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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 July 2015 (23.07.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/108799 A3

(51) International Patent Classification:
A61B 5/0402 (2006.01) *A61B 5/08* (2006.01)
A61B 5/0205 (2006.01)

(21) International Application Number:
PCT/US2015/010959

(22) International Filing Date:
12 January 2015 (12.01.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/928,498 17 January 2014 (17.01.2014) US

(71) Applicant: **THE GENERAL HOSPITAL CORPORATION** [US/US]; 55 Fruit Street, Boston, MA 02114 (US).

(72) Inventor: **ARMOUNDAS, Antonis, A.**; 14 Oak Meadow Road, Lincoln, MA 01773 (US).

(74) Agent: **COOK, Jack, M.**; Quarles & Brady LLP, 411 E. Wisconsin Avenue, Milwaukee, WI 53202 (US).

(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))*

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR PROCESSING CARDIAC SIGNALS AND DERIVING NON-CARDIAC PHYSIOLOGICAL INFORMATION

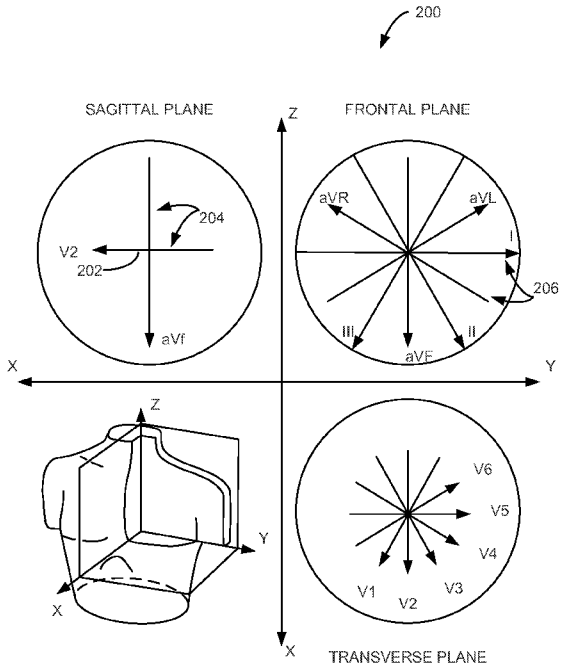


FIG. 2

(57) Abstract: A system and a method are provided for deriving elctrocardiographic (ECG] signals from a subject. The system includes an ECG apparatus configured to acquire ECG signals from the subject through a plurality of ECG leads, wherein the plurality of ECG leads includes lead groups that are traditionally presumed to be orthogonal. A processor or method are provided to analyze combinations of ECG leads from the plurality of ECG leads to determine a spectral signal-to-noise ratio (SNR] for each combination of ECG leads and select a combination of ECG leads that provides a desirable spectral SNR. The ECG signals derived from the combination of ECG leads selected as providing the desirable spectral SNR may be provided or may be used to derive and report respiratory rate information about the subject.

WO 2015/108799 A3

WO 2015/108799 A3

(88) Date of publication of the international search report:
12 November 2015

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/10959

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/0402, 5/0205, 5/08 (2015.01)
CPC - A61B 5/0006, 5/08, 5/72, 5/0402
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)
IPC(8) Classification(s): A61B 5/0205, 5/0402, 5/0452, 5/0472, 5/08 (2015.01)
CPC Classification(s): A61B 5/0006, 5/08, 5/72, 5/0205, 5/0402, 5/0452

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)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Public Patent Application Information Retrieval (PAIR); Google/Google Scholar; ProQuest; Pubmed/Medline: respiratory, respiration, breathing, rate, electrocardiogram, ECG, EKG, signal to noise ratio, SNR, minimize, maximize, non-orthogonal, not orthogonal, perpendicular, lead, electrode, estimate, calculate, etc.

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	US 2007/0032733 A1 (BURTON, D) February 8, 2007; paragraphs [0045]-[0046], [0049], [0220], [0316], [0408], [0438], [0442]-[0449]	11 --- 1-2, 12, 21, 23-24 --- 3-10, 13-20
Y --- A	US 6358214 B1 (TERESCHOUK, M) March 19, 2002; figure 5; column 6, lines 27-33; column 8, lines 18-23; column 9, lines 1-10; claim 1	1-2, 24 --- 3-10, 17-20
Y --- A	US 7113820 B2 (SCHLEGEL, TT et al.) September 26, 2006; column 3, lines 8-20, 40-44; column 4, lines 46-56; column 9, lines 65-67	2, 12, 21 --- 3-10, 13-20
Y	WO 2013/179018 A1 (OBS MEDICAL LIMITED) December 5, 2013; page 3, lines 4-26	23-24
Y --- A	US 2010/0100000 A1 (LEE, K et al.) April 22, 2010; figure 2d; paragraphs [0048], [0051]	21 --- 10

☐ 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
19 March 2015 (19.03.2015)	12 JUN 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/10959

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 1-21 and 23-24 are directed toward a method and system for determining a respiratory rate of a subject from electrocardiographic (ECG) signals acquired from the subject.

Group II: Claim 22 is directed toward a system for deriving electrocardiographic (ECG) signals from a subject and providing a report of the derived signals.

-***-Continued Within the Next Supplemental Box-***-

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.:
1-21, 23-24

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/US15/10959

-***-Continued from Box No. III - Observations where unity of invention is lacking -***-

The inventions listed as Groups I-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: the special technical features of Group I include (c) tracking a dominant spectral peak in the ECG signals from the combination of ECG leads; (d) correlating the dominate spectral peak with a respiratory rate of the subject; and (e) generating a report indicating the respiratory rate of the subject based on step (d), which are not present in Group II; the special technical features of Group II include ii) select a combination of ECG leads that provides a desirable spectral SNR; and a report generator configured to provide a report of the ECG signals derived from the combination of ECG leads selected in by the processor as providing the desirable spectral SNR, which are not present in Group I.

The common technical features of Groups I and II are a system with electrocardiographic (ECG) signals from a subject, the system comprising: an ECG apparatus configured to acquire ECG signals from the subject through a plurality of ECG leads, wherein the plurality of ECG leads includes lead groups that are traditionally presumed to be orthogonal; and a processor configured to: (i) analyze combinations of ECG leads from the plurality of ECG leads to determine a spectral signal-to-noise ratio (SNR) for each combination of ECG leads; and a report generator.

These common technical features are disclosed by US 2007/0032733 A1 (BURTON). Burton discloses a system with electrocardiographic (ECG) signals from a subject (apparatus for detecting various disorders in a subject from a physiological electrocardiogram signal; abstract), the system comprising: an ECG apparatus configured to acquire ECG signals from the subject through a plurality of ECG leads (the system includes means for monitoring an ECG signal such as a standard ECG recorder device; a 3-lead device acquires ECG data from the subject; paragraphs [0045], [0444]), wherein the plurality of ECG leads includes lead groups that are traditionally presumed to be orthogonal (ECG electrodes may be positioned in an orthogonal arrangement whereby improved signal to noise ratio may be achieved for accurate QRS analysis; paragraph [0045]), and a processor configured to: (i) analyze combinations of ECG leads from the plurality of ECG leads to determine a spectral signal-to-noise ratio (SNR) for each combination of ECG leads (the ECG electrodes are positioned (combined) in an arrangement to improve signal to noise ratio (SNR); the system monitors and compares signals to predetermined thresholds and whether the thresholds are exceeded; paragraphs [0045], [0049]); and a report generator (means to display (report) ECG derived data; paragraphs [0438], [0466]).

Since the common technical features are previously disclosed by the Burton reference, the common features are not special and so Groups I and II lack unity.