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(54) **SLEEP DIAGNOSTIC SYSTEM AND METHOD**

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

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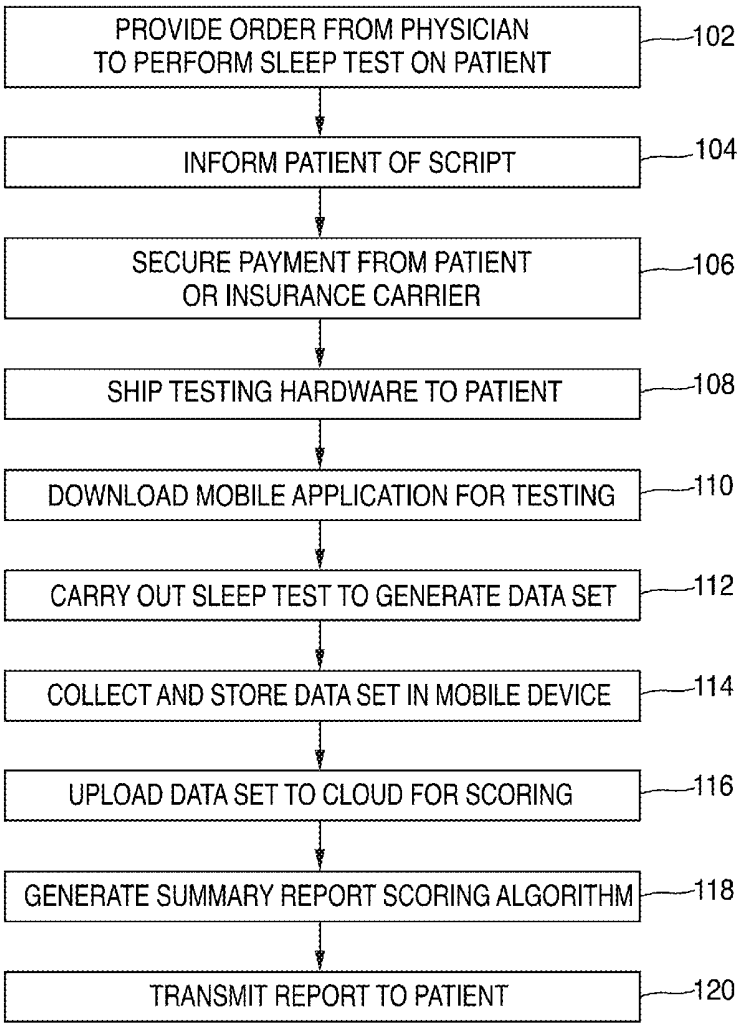
(57) **ABSTRACT**

A system and method for conducting a sleep test includes initiating a sleep test script, and providing the script to a patient. Testing hardware is shipped hardware from a provider to the patient, and instructions are provided to the patient for connecting the testing hardware to a mobile computing device. A mobile sleep application is downloaded and installed onto the mobile computing device. The testing hardware is connected to the testing hardware and to the mobile computing device, and the sleep test is conducted using the mobile sleep application operating on the mobile computing device.



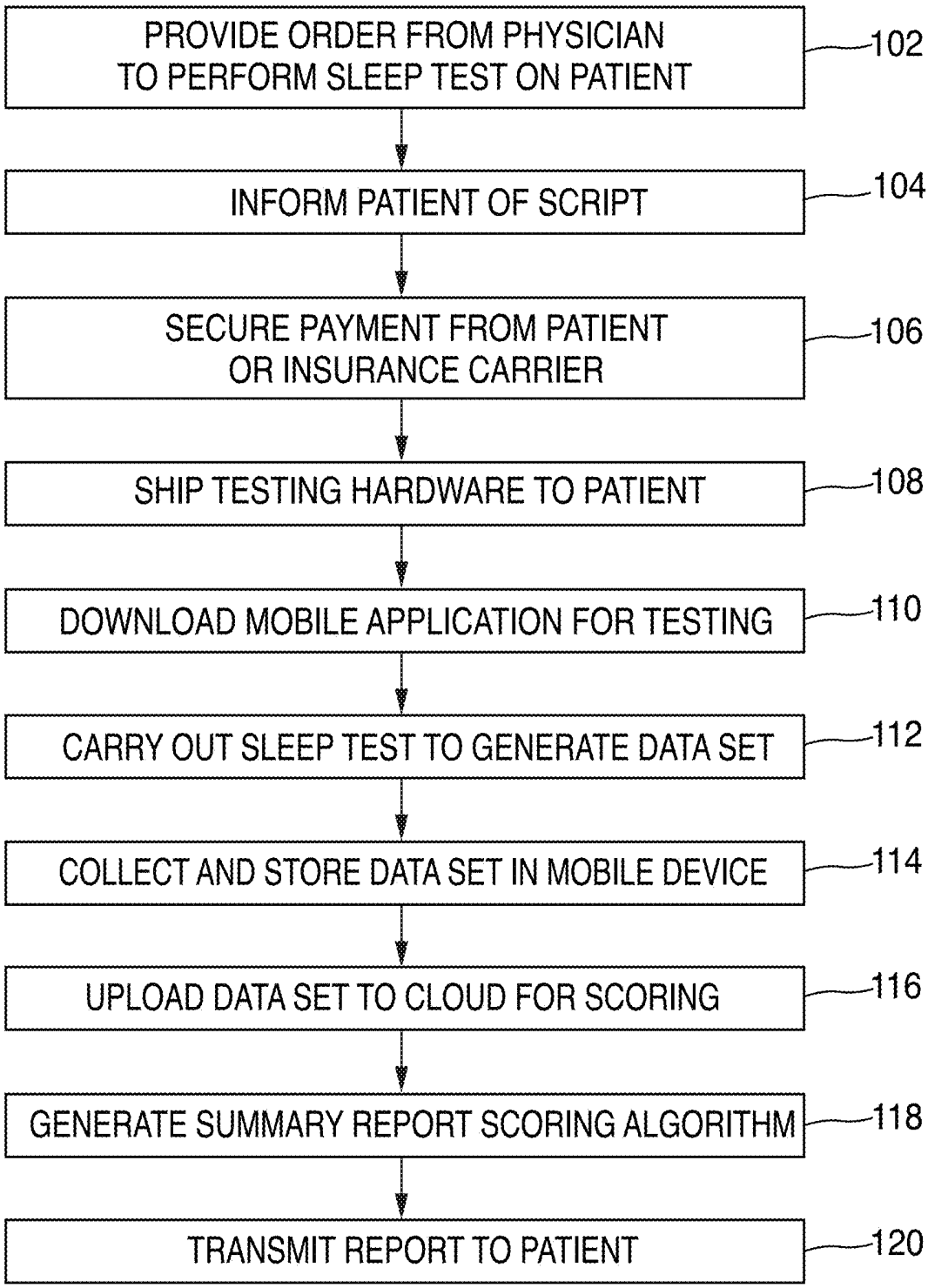

PROVIDE ORDER FROM PHYSICIAN TO PERFORM SLEEP TEST ON PATIENT
102
INFORM PATIENT OF SCRIPT
104
SECURE PAYMENT FROM PATIENT OR INSURANCE CARRIER
106
SHIP TESTING HARDWARE TO PATIENT
108
DOWNLOAD MOBILE APPLICATION FOR TESTING
110
CARRY OUT SLEEP TEST TO GENERATE DATA SET
112
COLLECT AND STORE DATA SET IN MOBILE DEVICE
114
UPLOAD DATA SET TO CLOUD FOR SCORING
116
GENERATE SUMMARY REPORT SCORING ALGORITHM
118
TRANSMIT REPORT TO PATIENT
120

FIG. 1

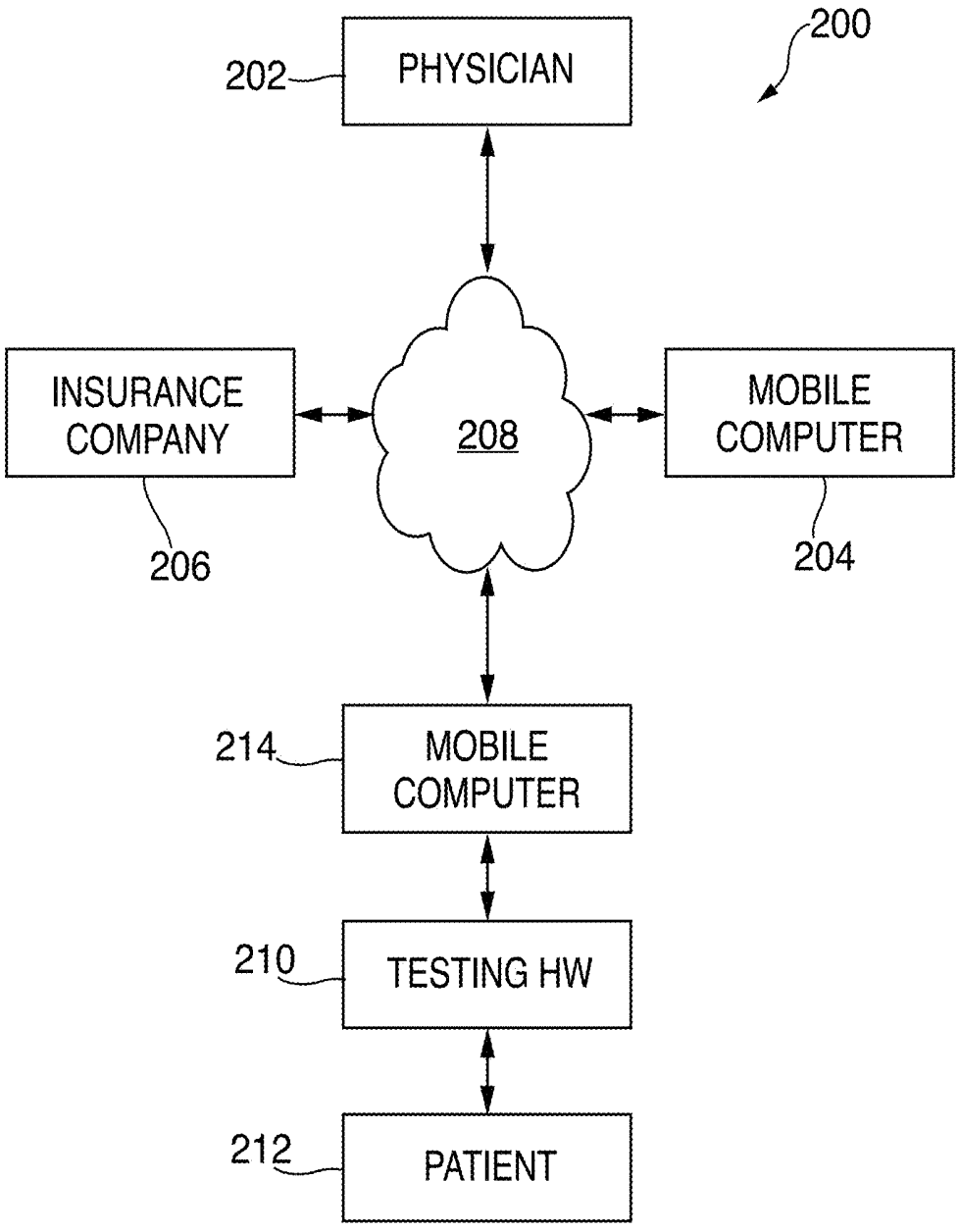

200
202
PHYSICIAN
INSURANCE COMPANY
206
208
MOBILE COMPUTER
204
214
MOBILE COMPUTER
210
TESTING HW
212
PATIENT

FIG. 2

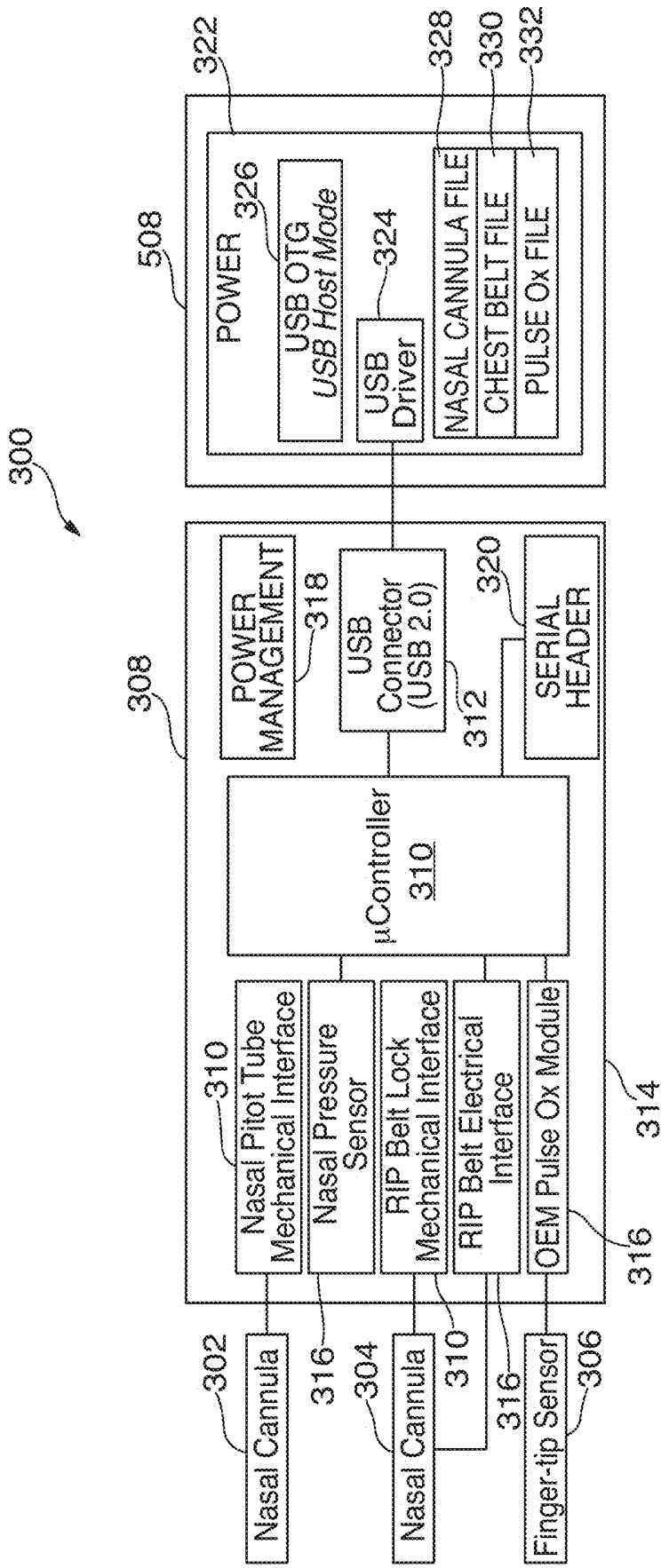

300
322
328
330
332
508
POWER 326
USB OTG
USB Host Mode
USB
Driver
324
NASAL CANNULA FILE
CHEST BELT FILE
PULSE Ox FILE
308
POWER
MANAGEMENT
318
USB
Connector
(USB 2.0)
312
320
SERIAL
HEADER
µController
310
310
Nasal Pitot Tube
Mechanical Interface
Nasal Pressure
Sensor
RIP Belt Lock
Mechanical Interface
RIP Belt Electrical
Interface
OEM Pulse Ox Module
314
316
316
316
302
304
306
Nasal Cannula
Nasal Cannula
Finger-tip Sensor

FIG. 3

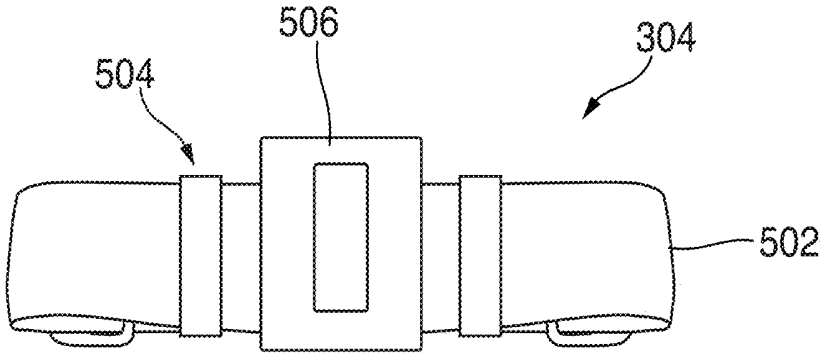


FIG. 4

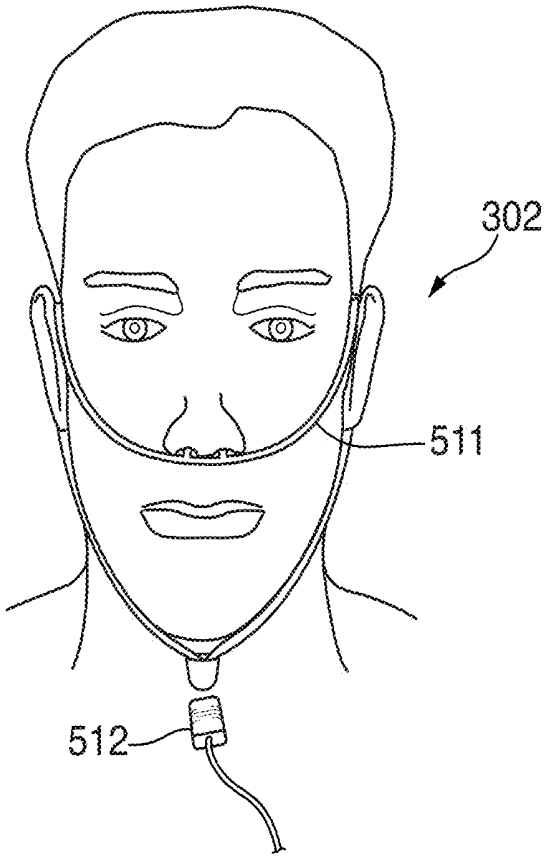


FIG. 5

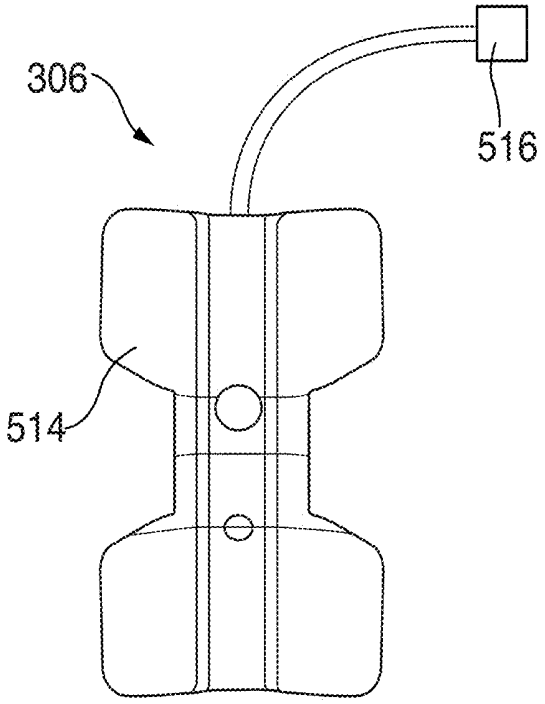


FIG. 6

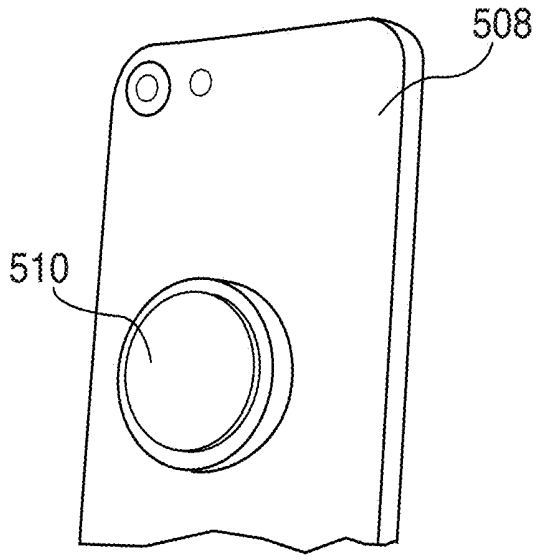


FIG. 7

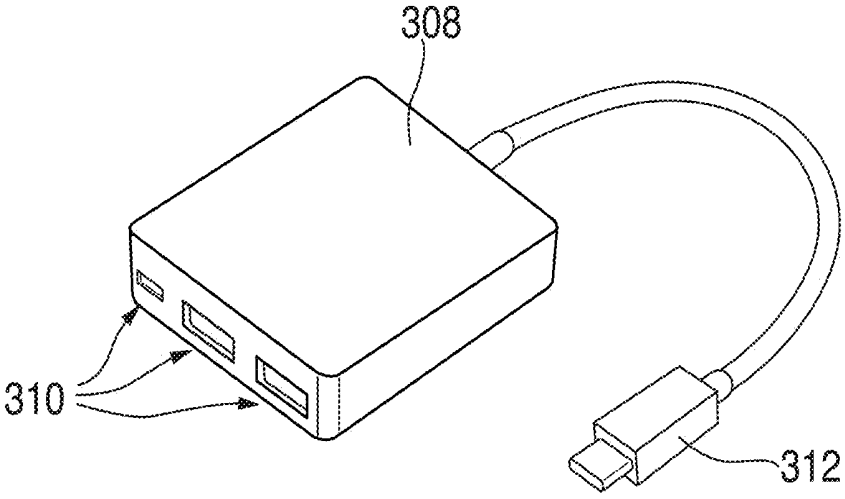

308
310
312

FIG. 8

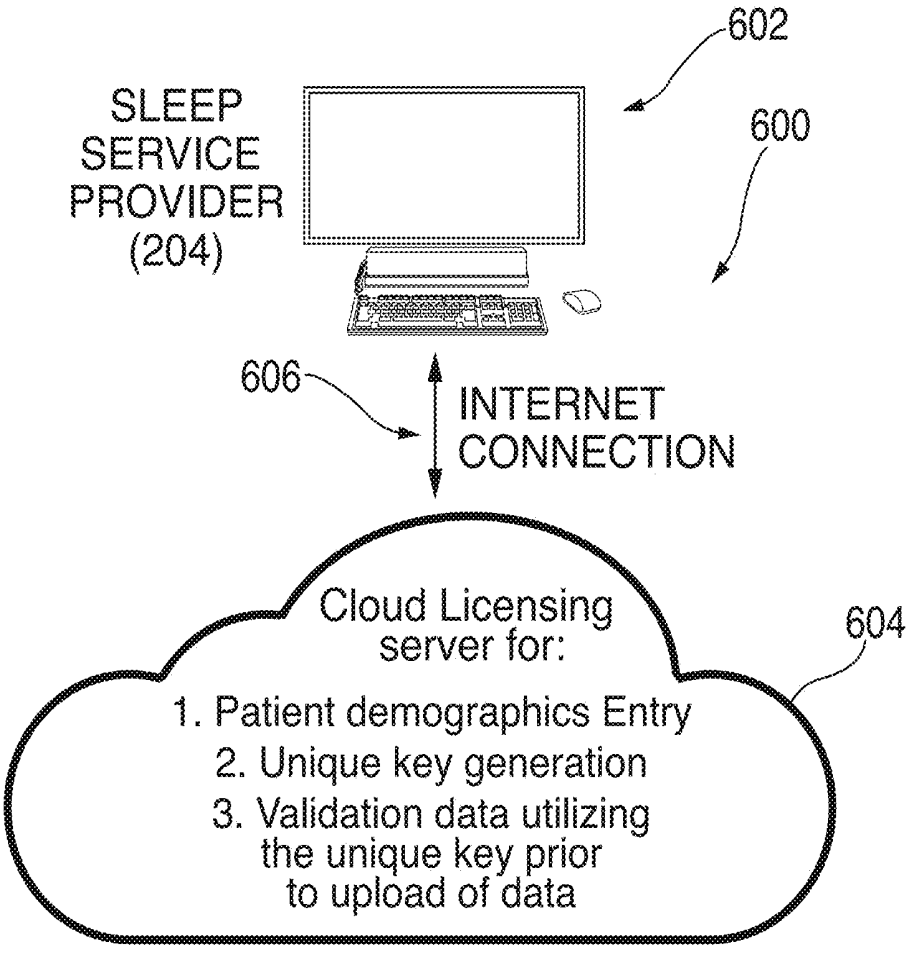

602
600
SLEEP SERVICE PROVIDER (204)
606
INTERNET CONNECTION
Cloud Licensing server for:
1. Patient demographics Entry
2. Unique key generation
3. Validation data utilizing the unique key prior to upload of data
604

FIG. 9

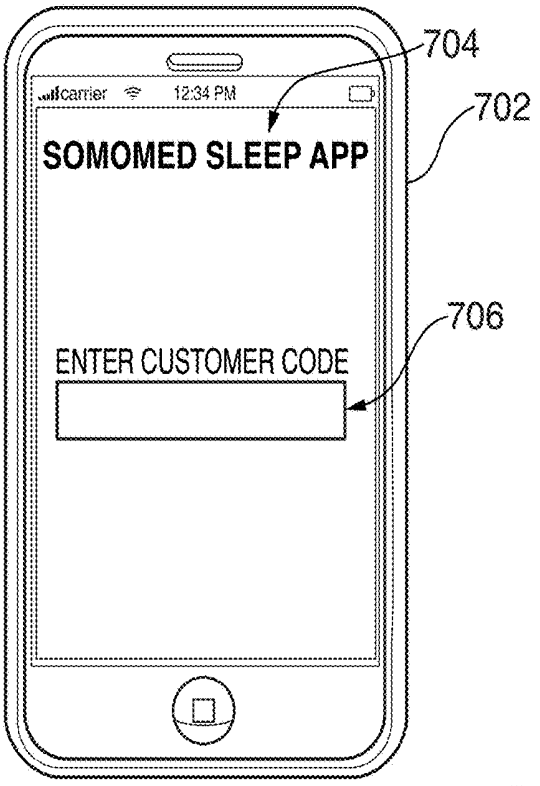


FIG. 10

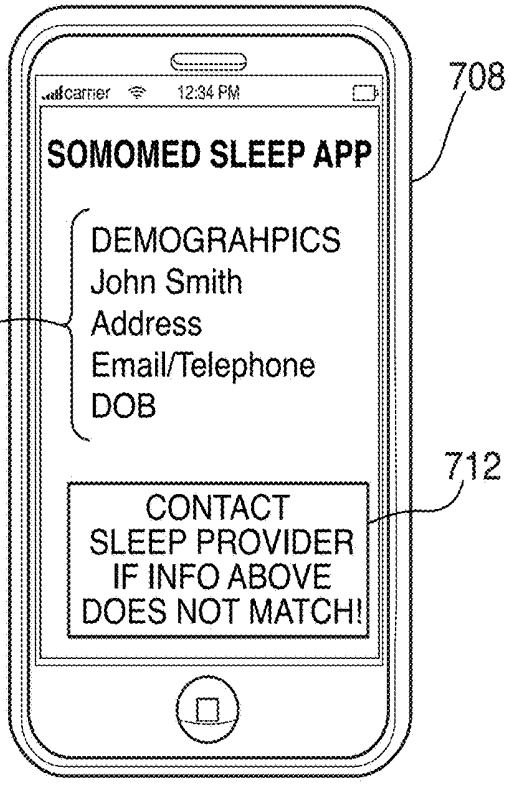


FIG. 11

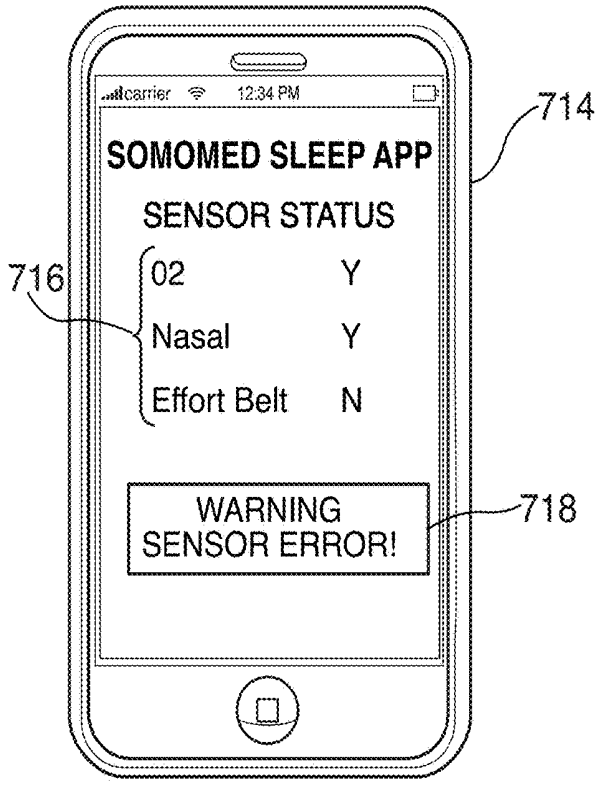


FIG. 12

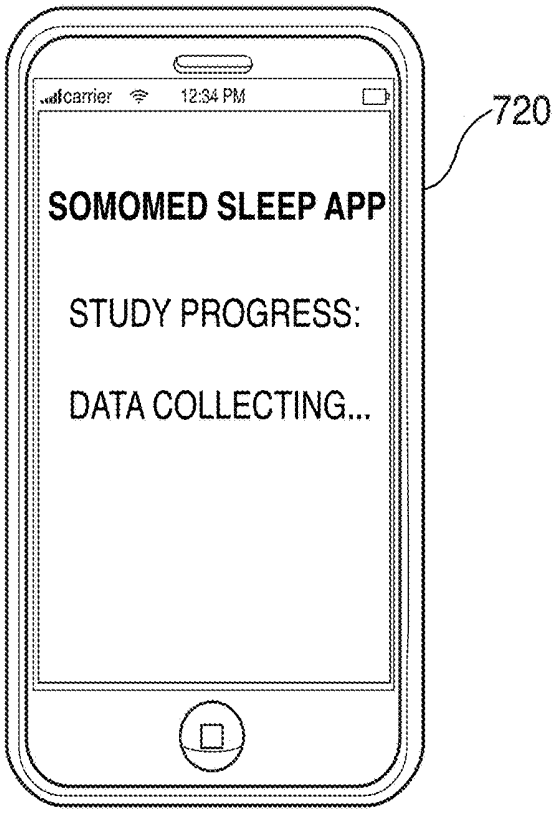


FIG. 13

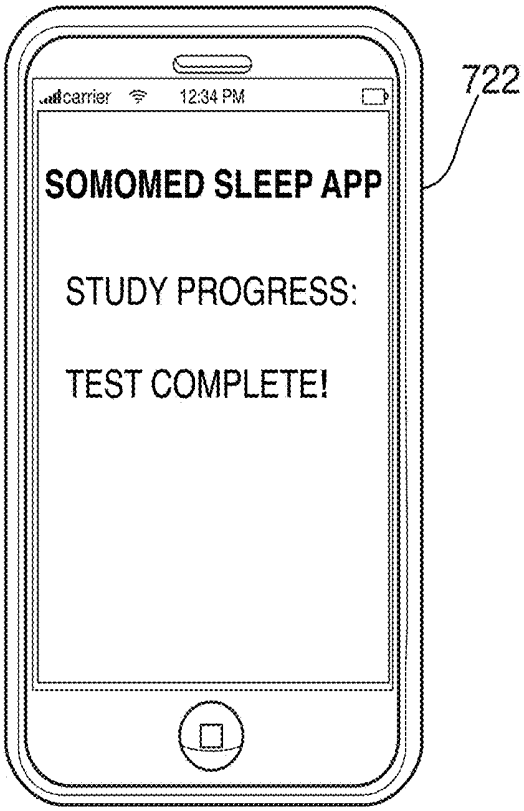


FIG. 14

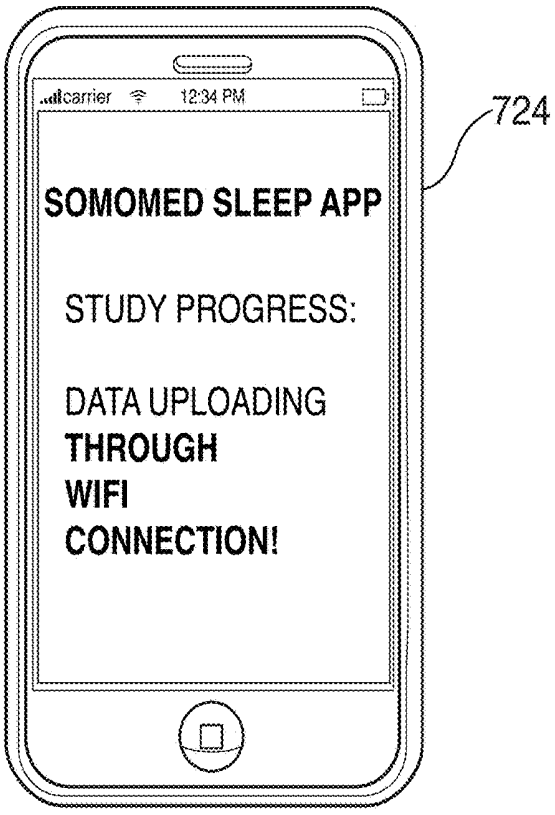


FIG. 15

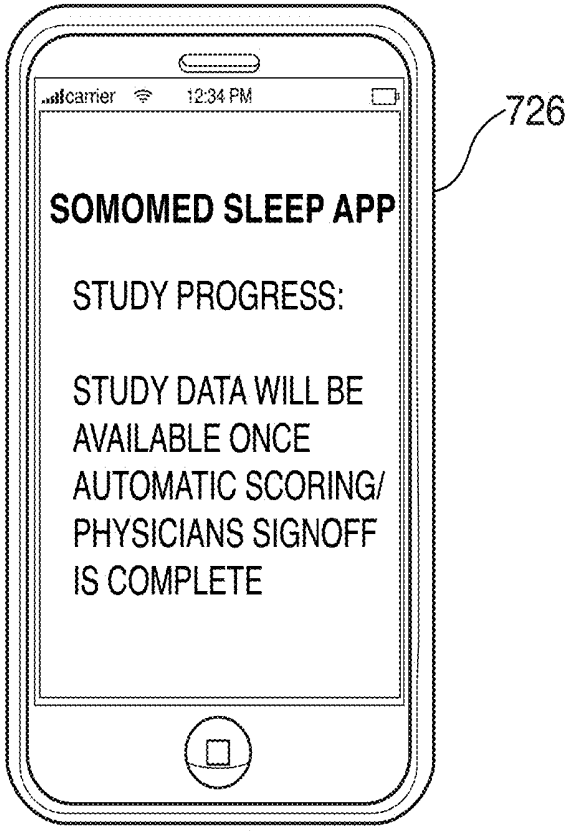

carrier
12:34 PM
SOMOMED SLEEP APP
STUDY PROGRESS:
STUDY DATA WILL BE AVAILABLE ONCE AUTOMATIC SCORING/ PHYSICIANS SIGNOFF IS COMPLETE
726

FIG. 16

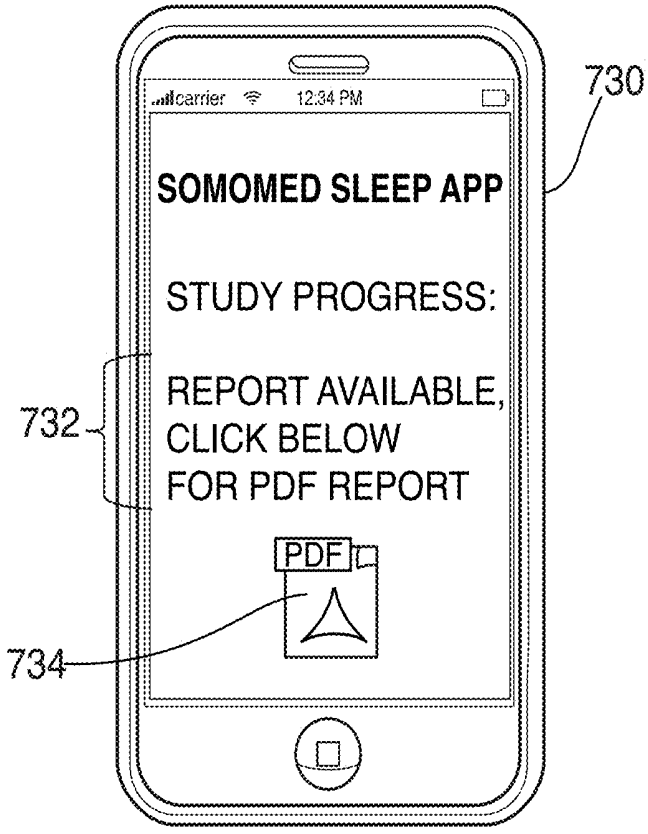

carrier
12:34 PM
SOMOMED SLEEP APP
STUDY PROGRESS:
REPORT AVAILABLE, CLICK BELOW FOR PDF REPORT
PDF
730
732
734

FIG. 17

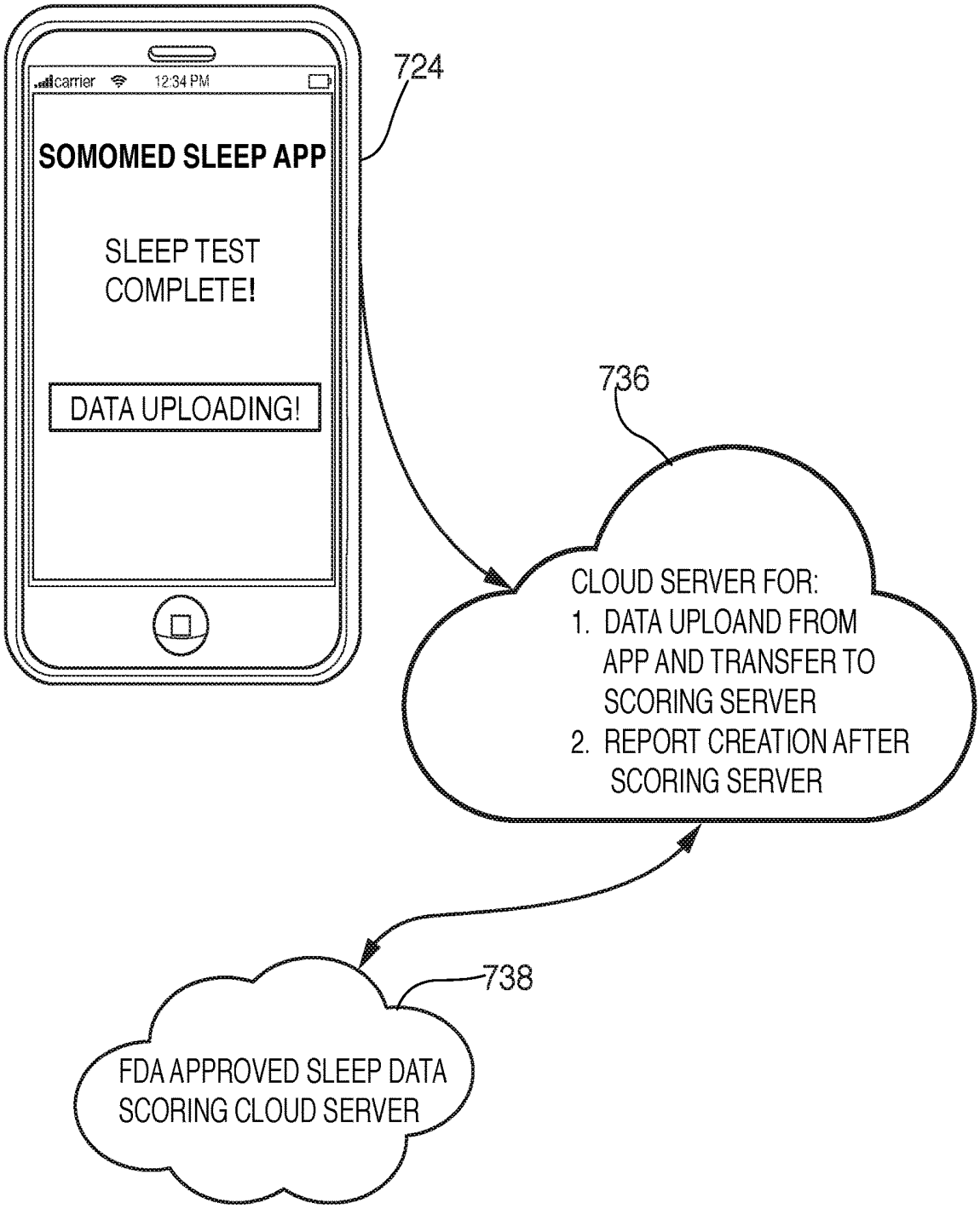

724
carrier
12:34 PM
SOMOMED SLEEP APP
SLEEP TEST COMPLETE!
DATA UPLOADING!
736
CLOUD SERVER FOR:
1. DATA UPLOAND FROM APP AND TRANSFER TO SCORING SERVER
2. REPORT CREATION AFTER SCORING SERVER
738
FDA APPROVED SLEEP DATA SCORING CLOUD SERVER

FIG. 18

SLEEP DIAGNOSTIC SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims the benefit of U.S. Provisional Patent Application No. 62/679,420, filed on Jun. 1, 2018, which is incorporated herein in its entirety by this reference.

BACKGROUND OF THE INVENTION

[0002] Approximately 65 Million American adults suffer from sleep disordered breathing conditions where 1 in 5 adults has obstructive sleep apnea or central sleep apnea conditions. Of this population, approximately only 1 in 15 adults are properly screened, tested and then treated for this condition, but leaves a large gap of patients untested. As the population continues to increase and obesity prevalence increases, sleep disordered breathing conditions will continue to rise as a medical condition required to be treated. Untreated sleep disordered breathing conditions has been shown to increase chance of heart disease, stroke, diabetes, hypertension, depression, cancer, and other medical conditions.

[0003] The current method of evaluating and screening patients for sleep apnea utilizes two different testing methodologies, either an in-lab based monitored sleep test or an unmonitored home sleep test. For many years the gold standard of sleep diagnostic testing was determined to be an in-lab study, but due to customer convenience and cost to the patient, home sleep testing was introduced to the market approximately 5 years back and has been gaining acceptance through the medical community. Though a home sleep test cannot evaluate patients for the full spectrum of sleep disorders, it is an effective tool in screening patients for obstructive sleep apnea. Most devices in this space consist of a small electronic module capable of detecting body signals such as, pulse rate, blood oxygen level, breathing effort, and nasal air flow.

[0004] The data from the overnight sleep test is stored on the module and the patient either ships the unit back to the service provider or drops the unit off physically. Once the provider receives the device, they will manually download the data from the device into a scoring program capable of viewing and commenting on various sleep markers. Once the full night's data is evaluated, the results of the data are summarized and sent to a board certified sleep physician in order to review and sign off on the report and treatment plan. This report is then typically sent back to the ordering physician and/or patient directly for further review. The following steps summarize the typical process, which includes an from a physician to sleep lab or home study provider, contacting the patient to inform them of the script receipt and scheduling of test, the provider obtaining authorization from the patient's insurance company, if required, picking up or shipping a home sleep test device from the provider office to the patient. The patient then utilizes the device for 1-2 nights to acquire data, and either drops off or ships device back to provider. The provider scores data and sends to sleep physician for review. The provider then sends signed results back to the referring physician.

BRIEF SUMMARY OF THE INVENTION

[0005] With the proliferation of smart phone use globally, there is a consensus that introducing medical based testing through the smart phone would be able to screen and reach a larger section of the population more cost effectively. The current estimate of smart phone users globally by the end of 2018 is expected to be 2.5-3 billion people.

[0006] The present disclosure describes an alternative and novel system and method for home sleep testing. In one embodiment, patients are diagnosed utilizing a patient's smart phone to conduct the sleep test at home by collecting, preprocessing and communicating sleep data and conclusions between the patient and the doctor or data center that processes the data. This novel approach includes at least the following steps:

[0007] (a) Order from physician to sleep lab or home study provider, which is optional and may also be initiated by the prospective patient's desire to determine their quality of sleep;

[0008] (b) Patient is contacted to inform them of the script receive and scheduling of test, which can alternatively include the patient's downloading of a smartphone app and order of any testing hardware that is required;

[0009] (c) Provider obtains authorization from their insurance company or patient pays cash for test;

[0010] (d) Provider ships out ancillary leads to plug into their smart phone jack;

[0011] (e) Patient downloads app with single use license from the lab;

[0012] (f) Data is automatically uploaded from patients phone to a scoring algorithm stored in the cloud and scored;

[0013] (g) Summary report is generated for physician to sign off on, which is optional and may be replaced, for certain tests and in certain countries, with an automated processing and report form the sleep analysis system server, and

[0014] (h) Results are transmitted to patients physician and sent back via smart phone app to patient.

[0015] It is noted that, globally, in other markets outside the US, a physician sign off may not be required, which may also be the case or an option for patients that pay for their service without contribution from an insurance company. The current home sleep test units and sensors are shipped to a patients home and typically weigh 3 lbs or more with the unit, sensors and packaging. The new implementation, as described in the present disclosure, saves on shipping costs by only having to ship out the sensors themselves, which reduces shipping costs to less than 0.25 lb. In order to provide home sleep testing to a larger percentage of the population, a mobile app based sleep testing solution can provide effective testing, scoring, and clinical results to patients in a cost effective manner than existing portable sleep testing units.

[0016] In one aspect, therefore, the present disclosure describes a method for conducting a sleep test. The method includes initiating a sleep test script, and providing the script to a patient. Testing hardware is shipped hardware from a provider to the patient, and instructions are provided to the patient for connecting the testing hardware to a mobile computing device. A mobile sleep application is downloaded and installed onto the mobile computing device. The testing hardware is connected to the testing hardware and to the

mobile computing device, and the sleep test is conducted using the mobile sleep application operating on the mobile computing device.

[0017] In another aspect, the present disclosure describes a sleep diagnostic system that includes a set of testing hardware, the testing hardware comprising: a plurality of sensors adapted for mounting onto a patient's body, the plurality of sensors configured to provide signals indicative of patient parameters, and a sensor interface device, the sensor interface device being connectable via mechanical and electrical connections to the plurality of sensors, the sensor interface device being adapted to further mechanically and electrically connect to a mobile computing device. A mobile sleep application stored on non-transient computer media includes computer executable instructions that are executable by a processor of the mobile computing device, and a cloud environment operating on at least one cloud server, the at least one cloud server being communicatively connected with the mobile computing device for data transfer therebetween. During a sleep test, information acquired form the plurality of sensors is stored as a data set on a memory device of the mobile computing device and transmitted to the cloud environment upon test completion for processing.

[0018] In yet another aspect, the disclosure describes a method for conducting a sleep test for a patient at home. The method includes receiving at a provider a prescription from a physician relative to a patient for conducting a sleep test, collecting patient information at the provider relative to the patient, providing information to the patient from the provider relative to downloading and installing onto a mobile computing device of the patient a sleep monitoring mobile application sending to the patient from the provider a set of testing hardware, the set of testing hardware including a plurality of external sensors and a sensor interface device, the plurality of external sensors being connectable via wired connections to the sensor interface device, and the sensor interface device being connectable via wired connection to the mobile computing device of the patient, wherein the patient is adapted to connect the set of testing hardware to the mobile computing device, conduct a sleep test, and acquire a set of data that is stored in encrypted form within the sleep monitoring mobile application, and receiving at the provider the set of data after completion of the sleep test.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0019] FIG. **1** is a flowchart for a method in accordance with the disclosure.

[0020] FIG. **2** is a schematic for a sleep diagnostic system in accordance with the disclosure.

[0021] FIG. **3** is a diagram for one embodiment of a sleep diagnostic system in accordance with the disclosure.

[0022] FIG. **4** is an outline view of a piezo sensor in accordance with the disclosure.

[0023] FIG. **5** is an outline view of a nasal air flow pitot tube assembly in accordance with the disclosure.

[0024] FIG. **6** is an outline view of a pulse oximeter in accordance with the disclosure.

[0025] FIG. **7** is a mobile device mount in accordance with the disclosure.

[0026] FIG. **8** is an exemplary embodiment of a sensor interface device in accordance with the disclosure.

[0027] FIG. **9** is a schematic diagram of a provider system in accordance with the disclosure.

[0028] FIGS. **10-17** are exemplary user interface screens for a mobile application in accordance with the disclosure.

[0029] FIG. **18** is a flow diagram of a process in accordance with an embodiment of the present disclosure.

DETAILED DESCRIPTION OF THE INVENTION

[0030] With the proliferation of smart phone use globally, there is a consensus that introducing medical based testing through the smart phone would be able to screen and reach a larger section of the population more cost effectively. The current estimate of smart phone users globally by the end of 2018 is expected to be 2.5-3 billion people.

[0031] The present disclosure describes a system and method for conducting a home sleep test model to diagnose patients utilizing a patient's smart phone to conduct the sleep test at home by collecting, preprocessing and communicating sleep data and conclusions between the patient and the doctor or data center that processes the data.

[0032] A method for conducting the sleep test in accordance with the disclosure is shown in the flowchart of FIG. **1**. The method includes providing or acquiring an order from a physician to a sleep lab or home study provider to perform a sleep test on a patient at **102**. It is contemplated that the physician order may be optional for situations where the patient may initiate a test on their own if they desire to determine the quality of their sleep. The patient is contacted to inform them of the script at **104**. Patient contact at **104** may also convey other useful information to the patient such as instructions for receiving and scheduling a sleep test, directions for downloading a smartphone app that will be used during testing, instructions for fitting and wearing the various sensors, directions on setting up the test, information on how sleep data will be processed and the results of the test communicated to the patient, and other useful and relevant information. Patient contact may also be used to receive information on the appropriate size and type of sensors that will best suit the patient.

[0033] If applicable, the provider may obtain authorization from the insurance company of the patient, or patient may pay for the test themselves at **106**. The provider may then ship to the patient hardware in the form of a sensor interface device, the sensors themselves, and other supplies needed for the patient to use the sensors at **108**. Before conducting the test, the patient can download the provider's mobile phone application at **110**, which can include a single-use license from the provider. The patient can then carry out the test at **112**, which will result in a body of data from the various sensors being acquired and saved in the mobile phone via the mobile application at **114**. The body of data, or data set, is then uploaded from the patient's mobile phone to a secure cloud at **116**, where a scoring algorithm that is stored in the cloud can sort, normalize and score the data automatically. A summary report is generated at **118** that is made available for a physician to view and authorize. It is contemplated that the physician's review and authorization is optional and may be replaced, for certain tests and in certain countries, with an automated processing and report form the sleep analysis system server operating in the cloud. The results are then transmitted to the patient via the mobile app at **120**.

[0034] It is noted that, globally, in markets outside the U.S., a physician sign off may not be required, which may also be the case or an option for patients that pay for their service without contribution from an insurance company. The current home sleep test units and sensors are shipped to a patients home and typically weigh 3 lbs or more with the unit, sensors and packaging. The new system and method in accordance with the disclosure leverages the computing and communication capabilities of a mobile computing device such as a mobile phone, which also include internal sensors, and augments those capabilities with other sensors that are sent to the patient and that are connectable to the mobile phone. In this way, shipping costs and complexity for conducting the test is reduced to the point where the patient can administer the test on themselves at home.

[0035] A schematic for a sleep diagnosis system **200** in accordance with the disclosure is shown in FIG. **2**. The system **200** includes the various parties that may participate in the method described and shown in FIG. **1**, which can include a physician **202**, a provider **204**, optionally, an insurance company or carrier **206**, and a secure cloud environment **208**. The cloud **208** may facilitate communication and exchange of information between the physician **202**, the provider **204** and the insurance carrier **206**. As described above, the physician **202** may generate a prescription for a sleep test, information for which may be disseminated to the provider **204** and the insurance company **206** by traditional channels, for example, mail or facsimile transmission, or may alternatively be transmitted electronically through the cloud **208** in a secure fashion. Authorization of the prescription, and generation of an order with the provider **204** may also be shared in the same fashions to generate a shipment of instructions and sensor hardware **210** from the provider **204** to a patient **212**. The sensor hardware **210**, which after use may be returned to the provider **204**, interfaces between the patient **212**, to acquire vital information about the patient during the sleep test, and the patient's mobile computing device **214**, for example, smart phone, which acquires and transmits the data thus acquired to the cloud **208**.

[0036] In order to provide home sleep testing to a larger percentage of the population, a mobile app based sleep testing solution installed and operating on the mobile computer **214** provides effective testing, scoring, and clinical results to patients in a cost effective manner than existing portable sleep testing units.

[0037] In one embodiment, the testing hardware **210** can include sensors and appropriate wiring to connect the sensors to the mobile computer **214**. These sensors can include both external sensors mounted onto the patient's body, and also internal sensors of the mobile computer. In the illustrated embodiment, external sensors can include a blood oxygen level sensor, a breath rate sensor, and a nasal air flow sensors, all with adapters that allows connection of the sensors to clothing or around a patients face. These sensors, as well as onboard sensors of the mobile device, can provide sufficient information for a diagnosis based on the results of a sleep test. Various examples of external sensors that are contemplated for use in a system in accordance with the disclosure are described in the paragraphs that follow.

[0038] Before turning to the sensors, various system diagrams on the connections and operation of the mobile computer will be described. A block diagram for a sleep diagnosis system **300** is shown in FIG. **1**. The system **300** includes external sensors such as a nasal air flow sensor or nasal cannula **302**, a respiratory rate sensor **304**, and a blood oxygen level sensor **306**, examples of which are shown in FIGS. **5**, **4** and **6**, respectively.

[0039] For example, the respiratory sensor **304** may include an adjustable belt **502** word around the torso of the patient. The belt **502**, shown in FIG. **4**, may include a piezo-sensor **504** that provides a signal when the patient takes a breath. A holster **506** may also be connected to the belt to mount the smart phone **508** (see FIG. **7**) via a magnetic clip **510** to the belt **502** and, thus, to the patient during the test. The breath rate and chest movement are measured by a piezo electric strain gauge mounted to a flexible/elastic belt assembly. As the chest moves during breathing, the sensor will pic the breath movement and convert this signal to an electrical voltage which can be recorded by the cell phone utilizing the app.

[0040] The nasal cannula **302** shown in FIG. **5** may include tubing **511** that provides air to the patient and also a flow meter **512** for measuring the breathing rate of the patient during the test. The nasal air flow pitot tube assembly also utilizes a piezo electric sensor to detect the nasal air flow from the patient, and can further include a pressure transducer or pressure transmitter that detects the flow of air as the subject is breathing during sleep. These signals are converted to voltage signals, which can be recorded by the cell phone utilizing the app. This new version of the air flow sensor will have over ear pieces that is part of the tubing assembly, which keeps the nasal cannula within the nostrils without coming out during sleep or head movement. Traditional cannulas just wrap the tubing over the patients ears, but patients manually will have to apply tape onto their faces to keep the tubing in place during the nights study.

[0041] Finally, the blood oxygen sensor **306**, shown in FIG. **6**, may include a finger sensor **514** that measures blood oxygen level during the test and provides a signal to a connector **516**. The **02** is detected by a pulse oximeter utilizing light in different wavelengths to detect the flow of oxygenated blood, this will provide output in a current waveform which will be recorded by the cell phone utilizing the app.

[0042] These and other sensors are connected via wiring to a sensor interface device **308**, an example of which is shown in FIG. **8**, and block, diagram for which is shown in FIG. **3**. The sensor interface device **308** fulfills a dual role—it provides a mechanical connection between the sensors **302**, **304** and **306**, through sensor plugs **310** (FIG. **8**), and the mobile computer, through a connector plug **312** while also powering the sensors, and it also includes an integrated controller **310** that includes the various sensor transfer functions to decode sensor signals and provide digital information indicative of the sensor signals to a USB (universal serial bus) interface **312**.

[0043] More specifically, the interface device **308** includes a chassis **314** onto which the micro-controller **310** is mounted and operates. Power is provided from the smartphone **508** through the USB interface **312** to power the sensors and the controller. The mechanical interfaces or plugs **310** are attached to the chassis **314**, and signals from the sensors are provided through electrical interfaces **316** directly to the micro-controller **310**. Onboard power management devices **318** for conditioning and controlling electrical power operating the various components, and headers

320 for managing the transfer of digital information to the smartphone **508** can also be used on the chassis **314**.

[0044] The smartphone **508** may include an application environment **322** that includes a USB interface or driver **324** operating to convey information containing sensor readings from the micro-controller **310** into the environment for processing and storage. Specifically, a host controller **326** may receive, categorize and store information from the various sensors into dedicated memory locations for each sensor, for example, a nasal air flow data location **328**, the breathing sensor data location **330**, and the blood oxygen data location **332** while the test is underway. The host controller **326** may also monitor and record information during a test from onboard sensors of the smartphone **508**, and store information from those onboard sensors as well in dedicated memory locations.

[0045] It should be appreciated that the sleep mobile application, and also any other modules discussed herein, in certain embodiments, may be embodied as a computer application or program. The computer program may exist in a variety of forms both active and inactive. For example, the computer program can exist as software program(s) comprised of program instructions in source code, object code, executable code or other formats; firmware program(s); or hardware description language (HDL) files. Any of the above can be embodied on a computer readable medium, which includes computer readable storage devices and media, and signals, in compressed or uncompressed form. Exemplary computer readable storage devices and media include conventional computer system RAM (random access memory), ROM (read-only memory), EPROM (erasable, programmable ROM), EEPROM (electrically erasable, programmable ROM), and magnetic or optical disks or tapes. Exemplary computer readable signals, whether modulated using a carrier or not, are signals that a computer system hosting or running the present teachings can be configured to access, including signals downloaded through the Internet or other networks. Concrete examples of the foregoing include distribution of executable software program(s) of the computer program on a CD-ROM or via Internet download. In a sense, the Internet itself, as an abstract entity, is a computer readable medium. The same is true of computer networks in general.

[0046] With respect to onboard sensors, for example, the mobile application may further utilize the phone gyroscope, the body position will also be determined during sleep. This is handled through a holding plate **510** (FIG. **7**) on the belt **502** (FIG. **4**) which keeps the phone **508** on the patient's chest during the nights study. Further, utilizing the built in microphone of the smartphone, we can also capture sounds typically during a patients sleep patterns which is typically snoring. This snoring signal would overlay on the breathing effort to compare the signals. Depending on the location of the phone on the patient's body, an accelerometer may also be used to measure vibration caused by the snoring in case the microphone is muffled under the patient's covers while sleeping.

[0047] The various external sensors may be integrated into one single connector for an iPhone lightning jack or micro usb connector capable of providing power to all four sensors through the phone. These two connector types would support all standard smart phone jacks. It is also a further development to isolate the individual sensors into a separate battery based Bluetooth module to enable communications between the sensors and the app utilizing wireless communications. The phone circuit power will also provide any necessary voltage for the individual sensors. There will be a separate pigtail connectors coming off the base unit with iPhone lightning jack, micro usb, or other so that this single connector can be used with multiple phone types.

[0048] It is a further embodiment of the present disclosure to have a licensing key server which will allow the sleep service providers to upload information on a patient including name, address, date of birth, contact info, email, Insurance info etc. After a patient profile has been created, the sleep lab personnel can then create a unique security key which will be valid for a single or two night usage depending on selection which will then be texted/emailed to the patient directly. This unique key will have to be entered into the app before further functions are enabled and the sleep diagnostic test can begin.

[0049] An exemplary embodiment of a system that can accomplish having all data within the app to remain encrypted for security HIPPA compliance of patient specific medical data is shown in FIG. **9**, which illustrates a system **600** for secure transfer of data. In this embodiment, all PHI (personal health information) will remain encrypted within the app and in all transmissions between the mobile phone and the cloud servers utilized to score and create a clinical report will remain encrypted. The encapsulation of this PHI data will be created using "trusted" security keys between each individual app and the cloud utilizing specific secret keys to establish and ensure data integrity and proper transfer. Specifically, a computer system **602** of the service provider may communicate with a server **604** in the secure cloud, for example, the cloud **208** (FIG. **2**) through a direct internet connection **606**. The server **604** may track patient information, generate unique keys, and validate any patient data received against the patient information and after verifying the key to ensure patient confidentiality and data accuracy.

[0050] A further aspect of the present disclosure is a mobile application that provides screens or user interfaces to allow the user to ensure security by utilizing a secret key, provide instructional details on how to connect the sensors to their body and phone, to provide tools to determine whether or not the sensors are functioning and/or are connected properly, to validate whether the phone collected sleep data properly and consistently during a sleep session or over a predefined period, for example, overnight, provide diagnostic tools and messages to provide feedback to the user while either collecting, processing, or uploading data, to provide a report formatted with the test results through the app once scored, and other features. Exemplary views of such user interfaces are provided in FIGS. **10-17**.

[0051] More specifically, an initial screen **702** is shown in FIG. **10**. The initial screen **702** and the remaining screens that are discussed herein may be coded in any appropriate method such that they are presented to a user for input and output of information before, during and after the test is conducted. With reference to the initial screen **702** shown in FIG. **10**, the screen may include a title block **704** and an entry field **706** into which the user may enter, for example, using the smartphone's text input functionality, a customer code or other identifier provided to the patient by the provider. The customer code at **706** may also include or embody an encryption key and also license information for a single use of the app by the patient. Upon entry of the

customer code, the patient is presented with a patient information screen **708**, shown in FIG. **11**.

[0052] The patient information screen **708** presents to the patient the demographic and identifying information **710** that the provider has on file for the particular patient, for verification, and prompts the user to contact the provider using a banner **712** to contact the provider in the event information at **710** is in any way inaccurate. Upon confirmation of the patient's information by the patient, an initiation screen **714** is presented. At the initiation screen, the application may first diagnose the connective state and operation of the various external sensors that will be used during the test, and provide a list or dashboard **716** that lists the various sensors that are required and indicate an online state or condition of each sensor. In the illustrated example, a "Y" or "N" is used to qualitatively characterize the condition of each sensor, but any other method can be used that includes visible and/or audible prompts generated by the application. In the event one sensor is not reporting a condition that is suitable to initiate the test, a warning **718** is displayed. The warning may be selectable to launch a tutorial to aid the user in properly connecting the sensors to their smartphone using the testing hardware that was supplied to the patient by the provider.

[0053] When all the sensor warnings have been cleared, for example, by ensuring that all sensors are connected properly, the test may be initiated. During the test, a progress screen **720** as shown in FIG. **13** may inform the user that data is being collected. Upon completion of the test, a completion screen **722** may inform the user that the test has been completed, as shown in FIG. **14**, and that the collected data is being uploaded at a status screen **724** in a secure fashion, as shown in FIG. **15**. Upon successful uploading of the data, an information screen **726** may provide information to the patient through a banner **728** or other method, informing the patient of the signoff process data processing will follow, e.g., that the data will become available after a physician's signoff, as shown in FIG. **16**. When the data processing and report compilation is complete, the application may provide a notification to the user to access the application and, in the application, provide a results screen **730** that includes a banner **732** informing the user that the data processing is complete and providing a download link **734** for the user to download, save and view the results of the test.

[0054] While the data is uploading at the status screen **724**, also shown in FIG. **18**, the data may be uploaded from the user's mobile phone in an encrypted fashion directly to a cloud server **736**. The uploading can be carried out in any traditional fashion using wireless data signals transmitted over an internet connection. At the cloud server **736**, the data may be checked for completeness and sent to an automatic scoring server, which may process or preprocess the data to determine whether any trends can be surmised form the data. This process may be carried out automatically. The observations of the scoring server may then be used to automatically compile a sleep report for the particular patient based on the particular data set that was provided, and the sleep report may be sent from the scoring server to an approved scoring server **738** for final validation of the conclusions. When the final validation is complete, the report may optionally be provided to a physician for final review and approval before being returned to the patient.

[0055] In this respect, in one aspect, the present disclosure describes transmitting the collected data securely and in an encrypted format to a cloud based FDA approved algorithmic software in order to analyze and mark specific sleep events within the patient's home sleep test. This algorithm will analyze events such as apnea hypopnea index, snoring, or cardiac events. The data from the scoring algorithm will then be transferred to a data report processing server. The server will compile the event data and automatically generate a template report showing patients clinic assessment from the sleep test. In certain alternative embodiments, which may include additional sensor types such as EKG pickups, heartrate monitors, motion sensors, temperature sensors, perspiration sensors and the like, the algorithmic software may be used to additionally diagnose or provide conclusions related to seizure and brain activity during sleep, intensity of dreams, cardiac-related issues, and others.

[0056] It is another object of the present disclosure to utilize the data report processing server to automatically assess data as calculated by the scoring server and determine a patient's level of Apnea severity. The typical categories will be no apnea, mild apnea, moderate apnea, and severe apnea. The server will automatically format a sample clinical report as shown below, which includes information and represents an exemplary report that can either be generated automatically by the system and approved by an attending physician or provided for reference directly to the patient.

[0057] SomnoMed Sleep App

[0058] PATIENT NAME: Smith, John

[0059] PATIENT #: fad-JS-54

[0060] DATE OF BIRTH: 1955-08-19

[0061] REFERRER: Bob Jones MD

[0062] DATE OF STUDY: 2018-05-25

[0063] DATE OF INTERPRETATION: 2018-05-30 18:14:43

[0064] INTERPRETING PHYSICIAN: William Smith MD

[0065] TECH: Adam Warrant

[0066] HOME STUDY INTERPRETATION Physician Interpretation: Impressions

[0067] 1. Severe obstructive sleep apnea syndrome

[0068] 2. Snoring was recorded.

[0069] Recommendations

[0070] 1. The patient should be scheduled for a therapeutic sleep study with CPAP/Bilevel titration.

[0071] 2. Begin a medically supervised program to achieve and maintain ideal body weight.

[0072] 3. Sleep in a non-supine position

[0073] 4. Avoid bedtime alcohol and sedatives

[0074] 5. Avoid operating heavy equipment

[0075] 6. Avoid driving while feeling drowsy

[0076] Signed Electronically 2018-05-30 18:14:43

[0077] William Smith, M.D.

[0078] Pulmonary Disease/Sleep Medicine

[0079] Recommendation of this report should be communicated to the patient by the referring physician. The interpreting physician is available for questions regarding this report.

[0080] TECHNICAL REPORT:

[0081] Patient History:

[0082] Laura Smith is a 62 year old male who is 68 inches tall and weighs 185 pounds. The patient has a neck circumference of N/A inches, and a BMI of 27.8. The patient

complaints include snoring and fatigue. The patient has an Epworth Sleepiness Scale score of 5/24, and is not a user of tobacco products.

[0083] Medications: None listed

[0084] Allergies: NKDA

[0085] Day of Study: Medications: None listed Nap: No

[0086] Alcohol: No

[0087] Caffeine: Yes

[0088] Protocol:

[0089] The study was performed using the SomnoMed system. The channels recorded were: Airflow acquired with a nasal pressure cannula. Oxygen saturation (SpO2) was monitored using a pulse oximeter. Thoracic respiratory movements were recorded by respiratory inductive plethysmography. The tracing was scored using 30 second epochs. Hypopneas were scored per AASM definition.

[0090] Position:

[0091] The patient slept in the supine, right side position (s).

[0092] Sleep Latency:

[0093] The patient's sleep onset latency after lights out was 0.0 minutes. The Stage R sleep latency from sleep onset was N/A minutes.

[0094] Total Sleep Time:

[0095] Because of the nature of a home sleep test, a 100% of the data is scored as Stage 2 sleep.

[0096] Respiratory:

[0097] The patient was observed to have had a total number of 74 apneas and hypopneas with an AHI index of 34.7 per hour during total sleep time. The normal AHI index is less than 5 per hour. There were 24 obstructive apneas, 0 mixed apneas, 9 central apneas, and 41 hypopneas.

[0098] Oxygenation:

[0099] The patient had an average oxygen saturation of 93%. The minimum oxygen level was 75%. Pulse Oximeters are accurate to a low SpO2 of 70% (+,−3).

[0100] All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

[0101] The use of the terms "a" and "an" and "the" and "at least one" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The use of the term "at least one" followed by a list of one or more items (for example, "at least one of A and B") is to be construed to mean one item selected from the listed items (A or B) or any combination of two or more of the listed items (A and B), unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0102] Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

1. A method for conducting a sleep test, comprising:

initiating a sleep test script, and providing the script to a patient;

shipping testing hardware from a provider to the patient, and providing instructions to the patient for connecting the testing hardware to a mobile computing device;

downloading an installing a mobile sleep application onto the mobile computing device;

connecting the testing hardware to the mobile computing device; and

conducting the sleep test using the mobile sleep application operating on the mobile computing device.

2. The method of claim **1**, further comprising collecting a data set during the test, and uploading the data set to a cloud server.

3. The method of claim **2**, wherein the testing hardware includes a plurality of external sensors and a sensor interface device, and wherein the method further comprises connecting the plurality of external sensors to the sensor interface device, and connecting the sensor interface device to the mobile computing device such that signals and/or information provided from the plurality of external sensors is conveyed to the mobile computing device and is input into the mobile sleep application.

4. The method of claim **2**, further comprising scoring the data automatically in the cloud server.

5. The method of claim **1**, further comprising using at least one onboard sensor integrated with the mobile computing device during the sleep test.

6. The method of claim **5**, wherein the testing hardware includes a breathing sensor, a nasal airflow sensor and a blood oxygen sensor.

7. The method of claim **6**, wherein the at least one onboard sensor is selected from the group comprising a microphone and an inertial sensor.

8. The method of claim **7**, wherein the microphone is used to provide information relative to snoring during the sleep test, and wherein the inertial sensor is used to provide a patient position during the sleep test.

9. A sleep diagnostic system, comprising:

a set of testing hardware, the testing hardware comprising:

a plurality of sensors adapted for mounting onto a patient's body, the plurality of sensors configured to provide signals indicative of patient parameters, and

a sensor interface device, the sensor interface device being connectable via mechanical and electrical connections to the plurality of sensors, the sensor interface device being adapted to further mechanically and electrically connect to a mobile computing device;

a mobile sleep application stored on non-transient computer media, the mobile sleep application including computer executable instructions that are executable by a processor of the mobile computing device;

a cloud environment operating on at least one cloud server, the at least one cloud server being communicatively connected with the mobile computing device for data transfer therebetween;

wherein, during a sleep test, information acquired form the plurality of sensors is stored as a data set on a memory device of the mobile computing device and transmitted to the cloud environment upon test completion for processing.

10. The sleep diagnostic system of claim **9**, wherein the plurality of sensors includes a breathing sensor, the breathing sensor associated with an adjustable belt that is mountable around a torso of a user.

11. The sleep diagnostic system of claim **10**, further comprising a holster adapted to connect the mobile computing device to the adjustable belt.

12. The sleep diagnostic system of claim **11**, wherein the mobile sleep application further includes instructions for accessing and acquiring data from onboard sensors of the mobile computing device during the sleep test.

13. The sleep diagnostic system of claim **9**, wherein each of the plurality of sensors includes a wired connection that mates with a corresponding plug disposed on a chassis of the sensor interface device.

14. The sleep diagnostic system of claim **13**, wherein the sensor interface device includes a wired connection that is adapted to mate with a corresponding plug disposed on the mobile computing device.

15. A method for conducting a sleep test for a patient at home, the method comprising:

receiving at a provider a prescription from a physician relative to a patient for conducting a sleep test;

collecting patient information at the provider relative to the patient;

providing information to the patient from the provider relative to downloading and installing onto a mobile computing device of the patient a sleep monitoring mobile application;

sending to the patient from the provider a set of testing hardware, the set of testing hardware including a plurality of external sensors and a sensor interface device, the plurality of external sensors being connectable via wired connections to the sensor interface device, and the sensor interface device being connectable via wired connection to the mobile computing device of the patient, wherein the patient is adapted to connect the set of testing hardware to the mobile computing device, conduct a sleep test, and acquire a set of data that is stored in encrypted form within the sleep monitoring mobile application; and

receiving at the provider the set of data after completion of the sleep test.

16. The method of claim **15**, further comprising automatically scoring the set of data on a cloud server of the provider to generate a report, and transmitting the report to the physician for approval.

17. The method of claim **15**, wherein the set of data further includes data acquired by at least one onboard sensor of the mobile computing device.

18. The method of claim **17**, wherein the plurality of external sensors includes a breathing sensor, a nasal airflow sensor and a blood oxygen sensor.

19. The method of claim **18**, wherein the at least one onboard sensor is selected from the group comprising a microphone and an inertial sensor.

20. The method of claim **9**, wherein the microphone is used to provide information relative to snoring during the sleep test, and wherein the inertial sensor is used to provide a patient position during the sleep test.

* * * * *

专利名称(译)	睡眠诊断系统和方法		
公开(公告)号	US20190365315A1	公开(公告)日	2019-12-05
申请号	US16/428356	申请日	2019-05-31
发明人	RAMABADRAN, ARUN VIKRAM		
IPC分类号	A61B5/00 A61B5/087 A61B5/1455		
CPC分类号	A61B5/4818 A61B5/087 A61B2562/0219 A61B5/0022 A61B5/6831 A61B5/6898 A61B5/14552 A61B5/6823 A61B2562/0204 A61B5/0826 A61B5/1455 A61B5/4806		
优先权	62/679420 2018-06-01 US		
外部链接	Espacenet USPTO		

摘要(译)

一种进行睡眠测试的系统和方法，包括启动睡眠测试脚本，并将该脚本提供给患者。 测试硬件是从提供者运送到患者的硬件，并且向患者提供了用于将测试硬件连接到移动计算设备的指令。 将移动睡眠应用程序下载并安装到移动计算设备上。 测试硬件连接到测试硬件和移动计算设备，并且使用在移动计算设备上运行的移动睡眠应用来进行睡眠测试。