



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/825,266	03/14/2023	11602284	CMD-117	1338

81177 7590 02/22/2023
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional inventors):

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

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Cleveland Medical Devices Inc., Cleveland, OH;

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 and facilitate 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.

FEE ADDRESS INDICATION FORM

Application Number	17825266	Art Unit	3791
Filing Date	26-May-2022	Examiner Name	NAVIN NATNITHITHADHA
First Name Inventor	Hani Kayyali	Attorney Doc. Number	CMD-117

INSTRUCTIONS: In order for the fee address identified on this form to be effective, the issue fee must have been paid for the application listed on this form. Only an address represented by a customer number can be established as the fee address for maintenance fee purposes (hereafter, fee address). A fee address should be established when correspondence related to maintenance fees should be mailed to a different address than the correspondence address for the application. For more information on customer numbers, see the Manual of Patent Examining Procedure (MPEP) § 403.

Please recognize as the Fee Address under the provisions of 37 CFR 1.363 the address associated with:

Customer Number:	81177
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Signature :

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application.

Signature	/Brian Kolkowski/	Date	02-03-2023
Name	Brian Kolkowski	Registration Number	36847

Electronic Patent Application Fee Transmittal

Application Number:	17825266			
Filing Date:	26-May-2022			
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-117			
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPL ISSUE FEE	2501	1	480	480
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				480

Electronic Acknowledgement Receipt

EFS ID:	47477130
Application Number:	17825266
International Application Number:	
Confirmation Number:	1338
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-117
Receipt Date:	03-FEB-2023
Filing Date:	26-MAY-2022
Time Stamp:	13:39:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$480
RAM confirmation Number	E202323D39293834
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 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

ResMed

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	62560	no	2
			7e0aef0505c38f1f6cd9f771d780b0867c57746f		
Warnings:					
Information:					
2	Maintenance Fee Address Change	web85feeaddress.pdf	42650	no	1
			db5a138c098bf174e63f149434e002b1b3aef43a		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	40426	no	2
			cbe28d9fa0df0e13ef98073c3100b81aa102de72		
Warnings:					
Information:					
Total Files Size (in bytes):			145636		
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.					

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
17825266	26-May-2022	Hani Kayyali	CMD-117	1338

TITLE OF INVENTION :

Devices and Methods for Sleep Disorder Diagnosis and Treatment

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Small	Utility under 35 USC 111(a)	3791	544000	NAVIN NATNITHITHADHA
Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
\$480	\$0	\$480	01-May-2023	\$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
81177 Cleveland Medical Devices Inc. 4415 Euclid Ave. Ste. 500 Cleveland OH 44103 UNITED STATES 216-649-0376 bkolkowski@clevemed.com	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☒ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status**Change in Entity Status**

Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.

Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.



Applicant asserting small entity status. See 37 CFR 1.27.

Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.



Applicant changing to regular undiscounted fee status.

Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.



Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:

☒ Issue Fee

☐ I authorize USPTO to apply my previously paid issue fee to the current fees due

☐ Publication Fee

☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____

☐ Advance Order - # of copies _____

☐ If in **addition** to the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number _____.
The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed

NOTE: If no name is listed, no name will be printed
For printing on the patent front page, list to be displayed as entered

1. Brian Kolkowski
2.
3.

5.Assignee Name(s) and Residence Data To Be Printed

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

Name	City	State	Country	Category
Cleveland Medical Devices Inc.	Cleveland	OHIO	UNITED STATES	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Brian Kolkowski/	Date	02-03-2023
Name	Brian Kolkowski	Registration Number	36847



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

NOTICE OF ALLOWANCE AND FEE(S) DUE

81177 7590 02/01/2023
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER

3791

DATE MAILED: 02/01/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/825,266	05/26/2022	Hani Kayyali	CMD-117	1338

TITLE OF INVENTION: Devices and Methods for Sleep Disorder Diagnosis and Treatment

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	05/01/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

81177 7590 02/01/2023
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/825,266	05/26/2022	Hani Kayyali	CMD-117	1338

TITLE OF INVENTION: Devices and Methods for Sleep Disorder Diagnosis and Treatment

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	05/01/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
NATNITHITHADHA, NAVIN	3791	600-544000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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.
17/825,266	05/26/2022	Hani Kayyali	CMD-117	1338
81177	7590	02/01/2023	EXAMINER	
Cleveland Medical Devices Inc. 4415 Euclid Ave. Ste. 500 Cleveland, OH 44103			NATNITHITHADHA, NAVIN	
			ART UNIT	PAPER NUMBER
			3791	
DATE MAILED: 02/01/2023				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. 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 30 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. 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.

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 disclosure of these records is required by the Freedom of Information Act.
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 inspection 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.

Notice of Allowability	Application No. 17/825,266	Applicant(s) Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791	AIA (FITF) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment and Remarks, filed 04 January 2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ 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.

3. ☒ The allowed claim(s) is/are 21-40. As a result of the allowed claim(s), 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.

4. ☐ 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)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____.	7. ☐ Other ____.
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. ____.	

/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	
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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 04 January 2023, the status of the claims is as follows:

Claims 21, 25, 26, and 30 are currently amended;

Claims 22-24, 27-29, and 31-40 are previously presented; and

Claims 1-20 are cancelled.

3. The objections of claims 21, 25, and 26 are withdrawn in view of the Amendment, filed 04 January 2023.

4. The rejection of claims 21-40 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention, is withdrawn in view of the Amendment, filed 04 January 2023.

5. The rejection of claims 30 and 40 under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends, is withdrawn in view of the Amendment, filed 04 January 2023.

Art Unit: 3791

6. Applicant's request for reconsideration of the finality of the rejection of the last Office action, see Remarks, p. 7, filed 04 January 2023, is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

7. Applicant's arguments, see Remarks, pp. 10-14, filed 04 January 2023, with respect to the rejection of claims 21-28 and 31-38 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell et al., U.S. Patent Application Publication No. 2007/0161913 A1 ("Farrell"), in view of Pirzada et al., U.S. Patent Application Publication No. 2007/0155208 A1 ("Pirzada"), have been fully considered, and are persuasive in view of the Amendment, filed 04 January 2023. The rejection of claims 21-28 and 31-38 has been withdrawn.

Reasons for Allowance

8. Claims 21-40 are allowed.

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

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 Monday - Friday 6:00 am - 8:30 am & 10:30 am - 4:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jason M Sims can be reached on 571-272-7540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791
01/19/2023**

<i>Applicant-Initiated Interview Summary</i>	Application No. 17/825,266	Applicant(s) Kayyali et al.		
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791	AIA (First Inventor to File) Status No	Page 1 of 2

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
NAVIN NATNITHITHADHA	Primary Examiner	Telephonic
Brian M. Kolkowski	Attorney of Record	

Date of Interview: 03 January 2023

Issues Discussed:

35 U.S.C. 103

Attorney traversed the rejection under 35 U.S.C. 103(a) as being unpatentable over Farrell et al., U.S. Patent Application Publication No. 2007/0161913 A1 ("Farrell"), in view of Pirzada et al., U.S. Patent Application Publication No. 2007/0155208 A1 ("Pirzada"), and argued that Pirzada is not prior art under 35 U.S.C. 102. The priority date of the present invention is 04 November 2005, and Pirzada has a filing date of 30 December 2006, and a domestic priority of 03 January 2006. Thus, Pirzada's effective filing date of 03 January 2006 is after the present application's effective filing date of 04 November 2005. Examiner found Attorney's arguments persuasive and agreed to withdrawn the rejection under 35 U.S.C. 103(a).

Other

Attorney traversed the finality of the prior Office Action, mailed 21 October 2022, and argued that no amendment made by in the Amendment, filed 20 September 2022, changed the scope of the claims that necessitated the rejection under 35 U.S.C. 103(a).

Examiner found Attorney's arguments persuasive and agreed to withdraw the finality of the prior Office Action.

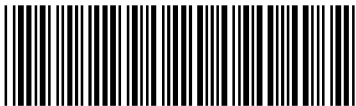
Attorney agreed to file a response to the prior Office Action.

/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	
Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04 Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing	

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

<i>Applicant-Initiated Interview Summary</i>	Application No. 17/825,266	Applicant(s) Kayyali et al.		
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791	AIA (First Inventor to File) Status No	Page 2 of 2

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Issue Classification 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791	

CPC						
Symbol					Type	Version
A61B	/	5	/	085	F	2013-01-01
A61B	/	5	/	4815	I	2013-01-01
A61M	/	2016	/	0027	A	2013-01-01
A61M	/	2230	/	04	A	2013-01-01
A61M	/	2205	/	3584	A	2013-01-01
A61M	/	2230	/	14	A	2013-01-01
A61M	/	2205	/	3553	A	2013-01-01
A61M	/	2230	/	205	A	2013-01-01
A61M	/	2230	/	60	A	2013-01-01
A61M	/	2205	/	3561	A	2013-01-01
A61M	/	16	/	0051	A	2013-01-01
A61M	/	2016	/	0039	A	2013-01-01
A61M	/	16	/	0069	A	2014-02-04
A61M	/	2230	/	10	A	2013-01-01
A61M	/	2230	/	202	A	2013-01-01
A61B	/	5	/	02055	A	2013-01-01
A61M	/	2202	/	0208	A	2013-01-01
A61M	/	2205	/	3592	A	2013-01-01

CPC Combination Sets					
Symbol				Type	Set

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure 8

Issue Classification 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61B	/	5	/ 085
A61B	/	5	/ 0205

NON-CLAIMED			
	/		/

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791 (Primary Examiner)	19 January 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 8

Issue Classification 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10		19	8	28	20	37						
	2		11		20	12	29	17	38						
	3		12	1	21	9	30	13	39						
	4		13	2	22	14	31	11	40						
	5		14	3	23	10	32								
	6		15	4	24	18	33								
	7		16	6	25	15	34								
	8		17	5	26	19	35								
	9		18	7	27	16	36								

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791 (Primary Examiner) _____ (Date) 19 January 2023		O.G. Print Claim(s) 1	O.G. Print Figure 8

Search Notes 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/085 or A61B5/4815 or A61B5/02055 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	09/07/2022	/NN/
A61B5/085 or A61B5/4815 or A61B5/02055 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	10/17/2022	/NN/
A61B5/085 or A61B5/4815 or A61B5/02055 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	01/17/2023	/NN/

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/N.N/ Primary Examiner, Art Unit 3791	
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<i>Search Notes</i> 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

Search Notes		
Search Notes	Date	Examiner
SEARCH (attached): USPAT, US-PGPUB, USOCR, FIT, FPRS, EPO , JPO Derwent, IBM_TDB, Keyword, Applicant, Assignee, Forward/ Backward Citation, CPC searches	09/07/2022	/NN/
SEARCH (attached): USPAT, US-PGPUB, USOCR, FIT, FPRS, EPO , JPO Derwent, IBM_TDB, Keyword, Applicant, Assignee, Forward/ Backward Citation, Art of Record, CPC searches	10/17/2022	/NN/
SEARCH (attached): USPAT, US-PGPUB, USOCR, FIT, FPRS, EPO , JPO Derwent, IBM_TDB, Keyword, Applicant, Assignee, Forward/ Backward Citation, Art of Record, CPC, Interference searches	01/17/2023	/NN/

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	A61B5/085 or A61B5/4815 or A61B5/02055 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	01/18/2023	/NN/

/N.N/ Primary Examiner, Art Unit 3791	
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Bibliographic Data

Application No: 17/825,266

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged:

/NAVIN
NATNITHITHADHA/

Examiner's Signature

/NN/

Initials

Title:

Devices and Methods for Sleep Disorder Diagnosis and Treatment

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
05/26/2022	600	3791	CMD-117
RULE			

APPLICANTS

Cleveland Medical Devices Inc., Cleveland, OH,

INVENTORS

Hani Kayyali, Shaker Heights, OH, UNITED STATES

Robert Schmidt, Ft. Myers, FL, UNITED STATES

Mohammad Modarres-Zadeh, Tampa, FL, UNITED STATES

Brian Kolkowski, Leroy, OH, UNITED STATES

CONTINUING DATA

This application is a CON of 16057963 08/08/2018 PAT 11375921

16057963 is a CON of 13440116 04/05/2012 PAT 10076269

13440116 is a CON of 11266899 11/04/2005 PAT 8172766

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

06/01/2022

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

ADDRESS

Cleveland Medical Devices Inc.

4415 Euclid Ave. Ste. 500

Cleveland, OH 44103

UNITED STATES

FILING FEE RECEIVED

\$830

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L208	7191	((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	OFF	2023/01/19 02:20 PM
L209	0	("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	ON	2023/01/19 02:20 PM
L210	0	("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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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.					
L211	0	((("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	ON	2023/01/19 02:20 PM
L212	0	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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 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.					
L213	0	((("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 L6	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L214	0	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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.					
L215	0	((("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 L8	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L216	5	("20050217674" "56450 43" "6029664" "613867	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM

		5 "6229581").PN.					
L217	0	((("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 biometer\$3 OR measur\$5 OR monitor\$3 OR signal\$3 OR wave OR waveform OR data OR value))) AND (("600"/\$) OR ("128"/\$)).ccls.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L218	0	((("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 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) AND (("600"/\$) OR ("128"/\$)).ccls.					
L219	0	((("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 L12	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L220	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	ON	2023/01/19 02:20 PM
L221	0	(quantitative\$3) AND (realtime OR (real ADJ2 time)) AND L14	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L222	7	(realtime OR (real ADJ2	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19

		time)) AND L14					02:20 PM
L223	4	(quantitative\$3) AND L14	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L224	5	("20050217674" "5645043" "6029664" "6138675" "6229581").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L225	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	ON	2023/01/19 02:20 PM
L226	15	L19 NOT L18	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L227	107	((("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	ON	2023/01/19 02:20 PM

L228	107	((("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 L21	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L229	109	((("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	ON	2023/01/19 02:20 PM
L230	109	((("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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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 L26					
L231	1	(US-20050115561-\$.did.	(US-PGPUB)	OR	ON	ON	2023/01/19 02:20 PM
L232	1	L28 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	ON	2023/01/19 02:20 PM
L233	1	L28 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	ON	2023/01/19 02:20 PM
L234	1	(US-20050115561-\$.did.	(US-PGPUB)	OR	ON	ON	2023/01/19 02:20 PM
L235	1	L31 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	ON	2023/01/19 02:20 PM
L236	1	L31 AND (realtime OR (real ADJ2 time))	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L237	1	L31 AND (wireless\$3 OR transmi\$6 OR transceiver OR communicat\$5)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L238	1	L31 AND (wireless\$3)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L239	1	L31 AND ("EEG" OR electroenceph\$ OR brain OR brainwave\$5)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L240	1	L31 AND ("ECG" OR "EKG" OR electrocardiograph\$)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L241	5	("20050217674" "5645043" "6029664" "6138675" "6229581").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM

L242	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	ON	2023/01/19 02:20 PM
L243	18	("20030000528" "20040163648" "20040254493" "20050081847" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "6029664" "6138675" "6229581" "6431171" "6889691" "7190995" "7204250" "7575005").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L244	18	L39 NOT L40	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L245	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "5961447" "6029664" "6	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM

		138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7668579" "7670295").PN.					
L246	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	ON	2023/01/19 02:20 PM
L247	36	L42 OR L43	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L248	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "72258	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM

		09 "7309314 "7575005 "7668579 "7670295").PN.					
L249	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	ON	2023/01/19 02:20 PM
L250	36	L45 OR L46	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L251	30	L47 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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 biodetect\$4))					
L252	30	L48 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 biodetect\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L253	0	((("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	ON	2023/01/19 02:20 PM
L254	0	((("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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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) SAME (belt OR strap OR piezoelect\$5))					
L255	0	((("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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		compress\$4) SAME (belt OR strap OR piezoelect\$5))					
L256	0	L52 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 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	ON	2023/01/19 02:20 PM
L257	0	((("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 biodelect\$5 OR biosensor\$3 OR biosensing OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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))					
L258	0	L54 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	ON	2023/01/19 02:20 PM
L259	0	((("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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		((("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))					
L260	0	L56 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	ON	2023/01/19 02:20 PM
L261	13	L47 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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 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))					
L262	0	((("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 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		OR band))					
L263	0	L59 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	ON	2023/01/19 02:20 PM
L264	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-	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		\$.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-7668579-\$ or US-7018341-\$ or US-6832609-\$.did.					
L265	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 L61	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L266	37	(transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) AND L61	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L267	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 L61	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L268	0	((("600"/\$) OR ("128"/\$)).ccls. AND ((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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)					
L269	0	((("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 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band))					
L270	0	((("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 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	ON	2023/01/19 02:20 PM
L271	0	L67 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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))					
L272	0	L67 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	ON	2023/01/19 02:20 PM
L273	0	((("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 biotdetect\$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	ON	2023/01/19 02:20 PM
L274	0	((("600"/\$) OR ("128"/\$)).ccls. AND ((("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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))					
L275	0	L71 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	ON	2023/01/19 02:20 PM
L276	1	("20020185130").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L277	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043")	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM

		"5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7668579" "7670295").PN.					
L278	15	((jonathan NEAR2wright) OR (anthony NEAR2 ujhazy)).inv. AND CPAP AND pulse AND (respiratory ADJ2 movement)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L279	15	L75 AND (sleep\$3 WITH (disorder OR symptom OR condition OR illness))	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L280	0	L75 AND (realtime OR (real ADJ2 time))	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L281	15	L75 AND (nebuliz\$3 OR medication OR medicine OR drug OR agent)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L282	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-	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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.					
L283	24	L79 NOT L74	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L284	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-	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		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.					
L285	34	("20020185130" "2003000528" "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	OFF	2023/01/19 02:20 PM
L286	51	L81 OR L82	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/01/19 02:20 PM
L287	32	((severit\$4 OR level OR depth OR stag\$3) WITH (apne\$4 OR hypopne\$5 OR hypoapne\$5 OR hyperapne\$5)) AND L83	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L288	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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		hyperapne\$5) AND L83					
L289	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 L85	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L290	10	((("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 L83	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L291	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 L83	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L292	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	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		receiv\$3 OR antenna)) SAME acquisition) AND (600/484,529-543).ccls.					
L293	181	((("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	ON	2023/01/19 02:20 PM
L294	181	((("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 L90	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L295	46	("10076269" "10543328 "20020185130" "2004 0138576" "2004016364 8" "20040210153" "200 40254493" "200500857 38" "20050115561" "20 050217674" "20050268 916" "20060042627" "2 0060084877" "2006013 5878" "20070135724" " 20070161913" "200702 09662" "20080066753" " 20080257349" "20080 276939" "20100043795 "20100258126" "5353 788" "5704345" "58030 78" "6138675" "615212 9" "6336454" "6431171" "6532957" "6532959" " 6832609" "7018341" "7	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		190995" "7204250" "7225809" "7575005" "7662101" "7757690" "7878198" "7942824" "8069852" "8172766" "8356594" "8545416" "9533114").PN.					
L296	162294	(A61B5/085 or A61B5/4815 or A61B5/02055 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; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L297	3	"20070161913"	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L298	1	("20070161913").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L299	0	L182 AND (phone OR cellular OR (base adj2 station) OR "PDA" OR telephone)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L300	1	L182 AND (software OR program\$5 OR algorithm\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L301	1	("20080257349").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L302	0	((cell OR cellular OR phone OR telephon\$5) SAME (chip OR card)) AND L185	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L303	0	((cell OR cellular OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19

		phone OR telephon\$5)) AND L185					02:20 PM
L304	0	((cell OR cellular OR phone OR telephon\$5 OR SIM) NEAR5 card) AND L70	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L305	7191	((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	OFF	2023/01/19 02:20 PM
L306	19	L189 AND (cellular NEAR5 card)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L307	129	L180 AND (cellular NEAR5 card)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L308	37	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) AND (((sleep\$3 NEAR8 (disorder OR illness OR condition OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM

		obstructi\$4)) OR apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) SAME (treat\$5 OR therap\$6)) AND ((cell OR cellular) NEAR5 card)					
L309	37	L192 AND ((cell OR cellular) NEAR5 card)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L310	2	("8172766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L311	0	L194 AND ((cell OR cellular) NEAR5 card)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L312	3	("8545416").pn.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L313	1	("8545416").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L314	1	((US-20070155208- A1).did. AND PGPB.dbnm.)	(US-PGPUB)	OR	ON	ON	2023/01/19 02:20 PM
L315	1	L198 AND ((cell OR cellular OR SIM) NEAR5 card)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L316	53	((US-20070135724-A1 OR US-20060042627- A1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/01/19 02:20 PM

		20060070624-A1 OR US-20070209662-A1 OR US-20040200474- A1 OR US- 20050115561-A1 OR US-20080269583-A1 OR US-20080066753- A1 OR US- 20070161913-A1 OR US-20080257349-A1 OR US-20060135878- A1 OR US- 20060084877-A1 OR US-20040138576-A1 OR US-20020185130- A1 OR US- 20040116784-A1 OR US-20100043795-A1 OR US-20100258126- A1 OR US- 20030135127-A1 OR US-20080276939-A1 OR US-20060247546- A1 OR US- 20050268916-A1 OR US-20050165323-A1 OR US-20040254493- A1 OR US- 20040163648-A1 OR US-20050217674-A1 OR US-20030000528- A1 OR US- 20050081847-A1 OR US-20050085738-A1 OR US-20020032386- A1 OR US- 20050197588-A1 OR US-20070155208- A1).did. AND PGPB.dbnm.) OR ((US- 5961447-A OR US- 7195013-B2 OR US- 7309314-B2 OR US- 7668579-B2 OR US- 7018341-B2 OR US- 6832609-B2 OR US- 7662101-B2 OR US- 7878198-B2 OR US- 7575005-B2 OR US- 7190995-B2 OR US- 6889691-B2 OR US- 6229581-B1 OR US- 6138675-A OR US- 6029664-A OR US- 5645043-A OR US- 6431171-B1 OR US- 7204250-B1 OR US- 6551252-B2 OR US-	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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		7225809-B1 OR US-7670295-B2 OR US-8172766-B1).did. AND USPT.dbnm.) OR ((US-8172766-B1).did. AND DWPI.dbnm.)					
L317	3	"20070161913"	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/19 02:20 PM
L318	3	L201 AND (program OR software OR algorithm)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L319	3	L201 AND (display)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L320	0	L201 AND (cellphone OR phone OR telephone)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM

L321	1	((US-20070155208-A1).did. AND PGPB.dbnm.)	(US-PGPUB)	OR	ON	ON	2023/01/19 02:20 PM
L322	1	L205 AND ((cellphone OR phone) SAME (display))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM
L323	1	L205 AND ((cellphone OR phone) AND (display))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/19 02:20 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

01/19/2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	App. of Kayyali et al.	)	
		)	
Serial No.:	17/825,266	)	
		)	Art Unit: 3791
Filed:	May 26, 2022	)	
		)	Docket No.: CMD-117
For:	Devices and methods for	)	
	sleep disorder diagnosis	)	
	and treatment	)	
		)	
Examiner:	Navin Natnithithadha	)	
		)	

January 4, 2023

AMENDMENT AFTER FINAL

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This Amendment After Final is responsive to an Office Action dated October 21, 2022. The Applicants submit that the Amendment is timely and no extension of time is needed. The following amendments and remarks are respectfully submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	App. of Kayyali et al.	)	
		)	
Serial No.:	17/825,266	)	
		)	Art Unit: 3791
Filed:	May 26, 2022	)	
		)	Docket No.: CMD-117
For:	Devices and methods for	)	
	sleep disorder diagnosis	)	
	and treatment	)	
		)	
Examiner:	Navin Natnithithadha	)	
		)	

January 4, 2023

AMENDMENT AFTER FINAL

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This Amendment After Final is responsive to an Office Action dated October 21, 2022. The Applicants submit that the Amendment is timely and no extension of time is needed. The following amendments and remarks are respectfully submitted.

IN THE CLAIMS:

Please amend claims 21, 25, 26 and 30 as follows:

1-20. (canceled)

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

a non-transitory computer readable medium, the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the index on the cell phone, the index based in part on [[a]] data of severity of sleep disorder symptoms of the subject and [[a]] data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone ~~on to which the first software is downloaded~~, the cell phone comprising at least [[a]] one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display;

the PAP device with an enclosure further comprising:

a blower having an air output,

an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data,

a second processor adapted for receiving the airflow sensor data, ~~and for~~ and for calculating the data of a severity of the symptoms of the subject and/or[[,]] the index, and ~~further for~~ further for calculating the data of usage of the PAP device,

a mask or a nasal cannula, and

at least one second radio frequency wireless transceiver, the at least one second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor; and

a remote internet site, the remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.

22. (previously presented) The system of Claim 21, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.

23. (previously presented) The system of Claim 21, wherein the at least one second radio frequency wireless transceiver is configured to transmit the data to the remote internet site and/or the cell phone of the data of the severity of the symptoms of the subject and/or the index, and the data of usage via in part by cell towers.

24. (previously presented) The system of Claim 23, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is configured for calculating the data of severity of the symptoms of the subject, wherein the PAP is further adapted to be reprogram or modify the at least one second software from the remote internet site or a second remote internet site.

25. (currently amended) The system of Claim 21, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the ~~the~~ data measured, calculated and then transmitted to the remote internet site.

26. (currently amended) The system of Claim 24, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the ~~the~~ data measured, calculated and then transmitted to the remote internet site.

27. (previously presented) The system of Claim 21, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.

28. (previously presented) The system of Claim 27, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.

29. (previously presented) The system of Claim 21, wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

30. (currently amended) The system of Claim 29~~8~~, wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

31. (previously presented) The system of Claim 21, wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage

related to the subject's treatment and the treatment's efficacy, in whole or part, calculated by the PAP device.

32. (previously presented) The system of Claim 30, wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, calculated by the PAP device.

33. (previously presented) The system of Claim 21, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.

34. (previously presented) The system of Claim 31, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.

35. (previously presented) The system of Claim 21, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.

36. (previously presented) The system of Claim 34, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.

37. (previously presented) The system in Claim 21, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

38. (previously presented) The system in Claim 36, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

39. (previously presented) The system in Claim 29, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.

40. (previously presented) The system in Claim 30, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.

REMARKS

In the Office Action of October 21, 2022, claims 21-40 were rejected. Claims 21, 25, 26 and 30 are herein amended. The Applicants believe these amendments place this application in condition for allowance.

Examiner Interview

The Applicants attorney spoke with Examiner Natnithithadha on the morning of January 3rd regarding the Office Action pending in this case. Three substantive areas were discussed during the interview upon which the Applicants believe agreement was made:

- 1) The Applicants agree that the suggestions for the Claim Objections and 35 U.S.C. 112 Rejections made by the Examiner were well taken and thus the Applicants have incorporated the amendments suggested by the Examiner in the current Office Action to overcome these Objections and §112 Rejections.
- 2) The Examiner agreed that the Finality of the current Office Action was a mistake given there was no amendment made by the Applicants in their September 20, 2022 amendment that changed the scope of the claims and necessitated the substantive §103 Rejection based on Farrell and Prizada.
- 3) The Examiner agreed that Pirzada is not a valid “prior art” reference against the presently claimed invention. The priority data of the present invention is November 4, 2005. Pirzada has a filing data of December 30, 2006, and even the provisional application which may or may not include many of the teachings of the utility filing of Prizada was January 3, 2006 thereby two-months after the priority date of the present invention.
- 4) Finally it was procedurally agreed that the Applicants would file a response traversing these issues to put it on the record in this case.

Claim Objections

Claims 21, 25 and 26 were objected to due to a number of informalities. The Applicants thank the Examiner for his helpful suggestions and submit the amendments to the claims make these objections moot. The Applicants urge withdrawal of these objections.

Claim Rejections – 35 U.S.C. §112

Claims 21-40 were rejected under 35 USC 112(b) or 35 USC 112(pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

The Applicants thank the Examiner for his helpful suggestions to overcome this rejection. The Applicants have incorporated the Examiner's suggestions in their entirety. The Applicants believe this rejection is now moot and urge withdrawal of this rejection.

Claims 30 and 40 were rejected under 35 USC 112(d) or 35 USC 112(pre-AIA), fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

The Applicants thank the Examiner for his helpful suggestions to overcome this rejection. Clearly this was a mistaken dependency and instead of Claim 30 depending on Claim 29 it has been corrected to depend on Claim 28. The Applicants believe this rejection is now moot and urge withdrawal of this rejection.

None of the above amendments adds new matter to the scope of the claims or broadens the claims in themselves.

Claim Rejections – 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 21-28 and 31-38 were rejected under pre-AIA 35 U.S.C. §103(a) as being unpatentable over Farrell et al., U.S. Pat. Appln. Pub. No. 2007/0161913 (“Farrell”), in view of Pirzada et al., U.S. Appln. Pub. No. 2007/0155208 (“Pirzada”). The Applicants traverse.

First it should be noted that the Examiner agreed that Pirzada is not a valid “prior art” reference against the presently claimed invention. The priority data of the present invention is November 4, 2005. Pirzada has a filing data of December 30, 2006, and even the provisional

application (on which Prizada claims priority) which may or may not include many of the teachings of the utility application filing of Prizada was January 3, 2006 thereby two-months after the priority date of the present invention. Just on this information alone this rejection should be withdrawn.

Further it should be noted that the Examiner admitted in his September 13, 2022 Office Action on pg. 12 that

[N]either Farrell nor the prior art of record teaches the positive airway pressure (PAP) sleep disorder treatment system of base claim 21, including the following, in combination with all other limitations of the base claim: “a first software stored on a non-transitory medium and executable by a first processor, the software configured to be used with and to display to the subject for viewing an index based in part on a data of severity of symptom data and data of usage related to a subject’s treatment efficacy with the PAP device calculated by and received from a PAP device on a cell phone, the cell phone comprising at least a first radio frequency wireless transceiver, the first processor and a display;...”

While the Claims were amended to incorporate recommended changes by the Examiner to overcome the 101 and 112 claim rejections and claim objections – these amendments did not change the scope of the claims – meaning as the Examiner pointed out none of the prior art of record teaches these limitations.

Also importantly it should be noted that the apparatus in Farrell the Examiner claims teaches the claim limitations of the PAP device with an enclosure further comprising a blower having an air output, an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data, a second processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device, a mask or a nasal cannula, and at least one second radio frequency wireless transceiver, the at least one second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor as claimed requires significantly more sensors to make such determinations. For instance, one skilled in the art would understand that not only the pressure 4p or flow sensor 4f are part of the apparatus taught in Farrell teaches that mask flow may be measured using these sensors, para. 24, Farrell also teaches a plethora of other sensors that are used to understand sleep disordered breathing (SBD) including but not limited to a sense tube 14

(not internal to the PAP device) used to measure these pressure levels in the mask, a pulse oximeter 20 and respiratory movement sensors 22 such as a chest band. The present invention claims a different PAP device for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device than Farrell. Farrell in para. 28 makes it clear that the apparatus is understood to be the combination of devices and/or computers to accomplish the goals of the invention (obviously including the multitude of sensors outlined in Farrell). Those goals are described in para. 11 of Farrell and are centered around early treatment and diagnosis of cardiovascular disease (CVD) and the ability to solve the lack of understanding of the mechanics of CVD when combined with the comorbidity of SDB.

Finally Farrell does not teach the limitations of the present invention of a remote internet site, the remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver as claimed. First nowhere in Farrell is a remote internet site described, and further in para. 47 of Farrell relied on by the Examiner it is clear that Farrell teaches not only periodically accessing the data but that the data may be accessed *directly* clearing by getting the apparatus (equipment) back and looking at the display on the PAP or remotely over a secure electronic network to a database – this is not the internet in that no one skilled in the art would describe the internet as a secure electronic network. One skilled in the art rather would interpret this teaching is a requiring a pager or some other form of secure connection at the time of the present invention.

With respect to the following dependent claims the Applicants incorporate their above statements with respect to Farrell and Prizada. Furthermore with respect to Claims 22, 23, 24, 31, and 32, the Examiner uses Prizada to teach the individual limitations of these claims – Prizada is not a prior art reference and further the Examiner does not establish motivation to combine the teachings for this purpose.

With respect to Claims 25 and 26, the Examiner uses Farrell to teach wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the data measured, calculated and then transmitted to the remote internet site as claimed. Clearly Farrell is not transmitting data to a remote internet site so the PAP device can be

adjusted remotely. In Farrell the data is either periodically viewed on the displays of the apparatus or transferred from the apparatus over a secure network to a database where it is reviewed. There is no basis for the Examiner to assume that such a transfer is to a remote internet site nor is it inherent.

With respect to Claims 27 and 28, the Examiner uses Farrell to teach wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely as claimed. The Examiner cites to paras. 25 and 47 for these teachings, however, para. 25 teaches of a controller or processor on the PAP device and there is No teaching of remotely reprogramming or modifying the software on the controller or processor of the PAP device. Para. 47 teaches of using a secure network to access data on a database as part of this apparatus. Nowhere in paras. 25 and 47 of Farrell is there any teaching of the use a software to be executed by a cellular phone which can display the severity of symptom data or an index based in part on this symptom data to a subject using the PAP device for therapy.

With respect to Claims 33 and 34, the Examiner uses Farrell to teach wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor as claimed. The Examiner cites to para. 25 of Farrell for this teaching – however there is no mention of an extended horizon, adaptive, predictive controller nor does the teaching inherently disclose this.

With respect to Claims 35 and 36, the Examiner uses Farrell to teach wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy as claimed. The Examiner cites to para. 27 of Farrell for this teaching but para. 27 read in verbatim “Other optional input and/or output devices 22 may be included to display output signals and enter input signals for the microprocessor 16. Various appropriate input and output devices such as keypads and display screens and other alternatives are known in the art” Clearly Farrell is referring to inputs and outputs on the apparatus – not a remote internet site hosted on a remote communication system for reprocessing and/or outputting data received from the first or second radio frequency wireless transceivers. Further clearly the remote internet site – not the

apparatus – is configured to output to a printer or a second display for review by a clinician. One skilled in the art would clearly understand these are not the same teachings in the present invention.

Given the above comments the Applicants urge withdrawal of this rejection.

CONCLUSION

The Applicants urge issuance of this Application given the above amendments place this Application in condition for allowance.

Respectfully submitted,

1/4/2023
Dated _____

/Brian Kolkowski/

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Electronic Acknowledgement Receipt

EFS ID:	47315375
Application Number:	17825266
International Application Number:	
Confirmation Number:	1338
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-117
Receipt Date:	04-JAN-2023
Filing Date:	26-MAY-2022
Time Stamp:	14:03:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-117_4Jan2023_amendme nt.pdf	250956 408ac5eb7de55d36680fb82e795e1c71191 ee953	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Response After Final Action	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	14
Warnings:			
Information:			
Total Files Size (in bytes):		250956	
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/825,266	Filing Date 05/26/2022	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) 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 \$50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		x \$240 =	
☐ 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)	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	01/04/2023		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	x \$40 = 0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0	x \$192 = 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
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =
	☐ 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.						LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/JEFFERY L OLSEN/
*** 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.						

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/825,266	05/26/2022	Hani Kayyali	CMD-117	1338

81177 7590 10/21/2022
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3791

MAIL DATE	DELIVERY MODE
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10/21/2022

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.

17/825,266

Applicant(s)

Kayyali et al.

Examiner

NAVIN NATNITHITHADHA

Art Unit

3791

AIA (FITF) 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 20 September 2022.
☐ 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 ____ 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)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
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 20 September 2022, the status of the claims is as follows:

Claims 21-26 and 31-36 are currently amended;

Claims 27-30 and 37-40 are previously presented; and

Claims 1-20 are cancelled.

3. The objections of claims 21-26, 31, 32, 35, and 36 are withdrawn in view of the Amendment, filed 20 September 2022.
4. The rejection of claims 21-40 under 35 U.S.C. 101, because the claim(s) does/do not fall within at least one of the four categories of patent eligible subject matter, is withdrawn in view of the Amendment, filed 20 September 2022.
5. The rejection of claims 21-40 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention, is withdrawn in view of the Amendment, filed 20 September 2022.

Claim Objections

6. Claim 21 is objected to because of the following informalities: in lines 22-26, "a second processor adapted for receiving the airflow sensor data, and calculating the data

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of a severity of the symptoms of the subject and/or, the index, and further calculating the data of usage of the PAP device,” is a typographical/grammatical error, and should be amended to “a second processor adapted for receiving the airflow sensor data, ~~and~~ for calculating the data of a severity of the symptoms of the subject and/or[[,]] the index, and ~~further for~~ for calculating the data of usage of the PAP device,”. Appropriate correction is required.

7. Claim 21 is objected to because of the following informalities: in lines 28-29, “the second radio frequency wireless transceiver” lacks proper antecedent basis, and should be amended to “the at least one second radio frequency wireless transceiver”.

Appropriate correction is required.

8. Claims 25 and 26 are objected to because of the following informalities: in line 4, “based in part on the the data measured” is a typographical error, and should be amended to “based in part on the ~~the~~ data measured”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. **Claims 20-40 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for**

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applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 21 recites the following limitations in lines 8-16:

the first software used for displaying the index on the cell phone, the index based in part on a data of severity of sleep disorder symptoms of the subject and a data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone on to which the first software is downloaded, the cell phone on to which the first software is downloaded is further configured to operate with the cell phone comprising at least a first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display; ...

However, the claim is unclear as to as to whether the claim requires one of the first radio frequency wireless transceiver, the first processor, the software when downloaded and a display, or all of those components. Furthermore, in the limitation “the cell phone on to which the first software is downloaded is further configured to operate with the cell phone comprising at least a first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display”, it is not clear what structural element is being further limited. Furthermore, the phrases “on to which the first software is downloaded” further limits the cell phone in multiple instances in the claim; and thus, the phrases are redundant and creates grammatical errors with the other phrases in the claimed limitations. Examiner suggests the following amendment to the claim:

the first software used for displaying the index on the cell phone, the index based in part on [[a]]data of severity of sleep disorder symptoms of the subject and [[a]]data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone ~~on to which the first software is downloaded~~, the cell phone ~~on to which the first software is~~

~~downloaded is further configured to operate with the cell phone~~ comprising at least ~~[[a]]~~one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display; ...

11. The following is a quotation of 35 U.S.C. 112(d):

(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

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

Subject to the following paragraph [i.e., the fifth paragraph of pre-AIA 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

12. **Claims 30 and 40 are rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C.**

112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

The limitations “wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis” of claim 30 is the same limitations as that for claim 29, for which claim 30 is dependent on. Thus, claim 30 does not further limit the subject matter of the claim upon which it depends. Claim 40 is rejected for its dependency on claim 30.

Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 103

13. 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, 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 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.

14. 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

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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).

15. **Claims 21-28 and 31-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell et al., U.S. Patent Application Publication No. 2007/0161913 A1 ("Farrell"), in view of Pirzada et al., U.S. Patent Application Publication No. 2007/0155208 A1 ("Pirzada").**

As to Claim 21, Farrell teaches the following:

A positive airway pressure (PAP) sleep disorder treatment system ("apparatus for treating and monitoring sleep disordered breathing ("SDB")", not labeled) (see "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." in para. [0002], and see fig. 1) comprising:

a non-transitory computer readable medium ("a memory and/or other instruction or data storage medium", not labeled, see para. [0025]), the non-transitory computer readable medium comprising a first software ("software", not labeled, see para. [0025]), the first software executable by a first processor ("controller") 15 and configured to be used with a "hand held device 12" to display to a subject for viewing on the "hand held device 12" on to which the first software is downloaded **an index of treatment efficacy of the subject using a PAP device**, the first software used for displaying the index on the "hand held device 12", the index based in part on a data of severity of sleep disorder symptoms of the subject and a data of

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usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by

the PAP device (see “The apparatus preferably also includes a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12.” in para. [0026]; see “Embodiments of the invention may include automated measuring apparatus that can generate signals associated with the automatically determined cardiovascular information for a processor of the device. Alternatively, the device may be pre-programmed to prompt or query for such information on a display or from another remote device, before use and/or periodically such as monthly, after three or six months, or some other timed period which may be based on use of the device (e.g., after 30 nights of use, etc.), so that such information may be measured or determined separately and input by a user on a keypad or other data entry device.” in para. [0042]; and see “Preferably, the cardiovascular and SDB information may be periodically remotely transferred to the physician or it may be accessed directly through displays on the device.” in para. [0047]) and received by the “hand held device 12” on to which the first software is downloaded, the “hand held device 12” on to which the first software is downloaded is further configured to operate with the “hand held device 12” comprising

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at least a first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display (see para. [0026]);

the PAP device ("pressure delivery device", not labeled, see large enclosure in fig. 1) with an enclosure (see "With reference to FIG. 1, the invention involves a pressure delivery device 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. Exhaust gas is vented via exhaust 13. 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." in para. [0024]) further comprising:

a blower ("servo-controlled blower") 2 having an air output (see fig. 1),

an airflow sensor ("flow sensor") 4f internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data (see para. [0024]),

a second processor ("microprocessor 16") adapted for receiving the airflow sensor data, and calculating the data of a severity of the symptoms of the subject and/or, the index, based in part on the a subject's symptoms ("(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, [0039] (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") measured during use of the PAP device, and further calculating the data of usage ("session-by-session, day-by-day, hour-by-hour, etc") of the PAP device (see "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: [0038] (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, [0039] (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.” in para. [0036]),

a mask or a nasal cannula (“mask”) 6 (see fig. 1), and

at least one second radio frequency wireless transceiver (see “... a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as handheld display and control devices 12.” in para. [0026]), the second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor (see para. [0026]); and

a remote internet site (“secure electronic network to a database”, not labeled), the remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject’s treatment and the treatment’s efficacy, in whole or part, generated by the PAP device and transmitted via the second radio frequency wireless transceiver (see “Preferably, the cardiovascular and SDB information may be periodically remotely transferred to the physician or it may be accessed directly through displays on the device. In this way, a physician may keep up with and observe the changing cardiovascular condition of the patient with minimal direct oversight or intervention. Optionally, the device can be programmed with thresholds for comparison to the recorded

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cardiovascular information to trigger an alarm or send a message or generate a warning for the user, clinician or physician either directly on the device, or remotely, for example, over a secure electronic network to a database.” in para. [0047]).

Farrell does not teach the following:

the first software ... configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded ... , the first software used for displaying the index on the cell phone, ... the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone on to which the first software is downloaded, ...

However, **Pirzada teaches a cell phone with downloaded software can be used with a PAP machine to display data calculated by the PAP device (see para. [0034], [0069], and [0083]).** Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Farrell’s software to be used with a cell phone and display data calculated by the PAP device, as taught by Pirzada, because Farrell teaches a PAP sleep disorder treatment system using a handheld display devices, in general, which encompasses cell phones, and Pirzada’s system illustrates the use of cell phones with PAP sleep disorder treatment system.

As to Claim 22, Pirzada teaches the following:

wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol (see para. [0037]).

As to Claim 23, Pirzada teaches the following:

wherein the at least one second radio frequency wireless transceiver is configured to transmit the data to the remote site and/or the cell phone of the data of the severity of the symptoms of the subject and/or the index, and the data of usage via in part by cell towers (“cellular based telephone communication”) 54 (see para. [0060]).

As to Claim 24, Pirzada teaches the following:

the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is configured for calculating the data of severity of the symptoms of the subject, wherein the PAP is further adapted to be reprogram or modify the at least one second software from the remote internet site or a second remote internet site (see para. [0036], [0060], [0068]-[0069]).

As to Claim 25, Farrell teaches the following:

wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the disorder symptoms of the subject and/or the index, based in part on the the data measured, calculated and then transmitted to the remote internet site (see para. [0047]).

As to Claim 26, Farrell teaches the following:

wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the the

data measured, calculated and then transmitted to the remote internet site (see para. [0028]).

As to Claim 27, Farrell teaches the following:

wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely (see para. [0028] and [0047]).

As to Claim 28, Farrell teaches the following:

wherein the first software is configured to be stored on and executed by the “handheld device 21” and is further adapted to be reprogrammed or modified remotely (see para. [0028] and [0047]).

As to Claim 31, Pirzada teaches the following:

wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage related to the subject’s treatment and the treatment’s efficacy, in whole or part, calculated by the PAP device (see para. [0034], [0069], and [0083]).

As to Claim 32, Pirzada teaches the following:

wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage related to the subject’s treatment and the treatment’s efficacy, in whole or part, calculated by the PAP device (see para. [0034], [0069], and [0083]).

As to Claims 33 and 34, Farrell teaches the following:

wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor (see para. [0025]).

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

wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy (see para. [0027]).

As to Claims 37 and 38, Farrell teaches the following:

wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device (see para. [0036]).

Allowable Subject Matter

16. Claims 29 and 39 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.

17. Claims 29 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office Action.

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

As to Claims 29 and 39, neither Farrell, Pirzada, nor the prior art of record teaches the system of base claims 21, including the following in combination with all other limitations of the base claim 21:

wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

Conclusion

19. Applicant's amendment 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.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is

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(571)272-4732. The examiner can normally be reached Monday - Friday 6:00 am - 8:30 am & 10:30 am - 4:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jason M Sims can be reached on 571-272-7540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791
10/19/2022**

<i>Notice of References Cited</i>	Application/Control No. 17/825,266		Applicant(s)/Patent Under Reexamination Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA		Art Unit 3791	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-20070155208-A1	07-2007	PIRZADA; Shahzad	A61B5/0008	439/144
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

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.

Search Notes 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/085 or A61B5/4815 or A61B5/02055 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	09/07/2022	/NN/
A61B5/085 or A61B5/4815 or A61B5/02055 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	10/17/2022	/NN/

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
SEARCH (attached): USPAT, US-PGPUB, USOCR, FIT, FPRS, EPO, JPO Derwent, IBM_TDB, Keyword, Applicant, Assignee, Forward/Backward Citation, CPC searches	09/07/2022	/NN/
SEARCH (attached): USPAT, US-PGPUB, USOCR, FIT, FPRS, EPO, JPO Derwent, IBM_TDB, Keyword, Applicant, Assignee, Forward/Backward Citation, Art of Recrod, CPC searches	10/17/2022	/NN/

/N.N/ Primary Examiner, Art Unit 3791	
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<i>Search Notes</i> 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	A61B5/085 or A61B5/4815 or A61B5/02055 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		/NN/

/N.N/ Primary Examiner, Art Unit 3791	
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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L201	2	"20070161913"	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/19 09:44 AM
L202	2	L201 AND (program OR software OR algorithm)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/19 09:45 AM
L203	2	L201 AND (display)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/19 10:03 AM
L204	0	L201 AND (cellphone OR phone OR telephone)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/19 10:04 AM
L205	1	((US-20070155208-	(US-PGPUB)	OR	ON	ON	2022/10/19

		A1).did. AND PGPB.dbnm.)					01:43 PM
L206	1	L205 AND ((cellphone OR phone) SAME (display))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/19 01:44 PM
L207	1	L205 AND ((cellphone OR phone) AND (display))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/19 01:45 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	App. of Kayyali et al.	)	
		)	
Serial No.:	17/825,266	)	
		)	Art Unit: 3791
Filed:	May 26, 2022	)	
		)	Docket No.: CMD-117
For:	Devices and methods for	)	
	sleep disorder diagnosis	)	
	and treatment	)	
		)	
Examiner:	Navin Natnithithadha	)	
		)	

September 20, 2022

AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This Amendment is being in response to an Office Action dated September 13, 2022. The Applicants submit that the Amendment is timely and no extension of time is needed. The following amendments and remarks are respectfully submitted.

IN THE CLAIMS:

Please amend claims 21-26, 31-32 and 33-36 as follows:

1-20. (canceled)

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

~~a first software stored on a non-transitory computer readable medium and executable by a first processor,~~ the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone and to display to [[the]] a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the [[an]] index on the cell phone, the index based in part on a data of severity of sleep disorder symptoms of the subject data and a data of usage related to a subject's treatment efficacy with of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received from a PAP device on aby the cell phone on to which the first software is downloaded, the cell phone on to which the first software is downloaded is further configured to operate with the cell phone comprising at least a first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display;

the PAP device with an enclosure further comprising:

a blower having an air output,

an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data,

a second processor adapted for receiving the airflow sensor data, and calculating ~~both the data of a severity of the subject's sleep disorder symptoms of the subject~~

and/or, ~~[[an]]the~~ index, ~~based in part on the~~ ~~[[a]]~~ subject's symptoms ~~measured during use of the PAP device~~, and further calculating the data of usage of the PAP device,

a mask or a nasal cannula, and

at least ~~[[a]]one~~ second radio frequency wireless transceiver, the second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms ~~data of the severity of the subject's sleep disorder symptoms~~ ~~[[,]]~~ and/or the index, and the data of usage calculated by the second processor; and

a remote internet site, the remote internet site adapted to receive the data of the severity of the ~~subject's sleep disorder symptoms~~ of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.

22. (currently amended) The system of Claim 21, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.

23. (currently amended) The system of Claim 21, wherein the at least one second radio frequency wireless transceiver is configured to transmit the data to the remote ~~Internet~~ internet site and/or the cell phone of the data of the severity of the ~~subject's sleep disorder symptoms~~ of the subject and/or the index, and the data of usage via in part by cell towers.

24. (currently amended) The system of Claim 23, the PAP device further comprising at least ~~[[a]]one~~ second software stored on a memory and executed by the second processor, the at least one second software which is configured for calculating the data of severity of the symptoms of the subject ~~data~~, wherein the PAP is further adapted to be reprogram or modify the at least one second software from the remote ~~Internet~~ internet site or a second remote ~~Internet~~ internet site.

25. (currently amended) The system of Claim 21, wherein the PAP device further comprises ~~an~~at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the ~~symptom~~-data of the severity of the ~~subject's sleep disorder~~ symptoms of the subject and/or the index, based in part on the ~~[[a]] the data~~subject's symptoms-measured, calculated and then transmitted to the remote internet site.

26. (currently amended) The system of Claim 24, wherein the PAP device further comprises ~~an~~at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the ~~symptom~~-data of the severity of the ~~subject's sleep disorder~~ symptoms of the subject and/or the index, based in part on the ~~[[a]] the data~~subject's symptoms-measured, calculated and then transmitted to the remote internet site.

27. (previously presented) The system of Claim 21, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.

28. (previously presented) The system of Claim 27, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.

29. (previously presented) The system of Claim 21, wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

30. (previously presented) The system of Claim 29, wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform

technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

31. (currently amended) The system of Claim 21, wherein the remote ~~Internet~~internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the ~~subject's sleep disorder symptoms of the subject~~, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, ~~generated~~calculated by the PAP device.

32. (currently amended) The system of Claim 30, wherein the remote ~~Internet~~internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the ~~subject's sleep disorder symptoms of the subject~~, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, ~~generated~~calculated by the PAP device.

33. (currently amended) The system of Claim 21, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the ~~subject's sleep disorder symptoms of the subject~~ calculated by the second processor.

34. (currently amended) The system of Claim 31, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the ~~subject's sleep disorder symptoms of the subject~~ calculated by the second processor.

35. (currently amended) The system of Claim 21, wherein the remote ~~Internet~~internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, which is configured for review by a clinician to determine the treatment efficacy.

36. (currently amended) The system of Claim 34, wherein the remote ~~Internet~~internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, which is configured for review by a clinician to determine the treatment efficacy.

37. (previously presented) The system in Claim 21, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

38. (previously presented) The system in Claim 36, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

39. (previously presented) The system in Claim 29, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.

40. (previously presented) The system in Claim 30, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.

REMARKS

In the Office Action of September 13, 2022, claims 21-40 were rejected. Claims 21-26, 31-32 and 33-36 are herein amended. The Applicants believe these amendments place this application in condition for allowance.

Claim Objections

Claims 21-26, 31-32 and 35-36 were objected to due to a number of informalities. The Applicants thank the Examiner for his helpful suggestions and submit the amendments to the claims make these objections moot. The Applicants urge withdrawal of these objections.

Claim Rejections – 35 U.S.C. 101

Claims 21-40 were rejected under 35 USC 101 because the claim(s) does/do not fall within at least one of the four categories of patent eligible subject matter. The Applicants thank the Examiner for his helpful suggestion to overcome this rejection. The Applicants amended the claim to incorporate this suggestion making this rejection moot. The Applicants urge withdrawal of this rejection.

Claim Rejections – 35 U.S.C. 112

Claims 21-40 were rejected under 35 USC 112(b) or 35 USC 112(pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

The Applicants thank the Examiner for his helpful suggestions to overcome this rejection. The Applicants have incorporated the Examiner's suggestions almost entirely. In a couple of instances the Applicants have found additional errors in the claim language and amended accordingly within the spirit of the Examiners original rejections. The Applicants believe this rejection is now moot and urge withdrawal of this rejection.

CONCLUSION

The Applicants urge issuance of this Application given the above amendments place this Application in condition for allowance.

Respectfully submitted,

9/20/2022
Dated _____

/Brian Kolkowski/

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Electronic Acknowledgement Receipt

EFS ID:	46650650
Application Number:	17825266
International Application Number:	
Confirmation Number:	1338
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-117
Receipt Date:	20-SEP-2022
Filing Date:	26-MAY-2022
Time Stamp:	10:42:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-117_20Sept2022_amendment.pdf	145680 bc5ecc634be6bbb1a56af082f765d4a5977c032b	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Request for Reconsideration-After Non-Final Rejection	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	8
Warnings:			
Information:			
Total Files Size (in bytes):		145680	
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 displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 17/825,266		Filing Date 05/26/2022		☐ 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 \$50 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$240 =					
☐ 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	09/20/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0			x \$50 =		0	
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0			x \$240 =		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		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=			x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=			x \$0 =			
	☐ 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.								LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/FREDERICK E BRISCOE/			
*** 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.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/825,266	05/26/2022	Hani Kayyali	CMD-117	1338
81177	7590	09/13/2022		
Cleveland Medical Devices Inc. 4415 Euclid Ave. Ste. 500 Cleveland, OH 44103			EXAMINER NATNITHITHADHA, NAVIN	
			ART UNIT	PAPER NUMBER
			3791	
			MAIL DATE	DELIVERY MODE
			09/13/2022	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

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 Preliminary Amendment, filed 10 June 2022, the status of the claims is as follows:

Claims 21-40 are new; and

Claims 1-20 are cancelled.

Claim Objections

3. Claim 21 is objected to because of the following informalities: in line 4, the recitation “based in part on the a subject’s symptoms measured...” is grammatically incorrect, and should be amended to “based in part on the [[a]]subject’s symptoms measured...”. Appropriate correction is required.
4. Claim 21 is objected to because of the following informalities: in lines 13-17, the recitation “a second processor adapted for receiving the airflow sensor data, and calculating both the data of a severity of the subject’s sleep disorder symptoms and/or an index, based in part on the a subject’s symptoms measured during use of the PAP device, and further data of usage of the PAP device, ...” lacks clarity as to what structural element is performing the function of “further data of usage of the PAP device”, and should be amended to “a second processor adapted for receiving the airflow sensor data, and calculating ~~both~~ the data of a the severity of the subject’s sleep disorder symptoms and/or an index[[,]] based in part on the a subject’s symptoms

measured during use of the PAP device, and ~~further calculating the~~ data of usage of the PAP device, ...”. Appropriate correction is required.

5. Claim 21 is objected to because of the following informalities: in line 20, the recitation “the subject’s sleep disorder symptoms, and/or index,...” is grammatically incorrect, and should be amended to “the subject’s sleep disorder symptoms[.]] and/or index,...”. Appropriate correction is required.

6. Claim 21 is objected to because of the following informalities: in line 18, the recitation “at least a second radio frequency wireless transceiver” is typographical/grammatical error, and should be amended to “at least [[a]]one second radio frequency wireless transceiver”. Appropriate correction is required.

7. Claims 22 and 23 are objected to because of the following informalities: in line 1 of both claims, the recitation “the second radio frequency wireless transceiver” lacks proper antecedent bases, and should be amended to “the at least one second radio frequency wireless transceiver”. Appropriate correction is required.

8. Claim 24 is objected to because of the following informalities: in lines 1-2, the recitation “at least a second software” is typographical/grammatical error, and should be amended to “at least [[a]]one second radio frequency wireless transceiver”.

Appropriate correction is required.

9. Claims 24 is objected to because of the following informalities: in line 4, the recitation “the second software” lacks proper antecedent bases, and should be amended to “the at least one second software”. Appropriate correction is required.

10. Claims 25 and 26 are objected to because of the following informalities: in lines 2-3 of both claims, the recitation “based in part on the a subject’s symptoms

measured...” is grammatically incorrect, and should be amended to “based in part on the [[a]]subject’s symptoms measured...”. Appropriate correction is required.

11. Claims 31, 32, 35, and 36 are objected to because of the following informalities: in line 1 of both claims, the recitation “the remote Internet site” is a typographical error, and should be amended to “the remote ~~Internet~~internet site”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. **Claims 21-40 are rejected under 35 U.S.C. 101 because the claim(s) does/do not fall within at least one of the four categories of patent eligible subject matter.**

Step 1 of the Patent Subject Matter Eligibility Guidance (see MPEP 2106.03):

Claim(s) 21-40 does/do not fall within at least one of the four categories of patent eligible subject matter because the claim is directed to a computer program. MPEP 2106.03(II) states the following:

A claim whose BRI covers both statutory and non-statutory embodiments embraces subject matter that is not eligible for patent protection and therefore is directed to non-statutory subject matter. Such claims fail the first step (Step 1: NO) and should be rejected under 35 U.S.C. 101, for at least this reason.

In addition, MPEP 2106.03(I) states the following:

Non-limiting examples of claims that are not directed to any of the statutory categories include:

- Products that do not have a physical or tangible form, such as information (often referred to as “data per se”) or a computer program

per se (often referred to as “software per se”) when claimed as a product without any structural recitations; ...

... Similarly, software expressed as code or a set of instructions detached from any medium is an idea without physical embodiment. See *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 449, 82 USPQ2d 1400, 1407 (2007); see also *Benson*, 409 U.S. 67, 175 USPQ2d 675 (An “idea” is not patent eligible)...

Claims 21-40 contain both statutory and non-statutory embodiments. While claims 21-40 contain statutory subject matter, the claims also include computer program per se, i.e. “a first software”, which does not have a physical or tangible form. Thus, the claims are directed to non-statutory subject matter.

Examiner suggests amending claim 21 to properly recite a physical element that stores the software as follows:

21. A positive airway pressure (PAP) sleep disorder treatment system comprising:
~~a first software stored on a non-transitory computer readable medium and executable by a first processor, the non-transitory computer readable medium storing a first software,~~ the software configured to be used with and to display to the subject for viewing an index based in part on a data of severity of symptom data and data of usage related to a subject’s treatment efficacy with the PAP device calculated by and received from a PAP device on a cell phone, the cell phone comprising at least a first radio frequency wireless transceiver, the first processor and a display; ...

Claims 22-40 are rejected based on their dependencies, either directly or indirectly, to base claim 21.

Claim Rejections - 35 USC § 112

14. The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 21-40 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 21 recites the limitation "the PAP device" in line 5. There is insufficient antecedent basis for this limitation in the claim. It is not clear whether the "positive airway (PAP) sleep disorder treatment system" defined in line 1 is the basis for "the PAP device" in line 5.

Claim 21 recites the limitation "a PAP device on a cell phone" in line 6. It is not clear whether this limitation refers to the "PAP device" in line 5.

Claim 21 recites "the cell phone comprising at least a first radio frequency wireless transceiver, the first processor and a display". However, it is not clear whether "the cell phone", "the first processor" and "display" are parts of the claimed system as they are not defined as being part of the system.

Claim 21 recites "the software configured to be used with and to display to the subject for viewing an index based in part..." However, it is not clear how a "software" is able to "display to the subject", as this is a function for the "display" defined in line 7.

Claim 21 recites "a second processor adapted for receiving the airflow sensor data, and calculating both the data of a severity of the subject's sleep disorder symptoms and/or an index, based in part on the a subject's symptoms measured during use of the PAP device, and further data of usage of the PAP device, ..." However, this

recitation is unclear as to what structural element is performing “further data of usage of the PAP device. Examiner suggests amending the recitation to “a second processor adapted for receiving the airflow sensor data, and calculating ~~both~~ the data of a the severity of the subject’s sleep disorder symptoms and/or an index[[,]] based in part on the a subject’s symptoms measured during use of the PAP device, and ~~further~~ calculating the data of usage of the PAP device, ...”.

Claim 21 recites “...receive the data of the severity of the subject’s sleep disorder symptoms and/or the index, and the data of usage both related to the subject’s treatment and the treatment’s efficacy,...” It is not clear what “both” refers to as there are essentially three data parameters defined. Examiner suggest amending the recitation to “...receive the data of the severity of the subject’s sleep disorder symptoms and/or the index, and the data of usage ~~both related to the subject’s treatment and the treatment’s efficacy~~,...” The limitation “related to the subject’s treatment and the treatment’s efficacy” should further limit “the data of the severity of the subject’s sleep disorder symptoms and/or the index, and the data of usage” when the latter is first defined.

Claims 22-40 are rejected due to their dependencies, either directly or indirectly to base claim 21.

Claim 24 recites “at least a second software stored on a memory and executed by the second processor, the software which is configured for calculating the symptom data, wherein the PAP is further adapted to be reprogram or modify the second software from the remote Internet site or a second remote Internet site”. It is not clear

which one of the first or the at least a second software, the recitation “the software” is referring to.

Claim 26 recites “calculated transmitted to the remote internet site”. It is not clear whether this one function or two functions of calculating and transmitting. It is also not clear what structural element is performing either or both functions of calculating and transmitting.

Claims 31 and 32 recite “a second index” in line 3 of both claims. However, there is no structure defined that calculates this “second index”.

Claims 35 and 36 recite “a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, the reprocessed and/or outputted data, which is configured for review by a clinician to determine the treatment efficacy”. However, this recitation is unclear as to what element is acting on the “the reprocessed and/or outputted data, which is configured for review by a clinician to determine the treatment efficacy”. Examiner suggests amending the recitation to “a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the display is configured to display the reprocessed and/or outputted data, ~~which is configured~~ for review by a clinician to determine the treatment efficacy”.

Allowable Subject Matter

16. Claims 21-40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office Action.

17. Claims 21-40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office Action.

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

As to Claims 21-40, the closest prior art reference is Farrell et al., U.S. Patent Application Publication no. 2007/0161913 A1 ("Farrell"). Farrell teaches the following:

A positive airway pressure (PAP) sleep disorder treatment system ("apparatus for treating and monitoring sleep disordered breathing ("SDB")", not labeled) (see "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." in para. [0002], and see fig. 1) comprising:

...

the PAP device ("pressure delivery device", not labeled, see large enclosure in fig. 1) with an enclosure (see "With reference to FIG. 1, the invention involves a pressure delivery device 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". Exhaust gas is vented via exhaust 13. 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.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.” in para. [0024])further comprising:

a blower (“servo-controlled blower”) 2 having an air output (see fig. 1),

an airflow sensor (“flow sensor”) 4f internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data (see para. [0024]),

a second processor (“microprocessor 16”) adapted for receiving the airflow sensor data, and calculating both the data of a severity of the subject’s sleep disorder symptoms and/or an index, based in part on the a subject’s symptoms measured during use of the PAP device, and further data of usage of the PAP device (see “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: [0038] (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, [0039] (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.” in para. [0036]),

a mask or a nasal cannula (“mask”) 6 (see fig. 1), and

at least a second radio frequency wireless transceiver (see “... a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12.” in para. [0026]), the second radio frequency wireless transceiver adapted for transmitting the symptom data of the severity of the subject’s sleep disorder symptoms, and/or the index, and the data of usage calculated by the second processor; and

a remote internet site (“secure electronic network to a database”, not labeled), the remote internet site adapted to receive the data of the severity of the subject’s sleep disorder symptoms and/or the index, and the data of usage both related to the subject’s treatment and the treatment’s efficacy, in whole or part, generated by the PAP device and transmitted via the second radio frequency wireless transceiver (see “Preferably, the cardiovascular and SDB information may be periodically remotely transferred to the physician or it may be accessed directly through displays on the device. In this way, a physician may keep up with and observe the changing

cardiovascular condition of the patient with minimal direct oversight or intervention. Optionally, the device can be programmed with thresholds for comparison to the recorded cardiovascular information to trigger an alarm or send a message or generate a warning for the user, clinician or physician either directly on the device, or remotely, for example, over a secure electronic network to a database.” in para. [0047]).

However, neither Farrell nor the prior art of record teaches the positive airway pressure (PAP) sleep disorder treatment system of base claim 21, including the following, in combination with all other limitations of the base claim:

a first software stored on a non-transitory computer readable medium and executable by a first processor, the software configured to be used with and to display to the subject for viewing an index based in part on a data of severity of symptom data and data of usage related to a subject's treatment efficacy with the PAP device calculated by and received from a PAP device on a cell phone, the cell phone comprising at least a first radio frequency wireless transceiver, the first processor and a display; ...

Conclusion

19. 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 Monday - Friday 6:00 am - 8:30 am & 10:30 am - 4:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jason M Sims can be reached on 571-272-7540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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**/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791
09/09/2022**

<i>Notice of References Cited</i>	Application/Control No. 17/825,266		Applicant(s)/Patent Under Reexamination Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA		Art Unit 3791	Page 1 of 4

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*	B	US-9533114-B1	01-2017	Kayyali; Hani	A61B5/4818	1/1
*	C	US-10543328-B1	01-2020	Kayyali; Hani	A61M16/0069	1/1
*	D	US-8172766-B1	05-2012	Kayyali; Hani	A61B5/02055	128/204.26
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*	G	US-7757690-B2	07-2010	Stahmann; Jeffrey E.	A61B5/0031	607/42
*	H	US-7662101-B2	02-2010	Lee; Kent	A61B5/4818	600/529
*	I	US-20080276939-A1	11-2008	Tiedje; Mikael	A61M16/024	700/282
*	J	US-20080257349-A1	10-2008	Hedner; Jan	G16H20/40	128/204.23
*	K	US-20080066753-A1	03-2008	Martin; Dion Charles Chewe	A61M16/0057	128/204.23
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NON-PATENT DOCUMENTS

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	Examiner NAVIN NATNITHITHADHA		Art Unit 3791	Page 2 of 4

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*	C	US-20060084877-A1	04-2006	Ujhazy; Anthony John	A61B5/0826	600/483
*	D	US-20070135724-A1	06-2007	Ujhazy; Anthony John	A61M16/0051	600/529
*	E	US-20100043795-A1	02-2010	UJHAZY; Anthony John	A61M16/0057	128/204.23
*	F	US-20100258126-A1	10-2010	Ujhazy; Anthony John	A61M16/0057	128/204.23
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*	C	US-6152129-A	11-2000	Berthon-Jones; Michael	A61M16/0057	128/204.23
*	D	US-5803078-A	09-1998	Brauner; Mark E.	A61M16/0484	128/207.14
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<i>Search Notes</i> 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/085 or A61B5/4815 or A61B5/02055 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	09/07/2022	/NN/

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
SEARCH (attached): USPAT, US-PGPUB, USOCR, FIT, FPRS, EPO , JPO Derwent, IBM_TDB, Keyword, Applicant, Assignee, Forward/ Backward Citation, CPC searches	09/07/2022	/NN/

/N.N/ Primary Examiner, Art Unit 3791	
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<i>Search Notes</i> 	Application/Control No. 17/825,266	Applicant(s)/Patent Under Reexamination Kayyali et al.
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	A61B5/085 or A61B5/4815 or A61B5/02055 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		/NN/

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L92	7140	((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	OFF	2022/09/09 01:29 PM
L93	0	("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	ON	2022/09/09 01:29 PM
L94	0	("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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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.					
L95	0	((("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	ON	2022/09/09 01:29 PM
L96	0	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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 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.					
L97	0	((("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 L6	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L98	0	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat\$4 OR respirator) WITH (adjust\$4 OR control\$4 OR regulat\$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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.					
L99	0	((("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 L8	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L100	5	("20050217674" "56450 43" "6029664" "613867	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM

		5 "6229581").PN.					
L101	0	((("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 biometer\$3 OR measur\$5 OR monitor\$3 OR signal\$3 OR wave OR waveform OR data OR value))) AND (("600"/\$) OR ("128"/\$)).ccls.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L102	0	((("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 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		apne\$3 OR hypoapne\$3 OR hyperapne\$3 OR hypopne\$3) AND (("600"/\$) OR ("128"/\$)).ccls.					
L103	0	((("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 L12	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L104	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	ON	2022/09/09 01:29 PM
L105	0	(quantitative\$3) AND (realtime OR (real ADJ2 time)) AND L14	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L106	7	(realtime OR (real ADJ2	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09

		time)) AND L14					01:29 PM
L107	4	(quantitative\$3) AND L14	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L108	5	("20050217674" "5645043" "6029664" "6138675" "6229581").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L109	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	ON	2022/09/09 01:29 PM
L110	15	L19 NOT L18	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L111	107	((("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	ON	2022/09/09 01:29 PM

L112	107	((("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 L21	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L113	109	((("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	ON	2022/09/09 01:29 PM
L114	109	((("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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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 L26					
L115	1	(US-20050115561-\$.did.	(US-PGPUB)	OR	ON	ON	2022/09/09 01:29 PM
L116	1	L28 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	ON	2022/09/09 01:29 PM
L117	1	L28 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	ON	2022/09/09 01:29 PM
L118	1	(US-20050115561-\$.did.	(US-PGPUB)	OR	ON	ON	2022/09/09 01:29 PM
L119	1	L31 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	ON	2022/09/09 01:29 PM
L120	1	L31 AND (realtime OR (real ADJ2 time))	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L121	1	L31 AND (wireless\$3 OR transmi\$6 OR transceiver OR communicat\$5)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L122	1	L31 AND (wireless\$3)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L123	1	L31 AND ("EEG" OR electroenceph\$ OR brain OR brainwave\$5)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L124	1	L31 AND ("ECG" OR "EKG" OR electrocardiograph\$)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L125	5	("20050217674" "5645043" "6029664" "6138675" "6229581").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM

L126	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	ON	2022/09/09 01:29 PM
L127	18	("20030000528" "20040163648" "20040254493" "20050081847" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "6029664" "6138675" "6229581" "6431171" "6889691" "7190995" "7204250" "7575005").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L128	18	L39 NOT L40	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L129	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "5961447" "6029664" "6	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM

		138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7668579" "7670295").PN.					
L130	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	ON	2022/09/09 01:29 PM
L131	36	L42 OR L43	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L132	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043" "5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "72258	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM

		09 "7309314 "7575005 "7668579 "7670295").PN.					
L133	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	ON	2022/09/09 01:29 PM
L134	36	L45 OR L46	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L135	30	L47 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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 biodetect\$4))					
L136	30	L48 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 biodetect\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L137	0	((("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	ON	2022/09/09 01:29 PM
L138	0	((("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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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 biotransducer OR biometer\$3)) AND ((respir\$6 OR breath\$3 OR exhal\$6 OR expir\$6) SAME (belt OR strap OR piezoelect\$5))					
L139	0	((("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 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		compress\$4) SAME (belt OR strap OR piezoelect\$5))					
L140	0	L52 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 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	ON	2022/09/09 01:29 PM
L141	0	((("600"/\$) OR ("128"/\$)).cccls. 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 biodelect\$5 OR biosensor\$3 OR biosensing OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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))					
L142	0	L54 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	ON	2022/09/09 01:29 PM
L143	0	((("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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		((("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))					
L144	0	L56 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	ON	2022/09/09 01:29 PM
L145	13	L47 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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 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))					
L146	0	((("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 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		OR band))					
L147	0	L59 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	ON	2022/09/09 01:29 PM
L148	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-	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		\$.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-7668579-\$ or US-7018341-\$ or US-6832609-\$.did.					
L149	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 L61	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L150	37	(transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio OR radiofrequenc\$3 OR antenna OR telemet\$4) AND L61	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L151	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 L61	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L152	0	((("600"/\$) OR ("128"/\$)).cccls. AND ((transmi\$6 OR transceiv\$5 OR wireless\$3 OR radio	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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)					
L153	0	((("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 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		OR abdomen) SAME (belt OR strap OR piezoelect\$5 OR vest OR band))					
L154	0	((("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 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	ON	2022/09/09 01:29 PM
L155	0	L67 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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))					
L156	0	L67 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	ON	2022/09/09 01:29 PM
L157	0	((("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 biotdetect\$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	ON	2022/09/09 01:29 PM
L158	0	((("600"/\$) OR ("128"/\$)).ccls. AND ((("CPAP" OR "PAP" OR (positiv\$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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))					
L159	0	L71 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	ON	2022/09/09 01:29 PM
L160	1	("20020185130").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L161	27	("20030000528" "20040163648" "20040254493" "20050081847" "20050085738" "20050115561" "20050165323" "20050217674" "20050268916" "20050188991" "20060247546" "5645043")	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM

		"5961447" "6029664" "6138675" "6229581" "6431171" "6551252" "6889691" "7190995" "7195013" "7204250" "7225809" "7309314" "7575005" "7668579" "7670295").PN.					
L162	15	((jonathan NEAR2wright) OR (anthony NEAR2 ujhazy)).inv. AND CPAP AND pulse AND (respiratory ADJ2 movement)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L163	15	L75 AND (sleep\$3 WITH (disorder OR symptom OR condition OR illness))	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L164	0	L75 AND (realtime OR (real ADJ2 time))	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L165	15	L75 AND (nebuliz\$3 OR medication OR medicine OR drug OR agent)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L166	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-	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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.					
L167	24	L79 NOT L74	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L168	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-	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		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.					
L169	34	("20020185130" "2003000528" "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	OFF	2022/09/09 01:29 PM
L170	51	L81 OR L82	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/09/09 01:29 PM
L171	32	((severit\$4 OR level OR depth OR stag\$3) WITH (apne\$4 OR hypopne\$5 OR hypoapne\$5 OR hyperapne\$5)) AND L83	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L172	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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		hyperapne\$5) AND L83					
L173	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 L85	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L174	10	((("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 L83	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L175	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 L83	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L176	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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM

		receiv\$3 OR antenna)) SAME acquisition) AND (600/484,529-543).ccls.					
L177	181	((("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	ON	2022/09/09 01:29 PM
L178	181	((("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 L90	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:29 PM
L179	46	("10076269" "10543328 "20020185130" "2004 0138576" "2004016364 8" "20040210153" "200 40254493" "200500857 38" "20050115561" "20 050217674" "20050268 916" "20060042627" "2 0060084877" "2006013 5878" "20070135724" " 20070161913" "200702 09662" "20080066753" " 20080257349" "20080 276939" "20100043795 "20100258126" "5353 788" "5704345" "58030 78" "6138675" "615212 9" "6336454" "6431171" "6532957" "6532959" " 6832609" "7018341" "7	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/09 01:30 PM

		190995" "7204250" "7225809" "7575005" "7662101" "7757690" "7878198" "7942824" "8069852" "8172766" "8356594" "8545416" "9533114") .PN.					
L180	153630	(A61B5/085 or A61B5/4815 or A61B5/02055 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; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/09 01:33 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/825,266	05/26/2022	Hani Kayyali	CMD-117	1338

81177 7590 08/05/2022
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

EXAMINER

CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
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3791

MAIL DATE	DELIVERY MODE
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08/05/2022

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.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of:
KAYYALI, HANI, et al. :
Application No. 17/825,266 :
Filed: May 26, 2022 :
Attorney Docket No. CMD-117 :
DECISION ON PETITION
TO MAKE SPECIAL UNDER
37 CFR 1.102(c)(1)

This is a decision on the petition under 37 CFR 1.102(c)(1), filed May 26, 2022, to make the above-identified application special based on applicant's age as set forth in MPEP § 708.02, Section II.

The petition is **GRANTED**.

A grantable petition to make an application special under 37 CFR 1.102(c)(1) and MPEP § 708.02, Section II: Applicant's Age, must be accompanied by evidence showing that the applicant is 65 years of age, or more, such as applicant's statement or a statement from a registered practitioner that he or she has evidence that the applicant is 65 years of age or older. No fee is required.

The instant petition includes a statement from a registered practitioner that he/her has evidence that inventor Robert Schmidt, is over 65 years of age.

Telephone inquiries concerning this decision should be directed to Dale Hall at 571-272-3586.

All other inquiries concerning either the examination or status of the application should be directed to the Technology Center.

/Dale A. Hall/
Paralegal Specialist, OPET

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 17/825,266		Filing Date 05/26/2022		☐ 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 \$50 =								
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *		x \$240 =								
☐ 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	06/10/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)				
	Total (37 CFR 1.16(i))	* 19	Minus	** 20	= 0	x \$50 =		0				
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0	x \$240 =		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		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)				
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =						
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =						
	☐ 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.						LIE						
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/PEARLIE A FENNEL/						
*** 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.

Electronic Acknowledgement Receipt

EFS ID:	45924887
Application Number:	17825266
International Application Number:	
Confirmation Number:	1338
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-117
Receipt Date:	10-JUN-2022
Filing Date:	26-MAY-2022
Time Stamp:	11:18:10
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	Preliminary Amendment	CMD-117_10Jun2022_preliminary_amendment.pdf	128249 7ab1495ef2c9bfbcc16cdf221d08a064cf5d4e66	no	6

Warnings:

ResMed

Information:	
Total Files Size (in bytes):	128249
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.	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	App. of Kayyali et al.	)	
		)	
Serial No.:	17/825,266	)	
		)	Art Unit: 3791
Filed:	May 26, 2022	)	
		)	Docket No.: CMD-117
For:	Devices and methods for	)	
	sleep disorder diagnosis	)	
	and treatment	)	
		)	
Examiner:	Not yet assigned	)	
		)	

June 10, 2022

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This Preliminary Amendment is being in the above-captioned application to replace claims and place them in better condition for prosecution. The Applicants respectfully request the amendments be entered. The following amendments and remarks are respectfully submitted.

IN THE CLAIMS:

Please cancel claims 1-20, and add new claims 21-40 as follows:

1-20. (canceled)

21. (new) A positive airway pressure (PAP) sleep disorder treatment system comprising:

a first software stored on a non-transitory computer readable medium and executable by a first processor, the software configured to be used with and to display to the subject for viewing an index based in part on a data of severity of symptom data and data of usage related to a subject's treatment efficacy with the PAP device calculated by and received from a PAP device on a cell phone, the cell phone comprising at least a first radio frequency wireless transceiver, the first processor and a display;

the PAP device with an enclosure further comprising:

a blower having an air output,

an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data,

a second processor adapted for receiving the airflow sensor data, and calculating both the data of a severity of the subject's sleep disorder symptoms and/or an index, based in part on the a subject's symptoms measured during use of the PAP device, and further data of usage of the PAP device,

a mask or a nasal cannula, and

at least a second radio frequency wireless transceiver, the second radio frequency wireless transceiver adapted for transmitting the symptom data of the severity of the subject's sleep disorder symptoms, and/or the index, and the data of usage calculated by the second processor; and

a remote internet site, the remote internet site adapted to receive the data of the severity of the subject's sleep disorder symptoms and/or the index, and the data of usage both related

to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the second radio frequency wireless transceiver.

22. (new) The system of Claim 21, wherein the second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone to communicate using Bluetooth wireless protocol.

23. (new) The system of Claim 21, wherein the second radio frequency wireless transceiver is configured to transmit the data to the remote Internet site and/or the cell phone of the data of the severity of the subject's sleep disorder symptoms and/or the index, and the data of usage via in part by cell towers.

24. (new) The system of Claim 23, the PAP device further comprising at least a second software stored on a memory and executed by the second processor, the software which is configured for calculating the symptom data, wherein the PAP is further adapted to be reprogram or modify the second software from the remote Internet site or a second remote Internet site.

25. (new) The system of Claim 21, wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the symptom data of the severity of the subject's sleep disorder symptoms and/or the index, based in part on the a subject's symptoms measured, calculated transmitted to the remote internet site.

26. (new) The system of Claim 24, wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the symptom data of the severity of the subject's sleep disorder symptoms and/or the index, based in part on the a subject's symptoms measured, calculated transmitted to the remote internet site.

27. (new) The system of Claim 21, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.

28. (new) The system of Claim 27, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.

29. (new) The system of Claim 21, wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

30. (new) The system of Claim 29, wherein the airflow sensor data is processed by the second processor, in part, 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 discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

31. (new) The system of Claim 21, wherein the remote Internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the subject's sleep disorder symptoms, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device.

32. (new) The system of Claim 30, wherein the remote Internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the subject's sleep disorder symptoms, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device.

33. (new) The system of Claim 21, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the subject's sleep disorder symptoms calculated by the second processor.

34. (new) The system of Claim 31, wherein the PAP device further comprises an adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the subject's sleep disorder symptoms calculated by the second processor.

35. (new) The system of Claim 21, wherein the remote Internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, the reprocessed and/or outputted data, which is configured for review by a clinician to determine the treatment efficacy.

36. (new) The system of Claim 34, wherein the remote Internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, the reprocessed and/or outputted data, which is configured for review by a clinician to determine the treatment efficacy.

37. (new) The system in Claim 21, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

38. (new) The system in Claim 36, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

39. (new) The system in Claim 29, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.

40. (new) The system in Claim 30, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.

REMARKS

The Applicants respectfully submits that above amendments properly place the application in condition for prosecution and allowance, and such action is earnestly solicited.

Respectfully submitted,

6/10/2022
Dated _____

/Brian Kolkowski/

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
17/825,266	05/26/2022		830	CMD-117	20	3

CONFIRMATION NO. 1338

81177

Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

FILING RECEIPT



0000000134244694

Date Mailed: 06/02/2022

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

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Assignment For Published Patent Application

Cleveland Medical Devices Inc., Cleveland, OH

Power of Attorney: The patent practitioners associated with Customer Number 81177

Domestic Priority data as claimed by applicant

This application is a CON of 16/057,963 08/08/2018
which is a CON of 13/440,116 04/05/2012 PAT 10076269
which is a CON of 11/266,899 11/04/2005 PAT 8172766

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/01/2022

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/825,266**

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

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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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.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/825,266			
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	80		N/A			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	350		N/A			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A			
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *	x 50	= 0.00	OR				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x 240	= 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	830		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.									

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I hereby appoint:

☒

Practitioners associated with Customer Number:

81177

OR

☐

Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

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State

Zip

Country

Telephone

Email

Assignee name and address:

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

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SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee.

Signature/Brian M. Kolkowski 36,847/

Date 2022-05-26

Name Brian M. Kolkowski

Telephone (216) 649-0376

Title Executive Vice President, General Counsel

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 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.**

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STATEMENT UNDER 37 CFR 3.73(c)Applicant/Patent Owner: Cleveland Medical Devices Inc.Application No./Patent No.: submitted herewith Filed/Issue Date: _____Titled: Devices and Methods for Sleep Disorder Diagnosis and TreatmentCleveland Medical Devices Inc., a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

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[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Exhibit 1002 - Page 180

STATEMENT UNDER 37 CFR 3.73(c)

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☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

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The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Brian Kolkowski 36,847/

Signature

Brian Kolkowski

Printed or Typed Name

2022-05-26

Date

Executive VP, General Counsel, 36847

Title or Registration Number

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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 disclosure of these records is required by the Freedom of Information Act.
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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.
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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 inspection 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.

**Assignment of Rights, Title and Interest in Invention
(Multiple inventors; single assignee)**

Docket No.
CMD-087

This is an Assignment of the following rights, title and interest: (check all that apply):

- ☒ *United States of America rights, title and interest in the invention*
- ☐ *Foreign rights, title and interest in the invention*
- ☐ *United States Patent Application Serial No.* _____
- Date of Execution:* _____ *Date of Filing:* _____
- ☐ *United States Provisional Patent Application Serial No.* _____
- ☐ *United States Patent No(s).* _____
- ☐ *International (PCT) Patent Application Serial No.* _____
- ☐ *Other (specify)* _____

Title of the Invention

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

Inventors (assignors)

<i>Name</i>	<i>Address</i>
Hani Kayyali	3066 Woodbury Road Shaker Heights, OH 44120
Robert Schmidt	1721 Fulton Road Cleveland, OH 44113
Mohammad Modarres-Zadeh	3081 Chelsea Drive Cleveland Heights, OH 44113
Brian Kolkowski	6340 Taylor Road Leroy, OH 44077

Assignee

<i>Name</i>	<i>Address</i>
Cleveland Medical Devices, Inc.	4415 Euclid Avenue, Suite 400 Cleveland, Ohio 44103

Assignment of Rights, Title and Interest in Invention
(Multiple inventors; single assignee)

Docket No.
CMD-087

Whereas, we, the above-identified Inventors, have invented certain new and useful improvements in the Invention identified above and described in the above-identified patent application(s) and/or patent(s) (hereinafter referred to as "Invention");

And, whereas we desire to assign our above-identified rights, title and interest in the Invention to the above-identified Assignee;

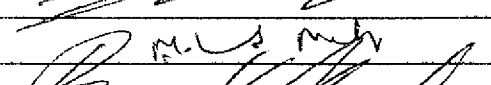
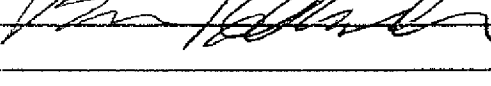
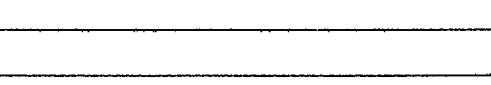
Now, this indenture witnesseth, that for good and valuable consideration, the receipt whereof is hereby acknowledged:

We hereby assign, sell and transfer our above-identified rights, title and interest in said Invention, said application(s) as identified above, including any divisions, continuations, and continuations-in-part thereof, and in and to any and all Letters Patent of the United States, and countries foreign thereto, which may be granted or have granted for said Invention, and in and to any and all reissues and reexaminations thereof, and in and to any and all priority rights, Convention rights, and other benefits accruing or to accrue to us with respect to the filing of applications for patents or securing of patents in the United States and countries foreign thereto, unto said Assignee;

And we hereby authorize and request the Director of the United States Patent and Trademark Office to issue any United States Letters Patent which may issue for said Invention to said Assignee, as assignee of the whole right, title and interest thereto;

And we further agree to sign and execute all necessary and lawful future documents, including applications for foreign patents, for filing divisions, continuations and continuations-in-part of said application for patent, and/or, for obtaining any reissue or reissues of any Letters Patent which may be granted for my aforesaid Invention, as the Assignee or its Designee(s) may from time to time require and prepare at its own expense.

Inventors' Signatures (If Notarization is desired, do not sign here and proceed to next page)

Name	Signature/Date
Hani Kayyali	 10/31/05
Robert Schmidt	 10/31/2005
Mohammad Modarres-Zadeh	 10/31/2005
Brian Kolkowski	 10/31/05

Assignment of Rights, Title and Interest in Invention
(Multiple inventors; single assignee)

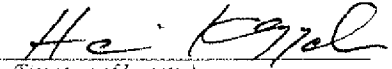
Docket No.
CMD-087

Notarization

(Although notarization is not necessary, it will be considered prima facie evidence of execution pursuant to 35 U.S.C. 261.)

Executed this 31st day of October, in the year 2005

at


(Signature of Inventor)

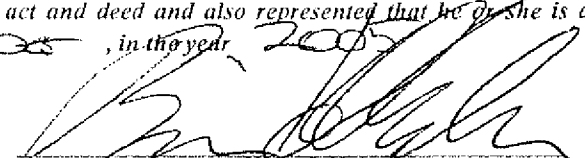
State of Ohio

County of Cuyahoga

Before me personally appeared Hani Kayyali

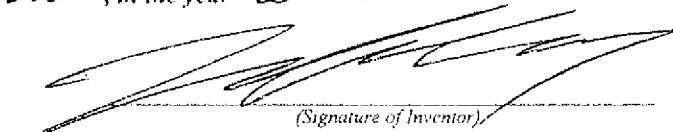
who acknowledged the foregoing instrument to be a free act and deed and also represented that he or she is authorized to execute the same this 31 day of October, in the year 2005

BRIAN M. KOLKOWSKI, ATTORNEY
NOTARY PUBLIC, STATE OF OHIO
MY COMMISSION HAS NO EXPIRATION DATE


(Notary Public)

Executed this 31st day of October, in the year 2005

at


(Signature of Inventor)

State of Ohio

County of Cuyahoga

Before me personally appeared Robert Schmidt

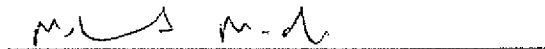
who acknowledged the foregoing instrument to be a free act and deed and also represented that he or she is authorized to execute the same this day of in the year

BRIAN M. KOLKOWSKI, ATTORNEY
NOTARY PUBLIC, STATE OF OHIO
MY COMMISSION HAS NO EXPIRATION DATE


(Notary Public)

Executed this 31 day of October, in the year 2005

at


(Signature of Inventor)

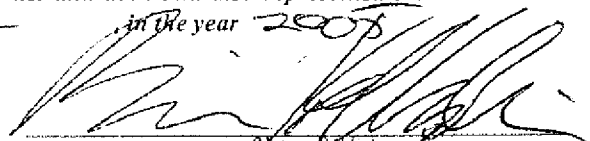
State of Ohio

County of Cuyahoga

Before me personally appeared Mohammad Modarres-Zadeh

who acknowledged the foregoing instrument to be a free act and deed and also represented that he or she is authorized to execute the same this 31 day of Oct, in the year 2005

BRIAN M. KOLKOWSKI, ATTORNEY
NOTARY PUBLIC, STATE OF OHIO
MY COMMISSION HAS NO EXPIRATION DATE


(Notary Public)

Assignment of Rights, Title and Interest in Invention
(Multiple inventors; single assignee)

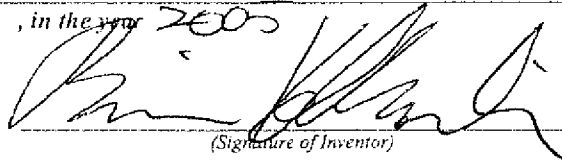
Docket No.
CMD-087

Notarization

(Although notarization is not necessary, it will be considered prima facie evidence of execution pursuant to 35 U.S.C. 261.)

Executed this 31 day of October, in the year 2005

at



(Signature of Inventor)

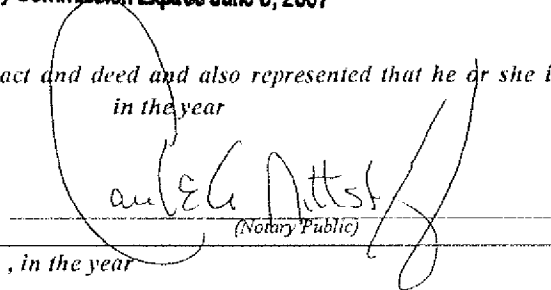
State of Ohio

County of Cuyahoga

CAROLE A. NITTSKOFF
NOTARY PUBLIC for Cuyahoga County, OH
My Commission Expires June 8, 2007

Before me personally appeared Brian Kolkowski

who acknowledged the foregoing instrument to be a free act and deed and also represented that he or she is authorized to execute the same this day of in the year



(Notary Public)

Executed this day of, in the year

at

(Signature of Inventor)

State of Ohio

County of Cuyahoga

Before me personally appeared

who acknowledged the foregoing instrument to be a free act and deed and also represented that he or she is authorized to execute the same this day of in the year

(Notary Public)

Executed this day of, in the year

at

(Signature of Inventor)

State of Ohio

County of Cuyahoga

Before me personally appeared

who acknowledged the foregoing instrument to be a free act and deed and also represented that he or she is authorized to execute the same this day of in the year

(Notary Public)

Doc code: PET.OP.AGE

Description: Petition to make special based on age/health

PTO/SB/130 (01-19)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION UNDER 37 CFR 1.102(c)(1)					
Application Information					
Application Number	submitted herewith	Confirmation Number		Filing Date	
Attorney Docket Number (optional)	CMD-117	Art Unit	Not yet assigned	Examiner	Not yet assigned
First Named Inventor	Hani Kayyali				
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment				
Attention: Office of Petitions An application may be made special for advancement of examination upon filing of a petition showing that the applicant is 65 years of age, or more. No fee is required with such a petition. See 37 CFR 1.102(c)(1) and MPEP 708.02 (II). APPLICANT HEREBY PETITIONS TO MAKE SPECIAL FOR ADVANCEMENT OF EXAMINATION IN THIS APPLICATION UNDER 37 CFR 1.102(c)(1) and MPEP 708.02 (II) ON THE BASIS OF THE APPLICANT'S AGE. A grantable petition requires one of the following items: (1) Statement by one named inventor in the application that he/she is 65 years of age, or more; or (2) Certification by a registered attorney/agent having evidence such as a birth certificate, passport, driver's license, etc. showing one named inventor in the application is 65 years of age, or more.					
Name of inventor who is 65 years of age, or older					
Given Name	Middle Name	Family Name	Suffix		
Robert		Schmidt			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the format of the signature. Select (1) or (2): ☐ (1) I am an inventor in this application and I am 65 years of age, or more. ☒ (2) I am an attorney or agent registered to practice before the Patent and Trademark Office, and I certify that I am in possession of evidence, and will retain such in the application file record, showing that the inventor listed above is 65 years of age, or more.					
Signature	/Brian Kolkowski/		Date (YYYY-MM-DD)	2022-05-26	
Name	Brian Kolkowski		Registration Number	36847	

This collection of information is required by 37 CFR 1.102(c)(1). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) a petition to make special based on age for advancement of examination. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed 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 COMPLETED FORMS TO THE CHIEF INFORMATION OFFICER. **Submit completed forms electronically over EFS-Web, or mail 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.

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/Mark Pennington

Attorney Docket Number:

CMD-117

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400

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 (\$)				830

Electronic Acknowledgement Receipt

EFS ID:	45811333
Application Number:	17825266
International Application Number:	
Confirmation Number:	1338
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-117
Receipt Date:	26-MAY-2022
Filing Date:	
Time Stamp:	13:21:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$830
RAM confirmation Number	E20225PD22254086
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-117_26May2022_continuation-specification.pdf	304900	yes	46
			a8ce3271ac02cd9d162bc7b9153dca4d11ada9a		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	42	
	Claims		43	45	
	Abstract		46	46	
Warnings:					
Information:					
2	Drawings-only black and white line drawings	CMD-117_26May2022_continuation-drawings.pdf	1623525	no	6
			ef463078d57b77a102d3672cc02241493d16e56a		
Warnings:					
Information:					
3	Application Data Sheet	CMD-117_26May2022_ADS.pdf	1823636	no	9
			9ae8f419aa46bc7fe35de8163147c8512f9ec2aa		
Warnings:					
Information:					
4	Oath or Declaration filed	CMD-117_2018_parent-declarations.pdf	202634	no	4
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Warnings:					
Information:					
5	Power of Attorney	CMD-117_26May2022_POA.pdf	482305	no	2
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				ResMed	

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Warnings:					
Information:					
6	Assignee showing of ownership per 37 CFR 3.73	CMD-117_26May2022_373statement.pdf	125595 90aeb837c6124bd967069933668bad83461fbdec	no	3
Warnings:					
Information:					
7	Assignee showing of ownership per 37 CFR 3.73	CMD-117_31Oct2005_assignment.pdf	154087 6f1c2d6bdcf44d195f033b9fadfb3b2158ad00d9	no	4
Warnings:					
Information:					
8	Petition to make special based on Age/Health	CMD-117_26May2022_PTMS-age.pdf	227743 9c27e63978a61f25a928f853c5a1a71f99ec819d	no	1
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	44378 cc68f2cc64e8d22e98a1a8d49037437581571f37	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			4988803		
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.					

DEVICES AND METHODS FOR SLEEP DISORDER DIAGNOSIS AND TREATMENT

The U.S. Government has a paid-up license in this invention and the right
5 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.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application Serial No.
10 16/057,963, which was filed on August 8, 2018, and which is a continuation of
U.S. Patent Application Serial No. 13/440,116, which was filed on April 5, 2012,
issued as U.S. Patent No. 10,076,269 on September 18, 2018, and which is a
continuation of U.S. Patent Application Serial No. 11/266,899, which was filed on
November 4, 2005, and issued as U.S. Patent No. 8,172,766 on May 8, 2012. The
15 specifications and drawings of each of the above patents and applications are
hereby incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

20 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.

25 2. TECHNICAL BACKGROUND

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 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, 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 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 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 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

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 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
5 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.,
10 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
15 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
20 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
25 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

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.

5 Measurement of airflow is preferably measured 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
10 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 dioxide monitoring, and the like.

15 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 with or without human intervention adjusting an apparatus for providing positive
20 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 the treatment device based in part on the data or signals from the diagnosis
25 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.

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
5 example of chemically treating the subject's sleeping disorder would be to have a 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
10 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.

In another embodiment, the present invention includes a sleep apnea
15 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.

In still another embodiment, the present invention includes a sleep apnea
20 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.

In still another embodiment, the present invention includes a sleeping
25 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

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
5 output of a level of severity of a subject's sleeping disorder or symptoms 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.

10 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 physically or chemically treating a subject's sleeping disorder or symptoms,
15 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 creating a quantitative output of a level of severity of a subject's sleeping disorder
20 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.

Additional features and advantages of the invention will be set forth in the
25 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.

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
5 included to provide a further understanding of the invention, and are incorporated 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.

10

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.

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FIG. 2 is a block diagram of an embodiment of the signal processing module of the sleeping disorder treatment system of the present invention.

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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.

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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.

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.

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.

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

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 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 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

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.

5 Obstructive sleep apnea is characterized by repetitive pauses in breathing 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
10 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 shuts down there's no respiratory effort and no breathing. This is in contrast with
15 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 physical blockage - though the effects are highly similar.

20 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 is treated.

25 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

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
5 acquire brain wave signals similar to those which can be obtained through, for 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
10 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
15 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
20 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
25 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
5 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
10 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
15 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. The respiration belts may contain a strain gauge, a pressure transducer or other
20 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 known to those skilled in the art. Preferably, the respiration belts are positioned
25 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.

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
5 consisting of a standard oxygen nasal cannula or facemask respectively connected 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
10 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 indirectly measure a subject's respirations.

15 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 (650nm and 805nm). The light is partly absorbed by haemoglobin, by amounts
20 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 the subject's index finger.

25 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.

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

5 analyze the signals. Physiological data is transmitted between the physiological 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
10 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,
15 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.

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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
25 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
5 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
10 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
15 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
20 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
25 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
5 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
10 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
15 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
20 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
25 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
5 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
10 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 +/- microvolts to millivolts. They also can be configured to accept digital inputs, for
15 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 if the signal processing module remains powered) can be used. The EEPROM 261
20 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 programming means 60 through the connector 64 or through radio frequency
25 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

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
5 correction and housekeeping functions. Advantageously, the digital data stream 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
10 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. The module transmitter 28 employs frequency synthesis to generate the carrier
15 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 18 which is then transmitted through the module antenna 20. The generation of
20 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 EEPROM 261 can be programmed such that the module microcontroller 26 can
25 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

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 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.

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 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 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

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 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 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 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 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

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, 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
5 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
10 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
15 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.

20 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
25 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
5 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
10 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
15 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
20 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
25 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

5 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^{16} or 65536 distinct levels. With an A/D converter 242 input range of ± 0.3 volts, each level represents $92 \mu\text{V}$. If insufficient gain is applied to the

10 external input 12 such that the total signal swing is only $200 \mu\text{V}$, 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 expected external input 12 as processed and filtered by the preceding elements as

15 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 measured external input 12. For instance, the module microcontroller 26 might

20 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 expensive, large, and power-hungry components such as very high resolution A/D

25 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

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 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
5 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
10 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 243 allows the system to readily adapt to changing measurement requirements,
15 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 the firmware.

20 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 which have mode-specific configuration. For example, the signal processing
25 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

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
5 configuration of the I/O ports and internal variables 102. Next, the module 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
10 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 of operation for the signal processing module 16.

15 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 reside in EEPROM 261 or in module microcontroller 26 memory. The module
20 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 execution of the interrupt service routine (ISR) 112, which is responsible for
25 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

"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 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 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 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.

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

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

5 module microcontroller 26, in response to the variation of the external inputs 12 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

10 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

15 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.

20 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

25 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
5 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
10 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
15 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
20 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
25 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
5 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
10 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 more preferably within 4 hours, still even more preferably within 1 hour, still
15 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.

Various algorithms known to those skilled in the art are used to filter out
20 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 schemes can be used.

25 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

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
5 are not limited to the following signal-processing techniques that are utilized to 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
10 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.

The standard deviation technique operates on the principle that there is an
15 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 control, a threshold standard deviation can be calculated for each pressure sensor
20 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 Average (ARMA) model. Advantageously, the controller is the ORICA™
25 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

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
5 the model order shifts allows the *ORICA* identifier to classify discrete models 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
10 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 models is to track the poles of the identified system model based on the subject
15 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 identification techniques based on fitting a mathematical model to the system can
20 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.

A third embodiment of a method for quantifying the power spectrum
25 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

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.

5 Therefore, it is possible to estimate the mean power spectrum by segmenting the 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
10 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.

15 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
20 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

$$25 \quad P(t, w) = \frac{1}{4\Pi^2} \iiint e^{-j\theta t - j\tau w + j\theta u} \phi(\theta, t) \\ \cdot s^*\left(u - \frac{1}{2}\tau\right) s\left(u + \frac{1}{2}\tau\right) du d\tau d\theta$$

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].

5 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 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 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. 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.

25 The present invention is envisioned to be particularly valuable in the 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 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
5 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
10 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
15 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
20 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,
25 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.

5 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.

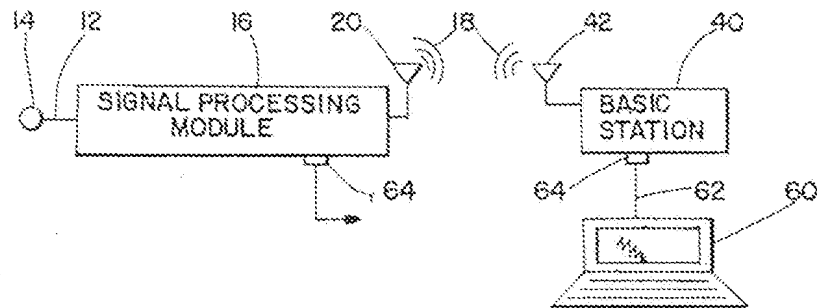


Fig. 1

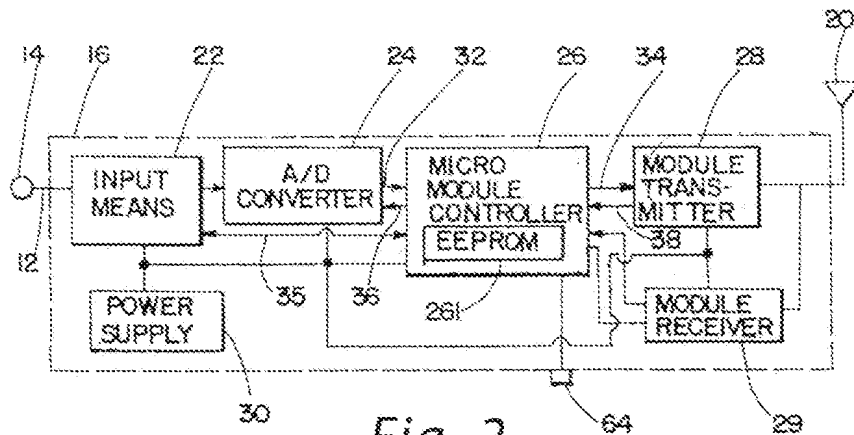


Fig. 2

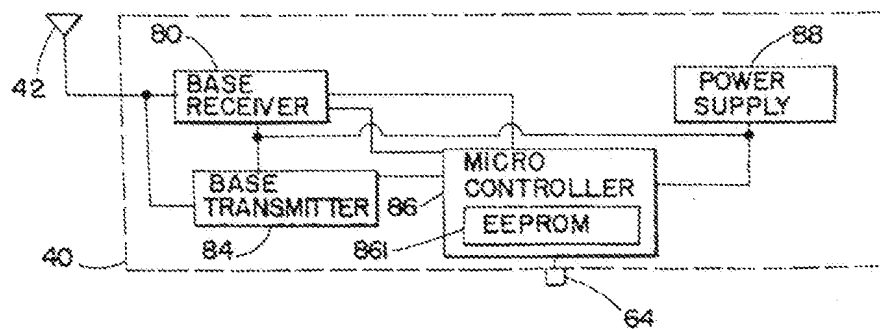
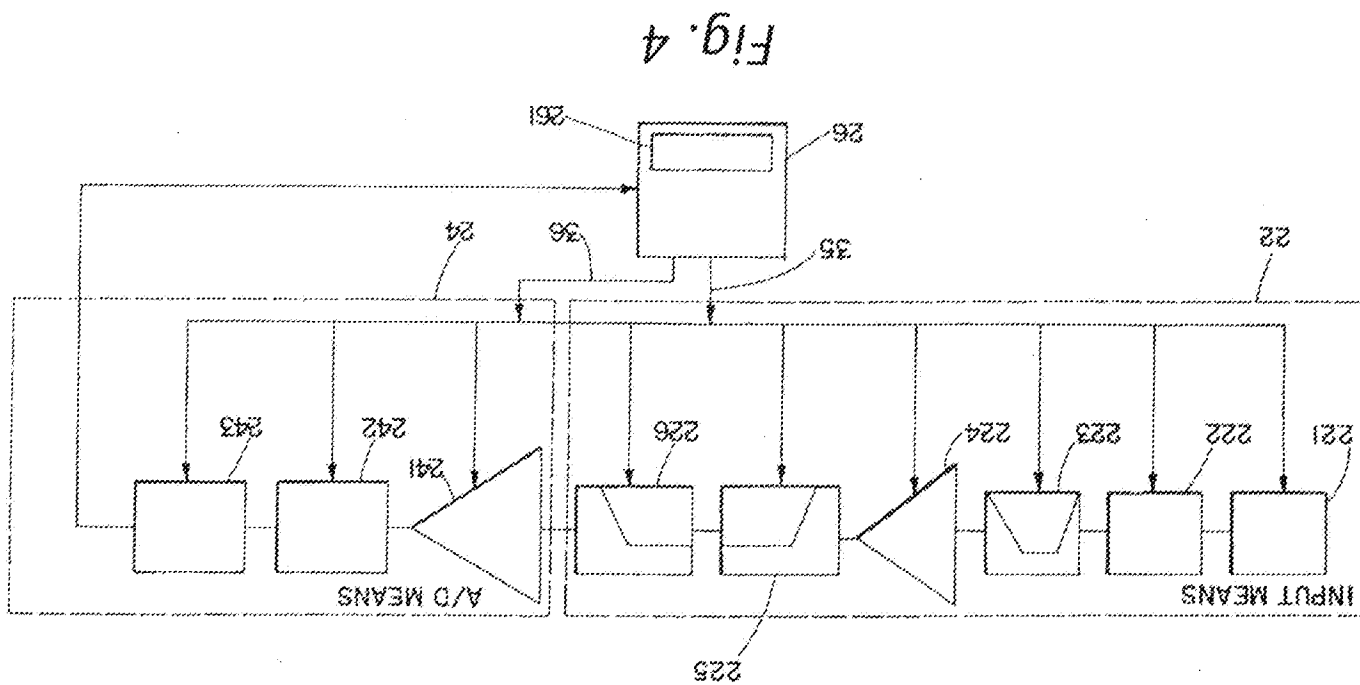


Fig. 3



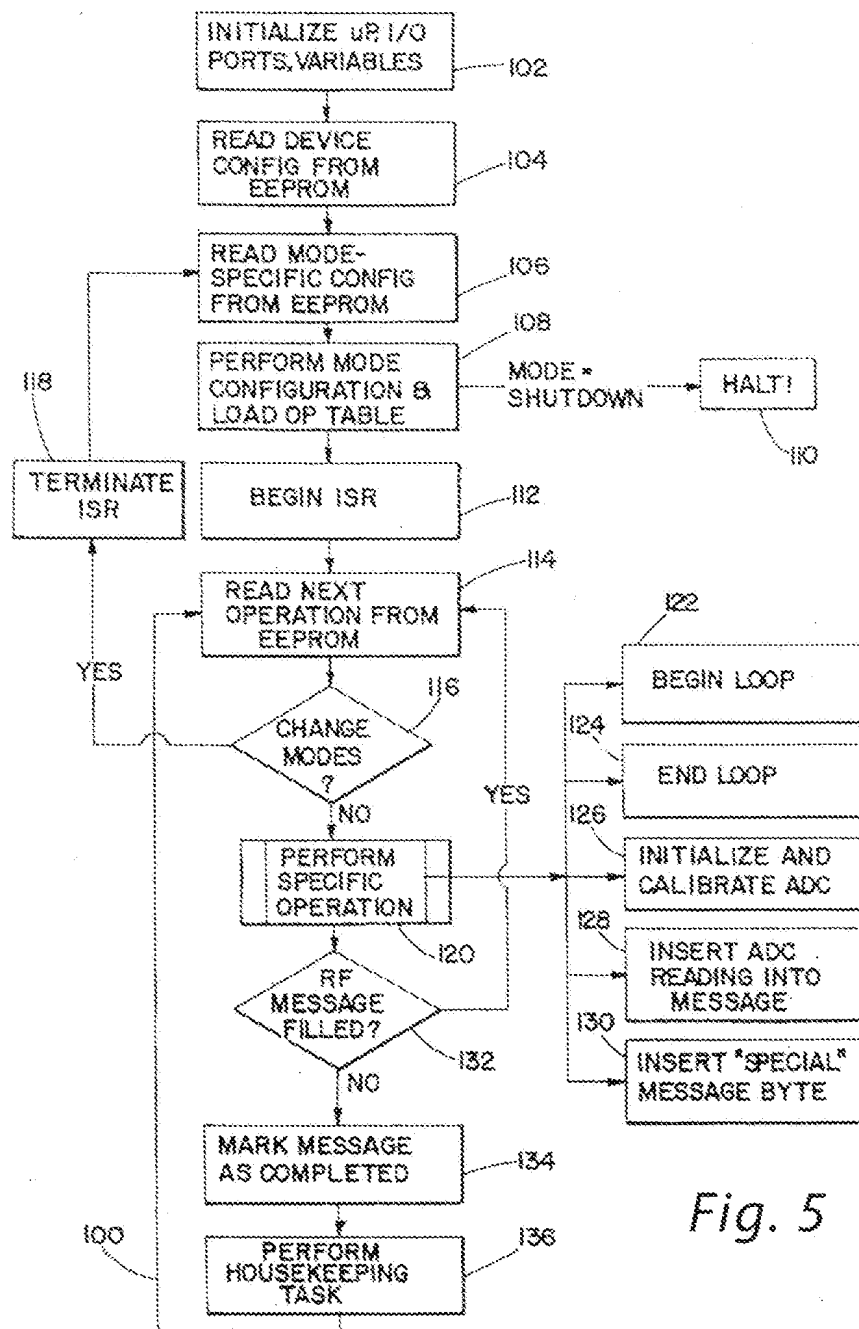


Fig. 5

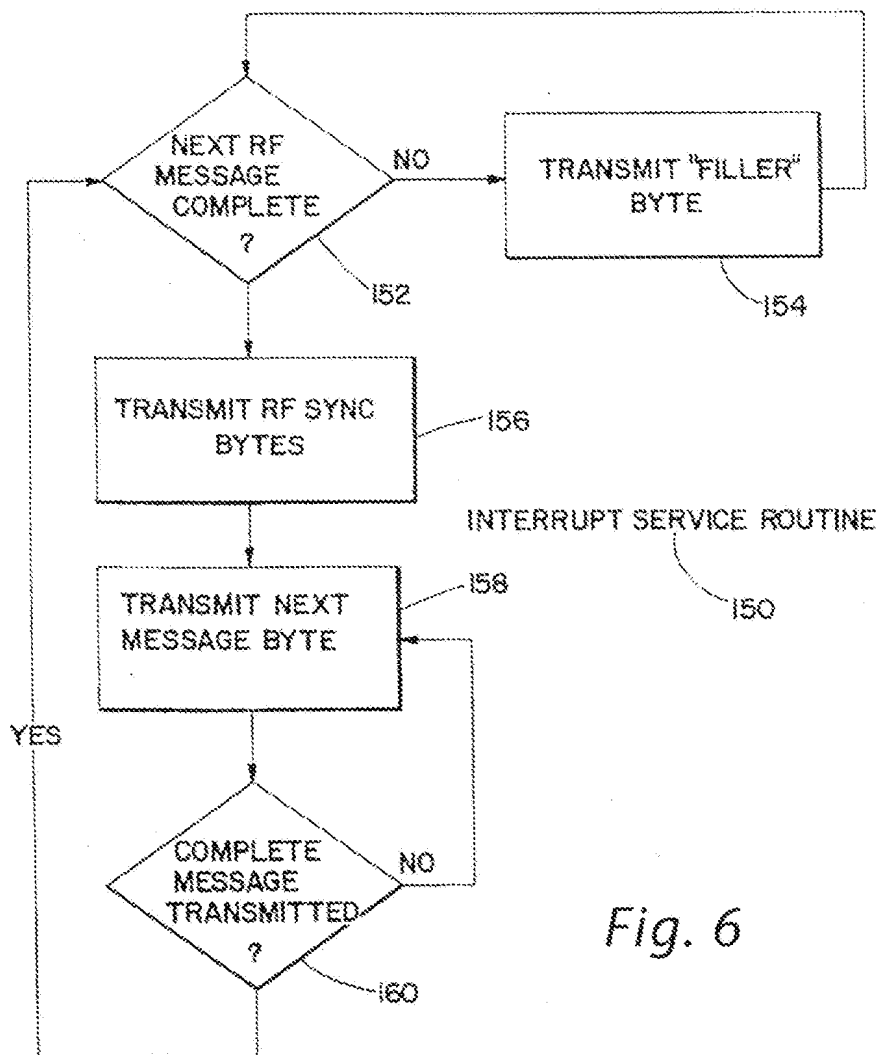


Fig. 6

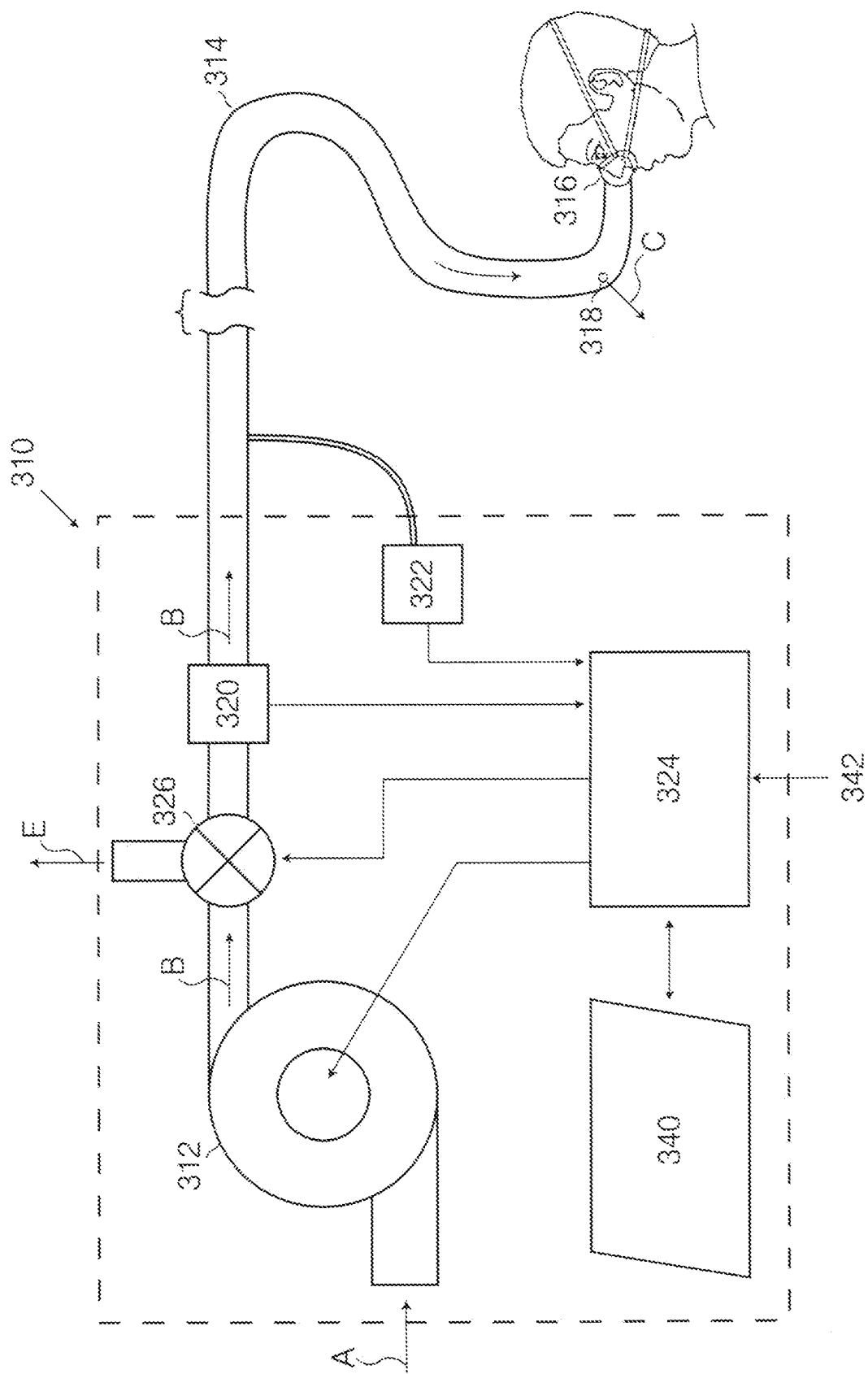


Fig. 7

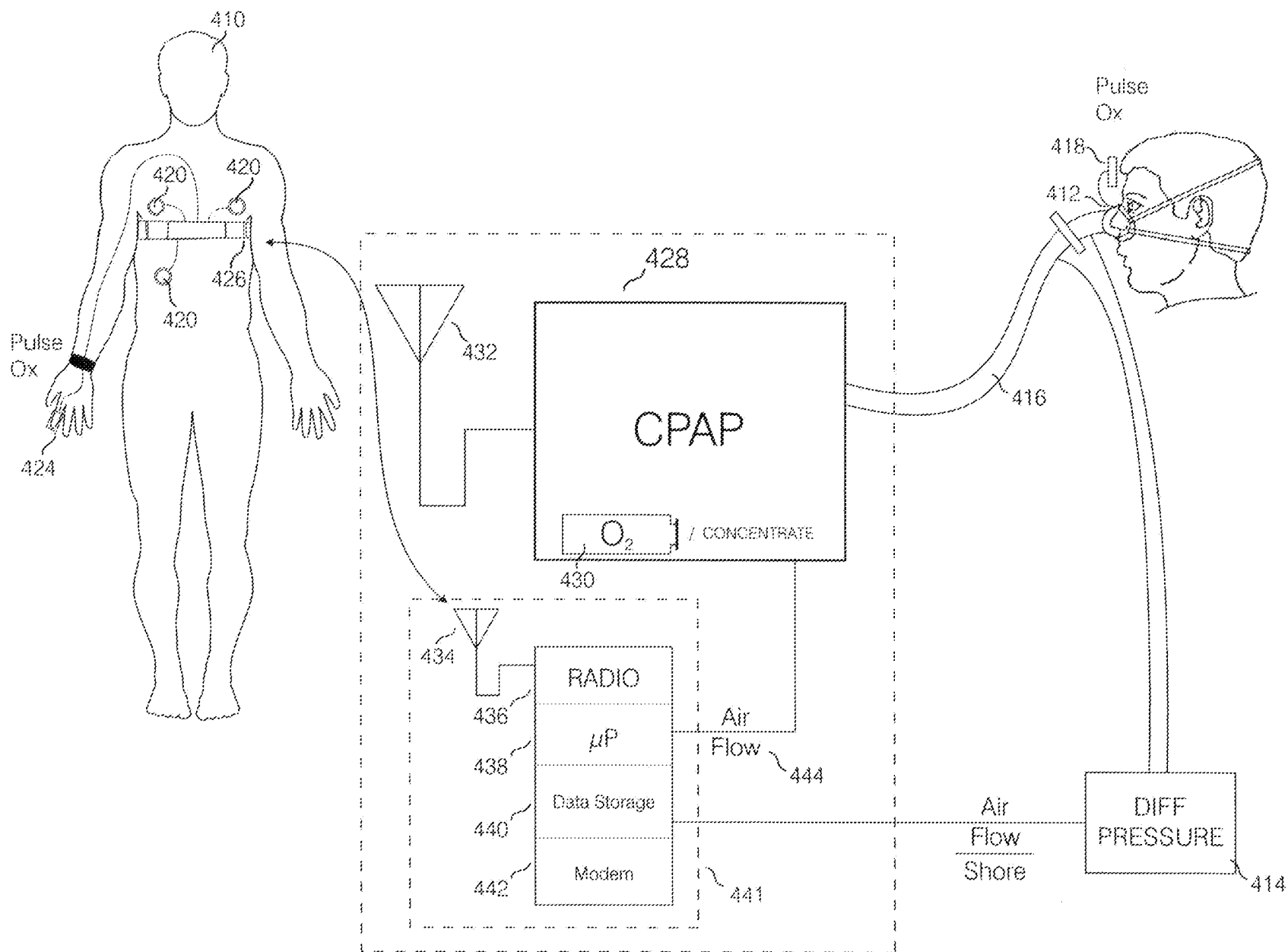


Fig. 8

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-117
		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.)
--------------------------	---

Inventor Information:

Inventor	1				Remove
Legal Name					
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	US

Mailing Address of Inventor:

Address 1	2692 Rocklyn Rd.				
Address 2					
City	Shaker Heights	State/Province	OH		
Postal Code	44122	Country	US		

Inventor	2				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Robert		Schmidt		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Ft. Myers	State/Province	FL	Country of Residence	US

Mailing Address of Inventor:

Address 1	17163 Knight Dr.				
Address 2					
City	Ft. Myers	State/Province	FL		
Postal Code	33967	Country	US		

Inventor	3				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Mohammad		Modarres-Zadeh		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-117	
		Application Number		
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment			

City	Tampa	State/Province	FL	Country of Residence	US
------	-------	----------------	----	----------------------	----

Mailing Address of Inventor:

Address 1	17910 Arbor Greene Dr.				
Address 2					
City	Tampa	State/Province	FL		
Postal Code	33647	Country	US		
Inventor	4				Remove
Legal Name					

Prefix	Given Name	Middle Name	Family Name	Suffix	
	Brian		Kolkowski		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Leroy	State/Province	OH	Country of Residence	US

Mailing Address of Inventor:

Address 1	6340 Taylor Rd.				
Address 2					
City	Leroy	State/Province	OH		
Postal Code	44077	Country	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-117	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	6	Suggested Figure for Publication (if any)	1

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-117
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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). Either enter 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	B1177		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim 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.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	16057963	2018-08-08

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		CMD-117	
		Application Number			
Title of Invention		Devices and Methods for Sleep Disorder Diagnosis and Treatment			
Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16057963	Continuation of	13440116	2012-04-05	10076269	2018-09-18
Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13440116	Continuation of	11266899	2005-11-04	8172766	2012-05-08
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 priority to a foreign application. 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. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-117
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-117
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant	1	Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section. Clear		
☒ Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.		Person who shows sufficient proprietary interest
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:		
Name of the Deceased or Legally Incapacitated Inventor:		
If the Applicant is an Organization check here. ☒		
Organization Name	Cleveland Medical Devices Inc.	
Mailing Address Information For Applicant:		
Address 1	4415 Euclid Ave., Suite 400	
Address 2		
City	Cleveland	State/Province OH
Country	US	Postal Code 44103
Phone Number	2167916720	Fax Number 2167916739
Email Address	bkolkowski@clevemed.com	
Additional Applicant Data may be generated within this form by selecting the Add button. Add		

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-117
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

Assignee	1		
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
			Remove
If the Assignee or Non-Applicant Assignee is an Organization check here.			☒
Organization Name	Cleveland Medical Devices Inc.		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	4415 Euclid Ave., Suite 400		
Address 2			
City	Cleveland	State/Province	OH
Country i	US	Postal Code	44103
Phone Number	2167916720	Fax Number	2167916739
Email Address	bkolkowski@clevemed.com		
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			Add

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is **not** checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Brian Kolkowski/		Date (YYYY-MM-DD)	2022-05-26	
First Name	Brian	Last Name	Kolkowski	Registration Number	36847
Additional Signature may be generated within this form by selecting the Add button.				Add	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	CMD-117
		Application Number	
Title of Invention	Devices and Methods for Sleep Disorder Diagnosis and Treatment		

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.

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.

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)****Title of
Invention**

Devices and methods for sleep disorder diagnosis and treatment

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 16/057,963filed on August 8, 2018

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: Hani KayyaliDate (Optional): 10/13/18Signature: Hani Kayyali

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

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.

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)****Title of
Invention**

Devices and methods for sleep disorder diagnosis and treatment

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 16/057,963filed on August 8, 2018

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: Robert Schmidt

Date (Optional) : _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of
Invention

Devices and methods for sleep disorder diagnosis and treatment

As the below named inventor, I hereby declare that:

This declaration
is directed to:

☐

The attached application, or

☒

United States application or PCT international application number 16/057,963

filed on August 8, 2018

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

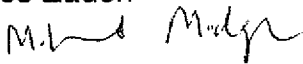
WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Mohammad Modarres-Zadeh

Date (Optional): 09/18/2018

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)****Title of
Invention**

Devices and methods for sleep disorder diagnosis and treatment

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 16/057,963filed on August 8, 2018

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001
by fine or imprisonment of not more than five (5) years, or both.**WARNING:**

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Brian Kolkowski

Date (Optional):

10/2/18

Signature:



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