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(54) Title: DEVICE, SYSTEM, AND METHOD FOR ASSESSING SLEEP DISORDERS

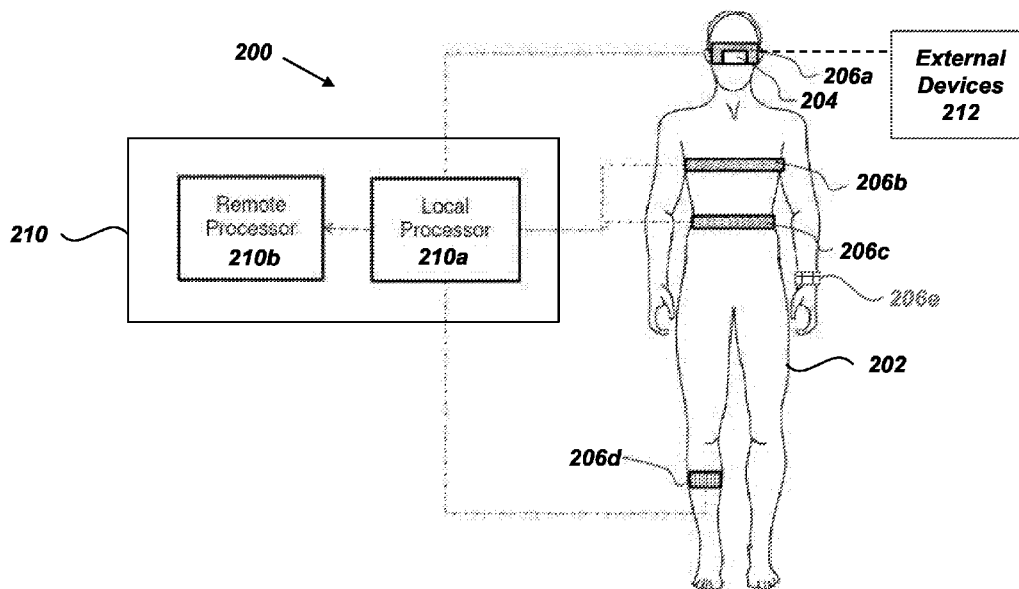


FIG. 2

(57) Abstract: Methods, systems, and devices for assessing breathing disorders such as apneas and hypopneas are provided. An airflow monitoring device can be positioned in thermal communication with respiratory airflow (nasal and/or oral airflow). The airflow monitoring device can include a thermistor configured to measure heating and cooling cycles of respiratory airflow and determine respiratory airflow velocity from analysis of thermistor cooling. This velocity, alone or in combination with other physiological parameters, such as blood oxygen saturation, respiration effort, heart rate, body movement, etc. can be employed to assess sleep disorders.



Declarations under Rule 4.17:

- *of inventorship (Rule 4.17(iv))*

Published:

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

(88) Date of publication of the international search report:

28 December 2017 (28.12.2017)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 17/00667

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/08 (2017.01)
CPC - A61B 5/0878, A61B 5/0816

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)

See Search History Document

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

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

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 2014/0005557 A1 (RICH et al) 02 January 2014 (02.01.2014) fig 4C, 5A, 5B, claim 11, para [0043]-[0046], [0080]-[0082], [0084], [0104], [0108], [0111]	1-4, 8, 10-14, 19 ----- 5-7, 15-18 ----- 9
Y ----- A	5,413,111 A (WILKINSON) 09 May 1995 (09.05.1995) fig 1, col 2, ln 66 to col 3, ln 6, col 3, ln 50-52	5-7, 15-18 ----- 9
A	US 2014/0275930 A1 (RICH et al) 18 September 2014 (18.09.2014) entire document	1-19
A	Us 6,368,287 B1 (HADAS) 09 April 2002 (09.04.2002) entire document	1-19

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

16 October 2017

Date of mailing of the international search report

08 NOV 2017

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 17/00667

Continuation of Box 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:

Special Technical Features

Group I includes the special technical feature of a respiratory airflow monitoring device, comprising: a body; a pair of first arms extending distally outwards from the body; and a first thermistor mounted to the body or at least one of the pair of first arms; wherein at least one of the first arms is moveable with respect to the other by a distance sufficient to position a human nasal septum therebetween; and wherein at least one of the first arms is biased towards the other such that, when a human nasal septum is received between the pair of first arms, the pair of first arms applies a compressive force to the nasal septum sufficient to retain the pair of first arms substantially in place, not required in Group II.

Group II includes the special technical feature of a method for determining a velocity of respiratory airflow of a patient, comprising: positioning a thermistor in fluid communication with respiratory airflow; allowing the thermistor to undergo heating due to a flow of expired respiratory airflow; measuring a temperature, T , of the thermistor while the thermistor is cooled due to a flow of inspired respiratory airflow at a temperature T_A ; and determining a velocity of respiratory airflow based upon the measured temperature of the thermistor T and the temperature of the inspired respiratory airflow T_A , not required in Group I.

Common Technical Features

Groups I and II share the common technical features of a thermistor. However, this shared technical feature fails to make a contribution over the prior art of US 2014/0005557 A1 to Rich, et al. (hereinafter 'Rich'), which teaches a thermistor being used as a respiration detector (para [0080]).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 17/00667

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 1-19 directed to an airflow monitoring device.

Group II: Claims 20-28 directed to a method for determining a velocity of respiratory airflow of a patient.

---Continued on Supplemental Page---

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.:
1-19

- 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.