PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

EPAS ID: PAT2889395

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	SECURITY INTEREST

CONVEYING PARTY DATA

Name	Execution Date
CLEVELAND MEDICAL DEVICES, INC.	05/30/2014

RECEIVING PARTY DATA

Name:	THE DIRECTOR OF THE OHIO DEVELOPMENT SERVICES AGENCY
Street Address:	77 SOUTH HIGH STREET, 29TH FLOOR
City:	COLUMBUS
State/Country:	OHIO
Postal Code:	43215

PROPERTY NUMBERS Total: 39

Property Type	Number
Patent Number:	5755230
Patent Number:	5970105
Patent Number:	6223061
Patent Number:	6993380
Patent Number:	7593767
Patent Number:	7845350
Patent Number:	7860561
Patent Number:	7865234
Patent Number:	7942824
Patent Number:	8172766
Patent Number:	8335561
Patent Number:	8424527
Patent Number:	8437843
Patent Number:	8545416
Application Number:	29364922
Application Number:	11505204
Application Number:	11526251
Application Number:	11729524
Application Number:	11811156
Application Number:	11811157
Application Number:	11999198

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

CORRESPONDENCE DATA

Fax Number: (513)579-6457

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

Phone: 5135796590
Email: mmusekamp@kmklaw.com
Correspondent Name: MARK E. MUSEKAMP
Address Line 1: ONE EAST 4TH STREET, SUITE 1400
Address Line 4: CINCINNATI, OHIO 45202

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

Total Attachments: 11
source=Executed IP Security Agreement#page1.tif
source=Executed IP Security Agreement#page2.tif
source=Executed IP Security Agreement#page3.tif
source=Executed IP Security Agreement#page4.tif
source=Executed IP Security Agreement#page5.tif
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INTELLECTUAL PROPERTY SECURITY AGREEMENT

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

Background Information

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

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

Provisions

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

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

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

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

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

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

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

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

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

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

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

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

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

[SIGNATURE PAGE FOLLOWS]

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

CLEVELAND MEDICAL DEVICES, INC.

By _____
Name: Hani Kayyali
Title: President

AGREED TO AND ACCEPTED:

THE DIRECTOR OF THE OHIO DEVELOPMENT SERVICES AGENCY

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

EXHIBIT A

SCHEDULES

Schedule 1 – Issued Patents and Patent Applications

Patents – Issued

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

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iii. Application No.: 11/453,709

iv. Filing Date: 06/15/2006

6. Automatic Continuous Positive Airway Pressure Treatment System with Fast Respiratory Response (CMD-044)

i. Patent No.: 7,845,350

ii. Issue Date: 12/07/2010

iii. Application No.: 11/498,643

iv. Filing Date: 08/03/2006

7. Method of Quantifying a Subject's Wake or Sleep State and System for Measuring (CMD-009)

i. Patent No.: 7,860,561

ii. Issue Date: 12/28/2010

iii. Application No.: 10/860,863

iv. Filing Date: 06/04/2004

8. Quantitative Method for the Therapeutic Treatment of Sleep Disorders (CMD-002)

i. Patent No.: 7,865,234

ii. Issue Date: 01/04/2011

iii. Application No.: 11/021,594

iv. Filing Date: 12/22/2004

9. Integrated Sleep Diagnostic and Therapeutic System and Method (CMD-057)

i. Patent No.: 7,942,824

ii. Issue Date: 05/17/2011

iii. Application No.: 11/879,934

iv. Filing Date: 07/19/2007

10. Integrated Sleep Diagnosis and Treatment Device and Method (CMD-023)

i. Patent No.: 8,172,766

ii. Issue Date: 05/08/2012

iii. Application No.: 11/266,899

iv. Filing Date: 11/04/2005

11. Quantitative Method for Assessment of Excessive Daytime Sleepiness (CMD-079)

i. Patent No.: 8,335,561

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ii. Issue Date: 12/18/2012

iii. Application No.: 12/957,098

iv. Filing Date: 11/30/2010

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

i. Patent No.: 8,424,527

ii. Issue Date: 04/23/2013

iii. Application No.: 12/231,741

iv. Filing Date: 09/05/2008

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

i. Patent No.: 8,437,843

ii. Issue Date: 05/07/2013

iii. Application No.: 11/454,482

iv. Filing Date: 06/16/2006

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

i. Patent No.: 8,545,416

ii. Issue Date: 10/01/2013

iii. Application No.: 11/880,046

iv. Filing Date: 07/19/2007

15. Sleep Diagnostic Device (CMD-074)

i. Patent No.: D663,430

ii. Issue Date: 07/10/2012

iii. Application No.: 29/364,922

iv. Filing Date: 06/30/2010

Patents – Pending Applications

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

i. Application No.: 11/505,204

ii. Filing Date: 08/16/2006

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

i. Application No.: 11/526,251

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ii. Filing Date: 09/22/2006

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

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

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ii. Filing Date: 03/29/2013

38. Integrated Diagnostic and Therapeutic System and Method for Improving Treatment of Subject with Complex and Central Sleep Apnea (CMD-092)
    i. Application No.: 13/975,792
    ii. Filing Date: 08/26/2013
39. Medical Device and Method with Improved Biometric Verification (CMD-093)
    i. Application No.: 14/173,897
    ii. Filing Date: 02/06/2014

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Schedule 2 – Trademark Registrations and Applications

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

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Schedule 3 – Copyright Registrations and Applications

None.

5402585.3

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UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/266,899	05/08/2012	8172766	CMD-023	8590

81177 7590 04/18/2012

Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 400
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 1846 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 Data Management (ODM) at (571)-272-4200.

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

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

OPAP APR 05 2012 PATENT AND TRADEMARK OFFICE

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (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)

81177 7590 01/05/2012
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 400
Cleveland, OH 44103

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.

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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Matthew Beutler	(Depositor's name)
/Matthew Beutler/	(Signature)
04/05/2012	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

TITLE OF INVENTION: INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$0	$0	$870	04/05/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
NATNITHITHADHA, NAVIN	3735	600-544000

04/06/2012 MBLANC01 00000003 11266899
01 FC:2501 870.00 OP

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/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form 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,
(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.
1 Brian M Kelkaski
2 Robert K. Schmidt
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 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.

(A) NAME OF ASSIGNEE: Cleveland Medical Devices Inc (B) RESIDENCE: (CITY and STATE OR COUNTRY) Cleveland, Ohio

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

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)
☒ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Brian M Kelkaski/ Date 4/5/2012
Typed or printed name Brian M Kelkaski Registration No. 36,847

This collection of information 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 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, 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.



PTO/SB/97 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U S Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office

on 04/05/2012.
Date

Signature

MATTHEW BEUTLER
Typed or printed name of person signing Certificate

67,494
Registration Number, if applicable

216-619-5946
Telephone Number

Note: Each paper must have its own certificate of transmission, or this certificate must identify each submitted paper.

This collection of information is required by 37 CFR 1.8. 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 1.8 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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11266899	KAYYALI ET AL.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3735

SEARCHED			
Class	Subclass	Date	Examiner
600	300,544,545,529-543,481,483,484	11/6/09	/NN/

SEARCH NOTES		
Search Notes	Date	Examiner
EAST (enclosed), USPAT, US-PGPUB, Inventor, IDS, Keyword searches	11/6/09	/NN/

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/N. N./ Examiner, Art Unit 3735	

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Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

81177 7590 01/05/2012

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

EXAMINER
NATNITHITHADHA, NAVIN

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 01/05/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

TITLE OF INVENTION: INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$0	$0	$870	04/05/2012

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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 and an extra copy of the form should be submitted. 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: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (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)

81177 7590 01/05/2012
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 400
Cleveland, OH 44103

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.

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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

TITLE OF INVENTION: INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$0	$0	$870	04/05/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
NATNITHITHADHA, NAVIN	3735	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/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form 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,
(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.
1 _____
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 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.

(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. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information 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 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, 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.

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.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

81177 7590 01/05/2012

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

EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 01/05/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 935 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 935 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.	Applicant(s)	
	11/266,899	KAYYALI ET AL.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- 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, filed 28 October 2011*.

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 *1-20*.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   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. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ 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).

7. ☐ 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)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Navin Natnithithadha/
Primary Examiner, Art Unit 3735

REASONS FOR ALLOWANCE

1. According to the Amendment, filed 28 October 2011, the status of the claims is as follows:

Claims 1-3 are currently amended;
Claim 19 is as originally filed;
Claims 4, 5, 7-11, 13-18, and 20 are previously presented; and
Claims 6 and 12 are withdrawn.

2. Applicant's arguments, see Remarks, pp. 6-14, filed 28 October 2011, with respect to the rejection of claims 1-3, 5, 7-9, 11, and 12 under 35 U.S.C. 103(a) as being unpatentable over Wright et al, U.S. Patent Application Publication No. 2002/018130 A1 ("Wright"), in view of Farrell et al, U.S. Patent No. 7,878,198 B2 ("Farrell"), have been fully considered, and are persuasive. The rejection of claims 1-3, 5, 7-9, 11, and 12 has been withdrawn.

3. Applicant's arguments, see Remarks, pp. 14-15, filed 28 October 2011, with respect to the rejection of claims 4, 10, and 13 under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Farrell, as applied to claims 1 and 7 above, and further in view of Tsukashima et al, U.S. Patent No. 7,101,341 B2 ("Tsukashima"), have been fully considered, and are persuasive. The rejection of claims 4, 10, and 13 has been withdrawn.

4. Applicant's arguments, see Remarks, pp. 16-23, filed 28 October 2011, with respect to the rejection of claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Farrell, and further in view of Tsukashima, have been fully considered, and are persuasive. The rejection of claims 4, 10, and 13 has been withdrawn.

5. Claims 6 and 12, directed to the system of allowable base claims 4 and 10, respectively, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability.

Because all claims previously withdrawn from consideration have been rejoined, the restriction requirement as set forth in the Office action mailed on 09 November 2009 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Claims 1-20 are allowed.

7. 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.”

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

(571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Navin Natnithithadha/
Primary Examiner, Art Unit 3735
12/24/2011

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

BIB DATA SHEET

CONFIRMATION NO. 8590

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/266,899	11/04/2005	600	3735	CMD-023

APPLICANTS

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

**** CONTINUING DATA ***************************

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
01/18/2006

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /NAVIN NATNITHITHADHA/ Examiner's Signature	☐ Met after Allowance /NN/ Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		OH	6	20	3

ADDRESS

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

TITLE

Integrated sleep diagnosis and treatment device and method

FILING FEE RECEIVED		
500	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11266899	KAYYALI ET AL.
Examiner	**Art Unit**
NAVIN NATNITHITHADHA	3735

ORIGINAL		INTERNATIONAL CLASSIFICATION															
CLASS	SUBCLASS	CLAIMED									NON-CLAIMED						
600	534	A	6	1	B	5 / 08 (2006.0)											
CROSS REFERENCE(S)		A	6	1	B	5 / 02 (2006.0)											
		A	6	2	B	7 / 00 (2006.0)											
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)	A	6	2	B	7 / 04 (2006.01.01)											
600	529	483	500														
128	204.23	204.26															

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17												
2	2	18	18												
3	3	19	19												
4	4	20	20												
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12	12														
13	13														
14	14														
15	15														
16	16														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/NAVIN NATNITHITHADHA/ Primary Examiner.Art Unit 3735	12/24/2011	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11266899	KAYYALI ET AL.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3735

SEARCHED

Class	Subclass	Date	Examiner
600	300,544,545,529-543,481,483,484	11/6/09	/NN/
600	300,544,545,529-543,481,483,484	5/13/10	/NN/
600	300,544,545,529-543,481,483,484	11/5/10	/NN/
600	300,544,545,529-543,481,483,484	2/1/11	/NN/
600	300,544,545,529-543,481,483,484	8/3/11	/NN/
600	300,544,545,529-543,481,483,484	12/23/11	/NN/
128	204.23,204.26	12/23/11	/NN/

SEARCH NOTES

Search Notes	Date	Examiner
EAST (enclosed), USPAT, US-PGPUB, Inventor, IDS, Keyword searches	11/6/09	/NN/
EAST (enclosed), USPAT, US-PGPUB, IDS, Art of Record, Keyword searches	5/13/10	/NN/
EAST (enclosed), USPAT, US-PGPUB, IDS, Art of Record, Keyword searches	11/5/10	/NN/
EAST (enclosed), USPAT, US-PGPUB, Art of Record, Keyword searches	2/1/11	/NN/
EAST (enclosed), USPAT, US-PGPUB, Art of Record, Keyword searches	8/3/11	/NN/
EAST: USPAT, US-PGPUB, EPO, JPO, Derwent, Art of Record, Keyword searches	12/23/11	/NN/
EAST: Interference search	12/24/11	/NN/

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
600	534,529,538,483,500	12/24/11	/NN/
128	204.23,204.26	12/24/11	/NN/

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	11/266,899	Art Unit:	3735
Filed:	November 4, 2005	Docket No.:	CMD-023
For:	Integrated sleep diagnosis and treatment device and method		
Examiner:	Navin Natnithithadha		

October 28, 2011

AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

Dear Sir:

This communication is being submitted in response to the non-final Office Action issued in the above-captioned case, the Office Action having a mail date of August 9, 2011 and a due date for timely response of November 9, 2011. The Applicants herein claim small entity status. The Applicants submit that this communication is being timely filed. While the Applicants believe that no extension of time is necessary for this communication, if the Commissioner finds that an extension of time is needed, the Applicants petition for such extension and authorize the Commissioner to deduct extension fees and any other fees as are found to be necessary from their deposit account 502704.

ResMed
Exhibit 1004 - Page 30

IN THE CLAIMS:

Please amend claims 1-3 as follows:

1. (currently amended) A sleeping disorder treatment system comprising

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

a continuous positive airway pressure device (CPAP) for treating a subject's sleeping disorder or symptoms, which can receive the output of the data acquisition system and produce a recommended positive pressure setting in response to the output of the data acquisition system, and which further requires human intervention prior to changing the positive pressure delivered to the subject. ~~be adjusted using in part the output from the data acquisition system.~~

2. (currently amended) The system in Claim 1, wherein the ~~CPAP is adjusted in real time~~human intervention is performed by a physician or other clinician.

3. (currently amended) The system in Claim 1, wherein ~~the CPAP is automatically adjusted by using data or a signal from the data acquisition system~~ the human intervention is performed by the subject being treated.

4. (previously presented) The system in Claim 1, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

ResMed
Exhibit 1004 - Page 31

5. (previously presented) The system in Claim 4, wherein the data acquisition system further collects a subject's brain wave signal.

6. (withdrawn) The system in Claim 4, wherein the physiological signal is an EKG signal.

7. (previously presented) A sleep apnea treatment system comprising

a data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor, the data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas; and

a continuous positive airway pressure (CPAP) device for treating the subject's sleep apnea, the CPAP device having an airflow sensor with a signal, wherein the CPAP device can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor.

8. (previously presented) The system in Claim 7, wherein the CPAP device is adjusted in real time.

9. (previously presented) The system in Claim 7, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

10. (previously presented) The system in Claim 7, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

11. (previously presented) The system in Claim 10, wherein the data acquisition system further collects a subject's brain wave signal.

12. (withdrawn) The system in Claim 10, wherein the physiological signal is an EKG signal.

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Exhibit 1004 - Page 32

13. (previously presented) The system in Claim 7, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

14. (previously presented) A sleep apnea treatment system comprising

a data acquisition system and a continuous positive airway pressure (CPAP) device with an airflow sensor having a signal and a transceiver,

the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor, the data acquisition device further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device, the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas

wherein the CPAP device can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device.

15. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted in real time.

16. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

17. (previously presented) The system in Claim 14, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio

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frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

18. (previously presented) The system in Claim 14, wherein the CPAP device further comprises a nebulizer.

19. (original) The system in Claim 18, wherein the nebulizer is used to deliver medication.

20. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted by a remote control device.

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REMARKS

The following remarks are submitted in response to the non-final Office Action issued in the above-captioned case, the Office Action having a mail date of August 9, 2011 and a due date for timely response of November 9, 2011. Claims 1-20 are currently pending, claims 6 and 12 have been withdrawn from consideration, and claims 1-5, 7-11 and 13-20 currently stand rejected. The Applicants respectfully traverse these rejections below.

CLAIM REJECTIONS – 35 U.SC. § 103

The Applicants note the Examiner's reminder of the Applicants' obligation under 37 C.F.R. §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. The Applicants submit that all claims of the current application are commonly owned by Cleveland Medical Devices Inc. and have been commonly owned by Cleveland Medical Devices Inc. since the time of filing of the present application.

Claims 1-3, 5, 7-9, 11 and 12 are patentable over U.S. Patent Application Publication No. 2002/0185130 to Wright et al. (hereinafter "Wright") in view of U.S. Patent No. 7,878,198 to Farrell et al. (hereinafter "Farrell").

Claim 1

With respect to claim 1, the Applicants note that claim 1 stands currently amended. The Applicants believe that this amendment now places claim 1 in condition for allowance and respectfully request that such action be taken by the Examiner. In particular, the Applicants respectfully submit that, among other limitations, the limitation of a CPAP device producing a "recommended positive pressure setting in response to the output of the data acquisition system, and which further requires human intervention prior to changing the positive pressure delivered to the subject" is not disclosed in Wright or Farrell, whether taken together or independently.

The Applicants further note that claim 1 requires that the data acquisition system be capable of "creating a quantitative output of the level of severity of a subject's sleeping disorder or symptoms." While paragraph [0045] of Wright states that the apparatus disclosed therein can generate an apnea hypopnea index, or AHI, and while AHI is an indicator of the level of severity

of a patient's sleep disordered breathing, one of ordinary skill in the art would recognize that the method of obtaining AHI described in paragraph [0045] does not even require the use of a respiration belt sensor and pulse oximeter sensor as does claim 1. Accordingly, since claim 1 requires a data acquisition system including respiration belt and pulse oximeter sensors, it cannot be said that paragraph [0045] is sufficient to disclose this limitation of claim 1.

In addition, paragraph [0062] of Wright indicates that in one form of sleep study that uses a portable device, a patient's AHI "is determined and each event is classified…[a]pneas can be classified as obstructive, central or mixed." However, this statement says nothing about how such determination and classification is accomplished. More particularly, this statement does not indicate whether determination of AHI and classification of apneas is accomplished in the traditional way of having a physician or sleep technologist examine the data after it is recorded or whether the portable device itself performs classification. Because claim 1 specifically requires that the data acquisition device itself be capable of "creating a quantitative output of the level of severity of a subject's sleeping disorder or symptoms," it cannot reasonably be said, without more evidence or explanation by the Examiner, that this vague statement in paragraph [0062] is sufficient to disclose the limitations required by claim 1.

In light of the above remarks it is clear that the disclosure of Wright, and, in particular, paragraphs [0045] and [0062] of Wright, do not disclose a "data acquisition system for creating an output of the level of severity of a subject's sleeping disorder or symptoms" as required by claim 1. This, in turn, is clear evidence that the Examiner has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claims at issue as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Applicants thus respectfully remind the examiner that "[o]mission of a relevant factor [e.g. one of the *Graham* factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

With further respect to claim 1, the Examiner openly admits that Wright does not teach a CPAP device that "can receive the output of the data acquisition system and produce a recommended positive pressure setting in response to the output" as required by claim 1. To bridge this evidentiary gap, the Examiner cites to Farrell. The Examiner contends that Farrell discloses adjustment of a CPAP device using the output of a data acquisition device by citing to col. 5, ll. 50-60 of Farrell. This portion of the Farrell disclosure states in relevant part that "the

therapeutic pressure levels…may be automatically adjusted or set by automatic detection of SDB related events…as disclosed in U.S. Pat. 5,704,345" (emphasis added). The Applicants have examined U.S. Pat. 5,704,345 to Berthon-Jones (hereinafter "Berthon-Jones") and have found that Berthon-Jones is silent as to the use of respiratory belt and pulse oximeter as sensors for detecting sleep disordered breathing, much less to adjust a CPAP based on the output of a data acquisition system to which such sensors are attached. Thus, because Farrell relies on incorporation of Berthon-Jones, neither Farrell nor Berthon-Jones disclose adjustment of a CPAP device using the output of a data acquisition system that has "inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor" as required by claim 1.

In addition, the Examiner notes that it would have been obvious to combine Wright and Farrell to arrive at the invention of claim 1 because "Wright suggests such a combination" by stating that "[o]ther known alternative methods to vary the pressure for delivering CPAP treatment to a patient to treat obstructive sleep apneas would be recognized by those skilled in the art and may be utilized as modes in the device." Wright, paragraph [0031] and Office Action 08/09/2011, page 11. However, this motivation to combine is really no motivation at all, since, as already pointed out above, the alleged "other known methods to vary the pressure for delivering CPAP treatment" disclosed in Farrell are silent as to the use of a respiratory belt and pulse oximeter as sensors for detecting sleep disordered breathing, much less to adjustment of a CPAP based on the output of a data acquisition system to which such sensors are attached. Furthermore, the mere statement in Wright that "other known alternative methods" may be used does not relieve the Examiner of his burden to provide specific evidence of such other alternative methods that read on the claims at issue. The Applicants would thus respectfully remind the Examiner that when, as here, the Examiner chooses to rely upon the combination of multiple references to support a rejection under 35 U.S.C. § 103(a) the Examiner must provide "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.." *In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (emphasis added).

For all of the above reasons, the Applicants respectfully request the rejection of claim 1 be withdrawn and that claim 1 be allowed.

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Claims 2 and 3

Inasmuch as claims 2 and 3 are dependent on claim 1, the Applicants hereby incorporate their above remarks regarding claim 1. Further, claims 2 and 3 currently stand amended, and the Applicants respectfully submit that neither Wright, nor Farrell, disclose the limitations of human intervention being performed by a physician or clinician, or by the subject being treated. Accordingly, the Applicants respectfully request that the rejection of claims 2 and 3 be withdrawn.

Claim 5

Inasmuch as claim 5 is dependent on claim 1, the Applicants hereby incorporate their above remarks regarding claim 1. The Applicants further note that while Wright does disclose a diagnosis unit that includes EEG and ECG, the mere disclosure of a claimed item in isolation is not sufficient to support a rejection for obviousness under § 103(a). This is because obviousness requires that the *invention as a whole* be considered from the perspective of one of ordinary skill in the art. Here, the Examiner has chosen to remain silent regarding both the level of ordinary skill in the art as well as the reasons one of ordinary skill in the art would have combined the references in such a way as to arrive at the invention embodied in claim 5. The Applicants would thus respectfully remind the Examiner that when, as here, the Examiner chooses to rely upon the combination of multiple references to support a rejection under 35 U.S.C. § 103(a) the Examiner must provide "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.." *In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (emphasis added). Since the Examiner has not done so in the present case, the Applicants respectfully submit that maintaining the rejection of claim 5 would be improper and that the rejection should be withdrawn.

Claim 7

Claim 7 requires that the data acquisition system be capable of "diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas." The Examiner asserts that this limitation is met by the disclosure of Wright at paragraphs [0035],

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[0045] and [0062]. Paragraph [0035] notes that the apparatus disclosed in Wright "generates one or several indices…useful for assessing appropriate treatment or diagnosing the condition of the patient." Thus, paragraph [0035] of Wright notes that the apparatus disclosed in Wright generates information that is merely *useful for* diagnosing the condition of a patient, but, significantly, is not capable of actually diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas as required by claim 7.

Paragraph [0045] of Wright states that the apparatus disclosed by Wright can generate an apnea hypopnea index, or AHI. However, while AHI is indeed an indicator of the level of severity of a patient's sleep disordered breathing, one of ordinary skill in the art would recognize that AHI alone is not sufficient to diagnose the type of sleep disordered breathing that a patient has, because AHI alone as described in paragraph [0045] does not distinguish between central apneas and obstructive apneas. Moreover, the method of obtaining AHI described in paragraph [0045] does not even require the use of a respiration belt sensor and pulse oximeter sensor as does claim 7. Accordingly, since claim 7 requires a data acquisition system including respiration belt and pulse oximeter sensors and that is capable of "diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas" it cannot be said that paragraph [0045] is sufficient to disclose this limitation of claim 7.

Paragraph [0062] of Wright indicates that in one form of sleep study that uses a portable device a patient's AHI "is determined and each event is classified…[a]pneas can be classified as obstructive, central or mixed." However, this statement says nothing about how such classification is accomplished. More particularly, this statement does not indicate whether classification is accomplished in the traditional way of having a physician or sleep technologist examine the data or whether the portable device itself performs classification. Because claim 7 specifically requires that the data acquisition device be capable of "diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas" it cannot reasonably be said that this vague statement in paragraph [0062] is sufficient to fully disclose the limitations required by claim 7.

In light of the above remarks it is clear that the disclosure of Wright, and, in particular, paragraphs [0035], [0045] and [0062] of Wright, do not disclose a "data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas" as required by claim 7. This, in turn, is clear evidence that the Examiner has

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neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claims at issue as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Applicants thus respectfully remind the examiner that "[o]mission of a relevant factor [e.g. one of the *Graham* factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

With further respect to claim 7, the Examiner openly admits that Wright does not teach a CPAP device that "can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor" as required by claim 7. To bridge this evidentiary gap, the Examiner cites to Farrell. The Examiner contends that Farrell discloses adjustment of a CPAP device using the output of a data acquisition device by citing to col. 5, ll. 50-60 of Farrell. This portion of the Farrell disclosure states in relevant part that "the therapeutic pressure levels…may be automatically adjusted or set by automatic detection of SDB related events…as disclosed in U.S. Pat. 5,704,345" (emphasis added). The Applicants have examined U.S. Pat. 5,704,345 to Berthon-Jones (hereinafter "Berthon-Jones") and have found that Berthon-Jones is silent as to the use of respiratory belt and pulse oximeter as sensors for detecting sleep disordered breathing, much less to adjust a CPAP based on the output of a data acquisition system to which such sensors are attached. Thus, because Farrell relies on incorporation of Berthon-Jones, neither Farrell nor Berthon-Jones disclose adjustment of a CPAP device using the output of a data acquisition system that has "inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor" as required by claim 7.

The Applicants respectfully remind the Examiner that although a rejection based on 35 U.S.C. §103(a) allows the Examiner to combine multiple references, the Examiner must still show that each and every element of the claimed invention is disclosed within the universe created by the combined references. Failure, as here, of the combined references to somehow teach each and every limitation of the claimed invention is clear evidence that the Examiner has failed to produce a prima facie case of obviousness. If obviousness cannot be properly shown, the Examiner must allow the claims. This is because if after examination of an application "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." 35 U.S.C. § 131 (emphasis added). The Applicants would also again respectfully note that failure of Wright, Farrell, and Berthon-Jones to disclose all of the limitations required by claim 7 is clear evidence that the Examiner has neither properly determined the scope and

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content of the prior art nor properly ascertained the differences between the prior art and the claims at issue as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Applicants thus again respectfully remind the examiner that "[o]mission of a relevant factor [e.g. one of the *Graham* factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

In addition, the Examiner notes that it would have been obvious to combine Wright and Farrell to arrive at the invention of claim 7 because "Wright suggests such a combination" by stating that "[o]ther known alternative methods to vary the pressure for delivering CPAP treatment to a patient to treat obstructive sleep apneas would be recognized by those skilled in the art and may be utilized as modes in the device." Wright, paragraph [0031] and Office Action 08/09/2011, page 11. However, this motivation to combine is really no motivation at all, since, as already pointed out above, the alleged "other known methods to vary the pressure for delivering CPAP treatment" disclosed in Farrell are silent as to the use of a respiratory belt and pulse oximeter as sensors for detecting sleep disordered breathing, much less to adjustment of a CPAP based on the output of a data acquisition system to which such sensors are attached. Furthermore, the mere statement in Wright that "other known alternative methods" may be used does not relieve the Examiner of his burden to provide specific evidence of such other alternative methods that read on the claims at issue. The Applicants would thus respectfully remind the Examiner that when, as here, the Examiner chooses to rely upon the combination of multiple references to support a rejection under 35 U.S.C. § 103(a) the Examiner must provide "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.." *In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (emphasis added).

For all of the above reasons, the Applicants respectfully request withdrawal of the rejection of claim 7 under 35 U.S.C. §103(a).

Claims 8 and 9

Inasmuch as claims 8 and 9 are dependent on claim 7, the Applicants incorporate their above remarks regarding claim 7. Further, inasmuch as the Examiner relies on Farrell's incorporation of Berthon-Jones to reject claims 8 and 9, the Applicants again respectfully point

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out that both Farrell and Berthon-Jones are silent as to adjustment of a CPAP device using the output of a data acquisition system that has "inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor." Farrell and Berthon-Jones are equally as silent regarding real-time or automatic adjustment of a CPAP device that receives output from the data acquisition system required by claims 8 and 9.

As before, the Applicants respectfully remind the Examiner that although a rejection based on 35 U.S.C. §103(a) allows the Examiner to combine multiple references, the Examiner must still show that each and every element of the claimed invention is disclosed within the universe created by the combined references. Failure, as here, of the combined references to somehow teach each and every limitation of the claimed invention is clear evidence that the Examiner has failed to produce a prima facie case of obviousness. If obviousness cannot be properly shown, the Examiner must allow the claims. This is because if after examination of an application "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." 35 U.S.C. § 131 (emphasis added). The Applicants would also again respectfully note that failure of Wright, Farrell, and Berthon-Jones to disclose all of the limitations required by claims 8 and 9 is clear evidence that the Examiner has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claims at issue as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Applicants thus again respectfully remind the examiner that "[o]mission of a relevant factor [e.g. one of the *Graham* factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

For all of the above reasons, the Applicants respectfully request withdrawal of the rejection of claims 8 and 9 under 35 U.S.C. §103(a).

Claims 11 and 12

The Examiner has noted in the 08/09/2011 Office Action Summary that claim 12 is currently withdrawn from consideration. However, since the Examiner has continued to prosecute claim 12, the Applicants have chosen to respond to the rejection of claim 12 in addition to that of claim 11.

Inasmuch as claims 11 and 12 are dependent on claim 7, the Applicants hereby incorporate their above remarks regarding claim 7. The Applicants further note that while

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Wright does disclose a "diagnosis unit" that can include EEG and ECG, the mere disclosure of a claimed item in isolation is not sufficient to support a rejection for obviousness under § 103(a). This is because obviousness requires that the *invention as a whole* be considered from the perspective of one of ordinary skill in the art. Here, the Examiner has chosen to remain silent regarding both the level of ordinary skill in the art as well as the reasons one of ordinary skill in the art would have combined the references in such a way as to arrive at the invention embodied in claims 11 and 12. The Applicants would thus respectfully remind the Examiner that when, as here, the Examiner chooses to rely upon the combination of multiple references to support a rejection under 35 U.S.C. § 103(a) the Examiner must provide "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.." *In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (emphasis added). Since the Examiner has not done so in the present case, the Applicants respectfully submit that maintaining the rejection of claims 11 and 12 would be improper and that the rejection should be withdrawn.

Claims 4, 10 and 13 are patentable over Wright in view of Farrell and further in view of U.S. Patent No. 7,101,341 to Tsukashima et al. (hereinafter "Tsukashima").

Claims 4 and 10

Inasmuch as claims 4 and 10 are dependent on claims 1 and 7 respectively, the Applicants hereby incorporate their above remarks regarding claim 1 and claim 7.

The Applicants further note that the Examiner appears to equate the "processing receiver 26" of Tsukashima to the data acquisition system of claims 1 and 7. However, the Examiner provides no reasoning or support for equating these two components. Accordingly, the Applicants respectfully request that, should the Examiner wish to maintain this rejection, such reasoning be set forth in the next Office Action in the form of an affidavit pursuant to 37 C.F.R. § 1.104(d)(2).

Still further, the Applicants would note that even if one assumes that the "processing receiver 26" of Tsukashima is equivalent to the claimed data acquisition system, the "processing

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receiver 26" (in addition to the "diagnosis unit" of Wright and Farrell) is still not disclosed as capable of "diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas"—a capability required by the data acquisition system of claims 4 and 10.

For the above-noted reasons, the Applicants respectfully request that the rejection of claims 4 and 10 be withdrawn.

Claim 13

As with claims 4 and 10, the Examiner appears in his rejection of claim 13 to again equate the "processing receiver 26" of Tsukashima to the data acquisition system of claim 7. However, as before, the Examiner provides no reasoning or support for equating these two components. Accordingly, the Applicants respectfully request that, should the Examiner wish to maintain this rejection, such reasoning be set forth in the next Office Action in the form of an affidavit pursuant to 37 C.F.R. § 1.104(d)(2).

With further respect to claim 13, the Examiner asserts that Tsukashima discloses a data acquisition system that comprises a "microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device" at col. 6, l. 55 to col. 7, l. 10. While the cited section of Tsukashima does discuss a specific microcontroller, it is silent as to the microcontroller being capable of "calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device" as required by claim 13. Further, given that wireless communication between the "processing receiver 26" and the CPAP device is disclosed by Tsukashima as being merely optional, it is not even a requirement that the microcontroller of Tsukashima be capable of "calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device." Thus, if the Examiner wishes to continue to rely on Tsukashima to reject claim 13, additional evidence or explanation should be provided by the Examiner.

Additionally, inasmuch as claim 13 is dependent on claim 7, the Applicants hereby incorporate their above remarks regarding claim 7.

For the above-noted reasons, the Applicants respectfully request that the rejection of claim 13 be withdrawn.

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Claims 14-20 are patentable over Wright in view of Farrell and further in view of Tsukashima.

Claim 14

Claim 14 requires that the data acquisition system be capable of "diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas." The Examiner asserts that this limitation is met by the disclosure of Wright at paragraphs [0035], [0045] and [0062]. Paragraph [0035] notes that the apparatus disclosed in Wright "generates one or several indices…useful for assessing appropriate treatment or diagnosing the condition of the patient." Thus, paragraph [0035] of Wright notes that the apparatus disclosed in Wright generates information that is merely *useful for* diagnosing the condition of a patient, but, significantly, is not capable of diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas as required by claim 14.

Paragraph [0045] of Wright states that the apparatus disclosed by Wright can generate an apnea hypopnea index, or AHI. However, while AHI is indeed an indicator of the level of severity of a patient's sleep disordered breathing, those of ordinary skill in the art recognize that AHI alone is not sufficient to diagnose the type of sleep disordered breathing that a patient has, because AHI alone as described in paragraph [0045] does not distinguish between central apneas and obstructive apneas. Moreover, the method of obtaining AHI described in paragraph [0045] does not even require the use of a respiration belt sensor and pulse oximeter sensor as does claim 14. Accordingly, since claim 14 requires a data acquisition system including respiration belt and pulse oximeter sensors and that is capable of "diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas" it cannot be said that paragraph [0045] is sufficient to disclose this limitation of claim 14.

Paragraph [0062] of Wright indicates that in one form of sleep study that uses a portable device a patient's AHI "is determined and each event is classified…[a]pneas can be classified as obstructive, central or mixed." However, this statement says nothing about how such classification is accomplished. More particularly, this statement does not indicate whether classification is accomplished in the traditional way of having a physician or sleep technologist examine the data or whether the portable device itself performs classification. Because claim 14 specifically requires that the data acquisition device be capable of "diagnosing and creating an

output of a level of severity of a subject's obstructive and central sleep apneas" it cannot reasonably be said that this vague statement in paragraph [0062] is sufficient to fully disclose the limitations required by claim 14.

In light of the above remarks it is clear that the disclosure of Wright, and, in particular, paragraphs [0035], [0045] and [0062] of Wright, do not disclose a "data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas" as required by claim 14. This, in turn, is clear evidence that the Examiner has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claims at issue as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Applicants thus respectfully remind the examiner that "[o]mission of a relevant factor [e.g. one of the *Graham* factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

With further respect to claim 14, the Examiner appears to assert that Wright discloses the limitation of claim 14 that the "data acquisition device further comprising a transceiver for wireless receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow sensor back to the CPAP device." However, the Examiner provides no explanation of how Wright (nor any other of the cited references) discloses this limitation. Such failure on the part of the Examiner to provide any evidentiary or explanatory support in rejecting this portion of claim 14 point is clear evidence that the Examiner has failed to both determine the scope and content of the prior art and ascertain the differences between the prior art and the claims at issue as required by *Graham*.

In addition, the Examiner openly admits that Wright does not teach a CPAP device that "can be adjusted using…signals…from the data acquisition device" as required by claim 14. *See also* Office Action 08/09/2011, page 22. To bridge this evidentiary gap, the Examiner cites to Farrell. The Examiner contends that Farrell discloses adjustment of a CPAP device using the output of a data acquisition device by citing to col. 5, ll. 50-60 of Farrell. This portion of the Farrell disclosure states in relevant part that "the therapeutic pressure levels…may be automatically adjusted or set by automatic detection of SDB related events…as disclosed in U.S. Pat. 5,704,345" (emphasis added). The Applicants have examined U.S. Pat. 5,704,345 to Berthon-Jones (hereinafter "Berthon-Jones") and have found that Berthon-Jones is silent as to

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the use of respiratory belt and pulse oximeter as sensors for detecting sleep disordered breathing, much less to adjust a CPAP based on the output of a data acquisition system to which such sensors are attached. Thus, because Farrell relies on incorporation of Berthon-Jones, neither Farrell nor Berthon-Jones disclose adjustment of a CPAP device using the output of a data acquisition system that has "inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor" as required by claim 14.

The Applicants respectfully remind the Examiner that although a rejection based on 35 U.S.C. §103(a) allows the Examiner to combine multiple references, the Examiner must still show that each and every element of the claimed invention is disclosed within the universe created by the combined references. Failure, as here, of the combined references to somehow teach each and every limitation of the claimed invention is clear evidence that the Examiner has failed to produce a prima facie case of obviousness. If obviousness cannot be properly shown, the Examiner must allow the claims. This is because if after examination of an application "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." 35 U.S.C. § 131 (emphasis added). The Applicants would also again respectfully note that failure of Wright, Farrell, and Berthon-Jones to disclose all of the limitations required by claim 14 is clear evidence that the Examiner has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claims at issue as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Applicants thus again respectfully remind the examiner that "[o]mission of a relevant factor [e.g. one of the *Graham* factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

The Examiner further openly admits that Wright in view of Farrell fails to teach a CPAP device that "can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device" as required by claim 14. To meet this limitation, the Examiner cites to Tsukashima at col. 4, ll. 26-44. This portion of Tsukashima states, in relevant part, that "wireless means also can be employed to communicate between the processing receiver 26 and the CPAP device 16" and that "[p]rocessing receiver 26 is connected to the CPAP device 16 by an electrical wire 24 for controlling the activation of air generated by the CPAP device."

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As an initial matter, in citing to Tsukashima in this way, the Examiner appears to equate the "processing receiver 26" of Tsukashima to the data acquisition system of claim 14. However, the Examiner provides no reasoning or support for equating these two components. Accordingly, the Applicants respectfully request that, should the Examiner wish to maintain this rejection, such reasoning be set forth in the next Office Action in the form of an affidavit pursuant to 37 C.F.R. § 1.104(d)(2). Still further, the Applicants would note that even if one assumes that the "processing receiver 26" of Tsukashima is equivalent to the claimed data acquisition system, the "processing receiver 26" (in addition to the "diagnosis unit" of Wright and Farrell) is still not described as capable of "diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas"—a capability required by the data acquisition system of claim 14.

In addition, and more significantly, while Tsukashima does disclose a CPAP connected to a "processing receiver 26," the "processing receiver 26" is disclosed as being connected to the CPAP only by an "electrical wire 24 for controlling the activation of air generated by the CPAP device." Tsukashima, col. 4, ll. 27-29. Thus, even if one assumes that the "processing receiver 26" is equivalent to the Applicants' claimed data acquisition system, and further assumes that the "processing receiver 26" of Tsukashima is wirelessly connected to the CPAP device, the "processing receiver 26" is still disclosed as controlling only the "activation of air generated by the CPAP." In other words, controlling mere activation of the CPAP air (i.e. cycling the CPAP on and off) is significantly different than claim 14, which requires that the CPAP device "be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device." As further evidence of this, Tsukashima also discloses that the CPAP device has separate "control means 20 for increasing and decreasing the volume of air generated by the apparatus and the output [at] optional humidification device." Tsukashima, col. 4, ll. 16-19. Thus, the language of Tsukashima itself indicates that activation and adjustment of CPAP output are two different things and are controlled separately in the disclosure of Tsukashima. As before, the failure of the Examiner to appreciate this difference between the claimed invention and the cited prior art is clear evidence that the Examiner has failed both to properly determine the scope and content of the prior art as well as properly ascertain the differences between the claims at issue and the prior art as required by *Graham*. Accordingly, the Applicants again respectfully remind the Examiner that "[o]mission of a relevant factor [e.g. one of the *Graham*

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factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

Further, the Examiner notes that it would have been obvious to combine Wright and Farrell with respect to claim 14 because "Wright suggests such a combination" by stating that "[o]ther known alternative methods to vary the pressure for delivering CPAP treatment to a patient to treat obstructive sleep apneas would be recognized by those skilled in the art and may be utilized as modes in the device." Wright, paragraph [0031] and Office Action 08/09/2011, page 11. However, this motivation to combine is really no motivation at all, since, as already pointed out above, the alleged "other known methods to vary the pressure for delivering CPAP treatment" disclosed in Farrell are silent as to the use of a respiratory belt and pulse oximeter as sensors for detecting sleep disordered breathing, much less to adjustment of a CPAP based on the output of a data acquisition system to which such sensors are attached. Furthermore, the mere statement in Wright that "other known alternative methods" may be used does not relieve the Examiner of his burden to provide specific evidence of such other alternative methods that read on the claims at issue.

The Examiner further asserts that it would have been obvious for one of ordinary skill in the art the time of the invention to combine Wright and Farrell with Tsukashima because "Tsukashima explicitly suggests such a modification is known in the art" by noting: "[a]s appreciated by those skilled in the art, wireless means for communicating between various components can be accomplished using radio frequency waves, microwaves, ultrasonic waves, or light optics." Tsukashima, col. 4, ll. 41-44 and Office Action 08/09/2011, page 26. However, this statement in Tsukashima is nothing more than a statement of the various ways in which wireless communication can be accomplished and is entirely silent regarding why and how one would choose to use wireless communication between a CPAP and the "data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas" of claim 1. The Applicants would thus respectfully remind the Examiner that when, as here, the Examiner chooses to rely upon the combination of multiple references to support a rejection under 35 U.S.C. § 103(a) the Examiner must provide "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

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applicant.." *In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (emphasis added).

For all of the above reasons, the Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. §103(a).

Claims 15 and 16

Inasmuch as claims 15 and 16 are dependent on claim 14, the Applicants incorporate their above remarks regarding claim 14. Further, inasmuch as the Examiner relies on Farrell's incorporation of Berthon-Jones to reject claims 15 and 16, the Applicants again respectfully point out that both Farrell and Berthon-Jones are silent as to adjustment of a CPAP device using the output of a data acquisition system that has "inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor." Farrell and Berthon-Jones are equally as silent regarding real-time or automatic adjustment of a CPAP device that receives output by radio frequency signals from the data acquisition system required by claim 14.

As before, the Applicants respectfully remind the Examiner that although a rejection based on 35 U.S.C. §103(a) allows the Examiner to combine multiple references, the Examiner must still show that each and every element of the claimed invention is disclosed within the universe created by the combined references. Failure, as here, of the combined references to somehow teach each and every limitation of the claimed invention is clear evidence that the Examiner has failed to produce a prima facie case of obviousness. If obviousness cannot be properly shown, the Examiner must allow the claims. This is because if after examination of an application "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." 35 U.S.C. § 131 (emphasis added). The Applicants would also again respectfully note that failure of Wright, Farrell, and Berthon-Jones to disclose all of the limitations required by claim 14 is clear evidence that the Examiner has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claims at issue as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Applicants thus again respectfully remind the examiner that "[o]mission of a relevant factor [e.g. one of the *Graham* factors] required by precedent is both legal error and arbitrary agency action." *In re Sang-su Lee*, 277 F.3d 1338, (Fed. Cir. 2002).

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For all of the above reasons, the Applicants respectfully request withdrawal of the rejection of claims 15 and 16 under 35 U.S.C. §103(a).

Claim 17

In rejecting claim 17, the Examiner cites to Wright, paragraph [0030] which notes that:

> "a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication. With such a device, a physician may, for example, remotely monitor, analyze or record the status or data history of a patient or diagnose the patient's condition using the device."

However, this statement is wholly silent regarding a data acquisition system comprising a "microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust treatment of the subject" as required by claim 17. Moreover, the Examiner provides no explanation regarding why one of ordinary skill in the art would consider this statement to inherently disclose such a limitation. With neither express disclosure from the cited art nor substantive explanation by the Examiner, the Applicants are unable to remark further on this rejection. Accordingly, the Applicants respectfully request that this rejection be withdrawn, or, if the Examiner wishes to maintain this rejection, properly supported by sufficient evidence and appropriate explanation. If such evidence or reasoning is within the personal knowledge of the Examiner, the Applicants respectfully request that such reasoning and evidence be set forth in the next Office Action in the form of an affidavit pursuant to 37 C.F.R. § 1.104(d)(2).

Claims 18 and 19

Inasmuch as claims 18 and 19 are dependent on claim 14, the Applicants hereby incorporate their above remarks regarding claim 14. The Applicants further note that while Tsukashima does disclose a nebulizer with a medicament storage chamber, the mere disclosure of a claimed item in isolation is not sufficient to support a rejection for obviousness under § 103(a). This is because obviousness requires that the *invention as a whole* be considered from the perspective of one of ordinary skill in the art. Here, the Examiner has chosen to remain silent

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regarding both the level of ordinary skill in the art as well as the reasons one of ordinary skill in the art would have combined the references in such a way as to arrive at the invention embodied in claims 18 and 19. The Applicants would thus respectfully remind the Examiner that when, as here, the Examiner chooses to rely upon the combination of multiple references to support a rejection under 35 U.S.C. § 103(a) the Examiner must provide "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.." *In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (emphasis added). Since the Examiner has not done so in the present case, the Applicants respectfully submit that maintaining the rejection of claims 18 and 19 would be improper and that the rejection of claims 18 and 19 should be withdrawn.

Claim 20

In rejecting claim 20, the Examiner again cites to Wright, paragraph [0030] which notes that:

> "a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication. With such a device, a physician may, for example, remotely monitor, analyze or record the status or data history of a patient or diagnose the patient's condition using the device."

However, this statement is wholly silent regarding the adjustment of a CPAP device "by a remote control device" as required by claim 20. While it does note that a device such as a Palm Pilot could be used to remotely monitor, analyze, record, or diagnose, none of these functions involve actual adjusting of a CPAP device. Further, the Examiner provides no explanation regarding why one of ordinary skill in the art would consider this statement to inherently disclose such a limitation. With neither express disclosure from the cited art nor substantive explanation by the Examiner, the Applicants are unable to remark further on this rejection. Accordingly, the Applicants respectfully request that this rejection be withdrawn, or, if the Examiner wishes to maintain this rejection, properly supported by sufficient evidence and appropriate explanation. If such evidence or reasoning is within the personal knowledge of the

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Examiner, the Applicants respectfully request that such reasoning and evidence be set forth in the next Office Action in the form of an affidavit pursuant to 37 C.F.R. § 1.104(d)(2).

CONCLUSION

For all the above reasons the Applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

10/28/11
Dated

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Electronic Acknowledgement Receipt

EFS ID:	11292669
Application Number:	11266899
International Application Number:	
Confirmation Number:	8590
Title of Invention:	Integrated sleep diagnosis and treatment device and method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Matthew Beutler
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-023
Receipt Date:	28-OCT-2011
Filing Date:	04-NOV-2005
Time Stamp:	16:36:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-023_10282011_Amendment.pdf	191281 a938d01dbcc9a3fd8c4bd59b9511d86db67f877f	yes	24

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	24
Warnings:			
Information:			
	Total Files Size (in bytes):	191281	

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

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

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

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
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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	Filing Date	☐ To be Mailed
11/266,899	11/04/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 10/28/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $30 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $125 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KIM DOWNING/

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.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

81177 7590 08/09/2011

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EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
08/09/2011	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.	Applicant(s)	
	11/266,899	KAYYALI ET AL.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *31 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2005* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. According to the Amendment, filed 31 May 2011, the status of the claims is as follows:

Claim 7 is currently amended;

Claims 1-5, 8-10, 15-18, and 20 are previously presented;

Claim 19 is as originally filed; and

Claims 6 and 12 are withdrawn.

2. The objection to claim 7 is WITHDRAWN in view of the Amendment, filed 31 May 2011.

Response to Arguments

3. Applicant's arguments, see Remarks, pp. 6-21, filed 31 May 2011, with respect to the rejection of claims 1-5, 7-11, and 13-20 under 35 U.S.C. 102(b) as being anticipated by Wright et al, U.S. Patent Application Publication No. 2002/018130 A1, have been fully considered, and are persuasive in part. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Applicant contends, see Remarks, pp. 7-8, the following:

> Regarding claim 1, the Examiner asserts that Wright discloses a "sleeping disorder treatment system comprising a data acquisition system." To meet the limitation of the claimed data acquisition system the Examiner cites to the "diagnosis unit" of Wright. Wright, paragraph 29. However, even if one assumes

> for the sake of argument that Wright does in fact disclose a sleeping disorder treatment system, in order to be a proper anticipatory reference the diagnosis unit of Wright must comprise part of this system and not be independent of it. But, as will be shown, the diagnosis unit of Wright is described throughout the Wright disclosure as a separate item from the apparatus to which Wright is directed.
>
> A close study of paragraph 29 of the disclosure of Wright shows that Wright is directed to an apparatus. This apparatus includes a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, an air delivery conduit 8, a communication port or module 10, an oximeter, and a sense tube 14. Significantly, "[t]he apparatus further includes a communications interface 16 for connection to a diagnosis unit." Wright, paragraph 29. Thus, Wright describes its apparatus as not comprising a diagnosis unit, but instead having only an interface for connection to a diagnosis unit. Indeed, in the sentence that immediately follows the above-cited sentence Wright independently describes the diagnosis unit by noting that "[t]he diagnosis unit includes a pulse oximeter 20, respiratory movement sensors 22, EEG & ECG 24." Significantly, nowhere in this description does Wright state that the diagnosis unit comprises part of the apparatus disclosed therein. Wright cannot thus be deemed to be either enabling or anticipatory with regard to claim 1.
>
> A further requirement of claim 1 is that the data acquisition system create an output of the level of severity of a subject' s sleeping disorder or symptoms based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. Thus, assuming arguendo that the "diagnosis unit" of Wright is equivalent to the data acquisition system of claim 1, the Examiner must show that the diagnosis unit of Wright creates an output of the level of severity of a subject's sleeping disorder or symptoms based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. To meet this limitation, the Examiner cites to paragraphs 29 and 30 of Wright. While paragraph 29 does indicate that the diagnosis unit of Wright includes a pulse oximeter 20 and respiratory movement sensors 22, it is silent regarding the use of signals from these sensors to create an output of the level of severity of a subject's sleeping disorder or symptoms. In this vein, the Applicants would respectfully remind the Examiner that the mere presence of certain claim elements in isolation is insufficient to make a proper showing of anticipation. This is, at least in part, because the mere presence alone of certain claim elements in isolation does not provide a disclosure sufficient to enable the claimed invention.

However, these arguments are not persuasive. Based on broadest reasonable interpretation, Wright teaches the claim limitation.

As for Applicant's argument directed to the claim limitation "sleeping disorder treatment system comprising a data acquisition system", Wright teaches a data acquisition system (not labeled, see the system shown in fig. 1) for diagnosing a sleep disorder (i.e. “The apparatus according to the invention may be used to monitor patient health characteristics including, for example, oral and/or nasal airflow, snore, abdominal movement, chest wall movement, oximetry, pulse rate, body position and flattening index via the diagnosis unit and sensors in the blower. As an alternative to the diagnosis unit apparatus according to the invention may be used in conjunction with a portable diagnosis system, for example, the EMBLETTA portable diagnosis system (FLAGA, Iceland), or the MESAM system (MAP, Germany). In a preferred embodiment, the flattening index is measured according to the method described in U.S. Pat. No. 5,704,345 (Berthon-Jones). The contents of U.S. Pat. No. 5,704,345 are hereby incorporated by cross-reference.”, see para. 34; and i.e. “Many stroke patients may be physically incapable of or experience discomfort in traveling to a sleep clinic for a sleep study. Hence there is a need to provide alternative methods and apparatus for treating the breathing disorders of stroke patients in rehabilitation. Furthermore, there are simply not enough places in sleep clinics to accommodate stroke patients. Thus in one aspect, the invention provides a simplified screening, diagnosis and treatment models suitable for patients in stroke rehabilitation which would not overburden the current sleep clinics.”, see para. 28), the data acquisition system comprising a data acquisition device (“diagnosis unit”) 18 having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor (i.e. “The diagnosis unit includes a

pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24", see para. 29). The inputs of Wright's data acquisition device are shown as lines from the "pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24". Although Wright labels the data acquisition device as a "diagnosis unit 18", this is merely a label of the unit and does not preclude the fact that the "diagnosis unit 18" performs the claimed function, i.e. "having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor". Clearly, from the system shown in Fig. 1, the system includes the "diagnosis unit 18" (see fig. 1).

As for Applicant's argument directed to the claim limitation " the data acquisition system for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors ", Wright teaches the data acquisition system for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors (i.e. "The apparatus generates one or several indices determined from an analysis of the patient's health characteristics useful for assessing appropriate treatment or diagnosing the condition of the patient.", see para. 35, and "Another index is an Apnea Hypopnea Index ("AHI") which is an indicator of the level of severity of a patient's sleep disordered breathing. The AHI is determined by adding the total number of apneas and hypopneas the patient experienced over a particular time period, such as during the study, and dividing that figure by the total time for that period. An example of an AHI scoring rule set is: (i) An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant=100s) for at least 10 consecutive

seconds. (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average for 10 consecutive seconds. Other forms of AHI index are known by those skilled in the art.", see para. 45; and i.e. "During one form of sleep study such as by a portable device, the patient's breathing is monitored. Their Apnea Hypopnea Index (AHI) is determined and each event is classified. Apneas can be classified as obstructive, central or mixed. Other events which can be identified include hypopneas, snoring & partial upper airway obstruction. Effort, position, oxygen saturation and flow limitation index can also be determined.", see para. 62).

Claim Rejections - 35 USC § 103

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

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

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

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

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

4. Claims 1-3, 5, 7-9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al, U.S. Patent Application Publication No. 2002/018130 A1 ("Wright"), in view of Farrell et al, U.S. Patent No. 7,878,198 B2 ("Farrell").

As to Claim 1, Wright teaches the following:

A sleeping disorder treatment system (i.e. "Methods and apparatus for assessing the condition of and treating patients for stroke during the delivery of continuous positive airway pressure (CPAP) are disclosed.", see Abstract; and see fig. 1) comprising

a data acquisition system (not labeled, see the system shown in fig. 1) for diagnosing a sleep disorder (i.e. "The apparatus according to the invention may be used to monitor patient health characteristics including, for example, oral and/or nasal airflow, snore, abdominal movement, chest wall movement, oximetry, pulse rate, body position and flattening index via the diagnosis unit and sensors in the blower. As an alternative to the diagnosis unit apparatus according to the invention may be used in conjunction with a portable diagnosis system, for example, the EMBLETTA portable diagnosis

system (FLAGA, Iceland), or the MESAM system (MAP, Germany). In a preferred embodiment, the flattening index is measured according to the method described in U.S. Pat. No. 5,704,345 (Berthon-Jones). The contents of U.S. Pat. No. 5,704,345 are hereby incorporated by cross-reference.", see para. 34; and i.e. "Many stroke patients may be physically incapable of or experience discomfort in traveling to a sleep clinic for a sleep study. Hence there is a need to provide alternative methods and apparatus for treating the breathing disorders of stroke patients in rehabilitation. Furthermore, there are simply not enough places in sleep clinics to accommodate stroke patients. Thus in one aspect, the invention provides a simplified screening, diagnosis and treatment models suitable for patients in stroke rehabilitation which would not overburden the current sleep clinics.", see para. 28r),

the data acquisition system comprising a data acquisition device ("diagnosis unit") 18 having inputs for receiving signals from sensors including a respiration belt sensor 22 and a pulse oximeter sensor 20 (i.e. "The diagnosis unit includes a pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24", see para. 29),

the data acquisition system for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors (i.e. "The apparatus generates one or several indices determined from an analysis of the patient's health characteristics useful for assessing appropriate treatment or diagnosing the condition of the patient.", see para. 35, and "Another index is an Apnea Hypopnea Index ("AHI") which is an indicator of the level of severity of a patient's sleep disordered breathing. The AHI is determined by adding the total number

of apneas and hypopneas the patient experienced over a particular time period, such as during the study, and dividing that figure by the total time for that period. An example of an AHI scoring rule set is: (i) An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant=100s) for at least 10 consecutive seconds. (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average for 10 consecutive seconds. Other forms of AHI index are known by those skilled in the art.", see para. 45; and i.e. "During one form of sleep study such as by a portable device, the patient's breathing is monitored. Their Apnea Hypopnea Index (AHI) is determined and each event is classified. Apneas can be classified as obstructive, central or mixed. Other events which can be identified include hypopneas, snoring & partial upper airway obstruction. Effort, position, oxygen saturation and flow limitation index can also be determined.", see para. 62); and

a continuous positive airway pressure device (CPAP) ("computer-controlled blower") 2 for treating a subject's sleeping disorder or symptoms (i.e. "Nasal CPAP treatment has been traditionally used for the management of patients with obstructive sleep apnea where CPAP acts as a pneumatic splint to maintain upper airway patency and therefore ensures free flow of air while the patient sleeps. The current invention describes the use of positive pressure ventilation, which may include CPAP, bi-level pressure, or variants thereof, for stroke patients.", see para. 26, and fig. 1).

The inputs of Wright's data acquisition device are shown as lines from the "pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24". Although Wright labels

the data acquisition device as a “diagnosis unit 18”, this is merely a label of the unit and does not preclude the fact that the ”diagnosis unit 18” performs the claimed function, i.e. “having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor”. Clearly, from the system shown in Fig. 1, the system includes the “diagnosis unit 18” (see fig. 1).

Wright does not explicitly teach the following:

a continuous positive airway pressure device (CPAP)… which can be adjusted using in part the output from the data acquisition system.

However, Farrell teaches the following:

a data acquisition system (uses sensor data to determine “apnea hypopnea index”, i.e. " Preferably, the device provides efficacy tracking by detecting and recording or scoring SDB events or related information or indices over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring. This is illustrated in step 44 of FIG. 2. Similarly, pressure and/or flow versus time data may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting. Methods for detecting and recording such information are known in the art, and may be implemented as described in U.S. Pat. No. 5,704,345. For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented as

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

a continuous positive airway pressure device (CPAP), which can be adjusted using in part the output from the data acquisition system (i.e. “Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones).”, see col. 5, ll. 50-60).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright CPAP device to be adjustable using output from physiological sensors because Wright suggests such a combination in the following passage (see para. 31, emphasis added by Examiner):

> The apparatus has two treatment modes, a first mode for treating obstructive apneas and a second mode for treating central apneas. *In the first mode, the device provides a generally constant pressure throughout a breathing cycle, but may vary the pressure in accordance with indications of partial or complete obstruction of the airway. One technique for accomplishing this using a combination of flow limitation and snore measurements is described in U.S. Pat. No. 5,704,345 (Berthon-Jones).* One apparatus embodying aspects of the invention described in the '345 patent is AUTOSET T.TM. (ResMed Ltd). *Other known alternative methods to vary the pressure for delivering CPAP treatment to a patient to*

treat obstructive apneas would be recognized by those skilled in the art and may be utilized as modes in the device.

As to Claims 2 and 3, Farrell teaches the following:

wherein the CPAP is adjusted in real time or automatically adjusted by using data or a signal from the data acquisition system (i.e. "…may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones).", see col. 5, ll. 50-55).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright CPAP device to be adjustable using output from physiological sensors for the same reasons as that provided for claim 1 above.

As to Claim 5, Wright teaches the following:

wherein the data acquisition system further collects a subject's brain wave signal ("EEG") 24 (i.e. "EEG & ECG 24", see para. 29).

As to Claim 7, Wright teaches the following:

A sleep apnea treatment system (i.e. "Methods and apparatus for assessing the condition of and treating patients for stroke during the delivery of continuous positive airway pressure (CPAP) are disclosed.", see Abstract; and see fig. 1) comprising

a data acquisition system (not labeled, see the system shown in fig. 1) comprising a data acquisition device ("diagnosis unit") 18 having inputs for receiving signals from sensors including a respiration belt sensor 22 and a pulse oximeter sensor

20 (i.e. “The diagnosis unit includes a pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24”, see para. 29),

the data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas (i.e. “The apparatus generates one or several indices determined from an analysis of the patient’s health characteristics useful for assessing appropriate treatment or diagnosing the condition of the patient.”, see para. 35, and “Another index is an Apnea Hypopnea Index ("AHI") which is an indicator of the level of severity of a patient's sleep disordered breathing. The AHI is determined by adding the total number of apneas and hypopneas the patient experienced over a particular time period, such as during the study, and dividing that figure by the total time for that period. An example of an AHI scoring rule set is: (i) An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant=100s) for at least 10 consecutive seconds. (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average for 10 consecutive seconds. Other forms of AHI index are known by those skilled in the art.”, see para. 45; and i.e. “During one form of sleep study such as by a portable device, the patient's breathing is monitored. Their Apnea Hypopnea Index (AHI) is determined and each event is classified. Apneas can be classified as obstructive, central or mixed. Other events which can be identified include hypopneas, snoring & partial upper airway obstruction. Effort, position, oxygen saturation and flow limitation index can also be determined.”, see para. 62); and

a continuous positive airway pressure (CPAP) device (“computer-controlled blower”) 2 for treating the subject's sleep apnea (i.e. “Nasal CPAP treatment has been traditionally used for the management of patients with obstructive sleep apnea where CPAP acts as a pneumatic splint to maintain upper airway patency and therefore ensures free flow of air while the patient sleeps. The current invention describes the use of positive pressure ventilation, which may include CPAP, bi-level pressure, or variants thereof, for stroke patients.”, see para. 26, and fig. 1),

the CPAP device 2 having an airflow sensor (“flow and pressure sensors”) 4 with a signal (“flow and pressure sensors 4”, see para. 29),

The inputs of Wright’s data acquisition device are shown as lines from the "pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24”. Although Wright labels the data acquisition device as a “diagnosis unit 18”, this is merely a label of the unit and does not preclude the fact that the ”diagnosis unit 18” performs the claimed function, i.e. “having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor”. Clearly, from the system shown in Fig. 1, the system includes the “diagnosis unit 18” (see fig. 1).

Wright does not explicitly teach the following:

wherein the CPAP device can be adjusted using both the output of the data acquisition system and the signal from the CPAP device' s airflow sensor.

However, Farrell teaches the following:

a data acquisition system (uses sensor data to determine “apnea hypopnea index”, i.e. " Preferably, the device provides efficacy tracking by detecting and recording

or scoring SDB events or related information or indices over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring. This is illustrated in step 44 of FIG. 2. Similarly, pressure and/or flow versus time data may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting. Methods for detecting and recording such information are known in the art, and may be implemented as described in U.S. Pat. No. 5,704,345. For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented as follows: (i) An apnea is scored if a 2 second moving average ventilation drops below 25% of a recent average ventilation (time constant=100s) for at least 10 consecutive seconds, (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average ventilation for 10 consecutive seconds. Similarly, the device may determine an index comparing central apneas versus obstructive apneas as disclosed in U.S. Pat. No. 6,832,609, the entire disclosure of which is incorporated by reference herein.", see col. 6, ll. 7-36); and

a continuous positive airway pressure device (CPAP), which can be adjusted using in part the output from the data acquisition system (i.e. “Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as

apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones).", see col. 5, ll. 50-60) and the signal from the CPAP device' s airflow sensor (i.e. "In another mode, the apparatus provides a higher pressure to the mask during the inspiratory portion of the breathing cycle, a so-called IPAP (inspiratory positive airway pressure), and a lower pressure to the mask during the expiratory portion of the breathing cycle, a so-called EPAP (expiratory positive airway pressure). Alternatively, the treatment delivered by the apparatus can smoothly vary in accordance with patient respiration to provide a smooth pressure waveform. For example, the device calculates a continuous phase variable to provide support in phase with the patient's breathing cycle and calculates the pressure to be delivered in accordance with a pressure waveform template. The delivery of such pressure is disclosed in U.S. Pat. No. 6,532,957. Still alternatively, pressure may be supplied in proportion to patient respiratory airflow.", see col. 5, ll. 30-44).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright CPAP device to be adjustable using output from physiological sensors because Wright suggests such a combination in the following passage (see para. 31, emphasis added by Examiner):

> The apparatus has two treatment modes, a first mode for treating obstructive apneas and a second mode for treating central apneas. *In the first mode, the device provides a generally constant pressure throughout a breathing cycle, but may vary the pressure in accordance with indications of partial or complete obstruction of the airway. One technique for accomplishing this using a combination of flow limitation and snore measurements is described in U.S. Pat. No. 5,704,345 (Berthon-Jones).* One apparatus embodying aspects of the invention described in the '345 patent is AUTOSET T.TM. (ResMed Ltd). *Other known alternative methods to vary the pressure for delivering CPAP treatment to a patient to*

treat obstructive apneas would be recognized by those skilled in the art and may be utilized as modes in the device.

As to Claims 8 and 9, Farrell teaches the following:

wherein the CPAP is adjusted in real time or automatically adjusted by using data or a signal from the data acquisition system (i.e. "…may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones).", see col. 5, ll. 50-55).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright CPAP device to be adjustable using output from physiological sensors for the same reasons as that provided for claim 1 above.

As to Claims 11 and 12, Wright teaches the following:

wherein the data acquisition system further collects a subject's brain wave signal, and wherein the physiological signal is an EKG signal (i.e. "EEG & ECG 24", see para. 29).

5. Claims 4, 10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Farrell, as applied to claims 1 and 7 above, and further in view of Tsukashima et al, U.S. Patent No. 7,101,341 B2 ("Tsukashima").

As to Claims 4, 10, and 13, Wright in view of Farrell teaches the subject matter of claims 1 and 7 above. Wright in view of Farrell does not teach the following:

wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP; and

wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

However, Tsukashima teaches the following:

A sleeping disorder treatment system (i.e. “The present invention provides a system and method for monitoring physiological parameters from a patient's exhaled breath and communicates this information to a processing computer/receiver that diagnoses the information. The system can use computational instructions to activate and de-activate an electrically connected treatment nebulizer/atomizer/humidifier device, and can be integrated with a continuous positive airway pressure (CPAP) device.”, see col. 3, ll. 40-47,and figs. 1 and 6), comprising:

a data acquisition system (“processing receiver”) 26 wirelessly transmitting an output by radio frequency to a receiver on a CPAP (“CPAP device") 16 (i.e. “Processing receiver 26 is connected to the CPAP device 16 by an electrical wire 24 for controlling the activation of air generated by the CPAP device 16 and transferred to the typical mask apparatus 36. Also, an electrical connection by means of a wire 31 to the processing receiver 26 is a treatment nebulizer/atomizer/humidifier device 32. As an alternate method, a wireless means 40 can be utilized instead to communicate between the processing receiver 26 with an antenna 28 to the treatment nebulizer/atomizer/humidifier device 32. Although not shown in detail in FIG. 1, a

wireless means also can be employed to communicate between the typical mask apparatus 36 and the processing receiver 26. In addition, a wireless means also can be employed to communicate between the processing receiver 26 and the CPAP device 16. As appreciated by those skilled in the art, wireless means for communicating between various components can be accomplished using radio frequency waves, microwaves, ultrasonic waves, or light optics.", see col. 4, ll. 26-44; and see fig. 1); and

the data acquisition system further comprises a microcontroller ("microprocessor") 70 for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device 16 to adjust a treatment of the subject (i.e. "FIG. 6 is a simplified electrical schematic of the general components in the processing receiver 26. In the center is the microprocessor 70 that processes the information supplied by the thermocouple and sensor and use internal instructions to control other devices. The microprocessor 70 is instructed to communicate the chemical parameter in real-time under a sampling frequency from said sensor to the microprocessor 70 (computer) receiver. The microprocessor has an EEPROM memory section that allows for specific programming to be incorporated as processing instructions. Furthermore, the microprocessor must have the capability to convert analog signals into digital information for decoding and processing. An example of a microprocessor that could be used in the processing receiver 26 is the PIC16F876 28-pin 8-Bin CMOS FLASH microcontrollers manufactured by Microchip Technology, Inc. This particular microprocessor has a 128K EEPROM Data memory bank for flash memory of specific instructions and utilizes a 35-word instruction set. It also has five 10-bit Analog-to-Digital

Inputs that are necessary for converting the information obtained from the pH sensor 46 and thermocouple 52 from its analog format into a digitized form for processing by the instruction sets of the microprocessor 70.", see col. 6, l. 55, to col. 7, l. 10; and see fig. 6).

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

6. Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Farrell, and further in view of Tsukashima.

As to Claim 14, Wright teaches the following:

A sleep apnea treatment system (i.e. "Methods and apparatus for assessing the condition of and treating patients for stroke during the delivery of continuous positive airway pressure (CPAP) are disclosed.", see Abstract; and see fig. 1) comprising

a data acquisition system (not labeled, see the system shown in fig. 1) and a continuous positive airway pressure (CPAP) device ("computer-controlled blower") 2

with an airflow sensor ("flow and pressure sensors") 4 having a signal ("flow and pressure sensors 4", see para. 29) and a transceiver,

the data acquisition system comprising a data acquisition device ("diagnosis unit") 18 having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor (i.e. "The diagnosis unit includes a pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24", see para. 29),

the data acquisition device further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device,

the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas (i.e. "The apparatus generates one or several indices determined from an analysis of the patient's health characteristics useful for assessing appropriate treatment or diagnosing the condition of the patient.", see para. 35, and "Another index is an Apnea Hypopnea Index ("AHI") which is an indicator of the level of severity of a patient's sleep disordered breathing. The AHI is determined by adding the total number of apneas and hypopneas the patient experienced over a particular time period, such as during the study, and dividing that figure by the total time for that period. An example of an AHI scoring rule set is: (i) An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant=100s) for at least 10 consecutive seconds. (ii) An

hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average for 10 consecutive seconds. Other forms of AHI index are known by those skilled in the art.", see para. 45; and i.e. "During one form of sleep study such as by a portable device, the patient's breathing is monitored. Their Apnea Hypopnea Index (AHI) is determined and each event is classified. Apneas can be classified as obstructive, central or mixed. Other events which can be identified include hypopneas, snoring & partial upper airway obstruction. Effort, position, oxygen saturation and flow limitation index can also be determined.", see para. 62).

The inputs of Wright's data acquisition device are shown as lines from the "pulse oximeter 20, respiratory movement sensor 22, EEG & ECG 24". Although Wright labels the data acquisition device as a "diagnosis unit 18", this is merely a label of the unit and does not preclude the fact that the "diagnosis unit 18" performs the claimed function, i.e. "having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor". Clearly, from the system shown in Fig. 1, the system includes the "diagnosis unit 18" (see fig. 1).

Wright does not teach the following:

wherein the CPAP device can be adjusted using… signals… from the data acquisition device.

However, Farrell teaches the following:

a data acquisition system (uses sensor data to determine "apnea hypopnea index", i.e. " Preferably, the device provides efficacy tracking by detecting and recording or scoring SDB events or related information or indices over time, for example, by

tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring. This is illustrated in step 44 of FIG. 2. Similarly, pressure and/or flow versus time data may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting. Methods for detecting and recording such information are known in the art, and may be implemented as described in U.S. Pat. No. 5,704,345. For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented as follows: (i) An apnea is scored if a 2 second moving average ventilation drops below 25% of a recent average ventilation (time constant=100s) for at least 10 consecutive seconds, (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average ventilation for 10 consecutive seconds. Similarly, the device may determine an index comparing central apneas versus obstructive apneas as disclosed in U.S. Pat. No. 6,832,609, the entire disclosure of which is incorporated by reference herein.", see col. 6, ll. 7-36); and

a continuous positive airway pressure device (CPAP), which can be adjusted using in part the output from the data acquisition system (i.e. “Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as

apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones).", see col. 5, ll. 50-60).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright CPAP device to be adjustable using output from physiological sensors because Wright suggests such a combination in the following passage (see para. 31, emphasis added by Examiner):

> The apparatus has two treatment modes, a first mode for treating obstructive apneas and a second mode for treating central apneas. *In the first mode, the device provides a generally constant pressure throughout a breathing cycle, but may vary the pressure in accordance with indications of partial or complete obstruction of the airway. One technique for accomplishing this using a combination of flow limitation and snore measurements is described in U.S. Pat. No. 5,704,345 (Berthon-Jones).* One apparatus embodying aspects of the invention described in the '345 patent is AUTOSET T.TM. (ResMed Ltd). *Other known alternative methods to vary the pressure for delivering CPAP treatment to a patient to treat obstructive apneas would be recognized by those skilled in the art and may be utilized as modes in the device.*

Wright in view of Farrell does not teach the following:

wherein the CPAP device can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device.

However, Tsukashima teaches the following:

A sleeping disorder treatment system (i.e. "The present invention provides a system and method for monitoring physiological parameters from a patient's exhaled breath and communicates this information to a processing computer/receiver that diagnoses the information. The system can use computational instructions to activate and de-activate an electrically connected treatment nebulizer/atomizer/humidifier

device, and can be integrated with a continuous positive airway pressure (CPAP) device.", see col. 3, ll. 40-47,and figs. 1 and 6), comprising:

a CPAP ("CPAP device") 16 can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from a data acquisition system ("processing receiver") 26 (i.e. "Processing receiver 26 is connected to the CPAP device 16 by an electrical wire 24 for controlling the activation of air generated by the CPAP device 16 and transferred to the typical mask apparatus 36. Also, an electrical connection by means of a wire 31 to the processing receiver 26 is a treatment nebulizer/atomizer/humidifier device 32. As an alternate method, a wireless means 40 can be utilized instead to communicate between the processing receiver 26 with an antenna 28 to the treatment nebulizer/atomizer/humidifier device 32. Although not shown in detail in FIG. 1, a wireless means also can be employed to communicate between the typical mask apparatus 36 and the processing receiver 26. In addition, a wireless means also can be employed to communicate between the processing receiver 26 and the CPAP device 16. As appreciated by those skilled in the art, wireless means for communicating between various components can be accomplished using radio frequency waves, microwaves, ultrasonic waves, or light optics.", see col. 4, ll. 26-44; and see fig. 1).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright in view of Farrell's apnea treatment system to have wireless transmission from the data acquisition system to the CPAP device as taught by Tsukashima in order to "achieve the goal of monitoring, diagnosing and

treating respiratory conditions in patients" (see Tsukashima, col. 3, ll. 59-62). In addition, Tsukashima explicitly suggests such a modification is known in the art as follows: "As appreciated by those skilled in the art, wireless means for communicating between various components can be accomplished using radio frequency waves, microwaves, ultrasonic waves, or light optics" (see col. 4, ll. 41-44).

As to Claims 15 and 16, Farrell teaches the following:

wherein the CPAP is adjusted in real time or automatically adjusted by using data or a signal from the data acquisition system (i.e. "…may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in U.S. Pat. 5,704,345 (Berthon-Jones).", see col. 5, ll. 50-55).

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright CPAP device to be adjustable using output from physiological sensors for the same reasons as that provided for claim 1 above.

As to Claim 17, Wright teaches the following:

wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject (i.e. "While this apparatus is described as a single unit, it is understood that a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication. With such a device, a physician may,

for example, remotely monitor, analyze or record the status or data history of a patient or diagnose the patient's condition using the device.", see para. 30).

As to Claim 20, Wright teaches the following:

wherein the CPAP device is adjusted by a remote control device (i.e. "While this apparatus is described as a single unit, it is understood that a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication. With such a device, a physician may, for example, remotely monitor, analyze or record the status or data history of a patient or diagnose the patient's condition using the device.", see para. 30).

As to Claims 18 and 19, Wright in view of Farrell does not teach the following:

wherein the CPAP device further comprises a nebulizer; and

wherein the nebulizer is used to deliver medication.

However, Tsukashima teaches the following:

wherein the CPAP device 16 further comprises a nebulizer ("treatment nebulizer/atomizer/humidifier device") 32, wherein the nebulizer 32 is used to deliver medication (i.e. "The treatment nebulizer/atomizer/humidifier device 32 is pneumatically connected to hose 18 at some point along its length between the CPAP device 16 and the typical mask apparatus 36. The treatment nebulizer/atomizer/humidifier device 32 has a medicament storage chamber 33 where various types of therapeutic

medicaments can be delivered to the pneumatic system and to the patient at intervals commanded by the processing receiver 26.", see col. 4, ll. 45-52; and see fig. 1). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Wright in view of Farrell's CPAP device to include a nebulizer as taught by Tsukashima in order to "...facilitate the diagnosis or treatment for patients suffering from respiratory disease, such as asthmaLaryngopharyngeal reflux (LPR)" (see Tsukashima, col. 1, ll. 7-10).

Conclusion

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Navin Natnithithadha/
Primary Examiner, Art Unit 3735
08/05/2011

Notice of References Cited	Application/Control No. 11/266,899	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,101,341	09-2006	Tsukashima et al.	600/532
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11266899	KAYYALI ET AL.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3735

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/06/2009	05/17/2010	11/08/2010	02/25/2011	08/04/2011				
	1	✓	✓	✓	✓	✓				
	2	✓	✓	✓	✓	✓				
	3	✓	✓	✓	✓	✓				
	4	✓	✓	✓	✓	✓				
	5	✓	✓	✓	✓	✓				
	6	N	N	N	N	N				
	7	✓	✓	✓	✓	✓				
	8	✓	✓	✓	✓	✓				
	9	✓	✓	✓	✓	✓				
	10	✓	✓	✓	✓	✓				
	11	✓	✓	✓	✓	✓				
	12	N	N	N	N	N				
	13	✓	✓	✓	✓	✓				
	14	✓	✓	✓	✓	✓				
	15	✓	✓	✓	✓	✓				
	16	✓	✓	✓	✓	✓				
	17	✓	✓	✓	✓	✓				
	18	✓	✓	✓	✓	✓				
	19	✓	✓	✓	✓	✓				
	20	✓	✓	✓	✓	✓				

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11266899	KAYYALI ET AL.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3735

SEARCHED

Class	Subclass	Date	Examiner
600	300,544,545,529-543,481,483,484	11/6/09	/NN/
600	300,544,545,529-543,481,483,484	5/13/10	/NN/
600	300,544,545,529-543,481,483,484	11/5/10	/NN/
600	300,544,545,529-543,481,483,484	2/1/11	/NN/
600	300,544,545,529-543,481,483,484	8/3/11	/NN/

SEARCH NOTES

Search Notes	Date	Examiner
EAST (enclosed), USPAT, US-PGPUB, Inventor, IDS, Keyword searches	11/6/09	/NN/
EAST (enclosed), USPAT, US-PGPUB, IDS, Art of Record, Keyword searches	5/13/10	/NN/
EAST (enclosed), USPAT, US-PGPUB, IDS, Art of Record, Keyword searches	11/5/10	/NN/
EAST (enclosed), USPAT, US-PGPUB, Art of Record, Keyword searches	2/1/11	/NN/
EAST (enclosed), USPAT, US-PGPUB, Art of Record, Keyword searches	8/3/11	/NN/

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
		)	
Serial No.:	11/266,899	)	
		)	Art Unit: 3735
Filed:	November 4, 2005	)	
		)	Docket No.: CMD-023
For:	Integrated sleep diagnosis and treatment device and method	)	
		)	
		)	
		)	
Examiner:	Navin Natnithithadha	)	
		)	

May 31, 2011

AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

Dear Sir:

This communication is being submitted in response to the non-final Office Action having mail date February 28, 2011 and a due date for response of May 31, 2011. The Applicants herein claim small entity status. The Applicants submit that this communication is being timely filed. While the Applicants believe that no extension of time is necessary for this communication, if the Commissioner finds that an extension of time is needed, the Applicants petition for such extension and authorize the Commissioner to deduct extension fees and any other fees as are found to be necessary from their deposit account 502704.

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IN THE CLAIMS:

Please amend claim 7 as follows:

1. (previously presented) A sleeping disorder treatment system comprising

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

a continuous positive airway pressure device (CPAP) for treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output from the data acquisition system.

2. (previously presented) The system in Claim 1, wherein the CPAP is adjusted in real time.

3. (previously presented) The system in Claim 1, wherein the CPAP is automatically adjusted by using data or a signal from the data acquisition system.

4. (previously presented) The system in Claim 1, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

5. (previously presented) The system in Claim 4, wherein the data acquisition system further collects a subject's brain wave signal.

6. (withdrawn) The system in Claim 4, wherein the physiological signal is an EKG signal.

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7. (currently amended) A sleep apnea treatment system comprising

a data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor, the data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas; and

a continuous positive airway pressure (CPAP) device for treating the subject's sleep apnea, the CPAP device having ~~with~~ an airflow sensor with a signal ~~for treating the subject's sleep apnea~~, wherein the CPAP device ~~which~~ can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor.

8. (previously presented) The system in Claim 7, wherein the CPAP device is adjusted in real time.

9. (previously presented) The system in Claim 7, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

10. (previously presented) The system in Claim 7, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

11. (previously presented) The system in Claim 10, wherein the data acquisition system further collects a subject's brain wave signal.

12. (withdrawn) The system in Claim 10, wherein the physiological signal is an EKG signal.

13. (previously presented) The system in Claim 7, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio

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frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

14. (previously presented) A sleep apnea treatment system comprising

a data acquisition system and a continuous positive airway pressure (CPAP) device with an airflow sensor having a signal and a transceiver,

the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor, the data acquisition device further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device, the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas

wherein the CPAP device can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device.

15. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted in real time.

16. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

17. (previously presented) The system in Claim 14, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

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18. (previously presented) The system in Claim 14, wherein the CPAP device further comprises a nebulizer.

19. (original) The system in Claim 18, wherein the nebulizer is used to deliver medication.

20. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted by a remote control device.

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REMARKS

This communication is being submitted in response to the non-final Office Action having mail date February 28, 2011 and a due date for response of May 31, 2011. Claims 1-20 are currently pending, claims 6 and 12 have been withdrawn from consideration, and claims 1-5, 7-11 and 13-20 currently stand rejected. The Applicants respectfully traverse these rejections below.

CLAIM OBJECTIONS

The Examiner objects to alleged informalities included in claim 7. The Applicants submit that claim 7 as amended above now overcomes this objection.

CLAIM REJECTIONS – 35 U.SC. § 102

Claims 1-5, 7-11 and 13-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wright et al., U.S. Patent Application Publication No. 2002/0185130 A1 (hereinafter "Wright"). For the reasons set forth below, the Applicants respectfully submit that these claims are not *prima facie* anticipated by Wright.

As has been previously noted by the applicants, a proper finding of anticipation requires the disclosure in a single prior art reference of each and every element of the claim under consideration. *W.L. Gore & Associates v. Garlock,* 721 F.2d 1540 (Fed. Cir. 1983). It is not enough that the prior art reference disclose all of the claimed elements in isolation, but rather anticipation requires, in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GmBH v. American Hoist & Derrick Co.,* 730 F.2d 1452 (Fed. Cir. 1984). Further, a proper finding of anticipation requires that the prior art enable the claimed invention, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n,* 808 F.2d 1471 (Fed. Cir. 1986). Thus, to reach a proper finding of anticipation, the Examiner must show that each and every claim limitation is present in a single prior art reference (the identity of invention requirement) and that the same prior art reference enables the claimed invention so as to place the invention in the possession of a person having ordinary skill in the art (the anticipatory enablement requirement).

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Since Wright does not contain each and every element of any of the claims at issue and since Wright is non-enabling with respect to the claims at issue, the Applicants respectfully request that this ground of rejection be withdrawn.

At the outset, and with respect to each of the claims addressed in greater detail below, the Applicants wish to note that the methods and apparatus disclosed in Wright are directed to treatment of stroke patients and determining a stroke index. *See, e.g.,* Wright, paragraphs 35-36, 43, 45, 73. On the other hand, all of the claims presently at issue in this application are directed to sleep disorder or sleep apnea treatment systems, regarding which Wright is wholly silent. Given the divergent goals of Wright and the claims at issue, it is difficult to see how Wright can be used to anticipate, much less to enable, the present invention.

Claims 1-5

Regarding claim 1, the Examiner asserts that Wright discloses a "sleeping disorder treatment system comprising a data acquisition system." To meet the limitation of the claimed data acquisition system the Examiner cites to the "diagnosis unit" of Wright. Wright, paragraph 29. However, even if one assumes for the sake of argument that Wright does in fact disclose a sleeping disorder treatment system, in order to be a proper anticipatory reference the diagnosis unit of Wright must comprise part of this system and not be independent of it. But, as will be shown, the diagnosis unit of Wright is described throughout the Wright disclosure as a separate item from the apparatus to which Wright is directed.

A close study of paragraph 29 of the disclosure of Wright shows that Wright is directed to an apparatus. This apparatus includes a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, an air delivery conduit 8, a communication port or module 10, an oximeter, and a sense tube 14. Significantly, "[t]he apparatus further includes a communications interface 16 for connection to a diagnosis unit." Wright, paragraph 29. Thus, Wright describes its apparatus as not comprising a diagnosis unit, but instead having only an interface for connection to a diagnosis unit. Indeed, in the sentence that immediately follows the above-cited sentence Wright independently describes the diagnosis unit by noting that "[t]he diagnosis unit includes a pulse oximeter 20, respiratory movement sensors 22, EEG & ECG 24." Significantly, nowhere in this description does Wright state that the diagnosis unit comprises part of the apparatus

disclosed therein. Wright cannot thus be deemed to be either enabling or anticipatory with regard to claim 1.

A further requirement of claim 1 is that the data acquisition system create an output of the level of severity of a subject's sleeping disorder or symptoms based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. Thus, assuming *arguendo* that the "diagnosis unit" of Wright is equivalent to the data acquisition system of claim 1, the Examiner must show that the diagnosis unit of Wright creates an output of the level of severity of a subject's sleeping disorder or symptoms based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. To meet this limitation, the Examiner cites to paragraphs 29 and 30 of Wright. While paragraph 29 does indicate that the diagnosis unit of Wright includes a pulse oximeter 20 and respiratory movement sensors 22, it is silent regarding the use of signals from these sensors to create an output of the level of severity of a subject's sleeping disorder or symptoms. In this vein, the Applicants would respectfully remind the Examiner that the mere presence of certain claim elements in isolation is insufficient to make a proper showing of anticipation. This is, at least in part, because the mere presence alone of certain claim elements in isolation does not provide a disclosure sufficient to enable the claimed invention.

As just noted above, the Examiner also cites to paragraph 30 of Wright to meet the limitation of claim 1 that a data acquisition system create an output of the level of severity of a subject's sleeping disorder or symptoms based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. While the Applicants have performed a thorough review of paragraph 30, they can find nothing therein indicating the use of the diagnosis unit of Wright to create an output of the level of severity of a subject's sleeping disorder or symptoms based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. If the Examiner knows of some way in which to interpret this paragraph to meet the above-noted limitation, the Applicants hereby request that the Examiner provide an explanation of this reasoning and reasons why this reasoning would be adopted by one having ordinary skill in the art. If the Examiner chooses instead to rely on his own knowledge in further describing how paragraph 30 might be used to meet the above-noted claim limitation, the Applicants hereby request that the Examiner provide an affidavit pursuant to 37 C.F.R. § 1.104(d)(2) detailing such knowledge.

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Since neither of paragraphs 29 or 30, whether taken together or separately, describe a data acquisition system that creates an output of the level of severity of a subject's sleeping disorder or symptoms based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor, Wright cannot be deemed to be either enabling or anticipatory with respect to claim 1.

A final requirement of claim 1 is that the sleeping disorder treatment system of that claim include a CPAP for treating a subject's sleeping disorder symptoms which can be adjusted using in part the output from the data acquisition system. As noted above, Wright fails as an initial point to even disclose a sleeping disorder treatment system that comprises a data acquisition system, much less a sleeping disorder treatment system wherein the data acquisition system creates an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on signals from sensors including a pulse oximeter sensor and a respiratory belt sensor. Still, even if one assumes these limitations are somehow met by Wright, the Examiner must nevertheless show that Wright teaches and enables adjustment of a CPAP device using in part output from a data acquisition system. To meet this requirement the Examiner cites to paragraphs 30-31, 34, and 42-43 of Wright. However, upon closer inspection, it will be seen that none of these paragraphs, whether taken together or independently, meet the limitation of a CPAP which can be adjusted using in part the output from the data acquisition system.

Regarding the Examiner's citation to paragraph 30 to meet the limitation of a CPAP which can be adjusted using in part the output from the data acquisition system, the Applicants have performed a thorough review of paragraph 30, and can find nothing therein directed to a CPAP which can be adjusted using in part the output from the data acquisition system. If the Examiner knows of some way in which to interpret this paragraph to meet the above-noted limitation, the Applicants hereby request that the Examiner provide an explanation of this reasoning and reasons why this reasoning would be adopted by one having ordinary skill in the art. If the Examiner chooses instead to rely on his own knowledge in further describing how paragraph 30 might be used to meet the above-noted claim limitation, the Applicants hereby request that the Examiner provide an affidavit pursuant to 37 C.F.R. § 1.104(d)(2) detailing such knowledge.

Regarding the Examiner's citation of paragraph 31, Wright does make mention of a device that "may vary the pressure [provided by the device] in accordance with indications of

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partial or complete obstruction of the airway." Wright then cites to U.S. Patent No. 5,704,345 as including one technique to accomplish this. Significantly, however, this patent is directed to techniques that normalize airflow measurements to detect airway obstructions and is silent on the use of sensors including a respiration belt sensor and a pulse oximeter sensor to determine airway obstructions, much less to adjust a CPAP in response to output of a data acquisition system. Paragraph 31 further states that "[o]ther known alternative methods to vary the pressure for delivering CPAP treatment to a patient to treat obstructive apneas would be recognized by those skilled in the art and may be utilized as modes in the device." However, this is nothing more than a generic blanket statement and includes nothing of sufficient specificity to allow Wright to be deemed to identically disclose and enable the claimed invention. Further, the Examiner has provided no explanation of how this statement could be construed to cover the claimed invention nor the level of skill in the art that would be required to "recognize" the claimed invention as a "mode" of the apparatus disclosed in Wright. Such lack of explanation on the part of the Examiner makes it difficult, if not impossible, for the Applicant to substantially respond to the Examiner's citation of paragraph 31.

While paragraph 34 does discuss monitoring of "patient health characteristics," it is silent as to the use of any of these parameters for use in adjusting a CPAP device, much less using these parameters in combination with a data acquisition system that creates an output of the level of severity of a subject's sleeping disorder or symptoms and adjusting a CPAP device using in part the output of the data acquisition system. Thus, paragraph 34 is largely inapposite.

The Examiner further cites paragraph 42 of Wright. However, paragraph 42 is directed to changing the type and accompanying capabilities of a CPAP that is used to treat a patient, and not to adjusting a CPAP using in part the output from a data acquisition system as is claimed.

Finally, the Examiner cites paragraph 43 of Wright. While paragraph 43 makes mention of "ResMed Ltd.'s AUTOSET T which can automatically increase the CPAP pressure during an obstructive apnea to stabilize the airway," the mere mention of a CPAP which can automatically increase pressure without any explanation of how the CPAP goes about achieving this end is clearly insufficient to render claim 1 anticipated, much less to reach the threshold required by the anticipatory enablement requirement.

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For all of the above reasons, the Applicants submit that claim 1 is neither identically disclosed nor enabled by the disclosure of Wright. Accordingly, the Applicants respectfully request withdrawal of the Examiner's rejection of claim 1 under 35 U.S.C. § 102(b).

Regarding claim 2, the Applicants would respectfully note that the mere mention in Wright of a CPAP that can automatically increase pressure without any explanation of how the CPAP goes about achieving this end is insufficient to render the real-time CPAP adjustment limitation of claim 2 anticipated, much less to make Wright an enabling disclosure of real-time CPAP adjustment. Further, inasmuch as claim 2 is dependent on claim 1, the Applicants incorporate their above remarks regarding claim 1.

Regarding claim 3, inasmuch as claim 3 is dependent on claim 1, the Applicants incorporate their above remarks regarding claim 1. Further, Wright is equally as silent regarding automatic adjustment of a CPAP using in part the output from the data acquisition system, as it is about mere adjustment (i.e. as contrasted to automatic adjustment) of a CPAP using in part the output from the data acquisition system.

Regarding claim 4, Wright is silent regarding the output of a data acquisition system being transmitted wirelessly by radio frequency to a receiver on a CPAP. While Wright does mention a "wireless communication transceiver and/or a network card, for communication with other devices or computers," Wright says nothing about using this wireless communication transceiver to wirelessly receive data from a data acquisition system, much less being part of a data acquisition system and being used to wirelessly transmit by radio frequency the output of a data acquisition system to a receiver on a CPAP. Further, inasmuch as claim 4 is dependent on claim 1, the applicants incorporate their above remarks regarding claim 1.

Regarding claim 5, inasmuch as claim 5 is dependent on claim 1, the Applicants incorporate their above remarks regarding claim 1. Further, the Applicants would respectfully remind the Examiner that it is not sufficient to establish anticipation for a prior art reference to disclose each of the claimed elements in isolation. Rather, an anticipatory reference must disclose each and every element of the claimed invention arranged as in the claim.

For all of the above reasons, the Applicants submit that claims 1-5 are neither identically disclosed nor enabled by the disclosure of Wright. Accordingly, the Applicants respectfully request withdrawal of the Examiner's rejection of claims 1-5 under 35 U.S.C. § 102(b).

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Claims 7-11 and 13

Regarding claim 7, the Examiner asserts that Wright discloses a "sleep apnea treatment system comprising a data acquisition system." To meet the limitation of the claimed data acquisition system the Examiner cites to the "diagnosis unit" of Wright. Wright, paragraph 29. However, even if one assumes for the sake of argument that Wright does in fact disclose a sleep apnea treatment system, in order to be a proper anticipatory reference the diagnosis unit of Wright must comprise part of this system and not be independent of it. But, as will be shown, the diagnosis unit of Wright is described throughout the Wright disclosure as a separate item from the apparatus to which Wright is directed.

A close study of paragraph 29 of the disclosure of Wright shows that Wright is directed to an apparatus. This apparatus includes a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, an air delivery conduit 8, a communication port or module 10, an oximeter, and a sense tube 14. Significantly, "[t]he apparatus further includes a communications interface 16 for connection to a diagnosis unit." Wright, paragraph 29. Thus, Wright describes its apparatus as not comprising a diagnosis unit, but instead having only an interface for connection to a diagnosis unit. Indeed, in the sentence that immediately follows the above-cited sentence Wright independently describes the diagnosis unit by noting that "[t]he diagnosis unit includes a pulse oximeter 20, respiratory movement sensors 22, EEG & ECG 24." Significantly, however, nowhere in this description does Wright state that the diagnosis unit comprises part of the apparatus disclosed therein. Wright cannot thus be deemed to be either enabling or anticipatory with regard to claim 7.

A further requirement of claim 7 is that the data acquisition system create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. Thus, assuming *arguendo* that the "diagnosis unit" of Wright is equivalent to the data acquisition system of claim 7, the Examiner must show that the diagnosis unit of Wright creates an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. To meet this limitation, the Examiner cites to paragraphs 29 and 30 of Wright. While paragraph 29 does indicate that the diagnosis unit of Wright includes a pulse oximeter 20 and respiratory movement sensors 22, it is silent regarding the use of signals from these sensors to create an output of the level of severity

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of a subject's obstructive and central sleep apneas. In this vein, the Applicants would respectfully remind the Examiner that the mere presence of certain claim elements in isolation is insufficient to make a proper showing of anticipation. This is, at least in part, because the mere presence alone of certain claim elements in isolation does not provide a disclosure sufficient to enable the claimed invention.

As just noted above, the Examiner also cites to paragraph 30 of Wright to meet the limitation of claim 7 that a data acquisition system create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. While the Applicants have performed a thorough review of paragraph 30, they can find nothing therein indicating the use of the diagnosis unit of Wright to create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. If the Examiner knows of some way in which to interpret this paragraph to meet the above-noted limitation, the Applicants hereby request that the Examiner provide an explanation of this reasoning and reasons why this reasoning would be adopted by one having ordinary skill in the art. If the Examiner chooses instead to rely on his own knowledge in further describing how paragraph 30 might be used to meet the above-noted claim limitation, the Applicants hereby request that the Examiner provide an affidavit pursuant to 37 C.F.R. § 1.104(d)(2) detailing such knowledge.

Still further, the Examiner cites to paragraphs 35-43 of Wright to meet the limitation of claim 7 that a data acquisition system create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiration belt sensor and a pulse oximeter sensor. While these paragraphs mention the use of the apparatus of Wright to generate types of stroke indices, none of these paragraphs mentions anything regarding the use of a data acquisition system to create an output of the level of a severity of a subject's obstructive and central apneas based in part on signals from sensors including a respiration belt sensor and a pulse oximeter sensor. Further, the stroke indices generated using the apparatus of Wright are generated using only the CPAP-like apparatus disclosed therein (i.e. the apparatus consisting of a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, an air delivery conduit 8, a communication port or module 10, an oximeter, a sense tube 14, and a communications interface 16) and not the diagnosis unit. Thus,

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it is clear that Wright does not disclose a data acquisition system for diagnosing and creating an output of the level of severity of a subject's obstructive and central sleep apneas.

Since none of paragraphs 29-30 nor 35-43, whether taken together or separately, describe a data acquisition system for diagnosing and creating an output of the level of severity of a subject's obstructive and central sleep apneas, Wright cannot be deemed to be either enabling or anticipatory with respect to claim 7.

A final requirement of claim 7 is that the sleep apnea treatment system of that claim include a CPAP for treating a subject's sleep apnea, the CPAP having an airflow sensor, wherein the CPAP can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor. As noted above, Wright fails as an initial point to even disclose a sleep apnea treatment system that comprises a data acquisition system, much less a sleep apnea treatment system wherein the data acquisition system is for diagnosing or creating an output of a level of severity of a subject's obstructive and central sleep apneas. Further, even if one assumes these limitations are somehow met by Wright, the Examiner must nevertheless show that Wright teaches and enables adjustment of a CPAP device using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor. To meet this requirement the Examiner cites to paragraphs 29-31, 34, and 42-43 of Wright. However, upon closer inspection, it will be seen that none of these paragraphs, whether taken together or independently, meet the limitation of a CPAP which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor.

While Wright does mention flow and pressure sensors in paragraph 29, Wright is silent as to the use of a signal from these sensors in combination with output of the data acquisition system to adjust a CPAP device. The Applicants respectfully remind the Examiner that mere disclosure of certain isolated elements of the claimed invention is insufficient to establish anticipation.

Regarding the Examiner's citation to paragraph 30 to meet the limitation of a CPAP which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor, the Applicants have performed a thorough review of paragraph 30, and can find nothing therein directed to a CPAP which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor. If the Examiner knows of some way in which to interpret this paragraph to meet the above-noted

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limitation, the Applicants hereby request that the Examiner provide an explanation of this reasoning and reasons why this reasoning would be adopted by one having ordinary skill in the art. If the Examiner chooses instead to rely on his own knowledge in further describing how paragraph 30 might be used to meet the above-noted claim limitation, the Applicants hereby request that the Examiner provide an affidavit pursuant to 37 C.F.R. § 1.104(d)(2) detailing such knowledge.

Regarding the Examiner's citation of paragraph 31, Wright does make mention of a device that "may vary the pressure [provided by the device] in accordance with indications of partial or complete obstruction of the airway." Wright then cites to U.S. Patent No. 5,704,345 as including one technique to accomplish this. Significantly, however, this patent is directed to techniques that normalize airflow measurements to detect airway obstructions and is silent on the use of sensors including a respiration belt sensor and a pulse oximeter sensor to determine airway obstructions, much less to adjust a CPAP in response to output of a data acquisition system and a CPAP airflow sensor. Paragraph 31 further states that "[o]ther known alternative methods to vary the pressure for delivering CPAP treatment to a patient to treat obstructive apneas would be recognized by those skilled in the art and may be utilized as modes in the device." However, this is nothing more than a generic blanket statement and includes nothing of sufficient specificity to allow Wright to be deemed to identically disclose and enable the claimed invention. Further, the Examiner has provided no explanation of how this statement could be construed to cover the claimed invention nor the level of skill in the art that would be required to "recognize" the claimed invention as a "mode" of the apparatus disclosed in Wright. Such lack of explanation on the part of the Examiner makes it difficult, if not impossible, for the Applicant to substantially respond to the Examiner's citation of paragraph 31.

While paragraph 34 does discuss monitoring of "patient health characteristics," it is silent as to the use of any of these parameters for use in adjusting a CPAP device, much less using these parameters in combination with a data acquisition system that creates an output of the level of severity of a subject's obstructive and central sleep apneas and adjusting a CPAP device using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor. Thus, paragraph 34 is largely inapposite.

The Examiner further cites paragraph 42 of Wright. However, paragraph 42 is directed to changing the type and accompanying capabilities of a CPAP that is used to treat a patient, and

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not to adjusting a CPAP using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor as is claimed.

Finally, the Examiner cites paragraph 43 of Wright. While paragraph 43 makes mention of "ResMed Ltd.'s AUTOSET T which can automatically increase the CPAP pressure during an obstructive apnea to stabilize the airway," the mere mention of a CPAP which can automatically increase pressure without any explanation of how the CPAP goes about achieving this end is clearly insufficient to render claim 7 anticipated, much less to reach the threshold required by the anticipatory enablement requirement.

Regarding claim 8, the Applicants would respectfully note that the mere mention in Wright of a CPAP that can automatically increase pressure without any explanation of how the CPAP goes about achieving this end is insufficient to render the real-time CPAP adjustment limitation of claim 8 anticipated, much less to make Wright an enabling disclosure of real-time CPAP adjustment. Further, inasmuch as claim 8 is dependent on claim 7, the Applicants incorporate their above remarks regarding claim 7.

Regarding claim 9, inasmuch as claim 9 is dependent on claim 7, the Applicants incorporate their above remarks regarding claim 7. Further, Wright is equally as silent regarding automatic adjustment of a CPAP using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor, as it is about mere adjustment (i.e. as contrasted to automatic adjustment) of a CPAP using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor.

Regarding claim 10, Wright is silent regarding the output of a data acquisition system being transmitted wirelessly by radio frequency to a receiver on a CPAP. While Wright does mention a "wireless communication transceiver and/or a network card, for communication with other devices or computers," Wright says nothing about using this wireless communication transceiver to wirelessly receive data from a data acquisition system, much less being part of a data acquisition system and being used to wirelessly transmit by radio frequency the output of a data acquisition system to a receiver on a CPAP. Further, inasmuch as claim 10 is dependent on claim 7, the applicants incorporate their above remarks regarding claim 7.

Regarding claim 11, inasmuch as claim 11 is dependent on claim 7, the Applicants incorporate their above remarks regarding claim 7. Further, the Applicants would respectfully remind the Examiner that it is not sufficient to establish anticipation for a prior art reference to

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disclose each of the claimed elements in isolation. Rather, an anticipatory reference must disclose each and every element of the claimed invention arranged as in the claim.

Regarding claim 13, the Examiner cites to paragraphs 29 and 30 to meet the limitation of the use of a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject. The Examiner appears to cite to the "computer-controlled blower 2" of Wright to meet this limitation. Implicit in this citation is the assumption that a "computer-controlled blower" includes a microcontroller for calibrating and controlling a wireless radio frequency transmitted to a CPAP device to adjust treatment of a subject. The Applicants respectfully submit that such an assumption is wholly unsupported by Wright. This is because Wright is entirely silent regarding whether its computer-controlled blower is even comprised of a microprocessor, much less whether this blower is used to calibrate and control a wireless radio frequency signal as claimed.

For all of the above reasons, the Applicants submit that claims 7-11 and 13 are neither identically disclosed nor enabled by the disclosure of Wright. Accordingly, the Applicants respectfully request withdrawal of the Examiner's rejection of claims 7-11 and 13 under 35 U.S.C. § 102(b).

Claims 14-20

Regarding claim 14, the Examiner asserts that Wright discloses a "sleep apnea treatment system comprising a data acquisition system." To meet the limitation of the claimed data acquisition system the Examiner cites to the "diagnosis unit" of Wright. Wright, paragraph 29. However, even if one assumes for the sake of argument that Wright does in fact disclose a sleep apnea treatment system, in order to be a proper anticipatory reference the diagnosis unit of Wright must comprise part of this system and not be independent of it. But, as will be shown, the diagnosis unit of Wright is described throughout the Wright disclosure as a separate item from the apparatus to which Wright is directed.

A close study of paragraph 29 of the disclosure of Wright shows that Wright is directed to an apparatus. This apparatus includes a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, an air delivery conduit 8, a communication port or module 10, an oximeter, and a sense tube 14. Significantly, "[t]he apparatus further includes a communications interface 16 for connection to a diagnosis unit." Wright, paragraph 29. Thus, Wright describes its

apparatus as not comprising a diagnosis unit, but instead having only an interface for connection to a diagnosis unit. Indeed, in the sentence that immediately follows the above-cited sentence Wright independently describes the diagnosis unit by noting that "[t]he diagnosis unit includes a pulse oximeter 20, respiratory movement sensors 22, EEG & ECG 24." Significantly, however, nowhere in this description does Wright state that the diagnosis unit comprises part of the apparatus disclosed therein. Wright cannot thus be deemed to be either enabling or anticipatory with regard to claim 14.

A further requirement of claim 14 is that the data acquisition device create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. Thus, assuming *arguendo* that the "diagnosis unit" of Wright is equivalent to the data acquisition device of claim 14, the Examiner must show that the diagnosis unit of Wright creates an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. To meet this limitation, the Examiner cites to paragraphs 29 and 30 of Wright. While paragraph 29 does indicate that the diagnosis unit of Wright includes a pulse oximeter 20 and respiratory movement sensors 22, it is silent regarding the use of signals from these sensors to create an output of the level of severity of a subject's obstructive and central sleep apneas. In this vein, the Applicants would respectfully remind the Examiner that the mere presence of certain claim elements in isolation is insufficient to make a proper showing of anticipation. This is, at least in part, because the mere presence alone of certain claim elements in isolation does not provide a disclosure sufficient to enable the claimed invention.

As just noted above, the Examiner also cites to paragraph 30 of Wright to meet the limitation of claim 14 that a data acquisition device create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. While the Applicants have performed a thorough review of paragraph 30, they can find nothing therein indicating the use of the diagnosis unit of Wright to create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiratory belt sensor and a pulse oximeter sensor. If the Examiner knows of some way in which to interpret this paragraph to meet the above-noted limitation, the Applicants hereby request that the Examiner provide an

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explanation of this reasoning and reasons why this reasoning would be adopted by one having ordinary skill in the art. If the Examiner chooses instead to rely on his own knowledge in further describing how paragraph 30 might be used to meet the above-noted claim limitation, the Applicants hereby request that the Examiner provide an affidavit pursuant to 37 C.F.R. § 1.104(d)(2) detailing such knowledge.

The Examiner further cites to paragraphs 34 and 42-43 of Wright to meet the limitation of claim 14 that a data acquisition device create an output of the level of severity of a subject's obstructive and central sleep apneas based in part on signals from sensors including a respiration belt sensor and a pulse oximeter sensor. While these paragraphs mention the use of the apparatus of Wright to generate types of stroke indices, none of these paragraphs mentions anything regarding the use of a data acquisition device to create an output of the level of a severity of a subject's obstructive and central apneas based in part on signals from sensors including a respiration belt sensor and a pulse oximeter sensor. Further, the stroke indices generated using the apparatus of Wright are generated using only the CPAP-like apparatus disclosed therein (i.e. the apparatus consisting of a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, an air delivery conduit 8, a communication port or module 10, an oximeter, a sense tube 14, and a communications interface 16) and not the diagnosis unit. Thus, it is clear that Wright does not disclose a data acquisition device for diagnosing and creating an output of the level of severity of a subject's obstructive and central sleep apneas.

Still further, claim 14 requires that the data acquisition device comprise a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device. To meet this limitation, the Examiner cites paragraphs 29-31 and 34 of Wright. While Wright does mention a "wireless communication transceiver and/or a network card, for communication with other devices or computers," Wright says nothing about using this wireless communication transceiver on a data acquisition device to receive radio frequency signals from a CPAP device based on the signal of an airflow sensor. Indeed, the only mention of a wireless transceiver in Wright is a the above- noted "wireless communication transceiver" that is associated with the CPAP-like apparatus disclosed in Wright and not with a data acquisition device as claimed. Wright is similarly silent regarding the use of a data acquisition device for transmitting radio

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frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device as is also set forth in claim 14.

A final requirement of claim 14 is that the CPAP device can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device. While the CPAP-like apparatus of Wright is disclosed as including "wireless communication transceiver and/or a network card, for communication with other devices or computers," Wright is nevertheless silent with regard to using radio frequency signals transmitted to this transceiver from a data acquisition device to adjust the CPAP-like apparatus of Wright. Wright is thus neither identical nor enabling with respect to this final limitation.

Regarding claim 15, the Applicants would respectfully note that the mere mention in Wright of a CPAP that can automatically increase pressure without any explanation of how the CPAP goes about achieving this end is insufficient to render the real-time CPAP adjustment limitation of claim 8 anticipated, much less to make Wright an enabling disclosure of real-time CPAP adjustment. Further, inasmuch as claim 15 is dependent on claim 14, the Applicants incorporate their above remarks regarding claim 14.

Regarding claim 16, inasmuch as claim 16 is dependent on claim 14, the Applicants incorporate their above remarks regarding claim 14. Further, Wright is equally as silent regarding automatic adjustment of a CPAP using radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device, as it is about mere adjustment (i.e. as contrasted to automatic adjustment) of a CPAP using radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device.

Regarding claim 17, the Examiner cites to paragraphs 29 and 30 to meet the limitation of the use of a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject. The Examiner appears to cite to the "computer-controlled blower 2" of Wright to meet this limitation. Implicit in this citation is the assumption that a "computer-controlled blower" includes a microcontroller for calibrating and controlling a wireless radio frequency transmitted to a CPAP device to adjust treatment of a subject. The Applicants respectfully submit that such an assumption is wholly unsupported by Wright. This is because Wright is entirely silent regarding whether its computer-controlled blower is even comprised of a microprocessor, much less whether this blower is used to calibrate and control a wireless radio frequency signal as claimed.

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Regarding claim 18, the Examiner cites to paragraphs 18 and 41 of Wright to meet the limitation of the CPAP device further comprising a nebulizer. While paragraphs 18 and 14 do briefly mention pharmacological agents and drug therapy, these paragraphs are silent as to the presence of a nebulizer. Thus it is clear that Wright cannot be said to be anticipatory of claim 18.

Regarding claim 19, the Examiner cites to paragraphs 18 and 14 of Wright to meet the limitation of the nebulizer of claim 18 being used to deliver medication. While paragraphs 18 and 41 do briefly mention pharmacological agents and drug therapy, these paragraphs are directed solely to monitoring effectiveness of a drug protocol and include no mention of the use of a CPAP device with a nebulizer to deliver medication. It is thus also clear that Wright cannot be said to be anticipatory of claim 19.

For all of the above reasons, the Applicants submit that claims 14-20 are neither identically disclosed nor enabled by the disclosure of Wright. Accordingly, the Applicants respectfully request withdrawal of the Examiner's rejection of claims 14-20 under 35 U.S.C. § 102(b).

CONCLUSION

For all the above reasons the Applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

5/31/2011
Dated

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Electronic Acknowledgement Receipt

EFS ID:	10200051
Application Number:	11266899
International Application Number:	
Confirmation Number:	8590
Title of Invention:	Integrated sleep diagnosis and treatment device and method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Matthew Beutler
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-023
Receipt Date:	31-MAY-2011
Filing Date:	04-NOV-2005
Time Stamp:	18:00:10
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	Amendment/Req. Reconsideration-After Non-Final Reject	CMD023CoverSheetMay2011.pdf	13763 41ebda7981f58ca4971568271c7dd748592 8713c	no	1

Warnings:	
Information:	

2	Claims	CMD023ClaimsMay2011.pdf	23273 f2c2ef7b6532cd16e7547643f5724045bb419845	no	4
Warnings:					
Information:					
3	Applicant Arguments/Remarks Made in an Amendment	CMD023RemarksMay2011.pdf	709887 5b91b4a1c3781833427ac2b7f08737bb784d6d4e	no	16
Warnings:					
Information:					
			Total Files Size (in bytes):	746923	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/266,899	11/04/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	05/31/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KELLY HARRIS/

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.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

81177 7590 02/28/2011

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

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
02/28/2011	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.	Applicant(s)	
	11/266,899	KAYYALI ET AL.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *29 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2005* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. According to the Amendment, filed 27 September 2010, the status of the claims is as follows:

Claims 1, 3, 5, 7, 11, 13, and 14 are currently amended;

Claims 2, 4, 8-10, 15-18, and 20 are previously presented;

Claim 19 is as originally filed; and

Claims 6 and 12 are withdrawn.

3. The objections to claims 5 and 11 are WITHDRAWN in view of the Amendment, filed 27 September 2010.

Response to Arguments

4. Applicant's arguments, see Appeal Brief, pp. 6-7, filed 29 November 2010, with respect to the rejection of claims 1-5, 7-11, and 13-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn.

5. Applicant's arguments, see Appeal Brief, pp. 8-10, filed 29 November 2010, with respect to the rejection of claims 1-5, 7-11, and 13-20 under 35 U.S.C. 102(e) as being anticipated by Stahmann et al, U.S. Patent Application Publication No. 2005/0115561 A1 ("Stahmann"), have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Objections

6. Claim 7 is objected to because of the following informalities:

In line 6, "a continuous positive airway pressure (CPAP) device with an airflow sensor with a signal for treating the subject's sleep apnea" is indefinite due to a typographical/grammatical error. Examiner suggests amending the limitation to "a continuous positive airway pressure (CPAP) device ~~with~~ including an airflow sensor, the CPAP device generates ~~with~~ a signal for treating the subject's sleep apnea". Appropriate correction is required.

Claim Rejections - 35 USC § 102

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

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

6. Claims 1-5, 7-11, and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al, U.S. Patent Application Publication No. 2002/018130 A1 ("Wright").

As to Claim 1, Wright teaches the following:

A sleeping disorder treatment system (see Abstract, para. 6, 15, and 49, and figs. 1 and 7) comprising

a data acquisition system ("diagnosis unit") for diagnosing a sleep disorder,

the data acquisition system comprising a data acquisition device 18 having inputs (see wires leading into unit 18) for receiving signals from sensors including a respiration belt sensor ("respiratory movement sensors", which are in the form of a belt, see fig. 1) 22 and a pulse oximeter sensor ("pulse oximeter") 20,

the data acquisition system for creating an output of the signals or a level of severity of a subject's steeping disorder or symptoms based in part on the signals from the sensors (see para. 29-30); and

a continuous positive airway pressure device (CPAP) ("main blower housing", see para. 29) for treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output from the data acquisition system (see para. 30-31, 34, and 42-43).

As to Claim 2, Wright teaches the following:

wherein the CPAP is adjusted in real time (see para. 43 and 72).

As to Claim 3, Wright teaches the following:

wherein the CPAP is automatically adjusted by using data or a signal from the data acquisition system (see para. 30-31, 34, and 42-43).

As to Claim 4, Wright teaches the following:

wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP (see para. 29-30).

As to Claim 5, Wright teaches the following:

wherein the data acquisition system further collects a subject's brain wave signal ("EEG") 24 (see para. 29).

As to Claim 7, Wright teaches the following:

A sleeping disorder treatment system (see Abstract, para. 6, 15, and 49, and figs. 1 and 7) comprising

a data acquisition system ("diagnosis unit") comprising a data acquisition device 18 having inputs (see wires leading into unit 18) for receiving signals from sensors including a respiration belt sensor ("respiratory movement sensors", which are in the form of a belt, see fig. 1) 22 and a pulse oximeter sensor ("pulse oximeter") 20,

the data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas (see para. 29-30 and 35-43); and

a continuous positive airway pressure device (CPAP) ("main blower housing", see para. 29) with an airflow sensor ("flow and pressure sensors") 4 with a signal for treating the subject's sleep apnea, which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor (see para. 29-31, 34, and 42-43).

As to Claims 8-11, Wright teaches the subject matter of these claims as discussed above for claims 2-5.

As to Claim 13, Wright teaches the following:

wherein the data acquisition system further comprises a microcontroller ("computer-controlled blower") 2 for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject (see para. 29-30).

As to Claim 14, Wright teaches the following:

A sleeping disorder treatment system (see Abstract, para. 6, 15, and 49, and figs. 1 and 7) comprising

a data acquisition system ("diagnosis unit") and a continuous positive airway pressure (CPAP) device ("main blower housing", see para. 29) with an airflow sensor ("flow and pressure sensors") 4 having a signal and a transceiver,

the data acquisition system comprising a data acquisition device 18 having inputs (see wires leading into unit 18) for receiving signals from sensors including a respiration belt sensor ("respiratory movement sensors", which are in the form of a belt, see fig. 1) 22 and a pulse oximeter sensor ("pulse oximeter") 20,

the data acquisition device 18 further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt 22 and pulse oximeter sensors 20 and the airflow signal sensor 4 back to the CPAP device (see para. 29-31 and 34),

the data acquisition device 18 for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas (see para. 34 and 42-43),

wherein the CPAP device can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device 18 (see para. 29-30).

As to Claims 15-17, Wright teaches the subject matter of these claims as discussed above for claims 2, 3, and 12.

As to Claims 18 and 19, Wright teaches the following:

wherein the CPAP device further comprises a nebulizer, wherein the nebulizer is used to deliver medication (see para. 18 and 41).

As to Claim 20, Wright teaches the following:

wherein the CPAP device is adjusted by a remote control device ("hand-held display and control devices") 12 (see para. 29-30).

Conclusion

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

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

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Navin Natnithithadha/
Examiner, Art Unit 3735
02/24/2011

/Charles A. Marmor, II/
Supervisory Patent Examiner, Art Unit 3735

Notice of References Cited	Application/Control No. 11/266,899	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0185130 A1	12-2002	Wright et al.	128/204.21
*	B	US-2004/0138576 A1	07-2004	Wright et al.	600/533
*	C	US-6,832,609 B2	12-2004	Wright et al.	128/204.23
*	D	US-7,018,341 B2	03-2006	Wright et al.	600/538
*	E	US-2006/0084877 A1	04-2006	Ujhazy et al.	600/483
*	F	US-7,662,101 B2	02-2010	Lee et al.	600/484
*	G	US-7,878,198 B2	02-2011	Farrell et al.	128/204.18
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	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.

Index of Claims	**Application/Control No.**	**Applicant(s)/Patent Under Reexamination**
11266899	11266899	KAYYALI ET AL.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3735

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/06/2009	05/17/2010	11/08/2010	02/25/2011					
	1	✓	✓	✓	✓					
	2	✓	✓	✓	✓					
	3	✓	✓	✓	✓					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	N	N	N	N					
	7	✓	✓	✓	✓					
	8	✓	✓	✓	✓					
	9	✓	✓	✓	✓					
	10	✓	✓	✓	✓					
	11	✓	✓	✓	✓					
	12	N	N	N	N					
	13	✓	✓	✓	✓					
	14	✓	✓	✓	✓					
	15	✓	✓	✓	✓					
	16	✓	✓	✓	✓					
	17	✓	✓	✓	✓					
	18	✓	✓	✓	✓					
	19	✓	✓	✓	✓					
	20	✓	✓	✓	✓					

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
11266899	11266899	KAYYALI ET AL.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3735

SEARCHED

Class	Subclass	Date	Examiner
600	300,544,545,529-543,481,483,484	11/6/09	/NN/
600	300,544,545,529-543,481,483,484	5/13/10	/NN/
600	300,544,545,529-543,481,483,484	11/5/10	/NN/
600	300,544,545,529-543,481,483,484	2/1/11	/NN/

SEARCH NOTES

Search Notes	Date	Examiner
EAST (enclosed), USPAT, US-PGPUB, Inventor, IDS, Keyword searches	11/6/09	/NN/
EAST (enclosed), USPAT, US-PGPUB, IDS, Art of Record, Keyword searches	5/13/10	/NN/
EAST (enclosed), USPAT, US-PGPUB, IDS, Art of Record, Keyword searches	11/5/10	/NN/
EAST (enclosed), USPAT, US-PGPUB, Art of Record, Keyword searches	2/1/11	/NN/

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

OK TO ENTER: /NN/ (02/25/2011)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	11/266,899	Art Unit:	3735
Filed:	November 4, 2005	Docket No.:	CMD-023
For:	Integrated sleep diagnosis and treatment device and method		
Examiner:	Navin Natnithithadha		

September 27, 2010

AMENDMENT AFTER FINAL

Commissioner of Patents and Trademarks
Alexandria, VA 22313

Dear Sir:

This Amendment is submitted in response to the final rejection having mail date May 25, 2010 with a shortened statutory period due date for response of August 25, 2010. The Applicants herein claim small entity status. The Applicants petition for a 1-month extension of time and provide the $65 fee for the extension. The Applicants herewithin also file a notice of appeal, and provide the $270 fee for the notice. The Applicants further provide a credit card payment form for the $335 dollars for the extension and notice of appeal. The Applicants similarly grant the Director permission to deduct these or any other fees as are found to be necessary from their deposit account 502704, and to credit any overpayments.

PAGE 9/19 * RCVD AT 9/27/2010 3:56:43 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-5/0 * DNIS:2738300 * CSID:2166490347 * DURATION (mm-ss):03-14

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	("20020185130").PN.	US-PGPUB; USPAT	OR	OFF	2011/02/25 07:22
L2	27	("20030000528" | "20040163648" | "20040254493" | "20050081847" | "20050085738" | "20050115561" | "20050165323" | "20050217674" | "20050268916" | "20050188991" | "20060247546" | "5645043" | "5961447" | "6029664" | "6138675" | "6229581" | "6431171" | "6551252" | "6889691" | "7190995" | "7195013" | "7204250" | "7225809" | "7309314" | "7575005" | "7668579" | "7670295").PN.	US-PGPUB; USPAT	OR	OFF	2011/02/25 07:23
L3	9	((jonathan NEAR2 wright) OR (anthony NEAR2 ujhazy)).inv. AND CPAP AND pulse AND (respiratory ADJ2 movement)	US-PGPUB; USPAT	OR	OFF	2011/02/25 07:29
L4	9	3 AND (sleep$3 WITH (disorder OR symptom OR condition OR illness))	US-PGPUB; USPAT	OR	ON	2011/02/25 07:32
L5	0	3 AND (realtime OR (real ADJ2 time))	US-PGPUB; USPAT	OR	ON	2011/02/25 07:50
L6	9	3 AND (nebuliz$3 OR medication OR medicine OR drug OR agent)	US-PGPUB; USPAT	OR	ON	2011/02/25 08:19

S70	205	(("600"/$) OR ("128"/$)).ccls. AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust $6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet $4 OR oxymet$4) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect $5))	US-PGPUB; USPAT	OR	ON	2011/02/03 22:15
S71	348	(("600"/$) OR ("128"/$)).ccls. AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust $6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet $4 OR oxymet$4 OR saturation) WITH (detect $5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor $3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung	US-PGPUB; USPAT	OR	ON	2011/02/03 22:18

		OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect $5 OR vest OR band))				
S72	348	S71 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	2011/02/03 22:19

EAST Search History (Interference)

< This search history is empty>

2/25/11 8:21:43 AM
C:\Documents and Settings\NNatnithihadha\My Documents\EAST\Workspaces\FY2010\11266899.wsp

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In Re:	Application of Kayyali et al.		
Serial No.:	11/266,899	Art Unit:	3735
Filed:	November 4, 2005	Docket No.:	CMD-023
For:	Integrated sleep diagnosis and treatment device and method		
Examiner:	Navin Natnithithadha		

November 29, 2010

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Dear Sir:

This Brief supports the appeal to the Board of Patent Appeals and Interferences from the final Office action with mail date May 25, 2010, in the above-captioned application. Appellants filed a response after final and a notice of appeal on September 27, 2010. The Appellants herein certify that they are a small entity and hereby authorize the Board to deduct the $270 fee for filing of the appeal brief from Deposit Account 502704. Further, if any other fees are due in connection with the filing of this Brief on Appeal, the Appellants request that the fees be deducted from above-noted deposit account.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Cleveland Medical Devices Inc., 4415 Euclid Avenue, Suite 400, Cleveland, Ohio 44103.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-5, 7-11 and 13-20 stand rejected and are the subject of this appeal. Claims 6 and 12 were withdrawn from consideration.

IV. STATUS OF AMENDMENTS

Amendments were made to the claims subsequent to the May 25, 2010 final rejection in the amendment after final rejection filed September 27, 2010. The amendments did not substantively alter the claims but instead cleaned up minor errors (e.g., repeated word "adjusted" in claim 3, duplicate instances of the word "the" in claims 5 and 11, and inadvertently canceled words "to the" in claim 13) and made clarifications. The Appellants pointed out in the remarks that accompanied the amendment that the amendments to the claims would be appropriate to enter as they could only serve to clear up issues for appeal. According to 37 CFR 1.116(b)(2), "An amendment presenting rejected claims in better form for consideration on appeal may be admitted."

As the Appellants have not received any notification from the examiner as to whether the amendments will be admitted, the claims appealed here are those presented with the amendment

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of February 9, 2010. They are the claims of that amendment that are reprinted in the claims appendix in this appeal brief.

The Appellants respectfully request, if the examiner sees fit to enter the September 27, 2010 clarifying amendments, that the Board consider the claims as amended, as the following arguments apply to the claims as they would be amended alike as to the claims as they presently stand.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The support references in this section refer to the specification as filed November 4, 2005.

Generally, the claimed embodiments of the invention are devices that diagnose and treat sleep disorders, such as sleep apnea, providing enhanced therapy of such disorders through improved control of a continuous positive airway pressure device (CPAP), the control being based in part on physiological signals measured from the device's user (called the "subject").

Of the claims that are the subject of this appeal, claims 1, 7 and 14 are independent.

Claim 1 is directed to a sleeping disorder treatment system (*see* page 4, line 9; page 9, lines 9 *et seq.*; page 41, lines 6 *et seq.*; and FIGs. 7-8) comprising a data acquisition system for diagnosing a sleep disorder (*see* page 14, line 20 through page 15, line 10; FIGs. 1-6, 8), the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors (*see* page 15, lines 13-16; page 16, line 28; page 29, line 26 *et seq.*; FIG. 8), a respiration belt (*see* page 7, lines 13-19; 426 in FIG. 8) and a pulse oximeter sensors (*see* page 7, line 11; page 14, lines 6-15; page 33, line 9; 424 in FIG. 8) for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the

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sensors (*see* page 6, lines 5-14; page 9, lines 10-12; page 33, lines 4-10; page 40, line 1-5); and a continuous positive airway pressure device (CPAP) for treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output from the data acquisition system (*see* page 6, lines 5-14; page 39, lines 4-14 and 19-28; page 40, lines 1-14; page 41, lines 6-23; FIGs. 7-8).

Claim 7 is directed to a sleep apnea treatment system (see page 6, lines 5-14; FIGs. 7-8) comprising a data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors (*see* page 15, lines 13-16; page 16, line 28; page 29, line 26 *et seq.*; FIG. 8), a respiration belt (*see* page 7, lines 13-19; 426 in FIG. 8) and a pulse oximeter sensors (*see* page 7, line 11; page 14, lines 6-15; page 33, line 9; 424 in FIG. 8), the data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas (*see* page 6, lines 5-14; page 9, lines 10-12; page 33, lines 4-10; page 38, line 24 *et seq.*; page 40, line 1-5); and a CPAP device with an airflow sensor with a signal for treating the subject's sleep apnea, which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor (*see* page 6, lines 5-14; page 13, line 20 *et seq.*, page 39, lines 4-14 and 19-28; page 40, lines 1-14; page 41, lines 6-23; FIGs. 7-8).

Claim 14 is directed to a sleep apnea treatment system (*see* page 6, lines 5-14; FIGs. 7-8) comprising a data acquisition system (*see* page 15, lines 13-16; page 16, line 28; page 29, line 26 *et seq.*; FIG. 8) and a CPAP device with an airflow sensor (*see* page 6, lines 5-14; page 13, line 20 *et seq.*, page 39, lines 4-14 and 19-28; page 40, lines 1-14; page 41, lines 6-23; FIGs. 7-8) having a signal and a transceiver (*see* page 16, lines 11-16; 432, 441, 434 in FIG. 8), the data acquisition system comprising a data acquisition device having inputs for receiving signals from

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sensors (*see* page 15, lines 13-16; page 16, line 28; page 29, line 26 *et seq.*; FIG. 8), a respiration belt (*see* page 7, lines 13-19; 426 in FIG. 8) and a pulse oximeter sensors (*see* page 7, line 11; page 14, lines 6-15; page 33, line 9; 424 in FIG. 8), the data acquisition device further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device (*see* page 16, lines 11-16; page 39, lines 19-28; page 41, lines 11-17; bidirectional arrow in FIG. 8), the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas (*see* page 6, lines 5-14; page 9, lines 10-12; page 33, lines 4-10; page 38, line 24 *et seq.*; page 40, line 1-5); and the CPAP device for treating the subject's sleep apnea, which can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device (*see* page 16, lines 11-16; page 39, lines 19-28; page 41, lines 11-17; bidirectional arrow in FIG. 8).

Dependent claims 2, 8, and 15 relate to real-time adjustment of the CPAP therapy (*see* page 34, line 22 through page 35, line 9). Dependent claims 3, 9, and 16 relate to automatic adjustment of the CPAP therapy by using data or a signal from the data acquisition system (*see* page 3, lines 21-24; page 38, line 25). Dependent claims 4 and 10 relate to wireless transmission of the output from the data acquisition system to a receiver on the CPAP by radio frequency (*see* page 15, lines 19 *et seq.*; FIG. 1; FIG. 8). Dependent claims 5 and 11 relate to the collection of a subject's brain wave signal by the data acquisition system (*see* page 17, line 21; page 21, line 23; page 25, line 14; page 33, lines 4-7). Dependent claims 13 and 17 relate to the use of a microcontroller in the data acquisition system for calibrating and controlling the wireless radio frequency signal being transmitted CPAP device to adjust a treatment of the subject (see page 17,

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line 1 *et seq.*; 26 in FIG. 2; 438 in FIG. 8). Dependent claim 18 relates to the inclusion of a nebulizer in the CPAP (*see* page 41, lines 22-23). Dependent claim 19 relates to the use of the nebulizer to deliver medication (*see* page 41, lines 22-23). Dependent claim 20 relates to the adjustment of the CPAP device by a remote control device (*see* page 33, line 22 to page 34, line 21; page 44, claim 20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. 35 U.S.C. § 112-First Rejection

Claims 1-5, 7-11, and 13-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

B. 35 U.S.C. § 102-Second Rejection

Claims 1-5, 7-11, and 13-20 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Stahmann et al., U.S. Patent Application Publication No. 2005/0115561 A1 ("Stahmann").

VII. ARGUMENT

A. Claims 1-5, 7-11, and 13-20 are patentable under 35 U.S.C. § 112, second paragraph, as being definite and particularly pointing out and distinctly claiming the subject matter which Appellants regard as the invention.

As stated in MPEP § 2173.02, "In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent."

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The Appellants quote for the record the authorities on the requirements of § 112, second paragraph: "The purpose of claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not 'indefinite' simply because it is hard to understand when viewed without benefit of the specification." *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 1369, 59 USPQ2d 1745 (Fed. Cir. 2001). "We have stated the standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement as follows: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2." *Exxon Research & Engineering Co. v. United States*, 265 F.3d 1371, 1375, 60 USPQ2d 1272 (Fed. Cir. 2001).

The Appellants note that in each of the independent claims 1, 7, 14, the data acquisition device [must] hav[e] inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor. Thus any device lacking the appropriate inputs capable of interfacing with such sensors will fail to read on the claims. One skilled in the art is therefore well apprised of what structural and/or functional limitations must be incorporated for a potentially infringing device to read on the claims as worded.

The claims not being indefinite, the Appellants respectfully request the § 112 rejection be reversed.

B. Claims 1-3, 5-9, 12, 14-17 and 19-20 are patentable under 35 U.S.C. § 102(e) over U.S. Patent Application Publication No. 2005/0115561 A1 to Stahmann et al. ("Stahmann").

Claims 1-5, 7-11 and 13-20 were rejected under 35 U.S.C. § 102(e) as being anticipated by Stahmann et al., U.S. Patent Application Publication No. 2005/0115561 A1. The Appellants

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respectfully submit that the claims as amended are not *prima facie* anticipated by Stahmann and ask the Board to reverse the rejection.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 202 USPTO 202 (Fed Cir. 1983). It is not enough that the prior art reference disclose all of the claimed elements in isolation, but rather anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, anticipation requires that the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ 2d. 1241 (Fed Cir. 1986). Thus, the standard for anticipation is identity of invention, and the anticipating disclosure must enable the claims of the application. Here, Stahmann is not identical to the claimed invention, nor does Stahmann enable the claimed invention. The Appellants argue each independent claim 1, 7, 14 separately.

With respect to claim 1, Stahmann does not teach a single data acquisition device having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor as claimed. Instead Stahmann teaches that the respiratory therapy device 200 (i.e., the CPAP of Stahmann) "may be coupled to an array of data acquisition devices 222" ([0191]).

Stahmann does not teach that the data acquisition device has an input for a respiration belt sensor—the Appellants cannot find a mention of a belt anywhere in Stahmann. The paragraph pointed to by the examiner to teach this limitation, [0219], instead teaches an accelerometer mounted to the housing 401 of an electrical stimulation generator 405, and since this housing is implanted in the patient (see Figure 4A and paragraph [0217]) it would be

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impossible for this housing to provide an interface with a chest effort belt, which is an external sensor.

Stahmann further does not teach that the data acquisition device has an input for a pulse oximeter sensor. Stahmann paragraphs [1383]-[1384] disclose the two ways contemplated by Stahmann for delivery of pulse oximeter signals—either from the sensor, wirelessly, to an implanted device, or from the sensor to the therapy device (CPAP). The present invention, by contrast, has the data acquisition device (having the multiple inputs for the multiple sensors) for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors, which output is then used to adjust the CPAP. The examiner points to the "ITCS device" of Stahmann as being a pulse oximeter. The ITCS device is not a pulse oximeter. It is defined in Stahmann [0225] as being "an implantable transthoracic cardiac sensing and/or stimulation (ITCS) device … configured to deliver an appropriate therapy in response to abnormal activity or conditions." It is illustrated in Figure 5A of Stahmann. From the description and the illustration, what is meant by an "ITCS" is a pacemaker. A person skilled in the art would not glean from Stahmann the limitations of the claims, i.e., a data acquisition device have inputs for the various sensors described including a pulse oximeter. Even if the ITCS device of Stahmann were to include a sensor for measuring "oxygen saturation" ([0231]) or "blood oxygen level" ([0261]), such would not be a "pulse oximeter" as such a device is generally understood in the art to persons skilled in the art. A "pulse oximeter" as understood in the art is an externally-worn device and the Appellants' specification indicates no differently. ("Preferably, pulse oximeters are placed on a subject's earlob[e] or fingertip. More preferably, the pulse oximeter is placed on the subject's index finger." Appellants' specification, page 14, lines 13-15.)

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The benefit of the present invention as claimed in all the independent claims is that it provides a single data acquisition device, external the to patient, which interfaces with sensors including a respiration belt and a pulse oximeter. The Stahmann disclosure not providing a single data acquisition device with interfaces for all such sensors, and neither, in particular, a respiration belt nor a pulse oximeter, the reference of Stahmann does not approach anticipation of the claimed invention.

With regard to claim 7, as pointed out above, Stahmann does not teach a single data acquisition device having the several inputs but rather an array of such devices 222. Again, Stahmann teaches various methods for measuring chest wall movement ([0345]-[0346]) including an implanted accelerometer and measurement of transthoracic impedance but none of them involve a belt. The ITCS of Stahmann is not a pulse oximeter as such would be understood in the art in light of the Appellants' specification. The Appellants further note that paragraphs [0199]-[0204] of Stahmann do not teach a CPAP being adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor as claimed but rather teach a CPAP controlled by an implanted cardiac therapy device (i.e., a pacemaker) or vice versa.

With regard to claim 14, in addition to what has already been pointed out above, the reference of Stahmann does not teach a CPAP device with an airflow sensor having a signal and a transceiver as claimed. Stahmann merely discloses (in [0216]) that the CPAP of Stahmann "may receive information from one or more data acquisition devices." Further, paragraph [0205] of Stahmann, rather than teaching the limitation of a data acquisition device having a transceiver for communicating wirelessly with the CPAP, teaches that the CPAP and a pacemaker may communicate with each other wirelessly.

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In view of the foregoing, the Appellants respectfully submit that the examiner has not made a *prima facie* case of anticipation and request reversal of this rejection.

Conclusion

For at least the reasons given above, Appellants assert that the examiner has failed to make a *prima facie* case of indefiniteness or anticipation, and respectfully request that the Board reverse the § 112 and § 102 rejections on claims 1-5, 7-11 and 13-20.

If fee is required for an extension of time under 27 C.F.R. §1.136 not accounted for above, such extension is requested, petitioned for, and the fee should also be charged to our Deposit Account, 502704.

Respectfully submitted,

11/25/2010
Dated

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VIII. CLAIMS APPENDIX

1. (rejected) A sleeping disorder treatment system comprising

a data acquisition system for diagnosing a sleep disorder, the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors, a respiration belt and a pulse oximeter sensors for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors; and

a continuous positive airway pressure device (CPAP) for treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output from the data acquisition system.

2. (rejected) The system in Claim 1, wherein the CPAP is adjusted in real time.

3. (rejected) The system in Claim 1, wherein the CPAP is adjusted automatically adjusted by using data or a signal from the data acquisition system.

4. (rejected) The system in Claim 1, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

5. (rejected) The system in Claim 4, wherein the the data acquisition system further collects a subject's brain wave signal.

6. (withdrawn) The system in Claim 4, wherein the physiological signal is an EKG signal.

7. (rejected) A sleep apnea treatment system comprising

a data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors, a respiration belt and a pulse oximeter sensors, the data acquisition

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system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas; and

a CPAP device with an airflow sensor with a signal for treating the subject's sleep apnea, which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor.

8. (rejected) The system in Claim 7, wherein the CPAP device is adjusted in real time.

9. (rejected) The system in Claim 7, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

10. (rejected) The system in Claim 7, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

11. (rejected) The system in Claim 10, wherein the the data acquisition system further collects a subject's brain wave signal.

12. (withdrawn) The system in Claim 10, wherein the physiological signal is an EKG signal.

13. (rejected) The system in Claim 7, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted CPAP device to adjust a treatment of the subject.

14. (rejected) A sleep apnea treatment system comprising

a data acquisition system and a CPAP device with an airflow sensor having a signal and a transceiver,

the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors, a respiration belt and a pulse oximeter sensors, the data

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acquisition device further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device, the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas; and

the CPAP device for treating the subject's sleep apnea, which can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device.

15. (rejected) The system in Claim 14, wherein the CPAP device is adjusted in real time.

16. (rejected) The system in Claim 14, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

17. (rejected) The system in Claim 14, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

18. (rejected) The system in Claim 14, wherein the CPAP device further comprises a nebulizer.

19. (rejected) The system in Claim 18, wherein the nebulizer is used to deliver medication.

20. (rejected) The system in Claim 14, wherein the CPAP device is adjusted by a remote control device.

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IX. EVIDENCE APPENDIX

None.

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X. RELATED PROCEEDINGS APPENDIX

No related appeals or interferences.

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Electronic Patent Application Fee Transmittal

Application Number:	11266899
Filing Date:	04-Nov-2005
Title of Invention:	Integrated sleep diagnosis and treatment device and method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Robert Knecht Schmidt
Attorney Docket Number:	CMD-023

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Filing a brief in support of an appeal	2402	1	270	270
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**270**

Electronic Acknowledgement Receipt

EFS ID:	8924812
Application Number:	11266899
International Application Number:	
Confirmation Number:	8590
Title of Invention:	Integrated sleep diagnosis and treatment device and method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Robert Knecht Schmidt
Filer Authorized By:	
Attorney Docket Number:	CMD-023
Receipt Date:	29-NOV-2010
Filing Date:	04-NOV-2005
Time Stamp:	17:12:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$270
RAM confirmation Number	4335
Deposit Account	502704
Authorized User	KOLKOWSKI,BRIAN M.

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 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	Appeal Brief Filed	CMD-023_2010-11-29_Appeal_brief.pdf	263227 334c7fab567eb53dc1ca63c9f9d31972497d1ed6	no	16
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29943 f9c05ed97dee0a8b8f7cbacb9d9a2b71d7d7796a	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	293170		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	11/266,899	Art Unit:	3735
Filed:	November 4, 2005	Docket No.:	CMD-023
For:	Integrated sleep diagnosis and treatment device and method		
Examiner:	Navin Natnithithadha		

September 27, 2010

AMENDMENT AFTER FINAL

Commissioner of Patents and Trademarks
Alexandria, VA 22313

Dear Sir:

This Amendment is submitted in response to the final rejection having mail date May 25, 2010 with a shortened statutory period due date for response of August 25, 2010. The Applicants herein claim small entity status. The Applicants petition for a 1-month extension of time and provide the $65 fee for the extension. The Applicants herewithin also file a notice of appeal, and provide the $270 fee for the notice. The Applicants further provide a credit card payment form for the $335 dollars for the extension and notice of appeal. The Applicants similarly grant the Director permission to deduct these or any other fees as are found to be necessary from their deposit account 502704, and to credit any overpayments.

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IN THE CLAIMS:

Please amend claims 1, 3, 5, 7, 11, 13, and 14 as follows:

1. (currently amended) A sleeping disorder treatment system comprising

a data acquisition system for diagnosing a sleep disorder, the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors[[,]] including a respiration belt sensor and a pulse oximeter sensor[[s]], the data acquisition system for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors; and

a continuous positive airway pressure device (CPAP) for treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output from the data acquisition system.

2. (previously presented) The system in Claim 1, wherein the CPAP is adjusted in real time.

3. (currently amended) The system in Claim 1, wherein the CPAP is ~~adjusted~~ automatically adjusted by using data or a signal from the data acquisition system.

4. (previously presented) The system in Claim 1, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

5. (currently amended) The system in Claim 4, wherein the [[the]] data acquisition system further collects a subject's brain wave signal.

6. (withdrawn) The system in Claim 4, wherein the physiological signal is an EKG signal.

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7. (currently amended) A sleep apnea treatment system comprising

a data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors[[,]] including a respiration belt sensor and a pulse oximeter sensor[[s]], the data acquisition system for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas; and

a continuous positive airway pressure (CPAP) device with an airflow sensor with a signal for treating the subject's sleep apnea, which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor.

8. (previously presented) The system in Claim 7, wherein the CPAP device is adjusted in real time.

9. (previously presented) The system in Claim 7, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

10. (previously presented) The system in Claim 7, wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

11. (currently amended) The system in Claim 10, wherein the [[the]] data acquisition system further collects a subject's brain wave signal.

12. (withdrawn) The system in Claim 10, wherein the physiological signal is an EKG signal.

13. (currently amended) The system in Claim 7, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

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14. (currently amended) A sleep apnea treatment system comprising

a data acquisition system and a continuous positive airway pressure (CPAP) device with an airflow sensor having a signal and a transceiver,

the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors[[,]] including a respiration belt sensor and a pulse oximeter sensor[[s]], the data acquisition device further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device, the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas[[;]] ~~and~~

wherein the CPAP device ~~for treating the subject's sleep apnea, which~~ can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device.

15. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted in real time.

16. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted automatically using data or a signal from the data acquisition system.

17. (previously presented) The system in Claim 14, wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

18. (previously presented) The system in Claim 14, wherein the CPAP device further comprises a nebulizer.

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19. (original) The system in Claim 18, wherein the nebulizer is used to deliver medication.

20. (previously presented) The system in Claim 14, wherein the CPAP device is adjusted by a remote control device.

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REMARKS

This Amendment is in response to the final rejection dated May 25, 2010. In this case claims 1-20 are pending, 6 and 12 are withdrawn from consideration, and 1-5, 7-11 and 13-20 are rejected. The Applicants respectfully traverse the rejections below.

AMENDMENTS APPROPRIATE TO ENTER

The Applicants respectfully submit that the amendments to the claims submitted herewith are appropriate for the Examiner to enter as they merely clarify the claims, thus clearing up issues for appeal.

CLAIM REJECTIONS – 35 U.SC. § 112

The Applicants thank the examiner for the helpful suggestions regarding amendments to the claims for clarity and submit that the present amendments should resolve any ambiguity that would have tended to make the claims indefinite. The Applicants note that the examiner is correct in that the particular sensors are not positively recited in the claims but that in each of the independent claims 1, 7, 14 the data acquisition device [must] hav[e] inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor. Thus any device lacking the appropriate inputs capable of interfacing with such sensors will fail to read on the claims.

The claims as amended not being indefinite, the Applicants respectfully request the § 112 rejection be withdrawn.

CLAIM REJECTIONS – 35 U.SC. § 102

Claims 1-5, 7-11 and 13-20 were rejected under 35 U.S.C. § 102(e) as being anticipated by Stahmann et al., U.S. Patent Application Publication No. 2005/0115561 A1. The Applicants respectfully submit that the claims as amended are not *prima facie* anticipated by Stahmann.

With respect to claim 1, Stahmann does not teach a single data acquisition device having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor as claimed. Instead Stahmann teaches that the respiratory therapy device 200 (i.e., the CPAP of Stahmann) "may be coupled to an array of data acquisition devices 222" ([0191]).

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Stahmann does not teach that the data acquisition device has an input for a respiration belt sensor—the Applicants cannot find a mention of a belt anywhere in Stahmann. The paragraph pointed to by the examiner to teach this limitation, [0219], instead teaches an accelerometer mounted to the housing 401 of an electrical stimulation generator 405, and since this housing is implanted in the patient (see Figure 4A and paragraph [0217]) it would be impossible for this housing to provide an interface with a chest effort belt, which is an external sensor.

Stahmann further does not teach that the data acquisition device has an input for a pulse oximeter sensor. Stahmann paragraphs [1383]-[1384] disclose the two ways contemplated by Stahmann for delivery of pulse oximeter signals—either from the sensor, wirelessly, to an implanted device, or from the sensor to the therapy device (CPAP). The present invention, by contrast, has the data acquisition device (having the multiple inputs for the multiple sensors) for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors, which output is then used to adjust the CPAP. The examiner points to the "ITCS device" of Stahmann as being a pulse oximeter. The ITCS device is not a pulse oximeter. It is defined in Stahmann [0225] as being "an implantable transthoracic cardiac sensing and/or stimulation (ITCS) device ... configured to deliver an appropriate therapy in response to abnormal activity or conditions." It is illustrated in Figure 5A of Stahmann. Clearly from the description and the illustration, what is meant by an "ITCS" is a pacemaker. A person skilled in the art would not glean from Stahmann the limitations of the claims, i.e., a data acquisition device have inputs for the various sensors described including a pulse oximeter. Even if the ITCS device of Stahmann were to include a sensor for measuring "oxygen saturation" ([0231]) or "blood oxygen level" ([0261]), such would not be a "pulse oximeter" as such a device is generally understood in the art to persons skilled in the art. A "pulse oximeter" as understood in the art is an externally-worn device and the Applicants' specification indicates no differently. ("Preferably, pulse oximeters are placed on a subject's earlob[e] or fingertip. More preferably, the pulse oximeter is placed on the subject's index finger." Applicants' specification, page 14, lines 13-15.)

The benefit of the present invention as claimed in all the independent claims is that it provides a single data acquisition device, external the to patient, which interfaces with sensors including a respiration belt and a pulse oximeter. The Stahmann disclosure does not providing a

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single data acquisition device with interfaces for all such sensors, and neither, in particular, a respiration belt nor a pulse oximeter, the reference of Stahmann does not approach anticipation of the claimed invention.

Furthermore, there is no evidence that any of the data acquisitions systems are used for diagnosing a sleep disorder, or provide signals from the proper sensors necessary to determine the level of severity of a subject's sleep disorder or symptoms as claimed.

With respect to claim 2, Stahmann does not teach or disclose a CPAP that is adjusted in real time as claimed. Instead Stahmann in para. 467 contemplates monitoring in real-time, but goes on to teach that the "therapy may be adapted between disordered breating episodes" or "from night-to-night" indicating to one skilled in the art that Stahmann anticipates a significant delay between monitoring, analysis and adjustment of the CPAP therapy device.

With respect to claim 3, Stahmann also does not teach or disclose a CPAP that is automatically adjusted using data from a data acquisition system as claimed. The Examiner points to no language or drawings of Stahmann providing such disclosure except for para. 467, and this para. of Stahmann does not teach or disclose this limitation as claimed.

With respect to claim 4, Stahman does not teach or disclose the output [of the data acquisition system] is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP as claimed.

With respect to claim 5, Stahman does not teach or disclose wherein the data acquisition system further collects a subject's brain wave signal as claimed. The term "automatic activation of therapy based on brain waves" in para. 1412 referenced by the Examiner does not teach that the data acquisition device collects a subject's brain wave signal along with the other sensor inputs as claimed. Instead the Stahmann disclosure refers to a device incorporating monitoring, diagnostics and therapeutics thereby indicating that if brain wave signals are used that they are directly input into this common unit that is used for monitoring, diagnosis and therapy – not input from a separate data acquisition system that is linked to a CPAP device.

With regard to claim 7, as pointed out above, Stahmann does not teach a single data acquisition device having the several inputs but rather an array of such devices 222. Again, Stahmann teaches various methods for measuring chest wall movement ([0345]-[0346]) including an implanted accelerometer and measurement of transthoracic impedance but none of them involve a belt. Further, the ITCS of Stahmann is not a pulse oximeter as such would be

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understood in the art in light of the Applicants' specification. The Applicants further note that paragraphs [0199]-[0204] of Stahmann do not teach a CPAP being adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor as claimed but rather teach a CPAP controlled by an implanted cardiac therapy device (i.e., a pacemaker) or vice versa. Instead, FIG. 3 of Stahmann shows a data acquisition system, however, the data acquisition system does not diagnose and create an output of a level of severity of a subject's obstructive and central sleep apneas as claimed nor does the CPAP device have an airflow sensor with a signal for treating the subject's sleep apnea, where the CPAP is adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor as further claimed.

With respect to claim 8, Stahmann does not teach or disclose a CPAP that is adjusted in real time as claimed. Instead Stahmann in para. 467 contemplates monitoring in real-time, but goes on to teach that the "therapy may be adapted between disordered breating episodes" or "from night-to-night" indicating to one skilled in the art that Stahmann anticipates a significant delay between monitoring, analysis and adjustment of the CPAP therapy device.

With respect to claim 9, Stahmann also does not teach or disclose a CPAP that is automatically adjusted using data from a data acquisition system as claimed. The Examiner points to no language or drawings of Stahmann providing such disclosure except for para. 467, and this para. of Stahmann does not teach or disclose this limitation as claimed.

With respect to claim 10, Stahman does not teach or disclose the output [of the data acquisition system] is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP as claimed.

With respect to claim 11, Stahman does not teach or disclose wherein the data acquisition system further collects a subject's brain wave signal as claimed. The term "automatic activation of therapy based on brain waves" in para. 1412 referenced by the Examiner does not teach that the data acquisition device collects a subject's brain wave signal along with the other sensor inputs as claimed. Instead the Stahmann disclosure refers to a device incorporating monitoring, diagnostics and therapeutics thereby indicating that if brain wave signals are used that they are directly input into this common unit that is used for monitoring, diagnosis and therapy – not input from a separate data acquisition system that is linked to a CPAP device.

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With respect to claim 13, the Examiner contends that para. 206 of Stahmann teaches a data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject as claimed. This is not the case. Para. 206, referring to FIG. 2B, teaches a therapy devices communicating wirelessly with an external processor – not a data acquisition system communicating with a therapy device by wireless radio frequency signal and there is no indication that the external controller has any function in calibrating and controlling the wireless radio frequency signal being transmitted to the respiratory therapy device in Stahmann let alone controlling calibrating and controlling a wireless radio frequency signal between a data acquisition system and a CPAP device as claimed.

With regard to claim 14, in addition to what has already been pointed out above, the reference of Stahmann does not teach a CPAP device with an airflow sensor having a signal and a transceiver as claimed. Stahmann merely discloses (in [0216]) that the CPAP of Stahmann "may receive information from one or more data acquisition devices." Further, paragraph [0205] of Stahmann, rather than teaching the limitation of a data acquisition device having a transceiver for communicating wirelessly with the CPAP, teaches that the CPAP and a pacemaker may communicate with each other wirelessly.

With respect to claim 15, Stahmann does not teach or disclose a CPAP that is adjusted in real time as claimed. Instead Stahmann in para. 467 contemplates monitoring in real-time, but goes on to teach that the "therapy may be adapted between disordered breating episodes" or "from night-to-night" indicating to one skilled in the art that Stahmann anticipates a significant delay between monitoring, analysis and adjustment of the CPAP therapy device.

With respect to claim 16, Stahmann also does not teach or disclose a CPAP that is automatically adjusted using data from a data acquisition system as claimed. The Examiner points to no language or drawings of Stahmann providing such disclosure except for para. 467, and this para. of Stahmann does not teach or disclose this limitation as claimed.

With respect to claim 17, the Examiner contends that para. 206 of Stahmann teaches a data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject as claimed. This is not the case. Para. 206, referring to FIG. 2B, teaches a therapy devices communicating wirelessly with an external processor – not a data acquisition system

PAGE 18/19 * RCVD AT 9/27/2010 3:56:43 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-5/0 * DNIS:2738300 * CSID:2166490347 * DURATION (mm-ss):03-14

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communicating with a therapy device by wireless radio frequency signal and there is no indication that the external controller has any function in calibrating and controlling the wireless radio frequency signal being transmitted to the respiratory therapy device in Stahmann let alone controlling calibrating and controlling a wireless radio frequency signal between a data acquisition system and a CPAP device as claimed.

With respect to claims 18 and 19, Stahman does not teach a CPAP device further comprising a nebulizer as claimed. The Examiner refers to para. 202 of Stahman that indicates the therapy device may deliver pharmacological agent[s]. This, however, gives no indication of of the method of delivery being a nebulizer – and one skilled in the art would not necessarily understand it to be such.

With respect to claim 20, Stahman does not teach a CPAP device that is adjusted by a remote control device as such device is understood by those skilled in the art and as read in light of the specification.

Given the above response, the Applicants request that this rejection be withdrawn.

CONCLUSION

For all the above reasons the Applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

9/23/2010
Dated

Brian M. Kolkowski
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TRANSMITTAL FORM

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Total Number of Pages in This Submission: 19

Application Number	11/266,899
Filing Date	November 4, 2005
First Named Inventor	Kayyali et al.
Art Unit	3735
Examiner Name	Navin Natnithithadha
Attorney Docket Number	CMD-023

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☑ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):
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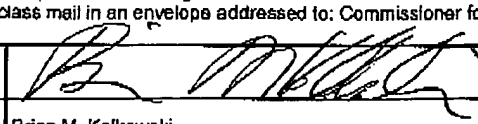
Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature			
Printed name	Brian M. Kolkowski		
Date	September 27, 2010	Reg. No.	36,847

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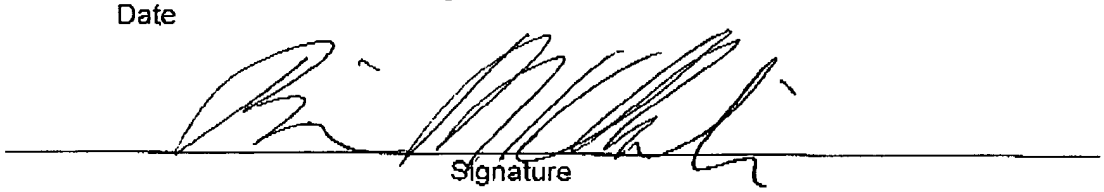
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2009 *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*	Docket Number (Optional) CMD-02
Application Number 11/266,899	Filed November 4, 2005
For Integrated sleep diagnosis and treatment device and method	
Art Unit 3735	Examiner Natnithithadha

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
☑ One month (37 CFR 1.17(a)(1))	$130	$65	$ 65.00
☐ Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐ Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐ Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐ Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

10/06/2010 SSANDARA 00000003 11266899
02 FC:2251 65.00 OP

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required above that paid by credit card or credit any overpayment, to Deposit Account Number 502704.

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I am the

☑ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 36,847

☐ attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature — September 27, 2010 (Date)

Brian M. Kolkowski (Typed or printed name) — 216-649-0376 (Telephone Number)

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of _____ forms are submitted.

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NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket Number (Optional): CMD-023

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Signature: [signature]

Typed or printed name: Brian M. Kolkowski

In re Application of: Kayyali et al.

Application Number	Filed
11/266,899	November 4, 2005

For: Integrated sleep diagnosis and treatment device and method

Art Unit	Examiner
3735	Natnithithadha

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 540.00

- [x] Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ 270.00
- [ ] A check in the amount of the fee is enclosed.
- [x] Payment by credit card. Form PTO-2038 is attached.
- [ ] The Director has already been authorized to charge fees in this application to a Deposit Account.
- [x] The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 502704.
- [ ] A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

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- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 36,847
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34.

[signature]
Signature

Brian M. Kolkowski
Typed or printed name

216-649-0376
Telephone number

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Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

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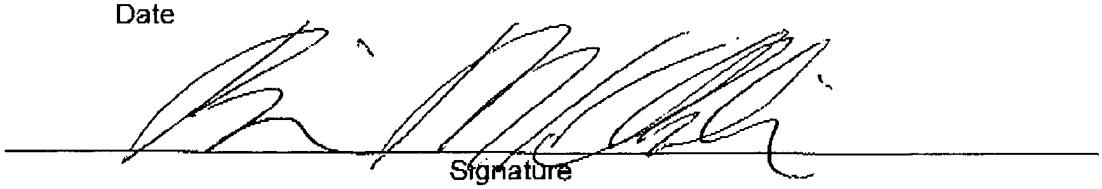
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/266,899	11/04/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	09/27/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							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".

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Legal Instrument Examiner:
/LINDA A. WASHINGTON/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

81177 7590 05/25/2010

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

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
05/25/2010	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.	Applicant(s)	
	11/266,899	KAYYALI ET AL.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *19 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ 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

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2005* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20100419*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. According to the Amendment, filed 09 February 2010, the status of the claims is as follows:

Claims 1-5, 7-11, and 13-17 are currently amended;

Claims 18-20 are as originally filed; and

Claims 6 and 12 are withdrawn.

2. The objections to claims 7-9, 13, 14, 16-18, and 20 are WITHDRAWN in view of the Amendment, filed 09 February 2010.

3. The 35 U.S.C. 112, second paragraph, rejection to claim 15 is WITHDRAWN in view of the Amendment, filed 09 February 2010.

Election/Restrictions

4. This application contains claims 6 and 12 drawn to an invention nonelected with traverse filed on 09 February 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

5. Applicant's arguments, see Remarks, pp. 6-8, filed 09 February 2010, with respect to the rejection of claims 1-5, 7-11, and 13-20 under 35 U.S.C. 102(e) as being

Chervin et al, U.S. Patent No. 7,190,995 B2 ("Chervin"), have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Objections

6. Claims 5 and 11 are objected to because of the following informalities:

In claim 5, line 1, "the" is a repeated word.

In claim 11, line 1, "the" is a repeated word.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> 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.

7. Claims 1-5, 7-11, and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is not clear whether the limitation "for creating an output of the signals or a level of severity of subject's sleeping disorder or symptoms based in part on the signals from the sensors" further the limits the "respiration belt" or the "pulse oximeter sensors". Furthermore, it is not clear whether the "respiration belt" or the "pulse oximeter sensors" are part of the "sleeping disorder treatment system" because

these devices are not positively recited. Appropriate correction is required. Examiner suggests using indentations, new paragraphs or positive recitations to clearly define the elements of the "sleeping disorder treatment system". Based on reasonable interpretation, these devices are not part of the "sleep apnea treatment system" but extraneous elements of the claimed invention.

Similarly, as to claim 7, it is not clear whether the "respiration belt" or the "pulse oximeter sensors" are part of the "sleeping disorder treatment system" because these devices are not positively recited. Appropriate correction is required.

Similarly, as to claim 14, it is not clear whether the "respiration belt" or the "pulse oximeter sensors" are part of the "sleeping disorder treatment system" because these devices are not positively recited. Appropriate correction is required.

Dependent claims 2-5, 8-11, 13, and 15-20 are rejected for the same reason as claims 1, 7, and 14.

Claim Rejections - 35 USC § 102

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

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the

United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 7-11, and 13-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Stahmann et al, U.S. Patent Application Publication No. 2005/0115561 A1 ("Stahmann").

As to Claim 1, Stahmann teaches the following:

A sleeping disorder treatment system (see Abstract) comprising

a data acquisition system ("advanced patient management system", or "APM") 170 for diagnosing a sleep disorder (see para. 175), the data acquisition system 170 comprising a data acquisition device 222 having inputs for receiving signals from sensors (see para. 175 and 191), a respiration belt (see para. 191 and 219) and a pulse oximeter sensors ("ITCS device", see para. 231 and 261) 500 for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors (see para. 33, 338, and 345); and

a continuous positive airway pressure device (CPAP) 220 for treating a subject's sleeping disorder or symptoms (see para. 203), which can be adjusted using in part the output from the data acquisition system (see para. 199-204).

As to Claims 2 and 3, Stahmann teaches the following:

wherein the CPAP is adjusted in real time (see para. 467), and wherein the CPAP is adjusted automatically adjusted by using data or a signal from the data acquisition system (see para. 467).

As to Claims 4-6, Stahmann teaches the following:

wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP (see para. 1412);

wherein the data acquisition system further collects a subject's brain wave signal (see para. 189 and 497);

wherein the physiological signal is an EKG signal (see para. 245, 780, and 943).

As to Claim 7, Stahmann teaches the following:

A sleep apnea treatment system (see Abstract) comprising

a data acquisition system ("advanced patient management system", or "APM") 170 comprising a data acquisition device 222 having inputs for receiving signals from sensors, a respiration belt (see para. 191 and 219) and a pulse oximeter sensors ("ITCS device", see para. 231 and 261) 500, the data acquisition system 170 for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apnea (see para. 33, 338, and 345); and

a CPAP device 220 with an airflow sensor with a signal for treating the subject's sleep apnea (see para. 203), which can be adjusted using both of the output of the data acquisition system and the signal from the CPAP device's airflow sensor (see para. 199-204).

As to Claims 8 and 9, Stahmann teaches the following:

wherein the CPAP 220 is adjusted in real time (see para. 467), and wherein the CPAP 220 is adjusted automatically adjusted by using data or a signal from the data acquisition system (see para. 467).

As to Claims 10 and 11, Stahmann teaches the following:

wherein the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP (see para. 1412); and

wherein the data acquisition system 170 further collects a subject's brain wave signal (see para. 189 and 497).

As to Claim 13, Stahmann teaches the following:

wherein the data acquisition system 170 further comprises a microcontroller 230, for calibrating and controlling the wireless radio frequency signal being transmitted CPAP device 220 to adjust a treatment of the subject (see para. 206).

As to Claim 14, Stahmann teaches the following:

A sleep apnea treatment system (see Abstract) comprising

a acquisition system ("advanced patient management system", or "APM") 170 and a CPAP device 220 with an airflow sensor having a signal and a transceiver (see para. 207-208),

the data acquisition system 170 comprising a data acquisition device 222 having inputs for receiving signals from sensors, a respiration belt arid a pulse oximeter sensors a respiration belt (see para. 191 and 219) and a pulse oximeter sensors ("ITCS device", see para. 231 and 261) 500, the data acquisition device 222 further comprising a transceiver 241 for wirelessly receiving radio frequency signals from the CPAP device 220 based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors 500 and the airflow signal sensor back to the CPAP device 220 (see para. 205), the data acquisition

device 222 for diagnosing and creating an, output of a level of severity of a subject's obstructive and central sleep apneas (see para. 33, 338, and 345); and

the CPAP device 220 for treating the subject's sleep apnea, which can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver 241 from the data acquisition device 222 (see para. 205-207).

As to Claims 15 and 16, Stahmann teaches the following:

wherein the CPAP 220 is adjusted in real time (see para. 467), and wherein the CPAP 220 is adjusted automatically adjusted by using data or a signal from the data acquisition system (see para. 467).

As to Claim 17, Stahmann teaches the following:

wherein the data acquisition system 170 further comprises a microcontroller 230, for calibrating and controlling the wireless radio frequency signal being transmitted CPAP device 220 to adjust a treatment of the subject (see para. 206).

As to Claims 18 and 19, Stahmann teaches the following:

wherein the CPAP device 220 further comprises a nebulizer, wherein the nebulizer is used to deliver medication (see para. 202).

As to Claim 20, Stahmann teaches the following:

wherein the CPAP device 220 is adjusted by a remote control device. (see para. 206)

Conclusion

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

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

10. Applicant's amendment, filed on 09 February 2010, 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.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/N. N./
Patent Examiner, Art Unit 3735
05/17/2010

Notice of References Cited	Application/Control No. 11/266,899	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,961,447 A	10-1999	Raviv et al.	600/300
*	B	US-6,551,252 B2	04-2003	Sackner et al.	600/536
*	C	US-2005/0085738 A1	04-2005	Stahmann et al.	600/529
*	D	US-2005/0115561 A1	06-2005	Stahmann et al.	128/200.24
*	E	US-7,195,013 B2	03-2007	Lurie, Keith G.	128/203.11
*	F	US-7,225,809 B1	06-2007	Bowen et al.	128/204.21
*	G	US-7,309,314 B2	12-2007	Grant et al.	600/529
*	H	US-7,668,579 B2	02-2010	Lynn, Lawrence A.	600/323
*	I	US-7,670,295 B2	03-2010	Sackner et al.	600/483
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11266899	KAYYALI ET AL.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3735

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/06/2009	05/17/2010							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	N	N							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	N	N							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	✓	✓							
	18	✓	✓							
	19	✓	✓							
	20	✓	✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11266899	KAYYALI ET AL.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3735

SEARCHED

Class	Subclass	Date	Examiner
600	300,544,545,529-543,481,483,484	11/6/09	/NN/
600	300,544,545,529-543,481,483,484	5/13/10	/NN/

SEARCH NOTES

Search Notes	Date	Examiner
EAST (enclosed), USPAT, US-PGPUB, Inventor, IDS, Keyword searches	11/6/09	/NN/
EAST (enclosed), USPAT, US-PGPUB, IDS, Art of Record, Keyword searches	5/13/10	/NN/

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

/N. N./ Examiner, Art Unit 3735	

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BIB DATA SHEET

CONFIRMATION NO. 8590

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/266,899	11/04/2005	600	3735	CMD-023

APPLICANTS

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

**** CONTINUING DATA ***************************

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
01/18/2006

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /NAVIN NATNITHITHADHA/ Examiner's Signature	☐ Met after Allowance /NN/ Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		OH	6	20	3

ADDRESS

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

TITLE

Integrated sleep diagnosis and treatment device and method

FILING FEE RECEIVED		
500	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	(US-20050115561-$).did.	US-PGPUB	OR	ON	2010/05/17 10:08
L2	1	1 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	2010/05/17 10:09
L3	1	1 AND (realtime OR (real ADJ2 time))	US-PGPUB; USPAT	OR	ON	2010/05/17 10:51
L4	1	1 AND (wireless$3 OR transmi$6 OR transceiver OR communicat$5)	US-PGPUB; USPAT	OR	ON	2010/05/17 10:54
L5	1	1 AND (wireless$3)	US-PGPUB; USPAT	OR	ON	2010/05/17 10:54
L6	1	1 AND ("EEG" OR electroenceph$ OR brain OR brainwave$5)	US-PGPUB; USPAT	OR	ON	2010/05/17 10:57
L7	1	1 AND ("ECG" OR "EKG" OR electrocardiograph$)	US-PGPUB; USPAT	OR	ON	2010/05/17 11:00
S21	82	(("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))	US-PGPUB; USPAT	OR	ON	2010/05/14 13:07

		AND (sleep$3 WITH (disorder OR condition OR disease OR illness OR apne $3 OR symptom)) AND ((600/529-543,484) OR ("128"/$)).ccls.				
S22	82	(("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 S21	US-PGPUB; USPAT	OR	ON	2010/05/14 13:08
S26	78	(("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	2010/05/14 17:11

S27	78	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH (adjust$4 OR control$4 OR regulat$4 OR chang$3)) AND ((pulse OR oximet$4 OR oxymet$4 OR saturation) WITH (sensor$3 OR sensing OR measur$6 OR detect$5 OR monitor$3 OR transducer OR probe)) AND (sleep$3 WITH (disorder OR condition OR disease OR illness OR apne$3 OR symptom)) AND S26	US-PGPUB; USPAT	OR	ON	2010/05/14 17:12
S28	1	(US-20050115561-$).did.	US-PGPUB	OR	ON	2010/05/14 19:30
S29	1	S28 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	2010/05/14 19:31
S30	1	S28 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	2010/05/14 19:33

EAST Search History (Interference)

<This search history is empty>

5/17/10 11:28:37 AM
C:\Documents and Settings\NNatnithihadha\My Documents\EAST\Workspaces\FY2010\11266899.wsp

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11266899
Filing Date	2005-11-04
First Named Inventor	Hani Kayyali
Art Unit	3735
Examiner Name	Navin Natnithithadha
Attorney Docket Number	CMD-023

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/NN/	1	20050188991	A1	2005-09-01	Sun et al.	Abstract, FIGs. 1-2, paragraphs 16, 18, 20, 22, 27, 31, 40, 41, 44

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11266899
	Filing Date	2005-11-04
	First Named Inventor	Hani Kayyali
	Art Unit	3735
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-023

	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Navin Natnithithadha/ (05/20/2010)	Date Considered	05/20/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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Art Unit	3735
Examiner Name	Navin Natnithithadha
Attorney Docket Number	CMD-023

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050188991	A1	2005-09-01	Sun et al.	Abstract, FIGs. 1-2, paragraphs 16, 18, 20, 22, 27, 31, 40, 41, 44

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11266899
	Filing Date	2005-11-04
	First Named Inventor	Hani Kayyali
	Art Unit	3735
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-023

	1		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11266899
Filing Date	2005-11-04
First Named Inventor	Hani Kayyali
Art Unit	3735
Examiner Name	Navin Natnithithadha
Attorney Docket Number	CMD-023

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Robert Knecht Schmidt/	Date (YYYY-MM-DD)	2010-04-19
Name/Print	Robert Knecht Schmidt	Registration Number	65458

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Electronic Patent Application Fee Transmittal

Application Number:	11266899
Filing Date:	04-Nov-2005
Title of Invention:	Integrated sleep diagnosis and treatment device and method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Robert Knecht Schmidt
Attorney Docket Number:	CMD-023

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	7440509
Application Number:	11266899
International Application Number:	
Confirmation Number:	8590
Title of Invention:	Integrated sleep diagnosis and treatment device and method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Robert Knecht Schmidt
Filer Authorized By:	
Attorney Docket Number:	CMD-023
Receipt Date:	19-APR-2010
Filing Date:	04-NOV-2005
Time Stamp:	15:26:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	1937
Deposit Account	502704
Authorized User	KOLKOWSKI,BRIAN M.

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	CMD-023_2010-04-19_IDS.pdf	761692 7c626dbdeefaf095b5ffb0056f5ed23f0eedcdac	no	4
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29933 215d356c047f43d427e46bbf43f43c33cc24de7a	no	2
Warnings:					
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<u>New International Application Filed with the USPTO as a Receiving Office</u>
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	
Serial No.:	11/266,899	Art Unit: 3735
Filed:	November 4, 2005	
For:	Integrated sleep diagnosis and treatment device and method	
Examiner:	Navi Natnithithadha	

February 9, 2010

Amendment

Commissioner of Patents and Trademarks
Alexandria VA 22313-1450

Dear Sir:

The Applicants respond to the non-final Office Action with mail date November 9, 2009, and submit this amendment is both timely and in compliance. While applicants believe no extension of time is necessary, if an extension is needed, the Applicants petition for such extension and authorize the Patent Office to deduct any costs from their deposit account 502704. The following amendments and remarks are respectfully submitted, and are believed to place this application in condition for allowance.

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CLAIM AMENDMENTS:

Please amend claims 1-20 as follows:

1. (currently amended) A sleeping disorder treatment system comprising

a ~~first device~~data acquisition system for diagnosing a sleep disorder, the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors, a respiration belt and a pulse oximeter sensors for creating an ~~quantitative~~ output of the signals or a level of severity of a subject's sleeping disorder or symptoms based in part on the signals from the sensors; and

a ~~second device for physically or chemically~~continuous positive airway pressure device (CPAP) for 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 or symptoms~~from the data acquisition system.

2. (currently amended) The system in Claim 1, wherein the ~~first device for physically or chemically treating a subject's sleeping disorder~~CPAP is adjusted in real time.

3. (currently amended) The system in Claim 1, wherein the ~~second device~~CPAP is adjusted automatically adjusted by using data or a signal from the ~~first device~~data acquisition system.

4. (currently amended) 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~~the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

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5. (currently amended) The system in Claim 4, wherein the ~~physiological signal~~the data acquisition system further collects a subject's ~~is a~~ brain wave signal.

6. (withdrawn) The system in Claim 4, wherein the physiological signal is an EKG signal.

7. (currently amended) A sleep apnea treatment system comprising

a ~~first device~~data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors, a respiration belt and a pulse oximeter sensors, the data acquisition system for diagnosing and creating an output of a level of severity of a subject's ~~sleep apnea~~obstructive and central sleep apneas; and

a CPAP device with an airflow sensor with a signal for treating the subject's sleep apnea, which can be adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor.

8. (currently amended) 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. (currently amended) The system in Claim 7, wherein the CPAP device is adjusted automatically using data or a signal from the ~~first device~~data acquisition system.

10. (currently amended) 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~~the output is transmitted wirelessly by radio frequency from the data acquisition system to a receiver on the CPAP.

11. The system in Claim 10, wherein the ~~physiological signal~~the data acquisition system further collects a subject's ~~is a~~ brain wave signal.

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12. (withdrawn) The system in Claim 10, wherein the physiological signal is an EKG signal.

13. (currently amended) The system in Claim 7, wherein ~~the first device sends a~~the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted~~based in part on the output level of severity to the~~ CPAP device to adjust a treatment of the subject.

14. (currently amended) A sleep apnea treatment system comprising

a ~~first device~~data acquisition system and a CPAP device with an airflow sensor having a signal and a transceiver,

the data acquisition system comprising a data acquisition device having inputs for receiving signals from sensors, a respiration belt and a pulse oximeter sensors, the data acquisition device further comprising a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device, the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas ~~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 the CPAP device for treating the subject's sleep apnea, which can be adjusted using the ~~output~~radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device.

15. (currently amended) The system in Claim 14, wherein ~~the second device~~ the CPAP device ~~for physically or chemically treating a subject's sleeping disorder~~is adjusted in real time.

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16. (currently amended) The system in Claim 14, wherein the CPAP device is adjusted automatically using data or a signal from the ~~first device~~data acquisition system.

17. (currently amended) 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~~wherein the data acquisition system further comprises a microcontroller for calibrating and controlling the wireless radio frequency signal being transmitted to the CPAP device to adjust a treatment of the subject.

18. (original) The system in Claim 14, wherein the CPAP device further comprises a nebulizer.

19. (original) The system in Claim 18, wherein the nebulizer is used to deliver medication.

20. (original) The system in Claim 14, wherein the CPAP device is adjusted by a remote control device.

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REMARKS

In the Office Action, the Examiner noted that claims 1-20 are pending in the application, claims 1-5, 7-11 and 13-20 were rejected, and claims 6 and 12 were subject to restriction. Claims 1-5, 7-11, and 13-17 have been amended. Claims 6 and 12 have been withdrawn. The Examiner's rejections are respectfully traversed below.

RESTRICTIONS:

The Applicants confirm that they elected to prosecute Group I claimes without traverse. The Applicants have withdrawn claims 6 and 12.

35 USC §112 Rejection:

Claim 15 was rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Applicants submit that claim 15 as currently amended overcomes this rejection.

35 USC §102 Rejection:

Claims 1-5, 7-11, and 13-20 were rejected under 35 U.S.C. § 102(e) as being anticipated by Chervin et al, U.S. Pat. No. 7,190,995. The Applicants Claims 1-5, 7-11 and 13-20 as now amended are not anticipated by Chervin.

With respect to Claims 1-5, Chervin does not teach or disclose an integrated system with both a data acquisition device for diagnosing a sleep disorder, the data acquisition system comprising a respiration belt and a pulse oximeter sensors and inputs for receiving signals from the sensors and for creating an output of the signals or a level of severity of a subject's sleeping disorder or symptoms (based on those signals); and a continuous positive airway pressure device (CPAP) for treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output from the data acquisition system as claimed.

Chervin instead discloses a method for determining "respiratory cycle-related EEG changes". Col 3, lines 23-24. Chervin's system and method are used to determine

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microarousals through the above measure. Col. 5, lines 30-64. Chervin needs EEG to determine microarousals. The present invention does not. Chervin mentions that its method can be "incorporated into" a CPAP device. The present invention uses a data acquisition device separate from the CPAP to adjust the CPAP.

With respect to Claim 2, in addition Chervin does not teach or disclose a system wherein CPAP is adjusted in real time as claimed. With respect to Claim 3, in addition Chervin does not teach or disclose a system wherein a CPAP is adjusted automatically adjusted by using data or a signal from a data acquisition system as claimed. With respect to Claim 4, in addition Chervin does not teach or disclose a system wherein the output is transmitted wirelessly by radio frequency from a data acquisition system to a receiver on the CPAP as claimed.

With respect to Claims 7-11, in addition to the above comments Chervin does not teach or disclose a system creating an output of a level of severity of both a subject's obstructive and central sleep apneas, or a CPAP that is adjusted using both the output of the data acquisition system and the signal from the CPAP device's airflow sensor as claimed. In addition to those comments above with respect to Claim 13, Chervin does not teach or disclose a data acquisition device further comprising a microcontroller for calibrating and controlling the wireless radio frequency signal being CPAP device to adjust a treatment of the subject as claimed.

Finally with respect to Claims 14-20, in addition to the above comments Chervin does not teach or disclose a system the data acquisition device comprising a respiration belt and a pulse oximeter sensors, inputs for receiving signals from the sensors, and a transceiver for wirelessly receiving radio frequency signals from the CPAP device based on the signal of the airflow sensor and transmitting radio frequency signals based on the inputs from the respiration belt and pulse oximeter sensors and the airflow signal sensor back to the CPAP device, the data acquisition device for diagnosing and creating an output of a level of severity of a subject's obstructive and central sleep apneas as claimed, or a CPAP device for treating the subject's sleep apnea, which can be adjusted using the radio frequency signals transmitted to the CPAP's transceiver from the data acquisition device as claimed.

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In addition to the above comments, with respect to Claims 18-19, Chervin does not teach or disclose a system wherein the CPAP device further comprises a nebulizer as claimed.

With respect to Claim 19, wherein the nebulizer is used to deliver medication as claimed.

With respect to Claim 20, wherein the CPAP device is adjusted by a remote control device as claimed.

Given the reasons set forth above, the Applicants respectfully request withdrawal of this rejection.

CONCLUSION:

The Applicants respectfully submit that this application is in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

2/9/2010
Dated

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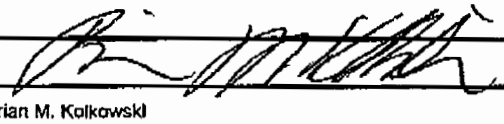
Application Number	11/266,899
Filing Date	November 4, 2005
First Named Inventor	Kayyali et al.
Art Unit	3735
Examiner Name	Natnithithadha
Attorney Docket Number	CMD-023

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☐ Fee Attached
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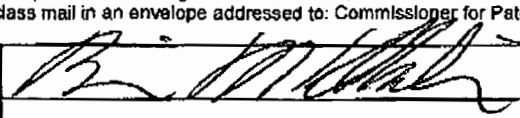
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Printed name	Brian M. Kolkowski		
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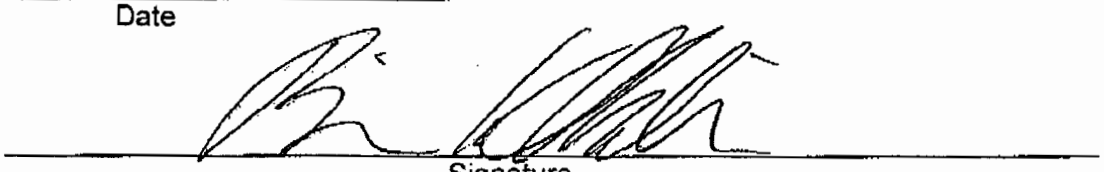
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216-649-0376 — Telephone Number

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This collection of information is required by 37 CFR 1.8. 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 1.8 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.

PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/266,899	11/04/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 02/09/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/ROCHELLE C. GETER/

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.
11/266,899	11/04/2005	Hani Kayyali	CMD-023	8590

81177 7590 11/09/2009

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

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
11/09/2009	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.	Applicant(s)	
	11/266,899	KAYYALI ET AL.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6 and 12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2005* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20051104; 20081205*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species: Group I, directed to a brain wave signal, and Group II, directed to an EKG signal. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-4, 7-10, and 13-20 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a

claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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

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

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

During a telephone conversation with Brian M. Kolkowski on 05 November 2009 a provisional election was made without traverse to prosecute the invention of species Group I, claims 5 and 11. Affirmation of this election must be made by applicant in

replying to this Office action. Claims 6 and 12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

2. Claims 7-9, 13, 14, 16-18, and 20 are objected to because of the following informalities: these claims contain abbreviations "CPAP" or "EEG" that should be defined for clarity purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> 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.

3. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the second device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

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

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5, 7-11, and 13-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Chervin et al, U.S. Patent No. 7,190,995 B2 ("Chervin").

Claims 1-5, 7-11, and 13-20: Chervin teaches the following:

A sleeping disorder treatment system 10 ("respiratory cycles-related EEG changes (RCREC)", see col. 5, ll. 30-49, and col. 17, ll. 10-25, and figs. 2 and 3) comprising

a first device 12, comprising at least two EEG sensor ("two to sixteen EEG electrodes 12 or sensors", see col. 6, ll. 52-58), for diagnosing and creating a quantitative output of a level of severity of a subject's sleeping disorder or symptoms based in part on the brain wave signal of the subject (see col. 5, l. 30, to col. 6, l. 14, and col. 6, l. 52, to col. 7, l. 21); and

a second device, such as a CPAP device, for physically or chemically treating a subject's sleeping disorder or symptoms, which can be automatically adjusted, in real-time, using in part the output of the level of severity of the subject's sleeping disorder and using data or a signal from the first device(see col. 17, ll. 10-25).

Conclusion

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

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

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Navin Natnithithadha/
Patent Examiner, Art Unit 3735
11/06/2009

Notice of References Cited	Application/Control No. 11/266,899	Applicant(s)/Patent Under Reexamination KAYYALI ET AL.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,431,171 B1	08-2002	Burton, David	128/204.18
*	B	US-2003/0000528 A1	01-2003	Eklund et al.	128/204.23
*	C	US-2004/0163648 A1	08-2004	Burton, David	128/204.21
*	D	US-2004/0254493 A1	12-2004	Chervin et al.	600/544
*	E	US-2005/0081847 A1	04-2005	Lee et al.	128/200.24
*	F	US-6,889,691 B2	05-2005	Eklund et al.	128/204.21
*	G	US-2005/0165323 A1	07-2005	Montgomery et al.	600/544
*	H	US-2005/0268916 A1	12-2005	Mumford et al.	128/207.13
*	I	US-2006/0247546 A1	11-2006	Imose, Kazuo	600/513
*	J	US-7,190,995 B2	03-2007	Chervin et al.	600/544
*	K	US-7,204,250 B1	04-2007	Burton, David	128/205.23
*	L	US-7,575,005 B2	08-2009	Mumford et al.	128/205.23
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	1126689912194139	KAYYALI ET AL.ARBEL ET AL.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHANAVIN NATNITHITHADHA	37353735

SEARCHED

Class	Subclass	Date	Examiner
600600	481,483,484,500-503,529,300300,544,545,529-543,481,483,484	10/23/0911/6/09	/NN//NN/

SEARCH NOTES

Search Notes	Date	Examiner
EAST (enclosed), USPAT, US-PGPUB, JPO, EPO, Derwent, IDS, Inventor, Keyword searchesEAST (enclosed), USPAT, US-PGPUB, Inventor, IDS, Keyword searches	10/23/0911/6/09	/NN//NN/

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

/N. N./ Examiner, Art Unit 3735/N. N./ Examiner, Art Unit 3735	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1902	((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	2009/11/06 23:09
S3	640	("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	2009/11/06 23:35

S4	389	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) AND (("EEG" OR electroencephal$6 OR brain OR scalp OR head OR brainwave$5) WITH (electrode OR sens$5 OR detect$4 OR transducer OR meter$3 OR bioelectrode OR biosens$5 OR biodetect $4 OR biotransducer OR biometer$3 OR measur$5 OR monitor $3)) AND (((sleep$3 NEAR8 (disorder OR illness OR condition OR obstructi$4)) OR apne$3 OR hypoapne $3 OR hyperapne$3 OR hypopne$3) SAME (treat$5 OR therap$6)) AND (("600"/$) OR ("128"/$)).ccls.	US-PGPUB; USPAT	OR	ON	2009/11/06 23:37
S5	245	(("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	US-PGPUB; USPAT	OR	ON	2009/11/06 23:40

		OR hypopne$3) SAME (treat$5 OR therap$6)) AND (("600"/$) OR ("128"/$)).ccls.				
S6	52	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH (adjust$4 OR control$4 OR regulat$4 OR chang $3)) SAME (("EEG" OR electroencephal$6 OR brain OR scalp OR head OR brainwave$5) WITH (electrode OR sens$5 OR detect$4 OR transducer OR meter$3 OR bioelectrode OR biosens$5 OR biodetect $4 OR biotransducer OR biometer$3 OR measur$5 OR monitor $3))) AND (((sleep$3 NEAR8 (disorder OR illness OR condition OR 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	2009/11/06 23:41
S7	52	((("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	US-PGPUB; USPAT	OR	ON	2009/11/06 23:41

		measur$5 OR monitor $3))) AND S6				
S8	58	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH (adjust$4 OR control$4 OR regulat$4 OR chang $3)) SAME (("EEG" OR electroencephal$6 OR brain OR scalp OR head OR brainwave$5) WITH (electrode OR sens$5 OR detect$4 OR transducer OR meter$3 OR bioelectrode OR biosens$5 OR biodetect $4 OR biotransducer OR biometer$3 OR measur$5 OR monitor $3 OR signal$3 OR wave OR waveform OR data OR value))) AND (((sleep$3 NEAR8 (disorder OR illness OR condition OR obstructi $4)) OR apne$3 OR hypoapne$3 OR hyperapne$3 OR hypopne$3) SAME (treat$5 OR therap$6)) AND (("600"/$) OR ("128"/$)).ccls.	US-PGPUB; USPAT	OR	ON	2009/11/06 23:44
S9	58	((("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	US-PGPUB; USPAT	OR	ON	2009/11/06 23:44

		OR biometer$3 OR measur$5 OR monitor $3 OR signal$3 OR wave OR waveform OR data OR value))) AND S8				
S10	5	("20050217674" | "5645043" | "6029664" | "6138675" | "6229581").PN.	US-PGPUB; USPAT	OR	OFF	2009/11/07 08:30
S11	214	((("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	2009/11/07 08:41
S12	100	((("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	US-PGPUB; USPAT	OR	ON	2009/11/07 08:42

		$4 OR biotransducer OR biometer$3 OR measur$5 OR monitor $3 OR signal$3 OR wave OR waveform OR data OR value))) AND ((sleep$3 NEAR8 (disorder OR illness OR condition OR obstructi $4)) OR apne$3 OR hypoapne$3 OR hyperapne$3 OR hypopne$3) AND (("600"/$) OR ("128"/ $)).ccls.				
S13	100	((("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$3 OR wave OR waveform OR data OR value))) AND S12	US-PGPUB; USPAT	OR	ON	2009/11/07 08:43
S14	20	(US-20080276939-$ 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-	US-PGPUB; USPAT	OR	ON	2009/11/07 09:04

		6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$).did.				
S15	0	(quantitative$3) AND (realtime OR (real ADJ2 time)) AND S14	US-PGPUB; USPAT	OR	ON	2009/11/07 09:05
S16	7	(realtime OR (real ADJ2 time)) AND S14	US-PGPUB; USPAT	OR	ON	2009/11/07 09:05
S17	4	(quantitative$3) AND S14	US-PGPUB; USPAT	OR	ON	2009/11/07 09:09

EAST Search History (Interference)

<This search history is empty>

11/7/09 12:00:14 PM
C:\Documents and Settings\NNatnithihadha\My Documents\EAST\Workspaces\FY2010\11266899.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11266899	KAYYALI ET AL.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3735

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/06/2009								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	N								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	N								
	13	✓								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								

Practitioner's Docket No. CMD-023 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application
of Kayyali et al.
Inventor(s)
for INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD
Title of invention

the specification of which is being transmitted herewith

OR

In re application of:

Serial No.: 0 /
Filed:
For:

Group No.:
Examiner:

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

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37 C.F.R. 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. 1.10*

☒ as "Express Mail Post Office to Addressee"
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TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Date: 11/4/2005

Adam Buchanan
Signature

Adam Buchanan
(type or print name of person certifying)

***WARNING:** Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NN/

ResMed
Exhibit 1004 - Page 226

NOTE: *"An information disclosure statement shall be considered by the Office if filed by the applicant:*

(1) Within three months of the filing date of a national application;

(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or

(3) Before the mailing date of a first Office action on the merits, whichever event occurs last."

37 C.F.R. 1.97(b).

NOTE: *"Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. 1.56(a).*

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) each inventor named in the application;

(2) each attorney or agent who prepares or prosecutes the application; and

(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. 1.56(c).

NOTE: *The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.*

WARNING: *"No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).*

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
   - 7A. ☐ EPO Search Report
   - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections , respectively, have been continued on ADDED PAGE(S).

NOTE: *"Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NN/

Exhibit 1004 - Page 227

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NN/

Reviewed
Exhibit 1004 - Page 228

Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)

NOTE: *With respect to the list required by paragraph (b) of 37 C.F.R. 1.98, the Notice of April 20, 1992 (1138 O.G. 37-41) points out that:*

"The list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicant intends to submit an information disclosure statement, and because it provides a readily available checklist for the examiner to indicate which identified documents have been considered. A copy of a separate list will also provide a simple means of communication to applicant to indicate the listed documents that have been considered and those listed documents that have not been considered. Use of form PTO-1449, "Information Disclosure Citation, is encouraged."

NOTE: *"An information disclosure statement may include two list[s ([and two certifications])] . . . in situations where some of the information listed was cited in a communication from a foreign patent office not more than three months prior to filing the statement and some was not, but was not known more than three months prior to filing the statement." Notice of April 20, 1992 (1138 O.G. 37-41, 40).*

NOTE: *With respect to the examiner's consideration of the Information Disclosure Statement, the Notice of April 20, 1992 (1138 O.G. 37-41) states:*

*"If information is listed in the specification rather than in a separate paper, or if the other content requirements *** are not complied with, the examiner will notify applicant in the next Office action that the information has not been considered. It should be noted, however, that no copy of a U.S. patent application is required to be submitted. *** Where a U.S. patent application is properly cited, the examiner should obtain access to that file within the Office.*

"Examiners must consider all citations submitted in conformance with the rules and this section and place their initials adjacent [sic] the citations on a list or in the boxes provided on a form PTO-1449. If the citations are submitted on a list other than a form PTO-1449, the examiner may write "all considered" and his or her initials to indicate that all citations have been considered. If any of the citations are considered, a copy of the submitted list or form, as reviewed by the examiner, will be returned to the applicant with the next communcation. The original copy of the form will be entered into the application file. The copy returned to applicant will serve both as acknowledgement of receipt of the information disclosure statement and as an indication that the references were considered by the examiner. Forms PTO-326 and PTOL-37 include a box to indicate the attachment of form PTO-1449.

*"Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted *** and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so. *** The examiner should not require that a translation be filed by applicant. The examiner should not make any comment such as that the non-English language information has only been considered to the extent understood, since this fact is inherent.*

"Since information is required to be listed in a separate paper rather than in the specification, there is no need to mark "All checked" or "Checked" in the margin of a specification containing citations.

"If a statement fails to comply with the requirements as discussed in this section for an item of information, a line should be drawn through the citation to show that it has not been considered. The other items of information listed that do comply with the rules and this section will be considered by the examiner and will be appropriately initialed.

* * * * *

"A citation listed on form PTO-1449 and considered by the examiner in accordance with this section will be printed on the patent. A citation listed in a separate paper, equivalent to but not on form PTO-1449, and considered by the examiner in accordance with this section will be printed on the patent if the list is on a separate sheet which is clearly identified as an information disclosure statement and the list lends itself to easy capture of the necessary information by the Office printing contractor, i.e., each item of information is listed on a single line, the lines are at least double-spaced from each other, the information is uniform in format for each listed item, the list includes a column for the examiner's initials to indicate that the information was considered. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact . . . "

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NN/
Exhibit 1004 - Page 229

PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 7

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Kayyali
Art Unit	
Examiner Name	
Attorney Docket Number	CMD-023

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/NN/	1	US- 5,645,043	07-05-197	Remmers et al.	
/NN/	2	US- 6,029,664	02-29-2000	Zdrojkowski et al.	
/NN/	3	US- 6,138,675	10-31-2000	Berthon-Jones	
/NN/	4	US- 6,229,581	10-09-2001	Rapoport et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Navin Natnithithadha/ (11/06/2009)	Date Considered	11/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NN/

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . . "

NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☐ Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NN/

Received
Exhibit 1004 - Page 231

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(c) ■ the practitioner who signs below on the basis of the information:

(check each applicable item)

■ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. 1.56(c))

☐ in the practitioner's file.

SIGNATURE OF PRACTITIONER

Reg. No.: 36,847

Brian M. Kolkowski

(type or print name of practitioner)

Tel. No.: (216) 649-0376

4415 Euclid Ave, Suite 400

P.O. Address

Customer No.:

Cleveland, OH 44103

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NN/

Exhibit 1004 - Page 232

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/266,899
Filing Date	11-04-2005
First Named Inventor	Kayyali
Art Unit	3736
Examiner Name	
Attorney Docket Number	CMD-023

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/NN/		US- 2005/0217674 A1	10-06-2005	Burton et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Navin Natnithithadha/ (11/06/2009)	Date Considered	11/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	
Serial No.:	11/266,899	Art Unit 3736
Filed:	November 4, 2005	
For:	Integrated Sleep Diagnosis And Treatment Device and Method	
Examiner:	Unknown	

April 20, 2009

STATUS UPDATE

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

The Applicants submit that the above application was filed nearly 3 ½ years ago and request an update as to its status.

Respectfully submitted,

4/20/2009
Dated

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

PAGE 2/2 * RCVD AT 4/20/2009 2:09:44 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-5/0 * DNIS:2738300 * CSID:2166490347 * DURATION (mm-ss):00-30

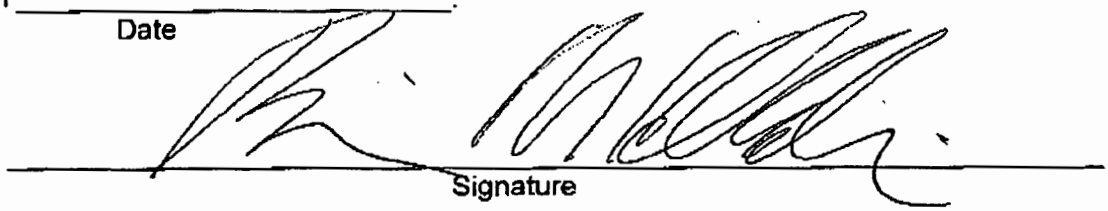
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PTO/SB/97 (03-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office

on April 20, 2009
Date



Signature

Brian M. Kolkowski

Typed or printed name of person signing Certificate

36,847 — Registration Number, if applicable

216-649-0376 — Telephone Number

Note: Each paper must have its own certificate of transmission, or this certificate must identify each submitted paper.

This collection of information is required by 37 CFR 1.8. 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 1.8 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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UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
11/266,899		3735	

OC000000033780124

Correspondence Address/Fee Address Change

The following fields have been set to Customer Number 81177 on 12/23/2008

- **Correspondence Address**
- **Maintenance Fee Address**
- **Power of Attorney Address**

The address of record for Customer Number 81177 is:

81177
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 400
Cleveland, OH 44103

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DEC 05 2008

PTO/SB/08a (11-08)
Approved for use through 12/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/266,899
Filing Date	11-04-2005
First Named Inventor	Kayyali
Art Unit	3736
Examiner Name	
Attorney Docket Number	CMD-023

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		US- 2005/0217674 A1	10-06-2005	Burton et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 2

Application Number	11/266,899
Filing Date	11-04-2005
First Named Inventor	Kayyali
Art Unit	3736
Examiner Name	
Attorney Docket Number	CMD-023

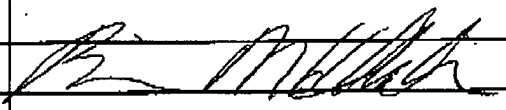
ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

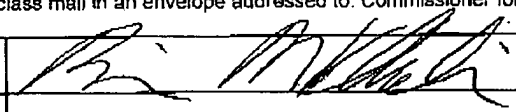
Supplemental IDS disclosing one reference brought to the attention of the applicant within the last 30 days. As no office action has yet issued in this case, the applicant believes no fees are due.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature			
Printed name	Brian M. Kolkowski		
Date	2008-12-05	Reg. No.	36,847

CERTIFICATE OF TRANSMISSION/MAILING

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Signature			
Typed or printed name	Brian M. Kolkowski	Date	2008-12-05

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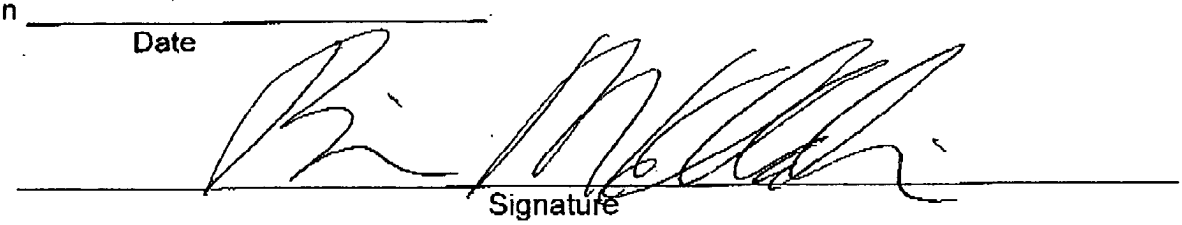
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Signature

Brian M. Kolkowski

Typed or printed name of person signing Certificate

36,847 — Registration Number, if applicable

216-649-0376 — Telephone Number

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	CMD-023
First Inventor	Hani Kayyali
Title	INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD
Express Mail Label No.	ED 554729241 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450**

1. ☑ Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. ☑ Applicant claims small entity status. See 37 CFR 1.27.
3. ☑ Specification [*Total Pages* 48] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. ☑ Drawing(s) (*35 U.S.C. 113*) [*Total Sheets* 6]
5. Oath or Declaration [*Total Sheets* 4]
   a. ☑ Newly executed (original or copy)
   b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 18 completed)*
      i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76
7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

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11/266899
110405

ACCOMPANYING APPLICATION PARTS

9. ☑ Assignment Papers (cover sheet & document(s))
10. ☑ 37 CFR 3.73(b) Statement *(when there is an assignee)* ☑ Power of Attorney
11. ☐ English Translation Document *(if applicable)*
12. ☑ Information Disclosure Statement (IDS)/PTO-1449 ☑ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☑ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☑ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: .....

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

For CONTINUATION OR DIVISIONAL APPS only; The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☐ Customer Number: _____ *OR* ☑ Correspondence address below

Name	Brian M. Kolkowski				
Address	Cleveland Medicla Devices, Inc.				
	4415 Euclid Ave, Suite 400				
City	Cleveland	*State*	Ohio	*Zip Code*	44103
Country	United States	*Telephone*	(216) 649-0376	*Fax*	(216) 649-0347

Name (Print/Type)	Brian M. Kolkowski	*Registration No. (Attorney/Agent)*	36,847
Signature		*Date*	11/4/05

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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 540

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Kayyali
Examiner Name	
Art Unit	
Attorney Docket No.	CMD-023

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 502704 Deposit Account Name: Orbital Research

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☑ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☑ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	500
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims _____ - 20 or HP = _____ Extra Claims x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims _____ - 3 or HP = _____ Extra Claims x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($) _____ Fee Paid ($) _____

3. APPLICATION SIZE FEE

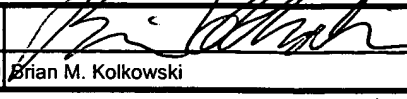
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets _____ - 100 = _____ Extra Sheets _____ / 50 = _____ Number of each additional 50 or fraction thereof (round up to a whole number) x Fee ($) _____ = Fee Paid ($) _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Recordation Fee	40

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 36,847	Telephone (216) 649-0376
Name (Print/Type)	Brian M. Kolkowski		Date 11/4/05

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali	Docket No. CMD-023

Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

I hereby certify that this Utility Patent Application Transmittal & Fee Transmittal

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Adam Buchanan

(Typed or Printed Name of Person Mailing Correspondence)

Adam Buchanan

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Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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Adam Buchanan

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali	Docket No. CMD-023

Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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(Date)

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(Typed or Printed Name of Person Mailing Correspondence)

Adam Buchanan
(Signature of Person Mailing Correspondence)

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali			Docket No. CMD-023
Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

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(Date)

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Adam Buchanan

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	CMD-023
First Inventor	Hani Kayyali
Title	INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD
Express Mail Label No.	ED 554729241 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

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   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. ☑ Drawing(s) (*35 U.S.C. 113*) [*Total Sheets* 6]
5. Oath or Declaration [*Total Sheets* 4]
   a. ☑ Newly executed (original or copy)
   b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 18 completed)*
      i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76
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      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

113219 U.S.PTO
11/266899
110405

ACCOMPANYING APPLICATION PARTS

9. ☑ Assignment Papers (cover sheet & document(s))
10. ☑ 37 CFR 3.73(b) Statement *(when there is an assignee)* ☑ Power of Attorney
11. ☐ English Translation Document *(if applicable)*
12. ☑ Information Disclosure Statement (IDS)/PTO-1449 ☑ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☑ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☑ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: .....

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

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19. CORRESPONDENCE ADDRESS

☐ Customer Number: _____ *OR* ☑ Correspondence address below

Name	Brian M. Kolkowski				
Address	Cleveland Medicla Devices, Inc.				
	4415 Euclid Ave, Suite 400				
City	Cleveland	*State*	Ohio	*Zip Code*	44103
Country	United States	*Telephone*	(216) 649-0376	*Fax*	(216) 649-0347

Name (Print/Type)	Brian M. Kolkowski	*Registration No. (Attorney/Agent)*	36,847
Signature		*Date*	11/4/05

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PTO/SB/17 (12-04v2)
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FEE TRANSMITTAL
For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 540

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Kayyali
Examiner Name	
Art Unit	
Attorney Docket No.	CMD-023

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 502704 Deposit Account Name: Orbital Research

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	500
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims _____ - 20 or HP = _____ Extra Claims x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims _____ - 3 or HP = _____ Extra Claims x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($) _____ Fee Paid ($) _____

3. APPLICATION SIZE FEE

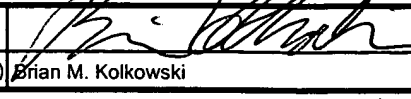
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4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Recordation Fee	40

SUBMITTED BY

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Name (Print/Type)	Brian M. Kolkowski		Date 11/4/05

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali	Docket No. CMD-023

Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali			Docket No. CMD-023
Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali	Docket No. CMD-023

Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali			Docket No. CMD-023
Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Hani Kayyali			Docket No. CMD-023
Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

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INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD

The U.S. Government has a paid-up license in this invention and the right in limited circumstances to require the patent owner to license others on reasonable terms provided for by the terms of grant number 2R44NS42451 awarded by the National Institutes of Health.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates to an integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment device. The present invention additionally relates to method of sleep diagnosis and treatment.

2. TECHNICAL BACKGROUND

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

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such as the Epworth and Standford 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

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some later time to determine whether the condition or the symptoms have been alleviated.

For example, the most common method of treating the sleeping disorder of sleep apnea is by apply a continuous positive gas pressure to the patient's airway, which has the effect of forcing the patient to breath through application of the pressure. More advanced, but still very basic devices have been developed that adjust this continuous positive gas pressure through sensors built into the device for creating the positive gas pressure, which measure gas flow through the device. These basic adjustable devices have been found to be expensive and largely ineffective.

None of the devices on the market can be used to adjust a patient's treatment, whether physical or chemical, based on the patient's current physiological state. Further none of the current devices can be used to adjust a patient's treatment, based on the patient's current symptoms. Still further, none of the current devices can be used to predict the onset of symptoms of various sleeping disorders and provide treatment in anticipation of such symptoms. Still even further, none of the current devices can be used to adjust a treatment device based on the subject's physiological signals.

It is therefore an object of the present invention to provide a system and method of treatment, which analyzes a subject's sleeping disorder or symptoms and adjusts a treatment device based, in part, on this analysis. It is still another object of the present invention to have a closed loop system or partly closed loop system or method, which automatically adjusts a treatment device based on analysis of a subject's sleeping disorder or symptoms. It is still another object of the present invention to provide a system or method for treating a subject's sleeping disorder or symptoms that is predictive. It is still further another object of the present invention to provide a system or method of treating a subject's sleeping disorder or symptoms that uses a subject's physiological signals, e.g., EEG, EKG, EMG, etc.

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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 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 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 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. 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

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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.

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 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 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 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

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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 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 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 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 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.

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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, 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 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 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 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.

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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.

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

FIG. 3 is a block diagram of an embodiment of a base station of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

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

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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 CO^2 and O^2, 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.

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

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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 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 neurogical disorder, is very different in cause than OSA, which is a physical blockage - though the effects are highly similar.

Mixed sleep apnoea, as the name suggests, is a combination of the OSA and CSA. An episode of mixed sleep apnoea usually starts with a central component and then becomes obstructive in nature. Generally the central component of the apnoea becomes less troublesome once the obstructive apnoea is treated.

Sensors which can be used are known to those skilled in the art. These sensors include electrodes for measuring electro-physiological signals such as EEG, ECG, EMG, EOG and the like. These electro-physiological signals can be obtained by any method known in the art, or subsequently developed by those skilled in the art to detect these types of signals. Sensors include but are not limited to electrodes or magnetic sensors. Since electro-physiological signals are, in general, electrical currents which produce associated magnetic fields, the present invention further anticipates methods of sensing those magnetic fields to acquire brain wave signals similar to those which can be obtained through, for 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

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electrodes for example when measuring brain wave or EEG signals may be placed at one or several locations on the subject(s)' scalp or body. The electrode(s) can be placed at various locations on the subject(s) scalp in order to detect EEG or brain wave signals. Common locations for the electrodes include frontal (F), parietal (P), anterior (A), central (C) and occipital (O). Preferably for the present invention at least one electrode is placed in the occipital position. In order to obtain a good EEG or brain wave signal it is desirable to have low impedances for the electrodes. Typical EEG electrodes connections may have an impedance in the range of from 5 to 10 K ohms. It is in generally desirable to reduce such impedance levels to below 2 K ohms. Therefore a conductive paste or gel may be applied to the electrode to create a connection with an impedance below 2 K ohms. Alternatively or in conjunction with the conductive gel, the subject(s)' skin may be mechanically abraded, the electrode may be amplified or a dry electrode may be used. Dry physiological recording electrodes of the type described in U.S. Patent Application 09/949,055 are herein incorporated by reference. Dry electrodes provide the advantage that there is no gel to dry out, no skin to abrade or clean, and that the electrode can be applied in hairy areas such as the scalp. Additionally if electrodes are used as the sensor(s), preferably at least two electrodes are used – one signal electrode and one reference electrode; and if further EEG or brain wave signal channels are desired, the number of electrodes required will depend on whether separate reference electrodes or a single reference electrode is used. For the various embodiments of the present invention, preferably an electrode is used and the placement of at least one of the electrodes is at or near the occipital lobe of the subject's scalp.

If electrodes are used to pick up the electro-physiological signals, these electrodes for example when measuring cardiac signals using an ECG, may be placed at specific points on the subject's body. The ECG is used to measure the rate and regularity of heartbeats as well as the size and position of the chambers,

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any damage to the heart and in diagnosing sleeping disorders. As the heart undergoes depolarization and repolarization, electrical currents spread throughout the body because the body acts as a volume conductor. The electrical currents generated by the heart are commonly measured by an array of preferably 12 electrodes, placed on the body surface. Although a full ECG test usually involves twelve electrodes, for the purposes of a sleep study only two are required. These are placed on the subject's left-hand ribcage, under the armpit and on the right-hand shoulder, near the clavicle bone. An ECG is important as a tool to detect the cardiac abnormalities that can be associated with respiratory-related sleeping disorders. Preferably electrodes are placed on each arm and leg, and six electrodes are placed at defined locations on the chest. The specific location of each electrode on a subject's body is well known to those skilled in the art and varies amongst individual and different types of subjects. These electrode leads are connected to a device contained in the signal processing module of the present invention that measures potential differences between selected electrodes to produce electrocardiographic tracings.

There are two basic types of ECG leads: bipolar and unipolar. Bipolar leads (standard limb leads) utilize a single positive and a single negative electrode between which electrical potentials are measured. Unipolar leads (augmented leads and chest leads) have a single positive recording electrode and utilize a combination of the other electrodes to serve as a composite negative electrode.

Other sensors can be used to measure various parameters of a subject's respirations. The subject's respirations can be measured by measurement of airflow, respiratory effort, oxygenation and ventilation, and the like. Measurement of airflow is preferably measuring using sensors or devices such as a pneumotachometer, strain gauges, thermal sensors, transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, and the like. These sensors or devices, also preferably measure nasal pressure, respiratory inductance

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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 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 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 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 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

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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.

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 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.

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 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

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used for transmission is primarily 902–928 MHz, but frequencies of 2.4–2.484 GHZ, or Wireless Medical Telemetry Bands (WMTS), 608–614 MHz, 1395–1400 MHz, or 1429–1432 MHz can also be used. In addition, IR or Bluetooth wireless technology can be used for data transmission. The communication between the signal processing unit and base station can also, or in addition, be hardwired, instead of wireless. The physiological sensors are generally hard wired to the signal processing unit, but due to the ongoing evolution in wireless sensor technology, signals from physiological sensors will likely be transmitted wirelessly to the signal processing unit, or alternatively, directly to the base station having an integrated signal processing unit.

Referring now to the drawings and, in particular to FIG. 1, there is shown a block diagram of the present invention. An external input 12 from sensor 14 is input to signal processing module 16. Although, one sensor 14 and one external input 12 are shown, the signal processing module 16 is capable of accepting multiple external inputs 12 from multiple sensors 14. The signal processing module 16 generates a signal 18 encoded with data corresponding to the external input 12. The signal processing module 16 transmits the signal 18 by wireless means to a base station 40. In FIG. 1, the wireless means is shown as radio frequency (RF). In this case, the signal processing module generates a radio frequency signal 18 by frequency modulating a frequency carrier and transmits the radio frequency signal through module antenna 20. The base station 40 receives the radio frequency signal 18 through base antenna 42, demodulates the radio frequency signal 18, and decodes the data. It is understood that other wireless means can be utilized with the present invention, such as infrared and optical, for example. Although one module antenna 20 and one base antenna 42 is shown in this embodiment, it is understood that two or more diversity antennas

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can be used and are included in the present invention. An external programming means 60, shown in FIG. 1 as a personal computer, contains software which is used to program the signal processing module 16 and the base station 40 through data interface cable 62. The data interface cable 62 is connected to the base station 40 and signal processing module 16 by respective connectors 64. The same data interface cable 62 or two different interface cables 62 can be used, one for the base station 40 and one for the signal processing module 16. The signal processing module 16 and the base station 40 can be programmed by connecting a data interface cable 62 between it and an external programming means 60 or by radio frequency (or other type) of signals transmitted between a base station 40 to the signal processing module 16 or to another base station 40. RF signals, therefore, can be both transmitted and received by both signal processing module 16 and base station 40. In this event the signal processing module 16 also includes a module receiver 29 while the base station 40 also includes a base transmitter 84, in effect making both the signal processing module 16 and the base station 40 into transceivers. In addition, the data interface cable 62 also can be used to convey data from the base station 40 to the external programming means 60. If a personal computer is the external programming means 60, it can monitor, analyze and display the data in addition to its programming functions. The base receiver 80 and module receiver 29 can be any appropriate receivers, such as direct or single conversion types. The base receiver 80 preferably is a double conversion superheterodyne receiver while the module receiver 29 preferably is a single conversion receiver. Advantageously, the receiver employed will have automatic frequency control to facilitate accurate and consistent tuning of the radio frequency signal 18 received thereby.

Referring now to FIG. 2, there is shown a block diagram of the signal processing module 16 with the sensor 14 and the module antenna 20. The signal processing module 16 comprises input means 22, analog-to-digital (A/D) means

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24, a module microcontroller 26 with a nonvolatile memory, advantageously, an EEPROM 261, a module transmitter 28, a module receiver 29 and a module power supply 30. Although the module antenna 20 is shown externally located from the signal processing module 16, it can also be incorporated therein. The module antenna 20 may be a printed spiral antenna printed on a circuit board or on the case of the signal processing module 16 or other type of antenna. A module power supply 30 provides electrical power to the signal processing module 16 which includes the input means 22, A/D means 24, module microcontroller 26 module transmitter 28 and module receiver 29.

The input means 22 is adjustable either under control of the module microcontroller 26 or by means of individually populatable components based upon the specific external input 12 characteristics and range enabling the input means 22 to accept that specific external input 12. For example, if the input is a 4-20 mA analog signal, the input means 22 is programmed by the module microcontroller 26 and/or populated with the components needed to accept that range and characteristic of signals. If the input characteristics change the programming and/or components change accordingly but the same platform circuit board design is utilized. In other words, the same platform design is utilized notwithstanding the character, range, or quantity (number of external inputs 12) [up to a predetermined limit] of the input. For example, bioelectric signals such as EEG, EMG, EKG, and EOG have typical amplitudes of a few microvolts up to a few tens of millivolts. For a given application, a specific frequency band of interest might be from 0.1 Hz to 100 Hz, whereas another application may require measurement of signals from 20 Hz to 10 KHz. Alternatively, measurement of vital signs such as body temperature and respiration rate may deal with signals in a range of +5 volts, with a frequency content from DC (0 Hz) to 20 Hz. For other applications such as industrial process monitoring, the information of interest may be contained in the signal as a

current, such as a 4 to 20 mA current loop sensor, or it may take the form of resistance, impedance, capacitance, inductance, conductivity, or some other parameter, The present invention provides a single device for measuring such widely disparate signal types and presents distinct economic advantages, especially to small enterprises such as a medical clinic located in a rural area, which would be empowered by this invention to conduct tests which would otherwise have required patient travel to a large medical center, with all the attendant cost thereof.

This is possible due to the selectively adaptable input means 22 and A/D means 24, the frequency agile module transmitter 28 and base transmitter 84, and the programmability of the module microcontroller 26 and EEPROM 261. One universal platform design then can be utilized for all applications. In addition, the signal processing module can comprise multiple copies of the input means 22 and the A/D means 24. Cost savings can be achieved by multiplexing at several different points in the input means 22 and the A/D means 24 allowing hardware to be shared among external inputs 12.

After receipt by the input means 22, the external input 12 is inputted to the A/D means 24. The A/D means 24 converts the input to a digital signal 32 and conditions it. The A/D means 24 utilizes at least one programmable A/D converter. This programmable A/D converter may be an AD7714 as manufactured by Analog Devices or similar. Depending upon the application, the input means 22 may also include at least one low noise differential preamp. This preamp may be an INA126 as manufactured by Burr-Brown or similar. The module microcontroller 26 can be programmed to control the input means 22 and the A/D means 24 to provide specific number of external inputs 12, sampling rate, filtering and gain. These parameters are initially configured by programming the module microcontroller 26 to control the input means 22 and the A/D means 24 via input communications line 35 and A/D communications line 36 based upon

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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 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 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 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 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

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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 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 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 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.

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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,

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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

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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

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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 carrrying the information which was present in the original signal, or in certain cases, a series of voltage measurements, which are then conveyed to the prefilter 223.

The prefilter 223 allows rejection of external inputs 12 of large signals which are outside the frequency band of interest, so that such signals do not saturate the low-noise preamplifier 224. The prefilter 223 can be advantageously arranged to be a relatively simple filter to provide cost, size, and power advantages, because it need only reject out of band signals to the extent necessary to protect the low-noise preamplifier 224. A typical application might use a simple "R-C" filter to reject offset voltages in an AC-coupled application, or to reject extremely high frequencies which fall well beyond the frequency band of interest, or a combination of the two. Configurability of this section can be limited to simply enabling or bypassing the prefilter 223, or may be more elaborate in allowing selection of cutoff frequencies. In the preferred embodiment this prefilter consists of a simple RC filter which can be bypassed under firmware control, to minimize noise injection; however, an alternate embodiment could incorporate electrically adjustable components such as electronic potentiometers or varactors to provide even more flexibility at the expense of size and noise injection. The prefiltered signal is then passed to the low-noise preamplifier 224.

The low-noise preamplifier 224 is advantageous in certain applications to allow application of gain to the external input 12 early in the signal chain, before significant noise is introduced by the inherent characteristics of certain components, such as thermal noise. Configurability of the gain applied at this step

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provides an advantage in allowing the present invention to accept larger external inputs 12 using a low gain (unity gain or lower), or alternatively to accurately measure very small external inputs 12 with minimal noise by using higher gain. This gain can be selectively chosen to be either a fixed value or unity gain under processor control by means of the signal selector built into the AD7714 used in the preferred embodiment, or can be designed to allow a selection of one of several gains by means of analog switches combined with a plurality of gain setting resistors. Gain applied at this stage has the net effect of dividing any downstream noise by the gain factor applied here. This more robust signal output by the preamplifier 224 is then passed to the AC coupling filter 225.

The AC coupling filter 225 is a highpass filter used to allow the system to reject the DC offset or steady state value of an external input 12 wherein the offset is not of interest, allowing additional gain to be applied to the changes in the external input 12. For instance, bioelectric signals such as EEG, EMG, or ECG are normally of interest only for the changes in those signals, and the absolute offset level is not of interest for diagnostic purposes. The cutoff frequency may be configured to allow adjustment of various parameters such as settling time, or may be adjusted to zero to effectively bypass the AC coupling filter 225. In the preferred embodiment, the filter may be bypassed by use of the signal selector switch in the AD7714; however, the use of adjustable components such as electronic potentiometers or varactors would allow more flexibility in choosing the cutoff frequency, at the expense of size and power consumption. The resulting signal, now stripped of any interfering DC offset if so configured, is then passed to the antialias filter 226.

The antialias filter 226 is a lowpass filter required to guard against false signals caused by aliasing between external input 12 content and sampling rate of downstream sampling functions such as multiplexing or analog-to-digital conversion. The Nyquist sampling theorem shows that any frequency content in

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the sampled signal which is higher than one-half the sampling rate of the sampling function will cause aliasing, which results in false signals. In practice the antialias filter 226 is more commonly set to a smaller fraction of the sampling rate, usually between 1/4 and 1/10 the sampling rate. Regardless of the rate or ratio used, the cutoff frequency of the antialias filter 226 must change when the sampling rate changes significantly, to retain the most advantageous ratio of the sampling rate to the filter passband. The programmable cutoff frequency of the antialias filter 226 is thus required to allow for variable sampling rates. In the preferred embodiment, the high sampling rate of the delta sigma modulator in the AD7714 permits the use of a simple fixed RC type filter, with the anitalias filtering begin provided as an inherent digital filter in the AD7714; however, an alternate embodiment might use a switched capacitor filter such as the MAX7409 or other filter with a programmable cutoff frequency. The resulting filtered signal is then conveyed to the programmable gain amplifier 241 in the A/D means 24.

The programmable gain amplifier 241 adjusts the external input 12 amplitude to match the amplitude accepted by the A/D converter 242. In the preferred embodiment this programmable gain amplifier is included in the AD7714 integrated circuit, but this function could also be provided with a dedicated programmable gain amplifier, or alternatively through the use of analog switches or adjustable components such as potentiometers or DACs. If too much gain is applied, the programmable gain amplifier 241 itself or downstream components will saturate, introducing severe distortion and usually rendering the external input 12 unmeasureable. If, on the other hand, insufficient gain is applied here, the quantization noise of the analog-to-digital conversion process comes to dominate the external input 12, causing a severe degradation in the signal-to-noise ratio. For instance, a typical 16-bit A/D converter 242 can distinguish between 2.sup.16 or 65536 distinct levels. With an A/D converter 242 input range of .+-.3 volts, each level reperesents 92 .mu.V. If insufficient gain is applied to the

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external input 12 such that the total signal swing is only 200 .mu.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 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 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 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

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adapt the A/D converter 242 to best meet the system demands of the moment.

In a similar fashion, selection of the resolution provided by the A/D converter 242 must balance faithful reproduction of the external input 12 against total digital data rate. Depending on the particular A/D converter 242 used, there may also be a tradeoff of the maximum achievable sampling rate against the selected resolution, wherein selection of a higher resolution lowers the maximum attainable sampling rate. Again the module microcontroller 26 can adjust this parameter to best meet the system requirements, selecting higher resolution when smaller changes in the measured signal amplitude must be reported, and lower resolution when the lack of such a requirement allows advantages in the form of either a higher sampling rate or a lower digital data rate. In the preferred embodiment, the AD7714 can be programmed to either 16 bit or 24 bit resolution, and the firmware running in the microcontroller can selectively transmit 8, 12, 16, or 24 bits of the acquired data. The digital filter 243, the module microcontroller 26, or other downstream process can also reject certain portions of the digital data stream to provide an effective decrease in resolution where this decrease is advantageous, especially when the data must later cross a bandwidth-limited link such as a RF, IR or optical link. The A/D converter 242 passes the signal, now in the form of a succession of digital values, to the digital filter 243 for further processing.

The digital filter 243 extracts external input 12 parameters of interest while rejecting other signals, commonly referred to as noise. Implementation of the digital filter 243 could alternatively be in the form of analog filters applied anywhere in the signal chain prior to the A/D converter 242, but implementation as a digital filter 243 provides advantages as to programmability, calibration, drift, and accuracy. The digital filter 243 could be implemented in many forms, depending upon the demands of the particular application. In the preferred embodiment, the digital filter is inherent in the analog to digital conversion

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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, 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.

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 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 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

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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.

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 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 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

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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 the 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

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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 loosing reception due to drift or sacrificing data transmission accuracy. The utilization of programmable firmware allows inexpensive and flexible operation for the inputting, conditioning and processing of any type, character and range of the external inputs. This also allows the module microcontroller 26, in response to the variation of the external inputs 12 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

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adaptation without the need to modify or alter hardware or select or use different hardware already present in the device. In other words all adaptation can be accomplished by software programming totally.

One or more sensors are used to develop the data or signals used in the present invention for determining a quantitative level of severity of a subject's sleeping disorder and/or symptoms. In various embodiments, preferably at least two EEG electrodes are used to develop this data. In other embodiments, preferably, at least two ECG electrodes are used. In still other embodiments, preferably a pulse oximeter is used. In still even other embodiments, preferably, either an O^2 or CO^2 blood gas monitor is used.

The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms. Using either the microcontroller 26 of a data acquisition system, a separate computer, base station or processor, a PDA, a processor on a device for treating the subject's sleeping disorder or a combination of these processors, the severity of the subject's sleeping disorder and/or symptoms is determined and is used at least in part to regulate the physical or chemical treatment of the subject. Also optionally, the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.

The processor or microprocessor of various embodiments of the present invention can be part of a remote communication station or base station. The remote communication station or base station can also be used only to relay a pre- or post-processed signal. Preferably, the remote communication station or base station can be any device known to receive RF transmissions such as those transmitted by the wireless data acquisition system described herein. The remote communication station or base station by way of example but not limitation can

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include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the remote communication station can further transmit data both to another device including the subject's treatment device and/or back. Further optionally, two different remote communication stations can be used, one for receiving transmitted data and another for sending data. For example, with the sleep diagnosis and treatment system of the present invention, the remote communication system of the present invention can be a wireless router, which establishes a broadband internet connection and transmits the physiological signal to a remote internet site for analysis, preferably for further input by the subject's physician or another clinician. Another example is where the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis. Another example is where the remote communication system is a computer or processor, which receives the data transmission and displays the data or records it on some recording medium, which can be displayed or transferred for analysis at a later time.

The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein. More preferably, this quantitative method is accomplished in real-time, allowing the subject's symptoms to be treated as they occur. By real-time it is meant that the quantitative diagnosis step is accomplished predictively or within a short period of time after symptoms occur which allows for immediate treatment, thereby

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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 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 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.

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 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

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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 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 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™ 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 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

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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 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 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 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. 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

spectrum of the signals from each epoch. Using this method it is possible to identify specific frequency content in the data. As the subject begins to experience the onset of various critical symptoms, the frequency spectrum of the measured and analyzed data will shift, which indicates to the control system that the symptom is beginning.

A fourth embodiment of a signal processing method which can provide indications to the control system that various symptoms are impending, to enable either actuation of the treatment device, is to analyze the sensor data using a time-frequency transform. A time-frequency transform enables both frequency resolution and estimation stability for highly non-stationary signals, which typifies some types of such as some of the data or signals related to various physiological conditions. This is accomplished by devising a joint function of both time and frequency, a distribution that describes the energy and density of a signal simultaneously in both time and frequency. The general form of the time-frequency transform is given by the following

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

This transform can be used to calculate instantaneous power spectra of a given signal. The actual transformation distribution is selected by changing the kernel, $\Phi(\theta,\tau)$. The function [e-1] is interesting since it is possible to identify any distribution invariant to time and frequency shifts by means of its kernel, and the properties of the kernel are strictly related to the properties of the distribution, given by [e-1].

The diagnostic device of the present invention is used to provide an output which is then used either automatically to adjust the treatment device or by a clinician or the subject to adjust the device which provides the physical or

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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.

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.

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FIG. 7 shows a schematic view of one embodiment of a device that can be used to physically treat a subject's sleep disorder, which can be further adjusted using the output of the level of severity of the subject's sleeping disorder. More particularly, FIG. 7 shows a particular type of physical treatment device known as continuous positive airway pressure (CPAP) device. This conventional pressure support system 310 shown in FIG. 7 includes a pressure generator 312, a blower, piston or bellows, that receives a supply of gas from a gas source, such as ambient atmosphere, as indicated by arrow A, or pressurized gas tanks (not shown) and creates a flow of breathing gas, as indicated by arrows B, having a pressure greater than the ambient atmospheric pressure. A patient or subject circuit 314, which is typically a flexible conduit, delivers the elevated pressure breathing gas to the airway of the subject. Typically the subject circuit is a single limb conduit or lumen having one end coupled to the pressure generator and a patient interface device 316 coupled to the other end.

The subject interface device 316 connects the subject circuit 314 with the airway of the subject so that the elevated pressure gas flow is delivered to the subject's airway. Examples of subject interface devices include but are not limited to nasal masks, nasal and oral masks, full face masks, nasal canulas, oral mouthpieces, tracheal tubes, endotracheal tubes, hoods and the like. The single limb subject circuit shown in FIG. 7 also includes an exhalation port 318, also commonly referred to as an exhalation vent, exhaust port, or exhaust vent, to allow gas, such as expired gas from the subject, to exhaust to the atmosphere, as indicated by arrow C. Generally, the exhaust vent 318 is located in the subject circuit 314 near the subject interface device 316 or in the subject interface device itself.

A more sophisticated pressure support device of the present invention includes a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit 314. The flow information

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can also be used to determine the volume of gas passing through the subject circuit 314. The information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to control the pressure or flow of gas provided to the subject, monitor the condition of the subject, monitor the usage of the pressure support device, any combination thereof, or the like.

FIG. 8 shows a schematic view of one embodiment of the sleep disorder treatment system of the present invention. In FIG. 8, a subject 410 is hooked up with a number of sensors 420, 424, 418, and 426. The subject 410 in this case is shown with a respiratory mask 412, which is connected by an air hose or subject circuit 416 to a continuous positive air pressure device 428 similar to that shown in FIG. 7. The signal or data from one or more of these sensors is picked up in this embodiment by a diagnostic device 441, which comprises a radio 436 and antenna 434; a microprocessor 438 for processing the data or signals to determine a level of severity of the subject's sleeping disorder or symptoms; the diagnostic device then transmits a signal based on this level of severity by either a tether 444 or radio signal (not shown) to an actuator (not shown) in the CPAP device 428, which controls the flow of air or gas to the subject. The CPAP device 428 optionally has an O^2 tank connected, which can be used to increase the concentration of O^2 in the air being delivered to the subject. In addition, optionally the treatment device 428 has a sensor in the air hose 416, which can measure the differential pressure 414 and thereby accurately measure air flow provided to the patient. Also optionally, the device can have a nebulizer (not shown) with a reservoir and pump to injecting medication into the nebulizer.

It will be apparent to those skilled in the art that various modifications and variations can be made to the present invention without departing from the spirit and scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

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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.

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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.

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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.

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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.

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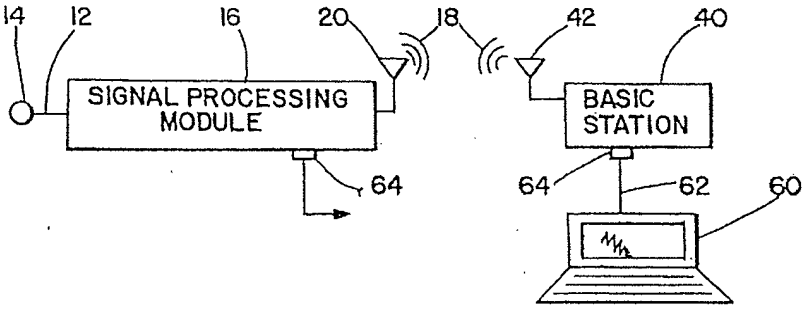


Fig. 1

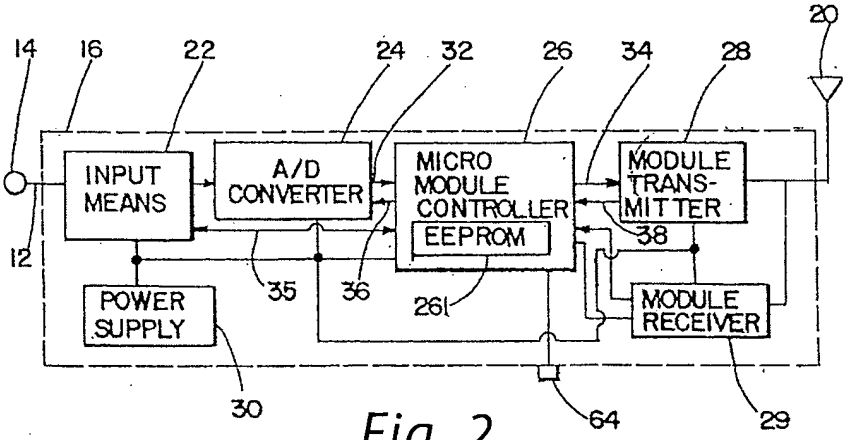


Fig. 2

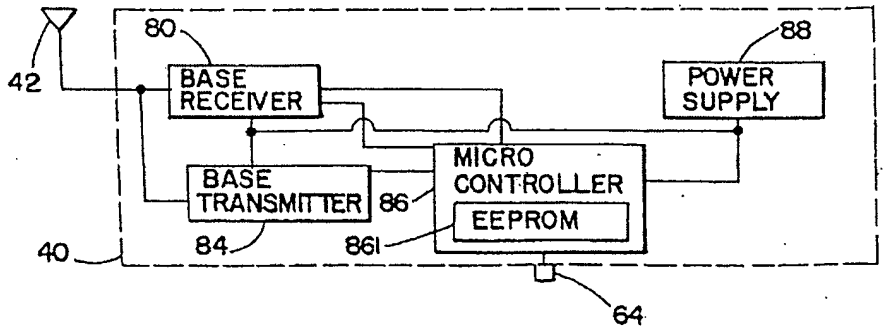


Fig. 3

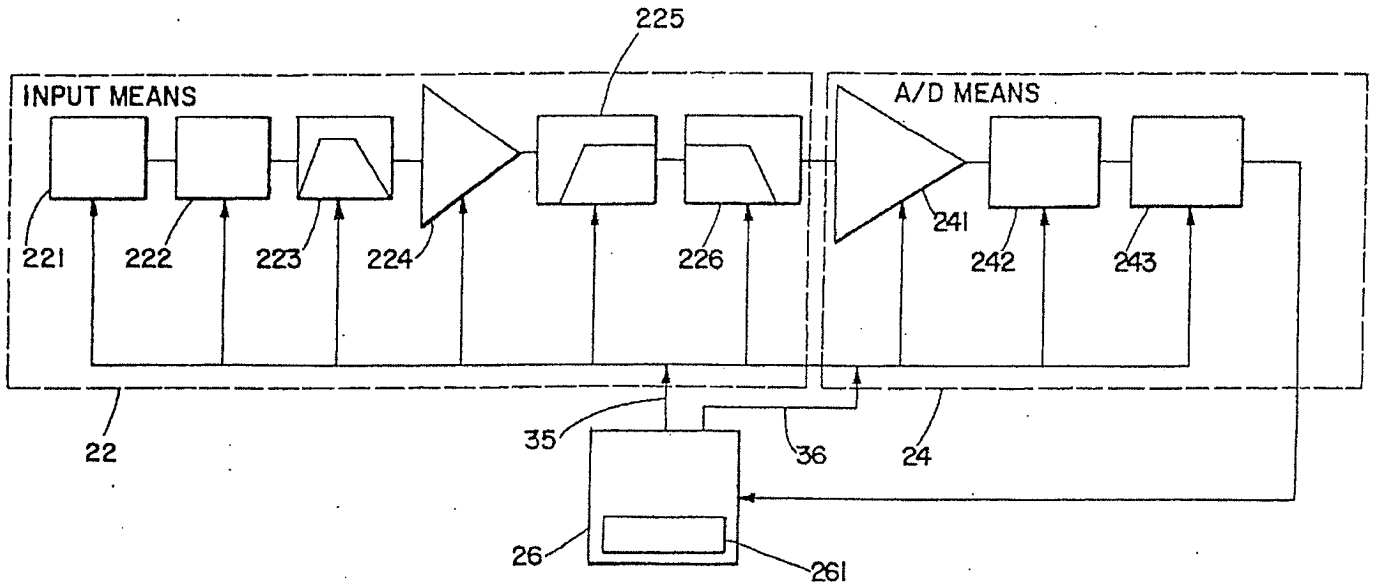

225
INPUT MEANS
A/D MEANS
221
222
223
224
226
241
242
243
22
35
36
24
26
261

Fig. 4

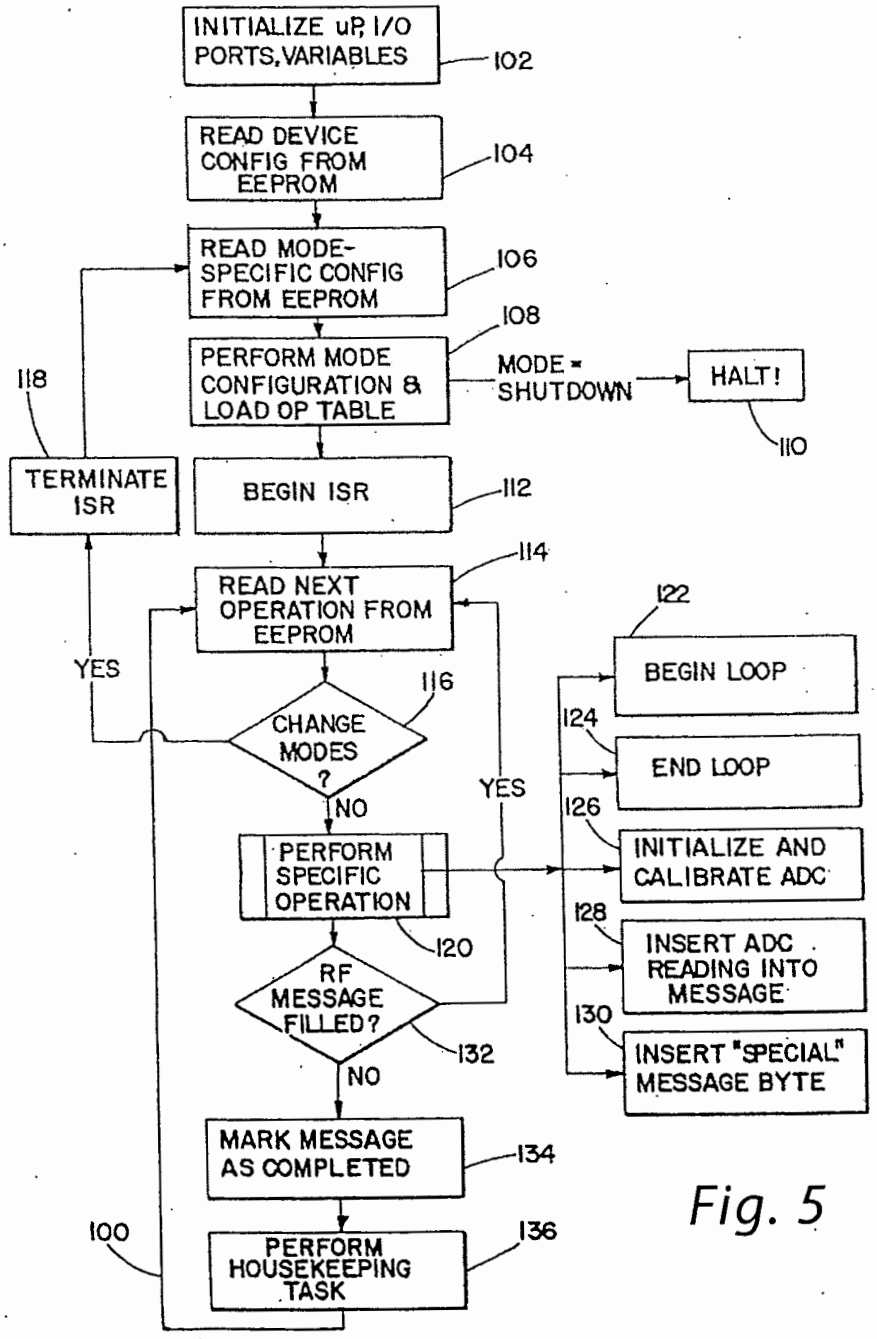

INITIALIZE uP, I/O PORTS, VARIABLES
102
READ DEVICE CONFIG FROM EEPROM
104
READ MODE-SPECIFIC CONFIG FROM EEPROM
106
108
PERFORM MODE CONFIGURATION & LOAD OP TABLE
MODE = SHUTDOWN
HALT!
110
118
TERMINATE ISR
BEGIN ISR
112
114
READ NEXT OPERATION FROM EEPROM
122
BEGIN LOOP
YES
116
CHANGE MODES ?
124
END LOOP
YES
NO
126
PERFORM SPECIFIC OPERATION
INITIALIZE AND CALIBRATE ADC
120
128
INSERT ADC READING INTO MESSAGE
RF MESSAGE FILLED?
132
130
INSERT "SPECIAL" MESSAGE BYTE
NO
MARK MESSAGE AS COMPLETED
134
100
PERFORM HOUSEKEEPING TASK
136

Fig. 5

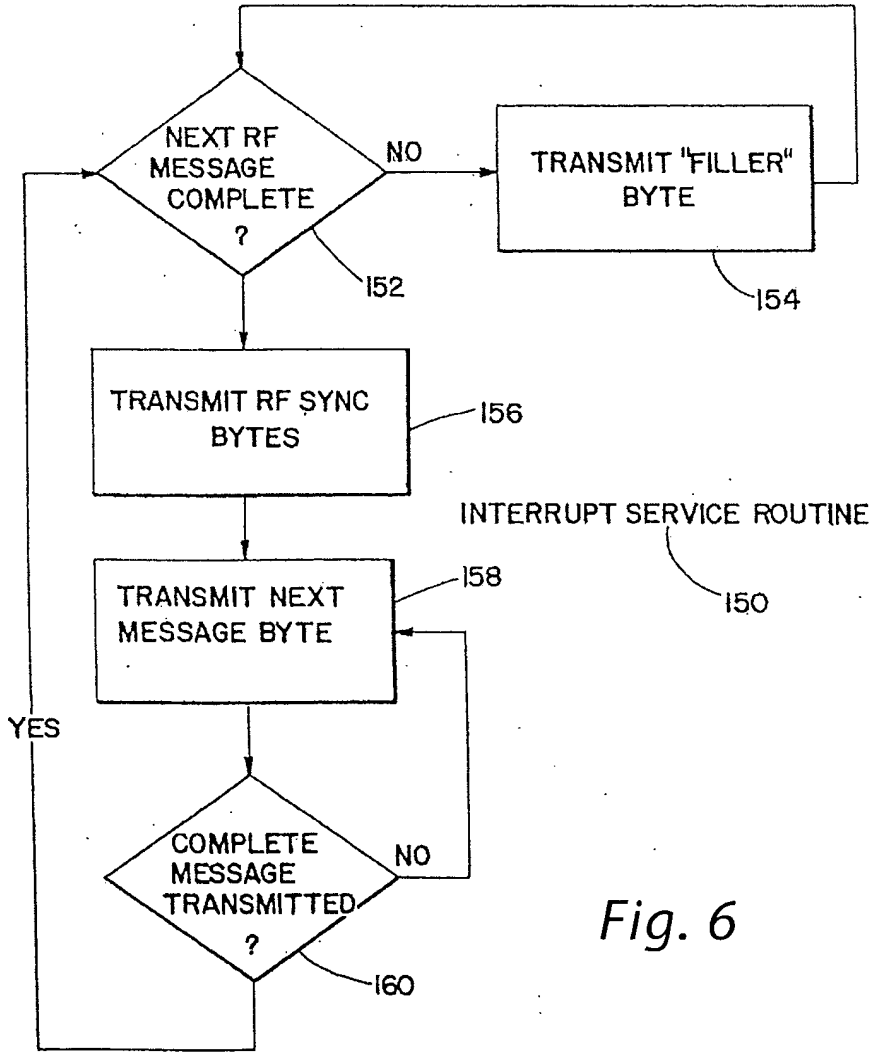

NEXT RF MESSAGE COMPLETE ?
NO
TRANSMIT "FILLER" BYTE
152
154
TRANSMIT RF SYNC BYTES
156
INTERRUPT SERVICE ROUTINE
150
TRANSMIT NEXT MESSAGE BYTE
158
YES
COMPLETE MESSAGE TRANSMITTED ?
NO
160

Fig. 6

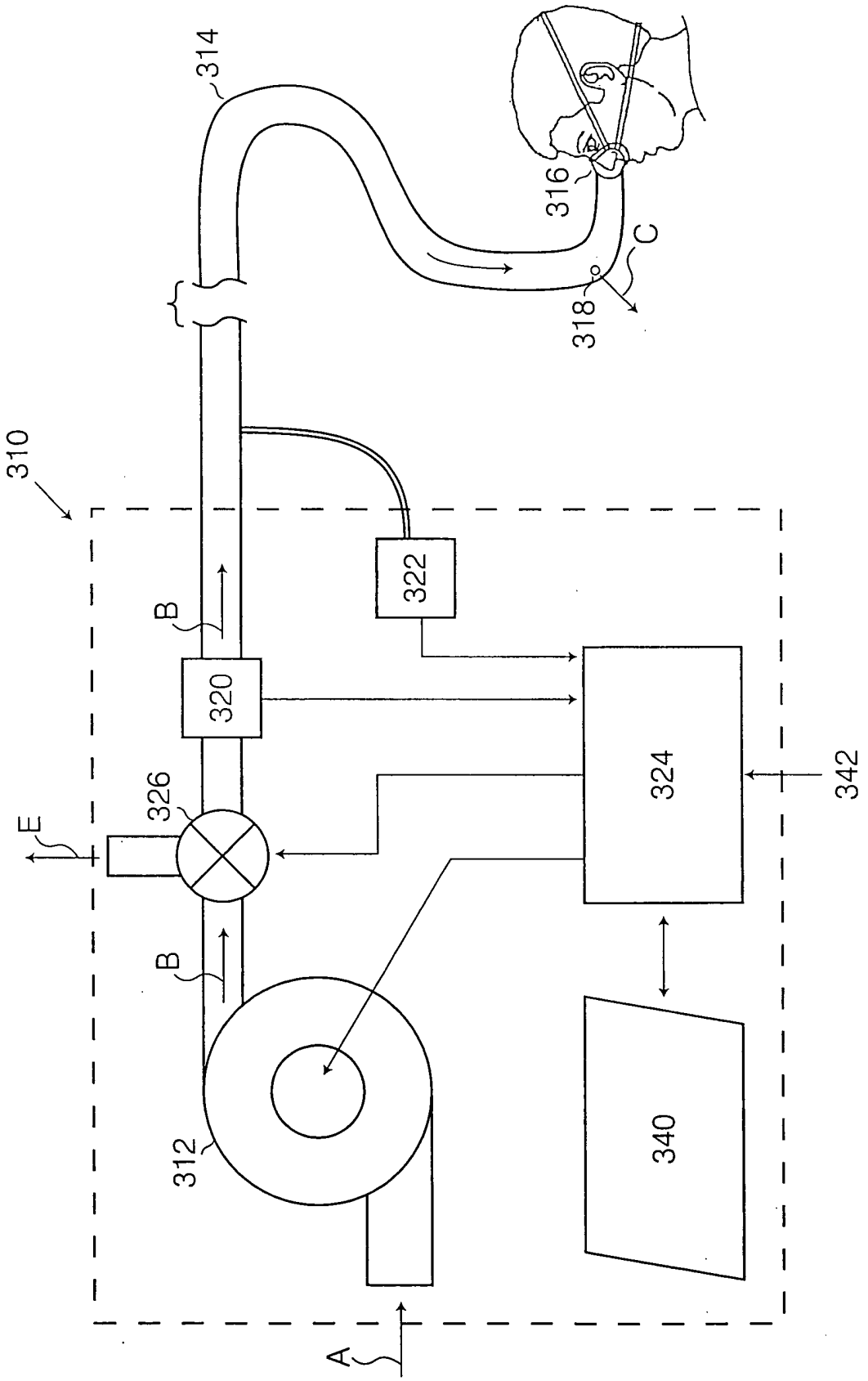


Fig. 7

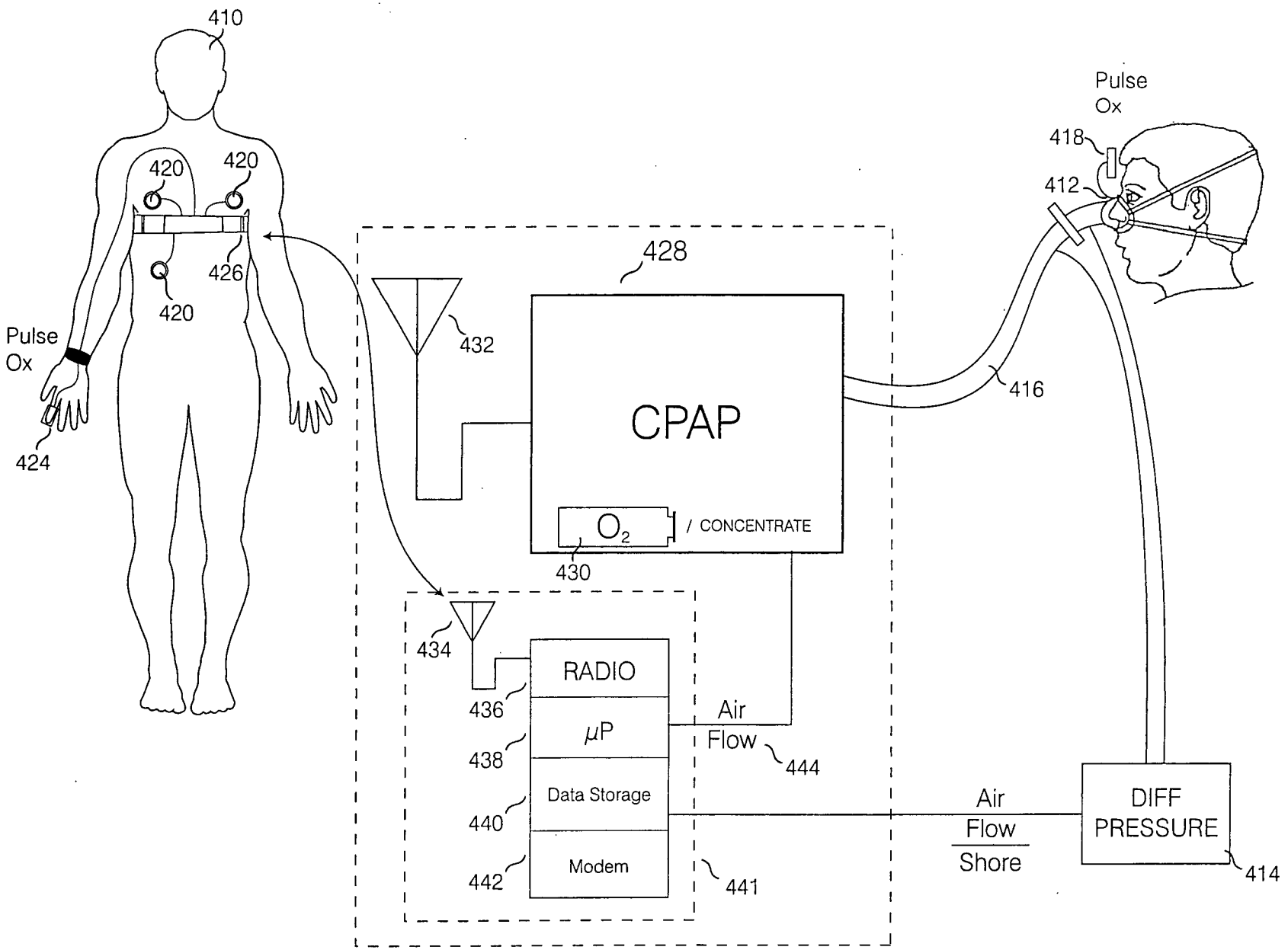

410
420
420
420
426
Pulse
Ox
424
428
432
CPAP
O_2 / CONCENTRATE
430
416
Pulse
Ox
418
412
434
RADIO
436
μP
438
Data Storage
440
Modem
442
441
Air
Flow
444
Air
Flow
Shore
DIFF
PRESSURE
414

Fig. 8

Docket No.
CMD-023

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____

and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, or plant breeder's rights certificate(s), or 365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
(Number)	(Country)	(Day/Month/Year Filed)	☐
(Number)	(Country)	(Day/Month/Year Filed)	☐
(Number)	(Country)	(Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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Fifth inventor's signature — Date

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Post Office Address

Full name of sixth inventor, if any

Sixth inventor's signature — Date

Residence

Citizenship

Post Office Address

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PATENT APPLICATION SERIAL NO _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

11/08/2005 FMETEKI1 00000029 502704 11266899

01 FC:2011 150.00 DA
02 FC:2111 250.00 DA
03 FC:2311 100.00 DA

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 466-247/69033

PTO/SB/06 (12-04)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 11266899

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	* 0	X$ 25 =		OR	X$50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	* 0	X100 =			X200 =	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	800		TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

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

PTO/SB/35 (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
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.

NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)

First Named Inventor	Hani Kayyali
Title	INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD
Attorney Docket Number	CMD-023

I hereby 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 agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

11/4/05
Date

Signature

(216) 649-0376
Telephone number

Brian M. Kolkowski
Typed or printed name

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

This collection of information is required by 37 CFR 1.213(a). 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 6 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 (1-800-786-9199) and select option 2.

Practitioner's Docket No. CMD-023 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application
of Kayyali et al.
Inventor(s)
for INTEGRATED SLEEP DIAGNOSIS AND TREATMENT DEVICE AND METHOD
Title of invention

the specification of which is being transmitted herewith

OR

In re application of:

Serial No.: 0 /
Filed:
For:

Group No.:
Examiner:

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☐ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. 1.10*

☒ as "Express Mail Post Office to Addressee"
Mailing Label No. EO554729241 US (mandatory.)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Date: 11/4/2005

Adam Buchanan
Signature

Adam Buchanan
(type or print name of person certifying)

***WARNING:** Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

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NOTE: *"An information disclosure statement shall be considered by the Office if filed by the applicant:*

(1) Within three months of the filing date of a national application;

(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or

(3) Before the mailing date of a first Office action on the merits, whichever event occurs last."

37 C.F.R. 1.97(b).

NOTE: *"Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. 1.56(a).*

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) each inventor named in the application;

(2) each attorney or agent who prepares or prosecutes the application; and

(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. 1.56(c).

NOTE: *The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.*

WARNING: *"No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).*

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
   - 7A. ☐ EPO Search Report
   - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections , respectively, have been continued on ADDED PAGE(S).

NOTE: *"Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

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Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)

NOTE: With respect to the list required by paragraph (b) of 37 C.F.R. 1.98, the Notice of April 20, 1992 (1138 O.G. 37-41) points out that:

"The list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicant intends to submit an information disclosure statement, and because it provides a readily available checklist for the examiner to indicate which identified documents have been considered. A copy of a separate list will also provide a simple means of communication to applicant to indicate the listed documents that have been considered and those listed documents that have not been considered. Use of form PTO-1449, "Information Disclosure Citation, is encouraged."

NOTE: "An information disclosure statement may include two list[s (]and two certifications[)] . . . in situations where some of the information listed was cited in a communication from a foreign patent office not more than three months prior to filing the statement and some was not, but was not known more than three months prior to filing the statement." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: With respect to the examiner's consideration of the Information Disclosure Statement, the Notice of April 20, 1992 (1138 O.G. 37-41) states:

*"If information is listed in the specification rather than in a separate paper, or if the other content requirements *** are not complied with, the examiner will notify applicant in the next Office action that the information has not been considered. It should be noted, however, that no copy of a U.S. patent application is required to be submitted. *** Where a U.S. patent application is properly cited, the examiner should obtain access to that file within the Office.*

"Examiners must consider all citations submitted in conformance with the rules and this section and place their initials adjacent [sic] the citations on a list or in the boxes provided on a form PTO-1449. If the citations are submitted on a list other than a form PTO-1449, the examiner may write "all considered" and his or her initials to indicate that all citations have been considered. If any of the citations are considered, a copy of the submitted list or form, as reviewed by the examiner, will be returned to the applicant with the next communcation. The original copy of the form will be entered into the application file. The copy returned to applicant will serve both as acknowledgement of receipt of the information disclosure statement and as an indication that the references were considered by the examiner. Forms PTO-326 and PTOL-37 include a box to indicate the attachment of form PTO-1449.

*"Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted *** and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so. *** The examiner should not require that a translation be filed by applicant. The examiner should not make any comment such as that the non-English language information has only been considered to the extent understood, since this fact is inherent.*

"Since information is required to be listed in a separate paper rather than in the specification, there is no need to mark "All checked" or "Checked" in the margin of a specification containing citations.

"If a statement fails to comply with the requirements as discussed in this section for an item of information, a line should be drawn through the citation to show that it has not been considered. The other items of information listed that do comply with the rules and this section will be considered by the examiner and will be appropriately initialed.

* * * * *

"A citation listed on form PTO-1449 and considered by the examiner in accordance with this section will be printed on the patent. A citation listed in a separate paper, equivalent to but not on form PTO-1449, and considered by the examiner in accordance with this section will be printed on the patent if the list is on a separate sheet which is clearly identified as an information disclosure statement and the list lends itself to easy capture of the necessary information by the Office printing contractor, i.e., each item of information is listed on a single line, the lines are at least double-spaced from each other, the information is uniform in format for each listed item, the list includes a column for the examiner's initials to indicate that the information was considered. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact . . . "

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PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 7

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Kayyali
Art Unit	
Examiner Name	
Attorney Docket Number	CMD-023

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US- 5,645,043	07-05-197	Remmers et al.	
	2	US- 6,029,664	02-29-2000	Zdrojkowski et al.	
	3	US- 6,138,675	10-31-2000	Berthon-Jones	
	4	US- 6,229,581	10-09-2001	Rapoport et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . . "

NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☐ Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☒ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. 1.56(c))

☐ in the practitioner's file.

SIGNATURE OF PRACTITIONER

Reg. No.: 36,847

Brian M. Kolkowski

(type or print name of practitioner)

Tel. No.: (216) 649-0376

4415 Euclid Ave, Suite 400

P.O. Address

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