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(54) **SYSTEM FOR IN-HOME SELF-ASSESSMENT OF RISK FOR ABNORMAL AIRFLOW DURING SLEEP**

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A61B 5/11	(2006.01)

(52) **U.S. Cl.**

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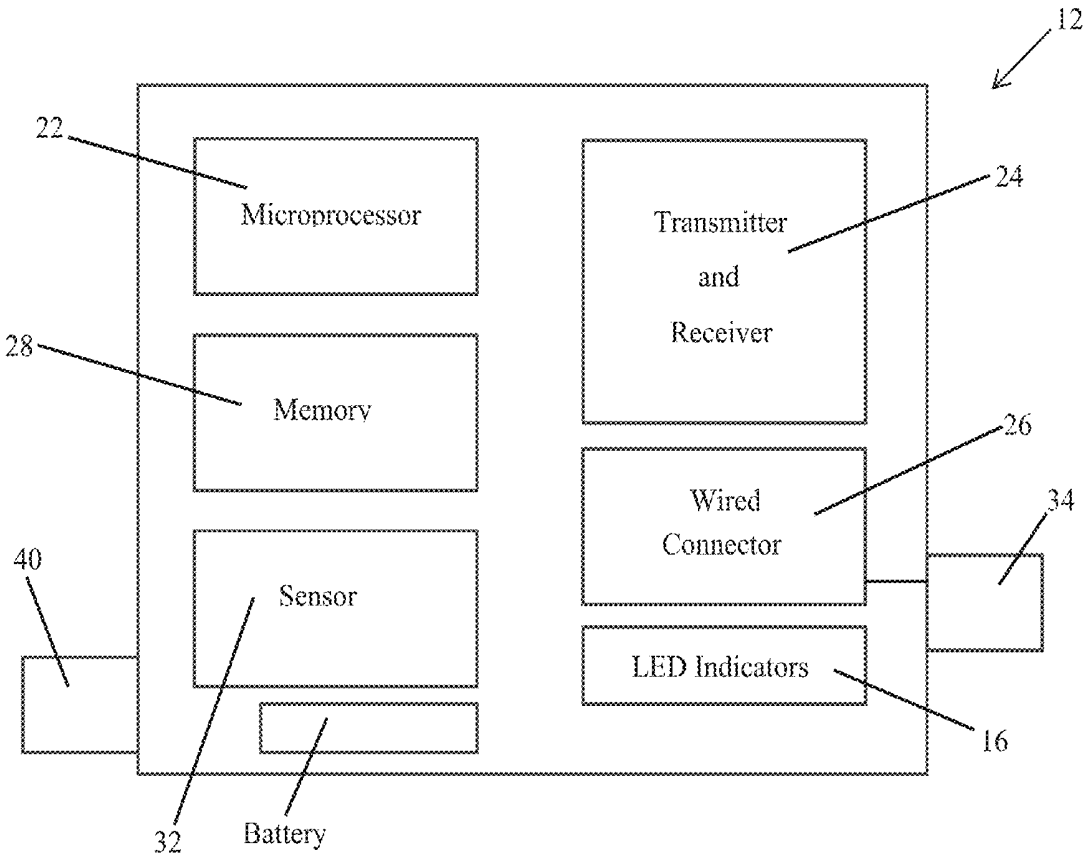
(57) **ABSTRACT**

A self-assessment system for assessing risk for experiencing abnormal airflow during sleep. A preferred embodiment of the system includes a cannula for sampling nasal airflow of a user. A data recording and communication device includes a sensor to receive airflow from the cannula, a converter to convert breathing airflow to an electronic signal, a recorder to record electronic signal data, and a transmitter to wirelessly transmit said electronic signal data. A mobile device includes a receiver to receive said electronic signal data transmitted from the recording and communication device, a database to store the electronic signal data, an interface to obtain questionnaire data from the user, a transmitter to wirelessly transmit the electronic signal and questionnaire data, and a mechanism to store or access instructional video information. A computer server includes a receiver to receive the electronic signal data and questionnaire data transmitted from the mobile device and a mechanism to generate a risk profile from the data received.



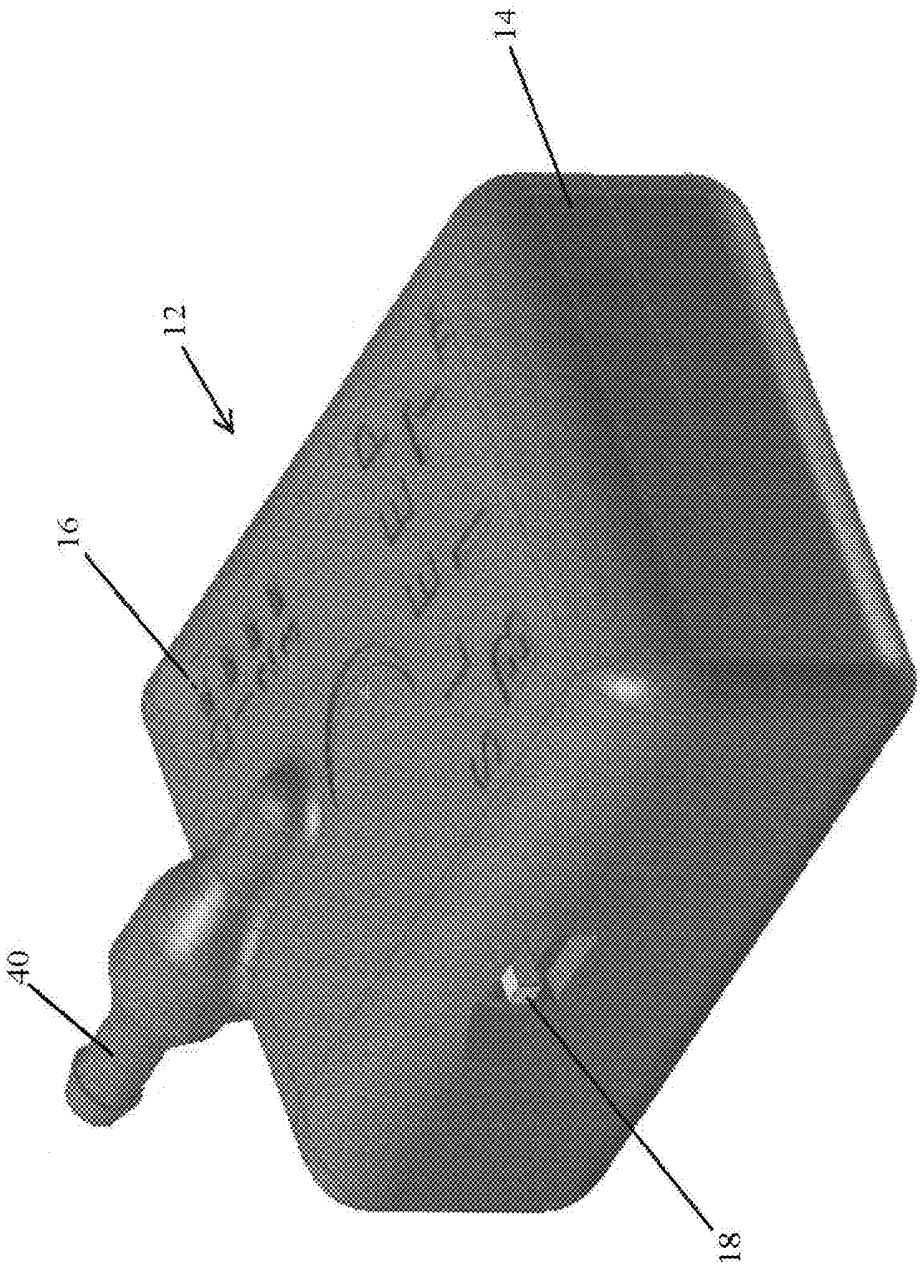
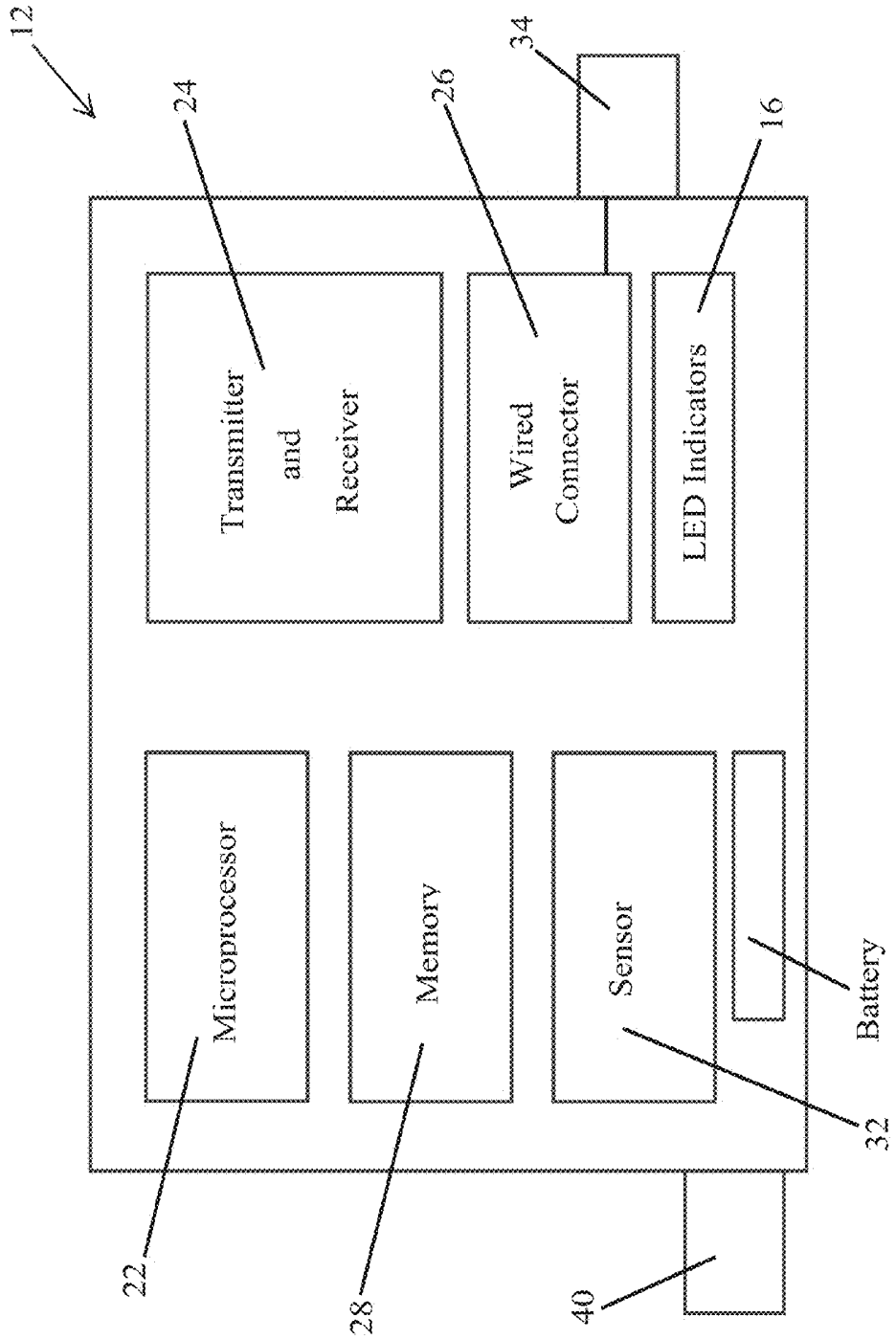


Figure 1

Figure 2


12
24
26
34
16
Transmitter and Receiver
Wired Connector
LED Indicators
Microprocessor
Memory
Sensor
Battery
22
28
32
40

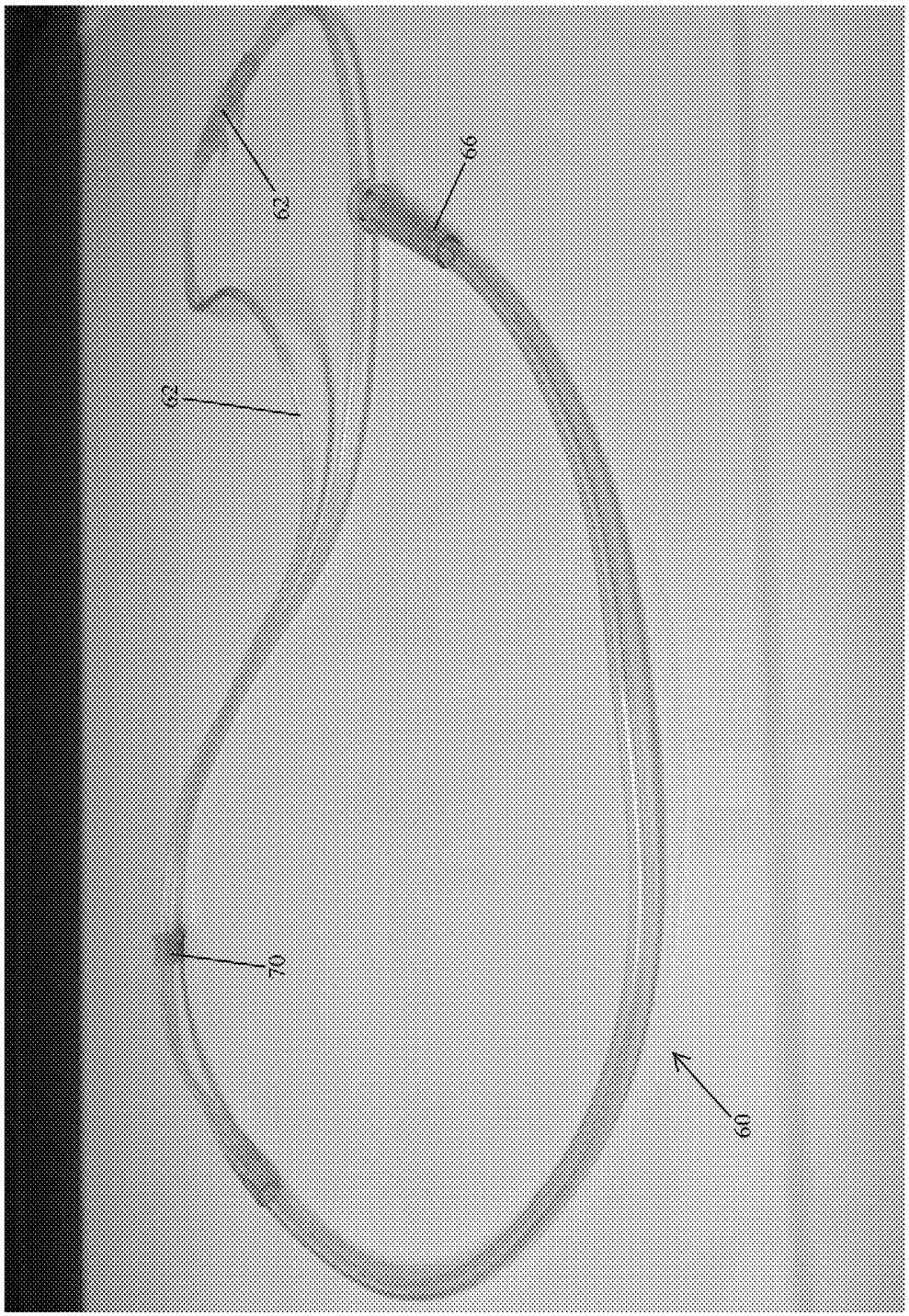


Figure 3

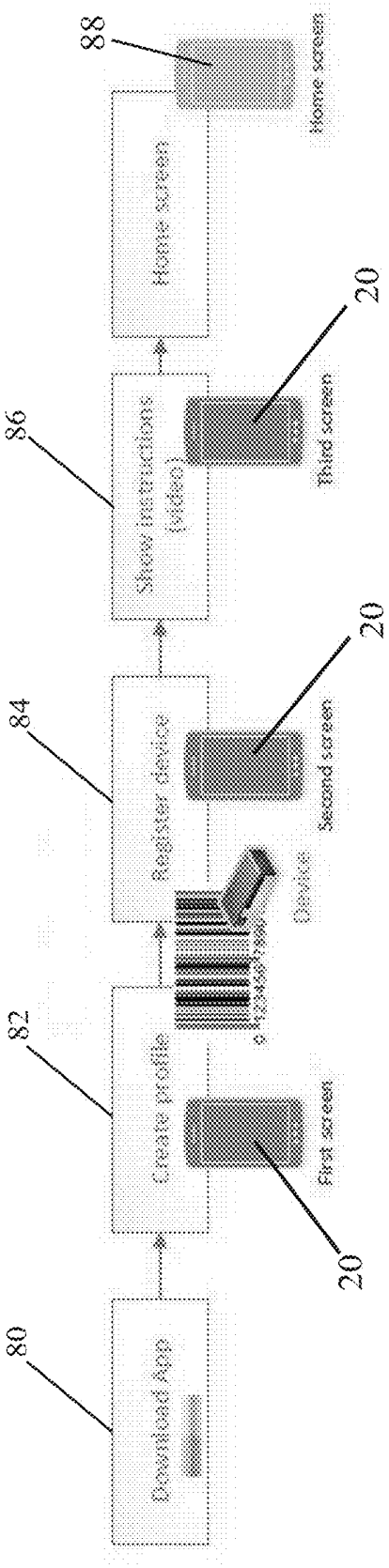

88
Home screen
Home screen
20
Third screen
86
Show instructions (video)
20
Second screen
84
Register device
Device
82
Create profile
First screen
20
80
Download App

Figure 4

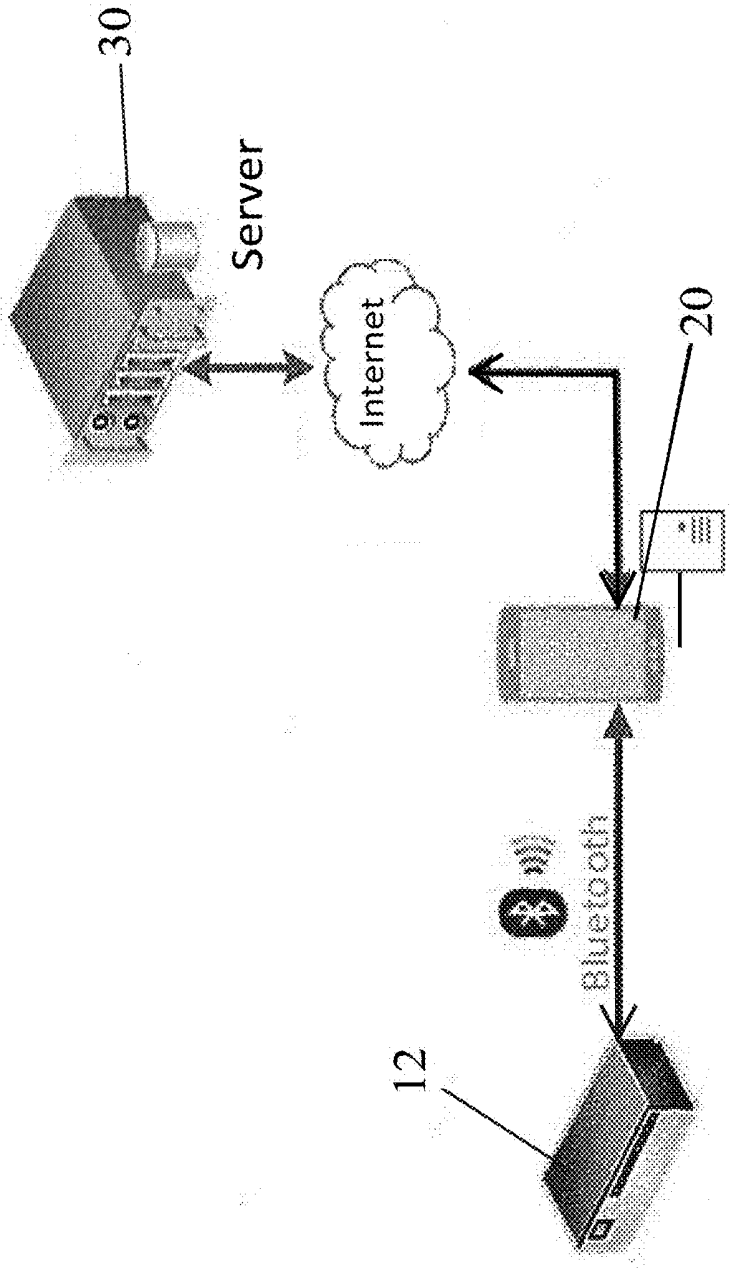


Figure 5

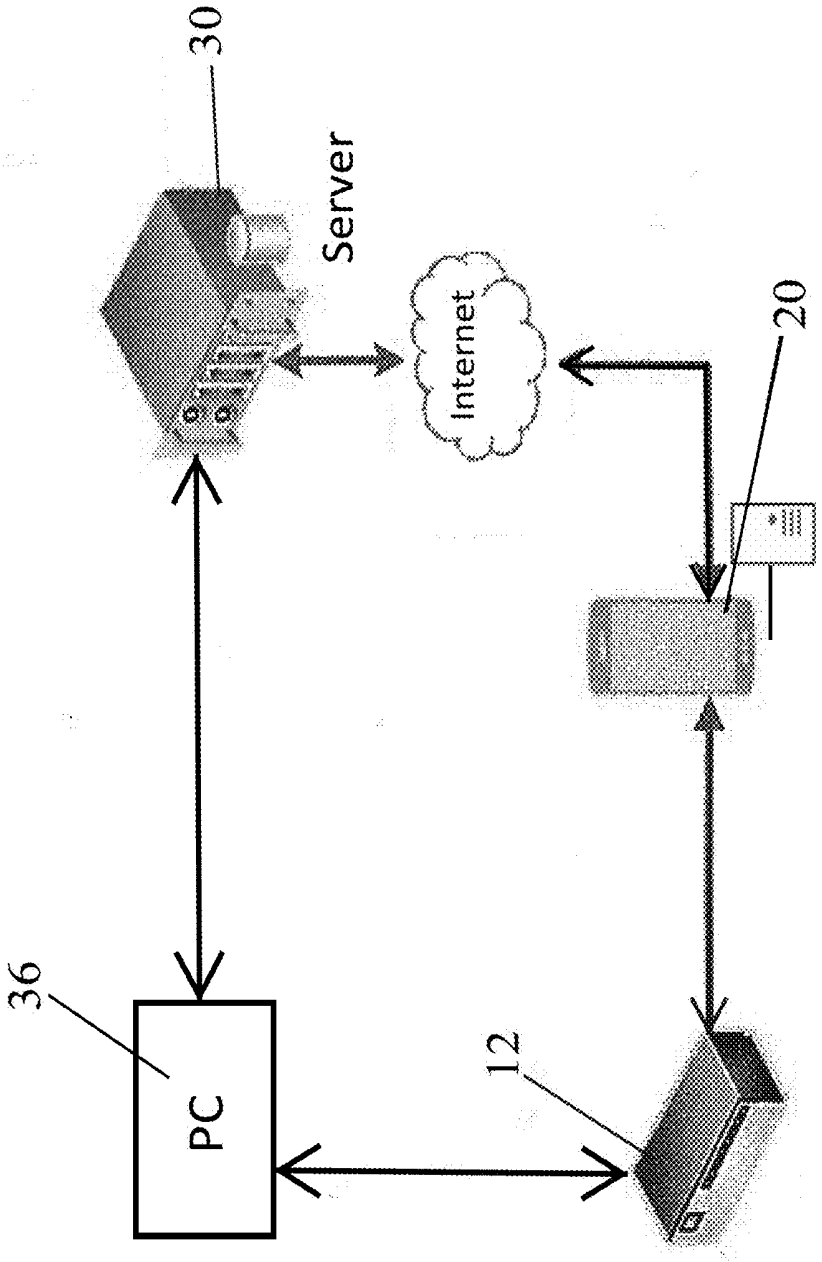


Figure 6

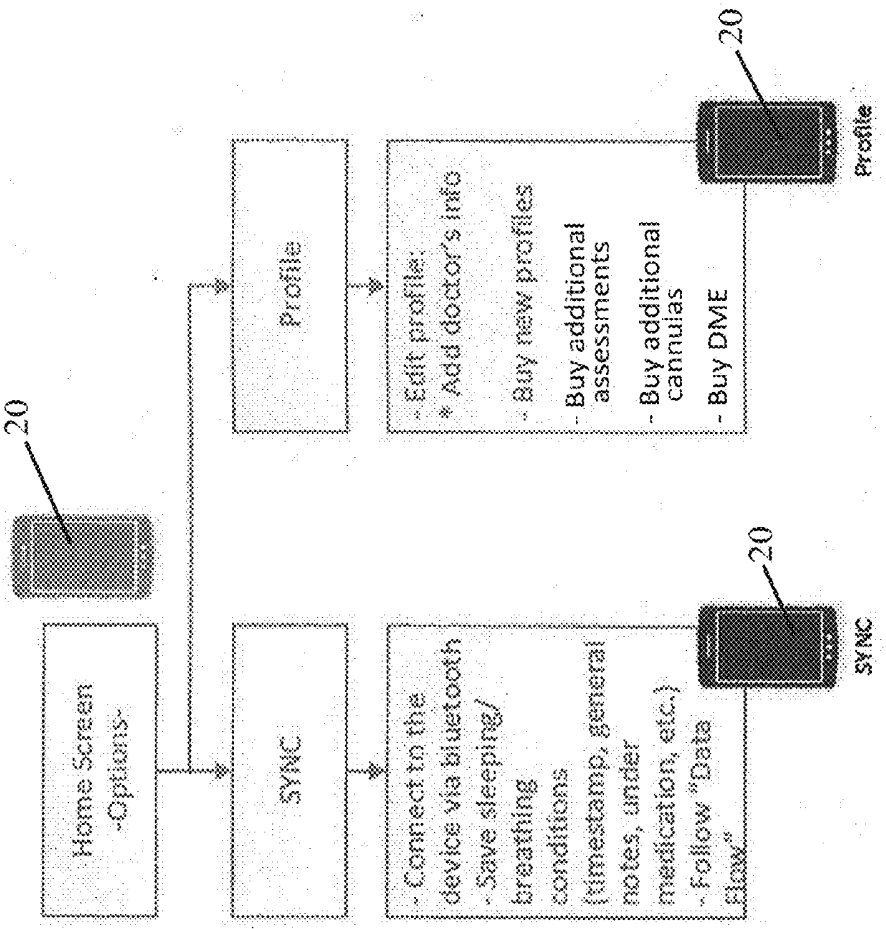

Home Screen
-Options-
20
SYNC
Profile
- Connect to the device via bluetooth
- Save sleeping/ breathing conditions (timestamp, general notes, under medication, etc.)
- Follow "Data Flow"
20
SYNC
- Edit profile:
* Add doctor's info
- Buy new profiles
- Buy additional assessments
- Buy additional cannulas
- Buy DME
20
Profile

Figure 7

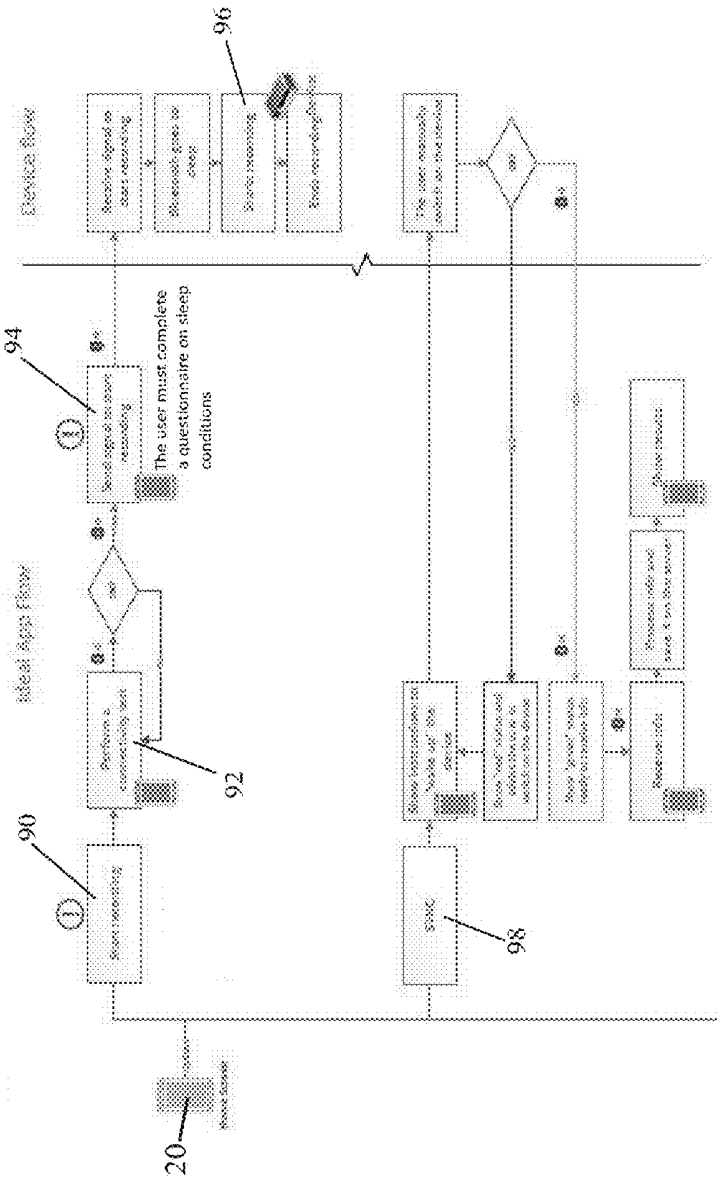

Device flow
Ideal App Flow
The user must complete a questionnaire on sleep conditions
20
90
92
94
96
98
100

Figure 8

SYSTEM FOR IN-HOME SELF-ASSESSMENT OF RISK FOR ABNORMAL AIRFLOW DURING SLEEP

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application Ser. No. 62/403,977, filed Oct. 4, 2016, which is incorporated herein in its entirety by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates to a self-assessment system for risk of experiencing episodes of abnormal airflow during sleep. In particular, the present invention is directed to a self-assessment system that captures data regarding airflow of a user during wakefulness or sleep and supplements the data with answers to health and lifestyle questions in order to analyze the combined information to produce a risk assessment for experiencing episodes of abnormal airflow during sleep.

2. Description of the Related Art

[0003] There are, according to the American Academy of Sleep Medicine, between 25 million and 35 million Americans with undiagnosed Obstructive Sleep Apnea (OSA), and a variety of over 50 different sleep disorders. Fifty-five million Americans suffer from insomnia at any one time. The medical community and the public in general are becoming more aware of sleep disorders' serious co-morbidities, such as metabolic problems, hypertension, stroke, mood disorders, and poor quality of life. A significant percentage of the public, however, has been reluctant to enter into screening due to cost and an intimidating and time consuming clinical process. There is no currently available non-prescription in-home self-assessment system for determining risk of experiencing episodes of abnormal airflow during sleep used either alone or in combination with airflow analysis, demographic, and health lifestyle information to produce a computerized analysis.

[0004] The present invention is a system which includes a collection of physical devices, software, and algorithms that capture a user's airflow during sleep and compares it to a normal breathing curve. Identification of abnormal airflow during breathing cycles is one of the strongest indicators of risk for possible sleep related breathing disorders. The present invention employs a proprietary cannula connected to a wireless communication enabled data logger/device and attendant smart device software application. The system is integrated and programmed for gathering and transmitting data and receiving commands. The present system, coupled with intuitive functional design, allows ease of use by the non-medically trained. Airflow data is captured by the device and communicated to a server via a specifically developed multi-platform mobile application. The computer software application or app allows the user easy video, voice, and written instruction upon smart device initiation. The system is capable of communicating user data captured, as well as providing real time risk assessment results. Proprietary algorithms analyze captured data, develop comparative curves, and transmit results to the user in an easy to understand format. To augment the physical data, a series of lifestyle or health questions for users has been developed based on years of certified sleep disorder specialists' research and practice. The combined analysis of the survey and airflow yields a risk assessment with a very high positive predictive value and minimal false negatives. This high degree of sensitivity and specificity is accomplished through the proprietary cannula and recorder device design and function and through the use of three unique proprietary algorithms that reflect over two decades of physician accumulated clinical and research-based knowledge of sleep medicine. One algorithm analyzes the raw airflow data, one analyzes and values user demographic and health and lifestyle responses, and one analyzes the outcome from the data and response analysis to create a further weighted and valued summary assessment of risk for the user experiencing abnormal airflow during sleep. The algorithms can be adjusted over time to reflect advances in system design, technology, and clinical and research based medical knowledge.

[0005] It is a principal objective of the present invention to provide a home assessment suite of components that, when used as a system, reliably captures airflow, augments the airflow data with user responses to a research and practice based lifestyle questionnaire, communicates the submitted information to a processor, analyzes the data with proprietary algorithms, and then displays risk assessments for personal user health decisions. The system can be remotely reprogrammed for advances or changes in device functionality without having to return the device for updates.

[0006] It is a further objective of the present invention to provide a system of home self-assessment which does not replace professional medical assessment and does not make a medical diagnosis, but acts as a preliminary screening mechanism for risk.

[0007] These and other objectives will be readily apparent upon reference to the drawings, the specifications, and claims submitted herewith.

SUMMARY OF THE INVENTION

[0008] The present invention is directed to a system for in-home self-assessment for risk of experiencing abnormal airflow during sleep.

[0009] The system includes a cannula for gathering airflow data from a user. The cannula has a main tube and an inside diameter specifically defined to deliver an air pressure range parameter.

[0010] In one preferred embodiment, the cannula is in turn connected to a data recording and communication device, which includes an internal circuit board with a microprocessor, a short distance wireless communication module, a data memory, capacitors and resistors, and an electromechanical sensor. An electrical analog to digital converter converts airflow pressure received to electronic signal data. The data recording and communication device records the electronic signals and is thereafter capable of transmitting the signals. A mobile device includes a receiver to receive the electronic signal data, which is transmitted from the recording and communication device. A database in the mobile device stores the electronic signal data. The mobile device also includes an interface in order to obtain demographic and health and lifestyle questionnaire responses from a series of questions which are presented to a user. The

mobile device also includes a transmitter to wirelessly transmit the electronic signal data and the questionnaire response data.

[0011] In an alternate preferred embodiment, the electronic signal data from the data recording device is transmitted to a personal computer, such as via a wired connection.

[0012] In a first embodiment, a computer server receives the electronic signal data and the questionnaire response data transmitted from the mobile device. In a second embodiment, the computer server receives the electronic signal data from a personal computer. The data collected at the computer server is analyzed using proprietary algorithms. The airflow pressure from a user is captured over time and compared against a normal airflow curve. A mechanism is provided to generate a summarized risk profile from the combination of the electronic signal data and the questionnaire response data received.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. **1** is a perspective view of a data recording and communication device which is a component of an in-home self-assessment system for risk of experiencing episodes of abnormal airflow during sleep of the present invention;

[0014] FIG. **2** is a schematic diagram of the components of the data recording and communication device;

[0015] FIG. **3** is a perspective view of a cannula which is a component of the self-assessment system for risk of experiencing episodes of abnormal airflow during sleep;

[0016] FIG. **4** is a sequential flow chart showing initial set-up of the self-assessment system for risk of experiencing episodes of abnormal airflow during sleep;

[0017] FIG. **5** is a schematic diagram of various components of a first preferred embodiment of the self-assessment system for risk of experiencing episodes of abnormal airflow during sleep;

[0018] FIG. **6** is a schematic diagram of various components of a second preferred embodiment;

[0019] FIG. **7** shows the various options presented to a user from a smart mobile device of the self-assessment system for risk of experiencing episodes of abnormal airflow during sleep; and

[0020] FIG. **8** is a sequential flow chart illustrating use of the self-assessment system for risk of experiencing episodes of abnormal airflow during sleep.

DETAILED DESCRIPTION OF THE INVENTION

[0021] The embodiments discussed herein are merely illustrative of specific manners in which to make and use the invention and are not to be interpreted as limiting the scope.

[0022] While the invention has been described with a certain degree of particularity, it is to be noted that many modifications may be made in the details of the invention's construction and the arrangement of its components without departing from the scope of this disclosure. It is understood that the invention is not limited to the embodiments set forth herein for purposes of exemplification.

[0023] Referring to the drawings in detail, FIG. **1** is a perspective view of a data recording and communication device **12** which is a component of the system **10**. The device **12** is comprised of an internal circuit board with a microprocessor **22**, a short distance wireless transmitter and receiver module **24** such as Bluetooth™, a connection **26** for wired transmission and receipt of data, a memory **28**, capacitors and resistors, as well as a register or sensor **32**. FIG. **2** illustrates a schematic diagram of the device **12** showing the various components. The wired connector **26** may include a port, such as a USB connection **34**.

[0024] In a preferred embodiment, an electromechanical sensor is utilized. The electromechanical sensor or register receives breathing airflow from a cannula and an electrical analog to digital converter converts breathing airflow pressure to an electronic data signal.

[0025] In an alternate embodiment, a thermal sensor senses temperature during inhale and exhale breathing cycles and converts it to an electronic data signal.

[0026] These components, along with software computer programs contained therein, have the capability to 1) record multiple nights of airflow data during sleep, 2) identify a sufficient quality airflow recording session to warrant communicating the data via Bluetooth™ to a smart mobile device **20**, 3) indicate outcomes to the user, and 4) initiate pairing communication with a smart device or, alternatively, with a personal computer for further transmission of the electronic signal data to a computer server **30**.

[0027] The data recording and communications device **12** has sufficient capacity and memory to record breathing airflow data for multiple nights. A sufficient quality airflow recording session is determined by a number of cycles of breathing data over a period of time with removal of inadequate or bad data received via proprietary algorithms.

[0028] As will be described in detail, the electronic signal data is transmitted, analyzed, and reported, which may be communicated with a mobile smart device.

[0029] All proprietary calculations occur on the computer server **30**. Upon completion of a server calculation routine, the server **30** sends risk profile information to the smart device **20** for display to the user. The server **30** uses proprietary algorithms to process the data and produce a combined assessment profile.

[0030] The internal circuit board with memory **28** on the recording and communication device **12** can be reprogrammed remotely by a system administrator to update any aspect of the device displays, communications, and commands.

[0031] As shown in FIGS. **1** and **2**, the device **12** includes a housing **14** having LED indicators **16**, which advise the user about power readiness, data status, and other user/system information. The external features provide functionality which are easily understandable to the user. Instructions and interpretations of the lighting sequence are also defined and displayed on the smart device screen.

[0032] Upon attaining sufficient data to analyze, the recording and communication device **12** indicates via LED lighting that sufficient quality data has been recorded for analysis. Various color lighting, blinking sequences, lighting groups, and lighting group blinking sequences from the LED indicators **16** signals the user of various results or actions required. The possible combinations are numerous; however, user instructions advise the user of the specific lighting settings. This flexible functionality coupled with specific user visual indicators results in ease of use for a first-time novice user.

[0033] A power button **18** activates the recording and communication device **12** and initiates linking of the recorder device with a smart device **20** or, alternatively, with

a personal computer **36**. The linking activity also qualifies the user, who must provide a use authorization code identifying the individual who acquired the data logger. The system **10** will not function without the user authorization.

[0034] The recording device **12** and mobile smart device **20** are paired via a serialized code which must be matched with an authorized recording device purchase number for the security benefit of the user and for maintaining integrity of data of the authorized user. The pairing specificity and the retention of all user information and data on a protected server ensure, enhance, maintain, and protect user data and assessment specificity and privacy. Such pairing thereby allows communication and data transfer between the recording device **12** and mobile smart device **20**.

[0035] The device housing **14** also has an integrated receiver **40** for a cannula. The integrated receiver **40** is of specific shape and dimension such that it will receive the cannula so that a positive seal is created, which does not allow air from breathing airflow to escape or air from outside the cannula to invade. No external clamps or other collar reinforcements are required.

[0036] FIG. **3** is a perspective view of the cannula **60**, which has a proprietary design both in length and cross-section, creating a unique and specific airflow registry to the data recording device. The cannula **60** connects and remains connected to the recording device **12** by mechanical means and friction with a main connector **66**. The cannula **60** fits to the user by placing the head-loop **62** around the user's ears with nose prongs or nostril pieces **64** positioned at the user's nostrils. An optional clip, such as an alligator clip, connects the cannula to night clothes of a user, in order to enhance data quality.

[0037] The length of a main tube **68** of the cannula is adjustable by an adjustment mechanism **70**. The main tube **68** has a selected length and diameter to deliver an air pressure range. Specific length of the main tube of the cannula **60** allows easy use of the connected recording device without entangling the user or separating from the recording device and allows for improved accuracy of data collection when used in coordination with the system. The cannula is encircled by a plastic band attached to a small alligator clip. Use of the clip to attach the cannula/recorder unit to an article of clothing worn over the chest helps to enhance airflow data recording quality.

[0038] The length and internal diameter of the cannula tubing are optimized to allow sufficient pressure at the sensor to pick up airflow without interference from outside factors. Stated in other words, the cannula dimensions are coordinated with cycles of breathing and pause.

[0039] FIGS. **4**, **5**, **6**, and **7** represent the system **10** and the components and application configuration which allow a user to connect with the system **10**, receive instructions, communicate data, and receive results.

[0040] FIG. **4** is a flow chart showing the initial set-up of the system **10**. A software application is downloaded on a mobile smart device **42**, such as a cell phone, as seen at box **80**. Thereafter, the user is prompted by a series of screens to interact with the device to create a user profile, as seen at box **82**. The user will also be prompted to enter an order number, which will be coordinated with the user profile. This may be communicated by entry of an alphanumeric code or by scanning. These actions will create an account for the particular user.

[0041] As shown at box **84**, the system will then be registered. A video or videos or links to a video or videos will be presented to the user, as shown at box **86**. Finally, a home screen will be presented to the user, as shown at box **88**.

[0042] FIG. **5** illustrates the data flow for a first preferred embodiment illustrating a fully wireless configuration of the present invention.

[0043] The recording device **12**, the smart device **20**, and the server **30** may be wirelessly connected. Transmission of data, instructions and results occurs between devices. Data is gathered from the user through the cannula **60** by the recording device **12** and has sufficient power and memory to record more than one typical sleep session. The recording device **12** measures the magnitude and frequency of breaths of an individual. Abnormal events are scored, such as a decline in magnitude compared to earlier breathing.

[0044] It is not a requirement that the mobile smart device **20** be powered during data gathering sleep sessions. Moreover, the mobile smart device **20** does not have to be under the user's pillow or even in the sleeper's vicinity. This is a unique feature of the system **10**, which results in improved functionality for users, avoids power drains on their smart device, and avoids data and usage charges by their data service or telephone service provider.

[0045] The mobile smart device **12** is the primary point of communication with the user. As shown on FIG. **4**, the user must initially download a mobile device software application (app) from which a User Profile is created. Thereafter, registry of the recording device is accomplished, as shown at box **84**. Instructional information (written, pictorial, video, and/or verbal) is provided to the user, as shown at box **86**.

[0046] As seen in a first preferred embodiment in FIG. **5**, upon data collection of sufficient quality, quantity and duration, data transfer occurs when the user pairs the recording device **12** with the mobile smart device **20**. This data is further communicated to the server **30**, such as through the internet. Analysis of the data collected is performed at the computer server **30** using proprietary algorithms. No calculation capacity need reside on the recording device **12** or mobile smart device **20**. The use of the computer server **30** provides unique protection of user demographic and health information beyond expected standards for a mobile device. Such features are both for security of user data and for reduction of processing capacity on the recording and communication device **12** and on the mobile smart device **20**.

[0047] FIG. **6** illustrates a second preferred embodiment of the invention utilizing a wired connection from the recording device **12** to a personal computer **36**. Upon data collection of sufficient quality, quantity, and duration, data transfer occurs between the recording device **12** and a central processing unit, such as a desktop or laptop computer **36**. The data is further communicated to a computer server **30**, such as through the internet. Analysis of the data is performed at the computer server using proprietary algorithms. No calculation capacity need reside on the recording device **12** nor on the central processing unit **36**.

[0048] A series of life and health questions are posed to the user by the mobile device. Answers to the lifestyle and health questionnaire are transmitted between the mobile smart device **20** and the computer server **30**.

[0049] A user risk profile generated is calculated using the combined input of both the airflow data results and the

questionnaire results. Calculations by the proprietary algorithms determine the final summarized risk profile.

[0050] A series of demographic, health, and lifestyle questions are posed to the user by the mobile device **20**. By way of example but not by way of limitation, questions posed to users may include whether a user is aware of snoring and to what extent and duration, whether a user feels sleepiness at various times, whether a user has experienced physical symptoms during sleep, whether a user has used tobacco or caffeine, whether a user takes certain medications, and various other history and lifestyle questions. It is possible to present information to a user in response to answers provided. For example, incentive educational facts may be presented to enhance the user experience.

[0051] Responses to the lifestyle and health questionnaire are transmitted between the mobile smart device **20** (where such questions are answered) and the computer server **30**. The questionnaire may be in two different forms: an abbreviated short form version and a more comprehensive longer form version. Two uniquely different health and lifestyle questionnaires have been developed: an abbreviated module using just a few questions that allows those users so inclined to move very rapidly through their assessment process, and a second highly comprehensive module that allows those users so inclined to provide more extensive health and lifestyle information that further enhances the accuracy of their risk assessment. Included in the more comprehensive module as a purposeful unique design feature are continually updatable educational sleep related facts that serve to enhance user value and experience and to incentivize and reward completion of the comprehensive assessment process.

[0052] The user risk profile is calculated using both the airflow data results and the questionnaire results. Calculations by the proprietary algorithms determine the final summarized risk profile.

[0053] The mobile device **20** may have home screens presented to the user that have various options, as shown in FIG. **7**. The functional aspects of the data and information flows are a series of user cycles, periodically synchronized with updated profiles.

[0054] For example, under the designation "Sync", the various sleeping and breathing data may be saved. Additionally, under the designation "Profile", there is an ability to edit the user profile and add further information.

[0055] It will be appreciated that the configuration shown is by way of demonstration and does not represent the full array of possible options that can be performed.

[0056] Finally, FIG. **8** illustrates a sequential flow chart illustrating use of the present invention. Initially, a command can be entered from the mobile device **20** to start recording a sleep cycle, as shown at box **90**. Thereafter, a connectivity test is performed, as shown at box **92**. If connection is made, a signal is sent from the mobile device to the recording device **12** to begin, as shown at box **94**. Thereafter the recording device **12** begins to record breathing data received through the cannula from the user, as shown at box **96**.

[0057] The system **10** also has a process to sync or synchronize data, as shown at box **98**. Data gathered from a breathing session is transmitted to the mobile device **20** and thereafter to the computer server **30**.

[0058] The system also has a process to edit a user profile, add profiles, or edit information, as shown at box **100**.

[0059] Whereas, the invention has been described in relation to the drawings attached hereto, it should be understood that other and further modifications, apart from those shown or suggested herein, may be made within the scope of this invention.

What is claimed is:

1. A breathing self-assessment system for risk of experiencing abnormal airflow during sleep, which system comprises:

a cannula for sampling nasal breathing airflow pressure of a user;

a data recording and communication device including

a. a sensor to receive breathing airflow from said cannula,

b. a converter to convert breathing airflow to electronic signal data,

c. a recorder to record said electronic signal data, and

d. a transmitter to transmit said electronic signal data;

a mobile device including

a. a receiver to receive said electronic signal data from said recording and communication device,

b. a database to store said electronic signal data,

c. an interface to obtain health and lifestyle questionnaire response data from a user,

d. a transmitter to wirelessly transmit said electronic signal data and said questionnaire response data, and

e. a mechanism to store or access instructional video information;

a computer server including

a. a receiver to receive said electronic signal data;

b. a receiver to receive said questionnaire response data transmitted from said mobile device, and

c. a mechanism to analyze and generate a risk profile from a combination of said electronic signal data and said questionnaire response data received.

2. A breathing self-assessment system as set forth in claim **1** wherein said data recording device receives and transmits wireless communication to and from said mobile device and wherein said mobile device receives and transmits wireless communication to and from said data recording device.

3. A breathing self-assessment system as set forth in claim **2** wherein said wireless communication is via Bluetooth.

4. A breathing self-assessment system as set forth in claim **1** including a personal computer in communication with said data recording and communication device via a wired connector and wherein said personal computer receives said electronic signal data from said recording and communication device.

5. The breathing self-assessment system as set forth in claim **1** wherein said sensor is an electromechanical sensor and wherein said converter is an electrical analog to digital converter.

6. The breathing self-assessment system as set forth in claim **1** wherein said sensor is a thermal registry sensor and wherein said converter is a temperature to digital converter.

7. The breathing self-assessment system as set forth in claim **1** wherein said mechanism to generate a risk profile includes capturing said breathing airflow from a user over time and comparing against normal airflow pressure curve models.

8. The breathing self-assessment system as set forth in claim **1** wherein said interface to obtain questionnaire data from a user includes a series of questions on sleep habits and other behaviors of said user.

9. The breathing self-assessment system as set forth in claim **1** wherein said mechanism to analyze and generate a risk profile removes inadequate or bad electronic signal data.

10. A data recording and communication device for a breathing self-assessment system, which device comprises:

a microprocessor having a memory;

a sensor to receive breathing airflow from a cannula;

an electrical analog to digital converter to convert breathing airflow to electronic signal data;

a recorder to record said electronic signal data;

a wireless transmitter and receiver; and

a portable power supply.

* * * * *

专利名称(译)	用于家庭内部自我评估睡眠期间异常气流风险的系统		
公开(公告)号	US20180092571A1	公开(公告)日	2018-04-05
申请号	US15/723999	申请日	2017-10-03
[标]发明人	WOOD STEVEN M WYLIE PAUL ARDREY BILL MYERS ALEX		
发明人	WOOD, STEVEN M. WYLIE, PAUL ARDREY, BILL MYERS, ALEX		
IPC分类号	A61B5/087 A61B5/00 G06F19/00 A61B5/11		
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优先权	62/403977 2016-10-04 US		
外部链接	Espacenet USPTO		

摘要(译)

一种自我评估系统，用于评估睡眠期间出现异常气流的风险。该系统的优选实施例包括用于对使用者的鼻气流进行采样的套管。一种数据记录和通信设备，包括：传感器，用于接收来自套管的气流;转换器，用于将呼吸气流转换为电子信号;记录器，用于记录电子信号数据;以及发送器，用于无线传输所述电子信号数据。移动设备包括：接收器，用于接收从记录和通信设备发送的所述电子信号数据;数据库，用于存储电子信号数据;接口，用于从用户获得问卷数据;发送器，用于无线发送电子信号和问卷数据，以及存储或访问教学视频信息的机制。计算机服务器包括：接收器，用于接收从移动设备发送的电子信号数据和问卷调查数据;以及机制，用于根据接收的数据生成风险简档。