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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/510,801	11/16/2023	Hani Kayyali	CMD-135	8871
81177	7590	05/30/2024		
Cleveland Medical Devices Inc. 4415 Euclid Ave. Ste. 500 Cleveland, OH 44103			EXAMINER NATNITHITHADHA, NAVIN	
			ART UNIT	PAPER NUMBER
			3791	
			MAIL DATE	DELIVERY MODE
			05/30/2024	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. 18/510,801	Applicant(s) Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791	AIA (FITF) Status No

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

Period for Reply

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

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

Status

1) ☒ Responsive to communication(s) filed on 05 April 2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☐ This action is **FINAL**.

2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

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

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

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

Application Papers

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

11) ☒ The drawing(s) filed on 16 November 2023 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

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

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4) ☐ Other: ____.

Paper No(s)/Mail Date ____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-19, in the reply filed on 05 April 2024 is acknowledged. The traversals in the Remarks, pp. 3-8, are found persuasive. Thus, the restriction requirement is withdrawn.

Claim Objections

3. Claims 18-20 are objected to because of the following informalities:

in claim 18, line 1, "the PAP" is lacks proper antecedent basis, and should be amended to "the PAP device";

in claim 19, line 1, "the PAP" is lacks proper antecedent basis, and should be amended to "the PAP device";

in claim 20, line 24, "the PAP" is lacks proper antecedent basis, and should be amended to "the PAP device".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

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

The factual inquiries for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

7. **Claims 1, 2, 4, 6-9, and 12-19 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell et al., U.S. Patent Application Publication No.**

2007/0161913 A1 ("Farrell"), in view of Geva et al., U.S. Patent Application**Publication No. 2004/0073098 A1 ("Geva").**

As to Claim 1, Farrell teaches the following:

A positive airway pressure (PAP) sleep disorder treatment system ("apparatus for treating and monitoring sleep disordered breathing ("SDB")", not labeled) (see "This invention relates to methods and apparatus for treating and monitoring sleep disordered breathing ("SDB") in patients with cardiovascular disease or otherwise monitoring the cardiovascular condition of SDB patients." in para. [0002], and see fig. 1) comprising:

a non-transitory computer readable medium ("integrated chips in the memory of the device", not labeled) comprising a first software ("software", not labeled), the first software adapted to be downloaded to a [**portable device**] ("hand-held display and control devices") 12 and executable by a first processor ("controller 15 or processor") 15 on the [**portable device**] (see "A controller 15 or processor is configured and adapted to implement the methodology described in more detail herein and may include integrated chips, a memory and/or other instruction or data storage medium. For example, programmed instructions with the control methodology may be coded on integrated chips in the memory of the device or such instructions may be loaded as software." in para. [0025]) to display to a subject for viewing on the [**portable device**] a treatment efficacy of the subject (see "pressure treatment protocols"

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in para. [0030]-[0033]) using a PAP device ("pressure delivery device", not labeled, see large enclosure in fig. 1), the treatment efficacy ("AHI (apnea hypopnea index)") based in whole or in part on data based on one or more measure(s) of the treatment efficacy received by the first software (see "For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented as follows: [0038] (i) An apnea is scored if a 2 second moving average ventilation drops below 25% of a recent average ventilation (time constant=100s) for at least 10 consecutive seconds, [0039] (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average ventilation for 10 consecutive seconds. Similarly, the device may determine an index comparing central apneas versus obstructive apneas as disclosed in U.S. Pat. No. 6,832,609, the entire disclosure of which is incorporated by reference herein." in para. [0036]), the **[portable device]** comprising at least one first radio frequency wireless transceiver ("wireless communication transceiver and/or a network card"), the first processor 15, the first software when downloaded, and a display ("its own display (e.g., LCD screen)", see para. [0026]) (see fig. 1, and see "The apparatus preferably also includes a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for

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communication with other devices or computers such as hand-held display and control devices 12. The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices.” in para. [0026]));

the PAP device (“pressure delivery device”, not labeled, see large enclosure in fig. 1) with an enclosure further comprising:

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

an airflow sensor (“flow sensor”) 4f being any type of sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP device and outputting airflow sensor data (see fig. 1),

a second processor (“microprocessor”) 16 within the enclosure adapted for receiving the airflow sensor data (see “The pressure sensor 4f and flow sensor 4p have only been shown symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure. Flow $F(t)$ and pressure $P_{\text{sub.mask}}(t)$ signals are sent to a controller or microprocessor 15 to derive a pressure request signal $P_{\text{sub.request}}(t)$.” in para. [0024]) and for calculating the one or more measures of the treatment efficacy comprising:

i) the data of a severity of the sleep disorder symptoms of the subject (see para. [0036]),

ii) the data of usage of the PAP device, and/or

iii) the index based on either i) or ii) or both i) and ii),

a mask or a nasal cannula ("mask") 6 connected to the enclosure (see fig.

1), and

at least one second radio frequency wireless transceiver

("communication port or module") 10 within the enclosure, the at least

one second radio frequency wireless transceiver 10 adapted for transmitting a

PAP data based in whole or part on at least one or more measures of treatment

efficacy calculated by the second processor (see "... a communication port

or module 10, for example, a wireless communication

transceiver and/or a network card, for communication with

other devices or computers such as hand-held display and

control devices 12." in para. [0026]); and

a remote internet site ("secure electronic network to a database",

not labeled), the remote internet site adapted for receiving PAP data or data based on

at least one of the one or more treatment efficacy measures, related to the subject's

treatment and the treatment's efficacy in whole or part, generated by the PAP device

and transmitted via the at least one second radio frequency wireless transceiver 10 (see

"Preferably, the cardiovascular and SDB information may be

periodically remotely transferred to the physician or it may be

accessed directly through displays on the device. In this way, a

physician may keep up with and observe the changing

cardiovascular condition of the patient with minimal direct

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

Farrell does not teach the following:

a first software adapted to be downloaded to a **cell phone** and executable by a first processor on the **cell phone** ...

However, Geva teaches the following:

A positive airway pressure (PAP) sleep disorder treatment system (see “FIG. 31 schematically illustrates utilizing the Automatic Sleep Stage (ASS) and Respiratory system with combination with a Continuous Positive Airway Pressure (CPAP) system, according to a preferred embodiment of the present invention.” in para. [0298]) comprising:

a first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone (see “Cellular phone 3002 contains software, the task of which is to carry out a preliminary classification process of the signals, i.e., for identify typical and irregular shapes in these signals, and transmit the latter signals to cellular base-station 3004, in which a dedicated server 3005 resides.” in para. [0294]).

Thus, it would have been obvious for one of ordinary skill in the art at the time the present application was effectively filed to modify Farrell's "hand-held display and control devices 12" to be a "cellular phone 3002", as taught by Geva, and uses Farrell's "software", because it is merely substituting one known portable device for another to yield predictable results, i.e. communicate data over a network from different locations (see Geva, para. [0292]).

As to Claim 2, Farrell teaches the following:

wherein the remote internet site is adapted to be hosted on a remote communication system with a third processor and a recording medium for reprocessing, storing and/or outputting data received from the first and/or second radio frequency wireless transceiver in whole or part, and to further output the reprocessed and/or the outputted data (see "Alternatively, the device may be pre-programmed to prompt or query for such information on a display or from another remote device, before use and/or periodically such as monthly, after three or six months, or some other timed period which may be based on use of the device (e.g., after 30 nights of use, etc.), so that such information may be measured or determined separately and input by a user on a keypad or other data entry device." in para. [0042]).

As to Claim 4, Geva teaches the following:

wherein the at least one second radio frequency wireless transceiver is adapted to transmit the data to the remote internet site ("dedicated server") 3005 in whole or in part via cell towers ("cellular base-station") 3004 (see fig. 30).

As to Claims 6 and 7, Farrell teaches the following:

the PAP device ("pressure delivery device", not labeled) further comprising at least one second software ("software", not labeled) stored on a memory and executed by the second processor 16, the at least one second software which is adapted for calculating the data in whole or in part, wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site ("secure electronic network to a database", not labeled) (see para. [0028], [0042], and [0047]).

As to Claim 8, Farrell teaches the following:

wherein the PAP device further comprises at least one electronic component ("microprocessor") 16 adapted to allow the PAP device to be adjusted remotely based on the data received by the remote internet site (see para. [0028], [0042], and [0047]).

As to Claim 9, Farrell teaches the following:

wherein the first software ("software", not labeled) is adapted to be reprogrammed or modified remotely (see para. [0028], [0042], and [0047]).

As to Claims 12 and 13, Farrell teaches the following:

wherein the remote internet site is adapted to retransmit the data to the first radio frequency wireless transceiver on the cell phone, in whole or in part, of i) and ii), or i), ii), and iii) related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device (see "Preferably, the cardiovascular and SDB information may be periodically remotely transferred to the physician or it may be accessed directly

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

As to Claim 14, Farrell teaches the following:

wherein the PAP device further comprises an adaptive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor (see “The AUTOSET T.TM. device continuously monitors the state of the patient's airway and determines an appropriate pressure to treat the patient, increasing it or decreasing it as necessary.” in para. [0005]).

As to Claim 15, Farrell teaches the following:

wherein the PAP device further comprises an adaptive predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor (see “The AUTOSET T.TM. device continuously monitors the state of the patient's airway and determines an appropriate pressure to treat the patient, increasing it or decreasing it as necessary.” in para. [0005]).

As to Claims 16 and 17, Farrell teaches the following:

wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy (see para. [0027]).

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

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

8. **Claims 3 and 5 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell, as applied to claims 2 and 4, respectively, above, further in view of Hedner et al., U.S. Patent Application Publication No. 2008/0257349 A1 (“Hedner”).**

As to Claims 3 and 5, Farrell teaches the subject matter of claims 2 and 4, respectively, above. Farrell does not teach the following:

wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.

However, using Bluetooth wireless protocol to transmit data between a PAP device and an external device is a well-known feature in the art. For example, Hedner teaches the following:

at least one second radio frequency wireless transceiver (“communication means (not shown)”, not labeled) of a PAP device (“ventilator device”) 4 and a first radio frequency wireless transceiver (“communication means (not shown)”,

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not labeled) of the cell phone (“external computational device”, not labeled)

are adapted to communicate using Bluetooth wireless protocol (see “The communication means can be of a serial type like for instance according to the standards RS232, RS485, USB, Ethernet, or Firewire, or of a parallel type like for instance according to the standards Centronics, ISA, PCI, or GPIB/HPIB. It may also be any wireless system of the standards in the IEEE 802.11 series, HiperLAN, Bluetooth, IR, GSM, GPRS, or UMTS, or any other appropriate fixed or wireless communication system.” in para. [0031]).

Thus, it would have been obvious for one of ordinary skill in the art at the time the present application was effectively filed to modify Farrell’s “... a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12.” (see Farrell, para. [0026]) to use Bluetooth wireless protocol, as taught by Hedner, because these are alternative standardized wireless communication formats known in the art (see Hedner, para. [0031]).

9. **Claim 20 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell et al., U.S. Patent Application Publication No. 2007/0161913 A1 (“Farrell”), in view of Lee et al., U.S. Patent Application Publication No. 2005/0061323 A1 (“Lee”), and further in view of Geva et al., U.S. Patent Application Publication No. 2004/0073098 A1 (“Geva”).**

As to Claim 20, Farrell teaches the following:

A positive airway pressure (PAP) sleep disorder treatment system ("apparatus for treating and monitoring sleep disordered breathing ("SDB")", not labeled) (see "This invention relates to methods and apparatus for treating and monitoring sleep disordered breathing ("SDB") in patients with cardiovascular disease or otherwise monitoring the cardiovascular condition of SDB patients." in para. [0002], and see fig. 1) comprising:

a non-transitory computer readable medium ("integrated chips in the memory of the device", not labeled) comprising a first software ("software", not labeled) adapted to be downloaded to a [**portable device**] ("hand-held display and control devices") 12 and executable by a first processor ("controller 15 or processor") 15 on the [**portable device**] (see "A controller 15 or processor is configured and adapted to implement the methodology described in more detail herein and may include integrated chips, a memory and/or other instruction or data storage medium. For example, programmed instructions with the control methodology may be coded on integrated chips in the memory of the device or such instructions may be loaded as software." in para. [0025]) to display to a subject for viewing on the [**portable device**] a treatment efficacy of the subject (see "pressure treatment protocols" in para. [0030]-[0033]) using a PAP device ("pressure delivery device", not labeled, see large enclosure in fig. 1), the treatment efficacy ("AHI (apnea hypopnea index)") based in whole or in part on a data based on one or more measure(s) of the treatment efficacy received by

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the first software (see “For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented as follows: [0038] (i) An apnea is scored if a 2 second moving average ventilation drops below 25% of a recent average ventilation (time constant=100s) for at least 10 consecutive seconds, [0039] (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average ventilation for 10 consecutive seconds.”)

Similarly, the device may determine an index comparing central apneas versus obstructive apneas as disclosed in U.S. Pat. No. 6,832,609, the entire disclosure of which is incorporated by reference herein.” in para. [0036]), the [**portable device**] comprising at least one first radio frequency wireless transceiver (“wireless communication transceiver and/or a network card”), the first processor 15, the first software when downloaded, and a display (“its own display (e.g., LCD screen)”, see para. [0026]) (see fig. 1, and see “The apparatus preferably also includes a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12. The apparatus may further

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include additional interface 16 for connection to additional diagnosis or patient information gathering devices.” in para. [0026]));

the PAP device (“pressure delivery device”, not labeled, see large enclosure in fig. 1) with an enclosure further comprising:

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

an airflow sensor (“flow sensor”) 4f being any type of sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data (see fig. 1),

a second processor (“microprocessor”) 16 within the enclosure adapted for receiving the airflow sensor data (see “The pressure sensor 4f and flow sensor 4p have only been shown symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure. Flow $F(t)$ and pressure $P_{\text{sub.mask}}(t)$ signals are sent to a controller or microprocessor 15 to derive a pressure request signal $P_{\text{sub.request}}(t)$.” in para. [0024]) and for calculating the one or more measures of the treatment efficacy comprising:

- i) the data of a severity of the sleep disorder symptoms of the subject (see para. [0036]),
- ii) the data of usage of the PAP device, and/or

iii) the index based in whole or in part on either i) or ii) or both i) and ii),
a mask or a nasal cannula ("mask") 6 connected to the enclosure (see fig. 1), and

at least one second radio frequency wireless transceiver ("communication port or module") 10, the at least one second radio frequency wireless transceiver 10 adapted for transmitting a PAP data based in whole or part on at least one of the one or more measures of treatment efficacy calculated by the second processor (see "... a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12." in para. [0026]); and

a non-transitory computer readable medium comprising a second software adapted to be executable a third processor on a portable, wearable patient acquisition device ("diagnosis unit") 18 comprising a pulse oximeter ("pulse oximeter") 20 and a [**respiratory movement sensor**] ("respiratory movement sensors") 22 to collect additional physiological data from a subject for combining with the data collected by the PAP, the first or the second software further adapted to forward the additional physiological data to combine with the data from the PAP device to determine the treatment efficacy of the subject using a PAP device (see "The apparatus preferably also includes a communication port or module 10, for example, a wireless communication transceiver and/or a network

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card, for communication with other devices or computers such as hand-held display and control devices 12. The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices. For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band, EEG & ECG 24, EOG 25 and/or electrodes 28 for detecting cardiac rhythm. The oximeter may optionally be included in the main blower housing. There is a sense tube 14 connected to the main housing of the blower to the mask that allows the apparatus to sense oxygen concentration and pressure levels in the mask 6. Optionally, an automated PCO.sub.2 measurement device 21 or other non-invasive blood gas monitor/device for measuring PCO.sub.2 may be linked to provide an input data signal to the microprocessor 16, for example, a device as taught in U.S. Pat. No. 5,630,413, the disclosure of which is incorporated by reference. Other automated measuring devices may also be included with the diagnosis unit as it relates to measuring other cardiovascular related information from the patient. In this regard, the device may, for example, be configured to communicate/receive such information from its own display (e.g., LCD screen) and input device (e.g., keypad or buttons) or via telemetry or other communication link from a blood pressure monitor, heart rate monitor, oximetry monitor, ECG device, ECG

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Event Monitor, Holter monitor, automated tape measure, automated weight scale, treadmill device, blood analyzer device, cardiac output analyzer device, VO.sub.2 max data device or peripheral arterial tone assessment device.” in para. [0026]);

a remote internet site (“secure electronic network to a database”, not labeled), the remote internet site adapted for receiving the PAP data or data based on the at least one of the one or more treatment efficacy measures, related to the subject’s treatment and the treatment’s efficacy in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver 10 (see “Preferably, the cardiovascular and SDB information may be periodically remotely transferred to the physician or it may be accessed directly through displays on the device. In this way, a physician may keep up with and observe the changing cardiovascular condition of the patient with minimal direct oversight or intervention. Optionally, the device can be programmed with thresholds for comparison to the recorded cardiovascular information to trigger an alarm or send a message or generate a warning for the user, clinician or physician either directly on the device, or remotely, for example, over a secure electronic network to a database.” in para. [0047]) and the additional physiological data collected with the portable, wearable patient acquisition device, and the additional physiological data collected with the portable, wearable patient acquisition device (see “For example, if the recorded or detected

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heart rate falls below an acceptable level, a warning or alarm may be generated. Similarly, if changes in weight, arrhythmia, blood pressure, blood sugar, heart variability, ECG data, etc. are recorded, automated warnings, alarms or messages may be generated by the device and manual or automated changes to the control of the device may be made such as a change in treatment protocol or a change to the set of monitored cardiovascular information such that additional cardiovascular information may be monitored.” in para. [0047]).

Farrell does not teach the following:

an accelerometer.

However, such a feature is well-known in the art to monitor respiratory movement. For example, Lee teaches the following:

A positive airway pressure (PAP) sleep disorder treatment system (see “A gas therapy system involves sensing the blood gas concentration of the patient and adapting a gas therapy based on the sensed gas concentration.” in Abstract) comprising:

an accelerometer for monitoring respiratory movement (see “The pulse generator 905 may optionally incorporate a motion detector that may be used to sense various respiration-related conditions. For example, the motion detector may be optionally configured to sense snoring, activity level, and/or chest wall movements associated with respiratory effort, for example. The motion detector may be implemented as

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an accelerometer positioned in or on the housing 901 of the pulse generator 905. If the motion sensor is implemented as an accelerometer, the motion sensor may also provide respiratory, e.g. rales, coughing, and cardiac, e.g. S1-S4 heart sounds, murmurs, and other acoustic information.” in para. [0077]).

Thus, it would have been obvious for one of ordinary skill in the art at the time the present application was effectively filed to modify Farrell’s “respiratory movement sensors 22” to be an accelerometer, as taught by Lee, because it is merely substituting one known portable device for another to yield predictable results, i.e. sensing respiratory movement to gather respiratory movement data.

Farrell in view of Lee does not teach the following:

a first software adapted to be downloaded to a **cell phone** and executable by a first processor on the **cell phone** ...

However, Geva teaches the following:

A positive airway pressure (PAP) sleep disorder treatment system (see “FIG. 31 schematically illustrates utilizing the Automatic Sleep Stage (ASS) and Respiratory system with combination with a Continuous Positive Airway Pressure (CPAP) system, according to a preferred embodiment of the present invention.” in para. [0298]) comprising:

a first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone (see “Cellular phone 3002 contains software, the task of which is to carry out a

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preliminary classification process of the signals, i.e., for identify typical and irregular shapes in these signals, and transmit the latter signals to cellular base-station 3004, in which a dedicated server 3005 resides.” in para. [0294]).

Thus, it would have been obvious for one of ordinary skill in the art at the time the present application was effectively filed to modify Farrell’s “hand-held display and control devices 12” to be a “cellular phone 3002”, as taught by Geva, and uses Farrell’s “software”, because it is merely substituting one known portable device for another to yield predictable results, i.e. communicate data over a network from different locations (see Geva, para. [0292]).

Allowable Subject Matter

10. Claims 10 and 11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office Action.

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

As to Claims 10 and 11, Farrell teaches the subject matter of claims 12 and 14, as discussed above. However, neither Farrell, Hedner, Geva, nor the prior art of record teaches the system of base claims 12 and 14, including the following, in combination with all other limitations of the base claims:

wherein the airflow sensor data is processed by the second processor, at least in part using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached Monday - Friday 6:00 am - 8:30 am & 10:30 am - 4:00 pm.

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

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

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**/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791
05/29/2024**