



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/440,116	04/05/2012	Hani Kayyali	CMD-087	4463

81177 7590 01/03/2017
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

EXAMINER

NATNITHADHA, NAVIN

ART UNIT	PAPER NUMBER
----------	--------------

3735

MAIL DATE	DELIVERY MODE
-----------	---------------

01/03/2017

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/440,116	Applicant(s) KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 21-40 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☒ Claim(s) 21-23 and 26-40 is/are rejected.
- 8) ☒ Claim(s) 24 and 25 is/are objected to.
- 9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____ | 4) ☐ Other: _____ |

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 December 2016 has been entered.

Response to Amendment

3. According to the Amendment, filed 06 December 2016, the status of the claims is as follows:

Claims 21, 28, 30, 32, 34, and 37 are currently amended;

Claims 22-27, 29, 31, 33, 35, 36, and 38-40 are previously presented; and

Claims 1-20 are cancelled.

4. Applicant's arguments, see Remarks, pp. 9-12, filed 06 December 2016, with respect to the rejection of claims 21-23, 26-29, 33-36, and 38 under pre-AIA 35 U.S.C. 102(b) as being unpatentable over Miles, U.S. Patent No. 5,353,788 A, have been fully considered, but are moot in view of the new ground(s) of rejection, which was necessitated by amendment, as discussed below.

5. Applicant's arguments, see Remarks, p. 15, filed 06 December 2016, with respect to the rejection of claim 30, 32, and 37 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Miles, U.S. Patent No. 5,353,788 A, as applied to claims 28 and 34, respectively, above, and further in view of Stahmann et al, U.S. Patent No. 7,757,690 B2, have been fully considered, but are moot in view of the new ground(s) of rejection, which was necessitated by amendment, as discussed below.

Claim Objections

6. Claims 21 and 28 are objected to because of the following informalities:

a) in claim 21, line 3, "comprising" is a grammatical error, and should be "comprising:", and in line 4, "gas," is a grammatical error, and should be "gas;," in order to have the use of punctuations consistent throughout the claim; and

b) in claim 28, "inputs" in line 3 and "an input" in line 6 makes the claim unclear as to whether these inputs are the within the same group (Examiner suggests amending these phrases with "first inputs" and "a second input"); and

c) in claim 28, "a treatment device" in line 7, "a positive airway pressure (PAP) device" in line 8, and "the treatment device" in line 8, are typographical errors that make the claim indefinite as to whether these devices are one of the same (Examiner suggest amending the claim to use either "positive airway pressure (PAP) device" or "treatment device" and not both, and defining the "positive airway pressure (PAP) device" or "treatment device" before the "data acquisition system" in order to provide proper antecedent basis).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28-40 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 28 recites the limitations “and further for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypopneas” and “the output adapted for providing data of the identified and differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device”. The original disclosure, pages 9 and 10, filed 05 April 2012, include paragraphs that merely mention central apneas and hyponeas and obstructive apneas and hypopneas. However, the disclosure is entirely silent on specifically how the processor and output perform the claimed functions above.

Claims 29-33 are rejected due to their dependencies to claim 28.

Claim 34 recites the limitations “an positive airway pressure apparatus for providing pressurized air and chemically treating a subject’s sleep disorder or symptoms with additional CO₂ resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity of the subject’s sleep disorder from the data acquisition system”. However, the disclosure is entirely silent on specifically how the positive airway pressure apparatus is able to provide pressurized air and chemically treat a subject’s sleep disorder or symptoms with additional CO₂ resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity.

Claims 35-40 are rejected due to their dependencies to claim 34.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

8. Claims 21-23, 26, and 27 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Miles, U.S. Patent No. 5,353,788 A ("Miles"), in view of Hedner et al, U.S. Patent Application Publication No. 2008/0257349 A1 ("Hedner").

As to Claim 21, Miles teaches the following:

A positive airway pressure (PAP) sleep disorder treatment device ("physiological monitor and actuating system") 22 ("This invention relates to a medical device and method for automatically determining the correct airflow pressure to be used for the treatment of a serious breathing problem during sleep known as obstructive sleep apnea.", see col. 1, ll. 9-13, "Data from sensors 21 are

Art Unit: 3735

collected in physiological monitor and actuating system 22. The monitoring and actuating system 22 includes the basic procedure and control program.”, see col. 4, ll. 37-40, and figs. 1 and 2) comprising:

a blower or source of pressured gas (“nasal-CPAP airflow generator (CPAP device)”) 1 (see col. 5, l. 1);

inputs (“PMA-device”) 12 for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor (“chest and abdominal respiration sensors”) 7 and a pulse oximeter sensor (“pulse oximeter sensor for measuring the oxygen saturation in the blood”) 5 (see fig. 2 and “The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices.”, see col. 4, ll. 39-41); and

a processor (“physiological monitor and actuating system”) 22 for receiving and processing signals from the respiratory effort and pulse oximeter sensors (“Data from sensors 21 are collected in physiological monitor and actuating system 22. The monitoring and actuating system 22 includes the basic procedure and control program. Depending on time, entered set-up parameters, and data received via sensors 21, system 22 will issue control signals via outputs 24 to control breathing air pressure at breathing mask 26.”, see col. 4, ll. 37-43) and further for determining an output pressure level of the PAP device 1 based at least in part on the signals from the respiratory effort 7 and pulse oximeter 5 sensors

Art Unit: 3735

("Among the vital signs monitored may be chest and abdominal movement, airflow, airflow pressure, breathing sounds, intrathoracic pressure, blood oxygen saturation, heart rate, overall physical movement, leg movement, eye movement, EEG, and sleeping position. All data gathered from the sensors are stored in the Data Collector 22 for later processing by the Analysis Program 25. One or more of the physiological data sensed are used for modifying the airflow pressure cycle. However, it is within the scope of the present invention to use additional or alternative physiological data in order to modify the airflow pressure cycle.", see col. 9, ll. 20-28).

Miles does not teach the following:

an enclosure comprising

a blower or source of pressured gas,

inputs...; and

a processor...

However, Hedner teaches the following:

A positive airway pressure (PAP) sleep disorder treatment device

("ventilation system") ("It is an object of the present invention to provide a system that remedies the above mentioned problems and provides an improved breathing gas ventilator technology for use in conjunction with ventilatory disorders, such as for instance

Art Unit: 3735

as a continuous positive airway pressure (CPAP) method, such as an automatic adaptive CPAP (AACPPAP).”, see para. [0012], and fig. 1)

comprising:

an enclosure (“mechanical ventilator”) 4 (“A ventilation system comprise a mechanical ventilator 4 supplying pressurized breathing gas...”, see para. [0025]) comprising

a blower or source of pressured gas (“Pressure/flow regulator”) 12 (“12 Pressure/flow regulator”, see para. [0096]),

inputs (“The processing unit 11 measures one or several input parameters 5, 6, 7, 8, and 9 obtained from the patient 1 describing the physiological status of the patient. Data indicative of patient status is obtained using sensors 5, 6, 7, 8, and 9 connected to the patient and transferred to the processing unit 11 via connection means 5a, 6a, 7a, 8a, and 9a. These input parameters may be for instance flow or pressure signals, data obtained from EEG, EMG, EOG, and ECG measurements, O.sub.2 and/or CO.sub.2 measurements in relation to the patient, body temperature, blood pressure, SpO2 (oxygen saturation), eye movements, and sound measurements. It should be understood that the invention is not limited to the above mentioned input parameters but other input parameters may be used. In

FIG. 1 not all sensors 5, 6, 7, 8, and 9 and sensor connection means 5a, 6a, 7a, 8a, and 9a are depicted, only a subset is shown in order to illustrate a schematical view of the system and the depicted locations are only given as examples and are in no way limiting to the invention.”, see para. [0027], and thus, the “ventilator 4” inherently includes inputs as ports, terminals, or interface for “connection means 5a, 6a, 7a, 8a, and 9a” to electrically connect to the “processing unit 11”); and
a processor (“processing unit”) 11 (see para. [0027]).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Miles structural components into one enclosure, as exemplified by Hedner, in order to obtain the well-known advantage of a more compact device and is matter of obvious engineering choice. See MPEP 2144.04(V)(B), and *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, “that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.”).

As to Claim 22, Miles teaches the following:

wherein the PAP device 1 is a continuous positive airway pressure device (CPAP) (“The present invention provides an automatic nasal-continuous-positive-airflow pressure (nasal-CPAP) calibration procedure for the treatment of patients suffering from obstructive sleep apnea.”, see col. 4, ll. 28-31).

As to Claim 23, Miles teaches the following:

wherein the PAP through the inputs can command a signal processing module to reconfigure the output of the data acquisition system (“Depending on time, entered set-up parameters, and data received via sensors 21, system 22 will issue control signals via outputs 24 to control breathing air pressure at breathing mask 26.”, see col. 4, ll. 40-43).

As to Claim 26, Miles teaches the following:

wherein the PAP device 1 further comprises an airflow sensor (“pressure transducer located in the CPAP device 1”) with a signal, and wherein the processor also receives and processes signals from the airflow sensor (see col. 4, ll. 55-59, and col. 5, ll. 3-36).

As to Claim 27, Miles teaches the following:

wherein the respiratory effort sensor is a respiratory inductance plethysmography belt (“chest and abdominal respiration (inductive plethysmography) ,”, see col. 7, ll. 40-41).

9. **Claims 28, 29, and 33 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Miles, U.S. Patent No. 5,353,788 A (“Miles”), in view of Wright et al, U.S. Patent No. 6,832,609 B2 (“Wright”).**

As to Claim 28, Miles teaches the following:

A sleep disorder treatment system (“This invention relates to a medical device and method for automatically determining the correct airflow pressure to be used for the treatment of a serious breathing problem during sleep known as obstructive sleep apnea.”, see col. 1, ll. 9-13, and figs. 1 and 2) comprising:

a data acquisition system (“physiological monitor and actuating system”) 22, the data acquisition system 22 comprising a data acquisition device (“physiological monitoring and actuating device HMS-5000 of Vitalog Monitoring Inc.”, or “PMA-device”) 12 having inputs (not labeled) adapted for receiving signals from sensors including a respiratory effort sensor (“chest and abdominal respiration sensors”) 7 and a pulse oximeter sensor (“pulse oximeter sensor for measuring the oxygen saturation in the blood”) 5 (“Patient 4 is connected to the physiological monitoring and actuating device HMS-5000 of Vitalog Monitoring Inc. 12 by a series of sensors 5 through 11 including (but not limited to) a pulse oximeter sensor for measuring the oxygen saturation in the blood 5, ECG leads 6, chest and abdominal respiration sensors 7, sleeping position sensor 8, nasal mask thermistor or

Art Unit: 3735

thermocouple airflow temperature sensors 9, throat microphone 10 and leg movement sensors 11. The physiological monitoring and actuating device is hereafter referred to as PMA-device. The PMA-device 12 is connected to the CPAP device 1 by an electrical cable 13. Through this cable 13 the PMA-device 12 receives (a) outputs from an air pressure transducer in the CPAP device 1, and (b) a quantitative airflow sensor also contained within the CPAP device 1. That airflow sensor measures the amount of air passed into the nasal mask 3 from the CPAP device 1. The pressure transducer measures the air pressure in the nasal mask 3.”, see col. 5, ll. 6-25, and thus, the “PMA-device 12” inherently includes inputs as ports, terminals, or interface for “pulse oximeter sensor for measuring the oxygen saturation in the blood 5, ECG leads 6, chest and abdominal respiration sensors 7, sleeping position sensor 8, nasal mask thermistor or thermocouple airflow temperature sensors 9, throat microphone 10 and leg movement sensors 11” to electrically connect to the internal electrical circuit of the “PMA-device 12”), and an input (not labeled) adapted for receiving a treatment device signal (“outputs”) from a sensor (“air pressure transducer in the CPAP device” or “quantitative airflow sensor also contained within the CPAP device 1”) from a treatment device (“CPAP device”) 1 (“The PMA-device 12 is connected to the CPAP device 1 by an electrical cable 13. Through this cable

Art Unit: 3735

13 the PMA-device 12 receives (a) outputs from an air pressure transducer in the CPAP device 1, and (b) a quantitative airflow sensor also contained within the CPAP device 1. That airflow sensor measures the amount of air passed into the nasal mask 3 from the CPAP device 1. The pressure transducer measures the air pressure in the nasal mask 3.”, see col. 5, ll. 16-25, and thus, the “PMA-device 12” inherently includes an input as a port, terminal, or interface for “receiv[ing] (a) outputs from an air pressure transducer in the CPAP device 1, and (b) a quantitative airflow sensor also contained within the CPAP device 1” to electrically connect to the internal electrical circuit of the “PMA-device 12”.); and

a positive airway pressure (PAP) device (“nasal-CPAP airflow generator (CPAP device)”) 1, the positive airway pressure (PAP) or treatment device 1 separate and in a different enclosure from the data acquisition device 12 (see fig. 2), that includes a hose (“large flexible tube”) 2 (see fig. 2), the sensor (“air pressure transducer in the CPAP device” or “quantitative airflow sensor also contained within the CPAP device 1”) with a signal for measuring air flow and/or pressure (see col. 5, ll. 16-25), an output for providing the treatment device signal derived in part on the airflow and/or pressure signal (“The cable 13 also contains a control line through which the PMA-device 12 controls the air pressure and airflow produced by the

Art Unit: 3735

CPAP device 1.", see col. 5, ll. 25-27), and a mask ("nasal mask") 3 for treating a subject's sleep disorder symptoms (see col. 4, l. 67, to col. 5, l. 5); and

a processor ("computer") 25 adapted for receiving data from the respiratory effort sensor, pulse oximeter sensor, and the sensor for measuring air flow and/or pressure ("At the end of the procedure, the recorded information is transferred from the PMA-device 12 to a computer. The computer will analyse the data, prepare a report, and help determine the final nasal-CPAP airflow pressure to be used in the long-term treatment of that patient.", see col. 5, ll. 31-36, and fig. 1),

the processor ("computer") 25 either part of or external to the data acquisition device 12 and having an output ("output device") 27 (see fig. 1), and

the output 27 adapted for providing data of the identified and differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device ("At the end of a treatment period, system 22 is connected to a processing system 25, such as a personal computer which may provide evaluation results on an output device 27 such as a printer or a visual display. The results of the treatment, including the recorded data and control signals are unloaded onto system 25 for further evaluation. Processing system 25 will prepare the treatment report and may determine the parameters for the next

treatment.”, see col. 4, ll. 46-54. The limitation “of the identified and differentiated apneas and hypopneas” is a matter of intended use of the “output device 27”, where the “output device 27” is capable of performing such function if modified to do so. See proposed modification below).

Miles does not teach the following:

further for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypopneas.

However, Wright teaches the following:

identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypopneas (“One such index is based upon a functional relationship between the number of central or obstructive apneas over a particular time period. When the patient is being treated with CPAP, the device continuously monitors whether the patient is having an apnea and if so, whether the apnea is central or obstructive. The apparatus determines an index from a comparison of the number of central and obstructive apneas or a function of the ratio of the number of central to obstructive apneas during a particular time period.

Methods and apparatus for distinguishing between central and obstructive apneas are described in U.S. Pat. No. 5,704,345.

Art Unit: 3735

In one technique, when an apnea is detected as occurring, the apparatus applies an oscillatory pressure waveform of known frequency and magnitude and accesses the patency of the airway from the flow which is induced in the airway. In one form, if the airway is patent during an apnea, then the apnea is judged to be central. However, if the airway is closed during an apnea, then the apnea is judged to be obstructive. In another technique, when an apnea is detected as occurring, the apparatus monitors the airflow for the presence of a signal of cardiac origin. If a cardiac signal is detected, then the airway is judged to be patent and the apnea classified as central. If no cardiac signal is detected, then the airway is judged to be closed and the apnea classified as obstructive.

Other methods for distinguishing between central and obstructive apneas include monitoring chest movement using respiratory bands and monitoring the movement of the suprasternal notch, for example, as taught in International Patent Application WO 01/19433 (Berthon-Jones et al.).”, see col. 5, ll. 4-33).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Miles treatment system to include “distinguishing between central and obstructive apneas” as taught by Wright because this is

a conventional advantage/approach of using CPAP in assisting stroke rehabilitation

("The advantages of the use of CPAP in assisting stroke rehabilitation are greater than that provided by oxygenation per se. For example, providing oxygen will in itself not prevent the patient from having an apnea. Reducing or eliminating apneas may reduce the damaging side-effects of apnea, such as unnecessary activation of the sympathetic nervous system, surging blood pressure and increases in blood flow. Furthermore, some CPAP devices can detect the presence of apneas, distinguish between central and obstructive apneas and provide an increased pressure if needed to stabilize an obstructed or partially obstructed airway.", see col. 3, ll. 15-24).

As to Claim 29, Miles teaches the following:

wherein the PAP device 1 further comprises an airflow sensor ("pressure transducer located in the CPAP device 1") with a signal, and a processor that receives and processes signals from the airflow sensor in addition to the output from the data acquisition system 22 to determine the output pressure level of the PAP device (see col. 4, ll. 55-59, and col. 5, ll. 3-36).

As to Claim 33, Miles teaches the following:

wherein the respiratory effort sensor is a respiratory inductance plethysmography belt ("chest and abdominal respiration (inductive plethysmography) , ", see col. 7, ll. 40-41).

10. **Claims 30 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Miles, U.S. Patent No. 5,353,788 A (“Miles”), in view of Wright et al, U.S. Patent No. 6,832,609 B2 (“Wright”), as applied to claim 28 above, and further in view of Stahmann et al, U.S. Patent No. 7,757,690 B2 (“Stahmann”).**

As to Claim 32, Miles in view of Wright teaches the subject matter of claim 28 above. Miles in view of Wright does not teach the following:

wherein the sensor data output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and the processor.

However, such a form of communication between a data acquisition system and a processor is well-known in the art. For example, Stahmann teaches the following:

output of a data acquisition system (“data acquisition unit”) 104 is transmitted wirelessly by bidirectional radio frequency between the data acquisition system 104 and a processor (“patient-internal 1210 and patient-external 1220 medical devices”) (see fig. 1A and “Referring to FIG. 1A, a system 100 in accordance with an embodiment of the present invention includes a data acquisition unit 104 configured to acquire data associated with a patient while the patient is awake. The data acquisition unit 104 is coupled to a therapy delivery system 106 configured to adjust a therapy delivered to the patient, during patient sleep, using the acquired data. One or more sensor(s) 102 are used to sense physiological signals useful to the data

Art Unit: 3735

acquisition unit 104.”, see col. 5, ll. 21-29; and “For example, the patient-internal and patient-external devices 1210, 1220 may be coupled through a short-range radio link, such as Bluetooth, IEEE 802.11, and/or a proprietary wireless protocol. The communications link may facilitate unidirectional or bidirectional communication between the patient-internal 1210 and patient-external 1220 medical devices.”, see col. 16, ll. 8-14).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Miles' wired communication between Miles' “physiological monitor and actuating system 22” and “computer 25” to be wireless and bidirectional, as taught by Stahmann, in order to enable the eliminate the need of cumbersome wired communication and to allow control and data signals to be communicated between the two devices.

As to Claim 30, Miles teaches the following:

wherein the data acquisition system through a receiver can command a signal processing module to reconfigure the output of the PAP (“Depending on time, entered set-up parameters, and data received via sensors 21, system 22 will issue control signals via outputs 24 to control breathing air pressure at breathing mask 26.”, see col. 4, ll. 40-43).

Allowable Subject Matter

Art Unit: 3735

11. Claims 24, 25, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claims 31 and 34-40 would be allowable if rewritten to overcome the rejection(s) under pre-AIA 35 U.S.C. 112, set forth in this Office Action.

13. The following is a statement of reasons for the indication of allowable subject matter:

As to Claims 24, 25, and 31, neither Miles, Hedner, Stahmann, nor the prior art of record teaches the device of claim 21, including the following in combination with all other limitations of the base claim: wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

As to Claims 34-40, neither Miles, Hedner, Stahmann, nor the prior art of record teaches the device of claim 34, including the following in combination with all other limitations of the claim: an positive airway pressure apparatus for providing pressurized air and chemically treating a subject's sleep disorder or symptoms with additional CO2 resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Mallari can be reached on (571) 272-4729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/
Primary Examiner, Art Unit 3735
12/29/2016

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant						☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE									
Final	Original	06/16/2015	03/01/2016	09/01/2016	01/04/2017						
	1	-	-	-	-						
	2	-	-	-	-						
	3	-	-	-	-						
	4	-	-	-	-						
	5	-	-	-	-						
	6	-	-	-	-						
	7	-	-	-	-						
	8	-	-	-	-						
	9	-	-	-	-						
	10	-	-	-	-						
	11	-	-	-	-						
	12	-	-	-	-						
	13	-	-	-	-						
	14	-	-	-	-						
	15	-	-	-	-						
	16	-	-	-	-						
	17	-	-	-	-						
	18	-	-	-	-						
	19	-	-	-	-						
	20	-	-	-	-						
	21	÷	✓	✓	✓						
	22	÷	✓	✓	✓						
	23	÷	✓	✓	✓						
	24	÷	✓	○	○						
	25	÷	✓	○	○						
	26	÷	✓	✓	✓						
	27	÷	✓	✓	✓						
	28	÷	✓	✓	✓						
	29	÷	✓	✓	✓						
	30	÷	✓	✓	✓						
	31	÷	✓	○	✓						
	32	÷	✓	✓	✓						
	33	÷	✓	✓	✓						
	34	÷	✓	✓	✓						
	35	÷	✓	✓	✓						
	36	÷	✓	✓	✓						

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
CLAIM		DATE							
Final	Original	06/16/2015	03/01/2016	09/01/2016	01/04/2017				
	37	÷	✓	✓	✓				
	38	÷	✓	✓	✓				
	39	÷	✓	○	✓				
	40	÷	✓	○	✓				

Search Notes 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

CPC- SEARCHED		
Symbol	Date	Examiner
A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592	2/24/2016	/NN/
A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60	2/24/2016	/NN/
61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592	8/23/2016	/NN/
A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60	8/23/2016	/NN/
A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592	12/28/2016	/NN/
A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60	12/28/2016	/NN/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST (enclosed): USPAT, US-PGPUB, EPO, JPO, Derwent, Inventor, Forward/Backward Citation, CPC, Keyword searches	2/24/2016	/NN/

	/N.N./ Primary Examiner.Art Unit 3735
--	--

SEARCH NOTES

Search Notes	Date	Examiner
EAST (enclosed): USPAT, US-PGPUB, EPO, JPO, Derwent, Inventor, Forward/Backward Citation, Art of Record, CPC, Keyword searches	8/23/2016	/NN/
EAST (enclosed): USPAT, US-PGPUB, EPO, JPO, Derwent, Inventor, Forward/Backward Citation, Art of Record, CPC, Keyword searches	12/28/2016	/NN/

INTERFERENCE SEARCH

US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592		
	A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60		

/N.N./
Primary Examiner.Art Unit 3735

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	70436	(A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592 OR A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60).CPC. OR ((600/484,529-543) OR ("128"/\$)).ccls.	US-PGPUB; USPAT	OR	OFF	2016/12/29 16:16
L5	189	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator)) AND (central WITH (obstructiv\$4 OR hypopne\$5 OR hypoapne\$5) WITH (distinguish\$5 OR identify\$3 OR identification OR differentiat\$5)) AND L4	US-PGPUB; USPAT	OR	ON	2016/12/29 16:16
L6	189	(central WITH (obstructiv\$4 OR hypopne\$5 OR hypoapne\$5) WITH (distinguish\$5 OR identify\$3 OR identification OR differentiat\$5)) AND L5	US-PGPUB; USPAT	OR	ON	2016/12/29 16:16
L7	1	((11/266899) or (13/440116)).APP.	US-PGPUB; USPAT	OR	OFF	2016/12/29 16:37
L8	1	((central OR complex OR obstructiv\$4) SAME (apne\$3 OR hypopne\$5 OR hypoapne\$5)) AND L7	US-PGPUB; USPAT	OR	ON	2016/12/29 16:37
S276	60	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US-20040116784-\$ or US-20100043795-\$ or US-20100258126-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-	US-PGPUB; USPAT	OR	ON	2016/12/29 09:48

		7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$ or US-7018341-\$ or US-6832609-\$ or US-7662101-\$ or US-7878198-\$ or US-8172766-\$ or US-5704345-\$ or US-5353788-\$ or US-8069852-\$ or US-7942824-\$ or US-8365730-\$.did. or (US-8545416-\$ or US-8356594-\$ or US-5237990-\$ or US-7757690-\$.did.				
S277	36	("20020185130" "20030000528" "20040138576" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050188991" "20050217674" "20050268916" "20060084877" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6832609" "6889691" "7018341" "7101341" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7662101" "7668579" "7670295" "7878198" "8172766").PN.	US-PGPUB; USPAT	OR	OFF	2016/12/29 09:48
S278	13301	(A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592 OR A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60).CPC.	US-PGPUB; USPAT	OR	OFF	2016/12/29 09:48
S279	38	("20040138576" "20050165323" "6029664" "7190995" "7204250" "7225809" "7878198" "5237990" "20020185130" "20060084877" "6229581" "7101341" "7668579" "20040254493" "20050085738" "7018341" "7670295" "20040163648" "5961447" "6431171" "8172766" "20050115561" "6138675" "20050188991" "20050217674" "20050268916" "20060247546" "5645043" "6832609" "7195013" "7757690" "20030000528" "6551252" "6889691" "7575005" "20050081847" "7309314" "7662101").PN.	US-PGPUB; USPAT	OR	OFF	2016/12/29 09:48
S280	62	S276 OR S277 OR S279	US-PGPUB; USPAT	OR	OFF	2016/12/29 09:49
S281	6980	((KAYYALI NEAR2 HANI) OR (SCHMIDT NEAR2 ROBERT) OR (((MODARRES-ZADEH") OR (MODARRES ADJ2 ZADEH)) NEAR2 MOHAMMAD) OR (KOLKOWSKI NEAR2 BRIAN)).INV.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/12/29 09:49
S282	1	((11/266899) or (13/440116)).APP.	US-PGPUB;	OR	OFF	2016/12/29 09:50

			USPAT			
S283	0	S282 AND enclosure	US-PGPUB; USPAT	OR	ON	2016/12/29 09:51
S284	1	S282 AND blower	US-PGPUB; USPAT	OR	ON	2016/12/29 09:51
S285	1	("5353788").PN.	US-PGPUB; USPAT	OR	OFF	2016/12/29 09:53
S286	60	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US-20040116784-\$ or US-20100043795-\$ or US-20100258126-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$ or US-7018341-\$ or US-6832609-\$ or US-7662101-\$ or US-7878198-\$ or US-8172766-\$ or US-5704345-\$ or US-5353788-\$ or US-8069852-\$ or US-7942824-\$ or US-8365730-\$).did. or (US-8545416-\$ or US-8356594-\$ or US-5237990-\$ or US-7757690-\$).did.	US-PGPUB; USPAT	OR	ON	2016/12/29 12:17
S287	36	("20020185130" "20030000528" "20040138576" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050188991" "20050217674" "20050268916" "20060084877" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6832609" "6889691" "7018341" "7101341" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7662101" "7668579" "7670295" "7878198" "8172766").PN.	US-PGPUB; USPAT	OR	OFF	2016/12/29 12:17
S288	38	("20040138576" "20050165323" "6029664" "7190995" "7204250" "7225809" "7878198" "5237990" "20020185130" "20060084877"	US-PGPUB; USPAT	OR	OFF	2016/12/29 12:17

		"6229581" "7101341" "7668579" "20040254493" "20050085738" "7018341" "7670295" "20040163648" "5961447" "6431171" "8172766" "20050115561" "6138675" "20050188991" "20050217674" "20050268916" "20060247546" "5645043" "6832609" "7195013" "7757690" "20030000528" "6551252" "6889691" "7575005" "20050081847" "7309314" "7662101").PN.				
S289	62	S286 OR S287 OR S288	US- PGPUB; USPAT	OR	OFF	2016/12/29 12:17
S290	2	((("20120245447") or ("8920332"))).PN.	US- PGPUB; USPAT	OR	OFF	2016/12/29 12:54
S291	6980	((KAYYALI NEAR2 HANI) OR (SCHMIDT NEAR2 ROBERT) OR (((("MODARRES- ZADEH") OR (MODARRES ADJ2 ZADEH)) NEAR2 MOHAMMAD) OR (KOLKOWSKI NEAR2 BRIAN)).INV.	US- PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/12/29 14:56
S292	1	(differentiat\$4 WITH central WITH obstructive WITH (apnea OR apneic OR hypoopne\$3 OR hypopne\$3)).clm. AND S291	US- PGPUB; USPAT	OR	ON	2016/12/29 14:57
S293	7053	((KAYYALI NEAR2 HANI) OR (SCHMIDT NEAR2 ROBERT) OR (((("MODARRES- ZADEH") OR (MODARRES ADJ2 ZADEH)) NEAR2 MOHAMMAD) OR (KOLKOWSKI NEAR2 BRIAN)).INV. OR (cleveland ADJ2 medical).as.	US- PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/12/29 15:01
S294	1	(differentiat\$4 WITH central WITH obstructive WITH (apnea OR apneic OR hypoopne\$3 OR hypopne\$3)).clm. AND S293	US- PGPUB; USPAT	OR	ON	2016/12/29 15:01
S295	1	(differentiat\$4 WITH (apnea OR apneic OR hypoopne\$3 OR hypopne\$3)).clm. AND S293	US- PGPUB; USPAT	OR	ON	2016/12/29 15:02
S296	70436	(A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592 OR A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60).CPC. OR ((600/484,529-543) OR ("128"/\$)).ccls.	US- PGPUB; USPAT	OR	OFF	2016/12/29 15:07
S297	251	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator)) AND (central WITH (obstructiv\$4 OR hypopne\$5 OR hypoapne\$5) WITH (distinguish\$5 OR determin\$6 OR differentiat\$5)) AND S296	US- PGPUB; USPAT	OR	ON	2016/12/29 15:07

S298	251	(central WITH (obstructiv\$4 OR hypopne\$5 OR hypoapne\$5) WITH (distinguish\$5 OR determin\$6 OR differentiat\$5)) AND S297	US-PGPUB; USPAT	OR	ON	2016/12/29 15:07
S299	189	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator)) AND (central WITH (obstructiv\$4 OR hypopne\$5 OR hypoapne\$5) WITH (distinguish\$5 OR identify\$3 OR identification OR differentiat\$5)) AND S296	US-PGPUB; USPAT	OR	ON	2016/12/29 15:10
S300	189	(central WITH (obstructiv\$4 OR hypopne\$5 OR hypoapne\$5) WITH (distinguish\$5 OR identify\$3 OR identification OR differentiat\$5)) AND S299	US-PGPUB; USPAT	OR	ON	2016/12/29 15:10
S301	1	((11/266899) or (13/440116)).APP.	US-PGPUB; USPAT	OR	OFF	2016/12/29 15:11
S302	0	(central WITH (obstructiv\$4 OR hypopne\$5 OR hypoapne\$5) WITH (distinguish\$5 OR identify\$3 OR identification OR differentiat\$5)) AND S301	US-PGPUB; USPAT	OR	ON	2016/12/29 15:11
S303	1	(central WITH obstructiv\$4 WITH (apne\$3 OR hypopne\$5 OR hypoapne\$5)) AND S301	US-PGPUB; USPAT	OR	ON	2016/12/29 15:12
S304	1	(central SAME obstructiv\$4 SAME (apne\$3 OR hypopne\$5 OR hypoapne\$5)) AND S301	US-PGPUB; USPAT	OR	ON	2016/12/29 15:12
S305	1	((central OR complex OR obstructiv\$4) SAME (apne\$3 OR hypopne\$5 OR hypoapne\$5)) AND S301	US-PGPUB; USPAT	OR	ON	2016/12/29 15:13

12/ 29/ 2016 4:44:37 PM
H:\ EAST\ Workspaces\ FY2016\ 13440116.wsp

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	13/440,116
Filing Date	2012-04-05
First Named Inventor	Hani Kayyali
Art Unit	3735
Examiner Name	Navin Natnithilhadha
Attorney Docket Number	CMD-087

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).
- a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
- i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ii. ☐ Other _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☐ Affidavit(s)/ Declaration(s)
- iii. ☐ Information Disclosure Statement (IDS)
- iv. ☐ Other _____
2. **Miscellaneous**
- a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months. Fee under 37 CFR 1.17(j) required)
- b. ☐ Other _____
3. **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
- The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to
- a. ☐ Deposit Account No. _____
- i. ☒ RCE fee required under 37 CFR 1.17(e)
- ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
- iii. ☐ Other _____
- b. ☐ Check in the amount of \$ _____ enclosed
- c. ☒ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Brian Kolkowski/	Date	2016-12-06
Name (Print/Type)	Brian Kolkowski	Registration No.	36847

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	Mark Pennington/	Date	2016-12-06
Name (Print/Type)	Mark Pennington		

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	13440116			
Filing Date:	05-Apr-2012			
Title of Invention:	Devices and Methods for Sleep Disorder Diagnosis and Treatment			
First Named Inventor/Applicant Name:	Hani Kayyali			
Filer:	Brian M. Kolkowski/Mark Pennington			
Attorney Docket Number:	CMD-087			
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
RCE- 1st Request	2801	1	600	600
Total in USD (\$)				600

Electronic Acknowledgement Receipt

EFS ID:	27707923
Application Number:	13440116
International Application Number:	
Confirmation Number:	4463
Title of Invention:	Devices and Methods for Sleep Disorder Diagnosis and Treatment
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-087
Receipt Date:	06-DEC-2016
Filing Date:	05-APR-2012
Time Stamp:	14:26:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 600
RAM confirmation Number	120716INTEFSW14275300
Deposit Account	502704
Authorized User	Mark Pennington

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

ResMed

37 CFR 1.19 (Document supply fees)
37 CFR 1.20 (Post Issuance fees)
37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-087_2016-12-06_amendment-after-final_RCE.pdf	317977	yes	16
			3c8070afb2aa2a9023c574d492be03610dc914e81		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Applicant Arguments/Remarks Made in an Amendment		7	16	
	Claims		2	6	
	Response After Final Action		1	1	
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	CMD-087_2016-12-06_RCE-form_scanned.pdf	476120	no	1
			fed8d9e5f44d74487c1c6a74ef3ea9a8ab04c640		
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30490	no	2
			6346a8184905c70b21c76c48e2b6e0859e71f5b8		
Warnings:					
Information:					
Total Files Size (in bytes):			824587		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

REMARKS

Claims 21-40 were rejected in the Office Action issued September 6, 2016. The Applicants have amended claims 21, 28, 30, 32, 34 and 37 and have further requested continued examination.

Anticipation under 35 USC §102

To provide legal context as well as an analytical framework for the Applicants' remarks, the Applicants wish, as an initial point, to respectfully remind the Examiner that a proper finding of anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 202 USPTO 202 (Fed Cir. 1983). It is not enough that the prior art reference disclose all of the claimed elements in isolation, but rather anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, anticipation requires that the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ 2d. 1241 (Fed Cir. 1986). The standard of anticipation is identity of invention. *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 33 U.S.P.Q.2d 1496, 1500 (Fed.Cir.1995). Identity of invention is a question of fact that requires a showing that each element of the claim in issue is found in a prior patent or publication, either expressly or inherently. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir.1983), cert. denied, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984). Inherency may not be established by probabilities or possibilities. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). Before burden is shifted to the applicant to disprove inherency, the examiner is required provide evidence or scientific reasoning to establish the reasonableness of the examiner's belief that a functional limitation is an inherent characteristic of the prior art. *Ex parte Skinner*, 2 USPQ 2d 1788, 1789 (BPAI 1986).

Thus, to reach a proper finding of anticipation, the Examiner must show that each and every claim limitation is present in a single prior art reference (the identity of invention requirement) and that the same prior art reference enables the claimed invention so as to place the invention in the possession of a person having ordinary skill in the art (the anticipatory enablement requirement). If the Examiner falls short in meeting any of these requirements then the Examiner has failed to establish a *prima facie* case and the Appellant is entitled to the patent. See *In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) (“If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent”). Further, refusal by the USPTO to issue the patent in the face of an Examiner’s failure to properly establish a *prima facie* case of anticipation or some other proper grounds for rejection places the Examiner and the USPTO in contravention of 35 U.S.C. § 131, which dictates that if after examination of an application “it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” (emphasis added).

Claims 21-23, 26-30 and 32-38 were rejected under pre-AIA 35 USC 102(b) as being anticipated by Miles, U.S. Patent No. 5,353,788 A (“Miles”). The Applicants traverse and submit the claims as amended are not anticipated by Miles.

With respect to claim 21, Miles does not teach or disclose a positive airway pressure (PAP) sleep disorder treatment device comprising an enclosure comprising a blower or source of pressurized gas, inputs for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor and a pulse oximeter sensor; and a processor for receiving and processing signals from the respiratory effort and pulse oximeter sensors and further for determining an output pressure level of the PAP device based at least in part on the signals from the respiratory effort and pulse oximeter sensors as claimed.

Miles instead teaches of CPAP device with an airflow generator tethered to a physiological monitoring and actuating (“PMA”) device manufactured by Vitalog Monitoring Inc. The physiological monitoring device for monitoring 7 different physiological signals including a respiratory effort and pulse oximeter sensor. The only sensor on the CPAP device being an airflow sensor, the signal being feed through the

tether 13 to the PMA device. The tether further being used to adjust the airflow of the CPAP when the patient is being tested. At the end of the testing procedure the raw data is transferred from the PMA device to an external computer, the computer analyzes “the data, prepare[s] a report, and help[s] determine the final airflow pressure to be used in the long-term treatment of the patient.” Miles, Col. 5, lines 1-36.

The pulse oximeter and respiratory belt in Miles are being feed directly into the PMA device 12, and not directly into inputs on the CPAP device as claimed. In addition, in Miles all of the data is feed to an external computer to help determine the final airflow pressure, and does not use a processor on the PAP device as claimed. Further, in Miles at least 8 sensors and their data are used to help determine the airflow pressure for the long term treatment, whereas in the claimed invention the respiratory effort and pulse oximeter sensors are the only sensors required for adjusting the pressure level of the PAP device as claimed.

Given these differences between the reference and the claimed invention, the Applicants request the Examiner withdraw this rejection.

With respect to claim 28, Miles does not teach or disclose a sleep disorder treatment system comprising a data acquisition system, the data acquisition system comprising a data acquisition device having inputs adapted for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor, and an input adapted for receiving a treatment device signal from a sensor from a treatment device; a positive airway pressure (PAP) device, the treatment device separate and in a different enclosure from the data acquisition device, that includes a hose, the sensor with a signal for measuring air flow and/or pressure, an output for providing the treatment device signal derived in part on the airflow and/or pressure signal, and a mask for treating a subject's sleep disorder symptoms; and a processor adapted for receiving data from the respiratory effort sensor, pulse oximeter sensor, and the sensor for measuring air flow and/or pressure and further for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypoopneas, the processor either part of or external to the data acquisition device and having an output, the output adapted for providing data of the identified and

differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device as claimed.

Miles instead teaches of CPAP device with an airflow generator tethered to a physiological monitoring and actuating (“PMA”) device manufactured by Vitalog Monitoring Inc. The physiological monitoring device for monitoring 7 different physiological signals including a respiratory effort and pulse oximeter sensor. The only sensor on the CPAP device being an airflow sensor, the signal being feed through the tether 13 to the PMA device. The tether further being used to adjust the airflow of the CPAP when the patient is being tested. At the end of the testing procedure the raw data is transferred from the PMA device to an external computer, the computer analyzes “the data, prepare[s] a report, and help[s] determine the final airflow pressure to be used in the long-term treatment of the patient.” Miles, Col. 5, lines 1-36.

In Miles at least 8 sensors and their data are feed from the PMA device 12 into an external computer and then used to help determine the airflow pressure for the long term treatment of the patient. In the present invention while the processor can be external from the data acquisition device and the PAP, the processor is used for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypoopneas and the output on the processor is adapted for providing data of the identified and differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device. There is no indication that Miles’ computer can provide such information and furthermore it is clear this is not inherent in the teachings of Miles.

Given these differences between the reference and the claimed invention, the Applicants request the Examiner withdraw this rejection.

With respect to Claim 34, Miles does not teach or disclose a sleep disorder treatment system comprising a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject’s sleep disorder or symptoms based in part on the signals from the sensors; and an positive airway pressure apparatus for providing pressurized air and chemically treating a subject’s sleep disorder or symptoms with additional CO₂ resulting

in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system as claimed.

Miles instead teaches of CPAP device with an airflow generator tethered to a physiological monitoring and actuating ("PMA") device manufactured by Vitalog Monitoring Inc. The physiological monitoring device for monitoring 7 different physiological signals including a respiratory effort and pulse oximeter sensor. The only sensor on the CPAP device being an airflow sensor, the signal being feed through the tether 13 to the PMA device. The tether further being used to adjust the airflow of the CPAP when the patient is being tested. At the end of the testing procedure the raw data is transferred from the PMA device to an external computer, the computer analyzes "the data, prepare[s] a report, and help[s] determine the final airflow pressure to be used in the long-term treatment of the patient." Miles, Col. 5, lines 1-36.

Miles does not teach of a data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors as claimed. Miles further does not teach of a positive airway pressure apparatus for providing [both] pressurized air and chemically treating a subject's sleep disorder or symptoms with additional CO₂ resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent as claimed. Still further, Miles does not teach of adjusting the level of additional carbon dioxide or of a pharmaceutical agent with an output of a level of severity of a subject's sleep disorder as claimed. Instead Miles teaches of adjusting a CPAP device over a series of air pressure settings and measuring physiological data from at least 8 sensors to [help] determine a final airflow level setting.

Given these differences between the reference and the claimed invention, the Applicants request the Examiner withdraw this rejection.

With respect to claim 22, Miles does not teach or disclose wherein the inputs on the PAP device and the outputs of the at least two sensors are in wireless radio frequency bidirectional communication as in the amended claimed. While the Examiner has cited Miles for this teaching, Miles, Col 4, Lines 28-31 does not teach this claim limitation.

With respect to claim 23, Miles does not teach or disclose wherein the PAP (of claim 22) through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors as claimed. The Examiner cites to Miles Col. 4, lines 40-43 for this teaching, but as the Examiner admits this “control[s] breathing air pressure at the breathing mask 26.” One skilled in the art would understand controlling breathing pressure of the CPAP is not the same as controlling the output of one of at least two sensors input into a PAP device.

With respect to claim 26, Miles does not teach or disclose a PAP device with to sensor inputs and an internal sensor wherein the PAP device further comprises an airflow sensor with a signal, and wherein the processor also receives and processes signals from the airflow sensor in addition to the signals from the respiratory effort and pulse oximeter sensors to determine the output pressure level of the PAP device as claimed.

With respect to claim 38, Miles does not disclose the sleep disorder treatment system of claims 34 and 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms through the receiver can command a signal processing module to reconfigure the output of the data acquisition system as claimed.

The Examiner cites to Miles Col. 4, lines 40-43 for this teaching, but as the Examiner admits this “control[s] breathing air pressure at the breathing mask 26.” One skilled in the art would understand controlling breathing pressure of the CPAP is not the same as controlling the output of one of at least two sensors input into a PAP device.

Given the above comments, the Applicants urge the Examiner to withdraw of these rejections to the dependent claims as well.

Obviousness under 35 U.S.C. § 103

To provide legal context as well as an analytical framework for the remarks that follow, the Applicant wishes at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the Examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an

assertion of *prima facie* obviousness the Examiner must perform the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that “secondary considerations” such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, “the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis.” MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the Examiner errs in performing any of the *Graham* factual inquiries, the Examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the Examiner committing error in performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

With specific regard to the Examiner’s obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Applicant would direct particular attention to the requirement that “[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill.” See MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the Examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the Examiner’s burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the Examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an “indication of the level of ordinary skill,” MPEP 2141(II)(C), the Examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the

Examiner in such a way as to render the claimed invention obvious. *See In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and Examiner for failing to provide “any evidentiary support or reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant” and further noting that *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) “did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references”).

Thus, in order for the Examiner to properly establish a *prima facie* case of obviousness the Examiner must first make the factual inquiries required by *Graham* and, if relying on a combination of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the Examiner falls short in meeting any of these requirements then the Examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. *See In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) (“If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent”). As stated in the United States Patent and Trademark Office’s own rules, “[a] *prima facie* case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard...” *See* 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the Examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination “it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” (emphasis added).

In all of the above, the Applicants wish to emphasize the high bar to which the Examiner is held during the examination process and hereby respectfully request that in the ongoing prosecution of the present application that the Examiner provide explicit and detailed analysis of any grounds of rejection relied upon. *See, e.g., KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (“[an obviousness] analysis should be made explicit,” citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

Claims 30, 32 and 37 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over Miles as applied to claim 28 and 34 above, and further in view of Stahmann et al, U.S. Pat. No. 7,757,690 B2 (“Stahmann”). The Applicants traverse and submit that claim 32 as amended is patentable over Miles in view of Stahmann.

The Applicants incorporate their comments above with respect Miles. With respect to claims 32 and 37, Stahmann does not teach or disclose wherein the sensor output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the PAP device as claimed. The Examiner instead cites to a bidirectional wireless communication between a fully or partially “implantable device” and an external medical device. The present invention does not claim an “implantable” medical device nor communications with such a device. Furthermore, Stahmann teaches moderating therapy during sleep using “physiologic data acquired during non-sleep”. The present invention in contrast adjust therapy for sleep using physiological data acquired during sleep. The Examiner appears to be comparing systems that function differently or somewhat in an opposite fashion.

With respect to claim 30, Miles does not teach or disclose wherein the PAP (of claim 22) through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors as claimed. The Examiner cites to Miles Col. 4, lines 40-43 for this teaching, but as the Examiner admits this “control[s] breathing air pressure at the breathing mask 26.” One skilled in the art would understanding controlling breathing pressure of the CPAP is not the same as controlling the output of one of at least two sensors input into a PAP device.

The Examiner purports that the motivation to combine Miles with Stahmann is “it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Miles’ wired communication between the CPAP and the PMA to be wireless and bidirectional, as taught by Psaros (sic) (Stahmann?). As pointed out above, the systems in Miles and Stahmann function differently and as such one skilled in the art would understand that the teaching in Stahmann is not readily applicable to Miles.

Given the above comments, the Applicants urge the Examiner to withdraw this rejection.

CONCLUSION:

The Applicant respectfully submits that this application is in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

05/27/2016
Dated

/Brian M. Kolkowski/
Brian M. Kolkowski
Reg. No.: 36,847
Attorney for the Applicant
Cleveland Medical Devices Inc.
4415 Euclid Avenue, Suite 400
Cleveland, Ohio 44103
Tel: (216) 649-0376
Fax: (216) 649-0347
Email: bkolkowski@clevemed.com

CLAIM AMENDMENTS:

Please amend claims 21, 28, 30, 32, 34 and 37 as follows:

1-20. (Canceled)

21. (currently amended) A positive airway pressure (PAP) sleep disorder treatment device comprising:

an enclosure comprising

a blower or source of pressurized gas,

~~a positive airway pressure (PAP) device, the PAP device comprising~~ inputs for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor and a pulse oximeter sensor; and

a processor for receiving and processing signals from the respiratory effort and pulse oximeter sensors and further for determining an output pressure level of the PAP device based at least in part on the signals from the respiratory effort and pulse oximeter sensors.

22. (previously presented) The device of claim 21 wherein the inputs on the PAP device and the outputs of the at least two sensors are in wireless radio frequency bidirectional communication.

23. (previously presented) The device of claim 22 wherein the PAP through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors .

24. (previously presented) The device of claim 21 wherein the signals from the respiratory effort and pulse oximeter sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique,

a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

25. (previously presented) The device of claim 24 in which signals from the sensors are processed using a short-time fourier transform technique.

26. (previously presented) The device of claim 21 wherein the PAP device further comprises an airflow sensor with a signal, and wherein the processor also receives and processes signals from the airflow sensor in addition to the signals from the respiratory effort and pulse oximeter sensors to determine the output pressure level of the PAP device.

27. (previously presented) The device of claim 21 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

28. (currently amended) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs adapted for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor, ~~the data acquisition system for creating a quantitative output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors~~ and an input adapted for receiving a treatment device signal from a sensor from a treatment device; and

a positive airway pressure (PAP) device, the treatment device separate and in a different enclosure from the data acquisition device, that includes a hose, the sensor with a signal for measuring air flow and/or pressure, an output for providing the treatment device signal derived in part on the airflow and/or pressure signal, and a mask for treating a subject's sleep disorder symptoms, ~~which can receive the output of the data acquisition~~

~~system with a processor and produce a recommended positive pressure setting in part in response to the output of the data acquisition system with the processor; and~~

a processor adapted for receiving data from the respiratory effort sensor, pulse oximeter sensor, and the sensor for measuring air flow and/or pressure and further for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypopneas, the processor either part of or external to the data acquisition device and having an output, the output adapted for providing data of the identified and differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device.

29. (previously presented) The sleep disorder treatment system of claim 28 wherein the PAP device further comprises an airflow sensor with a signal, and a processor that receives and processes signals from the airflow sensor in addition to the output from the data acquisition system to determine the output pressure level of the PAP device.

30. (currently amended) The sleep disorder treatment system of claim 32 wherein the ~~PAP~~data acquisition system through ~~the~~ a receiver can command a signal processing module to reconfigure the output of the ~~data acquisition system~~PAP.

31. (previously presented) The sleep disorder treatment system of claim 28 wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

32. (currently amended) The sleep disorder treatment system of claim 28 wherein the sensor data output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and ~~a receiver on the PAP device~~the processor.

33. (previously presented) The sleep disorder treatment system of claim 28 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

34. (currently amended) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors; and

an positive airway pressure apparatus for providing pressurized air and chemically treating a subject's sleep disorder or symptoms with ~~more than air~~ additional CO₂ resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

35. (previously presented) The sleep disorder treatment system of claim 34 wherein the at least one physiological sensor is a pulse oximeter sensor.

36. (previously presented) The sleep disorder treatment system of claim 35 further including a respiratory effort sensor.

37. (currently amended) The sleep disorder treatment system of claim 34 wherein the output the level of severity from~~of~~ the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the apparatus for chemically treating a subject's sleep disorder or symptoms.

38. (previously presented) The sleep disorder treatment system of claim 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms through the

receiver can command a signal processing module to reconfigure the output of the data acquisition system.

39. (previously presented) The sleep disorder treatment system of claim 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms is used to deliver carbon dioxide to the subject at a concentration higher than atmospheric concentration of carbon dioxide in air.

40. (previously presented) The sleep disorder treatment system of claim 34 wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
		)	
Serial No.:	13/440,116	)	
		)	Art Unit: 3735
Filed:	April 5, 2012	)	
		)	
For:	Devices and Methods for	)	
	Sleep Disorder Diagnosis	)	
	and Treatment	)	
		)	Attorney Docket No.: CMD-087
Examiner:	Navin Natnithithadha	)	
		)	

December 6, 2016

REQUEST FOR CONTINUED EXAMINATION AND AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

This communication is responsive to the final rejection in the Office action having mail date of September 6, 2016 with a due date for response of December 6, 2016. The Applicants certify that they are entitled to small entity status. The Applicants herewith submit a Request for Continued Examination under 35 U.S.C. § 132 and 37 C.F.R. § 1.114 along with the \$600 fee pursuant to 37 C.F.R. § 1.17e(1). The Applicants understand this amendment to satisfy the requirements of a submission under 37 C.F.R. § 1.114(c). While the Applicants believe that this response is timely and that there are no additional fees due with this communication, the Applicants nevertheless petition for any required extension of time and authorize the Commissioner to deduct any fees that may be found to be owed in conjunction herewith from their deposit account 502704.

The following amendments and remarks are respectfully submitted, and submit that no new matter is contained in the amendments.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
		)	
Serial No.:	13/440,116	)	
		)	Art Unit: 3735
Filed:	April 5, 2012	)	
		)	
For:	Devices and Methods for	)	
	Sleep Disorder Diagnosis	)	
	and Treatment	)	
		)	Attorney Docket No.: CMD-087
Examiner:	Navin Natnithithadha	)	
		)	

December 6, 2016

CORRECTED AMENDMENT AFTER FINAL REJECTION

Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

This communication is responsive to the final rejection in the Office action having mail date of September 6, 2016 with a due date for response of December 6, 2016, and is submitted to correct the amendment submitted earlier today with a Request for Continued Examination. The Amendment submitted earlier had an incorrect date on the signature page, and the present submission includes a corrected signature page with appropriate date. The remainder of this submission is identical to the earlier-submitted amendment, and is believed to satisfy the submission requirement for the RCE filed earlier. While the Applicants believe that this response is timely and that there are no additional fees due with this communication, the Applicants nevertheless petition for any required extension of time and authorize the Commissioner to deduct any fees that may be found to be owed in conjunction herewith from their deposit account 502704.

The following amendments and remarks are respectfully submitted, and submit that no new matter is contained in the amendments.

Electronic Acknowledgement Receipt

EFS ID:	27710411
Application Number:	13440116
International Application Number:	
Confirmation Number:	4463
Title of Invention:	Devices and Methods for Sleep Disorder Diagnosis and Treatment
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-087
Receipt Date:	06-DEC-2016
Filing Date:	05-APR-2012
Time Stamp:	15:50:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-087_2016-12-06_corrected-amendment-after-final.pdf	316599 35ed6c5bdf081dc6c465b2e6d0be9d42f25c398	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Applicant Arguments/Remarks Made in an Amendment	7	16
	Claims	2	6
	Response After Final Action	1	1
Warnings:			
Information:			
Total Files Size (in bytes):		316599	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			

REMARKS

Claims 21-40 were rejected in the Office Action issued September 6, 2016. The Applicants have amended claims 21, 28, 30, 32, 34 and 37 and have further requested continued examination.

Anticipation under 35 USC §102

To provide legal context as well as an analytical framework for the Applicants' remarks, the Applicants wish, as an initial point, to respectfully remind the Examiner that a proper finding of anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 202 USPTO 202 (Fed Cir. 1983). It is not enough that the prior art reference disclose all of the claimed elements in isolation, but rather anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, anticipation requires that the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ 2d. 1241 (Fed Cir. 1986). The standard of anticipation is identity of invention. *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 33 U.S.P.Q.2d 1496, 1500 (Fed.Cir.1995). Identity of invention is a question of fact that requires a showing that each element of the claim in issue is found in a prior patent or publication, either expressly or inherently. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir.1983), cert. denied, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984). Inherency may not be established by probabilities or possibilities. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). Before burden is shifted to the applicant to disprove inherency, the examiner is required provide evidence or scientific reasoning to establish the reasonableness of the examiner's belief that a functional limitation is an inherent characteristic of the prior art. *Ex parte Skinner*, 2 USPQ 2d 1788, 1789 (BPAI 1986).

Thus, to reach a proper finding of anticipation, the Examiner must show that each and every claim limitation is present in a single prior art reference (the identity of invention requirement) and that the same prior art reference enables the claimed invention so as to place the invention in the possession of a person having ordinary skill in the art (the anticipatory enablement requirement). If the Examiner falls short in meeting any of these requirements then the Examiner has failed to establish a *prima facie* case and the Appellant is entitled to the patent. See *In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) (“If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent”). Further, refusal by the USPTO to issue the patent in the face of an Examiner’s failure to properly establish a *prima facie* case of anticipation or some other proper grounds for rejection places the Examiner and the USPTO in contravention of 35 U.S.C. § 131, which dictates that if after examination of an application “it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” (emphasis added).

Claims 21-23, 26-30 and 32-38 were rejected under pre-AIA 35 USC 102(b) as being anticipated by Miles, U.S. Patent No. 5,353,788 A (“Miles”). The Applicants traverse and submit the claims as amended are not anticipated by Miles.

With respect to claim 21, Miles does not teach or disclose a positive airway pressure (PAP) sleep disorder treatment device comprising an enclosure comprising a blower or source of pressurized gas, inputs for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor and a pulse oximeter sensor; and a processor for receiving and processing signals from the respiratory effort and pulse oximeter sensors and further for determining an output pressure level of the PAP device based at least in part on the signals from the respiratory effort and pulse oximeter sensors as claimed.

Miles instead teaches of CPAP device with an airflow generator tethered to a physiological monitoring and actuating (“PMA”) device manufactured by Vitalog Monitoring Inc. The physiological monitoring device for monitoring 7 different physiological signals including a respiratory effort and pulse oximeter sensor. The only sensor on the CPAP device being an airflow sensor, the signal being feed through the

tether 13 to the PMA device. The tether further being used to adjust the airflow of the CPAP when the patient is being tested. At the end of the testing procedure the raw data is transferred from the PMA device to an external computer, the computer analyzes “the data, prepare[s] a report, and help[s] determine the final airflow pressure to be used in the long-term treatment of the patient.” Miles, Col. 5, lines 1-36.

The pulse oximeter and respiratory belt in Miles are being feed directly into the PMA device 12, and not directly into inputs on the CPAP device as claimed. In addition, in Miles all of the data is feed to an external computer to help determine the final airflow pressure, and does not use a processor on the PAP device as claimed. Further, in Miles at least 8 sensors and their data are used to help determine the airflow pressure for the long term treatment, whereas in the claimed invention the respiratory effort and pulse oximeter sensors are the only sensors required for adjusting the pressure level of the PAP device as claimed.

Given these differences between the reference and the claimed invention, the Applicants request the Examiner withdraw this rejection.

With respect to claim 28, Miles does not teach or disclose a sleep disorder treatment system comprising a data acquisition system, the data acquisition system comprising a data acquisition device having inputs adapted for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor, and an input adapted for receiving a treatment device signal from a sensor from a treatment device; a positive airway pressure (PAP) device, the treatment device separate and in a different enclosure from the data acquisition device, that includes a hose, the sensor with a signal for measuring air flow and/or pressure, an output for providing the treatment device signal derived in part on the airflow and/or pressure signal, and a mask for treating a subject's sleep disorder symptoms; and a processor adapted for receiving data from the respiratory effort sensor, pulse oximeter sensor, and the sensor for measuring air flow and/or pressure and further for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypoopneas, the processor either part of or external to the data acquisition device and having an output, the output adapted for providing data of the identified and

differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device as claimed.

Miles instead teaches of CPAP device with an airflow generator tethered to a physiological monitoring and actuating (“PMA”) device manufactured by Vitalog Monitoring Inc. The physiological monitoring device for monitoring 7 different physiological signals including a respiratory effort and pulse oximeter sensor. The only sensor on the CPAP device being an airflow sensor, the signal being feed through the tether 13 to the PMA device. The tether further being used to adjust the airflow of the CPAP when the patient is being tested. At the end of the testing procedure the raw data is transferred from the PMA device to an external computer, the computer analyzes “the data, prepare[s] a report, and help[s] determine the final airflow pressure to be used in the long-term treatment of the patient.” Miles, Col. 5, lines 1-36.

In Miles at least 8 sensors and their data are feed from the PMA device 12 into an external computer and then used to help determine the airflow pressure for the long term treatment of the patient. In the present invention while the processor can be external from the data acquisition device and the PAP, the processor is used for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypoopneas and the output on the processor is adapted for providing data of the identified and differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device. There is no indication that Miles’ computer can provide such information and furthermore it is clear this is not inherent in the teachings of Miles.

Given these differences between the reference and the claimed invention, the Applicants request the Examiner withdraw this rejection.

With respect to Claim 34, Miles does not teach or disclose a sleep disorder treatment system comprising a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject’s sleep disorder or symptoms based in part on the signals from the sensors; and an positive airway pressure apparatus for providing pressurized air and chemically treating a subject’s sleep disorder or symptoms with additional CO₂ resulting

in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system as claimed.

Miles instead teaches of CPAP device with an airflow generator tethered to a physiological monitoring and actuating ("PMA") device manufactured by Vitalog Monitoring Inc. The physiological monitoring device for monitoring 7 different physiological signals including a respiratory effort and pulse oximeter sensor. The only sensor on the CPAP device being an airflow sensor, the signal being feed through the tether 13 to the PMA device. The tether further being used to adjust the airflow of the CPAP when the patient is being tested. At the end of the testing procedure the raw data is transferred from the PMA device to an external computer, the computer analyzes "the data, prepare[s] a report, and help[s] determine the final airflow pressure to be used in the long-term treatment of the patient." Miles, Col. 5, lines 1-36.

Miles does not teach of a data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors as claimed. Miles further does not teach of a positive airway pressure apparatus for providing [both] pressurized air and chemically treating a subject's sleep disorder or symptoms with additional CO₂ resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent as claimed. Still further, Miles does not teach of adjusting the level of additional carbon dioxide or of a pharmaceutical agent with an output of a level of severity of a subject's sleep disorder as claimed. Instead Miles teaches of adjusting a CPAP device over a series of air pressure settings and measuring physiological data from at least 8 sensors to [help] determine a final airflow level setting.

Given these differences between the reference and the claimed invention, the Applicants request the Examiner withdraw this rejection.

With respect to claim 22, Miles does not teach or disclose wherein the inputs on the PAP device and the outputs of the at least two sensors are in wireless radio frequency bidirectional communication as in the amended claimed. While the Examiner has cited Miles for this teaching, Miles, Col 4, Lines 28-31 does not teach this claim limitation.

With respect to claim 23, Miles does not teach or disclose wherein the PAP (of claim 22) through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors as claimed. The Examiner cites to Miles Col. 4, lines 40-43 for this teaching, but as the Examiner admits this “control[s] breathing air pressure at the breathing mask 26.” One skilled in the art would understand controlling breathing pressure of the CPAP is not the same as controlling the output of one of at least two sensors input into a PAP device.

With respect to claim 26, Miles does not teach or disclose a PAP device with two sensor inputs and an internal sensor wherein the PAP device further comprises an airflow sensor with a signal, and wherein the processor also receives and processes signals from the airflow sensor in addition to the signals from the respiratory effort and pulse oximeter sensors to determine the output pressure level of the PAP device as claimed.

With respect to claim 38, Miles does not disclose the sleep disorder treatment system of claims 34 and 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms through the receiver can command a signal processing module to reconfigure the output of the data acquisition system as claimed.

The Examiner cites to Miles Col. 4, lines 40-43 for this teaching, but as the Examiner admits this “control[s] breathing air pressure at the breathing mask 26.” One skilled in the art would understand controlling breathing pressure of the CPAP is not the same as controlling the output of one of at least two sensors input into a PAP device.

Given the above comments, the Applicants urge the Examiner to withdraw of these rejections to the dependent claims as well.

Obviousness under 35 U.S.C. § 103

To provide legal context as well as an analytical framework for the remarks that follow, the Applicant wishes at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the Examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an

assertion of *prima facie* obviousness the Examiner must perform the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that “secondary considerations” such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, “the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis.” MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the Examiner errs in performing any of the *Graham* factual inquiries, the Examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the Examiner committing error in performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

With specific regard to the Examiner’s obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Applicant would direct particular attention to the requirement that “[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill.” See MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the Examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the Examiner’s burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the Examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an “indication of the level of ordinary skill,” MPEP 2141(II)(C), the Examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the

Examiner in such a way as to render the claimed invention obvious. *See In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and Examiner for failing to provide “any evidentiary support or reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant” and further noting that *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) “did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references”).

Thus, in order for the Examiner to properly establish a *prima facie* case of obviousness the Examiner must first make the factual inquiries required by *Graham* and, if relying on a combination of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the Examiner falls short in meeting any of these requirements then the Examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. *See In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) (“If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent”). As stated in the United States Patent and Trademark Office’s own rules, “[a] *prima facie* case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard...” *See* 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the Examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination “it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” (emphasis added).

In all of the above, the Applicants wish to emphasize the high bar to which the Examiner is held during the examination process and hereby respectfully request that in the ongoing prosecution of the present application that the Examiner provide explicit and detailed analysis of any grounds of rejection relied upon. *See, e.g., KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (“[an obviousness] analysis should be made explicit,” citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

Claims 30, 32 and 37 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over Miles as applied to claim 28 and 34 above, and further in view of Stahmann et al, U.S. Pat. No. 7,757,690 B2 (“Stahmann”). The Applicants traverse and submit that claim 32 as amended is patentable over Miles in view of Stahmann.

The Applicants incorporate their comments above with respect Miles. With respect to claims 32 and 37, Stahmann does not teach or disclose wherein the sensor output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the PAP device as claimed. The Examiner instead cites to a bidirectional wireless communication between a fully or partially “implantable device” and an external medical device. The present invention does not claim an “implantable” medical device nor communications with such a device. Furthermore, Stahmann teaches moderating therapy during sleep using “physiologic data acquired during non-sleep”. The present invention in contrast adjust therapy for sleep using physiological data acquired during sleep. The Examiner appears to be comparing systems that function differently or somewhat in an opposite fashion.

With respect to claim 30, Miles does not teach or disclose wherein the PAP (of claim 22) through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors as claimed. The Examiner cites to Miles Col. 4, lines 40-43 for this teaching, but as the Examiner admits this “control[s] breathing air pressure at the breathing mask 26.” One skilled in the art would understanding controlling breathing pressure of the CPAP is not the same as controlling the output of one of at least two sensors input into a PAP device.

The Examiner purports that the motivation to combine Miles with Stahmann is “it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Miles’ wired communication between the CPAP and the PMA to be wireless and bidirectional, as taught by Psaros (sic) (Stahmann?). As pointed out above, the systems in Miles and Stahmann function differently and as such one skilled in the art would understand that the teaching in Stahmann is not readily applicable to Miles.

Given the above comments, the Applicants urge the Examiner to withdraw this rejection.

CONCLUSION:

The Applicant respectfully submits that this application is in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

12/06/2016
Dated

/Brian M. Kolkowski/
Brian M. Kolkowski
Reg. No.: 36,847
Attorney for the Applicant
Cleveland Medical Devices Inc.
4415 Euclid Avenue, Suite 400
Cleveland, Ohio 44103
Tel: (216) 649-0376
Fax: (216) 649-0347
Email: bkolkowski@clevemed.com

CLAIM AMENDMENTS:

Please amend claims 21, 28, 30, 32, 34 and 37 as follows:

1-20. (Canceled)

21. (currently amended) A positive airway pressure (PAP) sleep disorder treatment device comprising:

an enclosure comprising

a blower or source of pressurized gas,

~~a positive airway pressure (PAP) device, the PAP device comprising~~ inputs for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor and a pulse oximeter sensor; and

a processor for receiving and processing signals from the respiratory effort and pulse oximeter sensors and further for determining an output pressure level of the PAP device based at least in part on the signals from the respiratory effort and pulse oximeter sensors.

22. (previously presented) The device of claim 21 wherein the inputs on the PAP device and the outputs of the at least two sensors are in wireless radio frequency bidirectional communication.

23. (previously presented) The device of claim 22 wherein the PAP through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors .

24. (previously presented) The device of claim 21 wherein the signals from the respiratory effort and pulse oximeter sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique,

a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

25. (previously presented) The device of claim 24 in which signals from the sensors are processed using a short-time fourier transform technique.

26. (previously presented) The device of claim 21 wherein the PAP device further comprises an airflow sensor with a signal, and wherein the processor also receives and processes signals from the airflow sensor in addition to the signals from the respiratory effort and pulse oximeter sensors to determine the output pressure level of the PAP device.

27. (previously presented) The device of claim 21 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

28. (currently amended) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs adapted for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor, ~~the data acquisition system for creating a quantitative output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors~~ and an input adapted for receiving a treatment device signal from a sensor from a treatment device; and

a positive airway pressure (PAP) device, the treatment device separate and in a different enclosure from the data acquisition device, that includes a hose, the sensor with a signal for measuring air flow and/or pressure, an output for providing the treatment device signal derived in part on the airflow and/or pressure signal, and a mask for treating a subject's sleep disorder symptoms, ~~which can receive the output of the data acquisition~~

~~system with a processor and produce a recommended positive pressure setting in part in response to the output of the data acquisition system with the processor; and~~

a processor adapted for receiving data from the respiratory effort sensor, pulse oximeter sensor, and the sensor for measuring air flow and/or pressure and further for identifying central apneas and hyponeas from the data, and differentiating the central apneas and hypopneas from obstructive apneas and hypopneas, the processor either part of or external to the data acquisition device and having an output, the output adapted for providing data of the identified and differentiated apneas and hypopneas in order to allow for modifying treatment with the PAP device.

29. (previously presented) The sleep disorder treatment system of claim 28 wherein the PAP device further comprises an airflow sensor with a signal, and a processor that receives and processes signals from the airflow sensor in addition to the output from the data acquisition system to determine the output pressure level of the PAP device.

30. (currently amended) The sleep disorder treatment system of claim 32 wherein the ~~PAP~~data acquisition system through ~~the~~ a receiver can command a signal processing module to reconfigure the output of the ~~data acquisition system~~PAP.

31. (previously presented) The sleep disorder treatment system of claim 28 wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

32. (currently amended) The sleep disorder treatment system of claim 28 wherein the sensor data output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and ~~a receiver on the PAP device~~the processor.

33. (previously presented) The sleep disorder treatment system of claim 28 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

34. (currently amended) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors; and

an positive airway pressure apparatus for providing pressurized air and chemically treating a subject's sleep disorder or symptoms with ~~more than air~~ additional CO₂ resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

35. (previously presented) The sleep disorder treatment system of claim 34 wherein the at least one physiological sensor is a pulse oximeter sensor.

36. (previously presented) The sleep disorder treatment system of claim 35 further including a respiratory effort sensor.

37. (currently amended) The sleep disorder treatment system of claim 34 wherein the output the level of severity from~~of~~ the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the apparatus for chemically treating a subject's sleep disorder or symptoms.

38. (previously presented) The sleep disorder treatment system of claim 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms through the

receiver can command a signal processing module to reconfigure the output of the data acquisition system.

39. (previously presented) The sleep disorder treatment system of claim 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms is used to deliver carbon dioxide to the subject at a concentration higher than atmospheric concentration of carbon dioxide in air.

40. (previously presented) The sleep disorder treatment system of claim 34 wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/440,116	Filing Date 04/05/2012	☐ To be Mailed
---	---	----------------------------------	---------------------------------------

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO**APPLICATION AS FILED – PART I**

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	12/06/2016	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X \$40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	X \$210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	X \$ =	
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/POLIN ANG/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/440,116	04/05/2012	Hani Kayyali	CMD-087	4463

81177 7590 09/06/2016
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

EXAMINER

NATNITHADHA, NAVIN

ART UNIT	PAPER NUMBER
----------	--------------

3735

MAIL DATE	DELIVERY MODE
-----------	---------------

09/06/2016

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/440,116	Applicant(s) KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 21-40 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 21-23,26-30 and 32-38 is/are rejected.
- 8) ☒ Claim(s) 24,25,31,39 and 40 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Response to Amendment

2. According to the Amendment, filed 27 May 2016, the status of the claims is as follows:

Claims 21-26, 28-32, 34, and 37-40 are currently amended;

Claims 27, 33, 35, and 36 are previously presented; and

Claims 1-20 are cancelled.

3. Applicant's arguments, see Remarks, pp. 7-13, filed 27 May 2016, with respect to the rejection of claims 21-31, 33-37, and 40 under pre-AIA 35 U.S.C. 102(e) as being anticipated by Farrell et al, U.S. Patent No. 7,878,198 B2 ("Farrell"), have been fully considered, but are moot in view of the new ground(s) of rejection, which was necessitated by amendment, as discussed below.

4. Applicant's arguments, see Remarks, pp. 16-17, filed 27 May 2016, with respect to the rejection of claim 32 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell, as applied to claim 28 above, and further in view of Tsukashima et al, U.S. Patent No. 7,101,341 B2, have been fully considered, but are moot in view of the new ground(s) of rejection, which was necessitated by amendment, as discussed below.

5. Applicant's arguments, see Remarks, pp. 17-18, filed 27 May 2016, with respect to the rejection of claims 38 and 39 under pre-AIA 35 U.S.C. 103(a) as being

Art Unit: 3735

unpatentable over Farrell, as applied to claim 37 above, and further in view of Burton et al, U.S. Patent No. 2005/0217674 A1, have been fully considered, but are moot in view of the new ground(s) of rejection, which was necessitated by amendment, as discussed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21-23, 26-29, 33-36, and 38 are rejected under pre-AIA 35

U.S.C. 102(b) as being unpatentable over Miles, U.S. Patent No. 5,353,788 A (“Miles”).

As to Claim 21, Miles teaches the following:

A sleep disorder treatment device (“This invention relates to a medical device and method for automatically determining the correct airflow pressure to be used for the treatment of a serious breathing problem during sleep known as obstructive sleep apnea.”, see col. 1, ll. 9-13, and figs. 1 and 2) comprising:

a positive airway pressure (PAP) device (“nasal-CPAP airflow generator (CPAP device)” 1 (see col. 4, l. 67, to col. 5, l.), the PAP device 1 comprising inputs (“PMA-device”) 12 for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor (“chest and abdominal respiration

sensors”) 7 and a pulse oximeter sensor (“pulse oximeter sensor for measuring the oxygen saturation in the blood”) 5 (see fig. 2 and “The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices.”, see col. 4, ll. 39-41); and

a processor (“physiological monitor and actuating system”) 22 for receiving and processing signals from the sensors (“Data from sensors 21 are collected in physiological monitor and actuating system 22. The monitoring and actuating system 22 includes the basic procedure and control program. Depending on time, entered set-up parameters, and data received via sensors 21, system 22 will issue control signals via outputs 24 to control breathing air pressure at breathing mask 26.”, see col. 4, ll. 37-43) and further for determining an output pressure level of the PAP device 1 based at least in part on the signals from the respiratory effort 7 and pulse oximeter 5 sensors (“Among the vital signs monitored may be chest and abdominal movement, airflow, airflow pressure, breathing sounds, intrathoracic pressure, blood oxygen saturation, heart rate, overall physical movement, leg movement, eye movement, EEG, and sleeping position. All data gathered from the sensors are stored in the Data Collector 22 for later processing by the Analysis Program 25. One or more of the physiological data sensed are used for modifying the airflow

Art Unit: 3735

pressure cycle. However, it is within the scope of the present invention to use additional or alternative physiological data in order to modify the airflow pressure cycle.”, see col. 9, ll. 20-28).

As to Claim 22, Miles teaches the following:

wherein the PAP device 1 is a continuous positive airway pressure device (CPAP) (“The present invention provides an automatic nasal-continuous-positive-airflow pressure (nasal-CPAP) calibration procedure for the treatment of patients suffering from obstructive sleep apnea.”, see col. 4, ll. 28-31).

As to Claim 23, Miles teaches the following:

wherein the PAP through the inputs can command a signal processing module to reconfigure the output of the data acquisition system (“Depending on time, entered set-up parameters, and data received via sensors 21, system 22 will issue control signals via outputs 24 to control breathing air pressure at breathing mask 26.”, see col. 4, ll. 40-43).

As to Claim 26, Miles teaches the following:

wherein the PAP device 1 further comprises an airflow sensor (“pressure transducer located in the CPAP device 1”) with a signal, and wherein the processor also receives and processes signals from the airflow sensor (see col. 4, ll. 55-59, and col. 5, ll. 3-36).

As to Claim 27, Miles teaches the following:

wherein the respiratory effort sensor is a respiratory inductance plethysmography belt ("chest and abdominal respiration (inductive plethysmography) ,", see col. 7, ll. 40-41).

As to Claim 28, Miles teaches the following:

A sleep disorder treatment system ("This invention relates to a medical device and method for automatically determining the correct airflow pressure to be used for the treatment of a serious breathing problem during sleep known as obstructive sleep apnea.", see col. 1, ll. 9-13, and figs. 1 and 2) comprising:

a data acquisition system ("physiological monitor and actuating system") 22, the data acquisition system 22 comprising a data acquisition device ("PMA-device") 12 (see fig. 2) having inputs for receiving signals from sensors including a respiratory effort sensor ("chest and abdominal respiration sensors") 7 and a pulse oximeter sensor ("pulse oximeter sensor for measuring the oxygen saturation in the blood") 5 (see fig. 2 and "The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices.", see col. 4, ll. 39-41), the data acquisition system 22 for creating a quantitative output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors (see col. 5, l. 6, to col. 6, l. 39); and

a positive airway pressure (PAP) device ("nasal-CPAP airflow generator (CPAP device)") 1 that includes a hose ("large flexible tube") 2 and a mask ("nasal mask") 3 for treating a subject's sleep disorder symptoms (see col. 4, l. 67, to col. 5, l. 5), which can receive the output of the data acquisition system 22 with a processor and produce a recommended positive pressure setting in response to the output of the data acquisition system 22 with the processor ("Among the vital signs monitored may be chest and abdominal movement, airflow, airflow pressure, breathing sounds, intrathoracic pressure, blood oxygen saturation, heart rate, overall physical movement, leg movement, eye movement, EEG, and sleeping position. All data gathered from the sensors are stored in the Data Collector 22 for later processing by the Analysis Program 25. One or more of the physiological data sensed are used for modifying the airflow pressure cycle. However, it is within the scope of the present invention to use additional or alternative physiological data in order to modify the airflow pressure cycle.", see col. 9, ll. 20-28).

As to Claim 29, Miles teaches the following:

wherein the PAP device 1 further comprises an airflow sensor ("pressure transducer located in the CPAP device 1") with a signal, and a processor that receives and processes signals from the airflow sensor in addition to the output from the data acquisition system 22 to determine the output pressure level of the PAP device (see col. 4, ll. 55-59, and col. 5, ll. 3-36).

As to Claim 33, Miles teaches the following:

wherein the respiratory effort sensor is a respiratory inductance plethysmography belt ("chest and abdominal respiration (inductive plethysmography) ,", see col. 7, ll. 40-41).

As to Claim 34, Miles teaches the following:

A sleep disorder treatment system ("This invention relates to a medical device and method for automatically determining the correct airflow pressure to be used for the treatment of a serious breathing problem during sleep known as obstructive sleep apnea.", see col. 1, ll. 9-13, and figs. 1 and 2) comprising:

a data acquisition system ("physiological monitor and actuating system") 22, the data acquisition system 22 comprising a data acquisition device ("PMA-device") 12 (see fig. 2) having inputs for receiving signals from at least one physiological sensor ("chest and abdominal respiration sensors") 7 or ("pulse oximeter sensor for measuring the oxygen saturation in the blood") 5, (see col. 5, l. 6, to col. 6, l. 39); and

an apparatus ("nasal-CPAP airflow generator (CPAP device)") 1 for chemically treating a subject's sleep disorder or symptoms with more than air (conventionally, CPAP devices can provide pressurized oxygen, which is a chemical, to the subject. Thus, the scope of this limitation does not distinguish over typical CPAP devices. Examiner suggests narrowing the claim limitation further to specific chemicals other than oxygen and/or other than the chemical components in air), which can be

Art Unit: 3735

adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system 22 ("Among the vital signs monitored may be chest and abdominal movement, airflow, airflow pressure, breathing sounds, intrathoracic pressure, blood oxygen saturation, heart rate, overall physical movement, leg movement, eye movement, EEG, and sleeping position. All data gathered from the sensors are stored in the Data Collector 22 for later processing by the Analysis Program 25. One or more of the physiological data sensed are used for modifying the airflow pressure cycle. However, it is within the scope of the present invention to use additional or alternative physiological data in order to modify the airflow pressure cycle.", see col. 9, ll. 20-28).

As to Claims 35 and 36, Miles teaches the following:

wherein the at least one physiological sensor is a pulse oximeter sensor ("pulse oximeter sensor for measuring the oxygen saturation in the blood") 5 and further including a respiratory effort sensor ("chest and abdominal respiration sensors") 7 (see fig. 2 and "The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices.", see col. 4, ll. 39-41).

As to Claim 38, Miles teaches the following:

wherein the apparatus for chemically treating a subject's sleep disorder or symptoms through the receiver can command a signal processing module to reconfigure the output of the data acquisition system ("Depending on time, entered set-up parameters, and data received via sensors 21, system 22 will issue control signals via outputs 24 to control breathing air pressure at breathing mask 26.", see col. 4, ll. 40-43).

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 3735

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

7. **Claims 30, 32, and 37 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Miles, U.S. Patent No. 5,353,788 A (“Miles”), as applied to claims 28 and 34, respectively, above, and further in view of Stahmann et al, U.S. Patent No. 7,757,690 B2 (“Stahmann”).**

As to Claims 32 and 37, Miles teaches the subject matter of claims 28 and 34, respectively, above. Miles does not teach the following:

wherein the output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the PAP device.

However, such a form of communication between a data acquisition system and a receiver is well-known in the art. For example, Stahmann teaches the following:

output of a data acquisition system (“data acquisition unit”) 104 is transmitted wirelessly by bidirectional radio frequency between the data acquisition system 104 and a receiver on a PAP device (“therapy delivery system”) 106 (see fig. 1A and “Referring to FIG. 1A, a system 100 in accordance with an embodiment of the present invention includes a data acquisition unit 104 configured to acquire data associated with a patient

Art Unit: 3735

while the patient is awake. The data acquisition unit 104 is coupled to a therapy delivery system 106 configured to adjust a therapy delivered to the patient, during patient sleep, using the acquired data. One or more sensor(s) 102 are used to sense physiological signals useful to the data acquisition unit 104.”, see col. 5, ll. 21-29; and “For example, the patient-internal and patient-external devices 1210, 1220 may be coupled through a short-range radio link, such as Bluetooth, IEEE 802.11, and/or a proprietary wireless protocol. The communications link may facilitate unidirectional or bidirectional communication between the patient-internal 1210 and patient-external 1220 medical devices.”, see col. 16, ll. 8-14).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Miles' wired communication between Miles' “physiological monitor and actuating system 22” and “nasal-CPAP airflow generator (CPAP device) 1” to be wireless and bidirectional, as taught by Psaros, in order to enable the eliminate the need of cumbersome wired communication and to allow control and data signals to be communicated between the two devices.

As to Claim 30, Miles teaches the following:

wherein the PAP through the inputs can command a signal processing module to reconfigure the output of the data acquisition system (“Depending on time,

Art Unit: 3735

entered set-up parameters, and data received via sensors 21, system 22 will issue control signals via outputs 24 to control breathing air pressure at breathing mask 26.”, see col. 4, ll. 40-43).

Allowable Subject Matter

8. Claims 24, 25, 31, 39, and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As to Claims 24, 25, 31, and 40, neither Miles nor the prior art of record teaches the device of claim 21, or the systems of claims 34 and 40, respectively, including the following in combination with all other limitations of the base claim: wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

As to Claim 39, neither Miles nor the prior art of record teaches the device of claim 37, including the following in combination with all other limitations of the base claim: wherein the apparatus for chemically treating a subject's sleep disorder or symptoms is used to deliver carbon dioxide to the subject at a concentration higher than atmospheric concentration of carbon dioxide in air.

Conclusion

9. Applicant's amendment, filed on 27 May 2016, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Mallari can be reached on (571) 272-4729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/
Primary Examiner, Art Unit 3735
09/01/2016

Notice of References Cited	Application/Control No. 13/440,116		Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA		Art Unit 3735	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-5,237,990 A	08-1993	Psaros; Georgios	A61M16/18	128/203.12
*	B	US-7,757,690 B2	07-2010	Stahmann; Jeffrey E.	A61B5/0031	128/204.18
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
CLAIM		DATE							
Final	Original	06/16/2015	03/01/2016	09/01/2016					
	1	-	-	-					
	2	-	-	-					
	3	-	-	-					
	4	-	-	-					
	5	-	-	-					
	6	-	-	-					
	7	-	-	-					
	8	-	-	-					
	9	-	-	-					
	10	-	-	-					
	11	-	-	-					
	12	-	-	-					
	13	-	-	-					
	14	-	-	-					
	15	-	-	-					
	16	-	-	-					
	17	-	-	-					
	18	-	-	-					
	19	-	-	-					
	20	-	-	-					
	21	÷	✓	✓					
	22	÷	✓	✓					
	23	÷	✓	✓					
	24	÷	✓	O					
	25	÷	✓	O					
	26	÷	✓	✓					
	27	÷	✓	✓					
	28	÷	✓	✓					
	29	÷	✓	✓					
	30	÷	✓	✓					
	31	÷	✓	O					
	32	÷	✓	✓					
	33	÷	✓	✓					
	34	÷	✓	✓					
	35	÷	✓	✓					
	36	÷	✓	✓					

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47									
CLAIM		DATE							
Final	Original	06/16/2015	03/01/2016	09/01/2016					
	37	÷	✓	✓					
	38	÷	✓	✓					
	39	÷	✓	○					
	40	÷	✓	○					

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	139	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) SAME (sensor\$4 OR transducer)) AND (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/09/01 12:26
L3	139	1 AND (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/09/01 12:27
L4	465	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (control\$4 OR regulat\$4 OR set OR setting OR automatic\$5)) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5))))	US-PGPUB; USPAT	OR	ON	2016/09/01 12:51
L5	96	((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) SAME ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (control\$4 OR regulat\$4 OR set OR setting OR automatic\$5))	US-PGPUB; USPAT	OR	ON	2016/09/01 12:53
L6	58	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US-20040116784-\$ or US-20100043795-\$ or US-20100258126-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-	US-PGPUB; USPAT	OR	ON	2016/09/01 13:07

ResMed

Exhibit 1005 - Page 354

		6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$ or US-7018341-\$ or US-6832609-\$ or US-7662101-\$ or US-7878198-\$ or US-8172766-\$ or US-5704345-\$ or US-5353788-\$ or US-8069852-\$ or US-7942824-\$ or US-8365730-\$).did. or (US-8545416-\$ or US-8356594-\$).did.				
L7	8	(bidirection\$5 WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR wireless\$4 OR transmi\$6 OR receiv\$4)) AND 6	US-PGPUB; USPAT	OR	ON	2016/09/01 13:08
L8	34	(bidirection\$5 WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR wireless\$4 OR transmi\$6 OR receiv\$4)) AND (("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (control\$4 OR regulat\$4 OR set OR setting OR automatic\$5)) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)))	US-PGPUB; USPAT	OR	ON	2016/09/01 13:11
L9	34	(bidirection\$5 WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR wireless\$4 OR transmi\$6 OR receiv\$4)) AND 8	US-PGPUB; USPAT	OR	ON	2016/09/01 13:16
L10	254	((bidirection\$5 OR ((two OR "2") ADJ2 way)) WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR wireless\$4 OR transmi\$6 OR receiv\$4)) SAME ((data ADJ2 acquisit\$5) OR sensor OR transducer OR monitor\$3) SAME ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (control\$4 OR regulat\$4 OR set OR setting OR automatic\$5))	US-PGPUB; USPAT	OR	ON	2016/09/01 13:21
L11	1	(US-5237990-\$).did.	USPAT	OR	ON	2016/09/01 13:39
L12	0	11 AND (wireless\$3 OR "RF" OR radio OR radiofrequenc\$3)	US-PGPUB; USPAT	OR	ON	2016/09/01 13:40
L14	185	((bidirection\$5 OR ((two OR "2") ADJ2 way)) WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR transmi\$6 OR receiv\$4)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth) SAME ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator))	US-PGPUB; USPAT	OR	ON	2016/09/01 13:42
L15	17	((bidirection\$5 OR ((two OR "2") ADJ2 way)) WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR transmi\$6 OR receiv\$4)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth)	US-PGPUB; USPAT	OR	ON	2016/09/01 13:54

		SAME ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure)))				
L16	569	((bidirection\$5 OR ((two OR "2") ADJ2 way)) WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR transmi\$6 OR receiv\$4)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth)) AND ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure))	US-PGPUB; USPAT	OR	ON	2016/09/01 13:56
L17	196	((bidirection\$5 OR ((two OR "2") ADJ2 way)) WITH (communicat\$4 OR telemet\$4 OR command\$4 OR signal\$3 OR transmi\$6 OR receiv\$4)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth)) AND ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure)) AND ((128/\$) OR (600/\$)).OCLS.	US-PGPUB; USPAT	OR	ON	2016/09/01 13:58
L18	16	((bidirection\$5 OR ((two OR "2") ADJ2 way)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth)) SAME ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure))) AND ((128/\$) OR (600/\$)).OCLS.	US-PGPUB; USPAT	OR	ON	2016/09/01 14:11
L19	36	("20020185130" "20030000528" "20040138576" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050188991" "20050217674" "20050268916" "20060084877" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6832609" "6889691" "7018341" "7101341" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7662101" "7668579" "7670295" "7878198" "8172766").PN.	US-PGPUB; USPAT	OR	OFF	2016/09/01 14:14
L20	60	6 OR 19	US-PGPUB; USPAT	OR	OFF	2016/09/01 14:14
L21	11	((bidirection\$5 OR ((two OR "2") ADJ2 way)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth)) AND 20	US-PGPUB; USPAT	OR	ON	2016/09/01 14:14
L22	174	((bidirection\$5 OR ((two OR "2") ADJ2 way)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth)) AND ("CPAP" OR (positive ADJ2 airway ADJ2 pressure))) AND ((128/\$) OR (600/\$)).OCLS.	US-PGPUB; USPAT	OR	ON	2016/09/01 14:18
L23	174	((bidirection\$5 OR ((two OR "2") ADJ2 way)) SAME (wireless\$4 OR "RF" OR radio OR radiofrequenc\$3 OR bluetooth)) AND 22	US-PGPUB; USPAT	OR	ON	2016/09/01 14:18
L24	1	(US-7757690-\$).did.	USPAT	OR	ON	2016/09/01 14:40
L25	1	(US-5353788-\$).did.	USPAT	OR	ON	2016/09/01 14:41
L26	1	(US-5237990-\$).did.	USPAT	OR	ON	2016/09/01 14:41
L27	3	24 OR 25 OR 26	US-	OR	OFF	2016/09/01

			PGPUB; USPAT			14:41
L28	2	27 NOT 6	US- PGPUB; USPAT	OR	OFF	2016/09/01 14:42
S210	2	((("7878198") or ("20020185130")).PN.	US- PGPUB; USPAT	OR	OFF	2016/08/24 11:59
S211	51	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US- 20040116784-\$ or US-20100043795-\$ or US-20100258126-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US- 6229581-\$ or US-6138675-\$ or US- 6029664-\$ or US-5645043-\$ or US- 6431171-\$ or US-7204250-\$ or US- 6551252-\$ or US-7225809-\$ or US- 7670295-\$ or US-5961447-\$ or US- 7195013-\$ or US-7309314-\$ or US- 7668579-\$ or US-7018341-\$ or US- 6832609-\$ or US-7662101-\$ or US- 7878198-\$ or US-8172766-\$).did.	US- PGPUB; USPAT	OR	ON	2016/08/31 09:39
S212	36	("20020185130" "20030000528" "20040138576" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050188991" "20050217674" "20050268916" "20060084877" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6832609" "6889691" "7018341" "7101341" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7662101" "7668579" "7670295" "7878198" "8172766").PN.	US- PGPUB; USPAT	OR	OFF	2016/08/31 09:39
S213	53	S211 OR S212	US- PGPUB; USPAT	OR	OFF	2016/08/31 09:39
S214	2	((("7878198") or ("20020185130")).PN.	US- PGPUB; USPAT	OR	OFF	2016/08/31 09:39
S215	53	S211 OR S212 OR S214	US- PGPUB; USPAT	OR	OFF	2016/08/31 09:40
S216	12529	(A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR	US- PGPUB; USPAT	OR	OFF	2016/08/31 09:40

		A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592 OR A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60).CPC.				
S217	573	((sleep\$3 NEAR8 (disorder OR illness OR condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) AND ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3)) AND ((band OR belt OR vest OR strap OR effort) WITH (inducti\$4 OR respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) AND S216	US-PGPUB; USPAT	OR	ON	2016/08/31 09:46
S218	39	((sleep\$3 NEAR8 (disorder OR illness OR condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) AND ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3)) AND ((band OR belt OR vest OR strap OR effort) WITH (inducti\$4 OR respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) AND S215	US-PGPUB; USPAT	OR	ON	2016/08/31 09:46
S219	39	((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3)) AND ((band OR belt OR vest OR strap OR effort) WITH (inducti\$4 OR respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) AND S218	US-PGPUB; USPAT	OR	ON	2016/08/31 09:46
S220	39	((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3)) AND ((band OR belt OR vest OR strap OR effort) WITH (inducti\$4 OR respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) AND S218	US-PGPUB; USPAT	OR	ON	2016/08/31 09:47
S221	1	("5704345").PN.	US-PGPUB; USPAT	OR	OFF	2016/08/31 09:52
S222	129	((sleep\$3 NEAR8 (disorder OR illness OR	US-	OR	ON	2016/08/31

		condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) AND ("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) WITH ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5))) AND S216	PGPUB; USPAT			09:55
S223	129	((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) WITH ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5))) AND S222	US-PGPUB; USPAT	OR	ON	2016/08/31 09:55
S224	1	(US-5353788-\$.did.	USPAT	OR	ON	2016/08/31 13:53
S225	0	S224 AND (fourier)	US-PGPUB; USPAT	OR	ON	2016/08/31 13:59
S226	221	("4655213" "4686975" "4807616" "4938212" "4944310" "4957107" "5042478" "5047930" "5065756" "5109839" "5117819" "5134995" "5146918" "5148802").PN. OR ("5353788").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2016/08/31 14:03
S227	86	S226 AND (fourier OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/08/31 14:06
S228	0	S224 AND (fourier OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/08/31 14:06
S229	160	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) WITH ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5))) AND (fourier OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/08/31 14:11
S230	160	S229 AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) WITH ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5))) AND (fourier OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/08/31 14:11
S231	1	(US-5353788-\$.did.	USPAT	OR	ON	2016/09/01 09:25
S232	0	S231 AND (wireles\$3)	US-PGPUB; USPAT	OR	ON	2016/09/01 09:25
S233	0	S231 AND (wireles\$3 OR radio OR	US-	OR	ON	2016/09/01

		radiofrequenc\$3 OR "RF")	PGPUB; USPAT			09:25
S234	0	(13/440116).APP.	US- PGPUB; USPAT	OR	OFF	2016/09/01 09:48
S235	1	(11/266899).APP.	US- PGPUB; USPAT	OR	OFF	2016/09/01 09:51
S236	1	S235 AND bidirection\$4	US- PGPUB; USPAT	OR	ON	2016/09/01 09:51
S237	0	S231 AND (chemical\$4)	US- PGPUB; USPAT	OR	ON	2016/09/01 09:55
S238	1	S235 AND quantitative\$4	US- PGPUB; USPAT	OR	ON	2016/09/01 09:59
S239	58	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US-20040116784-\$ or US-20100043795-\$ or US-20100258126-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$ or US-7018341-\$ or US-6832609-\$ or US-7662101-\$ or US-7878198-\$ or US-8172766-\$ or US-5704345-\$ or US-5353788-\$ or US-8069852-\$ or US-7942824-\$ or US-8365730-\$).did. or (US-8545416-\$ or US-8356594-\$).did.	US- PGPUB; USPAT	OR	ON	2016/09/01 10:17
S240	5	S239 AND (short NEAR5 fourier)	US- PGPUB; USPAT	OR	ON	2016/09/01 10:17
S241	55	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5))) AND (short NEAR5 fourier)	US- PGPUB; USPAT	OR	ON	2016/09/01 10:19
S242	55	S241 AND (short NEAR5 fourier)	US- PGPUB;	OR	ON	2016/09/01 10:19

			USPAT			
S243	55	S241 AND (short NEAR5 fourier)	US-PGPUB; USPAT	OR	ON	2016/09/01 10:19
S244	339	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5))) AND (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/09/01 10:25
S245	17	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) SAME (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6)))	US-PGPUB; USPAT	OR	ON	2016/09/01 10:25
S246	17	S245 AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) SAME (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6)))	US-PGPUB; USPAT	OR	ON	2016/09/01 10:25
S247	7	S245 AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) SAME (sensor\$4 OR transducer)) AND (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/09/01 10:32
S248	139	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ((pulse OR oximet\$4 OR oxymet\$4 OR pulseox OR pulseoximet\$4 OR pulseoxymet\$4 OR ((oxygen OR "O2") ADJ2 saturation)) SAME ((effort OR inductiv\$4) WITH (respir\$6 OR breath\$3 OR chest OR plethysmograph\$5)) SAME (sensor\$4 OR transducer)) AND (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/09/01 10:32
S249	139	S248 AND (fourier OR "STFT" OR "FFT" OR (standard ADJ2 deviat\$5) OR ARMAX OR (((time ADJ2 frequenc\$3) OR wavelet) NEAR3 analy\$6))	US-PGPUB; USPAT	OR	ON	2016/09/01 10:34

9/ 1/ 2016 2:51:05 PM

H:\ EAST\ Workspaces\ FY2016\ 13440116.wsp

Search Notes 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

CPC- SEARCHED		
Symbol	Date	Examiner
61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592	2/24/2016	/NN/
A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60	2/24/2016	/NN/
61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592	8/23/2016	/NN/
A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60	8/23/2016	/NN/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST (enclosed): USPAT, US-PGPUB, EPO, JPO, Derwent, Inventor, Forward/Backward Citation, CPC, Keyword searches	2/24/2016	/NN/
EAST (enclosed): USPAT, US-PGPUB, EPO, JPO, Derwent, Inventor, Forward/Backward Citation, Art of Record, CPC, Keyword searches	8/23/2016	/NN/

INTERFERENCE SEARCH

	/N.N./ Primary Examiner.Art Unit 3735
--	--

US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592		
	A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60		

	/N.N./ Primary Examiner.Art Unit 3735
--	--

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
		)	
Serial No.:	13/440,116	)	
		)	Art Unit: 3735
Filed:	April 5, 2012	)	
		)	
For:	Devices and Methods for	)	
	Sleep Disorder Diagnosis	)	
	and Treatment	)	
		)	Attorney Docket No.: CMD-087
Examiner:	Navin Natnithithadha	)	
		)	

May 27, 2016

AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Mam:

This amendment is being filed in response to an Office Action date February 29, 2016 with a due date of response of May 31, 2015. The Applicants believe no extension of time is needed but if this is not the case the Applicant contingently petition for an extension of time and authorize the USPTO to deduct any fees from their deposit account 502704. The following amendments to the specification and claims are respectfully submitted.

CLAIM AMENDMENTS:

Please amend claims 21-26, 28-32, 34 and 37-40 as follows:

1-20. (Canceled)

21. (Currently amended) A sleep disorder treatment device comprising:

a positive airway pressure (PAP) device, the PAP device comprising inputs for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor and a pulse oximeter sensor; and

a processor for receiving and processing signals from the sensors and further for determining an output pressure level of the PAP device based at least in part on the signals from the respiratory effort and pulse oximeter sensors.

22. (Currently amended) The device of claim 21 wherein ~~the PAP device is a continuous positive airway pressure device (CPAP)~~ the inputs on the PAP device and the outputs of the at least two sensors are in wireless radio frequency bidirectional communication.

23. (Currently amended) The device of claim 21 ~~further including inputs for receiving signals from EEG sensors wherein the PAP through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors.~~

24. (Currently amended) The device of claim 21 ~~further including inputs for receiving signals from EEG sensors wherein the signals from the respiratory effort and pulse oximeter sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.~~

25. (Currently amended) The device of claim 21 in which signals from the sensors are processed using a short-time fourier transforms technique.

26. (Currently amended) The device of claim 21 wherein the PAP device further comprises an airflow sensor with a signal, and wherein the processor also receives and processes signals from the airflow sensor in addition to the signals from the respiratory effort and pulse oximeter sensors to determine the output pressure level of the PAP device.

27. (Presiously presented) The device of claim 21 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

28. (Currently amended) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor, the data acquisition system for creating a quantitative output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors; and

a positive airway pressure (PAP) device that includes a hose and a mask for treating a subject's sleep disorder symptoms, which can receive the output of the data acquisition system with a processor and produce a recommended positive pressure setting in part in response to the output of the data acquisition system with the processor.

29. (Currently amended) The sleep disorder treatment system of claim 28 wherein the PAP device is a continuous positive airway pressure device (CPAP) wherein the PAP device further comprises an airflow sensor with a signal, and a processor that receives and processes signals from the airflow sensor in addition to the output from the data acquisition system to determine the output pressure level of the PAP device.

30. (Currently amended) The sleep disorder treatment system of claim ~~32~~²⁸ further including inputs for receiving signals from EEG sensors wherein the PAP through the receiver can command a signal processing module to reconfigure the output of the data acquisition system.

31. (Currently amended) The sleep disorder treatment system of claim 28 further including inputs for receiving signals from EEG sensors wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

32. (Currently amended) The sleep disorder treatment system of claim 28 wherein the output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency ~~from between~~ the data acquisition system ~~to and~~ a receiver on the PAP device.

33. (Previously presented) The sleep disorder treatment system of claim 28 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

34. (Currently amended) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors; and

an apparatus for chemically treating a subject's sleep disorder or symptoms with more than air, which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

35. (Previously presented) The sleep disorder treatment system of claim 34 wherein the at least one physiological sensor is a pulse oximeter sensor.

36. (Previously presented) The sleep disorder treatment system of claim 35 further including a respiratory effort sensor.

37. (Currently amended) The sleep disorder treatment system of claim 34 wherein the output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the apparatus for chemically treating a subject's sleep disorder or symptoms is a positive airway pressure (PAP) device capable of delivering gases to the subject at concentrations higher than atmospheric concentrations.

38. (Currently amended) The sleep disorder treatment system of claim 37 wherein the PAP device is used to deliver oxygen to the subject at a concentration higher than atmospheric concentration apparatus for chemically treating a subject's sleep disorder or symptoms through the receiver can command a signal processing module to reconfigure the output of the data acquisition system.

39. (Currently amended) The sleep disorder treatment system of claim 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms is used to deliver carbon dioxide to the subject at a concentration higher than atmospheric concentration of carbon dioxide in air.

40. (Currently amended) The sleep disorder treatment system of claim 34 wherein the at least one physiological sensor is an ECG sensor wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

REMARKS

Claims 21-40 were rejected in the Office Action issued February 29, 2016. The Applicants have amended claims 21-26, 28-32, 34 and 37-40. The Applicants thank the Examiner for withdrawing the restriction requirement.

Anticipation under 35 USC §102

To provide legal context as well as an analytical framework for the Applicants' remarks, the Applicants wish, as an initial point, to respectfully remind the Examiner that a proper finding of anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 202 USPTO 202 (Fed Cir. 1983). It is not enough that the prior art reference disclose all of the claimed elements in isolation, but rather anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, anticipation requires that the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ 2d. 1241 (Fed Cir. 1986). The standard of anticipation is identity of invention. *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 33 U.S.P.Q.2d 1496, 1500 (Fed.Cir.1995). Identity of invention is a question of fact that requires a showing that each element of the claim in issue is found in a prior patent or publication, either expressly or inherently. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir.1983), cert. denied, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984). Inherency may not be established by probabilities or possibilities. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). Before burden is shifted to the applicant to disprove inherency, the examiner is required provide evidence or scientific reasoning to establish the reasonableness of the examiner's belief that a functional limitation is an inherent characteristic of the prior art. *Ex parte Skinner*, 2 USPQ 2d 1788, 1789 (BPAI 1986).

Thus, to reach a proper finding of anticipation, the Examiner must show that each and every claim limitation is present in a single prior art reference (the identity of invention requirement) and that the same prior art reference enables the claimed invention so as to place the invention in the possession of a person having ordinary skill in the art (the anticipatory enablement requirement). If the Examiner falls short in meeting any of these requirements then the Examiner has failed to establish a *prima facie* case and the Appellant is entitled to the patent. See *In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) (“If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent”). Further, refusal by the USPTO to issue the patent in the face of an Examiner’s failure to properly establish a *prima facie* case of anticipation or some other proper grounds for rejection places the Examiner and the USPTO in contravention of 35 U.S.C. § 131, which dictates that if after examination of an application “it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” (emphasis added).

Claims 21-31, 33-37 and 40 were rejected under pre-AIA 35 USC 102(e) as being anticipated by Farrell et al., U.S. Patent No. 7,878,198 B2 (“Farrell”). The Applicants traverse and submit the claims as amended are not anticipated by Farrell.

With respect to claim 21, Farrell does not teach or disclose a sleep disorder treatment device comprising a positive airway pressure (PAP) device, the PAP device comprising inputs for receiving signals directly from outputs of at least two sensors including a respiratory effort sensor and a pulse oximeter sensor; and a processor for receiving and processing signals from the sensors and further for determining an output pressure level of the PAP device based at least in part on the signals from the respiratory effort and pulse oximeter sensors as claimed.

Farrell instead teaches of a traditional device where “[f]low $F(t)$ and pressure $P_{mask}(t)$ signals are sent to a control or microprocessor 15 to derive a pressure request signal $Prequest(t)$. Alternatively, a flow signal $f(t)$ and pressure signal $P_{mask}(t)$ may be estimated or calculated in relation to the blower motor by monitoring current supplied to the motor and/or speed of the motor”. Farrell Col. 4, lines 12-17. Farrell goes on to explain “[t]he apparatus may further include additional interface 16 for connection to

additional diagnosis or patient information gathering devices. For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band...other automated measuring devices may also be included with the diagnosis unit as it relates to measuring other cardiovascular related information from the patient". Farrell Col 4, lines 39-56. Farrell explains it collects this data with the diagnosis unit to "associate sleep disordered breathing information and cardiovascular information over time" as shown in FIG. 2, 46. Farrell makes clear that flow and pressure measurements of the delivered air are used to adjust the PAP device -- not respiratory effort (which is commonly used to look for central sleep apneas) and pulse oximetry, which shows the prolonged effects of multiple apnea events.

Furthermore, the pulse oximeter and respiratory belt in Farrell are being feed directly into the diagnostic device 18 (FIG. 2) and not directly into inputs on the PAP device as claimed.

With respect to claim 22, Farrell does not teach or disclose wherein the inputs on the PAP device and the outputs of the at least two sensors are in wireless radio frequency bidirectional communication as in the amended claimed. While the Examiner has cited Tsukashima, U.S. Pat. No. 7,101,341 elsewhere in the Office Action Tsukashima does not teach or disclose the use of bidirectional communication between inputs on a PAP device and outputs on the sensors themselves as claimed. Tsukashima Col 4, Lines 27-44.

With respect to claim 23, both Farrell and Tsukashima do not disclose wherein the PAP (of claim 22) through the inputs can command a signal processing module to reconfigure the output of at least one of the at least two sensors as claimed.

With respect to claims 24 and 25, Farrell does not teach or disclose wherein the signals from the respiratory effort and pulse oximeter sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis as claimed. Farrell does not teach processing signals using a fourier transform technique as claimed. The Examiner instead relies on Berthon-Jones U.S. Pat. No. 5,704,345, which is incorporated by reference. Berthon-Jones,

however, makes it clear that the discrete (not short-time as claimed) fourier transform is “performed by the processing element 132, *of the airflow signal f_i during the apnea* not the signals from the respiratory effort or pulse oximeter as claimed. Again, the Applicants further point out that the air flow and air pressure signals of the PAP device in Farrell are used to determine the output level of the PAP device – not the respiratory effort or pulse oximeter – these are merely used in Farrell to provide the physician with more information about the subject’s physiological characteristics during apnea incidents – not for adjusting the output through the processor of the PAP device as claimed.

With respect to claims 26 and 29, Farrell does not teach or disclose wherein the PAP device further comprises an airflow sensor with a signal, and wherein the processor also receives and processes signals from the airflow sensor in addition to the signals from the respiratory effort and pulse oximeter sensors to determine the output pressure level of the PAP device as claimed. Farrell adjusts the output of the PAP device based on airflow or air pressure either sensed in the delivery portion of the PAP device or estimated – not based on respiratory effort or pulse oximetry, which are only used in Farrell to provide the physician with more information about the subject’s physiological characteristics during apnea incidents and not for adjusting the output of the PAP device with the processor of the PAP device as claimed.

With respect to claims 27 and 33, Farrell does not teach or disclose a respiratory inductance plethysmography belt as claimed, but instead only a chest band – there is no indication this “chest band” is a RIP belt. Further, the signal from the “chest band” in Farrell only used to provide data for the physician – since it doesn’t provide “airflow” or air pressure as required to adjust the PAP device in Farrell.

With respect to claim 28, Farrell further does not teach or disclose a sleep disorder treatment system comprising a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor, the data acquisition system for creating a quantitative output of the level of severity of a subject’s sleep disorder or symptoms based in part on the signals from the sensors; and a positive airway pressure (PAP) device for treating a subject’s sleep disorder symptoms, which can receive the output of the data acquisition system and produce a recommended positive

pressure setting in part in response to the output of the data acquisition system as claimed.

The Applicants incorporate their above comments with respect to Farrell. Farrell instead teaches of a traditional device where “[f]low $F(t)$ and pressure $P_{mask}(t)$ signals are sent to a control or microprocessor 15 to derive a pressure request signal $Prequest(t)$. Alternatively, a flow signal $f(t)$ and pressure signal $P_{mask}(t)$ may be estimated or calculated in relation to the blower motor by monitoring current supplied to the motor and/or speed of the motor”. Farrell Col. 4, lines 12-17. Farrell goes on to explain “[t]he apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices. For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band...other automated measuring devices may also be included with the diagnosis unit as it relates to measuring other cardiovascular related information from the patient”. Farrell Col 4, lines 39-56. Farrell explains it collects this data with the diagnosis unit to “associate sleep disordered breathing information and cardiovascular information over time” as shown in FIG. 2, 46. Farrell makes clear that flow and pressure measurements of the delivered air are used to adjust the PAP device – not respiratory effort (which is commonly used to look for central sleep apneas) and pulse oximetry, which shows the prolonged effects of multiple apnea events.

There is no indication the diagnostic device 18 in Farrell creates a quantitative output of the level of severity of a subject’s sleep disorder or symptoms based in part on the signals from the respiratory effort and pulse oximeter sensors and that the PAP device produces a recommended positive pressure setting in part in response to the output of the data acquisition system as claimed.

With respect to claim 30, both Farrell and Tsukashima do not disclose the sleep disorder treatment system of claims 28 and 32 wherein the PAP through the receiver can command a signal processing module to reconfigure the output of the data acquisition system as claimed.

With respect to claim 31, Farrell does not teach or disclose wherein the signals from the respiratory effort and pulse oximeter sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation

technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis as claimed. Farrell does not teach processing signals using a fourier transform technique as claimed. The Examiner instead relies on Berthon-Jones U.S. Pat. No. 5,704,345, which is incorporated by reference. Berthon-Jones, however, makes it clear that the discrete (not short-time as claimed) fourier transform is “performed by the processing element 132, *of the airflow signal f_a during the apnea* not the signals from the respiratory effort or pulse oximeter as claimed. Again, the Applicants further point out that the air flow and air pressure signals of the PAP device in Farrell are used to determine the output level of the PAP device -- not the respiratory effort or pulse oximeter -- these are merely used in Farrell to provide the physician with more information about the subject’s physiological characteristics during apnea incidents -- not for adjusting the output through the processor of the PAP device as claimed.

With respect to claim 32, Farrell does not teach or disclose wherein the output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the PAP device as in the amended claimed. While the Examiner has cited Tsukashima, U.S. Pat. No. 7,101,341 elsewhere in the Office Action Tsukashima does not teach or disclose the use of bidirectional communication between the data acquisition system and a receiver on a PAP device as claimed. Tsukashima Col 4, Lines 27-44.

With respect to claim 34, Farrell does not teach or disclose a sleep disorder treatment system comprising a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject’s sleep disorder or symptoms based in part on the signals from the sensors; and an apparatus for chemically treating a subject’s sleep disorder or symptoms with more than air, which can be adjusted at least in part using the output of the level of severity of the subject’s sleep disorder from the data acquisition system as claimed.

The Applicants incorporate their above comments with respect to Farrell. Farrell instead teaches of a traditional PAP device where “[f]low $F(t)$ and pressure $P_{mask}(t)$ signals are sent to a control or microprocessor 15 to derive a pressure request signal

Prequest(t). Alternatively, a flow signal $f(t)$ and pressure signal $P_{mask}(t)$ may be estimated or calculated in relation to the blower motor by monitoring current supplied to the motor and/or speed of the motor". Farrell Col. 4, lines 12-17. Farrell goes on to explain "[t]he apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices. For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band...other automated measuring devices may also be included with the diagnosis unit as it relates to measuring other cardiovascular related information from the patient". Farrell Col 4, lines 39-56. Farrell explains it collects this data with the diagnosis unit to "associate sleep disordered breathing information and cardiovascular information over time" as shown in FIG. 2, 46. Farrell makes clear that flow and pressure measurements of the delivered air are used to adjust the PAP device -- not respiratory effort (which is commonly used to look for central sleep apneas) and pulse oximetry, which shows the prolonged effects of multiple apnea events.

There is no substantial evidence that the diagnostic device 18 in Farrell creates a quantitative output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the respiratory effort and pulse oximeter sensors with a data acquisition device, that Farrell's PAP device could be considered an apparatus for chemically treating a subject's sleep disorder or symptoms with more than air and that the can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system as claimed.

With respect to claim 37, Farrell does not teach or disclose wherein the output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the PAP device as in the amended claimed. While the Examiner has cited Tsukashima, U.S. Pat. No. 7,101,341 elsewhere in the Office Action Tsukashima does not teach or disclose the use of bidirectional communication between the data acquisition system and a receiver on a PAP device as claimed. Tsukashima Col 4, Lines 27-44.

With respect to claim 38, both Farrell and Tsukashima do not disclose the sleep disorder treatment system of claims 34 and 37 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms through the receiver can command a

signal processing module to reconfigure the output of the data acquisition system as claimed.

With respect to claim 40, Farrell does not teach or disclose wherein the signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis as claimed. Farrell does not teach processing signals using a fourier transform technique as claimed. The Examiner instead relies on Berthon-Jones U.S. Pat. No. 5,704,345, which is incorporated by reference. Berthon-Jones, however, makes it clear that the discrete (not short-time as claimed) fourier transform is “performed by the processing element 132, *of the airflow signal fn during the apnea* not the signals from the respiratory effort or pulse oximeter as claimed. Again, the Applicants further point out that the air flow and air pressure signals of the PAP device in Farrell are used to determine the output level of the PAP device – not the respiratory effort or pulse oximeter – these are merely used in Farrell to provide the physician with more information about the subject’s physiological characteristics during apnea incidents – not for adjusting the output through the processor of the PAP device as claimed.

Given the above comments, the Applicants urge the Examiner to withdraw this rejection.

Obviousness under 35 U.S.C. § 103

To provide legal context as well as an analytical framework for the remarks that follow, the Applicant wishes at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the Examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an assertion of *prima facie* obviousness the Examiner must perform the factual inquiries set

forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that “secondary considerations” such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, “the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis.” MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the Examiner errs in performing any of the *Graham* factual inquiries, the Examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the Examiner committing error in performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

With specific regard to the Examiner’s obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Applicant would direct particular attention to the requirement that “[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill.” See MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the Examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the Examiner’s burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the Examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an “indication of the level of ordinary skill,” MPEP 2141(II)(C), the Examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the Examiner in such a way as to render the claimed invention obvious. See *In re*

Vaidyanathan, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and Examiner for failing to provide “any evidentiary support or reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant” and further noting that *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) “did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references”).

Thus, in order for the Examiner to properly establish a *prima facie* case of obviousness the Examiner must first make the factual inquiries required by *Graham* and, if relying on a combination of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the Examiner falls short in meeting any of these requirements then the Examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. *See In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) (“If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent”). As stated in the United States Patent and Trademark Office’s own rules, “[a] *prima facie* case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard...” *See* 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the Examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination “it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” (emphasis added).

In all of the above, the Applicants wish to emphasize the high bar to which the Examiner is held during the examination process and hereby respectfully request that in the ongoing prosecution of the present application that the Examiner provide explicit and detailed analysis of any grounds of rejection relied upon. *See, e.g., KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (“[an obviousness] analysis should be made explicit,” citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

Claim 32 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over Farrell as applied to claim 28 above, and further in view of Tsukashima et al, U.S. Pat. No. 7,101,341 ("Tsukashima"). The Applicants traverse and submit that claim 32 as amended is patentable over Farrell in view of Tsukashima.

The Applicants incorporate their comments above with respect to both Farrell and Tsukashima. With respect to claim 32, Farrell does not teach or disclose wherein the output of the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver on the PAP device as in the amended claim. While the Examiner has cited Tsukashima, U.S. Pat. No. 7,101,341 elsewhere in the Office Action Tsukashima does not teach or disclose the use of bidirectional communication between the data acquisition system and a receiver on a PAP device as claimed. Tsukashima Col 4, Lines 27-44.

Further, Tsukashima only uses wireless transmission means for communicating between either the processing receiver and nebulizer, the mask and the processing receiver, or the processing receiver and the CPAP device. Tsukashima further does not disclose transmission between a data acquisition device and a PAP device as claimed, and still further does not creating a quantitative output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors from the data acquisition device, which is transmitted through *bidirectional data communication* between a data acquisition system and the PAP device as claimed. Additionally in Tsukashima, the external processing receiver adjusts the CPAP and in the claimed invention the PAP is adjusted internally based on the quantitative output of the level of severity of the subjects symptoms based on the sensor signals of the sensors connected to the data acquisition system. Farrell in view of Tsukashima is the "apple" in comparison with the "orange" of the system of the present invention -- and shows the Examiner is not viewing the claim as a "whole" but rather by its parts. Tsukashima does not have a "data acquisition system" but rather transmits raw data from the mask, which is part of the CPAP device directly to a processing receiver, which is separate from the CPAP device. The CPAP in Tsukashima has no processing capabilities.

The Examiner purports that the motivation to combine Farrell with Tsukashima is provided in Col. 4, Lines 41-44, which the Examiner quotes "[a]s appreciated by those

skilled in the art, wireless means for communicating between various components can be accomplished using radio frequency waves, microwaves, ultrasonic waves, or light optics.” What the Examiner doesn’t point out is those “components” are “the [CPAP] mask”, “the CPAP”, “the [external] processing receiver” and “the nebulizer”. The components don’t include a data acquisition device that provides a quantified output of level of severity of the patient’s symptoms based on a respiratory sensor and pulse oximeter. Instead the mask that holds the sensors consists of a “heat sink” sensor and a “pH sensing means”, which feeds the raw data to a external processing receiver, which then adjusts the CPAP or the nebulizer – clearly the Examiner is comparing apples with oranges and the claims as now amended makes this abundantly clear. The motivation the Examiner refers to in Tsukashima clearly only covers those “components” listed above – and does not refer to any component in general as the Examiner is trying to allude – the Applicants remind the Examiner that the claim must be viewed as a whole. Clearly the Examiner’s motivation is not supported by the teachings of Tsukashima.

Given the above comments, the Applicants urge the Examiner to withdraw this rejection.

Claims 38 and 39 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over Farrell as applied to claim 37 above, and further in view of Burton et al., U.S. Pat. Appl. No. 2005/0217674 (“Burton”). The Applicants traverse and submit that claims 38 and 39 as amended are patentable over Farrell in view of Burton.

The Applicants incorporate by reference their above comments with respect to Farrell. The amended claim 38 is addressed above. Furthermore with respect to claim 39, Farrell in view of Burton does not teach or disclose the sleep disorder treatment system of claims 34 and 37 wherein the apparatus for chemically treating a subject’s sleep disorder or symptoms is used to deliver carbon dioxide to the subject at a concentration higher than atmospheric concentration of carbon dioxide in air. Burton fails to disclose treating a subject’s sleep disorder with elevated levels of carbon dioxide. Further there is no motivation for one skilled in the art to have combined Farrell with Burton.

The Examiner relies on para. 153 of Burton as motivation to combine the references but para. 153 makes it clear that if central sleep apnea occurs that the CPAP device is "augmented" by "immediate cessation of pressure delivery" – not by providing elevated levels of carbon dioxide to the patient with an apparatus to chemically treat the subject's sleep disorder as claimed. Thus the Examiner's motivation is severely flawed.

Given the above comments, the Applicants urge the Examiner to withdraw this rejection.

CONCLUSION:

The Applicant respectfully submits that this application is in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

05/27/2016
Dated

/Brian M. Kolkowski/
Brian M. Kolkowski
Reg. No.: 36,847
Attorney for the Applicant
Cleveland Medical Devices Inc.
4415 Euclid Avenue, Suite 400
Cleveland, Ohio 44103
Tel: (216) 649-0376
Fax: (216) 649-0347
Email: bkolkowski@clevemed.com

Electronic Acknowledgement Receipt

EFS ID:	25909114
Application Number:	13440116
International Application Number:	
Confirmation Number:	4463
Title of Invention:	Devices and Methods for Sleep Disorder Diagnosis and Treatment
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-087
Receipt Date:	27-MAY-2016
Filing Date:	05-APR-2012
Time Stamp:	14:25:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-087_2016-05-27_amendment.pdf	6010443 c47457b73c00978cf69280a5a1662b49308af4fd	yes	18

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Amendment/Req. Reconsideration-After Non-Final Reject	1	1	
Claims	2	5	
Applicant Arguments/Remarks Made in an Amendment	6	18	

Warnings:

Information:

Total Files Size (in bytes):	6010443
-------------------------------------	---------

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/440,116	Filing Date 04/05/2012	☐ To be Mailed
---	---	----------------------------------	---------------------------------------

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO**APPLICATION AS FILED – PART I**

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	05/27/2016	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	x \$210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/VENICE WILLIAMS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/440,116	04/05/2012	Hani Kayyali	CMD-087	4463

81177 7590 02/29/2016
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

EXAMINER

NATNITHADHA, NAVIN

ART UNIT	PAPER NUMBER
----------	--------------

3735

MAIL DATE	DELIVERY MODE
-----------	---------------

02/29/2016

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/440,116	Applicant(s) KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 21-40 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☒ Claim(s) 21-40 is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 05 April 2012 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____ | 4) ☐ Other: _____ |

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

2. Applicant timely traversed the restriction (election) requirement in the reply filed on 14 August 2015.

Applicant's election with traverse of Group I, claims 1-6 and 15-20, in the reply filed on 14 August 2015 is acknowledged. The traversal is found persuasive.

Therefore, the restriction requirement is withdrawn.

Response to Amendment

3. According to the Amendment, filed 05 April 2012, the status of the claims is as follows:

Claims 21-40 are new; and

Claims 1-20 are cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before

Art Unit: 3735

the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 21-31, 33-37, and 40 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Farrell et al, U.S. Patent No. 7,878,198 B2 ("Farrell").

As to Claim 21, Farrell teaches the following:

A sleep disorder treatment device ("This invention relates to methods and apparatus for treating and monitoring sleep disordered breathing ("SDB") in patients with cardiovascular disease or otherwise monitoring the cardiovascular condition of SDB patients.", see col. 1, ll. 12-15, and fig. 1) comprising:

a positive airway pressure (PAP) device ("computer-controlled blower") 2, the PAP device 2 comprising inputs (via "interface") 16 for receiving signals from sensors including a respiratory effort sensor ("respiratory movement sensors 22 such as a chest band") 22 and a pulse oximeter sensor ("pulse oximeter") 20 (see fig. 1 and "The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices.", see col. 4, ll. 39-41); and

a processor ("controller or microprocessor") 15 for receiving and processing signals from the sensors ("For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band, EEG & ECG 24, EOG 25 and/or electrodes 28 for detecting cardiac rhythm.", see col. 4, ll. 39-45) and

Art Unit: 3735

further for determining an output pressure level of the PAP device 2 based on the signals from the sensors ("Flow $F(t)$ and pressure $P_{sub.mask}(t)$ signals are sent to a controller or microprocessor 15 to derive a pressure request signal $P_{sub.request}(t)$.", see col. 4, ll. 13-14; "Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones). For example, the IPAP or EPAP levels may be adjusted by the automated determination to hunt for a minimal pressure that will be required to prevent or alleviate obstruction. Other alternative methods to vary the therapeutic level of the pressure for treatment to a patient and to detect SDB events may be utilized and are known in the art.", see col. 5, ll. 50-60; and "Similarly, other cardiovascular related treatment or diagnostic device may be configured or programmed to make an assessment for SDB related information of the patient, for example, a blood pressure monitor, heart rate monitor, oximetry monitor, Holter Monitor or other ECG device or cardiac event monitor, automated tape measure, automated scale device for weight, treadmill device, blood analyzer device,

Art Unit: 3735

cardiac output analyzer device, VO.sub.2 max data device, peripheral arterial tone device etc.”, see col. 9, ll. 20-28).

As to Claim 22, Farrell teaches the following:

wherein the PAP device 2 is a continuous positive airway pressure device (CPAP) (includes “pressure delivery device”, not labeled, “...that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6.”, see col. 3, l. 66, to col. 4, l. 2; and “Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones).”, see col. 5, ll. 50-55).

As to Claims 23 and 24, Farrell teaches the following:

inputs for receiving signals from ECG and EEG sensors (“EEG & ECG”) 24 (“The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices. For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band, EEG & ECG 24, EOG 25 and/or electrodes 28 for detecting cardiac rhythm.”, see col. 4, ll. 39-45).

As to Claim 25, Farrell teaches the following:

in which signals from the sensors are processed using short-time fourier transforms ("Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones). For example, the IPAP or EPAP levels may be adjusted by the automated determination to hunt for a minimal pressure that will be required to prevent or alleviate obstruction.", see col. 5, ll. 50-58, which incorporates by reference, see col. 1, ll. 5-61, Berthon-Jones, U.S. Patent No. 5,704,345 A, "FIGS. 9c and 10c respectively show the discrete Fourier transform of FIGS. 9b and 10b. In FIG. 9c (open airway), there are strong peaks in the frequency spectrum at around 1.25 Hz and/or 2.5 Hz corresponding to the heart rate and its first harmonic. The peaks reach an amplitude of at least 0.01 l/sec. Conversely, in FIG. 10c (closed airway), the discrete Fourier transform shows little or no activity between 0.75 and 3 Hz... A Discrete Fourier transform (DFT) is performed, by the processing element 132, of the airflow signal fn during the apnea. Only terms up to 6 Hz need to be calculated. In the case where the heart rate is not known,

processing is as follows: if the amplitude of the DFT exceeds a Threshold value of 0.01 l/sec, as determined by the peak height detector 136 and the subsequent comparator element 138, at any frequency between 0.75 and 3 Hz (bandpass element 134), the airway is declared open; otherwise it is declared closed. Patency Index 1 represents the output of the peak height detector 136.”, see col. 13, l. 60, to col. 14, l. 24).

As to Claim 26, Farrell teaches the following:

wherein the PAP device 2 further comprises an airflow sensor (“flow sensor”) 4f with a signal, and wherein the processor 15 also receives and processes signals from the airflow sensor 2 (“Optionally, a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal $F(t)$, and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{sub.mask}}(t)$. The pressure sensor 4f and flow sensor 4p have only been shown symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure. Flow $F(t)$ and pressure $P_{\text{sub.mask}}(t)$ signals are sent to a controller or microprocessor 15 to derive a pressure request signal $P_{\text{sub.request}}(t)$.”, see col. 4, ll. 3-14).

As to Claim 27, Farrell teaches the following:

wherein the respiratory effort sensor 22 is a respiratory inductance plethysmography belt ("respiratory movement sensors 22 such as a chest band", see col. 4, ll. 42-43).

As to Claim 34, Farrell teaches the following:

A sleep disorder treatment system ("This invention relates to methods and apparatus for treating and monitoring sleep disordered breathing ("SDB") in patients with cardiovascular disease or otherwise monitoring the cardiovascular condition of SDB patients.", see col. 1, ll. 12-15, and fig. 1) comprising:

a data acquisition system ("computer-controlled blower") 2, the data acquisition system 2 comprising a data acquisition device ("interface") 16 having inputs for receiving signals from at least one physiological sensor ("respiratory movement sensors 22 such as a chest band") 22 or ("pulse oximeter") 20, the data acquisition system 2 for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors 22 or 20 ("Preferably, the device provides efficacy tracking by detecting and recording or scoring SDB events or related information or indices over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring. This is illustrated in step 44 of FIG. 2. Similarly, pressure and/or flow versus time data

Art Unit: 3735

may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting. Methods for detecting and recording such information are known in the art, and may be implemented as described in U.S. Pat. No. 5,704,345. For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented as follows:

(i) An apnea is scored if a 2 second moving average ventilation drops below 25% of a recent average ventilation (time constant=100s) for at least 10 consecutive seconds, (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average ventilation for 10 consecutive seconds. Similarly, the device may determine an index comparing central apneas versus obstructive apneas as disclosed in U.S. Pat. No. 6,832,609, the entire disclosure of which is incorporated by reference herein.”, see col. 6, ll. 7-36); and

an apparatus (“pressure delivery device”, not labeled, “...that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6.”, see col. 3, l. 66, to col. 4, l. 2) for chemically treating a subject's sleep

Art Unit: 3735

disorder or symptoms, which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder system ("Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones) .", see col. 5, ll. 50-60).

As to Claims 35 and 36, Farrell teaches the following:

wherein the at least one physiological sensor is a pulse oximeter sensor ("pulse oximeter") 20 and further including a respiratory effort sensor ("respiratory movement sensors 22 such as a chest band") 22 (see fig. 1 and col. 4, ll. 39-43).

As to Claim 37, Farrell teaches the following:

wherein the apparatus for chemically treating a subject's sleep disorder or symptoms is a positive airway pressure (PAP) device ("pressure delivery device", not labeled, "...that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6.", see col. 3, l. 66, to col. 4, l. 2) capable of delivering gases to the subject at concentrations higher than atmospheric concentrations ("As illustrated by step 42 in the flow chart of FIG. 2, the apparatus incorporates various pressure treatment

Art Unit: 3735

protocols that may be used to treat the condition of the patient. For example, in one mode, the device provides a generally constant pressure throughout a breathing cycle that may be therapeutic pressure or changes to such pressure set to treat SDB. In another mode, the apparatus provides a higher pressure to the mask during the inspiratory portion of the breathing cycle, a so-called IPAP (inspiratory positive airway pressure), and a lower pressure to the mask during the expiratory portion of the breathing cycle, a so-called EPAP (expiratory positive airway pressure). Alternatively, the treatment delivered by the apparatus can smoothly vary in accordance with patient respiration to provide a smooth pressure waveform. For example, the device calculates a continuous phase variable to provide support in phase with the patient's breathing cycle and calculates the pressure to be delivered in accordance with a pressure waveform template. The delivery of such pressure is disclosed in U.S. Pat. No. 6,532,957. Still alternatively, pressure may be supplied in proportion to patient respiratory airflow.", see col. 5, ll. 24-44).

As to Claim 40, Farrell teaches the following:

wherein the at least one physiological sensor is an ECG sensor ("ECG") 24 ("The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information

Art Unit: 3735

gathering devices. For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band, EEG & ECG 24, EOG 25 and/or electrodes 28 for detecting cardiac rhythm.”, see col. 4, ll. 39-45).

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 3735

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

5. Claim 32 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell et al, U.S. Patent No. 7,878,198 B2 ("Farrell"), as applied to claim 28 above, and further in view of Tsukashima et al, U.S. Patent No. 7,101,341 B2 ("Tsukashima").

As to Claim 32, Farrell teaches the subject matter of claim 28 above. Farrell does not teach the following:

wherein the output of the data acquisition system is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the PAP device.

However, Tsukashima teaches the following:

output of a data acquisition system ("processing receiver") 26 is transmitted wirelessly by radio frequency from the data acquisition system 26 to a receiver on the PAP device ("CPAP device") 16 ("Processing receiver 26 is connected to the CPAP device 16 by an electrical wire 24 for controlling the activation of air generated by the CPAP device 16 and transferred to the typical mask apparatus 36. Also, an electrical connection by means of a wire 31 to the processing receiver 26 is a treatment nebulizer/atomizer/humidifier device 32. As an alternate method, a wireless means 40 can be utilized instead to communicate between the processing receiver 26 with

Art Unit: 3735

an antenna 28 to the treatment nebulizer/atomizer/humidifier device 32. Although not shown in detail in FIG. 1, a wireless means also can be employed to communicate between the typical mask apparatus 36 and the processing receiver 26. In addition, a wireless means also can be employed to communicate between the processing receiver 26 and the CPAP device 16. As appreciated by those skilled in the art, wireless means for communicating between various components can be accomplished using radio frequency waves, microwaves, ultrasonic waves, or light optics.”, see col. 4, ll. 26-44; and see fig. 1).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Farrell’s apnea treatment system to have wireless transmission from the data acquisition system to the CPAP device as taught by Tsukashima in order to “achieve the goal of monitoring, diagnosing and treating respiratory conditions in patients” (see Tsukashima, col. 3, ll. 59-62). In addition, Tsukashima explicitly suggests such a modification is known in the art as follows: “As appreciated by those skilled in the art, wireless means for communicating between various components can be accomplished using radio frequency waves, microwaves, ultrasonic waves, or light optics” (see col. 4, ll. 41-44).

6. Claims 38 and 39 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell et al, U.S. Patent No. 7,878,198 B2 (“Farrell”), as applied

to claim 37 above, and further in view of Burton et al, U.S. Patent No.

2005/0217674 A1 (“Burton”).

As to Claims 38-39, Farrell teaches the subject matter of claim 37 above.

Farrell does not teach the following:

wherein the PAP device is used to deliver oxygen or carbon dioxide to the subject at a concentration higher than atmospheric concentration.

However, Burton teaches the following:

a PAP device (“For the purposes of explanation only, the present invention will be described in an embodiment which is adapted for use with a CPAP machine.”, see para. [0109]) is used to deliver oxygen or carbon dioxide to the subject at a concentration higher than atmospheric concentration (“The wireless monitoring capability enables the present invention to monitor RERA, TERA, and SBD-related (sleep breathing disorder) signals during a subject's sleep. Furthermore, the ability to monitor these electrodes during a subject's sleep might give some augmented information (in addition to the respiratory airflow, pressure and sound signals normally derived from the subject's mask) and the ability of the SPAP system to provide optimal therapeutic pressure or gas delivery control to minimize RERA or TERA, while also minimizing obstructive sleep apnea-hypopnea (OSAH) and UARs.”, see para. [0043]; and “In one embodiment, the controller also includes a processor

Art Unit: 3735

which receives the digital signal and determines the patient state and an appropriate setting for the gas delivery or other therapeutic device.”, see para. [0047])

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Farrell’s “pressure delivery device” to deliver a gas in order to, “if central sleep apnea is detected in combination with an increase or undesirable change or measure in ECG, pulse-wave or arrhythmia, the operation of the gas delivery device is augmented to stabilize the patient's condition” (see Burton, para. [0153]).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Mallari can be reached on (571) 272-4729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/
Primary Examiner, Art Unit 3735
02/24/2016

Notice of References Cited	Application/Control No. 13/440,116		Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA		Art Unit 3735	Page 1 of 3

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-5,645,043 A	07-1997	Long; Norris R.	F24C1/10	126/91R
*	B	US-5,961,447 A	10-1999	Raviv; Gil	A61B7/003	600/300
*	C	US-6,029,664 A	02-2000	Zdrojkowski; Ronald J.	A61M16/0051	128/204.21
*	D	US-6,138,675 A	10-2000	Berthon-Jones; Michael	A61B5/087	128/204.18
*	E	US-6,229,581 B1	05-2001	Yamamoto; Hideki	G02B27/1026	348/756
*	F	US-6,431,171 B1	08-2002	Burton; David	A61M15/00	128/204.18
*	G	US-2002/0185130 A1	12-2002	Wright, Jonathan Caldwell	A61B5/087	128/204.21
*	H	US-2003/0000528 A1	01-2003	Eklund, Ove	A61B5/087	128/204.23
*	I	US-6,551,252 B2	04-2003	Sackner; Marvin A.	A61B5/0205	600/301
*	J	US-2004/0138576 A1	07-2004	Wright, Jonathan Caldwell	A61B5/087	600/533
*	K	US-2004/0163648 A1	08-2004	Burton, David	A61B5/04085	128/204.21
*	L	US-2004/0254493 A1	12-2004	Chervin, Ronald D.	A61B5/048	600/544
*	M	US-6,832,609 B2	12-2004	Wright; Jonathan Caldwell	A61B5/087	128/204.18

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 13/440,116		Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA		Art Unit 3735	Page 2 of 3

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2005/0081847 A1	04-2005	Lee, Kent	A61B5/04012	128/200.24
*	B	US-2005/0085738 A1	04-2005	Stahmann, Jeffrey E.	A61B5/00	600/529
*	C	US-6,889,691 B2	05-2005	Eklund; Ove	A61B5/087	128/200.24
*	D	US-2005/0115561 A1	06-2005	Stahmann, Jeffrey E.	A61B5/0031	128/200.24
*	E	US-2005/0165323 A1	07-2005	Montgomery, Anthony R.	A61B5/0006	600/544
*	F	US-2005/0188991 A1	09-2005	Sun, Jianuo	A61B5/0002	128/204.23
*	G	US-2005/0217674 A1	10-2005	Burton, David	A61B5/04	128/204.23
*	H	US-2005/0268916 A1	12-2005	Mumford, John Robert	A61M16/06	128/207.13
*	I	US-7,018,341 B2	03-2006	Wright; Jonathan Caldwell	A61B5/087	128/204.18
*	J	US-2006/0084877 A1	04-2006	Ujhazy; Anthony John	A61M16/0051	600/483
*	K	US-7,101,341 B2	09-2006	Tsukashima; Ross	A61B5/083	422/84
*	L	US-2006/0247546 A1	11-2006	Imose; Kazuo	A61B5/087	600/513
*	M	US-7,190,995 B2	03-2007	Chervin; Ronald D.	A61B5/048	600/534

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 13/440,116		Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA		Art Unit 3735	Page 3 of 3

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7,195,013 B2	03-2007	Lurie; Keith G.	A61H31/00	128/202.28
*	B	US-7,204,250 B1	04-2007	Burton; David	A61B5/04085	128/205.23
*	C	US-7,225,809 B1	06-2007	Bowen; Kevin	A61M16/00	128/204.18
*	D	US-7,309,314 B2	12-2007	Grant; Brydon J. B.	A61B5/00	600/323
*	E	US-7,575,005 B2	08-2009	Mumford; John Robert	A61M16/06	128/205.23
*	F	US-7,662,101 B2	02-2010	Lee; Kent	A61B5/0205	600/484
*	G	US-7,668,579 B2	02-2010	Lynn; Lawrence A.	A61B5/002	600/323
*	H	US-7,670,295 B2	03-2010	Sackner; Marvin A.	A61B5/0205	600/481
*	I	US-7,878,198 B2	02-2011	Farrell; Michael	A61B5/0205	128/204.18
*	J	US-8,172,766 B1	05-2012	Kayyali; Hani	A61B5/02055	128/204.23
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant				☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE							
Final	Original	06/16/2015	03/01/2016						
	1	-	✓						
	2	-	✓						
	3	-	✓						
	4	-	✓						
	5	-	✓						
	6	-	✓						
	7	-	✓						
	8	-	✓						
	9	-	✓						
	10	-	✓						
	11	-	✓						
	12	-	✓						
	13	-	✓						
	14	-	✓						
	15	-	✓						
	16	-	✓						
	17	-	✓						
	18	-	✓						
	19	-	✓						
	20	-	✓						
	21	÷	✓						
	22	÷	✓						
	23	÷	✓						
	24	÷	✓						
	25	÷	✓						
	26	÷	✓						
	27	÷	✓						
	28	÷	✓						
	29	÷	✓						
	30	÷	✓						
	31	÷	✓						
	32	÷	✓						
	33	÷	✓						
	34	÷	✓						
	35	÷	✓						
	36	÷	✓						

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant				☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE							
Final	Original	06/16/2015	03/01/2016						
	37	÷	✓						
	38	÷	✓						
	39	÷	✓						
	40	÷	✓						

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	(US-20050217674-\$).did.	US-PGPUB	OR	ON	2016/02/24 21:42
L2	1	1 AND ((oxygen OR gas OR carbon OR "O2" OR "CO2") WITH (deliver\$4 OR administer\$4 OR administrat\$4 OR provid\$4 OR pump\$3 OR pressuriz\$6))	US-PGPUB; USPAT	OR	ON	2016/02/24 21:43
L3	35	("20050165323" "6889691" "7204250" "20050085738" "6551252" "7309314" "6029664" "20040254493" "7575005" "7670295" "7662101" "7101341" "6138675" "20050217674" "20040163648" "20050081847" "20040138576" "20060084877" "7878198" "5645043" "20030000528" "20050268916" "20060247546" "7190995" "20050188991" "7668579" "7018341" "20050115561" "5961447" "7195013" "7225809" "20020185130" "6229581" "6431171" "6832609").PN.	US-PGPUB; USPAT	OR	OFF	2016/02/24 21:56
L4	3	"11266899"	US-PGPUB; USPAT	OR	ON	2016/02/24 21:56
L5	1	(11/266899).APP.	US-PGPUB; USPAT	OR	OFF	2016/02/24 21:57
L7	36	3 OR 5	US-PGPUB; USPAT	OR	OFF	2016/02/24 21:57
L8	1	((11/266899) or (13/440116)).APP.	US-PGPUB; USPAT	OR	OFF	2016/02/24 22:00
L9	1	(US-8172766-\$).did.	USPAT	OR	ON	2016/02/24 22:00
L10	11462	(A61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592 OR A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60).CPC.	US-PGPUB; USPAT	OR	OFF	2016/02/24 22:00
S92	6879	((KAYYALI NEAR2 HANI) OR (SCHMIDT NEAR2 ROBERT) OR (((MODARRES-ZADEH") OR (MODARRES ADJ2 ZADEH)) NEAR2 MOHAMMAD) OR (KOLKOWSKI NEAR2 BRIAN)).INV.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2016/02/24 13:11

			DERWENT			
S93	1564	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ("EEG" OR electroencephal\$6 OR ((brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3))) AND (((sleep\$3 NEAR8 (disorder OR illness OR condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) AND (("600"/\$) OR ("128"/\$)).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S94	979	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND ("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3) AND (((sleep\$3 NEAR8 (disorder OR illness OR condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) SAME (treat\$5 OR therap\$6)) AND (("600"/\$) OR ("128"/\$)).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S95	606	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) AND ("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3)) AND (((sleep\$3 NEAR8 (disorder OR illness OR condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) SAME (treat\$5 OR therap\$6)) AND (("600"/\$) OR ("128"/\$)).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S96	127	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME ("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3))) AND (((sleep\$3 NEAR8 (disorder OR illness OR condition OR	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) SAME (treat\$5 OR therap\$6)) AND (("600"/\$) OR ("128"/\$)).ccls.				
S97	127	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME ((("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3))) AND S96	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S98	137	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME ((("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3 OR signal\$3 OR wave OR waveform OR data OR value))) AND (((sleep\$3 NEAR8 (disorder OR illness OR condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) SAME (treat\$5 OR therap\$6)) AND (("600"/\$) OR ("128"/\$)).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S99	137	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME ((("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3 OR signal\$3 OR wave OR waveform OR data OR value))) AND S98	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S100	5	("20050217674" "5645043" "6029664" "6138675" "6229581").PN.	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S101	447	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME ((("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodetect\$4 OR biotransducer OR	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		biometer\$3 OR measur\$5 OR monitor\$3 OR signal\$3 OR wave OR waveform OR data OR value))) AND (("600"/\$) OR ("128"/\$)).ccls.				
S102	236	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME (("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodelect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3 OR signal\$3 OR wave OR waveform OR data OR value))) AND ((sleep\$3 NEAR8 (disorder OR illness OR condition OR obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) AND (("600"/\$) OR ("128"/\$)).ccls.	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11
S103	236	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME (("EEG" OR electroencephal\$6 OR brain OR scalp OR head OR brainwave\$5) WITH (electrode OR sens\$5 OR detect\$4 OR transducer OR meter\$3 OR bioelectrode OR biosens\$5 OR biodelect\$4 OR biotransducer OR biometer\$3 OR measur\$5 OR monitor\$3 OR signal\$3 OR wave OR waveform OR data OR value))) AND S102	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11
S104	20	(US-20080276939-\$ or US-20080257349- \$ or US-20060247546-\$ or US- 20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648- \$ or US-20050217674-\$ or US- 20030000528-\$ or US-20050081847-\$ or US-20050085738-\$).did. or (US- 7575005-\$ or US-7190995-\$ or US- 6889691-\$ or US-6229581-\$ or US- 6138675-\$ or US-6029664-\$ or US- 5645043-\$ or US-6431171-\$ or US- 7204250-\$).did.	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11
S105	0	(quantitative\$3) AND (realtime OR (real ADJ2 time)) AND S104	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11
S106	7	(realtime OR (real ADJ2 time)) AND S104	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11
S107	4	(quantitative\$3) AND S104	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11
S108	5	("20050217674" "5645043" "6029664" "6138675" "6229581").PN.	US- PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S109	20	(US-20080276939-\$ or US-20080257349- \$ or US-20060247546-\$ or US-	US- PGPUB;	OR	ON	2016/02/24 13:11

		20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$).did.	USPAT			
S110	15	S109 NOT S108	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S111	184	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) AND ((respir\$6 OR breath\$3 OR thorac\$3 OR chest OR lung OR breast OR torso OR abdom\$5) WITH (belt OR strap OR vest OR garment OR cloth\$3)) AND ((pulse OR oximet\$4 OR oxymet\$4) WITH (sensor\$3 OR sensing OR measur\$6 OR detect\$5 OR monitor\$3 OR transducer OR probe)) AND (sleep\$3 WITH (disorder OR condition OR disease OR illness OR apne\$3 OR symptom)) AND ((600/529-543,484) OR ("128"/\$)).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S112	184	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) AND ((pulse OR oximet\$4 OR oxymet\$4) WITH (sensor\$3 OR sensing OR measur\$6 OR detect\$5 OR monitor\$3 OR transducer OR probe)) AND S111	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S113	168	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) AND ((respir\$6 OR breath\$3 OR thorac\$3 OR chest OR lung OR breast OR torso OR abdom\$5) SAME (belt OR strap OR vest OR garment OR cloth\$3)) AND ((pulse OR oximet\$4 OR oxymet\$4 OR saturation) WITH (sensor\$3 OR sensing OR measur\$6 OR detect\$5 OR monitor\$3 OR transducer OR probe)) AND (sleep\$3 WITH (disorder OR condition OR disease OR illness OR apne\$3 OR symptom)) AND ((600/529-543,484) OR ("128"/\$)).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S114	168	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) AND ((pulse OR oximet\$4 OR oxymet\$4 OR saturation) WITH (sensor\$3 OR sensing OR measur\$6 OR detect\$5 OR monitor\$3 OR transducer OR probe)) AND (sleep\$3 WITH (disorder OR condition OR disease OR illness OR	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		apne\$3 OR symptom)) AND S113				
S115	1	(US-20050115561-\$).did.	US-PGPUB	OR	ON	2016/02/24 13:11
S116	1	S115 AND ((respir\$6 OR breath\$3 OR thorac\$3 OR chest OR lung OR breast OR torso OR abdom\$5) SAME (belt OR strap OR vest OR garment OR cloth\$3))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S117	1	S115 AND ((respir\$6 OR breath\$3 OR thorac\$3 OR chest OR lung OR breast OR torso OR abdom\$5) WITH (sensor\$3 OR sensing OR detector OR probe OR monitor OR transducer))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S118	1	(US-20050115561-\$).did.	US-PGPUB	OR	ON	2016/02/24 13:11
S119	1	S118 AND ((pulse OR oximet\$4 OR oxymet\$4 OR saturation) WITH (sensor\$3 OR sensing OR measur\$6 OR detect\$5 OR monitor\$3 OR transducer OR probe))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S120	1	S118 AND (realtime OR (real ADJ2 time))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S121	1	S118 AND (wireless\$3 OR transmi\$6 OR transceiver OR communicat\$5)	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S122	1	S118 AND (wireless\$3)	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S123	1	S118 AND ("EEG" OR electroenceph\$ OR brain OR brainwave\$5)	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S124	1	S118 AND ("ECG" OR "EKG" OR electrocardiograph\$)	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S125	5	("20050217674" "5645043" "6029664" "6138675" "6229581").PN.	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S126	35	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$).did.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S127	18	("20030000528" "20040163648" "20040254493" "20050081847"	US-PGPUB;	OR	ON	2016/02/24 13:11

		"20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "6029664" "6138675" "6229581" "6431171" "6889691" "7190995" "7204250" "7575005").PN.	USPAT			
S128	18	S126 NOT S127	US- PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S129	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7668579" "7670295").PN.	US- PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S130	35	(US-20080276939-\$ or US-20080257349- \$ or US-20060247546-\$ or US- 20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648- \$ or US-20050217674-\$ or US- 20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386- \$ or US-20030135127-\$ or US- 20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662- \$ or US-20040200474-\$ or US- 20050115561-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US- 6029664-\$ or US-5645043-\$ or US- 6431171-\$ or US-7204250-\$ or US- 6551252-\$ or US-7225809-\$ or US- 7670295-\$ or US-5961447-\$ or US- 7195013-\$ or US-7309314-\$ or US- 7668579-\$).did.	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11
S131	36	S129 OR S130	US- PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S132	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7668579" "7670295").PN.	US- PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S133	35	(US-20080276939-\$ or US-20080257349- \$ or US-20060247546-\$ or US- 20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648- \$ or US-20050217674-\$ or US- 20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386- \$ or US-20030135127-\$ or US-	US- PGPUB; USPAT	OR	ON	2016/02/24 13:11

		20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$).did.				
S134	36	S132 OR S133	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S135	30	S134 AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND (pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6) WITH (belt OR strap OR piezoelect\$5 OR sensor\$3 OR sensing OR transducer OR electrode OR detect\$4 OR biosensor\$3 OR biosensing OR biotransducer OR bioelectrode OR biodelect\$4))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S136	30	S135 AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6) WITH (belt OR strap OR piezoelect\$5 OR sensor\$3 OR sensing OR transducer OR electrode OR detect\$4 OR biosensor\$3 OR biosensing OR biotransducer OR bioelectrode OR biodelect\$4))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S137	691	((("600"/\$) OR ("128"/\$)).ccls. AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND (pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6) SAME (belt OR strap OR piezoelect\$5))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S138	634	((("600"/\$) OR ("128"/\$)).ccls. AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodelect\$5 OR biosensor\$3 OR biosensing OR	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6) SAME (belt OR strap OR piezoelect\$5))				
S139	346	((("600"/\$) OR ("128"/\$)).ccls. AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand\$3 OR compress\$4) SAME (belt OR strap OR piezoelect\$5))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S140	346	S139 AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand\$3 OR compress\$4) SAME (belt OR strap OR piezoelect\$5))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S141	169	((("600"/\$) OR ("128"/\$)).ccls. AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand\$3 OR compress\$4) SAME (belt OR strap OR piezoelect\$5))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S142	169	S141 AND ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure)	US-PGPUB;	OR	ON	2016/02/24 13:11

		OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand\$3 OR compress\$4) SAME (belt OR strap OR piezoelect\$5))	USPAT			
S143	31	((("600"/\$) OR ("128"/\$)).ccls. AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND (((("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) SAME (pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) SAME (respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand\$3 OR compress\$4) SAME (belt OR strap OR piezoelect\$5))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S144	31	S143 AND (((("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) SAME (pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) SAME (respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand\$3 OR compress\$4) SAME (belt OR strap OR piezoelect\$5))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S145	13	S134 AND ((("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		(belt OR strap OR piezoelect\$5))				
S146	406	((("600"/\$) OR ("128"/\$)).ccls. AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND (("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band)))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S147	406	S146 AND (("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band)))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S148	45	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		7668579-\$ or US-7018341-\$ or US-6832609-\$).did.				
S149	26	((diagnosis OR diagnose OR diagnosing OR sever\$6 OR evaluat\$5 OR output\$5) WITH sleep\$4 WITH (disorder OR symptoms OR abnormal\$5 OR illness OR apnea OR apneic OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND S148	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S150	37	(transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) AND S148	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S151	18	((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) SAME ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND S148	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S152	984	((("600"/\$) OR ("128"/\$)).ccls. AND ((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) SAME ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S153	300	((("600"/\$) OR ("128"/\$)).ccls. AND ((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) SAME ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND (sleep\$4 WITH (disorder OR abnormal\$5 OR apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S154	300	((("600"/\$) OR ("128"/\$)).ccls. AND ((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) SAME ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND (sleep\$4 WITH (disorder OR abnormal\$5 OR	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		apne\$4 OR hypoapne\$5 OR hyperapne\$5 OR illness OR disease OR condition\$3)) AND (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band))				
S155	300	S154 AND ((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) SAME ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S156	300	S154 AND ((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) SAME ("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S157	424	((("600"/\$) OR ("128"/\$)).ccls. AND (("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S158	665	((("600"/\$) OR ("128"/\$)).ccls. AND (("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust\$6 OR regulat\$5 OR control\$5 OR set\$5)) AND ((pulse OR pulsewave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodetect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band))				
S159	665	S158 AND ((pulse OR pulswave\$5 OR oximet\$4 OR oxymet\$4 OR saturation) WITH (detect\$5 OR sensor\$3 OR sensing OR transducer OR meter\$3 OR probe OR monitor\$3 OR biodelect\$5 OR biosensor\$3 OR biosensing OR biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6 OR pulmonar\$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S160	1	("20020185130").PN.	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S161	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7668579" "7670295").PN.	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S162	12	((jonathan NEAR2 wright) OR (anthony NEAR2 ujhazy)).inv. AND CPAP AND pulse AND (respiratory ADJ2 movement)	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S163	12	S162 AND (sleep\$3 WITH (disorder OR symptom OR condition OR illness))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S164	0	S162 AND (realtime OR (real ADJ2 time))	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S165	12	S162 AND (nebuliz\$3 OR medication OR medicine OR drug OR agent)	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S166	50	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US-20040116784-\$ or US-20100043795-\$ or US-20100258126-	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

		\$.did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$ or US-7018341-\$ or US-6832609-\$ or US-7662101-\$ or US-7878198-\$).did.				
S167	24	S166 NOT S161	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S168	50	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US-20040116784-\$ or US-20100043795-\$ or US-20100258126-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$ or US-7018341-\$ or US-6832609-\$ or US-7662101-\$ or US-7878198-\$).did.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S169	34	("20020185130" "20030000528" "20040138576" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060084877" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6832609" "6889691" "7018341" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7662101" "7668579" "7670295" "7878198").PN.	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S170	51	S168 OR S169	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:11
S171	31	((severit\$4 OR level OR depth OR stag\$3) WITH (apne\$4 OR hypopne\$5 OR hypoapne\$5 OR hyperapne\$5)) AND S170	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11

S172	31	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME (signal\$3 OR data OR sens\$5 OR information OR parameter)) AND (apne\$4 OR hypopne\$5 OR hypoapne\$5 OR hyperapne\$5) AND S170	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S173	31	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME (signal\$3 OR data OR sens\$5 OR information OR parameter)) AND S172	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S174	9	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR chang\$3)) SAME (signal\$3 OR data OR sens\$5 OR information OR parameter)) AND ((apne\$4 OR hypopne\$5 OR hypoapne\$5 OR hyperapne\$5) WITH (index OR indices)) AND S170	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S175	6	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME ((radio OR radiofrequenc\$3 OR "RF" OR wireless\$3) WITH (transmi\$6 OR transceiv\$3 OR telemet\$5 OR communicat\$5 OR receiv\$3 OR antenna))) AND S170	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S176	0	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME ((radio OR radiofrequenc\$3 OR "RF" OR wireless\$3) WITH (transmi\$6 OR transceiv\$3 OR telemet\$5 OR communicat\$5 OR receiv\$3 OR antenna)) SAME acquisition) AND (600/484,529-543).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S177	178	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME ((radio OR radiofrequenc\$3 OR "RF" OR wireless\$3) WITH (transmi\$6 OR transceiv\$3 OR telemet\$5 OR communicat\$5 OR receiv\$3 OR antenna))) AND (apne\$4 OR hypopne\$5 OR hypoapne\$5 OR hyperapne\$5) AND ((600/484,529-543) OR (128/204.21-204.26)).ccls.	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S178	178	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) SAME ((radio OR radiofrequenc\$3 OR "RF" OR wireless\$3) WITH (transmi\$6 OR transceiv\$3 OR telemet\$5 OR communicat\$5 OR receiv\$3 OR antenna))) AND S177	US-PGPUB; USPAT	OR	ON	2016/02/24 13:11
S179	35	("20050165323" "6889691" "7204250" "20050085738" "6551252" "7309314" "6029664" "20040254493" "7575005" "7670295" "7662101" "7101341" "6138675" "20050217674" "20040163648" "20050081847" "20040138576"	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:26

		"20060084877" "7878198" "5645043" "20030000528" "20050268916" "20060247546" "7190995" "20050188991" "7668579" "7018341" "20050115561" "5961447" "7195013" "7225809" "20020185130" "6229581" "6431171" "6832609").PN.				
S180	5	((("7190995") or ("20050115561") or ("20020185130") or ("7878198") or ("7101341")).PN.	US-PGPUB; USPAT	OR	OFF	2016/02/24 13:32
S181	1	(US-7878198-\$).did.	USPAT	OR	ON	2016/02/24 13:50
S182	1	S181 AND ((determin\$6 OR calculat\$4 OR compute OR computing OR output\$4 OR derive OR deriving) WITH pressure)	US-PGPUB; USPAT	OR	ON	2016/02/24 13:51
S183	0	S181 AND ("FFT" OR fourier)	US-PGPUB; USPAT	OR	ON	2016/02/24 14:14
S184	1	S180 AND ("FFT" OR fourier)	US-PGPUB; USPAT	OR	ON	2016/02/24 14:14
S185	0	S181 AND ((atmospher\$5 OR environment OR baromet\$5) WITH (level OR pressure OR concentration))	US-PGPUB; USPAT	OR	ON	2016/02/24 14:45
S186	1	S181 AND (oxygen OR carbon OR "O2" OR "CO2")	US-PGPUB; USPAT	OR	ON	2016/02/24 14:49
S187	50	(US-20080276939-\$ or US-20080257349-\$ or US-20060247546-\$ or US-20050268916-\$ or US-20050165323-\$ or US-20040254493-\$ or US-20040163648-\$ or US-20050217674-\$ or US-20030000528-\$ or US-20050081847-\$ or US-20050085738-\$ or US-20020032386-\$ or US-20030135127-\$ or US-20050197588-\$ or US-20060042627-\$ or US-20060070624-\$ or US-20070209662-\$ or US-20040200474-\$ or US-20050115561-\$ or US-20080269583-\$ or US-20080066753-\$ or US-20070161913-\$ or US-20070135724-\$ or US-20060135878-\$ or US-20060084877-\$ or US-20040138576-\$).did. or (US-20020185130-\$ or US-20040116784-\$ or US-20100043795-\$ or US-20100258126-\$).did. or (US-7575005-\$ or US-7190995-\$ or US-6889691-\$ or US-6229581-\$ or US-6138675-\$ or US-6029664-\$ or US-5645043-\$ or US-6431171-\$ or US-7204250-\$ or US-6551252-\$ or US-7225809-\$ or US-7670295-\$ or US-5961447-\$ or US-7195013-\$ or US-7309314-\$ or US-7668579-\$ or US-7018341-\$ or US-6832609-\$ or US-7662101-\$ or US-7878198-\$).did.	US-PGPUB; USPAT	OR	ON	2016/02/24 15:05
S188	35	("20050165323" "6889691" "7204250" "20050085738" "6551252" "7309314" "6029664" "20040254493" "7575005" "7670295" "7662101" "7101341" "6138675"	US-PGPUB; USPAT	OR	OFF	2016/02/24 15:06

		"20050217674" "20040163648" "20050081847" "20040138576" "20060084877" "7878198" "5645043" "20030000528" "20050268916" "20060247546" "7190995" "20050188991" "7668579" "7018341" "20050115561" "5961447" "7195013" "7225809" "20020185130" "6229581" "6431171" "6832609").PN.				
S189	52	S187 OR S188	US- PGPUB; USPAT	OR	OFF	2016/02/24 15:06
S190	15	S189 AND ("FFT" OR fourier)	US- PGPUB; USPAT	OR	ON	2016/02/24 15:06
S191	0	S181 AND (burton)	US- PGPUB; USPAT	OR	ON	2016/02/24 15:07
S192	1	S181 AND (berthon)	US- PGPUB; USPAT	OR	ON	2016/02/24 15:08
S193	1	(11/165705).APP.	US- PGPUB; USPAT	OR	OFF	2016/02/24 15:09
S194	3	((("5704345") or ("6152129") or ("6532959")).PN.	US- PGPUB; USPAT	OR	OFF	2016/02/24 15:12
S195	1	S194 AND ("FFT" OR fourier)	US- PGPUB; USPAT	OR	ON	2016/02/24 15:12
S196	0	S194 AND ((oxygen OR carbon OR "O2" OR "CO2") WITH (deliver\$4 OR administer\$4 OR administrat\$4 OR provid\$4 OR pump\$3))	US- PGPUB; USPAT	OR	ON	2016/02/24 15:20
S197	15	S189 AND ((oxygen OR carbon OR "O2" OR "CO2") WITH (deliver\$4 OR administer\$4 OR administrat\$4 OR provid\$4 OR pump\$3))	US- PGPUB; USPAT	OR	ON	2016/02/24 15:20
S198	12	S189 AND (((oxygen OR carbon OR "O2" OR "CO2") WITH (deliver\$4 OR administer\$4 OR administrat\$4 OR provid\$4 OR pump\$3)) SAME ("CPAP" OR "PAP" OR (positive\$3 ADJ4 pressure)))	US- PGPUB; USPAT	OR	ON	2016/02/24 15:23
S199	11	S189 AND (((oxygen OR carbon OR "O2" OR "CO2") WITH (deliver\$4 OR administer\$4 OR administrat\$4 OR provid\$4 OR pump\$3)) AND ("CPAP" OR "PAP" OR (positive\$3 ADJ2 airway ADJ2 pressure)))	US- PGPUB; USPAT	OR	ON	2016/02/24 15:25

2/ 24/ 2016 10:01:52 PM
H:\ EAST\ Workspaces\ FY2016\ 13440116.wsp

Search Notes 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

CPC- SEARCHED		
Symbol	Date	Examiner
61B5/02055 OR A61B5/085 OR A61B5/4815 OR A61M16/0051 OR A61M16/0069 OR A61M2016/0027 OR A61M2016/0039 OR A61M2202/0208 OR A61M2205/3553 OR A61M2205/3561 OR A61M2205/3584 OR A61M2205/3592	2/24/2016	/NN/
A61M2230/04 OR A61M2230/10 OR A61M2230/14 OR A61M2230/202 OR A61M2230/205 OR A61M2230/60	2/24/2016	/NN/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST (enclosed): USPAT, US-PGPUB, EPO, JPO, Derwent, Inventor, Forward/Backward Citation, CPC, Keyword searches	2/24/2016	/NN/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/N.N./ Primary Examiner.Art Unit 3735
--	--

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
		)	
Serial No.:	13/440,116	)	
		)	
Filed:	April 5, 2012	)	Art Unit: 3735
		)	
For:	Devices and Methods for Sleep Disorder Diagnosis and Treatment	)	Attorney Docket No.: CMD-087
		)	
Examiner:	Navin Natnithithadha	)	
		)	

August 6, 2015

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This communication is responsive to the restriction requirement mailed June 17, 2015 with a due date for response of August 17, 2015. The Applicants believe and submit that this communication is timely filed and that no fees are due in connection with this communication. Nevertheless, if any fees are due, the Applicants authorize the Director to withdraw any necessary fees from deposit account 502704. The following remarks are respectfully submitted.

REMARKS

In the Office action, the examiner noted that claims 21-40 are pending in the application and that claims 21-40 are subject to restriction and/or election requirement.

I. RESTRICTION REQUIREMENT

The Examiner issued a restriction requirement in the above-captioned case on June 17, 2015. In this requirement, the Examiner required the Applicants to elect to prosecute claims from the following inventions:

- I. Group I: Claims 21-33 drawn to a sleep disorder treatment device and system, classified in 600/484; and
- II. Group II: Claims 28-33 drawn to a sleep disorder treatment system, classified in 600/481.

The Examiner has alleged that the inventions are distinct because they are “related as subcombinations disclosed as usable together in a single combination [and] subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable.” Office Action, 6/17/2015, pg. 2. With respect to the present claims, the Examiner merely argued that “subcombination Group II has separate utility such as chemically treating a subject’s sleep disorder or symptoms using the output of the level of severity of the subject’s sleep disorder. See MPEP § 806.05(d).” *Id.* The Examiner made no other allegations regarding independent or distinctness. With respect to a serious search burden imposed, the Examiner merely stated that a serious burden would exist if restriction were not required because “one or more” of the reasons for insisting upon restriction (as provided in MPEP § 8.11 and §§ 8.21.01-8.21.03) apply, merely listing these reasons. *Id.* at 3. The Examiner provided no indication as to which reason might apply, nor any argument providing substantive insight into the alleged serious burden that would arise if restriction were not required. The Examiner made no other statements and advanced no other reasoning to support his assertions of independence, distinctness, or serious burden. Further, the Examiner provided no indication whatsoever as to what the status of claims 34-40 is in regards to the restriction requirement.

II. APPLICANTS' TRAVERSAL

A. Provisional Election

The Applicants traverse the restriction while provisionally electing to prosecute Group I, which Applicants aver includes claims 21-33. The Applicants' traversal is respectfully set forth in detail below.

B. Standard of Review

Like other steps in the evidence-based, quasi-judicial process of patent prosecution, issuing and maintaining a restriction requirement demands that the examiner produce and sustain a *prima facie* case in support of restriction before the requirement for restriction can be properly enforced. As noted at 37 C.F.R. § 1.56(b)(2)(ii), “[a] *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard...” (emphasis added). While a restriction requirement does not directly relate to patentability of an application, 37 C.F.R. § 1.56(b)(2)(ii) contains an accurate statement of the requirements of the *prima facie* standard. A restriction requirement is likewise *prima facie* established only if the information, evidence, or reasoning advanced by the examiner compels a conclusion that restriction is proper under the preponderance of evidence, burden-of-proof standard.

The Applicants further specifically point out that the MPEP does not have the force of law and that standards and procedures disclosed therein are enforceable only to the extent that they can be traced back to some proper legal foundation, whether statute, rule, or judicial precedent. The MPEP expressly states in its foreword that “[t]he Manual does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.”

C. Impropriety of the Restriction Requirement

MPEP § 814 requires the examiner to “provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections” The same section further states that where restriction is between species, “[t]he particular limitations in the claims and the reasons why such limitations are considered to

support restriction of the claims to a particular disclosed species should be mentioned to make the requirement clear.” Thus, if an examiner fails to mention the particular limitations in the claims and the reasons why such limitations are considered to support restriction of the claims to a particular disclosed species, the examiner has failed to provide a clear and detailed record which may deprive the Applicants of their due process rights. In the present case, the Examiner has failed to mention any claim limitations and has failed to provide a sufficiently clear and detailed record.

Furthermore, MPEP § 808 states that “[e]very requirement to restrict has two aspects: (A) the reasons . . . why each invention as claimed is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the examiner if restriction is not required” (emphasis added). Thus, if the examiner fails to satisfy either one of these aspects the restriction requirement should be deemed improper and subsequently withdrawn. In the present case, the Examiner has demonstrated neither independence and distinctness of the claimed inventions, nor serious burden on the examiner if the restriction is not required. The reasons supporting this assertion by the Applicants are addressed in detail below.

1. Clear and Detailed Record Not Provided

As the Applicants note above, the MPEP requires the examiner to set forth the particular limitations in the claims and the reasons why such limitations are considered to support restriction of the claims to a particular disclosed species when a restriction between species is required, because failure to do so makes it unclear when double patenting rejections are appropriate in future applications.

In the present case, the Examiner has done nothing more than mention overlapping groups of claims, further ignoring an entire set of pending claims, without discussing any specific claim limitations other than to very briefly mention one potential separate use between the two groups. The Examiner’s incomplete set of claim groupings is insufficient to protect the applicants from future unwarranted double patenting rejections.

Because the Examiner has failed to provide a clear and detailed record that would adequately protect the Applicants’ rights, the restriction requirement is improper and should either be withdrawn, or be made fully explicit with reference to the distinctive features of the alleged patentably distinct species upon which the restriction requirement is based.

2. Independence *and* Distinctness not Properly Established

In the restriction requirement, the Examiner has only alleged that the “inventions listed in this action are independent *or* distinct.” Office Action, 6/17/2015, pg. 3 (emphasis added). However, the law requires the examiner to establish both independence *and* distinctness for a restriction requirement to be proper.

Both MPEP §§ 802.01(I) and 806.06 state that inventions are independent (and therefore unrelated) if there is “no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect” (emphasis added). Thus, showing that a relationship exists between the inventions in at least one of design, operation, or effect can overcome a finding of independence. All of the allegedly distinct species are similar in design, operation, and effect. They are all sleep disorder treatment systems. Accordingly, the groups identified by the Examiner for restriction are not unrelated or independent, and the Examiner has failed to establish a *prima facie* case for restriction. For at least this reason alone, the Applicants respectfully request that the restriction requirement be withdrawn.

As the Applicants note above, the MPEP states that one element of a proper restriction requirement is the Examiner’s setting forth “the reasons...why each invention as claimed is either independent or distinct from the other(s).” MPEP § 808 (emphasis added). Significantly, this language parts ways with both the language of the relevant rule as well as the relevant statute. 37 C.F.R. § 141 states that “[t]wo or more independent and distinct inventions may not be claimed in one national application,” while 35 U.S.C. § 121 states that “[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions” (emphases added).

The Applicants are aware that the USPTO has taken the position that MPEP § 802.01 purportedly justifies the use of “independent or distinct” as the controlling standard for restriction practice. The Applicants are also aware of the June 2005 “Green Paper” prepared by the USPTO in reevaluating its restriction practices. While one of the options considered in this Green Paper was the adoption of an “independent and distinct” standard, the USPTO ultimately decided to maintain the use of the “independent or distinct” standard. In the context of the conflict between “independent or distinct” and “independent and distinct”, the Applicants again respectfully emphasize the fact that the MPEP “does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.” Thus, regardless of the USPTO’s adoption

of the “independent or distinct” standard in the MPEP, the Applicants are justified in requiring that the examiner meet the statutory and regulatory standard of showing how and why claimed inventions are “independent and distinct” one from another. This is, at least in part, because the Applicants know of no legally sufficient grounds on which the USPTO can force adherence to the “independent or distinct” standard—particularly in the face of the clear statutory language of 35 U.S.C. § 121.

As further evidence in support of the Applicants’ assertion that “independent and distinct” should be the controlling standard, H.R. 9133, a predecessor bill to the 1952 Patent Act that was introduced in the House on July 17, 1950 in the 81st Congress but never acted on, uses the phrase “independent or distinct” in its version of Section 121. In contrast, however, H.R. 3760, which was introduced in the House on April 18, 1951 as part of the 82nd Congress instead utilized “independent and distinct” in its version of Section 121. Critically, it was the “independent and distinct” standard that was ultimately adopted when H.R. 7794 was passed by both the House and Senate to become the 1952 Patent Act.¹ It is this same “independent and distinct” standard that presently exists in 35 U.S.C. § 121. The sum of these actions is the clear and overt changing of the restriction standard embraced by the 1952 Patent Act from “independent or distinct” to “independent and distinct.” The Applicants thus submit that the USPTO’s continuing to implement the “independent or distinct” standard places the Agency’s actions squarely in conflict with the governing law. It follows that the Examiner’s basing the present restriction requirement on distinctness alone is also squarely in conflict with the governing law. Accordingly, the Applicants respectfully request that the restriction requirement be withdrawn.

3. Restriction Based on Subcombinations Usable Together Improper

MPEP § 806.05(d) states that “[t]wo or more claimed subcombinations, disclosed as usable together in a single combination, and which can be shown to be separately usable, are usually restrictable when the subcombinations do not overlap in scope and are not obvious variants.” However, the two Groups specified by the Examiner clearly overlap in scope, at the very least. Both independent claims 21 and 28 disclose the use of a positive airway pressure device, inputs for sensors including a respiratory effort sensor and a pulse oximeter sensor and an

¹ See *Life Sciences Law & Industry Report*, Vol. 3, No. 9, BNA, Inc., May 8, 2009 (author John T. Aquino).

output based on signals from the sensors, all in the scope of sleep disorder treatment devices. Thus, the claim groups clearly overlap in scope and should not be subject to restriction.

The Examiner's cited reasoning that "Group II has separate utility such as chemically treating a subject's sleep disorder or symptoms using the output of the level of severity of the subject's sleep disorder," (Office Action, 6/17/2015, pg. 2), applies to independent claim 34, which is not part of either Group I or Group II as defined by the Examiner. If the Examiner intended to create a third group comprising claims 34-40, then to support restriction, the examiner must show that *both* "(A) the combination does not require the particulars of the subcombination as claimed for patentability (e.g., to show novelty and unobviousness), and (B) the subcombination can be shown to have utility either by itself or in another materially different combination. See MPEP § 806.05(c). Furthermore, restriction is only proper when there would be a serious burden if restriction were not required, as evidenced by separate classification, status, or field of search." MPEP § 806.05(d). In the present case, even if the non-existent third group does have separate utility as the Examiner argues, the first prong is not met as the combination does require the particulars of the subcombination in regards to the limitations of claims 21 and 28 as discussed above. Therefore, the Applicants submit that the groups, as set forth by the Examiner, are not properly subject to restriction.

4. Serious Burden not Properly Established

As previously noted, serious burden on the examiner must be shown, in addition to a showing of independence and distinctness, before a restriction requirement will be deemed proper. Per the guidelines set forth in MPEP § 808.02, "serious burden" may be present only where claimed inventions (1) have separate classifications, (2) have separate status in the art, or (3) require different fields of search. Rather than providing a substantive reason for why a serious burden would exist, the Examiner merely listed five potential reasons without explaining which is/are applicable. See Office Action, 6/17/2015, pg. 3. The Applicants submit that such a statement fails to establish serious burden. Even a single species would require multiple search queries, and the Examiner has presented no evidence or reasoning to suggest that searches on one species would not bring up most or all relevant art for other species. The Examiner made no other mention of burden other than to broadly assert that one would exist, nor advanced any other reasoning to support why restriction would prevent a serious search burden other than to list a set of potential reasons. For this reason alone, the restriction requirement is improper.

Further, there is no support for the separate classification of the two groups defined by the Examiner, and certainly no reasoning advanced as to why a search for one group would not yield results pertinent to both groups. The Applicants further submit that both groups could be classified in 600/484, and that there is no foreseeable reason why the groups require the separate classification proposed by the Examiner. Thus, absent any reasoning or support from the Examiner, the Applicants submit that the separate classification is improper and that there is no basis for the generic assertion that a serious search burden would exist between the Examiner's groups.

5. Conclusion

Given what the Applicants believe was the Examiner's improper restriction, the lack of detail provided by the Examiner in the restriction requirement, and the Examiner's conclusory assertion that serious search burden would exist, the Applicants respectfully submit that the Examiner has not issued a proper restriction requirement.

III. REQUEST FOR AGENCY-WIDE CHANGE IN RESTRICTION PRACTICE

The Applicants respectfully submit that the present restriction requirement is representative of a larger pattern of abuse of restriction practice on the part of the USPTO as an improper way of failing to fulfill the Office's basic duty of examination of patent applications. It appears from this pattern, observable in numerous actions, that in at least certain art units examiners are under directive to issue a restriction requirement in every new application regardless of the merits of such a requirement in each individual case. Restriction requirements are now routinely issued with undeveloped or specious restriction rationales, or often without any supportive rationale at all. This practice is improper, and it shows that the sole purpose of the practice is to eliminate claims from examination rather than make proper restrictions justifiably based in independence and distinctness of claimed inventions and undue search burden. The Applicants respectfully submit that abusive restriction practice is now so widespread that it has become the rule rather than the exception.

The USPTO has acknowledged that its restriction practice is not ideal for stakeholders. Green Paper, page 1 ("The Office is cognizant that some applicants and the public may not view its current restriction practice as an ideal practice, particularly as it is presently applied"). However, the Applicants submit that the present blanket restriction practice is also not ideal for

the USPTO. Whatever restriction practice guidelines examiners are presently operating under, such guidelines appear to be motivated by a belief of the USPTO that such practices are effective at reducing examination costs. "The Office must consider the constraints its staffing and other resource limitations impose on the amount of additional workload that could be absorbed in the transition to a new restriction standard." *Id.*

However, the Applicants respectfully submit that by requiring restriction even where such restriction is not justified by law, the USPTO increases paperwork for examiners and applicants, increases the workload of examiners, and adds to its costs. The Applicants believe that if restriction practice is properly evaluated, the USPTO will be obliged to acknowledge that the current practice is unsustainable because it only adds to the examination backlog, even while penalizing applicants and other stakeholders and punishing examiners with additional work.

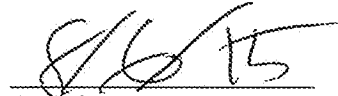
Moreover, the USPTO restriction practice is, and has been for many years, in clear contravention of statutory law and regulation which the Office is bound to operate under. As the Applicants have pointed out above, current practice of the USPTO in implementing an "independent or distinct" standard in restriction practice stands in clear conflict with both the governing law and governing regulations. Orbital Research Inc., the assignee of the Applicants' rights and real party in interest in the present traversal, has faced numerous restriction requirements (and anticipates facing numerous future restriction requirements), many of which have been wrongfully maintained, and thus leading to more costly fragmentary patent prosecution.

Accordingly, the Applicants respectfully request an agency-wide change in restriction practice that includes guidance and/or training in proper use of restriction practice, and specifically includes agency-wide adoption of the "independent and distinct" standard as required by law.

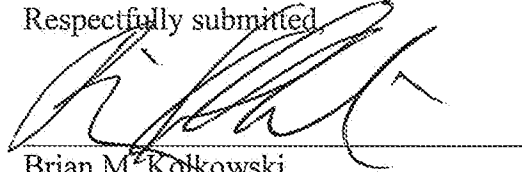
The Applicants request such change *not only* because they believe that properly abiding by the statutory and regulatory mandates will save the Applicants and other parties significant cost and inconvenience incurred in the fragmentary prosecution that results from what the Applicants believe are often speciously-maintained restriction requirements, *but also* because such practice would reduce costs for the Patent Office as well.

IV. CONCLUSION

In view of the above arguments, the Applicants believe that the restriction requirement has been improperly issued. Accordingly, the Applicants respectfully request withdrawal of the restriction requirement.


Dated

Respectfully submitted



Brian M. Kolkowski
Reg. No.: 36,847
Attorney for the Applicants
Cleveland Medical Devices Inc.
4415 Euclid Ave., Suite 400
Cleveland, OH 44103
(216) 649-0376
(216) 649-0397 FAX
bkolkowski@clevemed.com

Electronic Acknowledgement Receipt

EFS ID:	23136867
Application Number:	13440116
International Application Number:	
Confirmation Number:	4463
Title of Invention:	Devices and Methods for Sleep Disorder Diagnosis and Treatment
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-087
Receipt Date:	06-AUG-2015
Filing Date:	05-APR-2012
Time Stamp:	15:21:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	CMD-087_2015-08-06_election -w-traverse.pdf	4421220 37f593ebbd06d6ced36c5acd4a57a901638 95297	no	10

Warnings:

Information:

Total Files Size (in bytes):

4421220

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/440,116	04/05/2012	Hani Kayyali	CMD-087	4463

81177 7590 06/17/2015
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

EXAMINER

NATNITHADHA, NAVIN

ART UNIT	PAPER NUMBER
----------	--------------

3735

MAIL DATE	DELIVERY MODE
-----------	---------------

06/17/2015

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-33, drawn to a sleep disorder treatment device and system, classified in class 600, subclass 484.

II. Claims 28-33, drawn to a sleep disorder treatment system, classified in 600, subclass 600/481.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination Group II has separate utility such as chemically treating a subject's sleep disorder or symptoms using the output of the level of severity of the subject's sleep disorder. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a

Art Unit: 3735

claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

2. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph..

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Art Unit: 3735

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Mallari can be reached on (571) 272-4729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3735
06/15/2015

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
CLAIM		DATE							
Final	Original	06/16/2015							
	1	-							
	2	-							
	3	-							
	4	-							
	5	-							
	6	-							
	7	-							
	8	-							
	9	-							
	10	-							
	11	-							
	12	-							
	13	-							
	14	-							
	15	-							
	16	-							
	17	-							
	18	-							
	19	-							
	20	-							
	21	÷							
	22	÷							
	23	÷							
	24	÷							
	25	÷							
	26	÷							
	27	÷							
	28	÷							
	29	÷							
	30	÷							
	31	÷							
	32	÷							
	33	÷							
	34	÷							
	35	÷							
	36	÷							

<i>Index of Claims</i> 	Application/Control No. 13440116	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
CLAIM		DATE							
Final	Original	06/16/2015							
	37	÷							
	38	÷							
	39	÷							
	40	÷							

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

EPAS ID: PAT2889395

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	SECURITY INTEREST
CONVEYING PARTY DATA	
Name	Execution Date
CLEVELAND MEDICAL DEVICES, INC.	05/30/2014
RECEIVING PARTY DATA	
Name:	THE DIRECTOR OF THE OHIO DEVELOPMENT SERVICES AGENCY
Street Address:	77 SOUTH HIGH STREET, 29TH FLOOR
City:	COLUMBUS
State/Country:	OHIO
Postal Code:	43215
PROPERTY NUMBERS Total: 39	
Property Type	Number
Patent Number:	5755230
Patent Number:	5970105
Patent Number:	6223061
Patent Number:	6993380
Patent Number:	7593767
Patent Number:	7845350
Patent Number:	7860561
Patent Number:	7865234
Patent Number:	7942824
Patent Number:	8172766
Patent Number:	8335561
Patent Number:	8424527
Patent Number:	8437843
Patent Number:	8545416
Application Number:	29364922
Application Number:	11505204
Application Number:	11526251
Application Number:	11729524
Application Number:	11811156
Application Number:	11811157
Application Number:	11999198

ResMed
Exhibit 1005 - Page 448

Property Type	Number
Application Number:	12228461
Application Number:	12228462
Application Number:	12489961
Application Number:	12509858
Application Number:	12504820
Application Number:	12896983
Application Number:	12370996
Application Number:	12913567
Application Number:	13074901
Application Number:	13269944
Application Number:	13440116
Application Number:	13626011
Application Number:	13628151
Application Number:	13677469
Application Number:	13845441
Application Number:	13853436
Application Number:	13975792
Application Number:	14173897

CORRESPONDENCE DATA

Fax Number: (513)579-6457

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Phone: 5135796590

Email: mmusekamp@kmlaw.com

Correspondent Name: MARK E. MUSEKAMP

Address Line 1: ONE EAST 4TH STREET, SUITE 1400

Address Line 4: CINCINNATI, OHIO 45202

ATTORNEY DOCKET NUMBER:	OH5005/FI0031
NAME OF SUBMITTER:	MARK E. MUSEKAMP
SIGNATURE:	/Mark E. Musekamp/
DATE SIGNED:	06/09/2014
	This document serves as an Oath/Declaration (37 CFR 1.63).

Total Attachments: 11

source=Executed IP Security Agreement#page1.tif

source=Executed IP Security Agreement#page2.tif

source=Executed IP Security Agreement#page3.tif

source=Executed IP Security Agreement#page4.tif

source=Executed IP Security Agreement#page5.tif

source=Executed IP Security Agreement#page6.tif

source=Executed IP Security Agreement#page7.tif

source=Executed IP Security Agreement#page8.tif
source=Executed IP Security Agreement#page9.tif
source=Executed IP Security Agreement#page10.tif
source=Executed IP Security Agreement#page11.tif

INTELLECTUAL PROPERTY SECURITY AGREEMENT

This INTELLECTUAL PROPERTY SECURITY AGREEMENT (this “*IP Security Agreement*”), dated as of May 30, 2014, is made by CLEVELAND MEDICAL DEVICES, INC., an Ohio corporation (the “*Borrower*”), in favor of THE DIRECTOR OF THE OHIO DEVELOPMENT SERVICES AGENCY (the “*Director*”).

Background Information

As a condition precedent to the making of a loan by the Director under the Loan Agreement dated as of May 30, 2014 (the “*Loan Agreement*”) between the Borrower and the Director, the Borrower has executed and delivered to the Director that certain Security Agreement dated as of May 30, 2014, made by and among the Borrower and the Director (the “*Security Agreement*”); and

Under the terms of the Security Agreement, the Borrower has granted to the Director a security interest in, among other property, certain intellectual property of the Borrower, and has agreed to execute and deliver this IP Security Agreement, for recording with national, federal and state government authorities, including, but not limited to, the United States Patent and Trademark Office and the United States Copyright Office.

Provisions

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Borrower agrees with the Director as follows:

Section 1. Grant of Security. The Borrower hereby pledges and grants to the Director for the benefit of the Director a security interest in and to all of the right, title and interest of the Borrower in, to and under the following, wherever located, and whether now existing or hereafter arising or acquired from time to time (the “*IP Collateral*”):

(a) the patents and patent applications set forth in Schedule 1 hereto and all reissues, divisions, continuations, continuations-in-part, renewals, extensions and re-examinations thereof and amendments thereto (the “*Patents*”);

(b) the trademark registrations and applications set forth in Schedule 2 hereto, together with the goodwill connected with the use of and symbolized thereby and all extensions and renewals thereof (the “*Trademarks*”), excluding only United States intent-to-use trademark applications to the extent that and solely during the period in which the grant of a security interest therein would impair, under applicable federal law, the registrability of such applications or the validity or enforceability of registrations issuing from such applications;

(c) the copyright registrations, applications and copyright registrations and applications exclusively licensed to the Borrower set forth in Schedule 3 hereto, and all extensions and renewals thereof (the “*Copyrights*”);

(d) all rights of any kind whatsoever of the Borrower accruing under any of the foregoing provided by applicable law of any jurisdiction, by international treaties and conventions and otherwise throughout the world;

(e) any and all royalties, fees, income, payments and other proceeds now or hereafter due or payable with respect to any and all of the foregoing; and

(f) any and all claims and causes of action, with respect to any of the foregoing, whether occurring before, on or after the date hereof, including all rights to and claims for damages, restitution and injunctive and other legal and equitable relief for past, present and future infringement, dilution, misappropriation, violation, misuse, breach or default, with the right but no obligation to sue for such legal and equitable relief and to collect, or otherwise recover, any such damages.

Section 2. Recordation. The Borrower authorizes the Commissioner for Patents, the Commissioner for Trademarks and the Register of Copyrights and any other government officials to record and register this IP Security Agreement upon request by the Director.

Section 3. Loan Documents. This IP Security Agreement has been entered into pursuant to and in conjunction with the Security Agreement, which is hereby incorporated by reference. The provisions of the Security Agreement shall supersede and control over any conflicting or inconsistent provision herein. The rights and remedies of the Director with respect to the IP Collateral are as provided by the Loan Agreement, the Security Agreement and the other Loan Documents, and nothing in this IP Security Agreement shall be deemed to limit such rights and remedies.

Section 4. Execution in Counterparts. This IP Security Agreement may be executed by one or more of the parties to this Agreement on any number of separate counterparts (including by telecopy), and all of said counterparts taken together shall be deemed to constitute one and the same instrument.

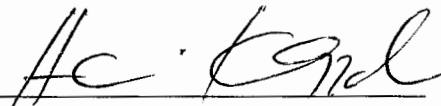
Section 5. Successors and Assigns. This IP Security Agreement will be binding on and shall inure to the benefit of the parties hereto and their respective successors and assigns.

Section 6. Governing Law. This IP Security Agreement and any claim, controversy, dispute or cause of action (whether in contract or tort or otherwise) based upon, arising out of or relating to this IP Security Agreement and the transactions contemplated hereby and thereby shall be governed by, and construed in accordance with, the laws of the United States and the State of Ohio, without giving effect to any choice or conflict of law provision or rule (whether of the State of Ohio or any other jurisdiction).

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Borrower has caused this IP Security Agreement to be duly executed and delivered as of the date first above written.

CLEVELAND MEDICAL DEVICES,
INC.

By 
Name: Hani Kayyali
Title: President

AGREED TO AND ACCEPTED:

THE DIRECTOR OF THE OHIO
DEVELOPMENT SERVICES
AGENCY

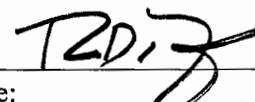
By 
Name:
Title: **Ryan D. Burgess**
Assistant Director

EXHIBIT A

SCHEDULES

Schedule 1 – Issued Patents and Patent Applications

Patents – Issued

1. Wireless EEG System for Effective Auditory Evoked Response
 - i. Patent No.: 5,755,230
 - ii. Issue Date: 05/26/1998
 - iii. Application No.: 08/529,646
 - iv. Filing Date: 09/18/1995
2. Apparatus and Method for Efficient Wireless Communications in the Presence of Frequency Error (CMD-98-1)
 - i. Patent No.: 5,970,105
 - ii. Issue Date: 10/19/1999
 - iii. Application No.: 09/075,610
 - iv. Filing Date: 05/11/1998
3. Apparatus for Low Power Radio Communications (15008)
 - i. Patent No.: 6,223,061
 - ii. Issue Date: 04/24/2001
 - iii. Application No.: 08/900,329
 - iv. Filing Date: 07/25/1997
4. Quantitative Sleep Analysis Method and System (CMD-001)
 - i. Patent No.: 6,993,380
 - ii. Issue Date: 01/31/2006
 - iii. Application No.: 10/454,156
 - iv. Filing Date: 06/04/2003
5. Ambulatory Sleepiness and Apnea Propensity Evaluation System (CMD-010)
 - i. Patent No.: 7,593,767
 - ii. Issue Date: 09/22/2009

- iii. Application No.: 11/453,709
- iv. Filing Date: 06/15/2006
- 6. Automatic Continuous Positive Airway Pressure Treatment System with Fast Respiratory Response (CMD-044)
 - i. Patent No.: 7,845,350
 - ii. Issue Date: 12/07/2010
 - iii. Application No.: 11/498,643
 - iv. Filing Date: 08/03/2006
- 7. Method of Quantifying a Subject's Wake or Sleep State and System for Measuring (CMD-009)
 - i. Patent No.: 7,860,561
 - ii. Issue Date: 12/28/2010
 - iii. Application No.: 10/860,863
 - iv. Filing Date: 06/04/2004
- 8. Quantitative Method for the Therapeutic Treatment of Sleep Disorders (CMD-002)
 - i. Patent No.: 7,865,234
 - ii. Issue Date: 01/04/2011
 - iii. Application No.: 11/021,594
 - iv. Filing Date: 12/22/2004
- 9. Integrated Sleep Diagnostic and Therapeutic System and Method (CMD-057)
 - i. Patent No.: 7,942,824
 - ii. Issue Date: 05/17/2011
 - iii. Application No.: 11/879,934
 - iv. Filing Date: 07/19/2007
- 10. Integrated Sleep Diagnosis and Treatment Device and Method (CMD-023)
 - i. Patent No.: 8,172,766
 - ii. Issue Date: 05/08/2012
 - iii. Application No.: 11/266,899
 - iv. Filing Date: 11/04/2005
- 11. Quantitative Method for Assessment of Excessive Daytime Sleepiness (CMD-079)
 - i. Patent No.: 8,335,561

- ii. Issue Date: 12/18/2012
- iii. Application No.: 12/957,098
- iv. Filing Date: 11/30/2010

12. Novel and Unique Device for Determining Airway Obstructions (CMD-065)

- i. Patent No.: 8,424,527
- ii. Issue Date: 04/23/2013
- iii. Application No.: 12/231,741
- iv. Filing Date: 09/05/2008

13. EEG Data Acquisition System with Novel Features (CMD-022)

- i. Patent No.: 8,437,843
- ii. Issue Date: 05/07/2013
- iii. Application No.: 11/454,482
- iv. Filing Date: 06/16/2006

14. Integrated Diagnostic and Therapeutic System and Method for Improving Treatment of Subject with Complex and Central Sleep Apnea (CMD-058)

- i. Patent No.: 8,545,416
- ii. Issue Date: 10/01/2013
- iii. Application No.: 11/880,046
- iv. Filing Date: 07/19/2007

15. Sleep Diagnostic Device (CMD-074)

- i. Patent No.: D663,430
- ii. Issue Date: 07/10/2012
- iii. Application No.: 29/364,922
- iv. Filing Date: 06/30/2010

Patents – Pending Applications

16. Humidification for Continuous Positive Airway Pressure Systems (CMD-045)

- i. Application No.: 11/505,204
- ii. Filing Date: 08/16/2006

17. Filtration or Purification for Continuous Positive Airway Pressure Systems and Methods (CMD-046)

- i. Application No.: 11/526,251

- ii. Filing Date: 09/22/2006
- 18. Data Acquisition System for Remote Testing with Novel Features (CMD-050)
 - i. Application No.: 11/729,524
 - ii. Filing Date: 03/29/2007
- 19. Method and Device for In-Home Sleep and Signal Analysis (CMD-055)
 - i. Application No.: 11/811,156
 - ii. Filing Date: 06/08/2007
- 20. Method and Device for Sleep Analysis (CMD-056)
 - i. Application No.: 11/811,157
 - ii. Filing Date: 06/08/2007
- 21. Positive Airway Pressure Treatment System with Display (CMD-059)
 - i. Application No.: 11/999,198
 - ii. Filing Date: 12/04/2007
- 22. Medical Device and Method with Improved Biometric Verification (CMD-060)
 - i. Application No.: 12/228,461
 - ii. Filing Date: 08/13/2008
- 23. Method and Device for Sleep Analysis and Therapy (CMD-061)
 - i. Application No.: 12/228,462
 - ii. Filing Date: 08/13/2008
- 24. Device for Sleep Diagnosis (CMD-067)
 - i. Application No.: 12/370,996
 - ii. Filing Date: 02/13/2009
- 25. Apnea Propensity Evaluation System (CMD-070)
 - i. Application No.: 12/489,961
 - ii. Filing Date: 06/23/2009
- 26. Electrode for Measuring Electrophysiological Signals (CMD-071)
 - i. Application No.: 12/509,858
 - ii. Filing Date: 07/27/2009
- 27. Remote Sleep Monitoring System (CMD-072)
 - i. Application No.: 12/504,820
 - ii. Filing Date: 07/17/2009

28. Method of Quantifying a Subject's Wake or Sleep State and System for Measuring (CMD-077)
 - i. Application No.: 12/896,983
 - ii. Filing Date: 10/04/2010
29. Automatic Continuous Positive Airway Pressure Treatment System with Fast Respiratory Response (CMD-078)
 - i. Application No.: 12/913,567
 - ii. Filing Date: 10/27/2010
30. Integrated Sleep Diagnostic and Therapeutic System and Method (CMD-082)
 - i. Application No.: 13/074,901
 - ii. Filing Date: 03/29/2011
31. Device and Sensors for Sleep Disorder Diagnosis (CMD-084)
 - i. Application No.: 13/269,944
 - ii. Filing Date: 10/10/2011
32. Devices and Methods for Sleep Disorder Diagnosis and Treatment (CMD-087)
 - i. Application No.: 13/440,116
 - ii. Filing Date: 05/05/2012
33. Methods and Devices for Carbon Dioxide-Based Sleep Disorder Therapy (CMD-085)
 - i. Application No.: 13/626,011
 - ii. Filing Date: 09/25/2012
34. Lead Wire Connector for Measuring Electrophysiological Signals (CMD-086)
 - i. Application No.: 13/628,151
 - ii. Filing Date: 09/27/2012
35. Quantitative Sleep Analysis System and Method (CMD-088)
 - i. Application No.: 13/677,469
 - ii. Filing Date: 11/15/2012
36. Novel and Unique Device for Determining Airway Obstructions (CMD-089)
 - i. Application No.: 13/845,441
 - ii. Filing Date: 03/18/2013
37. Data Acquisition System with Novel Features (CMD-090)
 - i. Application No.: 13/853,436

ii. Filing Date: 03/29/2013

38. Integrated Diagnostic and Therapeutic System and Method for Improving Treatment of Subject with Complex and Central Sleep Apnea (CMD-092)

i. Application No.: 13/975,792

ii. Filing Date: 08/26/2013

39. Medical Device and Method with Improved Biometric Verification (CMD-093)

i. Application No.: 14/173,897

ii. Filing Date: 02/06/2014

Schedule 2 – Trademark Registrations and Applications

1. Crystal Monitor®
2. Sapphire PSG
3. SleepScout
4. SleepView®
5. SleepViewSM
6. Crystal PSG
7. iPSG
8. DreamPort
9. e-Crystal PSG

Schedule 3 – Copyright Registrations and Applications

None.

5402585.3

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 13/440,116				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	95		N/A				
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	310		N/A				
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	125		N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *	x 30 =	0.00	OR					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x 125 =	0.00						
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00						
			TOTAL	530		TOTAL				
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=	OR	x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=	OR	x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
13/440,116	04/05/2012	3735	530	CMD-087	20	3

CONFIRMATION NO. 4463

81177

Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 400
Cleveland, OH 44103

FILING RECEIPT



OC000000053758492

Date Mailed: 04/23/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Hani Kayyali, Shaker Heights, OH;
Robert Schmidt, Cleveland, OH;
Mohammad Modarres-Zadeh, Tampa, FL;
Brian Kolkowski, Leroy, OH;

Assignment For Published Patent Application

CLEVELAND MEDICAL DEVICES INC, Cleveland, OH

Power of Attorney:

Brian Kolkowski--36847

Domestic Priority data as claimed by applicant

This application is a CON of 11/266,899 11/04/2005 PAT 8172766

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.)

If Required, Foreign Filing License Granted: 04/17/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/440,116**

Projected Publication Date: Request for Non-Publication Acknowledged

Non-Publication Request: Yes

Early Publication Request: No

**** SMALL ENTITY ****

Title

Devices and Methods for Sleep Disorder Diagnosis and Treatment

Preliminary Class

600

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER**Title 35, United States Code, Section 184****Title 37, Code of Federal Regulations, 5.11 & 5.15****GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage, facilitate, and accelerate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET Substitute for Form PTO-1360 (For use with Form PTO/SB/06)							Application Number 13440116		Filing Date				
							Applicant(s) Hani Kayyali						
							* May be used for additional claims or amendments						
CLAIMS	AS FILED		AFTER FIRST AMENDMENT		AFTER SECOND AMENDMENT			*		*		*	
	Indep	Depend	Indep	Depend	Indep	Depend		Indep	Depend	Indep	Depend	Indep	Depend
1	---	---											
2	---	---											
3	---	---											
4	---	---											
5	---	---											
6	---	---											
7	---	---											
8	---	---											
9	---	---											
10	---	---											
11	---	---											
12	---	---											
13	---	---											
14	---	---											
15	---	---											
16	---	---											
17	---	---											
18	---	---											
19	---	---											
20	---	---											
21	1												
22		1											
23		1											
24		1											
25		1											
26		1											
27		1											
28	1												
29		1											
30		1											
31		1											
32		1											
33		1											
34	1												
35		1											
36		1											
37		1											
38		1											
39		1											
40		1											
41													
42													
43													
44													
45													
46													
47													
48													
49													
50													
Total Indep	3		0		0								
Total Depend	17	↙	0	↙	0	↙							
Total Claims	20		0		0								

51						
52						
53						
54						
55						
56						
57						
58						
59						
60						
61						
62						
63						
64						
65						
66						
67						
68						
69						
70						
71						
72						
73						
74						
75						
76						
77						
78						
79						
80						
81						
82						
83						
84						
85						
86						
87						
88						
89						
90						
91						
92						
93						
94						
95						
96						
97						
98						
99						
100						

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 13/440,116				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	95		N/A				
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	310		N/A				
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	125		N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *	x 30 =	0.00	OR					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x 125 =	0.00						
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00						
			TOTAL	530		TOTAL				
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=	OR	x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=	OR	x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
13/440,116	04/05/2012	3735	530	CMD-087	20	3

CONFIRMATION NO. 4463

81177

Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 400
Cleveland, OH 44103

FILING RECEIPT



OC000000053758492

Date Mailed: 04/18/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Hani Kayyali, Shaker Heights, OH;
Robert Schmidt, Cleveland, OH;
Mohammad Modarres-Zadeh, Tampa, FL;
Brian Kolkowski, Leroy, OH;

Assignment For Published Patent Application

CLEVELAND MEDICAL DEVICES INC, Cleveland, OH

Power of Attorney:

Brian Kolkowski--36847

Domestic Priority data as claimed by applicant

This application is a CON of 11/266,899 11/04/2005 PAT 8172766

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.)

If Required, Foreign Filing License Granted: 04/17/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/440,116**

Projected Publication Date: Request for Non-Publication Acknowledged

Non-Publication Request: Yes

Early Publication Request: No

**** SMALL ENTITY ****

Title

Devices and Methods for Sleep Disorder Diagnosis and Treatment

Preliminary Class

600

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER**Title 35, United States Code, Section 184****Title 37, Code of Federal Regulations, 5.11 & 5.15****GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage, facilitate, and accelerate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET Substitute for Form PTO-1360 (For use with Form PTO/SB/06)							Application Number 13440116		Filing Date					
							Applicant(s) Hani Kayyali							
							* May be used for additional claims or amendments							
CLAIMS	AS FILED		AFTER FIRST AMENDMENT		AFTER SECOND AMENDMENT				*		*		*	
	Indep	Depend	Indep	Depend	Indep	Depend			Indep	Depend	Indep	Depend	Indep	Depend
1	---	---												
2	---	---												
3	---	---												
4	---	---												
5	---	---												
6	---	---												
7	---	---												
8	---	---												
9	---	---												
10	---	---												
11	---	---												
12	---	---												
13	---	---												
14	---	---												
15	---	---												
16	---	---												
17	---	---												
18	---	---												
19	---	---												
20	---	---												
21	1													
22		1												
23		1												
24		1												
25		1												
26		1												
27		1												
28	1													
29		1												
30		1												
31		1												
32		1												
33		1												
34	1													
35		1												
36		1												
37		1												
38		1												
39		1												
40		1												
41														
42														
43														
44														
45														
46														
47														
48														
49														
50														
Total Indep	3		0		0									
Total Depend	17	↙	0	↙	0	↙								
Total Claims	20		0		0									

51						
52						
53						
54						
55						
56						
57						
58						
59						
60						
61						
62						
63						
64						
65						
66						
67						
68						
69						
70						
71						
72						
73						
74						
75						
76						
77						
78						
79						
80						
81						
82						
83						
84						
85						
86						
87						
88						
89						
90						
91						
92						
93						
94						
95						
96						
97						
98						
99						
100						

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
		)	
Serial No.:	Continuation of 11/266,899	)	
		)	Art Unit: Unknown
Filed:	April 5, 2012	)	
		)	
For:	Devices and Methods for	)	
	Sleep Disorder Diagnosis	)	
	and Treatment	)	
		)	Attorney Docket No.: CMD-087
Examiner:	Unknown	)	
		)	

April 5, 2012

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

This preliminary amendment is being filed with a continuation application from parent application U.S. Patent Application No.: 11/266,899. The following amendments to the specification and claims are respectfully submitted.

IN THE SPECIFICATION:

Please make the following changes to the specification:

On page 1, substitute a new title of "DEVICES AND METHODS FOR SLEEP DISORDER DIAGNOSIS AND TREATMENT".

On page 1, between lines 7 and 8, insert the following paragraph:

"CROSS REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation of U.S. Patent Application No. 11/266,899 filed November 4, 2005."

CLAIM AMENDMENTS:

Please amend the claims as follows:

1-20. (Canceled)

21. (New) A sleep disorder treatment device comprising:

a positive airway pressure (PAP) device, the PAP device comprising inputs for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor;
and

a processor for receiving and processing signals from the sensors and further for determining an output pressure level of the PAP device based on the signals from the sensors.

22. (New) The device of claim 21 wherein the PAP device is a continuous positive airway pressure device (CPAP).

23. (New) The device of claim 21 further including inputs for receiving signals from ECG sensors.

24. (New) The device of claim 21 further including inputs for receiving signals from EEG sensors.

25. (New) The device of claim 21 in which signals from the sensors are processed using short-time fourier transforms.

26. (New) The device of claim 21 wherein the PAP device further comprises an airflow sensor with a signal, and wherein the processor also receives and processes signals from the airflow sensor.

27. (New) The device of claim 21 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

28. (New) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors including a respiratory effort sensor and a pulse oximeter sensor, the data acquisition system for creating a quantitative output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors; and

a positive airway pressure (PAP) device for treating a subject's sleep disorder symptoms, which can receive the output of the data acquisition system and produce a recommended positive pressure setting in response to the output of the data acquisition system.

29. (New) The sleep disorder treatment system of claim 28 wherein the PAP device is a continuous positive airway pressure device (CPAP).

30. (New) The sleep disorder treatment system of claim 28 further including inputs for receiving signals from ECG sensors.

31. (New) The sleep disorder treatment system of claim 28 further including inputs for receiving signals from EEG sensors.

32. (New) The sleep disorder treatment system of claim 28 wherein the output of the data acquisition system is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the PAP device.

33. (New) The sleep disorder treatment system of claim 28 wherein the respiratory effort sensor is a respiratory inductance plethysmography belt.

34. (New) A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the sensors; and

an apparatus for chemically treating a subject's sleep disorder or symptoms, which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder.

35. (New) The sleep disorder treatment system of claim 34 wherein the at least one physiological sensor is a pulse oximeter sensor.

36. (New) The sleep disorder treatment system of claim 35 further including a respiratory effort sensor.

37. (New) The sleep disorder treatment system of claim 34 wherein the apparatus for chemically treating a subject's sleep disorder or symptoms is a positive airway pressure (PAP) device capable of delivering gases to the subject at concentrations higher than atmospheric concentrations.

38. (New) The sleep disorder treatment system of claim 37 wherein the PAP device is used to deliver oxygen to the subject at a concentration higher than atmospheric concentration.

39. (New) The sleep disorder treatment system of claim 37 wherein the PAP device is used to deliver carbon dioxide to the subject at a concentration higher than atmospheric concentration.

40. (New) The sleep disorder treatment system of claim 34 wherein the at least one physiological sensor is an ECG sensor.

REMARKS

The Applicant respectfully submits that this application is in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

04/05/2012

Dated

/Brian M. Kolkowski/

Brian M. Kolkowski
Reg. No.: 36,847
Attorney for the Applicant
Cleveland Medical Devices Inc.
4415 Euclid Avenue, Suite 400
Cleveland, Ohio 44103
Tel: (216) 649-0376
Fax: (216) 649-0347
Email: bkolkowski@clevemed.com

Electronic Patent Application Fee Transmittal

Application Number:

Filing Date:

Title of Invention:

Devices and Methods for Sleep Disorder Diagnosis and Treatment

First Named Inventor/Applicant Name:

Hani Kayyali

Filer:

Brian M. Kolkowski/Matthew Beutler

Attorney Docket Number:

CMD-087

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	95	95
Utility Search Fee	2111	1	310	310
Utility Examination Fee	2311	1	125	125

Pages:

Claims:

Miscellaneous-Filing:

Petition:

Patent-Appeals-and-Interference:

ResMed

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				530

Electronic Acknowledgement Receipt

EFS ID:	12476265
Application Number:	13440116
International Application Number:	
Confirmation Number:	4463
Title of Invention:	Devices and Methods for Sleep Disorder Diagnosis and Treatment
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Matthew Beutler
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-087
Receipt Date:	05-APR-2012
Filing Date:	
Time Stamp:	13:00:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$530
RAM confirmation Number	12603
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part / Zip ResMed (if appl.)	Pages (if appl.)
-----------------	----------------------	-----------	-------------------------------------	--	---------------------

1	Application Data Sheet	CMD087ADS.pdf	1429103	no	5
			dd77da1fe863351a52f7e73d170eda13ef86f430		
Warnings:					
Information:					
2		CMD087Spec.pdf	462744	yes	45
			ff7096eef441950a8002eece7b79c613ea2ef18a		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	41	
	Claims		42	44	
	Abstract		45	45	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	CMD087Drawings.pdf	1623525	no	6
			ef463078d57b77a102d3672cc02241493d16e56a		
Warnings:					
Information:					
4		CMD087DecPwrAtty.pdf	2852829	yes	4
			825635149dec3678eb5b80c45303dbd33e706fce		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Oath or Declaration filed		1	2	
	Power of Attorney		3	4	
Warnings:					
Information:					
5	Preliminary Amendment	CMD087PrelimAmendment.pdf	68149	no	7
			00e30f7b4e586274f1e8c1d6ab2834fa913a6724		
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	32757	no	2
			619b7f104a85d0d51ecc2c191e1fd9e1cb553cc3		
Warnings:					

Information:	
Total Files Size (in bytes):	6469107
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-087
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1						Remove	
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name		Family Name		Suffix	
	Hani			Kayyali			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service							
City	Shaker Heights	State/Province	OH	Country of Residence i		US	
Citizenship under 37 CFR 1.41(b) i		US					
Mailing Address of Applicant:							
Address 1		2692 Rocklyn Rd.					
Address 2							
City	Shaker Heights	State/Province		OH			
Postal Code	44122	Country i	US				
Applicant 2						Remove	
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name		Family Name		Suffix	
	Robert			Schmidt			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service							
City	Cleveland	State/Province	OH	Country of Residence i		US	
Citizenship under 37 CFR 1.41(b) i		US					
Mailing Address of Applicant:							
Address 1		1721 Fulton Road					
Address 2							
City	Cleveland	State/Province		OH			
Postal Code	44113	Country i	US				
Applicant 3						Remove	
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name		Family Name		Suffix	
	Mohammad			Modarres-Zadeh			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service							
City	Tampa	State/Province	FL	Country of Residence i		US ResMed	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-087
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

Citizenship under 37 CFR 1.41(b) i		US	
Mailing Address of Applicant:			
Address 1	17910 Arbor Greene		
Address 2			
City	Tampa	State/Province	FL
Postal Code	33647	Country ⁱ	US
Applicant 4			Remove
Applicant Authority		☒ Inventor ☐ Legal Representative under 35 U.S.C. 117 ☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name	Family Name
	Brian		Kolkowski
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service			
City	Leroy	State/Province	OH
Citizenship under 37 CFR 1.41(b) i		US	
Mailing Address of Applicant:			
Address 1	6340 Taylor Road		
Address 2			
City	Leroy	State/Province	OH
Postal Code	44077	Country ⁱ	US
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. Add			

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence Information of this application.			
Customer Number	81177		
Email Address	bkolkowski@clevemed.com	Add Email	Remove Email

Application Information:

Title of the Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		
Attorney Docket Number	CMD-087	Small Entity Status Claimed ☒	
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	6	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-087
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☒	Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.			
Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	81177		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.			
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	11/266899	2005-11-04
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).			
			Remove
Application Number	Country i	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☒ Yes ☐ No
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.	
Assignee 1	Remove

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-087
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

If the Assignee is an Organization check here. ☒			
Organization Name	Cleveland Medical Devices Inc		
Mailing Address Information:			
Address 1	4415 Euclid Avenue		
Address 2	Suite 400		
City	Cleveland	State/Province	OH
Country i	US	Postal Code	44103
Phone Number	(216) 791-6720	Fax Number	(216) 791-6739
Email Address			
Additional Assignee Data may be generated within this form by selecting the Add button. Add			

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature	/Brian M. Kolkowski/			Date (YYYY-MM-DD)	2012-04-05
First Name	Brian	Last Name	Kolkowski	Registration Number	36847

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

5 The U.S. Government has a paid-up license in this invention and the right
in limited circumstances to require the patent owner to license others on
reasonable terms provided for by the terms of grant number 2R44NS42451
awarded by the National Institutes of Health.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

10 The present invention relates to an integrated sleep diagnosis and treatment
device, and more particularly to an integrated apnea diagnosis and treatment
device. The present invention additionally relates to method of sleep diagnosis
and treatment.

2. TECHNICAL BACKGROUND

15 Nearly one in seven people in the United States suffer from some type of
chronic sleep disorder, and only fifty percent (50%) of people are estimated to get
the recommended seven (7) to eight (8) hours of sleep each night. It is further
20 estimated that sleep deprivation and its associated medical and social costs (loss
of productivity, industrial accidents, etc) exceed \$150 billion dollars per year.
Excessive sleepiness can deteriorate the quality of life and is a major cause of
morbidity and mortality due to its role in industrial and transportation accidents.
Sleepiness further has undesirable effects on motor vehicle driving, employment,
25 higher earning and job promotion opportunities, education, recreation, and
personal life.

Sleeping disorders such as for example narcolepsy and sleep apnea are
currently diagnosed by two general methods. The first is via subjective methods

such as the Epworth and Stanford Sleepiness Scale, which generally involves questionnaires where the patients answer a series of qualitative questions regarding their sleepiness during the day. With these methods, however, it is found that the patients usually underestimate their level of sleepiness or they
5 deliberately falsify their responses because of their concern regarding punitive action, or as an effort to obtain restricted stimulant medication.

The second is via physiological based evaluations such as all night polysomnography to evaluate the patients sleep architecture (e.g., obtaining respiratory disturbance index to diagnose sleep apnea) followed by an all day test
10 such as the Multiple Sleep Latency Test (MSLT) or its modified version, Maintenance of Wakefulness Test (MWT). While the MSLT and MWT are more objective and therefore don't have the same limitations as mentioned for the subjective tests, the MSLT and MWT have their own limitations. Both the MSLT and MWT require an all-day stay at a specialized sleep clinic and involve
15 monitoring a number of nap opportunities at two hour intervals throughout the day. Further, the MSLT mean sleep latency is only meaningful if it is extremely short in duration (e.g., to diagnose narcolepsy), and only if the overnight polysomnogram does not show any sleep disordered breathing. Another problem with the MSLT mean sleep latency is the so-called "floor effect" where the sleep
20 latency in the pathologically sleepy patients can be almost zero (0) minutes, i.e., the patient falls asleep almost immediately following turning off the light in the MSLT test. This type of result has a tendency to limit the diagnostic resolution of the test. Finally, studies have shown that the MSLT is not particularly suited for gauging the effects of therapeutic intervention. This was demonstrated in studies
25 by Thorpy in 1992 and Van den Hoed et al. in 1981 showing no reliable reduction in sleepiness in patients given stimulant medications for narcolepsy.

With sleeping disorders such as sleep apnea medications or some physical form of therapy can be used to treat the disorder. The treatment is determined based on one of the above tests, and can be adjusted by re-testing of the patient at

some later time to determine whether the condition or the symptoms have been alleviated.

For example, the most common method of treating the sleeping disorder of sleep apnea is by apply a continuous positive gas pressure to the patient's airway, which has the effect of forcing the patient to breath through application of the pressure. More advanced, but still very basic devices have been developed that adjust this continuous positive gas pressure through sensors built into the device for creating the positive gas pressure, which measure gas flow through the device. These basic adjustable devices have been found to be expensive and largely ineffective.

None of the devices on the market can be used to adjust a patient's treatment, whether physical or chemical, based on the patient's current physiological state. Further none of the current devices can be used to adjust a patient's treatment, based on the patient's current symptoms. Still further, none of the current devices can be used to predict the onset of symptoms of various sleeping disorders and provide treatment in anticipation of such symptoms. Still even further, none of the current devices can be used to adjust a treatment device based on the subject's physiological signals.

It is therefore an object of the present invention to provide a system and method of treatment, which analyzes a subject's sleeping disorder or symptoms and adjusts a treatment device based, in part, on this analysis. It is still another object of the present invention to have a closed loop system or partly closed loop system or method, which automatically adjusts a treatment device based on analysis of a subject's sleeping disorder or symptoms. It is still another object of the present invention to provide a system or method for treating a subject's sleeping disorder or symptoms that is predictive. It is still further another object of the present invention to provide a system or method of treating a subject's sleeping disorder or symptoms that uses a subject's physiological signals, e.g., EEG, EKG, EMG, etc.

SUMMARY OF THE INVENTION

The present invention relates to an integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment
5 device. The present invention additionally relates to method of sleep diagnosis and treatment.

There are numerous embodiments of the present invention with a few of those listed below. The present invention further relates to a sleep diagnosis device integrated with a treatment device. The sleep disorder treatment system of
10 the present invention can use a diagnosis device to perform various forms of analysis to determine or diagnose a subject's sleeping disorder or symptoms of a subject's sleep disorder, and using this analysis or diagnosis can with or in some embodiments without human intervention treat the subject either physically or chemically to improve the sleeping disorder or the symptoms of the sleeping
15 disorder. The diagnostic part of the system can use many different types of sensors and methods for diagnosing the severity of the symptoms of or the sleep disorder itself. The treatment part of the system can use a device to physically or chemical treat the subject's symptoms or sleep disorder itself.

The diagnostic part of the system or device can use various sensors for
20 measuring the subject's brain wave signals, respirations and the like. Sensors for measuring the subject's brain wave signals include EEG electrodes and the like. Sensors for measuring the subject's respirations or oxygen levels include sensors to measure airflow, respiratory effort, oxygenation and ventilation, and the like. Measurement of airflow is preferably measured using sensors or devices such as a
25 pneumotachometer, strain gauges, thermal sensors, transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, and the like. These sensors or devices, also preferably measure nasal pressure, respiratory inductance plethysmography, thoracic impedance, expired carbon dioxide, tracheal sound and

the like. Measurement of respiratory effort is preferably measured by esophageal pressure, surface diaphragmatic EMG, and the like. Measurement of oxygenation and ventilation is preferably measured by pulse oximetry, transcutaneous oxygen monitoring, transcutaneous carbon dioxide monitoring, expired end carbon
5 dioxide monitoring, and the like.

Signals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject's sleep disorder and in some cases to diagnose the sleep disorder itself. One particular embodiment of the present invention involves diagnosing the level of severity of a subject's sleep apnea and
10 with or without human intervention adjusting an apparatus for providing positive airway pressure to the subject. The treatment device can be adjusted by either by a closed loop control system which uses, in part, the data or signals from the diagnosis device to actuate a physical or chemical treatment system for the subject, or an open loop control system which can alert a human who then adjusts
15 the treatment device based in part on the data or signals from the diagnosis device. Alternatively, signals from the sensors can be saved on a medium in order to be retrieved and analyzed at a later date. Media on which data can be saved include, but are not limited to chart recorders, hard drive, floppy disks, computer networks, optical storage, solid-state memory, magnetic tape, punch cards, etc.

20 The treatment device can be any device known to those skilled in the art. The treatment device can either physically or chemically treat the subject's sleeping disorder. An example of physically treating the subject's sleeping disorder would be a device to provide positive airway pressure to a subject. An example of chemically treating the subject's sleeping disorder would be to have a
25 medication reservoir where a drug is delivered to the subject in order to treat symptoms of the sleeping disorder. A few of the many embodiments of the present invention are as follows.

In one embodiment, the present invention includes a sleeping disorder

treatment system comprising a device for diagnosing and creating an output of a level of severity of a subject's sleeping disorder; and a device for physically or chemically treating a subject's sleeping disorder, which can be adjusted using the output of the level of severity of the subject's sleeping disorder.

5 In another embodiment, the present invention includes a sleep apnea treatment system comprising a device for diagnosing and creating an output of a level of severity of a subject's sleep apnea; and a continuous positive airway pressure (CPAP) device for treating the subject's sleep apnea, whose airflow rate can be automatically adjusted using the output.

10 In still another embodiment, the present invention includes a sleep apnea treatment system comprising a device for diagnosing sleep apnea comprising EEG sensors, and creating an output of a level of severity of a subject's sleep apnea; and a CPAP device for treating the subject's sleep apnea, which can be automatically adjusted using the output.

15 In still another embodiment, the present invention includes a sleeping disorder treatment system comprising a device for diagnosing and creating a output of a level of severity of a subject's sleeping disorder or symptoms, comprising at least two EEG electrodes for measuring the subject's electro-physiological signals; and a device for physically or chemically treating a
20 subject's sleeping disorder or symptoms, which can be adjusted using in part the output of the level of severity of the subject's sleeping disorder.

 In still another embodiment, the present invention includes a sleeping disorder treatment system comprising a device for diagnosing and creating a output of a level of severity of a subject's sleeping disorder or symptoms
25 comprising at least two ECG electrodes for measuring the subject's brain waves; and a device for physically or chemically treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output of the level of severity of the subject's sleeping disorder.

In still another embodiment, the present invention includes a sleeping disorder treatment system comprising a device for diagnosing and creating a output of a level of severity of a subject's sleeping disorder or symptoms comprising a sensor for measuring the subject's blood gases; and a device for
5 physically or chemically treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output of the level of severity of the subject's sleeping disorder.

Finally, in still another embodiment, the present invention includes a sleeping disorder treatment system comprising a device for diagnosing and
10 creating a quantitative output of a level of severity of a subject's sleeping disorder or symptoms comprising a pulse oximeter sensor; and a device for physically or chemically treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output of the level of severity of the subject's sleeping disorder.

15 Additional features and advantages of the invention will be set forth in the detailed description which follows, and in part will be readily apparent to those skilled in the art from that description or recognized by practicing the invention as described herein, including the detailed description which follows, the claims, as well as the appended drawings.

20 It is to be understood that both the foregoing general description and the following detailed description are merely exemplary of the invention, and are intended to provide an overview or framework for understanding the nature and character of the invention as it is claimed. The accompanying drawings are included to provide a further understanding of the invention, and are incorporated
25 in and constitute a part of this specification. The drawings illustrate various embodiments of the invention, and together with the description serve to explain the principles and operation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram an embodiment of part of the diagnostic device of sleeping disorder treatment system of the present invention.

5

FIG. 2 is a block diagram of an embodiment of the signal processing module of the sleeping disorder treatment system of the present invention.

FIG. 3 is a block diagram of an embodiment of a base station of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

10

FIG. 4 is a block diagram of an embodiment of a base station of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

15

FIG. 5 is a block diagram of an embodiment of the programming firmware in the signal processing module of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

20

FIG. 6 is a block diagram of an embodiment of the programming of the interrupt service routine in the firmware in the signal processing module of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

25

FIG.7 is a schematic view of a pressure support system.

FIG. 8 is a schematic view of one embodiment of the sleep disorder

treatment system of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

5 The present invention relates to an integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment device. The present invention additionally relates to various methods of an integrating sleep diagnosis and treatment.

 The sleep disorder treatment system of the present invention encompasses
10 numerous embodiments. Various embodiments of the present invention include a device for diagnosing and creating an output of a level of severity of the subject's sleeping disorder and/or symptoms. The present invention includes devices and sensors for diagnosing a subject's sleeping disorder and/or symptoms including
15 utilizing a subject's electro-physiological signals such as EEG, EKG, EMG, EOG and the like, a subject's blood gases such as CO² and O², and a subject's
respiratory patterns using an accelerometer, chest-motion detector and the like.

 Sleep apnea is defined as the cessation of breathing during sleep. There are three different types of sleep apnea: obstructive sleep apnea (OSA), central sleep apnea (CSA), and mixed sleep apnea (MSA). Of these three, OSA is the
20 most common; CSA is rare; mixed sleep apnea is a combination of the previous two with treatment being the same as OSA. Treatment of OSA and CSA vary substantially which makes a proper diagnosis of the correct type of sleep apnea (OSA or CSA) critical for an effective treatment.

 Obstructive sleep apnea is characterized by repetitive pauses in breathing
25 during sleep due to the obstruction and/or collapse of the upper airway (throat), usually accompanied by a reduction in blood oxygen saturation, and followed by an awakening to breathe. This is called an apnea event. Respiratory effort continues during the episodes of apnoea. Multiple episodes of Apnoea may occur

in one night, causing sleep disruption.

Central Sleep Apnea is defined as a neurological condition causing cessation of all respiratory effort during sleep, usually with corresponding decreases in blood oxygen saturation. The brainstem center controlling breathing
5 shuts down there's no respiratory effort and no breathing. This is in contrast with OSA where there is respiratory effort from the brain stem but a physical blockage prevents inhalation of oxygen. The subject is aroused from sleep by an automatic breathing reflex, so the subject may end up getting very little sleep at all. CSA, which is a neurological disorder, is very different in cause than OSA, which is a
10 physical blockage - though the effects are highly similar.

Mixed sleep apnoea, as the name suggests, is a combination of the OSA and CSA. An episode of mixed sleep apnoea usually starts with a central component and then becomes obstructive in nature. Generally the central component of the apnoea becomes less troublesome once the obstructive apnoea
15 is treated.

Sensors which can be used are known to those skilled in the art. These sensors include electrodes for measuring electro-physiological signals such as EEG, ECG, EMG, EOG and the like. These electro-physiological signals can be obtained by any method known in the art, or subsequently developed by those
20 skilled in the art to detect these types of signals. Sensors include but are not limited to electrodes or magnetic sensors. Since electro-physiological signals are, in general, electrical currents which produce associated magnetic fields, the present invention further anticipates methods of sensing those magnetic fields to acquire brain wave signals similar to those which can be obtained through, for
25 example, an electrode applied to the subject's scalp. The subject(s) referred to in the present invention can be any form of animal. Preferably the subject(s) are mammal, and most preferably human.

If electrodes are used to pick up the electro-physiological signals, these

electrodes for example when measuring brain wave or EEG signals may be placed at one or several locations on the subject(s)' scalp or body. The electrode(s) can be placed at various locations on the subject(s) scalp in order to detect EEG or brain wave signals. Common locations for the electrodes include frontal (F), parietal (P), anterior (A), central (C) and occipital (O). Preferably for the present invention at least one electrode is placed in the occipital position. In order to obtain a good EEG or brain wave signal it is desirable to have low impedances for the electrodes. Typical EEG electrodes connections may have an impedance in the range of from 5 to 10 K ohms. It is in generally desirable to reduce such impedance levels to below 2 K ohms. Therefore a conductive paste or gel may be applied to the electrode to create a connection with an impedance below 2 K ohms. Alternatively or in conjunction with the conductive gel, the subject(s)' skin may be mechanically abraded, the electrode may be amplified or a dry electrode may be used. Dry physiological recording electrodes of the type described in U.S. Patent Application 09/949,055 are herein incorporated by reference. Dry electrodes provide the advantage that there is no gel to dry out, no skin to abrade or clean, and that the electrode can be applied in hairy areas such as the scalp. Additionally if electrodes are used as the sensor(s), preferably at least two electrodes are used – one signal electrode and one reference electrode; and if further EEG or brain wave signal channels are desired, the number of electrodes required will depend on whether separate reference electrodes or a single reference electrode is used. For the various embodiments of the present invention, preferably an electrode is used and the placement of at least one of the electrodes is at or near the occipital lobe of the subject's scalp.

If electrodes are used to pick up the electro-physiological signals, these electrodes for example when measuring cardiac signals using an ECG, may be placed at specific points on the subject's body. The ECG is used to measure the rate and regularity of heartbeats as well as the size and position of the chambers,

any damage to the heart and in diagnosing sleeping disorders. As the heart undergoes depolarization and repolarization, electrical currents spread throughout the body because the body acts as a volume conductor. The electrical currents generated by the heart are commonly measured by an array of preferably 12 electrodes, placed on the body surface. Although a full ECG test usually involves twelve electrodes, for the purposes of a sleep study only two are required. These are placed on the subject's left-hand ribcage, under the armpit and on the right-hand shoulder, near the clavicle bone. An ECG is important as a tool to detect the cardiac abnormalities that can be associated with respiratory-related sleeping disorders. Preferably electrodes are placed on each arm and leg, and six electrodes are placed at defined locations on the chest. The specific location of each electrode on a subject's body is well known to those skilled in the art and varies amongst individual and different types of subjects. These electrode leads are connected to a device contained in the signal processing module of the present invention that measures potential differences between selected electrodes to produce electrocardiographic tracings.

There are two basic types of ECG leads: bipolar and unipolar. Bipolar leads (standard limb leads) utilize a single positive and a single negative electrode between which electrical potentials are measured. Unipolar leads (augmented leads and chest leads) have a single positive recording electrode and utilize a combination of the other electrodes to serve as a composite negative electrode.

Other sensors can be used to measure various parameters of a subject's respirations. The subject's respirations can be measured by measurement of airflow, respiratory effort, oxygenation and ventilation, and the like. Measurement of airflow is preferably measuring using sensors or devices such as a pneumotachometer, strain gauges, thermal sensors, transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, and the like. These sensors or devices, also preferably measure nasal pressure, respiratory inductance

plethysmography, thoracic impedance, expired carbon dioxide, tracheal sound and the like. Measurement of respiratory effort is preferably measured by esophageal pressure, surface diaphragmatic EMG, and the like. Measurement of oxygenation and ventilation is preferably measured by pulse oximetry, transcutaneous oxygen
5 monitoring, transcutaneous carbon dioxide monitoring, expired end carbon dioxide monitoring, and the like.

One example of such a sensor for measuring respirations either directly or indirectly is a respiration belt. Respiration belts can be used to measure a subject's abdominal and/or thoracic expansion over a measurement time period.
10 The respiration belts may contain a strain gauge, a pressure transducer or other sensors, which can indirectly measure a subject's respirations and the variability of respirations by providing a signal which correlates to the thoracic/abdominal expansion/contractions of the subject's abdominal cavity. Respiration belts may be placed at one or several locations on the subject's torso or in any other manner
15 known to those skilled in the art. Preferably, the respiration belts are positioned below the axilla and/or at the level of the umbilicus in order to measure rib cage and abdominal excursions. More preferably, if respiration belts are used then at least two belts are used one being positioned at the axilla and the other at the umbilicus.

20 Another example of such a sensor or method for measuring respirations either directly or indirectly is a nasal cannula or a facemask. The nasal cannula or facemask can be used to measure the subject's respiratory airflow. Nasal or oral airflow can be measured quantitatively and directly with a pneumotachograph consisting of a standard oxygen nasal cannula or facemask respectively connected
25 to a pressure transducer and placed in the nares or over the subject's mouth and nose respectively. Airflow can be estimated by measuring nasal or oral airway pressure that decreases during inspiration and increases during expiration. Inspiration and expiration produce fluctuations on the pressure transducer's signal

that is proportional to airflow. A modified nasal cannula or facemask may also be used which is connected to a carbon dioxide or oxygen sensor to measure respective concentrations of these gases. In addition a variety of other sensors can be connected with either a nasal cannula or facemask to either directly or
5 indirectly measure a subject's respirations.

Still another example of such a sensor or method of either directly or indirectly measuring respirations of the subject is the use of a pulse oximeter. The pulse oximeter can measure the oxygenation of the subject's blood by producing a source of light originating from the oximeter at two wavelengths
10 (650nm and 805nm). The light is partly absorbed by haemoglobin, by amounts which differ depending on whether it is saturated or desaturated with oxygen. By calculating the absorption at the two wavelengths the proportion of haemoglobin which is oxygenated can be estimated. Preferably, pulse oximeters are placed on a subject's earlob or fingertip. More preferably, the pulse oximeter is placed on
15 the subject's index finger.

Preferably, the signals from one or more of the aforementioned sensors are fed into some form of device with a processor or relayed to a processor for analyzing the one or more signals from these sensors through either a wireless system, a tethered system or some combination thereof.

20 One preferable embodiment of this device is a programmable wireless data acquisition system as shown in FIGS. 1-6 and described in more detail herein. This programmable wireless data acquisition system is used to receive the signals from one of more sensors and work with an internal or external processor to analyze the signals. Physiological data is transmitted between the physiological
25 sensors of types described above and the signal processing module using either wired but preferably wireless technology. Once processed, the physiological signals are transmitted wirelessly to the base station. Wireless signals are both received and transmitted via use of a preferably external antenna. Frequencies

used for transmission is primarily 902–928 MHz, but frequencies of 2.4–2.484 GHz, or Wireless Medical Telemetry Bands (WMTS), 608–614 MHz, 1395–1400 MHz, or 1429–1432 MHz can also be used. In addition, IR or Bluetooth wireless technology can be used for data transmission. The communication between the signal processing unit and base station can also, or in addition, be hardwired, instead of wireless. The physiological sensors are generally hard wired to the signal processing unit, but due to the ongoing evolution in wireless sensor technology, signals from physiological sensors will likely be transmitted wirelessly to the signal processing unit, or alternatively, directly to the base station having an integrated signal processing unit.

Referring now to the drawings and, in particular to FIG. 1, there is shown a block diagram of the present invention. An external input 12 from sensor 14 is input to signal processing module 16. Although, one sensor 14 and one external input 12 are shown, the signal processing module 16 is capable of accepting multiple external inputs 12 from multiple sensors 14. The signal processing module 16 generates a signal 18 encoded with data corresponding to the external input 12. The signal processing module 16 transmits the signal 18 by wireless means to a base station 40. In FIG. 1, the wireless means is shown as radio frequency (RF). In this case, the signal processing module generates a radio frequency signal 18 by frequency modulating a frequency carrier and transmits the radio frequency signal through module antenna 20. The base station 40 receives the radio frequency signal 18 through base antenna 42, demodulates the radio frequency signal 18, and decodes the data. It is understood that other wireless means can be utilized with the present invention, such as infrared and optical, for example. Although one module antenna 20 and one base antenna 42 is shown in this embodiment, it is understood that two or more diversity antennas

can be used and are included in the present invention. An external programming means 60, shown in FIG. 1 as a personal computer, contains software which is used to program the signal processing module 16 and the base station 40 through data interface cable 62. The data interface cable 62 is connected to the base station 40 and signal processing module 16 by respective connectors 64. The same data interface cable 62 or two different interface cables 62 can be used, one for the base station 40 and one for the signal processing module 16. The signal processing module 16 and the base station 40 can be programmed by connecting a data interface cable 62 between it and an external programming means 60 or by radio frequency (or other type) of signals transmitted between a base station 40 to the signal processing module 16 or to another base station 40. RF signals, therefore, can be both transmitted and received by both signal processing module 16 and base station 40. In this event the signal processing module 16 also includes a module receiver 29 while the base station 40 also includes a base transmitter 84, in effect making both the signal processing module 16 and the base station 40 into transceivers. In addition, the data interface cable 62 also can be used to convey data from the base station 40 to the external programming means 60. If a personal computer is the external programming means 60, it can monitor, analyze and display the data in addition to its programming functions. The base receiver 80 and module receiver 29 can be any appropriate receivers, such as direct or single conversion types. The base receiver 80 preferably is a double conversion superheterodyne receiver while the module receiver 29 preferably is a single conversion receiver. Advantageously, the receiver employed will have automatic frequency control to facilitate accurate and consistent tuning of the radio frequency signal 18 received thereby.

Referring now to FIG. 2, there is shown a block diagram of the signal processing module 16 with the sensor 14 and the module antenna 20. The signal processing module 16 comprises input means 22, analog-to-digital (A/D) means

24, a module microcontroller 26 with a nonvolatile memory, advantageously, an EEPROM 261, a module transmitter 28, a module receiver 29 and a module power supply 30. Although the module antenna 20 is shown externally located from the signal processing module 16, it can also be incorporated therein. The module antenna 20 may be a printed spiral antenna printed on a circuit board or on the case of the signal processing module 16 or other type of antenna. A module power supply 30 provides electrical power to the signal processing module 16 which includes the input means 22, A/D means 24, module microcontroller 26 module transmitter 28 and module receiver 29.

The input means 22 is adjustable either under control of the module microcontroller 26 or by means of individually populatable components based upon the specific external input 12 characteristics and range enabling the input means 22 to accept that specific external input 12. For example, if the input is a 4-20 mA analog signal, the input means 22 is programmed by the module microcontroller 26 and/or populated with the components needed to accept that range and characteristic of signals. If the input characteristics change the programming and/or components change accordingly but the same platform circuit board design is utilized. In other words, the same platform design is utilized notwithstanding the character, range, or quantity (number of external inputs 12) [up to a predetermined limit] of the input. For example, bioelectric signals such as EEG, EMG, EKG, and EOG have typical amplitudes of a few microvolts up to a few tens of millivolts. For a given application, a specific frequency band of interest might be from 0.1 Hz to 100 Hz, whereas another application may require measurement of signals from 20 Hz to 10 KHz. Alternatively, measurement of vital signs such as body temperature and respiration rate may deal with signals in a range of +5 volts, with a frequency content from DC (0 Hz) to 20 Hz. For other applications such as industrial process monitoring, the information of interest may be contained in the signal as a

current, such as a 4 to 20 mA current loop sensor, or it may take the form of resistance, impedance, capacitance, inductance, conductivity, or some other parameter, The present invention provides a single device for measuring such widely disparate signal types and presents distinct economic advantages, especially to small enterprises such as a medical clinic located in a rural area, which would be empowered by this invention to conduct tests which would otherwise have required patient travel to a large medical center, with all the attendant cost thereof.

This is possible due to the selectively adaptable input means 22 and A/D means 24, the frequency agile module transmitter 28 and base transmitter 84, and the programmability of the module microcontroller 26 and EEPROM 261. One universal platform design then can be utilized for all applications. In addition, the signal processing module can comprise multiple copies of the input means 22 and the A/D means 24. Cost savings can be achieved by multiplexing at several different points in the input means 22 and the A/D means 24 allowing hardware to be shared among external inputs 12.

After receipt by the input means 22, the external input 12 is inputted to the A/D means 24. The A/D means 24 converts the input to a digital signal 32 and conditions it. The A/D means 24 utilizes at least one programmable A/D converter. This programmable A/D converter may be an AD7714 as manufactured by Analog Devices or similar. Depending upon the application, the input means 22 may also include at least one low noise differential preamp. This preamp may be an INA126 as manufactured by Burr-Brown or similar. The module microcontroller 26 can be programmed to control the input means 22 and the A/D means 24 to provide specific number of external inputs 12, sampling rate, filtering and gain. These parameters are initially configured by programming the module microcontroller 26 to control the input means 22 and the A/D means 24 via input communications line 35 and A/D communications line 36 based upon

the input characteristics and the particular application. If the application changes, the A/D converter is reconfigured by reprogramming the module microcontroller 26. In this manner, the input means 22 and the A/D means 24 can be configured to accept analog inputs of 4-20 mA, +/-5 volts, +/-15 volts or a range from +/-
5 microvolts to millivolts. They also can be configured to accept digital inputs, for detection of contact closure, for example.

The module microcontroller 26 controls the operation of the signal processing module 16. In the present invention, the module microcontroller 26 includes a a serial EEPROM 261 but any nonvolatile memory (or volatile memory
10 if the signal processing module remains powered) can be used. The EEPROM 261 can also be a separate component external to the module microcontroller 26. Advantageously, the module microcontroller 26 may be PIC16C74A PIC16C74B or a PIC16C77 both manufactured by MicroChip, or an Amtel AT90S8515 or similar. The module microcontroller 26 is programmed by the external
15 programming means 60 through the connector 64 or through radio frequency signal from the base station 40. The same module microcontroller 26, therefore, can be utilized for all applications and inputs by programming it for those applications and inputs. If the application or inputs change, the module microcontroller 26 is modified by merely reprogramming. The digital signal 32 is
20 inputted to the module microcontroller 26. The module microcontroller 26 formats the digital signal 32 into a digital data stream 34 encoded with the data from the digital signal 32. The digital data stream 34 is composed of data bytes corresponding to the encoded data and additional data bytes to provide error correction and housekeeping functions. Advantageously, the digital data stream
25 34 is organized in data packets with the appropriate error correction data bytes coordinated on a per data packet basis. These packets can incorporate data from a single input channel or from several input channels in a single packet, or for some applications may advantageously include several temporally differing

measurements of one or a plurality of input channels in a single packet. The digital data stream 34 is used to modulate the carrier frequency generated by the transmitter 28.

The module transmitter 28 is under module microcontroller 26 control.

5 The module transmitter 28 employs frequency synthesis to generate the carrier frequency. In the preferred embodiment, this frequency synthesis is accomplished by a voltage controlled crystal reference oscillator and a voltage controlled oscillator in a phase lock loop circuit. The digital data stream 34 is used to frequency modulate the carrier frequency resulting in the radio frequency signal
10 18 which is then transmitted through the module antenna 20. The generation of the carrier frequency is controlled by the module microcontroller 26 through programming in the EEPROM 261, making the module transmitter 28 frequency agile over a broad frequency spectrum. In the United States and Canada a preferred operating band for the carrier frequency is 902 to 928 MHz. The
15 EEPROM 261 can be programmed such that the module microcontroller 26 can instruct the module transmitter 28 to generate a carrier frequency in increments between 902 to 928 MHz. as small as about 5 to 10 KHz. In the US and other countries of the world, the carrier frequency may be in the 2400 to 2483.5 MHz. band, 5.725 to 5.875 GHz. band, or the 24.0 to 24.25 GHz. band, or other
20 authorized band. This allows the system to be usable in non-North American applications and provides additional flexibility.

The voltage controlled crystal oscillator (not shown) in the module transmitter 28, not only provides the reference frequency for the module transmitter 28 but, advantageously also, provides the clock function 38 for the
25 module microcontroller 26 and the A/D means 24 assuring that all components of the signal processing module 16 are synchronized. An alternate design can use a plurality of reference frequency sources where this arrangement can provide certain advantages such as size or power consumption in the implementation.

The module receiver 29 in the signal processing module 16 receives RF signals from the base station 40. The signals from the base station 40 can be used to operate and control the signal processing module 16 by programming and reprogramming the module microprocessor 26 and EEPROM 261 therein.

5 The base station 40 has a base antenna 42 through which RF signals 18 are received. Base microcontroller 86 controls the operation of the base station 40 including base receiver 80, base transmitter 82, and base power supply 88. Base receiver 80 receives the RF signal 18 from base antenna 42. The base receiver 80 demodulates the RF signal 18 and the base microcontroller 86 removes any error
10 correction and performs other housekeeping tasks. The data is then downloaded through connector 64 to the external programming means 60 or other personal computer (PC) or data storage/viewing device for viewing in real time, storage, or analysis.

Referring now to FIG. 4, there is shown a block diagram of the input
15 means 22 and A/D means 24 of the signal processing module 16, which provides for the data acquisition function of the present invention. The signal processing module 16 is variably configurable through software programming initiated by the external programming means 60 to the EEPROM 261 of the microcontroller 26. The variable configurability enables the signal processing module 16 to receive
20 external inputs 12 having different characteristics and ranges and to provide variable sampling rate, filtering and gain of the external inputs 12 based upon such characteristics and range and/or the specific application. For example, if the present invention is utilized in a biomedical environment, EEG diagnosis and monitoring for instance, the sampling rate will need to be much higher than it
25 would be for an industrial setting measuring thermocouple readings. The ability to reconfigure the system for varying signal characteristics arises at three separate levels in the present invention. For maximum flexibility, such reconfiguration can be carried out during a series of measurements by means of the wireless link,

which is understood in this context to be bidirectional. Depending on the characteristics of the received signal 18, the base station 40 can command the signal processing module 16 to reconfigure the input means 22 and/or A/D means 24 to accept an external input 12 of larger amplitude, or a different frequency range, where signal characteristics change significantly during the course of a series of measurements. Alternatively, for cost, size, and power advantages, this adjustment could be carried out prior to a series of measurements, with the configuration information stored in memory in the signal processing module 16, where this memory is advantageously implemented in a nonvolatile form such as EEPROM 261, allowing the configuration information to be retained, for instance, across power outages and obviating the need for module receiver 29 and base transmitter 84, saving cost. A third alternative, which provides advantages in certain technical parameters, is to arrange the implementation of the signal processing module 16 such that minor changes in component values or parameters can reconfigure the same basic hardware to accept widely divergent external input 12 types. This reconfiguration could take place at the factory, providing cost and inventory advantages to the manufacturer, or it could be performed by the end user, providing similar cost advantages to the user in allowing one piece of equipment to perform multiple tasks.

A number of configurable components are shown in FIG. 4. Any given component of this arrangement, though, may be omitted, and, in some cases, the order of the components may be changed to gain certain advantages such as physical size, power consumption, or cost, without changing the basic spirit of the invention. Components in this FIG. 4 may be combined, either by having a single component carry out the function of two or more of the components shown or by combining functions within a single package such as an integrated circuit or hybrid module. Certain components may also operate with a fixed configuration, limiting the flexibility of certain parameters while retaining the advantages of

configurability in other components.

The external input 12 inputs to the input protection network 221, which protects the signal processing module 16 against damage caused by faults or unanticipated conditions encountered at the external inputs 12. Depending on the
5 rigors expected to be encountered in any given application and the tolerance to size and weight, the input protection network 221 may be omitted, may consist of a simple resistor network, or may include more elaborate protection such as diodes, zener diodes, transorbs, gas discharge tubes, and other components commonly known to those of ordinary skill in the art. Typically, the input
10 protection network 221 is not configurable but its configurability in the present invention provides advantages in certain applications. Configuration options can include adjustable limits on input voltage and/or current as well as rates of change of those parameters, and other electrical parameters as well. These configuration changes can be achieved by changes to component values on a common platform
15 for smallest size, or can be changed under processor control by means of various switches such as relays. A signal within normally expected ranges passes essentially unchanged to the measurement type means 222.

The measurement type means 222 allows selection of the external input 12 configuration. The measurement type means 222 may be used to configure the
20 input circuitry to accept external inputs 12 which are single-ended voltage (a voltage with respect to a common reference shared between several signals), differential voltage (voltage between two defined conductors), differential current (current flowing through a conductor), single-ended current (current flowing to a common reference), frequency, capacitance, inductance, resistance, impedance,
25 conductivity, or any other electrical parameter. The measurement type means 222 converts the external input 12 to a common parameter such as voltage or current, which can be interpreted by the succeeding blocks regardless of the original type of external signal 12 measured. One input channel can be built with several

different measurement type means, which can be selectively enabled by means of an analog switch, such as that found in the AD7714 chip in the present invention. It is understood that the AD7714 chip can provide many of the functions of the A/D means 24 and the input means 22 thus reducing the overall size of the signal processing module 16. In the preferred embodiment, the output of the measurement type means 222 is a varying voltage carrying the information which was present in the original signal, or in certain cases, a series of voltage measurements, which are then conveyed to the prefilter 223.

The prefilter 223 allows rejection of external inputs 12 of large signals which are outside the frequency band of interest, so that such signals do not saturate the low-noise preamplifier 224. The prefilter 223 can be advantageously arranged to be a relatively simple filter to provide cost, size, and power advantages, because it need only reject out of band signals to the extent necessary to protect the low-noise preamplifier 224. A typical application might use a simple "R-C" filter to reject offset voltages in an AC-coupled application, or to reject extremely high frequencies which fall well beyond the frequency band of interest, or a combination of the two. Configurability of this section can be limited to simply enabling or bypassing the prefilter 223, or may be more elaborate in allowing selection of cutoff frequencies. In the preferred embodiment this prefilter consists of a simple RC filter which can be bypassed under firmware control, to minimize noise injection; however, an alternate embodiment could incorporate electrically adjustable components such as electronic potentiometers or varactors to provide even more flexibility at the expense of size and noise injection. The prefiltered signal is then passed to the low-noise preamplifier 224.

The low-noise preamplifier 224 is advantageous in certain applications to allow application of gain to the external input 12 early in the signal chain, before significant noise is introduced by the inherent characteristics of certain components, such as thermal noise. Configurability of the gain applied at this step

provides an advantage in allowing the present invention to accept larger external inputs 12 using a low gain (unity gain or lower), or alternatively to accurately measure very small external inputs 12 with minimal noise by using higher gain. This gain can be selectively chosen to be either a fixed value or unity gain under processor control by means of the signal selector built into the AD7714 used in the preferred embodiment, or can be designed to allow a selection of one of several gains by means of analog switches combined with a plurality of gain setting resistors. Gain applied at this stage has the net effect of dividing any downstream noise by the gain factor applied here. This more robust signal output by the preamplifier 224 is then passed to the AC coupling filter 225.

The AC coupling filter 225 is a highpass filter used to allow the system to reject the DC offset or steady state value of an external input 12 wherein the offset is not of interest, allowing additional gain to be applied to the changes in the external input 12. For instance, bioelectric signals such as EEG, EMG, or ECG are normally of interest only for the changes in those signals, and the absolute offset level is not of interest for diagnostic purposes. The cutoff frequency may be configured to allow adjustment of various parameters such as settling time, or may be adjusted to zero to effectively bypass the AC coupling filter 225. In the preferred embodiment, the filter may be bypassed by use of the signal selector switch in the AD7714; however, the use of adjustable components such as electronic potentiometers or varactors would allow more flexibility in choosing the cutoff frequency, at the expense of size and power consumption. The resulting signal, now stripped of any interfering DC offset if so configured, is then passed to the antialias filter 226.

The antialias filter 226 is a lowpass filter required to guard against false signals caused by aliasing between external input 12 content and sampling rate of downstream sampling functions such as multiplexing or analog-to-digital conversion. The Nyquist sampling theorem shows that any frequency content in

the sampled signal which is higher than one-half the sampling rate of the sampling function will cause aliasing, which results in false signals. In practice the antialias filter 226 is more commonly set to a smaller fraction of the sampling rate, usually between 1/4 and 1/10 the sampling rate. Regardless of the rate or ratio used, the cutoff frequency of the antialias filter 226 must change when the sampling rate changes significantly, to retain the most advantageous ratio of the sampling rate to the filter passband. The programmable cutoff frequency of the antialias filter 226 is thus required to allow for variable sampling rates. In the preferred embodiment, the high sampling rate of the delta sigma modulator in the AD7714 permits the use of a simple fixed RC type filter, with the antialias filtering begin provided as an inherent digital filter in the AD7714; however, an alternate embodiment might use a switched capacitor filter such as the MAX7409 or other filter with a programmable cutoff frequency. The resulting filtered signal is then conveyed to the programmable gain amplifier 241 in the A/D means 24.

The programmable gain amplifier 241 adjusts the external input 12 amplitude to match the amplitude accepted by the A/D converter 242. In the preferred embodiment this programmable gain amplifier is included in the AD7714 integrated circuit, but this function could also be provided with a dedicated programmable gain amplifier, or alternatively through the use of analog switches or adjustable components such as potentiometers or DACs. If too much gain is applied, the programmable gain amplifier 241 itself or downstream components will saturate, introducing severe distortion and usually rendering the external input 12 unmeasurable. If, on the other hand, insufficient gain is applied here, the quantization noise of the analog-to-digital conversion process comes to dominate the external input 12, causing a severe degradation in the signal-to-noise ratio. For instance, a typical 16-bit A/D converter 242 can distinguish between 2.sup.16 or 65536 distinct levels. With an A/D converter 242 input range of .+-.3 volts, each level represents 92 .mu.V. If insufficient gain is applied to the

external input 12 such that the total signal swing is only 200 μV , the A/D converter 242 will convert at most three distinct levels, rendering fine features of the external input 12 totally illegible. The module microcontroller 26 therefore adjusts the gain applied in the programmable gain amplifier 241 such that the
5 expected external input 12 as processed and filtered by the preceding elements as described above, is amplified to cover as much of the A/D converter 242 input range as practical, or some other gain which optimizes signal features of interest. Additionally, in some applications it is advantageous to have the module microcontroller 26 adjust this gain dynamically depending upon the actual
10 measured external input 12. For instance, the module microcontroller 26 might increase the programmable gain amplifier 241 gain when a measured external input 12 is very small, and then decrease the gain to avoid saturation when the external input 12 amplitude increases. This automatic gain control provides an increase in the total dynamic range achievable by the system without requiring
15 expensive, large, and power-hungry components such as very high resolution A/D converters 242. The signal resulting from application of the specified gain is then passed to the A/D converter 242.

At least two parameters of a typical A/D converter 242 can be readily adjusted to achieve various goals as the situation dictates. First, the sampling rate
20 may be adjusted to balance the conflicting goals of high fidelity measurements and low digital data rate. Where a signal has no high frequency content of interest, the sampling rate may be adjusted to a very low rate to minimize the demands on downstream processes such as digital filtering or telemetering of the data. On the other hand, sampling an external signal 12 with significant high-frequency
25 content of interest demands a higher sampling rate. In the preferred embodiment, the sampling rate is programmable via the AD7714; in other implementations the sampling rate can be made adjustable by means of an externally applied sampling clock to an A/D converter. The adjustable sampling rate allows the controller to

adapt the A/D converter 242 to best meet the system demands of the moment.

In a similar fashion, selection of the resolution provided by the A/D converter 242 must balance faithful reproduction of the external input 12 against total digital data rate. Depending on the particular A/D converter 242 used, there may also be a tradeoff of the maximum achievable sampling rate against the selected resolution, wherein selection of a higher resolution lowers the maximum attainable sampling rate. Again the module microcontroller 26 can adjust this parameter to best meet the system requirements, selecting higher resolution when smaller changes in the measured signal amplitude must be reported, and lower resolution when the lack of such a requirement allows advantages in the form of either a higher sampling rate or a lower digital data rate. In the preferred embodiment, the AD7714 can be programmed to either 16 bit or 24 bit resolution, and the firmware running in the microcontroller can selectively transmit 8, 12, 16, or 24 bits of the acquired data. The digital filter 243, the module microcontroller 26, or other downstream process can also reject certain portions of the digital data stream to provide an effective decrease in resolution where this decrease is advantageous, especially when the data must later cross a bandwidth-limited link such as a RF, IR or optical link. The A/D converter 242 passes the signal, now in the form of a succession of digital values, to the digital filter 243 for further processing.

The digital filter 243 extracts external input 12 parameters of interest while rejecting other signals, commonly referred to as noise. Implementation of the digital filter 243 could alternatively be in the form of analog filters applied anywhere in the signal chain prior to the A/D converter 242, but implementation as a digital filter 243 provides advantages as to programmability, calibration, drift, and accuracy. The digital filter 243 could be implemented in many forms, depending upon the demands of the particular application. In the preferred embodiment, the digital filter is inherent in the analog to digital conversion

process inside the AD7714, but it is understood that the digital filter 243 could be implemented as firmware inside the module microcontroller 26 itself, or as a digital signal processor, or as a specialized integrated circuit, or by some other means. Regardless of implementation, the programmability of the digital filter
5 243 allows the system to readily adapt to changing measurement requirements, whether those changes are brought about by changes in the environment, changes in the external input 12 itself, or changes in the focus of the overall system. The resulting output from the digital filter 243 is a stream of digital values, ready for further processing such as assembly into the desired format for transmission by
10 the firmware.

Referring now to FIG. 5 there is shown a block diagram of the firmware of the present invention. The signal processing module 16 firmware defines several modes of operation 100. There are several "test" modes which are used during factory calibration of the device. In addition, there are several operation modes
15 which have mode-specific configuration. For example, the signal processing module 16 can be programmed to operate in a first operational mode in which it transmits calibration data (used to properly zero the analog inputs) for the first three seconds of operation (or for some other predetermined time), and then switches to a second operational mode which transmits analog signal information
20 as collected from the A/D converters 242. The configuration for each mode of operation is programmed in the non-volatile memory EEPROM 261.

Once power is first applied to the signal processing module 16, the module microcontroller 26 performs the basic device initialization, including proper configuration of the I/O ports and internal variables 102. Next, the module
25 microcontroller 26 reads the initial device configuration 104 from the EEPROM 261. This configuration controls the input means 22 of the signal processing module 16, including the number of external inputs (also herein referred to as channels), the resolution of the A/D converter 242, and the sampling rate of each

individual input channel. This configuration also controls the operation of the module transmitter 28 in the signal processing module 16, including the carrier frequency, modulation type, output power control, and the length in bytes of each transmitted RF message packet. This configuration also describes the initial mode
5 of operation for the signal processing module 16.

Once the initial configuration has been read, the module microcontroller 26 enters the first mode of operation described in the configuration. It reads the mode-specific configuration 106, which includes the state of the module transmitter 28 and the analog inputs as used in the mode. This configuration can
10 reside in EEPROM 261 or in module microcontroller 26 memory. The module microcontroller 26 then initializes all the peripheral devices according to this mode configuration 108. In the special case that this is the "shutdown" mode, the module microcontroller 26 will perform a software power-down 110.

Once the mode has been initialized, the module microcontroller 26 begins
15 execution of the interrupt service routine (ISR) 112, which is responsible for transmitting the data in the form of messages along the modulated RF carrier. Operation of the interrupt service routine is asynchronous and distinct from the mainline code, and is described later.

The module microcontroller 26 begins execution of the mode-specific
20 "opcodes" 114, which are a sequence of instructions contained either in EEPROM 261 or in the module microcontroller 26 memory. These opcodes are performed for each operational mode. The module microcontroller 26 reads the first operational code from the EEPROM 261 and interprets the opcode, performing an appropriate action: If the opcode instructs the module microcontroller 26 to
25 change modes 116, the module microcontroller 26 terminates the ISR 118 and returns to the mode initialization, and begins execution of a new operational mode; if the opcode instructs the module microcontroller 26 to begin a loop construct 120, the module microcontroller 26 begins the loop by initializing a

loop counter variable 122; if the opcode instructs the module microcontroller 26 to end a loop construct, the module microcontroller 26 increments the loop counter variable and determines if the loop is complete 124. If not, the module microcontroller 26 resets the index of current opcode to the beginning of the loop, otherwise it sets the index of the next opcode to after the loop; if the opcode instructs the module microcontroller 26 to initialize a single A/D converter 242, the module microcontroller 26 will perform the specified calibration 126; if the opcode instructs the module microcontroller 26 to read a single A/D converter 242, the module microcontroller 26 will take the reading and insert the data into the current message to be transmitted over the RF carrier 128; if the opcode instructs the module microcontroller 26 to insert a special byte of data into the RF message, the module microcontroller 26 will insert this data into the message 130. This special message byte may include an identifier to uniquely identify the signal processing module 16, an error check field such as a cyclic redundancy check, or some data representing the internal state of the signal processing module 16 such as the RF frequency, measured temperature, etc.

After each opcode has been read and interpreted, the module microcontroller 26 determines if the RF message has been completely filled and is ready to be transmitted over the RF carrier 132. If it has, the module microcontroller 26 marks a flag variable for the interrupt service routine to begin transmitting the RF message 134.

Next, the module microcontroller 26 performs any housekeeping tasks, such as updating the RF tuning parameters based on changes in temperature, updating timers, etc. 136. Finally, the module microcontroller 26 returns to execute the next opcode in the sequence 114.

Referring now to FIG. 6 there is shown a block diagram of the software programming function of the ISR 150. The ISR is responsible for transmitting the individual message bytes over the RF carrier. The ISR is executed by a hardware

interrupt which occurs immediately before every byte to be transmitted over the RF carrier. The ISR detects whether an RF message is completely filled 152. If the ISR detects (based on the flag variable) that an RF message is not yet completely filled by the main code, the ISR transmits a "filler" byte, or a byte
5 with an even number of "1" and "0" bits 154. This acts to maintain an even (50%) modulation duty cycle on the carrier frequency.

Once the ISR detects that the main code has filled an RF message to be transmitted, it transmits the RF sync bytes 156. These are two unique bytes transmitted at the beginning of every RF message which are easily identified by
10 the base station 40 as the start of a message.

Once the RF sync bytes have been transmitted, the ISR transmits each message byte of the RF message, in sequence 158. Once the RF message has been completely transmitted 160, the ISR resumes transmitting filler bytes until the next RF message is filled by the main code.

15 Because of the phase locked loop based frequency synthesizer used in the present invention, the module transmitter 28 and base transmitter 84 are frequency agile over the frequency range. Since the module receiver 29 and the base receiver 80 employ automatic frequency control, the present invention consumes relatively low power as the module transmitter 28 and base transmitter 84 can be
20 intermittently powered down without losing reception due to drift or sacrificing data transmission accuracy. The utilization of programmable firmware allows inexpensive and flexible operation for the inputting, conditioning and processing of any type, character and range of the external inputs. This also allows the module microcontroller 26, in response to the variation of the external inputs 12
25 or, in response to instructions received by RF signal through the module receiver 29, to adapt the signal processing module 16 based upon the variations allowing the signal processing means 16 to input, condition, process and transmit said external input notwithstanding said variation. The present invention performs this

adaptation without the need to modify or alter hardware or select or use different hardware already present in the device. In other words all adaptation can be accomplished by software programming totally.

One or more sensors are used to develop the data or signals used in the present invention for determining a quantitative level of severity of a subject's sleeping disorder and/or symptoms. In various embodiments, preferably at least two EEG electrodes are used to develop this data. In other embodiments, preferably, at least two ECG electrodes are used. In still other embodiments, preferably a pulse oximeter is used. In still even other embodiments, preferably, either an O² or CO² blood gas monitor is used.

The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms. Using either the microcontroller 26 of a data acquisition system, a separate computer, base station or processor, a PDA, a processor on a device for treating the subject's sleeping disorder or a combination of these processors, the severity of the subject's sleeping disorder and/or symptoms is determined and is used at least in part to regulate the physical or chemical treatment of the subject. Also optionally, the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.

The processor or microprocessor of various embodiments of the present invention can be part of a remote communication station or base station. The remote communication station or base station can also be used only to relay a pre- or post-processed signal. Preferably, the remote communication station or base station can be any device known to receive RF transmissions such as those transmitted by the wireless data acquisition system described herein. The remote communication station or base station by way of example but not limitation can

include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the remote communication station can further transmit data both to another device including the subject's treatment device and/or back. Further optionally, two different remote communication stations can be used, one for receiving transmitted data and another for sending data. For example, with the sleep diagnosis and treatment system of the present invention, the remote communication system of the present invention can be a wireless router, which establishes a broadband internet connection and transmits the physiological signal to a remote internet site for analysis, preferably for further input by the subject's physician or another clinician. Another example is where the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis. Another example is where the remote communication system is a computer or processor, which receives the data transmission and displays the data or records it on some recording medium, which can be displayed or transferred for analysis at a later time.

The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein. More preferably, this quantitative method is accomplished in real-time, allowing the subject's symptoms to be treated as they occur. By real-time it is meant that the quantitative diagnosis step is accomplished predictively or within a short period of time after symptoms occur which allows for immediate treatment, thereby

more effectively reducing the health affects of such disorder while at the same time also minimizing side effects of the treatment chosen. By real-time, preferably the diagnosis is accomplished within 24 hours of receiving the signals from the one or more sensors on the subject, more preferably within 8 hours, even
5 more preferably within 4 hours, still even more preferably within 1 hour, still even more preferably within 20 minutes, still even more preferably within 5 minutes, still even more preferably within 1 minute, still even more preferably within 10 seconds, still even more preferably within 1 second, still even more preferably within 0.1 seconds and most preferably within 0.01 seconds.

10 Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms. This filtered data is then is preferably analyzed using the techniques described in the following paragraph In addition to these sleeping disorder data or signal analysis techniques various controller
15 schemes can be used.

Various sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data. Various embodiments of the present invention include the approach to identifying these symptoms prior to onset by identifying various characteristic shifts in the power spectrum of the
20 sensors being used to monitor these physiological conditions. This characteristic shift in these signals or data can be identified and used to trigger an actuator on the physical or chemical treatment device(s) to provide for delivery of a certain level of treatment. The various embodiments of the present invention include but are not limited to the following signal-processing techniques that are utilized to
25 predict the onset of these symptoms. These are: (i) the standard deviation technique, (ii) a recursively fit ARMAX system identification model, (iii) the Short-Time Fourier Transform (SFFT) technique, and (iv) time-frequency signal analysis with a variety of different kernels. The present invention would also

include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis, which is similar to time-frequency analysis with a particular kernel function, to identify the shift in power spectrum associated with imminent flow separation that is discussed herein.

5 The standard deviation technique operates on the principle that there is an increase in pressure fluctuation as the flow begins to separate from the surface of an airfoil, due to either increasing angle of attack or unsteady flow. A sharp increase in the standard deviation of pressure data is observed immediately prior to stall. To trigger the deployment the flow effectors and initiate fluid flow
10 control, a threshold standard deviation can be calculated for each pressure sensor and programmed into the control strategy.

 The second embodiment of a method to identify the shift in measured power spectrum of the signal from the pressure transducer to identify stall utilizes a recursively identified system model, particularly an Auto-Regressive Moving
15 Average (ARMA) model. Advantageously, the controller is the *ORICA*TM controller, an extended horizon, adaptive, predictive controller, produced by Orbital Research, Inc. and patented under U.S. Patent No. 5,424,942, which is incorporated herein by reference. The ARMA recursive identification method attempts to fit specific models to the measured data or signals. Evaluation of this
20 data reveals distinct, identifiable model order shifts based, which can be used to actuate the treatment device at various levels. Further analysis of the frequency spectrum of the physiological data related to various sleeping disorders reveals recognizable changes in this data or signals. This clear characterization alongside the model order shifts allows the *ORICA* identifier to classify discrete models
25 based upon various physiological conditions of the subject, thus allowing precisely controlled treatments to be delivered to the subject or patient. A simple function minimization based upon the error associated with each model will enable adaptive model selection for the subject's physiological condition. As the

subject's physiological conditions moves toward various critical conditions or symptoms, the model with the best fit to the data will shift into a higher order model. This model shift foretells the onset of the symptom. A second sub-method of identifying impending symptoms using the ARMA and other related
5 models is to track the poles of the identified system model based on the subject over time. As the subject's physiological condition moves toward certain designated critical symptoms, the poles of the identified system model will move toward a condition of symptom onset, thereby indicating to the control system that certain critical symptoms are impending. Either of these two signal
10 identification techniques based on fitting a mathematical model to the system can be utilized to predict the onset of the subject's symptoms. The ARMA model can be adapted to resemble other canonical model forms thereby demonstrating similarity to other system identification methods based on Kalman filtering and similar approaches.

15 A third embodiment of a method for quantifying the power spectrum measured by the one or more sensors is by using Short-Time Fourier Transforms (STFT). A Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT), both provide frequency information of a digitized signal or data from the sensors. The DFT and FFT both
20 assume that the signal that is being measured is stationary in time. However, in the case of the subject being tested and treated, the measured signal or data is not stationary in time, which means a typical DFT / FFT approach is inapplicable. However, for short time periods the signal maybe considered to be stationary. Therefore, it is possible to estimate the mean power spectrum by segmenting the
25 physiological data or signals into epochs lasting anywhere from 0.1-5 seconds each, and then applying a discrete-time Fourier transform (DFT) to the windowed data. The DFT is used to calculate the power spectrum of the signal for that epoch. Then the spectral mean and median density are calculated from the power

spectrum of the signals from each epoch. Using this method it is possible to identify specific frequency content in the data. As the subject begins to experience the onset of various critical symptoms, the frequency spectrum of the measured and analyzed data will shift, which indicates to the control system that the symptom is beginning.

A fourth embodiment of a signal processing method which can provide indications to the control system that various symptoms are impending, to enable either actuation of the treatment device, is to analyze the sensor data using a time-frequency transform. A time-frequency transform enables both frequency resolution and estimation stability for highly non-stationary signals, which typifies some types of such as some of the data or signals related to various physiological conditions. This is accomplished by devising a joint function of both time and frequency, a distribution that describes the energy and density of a signal simultaneously in both time and frequency. The general form of the time-frequency transform is given by the following

$$P(t, w) = \frac{1}{4\pi^2} \iiint e^{-j\theta t - j\tau\omega + j\theta u} \phi(\theta, t) \cdot s^*\left(u - \frac{1}{2}\tau\right) s\left(u + \frac{1}{2}\tau\right) du d\tau d\theta$$

This transform can be used to calculate instantaneous power spectra of a given signal. The actual transformation distribution is selected by changing the kernel, $\Phi(\theta, \tau)$. The function [e-1] is interesting since it is possible to identify any distribution invariant to time and frequency shifts by means of its kernel, and the properties of the kernel are strictly related to the properties of the distribution, given by [e-1].

The diagnostic device of the present invention is used to provide an output which is then used either automatically to adjust the treatment device or by a clinician or the subject to adjust the device which provides the physical or

chemical treatment device which is another part of the system of the present invention. There are clearly many embodiments of the present invention, and we will attempt to describe a few herein.

Various embodiments of the present invention include a device for
5 physically or chemically treating a subject's sleeping disorder, which can be adjusted using the output of the level of severity of the subject's sleeping disorder. Physical and chemical methods to treat sleeping disorders are known to those skilled in the art. With the sleep disorder treatment system of the present invention those as well as new physical and chemical treatments can be used and
10 developed for treating a subject's sleeping disorder because the system of the present invention allows for direct treatment of the disease and particularly of symptoms as they occur. Physical methods to therapeutically treat sleeping disorders and symptoms of these disorders include continuous positive airway pressure (CPAP), electrical stimulation of the muscles and nerves, and the like.
15 Chemical methods to therapeutically treat sleeping disorders and symptoms while less common include various pharmaceutical agents with various delivery techniques including oral delivery, injection, transdermal delivery, injection with a controlled pump, inhalation therapy and the like.

The present invention is envisioned to be particularly valuable in the
20 treatment of sleep apneas. With the present invention it is envisioned that modifications can be made to a subject's treatment regiment as the severity or level or the subject's symptoms increase or decrease better regulating the therapeutic treatment of the subject's sleeping disorder. For example, with a subject who has sleep apnea, delivery of a physical treatment such as CPAP can
25 be adjusted during the treatment based on the sleep diagnosis results. The CPAP machine would preferably be set up to receive some type of signal, which would cause an adjustment in the flow rate or pressure of the breathing gas being delivered to the subject.

FIG. 7 shows a schematic view of one embodiment of a device that can be used to physically treat a subject's sleep disorder, which can be further adjusted using the output of the level of severity of the subject's sleeping disorder. More particularly, FIG. 7 shows a particular type of physical treatment device known as continuous positive airway pressure (CPAP) device. This conventional pressure support system 310 shown in FIG. 7 includes a pressure generator 312, a blower, piston or bellows, that receives a supply of gas from a gas source, such as ambient atmosphere, as indicated by arrow A, or pressurized gas tanks (not shown) and creates a flow of breathing gas, as indicated by arrows B, having a pressure greater than the ambient atmospheric pressure. A patient or subject circuit 314, which is typically a flexible conduit, delivers the elevated pressure breathing gas to the airway of the subject. Typically the subject circuit is a single limb conduit or lumen having one end coupled to the pressure generator and a patient interface device 316 coupled to the other end.

The subject interface device 316 connects the subject circuit 314 with the airway of the subject so that the elevated pressure gas flow is delivered to the subject's airway. Examples of subject interface devices include but are not limited to nasal masks, nasal and oral masks, full face masks, nasal canulas, oral mouthpieces, tracheal tubes, endotracheal tubes, hoods and the like. The single limb subject circuit shown in FIG. 7 also includes an exhalation port 318, also commonly referred to as an exhalation vent, exhaust port, or exhaust vent, to allow gas, such as expired gas from the subject, to exhaust to the atmosphere, as indicated by arrow C. Generally, the exhaust vent 318 is located in the subject circuit 314 near the subject interface device 316 or in the subject interface device itself.

A more sophisticated pressure support device of the present invention includes a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit 314. The flow information

can also be used to determine the volume of gas passing through the subject circuit 314. The information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to control the pressure or flow of gas provided to the subject, monitor the condition of the subject, monitor the usage of the pressure support device, any combination thereof, or the like.

FIG. 8 shows a schematic view of one embodiment of the sleep disorder treatment system of the present invention. In FIG. 8, a subject 410 is hooked up with a number of sensors 420, 424, 418, and 426. The subject 410 in this case is shown with a respiratory mask 412, which is connected by an air hose or subject circuit 416 to a continuous positive air pressure device 428 similar to that shown in FIG. 7. The signal or data from one or more of these sensors is picked up in this embodiment by a diagnostic device 441, which comprises a radio 436 and antenna 434; a microprocessor 438 for processing the data or signals to determine a level of severity of the subject's sleeping disorder or symptoms; the diagnostic device then transmits a signal based on this level of severity by either a tether 444 or radio signal (not shown) to an actuator (not shown) in the CPAP device 428, which controls the flow of air or gas to the subject. The CPAP device 428 optionally has an O² tank connected, which can be used to increase the concentration of O² in the air being delivered to the subject. In addition, optionally the treatment device 428 has a sensor in the air hose 416, which can measure the differential pressure 414 and thereby accurately measure air flow provided to the patient. Also optionally, the device can have a nebulizer (not shown) with a reservoir and pump to injecting medication into the nebulizer.

It will be apparent to those skilled in the art that various modifications and variations can be made to the present invention without departing from the spirit and scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

WHAT IS CLAIMED:

1. A sleeping disorder treatment system comprising

a first device for diagnosing and creating a quantitative output of a level of severity of a subject's sleeping disorder or symptoms; and

a second device for physically or chemically treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output of the level of severity of the subject's sleeping disorder.
2. The system in Claim 1, wherein the first device for physically or chemically treating a subject's sleeping disorder is adjusted in real time.
3. The system in Claim 1, wherein the second device is adjusted automatically adjusted by using data or a signal from the first device.
4. The system in Claim 1, wherein the quantitative output of the level of severity of the subject's sleeping disorder or symptoms is based in part on a physiological signal of the subject.
5. The system in Claim 4, wherein the physiological signal is a brain wave signal.
6. The system in Claim 4, wherein the physiological signal is an EKG signal.

7. A sleep apnea treatment system comprising

a first device for diagnosing and creating an output of a level of severity of a subject's sleep apnea; and

a CPAP device for treating the subject's sleep apnea, which can be adjusted using the output.
8. The system in Claim 7, wherein the CPAP device for physically or chemically treating a subject's sleeping disorder is adjusted in real time.
9. The system in Claim 7, wherein the CPAP device is adjusted automatically using data or a signal from the first device.
10. The system in Claim 7, wherein the output of the level of severity of the subject's sleeping disorder or symptoms is based in part on a physiological signal of the subject.
11. The system in Claim 10, wherein the physiological signal is a brain wave signal.
12. The system in Claim 10, wherein the physiological signal is an EKG signal.
13. The system in Claim 7, wherein the first device sends a wireless signal based in part on the output level of severity to the CPAP device to adjust a treatment of the subject.

14. A sleep apnea treatment system comprising

a first device for diagnosing comprising at least two EEG sensors, and creating an output of a level of severity of a subject's sleep apnea; and

a CPAP device for treating the subject's sleep apnea, which can be adjusted using the output.
15. The system in Claim 14, wherein the second device for physically or chemically treating a subject's sleeping disorder is adjusted in real time.
16. The system in Claim 14, wherein the CPAP device is adjusted automatically using data or a signal from the first device.
17. The system in Claim 14, wherein the first device sends a wireless signal based in part on the output level of severity to the CPAP device to adjust a treatment of the subject.
18. The system in Claim 14, wherein the CPAP device further comprises a nebulizer.
19. The system in Claim 18, wherein the nebulizer is used to deliver medication.
20. The system in Claim 14, wherein the CPAP device is adjusted by a remote control device.

ABSTRACT

The present invention relates to an integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment device. The present invention additionally relates to method of sleep diagnosis and treatment.

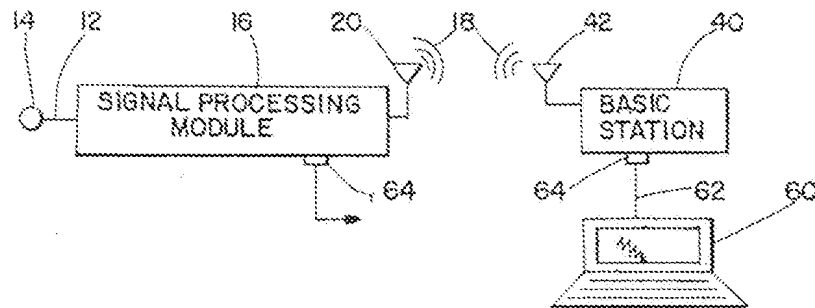


Fig. 1

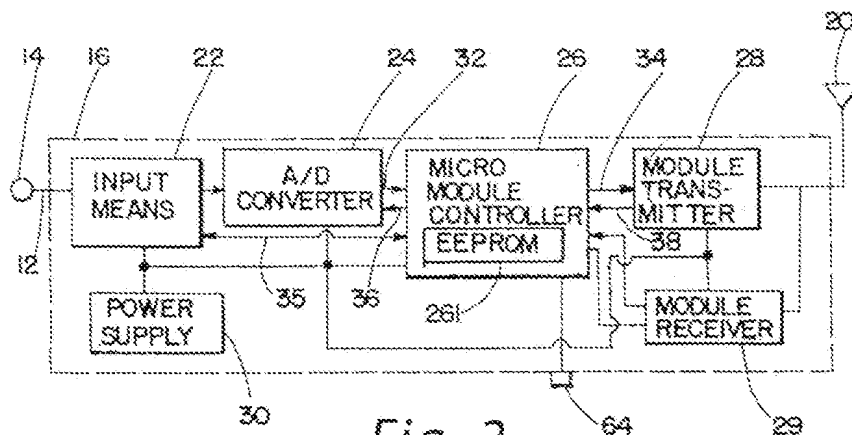


Fig. 2

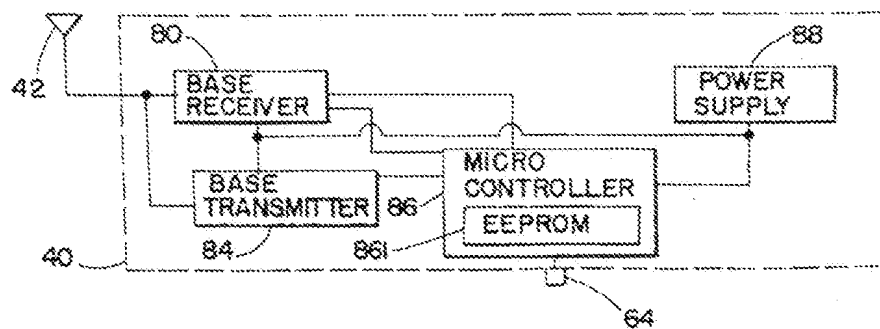
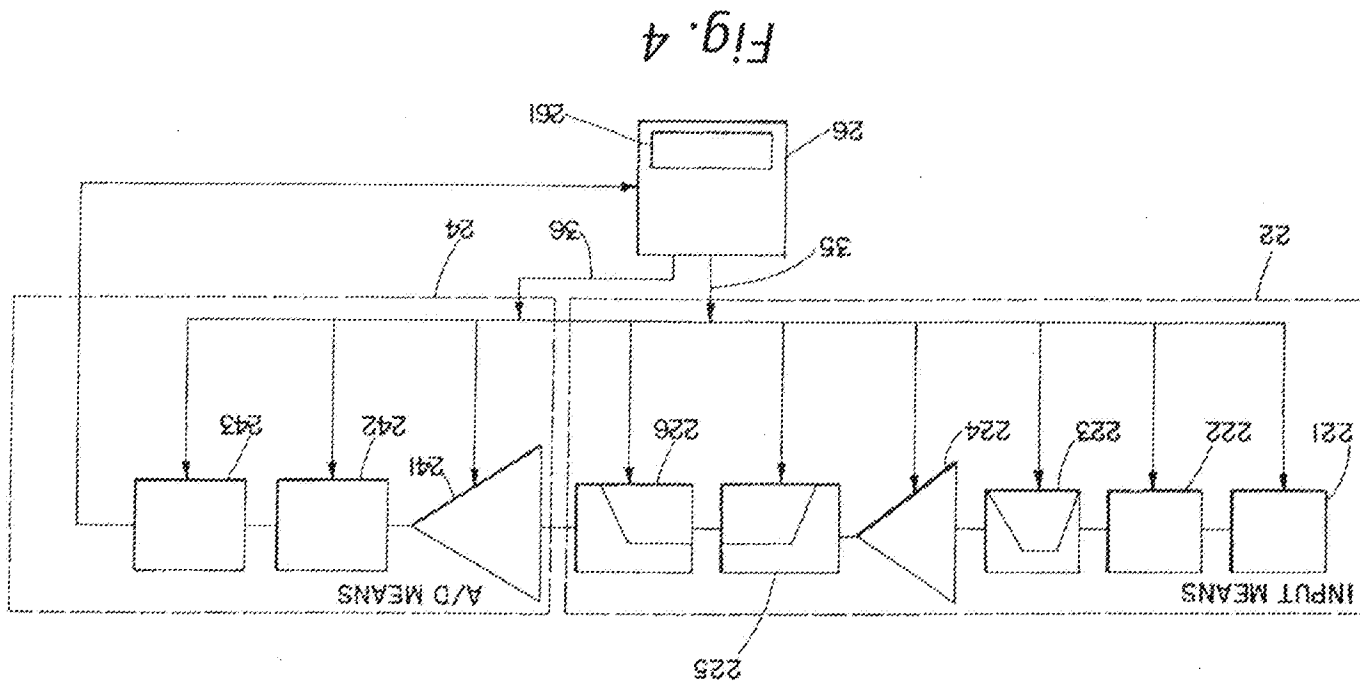


Fig. 3



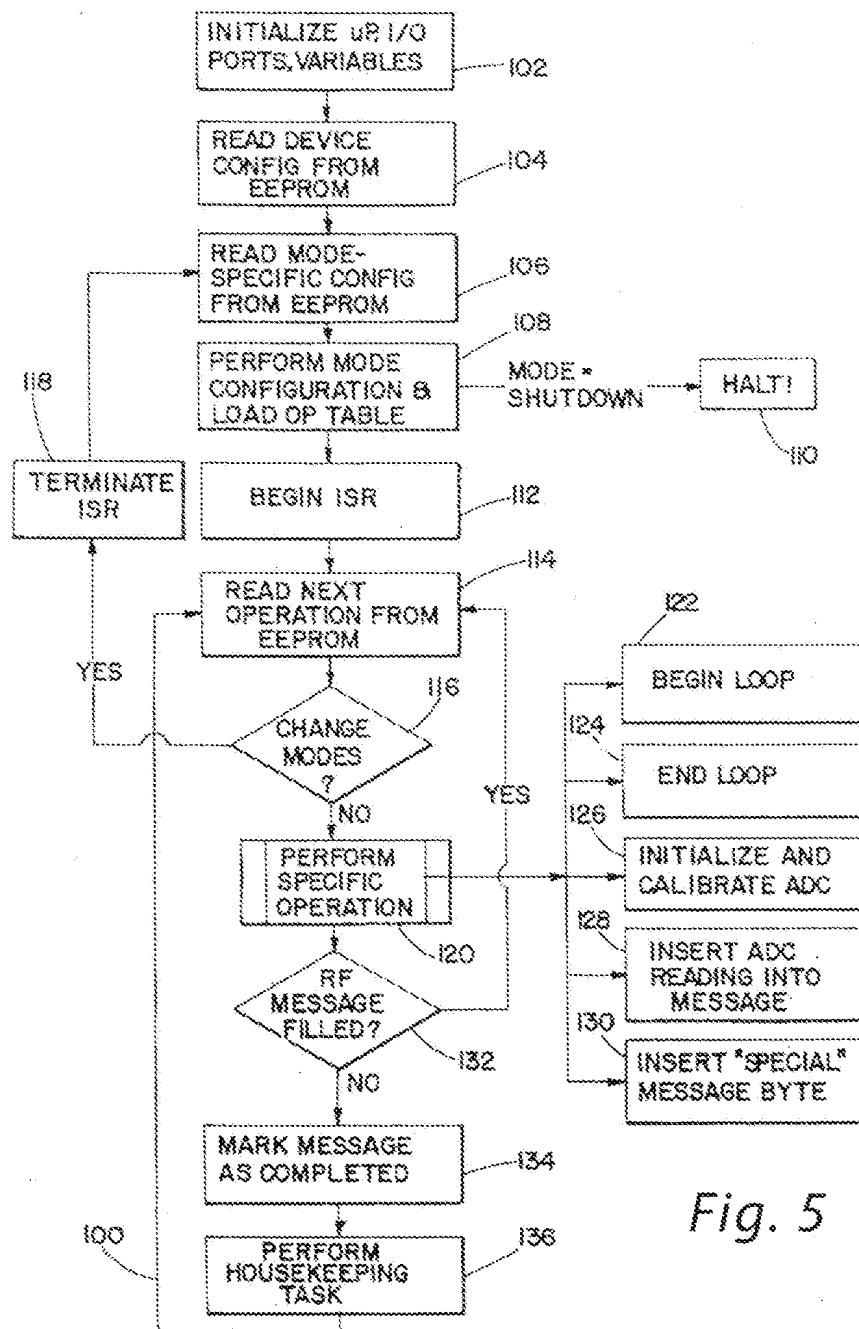


Fig. 5

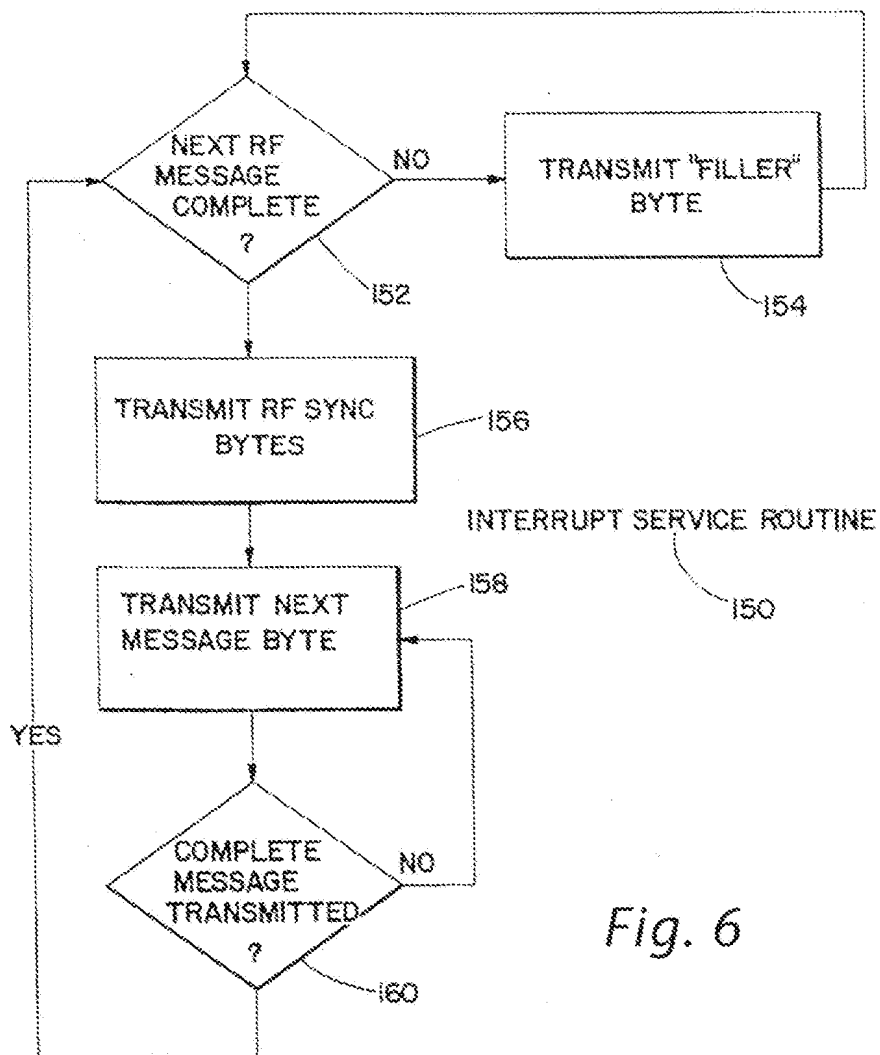


Fig. 6

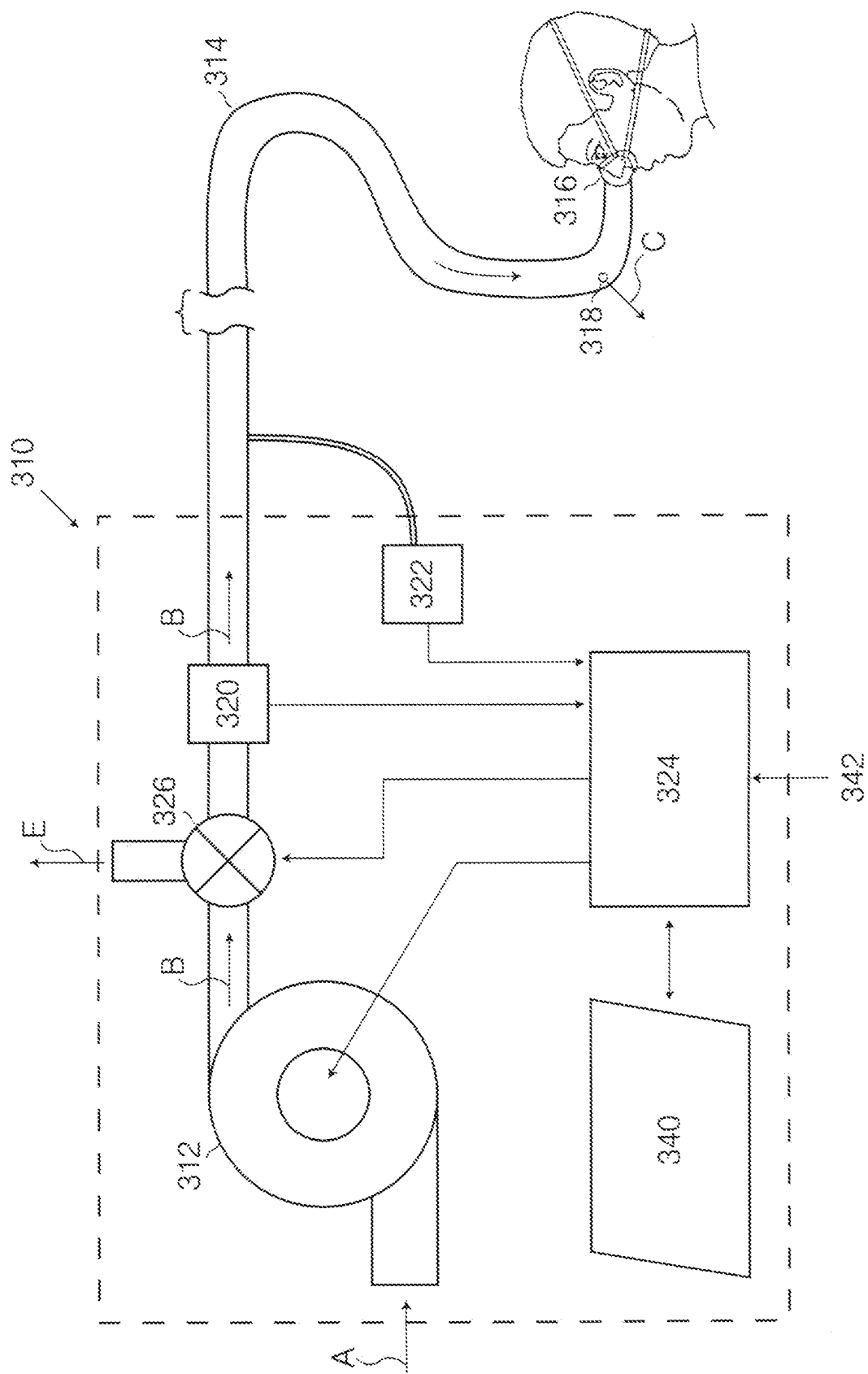


Fig. 7

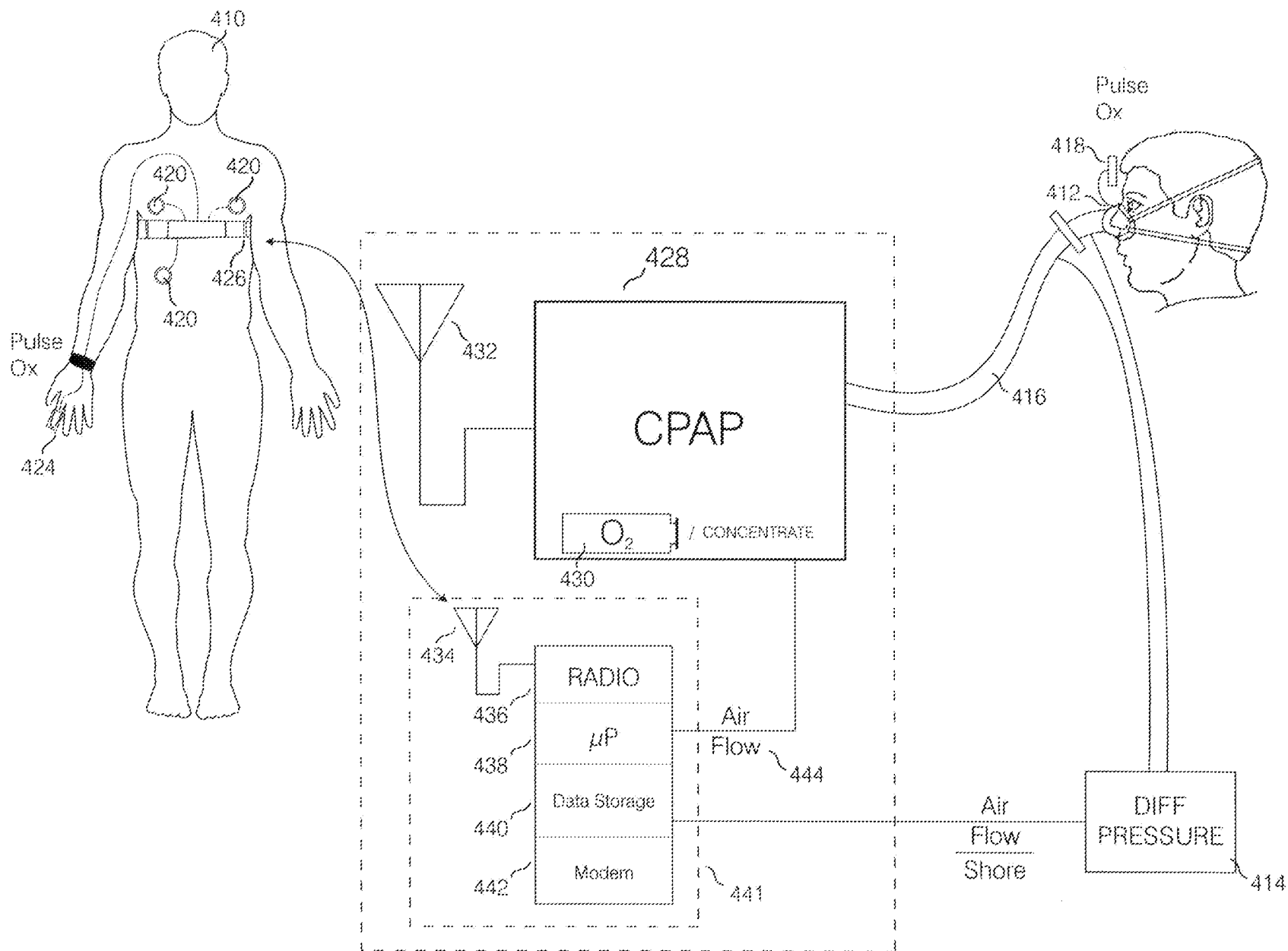


Fig. 8

Docket No.
CMD-087

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____ and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, or plant breeder's rights certificate(s), or 365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

..... (Application Serial No.)	 (Filing Date)
-----------------------------------	------------------------

..... (Application Serial No.)	 (Filing Date)
-----------------------------------	------------------------

..... (Application Serial No.)	 (Filing Date)
-----------------------------------	------------------------

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

..... (Application Serial No.)	 (Filing Date)	 (Status) (patented, pending, abandoned)
-----------------------------------	------------------------	---

..... (Application Serial No.)	 (Filing Date)	 (Status) (patented, pending, abandoned)
-----------------------------------	------------------------	---

..... (Application Serial No.)	 (Filing Date)	 (Status) (patented, pending, abandoned)
-----------------------------------	------------------------	---

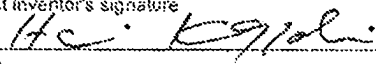
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

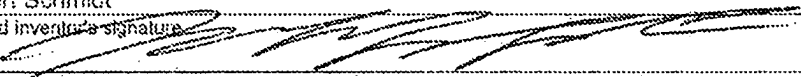
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

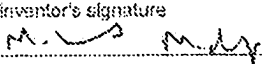
Brian M. Kolkowski, Reg. No. 36,847

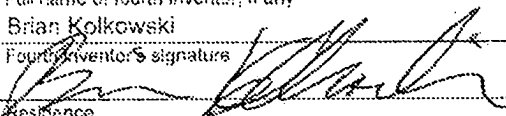
Send Correspondence to: Brian M. Kolkowski, Esq.
Cleveland Medical Devices, Inc.
4415 Euclid Ave, Suite 400
Cleveland, Ohio 44103

Direct Telephone Calls to: *(name and telephone number)*
Brian M. Kolkowski, (216) 649-0376

Full name of sole or first inventor	Hani Kayyali	
Sole or first inventor's signature		Date 10/31/05
Residence	Shaker Heights, OH, USA	
Citizenship	United States	
Post Office Address	3066 Woodbury Road	
	Shaker Heights, OH 44120	

Full name of second inventor, if any	Robert Schmidt	
Second inventor's signature		Date Oct 31, 2005
Residence	Cleveland, OH, USA	
Citizenship	United States	
Post Office Address	1721 Fulton Road	
	Cleveland, OH 44113	

Full name of third inventor, if any	
Mohammad Modarres-Zadeh	
Third inventor's signature	Date
	10/31/05
Residence	
Cleveland Heights, OH, USA	
Citizenship	
United States	
Post Office Address	
3081 Chelsea Drive	
Cleveland Heights, OH 44113	

Full name of fourth inventor, if any	
Brian Kolkowski	
Fourth inventor's signature	Date
	10/31/05
Residence	
Leroy, OH, USA	
Citizenship	
United States	
Post Office Address	
6340 Taylor Road	
Leroy, OH 44077	

Full name of fifth inventor, if any	
Fifth inventor's signature	
Date	
Residence	
Citizenship	
Post Office Address	

Full name of sixth inventor, if any	
Sixth inventor's signature	
Date	
Residence	
Citizenship	
Post Office Address	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 13/440,116		Filing Date 04/05/2012		☐ To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY ☒ OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)			
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	95		N/A				
☒ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	310		N/A				
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	125		N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	* 0	X \$30 =	0	OR	X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	* 0	X \$125 =	0		X \$ =				
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	04/05/2012	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 20 Minus	** 20	= 0	X \$30 =	0	OR	X \$ =		
	Independent (37 CFR 1.16(h))	* 3 Minus	*** 3	= 0	X \$125 =	0	OR	X \$ =		
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* Minus	**	=	X \$ =		OR	X \$ =		
	Independent (37 CFR 1.16(h))	* Minus	***	=	X \$ =		OR	X \$ =		
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.										
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".										
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.