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

[Continued on next page]

(54) Title: CLINICAL RESPONSE DATA MAPPING

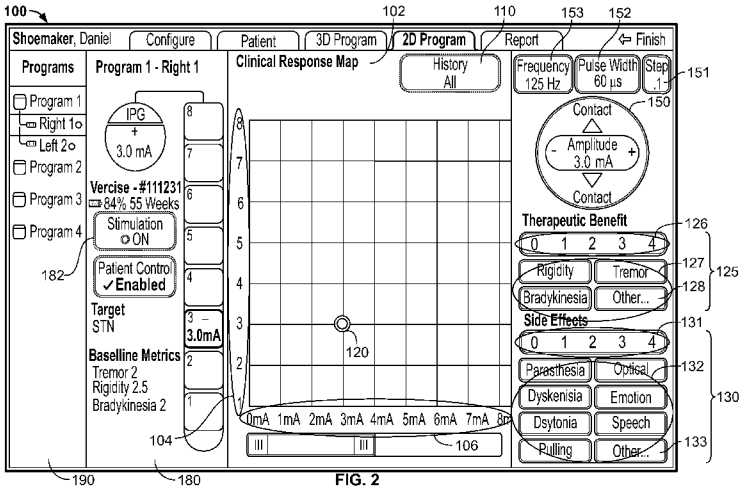

FIG. 2

(57) Abstract: A system and method include a processor that, based on at least a subset of stored data of clinical effects of one or more stimulations of anatomical tissue performed using electrodes of an implanted leadwire, generates and outputs at least one graphical marking representing the at least the subset of the stored data. Each of the at least one graphical marking represents a respective portion of the at least the subset of the stored data and is output in association with a respective set of values for each of at least two parameters by which one or more the stimulations were performed. The markings are plotted in a graph defined by axes corresponding to values of respective stimulation parameters. Alternative, the markings are arranged in a column of a tabular report. The markings are two-toned to provide respective information for both therapeutic and adverse side effects.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/028264

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/372
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 2012/302912 A1 (MOFFITT MICHAEL A [US] ET AL) 29 November 2012 (2012-11-29) paragraphs [0026] - [0164]; figures 1-3,9-18	1,3-17, 47,48 2
Y	US 2006/235472 A1 (GOETZ STEVEN M [US] ET AL) 19 October 2006 (2006-10-19) paragraph [0047]	2
A	US 2012/316619 A1 (GOETZ STEVEN M [US] ET AL) 13 December 2012 (2012-12-13) the whole document	1-17,47, 48

☐ 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
20 June 2014	11/11/2014

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	Schöffmann

INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012302912 A1	29-11-2012	CA 2837225 A1	06-12-2012
		EP 2714187 A2	09-04-2014
		JP 2014518722 A	07-08-2014
		US 2012302912 A1	29-11-2012
		US 2012303087 A1	29-11-2012
		WO 2012166656 A2	06-12-2012
US 2006235472 A1	19-10-2006	EP 2001553 A1	17-12-2008
		US 2006235472 A1	19-10-2006
		WO 2007108863 A1	27-09-2007
US 2012316619 A1	13-12-2012	EP 1991310 A1	19-11-2008
		US 2007203541 A1	30-08-2007
		US 2012316619 A1	13-12-2012
		US 2014088666 A1	27-03-2014
		WO 2007097861 A1	30-08-2007

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-17, 47, 48

A computer-implemented clinical data output method generating and outputting at least one graphical marking representing stored data and is output in association with a respective set of values for which one or more the stimulations were performed, wherein the outputting of the at least one graphical marking includes plotting each of the at least one graphical marking at a respective coordinate of a graph;
the graph includes a first axis corresponding to values of a first parameter and a second axis corresponding to values of a second parameter; and, the association with the respective set of values is via the location at which the respective graphical marking is plotted.

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2. claims: 18-20

as in claim 6 and further comprising:
displaying, by the processor, a plurality of clinical effect detail indicators, each corresponding to one of a respective clinical effect type and a respective degree of clinical effect; and
responsive to a user-selection of one of the plurality of clinical effect detail indicators while one of the coordinates of the graph is selected:
updating, by the processor, the stored data of clinical effects; and
one of generating and updating, by the processor, a graphical marking for display at the selected coordinate.

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3. claims: 21-27

as in claim 6 and further comprising:
responsive to user manipulation of a navigation control, shifting focus, by the processor, from a first one of the coordinates of the graph to a second one of the coordinates of the graph, wherein the navigation control includes:
a first navigation component, each selection of which the processor is configured to interpret as an instruction to shift coordinate focus in the graph in a first direction along the first axis;
a second navigation component, each selection of which the processor is configured to interpret as an instruction to shift coordinate focus in the graph in a second direction along the first axis;
a third navigation component, each selection of which the processor is configured to interpret as an instruction to shift coordinate focus in the graph in a first direction along the second axis; and

a fourth navigation component, each selection of which the processor is configured to interpret as an instruction to shift coordinate focus in the graph in a second direction along the second axis.

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4. claims: 28, 29

as in claim 6 and further comprising:
displaying, by the processor, a graphical representation of an anatomical structure in which the leadwire is implanted, wherein the graph is displayed within at least a portion of the graphical representation of the anatomical structure.

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5. claim: 30

as in claim 6 and further comprising:
responsive to selection of one of the coordinates,
displaying, by the processor a concentric stimulation magnitude indicator that is centered on the first axis at a value of the first axis corresponding to the selected coordinate and whose outer perimeter one of reaches and crosses the selected coordinate.

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6. claim: 31

as in claim 6 and further comprising:
interpolating, by the processor, the stored data of clinical effects on which basis the graphical markings of the graph are generated to calculate values for the subset of coordinates; and
displaying, by the processor and in the graph, a graphical screen that gradually varies with respect to a graphical characteristic, the variation in the graphical screen being based on the calculated values obtained by the interpolation.

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7. claims: 32-34

as in claim 6 and further comprising:
displaying, by the processor and one of in the graph, on at least one of the axes, and alongside the at least one of the axes, at least one limit marker, each of the at least one limit marker representing a respective limit to which modification of a value of a respective one of the at least two parameters is permitted.

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8. claims: 35-38

as in claim 6 and wherein:
the user input of the at least one limit is received in

association with a user profile associated with predefined clinician rights; and
in accordance with the obtained user input, an instruction, received in association with a user profile associated with predefined patient rights, to set any of the at least two parameters to a value that is beyond a respective one of the at least one limit that corresponds to the respective parameter, is not followed.

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9. claim: 39

as in claim 6 and wherein:
the coordinates of the graph are selectable;
a plurality of leadwires are implanted;
a plurality of stimulation programs are user-definable via a programming module, each of the plurality of stimulation programs defining respective stimulation parameters for each of the plurality of leadwires; and
the method further comprises:
displaying the graph in a user interface screen in which a list of the defined programs is displayed, each of the displayed listings of the defined programs being selectable for toggling between an expanded view in which the plurality of leadwires are listed as child nodes of the selected listing and a collapsed view in which no child nodes of the respective listing are displayed, and each of the displayed listings of the respective leadwires is selectable from within the expanded view of one of the program listings for which the respective leadwire listing is displayed; and
in accordance with a selection of one of the coordinates of the graph, updating settings of the leadwire of a selected one of the leadwire listings for a selected one of the program listings with values of the first and second parameters corresponding to the selected coordinate.

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10. claims: 40-46, 49-52

claims: 1, 40-46, 49-52
as in claim 1 and further comprising:
- user input filter criteria
- a plurality of concentrically arranged graphical components that each corresponds to a respective one of the plurality of types of clinical effects data; or
- A computer-implemented stimulation program visualization method
- (claim 46) in which the plurality of leadwires are listed as child nodes of the selected listing and a collapsed view in which no child nodes of the respective listing are displayed; or
- (claims 49-52) a computer processor and storage medium configured to, based on at least a subset of stored data of clinical effects of one or more stimulations of anatomical tissue performed using electrodes of an implanted leadwire,

generate and output at least one graphical marking representing the at least the subset of the stored data, wherein each of the at least one graphical marking represents a respective portion of the at least the subset of the stored data and is output in association with a respective set of values for each of at least two parameters by which one or more the stimulations were performed;

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/028264

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:

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.:

1-17, 47, 48

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.