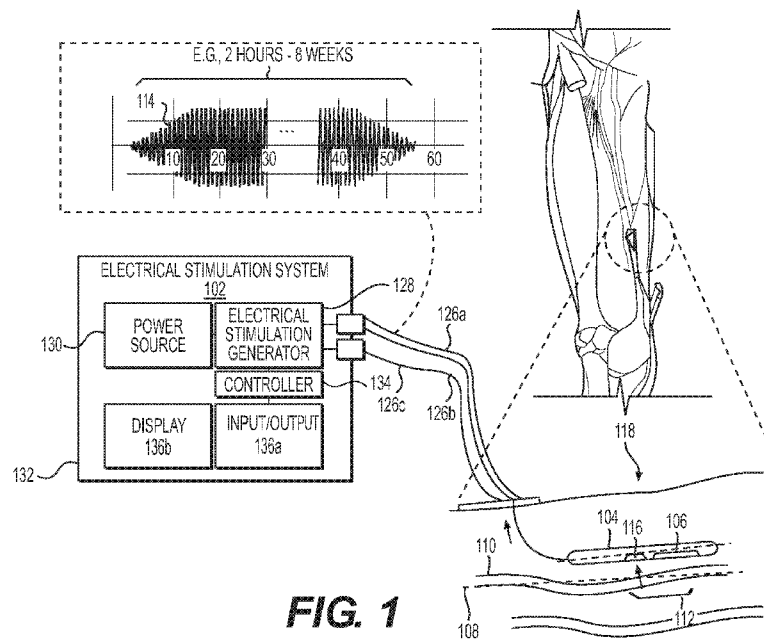


FIG. 1

(57) Abstract: The exemplified systems and methods facilitate a nerve conduction block at a target nerve using electrical stimulation applied from one or more electrodes located on a percutaneous lead that are placed in parallel, or substantially in parallel, and without direct contact, to a long axis of the peripheral nerve over an overlapping nerve region of greater than about 3 millimeters. The exemplified system and method can be further configured to block nerve condition without eliciting onset activity and co-excitation of non-targeted structures. The exemplified method and system can be performed using conventional percutaneous leads, though an improved percutaneous lead design is disclosed herein. In an aspect, an introducer is disclosed that facilitates accurate and consistent insertion of the percutaneous lead to the specified or intended position relative to the target nerve. In another aspect, a treatment kit comprising the various system components to treat pain is disclosed.



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INTERNATIONAL SEARCH REPORT

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PCT/US2019/022626

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61N1/36 A61N1/05 A61B17/34  
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 A61B  
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	US 2008/071321 A1 (BOGGS JOSEPH W II [US] ET AL) 20 March 2008 (2008-03-20)	32-35, 37, 41-49, 51,55-59 36, 38-40, 50,52-54
Y	the whole document	
L	----- US 2007/191915 A1 (STROTHER ROBERT B [US] ET AL) 16 August 2007 (2007-08-16) ----- -/--	32-59

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  1 July 2019	Date of mailing of the international search report  23/10/2019
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Ließmann, Frank

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2019/022626

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>MANFRED FRANKE ET AL: "Combined KHFA?+?DC nerve block without onset or reduced nerve conductivity a", JOURNAL OF NEURAL ENGINEERING, INSTITUTE OF PHYSICS PUBLISHING, BRISTOL, GB, vol. 11, no. 5, 13 August 2014 (2014-08-13), page 56012, XP020271689, ISSN: 1741-2552, DOI: 10.1088/1741-2560/11/5/056012 [retrieved on 2014-08-13] page 3, right-hand column, paragraph 3 - page 4, right-hand column, paragraph 1</p> <p>-----</p>	36, 38-40, 50,52-54
A	<p>KEN STEFFEN FRAHM ET AL: "Nerve Fiber Activation During Peripheral Nerve Field Stimulation: Importance of Electrode Orientation and Estimation of Area of Paresthesia : Modeling Optimal Nerve Fiber Activation During PNFS", NEUROMODULATION, vol. 19, no. 3, 19 November 2015 (2015-11-19), pages 311-318, XP055600554, US ISSN: 1094-7159, DOI: 10.1111/ner.12371 the whole document</p> <p>-----</p>	32-59
A	<p>KEVIN L. KILGORE ET AL: "Reversible Nerve Conduction Block Using Kilohertz Frequency Alternating Current : Reversible KHFA? Nerve Block", NEUROMODULATION, vol. 17, no. 3, 7 August 2013 (2013-08-07), pages 242-255, XP055517592, US ISSN: 1094-7159, DOI: 10.1111/ner.12100 the whole document</p> <p>-----</p>	32-59

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2019/022626

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008071321	A1	20-03-2008	NONE
US 2007191915	A1	16-08-2007	AU 2008205293 A1 17-07-2008
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			WO 2008085965 A2 17-07-2008

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2019/022626

## 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.: 1-31, 60-71, 95-115, 181-195  
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 surgery and/or 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:

see additional 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 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.:  
32-59

### 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.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 32-59

A system providing a specific waveform parameter for the electrical stimulation for blocking pain.

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2. claims: 72-94, 116-134

A system wherein a ramp rate of less than about 2 milliamps/second is used for gradually increasing an intensity of an electrical stimulation signal.

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3. claims: 135-177

A percutaneous lead wherein an outer surface of a first concentric member having a first insulated body having a first length contacting an inner surface of a second concentric member and wherein the second concentric member has an second insulated body having a second length that is less than and overlaps with the first length.

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4. claims: 178-180

An percutaneous lead having a lumen in the insulated body that is configured to receive and mate with a removable stiffening stylet.

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5. claims: 196-219

An apparatus configured to place a percutaneous lead with a fixed curve region or a flexible region that is bendable to form a curve to direct a percutaneous lead to an angle.

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