INTEGRATED SLEEP DIAGNOSTIC AND THERAPEUTIC SYSTEM AND METHOD

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CROSS REFERNCE TO RELATED APPLICATIONS

This application is a continuation in part of U.S. Patent application serial no. 11/266,899 filed on November 4, 2005.

BACKGROUND OF THE INVENTION

Nearly one in seven people in the United States suffer from some type of chronic sleep disorder, and only 50% of people are estimated to get the recommended seven to eight hours of sleep each night. It is further estimated that sleep deprivation and its associated medical and social costs (loss of productivity, industrial accidents, etc.) exceed $150 billion per year. Excessive sleepiness can deteriorate the quality of life and is a major cause of morbidity and mortality due to its role in industrial and transportation accidents. Sleepiness further has undesirable effects on motor vehicle driving, employment, higher earning and job promotion opportunities, education, recreation, and personal life.

Primary sleep disorders affect approximately 50 million Americans of all ages and include narcolepsy, restless legs/periodic leg movement, insomnia, and most commonly, sleep apnea. Sleep apnea is defined as the cessation of breathing during sleep. The three major types of sleep apnea are obstructive sleep apnea (OSA), central sleep apnea (CSA), and complex sleep apnea (CompSA). Of these three, CSA is rare, while OSA is the most common. CompSA is a relatively new disease state that manifests itself after therapy is applied. Patients with CompSA are characterized by the emergence of new CSA events after the application of Continuous Positive Airway Pressure (CPAP). OSA's prevalence in society is comparable with diabetes, asthma, and the lifetime risk of colon cancer. OSA is grossly under diagnosed; an estimated 80-90% of persons afflicted have not received a clinical diagnosis. OSA is characterized by repetitive pauses in breathing during sleep due to the obstruction and/or collapse of the upper airway (throat), usually accompanied by a reduction in blood oxygen saturation, and often

followed by an awakening to breathe (an apnea event). Respiratory effort continues during the episodes of OSA. Multiple episodes of apnea may occur in one night, causing sleep disruption. CSA is a neurological condition causing cessation of all respiratory effort during sleep, usually with corresponding decreases in blood oxygen saturation. In contrast to OSA, where there is respiratory effort from the brain stem but a physical blockage prevents inhalation of oxygen, in CSA the brainstem center controlling breathing shuts down, resulting in no respiratory effort and no breathing. The subject is aroused from sleep by an automatic breathing reflex. Frequent activation of the reflex results in very little sleep for the subject. The neurological mechanism behind CSA is very different from the physical cause of OSA. Although the effects of CSA and OSA are highly similar, effective treatment can differ. CompSA can be thought of as a combination of OSA and CSA. As mentioned before, CompSA is characterized by an emergence of CSA events after CPAP initiation.

Medications, hygiene, or some physical form of therapy can be used to treat apneas. Treatment of OSA and CSA vary substantially, which makes a proper diagnosis of the correct type of sleep apnea (OSA, CSA, or CompSA) critical for an effective treatment. Apnea treatment is provided based on the type of apnea, and can be adjusted by re-testing the subject at some later time to determine whether the condition or the symptoms have been alleviated. The most common method of treating OSA is continuous positive airway pressure (CPAP) and positive airway pressure (PAP) devices applied to the subject's airway to force the subject to breathe. When using a simple CPAP device to treat OSA, the air pressure acts as a splint, holding the airway open and reducing or removing the obstruction. The optimal pressure is determined by a sleep technician during a single titration night. The sleep technician manually adjusts the device to deliver a minimum pressure sufficient to force the airway open and reduce the number of apneas. Once the optimal pressure is determined, the device is programmed to consistently provide this pressure, and the patient is sent home.

Slightly more advanced PAP devices automatically adjust the air pressure based on sensors built into the device. The sensors measure gas flow, pressure, or other fluid characteristics in the device or its mask, and adjust the delivered pressure based on various algorithms known in the art. These auto-PAP devices rely on the single physiological variable (the measured or estimated fluid characteristics) to predict or detect an apnea event.

None of the devices on the market can be used to adjust the gas flow delivered to a subject based on a comprehensive evaluation of the subject's current physiological state or the subject's current symptoms. Further, none of the current devices can use a rich data set to predict or detect apnea and provide appropriate treatment. Still further, none of the current CPAP or PAP titration methods use a rich set of data over single or multiple nights to set the optimal pressure and other parameters. Still even further, none of the current devices can be used to automatically adjust a treatment device based on the subject's physiological signals. Still even further, none of the current titration devices can be used in the subject's home.

It is therefore an object of the present invention to adjust the treatment gas flow or pressure delivered to the subject based on the subject's current physiological state or symptoms. It is another object of the present invention to use a rich data set over multiple nights to titrate the CPAP treatment. It is another object of the present invention to use a closed-loop or partially closed-loop system to automatically titrate the CPAP treatment based on the subject's physiological signals. It is still another object of the present invention to treat a subject's apnea in a predictive manner. It is still another object of the present invention to provide a system or method of treating a subject's apnea using the subject's physiological signals. It is still another object of the present invention to provide a device and method of titration in the subject's home. It is still another object of the present invention to provide a device and method of titration in the hospital's acute or sub-acute settings, such as for postoperative management of care.

SUMMARY OF THE INVENTION

The present invention relates to an integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment device. The present invention additionally relates to methods of sleep diagnosis and treatment.

There are numerous embodiments of the present invention with a few of those listed below. The present invention further relates to a sleep diagnosis device integrated with a treatment device. The sleep disorder treatment system of the present invention can use a diagnosis device to perform various forms of analysis to determine or diagnose a subject's sleeping disorder or symptoms of a subject's sleep disorder, and using this analysis or diagnosis can with, or in some embodiments without, human intervention treat the subject either physically

or chemically to improve the sleeping disorder or the symptoms of the sleeping disorder. The diagnostic part of the system can use many different types of sensors and methods for diagnosing the severity of the symptoms of or the sleep disorder itself. The treatment part of the system can use a device to physically or chemically treat the subject's symptoms or sleep disorder itself.

The diagnostic part of the system or device can use various sensors for measuring the subject's respirations, cardiac signals, brain wave signals, blood gases, EMG, EOG, airway pressure, and the like. Any sensor that can or has been used with a full polysomnogram (PSG) may likewise be used alone or in combination with other sensors. Sensors for measuring the subject's brain wave signals include EEG electrodes and the like. Sensors for measuring the subject's respirations or oxygen levels include sensors to measure airflow, respiratory effort, oxygenation and ventilation, and the like. Measurement of airflow is preferably measured using sensors or devices such as a pneumotachometer, strain gauges, thermal sensors, transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, and the like. These sensors or devices, also preferably measure nasal pressure, respiratory inductance plethysmography, thoracic impedance, expired carbon dioxide, tracheal sound and the like. Measurement of respiratory effort is preferably measured by esophageal pressure, surface diaphragmatic EMG, inductive plethysmography, and the like. Measurement of oxygenation and ventilation is preferably measured by pulse oximetry, transcutaneous oxygen monitoring, transcutaneous carbon dioxide monitoring, expired end carbon dioxide monitoring, and the like.

Signals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject's sleep disorder and in some cases to diagnose the sleep disorder itself. One particular embodiment of the present invention involves diagnosing the level of severity of a subject's sleep apnea and with or without human intervention adjusting an apparatus for providing positive airway pressure to the subject. The treatment device can be adjusted by either by a closed loop control system (automatically) which uses, in part, the data or signals from the diagnosis device to actuate a physical or chemical treatment system for the subject, or an open loop control system (manually) which can alert a human who then adjusts the treatment device based in part on the data or signals from the diagnosis device. Alternatively, signals from the sensors can be saved on a medium in order to be retrieved and analyzed at a later date. Media on which data can be saved include, but are not limited to chart recorders, hard drive, floppy disks,

computer networks, optical storage, solid-state memory, magnetic tape, punch cards, etc.

The diagnostic device can be linked to the treatment device electronically. By electronically linking, it is envisioned that the devices can be linked through a tether, wireless link or some combination thereof. These wireless links can be RF, IR, RF cellular, RF internet, and the like. The diagnostic device preferably incorporates electronics which allow for the wireless transmission of signals from the diagnostic device to an intermediary device or to the treatment device itself. The intermediary device may be a cell phone, a modem, a wireless router, a router, a PDA, a computer, a processor, combinations thereof, and the like. The diagnostic device may transmit signals over any known communications systems or combination thereof to a remote location or to the treatment device itself as well. The communications can include for example cellular systems, copper wire systems, fiber optic systems, broad band cable systems, the internet, combinations thereof and the like.

Signals from these sensors can also be transmitted to a remote location to allow for remote review or processing of signals for diagnostic or treatment purposes. This allows for attended home titration of the treatment device or remotely attended hospital in-patient titration of the treatment device. The treatment devices can then either be adjusted automatically or manually from the remote location, or automatically adjusted at the location of the subject being titrated. Because this titration or adjustment system allows for the more robust collection of data from the subjects, this system can be better used to titrate the treatment device or devices, and in particular can be used to better adjust a PAP or CPAP device. Since traditional PAP or CPAP devices rely on limited sensor input to adjust the treatment device, mainly airflow pressure at some point on the device, this robust data collected during the titration with the diagnostic device can be used to teach or train the treatment device to correlate the more robust data from the diagnostic device to limited sensor signatures from the PAP or CPAP device to allow for more accurate control. One method of teaching or training the treatment device would be to teach or train a neural network on the treatment device. Another method of titrating the treatment device would be to use a wavelet algorithm to adjust the processor or controller on the treatment device or more preferably to adjust the PAP or CPAP device

The treatment device can be any device known to those skilled in the art. The treatment device can either physically or chemically treat the subject's sleeping disorder. An example of

physically treating the subject's sleeping disorder would be a device to provide positive airway pressure to a subject. The treatment device can either be a traditional PAP or CPAP, or can include various devices for chemical or medical treatment of the subject. The treatment device could include a O_2 tank or source, a CO_2 tank or source, a medication or chemical reservoir, combinations thereof, and the like. The subject may also have two or more treatment devices that are titrated at the same time. For example, the subject could have a PAP device that is being titrated at the same time as a functional electrical stimulation (FES) device. The PAP device preferably being used to treat the general obstructive apneas and the FES device preferably for treating central apneas. This application also covers the treatment device for use with these features as well as the treatment device for use with additional sensors. Preferably, a new CPAP or PAP with a respiratory effort belt is used. Another example of chemically treating the subject's sleeping disorder would be to have a medication reservoir where a drug is delivered to the subject in order to treat symptoms of the sleeping disorder. Preferably, this medication reservoir is placed inline with the airflow of a PAP or CPAP device to deliver a nebulized medication or drug to the subject's lungs. Also preferably, the PAP or CPAP device can be used to deliver CO_2 to trigger a breathing response to treat specific central apneas. A few of the many embodiments of the present invention are as follows.

In one embodiment, the present invention includes a sleep apnea treatment system comprising: a data acquisition system comprising at least one sensor having a signal, the sensor for determining a physiological characteristic of a subject, and at least one electronic component for receiving the signal and retransmitting the signal from the at least one sensor or transmitting a signal based at least in part on the signal from the at least one sensor; and a CPAP device for treating the subject's sleep apnea, the CPAP device comprising an electrical connection for receiving the retransmitted or transmitted signal.

In another embodiment, the present invention includes a treatment device for treating a sleep-related breathing disorder, the treatment device comprising a data acquisition system comprising at least one sensor having a signal, the sensor for determining a physiological characteristic of a subject, and at least one electronic component for receiving the signal and retransmitting the signal from the at least one sensor or transmitting a signal based at least in part on the signal from the at least one sensor; and a PAP device for treating the subject's sleep-

related breathing disorder, the PAP device comprising an electrical connection for receiving the retransmitted or transmitted signal, wherein the PAP device is titrated or adjusted based on at least in part the retransmitted or transmitted signal. The first device allows for collection of physiological data from the subject, which is then used to adjust the PAP device to effectively treat the subject's sleep-related breathing disorder.

Another embodiment of the present invention includes a sleep apnea treatment system comprising a data acquisition system and sleep screening device comprising two or more sensors each having a signal, the sensors each for determining a physiological characteristic of a subject, and at least one electronic component for receiving the signal and wirelessly retransmitting the signal from the at least one sensor or wirelessly transmitting a signal based at least in part on the signal from the at least one sensor; and a CPAP device for treating the subject's sleep apnea, the CPAP device comprising a wireless receiver or transceiver for receiving the retransmitted or transmitted signal wherein the CPAP device is titrated or adjusted based on at least in part the retransmitted or transmitted signal. The ability to wirelessly transmit and receive signals enables the sleep apnea treatment system to operate without tethering the subject. The freedom afforded by such a wireless system can increase subject compliance because the system is easier to use and less restrictive.

Another embodiment of the present invention includes a sleep apnea treatment system comprising a data acquisition system comprising at least one sensor having an electrical signal, the sensor for determining a physiological characteristic of a subject, and at least one electronic component for receiving the electrical signal from the at least one sensor, generating a processed signal based at least in part on the signal from the at least one sensor, and transmitting the processed signal; a CPAP device for treating the subject's sleep apnea, the CPAP device comprising an electrical connection for receiving a transmitted signal; and a remote monitoring station comprising a transceiver for receiving the processed signal from the data acquisition system and transmitting a command signal based at least in part on the transmitted processed signal to the CPAP device wherein the CPAP device is titrated or adjusted based on at least in part the transmitted command signal.

Still another embodiment of the present invention includes a sleep apnea treatment system comprising: a data acquisition system comprising at least three sensors, the sensors for

determining at least respiratory effort, pulse oximetry, and airflow of a subject, and at least one electronic component for receiving the signals and retransmitting the signal from the sensors or retransmitting a signal based at least in part on the signal from the at least one of the at least three sensors; and a CPAP device for treating the subject's sleep apnea, the CPAP device comprising an electrical connection for receiving the retransmitted or transmitted signal wherein the CPAP device is titrated or adjusted based on at least in part the retransmitted or transmitted signal.

Another embodiment of the present invention includes a sleep apnea treatment system comprising a data acquisition system comprising at least three sensors, the sensors for determining at least respiratory effort, pulse oximetry, and airflow of a subject, and at least one electronic component for receiving the signals and retransmitting the signals from the sensors or transmitting a signal based at least in part on the signal from the at least one of the at least three sensors; and a CPAP device for treating the subject's sleep apnea, the CPAP device comprising an electrical connection for receiving the retransmitted or transmitted signal, a display means capable of visually representing the retransmitted or transmitted signal, and an interface means allowing a user input wherein the CPAP device is titrated or adjusted based on at least in part the retransmitted or transmitted signal and at least in part on the user input.

Still another embodiment of the present invention includes a sleep-related breathing disorder treatment system comprising a data acquisition system comprising at least one physiological sensor having a signal and at least one electronic component for receiving the signal and wirelessly retransmitting the signal or wirelessly transmitting a signal based at least in part on the signal from the at least one sensor; a treatment interface device comprising at least one electronic component for wirelessly receiving the signal transmitted from the data acquisition system, optionally processing the signal from the data acquisition system, and retransmitting the signal from the data acquisition system or transmitting a signal based at least in part on at least one of the signals from the data acquisition system; and a PAP device for treating the subject's sleep-related breathing disorder, the PAP device comprising an electrical connection for receiving the signal transmitted from the treatment interface device wherein the PAP device is titrated or adjusted based on at least in part the signal transmitted from the treatment interface device.

Still another embodiment of the present invention includes a sleep-related breathing

disorder treatment system comprising a data acquisition system comprising at least two sensors, the sensors for determining at least one physiological characteristic of a subject and a video signal, and at least one electronic component for receiving the signals and retransmitting the signals or transmitting a signal based at least in part on at least one of the signals from the sensors; and a PAP device for treating the subject's sleep-related breathing disorder, the PAP device comprising an electrical connection for receiving the retransmitted or transmitted signals wherein the PAP device is titrated or adjusted based on at least in part the retransmitted or transmitted signals.

Yet another embodiment of the present invention includes the steps of: attaching at least one sensor to a subject; connecting the at least one sensor to a data acquisition system, the data acquisition system being capable of receiving an electrical signal from the at least one sensor and retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor; collecting data from the at least one sensor attached to the subject while the subject attempts to sleep; retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor from the data acquisition system to a PAP or CPAP device, the PAP or CPAP device being capable of receiving the retransmitted or transmitted signal and delivering a flow of pressurized gas to the subject; and periodically using at least part of the retransmitted or transmitted signal to adjust or titrate the flow of pressurized gas delivered by the PAP or CPAP to the subject. The steps of attaching at least one sensor to a subject and of connecting the at least one sensor to a first device can also be switched in this (and every similar) embodiment, meaning that the sensors could be connected to the data acquisition system and then applied to the subject. It is understood that the step of applying at least one sensor to a subject can be accomplished by applying any physiological sensor.

Another embodiment of the present invention includes the steps of: providing at least one sensor, a data acquisition system, and a PAP or CPAP device to a subject, the data acquisition system being capable of receiving an electrical signal from the at least one sensor and retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor, and the PAP or CPAP device capable of receiving a command signal and delivering a flow of pressurized gas to the subject; attaching the at least one

sensor to the subject; connecting the at least one sensor to the data acquisition system; collecting preliminary electrical signals for a predetermined amount of time from the at least one sensor attached to the subject while the subject attempts to sleep; using the collected preliminary electrical signals to confirm that the subject suffers from a sleep-related breathing disorder that can be treated with a PAP or CPAP device; continuing to collect the electrical signal from the at least one sensor attached to the subject while the subject sleeps; retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor from the first device to a remote monitoring station and the PAP or CPAP device; periodically reviewing at least part of the retransmitted or transmitted signal from the remote monitoring station and using the retransmitted or transmitted signal to calculate a command signal designed to titrate or adjust the PAP or CPAP device; and periodically delivering a command signal from the remote monitoring station to the PAP or CPAP device to adjust the flow of pressurized gas delivered by the PAP or CPAP device to the subject.

Another embodiment of the present invention includes the steps of: providing at least one sensor, a data acquisition system, and a PAP or CPAP device to a subject, the data acquisition system being capable of receiving an electrical signal from the at least one sensor and retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor, and the PAP or CPAP device capable of receiving the retransmitted or transmitted signal and delivering a flow of pressurized gas to the subject; attaching the at least one sensor to the subject; connecting the at least one sensor to the data acquisition system; collecting preliminary electrical signals for a predetermined amount of time from the at least one sensor attached to the subject while the subject attempts to sleep; using the collected preliminary electrical signals to confirm that the subject suffers from a sleep-related breathing disorder that can be treated with a PAP or CPAP device; continuing to collect the electrical signal from the at least one sensor attached to the subject while the subject attempts to sleep; retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor from the first device to the PAP or CPAP device; periodically using at least part of the retransmitted or transmitted signal to titrate or adjust the flow of pressurized gas delivered by the PAP or CPAP to the subject; and collecting the data acquisition system and the at least one sensor from the subject.

Another embodiment of the present invention includes the steps of: providing at least one sensor, a data acquisition system, and a PAP or CPAP device to a subject, the data acquisition system being capable of receiving an electrical signal from the at least one sensor and retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor, and the PAP or CPAP device capable of receiving a command signal and delivering a flow of pressurized gas to the subject; attaching the at least one sensor to the subject; connecting the at least one sensor to the data acquisition system; collecting electrical signals from the at least one sensor attached to the subject while the subject attempts to sleep; retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor from the first device to a remote monitoring station and the PAP or CPAP device; periodically reviewing at least part of the retransmitted or transmitted signal from the remote monitoring station and using the retransmitted or transmitted signal to calculate a command signal designed to titrate or adjust the PAP or CPAP device; and periodically delivering a command signal from the remote monitoring station to the PAP or CPAP device to adjust the flow of pressurized gas delivered by the PAP or CPAP device to the subject.

Still another embodiment of the present invention includes the steps of: providing at least one sensor, a data acquisition system, and a PAP or CPAP device to a subject, the data acquisition system being capable of receiving an electrical signal from the at least one sensor and retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor, and the PAP or CPAP device capable of receiving a command signal and delivering a flow of pressurized gas to the subject; attaching the at least one sensor to the subject; connecting the at least one sensor to the data acquisition system; collecting electrical signals from the at least one sensor attached to the subject while the subject attempts to sleep; retransmitting the signal or transmitting a processed signal based at least in part on the electrical signal from the at least one sensor from the first device to a remote monitoring station and the PAP or CPAP device; automatically determining a set of final values for the flow of pressurized gas delivered by the PAP or CPAP device; transmitting the set of final values for the flow of pressurized gas to the monitoring station; remotely evaluating and approving the set of final values for the flow of pressurized gas; and remotely programming the PAP or CPAP device

to deliver a flow of pressurized gas defined by the approved set of final values.

Finally, in still another embodiment, the present invention includes a sleeping disorder treatment system comprising a device for diagnosing and creating a quantitative output of a level of severity of a subject's sleeping disorder or symptoms comprising a pulse oximeter sensor; and a device for physically or chemically treating a subject's sleeping disorder or symptoms, which can be adjusted using in part the output of the level of severity of the subject's sleeping disorder.

Additional features and advantages of the invention will be set forth in the detailed description that follows, and in part will be readily apparent to those skilled in the art from that description or recognized by practicing the invention as described herein, including the detailed description that follows, the claims, as well as the appended drawings.

It is to be understood that both the foregoing general description and the following detailed description are merely exemplary of the invention, and are intended to provide an overview or framework for understanding the nature and character of the invention as it is claimed. The accompanying drawings are included to provide a further understanding of the invention, and are incorporated in and constitute a part of this specification. The drawings illustrate various embodiments of the invention and, together with the description, serve to explain the principles and operation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 Block diagram an embodiment of part of the diagnostic device of sleeping disorder treatment system of the present invention.

FIG. 2 Block diagram of one embodiment of the signal processing step of the present invention.

FIG. 3 Block diagram of one embodiment of the base station used in the present invention.

FIG. 4 Block diagram of an embodiment of a base station of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

FIG. 5 Block diagram of an embodiment of the programming firmware in the signal

processing module of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

FIG. 6 Block diagram of an embodiment of the programming of the interrupt service routine in the firmware in the signal processing module of part of the diagnostic device of the sleeping disorder treatment system of the present invention.

FIG. 7 Flowchart of one embodiment of the sleep disorder treatment system of the present invention showing analysis of the physiological signals and adjustment of the treatment device.

FIG. 8 Schematic view of one embodiment of the sleep disorder treatment system of the present invention.

FIG. 9 Schematic representation of one embodiment of the present invention used with a subject to acquire EEG signals from the subject and then transmit them to the receiver and attached computer.

FIG. 10 Schematic representation of one embodiment of the present invention showing the remote data acquisition method.

FIG. 11 Block diagram of one embodiment of the present invention showing the motion artifact rejection process.

FIG. 12 Flowchart illustrating one preprocessing function of the present invention.

FIG. 13 Analysis tree for Discrete Wavelet Transform (DWT)/Stationary Wavelet Transform (SWT) and wavelet packet decomposition.

FIG. 14 Schematic diagram illustrating a three-level Discrete Wavelet Transform (DWT) filter bank.

FIG. 15 Illustration of the frequency bands for the analysis trees shown in FIG. 13.

FIG. 16 Schematic diagram of one embodiment of the data acquisition system of the present invention for estimating the physiological state based on wavelet analysis.

FIG. 17 Schematic diagram illustrating the function of a comparator unit.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is related to a device and method of titrating a sleep disorder treatment, particularly positive airway pressure (PAP) and continuous positive airway pressure (CPAP) treatment for sleep apneas. The present invention is further related to the devices used in executing the method. The present invention includes various embodiments of a method of titrating a sleep disorder treatment device. These embodiments include but are not limited to one or more of the steps described herein. The present invention further includes various embodiments of a device used to titrate a sleep disorder treatment, particularly a PAP or CPAP device. The subjects referred to in the present invention can be any form of animal. Preferably the subject is a mammal, and more preferably a human. Most preferably, the subject is a human being treated for a sleep-related breathing disorder with a PAP or CPAP device.

Various embodiments of the present invention include a step of applying at least one sensor to the subject. The sensors can be applied at any location. Preferably, the sensors are applied in a physician's office or place of business. The physician's place of business includes but is not limited to an office building, a freestanding sleep center, location within a hospital, mobile vehicle or trailer, leased space, or similar location. Just as preferably, the sensors will be mailed to the subject's home or other sleeping location, and the subject will then apply them independently. The subject's sleeping location includes but is not limited to the subject's home, apartment, and the like, as well as a hotel, nursing facility, or other location where an individual could sleep and where this analysis could be done more controllably and/or less expensively than in a sleep lab or hospital setting.

Similarly, the sensors can be applied by a variety of individuals, including but not limited to a physician, nurse, sleep technician, or other healthcare professional. Just as preferably, the sensors could be applied by the subject or the subject's spouse, friend, roommate, or other individual capable of attaching the various sensors. More preferably, the sensors could be applied by the subject or the subject's spouse, friend, roommate, or other individual capable of attaching the various sensors with guidance and instruction. Such guidance and instruction can include static information such as pamphlets, audio recordings (on cassettes, compact discs, and the like), video recordings (on videocassettes, digital video discs, and the like), websites, and the

like, as well as dynamic information such as direct real-time communication via telephone, cell phone, videoconference, and the like.

The sensors that are used with various embodiments of the present invention are described herein but can also be any of those known to those skilled in the art for the applications of this method. The collected physiological, kinetic, and environmental signals can be obtained by any method known in the art. Preferably, those sensors include, but are not limited, to wet or dry electrodes, photodetectors, accelerometers, pneumotachometers, sphygmomanometers (for measuring blood pressure), strain gauges, thermal sensors, pH sensors, chemical sensors, gas sensors (such as oxygen and carbon dioxide sensors), transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, microphones, audio recorders, video cameras, and the like. Optionally, the data includes a video channel. The invention is envisioned to include those sensors subsequently developed by those skilled in the art to detect these types of signals. For example, the sensors can be magnetic sensors. Because electro-physiological signals are, in general, electrical currents that produce associated magnetic fields, the present invention further anticipates methods of sensing those magnetic fields to acquire the signal. For example, new magnetic sensors could collect brain wave signals similar to those that can be obtained through a traditional electrode applied to the subject's scalp.

Various embodiments of the present invention include a step for applying sensors to the subject. This step can be performed or accomplished in a number of ways. In the simplest form, one sensor is applied to the subject to measure a single channel of physiological or kinetic data. In a more complex form, two sensors are applied to the subject and one additional sensor is contained within the PAP or CPAP device. Preferably, the set of sensors includes one pulse oximeter applied to the subject's index finger, one thoracic respiratory effort belt applied around the subject's chest, and one airflow or air pressure transducer contained within the PAP or CPAP device. In a still more complex form of this step, multiple sensors are applied to the subject to collect data sufficient for a full PSG test. If PSG data are to be collected, the preferred minimal set of sensors includes sensors for two EEG channels, one EOG channel, one chin EMG channel, one airflow channel, one ECG channel, one thoracic respiratory effort channel, one abdominal respiratory effort channel, one pulse oximetry channel, and one shin or leg EMG channel. More preferably, the minimal set of PSG sensors is augmented with at least one additional channel of

EOG, one channel of snore, one channel of body position (ex., an accelerometer), one channel of video, and optionally one channel of audio.

Electro-physiological signals such as EEG, ECG, EMG, EOG, electroneurogram (ENG), electroretinogram (ERG), and the like can be collected via electrodes placed at one or several relevant locations on the subject's body. For example when measuring brain wave or EEG signals, electrodes may be placed at one or several locations on the subject's scalp. In order to obtain a good electro-physiological signal, it is desirable to have low impedances for the electrodes. Typical electrodes placed on the skin may have an impedance in the range of from 5 to 10 kΩ. It is in generally desirable to reduce such impedance levels to below 2 kΩ. A conductive paste or gel may be applied to the electrode to create a connection with an impedance below 2 kΩ. Alternatively or in conjunction with the conductive gel, a subject's skin may be mechanically abraded, the electrode may be amplified, or a dry electrode may be used. Dry physiological recording electrodes of the type described in U.S. Patent 7,032,301 are herein incorporated by reference. Dry electrodes are advantageous because they use no gel that can dry out, skin abrasion or cleaning is unnecessary, and the electrode can be applied in a hairy area such as the scalp. Additionally if electrodes are used as the sensors, preferably at least two electrodes are used for each channel of data – one signal electrode and one reference electrode. Optionally, a single reference electrode may be used for more than one channel.

When electrodes are used to collect EEG or brain wave signals, common locations for the electrodes include frontal (F), parietal (P), mastoid process (A), central (C), and occipital (O). Preferably for the present invention, when electrodes are used to collect EEG or brain wave data, at least one electrode is placed in the occipital position and referenced against an electrode placed on the mastoid process (A). More preferably, when electrodes are used to collect EEG or brain wave data, electrodes are placed to obtain a second channel of data from the central location. If further EEG or brain wave signal channels are desired, the number of electrodes required will depend on whether separate reference electrodes or a single reference electrode is used.

If electrodes are used to collect cardiac signals using an ECG, they may be placed at specific points on the subject's body. The ECG is used to measure the rate and regularity of heartbeats, determine the size and position of the heart chambers, assess any damage to the heart,

and diagnose sleeping disorders. An ECG is important as a tool to detect the cardiac abnormalities that can be associated with respiratory-related disorders.

As the heart undergoes depolarization and repolarization, electrical currents spread throughout the body because the body acts as a volume conductor. The electrical currents generated by the heart are commonly measured by an array of twelve electrodes placed on the arms, legs, and chest. Although a full ECG test typically involves twelve electrodes, only two are required for many tests such as a sleep study. When electrodes are used to collect ECG with the present invention, preferably only two electrodes are used. When two electrodes are used to collect ECG, preferably one is placed on the subject's left-hand ribcage under the armpit, and the other preferably on the right-hand shoulder near the clavicle bone. Optionally, a full set of twelve ECG electrodes may be used, such as if the subject is suspected to have a cardiac disorder. The specific location of each electrode on a subject's body is well known to those skilled in the art and varies between both individuals and types of subjects. If electrodes are used to collect ECG, preferably the electrode leads are connected to a component of the data acquisition system that includes a processing or pre-processing module that measures potential differences between selected electrodes to produce ECG tracings.

The two basic types of ECG leads are bipolar and unipolar. Bipolar leads (standard limb leads) have a single positive and a single negative electrode between which electrical potentials are measured. Unipolar leads (augmented leads and chest leads) have a single positive recording electrode and use a combination of the other electrodes to serve as a composite negative electrode. Either type of lead is acceptable for collecting ECG signals in the present invention.

Other sensors can be used to measure various parameters of a subject's respirations. Measurement of airflow is preferably measured using sensors or devices such as a pneumotachometer, strain gauges, thermal sensors, transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, and the like. These sensors or devices also preferably measure nasal pressure, respiratory inductance plethysmography, thoracic impedance, expired carbon dioxide, tracheal sound, snore sound, blood pressure and the like. Measurement of respiratory effort is preferably measured by a respiration piezo-electric sensor, inductive plethysmography esophageal pressure, surface diaphragmatic EMG, and the like. Measurement of oxygenation and ventilation is preferably measured by pulse oximetry, transcutaneous oxygen

monitoring, transcutaneous carbon dioxide monitoring, expired end carbon dioxide monitoring, and the like.

Optionally, sensors for directly or indirectly measuring respirations can be located in the conduit connecting the PAP or CPAP blower to the gas delivery mechanism. These sensors can include airflow sensors, air pressure sensors, or other sensors to measure characteristics of the gas. Further optionally, sensors can be located near the blower mechanism. These blower sensors can estimate or indirectly measure airflow or air pressure by measuring fan speed or power consumption. Methods of determining airflow or air pressure from sensors placed in or on a PAP or CPAP device are generally known in the art, and any such method is appropriate for the present invention.

One example of such a sensor for measuring respirations either directly or indirectly is a respiration belt. Respiration belts can be used to measure a subject's abdominal and/or thoracic expansion over a measurement time period. The respiration belts may contain a strain gauge, piezo-electric, pressure transducer, or other sensors that can indirectly measure a subject's respirations and the variability of respirations by providing a signal that correlates to the thoracic/abdominal expansion/contractions of the subject's thoracic/abdominal cavity. If respiration belts are used, they may be placed at one or several locations on the subject's torso or in any other manner known to those skilled in the art. Preferably, when a thoracic respiration belt is used, it is positioned below the axilla to measure rib cage excursions. When an abdominal respiration belt is used, it is positioned at the level of the umbilicus to measure abdominal excursions. Optionally, at least two belts are used, with one positioned at the axilla and the other at the umbilicus.

Another example of a sensor or method for measuring respirations either directly or indirectly is a nasal cannula or a facemask used to measure the subject's respiratory airflow. Nasal or oral airflow can be measured quantitatively and directly with a pneumotachograph consisting of a pressure transducer connected to either a standard oxygen nasal cannula placed in the nose, a facemask over the subject's mouth and nose, or the PAP or CPAP gas delivery mechanism. Airflow can be estimated by measuring nasal or oral airway pressure that decreases during inspiration and increases during expiration. Inspiration and expiration produce fluctuations on the pressure transducer's signal that is proportional to airflow. A single pressure

transducer can be used to measure the combined oral and nasal airflow. Alternatively, the oral and nasal components of these measurements can be acquired directly through the use of at least two pressure transducers, one transducer for each component. Optionally, the pressure transducer(s) are internal to the patient interface box. If two transducers are used for nasal and oral measurements, preferably each has a separate air port into the patient interface box.

When respirations are measured via airflow or air pressure transducers, preferably the sensors are internal to the PAP or CPAP device itself, either in the PAP or CPAP gas delivery mechanism (i.e., the mask or cannula), or positioned near the blower as described above. Transducers in the PAP or CPAP mask or cannula operate identically to the masks and cannulae described above. Optionally, sensors can be located in the conduit connecting the PAP or CPAP blower to the gas delivery mechanism. Methods of determining airflow or air pressure from sensors placed in or on a PAP or CPAP device are generally known in the art, and any such method is appropriate for the present invention.

Sensors placed on a mask or cannula can also be used to determine other physiological characteristics. Software filtering can obtain "snore signals" from a single pressure transducer signal by extracting the high frequency portion of the transducer signal. This method can eliminate the need for a separate sensor, such as a microphone or another transducer, and also reduces the system resources required to detect both snore and airflow. A modified nasal cannula or facemask connected to a carbon dioxide or oxygen sensor may be used to measure respective concentrations of these gases. In addition, a variety of other sensors can be connected with either a nasal cannula or facemask to measure a subject's respirations directly or indirectly.

Still another example of a sensor or method of directly or indirectly measuring respirations of the subject is a pulse oximeter. The pulse oximeter can measure the oxygenation of the subject's blood by producing a source of light at two wavelengths (typically at 650nm and 905, 910, or 940nm). Hemoglobin partially absorbs the light by amounts that differ depending on whether it is saturated or desaturated with oxygen. Calculating the absorption at the two wavelengths leads to an estimate of the proportion of oxygenated hemoglobin. Preferably, pulse oximeters are placed on a subject's earlobe or fingertip. More preferably, the pulse oximeter is placed on the subject's index finger. In one embodiment of the present invention, a pulse oximeter is built-in or hard-wired to the interface box. Alternatively, the pulse oximeter can be a

separate unit in communication with either the interface box or the base station via either a wired or wireless connection.

Kinetic data can be obtained by accelerometers placed on the subject. Alternatively, several accelerometers can be placed in various locations on the subject, for example on the head, wrists, torso, and legs. These accelerometers can provide both motion and general position/orientation data by measuring gravity. These accelerometers can be used to detect when patients go to sleep or to detect movements during sleep which are important factors in assessing the actual sleep time which is an important parameter used to generate an accurate assessment of nocturnal respiratory events (such as apnea/hypopnea events, which is the sum of all apneas and hypopneas divided by sleep time; or apnea/hypopnea index [AHI]). A video signal can also provide some kinetic data after processing. Alternatively, stereo video signals can provide three-dimensional position and motion information. Kinetic data includes but is not limited to frequent tossing and turning indicative of an unsuitable mattress, excessive movement of bedding indicating unsuitable sleeping temperatures, unusual movement patterns indicating pain, and the subject's sleeping position.

Other sensors can be used to measure various parameters of a subject's physiological, kinetic, or environmental conditions. These other parameters are preferably measured using sensors or devices such as a photodetectors, light meters, accelerometers, pneumotachometers, sphygmomanometers (for measuring blood pressure), strain gauges, thermal sensors, pH sensors, chemical sensors, gas sensors (such as carbon monoxide detectors), transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, audio monitors, microphones, reflective markers, video monitors, hygrometers, and the like. Because the system is programmable, potentially any transducer-type sensor that outputs an electrical signal can be used with the system.

Various embodiments of the present invention include the step of connecting sensors to a data acquisition system. The sensors can be connected to the data acquisition system either before or after they are applied to the subject. The sensors can be permanently hardwired to at least part of the data acquisition system. More preferably, the sensors are connected to at least part of the data acquisition system via a releasable connector. Optionally, the sensors can be connected to at least part of the data acquisition system via non-releasable connector that does

not permit disconnection without destruction of the connector. The physiological sensors are generally hardwired (permanently or via a connector) to the data acquisition system, but the ongoing evolution in wireless sensor technology may allow sensors to contain transmitters. Optionally, such sensors are wirelessly connected to the data acquisition system. As such, these sensors and the wireless connection method are considered to be part of the present invention. With the advances in microelectromechanical systems (MEMS) sensor technology, the sensors may have integrated analog amplification, integrated A/D converters, and integrated memory cells for calibration, allowing for some signal conditioning directly on the sensor before transmission.

Preferably, the sensors are all connected in the same way at the same time, although this certainly is not required. It is possible, but less preferable, to connect the sensors with a combination of methods (i.e., wired or wireless) at a combination of times (i.e., some before application to the subject, and some after application to the subject). The sensors can be connected to various parts of the data acquisition system. For example, a thoracic respiratory effort belt can be connected to a patient interface box while a pulse oximeter can be connected a base station. Further, some sensors may not be attached to the subject at all. Examples of such sensors include airflow sensors that are part of the PAP or CPAP device and video cameras or microphones that are placed in the subject's sleeping area. Although these sensors are not attached to the subject, they are still connected to at least one component of the data acquisition system.

Various embodiments of the present invention use a data acquisition system capable of both (a) receiving signals from the sensors applied to or placed near the subject; and (b) retransmitting the signals or transmitting another signal based at least in part on at least one of the collected signals. In its simplest form, the data acquisition system preferably should interface with the sensors and retransmit the signals from the sensors. Preferably, the data acquisition system wirelessly transmits the signals from the sensors. Optionally, the data acquisition system also pre-processes the signals from the sensors and transmits the pre-processed signals. Further optionally, the data acquisition is also capable of storing the signals from the sensors and/or any pre-processed signals.

Optionally, the data acquisition system can be a single box, such as a patient interface

box, containing a sensor interface module, a pre-processor module, and a transmitter module. Further optionally, the data acquisition system could consist of several boxes that communicate with each other, each box containing one or more modules. For example, the data acquisition system could consist of: (a) a patient interface box containing a sensor interface module, a pre-processor, a transmitter, and a receiver; and (b) a base station box containing a second pre-processor, a transmitter, and a receiver. In this example, the transmitter and receiver of the patient interface box are used to communicate with the base station box. The transmitter and receiver of the base station box are used to both communicate with the patient interface box and a remote monitoring station, remote analysis station, remote data storage station, and the like. Similarly, the data acquisition could consist of (a) a patient interface box containing a sensor interface module, a transmitter, and a receiver; (b) a processor box containing a pre-processor, a transmitter, and a receiver; and (c) a base station box containing only a receiver and a transmitter. In these configurations, it is not necessary for the transmitters to be of the same type. For example, the transmitter in the patient interface box can be a wired, Bluetooth, or other transmitter designed for short distances, and the transmitter in the base station box can be a WiFi, IEEE 802.11, TCP/IP, or other transmitter designed to establish connections over larger distances.

Several data acquisition systems are suitable for use with the present invention. Preferably, the data acquisition system is a device from Cleveland Medical Devices, Inc. (CleveMed). All current suitable CleveMed data acquisition systems include a patient interface box and a base station. The three CleveMed patient interface boxes described below allow for data backup and storage on a removable SD memory card, with a single 1 GB card providing over 60 hours of recording. The current CleveMed data acquisition systems also each include a base station weighing 130 g that is powered by USB. The USB cable also provides a wired link between the base station and a PC. The CleveMed patient interfaces and base stations contain integrated wireless technology for real-time data transmission within 100 feet line of sight. The CleveMed patient interface boxes currently suitable for use with the present invention include the SleepScout™, Crystal Monitor® 20, and Sapphire™ PSG systems.

The SleepScout™ is a wireless patient interface box that includes a total of 9 input channels for ECG, EMG, thoracic and abdominal respiratory efforts, snore and a generic

auxiliary DC input. Two of the channels are fully-programmable, adding flexibility by allowing for any combination of EEG, ECG, EOG or EMG. SleepScout™ also includes several built-in sensors, including body position, pulse oximetry, pressure-based airflow, and a differential pressure transducer that allows for PAP or CPAP titration studies. The SleepScout™ patient interface box weighs 190 g and is powered by two AA lithium batteries. The SleepScout™ transmits data in the 2.4 - 2.484 GHz ISM band.

The CleveMed Sapphire™ is a wireless patient interface box that includes a total of 22 input channels, including 6 EEG, 2 EOG, 5 EMG, as well as ECG, temperature, body position, and respiratory effort. Six of the channels are EEG, allowing the Sapphire™ to meet guidelines for conducting polysomnogram tests. The Sapphire™ also includes several built-in sensors, including body position, pulse oximetry, and a generic auxiliary DC input. The Sapphire™ patient interface box weighs 538 g and is powered by two AA lithium batteries. The Sapphire™ transmits data in multiple bands, allowing dynamic selection of Wireless Medical Telemetry Service (WTMS) bands (608-614 MHz, 1427-1432 MHz) and two ISM bands (902-928 MHz or 2.4-2.485 GHz), depending on the availability and saturation of transmission bands in the testing location.

The CleveMed Crystal® Monitor 20 is a family of wireless patient interface boxes. Each Crystal® Monitor 20 includes a total of 14 input channels, including two each for EEG, EOG, and EMG, as well as ECG and thoracic and abdominal respiratory efforts. The Crystal® Monitor 20 also includes several built-in sensors, including body position, pulse oximetry, pressure-based airflow, and a generic auxiliary DC input. The Crystal® Monitor 20 patient interface box weighs 210 g and is powered by two AA lithium batteries. The Crystal® Monitor 20 family transmits data in multiple bands; the Crystal® 20-B transmits in the 900 MHz ISM band, and the Crystal® 20-S transmits in the 2.4 GHz ISM band. Selection of the appropriate Crystal® Monitor depends upon the availability and saturation of transmission bands in the testing location.

The data acquisition system is preferably portable. By portable, it is meant, among other things, that the device is capable of being transported relatively easily. Relative ease in transport means that the device is easily worn and carried, generally in a carrying case, to the point of use or application and then worn by the subject without significantly affecting any range of motion.

Furthermore, any components of the data acquisition system that are attached to or worn by the subject, such as the sensors and patient interface box, should also be lightweight. Preferably, these subject-contacting components of the device (including the sensors and the patient interface box) weigh less than about 10 lbs., more preferably less than about 7.5 lbs., even more preferably less than about 5 lbs., and most preferably less than about 2.5 lbs. The subject-contacting components of the device preferably are battery-powered and use a data storage memory card and/or wireless transmission of data, allowing the subject to be untethered. Furthermore, the entire data acquisition system (including the subject-contacting components as well as any other sensors, a base station, or other components) preferably should be relatively lightweight. By relatively lightweight, it is meant preferably the entire data acquisition system, including all components such as any processors, computers, video screens, cameras, and the like preferably weigh less in total than about 20 lbs., more preferably less than about 15 lbs., and most preferably less than about 10 lbs. This data acquisition system preferably can fit in a reasonably sized carrying case so the subject or assistant can easily transport the system. By being lightweight and compact, the device should gain greater acceptance for use by the subject.

Various embodiments of the present invention use a data acquisition system capable of storing and/or retransmitting the signals from the sensors or storing and/or transmitting another signal based at least in part on at least one of the signals. The data acquisition system can be programmed to send all signal data to the removable memory, to transmit all data, or to both transmit all data and send a copy of the data to the removable memory. When the data acquisition system is programmed to store a signal or pre-processed signal, the signals from the sensors can be saved on a medium in order to be retrieved and analyzed at a later date. Media on which data can be saved include, but are not limited to chart recorders, hard drive, floppy disks, computer networks, optical storage, solid-state memory, magnetic tape, punch cards, etc. Preferably, data are stored on removable memory. For both storing and transmitting or retransmitting data, flexible use of removable memory can either buffer signal data or store the data for later transmission. Preferably, nonvolatile removable memory can be used to customize the system's buffering capacity and completely store the data.

If the data acquisition system is configured to transmit the data, the removable memory acts as a buffer. In this situation, if the data acquisition system loses its connection with the

receiving station, the data acquisition system will temporarily store the data in the removable memory until the connection is restored and data transmission can resume. If, however, the data acquisition system is configured to send all data to the removable memory for storage, then the system does not transmit any information at that time. In this situation, the data stored on the removable memory can be retrieved by either transmission from the data acquisition system, or by removing the memory for direct reading.

The method of directly reading will depend on the format of the removable memory. Preferably the removable memory is easily removable and can be removed instantly or almost instantly without tools. The memory is preferably in the form of a card and most preferably in the form of a small easily removable card with an imprint (or upper or lower surface) area of less than about two in^2. If the removable memory is being used for data storage, preferably it can write data as fast as it is produced by the system, and it possesses enough memory capacity for the duration of the test. These demands will obviously depend on the type of test being conducted, tests requiring more sensors, higher sampling rates, and longer duration of testing will require faster write speeds and larger data capacity. The type of removable memory used can be almost any type that meets the needs of the test being applied. Some examples of the possible types of memory that could be used include but are not limited to Flash Memory such as CompactFlash, SmartMedia, Miniature Card, SD/MMC, Memory Stick, or xD-Picture Card. Alternatively, a portable hard drive, CD-RW burner, DVD-RW burner or other data storage peripheral could be used. Preferably, a SD/MMC – flash memory card is used due to its small size. A PCMCIA card is least preferable because of the size and weight.

When the data acquisition system is programmed to retransmit the signals from the sensors, preferably the data acquisition system transmits the signals to a processor for analysis. More preferably, the data acquisition system immediately retransmits the signals to a processor for analysis. Optionally, the data acquisition system receives the signals from one or more of the aforementioned sensors and stores the signals for later transmission and analysis. Optionally, the data acquisition system both stores the signals and immediately retransmits the signals.

When the data acquisition system is programmed to retransmit the signals from the sensors or transmit a signal based at least in part on the signal from the sensors (collectively "to transmit" in this section), the data acquisition system can transmit through either a wireless

system, a tethered system, or some combination thereof. When the system is configured to transmit data, preferably the data transmission step utilizes a two-way (bi-directional) data transmission. Using two-way data transmission significantly increases data integrity. By transmitting redundant information, the receiver (the processor, monitoring station, or the like) can recognize errors and request a renewed transmission of the data. In the presence of excessive transmission problems, such as transmission over excessive distances or obstacles absorbing the signals, the data acquisition system can control the data transmission or independently manipulate the data. With control of data transmission it is also possible to control or re-set the parameters of the system, e.g., changing the transmission channel or encryption scheme. For example, if the signal transmitted is superimposed by other sources of interference, the receiving component could secure a flawless transmission by changing the channel. Another example would be if the transmitted signal is too weak, the receiving component could transmit a command to increase the transmitting power. Still another example would be for the receiving component to change the data format of the transmission, e.g., in order to increase the redundant information in the data flow. Increased redundancy allows easier detection and correction of transmission errors. In this way, safe data transmissions are possible even with the poorest transmission qualities. This technique opens a simple way to reduce the transmission power requirements, thereby reducing the energy requirements and providing longer battery life. Another advantage of a bi-directional digital data transmission lies in the possibility of transmitting test codes in order to filter out external interferences, for example, refraction or scatter from the transmission current. In this way, it is possible to reconstruct falsely transmitted data.

Data compression using lossless encoding techniques can provide basic throughput optimization, while certain lossy encoding techniques will offer far greater throughput while still providing useful data. Lossy encoding techniques may include but are not limited to decimation, or transmission of a compressed image of the data. The preferred method for encoding will include special processing from the transmitter that will preprocess the data according to user-selectable options, such as digital filtering, and take into the account the desired visual representation of that information, such as pixel height and target image width. Facilities can be made within the system to control the encoding in order to optimize utilization on any given

network. Control over the encoding methods may include, but is not limited to selection of a subset of the entire set of signals, target image size, and decimation ratio.

Data encryption can be applied to secure data transmissions over any network. Encryption methods may include but are not limited to simple obfuscation and sophisticated ciphers. The preferred embodiment of secure data transmission that is compatible with HIPAA and HCFA guidelines will be implemented using a virtual private network. More preferably, the virtual private network will be implemented using a specialized security appliance, such as the PIX 506E, from Cisco Systems, Inc, capable of implementing IKE and IPSec VPN standards using data encryption techniques such as 168-bit 3DES, 256-bit AES, and the like. Still more preferably, secure transmission will be provided by a third party service provider or by the healthcare facility's information technology department. The system will offer configuration management facilities to allow it to adapt to changing guidelines for protecting patient health information (PHI).

Several preferable embodiments of this method employ a wireless data acquisition system. This wireless data acquisition system consists of several components, each wirelessly connected. Data is collected from the sensors described above by a patient interface box. The patient interface box then wirelessly transmits the data to a separate signal pre-processing module, which then wirelessly transmits the pre-processed signal to a receiver. Alternatively, the patient interface box processes the signal and then directly transmits the processed signal directly to the receiver using wireless technology. Further alternatively, the patient interface box wirelessly transmits the signals to the receiver, which then pre-processes the signal. Preferably, the wireless technology used by the data acquisition system components is radio frequency based. Most preferably, the wireless technology is digital radio frequency based. The signals from the sensors and/or the pre-processed signals are transmitted wirelessly to a receiver, which can be a base station, a transceiver hooked to a computer, a personal digital assistant (PDA), a cellular phone, a wireless network, or the like. Most preferably, the physiological signals are transmitted wirelessly in digital format to a receiver.

Wireless signals between the wireless data acquisition system components are both received and transmitted via frequencies preferably less than about 2.0 GHz. More preferably, the frequencies are primarily 902–928 MHz, but Wireless Medical Telemetry Bands (WMTS),

608–614 MHz, 1395–1400 MHz, or 1429–1432 MHz can also be used. The present invention may also use other less preferable frequencies above 2.0GHz for data transmission, including but not limited to such standards as Bluetooth, WiFi, IEEE 802.11, and the like.

When a component of the wireless data acquisition system is configured to wirelessly transmit data, it is preferably capable of conducting a RF sweep to detect an occupied frequency or possible interference. The system is capable of operating in either "manual" or "automatic" mode. In the manual mode, the system conducts an RF sweep and displays the results of the scan to the system monitor. The user of the system can then manually choose which frequency or channel to use for data transmission. In automatic mode, the system conducts a RF sweep and automatically chooses which frequencies to use for data transmission. The system also preferably employs a form of frequency hopping to avoid interference and improve security. The system scans the RF environment then picks a channel over which to transmit based on the amount of interference occurring in the frequency range.

In this application, transmitting the data wirelessly means that the data is transmitted wirelessly at least in part of the data transfer process. This means, for example, that the data may be transmitted wirelessly from the patient interface box to the base station, which then transmits the data via either a wireless method, such as a wireless cellular card, local wireless network, satellite communication system, and the like, or a wired method, such as a wired internet connection, the testing facility's LAN, and the like. Transmitting the data wirelessly also means, for example, that the data may be transmitted via wired connection from the patient interface box to a base station, which then wirelessly transmits the data wirelessly via any wireless method, such as Bluetooth, IEEE 802.11, wireless cellular card, satellite communication system, and the like to a database that distributes the data over a hardwired system to a sleep unit or lab. Transmitting the data wirelessly also means, for example, that the data may be wirelessly transmitted directly from the patient interface box via WiFi or IEEE 802.11, Bluetooth, wireless cellular card, and the like to a processor, which then transmits the processed data to the sleep unit or laboratory. Preferably, the patient interface box wirelessly transmits the data. This allows for a simplified subject hookup and improved subject mobility.

Preferably, the data acquisition system retransmits the signals from the sensors applied to the subject or transmits a signal based at least in part on at least one of the physiological, kinetic,

or environmental signals at substantially a same time as the signal is received or generated. At substantially the same time preferably means within approximately one hour. More preferably, at substantially the same time means within thirty minutes. Still more preferably, at substantially the same time means within ten minutes. Still more preferably, at substantially the same time means within approximately one minute. Still more preferably, at substantially the same time means within milliseconds of when the signal is received or generated. Most preferably, a substantially same time means that the signal is transmitted or retransmitted at a nearly instantaneous time as it is received or generated. Transmitting or retransmitting the signal at substantially the same time allows the physician or monitoring service to review the subject's physiological and kinetic signals and the environmental signals and if necessary to make a determination, which could include modifying the subject's treatment protocols or asking the subject to adjust the sensors.

The receiver (base station, remote communication station, or the like) of various embodiments of the wireless data acquisition system can be any device known to receive RF transmissions used by those skilled in the art to receive transmissions of data. By way of example but not limitation, the receiver can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the receiver can further transmit data to another device and/or back. Further optionally, two different receivers can be used, one for receiving transmitted data and another for sending data. For example, with the wireless data acquisition system used in the present invention, the receiver can be a wireless router that establishes a broadband internet connection and transmits the physiological signal to a remote Internet site for analysis, preferably by the subject's physician or another clinician. Other examples of a receiver are a PDA, computer, or cell phone that receives the data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, or cable to a remote processor or remote monitoring site for analysis. Other examples of a receiver are a computer or processor that receives the data transmission and displays the data or records it on some recording medium that can be displayed

or transferred for analysis at a later time. Optionally, two or more receivers can be used simultaneously. For example, the patient interface box can transmit signals to a base station receiver that processes and retransmits the signals, as well as a PDA receiver that displays the signals for a clinician to review.

One or more aforementioned sensors are used to develop the data or signals used in the present invention for, optionally, determining a quantitative level of severity of a subject's sleeping disorder and/or symptoms, and more preferably to develop a quantitative measurement of the level of severity of a subject's sleep apnea.

The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms. Using either a microcontroller of a data acquisition system, a separate computer, base station or processor, a PDA, a processor on a device for treating the subject's sleeping disorder or a combination of these processors, the severity of the subject's sleeping disorder and/or symptoms including apneas is determined and is used at least in part to regulate the physical or chemical treatment of the subject. Also optionally, the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.

The processor or microprocessor of various embodiments of the present invention can be part of a remote communication station or base station. The remote communication station or base station can also be used only to relay a pre- or post-processed signal. Preferably, the remote communication station or base station can be any device known to receive RF transmissions such as those transmitted by the wireless data acquisition system described herein. The remote communication station or base station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the remote communication station can further transmit data both to another device including the subject's treatment device and/or back. Further optionally, two

different remote communication stations can be used, one for receiving transmitted data and another for sending data. For example, with the sleep diagnosis and treatment system of the present invention, the remote communication system of the present invention can be a wireless router, which establishes a broadband internet connection and transmits the physiological signal to a remote internet site for analysis, preferably for further input by the subject's physician or another clinician. Another example is where the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis. Another example is where the remote communication system is a computer or processor, which receives the data transmission and displays the data or records it on some recording medium, which can be displayed or transferred for analysis at a later time.

The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein. More preferably, this quantitative method is accomplished in real-time, allowing the subject's symptoms to be treated as they occur. By real-time it is meant that the quantitative diagnosis step is accomplished predictively or within a short period of time after symptoms occur which allows for immediate treatment, thereby more effectively reducing the health affects of such disorder while at the same time also minimizing side effects of the treatment chosen. By real-time, preferably the diagnosis is accomplished within 24 hours of receiving the signals from the one or more sensors on the subject, more preferably within 8 hours, even more preferably within 4 hours, still even more preferably within 1 hour, still even more preferably within 20 minutes, still even more preferably within 5 minutes, still even more preferably within 1 minute, still even more preferably within 10 seconds, still even more preferably within 1 second, still even more preferably within 0.1 seconds and most preferably within 0.01 seconds.

Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms. This filtered data is then is preferably analyzed using the techniques described in the following paragraph In addition to these sleeping disorder data or signal analysis techniques

various controller schemes can be used.

Various sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data. Various embodiments of the present invention include the approach to identifying these symptoms prior to onset by identifying various characteristic shifts in the power spectrum of the sensors being used to monitor these physiological conditions. This characteristic shift in these signals or data can be identified and used to trigger an actuator on the physical or chemical treatment device(s) to provide for delivery of a certain level of treatment. The various embodiments of the present invention include but are not limited to the following signal-processing techniques that are utilized to predict the onset of these symptoms. These are: (i) the standard deviation technique, (ii) a recursively fit ARMAX system identification model, (iii) the Short-Time Fourier Transform (SFFT) technique, and (iv) time-frequency signal analysis with a variety of different kernels. The present invention would also include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis, which is similar to time-frequency analysis with a particular kernel function, to identify the shift in power spectrum associated with imminent flow separation that is discussed herein.

The standard deviation technique operates on the principle that there is an increase in pressure fluctuation as the flow begins to separate from the surface of an airfoil, due to either increasing angle of attack or unsteady flow. A sharp increase in the standard deviation of pressure data is observed immediately prior to stall. To trigger the deployment the flow effectors and initiate fluid flow control, a threshold standard deviation can be calculated for each pressure sensor and programmed into the control strategy.

The second embodiment of a method to identify the shift in measured power spectrum of the signal from the pressure transducer to identify stall utilizes a recursively identified system model, particularly an Auto-Regressive Moving Average (ARMA) model. Advantageously, the controller is the ORICA^{TM} controller, an extended horizon, adaptive, predictive controller, produced by Orbital Research, Inc. and patented under U.S. Patent No. 5,424,942, which is incorporated herein by reference. The ARMA recursive identification method attempts to fit specific models to the measured data or signals. Evaluation of this data reveals distinct, identifiable model order shifts based, which can be used to actuate the treatment device at

various levels. Further analysis of the frequency spectrum of the physiological data related to various sleeping disorders reveals recognizable changes in this data or signals. This clear characterization alongside the model order shifts allows the *ORICA* identifier to classify discrete models based upon various physiological conditions of the subject, thus allowing precisely controlled treatments to be delivered to the subject or patient. A simple function minimization based upon the error associated with each model will enable adaptive model selection for the subject's physiological condition. As the subject's physiological conditions moves toward various critical conditions or symptoms, the model with the best fit to the data will shift into a higher order model. This model shift foretells the onset of the symptom. A second sub-method of identifying impending symptoms using the ARMA and other related models is to track the poles of the identified system model based on the subject over time. As the subject's physiological condition moves toward certain designated critical symptoms, the poles of the identified system model will move toward a condition of symptom onset, thereby indicating to the control system that certain critical symptoms are impending. Either of these two signal identification techniques based on fitting a mathematical model to the system can be utilized to predict the onset of the subject's symptoms. The ARMA model can be adapted to resemble other canonical model forms thereby demonstrating similarity to other system identification methods based on Kalman filtering and similar approaches.

A third embodiment of a method for quantifying the power spectrum measured by the one or more sensors is by using Short-Time Fourier Transforms (STFT). A Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT), both provide frequency information of a digitized signal or data from the sensors. The DFT and FFT both assume that the signal that is being measured is stationary in time. However, in the case of the subject being tested and treated, the measured signal or data is not stationary in time, which means a typical DFT / FFT approach is inapplicable. However, for short time periods the signal maybe considered to be stationary. Therefore, it is possible to estimate the mean power spectrum by segmenting the physiological data or signals into epochs lasting anywhere from 0.1-5 seconds each, and then applying a discrete-time Fourier transform (DFT) to the windowed data. The DFT is used to calculate the power spectrum of the signal for that epoch. Then the spectral mean and median density are calculated from the power spectrum of the signals from

each epoch. Using this method it is possible to identify specific frequency content in the data. As the subject begins to experience the onset of various critical symptoms, the frequency spectrum of the measured and analyzed data will shift, which indicates to the control system that the symptom is beginning.

A fourth embodiment of a signal processing method which can provide indications to the control system that various symptoms are impending, to enable either actuation of the treatment device, is to analyze the sensor data using a time-frequency transform. A time-frequency transform enables both frequency resolution and estimation stability for highly non-stationary signals, which typifies some types of such as some of the data or signals related to various physiological conditions. This is accomplished by devising a joint function of both time and frequency, a distribution that describes the energy and density of a signal simultaneously in both time and frequency. The general form of the time-frequency transform is given by the following

$$P(t,w) = \frac{1}{4\Pi^2} \iiint e^{-j\theta t - j\tau\omega + j\theta u} \phi(\theta,t)$$

$$\cdot s^*\left(u - \frac{1}{2}\tau\right) s\left(u + \frac{1}{2}\tau\right) \, du \, d\tau \, d\theta$$

This transform can be used to calculate instantaneous power spectra of a given signal. The actual transformation distribution is selected by changing the kernel, $\Phi(\theta,\tau)$. The function [e-1] is interesting since it is possible to identify any distribution invariant to time and frequency shifts by means of its kernel, and the properties of the kernel are strictly related to the properties of the distribution, given by [e-1].

The diagnostic device of the present invention is used to provide an output which is then used either automatically to adjust the treatment device or by a clinician or the subject to adjust the device which provides the physical or chemical treatment device which is another part of the system of the present invention. There are clearly many embodiments of the present invention, and we will attempt to describe a few herein.

Also optionally, the signals or data received from the sensors through the data acquisition system can be used to train the treatment or therapeutic device. During a titration or adjustment period the (rich) diagnostic data can be used to train the treatment or therapeutic device to recognize more detailed physiological symptoms or signs of a sleeping disorder, or more

particularly a sleep disorder by correlating the more robust or rich diagnostic data collected with the data acquisition device with the more limited sensor data from the therapeutic or treatment device. For example, certain conditions which routinely are recognized by a number of sensors can be correlated to the signature of the more limited data from the sensors on the therapeutic or treatment device. For instance, while a central sleep apnea is best recognized by a respiratory effort belt and pulse oximetry. Data from a diagnostic period of time can be compared with the sensor data from the treatment device to determine the signature from such data that indicates a central apnic event occurred. Preferably, the treatment device can include a neural network as part of its control mechanism which allows the treatment device to correlate the limited sensor data with the more robust data from the diagnostic period. Optionally, the treatment device can further include a library of events recorded from one or more subjects that allow for more accurate control of the treatment device, and more effective treatment of the subject.

Various embodiments of the present invention include a treatment interface device comprising at least one electronic component for receiving a signal transmitted from the data acquisition system, optionally processing the signal from the data acquisition system, and retransmitting the signal from the data acquisition system or transmitting a signal based at least in part on at least one of the signals from the data acquisition system. The treatment interface device operates essentially as part of the data acquisition system, with the exception that it also transmits to a treatment device (i.e., a PAP or CPAP device). Preferably, the treatment interface device can be used for the titration and then detached from the treatment device or removed from the subject's sleeping location. This would allow the treatment interface device to be used during titration, collected from the subject, and then reused for titration with another subject.

Preferably, the treatment interface device receives a signal from a component of the data acquisition system and transmits a command signal to the PAP or CPAP device. Like a component of the data acquisition system, the treatment interface device preferably contains a transmitter and a receiver. More preferably, the treatment interface device contains a wireless receiver and/or a wireless transmitter. The transmissions sent and received by the treatment interface device do not necessarily use the same method. For example, the treatment interface device could include both a wireless receiver to receive wireless transmissions from the data acquisition system and a USB transmitter to transmit command signals to the PAP or CPAP

device. Optionally, the treatment interface device also contains a receiver or transceiver to receive data from the PAP or CPAP device. Such data could include, for example, PAP or CPAP device status information (ex., whether the device is on or off, error codes, blower speed, etc.), fluid characteristics of the pressurized gas delivered to the patient (ex., airflow, air pressure, humidity, etc.), and the like.

The treatment interface device also preferably contains a processor. Preferably, the treatment interface device uses a processor to execute an algorithm for titrating or adjusting the PAP or CPAP device. The treatment interface device processor can be used to relate all the received signals (from the subject, the environment, and the PAP or CPAP device) to each other, and to predict or determine the next appropriate treatment setting. For example, the treatment interface device could receive a pulse oximetry signal, a thoracic effort signal, and a room temperature signal from a data acquisition system, and an airflow signal from the PAP or CPAP device. The treatment interface device processor would then use the signals to calculate the next appropriate treatment setting. For example, the treatment interface device processor could use the airflow, pulse oximetry signal, thoracic effort, and room temperature to determine that the PAP pressure should be increased by 2 cm H_2O. The treatment interface device processor would then create a command signal to instruct the PAP device to increase the pressure appropriately. The treatment device processor is preferably capable of executing closed-loop titration, thereby automatically determining a set of final treatment values for the treatment device. The set of final treatment values for the treatment device are the parameters programmed into the treatment device (i.e., the PAP or CPAP), which the treatment device uses during operation. Once the set of final treatment values are programmed into the treatment device, the treatment device will continue to operate according to the set of final treatment values. For example, if the treatment device were a CPAP device, the set of final treatment values would be the gas pressure delivered to the patient. Similarly, if the treatment device were a bi-PAP device, the set of final treatment values would be the inspiration gas pressure and the expiration gas pressure. The set of final treatment values depends on both the type of treatment device and the results of the titration process. Essentially, the titration process is designed to determine the set of final treatment values for a given treatment device and a given subject. If the treatment interface device contains a processor, it is preferably capable of using a variety of techniques to conduct the

titration, including but not limited to lookup tables, relationship algorithms, neural networks, wavelets, fast-Fourier transforms, and the like.

Various embodiments of the present invention include a treatment interface device capable of automatically conducting titration of the treatment device. In this case, the treatment device interface preferably uses a processor to enable closed-loop control for executing the titration adjustments, determining the set of final treatment values, and programming the treatment device to deliver the set of final treatment values. Optionally, the set of final treatment values is sent to a clinician for approval. Various other embodiments of the present invention include a treatment interface device capable of using closed-loop control to run the titration and determine the set of final treatment values, but the treatment interface device is not capable of independently programming the treatment device. In this case, a clinician must review the set of final treatment values, approve or adjust them, and then program the treatment device. Various other embodiments of the present invention include a treatment interface device that is only capable of conducting an open-loop titration. In this case, a clinician must conduct the titration, determine the set of final treatment values, and program the treatment device. Thus, the treatment interface device only provides the clinician with a means to control the treatment device and obtain information from it.

Various embodiments of the present invention include a PAP or CPAP device comprising an electrical connection or component for receiving a retransmitted or transmitted signal. The PAP or CPAP device can be any device known in the art that is capable of delivering a flow of gas to the subject and is capable of being titrated or adjusted. The PAP or CPAP device may receive a signal containing command information only. For example, the PAP or CPAP device could receive a command signal to increase the pressure of gas delivered to the subject, to decrease the gas pressure, or to cease operations. Optionally, the device may receive a signal containing data requiring further processing by the PAP or CPAP device. For example, the data acquisition system could transmit a signal containing pulse oximetry and respiration characteristics, which the PAP or CPAP device further processes to relate to an internal airflow signal and determine the next appropriate gas pressure setting.

The PAP or CPAP device could contain any component known in the art to receive the signals sent from the data acquisition system. For example, if the data acquisition system

provides a signal transmitted via USB, the PAP or CPAP device could contain a receiver component for obtaining the transmitted USB signals. Optionally, the PAP or CPAP device may be a wireless receiver. In this case, for example, the PAP or CPAP device wirelessly receives the signals from a transmitting component of the data acquisition system (the patient interface box, the base station, or other component capable of wirelessly transmitting signals), optionally processes the signal, and makes an adjustment to the flow of gas provided to the subject. Further optionally, the PAP or CPAP device contains a component for receiving a signal transmitted from a remote monitoring station. In this case, for example, a remote monitor receives data from the data acquisition system, determines the next appropriate gas pressure setting, and transmits the setting to the PAP or CPAP device.

Various embodiments of the present invention include a PAP or CPAP device capable of processing the received signal. Such processing can be used to relate the received signals to each other and any additional signals collected by the PAP or CPAP device itself. For example, the PAP or CPAP processor could receive a pulse oximetry signal from a data acquisition system, an airflow signal from the PAP or CPAP device itself, and a signal to increase the gas pressure from a remote monitor. The PAP or CPAP processor would then relate the signals to each other, thereby creating a lookup table of values or a more sophisticated relationship algorithm. The PAP or CPAP processor is optionally capable of creating a neural network and training the network with data collected from an individual subject over several nights. Such a neural network could "teach" the PAP or CPAP device to accurately predict apnea events (confirmed with physiological sensors) based only on gas flow characteristics. In this way, the PAP or CPAP device can continue to operate correctly based on gas flow characteristics alone, and the physiological sensors become redundant.

Various embodiments of the present invention include the step of processing or pre-processing the signals received from the sensors attached to the subject. The processor or preprocessor of various embodiments of the present invention can be independent, or combined with any other component. For example, a processor or preprocessor could be a part of the patient interface box, base station, treatment interface, or PAP or CPAP device. Optionally, the processor or preprocessor could be distributed between two or more components of the device. Optionally, preprocessing can correct artifacts, derive a total sleep time, derive a snore signal,

filter a signal, or compress and/or encrypt the data for transmission as described above. Preferably, the preprocessing step corrects for artifacts present in the sensor signals. Optionally, a step of more powerful processing can perform one or more of the preprocessing functions. Further optionally, more powerful processing can determine the appropriate pressure to be delivered by the PAP or CPAP to the subject. Further optionally, more powerful processing can determine whether the patient has central or obstructive sleep apnea. For example, in the case of CSA, the processing can provide a recommendation to stop CPAP treatment and use another treatment specific to CSA.

Various embodiments of the present invention include a system capable of determining the location of obstructions in the airways of subjects. This feature is helpful because one OSA treatment modality is surgical procedures that rely on excising part of the tissue causing the obstruction. In these embodiments, the system detects an obstructive apnea event, and then determines the location of the obstruction using acoustic reflectance methods. A sound wave created by an oscillating piston (tuning fork, membrane, loudspeaker, and the like), an aperture (whistle, reed, and the like), or any other method of producing a sound of known frequency is introduced into the flow of pressurized gas delivered to the patient. The sound wave can be generated inside the PAP or CPAP device, inside the mask, or at any other suitable location. Preferably, the sound is outside the audible frequency range to minimize disturbance to the subject. A pressure transducer in the system will then receive the pressure signals generated by the echo waves bouncing back from the obstructed wall inside the airways. Effectively, the data acquisition system will “listen” to the echoes coming back from inside the subject's airways. Using the delay between the known time of the original sound wave and the detected echo, the system can calculate the location of the obstruction. Measuring the pressure of the reflected sound wave can allow the system to distinguish between the obstruction and other anatomical features of the airway. It is expected that the obstruction site will generate the biggest pressure amplitude, thereby differentiating it from other nearby structures. Also, the system could be configured to "listen" for charges in frequencies or detect an echo signature to determine the density of the tissue the sounds waves are reflected from. Thus allowing for the determination between hard and soft tissue.

Signal quality of the signals from all the sensors can be affected by the posture and

movement of the subject. For methods of the present invention, it is important to reduce motion artifacts from the sensor placement. Errors in the form of noise can occur when biopotential data acquisition is performed on a subject. For example, a motion artifact is noise that is introduced to a biopotential signal via motion of an electrode placed on the skin of a subject. A motion artifact can also be caused by bending of the electrical leads connected to any sensor. The presence of motion artifacts can result in misdiagnosis, prolong procedure duration and can lead to delayed or inappropriate treatment decisions. Thus, it is imperative to remove motion artifact from the biopotential signal to prevent these problems from occurring during treatment.

The present method of collecting signals from a subject includes a means of reducing motion artifacts. When physiological electrodes are used, preferably they are used with conductive gels or adhesives. More preferably, dry electrodes are used with or without conductive gels or adhesives. Still more preferably, the device's firmware and/or software uses body motion information for artifact correction. Most preferably, a combination of the above methods is used.

The most common methods for reducing the effects of motion artifacts in sensors such as electrodes have focused on skin deformation. These methods include removing the upper epidermal layer of the skin by abrasion, puncturing the skin near the electrode, or measuring skin stretch at the electrode site. The methods for skin abrasion ensure good electrical contact between the electrode and the subject's skin. In this method, an abrasive pad is mechanically rotated on the skin to abrade the skin surface before electrode placement. Similarly, medical electrodes have been used with an abrading member to prepare the skin after application of the electrode whereby an applicator gun rotates the abrading member. Methods of skin preparation that abrade the skin with a bundle of fibers have also been disclosed. These methods provide a light abrasion of the skin to reduce the electrical potential and minimize the impedance of the skin, thereby reducing motion artifacts.

Skin abrasion methods can cause unnecessary subject discomfort, prolong procedure preparation time and can vary based on operator experience. Furthermore, skin abrasions methods can lead to infection, and do not provide an effective solution to long term monitoring. Dry physiological recording electrodes could be used as an alternative to gel electrodes. Dry physiological recording electrodes of the type described in U.S. Patent 7,032,301 are herein

incorporated by reference. Dry physiological electrodes do not require any of the skin abrasion techniques mentioned above and are less likely to produce motion artifacts in general.

Although the above-mentioned methods reduce motion artifacts, they do not completely eliminate them and they are less effective for sensors that do not measure a biopotential signal, such as respiratory effort belts, flow meters, environmental sensors, and the like. The invention preferably incorporates a step to more completely remove motion and other artifacts by firmware and/or software correction that utilizes information collected preferably from a sensor or device to detect body motion, and more preferably from an accelerometer. In certain embodiments of the present invention, a 3-D accelerometer is directly connected to the data acquisition system. The data acquisition system receives signal inputs from the accelerometer and at least one set of other physiological or kinetic signals. The microprocessor applies particular tests and algorithms comparing the two signal sets to correct any motion artifacts that have occurred. The processor in one embodiment applies a time synchronization test, which compares the at least one set of physiological or kinetic signal data to the accelerometer signal data synchronized in time to detect motion artifacts and then remove those artifacts. Alternatively, the processor may apply a more complicated frequency analysis. Frequency analysis preferably in the form of wavelet analysis can be applied to the accelerometer and at least one set of physiological or kinetic signals to yield artifact detection. Yet another alternative is to create a neural net model to improve artifact detection and rejection. This allows for the system to be taught over time to detect and correct motion artifacts that typically occur during a test study. The above illustrations are only examples of possible embodiments of the present invention and are not limitations. The accelerometer data need not be analyzed before wireless transmission; it could be analyzed by a base station, computer, or the like after transmission. As should be obvious to those skilled in the art, a 2-D accelerometer or an appropriate array of accelerometers could also be used. Gyroscopes could be used as well for these purposes.

Sensors can be used to detect motion of the subject's body or a portion of the subject's body. The motion information can then be used to detect the posture and movement of the subject. This motion information may indicate that the subject has a sleeping disorder unrelated to breathing, such as restless legs syndrome (RLS) or other parasomnia. The motion information can be used to correct for error in the form of noise or motion artifact in the other sensor

channels. To detect motion, various embodiments of the present invention include sensors, devices, and methods of determining the posture and movement of the subject. This information can be used when analyzing the physiological signals. The posture and movement of the subject is preferably determined by signals received from an accelerometer or an array of two or more accelerometers. Accelerometers are known in the art and are suitable for use as motion-monitoring units. Various other types of sensors can be additionally or alternatively used to sense the criteria (e.g., vibration, force, speed, and direction) used in determining motion. For particularly low power designs, the one or more sensors used can be largely mechanical.

Body movement of the subject will result in a high amplitude signal from the accelerometer. The data acquisition system can also monitor the sensor signals for any indication that the subject has moved, for example from a supine position to an upright position. For example, the integrated velocity signal computed from the vertical acceleration component of the sensor data can be used to determine that the subject has just stood up from a chair or sat up in bed. A sudden change in the vertical signal, particularly following a prolonged period with little activity while the subject is sleeping or resting, confirms that a posture-changing event occurred. The data acquisition system can also monitor the sleep-wake cycle of the patient. Sleep-wake data will be used to determine the total sleep time for the calculation of the apnea/hypopnea index and other sleep related indices.

In addition, a video camera can be used to detect subject movement and position, and the information then used to correct any artifacts that may have arisen from such movement. Preferably, the camera is a digital camera. More preferably, the camera is a wireless digital camera. Still more preferably, the camera is a wireless digital infrared camera. Preferably, the video acquired from the camera is processed so that the subject's movement and position are isolated from other information in the video. The movement and position data that are acquired from the video is then preferably analyzed by software algorithms. This analysis will yield the information needed to make artifact corrections of the physiological signals. Optionally, alternative analysis of the video signal can indicate additional sleeping disorders, such as restless legs syndrome (RLS), sleepwalking, or other parasomnia.

One specific embodiment of the present invention using video subject movement detection involves the use of specially marked electrodes. The electrodes can be any appropriate

electrode known in the art. The only change to the electrode is that they preferably have predetermined high contrast marks on them to make them more visible to the video camera. These marking could be manufactured into the electrodes or simply be a sticker that is placed on the back of the electrodes. These markings enable the video system to accurately distinguish the electrodes from the rest of the video image. Using the markers on each visible electrode, the system can calculate of the movement of each individual electrode, thus allowing for more accurate artifact correction.

In another specific embodiment of the invention, the system can detect subject movement by monitoring the actual movement of the subject's body. Software is applied to the video that first isolates the position of the subject's body, including limbs, and then continues to monitor the motion of the subject.

There are numerous advantages to using video over other means of artifact detection and correction. Foremost, video allows for the calculation of movement artifacts from each individual electrode without the need for accelerometers. This makes the use of video very cost effective in relation to other available methods. The video also can be used in conjunction with the accelerometer data to correct for motion artifacts, thus increasing the precision and accuracy of the system's motion artifact correction capabilities.

Current auto-titrating machines adjust PAP or CPAP pressure based on airflow / pressure alone. The advantage of using multiple parameters over just an airflow or pressure parameter is that the PAP or CPAP can now confirm events and differentiate between central apnea and hypopneas and obstructive apneas and hypopneas. For example, when airflow drops, existing commercial systems will "assume" the event is obstructive; however, the current invention will "know" whether it is obstructive or central by further investigating two other parameters. If pulse ox drops below 3% and thoracic effort persists, then the apnea/hypopnea is obstructive. If the pulse ox drops below 3% and the thoracic effort ceases then the apnea/hypopnea is central. If pulse ox does not drop by 3% then the event cannot be considered an hypopnea at all.

It is a benefit for auto-titrating machines to confirm or to know central apneas vs. obstructive apneas, since central events are indicative of more serious cardiovascular problems and, more often than not, they cannot be properly treated with conventional CPAP treatment. Additional treatment such as oxygen is needed. It is suspected that up to 15% of patients

develop central events once they are placed on PAP or CPAP. The development of central events after PAP or CPAP administration is thought to be generated by a newly discovered and newly created disease called Complex Sleep Apnea (CompSA), which requires a very different treatment than the traditional CPAP.

A method to automatically titrate PAP or CPAP pressure is based on the above physiological parameters that are specific to the subject. The shapes of physiological signals often differ between subjects, especially during events such as hypopneas, apneas, upper airway resistance, central apneas, and others. The ability to wear a portable data acquisition system or device for a few days will allow the PAP or CPAP to be trained on the physiological signals that are specific to that subject. This "subject specific" information can then be used to better optimize auto-titration since it can now better detect hypopneas, apneas, etc.

Preferably, the titration method of the present invention includes a step whereby the titration analysis runs over a minimum period of time, preferably at least 15 minutes, before pressure adjustment occurs. This period is needed to make sure pressure is not titrated up or down without sufficient confirmation of the event. For example, in the event a subject holds their breath for whatever reason, perhaps a bad dream, if the adjustments are made quickly a traditional system may unnecessarily increase pressure because the system has falsely detected an apnea. This is why it is necessary to wait a sufficient period of time, so that non-pathogenic irregular breathing does not affect the PAP or CPAP titration.

Various embodiments of the present invention include the step of conducting PAP or CPAP titration that is attended from a remote location. Such remote attendance can be accomplished in several ways, for example by an individual in a remote location (a remote monitor) periodically or continuously viewing the data transmitted from the data acquisition system, including signals from the sensors and a preprocessed signal or signals based at least in part on at least one of the sensors. Remote monitoring can be achieved at various levels, including but not limited to, post-titration approval, titration approval, and active titration. Further, each level of monitoring can be either periodic or continuous, and can incorporate automatic alerts. Several illustrative examples of monitoring are described below.

In a post-titration approval monitoring scheme, the remote monitor receives a report of the titration process after completion. In this example, the subject receives a completely

automated titration system that independently determines the appropriate pressure of the delivered gas. While the subject sleeps or attempts to sleep, the system automatically adjusts to find the set of final treatment values (i.e., the optimal gas pressure). Then the PAP or CPAP device programs itself to continue delivering the set of final treatment values. The system also sends the collected data and set of final treatment values to the remote monitor, who reviews the collected data and approves or rejects the system's set of final treatment values. If the monitor approves the system's set of final treatment values, the subject can return all the equipment other than the PAP or CPAP device and then use the PAP or CPAP device for ongoing treatment.

In this scenario, the remote monitor is not actively engaged in the titration process. This type of monitoring is typically periodic, with the remote monitor reviewing the data at a single point (after the end of the titration), or at multiple points, for example at the end of each night during a multi-night titration. This type of monitoring could also be continuous, in that the remote monitor continuously receives data from the titration system. Post-titration approval monitoring is generally suited to subjects with relatively simple apnea and few complicating factors. Preferably, the review portion of the post-titration approval monitoring takes place within a few weeks of the titration night(s). More preferably, the review takes place within one week; more preferably within three days; still more preferably within one day; still more preferably within six hours; still more preferably within one hour of the end of the titration nights.

In a titration approval monitoring scheme, the remote monitor receives a report of the titration process after completion. In contrast to the post-titration approval, however, the remote monitor must approve the set of final treatment values before the PAP or CPAP device is programmed to continue delivering that pressure. In this example, the subject could receive an automated titration system that independently determines the set of final treatment values by automatically adjusting while the subject sleeps. The system then sends the collected data and set of final treatment values to the remote monitor, who reviews the collected data and approves or modifies the system's set of final treatment values. If the monitor approves the system's set of final treatment values, the remote monitor programs the PAP or CPAP device to continue using set of final treatment values. Optionally, the subject could receive a semi-automated titration system that periodically changes treatment values. The system sends the collected data and

corresponding treatment values to the remote monitor, who reviews all the data and determines the set of final treatment values. After the remote monitor determines the set of final treatment values, the PAP or CPAP device is programmed to deliver it.

This type of monitoring is typically periodic, with the remote monitor reviewing the data at a single point (after the end of the titration), or at multiple points, for example at the end of each night during a multi-night titration, or several times during the titration nights. This type of monitoring could also be continuous, in that the remote monitor continuously receives data from the titration system. Preferably, the remote monitor determines the optimal gas pressure within one day; still more preferably within six hours; still more preferably within one hour of the end of the titration nights, and most preferably within 20 minutes of the end of the titration.

In an active titration monitoring scheme, the remote monitor receives signals from the system during the titration phase. Preferably, the remote monitor receives data every hour; more preferably the remote monitor receives data every twenty minutes; more preferably every five minutes; and most preferably the remote monitor receives continuous streaming data during the titration phase. In contrast to the post-titration approval and titration approval, the remote monitor is actively engaged in the titration process. In this example of monitoring, the subject could receive a titration system that collects and transmits data to the remote monitor. The remote monitor then reviews the data and determines the next level of gas pressure for the titration. The remote monitor transmits the appropriate command to the PAP or CPAP device (ex., to increase or decrease the gas pressure), and data collection continues until the treatment value requires adjustment. After the remote monitor has completed the titration and determined a set of final treatment values, the PAP or CPAP device is programmed to continue using the set of final treatment values. This type of monitoring can be periodic, with the remote monitor reviewing the data at multiple points, for example just before each change in PAP or CPAP gas pressure. This type of monitoring could also be continuous, with the remote monitor continuously receiving and reviewing data.

Other types of remote monitoring can include only monitoring at the beginning of the titration to assess the quality of the collected signals. For example, the subject can set up the titration system, and the remote monitor can view preliminary data for adequacy. If a sensor has been improperly placed or incorrectly connected, the remote monitor can instruct the subject to

take remedial action. In this way, the remote monitor can ensure receipt of sufficient and adequate data to perform the titration correctly.

Each level of monitoring can include an alert function wherein the monitor receives alerts of predetermined events. For example, the monitor could be alerted when the subject's oxygen saturation drops below a predetermined threshold, when the PAP or CPAP device is instructed to deliver a gas pressure over a safety threshold, every time the system changes the pressure, when an electrode's impedance increases, if a sensor malfunctions, or for any other event. The system can also be programmed to alert the remote monitor of more complex events, such as detection of an apnea event after the PAP or CPAP has reached a defined gas pressure setting, a drop in oxygen concentration combined with cessation of thoracic breathing activity, or a sensor has moved and no back-up sensors are available. Preferably, the alert function is provided in all of the monitoring schemes described above.

Preferably, the remote monitor is capable of communicating with the subject, subject's assistant, or other individual near the subject. Such communication allows the remote monitor to provide instructions to the subject, subject's assistant, or other individual near the subject, for example, to adjust a sensor, close window blinds, remove a source of noise, turn off any equipment, or wake the subject. More preferably, the remote monitor is capable of two-way communication with the subject, subject's assistant, or other individual near the subject. Such communication allows the subject, subject's assistant, or other individual close to the subject to ask the remote monitor questions, for example, to clarify instructions.

Various embodiments of the present invention include a step of monitoring a subject from a separate monitoring location. Data transmitted in a remote monitoring application may include, but are not limited to, physiological data, kinetic data, environmental data, PAP or CPAP device data, audio, and video recording. It is preferable that both audio and video communications be components of the envisioned system in order to provide interaction between the subject and remote monitor.

Preferably, the data is transmitted from a base station to a database or remote monitoring location with a wireless module or card through a cellular service provider. The envisioned remote monitoring application may allow for multiple remote monitoring locations anywhere in the world. Remote data collection to monitoring station configurations may include, but are not

limited to one-to-one, one-to-many, many-to-one, or many-to-many. The envisioned system may include a central server, or group of servers that can collect data from one or more remote sites and offer delivery to multiple viewing clients.

It is preferable that the remote monitoring application employ a wireless network link between the subject and caregiver such as a cellular wireless network. Other wireless techniques include but are not limited to satellite communications, direct radio, infrared links, and the like. Data transmission through a wired network such as dial-up modem, digital subscriber line (DSL), or fiber-optic, while less preferable, can also be used. Bandwidth management facilities will be employed to facilitate remote monitoring in low-speed communication networks. Several data compression techniques are envisioned to maximize system utilization in low-bandwidth environments.

The envisioned remote monitoring step will require data processing, storage, and transmission. This step may be completed or accomplished in one or more modules of the data acquisition system. The preferred embodiment realizes the remote system as two separate components with a patient interface module that can collect, digitize, store, and transmit data to a base station module that can store, process, compress, encrypt, and transmit data to a remote monitoring location. The preferred embodiment of the remote monitoring system will consist of several system modules. A patient interface module will collect physiological and kinetic data from the subject and transmit the signals to a base station module. The base station module will receive the physiological and kinetic data from the patient interface module, and will also preferably directly connect to any environmental sensors and any PAP or CPAP sensors. The base station module will preferably consist of an embedded computer equipped with a cellular wireless data/voice card and a night-vision video acquisition system. The embedded computer will collect, analyze, compress, and encrypt the data and relay them to one or more viewing caregivers. The remote monitoring systems will broadcast their dynamically assigned IP addresses to a dedicated address server, which will be used for lookup by the viewing caregivers. Computer software used by caregivers will enumerate each remote monitoring system in the field using the aforementioned address server and allow caregivers to select one or more for monitoring. The software will have the ability to control data acquisition including start and stop of acquisition, as well as system reconfiguration.

The software preferably will also provide real-time control over the display of data including page width, amplitude, color, montage, and the like. The software will also provide both real-time video and audio communication with the subject using dual services from the cellular card. Video will preferably be transmitted through the data connection, and audio will preferably be transmitted through the voice connection.

While the equipment and methods used in the various embodiments of the present invention can be used in rooms or buildings adjacent to the subject's sleeping location, due to the equipment's robust nature these methods are preferably performed over greater distances. Preferably, the subject's sleeping location and the remote locations, for example the location of the remote monitor, are separate buildings. Preferably, the subject's sleeping location is at least 1 mile from the remote location(s) receiving the data; more preferably, the subject's sleeping location is at least 5 miles from the remote location(s) receiving the data; even more preferably, the subject's sleeping location is at least twenty miles from the remote location(s) receiving the data; still more preferably, the subject's sleeping location is at least fifty miles from the remote location(s) receiving the data; still even more preferably, the subject's sleeping location is at least two hundred-fifty miles from the remote location(s) receiving the data; more preferably, the subject's sleeping location is in a different state from the remote location(s) receiving the data; and most preferably, the subject's sleeping location is in a different country from the remote location(s) receiving the data.

Various embodiments of the present invention include the step of evaluating the received signals to determine if they are adequate for later analysis. This step can be performed or accomplished a number of ways. In the simplest form, the signal can be evaluated once just prior to the start of the sleep study. In another form, the signal is evaluated periodically during the study to determine its quality. Preferably, the signal(s) are evaluated both at the start of the study and periodically during the study. Most preferably, the signals are evaluated at the beginning of the study and continuously during the study. If the signals are evaluated for adequacy, preferably the subject can be contacted to adjust the sensor as necessary. In this way, corrective action can adjust an inadequate signal to increase the value of the sleep study data and enable later analysis.

The data collected for the sleep analysis conducted under the various methods of the

present invention can be viewed by any number of medical personnel and the subject themselves, if appropriate. Preferably, the data is available to a sleep technician, to a doctor making the analysis/diagnosis based on the data, and others involved in these methods. This data can be reviewed at multiple locations including but not limited to the doctor's home or office, or anywhere else the doctor or other individuals associated with the analysis/diagnosis have access to the internet or an intranet.

Referring now to the drawings and, in particular to FIG. 1, there is shown a block diagram of the present invention. An external input 12 from sensor 14 is input to signal processing module 16. Although, one sensor 14 and one external input 12 are shown, the signal processing module 16 is capable of accepting multiple external inputs 12 from multiple sensors 14. The signal processing module 16 generates a signal 18 encoded with data corresponding to the external input 12. The signal processing module 16 transmits the signal 18 by wireless means to a base station 40. In FIG. 1, the wireless means is shown as radio frequency (RF). In this case, the signal processing module generates a radio frequency signal 18 by frequency modulating a frequency carrier and transmits the radio frequency signal through module antenna 20. The base station 40 receives the radio frequency signal 18 through base antenna 42, demodulates the radio frequency signal 18, and decodes the data. It is understood that other wireless means can be utilized with the present invention, such as infrared and optical, for example. Although one module antenna 20 and one base antenna 42 is shown in this embodiment, it is understood that two or more diversity antennas can be used and are included in the present invention. An external programming means 60, shown in FIG. 1 as a personal computer, contains software which is used to program the signal processing module 16 and the base station 40 through data interface cable 62. The data interface cable 62 is connected to the base station 40 and signal processing module 16 by respective connectors 64. The same data interface cable 62 or two different interface cables 62 can be used, one for the base station 40 and one for the signal processing module 16. The signal processing module 16 and the base station 40 can be programmed by connecting a data interface cable 62 between it and an external programming means 60 or by radio frequency (or other type) of signals transmitted between a base station 40 to the signal processing module 16 or to another base station 40. RF signals, therefore, can be both transmitted and received by both signal processing module 16 and base

station 40. In this event the signal processing module 16 also includes a module receiver 29 while the base station 40 also includes a base transmitter 84, in effect making both the signal processing module 16 and the base station 40 into transceivers. In addition, the data interface cable 62 also can be used to convey data from the base station 40 to the external programming means 60. If a personal computer is the external programming means 60, it can monitor, analyze and display the data in addition to its programming functions. The base receiver 80 and module receiver 29 can be any appropriate receivers, such as direct or single conversion types. The base receiver 80 preferably is a double conversion superheterodyne receiver while the module receiver 29 preferably is a single conversion receiver. Advantageously, the receiver employed will have automatic frequency control to facilitate accurate and consistent tuning of the radio frequency signal 18 received thereby.

Referring now to FIG. 2, there is shown a block diagram of the signal processing module 16 with the sensor 14 and the module antenna 20. The signal processing module 16 comprises input means 22, analog-to-digital (A/D) means 24, a module microcontroller 26 with a nonvolatile memory, advantageously, an EEPROM 261, a module transmitter 28, a module receiver 29 and a module power supply 30. Although the module antenna 20 is shown externally located from the signal processing module 16, it can also be incorporated therein. The module antenna 20 may be a printed spiral antenna printed on a circuit board or on the case of the signal processing module 16 or other type of antenna. A module power supply 30 provides electrical power to the signal processing module 16 which includes the input means 22, A/D means 24, module microcontroller 26 module transmitter 28 and module receiver 29.

The input means 22 is adjustable either under control of the module microcontroller 26 or by means of individually populatable components based upon the specific external input 12 characteristics and range enabling the input means 22 to accept that specific external input 12. For example, if the input is a 4-20 mA analog signal, the input means 22 is programmed by the module microcontroller 26 and/or populated with the components needed to accept that range and characteristic of signals. If the input characteristics change the programming and/or components change accordingly but the same platform circuit board design is utilized. In other words, the same platform design is utilized notwithstanding the character, range, or quantity (number of external inputs 12) [up to a predetermined limit] of the input. For example,

bioelectric signals such as EEG, EMG, EKG, and EOG have typical amplitudes of a few microvolts up to a few tens of millivolts. For a given application, a specific frequency band of interest might be from 0.1 Hz to 100 Hz, whereas another application may require measurement of signals from 20 Hz to 10 KHz. Alternatively, measurement of vital signs such as body temperature and respiration rate may deal with signals in a range of +5 volts, with a frequency content from DC (0 Hz) to 20 Hz. For other applications such as industrial process monitoring, the information of interest may be contained in the signal as a current, such as a 4 to 20 mA current loop sensor, or it may take the form of resistance, impedance, capacitance, inductance, conductivity, or some other parameter, The present invention provides a single device for measuring such widely disparate signal types and presents distinct economic advantages, especially to small enterprises such as a medical clinic located in a rural area, which would be empowered by this invention to conduct tests which would otherwise have required subject travel to a large medical center, with all the attendant cost thereof.

This is possible due to the selectively adaptable input means 22 and A/D means 24, the frequency agile module transmitter 28 and base transmitter 84, and the programmability of the module microcontroller 26 and EEPROM 261. One universal platform design then can be utilized for all applications. In addition, the signal processing module can comprise multiple copies of the input means 22 and the A/D means 24. Cost savings can be achieved by multiplexing at several different points in the input means 22 and the A/D means 24 allowing hardware to be shared among external inputs 12.

After receipt by the input means 22, the external input 12 is inputted to the A/D means 24. The A/D means 24 converts the input to a digital signal 32 and conditions it. The A/D means 24 utilizes at least one programmable A/D converter. This programmable A/D converter may be an AD7714 as manufactured by Analog Devices or similar. Depending upon the application, the input means 22 may also include at least one low noise differential preamp. This preamp may be an INA126 as manufactured by Burr-Brown or similar. The module microcontroller 26 can be programmed to control the input means 22 and the A/D means 24 to provide specific number of external inputs 12, sampling rate, filtering and gain. These parameters are initially configured by programming the module microcontroller 26 to control the input means 22 and the A/D means 24 via input communications line 35 and A/D communications line 36 based upon the input

characteristics and the particular application. If the application changes, the A/D converter is reconfigured by reprogramming the module microcontroller 26. In this manner, the input means 22 and the A/D means 24 can be configured to accept analog inputs of 4-20 mA, +/-5 volts, +/-15 volts or a range from +/-microvolts to millivolts. They also can be configured to accept digital inputs, for detection of contact closure, for example.

The module microcontroller 26 controls the operation of the signal processing module 16. In the present invention, the module microcontroller 26 includes a serial EEPROM 261 but any nonvolatile memory (or volatile memory if the signal processing module remains powered) can be used. The EEPROM 261 can also be a separate component external to the module microcontroller 26. Advantageously, the module microcontroller 26 may be PIC16C74A PIC16C74B or a PIC16C77 both manufactured by MicroChip, or an Amtel AT90S8515 or similar. The module microcontroller 26 is programmed by the external programming means 60 through the connector 64 or through radio frequency signal from the base station 40. The same module microcontroller 26, therefore, can be utilized for all applications and inputs by programming it for those applications and inputs. If the application or inputs change, the module microcontroller 26 is modified by merely reprogramming. The digital signal 32 is inputted to the module microcontroller 26. The module microcontroller 26 formats the digital signal 32 into a digital data stream 34 encoded with the data from the digital signal 32. The digital data stream 34 is composed of data bytes corresponding to the encoded data and additional data bytes to provide error correction and housekeeping functions. Advantageously, the digital data stream 34 is organized in data packets with the appropriate error correction data bytes coordinated on a per data packet basis. These packets can incorporate data from a single input channel or from several input channels in a single packet, or for some applications may advantageously include several temporally differing measurements of one or a plurality of input channels in a single packet. The digital data stream 34 is used to modulate the carrier frequency generated by the transmitter 28.

The module transmitter 28 is under module microcontroller 26 control. The module transmitter 28 employs frequency synthesis to generate the carrier frequency. In the preferred embodiment, this frequency synthesis is accomplished by a voltage controlled crystal reference oscillator and a voltage controlled oscillator in a phase lock loop circuit. The digital data stream 34 is used to frequency modulate the carrier frequency resulting in the radio frequency signal 18

which is then transmitted through the module antenna 20. The generation of the carrier frequency is controlled by the module microcontroller 26 through programming in the EEPROM 261, making the module transmitter 28 frequency agile over a broad frequency spectrum. In the United States and Canada a preferred operating band for the carrier frequency is 902 to 928 MHz. The EEPROM 261 can be programmed such that the module microcontroller 26 can instruct the module transmitter 28 to generate a carrier frequency in increments between 902 to 928 MHz. as small as about 5 to 10 KHz. In the US and other countries of the world, the carrier frequency may be in the 2400 to 2483.5 MHz. band, 5.725 to 5.875 GHz. band, or the 24.0 to 24.25 GHz. band, or other authorized band. This allows the system to be usable in non-North American applications and provides additional flexibility.

The voltage controlled crystal oscillator (not shown) in the module transmitter 28, not only provides the reference frequency for the module transmitter 28 but, advantageously also, provides the clock function 38 for the module microcontroller 26 and the A/D means 24 assuring that all components of the signal processing module 16 are synchronized. An alternate design can use a plurality of reference frequency sources where this arrangement can provide certain advantages such as size or power consumption in the implementation.

The module receiver 29 in the signal processing module 16 receives RF signals from the base station 40. The signals from the base station 40 can be used to operate and control the signal processing module 16 by programming and reprogramming the module microprocessor 26 and EEPROM 261 therein.

The base station 40 has a base antenna 42 through which RF signals 18 are received. Base microcontroller 86 controls the operation of the base station 40 including base receiver 80, base transmitter 82, and base power supply 88. Base receiver 80 receives the RF signal 18 from base antenna 42. The base receiver 80 demodulates the RF signal 18 and the base microcontroller 86 removes any error correction and performs other housekeeping tasks. The data is then downloaded through connector 64 to the external programming means 60 or other personal computer (PC) or data storage/viewing device for viewing in real time, storage, or analysis.

Referring now to FIG. 4, there is shown a block diagram of the input means 22 and A/D means 24 of the signal processing module 16, which provides for the data acquisition function of the present invention. The signal processing module 16 is variably configurable through software

programming initiated by the external programming means 60 to the EEPROM 261 of the microcontroller 26. The variable configurability enables the signal processing module 16 to receive external inputs 12 having different characteristics and ranges and to provide variable sampling rate, filtering and gain of the external inputs 12 based upon such characteristics and range and/or the specific application. For example, if the present invention is utilized in a biomedical environment, EEG diagnosis and monitoring for instance, the sampling rate will need to be much higher than it would be for an industrial setting measuring thermocouple readings. The ability to reconfigure the system for varying signal characteristics arises at three separate levels in the present invention. For maximum flexibility, such reconfiguration can be carried out during a series of measurements by means of the wireless link, which is understood in this context to be bidirectional. Depending on the characteristics of the received signal 18, the base station 40 can command the signal processing module 16 to reconfigure the input means 22 and/or A/D means 24 to accept an external input 12 of larger amplitude, or a different frequency range, where signal characteristics change significantly during the course of a series of measurements. Alternatively, for cost, size, and power advantages, this adjustment could be carried out prior to a series of measurements, with the configuration information stored in memory in the signal processing module 16, where this memory is advantageously implemented in a nonvolatile form such as EEPROM 261, allowing the configuration information to be retained, for instance, across power outages and obviating the need for module receiver 29 and base transmitter 84, saving cost. A third alternative, which provides advantages in certain technical parameters, is to arrange the implementation of the signal processing module 16 such that minor changes in component values or parameters can reconfigure the same basic hardware to accept widely divergent external input 12 types. This reconfiguration could take place at the factory, providing cost and inventory advantages to the manufacturer, or it could be performed by the end user, providing similar cost advantages to the user in allowing one piece of equipment to perform multiple tasks.

A number of configurable components are shown in FIG. 4. Any given component of this arrangement, though, may be omitted, and, in some cases, the order of the components may be changed to gain certain advantages such as physical size, power consumption, or cost, without changing the basic spirit of the invention. Components in this FIG. 4 may be combined, either by

having a single component carry out the function of two or more of the components shown or by combining functions within a single package such as an integrated circuit or hybrid module. Certain components may also operate with a fixed configuration, limiting the flexibility of certain parameters while retaining the advantages of configurability in other components.

The external input 12 inputs to the input protection network 221, which protects the signal processing module 16 against damage caused by faults or unanticipated conditions encountered at the external inputs 12. Depending on the rigors expected to be encountered in any given application and the tolerance to size and weight, the input protection network 221 may be omitted, may consist of a simple resistor network, or may include more elaborate protection such as diodes, zener diodes, transorbs, gas discharge tubes, and other components commonly known to those of ordinary skill in the art. Typically, the input protection network 221 is not configurable but its configurability in the present invention provides advantages in certain applications. Configuration options can include adjustable limits on input voltage and/or current as well as rates of change of those parameters, and other electrical parameters as well. These configuration changes can be achieved by changes to component values on a common platform for smallest size, or can be changed under processor control by means of various switches such as relays. A signal within normally expected ranges passes essentially unchanged to the measurement type means 222.

The measurement type means 222 allows selection of the external input 12 configuration. The measurement type means 222 may be used to configure the input circuitry to accept external inputs 12 which are single-ended voltage (a voltage with respect to a common reference shared between several signals), differential voltage (voltage between two defined conductors), differential current (current flowing through a conductor), single-ended current (current flowing to a common reference), frequency, capacitance, inductance, resistance, impedance, conductivity, or any other electrical parameter. The measurement type means 222 converts the external input 12 to a common parameter such as voltage or current, which can be interpreted by the succeeding blocks regardless of the original type of external signal 12 measured. One input channel can be built with several different measurement type means, which can be selectively enabled by means of an analog switch, such as that found in the AD7714 chip in the present invention. It is understood that the AD7714 chip can provide many of the functions of the A/D

means 24 and the input means 22 thus reducing the overall size of the signal processing module 16. In the preferred embodiment, the output of the measurement type means 222 is a varying voltage carrying the information which was present in the original signal, or in certain cases, a series of voltage measurements, which are then conveyed to the prefilter 223.

The prefilter 223 allows rejection of external inputs 12 of large signals which are outside the frequency band of interest, so that such signals do not saturate the low-noise preamplifier 224. The prefilter 223 can be advantageously arranged to be a relatively simple filter to provide cost, size, and power advantages, because it need only reject out of band signals to the extent necessary to protect the low-noise preamplifier 224. A typical application might use a simple "R-C" filter to reject offset voltages in an AC-coupled application, or to reject extremely high frequencies which fall well beyond the frequency band of interest, or a combination of the two. Configurability of this section can be limited to simply enabling or bypassing the prefilter 223, or may be more elaborate in allowing selection of cutoff frequencies. In the preferred embodiment this prefilter consists of a simple RC filter which can be bypassed under firmware control, to minimize noise injection; however, an alternate embodiment could incorporate electrically adjustable components such as electronic potentiometers or varactors to provide even more flexibility at the expense of size and noise injection. The prefiltered signal is then passed to the low-noise preamplifier 224.

The low-noise preamplifier 224 is advantageous in certain applications to allow application of gain to the external input 12 early in the signal chain, before significant noise is introduced by the inherent characteristics of certain components, such as thermal noise. Configurability of the gain applied at this step provides an advantage in allowing the present invention to accept larger external inputs 12 using a low gain (unity gain or lower), or alternatively to accurately measure very small external inputs 12 with minimal noise by using higher gain. This gain can be selectively chosen to be either a fixed value or unity gain under processor control by means of the signal selector built into the AD7714 used in the preferred embodiment, or can be designed to allow a selection of one of several gains by means of analog switches combined with a plurality of gain setting resistors. Gain applied at this stage has the net effect of dividing any downstream noise by the gain factor applied here. This more robust signal output by the preamplifier 224 is then passed to the AC coupling filter 225.

The AC coupling filter 225 is a highpass filter used to allow the system to reject the DC offset or steady state value of an external input 12 wherein the offset is not of interest, allowing additional gain to be applied to the changes in the external input 12. For instance, bioelectric signals such as EEG, EMG, or ECG are normally of interest only for the changes in those signals, and the absolute offset level is not of interest for diagnostic purposes. The cutoff frequency may be configured to allow adjustment of various parameters such as settling time, or may be adjusted to zero to effectively bypass the AC coupling filter 225. In the preferred embodiment, the filter may be bypassed by use of the signal selector switch in the AD7714; however, the use of adjustable components such as electronic potentiometers or varactors would allow more flexibility in choosing the cutoff frequency, at the expense of size and power consumption. The resulting signal, now stripped of any interfering DC offset if so configured, is then passed to the antialias filter 226.

The antialias filter 226 is a lowpass filter required to guard against false signals caused by aliasing between external input 12 content and sampling rate of downstream sampling functions such as multiplexing or analog-to-digital conversion. The Nyquist sampling theorem shows that any frequency content in the sampled signal which is higher than one-half the sampling rate of the sampling function will cause aliasing, which results in false signals. In practice the antialias filter 226 is more commonly set to a smaller fraction of the sampling rate, usually between 1/4 and 1/10 the sampling rate. Regardless of the rate or ratio used, the cutoff frequency of the antialias filter 226 must change when the sampling rate changes significantly, to retain the most advantageous ratio of the sampling rate to the filter passband. The programmable cutoff frequency of the antialias filter 226 is thus required to allow for variable sampling rates. In the preferred embodiment, the high sampling rate of the delta sigma modulator in the AD7714 permits the use of a simple fixed RC type filter, with the anitalias filtering begin provided as an inherent digital filter in the AD7714; however, an alternate embodiment might use a switched capacitor filter such as the MAX7409 or other filter with a programmable cutoff frequency. The resulting filtered signal is then conveyed to the programmable gain amplifier 241 in the A/D means 24.

The programmable gain amplifier 241 adjusts the external input 12 amplitude to match the amplitude accepted by the A/D converter 242. In the preferred embodiment this

programmable gain amplifier is included in the AD7714 integrated circuit, but this function could also be provided with a dedicated programmable gain amplifier, or alternatively through the use of analog switches or adjustable components such as potentiometers or DACs. If too much gain is applied, the programmable gain amplifier 241 itself or downstream components will saturate, introducing severe distortion and usually rendering the external input 12 immeasurable. If, on the other hand, insufficient gain is applied here, the quantization noise of the analog-to-digital conversion process comes to dominate the external input 12, causing a severe degradation in the signal-to-noise ratio. For instance, a typical 16-bit A/D converter 242 can distinguish between 2^{16} or 65536 distinct levels. With an A/D converter 242 input range of +/- 3 volts, each level represents 92 μV. If insufficient gain is applied to the external input 12 such that the total signal swing is only 200 μV, the A/D converter 242 will convert at most three distinct levels, rendering fine features of the external input 12 totally illegible. The module microcontroller 26 therefore adjusts the gain applied in the programmable gain amplifier 241 such that the expected external input 12 as processed and filtered by the preceding elements as described above, is amplified to cover as much of the A/D converter 242 input range as practical, or some other gain which optimizes signal features of interest. Additionally, in some applications it is advantageous to have the module microcontroller 26 adjust this gain dynamically depending upon the actual measured external input 12. For instance, the module microcontroller 26 might increase the programmable gain amplifier 241 gain when a measured external input 12 is very small, and then decrease the gain to avoid saturation when the external input 12 amplitude increases. This automatic gain control provides an increase in the total dynamic range achievable by the system without requiring expensive, large, and power-hungry components such as very high resolution A/D converters 242. The signal resulting from application of the specified gain is then passed to the A/D converter 242.

At least two parameters of a typical A/D converter 242 can be readily adjusted to achieve various goals as the situation dictates. First, the sampling rate may be adjusted to balance the conflicting goals of high fidelity measurements and low digital data rate. Where a signal has no high frequency content of interest, the sampling rate may be adjusted to a very low rate to minimize the demands on downstream processes such as digital filtering or telemetering of the data. On the other hand, sampling an external signal 12 with significant high-frequency content

of interest demands a higher sampling rate. In the preferred embodiment, the sampling rate is programmable via the AD7714; in other implementations the sampling rate can be made adjustable by means of an externally applied sampling clock to an A/D converter. The adjustable sampling rate allows the controller to adapt the A/D converter 242 to best meet the system demands of the moment.

In a similar fashion, selection of the resolution provided by the A/D converter 242 must balance faithful reproduction of the external input 12 against total digital data rate. Depending on the particular A/D converter 242 used, there may also be a tradeoff of the maximum achievable sampling rate against the selected resolution, wherein selection of a higher resolution lowers the maximum attainable sampling rate. Again the module microcontroller 26 can adjust this parameter to best meet the system requirements, selecting higher resolution when smaller changes in the measured signal amplitude must be reported, and lower resolution when the lack of such a requirement allows advantages in the form of either a higher sampling rate or a lower digital data rate. In the preferred embodiment, the AD7714 can be programmed to either 16 bit or 24-bit resolution, and the firmware running in the microcontroller can selectively transmit 8, 12, 16, or 24 bits of the acquired data. The digital filter 243, the module microcontroller 26, or other downstream process can also reject certain portions of the digital data stream to provide an effective decrease in resolution where this decrease is advantageous, especially when the data must later cross a bandwidth-limited link such as a RF, IR or optical link. The A/D converter 242 passes the signal, now in the form of a succession of digital values, to the digital filter 243 for further processing.

The digital filter 243 extracts external input 12 parameters of interest while rejecting other signals, commonly referred to as noise. Implementation of the digital filter 243 could alternatively be in the form of analog filters applied anywhere in the signal chain prior to the A/D converter 242, but implementation as a digital filter 243 provides advantages as to programmability, calibration, drift, and accuracy. The digital filter 243 could be implemented in many forms, depending upon the demands of the particular application. In the preferred embodiment, the digital filter is inherent in the analog to digital conversion process inside the AD7714, but it is understood that the digital filter 243 could be implemented as firmware inside the module microcontroller 26 itself, or as a digital signal processor, or as a specialized

integrated circuit, or by some other means. Regardless of implementation, the programmability of the digital filter 243 allows the system to readily adapt to changing measurement requirements, whether those changes are brought about by changes in the environment, changes in the external input 12 itself, or changes in the focus of the overall system. The resulting output from the digital filter 243 is a stream of digital values, ready for further processing such as assembly into the desired format for transmission by the firmware.

Referring now to FIG. 5 there is shown a block diagram of the firmware of the present invention. The signal processing module 16 firmware defines several modes of operation 100. There are several "test" modes which are used during factory calibration of the device. In addition, there are several operation modes which have mode-specific configuration. For example, the signal processing module 16 can be programmed to operate in a first operational mode in which it transmits calibration data (used to properly zero the analog inputs) for the first three seconds of operation (or for some other predetermined time), and then switches to a second operational mode which transmits analog signal information as collected from the A/D converters 242. The configuration for each mode of operation is programmed in the non-volatile memory EEPROM 261.

Once power is first applied to the signal processing module 16, the module microcontroller 26 performs the basic device initialization, including proper configuration of the I/O ports and internal variables 102. Next, the module microcontroller 26 reads the initial device configuration 104 from the EEPROM 261. This configuration controls the input means 22 of the signal processing module 16, including the number of external inputs (also herein referred to as channels), the resolution of the A/D converter 242, and the sampling rate of each individual input channel. This configuration also controls the operation of the module transmitter 28 in the signal processing module 16, including the carrier frequency, modulation type, output power control, and the length in bytes of each transmitted RF message packet. This configuration also describes the initial mode of operation for the signal processing module 16.

Once the initial configuration has been read, the module microcontroller 26 enters the first mode of operation described in the configuration. It reads the mode-specific configuration 106, which includes the state of the module transmitter 28 and the analog inputs as used in the mode. This configuration can reside in EEPROM 261 or in module microcontroller 26 memory.

The module microcontroller 26 then initializes all the peripheral devices according to this mode configuration 108. In the special case that this is the "shutdown" mode, the module microcontroller 26 will perform a software power-down 110.

Once the mode has been initialized, the module microcontroller 26 begins execution of the interrupt service routine (ISR) 112, which is responsible for transmitting the data in the form of messages along the modulated RF carrier. Operation of the interrupt service routine is asynchronous and distinct from the mainline code, and is described later.

The module microcontroller 26 begins execution of the mode-specific "opcodes" 114, which are a sequence of instructions contained either in EEPROM 261 or in the module microcontroller 26 memory. These opcodes are performed for each operational mode. The module microcontroller 26 reads the first operational code from the EEPROM 261 and interprets the opcode, performing an appropriate action: If the opcode instructs the module microcontroller 26 to change modes 116, the module microcontroller 26 terminates the ISR 118 and returns to the mode initialization, and begins execution of a new operational mode; if the opcode instructs the module microcontroller 26 to begin a loop construct 120, the module microcontroller 26 begins the loop by initializing a loop counter variable 122; if the opcode instructs the module microcontroller 26 to end a loop construct, the module microcontroller 26 increments the loop counter variable and determines if the loop is complete 124. If not, the module microcontroller 26 resets the index of current opcode to the beginning of the loop, otherwise it sets the index of the next opcode to after the loop; if the opcode instructs the module microcontroller 26 to initialize a single A/D converter 242, the module microcontroller 26 will perform the specified calibration 126; if the opcode instructs the module microcontroller 26 to the read a single A/D converter 242, the module microcontroller 26 will take the reading and insert the data into the current message to be transmitted over the RF carrier 128; if the opcode instructs the module microcontroller 26 to insert a special byte of data into the RF message, the module microcontroller 26 will insert this data into the message 130. This special message byte may include an identifier to uniquely identify the signal processing module 16, an error check field such as a cyclic redundancy check, or some data representing the internal state of the signal processing module 16 such as the RF frequency, measured temperature, etc.

After each opcode has been read and interpreted, the module microcontroller 26

determines if the RF message has been completely filled and is ready to be transmitted over the RF carrier 132. If it has, the module microcontroller 26 marks a flag variable for the interrupt service routine to begin transmitting the RF message 134.

Next, the module microcontroller 26 performs any housekeeping tasks, such as updating the RF tuning parameters based on changes in temperature, updating timers, etc. 136. Finally, the module microcontroller 26 returns to execute the next opcode in the sequence 114.

Referring now to FIG. 6 there is shown a block diagram of the software programming function of the ISR 150. The ISR is responsible for transmitting the individual message bytes over the RF carrier. The ISR is executed by a hardware interrupt which occurs immediately before every byte to be transmitted over the RF carrier. The ISR detects whether an RF message is completely filled 152. If the ISR detects (based on the flag variable) that an RF message is not yet completely filled by the main code, the ISR transmits a "filler" byte, or a byte with an even number of "1" and "0" bits 154. This acts to maintain an even (50%) modulation duty cycle on the carrier frequency.

Once the ISR detects that the main code has filled an RF message to be transmitted, it transmits the RF sync bytes 156. These are two unique bytes transmitted at the beginning of every RF message which are easily identified by the base station 40 as the start of a message.

Once the RF sync bytes have been transmitted, the ISR transmits each message byte of the RF message, in sequence 158. Once the RF message has been completely transmitted 160, the ISR resumes transmitting filler bytes until the next RF message is filled by the main code.

Because of the phase locked loop based frequency synthesizer used in the present invention, the module transmitter 28 and base transmitter 84 are frequency agile over the frequency range. Since the module receiver 29 and the base receiver 80 employ automatic frequency control, the present invention consumes relatively low power as the module transmitter 28 and base transmitter 84 can be intermittently powered down without loosing reception due to drift or sacrificing data transmission accuracy. The utilization of programmable firmware allows inexpensive and flexible operation for the inputting, conditioning and processing of any type, character and range of the external inputs. This also allows the module microcontroller 26, in response to the variation of the external inputs 12 or, in response to instructions received by RF signal through the module receiver 29, to adapt the signal processing

module 16 based upon the variations allowing the signal processing means 16 to input, condition, process and transmit said external input notwithstanding said variation. The present invention performs this adaptation without the need to modify or alter hardware or select or use different hardware already present in the device. In other words all adaptation can be accomplished by software programming totally.

One or more sensors are used to develop the data or signals used in the present invention for determining a quantitative level of severity of a subject's sleeping disorder and/or symptoms. In various embodiments, preferably at least two EEG electrodes are used to develop this data. In other embodiments, preferably, at least two ECG electrodes are used. In still other embodiments, preferably a pulse oximeter is used. In still even other embodiments, preferably, either an O_2 or CO_2 blood gas monitor is used.

The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms. Using either the microcontroller 26 of a data acquisition system, a separate computer, base station or processor, a PDA, a processor on a device for treating the subject's sleeping disorder or a combination of these processors, the severity of the subject's sleeping disorder and/or symptoms is determined and is used at least in part to regulate the physical or chemical treatment of the subject. Also optionally, the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.

The processor or microprocessor of various embodiments of the present invention can be part of a remote communication station or base station. The remote communication station or base station can also be used only to relay a pre- or post-processed signal. Preferably, the remote communication station or base station can be any device known to receive RF transmissions such as those transmitted by the wireless data acquisition system described herein. The remote communication station or base station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, a computer with wireless capabilities, a PDA with

wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the remote communication station can further transmit data both to another device including the subject's treatment device. Further optionally, two different remote communication stations can be used, one for receiving transmitted data and another for sending data. For example, with the sleep diagnosis and treatment system of the present invention, the remote communication system of the present invention can be a wireless router, which establishes a broadband internet connection and transmits the physiological signal to a remote internet site for analysis, preferably for further input by the subject's physician or another clinician. Another example is where the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis. Another example is where the remote communication system is a computer or processor, which receives the data transmission and displays the data or records it on some recording medium, which can be displayed or transferred for analysis at a later time.

The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein. More preferably, this quantitative method is accomplished in real-time, allowing the subject's symptoms to be treated as they occur. By real-time it is meant that the quantitative diagnosis step is accomplished predictively or within a short period of time after symptoms occur which allows for immediate treatment, thereby more effectively reducing the health affects of such disorder while at the same time also minimizing side effects of the treatment chosen. By real-time, preferably the diagnosis is accomplished within 24 hours of receiving the signals from the one or more sensors on the subject, more preferably within 8 hours, even more preferably within 4 hours, still even more preferably within 1 hour, still even more preferably within 20 minutes, still even more preferably within 5 minutes, still even more preferably within 1 minute, still even more preferably within 10 seconds, still even more preferably within 1 second, still even more preferably within 0.1 seconds and most preferably within 0.01 seconds.

FIG. 7 shows a flow diagram of one example titration algorithm that adjusts the pressure

of a CPAP device based on at least the measured airflow, respiratory effort, and blood oxygen concentration. The algorithm in FIG. 7 consists of a counting phase and an adjustment phase. The adjustment phase operates in titration mode, during which large pressure adjustments are made, and tuning mode, during which fine pressure adjustments are made to establish the optimum air pressure.

First, a time interval and all event counters are reset 202. The system then establishes a baseline 206, which is used for comparisons throughout the time interval. If the time interval has elapsed 210, the system evaluates the event counters and makes adjustments as necessary. The time interval 210 in FIG. 7 is shown as 15 minutes, but any time period may be suitable. For example, early in the titration phase, smaller intervals of 5 minutes may be more appropriate, while later in the titration phase intervals of 30 minutes or more may be used.

If the time interval has not elapsed 210, the subject's airflow is compared to the baseline 214. If the subject's current airflow drops below 70% of the baseline for 10 seconds or more 214, the system evaluates the effects of a severe reduction in airflow. If the airflow drops to below 10% of the baseline 218, the decrease in airflow may indicate an instance of apnea. In this situation, the subject's oxygen saturation is compared to the baseline 222. If the subject's oxygen saturation has not decreased more than 3% 222, the decrease in airflow is not an event at all, and the system returns to monitoring the subject's airflow 210. If the subject's oxygen saturation does decrease more than 3% 222, the system checks for a breathing effort 226. If the subject is attempting to breathe, the event is considered an obstructive sleep apnea (OSA), and the OSA_n count is increased by one 230. The system then returns to monitoring the subject's airflow 210. If, however, the subject is not attempting to breathe, the system continues to look for breathing effort 226. If the subject does not attempt to breathe for more than 4 seconds 234 the event is considered a central sleep apnea (CSA), and the CSA_n count is increased by one 238. The system then returns to monitoring the subject's airflow 210. In contrast, if the subject does attempt to breathe within 4 seconds 234 the event is considered a mixed sleep apnea, and the $Mixed_n$ count is increased by one 242. The system then returns to monitoring the subject's airflow 210.

Returning to the airflow comparison 218, if the subject's airflow is reduced to 70% of the baseline for 10 seconds or more, but the airflow does not drop to 10% of the baseline, the system

evaluates the effects of a mild reduction in airflow. If the airflow does not drop to below 10% of the baseline 218, the mild decrease in airflow may indicate an instance of hypopnea. In this situation, the subject's oxygen saturation is compared to the baseline 246. If the subject's oxygen saturation has not decreased more than 4% 246, the decrease in airflow is not an event at all, and the system returns to monitoring the subject's airflow 210. If the subject's oxygen saturation does decrease more than 4% 246, the system checks for a breathing effort 250. If the subject is attempting to breathe, the event is considered an obstructive sleep hypopnea (OSH), and the OSA_n count is increased by one 258. The system then returns to monitoring the subject's airflow 210. If, however, the subject is not attempting to breathe, the event is considered a central sleep hypopnea (CSH), and the CSH_n count is increased by one 254. The system then returns to monitoring the subject's airflow 210.

The system continues to monitor the subject throughout the time interval 210. After the time interval is over, the system evaluates the subject's condition and calculates the next change in pressure. If the pressure should be adjusted 260, an adjustment algorithm is applied. In FIG. 7, the system looks for any event 260, but in other embodiments of the present invention the system could evaluate only a few variables, for example the number of CSA events. Optionally, the system could evaluate the ratio of counted events, changes in the number of events between timeperiods, or any other condition capable of being recorded or calculated by the system. In FIG. 7, If no events have been detected (i.e., all event counters OSA_n, CSA_n, OSH_n, CSH_n, and $Mixed_n$ are 0) 260, the subject's condition is acceptable, and no treatment changes are required. The system then returns and resets the time interval and all event counters OSA_n, CSA_n, OSH_n, CSH_n and $Mixed_n$ 202. At this point, the system is also capable of recording the previous counter values, recording the total number of events, and the like. In this way, the system can compare the subject's status between intervals. For example, the subject's status during the first time interval can be compared to the status during the current or final interval, or the subject's status can be evaluated over consecutive intervals. Such comparisons can provide information on, for example, trends, and overall effectiveness of the treatment.

If an adjustment is appropriate 260, the system determines if any central or central-based events have occurred 262. If the subject has experienced a central sleep apnea, central sleep hypopnea, or mixed apnea event, the system sets the current pressure as a maximum

threshold, and sets a flag to initiate the tuning phase of the titration 266. The new maximum pressure P_{max} is the highest value of pressure that the system can now attain. Under no circumstances will the system automatically increase the air pressure beyond P_{max}, although in some embodiments the pressure could be manually adjusted above the maximum value. After setting the maximum pressure and initiating the tuning mode, the system decreases the CPAP pressure by 2 cm H_2O 270. The system then returns and resets the time interval and all event counters OSA_n, CSA_n, OSH_n, CSH_n and $Mixed_n$ 202.

If no central or central-based events have occurred, the system checks to see if it is in tuning mode 274. If the system is in tuning mode, and the subject has experienced an obstructive event (but not a central or central-based event) 274, the system compares the result of the next pressure change to the maximum pressure 290 (established previously at 266). If the next pressure increase of 1 cm H_2O will be less than the maximum allowable pressure P_{max} 266, the system increases the pressure by 1 cm H_2O. After making the adjustment, the system then returns to the counting phase and resets the time interval and all event counters OSA_n, CSA_n, OSH_n, CSH_n and $Mixed_n$ 202. In contrast, if the next pressure increase will be greater than or equal to the maximum allowable pressure P_{max} 266, the titration is complete. The system no longer adjusts the gas pressure, although it may continue to count the subject's events and record other data through the remainder of the night.

If the system is not in tuning mode 274, the system evaluates if the obstructive events were apneas or hypopneas 278. If the events were apneas, the system increases the gas pressure by 2 cm H_2O 282. If the events were hypopneas, the system increases the gas pressure by only 1 cm H_2O 286. In either case, after adjusting the pressure accordingly, the system then returns and resets the time interval and all event counters OSA_n, CSA_n, OSH_n, CSH_n and $Mixed_n$ 202.

The adjustment algorithm shown in FIG. 7 is relatively simple. More sophisticated calculations and decisions can also be used. For example, the system can evaluate the trends occurring across time periods by considering how the numbers of detected events changes, or the system can use the ratio of central-type events to obstructive-type events to refine the changes in pressure. The system could also, for example, consider the number and type of adjustments previously made. Such a step would prevent system oscillation that can occur near the end of titration as the system attempts to refine the optimal pressure. The system could use a variety of

analysis and calculation techniques, including lookup tables, fast-Fourier transforms, wavelet analysis, neural networks, and the like.

Although FIG. 7 depicts control of a CPAP machine, any appropriate treatment device may be used. In this situation, the treatment device control algorithm would be adjusted to consider the capabilities of the treatment device. For example, if the treatment device is a more advanced bi-level PAP machine, the treatment device control algorithm could adjust the inspiration air pressure only. The action taken can also vary. For example, the pressure can be increased by differing amounts depending on the phase of titration, or the number of prior adjustments, or the severity of the breathing events. As further illustration, if the system determines that the subject has an sleep-related breathing disorder that is untreatable with the current treatment device (for example, a CPAP device cannot deliver a sufficiently high pressure, or the treatment device is inappropriate for the subject's condition), the system can shut down or provide a safe pressure for the remainder of the night before recommending another treatment method.

Although the titration phase of FIG. 7 is triggered only by the end of the time interval 210, various other conditions could also require pressure adjustments. For example, if the system detects a severe central apnea event, the gas pressure could be immediately reduced. Similarly, if the system detects several severe apneas in a single time period, the titration phase could begin before the end of the time period. Other safety mechanisms can be programmed into the system as well. For example, the system can be programmed to ignore the sensor signals if the data becomes corrupted (for example, if the sensor becomes disconnected).

FIG. 8 shows a schematic view of one embodiment of the sleep disorder treatment system of the present invention. In FIG. 8, a number of sensors 420, 424, 418, and 426 are connected to a subject 410. The subject 410 in this case is a human shown with a respiratory mask 412, which is connected by an air hose or subject circuit 416 to a continuous positive air pressure device 428. In this embodiment, the signal or data from one or more of these sensors is collected by a diagnostic device 441, which comprises a radio 436; an antenna 434; and a microprocessor 438 for processing the data or signals to determine a level of severity of the subject's sleeping

disorder or symptoms. The diagnostic device 441 calculates a level of severity for the subject's symptoms and physiological condition. The diagnostic device 441 then transmits a signal based on this level of severity by either a tether 444 or radio signal (not shown) to an actuator (not shown) in the CPAP device 428, which controls the flow of air or gas provided to the subject by the air hose or subject circuit 416. The CPAP device 428 optionally connects to an oxygen tank 430, which can be used to increase the concentration of oxygen in the air being delivered to the subject. Further optionally, the CPAP device 428 connects to a carbon dioxide tank 431, which can be used to increase the concentration of carbon dioxide in the air being delivered to the subject. The CPAP device 428 could connect to both the oxygen tank 430 and the carbon dioxide tank 431, only one of the tanks, or neither. In addition, optionally the treatment device 428 has a sensor in the air hose 416, which can measure the differential pressure 414 and thereby accurately measure air flow provided to the subject. Also optionally, the device can have a nebulizer (not shown) with a reservoir and pump to injecting medication into the nebulizer.

FIG. 9 shows a diagram outlining the treatment titration system in more detail. In FIG.9, a patient interface box 16 receives signals (not shown) from a respiratory belt 500 and a pulse oximeter 504 placed on the subject. The sensors 500 and 504 can be any of the sensors described herein or known in the art. In a simple embodiment of the present invention, the patient interface box 16 generates a wireless signal 18 encoded with data corresponding to the signals from the respiratory belt 500 and a pulse oximeter 504. The patient interface box 16 transmits the wireless signal 18 to base station 40. In FIG.9, the wireless signal 18 is shown as radio frequency (RF). In this case, the patient interface box 16 generates a radio frequency signal 18 by frequency modulating a frequency carrier and transmits the radio frequency signal through the module antenna 20. The base station 40 receives the radio frequency signal 18 through base antenna 42, demodulates the radio frequency signal 18, and decodes the data. It is understood that other wireless means can be utilized with the present invention, such as infrared and optical, for example. RF wireless transmission is preferred. Although one module antenna 16 and one base antenna 42 are shown in this embodiment, it is understood that two or more types of antennas can be used and are included in the present invention. An external programming means 60, shown in FIG. 9 as a personal computer, contains software that is used to program the patient interface box 16 and the base station 40 through data interface cable 62.

The data interface cable 62 is connected to the base station 40 by connector 64. Instead of a data interface cable 62, the patient interface box 16 and the base station 40 can be programmed by radio frequency (or other type) of signals transmitted between an external programming means 60 and a base station 40 and the patient interface box 16 or to another base station 40. RF signals, therefore, can be both transmitted and received by both patient interface box 16 and base station 40. In this event the patient interface box 16 also includes a module receiver 29 (shown in FIG. 2) while the base station 40 also includes a base transmitter 84 (shown in FIG. 3), in effect making both the patient interface box 16 and the base station 40 into transceivers. In addition, the data interface cable 62 also can be used to convey data from the base station 40 to the external programming means 60. If a personal computer is the external programming means 60, it can monitor, analyze, and display the data in addition to its programming functions. The base receiver 80 and module receiver 29 (shown in FIG. 3 and FIG. 2, respectively) can be any appropriate receivers, such as direct or single conversion types. The base receiver 80 preferably is a double conversion superheterodyne receiver while the module receiver 29 preferably is a single conversion receiver. Advantageously, the receiver employed will have automatic frequency control to facilitate accurate and consistent tuning of the radio frequency signal 18 received thereby.

The external programming means 60 also contains a processor used to calculate the next appropriate gas flow level to be delivered to the subject. In the illustrated embodiment, the external programming means 60 uses data originally collected from the respiratory belt 500 and the pulse oximeter 504 to calculate the appropriate flow level. The external programming means 60 is capable of performing a variety of analysis and calculation techniques, including lookup tables, fast-Fourier transforms, wavelet analysis, use of a neural network, and the like. Optionally, the data processing and calculation can be performed by the base station 40. Further optionally, the processing and calculation can be distributed between the patient interface box 16, the base station 40, and the external programming means 60.

After the appropriate flow level has been calculated, the external programming means 60 transmits a command signal to the treatment device interface 518, which then relays the command signal to the treatment device 522 via a connection 518. In FIG. 9, the external programming means 60 transmits the command signal to the treatment device interface 518 via

wireless RF signal 512. The RF signal 512 is received by an RF antenna 514 on the treatment device interface 518. Optionally, the command signal can be transmitted by any other wireless means. Although the command signal transmission 512 is shown in FIG. 9 to be of the same type as the sensor signal transmission 18, this is not necessary. Optionally, the two wireless transmissions can be of different types. Optionally, the command signal can be transmitted from the external programming means 60 by a wired connection to the treatment device interface 518.

The treatment device interface 518 connects to the treatment device 522 with a connector 518. In FIG. 9, the treatment device 522 is shown as a CPAP device, but the treatment device 522 may be any device known in the art for the treatment of sleep-related breathing disorders, including but not limited to a bi-level PAP device, an auto-PAP or auto-CPAP device, an ASV device, and the like. FIG. 9 also shows the connector 518 as a USB connection. Optionally, the treatment device interface 518 can be completely enclosed within the treatment device 522 itself. In this case, the treatment device would be essentially modified to directly receive the command signal from the external programming means 60. Once the treatment device 522 receives the command signal the treatment device performs the command and changes the treatment provided to the subject. In FIG. 9, the treatment device 522 is a CPAP device, which increases or decreases the pressure of the gas delivered to the subject via conduit 526 and mask 530.

Optionally, the treatment device 522 may contain additional sensors. For example, if the treatment device 522 is a CPAP device, it may contain an air flow or air pressure sensor (not shown). If the treatment device 522 contains a sensor, that sensor information would be integrated into the command calculation process. This integration can take place in any of the system components. For example, the treatment device sensor information could be included in a processing step performed within the treatment device 522, at the external programming means 60, or at the base station 40.

FIG. 10 is schematic of the remote data acquisition device and system of the present invention. In FIG. 10, a wireless data acquisition system 50 is used to receive, filter, and optionally analyze signals 27 from sensors (not shown) on a subject (not shown). The wireless data acquisition system 50 transmits a signal based, at least in part, on one or more of the signals from the sensors on the subject. The data acquisition system 50 transmits a signal 55 preferably in real time from the subject's home 52 to a server 70 for analysis. The signal 55 is transmitted

over the internet or other communication system 58. Such other communication systems include satellites, cellular networks, local area networks (LAN), other wide area networks (WAN), or other telecommunications system. If the signal 55 is transmitted over the internet 58, preferably the signal 55 is transmitted using a cellular card provided by cellular providers such as for example Sprint, Cingular, AT&T, T-Mobile, Alltel, Verizon or the like. The signal 55 that is transmitted over the internet or other communication system 58 can be compressed to provide better resolution or greater efficiency. The server 70 performs data analysis (not shown). The analyzed data 73 is then entered into a database 76. The analyzed data 73 in the database 76 is then accessible and can be requested 79 and sent to multiple review stations 82 anywhere in the world via the internet or other communications system 58 for further analysis and review by clinicians, technicians, researchers, doctors and the like. Signal 84 is a command signal for adjusting a parameter of the treatment device. For example the signal 84 could instruct the PAP device to increase the pressure delivered to the subject. The communications systems used for data transmission need not be the same at all stages. For example, the a cellular network can be used to transmit data between the subject's home 52 and the remote analysis server 70. Then the internet can be used to transmit data between the remote analysis server 70 and the database 76. Finally in this example, a LAN can be used to transmit data between the database 76 and a review station 82.

FIG. 9 shows a diagram outlining the wireless data acquisition system in more detail. In FIG.9, a patient interface box 85 receives signal (not shown) from a sensor 91. This sensor 91 can be an EEG electrode (as shown) or any of the other sensors described herein or known in the art. Although one type of sensor 91 is shown, the patient interface box 85 is capable of accepting multiple signals from multiple sensors 91. In a very simple embodiment of the present invention, the patient interface box 85 generates a wireless signal 94 encoded with data corresponding to the signal from the sensor 91. The patient interface box 85 transmits the wireless signal 94 to base station 97. In FIG.9, the wireless signal 94 is shown as radio frequency (RF). In this case, the patient interface box 85 generates a radio frequency signal 94 by frequency modulating a frequency carrier and transmits the radio frequency signal through module antenna 100. The base station 97 receives the radio frequency signal 94 through base antenna 103, demodulates the radio frequency signal 94, and decodes the data. It is understood

that other wireless means can be utilized with the present invention, such as infrared and optical, for example. RF wireless transmission is preferred. Although one module antenna 100 and one base antenna 103 are shown in this embodiment, it is understood that two or more types of antennas can be used and are included in the present invention. An external programming means 106, shown in FIG. 9as a personal computer, contains software that is used to program the patient interface box 85 and the base station 97 through data interface cable 109. The data interface cable 109 is connected to the base station 97 by connector 112. Instead of a data interface cable 109, the patient interface box 85 and the base station 97 can be programmed by radio frequency (or other type) of signals transmitted between an external programming means 106 and a base station 97 and the patient interface box 85 or to another base station 97. RF signals, therefore, can be both transmitted and received by both patient interface box 85 and base station 97. In this event the patient interface box 85 also includes a module receiver 133 (shown on FIG. 2) while the base station 97 also includes a base transmitter 84, in effect making both the patient interface box 85 and the base station 97 into transceivers. In addition, the data interface cable 109 also can be used to convey data from the base station 97 to the external programming means 106. If a personal computer is the external programming means 106, it can monitor, analyze, and display the data in addition to its programming functions. The base receiver 80 and module receiver 133 (shown on FIG. 5) can be any appropriate receivers, such as direct or single conversion types. The base receiver 80 preferably is a double conversion superheterodyne receiver while the module receiver 133 (shown on FIG. 5) preferably is a single conversion receiver. Advantageously, the receiver employed will have automatic frequency control to facilitate accurate and consistent tuning of the radio frequency signal 94 received thereby.

FIG. 11 is a diagram of an artifact rejection module 750 that can be used in either the data acquisition system (not shown) or a computer or processor (not shown) linked to the data acquisition unit of the present invention. In FIG. 11, a subject's EEG signal 752 is preferably continuously fed 754 into artifact rejection algorithms within the data acquisition unit processor. Simultaneously sensor signals 760 from the subject's movement or motion are also fed into the artifact rejection processor so the EEG signal can be corrected 762 for effects of abnormal or prejudicial motion by the subject. The sensors for determining the subject's motion are described above, but the most preferred is an accelerometer that is incorporated into the EEG

data acquisition unit itself.

A method for the detection and treatment of disordered breathing during sleep employing wavelet analysis is provided in which data related to respiratory patterns are analyzed with wavelet analysis. Thus allowing for automatic continuous titration and adjustment of PAP and other treatment module therapy.

More specifically, this method according to one embodiment of the present invention comprises the following steps: placing a mask with a tube over a subject's airway, the mask being in communication with a source of a pressurized breathing gas controlled by a PAP, thereby establishing a respiratory circuit; periodically sampling the gas flow in the circuit; periodically sampling one or several other parameters related to the subjects physiological state; periodically calculating values for one or several parameters distinctive of a physiological pattern; periodically feeding the parameter values to a processing unit programmed to recognize physiological patterns characteristic of sleep disorders; analyzing the parameter values with wavelet analysis; controlling pressurized breathing gas supply and other treatment modules or devices in response to the output from the processing unit utilizing wavelet analysis.

Each sensor and/or transducer may generate an analog signal representative of variables being monitored. The monitoring means may include means for amplifying and/or performing analog processing on the analog signal. The latter may perform filtering and/or other wave shaping functions. The processed signal may be fed to an analog to digital converter to convert each analog signal to a corresponding digital signal. Each digital signal may be fed to a digital processor such as a microprocessor or microcomputer. The digital processor includes software for deriving subject's respiratory state. The software may include means such as an algorithm for determining from the data a gas pressure value which substantially prevents a deterioration of the respiratory state. Preferably the algorithm utilizes wavelet analysis to detect and correct the respiratory event by changing one or several treatment parameters. The result may be used to control delivery of gas to the subject to cancel out or substantially compensate the effects of a sleeping or breathing disorder. In the event that the disorder is not substantially corrected the software may be adapted to activate delivery of a drug such as albuterol, or ipratropium bromide, or the like. This may circumvent what may otherwise be a fatal or severe asthma attack. Other drugs or substances may be used depending on the subject's special needs. Such as oxygen (O2)

or carbon dioxide (CO2) gas could be delivered to the subject. As mentioned earlier these gases can be used to aid in respiration. As oxygen can mitigate or relieve the effects of many apneas, while a dose of carbon dioxide gas can be used to trigger respiratory effort in central and complex apneas. The software may additionally be adapted to determine quantity requirements of the drug, gas or other therapeutic agent. The latter may be based on the subject's history and the extent to which the disorder fails to respond to traditional gas pressure treatment. These drugs and therapeutic agents could be delivered by any means known in the art, but could include nebulizers, pressurized gas delivering, intravenous auto injection, or simply allowing the air to flow over a piece of dry ice to sublimate carbon dioxide into the subject's breathing air.

For a better understanding of the detailed description of the invention, it is necessary to present an overview of the wavelet analysis of the present invention.

The wavelet analysis of the present invention, preferably represents a signal as a weighted sum of shifted and scaled versions of the original mother wavelet, without any loss of information. A single wavelet coefficient is obtained by computing the correlation between the scaled and time shifted version of the mother wavelet and the analyzed part of a signal. For efficient analysis, scales and shifts take discrete values based on powers of two (i.e., the dyadic decomposition). For implementation, filter bank and quadrature mirror filters are utilized for a hierarchical signal decomposition, in which a given signal is decomposed by a series of low- and high-pass filters followed by downsampling at each stage, see FIG. 3. This analysis is referred to as Discrete Wavelet Transform (DWT). The particular structure of the filters is determined by the particular wavelet family used for data analysis and by the conditions imposed for a perfect reconstruction of the original signal.

The approximation is the output of the low-pass filter, while the detail is the output of the high-pass filter. In a dyadic multiresolution analysis, the decomposition process is iterated such that the approximations are successively decomposed. The original signal can be reconstructed from its details and approximation at each stage (e.g., for a 3-level signal decomposition, a signal S can be written as S=A3+D3+D2+D1), see FIG. 13. The decomposition may proceed until the individual details consist of a single sample. The nature of the process generates a set of vectors (for instance a.sub.3, d.sub.3, d.sub.2, and d.sub.1 in the three level signal decomposition), containing the corresponding coefficients. These vectors are of different lengths, based on

powers of two, see FIG. 14. These coefficients are the projections of the signal onto the mother wavelet at a given scale. They contain signal information at different frequency bands (e.g., a.sub.3, d.sub.3, d.sub.2, and d.sub.1) determined by the filter bank frequency response. DWT leads to an octave band signal decomposition that divides the frequency space into the bands of unequal widths based on powers of two, see FIG. 15.

The Stationary Wavelet Transform (SWT) is obtained in a similar fashion, however, the downsampling step is not performed. This leads to a redundant signal decomposition with better potential for statistical analysis. The frequency space division is the same as for DWT, see FIG. 6.

Despite its high efficiency for signal analysis, DWT and SWT decompositions do not provide sufficient flexibility for a narrow frequency bandwidth data analysis (FIG. 13). Wavelet packets, as a generalization of standard DWT, alleviate this problem. At each stage, details as well as approximations are further decomposed into low and high frequency signal components. FIG. 13 shows the wavelet packet decomposition tree. Accordingly, a given signal can be written in a more flexible way than provided by the DWT or SWT decomposition (e.g., at level 3 we have S=A1+AD2+ADD3+DDD3, where DDD3 is the signal component of the narrow high frequency band ddd.sub.3). Wavelet packet analysis results in signal decomposition with equal frequency bandwidths at each level of decomposition. This also leads to an equal number of the approximation and details coefficients, a desirable feature for data analysis and information extraction. FIG. 15 illustrates frequency bands for the 3-level wavelet packet decomposition.

Specifically in our application wavelets were adopted due to their suitablity for the analysis of non-stationary or transitory features, which characterize most signals found in biomedical applications. Wavelet analysis uses wavelets as basis functions for signal decomposition.

In the present invention the use of wavelet transform significantly reduces the computational complexity when performing the task of assessing the subjects' physiological state based on the acquired signal or signals. Neither a large number of reference signals nor an extensive amount of clinical data is needed to produce the index disclosed herewith.

This invention involves an observed data set acquired in real-time from a subject. This data set is further compared, in real time, with one or more reference data sets which characterize

distinct physiological states. The comparison yields an index that is later referred to WAVelet index (abbreviated WAV). The WAVelet index can then be used to assist in distinguishing among the various physiological states, in distinguishing increasing and decreasing rates of respiration, and in distinguishing increasing and decreasing level of both obstructive and central airway apneas, and in distinguishing increasing and decreasing respiratory flow rates and the like.

The observed and reference data sets are statistical representations of the wavelet coefficients obtained by applying a wavelet transform onto corresponding observed and reference signals. These coefficients may be obtained through a wavelet transform of the signal such as standard dyadic discrete wavelet transform (DWT), discrete stationary wavelet transform (SWT), or wavelet packet transform. In this respect, filters yielding coefficients in a frequency band, chosen such that their statistical representation differentiates between respiratory states, can be used for this type of analysis. The choice of this transformation determines the computational complexity of the method and the resolution of the final index. The observed and reference data sets are obtained by calculating a statistical representation of the transformation coefficients.

The reference data sets represent distinct physiological states taken from the continuum from normal (i.e. no irregularities) to full apnea (i.e. complete lack of ventilation). They can be extracted off-line from a group of subjects or subjects. They are then stored for real-time implementation. The transformation selected maximizes the dissimilarity between each of the reference data sets.

The comparison between the observed data set against the reference data sets can be based on the computation of the correlation between these functions. However, a computationally less demanding solution is to quantify the similarity between these functions by computing the L1 (Manhattan), L2 (Euclidean), or any distance metrics. In the preferred embodiment, where two reference data sets are used, the result of this comparison yields two values, each expressing the likelihood of the subject's physiological states are normal or irregular and to what degree. These two values are further combined into a single value corresponding to a univariate index of normal/irregular physiological states state, the WAVelet index. This value corresponds to the type and level of the condition, which is used to create a proper control signal

to the gas flow generator, or turbine, or to other treatment modules.

Most any variant of PAP or CPAP therapy, such as bi-level CPAP therapy or therapy in which the mask pressure is modulated within a breath, can also be monitored and/or controlled using the methods described herein. Less complex variants of PAP or CPAP therapy could be used, but the benefits would be much less apparent.

The following figures give a more detailed description of example control algorithms of the present invention. This example deals specifically with control of respiratory gas flow using high noise physiological signals, although other treatment parameters can be modified using the same method with proper modification. Also, the respiratory gas flow control and the other treatment methods can be used concurrently to correct the subject's physiological state. Some parts of this example embodiment may not be needed in some applications depending on the level of noise associated with a particular physiological signal. FIG. 16 gives an overview of the wavelet analysis functions of the present invention in its preferred embodiment. The invention is based on the wavelet decomposition of the sensor signals in the wavelet analyzer unit 862. This unit 862 applies the wavelet transform onto the finite signal delivered by the preprocessing unit 860, and then extracts the observed data set 872 correlated to the respiratory state from the corresponding wavelet coefficients. This feature function is further delivered to the comparator unit 864, where it is compared with two reference data sets 874, 876 corresponding to the respiratory state. These reference data sets are calculated off-line and stored in 66 for the real time comparison in the comparator 864. The result of comparison is further integrated into an index of respiration, which is the input of the scaling 868 and filtering 870 units.

Parts of the processing unit 878 contained in the controller 38 that involve signal analysis are detailed in the following.

Pre-Processing Unit

The basic function of the pre-processing unit 80 is to further "clean-up" the signal being analyzed and to reject finite signals that contain artifacts or are corrupted. The exact operation of the preprocessing unit will heavily depend on the type of sensor and physiological parameter being monitored. The following description is supplied to give a simple overview of the basic function of the preprocessing unit and a possible method of implementation.

Once a finite signal has been acquired, it is sent to the pre-processing unit, see FIG. 12.

It's first stored as a vector x 882 of length N. The mean value 6 x _ = k = 1 N x k is removed 884. The root mean square amplitude 86 of the finite signal is then calculated as: 7 rms = 1 N k = 1 N (x k) 2 (9).

Finite signals with amplitudes greater than some maximum value and less than some minimum value are then rejected. It is assumed that they either contain artifacts or the data is corrupted possibly due disconnection of a sensor. If the amplitude is within the two bounds 892, a flag 894 indicating that the finite signal is not corrupted takes the value 1. In this case, the finite signal is normalized 896 as: 8 x k = x k rms , k = 1 , , N (10).

The amplitude normalization allows better focus on the phase and frequency content of the finite signal, rather than its amplitude. So amplitude normalization is especially well suited for bio-potential measurements such as EEG, EMG, or ECG.

If an artifact is present8 88, the flag is put to 0 and the algorithm proceeds to the scaling unit 811. If normal breathing is detected 890, the flag takes the value 1 and the variable WAV_unfilt 898 takes the value of 0. The apparatus then proceeds to send the signal to the filtering unit 870. The apparatus then proceeds to the next stage, (i.e. the wavelet analyzer unit denoted by 862 in FIG. 12 and FIG. 16).

Wavelet Analyzer Unit

The wavelet analyzer unit 862 first calculates the wavelet coefficients applying the SWT and the wavelet filter to the pre-processed finite signal. The coefficients are obtained by convolution of the signal with the wavelet filter.

The coefficients corresponding to the band selected in the off-line analysis as the most discriminating (in this embodiment: d, are then stored in a vector C. The probability density function is then obtained by calculating the histogram of the coefficients in vector C. The vector of histogram contains b coefficients, where b is chosen number of bins (e.g. 100). Each element of this vector is then divided by the total number of coefficients in d.sub.1 band, i.e. by the length of a vector C. The result is a vector pdf of length b, which represents the probability density function of wavelet coefficients in d.sub.1 band obtained by the wavelet decomposition of the finite signal x.

Comparator Unit

The resulting pdf vector is input into comparator unit 864, see FIG. 17. This unit

compares the pdf vector of a current signal 872 with two reference vectors pdf.sub.w and pdf.sub.a representing two known respiratory states non-apneic 874 and apneic 876.

The non-apneic reference data set 74 is derived from a combination of signals obtained from a group of healthy subjects (population norming). This reference data set can be then stored on a mass storage device for future real time comparison. Another possibility is to record the subject's respiratory signals while the subject is in a non-apneic state, and then derive the reference data set (self-norming).

The apneic reference data set 876 is the PDF of the wavelet coefficients of an apneic signal, which is either derived or recorded from an actual subject which mimics the most severe level of apneas.

The comparison 900 between the pdf 872 calculated in the wavelet analyzer unit 862 and the two reference data sets pdf.sub.w 874 and pdf.sub.a 876 is achieved using the L1 distance metric. This comparison yields two values i.sub.w 902 and i.sub.a 906.

An index i 908 is then generated by calculating 904 the difference between i.sub.w 902 and i.sub.a 906:

i=i.sub.a-i.sub.w (12)

The output of the comparator unit is then input to the scaling unit 868.

Scaling Unit

The index i 908 is scaled in order to take values between 0% (corresponding to an apneic signal) and 100% (corresponding to the non-apneic baseline) with higher values indicating higher level of respiratory function:

i=i.multidot.scale+offset (13)

scale and offset are two fixed values calculated in the offline analysis. The result of the scaling is further stored into the variable WAV_unfilt 898.

Filtering Unit

The variable WAV_unfilt 898 contains the unfiltered version of the final WAVelet index. The random character of the some signals dictates that in order to extract a more representative trend of the subject's respiratory state it may be necessary to smooth this variable using a filter.

A new value WAV_unfilt is delivered by the scaling unit 868 for every finite signal (i.e. every second or every fraction of a second in the preferred embodiment). However, note that if

the current epoch is corrupted with an artifact, the variable WAV_unfilt can take an arbitrary value, as it will not be used to derive the final value of the index.

The result of the averaging filter is stored in the variable WAV. However, when calculating the average, only uncorrupted finite signals are taken into account by investigating the corresponding flag variable. The WAV variable is finally sent to the controller 838 which then produces the appropriate command signal.

It will be apparent to those skilled in the art that various modifications and variations can be made to the present invention without departing from the spirit and scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

WHAT WE CLAIM IS:

1. A sleep-related breathing disorder treatment system comprising:

a data acquisition system comprising at least one sensor having a signal, the sensor for determining a physiological characteristic of a subject, and at least one electronic component for receiving the signal and retransmitting the signal from the at least one sensor or transmitting a signal based at least in part on the signal from the at least one sensor; and

a PAP or CPAP device for treating the subject's sleep related breathing disorder, the PAP or CPAP device comprising an electrical component for receiving the retransmitted or transmitted signal

wherein the PAP or CPAP device is titrated or adjusted based on at least in part the retransmitted or transmitted signal.

2. The device of claim 1, wherein the signal is transmitted or retransmitted wirelessly.

3. The device of claim 1, wherein the signal is transmitted or retransmitted via USB.

4. The device of claim 1, wherein the data acquisition system further includes at least one additional sensor, the additional sensor for collecting a video signal.

5. The device of claim 1, wherein the data acquisition system comprises at least three sensors having signals, the sensors for determining at least respiratory effort, pulse oximetry, and airflow of a subject; and at least one electronic component for receiving the signals and retransmitting the signals or transmitting a signal based at least in part on the signal from the at least one of the at least three sensors.

6. The device in claim 1, wherein the PAP or CPAP device is automatically titrated or adjusted based on at least in part the retransmitted or transmitted signal.

7. A sleep-related breathing disorder treatment system comprising:
a data acquisition system comprising at least one sensor having an electrical signal, the sensor for determining a physiological characteristic of a subject; and at least one electronic component for receiving the electrical signal from the at least one sensor, generating a processed signal based at least in part on the signal from the at least one sensor, and transmitting the processed signal;

a PAP or CPAP device for treating the subject's sleep-related breathing disorder, the PAP or CPAP device comprising an electrical component for receiving a transmitted signal; and

a remote monitoring station comprising a transceiver for receiving the processed signal from the data acquisition system and transmitting a command signal based at least in part on the transmitted processed signal to the PAP or CPAP device

wherein the PAP or CPAP device is titrated or adjusted based on at least in part the transmitted command signal.

8. The device of claim 7, wherein the at least one electronic component of the data acquisition system is capable of wirelessly transmitting the processed signal.

9. The device of claim 7, wherein the at least one electronic component of the data acquisition system is capable of transmitting the processed signal via USB.

10. The device of claim 7, wherein the data acquisition system further includes at least one additional sensor, the additional sensor for collecting a video signal.

11. The device of claim 7, wherein the data acquisition system comprises at least

three sensors having signals, the sensors for determining at least respiratory effort, pulse oximetry, and airflow of a subject; and at least one electronic component for receiving the electrical signal from the at least thee sensors, generating a processed signal based at least in part on the signal from at least one of the at least three sensors, and transmitting the processed signal.

12. The device of claim 7, wherein the remote monitoring station is at least five miles from the subject.

13. The device of claim 7, wherein the PAP or CPAP device is titrated or adjusted based on at least in part the transmitted command signal and at least in part on the signal transmitted from the data acquisition system.

14. A sleep-related breathing disorder treatment system comprising:

a data acquisition system comprising at least one sensor, the sensor for determining a physiological characteristic of a subject, and at least one electronic component for receiving the signal and retransmitting the signals or transmitting a signal based at least in part on the signal from the at least one sensor;

a treatment interface device comprising at least one electronic component for receiving the signal retransmitted or transmitted from the data acquisition system, optionally processing the signals from the data acquisition system, and retransmitting the signals or transmitting a signal based at least in part on the signal; and

a PAP or CPAP device for treating the subject's sleep-related breathing disorder, the PAP or CPAP device comprising an electrical connection for receiving the signal transmitted from the treatment interface device

wherein the PAP or CPAP device is titrated or adjusted based on at least in part the signal transmitted from the treatment interface device.

15. The device of claim 14, wherein the at least one electronic component of the data acquisition system is capable of wirelessly transmitting the processed signal.

16. The device of claim 14, wherein the at least one electronic component of the data acquisition system is capable of transmitting the processed signal via USB.

17. The device of claim 14, wherein the data acquisition system further includes at least one additional sensor, the additional sensor for collecting a video signal.

18. The device of claim 14, wherein the first device comprises at least three sensors having signals, the sensors for determining at least respiratory effort, pulse oximetry, and airflow of a subject; and at least one electronic component for receiving the electrical signals from the at least three sensors, generating a processed signal based at least in part on the signal from at least one of the at least three sensors, and transmitting the processed signal.

19. The device of claim 14, wherein the PAP or CPAP device is automatically titrated or adjusted.

20. The device of claim 14, wherein the PAP or CPAP titration or adjustment is remotely monitored.

ABSTRACT

The present invention relates to an integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment device. The present invention additionally relates to methods of sleep diagnosis and treatment. The sleep disorder treatment system of the present invention can use a diagnosis device to perform various forms of analysis to determine or diagnose a subject's sleeping disorder or symptoms of a subject's sleep disorder, and using this analysis or diagnosis can with or in some embodiments without human intervention treat the subject either physically or chemically to improve the sleeping disorder or the symptoms of the sleeping disorder. The diagnostic part of the system can use many different types of sensors and methods for diagnosing the severity of the symptoms of or the sleep disorder itself. The treatment part of the system can use a device to physically or chemically treat the subject's symptoms or sleep disorder itself.

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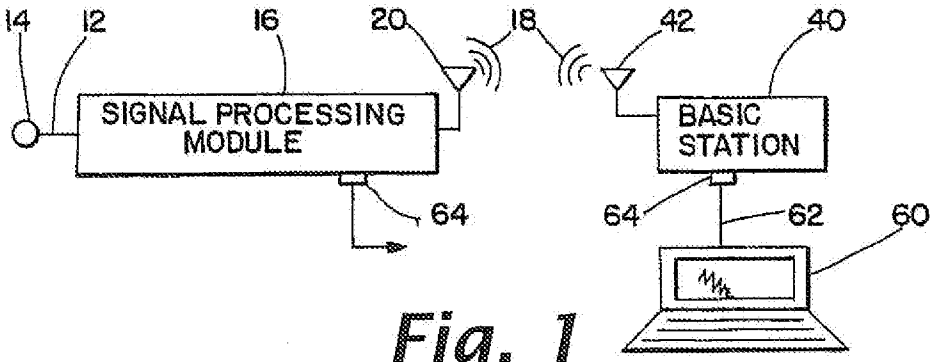


Fig. 1

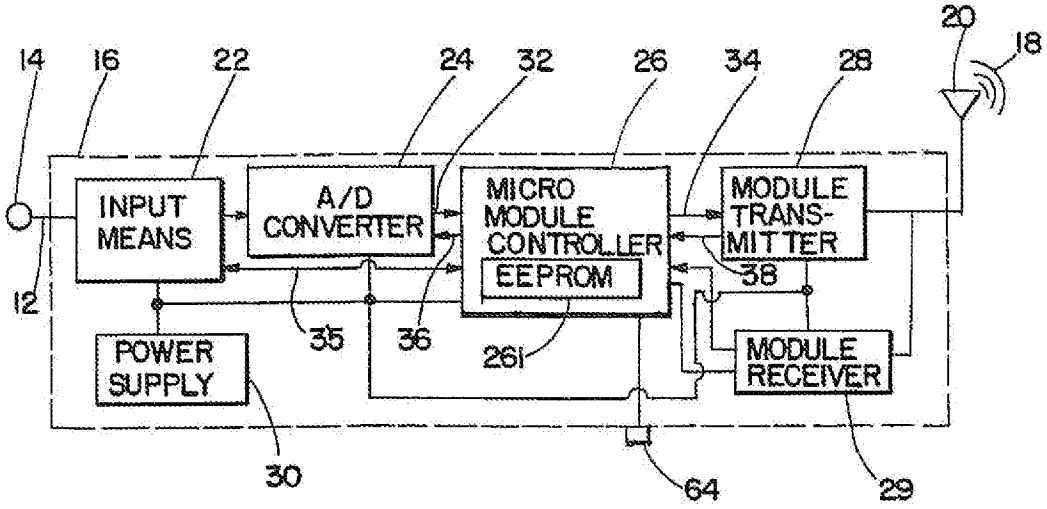


Fig. 2

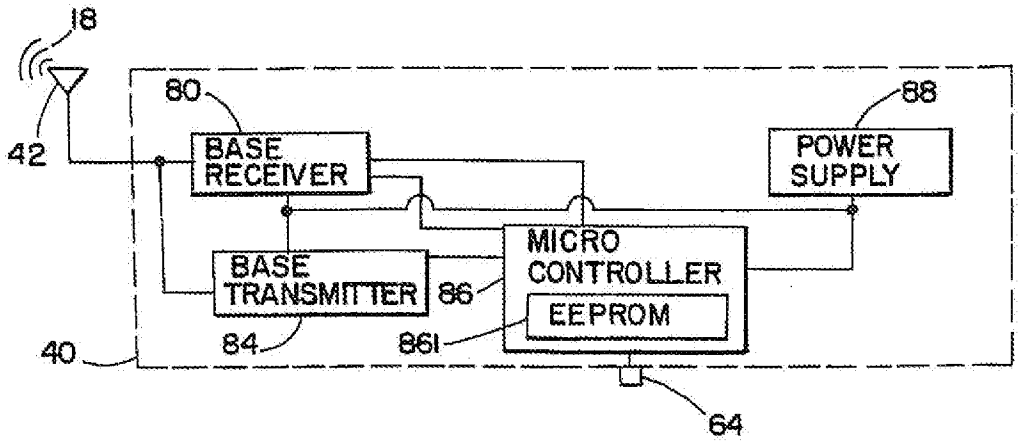


Fig. 3

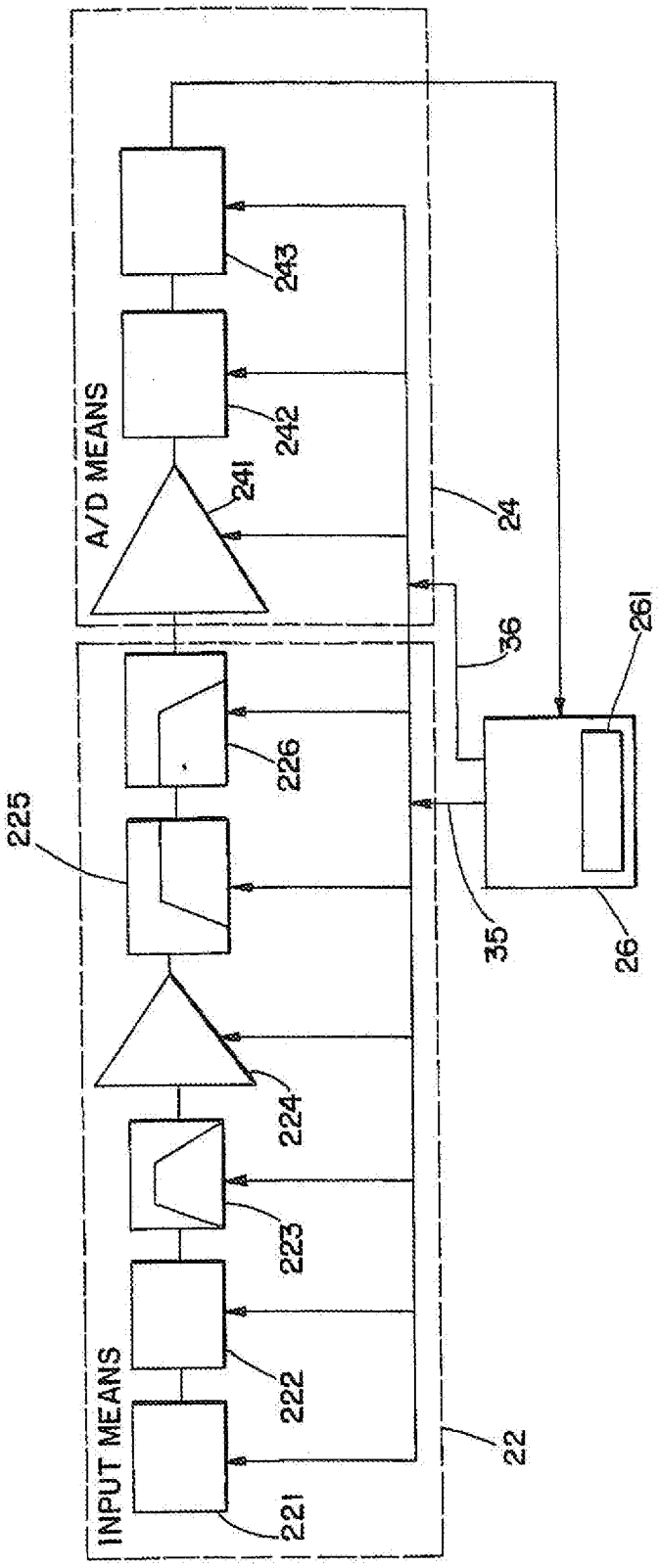

A/D MEANS
INPUT MEANS
221
222
223
224
225
226
241
242
243
22
24
26
261
35
36

Fig. 4

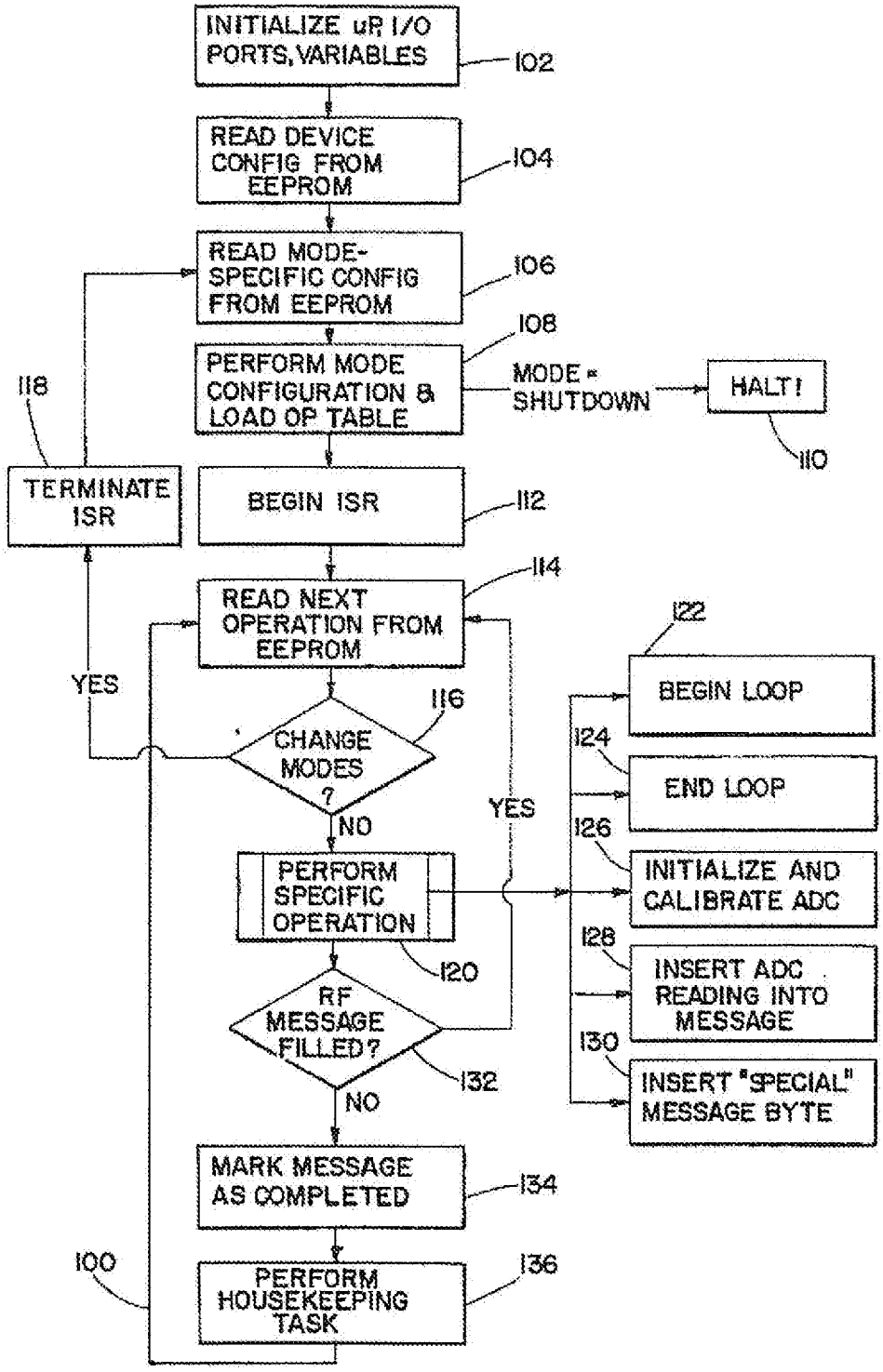

INITIALIZE uP I/O PORTS, VARIABLES
102
READ DEVICE CONFIG FROM EEPROM
104
READ MODE-SPECIFIC CONFIG FROM EEPROM
106
PERFORM MODE CONFIGURATION & LOAD OP TABLE
108
MODE = SHUTDOWN
HALT!
110
118
TERMINATE ISR
BEGIN ISR
112
READ NEXT OPERATION FROM EEPROM
114
YES
CHANGE MODES ?
116
NO
YES
PERFORM SPECIFIC OPERATION
120
RF MESSAGE FILLED?
132
NO
MARK MESSAGE AS COMPLETED
134
100
PERFORM HOUSEKEEPING TASK
136
122
BEGIN LOOP
124
END LOOP
126
INITIALIZE AND CALIBRATE ADC
128
INSERT ADC READING INTO MESSAGE
130
INSERT "SPECIAL" MESSAGE BYTE

Fig. 5

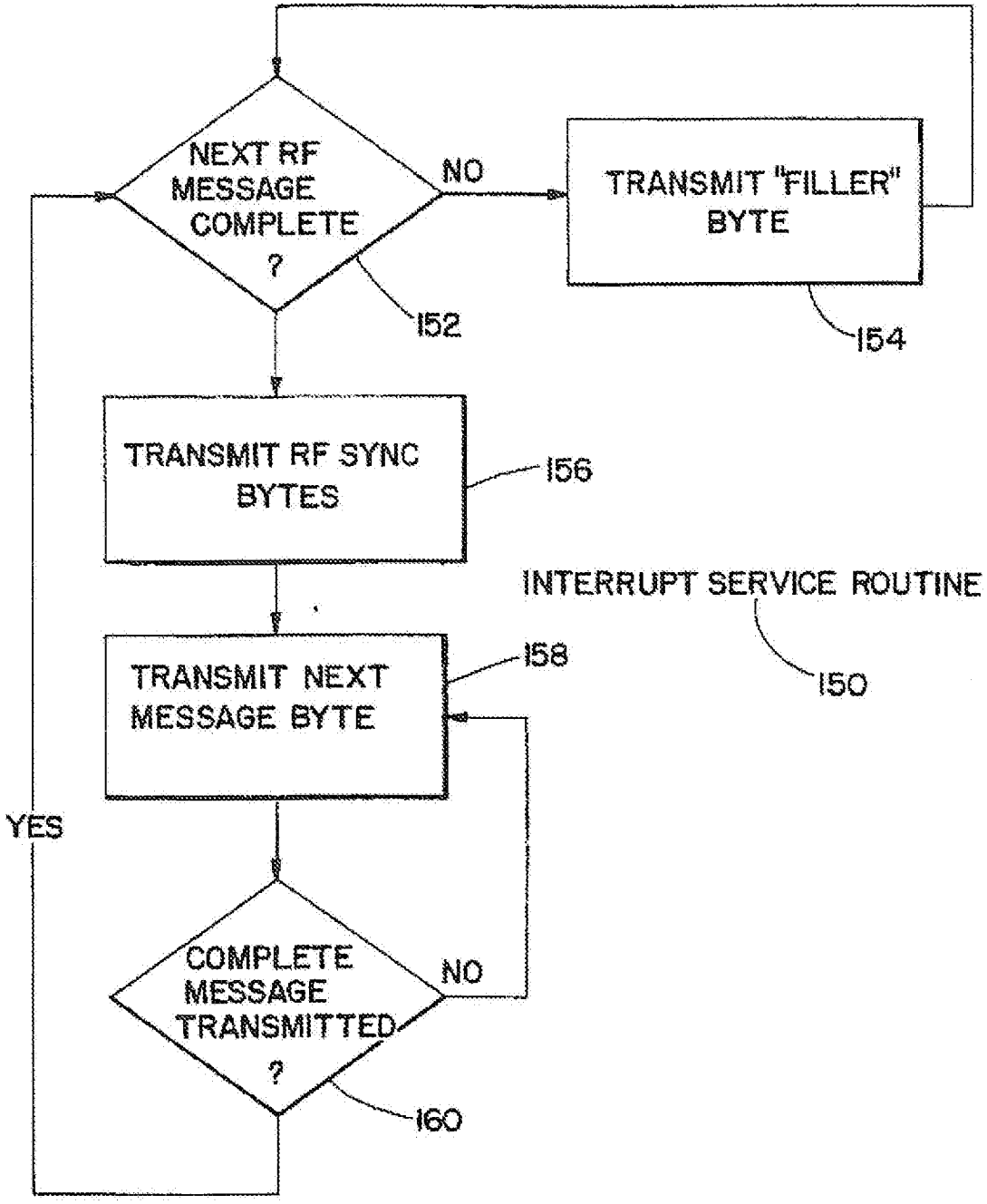

NEXT RF MESSAGE COMPLETE ?
NO
TRANSMIT "FILLER" BYTE
152
154
TRANSMIT RF SYNC BYTES
156
INTERRUPT SERVICE ROUTINE
150
TRANSMIT NEXT MESSAGE BYTE
158
YES
COMPLETE MESSAGE TRANSMITTED ?
NO
160

Fig. 6

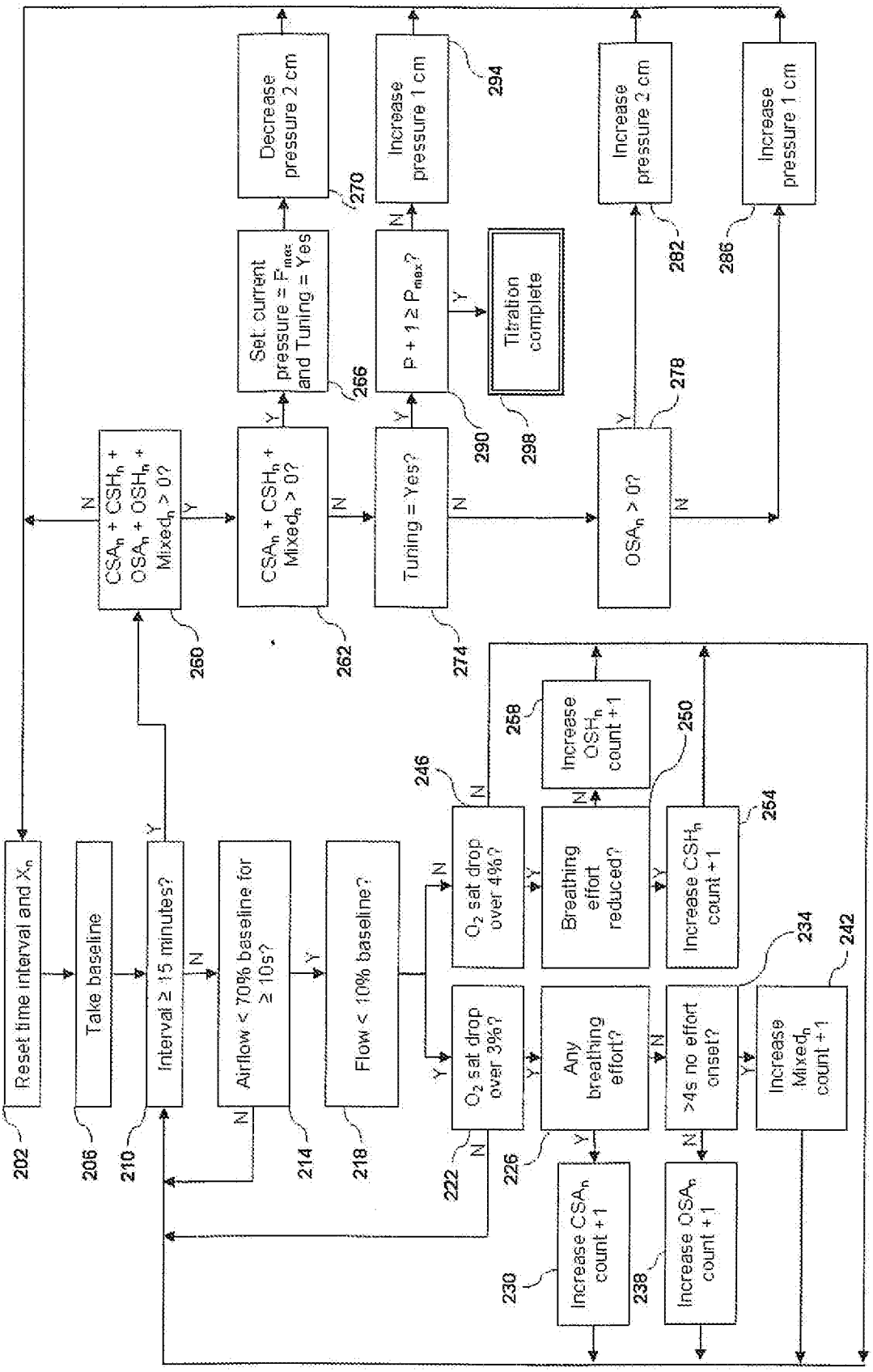

Reset time interval and X_n
202
Take baseline
206
Interval ≥ 15 minutes?
210
Airflow < 70% baseline for ≥ 10s?
214
Flow < 10% baseline?
218
O_2 sat drop over 3%?
222
Any breathing effort?
226
Increase CSA_n count + 1
230
O_2 sat drop over 4%?
246
Breathing effort reduced?
250
Increase OSH_n count + 1
258
>4s no effort onset?
234
Increase CSH_n count + 1
254
Increase $Mixed_n$ count + 1
242
Increase OSA_n count + 1
238
$CSA_n + CSH_n + OSA_n + Mixed_n > 0$?
260
$CSA_n + CSH_n + Mixed_n > 0$?
262
Tuning = Yes?
274
$OSA_n > 0$?
278
Set current pressure = F_{max} and Tuning = Yes
266
$P + 1 \geq P_{max}$?
290
Titration complete
298
Decrease pressure 2 cm
270
Increase pressure 1 cm
294
Increase pressure 2 cm
282
Increase pressure 1 cm
286
Y
N

Fig. 7

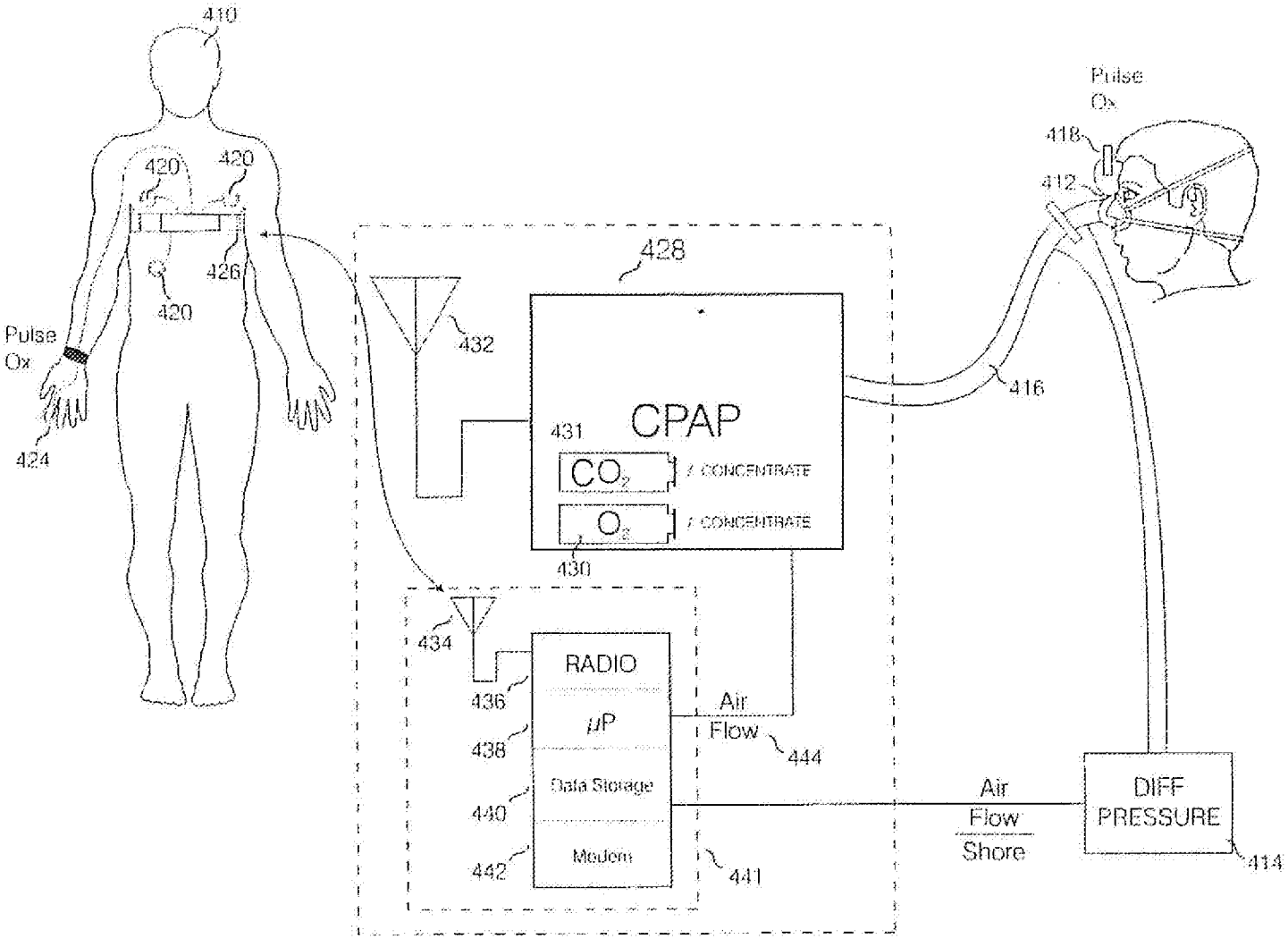


Fig. 8

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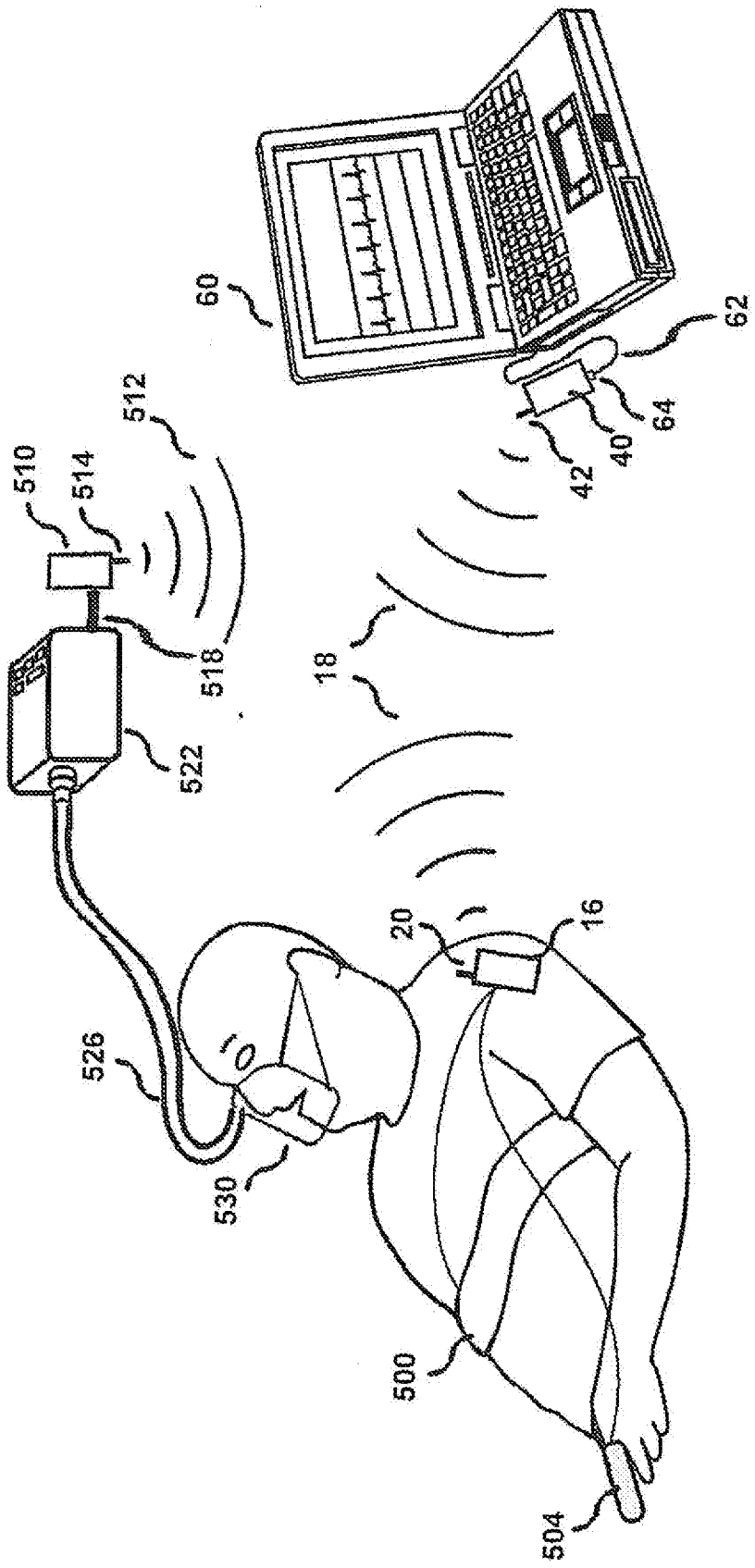


Fig. 9

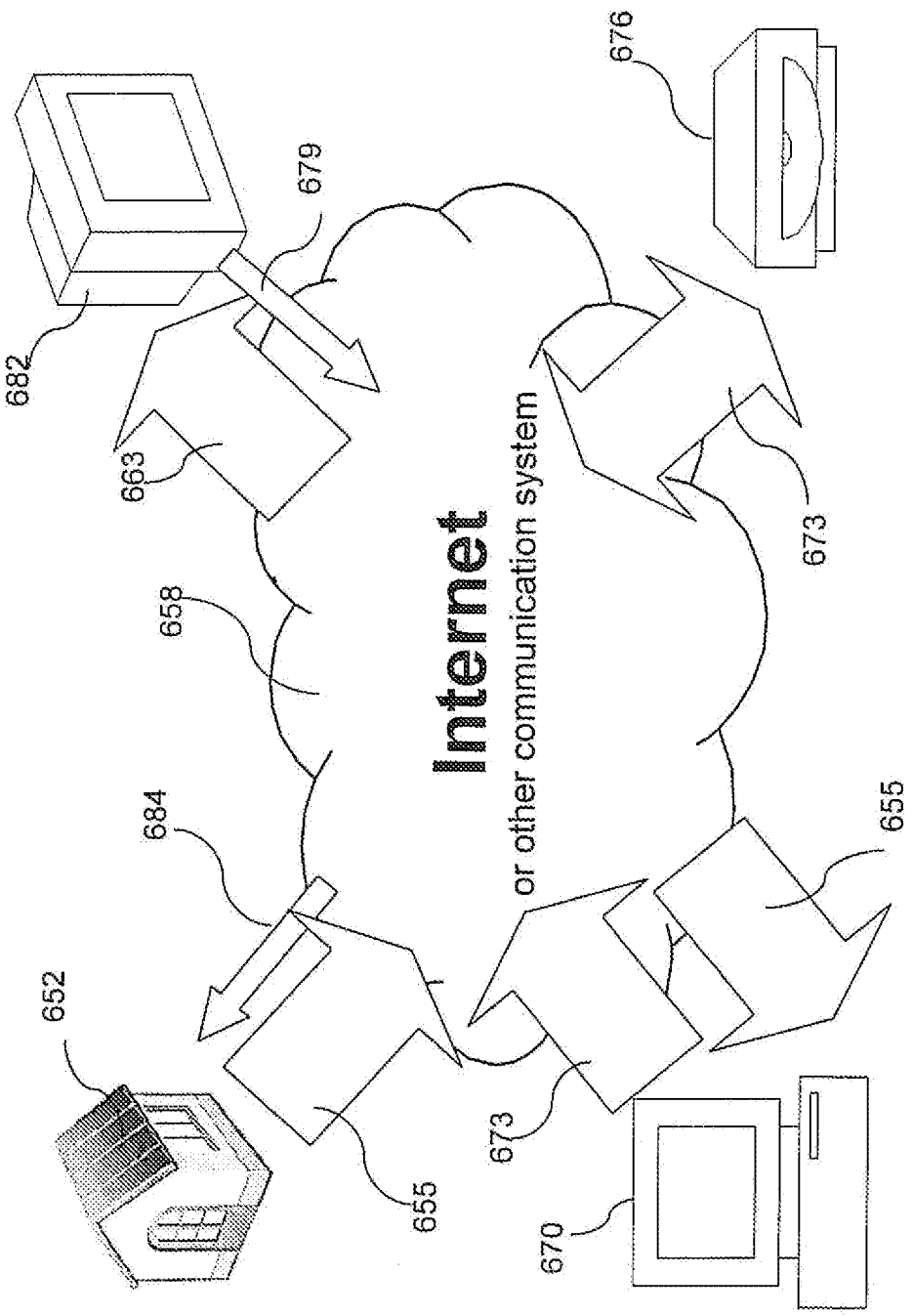

Internet
or other communication system
652
655
658
663
670
673
676
679
682
684

Fig. 10

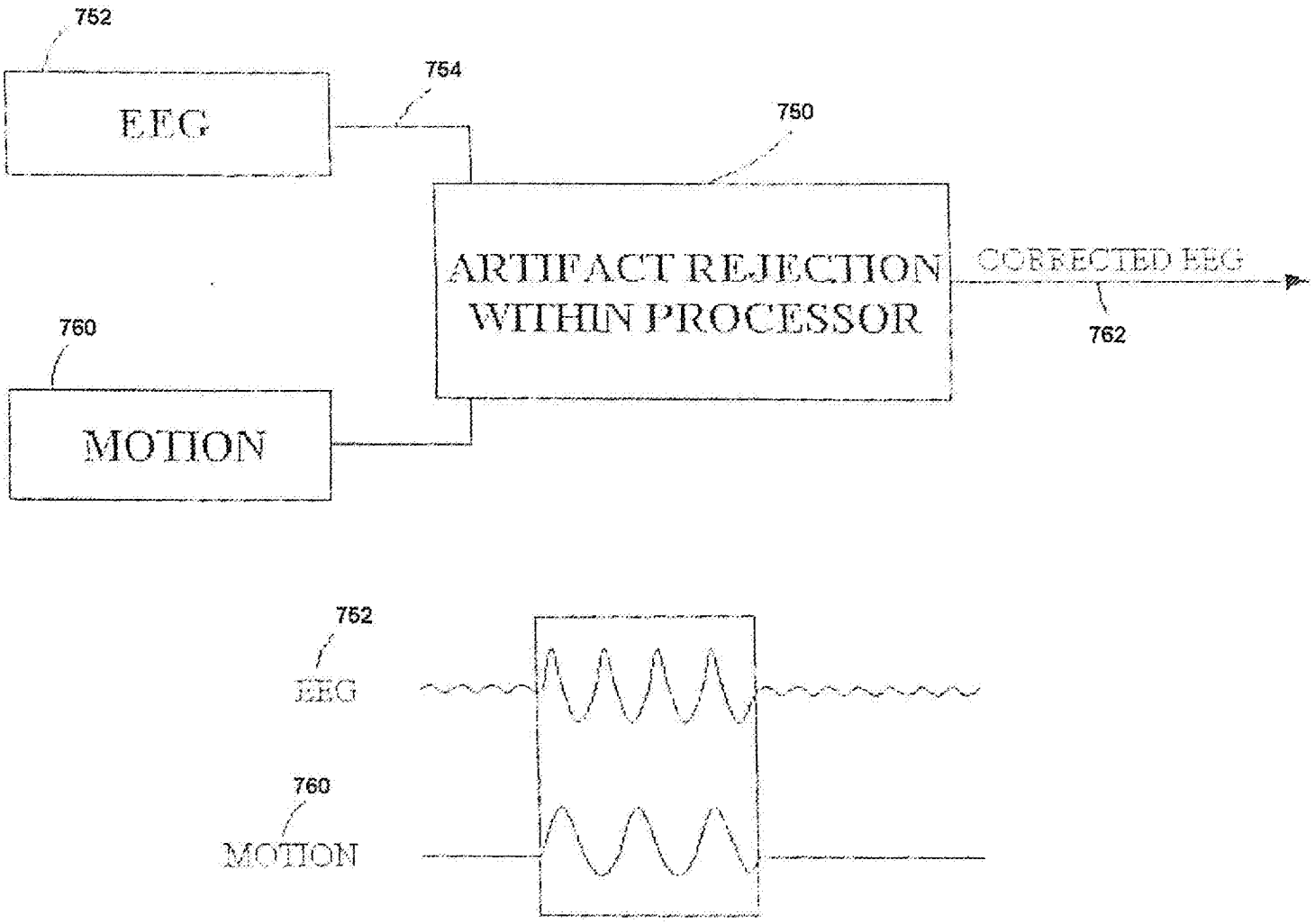


Fig. 11

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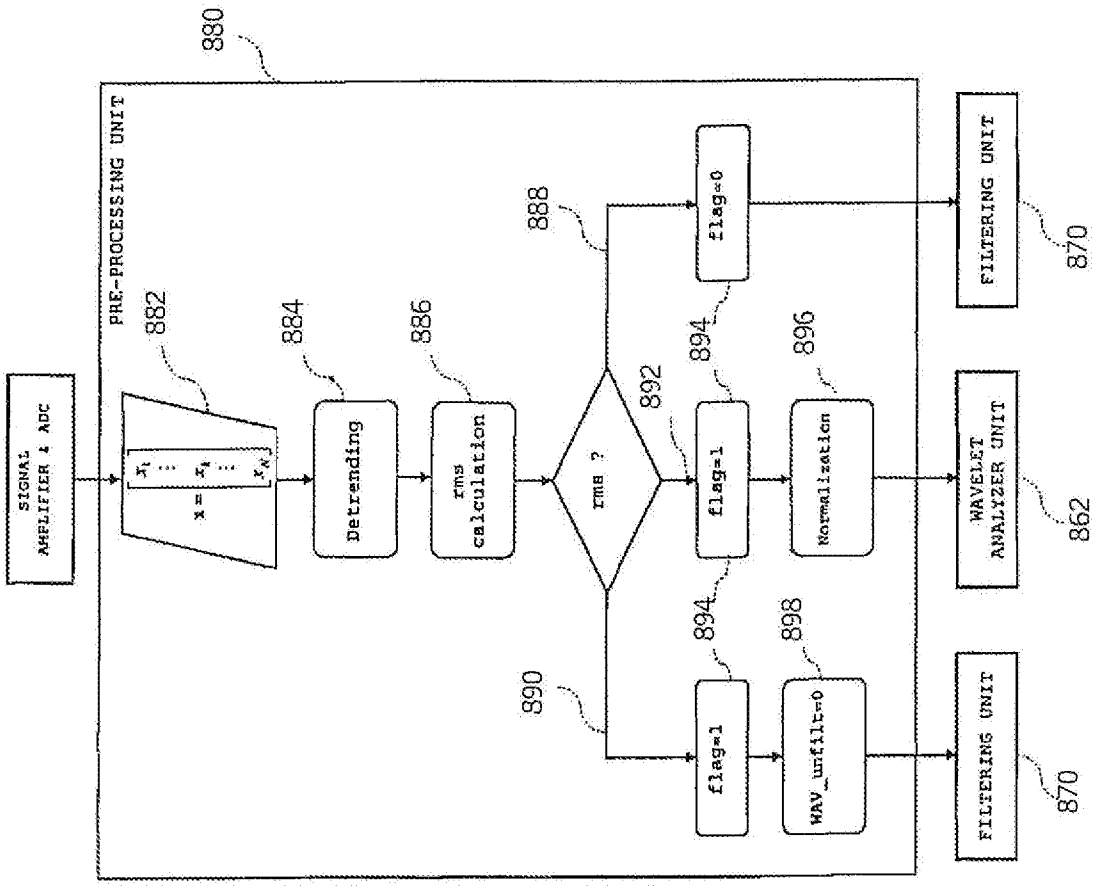

SIGNAL AMPLIFIER & ADC
PRE-PROCESSING UNIT
880
882
884
886
888
890
892
894
896
898
Detrending
rms calculation
rms ?
flag=0
flag=1
flag=1
Normalization
WAV_unfilt=0
FILTERING UNIT
WAVELET ANALYZER UNIT
FILTERING UNIT
870
862
870

Fig. 12

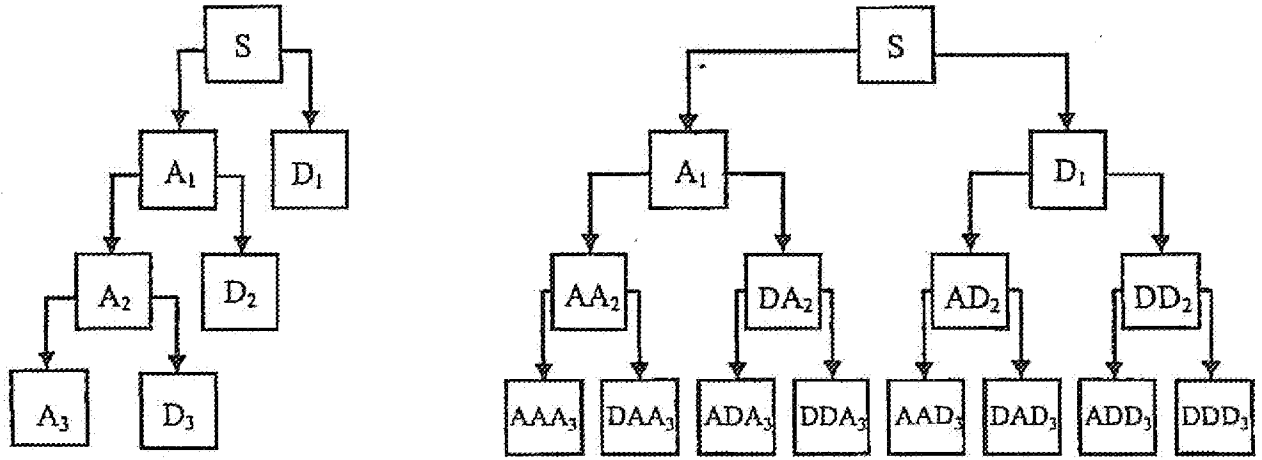


Fig. 13

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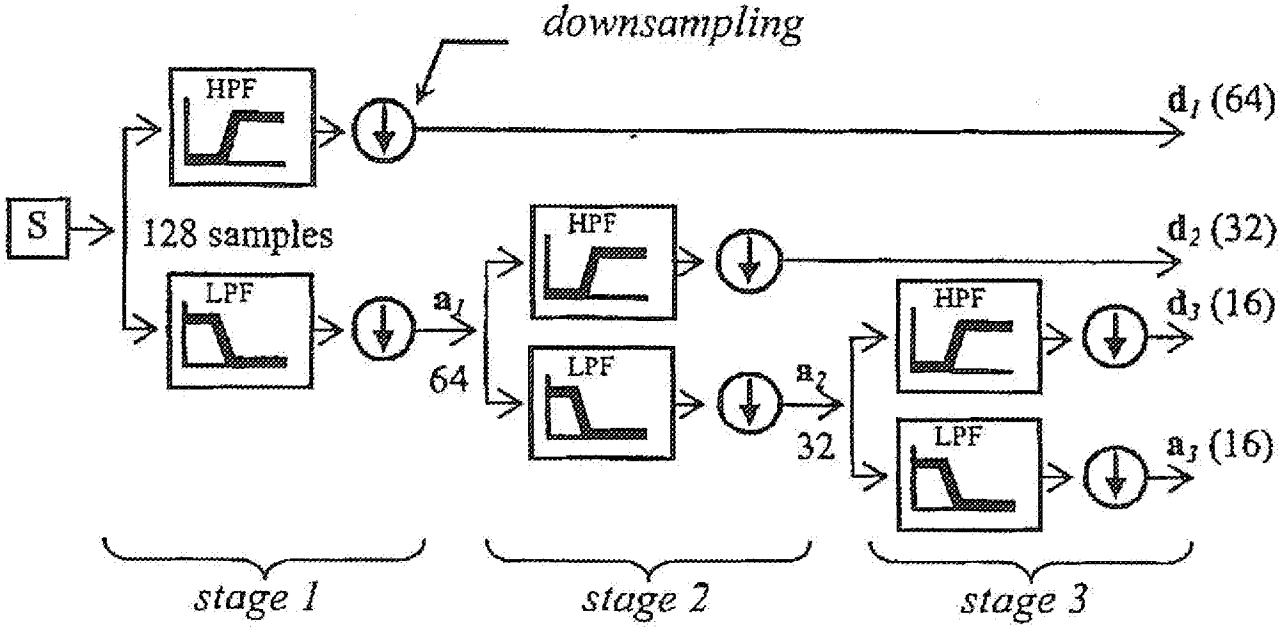


Fig. 14

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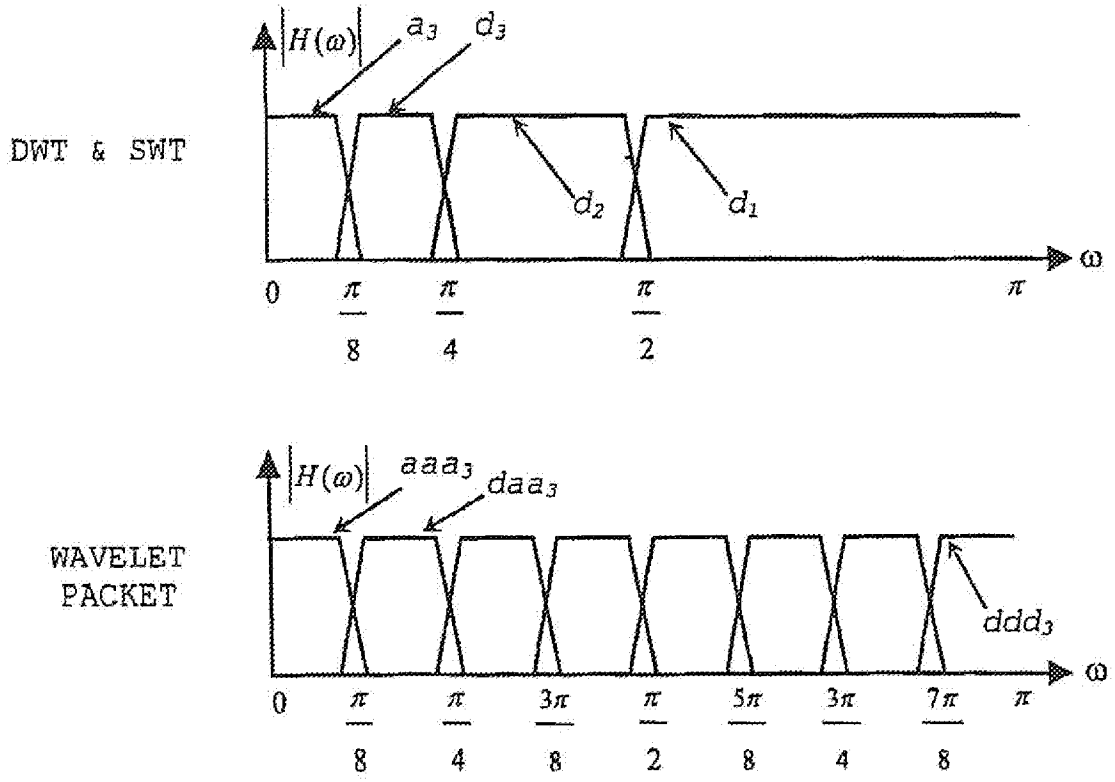


Fig. 15

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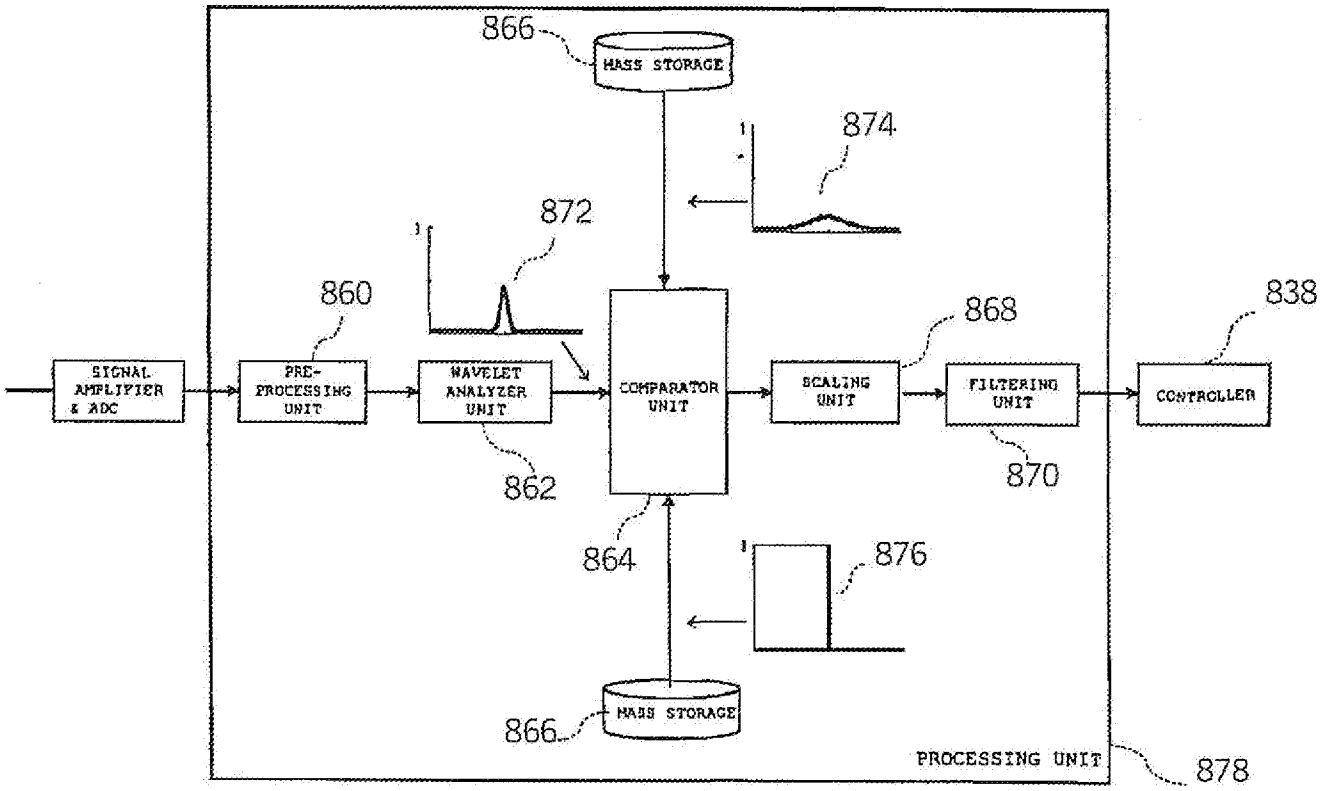


Fig. 16

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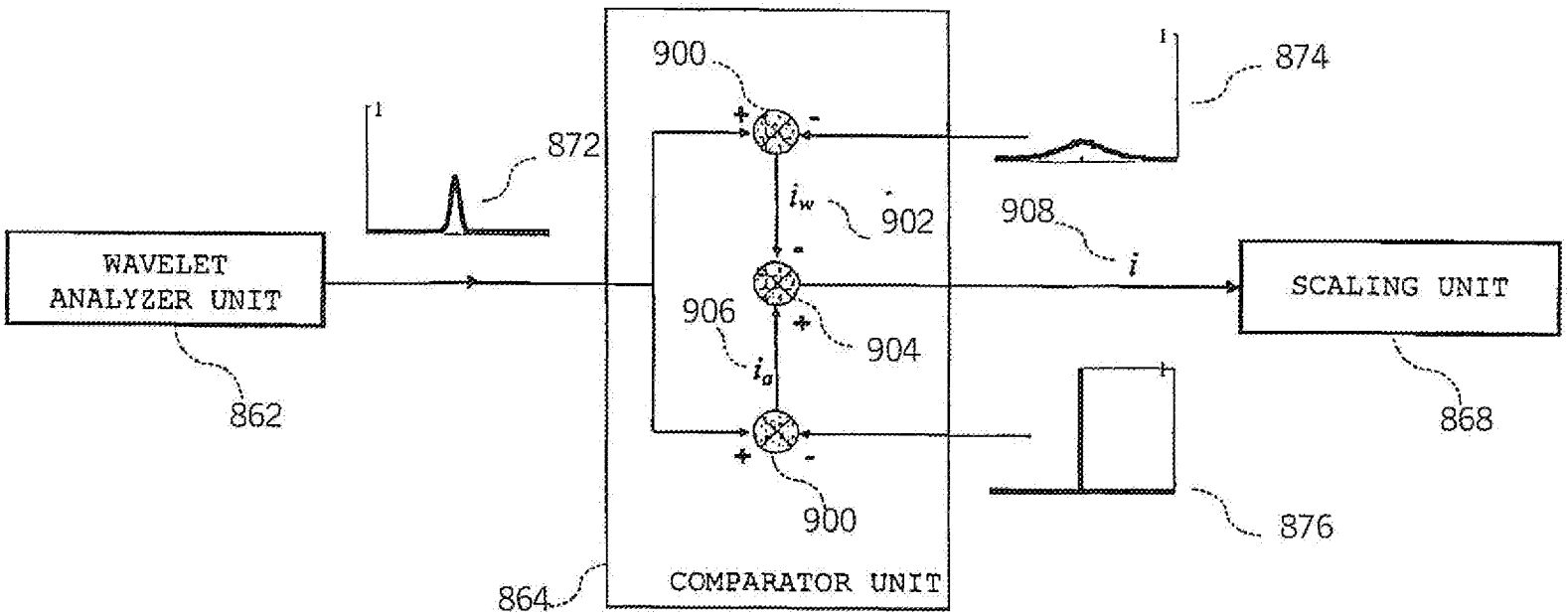


Fig. 17

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Docket No.
CMD-~~057~~ 092

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Integrated Sleep Diagnostic and Therapeutic System and Method

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____

and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, or plant breeder's rights certificate(s), or 365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
11/266,899	11/4/2005	pending

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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Sole or first inventor's signature Date 7/19/07
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Full name of second inventor, if any Dan Bishop
Second Inventor's signature Date 7/19/07
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Tallmadge, OH 44278

Full name of third inventor, if any
Brian M. Kolkowski

Third inventor's signature

Date
7/19/07

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Citizenship
USA

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6340 Taylor Road

Leroy, OH 44077

Full name of fourth inventor, if any

Fourth inventor's signature

Date

Residence

Citizenship

Post Office Address

Full name of fifth inventor, if any

Fifth inventor's signature

Date

Residence

Citizenship

Post Office Address

Full name of sixth inventor, if any

Sixth inventor's signature

Date

Residence

Citizenship

Post Office Address

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Hani		Kayyali	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Shaker Heights	OH	US

Mailing Address of Inventor:

Address 1	2692 Rocklyn Rd.
Address 2	

City	State/Province	Postal Code	Country
Shaker Heights	OH	44122	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Dan		Bishop	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Tallmadge	OH	US

Mailing Address of Inventor:

Address 1	762 Beachler Rd
Address 2	

City	State/Province	Postal Code	Country
Tallmadge	OH	44122	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Brian	M.	Kolkowski	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

City	Leroy	State/Province	OH	Country of Residence	US

Mailing Address of Inventor:

Address 1	6340 Taylor Rd.		
Address 2			
City	Leroy	State/Province	OH
Postal Code	44077	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	31177		
Email Address	bkolkowski@clevemed.com	Add Email	Remove Email

Application Information:

Title of the Invention	Integrated Sleep Diagnostic and Therapeutic System and Method		
Attorney Docket Number	CMD-101	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	15	Suggested Figure for Publication (if any)	9

Filing By Reference:

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

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

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

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☒ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	31177		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	13074901	2011-03-29

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13074901	Continuation of	11879934	2007-07-19	7942824	2011-05-17

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11879934	Continuation in part of	11266899	2005-11-04	8172766	2012-05-08

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

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

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

Authorization or Opt-Out of Authorization to Permit Access:

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

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

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

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

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

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

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

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

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

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

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

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

Applicant Information:

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

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Applicant:

Address 1			
Address 2			
City		**State/Province**	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

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

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	Cleveland Medical Devices Inc.

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	4415 Euclid Ave., Suite 400		
Address 2			
City	Cleveland	**State/Province**	OH
Country i	US	Postal Code	44103
Phone Number	2167916720	Fax Number	2167916739
Email Address	bkolkowski@clevemed.com		

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

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

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

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

Signature	/Brian Kolkowski/			Date (YYYY-MM-DD)	
First Name	Brian	Last Name	Kolkowski	Registration Number	36847

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	CMD-101
	Application Number	
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	70	70
UTILITY SEARCH FEE	2111	1	300	300
UTILITY EXAMINATION FEE	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**730**

Electronic Acknowledgement Receipt

EFS ID:	29690310
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	05-JUL-2017
Filing Date:	
Time Stamp:	15:07:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-101_2017-07-05_application.pdf	2345230 229bb183b57faabb80bea33e9496e49296b81aaf	yes	102

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Specification	1	82
	Claims	83	86
	Abstract	87	87
	Drawings-only black and white line drawings	88	102

Warnings:					
Information:					
2	Oath or Declaration filed	CMD-101_2011-03-29_declaration_POA.pdf	1108293 5838b297cc8301ac3d39f669bd28abbdcde42a35	no	4
Warnings:					
Information:					
3	Application Data Sheet	CMD-101_2017-07-05_ADS.pdf	1823381 53a499b917da3af30983d5bd88a389767f2050d3	no	9
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	35135 4076d4bb977d92d878e419e7c999eb702a12f6b0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	5312039		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

SCORE Placeholder Sheet for IFW Content

Application Number: 15641715 Document Date: 07/05/2017

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

- Drawings – Other than Black and White Line Drawings

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

To access the documents in the SCORE database, refer to instructions below.

At the time of document entry (noted above):

- Examiners may access SCORE content via the eDAN interface.
- Other USPTO employees can bookmark the current SCORE URL (http://Score.uspto.gov/ScoreAccessWeb/).
- External customers may access SCORE content via the Public and Private PAIR interfaces.

Form Revision Date: September 30, 2013

Electronic Patent Application Fee Transmittal

Application Number:	15641715
Filing Date:	
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	70	70
UTILITY SEARCH FEE	2111	1	300	300
UTILITY EXAMINATION FEE	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**730**

Electronic Acknowledgement Receipt

EFS ID:	29697349
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	06-JUL-2017
Filing Date:	
Time Stamp:	07:00:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$730
RAM confirmation Number	070617INTEFSW07030600
Deposit Account	502704
Authorized User	Mark Pennington

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Fee Worksheet (SB06)	fee-info.pdf	35339 7e9a1624cf142033d69c2655e02259bd64ab7564	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	35339		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/641,715	07/05/2017	Hani Kayyali	CMD-101

CONFIRMATION NO. 5750

81177
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

INFORMAL NOTICE

OC00000092757473

Date Mailed: 07/13/2017

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

A new inventor's oath or declaration that identifies this application (e.g., by Application Number and filing date) is required. The inventor's oath or declaration does not comply with 37 CFR 1.63 in that it:

- does not state that the above-identified application was made or authorized to be made by the person executing the oath or declaration.

  Hani Kayyali
  Dan Bishop
  Brian M. Kolkowski

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/afessehaye/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/641,715

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

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

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/641,715	07/05/2017	3771	730	CMD-101	20	3

CONFIRMATION NO. 5750

81177
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

FILING RECEIPT

OC000000092757472

Date Mailed: 07/13/2017

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Hani Kayyali, Shaker Heights, OH;
Dan Bishop, Tallmadge, OH;
Brian M. Kolkowski, Leroy, OH;

Applicant(s)

Hani Kayyali, Shaker Heights, OH;
Dan Bishop, Tallmadge, OH;
Brian M. Kolkowski, Leroy, OH;

Assignment For Published Patent Application

Cleveland Medical Devices Inc., Cleveland, OH

Power of Attorney:
Brian Kolkowski--36847

Domestic Priority data as claimed by applicant

This application is a CON of 13/074,901 03/29/2011
which is a CON of 11/879,934 07/19/2007 PAT 7942824
which is a CIP of 11/266,899 11/04/2005 PAT 8172766

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 07/13/2017
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/641,715**
Projected Publication Date: Request for Non-Publication Acknowledged
Non-Publication Request: Yes
Early Publication Request: No
**** SMALL ENTITY ****
Title

Integrated Sleep Diagnostic and Therapeutic System and Method

Preliminary Class

128

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative,

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
		)	
Serial No.:	15/641,715	)	
		)	Art Unit: 3735
Filed:	July 5, 2017	)	
		)	Docket No.: CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method	)	
		)	
		)	
		)	
Examiner:	Not yet assigned	)	
		)	

August 11, 2017

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This preliminary amendment is being filed in the above captioned application to replace the claims. The Applicants believe that no fees are due in conjunction herewith, but if any fees are found to be owed, the Applicants authorize the Director to withdraw the funds from their deposit account: 502704. The following amendments are respectfully submitted.

Electronic Acknowledgement Receipt

EFS ID:	30053274
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	11-AUG-2017
Filing Date:	05-JUL-2017
Time Stamp:	12:01:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-101_2017-08-11_Preliminary-Amendment.pdf	87450 2d06fea55a67751642952c23c0d0a00c70c99eb5	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	9	9
	Claims	3	8
	Specification	2	2
	Preliminary Amendment	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	87450	

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

REMARKS

The Applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

8/11/17
Dated

/Brian M. Kolkowski/
Brian M. Kolkowski
Reg. No.: 36.847
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ResMed Corp. - Ex. 1002
Page 135

IN THE CLAIMS:

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

1. (cancelled)
2. (cancelled)
3. (cancelled)
4. (cancelled)
5. (cancelled)
6. (cancelled)
7. (cancelled)
8. (cancelled)
9. (cancelled)
10. (cancelled)
11. (cancelled)
12. (cancelled)
13. (cancelled)
14. (cancelled)
15. (cancelled)
16. (cancelled)
17. (cancelled)
18. (cancelled)
19. (cancelled)
20. (cancelled)

21. (new) A method of treating a sleep-related breathing disorder comprising steps of:

attaching to or positioning a first sensor for collecting data from a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

connecting, during manufacturing, before or after attaching or positioning the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject; and

adjusting or titrating the therapy to the subject using at least part of the data from both the first and second sensor signals to improve therapy to the subject during a second time period after the first time period when data is no longer collected.

22. (new) The method of claim 21, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and the data from the second integrated sensor is transmitted wirelessly directly from the PAP or CPAP device to the data acquisition box in real time.

23. (new) The method of claim 21, with the further step wherein the data from the first and second sensors is at least in part transmitted from the data acquisition system by cellular service to a remote data storage station for review remotely by medical personnel, and the medical personnel provides a command signal transmitted by cellular service for titrating or adjusting the PAP or CPAP device automatically if necessary to adjust the flow or by communicating with an individual near the subject or with the

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subject to adjust the PAP or CPAP device.

24. (new) The method of claim 21, wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

25. (new) The method of claim 21, wherein the data acquisition system comprises the first and an additional third sensors having signals, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

26. (new) The method of claim 21, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals that are specific to the subject being treated for improved treatment during the second time period when data is no longer collected from the first sensor.

27. (new) A method of determining the effectiveness of the therapy used in treating a sleep-related breathing disorder comprising steps of:

attaching to or positioning a first sensor for collecting data from a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

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Page 138

connecting, during manufacturing, before or after attaching or positioning the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject;

determining an effectiveness of the therapy delivered by the separate PAP or CPAP device using at least part of the data from both the first and second sensor signals.

28. (new) The method of claim 27, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and can communicate directly with each other through the wireless connection in real-time.

29. (new) The method of claim 27, wherein the data from the first and second sensors is in part transmitted from both devices in real-time.

30. (new) The method of claim 27, wherein the steps of the method can be used to adjust and titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas after the time period when data is no longer collected from the first sensor.

31. (new) The method of claim 27, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals from the data acquisition system that are specific to the subject being treated for improved treatment during the

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Page 139

second time period when data is no longer collected from the first sensor.

32. (new) The method of claim 33, wherein the PAP or CPAP device is adjusted or titrated by utilizing more robust data collection by relating the data from the first sensor to the second sensor for improved treatment during the second time period when data is no longer collected from the first sensor.

33. (new) The method of claim 27, wherein the data acquisition system comprises an additional third sensor having a signal, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second integrated sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

34. (new) The method of claim 33, wherein the data acquisition system comprises an additional fourth sensor for determining body position of the subject.

35. (new) A method of treating a sleep-related breathing disorder comprising steps of:

providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a first sensor during a time period, the first sensor which is integrated into the PAP or CPAP device;

transmitting the data or information based on the data from the first sensor to a cellular phone;

outputting apnea events calculated using the data from the first sensor on a display of the cellular phone; and

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retransmitting the data or information based on the data as well as the calculated apnea events to a remote station for review by a clinician, technician or physician.

36. (new) The method of claim 35, wherein the cellular phone and the PAP or CPAP device each have a wireless RF connection and can communicate directly with each other through the wireless connection in real time.

37. (new) The method of claim 35, wherein the therapy can be modified based in part on the retransmitted data or information.

38. (new) The method of claim 35, wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

39. (new) The method of claim 35, wherein the therapy can be adjusted or titrated from the remote location by the technican, clinician or physician.

40. (new) The method of claim 35, wherein the PAP or CPAP is adjusted or titrated in real-time.

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Page 141

IN THE SPECIFICATION:

Please amend the paragraph on page 1, lines 6-6-8 as follows:

"**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. Patent application serial no. 13/074,901 filed on March 29, 2011, which is a continuation of U.S. Patent application serial no. 11/879,934 filed on July 19, 2007 and issued as U.S. Patent no. 7,942,824 on May 17, 2011, which is a continuation-in-part of U.S. Patent application serial no. 11/266,899 filed on November 4, 2005 and issued as U.S. Patent no. 8,172,766 on May 8, 2012."

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/641,715	Filing Date 07/05/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 08/11/2017

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/VICTOR BARLOW/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/641,715	Filing Date 07/05/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	**140**
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	**140**

APPLICATION AS AMENDED – PART II

AMENDMENT **08/11/2017**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	**0**

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
GLORIA J. TRAMMELL

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PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Integrated sleep diagnostic and therapeutic system and method

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/641,715 filed on July 5, 2017.

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

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

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

WARNING:

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

LEGAL NAME OF INVENTOR

Inventor: Hani Kayyali Date (Optional): 10/3/18

Signature: Hc Kayali

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

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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LEGAL NAME OF INVENTOR

Inventor: Dan Bishop Date (Optional): 10/8/2018

Signature: [signature]

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

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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LEGAL NAME OF INVENTOR

Inventor: Brian M. Kolkowski Date (Optional): 10/2/15

Signature:

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

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	34031900
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	17-OCT-2018
Filing Date:	05-JUL-2017
Time Stamp:	10:27:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	CMD-101_2018-10-17_new-declarations-combined.pdf	152820 cb3aedf4066eddccbd33f202ae815e1aca73bdae	no	3

Warnings:

Information:	
Total Files Size (in bytes):	152820

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 08/17/2020

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

EXAMINER	
VIVIAN, CHARLES M	

ART UNIT	PAPER NUMBER
3785	

MAIL DATE	DELIVERY MODE
08/17/2020	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. 15/641,715	Applicant(s) Kayyali et al.	
	Examiner CHARLES VIVIAN	Art Unit 3785	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 July 2017.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 21-40 is/are pending in the application.

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

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 21-40 is/are rejected.

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

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

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

Application Papers

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

11)☑ The drawing(s) filed on 05 June 2017 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Status of Claims

2. This office action is in response to the filing of the application on 7/5/2017. Since the initial filing, no claims have been amended, claims 21-40 have been added, and claims 1-20 have been canceled. Thus, claims 21-40 are pending in the application.

Claim Objections

3. Claims 32 and 39 are objected to because of the following informalities:

- Claim 32 depends from subsequent claim 33 which is not permitted (see MPEP 608.01(n)).
- Claim 39 recites "technican" in line 2 which should read "technician" to correct a misspelling.
- Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have

been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

5. Claims 21-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 and 14 of U.S. Patent No. 9,730,632 (hereinafter '632). Although the claims at issue are not identical, they are not patentably distinct from each other because the claims of the current application would be anticipated by or obvious in view of the claims of '632.

6. For example, Applicant's current claim 21 is a broader version of the claim presented in claim 1 of '632 in that the only difference is the addition of "during manufacturing" to the markush group in the "connecting... the first sensor to a data acquisition system" step and replacing "the flow of pressurized gas delivered by the separate PAP or CPAP device" with the broader "the therapy to the subject".

7. Additionally, Applicant's current claims 22-26 are broader versions of the claims presented respectively in claims 2-6 of '632 for the same reasons described above with respect to Applicant's current claim 21.

8. Additionally, Applicant's current claim 27 is a broader version of the claim presented in claim 1 of '632 in that the only difference is the addition of "during manufacturing" to the markush group in the "connecting... the first sensor to a data acquisition system" step and replacing the "adjusting" with the broader "determining" step (determining whether an adjustment is to be made based on measured and calculated data is inherently a part of actually making that adjustment based on measured and calculated data).

9. Additionally, Applicant's current claims 28-31 are broader versions of the claims presented respectively in claims 2-4 and 6 of '632 for the same reasons described above with respect to Applicant's current claim 27.

10. Additionally, Applicant's current claims 32-33 is a broader version of claim 5 of '632 for the same reasons described above with respect to current claim 27.

11. Additionally, Applicant's current claim 34 is an obvious variant of claim 1 of '632 for the same reasons described above with respect to current claim 27 in combination with claim 14 of '632.

Claim Rejections - 35 USC § 103

12. 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 negatived by the manner in which the invention was made.

13. Claims 35-37 and 39-40 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rapoport et al (hereinafter Rapoport) in view of U.S. Patent Application Pub. No. 2005/0222502 to Cooper (hereinafter Cooper).

14. Regarding claim 35, Rapoport discloses **providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a first sensor during a time period** (the device collects and stores data while the patient sleeps and receives CPAP treatment (col. 16, lines 12-29)), **the first sensor which is integrated into the PAP or CPAP device** (the therapy device has optional position sensors 112 built into the mask (col. 13, lines 33-34) and pulse oximetry sensors 120 (as seen in Fig. 19); **and retransmitting the data or information based on the data as well as the calculated apnea events to a remote station for review by a clinician, technician or physician** (At step 164, the patient returns the

therapy device or its data storage module for analysis of the stored data... Then the stored flow data are analyzed at step 166 to determine... the number and severity of apneas (col. 16, lines 30-35))

15. Rapoport does not specifically disclose transmitting the data or information based on the data from the first sensor to a cellular phone; outputting apnea events calculated using the data from the first sensor on a display of the cellular phone.

16. However, Cooper teaches **transmitting the data or information based on the data from the first sensor to a cellular phone** ("the processing system 10 is adapted to... store and optionally process any sampled signals... Thus the processing system may be formed from a... mobile phone" (paragraph 0121, lines 1-10)); **outputting apnea events calculated using the data from the first sensor on a display of the cellular phone** ("Analysis simultaneous transitions in blood volume and blood oxygen transitions may be used for characterising apnea events. Deregulation in a respiratory parameter could then suitably be displayed to an inbuilt LCD screen" (paragraph 0130, lines 9-13)).

17. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rapoport to include "transmitting the data or information based on the data from the first sensor to a cellular phone; outputting apnea events calculated using the data from the first sensor on a display of the cellular phone" as taught by Cooper. One would be motivated to do this to allow for effective monitoring of sleep apnea events (Cooper Abstract).

18. Regarding claim 36, the modified method of Rapoport teaches **wherein the cellular phone and the PAP or CPAP device each have a wireless RF connection**

and can communicate directly with each other through the wireless connection in real time (Cooper describes that the processing device may be a mobile phone (Cooper paragraph 121, line 10); and if the mobile phones inherently communicate via wireless RF).

19. Regarding claim 37, the modified method of Rapoport teaches wherein the therapy can be modified based in part on the retransmitted data or information ("At step 170, a decision is made whether the analysis determines that there are still a significant number of sleep-disordered breathing episodes during the night…If the therapy device did not restore normal breathing, then the patient is referred to a sleep lab for more comprehensive study, step 160 (Rapoport, col. 16, lines 47-56)).

20. Regarding claim 39, the modified method of Rapoport teaches **wherein the therapy can be adjusted or titrated from the remote location by the technician, clinician or physician** ("if the peak therapy pressures fluctuate significantly, then the patient is provided with a prescription for a self-adjusting controlled positive pressure therapy device for continued home use, step 174" (Rapoport col 16, lines 60-63); this section describes how a physician at a remote location can cause an adjustment in the therapy via a prescription).

21. Regarding claim 40, the modified method of Rapoport teaches **wherein the PAP or CPAP is adjusted or titrated in real-time** ("a self-adjusting controlled positive pressure therapy device" (Rapoport col 16, lines 62-63)).

22. Claim 38 rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Rapoport in view of Cooper and in further view of U.S. Patent Application Pub. No. 2005/0115561 to Stahmann et al. (hereinafter Stahmann).

23. Regarding claim 38, the modified method of Rapoport does not specifically teach wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

24. However Strahmann teaches **wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central, and complex sleep apneas after the time period when data is no longer collected from the first sensor** (Figures 12 and 13; paragraphs 281-287, Table 2 shows multiple parameters that can be used to detect disordered breathing; wherein therapy can be adjusted, titrated, or terminated (p956-958; 963-966); 317-319, wherein disordered breathing can be classified as obstructive, central or mixed apnea). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Rapoport and Cooper with the detection of different types of apneas as taught by Stahmann in order to provide improved patient monitoring, diagnosis, and therapy (Stahmann Abstract).

Allowable Subject Matter

1. Claims 21-34 would be allowable provided that the current double patenting rejection were overcome, such as by the filing of a timely terminal disclaimer.

2. The following is a statement of reasons for the indication of allowable subject matter: Claims 21-34 are allowable because they are directed to a method of treating a sleep-related breathing disorder wherein the system includes a first sensor connected to

a data acquisition system separate from a PAP/CPAP device that includes a second sensor. The first sensor transmits data to the PAP/CPAP device to use with the data from the second sensor (on the PAP/CPAP) to titrate the flow of pressurized gas delivered to the patient. The second sensor transmits data to the separate data acquisition system.

3. The prior art, Rapoport, teaches a PAP/CPAP device with a flow and pressure sensor (second) sensor and a diagnostic device (with a pulse oximeter). However, the therapeutic device and diagnostic devices are not used together at the same time such that sensors may transmit information between the devices.

4. U.S. Pat. No. 6,752,766 to Kowallik et al. teaches the data acquisition device and the CPAP device as separate, however, in combination with Rapoport does not teach a second sensor on the CPAP device that transmits data to the data acquisition device.

5. Thus, the prior art of record neither renders obvious nor anticipates the combination of claim elements in light of the specification.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application Pub. No. 2005/0197588 relates to a sleep disordered breathing alert system that can send data to cell phone. U.S. Patent Application Pub. No. 2005/0119586 relates to a respiratory event detection system that can communicate over cell phone.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHARLES VIVIAN whose telephone number is

(571)272-2440. The examiner can normally be reached on 0700-1600 M-Th; 0700-1500 2nd F.

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, Samchuan Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/C.M.V./
Examiner, Art Unit 3785

/SAMCHUAN C YAO/
Supervisory Patent Examiner, Art Unit 3785

Notice of References Cited	Application/Control No. 15/641,715	Applicant(s)/Patent Under Reexamination Kayyali et al.	
	Examiner CHARLES VIVIAN	Art Unit 3785	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-6299581-B1	10-2001	Rapoport; David M.	A61B5/0002	128/204.21
*	B	US-6752766-B2	06-2004	Kowallik; Peter	A61M16/0051	600/538
*	C	US-20050119586-A1	06-2005	Coyle, Michael	A61B5/4818	600/538
*	D	US-20050115561-A1	06-2005	Stahmann, Jeffrey E.	A61N1/3627	128/200.24
*	E	US-20050197588-A1	09-2005	Freeberg, Scott	A61N1/3601	600/529
*	F	US-20050222502-A1	10-2005	Cooper, Philip George	A61B5/1495	600/323
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	CHARLES VIVIAN	3785

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

CLAIMS

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

CLAIM		DATE								
Final	Original	08/14/2020								
	1	-								
	2	-								
	3	-								
	4	-								
	5	-								
	6	-								
	7	-								
	8	-								
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	31	✓								
	32	✓								
	33	✓								
	34	✓								
	35	✓								
	36	✓								
	37	✓								
	38	✓								
	39	✓								
	40	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	CHARLES VIVIAN	3785

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61M 16/00; 16/0003	08/14/2020	Charles Vivian
A61B 5/4818; 5/4836	08/14/2020	Charles Vivian

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
128	204.23	08/14/2020	Charles Vivian

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

Search Notes		
Search Notes	**Date**	**Examiner**
Inventor Name Search	08/14/2020	Charles Vivian
Keyword search terms: cell, cellular, mobile, phone, telephone, smartphone	08/14/2020	Charles Vivian

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

/CHARLES M VIVIAN/ Examiner, Art Unit 3785	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	4	(US-20050222502-$ or US-20050115561-$).did. or (US-6752766-$ or US-6299581-$).did.	US-PGPUB; USPAT	OR	ON	2020/08/14 10:42
L3	1	"9730632".pn.	US-PGPUB; USPAT	OR	ON	2020/08/14 11:10
L6	34	((("KAYYALI") near3 ("Hani")) OR (("BISHOP") near3 ("Dan")) OR (("KOLKOWSKI") near3 ("Brian"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/08/14 12:47
L7	1,735	A61M16/0003.cpc.	US-PGPUB; USPAT	OR	ON	2020/08/14 12:48
L8	0	A61B5/5836.cpc.	US-PGPUB; USPAT	OR	ON	2020/08/14 12:55
L9	5,416	A61B5/4836.cpc.	US-PGPUB; USPAT	OR	ON	2020/08/14 12:55
L10	1,829	A61M16/00.cpc.	US-PGPUB; USPAT	OR	ON	2020/08/14 12:57
L11	0	128/204.230.ccls.	US-PGPUB; USPAT	OR	ON	2020/08/14 13:12
L12	0	128/204.ccls.	US-PGPUB; USPAT	OR	ON	2020/08/14 13:13
L13	2,233	128/204.23.ccls.	US-PGPUB; USPAT	OR	ON	2020/08/14 13:14
S1	3	"6299581".pn. or "6752766".pn. or "20050115561".pn.	US-PGPUB; USPAT	OR	ON	2020/06/25 09:33
S2	2,632	A61B5/4818.cpc.	US-PGPUB; USPAT	OR	ON	2020/08/13 14:12
S3	738	S2 and (((cell or cellular) adj (phone or telephone)) or smartphone or PDA)	US-PGPUB; USPAT	OR	ON	2020/08/13 14:17
S4	812	S2 and (((cell or cellular or mobile) adj (phone or telephone)) or smartphone or PDA)	US-PGPUB; USPAT	OR	ON	2020/08/13 14:20

EAST Search History (Interference)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.	)	
Serial No.:	15/641,715	)	Art Unit: 3735
Filed:	July 5, 2017	)	Docket No.: CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method	)	
Examiner:	Charles Vivian	)	

November 17, 2020

AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This amendment is being filed in the above captioned application in response to a non-final Office Action dated August 17, 2020. The Applicants believe that no extension of time is necessary, however, if one is due the Applicants herein petition for the extension of time and authorize any fees to be deducted from their deposit account. The Applicants believe that no fees are due in conjunction herewith, but if any fees are found to be owed, the Applicants authorize the Director to withdraw the funds from their deposit account: 502704. The following amendments are respectfully submitted.

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Electronic Acknowledgement Receipt

EFS ID:	41145619
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	17-NOV-2020
Filing Date:	05-JUL-2017
Time Stamp:	14:36:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-101_17Nov2020_Amendment.pdf	181725 567b4f45a852efb23d426f06e54490915fe20819	yes	15

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	8	15
	Claims	2	7
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	181725	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

REMARKS

In this case claims 21-40 are pending and 21-40 are rejected. Claims 35-40 have been amended. The Applicants respectfully traverse the rejections below.

Non-Statutory Double Patenting

Claims 21-34 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 and 14 of U.S. Pat. No. 9,730,632. The Applicants submit that they will file a terminal disclaimer to overcome this rejection once all claims have been resolved.

Claim Rejections – 35 U.S.C. § 103

To provide legal context as well as an analytical framework for the remarks that follow, the Applicant wishes at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an assertion of *prima facie* obviousness the examiner must perform the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that "secondary considerations" such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, "the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis." MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the examiner errs in performing any of the *Graham* factual inquiries, the examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the examiner committing error in

performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

With specific regard to the examiner's obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Applicant would direct particular attention to the requirement that "[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill." *See* MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the examiner's burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an "indication of the level of ordinary skill," *MPEP 2141(II)(C)*, the examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the examiner in such a way as to render the claimed invention obvious. *See In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and examiner for failing to provide "any evidentiary support or reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant" and further noting that *KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* "did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references").

Thus, in order for the examiner to properly establish a *prima facie* case of obviousness the examiner must first make the factual inquiries required by *Graham* and, if relying on a combination of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the

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examiner falls short in meeting any of these requirements then the examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. *See In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) ("If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent"). As stated in the United States Patent and Trademark Office's own rules, "[a] prima facie case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard..." *See* 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor" (emphasis added).

In all of the above, the Applicants wish to emphasize the high bar to which the examiner is held during the examination process and hereby respectfully request that in the ongoing prosecution of the present application that the examiner provide explicit and detailed analysis of any grounds of rejection relied upon. *See, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* ("[an obviousness] analysis should be made explicit," citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

Claims 35-37 and 39-40 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rappaport et al ("Rappaport") in view of U.S. Pat. Pub. No. 2005/0222502 to Cooper ("Cooper"). The Applicants traverse and submit the claims as now amended overcome this rejection.

More specifically, with respect to Claim 35, Rappaport and Cooper alone or together do not teach nor disclose a method of treating a sleep-related breathing disorder comprising steps of providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a flow or pressure sensor during a time period, the flow or pressure sensor which is integrated into the PAP or CPAP device; transmitting the data or information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link; outputting apnea events calculated by either the PAP or CPAP device, or the cellular phone using

software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to better understand an efficacy of the therapy; and retransmitting the data or information based on the data as well as the calculated apnea events from either the PAP or CPAP device, and/or the cellular phone to a remote station via a cellular system or an Internet for review by a clinician, technician or physician as claimed.

The self-adjusting or autotitrating device in Rappaport, an example is shown in FIG. 18 and an example of the algorithm used by the device in FIG. 17, is then used to collect data as to determine how to alleviate apneas. The PAP device 86 has a flow sensor 72 and a pressure sensor 90. The data collected with these sensors is run through various electronics 76, 78, 80 on the PAP device and through an algorithm as shown in FIG. 17 through which the patient is tested at various flow pressures to determine whether the patients apnea(s) are alleviated. This data is then stored in memory 81. FIG. 22 shows the patient then returns the auto-PAP with the stored data 164. The stored data is then analyzed 166 to determine the proper set pressure for the patient 168. In Rappaport "[the] patient sleeps at home with the therapy device for the required number of nights…[and] returns the therapy device or its storage module for analysis of the stored data." This data (and this data alone) from the self-adjusting device is then used to adjust the PAP or CPAP device.

Rappaport does not teach or disclose calculating apnea events rather the PAP in Rappaport determines whether apnea(s) are alleviated at various pressures. Rappaport collects flow and pressure data 162 at these various pressures. Further, the apparatus in Rappaport needs to be returned by the patient to the remote location for the data to be downloaded and analyzed 164. The data is then analyzed at the remote location to determine the amount of flow limiting and apnea present 166. The present invention instead analyzes the number of apnea events either with the PAP or cellular phone from the flow or pressure sensor data onsite. This data is then forwarded to the remote location either by the cellular phone or the PAP, and the number of apnea events are displayed for the subject to better understand the efficacy of their treatment.

The specific embodiment of the apparatus in Cooper for patient monitoring that the Examiner refers to is where the sensor is a photodiode, likely a pulse oximeter, where

data is collected and "blood flow cycling with hypopnea and voltage transition characteristic of arousal peaks in the blood volume signal" are Examiner. This calculation can be performed either remotely or via a mobile phone processor. Clearly these calculations are not based on flow or pressure data. Further, the respiratory parameters are not used for the patient to better understand the efficacy of a PAP or CPAP treatment.

With respect to the method of claim 36, Rappaport nor Cooper teach or disclose wherein the cellular phone and the PAP or CPAP device each have a Bluetooth wireless RF connection and can communicate directly with each other through the wireless connection in real time as claimed.

With respect to the method of claim 37, Rappaport nor Cooper teach or disclose wherein the therapy can be modified based in part on the wirelessly retransmitted data or information as claimed.

With respect to the method of claim 39, Rappaport nor Cooper teach or disclose wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technican, clinician or physician as claimed. The Examiner admits that the adjustment must be done through prescription.

With respect to the method of claim 40, Rappaport nor Cooper teach or disclose wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician as claimed.

In an attempt to explain the purported combination of these references, the Examiner merely makes a unsupported conclusory observations. The Applicants, however, remind the Examiner that these observations must be supported.

The Examiner states "Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the method of Rappaport to include "transmitting the data or information based on the data from the first sensor to a cellular phone; outputting the apnea events calculated using data from the first sensor on a display of the cellular phone as taught by Cooper." There is no rational basis for this argument. Clearly, the present invention displays the apnea events so the subject can understand the efficacy of their therapy and either forwards the data or transmits it from

the PAP to a remote location so the subject's therapy provide can review the data and provide for therapy adjustment if necessary. Furthermore with the present invention this can all be done remotely without the need for the patient to return the PAP device for the data analysis and calculation.

Further, the Examiner has so far failed to explicitly define or establish the level of ordinary skill in the art, and none of the references adequately provides the level implicitly. As before, numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Rappaport and Cooper references? What are the similarities between the claimed invention and Rappaport and Cooper? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relies upon a conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to support his analysis of the Graham factors, but has failed to do so. The Applicants therefore respectfully request the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary skill in the art or to the Examiner's conclusions. The Applicants further suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and request that the Examiner therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which the rejection is based. *See* 37 C.F.R. § 1.104(d) (2).

The Applicants further respectfully submit that the Examiner has not given any valid teaching, suggestion, or motivation in or external to the references, or from the references cited as a whole, for the person of ordinary skill to have modified the reference of Rapoport to include the teachings of Cooper. The Applicants respectfully request that the Examiner either support the conclusions of motivation with references or, if such allegation is based on personal knowledge, provide an affidavit as to such including the factual underpinning for such conclusions. *See* 37 C.F.R. § 2144.03. In *re Eynde* states

that "[t]he facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." *In re Eynde*, 480 F.2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973). Similarly, *KSR Int'l Co. v. Teleflex, Inc.* requires that "[obviousness] analysis should be made explicit." *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007). *KSR* goes on to explain that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning." It is often "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15.

Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Claim 38 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over Rappaport in view of Cooper, and further in view of U.S. Patent Pub. 2005/0115561 to Stahmann et al. ("Stahman"). The Applicants traverse and submit the claim overcomes this rejection.

The Applicants incorporate their above remarks with respect to Rappaport and Cooper.

With respect to the method of Claim 38, Rappaport, Cooper nor Stahmann teach or disclose wherein the steps of the method can be used train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor as claimed.

Just because Stahmann may teach differences between classifying obstructive, mixed and central apneas doesn't mean that identifying the differences automatically leads to be able to train the PAP to adjust or titrate itself. Furthermore, the present invention does so using flow or pressure sensors – not the detailed and complex system of Stahman.

Given the above comments, the Applicants request the Examiner withdraw this rejection.

Conclusion

Given the reasons set forth above, the Applicants request the Examiner withdraw the above rejections. For all the above reasons the Applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

__November 17, 2020__
Dated

__/Brian M. Kolkowski/_____
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IN THE CLAIMS:

Please amend claims 35-40 as follows:

1. (cancelled)
2. (cancelled)
3. (cancelled)
4. (cancelled)
5. (cancelled)
6. (cancelled)
7. (cancelled)
8. (cancelled)
9. (cancelled)
10. (cancelled)
11. (cancelled)
12. (cancelled)
13. (cancelled)
14. (cancelled)
15. (cancelled)
16. (cancelled)
17. (cancelled)
18. (cancelled)
19. (cancelled)
20. (cancelled)

21. (previously presented) A method of treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

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concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject; and

adjusting or titrating the therapy to the subject using at least part of the data from both the first and second sensor signals to improve therapy to the subject during a second time period after the first time period when data is no longer collected.

22. (previously presented) The method of claim 21, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and the data from the second integrated sensor is transmitted wirelessly directly from the PAP or CPAP device to the data acquisition box in real time.

23. (previously presented) The method of claim 21, with the further step wherein the data from the first and second sensors is at least in part transmitted from the data acquisition system by cellular service to a remote data storage station for review remotely by medical personnel, and the medical personnel provides a command signal transmitted by cellular service for titrating or adjusting the PAP or CPAP device automatically if necessary to adjust the flow or by communicating with an individual near the subject or

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with the subject to adjust the PAP or CPAP device.

24. (previously presented) The method of claim 21, wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

25. (previously presented) The method of claim 21, wherein the data acquisition system comprises the first and an additional third sensors having signals, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

26. (previously presented) The method of claim 21, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals that are specific to the subject being treated for improved treatment during the second time period when data is no longer collected from the first sensor.

27. (previously presented) A method of determining the effectiveness of the therapy used in treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

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connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject;

determining an effectiveness of the therapy delivered by the separate PAP or CPAP device using at least part of the data from both the first and second sensor signals.

28. (previously presented) The method of claim 27, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and can communicate directly with each other through the wireless connection in real-time.

29. (previously presented) The method of claim 27, wherein the data from the first and second sensors is in part transmitted from both devices in real-time.

30. (previously presented) The method of claim 27, wherein the steps of the method can be used to adjust and titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas after the time period when data is no longer collected from the first sensor.

31. (previously presented) The method of claim 27, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals from the data acquisition system that are specific to the subject being treated for improved

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treatment during the second time period when data is no longer collected from the first sensor.

32. (previously presented) The method of claim 33, wherein the PAP or CPAP device is adjusted or titrated by utilizing more robust data collection by relating the data from the first sensor to the second sensor for improved treatment during the second time period when data is no longer collected from the first sensor.

33. (previously presented) The method of claim 27, wherein the data acquisition system comprises an additional third sensor having a signal, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second integrated sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

34. (previously presented) The method of claim 33, wherein the data acquisition system comprises an additional fourth sensor for determining body position of the subject.

35. (currently amended) A method of treating a sleep-related breathing disorder comprising steps of:

providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a ~~first~~ flow or pressure sensor during a time period, the ~~first~~ flow or pressure sensor which is integrated into the PAP or CPAP device;

transmitting the data or information based on the data from the ~~first~~ flow or pressure sensor to a cellular phone via a radio frequency wireless link;

outputting apnea events calculated by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the ~~first~~ flow or pressure sensor on a display of the cellular phone for the subject to better understand the efficacy of the therapy; and

retransmitting the data or information based on the data as well as the calculated apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or an Internet for review by a clinician, technician or physician.

36. (currently amended) The method of claim 35, wherein the cellular phone and the PAP or CPAP device each have a Bluetooth wireless RF connection and can communicate directly with each other through the wireless connection in real time.

37. (currently amended) The method of claim 35, wherein the therapy can be modified based in part on the wirelessly retransmitted data or information.

38. (currently amended) The method of claim 35, wherein the steps of the method can be used train the PAP or CPAP to adjust or titrate ~~the PAP or CPAP device~~itself to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

39. (currently amended) The method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician.

40. (currently amended) The method of claim 35, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician.

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/641,715	Filing Date 07/05/2017	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $80 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $420 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	11/17/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ANGELONA D JONES/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 04/12/2021

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

EXAMINER	
STANDARD, MATTHEW	

ART UNIT	PAPER NUMBER
3785	

MAIL DATE	DELIVERY MODE
04/12/2021	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. 15/641,715	Applicant(s) Kayyali et al.	
	Examiner MATTHEW STANDARD	Art Unit 3785	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 11/17/2020.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 21-40 is/are pending in the application.

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

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 21-40 is/are rejected.

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

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Response to Amendment

2. This office action is in response to the amendment filed 11/17/2020. Claims 35-40 have been amended. No new claims have been added. Claims 1-20 have been cancelled. Therefore, claims 21-40 are presently pending in this application.

Response to Amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Specification

4. The disclosure is objected to because of the following informalities:

- Claim 32 depends from subsequent claim 33 which is not permitted (see MPEP 608.01(n)).
- Claim 35, line 15 recites "**an Internet**" which should read --the Internet--

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

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

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claim 35** is rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. In regard to **Claim 35**, lines 9-10 recite the limitation "**outputting apnea events calculated by … the cellular phone**". Page 30, lines 9-8 of applicant's originally filed specification discloses sensor signals may be analyzed by a processor in a cell phone in order to 'determine' apneas, although doesn't use the word "calculate". Page 38, lines 11-23 discloses said processing including receiving sensor inputs and predicting apnea events. The word "calculated" would embrace a mathematical calculation performed by the phone which does have support in the originally filed specification. Examiner recommends claim language which more closely matches language found in the original specification.

8. **Claims 36-40** are rejected due to depending on the rejected claim 35.

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

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

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

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

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

11. In regard to **Claim 35**, lines 13-14 recite "**retransmitting the data or information based on the data as well as the calculated apnea events**". However, "**apnea events calculated by either the PAP or CPAP device, or the cellular phone**" (lines 9-10) are not claimed to have been first transmitted in order for them to be retransmitted such as the **"data or informationed based on the data**" in lines 7-8. Therefore, it is unclear whether the calculated apnea events are transmitted at some point during the method in order for them to be retransmitted or if they are transmitted along with the retransmission of the data. This limitation will be interpreted as the apnea events being transmitted along with the retransmission of the data or information based on the data. Examiner recommends support be cited for the amendment to this limitation. Therefore, because the apnea events are recited as being "retransmitted" but never as "transmitted" in the first place, the bounds of the claims are unclear (e.g. does the method step of transmission need to occur in order for retransmission to occur after).

12. In regard to **Claim 35**, lines 9-12 recites the limitation "**outputting apnea events …on a display of the cellular phone for the subject to better understand the efficacy of the therapy**". It is not clear how exactly this method step is modifying the method. It is not clear to what degree a subject should understand the efficacy of the treatment when the events are output for the subject to "better understand". Thus, the metes and bounds of the claim are unclear and the claim is indefinite.

13. In regard to **Claim 36**, a limitation contains the trademark/tradename "**Bluetooth**". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe wireless connection and, accordingly, the identification/description is indefinite.

14. **Claim 38** recites the limitation "**the second time**" in line 4. There is insufficient antecedent basis for this limitation in the claim.

15. **Claims 36-40** are rejected due to depending on the rejected claim 35.

Claim Rejections - 35 USC § 103

16. 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 negatived by the manner in which the invention was made.

17. **Claims 35 and 37** are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Rapoport (US Patent 6299581) in view of Cooper (US PG Pub 20050222502), and further in view of Geva (US PG Pub 20040073098).

18. In regard to **Claim 35**, Rapoport discloses a method comprising **providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device** (Fig. 9, CPAP device including patient interface 20 conduit 21, flow generator 22 and signal processor 24) **while data is being collected from a flow or pressure sensor during a time period** (Col. 16, lines 12-29 discloses the device collects and stores data, including flow and pressure data, while the patient sleeps and receives CPAP treatment. Fig. 9 shows flow sensor 23), **the flow or pressure sensor which is integrated into the PAP or CPAP device** (Fig. 9 depicts flow sensor 23 which is integrated into the system. This is interpreted as being "integrated" into the CPAP as it appears similarly arranged with the conduit 21 as the arrangement of applicant's Fig. 8 depicting the placement of sensor 414 in line with conduit 416) and also discloses **apnea events calculated by either the PAP or CPAP device** (Col. 13, lines 19-24 discloses analyzing flow data outputted to a processor of the CPAP device and Col. 11, lines 38-46 discloses detecting apneas in the recorded data for altering treatment).

19. Rapoport does not specifically discloses **transmitting the data or information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link, outputting apnea events calculated by either the PAP or CPAP device or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone and retransmitting the data or information based on the data as well as the calculated apnea events to a remote station for review by a clinician, technician or physician**

20. However, Cooper teaches **transmitting the data or information based on the data to a cellular phone** (Paragraph [0121] discloses storing and optional processing data with a mobile

phone) **via a radio frequency wireless link** (Paragraph [0129] processing system, which may be a mobile phone, may have a wireless communication, which in the case of mobile phones are radio frequencies) and **outputting apnea events calculated by either the PAP or CPAP device or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone** (Paragraph [0130] discloses outputting data related to apnea events to a display of the processing system 10, which again is a mobile phone a disclosed in Paragraph [0121]. Supplying data for display will provide a better understanding towards the efficacy of the therapy when compared to displaying no data. Thus, this limitation is being interpreted as an inherent quality of a display outputting data. If this is not intended to be construed as inherent, but lacks literal support in applicant's specification then a 112(a) issue may arise).

21. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rapoport which discloses calculating apnea events to include the method steps of transmitting data to a cellular phone for processing and displaying of data on the cellular phone as taught by Cooper. One would be motivated to do this to allow the data to be suitably displayed for review on a mobile device screen.

22. Rapaport as modified by Cooper does not disclose **retransmitting the data or information based on the data as well as the calculated apnea events to a remote station via a cellular system or an Internet for review by a clinician, technician or physician**

23. However, Geva teaches a system for biomedical signal analysis (Paragraph [0002] discloses this includes respiratory signals) wherein transmitting **the data or information based on the data as well as the calculated apnea events** (Paragraph [0025] discloses transmitting

both segments of the raw data and parameters derived, interpreted as calculated, from raw data indicating physiological irregularities) **to a remote station via a cellular system or an Internet for review by a clinician, technician or physician** (Paragraph [0023] discloses transmitting events over a cellular network. Paragraph [0294] discloses data is displayed on a clinician's cell phone for review).

24. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rapaport (Col. 16, lines 30-35 discloses step 164) to include the method step of retransmitting the data and transmitting the calculated apnea events wirelessly via a cellular system as taught by Geva in order to save the patient from excess traveling and to quickly provide a clinician with the patient's data.

25. In regard to **Claim 37**, Rapoport as modified by Cooper and Geva discloses the method of claim 35, **wherein the therapy can be modified based in part on the retransmitted data or information** (Rapoport; Col. 16 lines 47-56 discloses "At step 170, a decision is made whether the analysis determines that there are still a significant number of sleep-disordered breathing episodes during the night…If the therapy device did not restore normal breathing, then the patient is referred to a sleep lab for more comprehensive study).

26. **Claim 36** is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Rapoport (US Patent 6299581) in view of Cooper (US PG Pub 20050222502) and Geva (US PG Pub 20040073098), as applied to claim 35, in further view of Brand (US PG Pub 20030183226)

27. In regard to **Claim 36**, the modified method of Rapoport teaches **wherein the cellular phone and the PAP or CPAP device each have a wireless RF connection and can communicate directly with each other through the wireless connection in real time** (Cooper; Paragraph

[0121] describes that the processing device may be a mobile phone and both devices must have RF connections in order to establish that communication).

28. Rapoport as modified by Cooper and Reva does not disclose the wireless RF connection is specifically **Bluetooth.**

29. However, Brand teaches a medical device paired to a phone via **Bluetooth** (Paragraph [0079]).

30. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method step of transmitting via RF frequency as disclosed by Rapaport as modified by Cooper and Reva with the method step of using specifically Bluetooth as Brand teaches Bluetooth is a known RF frequency communication means of a phone known to be used in conjunction with medical devices (Brand – Paragraph [0079]).

31. **Claim 38** rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Rapoport (US Patent 6299581) in view of Cooper (US PG Pub 20050222502) and Geva (US PG Pub 20040073098), as applied to claim 35, in view of Behbehani (US Patent 5953713)

32. In regard to **Claim 38**, Rapoport as modified by Cooper and Geva discloses the method of claim 35, but does not disclose **wherein the steps of the method can be used to train the PAP or CPAP to adjust or titrate the itself to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.**

33. However, Behbehani teaches a PAP system (Col. 3, lines 20-21) employing a neural network (Col. 3, lines 40-47) **used to train the PAP or CPAP to adjust or titrate the itself** (Col. 2, lines 30-39 discloses training via a neural network to identify sleep disorder breathing and in

response adjusting pressure) **to better identify and distinguish between obstructive, central and complex sleep apneas** (Col. 1, lines 32-39 discloses obstructive, central and mixed apneas) **during the second time period when data is no longer collected from the first sensor** (Col. 3, lines 31-47 discloses training data from a pressure transducer that is not useful to the PAP device, i.e. in use while sleeping, but rather during some other time when training the network with banked data)**.**

34. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rapoport as modified by Cooper and Geva with the method step of applying a neural network to sleep data taught by Behbehani in order improve detection of apneic events (Behbehani; Col. 2, lines 26-29).

35. **Claims 39 and 40** is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Rapoport (US Patent 6299581) in view of Cooper (US PG Pub 20050222502) and Geva (US PG Pub 20040073098), as applied to claim 35, in further view of Burton (US Patent 6349724)

36. In regard to **Claim 39**, Rapoport as modified by Cooper and Geva discloses the method of claim 35, but does not disclose **wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician**.

37. However, Burton discloses a CPAP device (Col. 2, lines 31-34) **wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician** (Col. 7, lines 18-28 discloses altering therapy parameters at a remote location via wireless phone systems).

38. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rapoport as modified by Cooper and Geva with

the method step of remotely adjusting therapy as taught by Burton in order to allow health care workers to take immediate action towards a patient's condition even if they are in another room or building (Burton Col. 1, lines 65-67 disclose the desire for immediate action and Col. 2, lines 13-15 disclose remote telemetry).

39. In regard to **Claim 40**, Rapoport as modified by Cooper and Geva discloses the method of claim 35, but does not disclose **wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician**.

40. However, Burton discloses a CPAP device (Col. 2, lines 31-34) **wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician** (Col. 2, lines 13-15 & Col. 7, lines 18-28 discloses altering therapy parameters at a remote location via wireless phone systems. "Health care workers" is interpreted as clinicians or physicians).

41. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rapoport as modified by Cooper and Geva with the method step of remotely adjusting therapy in real-time as taught by Burton in order to allow health care workers to take immediate action towards a patient's condition even if they are in another room or building (Burton Col. 1, lines 65-67 disclose the desire for immediate action and Col. 2, lines 13-15 disclose remote telemetry).

Double Patenting

42. **Claims 21-34** are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 9730632 (hereinafter referred to as '632). Although the claims at issue are not identical, they are not patentably distinct from each other

because the claims of the current application would be anticipated by or obvious in view of the claims of '632.

43. The nonstatutory double patenting rejections is maintained as laid out in the previous office action mailed 08/17/2020.

Allowable Subject Matter

44. **Claims 21-34** would be allowable provided that the current double patenting rejection were overcome, such as by the filing of a timely terminal disclaimer.

45. The statement of reasons for the indication of allowable subject matter can be found in the previous office action mailed 08/17/2020.

Response to Arguments

46. Applicant's remarks, filed 11/17/2020, state that a terminal disclaimer will be filed to overcome the non-statutory double patenting rejections to claims 21-34 once all claims have been resolved. The rejection is maintained until a terminal disclaimer is filed.

47. Applicant's arguments, see "Remarks", filed 11/17/2020, with respect to the rejections of claims 35-40 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of newly applied references in light of the amendments to the claims.

Conclusion

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

- Weber (US PG Pub 20130331726) discloses system for tracking compliance for sleep apnea.

- Tsukashima (US Patent 7101341) discloses respiratory monitoring.

49. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW STANDARD whose telephone number is (571)270-1501. The examiner can normally be reached on 9:00 - 5:00 M-F.

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, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/MATTHEW STANDARD/
Examiner, Art Unit 3785

/SAMCHUAN C YAO/
Supervisory Patent Examiner, Art Unit 3785

Notice of References Cited	Application/Control No. 15/641,715	Applicant(s)/Patent Under Reexamination Kayyali et al.	
	Examiner MATTHEW STANDARD	Art Unit 3785	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20040073098-A1	04-2004	Geva, Amir	A61B5/24	600/300
*	B	US-6349724-B1	02-2002	Burton; David	F04D25/166	128/204.18
*	C	US-5953713-A	09-1999	Behbehani; Khosrow	A61M16/026	706/16
*	D	US-20030183226-A1	10-2003	Brand, Peter John	A61M16/161	128/200.23
*	E	US-20130331726-A1	12-2013	Weber; Claude	A61M16/06	600/538
*	F	US-7101341-B2	09-2006	Tsukashima; Ross	A61B5/083	422/84
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	MATTHEW STANDARD	3785

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61M 16/00; 16/0003	08/14/2020	Charles Vivian
A61B 5/4818; 5/4836	08/14/2020	Charles Vivian
A61M 16/00; 16/0003	03/24/2021	MS
A61B 5/4818; 5/4836	03/24/2021	MS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
128	204.23	08/14/2020	Charles Vivian

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

Search Notes		
Search Notes	**Date**	**Examiner**
Inventor Name Search	08/14/2020	Charles Vivian
Keyword search terms: cell, cellular, mobile, phone, telephone, smartphone	08/14/2020	Charles Vivian
Updated Inventor and Applicant search	03/17/2021	MS
See EAST search history	03/24/2021	MS

/MATTHEW STANDARD/ Examiner, Art Unit 3785	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	MATTHEW STANDARD	3785

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MATTHEW STANDARD/ Examiner, Art Unit 3785	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	MATTHEW STANDARD	3785

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

CLAIMS

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

CLAIM		DATE								
Final	Original	08/14/2020	03/25/2021							
	1	-	-							
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	36	✓	✓							
	37	✓	✓							
	38	✓	✓							
	39	✓	✓							
	40	✓	✓							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	3	("6299581" "20050222502" "20050115561").pn.	US-PGPUB; USPAT; USOCR	OR	ON	2021/03/17 16:48
S2	36	((("KAYYALI") near3 ("Hani")) OR (("BISHOP") near3 ("Dan")) OR (("KOLKOWSKI") near3 ("Brian"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2021/03/17 17:18
S4	98	((("Cleveland") near3 ("Medical") near3 ("Device"))).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/17 17:20
S5	37,121	(A61M16/00 A61M16/0003 A61B5/4818 A61B5/4836).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 13:27
S6	6	S5 and ((flow with (data information)) same (Bluetooth) same (clinician doctor physician technician))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 13:29
S8	1	(A61M16/$).cpc. and ((flow with (data information)) same (radio) same (clinician doctor physician technician))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 13:33
S9	40	(A61M16/$).cpc. and ((flow with (data information)) same (wireless Internet) same (clinician doctor physician technician))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 13:34
S10	6	"7101341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 13:36
S11	886	(A61M16/$).cpc. and ((data information) same (wireless$2 transmit transmission transmitting send$3) same (smartphone phone cellular))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 13:54

S12	1,013	(A61M16/$).cpc. and ((data information) same (wireless$2 transmit transmission transmitting send$3 transfer$3 communicat$3) same (smartphone phone cellular))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 13:54
S13	228	(A61M16/$).cpc. and ((data information) same (bluetooth (blue adj tooth) blue-tooth) same (smartphone phone cellphone))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 14:08
S14	405	(A61M16/$).cpc. and ((data information) same (display) same (smartphone phone cellphone))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 14:52
S15	185	(A61M16/$).cpc. and ((data information) same ((display) with (smartphone phone cellphone)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 14:53
S16	148	(A61B5/4818).cpc. and ((data information) same ((display output) with (smartphone phone cellphone)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 15:21
S17	651	(A61M16/$ A61B5/4818 A61B5/4836).cpc. and ((data information findings) same ((display output report review) with (smartphone phone cellphone)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 15:28
S18	1	"6349724".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2021/03/24 16:25
S19	405	S5 and (automatic$4 with (detect$3 determination determin$3 diagnos$3) with apnea)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 16:45
S20	1,561	(A61M16/$ A61B5/4818 A61B5/4836).cpc. and (neural near3 network)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2021/03/24 16:54

EAST Search History (Interference)

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3/25/2021 11:25:41 AM
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	15/641,715	Art Unit:	3735
Filed:	July 5, 2017	Docket No.:	CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method		
Examiner:	Matthew Standard		

July 12, 2021

AMENDMENT AFTER FINAL

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This amendment is being filed in the above captioned application in response to a final Office Action dated April 12, 2021. The Applicants believe that no extension of time is necessary, however, if one is due the Applicants herein petition for the extension of time and authorize any fees to be deducted from their deposit account. The Applicants herein file a Notice of Appeal with respect to Claims 35-40, and use their credit card to pay for Appeal fees due. The Applicants believe that no fees are due in conjunction herewith, but if any fees are found to be owed, the Applicants authorize the Director to withdraw the funds from their deposit account: 502704. The following amendments are respectfully submitted.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/641,715	Filing Date 07/05/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/12/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	OPAC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/BRIDGET C. MONROE/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	15641715
Filing Date	05-Jul-2017
First Named Inventor	Hani Kayyali
Attorney Docket Number	CMD-101
Title of Invention	Integrated Sleep Diagnostic and Therapeutic System and Method

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Cleveland Medical Devices Inc.	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

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as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○	I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

◉ Small Entity

○ Micro Entity

○ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 36847

○ A sole inventor

○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

○ A joint inventor; all of whom are signing this request

Signature	/Brian Kolkowski/
Name	Brian Kolkowski

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	15641715
Filing Date:	05-Jul-2017
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 15641715

Filing Date: 05-Jul-2017

Applicant/Patent under Reexamination: Kayyali

Electronic Terminal Disclaimer filed on July 12, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	43218534
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	12-JUL-2021
Filing Date:	05-JUL-2017
Time Stamp:	10:10:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$170
RAM confirmation Number	E20217BA10482977
Deposit Account	502704
Authorized User	Mark Pennington

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33404 2d157dad6cfe1cce213c5ec8893b04198b00de65	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30490 4e65d05c510de1ac6e49478db9aa57d1b943b78e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	63894		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	15/641,715	Art Unit:	3735
Filed:	July 5, 2017	Docket No.:	CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method		
Examiner:	Matthew Standard		

July 12, 2021

AMENDMENT AFTER FINAL

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This amendment is being filed in the above captioned application in response to a final Office Action dated April 12, 2021. The Applicants believe that no extension of time is necessary, however, if one is due the Applicants herein petition for the extension of time and authorize any fees to be deducted from their deposit account. The Applicants herein file a Notice of Appeal with respect to Claims 35-40, and use their credit card to pay for Appeal fees due. The Applicants believe that no fees are due in conjunction herewith, but if any fees are found to be owed, the Applicants authorize the Director to withdraw the funds from their deposit account: 502704. The following amendments are respectfully submitted.

IN THE CLAIMS:

Please amend claims 32, 35, 36 and 38 as follows:

1. (cancelled)
2. (cancelled)
3. (cancelled)
4. (cancelled)
5. (cancelled)
6. (cancelled)
7. (cancelled)
8. (cancelled)
9. (cancelled)
10. (cancelled)
11. (cancelled)
12. (cancelled)
13. (cancelled)
14. (cancelled)
15. (cancelled)
16. (cancelled)
17. (cancelled)
18. (cancelled)
19. (cancelled)
20. (cancelled)

21. (previously presented) A method of treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject; and

adjusting or titrating the therapy to the subject using at least part of the data from both the first and second sensor signals to improve therapy to the subject during a second time period after the first time period when data is no longer collected.

22. (previously presented) The method of claim 21, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and the data from the second integrated sensor is transmitted wirelessly directly from the PAP or CPAP device to the data acquisition box in real time.

23. (previously presented) The method of claim 21, with the further step wherein the data from the first and second sensors is at least in part transmitted from the data acquisition system by cellular service to a remote data storage station for review remotely by medical personnel, and the medical personnel provides a command signal transmitted by cellular service for titrating or adjusting the PAP or CPAP device automatically if necessary to adjust the flow or by communicating with an individual near the subject or

with the subject to adjust the PAP or CPAP device.

24. (previously presented) The method of claim 21, wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

25. (previously presented) The method of claim 21, wherein the data acquisition system comprises the first and an additional third sensors having signals, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

26. (previously presented) The method of claim 21, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals that are specific to the subject being treated for improved treatment during the second time period when data is no longer collected from the first sensor.

27. (previously presented) A method of determining the effectiveness of the therapy used in treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

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connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject;

determining an effectiveness of the therapy delivered by the separate PAP or CPAP device using at least part of the data from both the first and second sensor signals.

28. (previously presented) The method of claim 27, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and can communicate directly with each other through the wireless connection in real-time.

29. (previously presented) The method of claim 27, wherein the data from the first and second sensors is in part transmitted from both devices in real-time.

30. (previously presented) The method of claim 27, wherein the steps of the method can be used to adjust and titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas after the time period when data is no longer collected from the first sensor.

31. (previously presented) The method of claim 27, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals from the data acquisition system that are specific to the subject being treated for improved

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treatment during the second time period when data is no longer collected from the first sensor.

32. (currently amended) The method of claim ~~33~~27, wherein the PAP or CPAP device is adjusted or titrated by utilizing more robust data collection by relating the data from the first sensor to the second sensor for improved treatment during the second time period when data is no longer collected from the first sensor.

33. (previously presented) The method of claim 27, wherein the data acquisition system comprises an additional third sensor having a signal, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second integrated sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

34. (previously presented) The method of claim 33, wherein the data acquisition system comprises an additional fourth sensor for determining body position of the subject.

35. (currently amended) A method of treating a sleep-related breathing disorder comprising steps of:

providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a ~~first~~ flow or pressure sensor during a time period, the flow or pressure sensor which is integrated into the PAP or CPAP device;

transmitting the data, or information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link;

outputting apnea events ~~calculated~~determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to ~~better understand~~see the efficacy of the therapy; and

retransmitting the data or information based on the data as well as ~~the calculated~~transmitting or retransmitting the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or ~~an~~the Internet for review by a clinician, technician or physician.

36. (currently amended) The method of claim 35, wherein the cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time.

37. (previously presented) The method of claim 35, wherein the therapy can be modified based in part on the wirelessly retransmitted data or information.

38. (currently amended) The method of claim 35, wherein the steps of the method can be used train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during ~~the~~a second time period when data is no longer collected from the first sensor.

39. (previously presented) The method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician.

40. (previously presented) The method of claim 35, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician.

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REMARKS

In this case claims 21-40 are pending and 21-40 are rejected. Claims 32, 35, 36 and 38 have been amended. The Applicants respectfully traverse the rejections below.

Non-Statutory Double Patenting

Claims 21-34 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 and 14 of U.S. Pat. No. 9,730,632. The Applicants submit they have filed a terminal disclaimer to overcome this rejection. This rejection is now moot. The Applicants ask the Examiner to withdraw this rejection.

Specification

Claim 32 was objected to for depending on Claim 33. The Applicants corrected this mistake and Claim 32 now depends on Claim 27.

Claim 35 was objected to for the term "an Internet". The Applicants have now amended the claim to read "the Internet".

This objection is now moot and the Applicants ask the Examiner to withdraw this rejection.

Claim Rejections – 35 U.S.C. § 112

Claim 35 was rejected under 35 USC 112(a) or 35 USC 112(pre-AIA), first paragraph, as failing to comply with the written description requirement.

The Examiner objects to the term "calculate" and instead suggests the term "determine". The Applicants thank the Examiner for his helpful suggestion and submit this rejection is now moot, and asks the Examiner to withdraw this rejection.

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

The Examiner objects to the use of the term "retransmitting the data or information based on the data as well as the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician."

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The Applicants submit that this language is clear, but have suggested an amendment that might make this language clearer.

The Examiner further objects to the limitation "outputting apnea events determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to better understand the efficacy of the therapy". The Examiner object's to the term "better understand" as to the metes and bounds. The Applicants have changed the term to "see". The Applicants believe one skilled in the art would understand that by outputting the number of apnea events while undergoing therapy mean to eliminate such events to a subject's phone after therapy would alert the subject and better help them understand the efficacy of their last night's therapy.

The Examiner objects to the use of the term Bluetooth as it is a trademark in Claim 36. The Applicants would point out that Bluetooth is also understood to be a standard and have amended the claim to make this clear.

The Examiner objects to the antecedent basis for the term "the second time period" in Claim 38. This has been amended to read "a second time period".

The Applicants submit that their clarifying amendments overcome the 112 rejections, and request for withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 103

To provide legal context as well as an analytical framework for the remarks that follow, the Applicant wishes at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an assertion of *prima facie* obviousness the examiner must perform the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences

between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that "secondary considerations" such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, "the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis." MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the examiner errs in performing any of the *Graham* factual inquiries, the examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the examiner committing error in performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

With specific regard to the examiner's obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Applicant would direct particular attention to the requirement that "[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill." *See* MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the examiner's burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an "indication of the level of ordinary skill," *MPEP 2141(II)(C)*, the examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the examiner in such a way as to render the claimed invention obvious. *See In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and examiner for failing to provide "any evidentiary support or

reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant" and further noting that *KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* "did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references").

Thus, in order for the examiner to properly establish a *prima facie* case of obviousness the examiner must first make the factual inquiries required by *Graham* and, if relying on a combination of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the examiner falls short in meeting any of these requirements then the examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. *See In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) ("If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent"). As stated in the United States Patent and Trademark Office's own rules, "[a] prima facie case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard..." *See* 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor" (emphasis added).

In all of the above, the Applicants wish to emphasize the high bar to which the examiner is held during the examination process and hereby respectfully request that in the ongoing prosecution of the present application that the examiner provide explicit and detailed analysis of any grounds of rejection relied upon. *See, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* ("[an obviousness] analysis should be made explicit," citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

Claims 35 and 37 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rappaport et al ("Rappaport") in view of

U.S. Pat. Pub. No. 2005/0222502 to Cooper ("Cooper"), and further in view of U.S. Pat. Pub. No. 2004/0073098 to Geva ("Geva") . The Applicants traverse and submit the claims as now amended overcome this rejection.

More specifically, with respect to Claim 35, Rappaport, Cooper or Geva alone or together do not teach nor disclose a method of treating a sleep-related breathing disorder comprising steps of providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a flow or pressure sensor during a time period, the flow or pressure sensor which is integrated into the PAP or CPAP device; transmitting the data or information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link; outputting apnea events determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to see an efficacy of the therapy; and retransmitting the data or information based on the data as well as transmitting or retransmitting the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician as claimed.

The self-adjusting or autotitrating device in Rappaport, an example is shown in FIG. 18 and an example of the algorithm used by the device in FIG. 17, is then used to collect data as to determine how to alleviate apneas. The PAP device 86 has a flow sensor 72 and a pressure sensor 90. The data collected with these sensors is run through various electronics 76, 78, 80 on the PAP device and through an algorithm as shown in FIG. 17 through which the patient is tested at various flow pressures to determine whether the patients apnea(s) are alleviated. This data is then stored in memory 81. FIG. 22 shows the patient then returns the auto-PAP with the stored data 164. The stored data is then analyzed 166 to determine the proper set pressure for the patient 168. In Rappaport "[the] patient sleeps at home with the therapy device for the required number of nights…[and] returns the therapy device or its storage module for analysis of the stored data." This data (and this data alone) from the self-adjusting device is then used to adjust the PAP or CPAP device. The data from Rappaport is not shared with the patient let alone sent to the patients cellular phone.

Rappaport does not teach or disclose determining apnea events rather the PAP in Rappaport indicates whether apnea(s) are alleviated at various pressures. Rappaport collects flow and pressure data 162 at these various pressures. Further, the apparatus in Rappaport needs to be returned by the patient to the remote location for the data to be downloaded and analyzed 164. The data is then analyzed at the remote location to determine the amount of flow limiting and apnea present 166. The present invention instead analyzes the number of apnea events either with the PAP or cellular phone from the flow or pressure sensor data onsite. This data is then forwarded to the remote location either by the cellular phone or the PAP, and the number of apnea events are displayed for the subject to better understand the efficacy of their treatment.

Cooper monitors various respiratory events by deriving these events from the signal on a pulse oximeter – not a pressure or flow sensor within a therapy device. In fact Cooper does not monitor flow or pressure on a therapy device such as a PAP or any therapy device for that matter. The apparatus in Cooper uses the cellular phone for data collection for diagnostics not to display information about efficacy of therapy to the patient carrying the cellular phone. Any apnea events in Cooper are derived from the pulse oximeter signal not from a flow or pressure sensor. The specific embodiment of the apparatus in Cooper for patient monitoring that the Examiner refers to is where the sensor is a photodiode, likely a pulse oximeter, where data is collected and "blood flow cycling with hypopnea and voltage transition characteristic of arousal peaks in the blood volume signal" are Examiner. This calculation can be performed either remotely or via a mobile phone processor. Clearly these calculations are not based on flow or pressure data. Further, the respiratory parameters are not used for the patient to better understand the efficacy of a PAP or CPAP treatment. The respiratory events in Cooper are calculated and displayed after the data is transferred to a remote system for analysis so whomever is monitoring the system in Cooper can review it on a built in LCD screen or so an alarm is set off to warn those monitoring the patient. The respiratory events are not displayed on the cellular phone as alleged by the Examiner. The data in Cooper is further transferred to the remote system either wirelessly or by the removal and physical transfer of memory. There is no indication this is accomplished via the Internet or a cellular system.

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Geva, FIG. 30, on which para. 0294 (referenced by the Examiner) is based teaches an electrode system whereby the electrode (EKG) data is uploaded to a first cellular phone where the data may be pre-processed by software on the cellular phone, the data is then transferred to a remote server where it is fully processed and then afterwards send to a physicians cellular phone for review by a physician.

The present invention on the other hand collects pressure or flow data from a PAP device which is used to determine the efficacy of the therapy by looking at the apnea event that occur in the presence of the therapy. These apnea events can be determined either at the PAP or by the cellular phone, these along with other data from the therapy are then sent on to a remote station for review by a clinician, technician or physician. These apnea events are also displayed for the subject to see the efficacy of their therapy. The data and the apnea events can use the cellular phone to retransmit the information to the remote station or the PAP can transmit the information to a cellular phone and then send it a second time or retransmit the information to the remote station as well. The present invention allows not only the patient but their clinicians to be aware of the efficacy of the patient's therapy as presently configured, and to adjust or titrate the therapy efficiently and remotely. The present invention allows for RF transmission of flow or pressure data from the patient's therapy device to software on their cellular phone, for retransmission, determination and/or display on or by the cellular phone. The determination or calculation of these apnea events are performed on either the PAP device or the patient's cellular phone.

Nowhere in any of the references do they teach or disclose using flow or pressure sensors on a patient's PAP device for tracking the efficacy of the therapy and sharing that information with the patient on their cellular phone while at the same time sharing that information with the patient's clinician so the therapy can be adjusted if necessary, and doing so wirelessly, in real-time, through the Internet and/or cellular systems.

This Application was initially filed in 2005, and a CIP was filed in 2007. There was nothing like this using cellular phones, PAP therapy, cellular systems and the Internet at that time so it is clear the Examiner is using a hindsight approach with the Applicants claims as a roadmap and is not viewing the claims as a whole.

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With respect to the method of claim 37, Rappaport, Cooper nor Geva teach or disclose wherein the therapy can be modified based in part on the wirelessly retransmitted data or information as claimed. The Examiner relies on Rappaport for this teaching. The Examiner cites to the teaching on Col. 16, lines 47-56 of Rappaport which indicates that if the analysis determines that there are still a significant number of sleep-disordered breathing episodes during the night and the therapy devices does not restore normal breathing, then the patient is referred to a sleep lab for a more comprehensive study, step 160. One skilled in the art would understand this does not teach modifying therapy based on wirelessly transmitted information as set forth in claim 35.

In an attempt to explain the purported combination of these references, the Examiner merely makes a unsupported conclusory observations. The Applicants, however, remind the Examiner that these observations must be supported.

The Examiner states "Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the method of Rappaport to include "transmitting the data or information based on the data from the first sensor to a cellular phone; outputting the apnea events calculated using data from the first sensor on a display of the cellular phone as taught by Cooper." There is no rational basis for this argument. First and foremost since Cooper does not output the calculated data on a cellular phone available to the patient. Second, because obviously this is a hindsight analysis by the Examiner. The Examiner then states it would be obvious to combine Geva with Rappaport "to include the method step of retransmitting the data and transmitting the calculated apnea events wirelessly via a cellular system as taught by Geva in order to save the patient from excess travel and to quickly provide the physician with the patient's data." There is no rational basis for this argument as well. First, Geva does not retransmit the calculated apnea events from either the patient's cell phone or their therapy device as the present invention does. Instead Geva does the complete analysis of the subject's electrode data (diagnostic) at the remote station. Again this is clearly hindsight analysis where the Examiner is using the Applicants claims as a roadmap for his rejection. Clearly, the present invention displays the apnea events so the subject can understand the efficacy of their therapy and either forwards the data or transmits it from the PAP to a remote location so the subject's therapy provide can

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review the data and provide for therapy adjustment if necessary. Furthermore with the present invention this can all be done remotely without the need for the patient to return the PAP device for the data analysis and calculation.

Further, the Examiner has so far failed to explicitly define or establish the level of ordinary skill in the art, and none of the references adequately provides the level implicitly. As before, numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Rappaport, Geva and Cooper references? What are the similarities between the claimed invention and Rappaport, Geva and Cooper? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relies upon a conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to support his analysis of the Graham factors, but has failed to do so. The Applicants therefore respectfully request the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary skill in the art or to the Examiner's conclusions. The Applicants further suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and request that the Examiner therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which the rejection is based. *See* 37 C.F.R. § 1.104(d) (2).

The Applicants further respectfully submit that the Examiner has not given any valid teaching, suggestion, or motivation in or external to the references, or from the references cited as a whole, for the person of ordinary skill to have modified the reference of Rapoport to include the teachings of Cooper and Geva. The Applicants respectfully request that the Examiner either support the conclusions of motivation with references or, if such allegation is based on personal knowledge, provide an affidavit as to such including the factual underpinning for such conclusions. *See* 37 C.F.R. § 2144.03. In *re Eynde* states that "[t]he facts constituting the state of the art are normally subject to the

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possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." *In re Eynde*, 480 F.2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973). Similarly, *KSR Int'l Co. v. Teleflex, Inc.* requires that "[obviousness] analysis should be made explicit." *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007). *KSR* goes on to explain that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning." It is often "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15.

Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Claim 36 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rappaport et al ("Rappaport") in view of U.S. Pat. Pub. No. 2005/0222502 to Cooper ("Cooper"), and further in view of U.S. Pat. Pub. No. 2004/0073098 to Geva ("Geva"), as applied to claim 35 , in further view of U.S. Pat. Pub. 2003/0183226 to Brand ("Brand"). The Applicants traverse and submit the claim overcomes this rejection

The Applicants incorporate their above remards with respect to Rappaport, Cooper, and Geva.

With respect to Claim 36, Rappaport, Cooper, Geva nor Brand teach or disclose the method wherein the cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time as claimed. The Examiner cites to Brand for this teaching. However para. 0079 of Brand does not teach a wireless connection in real time as claimed, and Brand does not teach the communication of the type of data and its transmission as with the present invention. In Brand the data that is being transmitted is whether an respiratory inhaler is being used and what types and amounts of dosing is being provided to the patient. In the present invention the volume of data is significantly

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larger making it unlikely the communications system of Brand could be used for data transmission in the present invention.

In an attempt to explain the purported combination of these references, the Examiner merely makes a unsupported conclusory observations. The Applicants, however, remind the Examiner that these observations must be supported.

The Examiner states "Brand teaches Bluetooth standard is a known RF frequency communication means of a phone known to be used in conjunction with medical devices." There is no rational basis for this argument. The question is not whether Bluetooth can be shown to transfer data between medical devices and a cellular phone in real time, but rather whether Bluetooth standard can be used to transfer fairly large volumes of data between a PAP and a cellular phone in real time. If this was an invention for digitizing radiological images, which require very large volumes of data would Brand support this teaching for Bluetooth standard in real time. No. Similarly it does not support this combination of references being used to attack the present invention. Clearly this is a hindsight analysis by the Examiner where the Examiner is using the Applicants claims as a roadmap for his rejection.

Further, the Examiner has so far failed to explicitly define or establish the level of ordinary skill in the art, and none of the references adequately provides the level implicitly. As before, numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Rappaport, Cooper, Geva and Brand references? What are the similarities between the claimed invention and Rappaport, Cooper, Geva and Brand? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relies upon a conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to support his analysis of the Graham factors, but has failed to do so. The Applicants therefore respectfully request the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary

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skill in the art or to the Examiner's conclusions. The Applicants further suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and request that the Examiner therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which the rejection is based. *See* 37 C.F.R. § 1.104(d) (2).

The Applicants further respectfully submit that the Examiner has not given any valid teaching, suggestion, or motivation in or external to the references, or from the references cited as a whole, for the person of ordinary skill to have modified the reference of Rapoport to include the teachings of Cooper, Geva and Brand. The Applicants respectfully request that the Examiner either support the conclusions of motivation with references or, if such allegation is based on personal knowledge, provide an affidavit as to such including the factual underpinning for such conclusions. *See* 37 C.F.R. § 2144.03. In *re Eynde* states that "[t]he facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." *In re Eynde*, 480 F.2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973). Similarly, *KSR Int'l Co. v. Teleflex, Inc.* requires that "[obviousness] analysis should be made explicit." *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007). *KSR* goes on to explain that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning." It is often "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15.

Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Claim 38 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over Rappaport in view of Cooper, and Geva, as applied to claim 35, in view of U.S. Pat. No. 5,953713 to Behbehani ("Behbehani"). The Applicants traverse and submit the claim overcomes this rejection.

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The Applicants incorporate their above remarks with respect to Rappaport, Cooper and Geva. Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Claims 39 and 40 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over Rappaport in view of Cooper, and Geva, as applied to claim 35, in view of U.S. Pat. No. 6,349,724 to Burton ("Burton"). The Applicants traverse and submit the claim overcomes this rejection.

The Applicants incorporate their above remarks with respect to Rappaport, Cooper and Geva. The Examiner relies on Burton for the teachings of the limitations of Claims 39 and 40. Burton, however, does not teach or disclose the method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician as claimed, or wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician as claimed.

Burton uses various sensors for diagnosis or long term studies, or for alerting a health care worker about the patient's condition requiring immediate action. That, however, is not the same as real-time adjustment of a PAP by the technician, clinician or physician in real-time who are viewing the data at a remote location or station.

The Examiner points to a number of teachings in Burton for titrating a patient through a wireless connection. In Col. 2, lines 13-15 of Burton it teaches that data may be sent to a remote site by "telemetry, telephony or by mailing the data card." The Examiner further points to Col. 7, lines 18-28 of Burton which states "[t]he ramp times, ramp delay times and other parameters can be programmed into the controller/microprocessor 82 by means of information stored on a data card 210 inserted into a data card port 115. Alternatively the microprocessor may be programmed by a computer 200…the computer may be remotely located at a hospital or sleep clinic and connected through the internet by wire or wireless phone systems or positioned adjacent the dual pressure gas delivery device."

This however is not the same wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician. Burton teaches of reprogramming the PAP by a number of means but

particularly the "ramp times", and "ramp delay times". These are comfort settings that allow the therapy not to be as intrusive and can allow the therapy to start after the patient falls asleep – not the therapy itself. This is not adjusting or titrating the therapy. This further is being done by a computer and not by a "clinician, technician or physician at a remote location".

Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Conclusion

Given the reasons set forth above, the Applicants request the Examiner withdraw the above rejections. For all the above reasons the Applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

July 12, 2021
Dated

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PTO/AIA/31 (03-14)
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NOTICE OF APPEAL FROM THE EXAMINER TO THE PATENT TRIAL AND APPEAL BOARD

Docket Number (Optional): CMD-101

I hereby certify that this correspondence is being facsimile transmitted to the USPTO, EFS-Web transmitted to the USPTO, or deposited with the United States Postal Service with sufficient postage in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, on Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on July 12, 2021.

Signature: /Mark Pennington/

Typed or printed name: Mark Pennington

In re Application of: Kayyali et al.

Application Number	Filed
15/641,715	7/5/2017

For: Integrated sleep diagnostic and therapeutic system and method

Art Unit	Examiner
3785	Matthew Standard

Applicant hereby **appeals** to the Patent Trial and Appeal Board from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 840

☑ Applicant asserts small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by 50%, and the resulting fee is: $ 420

☐ Applicant certifies micro entity status. See 37 CFR 1.29. Therefore, the fee shown above is reduced by 75%, and the resulting fee is: $ _____
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

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

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

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____.

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☐ A petition for an extension of time under 37 CFR 1.136(a) (PTO/AIA/22 or equivalent) is enclosed.
For extensions of time in reexamination proceedings, see 37 CFR 1.550.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant

☑ attorney or agent of record
Registration number 36847

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

Signature: /Brian Kolkowski/

Typed or printed name: Brian Kolkowski

Telephone Number: (216) 649-0376

Date: 7/12/2021

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 41.20(b)(1) and 41.31. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Patent Application Fee Transmittal

Application Number:	15641715
Filing Date:	05-Jul-2017
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
NOTICE OF APPEAL	2401	1	420	420
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**420**

Electronic Acknowledgement Receipt

EFS ID:	43218892
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	12-JUL-2021
Filing Date:	05-JUL-2017
Time Stamp:	10:37:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$420
RAM confirmation Number	E20217BA37463272
Deposit Account	502704
Authorized User	Mark Pennington

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-101_12Jul2021_amendment.pdf	299928 05c61ae56eb27a4803bce3e31d5c51cfa994762e	yes	21
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Response After Final Action		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	21	
Warnings:					
Information:					
2	Notice of Appeal Filed	CMD-101_12Jul2021_PTAB-appeal-notice.pdf	196733 c571525e7a9aa526796cd2fcc90a4568a46c29b6	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30233 a55b6753213060c3336dd4091be0d8545b2ffffb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	526894		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

In Re:	Application of Kayyali et al.	
Serial No.:	15/641,715	Art Unit: 3785
Filed:	July 5, 2017	Attorney Docket No.: CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method	
Examiner:	Matthey Standard	

September 9, 2021

Mail Stop: PATENT BOARD
Patent Trial and Appeal Board
US Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

This Brief supports the appeal to the Patent Trial and Appeal Board from the Office Action containing a final rejection with mail date April 12, 2021, in the above-captioned application. Appellants filed a timely response along with a Notice of Appeal with fee on July 12, 2021. The Appellants certify that they are entitled to small entity status. The Appellants believe that this Brief is timely and that no fees are presently due, but nonetheless hereby petition for any necessary extension of time and authorize the Board to deduct any other fees due in connection herewith from deposit account number 502704. As of the date of filing this Appeal Brief no advisory action has been received.

I. REAL PARTY IN INTEREST

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

II. RELATED APPEALS AND INTERFERENCES

There are no pending or past appeals known to the Appellants, Assignee, or counsel for the Appellants that may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the present appeal.

III. SUMMARY OF CLAIMED SUBJECT MATTER

Of the claims that are the subject of this appeal, claims 21, 27, and 35 are independent.

Claim 21 is directed to a method of treating a sleep-related breathing **(*see e.g.*, pg. 5, line 30 – pg. 6., line 17)** disorder comprising steps of: attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy **(*see e.g.*, pg. 14, line 15 – pg. 20, line 24)**; concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor **(*see e.g.*, pg. 5, line 2 – pg. 6, line 17; pg. 79, lines 2-5)**; connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor **(*see e.g.*, pg. 20, line 25 – pg. 24, line 15)**; collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep **(*see e.g.*, pg. 15, line 18 – pg. 17, line 162; pg. 20, lines 5-10)**; collecting data from a second sensor during the first time period **(*see e.g.*, pg. 15, line 18 – pg. 17, line 162; pg. 20, lines 5-10)**, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device **(*see e.g.*, pg. 19, lines 3-13; pg. 21, lines 16-17)** and transmitting the data from the second sensor to the data acquisition system **(*see e.g.*, pg. 20, line 25 – pg. 21, line 5; pg. 21, lines 21-22)**, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject **(*see e.g.*, pg. pg. 36, lines 2-5; pg. 37, lines 18-21)**; and adjusting or titrating the therapy to the subject using at least part of the data from both the first and second sensor signals to improve therapy to the subject during a second time period after the first time

period when data is no longer collected **(*see e.g.*, pg. 37, lines 18-28; pg. 44, line 5 – pg. 47, line 20)**.

Claim 27 is directed to a method of determining the effectiveness of the therapy used in treating a sleep-related breathing disorder **(*see e.g.*, pg. 67, lines 22-27)** comprising steps of: attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy **(*see e.g.*, pg. 14, line 15 – pg. 20, line 24)**; concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor **(*see e.g.*, pg. 5, line 2 – pg. 6, line 17; pg. 79, lines 2-5)**; connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor **(*see e.g.*, pg. 20, line 25 – pg. 24, line 15)**; collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep **(*see e.g.*, pg. 15, line 18 – pg. 17, line 162; pg. 20, lines 5-10)**; collecting data from a second sensor during the first time period **(*see e.g.*, pg. 15, line 18 – pg. 17, line 162; pg. 20, lines 5-10)**, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device **(*see e.g.*, pg. 19, lines 3-13; pg. 21, lines 16-17)** and transmitting the data from the second sensor to the data acquisition system **(*see e.g.*, pg. 20, line 25 – pg. 21, line 5; pg. 21, lines 21-22)**, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject **(*see e.g.*, pg. pg. 36, lines 2-5; pg. 37, lines 18-21)**; determining an effectiveness of the therapy delivered by the separate PAP or CPAP device using at least part of the data from both the first and second sensor signals **(*see e.g.*, pg. 67, lines 22-27)**.

Claim 35 is directed to a method of treating a sleep-related breathing disorder **(*see e.g.*, pg. 5, line 30 – pg. 6., line 17)** comprising steps of: providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a flow or pressure sensor during a time period **(*see e.g.*, pg. 5, line 2 – pg. 6, line 17; pg. 79, lines 2-5)**, the flow or pressure sensor which is integrated into the PAP or CPAP device **(*see e.g.*, pg. 19, lines 3-13; pg. 21, lines 16-17)**; transmitting the data, or information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link **(*see e.g.*, pg. 20, line 25 – pg. 21, line 5; pg. 21, lines 21-22; pg. 27, lines 14-27)**; outputting apnea events

determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to see the efficacy of the therapy **(*see e.g.*, pg. 30, line 19 – pg. 31, line 12; pg. 39, lines 9-29; pg. 32, lines 18-26; pg. 47, lines 3-12)**; and retransmitting the data or information based on the data as well as transmitting or retransmitting the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician **(*see e.g.*, pg. 29, lines 8-12; pg. 45, lines 4-8; pg. 45, lines 20-27)**.

IV. ARGUMENT

A. In light of the claim rejections argued herein, the Appellants submit that claims 21, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 38, 39, and 40 are each argued separately each stand and fall separately.

B. Non-Statutory Double Patenting

Claims 21-34 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 and 14 of U.S. Pat. No. 9,730,632. An electronic terminal disclaimer was filed, and accepted, on July 12, 2021. No subsequent disapproval of the disclaimer, or Advisory Action has been received to provide an indication as to the status of the claims and the present rejection. Thus, in light of the electronic Terminal Disclaimer filed, the Appellants respectfully submit that the nonstatutory doubly patenting rejections have been overcome and are thus moot.

C. Specification

Claim 32 was objected to for depending on Claim 33. The Appellants corrected this mistake and amending Claim 32 so that it now depends on Claim 27 in the Amendment After Final Rejection submitted July 12, 2021.

Claim 35 was objected to for the term "an Internet". The Appellants also amended this claim to read "the Internet" in the Amendment After Final Rejection submitted July 12, 2021.

Similar to above, the Appellants note that no Advisory Action or any other indication has been given by the Office as to the status of the amendments submitted July 12, 2021, or the

objections in light of such amendments. Given that the amendments do not substantively alter the claimed subject matter and only serve to correct the minor dependency and grammatical/antecedent issues pointed out by the Examiner, the Appellants respectfully submit that the amendments should be entered to overcome the objections, thereby rendering them moot.

D. Claims Rejections – 35 USC §112

1. Claim 35 was rejected under 35 USC 112(a) or 35 USC 112(pre-AIA), first paragraph, as failing to comply with the written description requirement.

The Examiner objected to the term "calculate" and instead suggested the term "determine". The Appellants thanked the Examiner for his helpful suggestion and submitted the suggested amendment in the Amendment After Final on July 12, 2021, in light of which the Appellants submit that rejection is now moot, though no positive indication has been provided as to the status of the amendments or rejections.

2. Claims 35-40 was rejected under 35 USC 112(b) or 35 USC 112(pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor(s) consider their invention.

The Examiner objected to the use of the term "retransmitting the data or information based on the data as well as the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician."

The Appellants submit that this language is clear, but previously suggested an amendment that might make this language clearer. Again, absent any indication regarding the status of the amendments or rejections, the Appellants respectfully submit that the rejection is moot in light of the previously submitted amendments.

The Examiner further objects to the limitation "outputting apnea events determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to better understand the efficacy of the therapy". The Examiner object's to the term

"better understand" as to the metes and bounds. The Appellants have changed the term to "see". The Appellants believe one skilled in the art would understand that by outputting the number of apnea events while undergoing therapy mean to eliminate such events to a subject's phone after therapy would alert the subject and better help them understand the efficacy of their last night's therapy.

The Examiner objects to the use of the term Bluetooth as it is a trademark in Claim 36. The Appellants would point out that Bluetooth is also understood to be a standard and have amended the claim to make this clear.

The Examiner objects to the antecedent basis for the term "the second time period" in Claim 38. This has been amended to read "a second time period".

The Appellants submit that their clarifying amendments submitted July 12, 2021 sufficiently overcome the § 112 rejections, and that the rejections are moot in light thereof.

E. Claim Rejections – 35 U.S.C. § 103

1. Background and standard of Review

To provide legal context as well as an analytical framework for the remarks that follow, the Appellants wish at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the examiner does not produce a *prima facie* case, the applicants are under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an assertion of *prima facie* obviousness the examiner must perform the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that "secondary considerations" such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, "the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis." MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the examiner errs in performing any of the *Graham* factual inquiries, the examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the examiner committing error in performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

With specific regard to the examiner's obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Appellants would direct particular attention to the requirement that "[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill." *See* MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the examiner's burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an "indication of the level of ordinary skill," *MPEP 2141(II)(C)*, the examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the examiner in such a way as to render the claimed invention obvious. *See In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and examiner for failing to provide "any evidentiary support or reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant" and further noting that *KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* "did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references").

Thus, in order for the examiner to properly establish a *prima facie* case of obviousness the examiner must first make the factual inquiries required by *Graham* and, if relying on a combination

of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the examiner falls short in meeting any of these requirements, then the examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. *See In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) ("If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent"). As stated in the United States Patent and Trademark Office's own rules, "[a] prima facie case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard..." *See* 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor" (emphasis added).

In all of the above, the Appellants wish to emphasize the high bar to which the examiner is held during the examination process and note that they had respectfully requested that the Examiner provide explicit and detailed analysis of any grounds of rejection relied upon. *See, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* ("[an obviousness] analysis should be made explicit," citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

2. Claims 35 and 37 are patentable under 35 U.S.C. § 103 over Rappaport in view of Cooper and Geva

Claims 35 and 37 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rappaport et al ("Rappaport") in view of U.S. Pat. Pub. No. 2005/0222502 to Cooper ("Cooper"), and further in view of U.S. Pat. Pub. No. 2004/0073098 to Geva ("Geva") . The Appellants traverse and submit the claims as now amended overcome this rejection.

More specifically, with respect to Claim 35, Rappaport, Cooper or Geva alone or together do not teach nor disclose a method of treating a sleep-related breathing disorder comprising steps of providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a flow or pressure sensor during a time period, the flow or pressure sensor which is integrated into the PAP or CPAP device; transmitting the data or

information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link; outputting apnea events determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to see an efficacy of the therapy; and retransmitting the data or information based on the data as well as transmitting or retransmitting the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician as claimed.

The self-adjusting or autotitrating device in Rappaport, an example is shown in FIG. 18 and an example of the algorithm used by the device in FIG. 17, is then used to collect data as to determine how to alleviate apneas. The PAP device 86 has a flow sensor 72 and a pressure sensor 90. The data collected with these sensors is run through various electronics 76, 78, 80 on the PAP device and through an algorithm as shown in FIG. 17 through which the patient is tested at various flow pressures to determine whether the patients apnea(s) are alleviated. This data is then stored in memory 81. FIG. 22 shows the patient then returns the auto-PAP with the stored data 164. The stored data is then analyzed 166 to determine the proper set pressure for the patient 168. In Rappaport "[the] patient sleeps at home with the therapy device for the required number of nights…[and] returns the therapy device or its storage module for analysis of the stored data." This data (and this data alone) from the self-adjusting device is then used to adjust the PAP or CPAP device. The data from Rappaport is not shared with the patient let alone sent to the patients cellular phone.

Rappaport does not teach or disclose determining apnea events rather the PAP in Rappaport indicates whether apnea(s) are alleviated at various pressures. Rappaport collects flow and pressure data 162 at these various pressures. Further, the apparatus in Rappaport needs to be returned by the patient to the remote location for the data to be downloaded and analyzed 164. The data is then analyzed at the remote location to determine the amount of flow limiting and apnea present 166. The present invention instead analyzes the number of apnea events either with the PAP or cellular phone from the flow or pressure sensor data onsite. This data is then forwarded to the remote location either by the cellular phone or the PAP, and the number of apnea events are displayed for the subject to better understand the efficacy of their treatment.

Cooper monitors various respiratory events by deriving these events from the signal on a pulse oximeter – not a pressure or flow sensor within a therapy device. In fact Cooper does not monitor flow or pressure on a therapy device such as a PAP or any therapy device for that matter. The apparatus in Cooper uses the cellular phone for data collection for diagnostics not to display information about efficacy of therapy to the patient carrying the cellular phone. Any apnea events in Cooper are derived from the pulse oximeter signal not from a flow or pressure sensor. The specific embodiment of the apparatus in Cooper for patient monitoring that the Examiner referred to is where the sensor is a photodiode, likely a pulse oximeter, where data is collected and "blood flow cycling with hypopnea and voltage transition characteristic of arousal peaks in the blood volume signal". This calculation can be performed either remotely or via a mobile phone processor. Clearly these calculations are not based on flow or pressure data. Further, the respiratory parameters are not used for the patient to better understand the efficacy of a PAP or CPAP treatment. The respiratory events in Cooper are calculated and displayed after the data is transferred to a remote system for analysis so whomever is monitoring the system in Cooper can review it on a built in LCD screen or so an alarm is set off to warn those monitoring the patient. The respiratory events are not displayed on the cellular phone as alleged by the Examiner. The data in Cooper is further transferred to the remote system either wirelessly or by the removal and physical transfer of memory. There is no indication this is accomplished via the Internet or a cellular system.

Geva, FIG. 30, on which para. 0294 (referenced by the Examiner) is based teaches an electrode system whereby the electrode (EKG) data is uploaded to a first cellular phone where the data may be pre-processed by software on the cellular phone, the data is then transferred to a remote server where it is fully processed and then afterwards send to a physicians cellular phone for review by a physician.

The present invention on the other hand collects pressure or flow data from a PAP device which is used to determine the efficacy of the therapy by looking at the apnea event that occur in the presence of the therapy. These apnea events can be determined either at the PAP or by the cellular phone, these along with other data from the therapy are then sent on to a remote station for review by a clinician, technician or physician. These apnea events are also displayed for the subject to see the efficacy of their therapy. The data and the apnea events can use the cellular phone to retransmit the information to the remote station or the PAP can transmit the information

to a cellular phone and then send it a second time or retransmit the information to the remote station as well. The present invention allows not only the patient but their clinicians to be aware of the efficacy of the patient's therapy as presently configured, and to adjust or titrate the therapy efficiently and remotely. The present invention allows for RF transmission of flow or pressure data from the patient's therapy device to software on their cellular phone, for retransmission, determination and/or display on or by the cellular phone. The determination or calculation of these apnea events are performed on either the PAP device or the patient's cellular phone.

Nowhere in any of the references do they teach or disclose using flow or pressure sensors on a patient's PAP device for tracking the efficacy of the therapy and sharing that information with the patient on their cellular phone while at the same time sharing that information with the patient's clinician so the therapy can be adjusted if necessary, and doing so wirelessly, in real-time, through the Internet and/or cellular systems.

This Application was initially filed in 2005, and a CIP was filed in 2007. There was nothing like this using cellular phones, PAP therapy, cellular systems and the Internet at that time so it is clear the Examiner used a hindsight approach with the Appellants claims as a roadmap and is not viewing the claims as a whole.

With respect to the method of claim 37, Rappaport, Cooper nor Geva teach or disclose wherein the therapy can be modified based in part on the wirelessly retransmitted data or information as claimed. The Examiner relied on Rappaport for this teaching. The Examiner cited to the teaching on Col. 16, lines 47-56 of Rappaport which indicates that if the analysis determines that there are still a significant number of sleep-disordered breathing episodes during the night and the therapy devices does not restore normal breathing, then the patient is referred to a sleep lab for a more comprehensive study, step 160. One skilled in the art would understand this does not teach modifying therapy based on wirelessly transmitted information as set forth in claim 35.

In an attempt to explain the purported combination of these references, the Examiner merely made unsupported conclusory observations. The Appellants, however, remind the Examiner that these observations must be supported.

The Examiner stated "Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the method of Rappaport to include "transmitting the data or information based on the data from the first sensor to a cellular phone;

outputting the apnea events calculated using data from the first sensor on a display of the cellular phone as taught by Cooper." There is no rational basis for this argument. First and foremost since Cooper does not output the calculated data on a cellular phone available to the patient. Second, because obviously this is a hindsight analysis by the Examiner. The Examiner then stated it would be obvious to combine Geva with Rappaport "to include the method step of retransmitting the data and transmitting the calculated apnea events wirelessly via a cellular system as taught by Geva in order to save the patient from excess travel and to quickly provide the physician with the patient's data." There is no rational basis for this argument as well. First, Geva does not retransmit the calculated apnea events from either the patient's cell phone or their therapy device as the present invention does. Instead Geva does the complete analysis of the subject's electrode data (diagnostic) at the remote station. Again this is clearly hindsight analysis where the Examiner is using the Appellants claims as a roadmap for his rejection. Clearly, the present invention displays the apnea events so the subject can understand the efficacy of their therapy and either forwards the data or transmits it from the PAP to a remote location so the subject's therapy provide can review the data and provide for therapy adjustment if necessary. Furthermore with the present invention this can all be done remotely without the need for the patient to return the PAP device for the data analysis and calculation.

Further, the Examiner has so far failed to explicitly define or establish the level of ordinary skill in the art, and none of the references adequately provides the level implicitly. As before, numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Rappaport, Geva and Cooper references? What are the similarities between the claimed invention and Rappaport, Geva and Cooper? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relied upon a conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to support his analysis of the Graham factors, but has failed to do so. The Appellants therefore respectfully requested the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary skill in the art or to the Examiner's conclusions. This was not done. The Appellants further

suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and requested that the Examiner therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which the rejection is based. *See* 37 C.F.R. § 1.104(d) (2). No affidavit was provided.

The Appellants further respectfully submit that the Examiner has not given any valid teaching, suggestion, or motivation in or external to the references, or from the references cited as a whole, for the person of ordinary skill to have modified the reference of Rapoport to include the teachings of Cooper and Geva. The Appellants respectfully requested that the Examiner either support the conclusions of motivation with references or, if such allegation is based on personal knowledge, provide an affidavit as to such including the factual underpinning for such conclusions. *See* 37 C.F.R. § 2144.03. No affidavit was provided. In *re Eynde* states that "[t]he facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." *In re Eynde*, 480 F.2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973). Similarly, *KSR Int'l Co. v. Teleflex, Inc.* requires that "[obviousness] analysis should be made explicit." *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007). *KSR* goes on to explain that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning." It is often "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15.

Given the above comments, the Appellants request reversal of this rejection.

3. Claim 36 is patentable under 35 U.S.C. § 103 over Rappaport in view of Cooper, Geva, and Brand

Claim 36 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rappaport et al ("Rappaport") in view of U.S. Pat. Pub. No. 2005/0222502 to Cooper ("Cooper"), and further in view of U.S. Pat. Pub. No. 2004/0073098 to Geva ("Geva"), as applied to claim 35 , in further view of U.S. Pat. Pub. 2003/0183226 to Brand ("Brand"). The Appellants traverse and submit the claim overcomes this rejection

The Appellants incorporate their above remarks with respect to Rappaport, Cooper, and Geva.

With respect to Claim 36, Rappaport, Cooper, Geva nor Brand teach or disclose the method wherein the cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time as claimed. The Examiner cited to Brand for this teaching. However para. 0079 of Brand does not teach a wireless connection in real time as claimed, and Brand does not teach the communication of the type of data and its transmission as with the present invention. In Brand the data that is being transmitted is whether an respiratory inhaler is being used and what types and amounts of dosing is being provided to the patient. In the present invention the volume of data is significantly larger making it unlikely the communications system of Brand could be used for data transmission in the present invention.

In an attempt to explain the purported combination of these references, the Examiner merely made unsupported conclusory observations. The Appellants, however, remind the Examiner that these observations must be supported.

The Examiner stated "Brand teaches Bluetooth standard is a known RF frequency communication means of a phone known to be used in conjunction with medical devices." There is no rational basis for this argument. The question is not whether Bluetooth can be shown to transfer data between medical devices and a cellular phone in real time, but rather whether Bluetooth standard can be used to transfer fairly large volumes of data between a PAP and a cellular phone in real time. If this was an invention for digitizing radiological images, which require very large volumes of data would Brand support this teaching for Bluetooth standard in real time. No. Similarly it does not support this combination of references being used to attack the present invention. Clearly this is a hindsight analysis by the Examiner where the Examiner is using the Appellants claims as a roadmap for his rejection.

Further, the Examiner has so far failed to explicitly define or establish the level of ordinary skill in the art, and none of the references adequately provides the level implicitly. As before, numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Rappaport, Cooper, Geva and Brand references? What are the similarities between the claimed invention and Rappaport, Cooper, Geva and Brand? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relied upon a

conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to support his analysis of the Graham factors, but has failed to do so. The Appellants therefore respectfully requested the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary skill in the art or to the Examiner's conclusions. This was not done. The Appellants further suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and requested that the Examiner therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which the rejection is based. *See* 37 C.F.R. § 1.104(d)(2). No affidavit was provided.

The Appellants further respectfully submit that the Examiner has not given any valid teaching, suggestion, or motivation in or external to the references, or from the references cited as a whole, for the person of ordinary skill to have modified the reference of Rapoport to include the teachings of Cooper, Geva and Brand. The Appellants respectfully requested that the Examiner either support the conclusions of motivation with references or, if such allegation is based on personal knowledge, provide an affidavit as to such including the factual underpinning for such conclusions. *See* 37 C.F.R. § 2144.03. No affidavit was provided. In *re Eynde* states that "[t]he facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." *In re Eynde*, 480 F.2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973). Similarly, *KSR Int'l Co. v. Teleflex, Inc.* requires that "[obviousness] analysis should be made explicit." *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007). *KSR* goes on to explain that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning." It is often "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15.

Given the above comments, the Appellants request reversal of this rejection.

4. Claim 38 is patentable under 35 U.S.C. § 103 over Rappaport in view of Cooper, Geva, and Behbehani

Claim 38 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over Rappaport in view of Cooper, and Geva, as applied to claim 35, in view of U.S. Pat. No. 5,953713 to Behbehani ("Behbehani"). The Appellants traverse and submit the claim overcomes this rejection.

The Appellants incorporate their above remarks with respect to Rappaport, Cooper and Geva. Given the above comments, the Appellants request reversal of this rejection.

5. Claims 39 and 40 are patentable under 35 U.S.C. § 103 over Rappaport in view of Cooper, Geva, and Burton

Claims 39 and 40 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over Rappaport in view of Cooper, and Geva, as applied to claim 35, in view of U.S. Pat. No. 6,349,724 to Burton ("Burton"). The Appellants traverse and submit the claim overcomes this rejection.

The Appellants incorporate their above remarks with respect to Rappaport, Cooper and Geva. The Examiner relied on Burton for the teachings of the limitations of Claims 39 and 40. Burton, however, does not teach or disclose the method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician as claimed, or wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician as claimed.

Burton uses various sensors for diagnosis or long term studies, or for alerting a health care worker about the patient's condition requiring immediate action. That, however, is not the same as real-time adjustment of a PAP by the technician, clinician or physician in real-time who are viewing the data at a remote location or station.

The Examiner pointed to a number of teachings in Burton for titrating a patient through a wireless connection. In Col. 2, lines 13-15 of Burton it teaches that data may be sent to a remote site by "telemetry, telephony or by mailing the data card." The Examiner further pointed to Col. 7, lines 18-28 of Burton which states "[t]he ramp times, ramp delay times and other parameters can be programmed into the controller/microprocessor 82 by means of information stored on a data card 210 inserted into a data card port 115. Alternatively the microprocessor may be

programmed by a computer 200…the computer may be remotely located at a hospital or sleep clinic and connected through the internet by wire or wireless phone systems or positioned adjacent the dual pressure gas delivery device."

This however is not the same wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician. Burton teaches of reprogramming the PAP by a number of means but particularly the "ramp times", and "ramp delay times". These are comfort settings that allow the therapy not to be as intrusive and can allow the therapy to start after the patient falls asleep – not the therapy itself. This is not adjusting or titrating the therapy. This further is being done by a computer and not by a "clinician, technician or physician at a remote location".

Given the above comments, the Appellants request reversal of this rejection.

6. § 103 Conclusion

In light of the above remarks, the Appellants submit that the claims are not obvious in light of the references. Accordingly, the Appellants respectfully request reversal of the rejections.

F. Conclusion

For at least the reasons noted above, the Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case for the rejections. Accordingly, the Appellants respectfully request that the Board reverse the Examiner's rejections.

Respectfully submitted,

September 9, 2021
Dated

/Brian Kolkowski 36,847/

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V. CLAIMS APPENDIX

21. (rejected) A method of treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject; and

adjusting or titrating the therapy to the subject using at least part of the data from both the first and second sensor signals to improve therapy to the subject during a second time period after the first time period when data is no longer collected.

22. (rejected) The method of claim 21, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and the data from the second integrated sensor is transmitted wirelessly directly from the PAP or CPAP device to the data acquisition box in

real time.

23. (rejected) The method of claim 21, with the further step wherein the data from the first and second sensors is at least in part transmitted from the data acquisition system by cellular service to a remote data storage station for review remotely by medical personnel, and the medical personnel provides a command signal transmitted by cellular service for titrating or adjusting the PAP or CPAP device automatically if necessary to adjust the flow or by communicating with an individual near the subject or with the subject to adjust the PAP or CPAP device.

24. (rejected) The method of claim 21, wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

25. (rejected) The method of claim 21, wherein the data acquisition system comprises the first and an additional third sensors having signals, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

26. (rejected) The method of claim 21, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals that are specific to the subject being treated for improved treatment during the second time period when data is no longer collected from the first sensor.

27. (rejected) A method of determining the effectiveness of the therapy used in treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject;

determining an effectiveness of the therapy delivered by the separate PAP or CPAP device using at least part of the data from both the first and second sensor signals.

28. (rejected) The method of claim 27, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and can communicate directly with each other through the wireless connection in real-time.

29. (rejected) The method of claim 27, wherein the data from the first and second sensors is in part transmitted from both devices in real-time.

30. (rejected) The method of claim 27, wherein the steps of the method can be used to adjust and titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas after the time period when data is no longer collected from the first sensor.

31. (rejected) The method of claim 27, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals from the data acquisition system that are specific to the subject being treated for improved treatment during the second time period when data is no longer collected from the first sensor.

32. (rejected) The method of claim 27, wherein the PAP or CPAP device is adjusted or titrated by utilizing more robust data collection by relating the data from the first sensor to the second sensor for improved treatment during the second time period when data is no longer collected from the first sensor.

33. (rejected) The method of claim 27, wherein the data acquisition system comprises an additional third sensor having a signal, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second integrated sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

34. (rejected) The method of claim 33, wherein the data acquisition system comprises an additional fourth sensor for determining body position of the subject.

35. (rejected) A method of treating a sleep-related breathing disorder comprising steps of:

providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a flow or pressure sensor during a time period, the flow or pressure sensor which is integrated into the PAP or CPAP device;

transmitting the data, or information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link;

outputting apnea events determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to see the efficacy of the therapy; and

retransmitting the data or information based on the data as well as transmitting or retransmitting the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician.

36. (rejected) The method of claim 35, wherein the cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time.

37. (rejected) The method of claim 35, wherein the therapy can be modified based in part on the wirelessly retransmitted data or information.

38. (rejected) The method of claim 35, wherein the steps of the method can be used train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during a second time period when data is no longer collected from the first sensor.

39. (rejected) The method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician.

40. (rejected) The method of claim 35, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician.

Electronic Acknowledgement Receipt

EFS ID:	43718316
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	09-SEP-2021
Filing Date:	05-JUL-2017
Time Stamp:	10:38:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Appeal Brief Filed	CMD-101_9Sep2021_PTAB-Appeal-brief.pdf	353884 3e13071de317e790c44a4e9cab3b42dd27614876	no	22

Warnings:

Information:	
Total Files Size (in bytes):	353884

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 09/23/2021

Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
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EXAMINER	
HEFFNER, NED T	

ART UNIT	PAPER NUMBER
3785	

MAIL DATE	DELIVERY MODE
09/23/2021	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.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 15/641,715	**Applicant(s)** Kayyali et al.	
	Examiner NED T HEFFNER	**Art Unit** 3785	**AIA (FITF) Status** No

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

THE REPLY FILED 12 July 2021 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☑ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☑ The Notice of Appeal was filed on 12 September 2021. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☑ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☑ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See Continuation Sheet (See 37CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicants reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☑ For purposes of appeal, the proposed amendment(s):(a) ☑ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:21-40.
    Claim(s) withdrawn from consideration:_____.

/NED T HEFFNER/ Examiner, Art Unit 3785	/SAMCHUAN C YAO/ Supervisory Patent Examiner, Art Unit 3785

Continuation of 3. NOTE: The proposed amendment to claim 35 raises the new issue of outputting for a subject to see efficacy, outputting apnea events determined by a device and retransmitting based on transmitting or retransmitting determined events such as would require further search and consideration.

Further Examiner respectfully points out that the proposed amendment to claim 35 would raise the issue of indefiniteness under 35 USC 112(b) in that the claim recites alternately "retransmitting based on [...] or retransmitting the determined apnea events" however apnea events are not claimed to have first been transmitted in order for them to be retransmitted, therefore it is unclear whether the apnea events are transmitted at some point during the method or if they are transmitted data.

Continuation of REQUEST FOR RECONSIDERATION/OTHER 12. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Examiner acknowledges that the proposed amendment would obviate the outstanding rejection under 35 USC 112(a). However Examiner respectfully points out that the proposed amendment to claim 35 would raise the issue of indefiniteness under 35 USC 112(b) in that the claim recites alternately "retransmitting based on [. ..] or retransmitting the determined apnea events" however apnea events are not claimed to have first been transmitted in order for them to be retransmitted, therefore it is unclear whether the apnea events are transmitted at some point during the method or if they are transmitted data. Further Examiner respectfully points out that the proposed amendment to claim 35 raises the new issue of outputting for a subject to see efficacy, outputting apnea events determined by a device and retransmitting based on transmitting or retransmitting determined events such as would require further search and consideration.

DO NOT ENTER: /N.T.H/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	15/641,715	Art Unit:	3735
Filed:	July 5, 2017	Docket No.:	CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method		
Examiner:	Matthew Standard		

July 12, 2021

AMENDMENT AFTER FINAL

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This amendment is being filed in the above captioned application in response to a final Office Action dated April 12, 2021. The Applicants believe that no extension of time is necessary, however, if one is due the Applicants herein petition for the extension of time and authorize any fees to be deducted from their deposit account. The Applicants herein file a Notice of Appeal with respect to Claims 35-40, and use their credit card to pay for Appeal fees due. The Applicants believe that no fees are due in conjunction herewith, but if any fees are found to be owed, the Applicants authorize the Director to withdraw the funds from their deposit account: 502704. The following amendments are respectfully submitted.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 06/21/2022

Cleveland Medical Devices Inc.
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EXAMINER	
HEFFNER, NED T	

ART UNIT	PAPER NUMBER
3785	

MAIL DATE	DELIVERY MODE
06/21/2022	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Application Number: 15/641,715
Filing Date: 5 Jul 2017
Appellant(s): Hani Kayyali, Dan Bishop and Brian M. Kollowski

Brian M. Kollowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/09/2021.

(1) Grounds of Rejection to be Reviewed on Appeal

Every ground of rejection set forth in the Office action dated 04/12/2021 from which the appeal is taken is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The outstanding rejection of claims 21-34 under the doctrine of nonstatutory double patenting.

(2) Response to Argument

In Item IV. C. of the Appeal Brief of 09/09/2021, Appellant points out the outstanding objections to claims 32 and 35 due to informalities and raises the issue that the claims have been amended to correct the informalities by the Amendment of 07/12/2021. Examiner respectfully points out that the Amendment of 07/21/2021 has not been entered due to raising new issues thus Examiner respectfully maintains that the remarks regarding the claims of 07/21/2021 are not commensurate with the claims as presented on 11/17/2020 and are moot.

In Item IV. D. 1, Appellant points out the outstanding rejection of claim 35 under 35 USC 112 and raises the issue that the claim has been amended to change the term "calculate" to "determine" by the Amendment of 07/12/2021. Examiner respectfully points out that the Amendment of 07/21/2021 has not been entered due to raising new issues thus Examiner respectfully maintains that the remarks regarding the claims of 07/21/2021 are not commensurate with the claims. As such Examiner respectfully maintains that the outstanding rejection of claim 35 under 35 USC 112 as failing to comply with the written description requirement remains proper.

In Item IV. D. 2, Appellant points out the outstanding rejection of claims 35-40 under 35 USC 112 and raises the issue that the claims have been amended to overcome the rejections by the Amendment of 07/12/2021. Examiner respectfully points out that the Amendment of 07/21/2021 has not been entered due to raising new issues thus Examiner respectfully maintains that the remarks regarding the claims of 07/21/2021 are not commensurate with the claims. As such Examiner respectfully maintains that the outstanding rejection of claims 35-40 under 35 USC 112 as being indefinite remains proper.

In Item IV. E. 1 Appellant points out MPEP 2142 and 2141 and raises the issue, in the 7th page, first paragraph, of alleged failure to appreciate differences between the claimed invention and prior art. Examiner respectfully maintains that in Item IV. E. 1 Appellant does not point out the claim language relative to which Appellant alleges that an error is made. Thus, Examiner maintains that the remarks amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

In the seventh page, second and third paragraphs, Appellant points out MPEP 2141 and raises the issue that the Examiner fails to determine the level of ordinary skill in the art. Examiner respectfully disagrees on the basis that Examiner points out that the prior art itself reflects an appropriate level of ordinary skill in the art, the art of Rapoport being from the field of continuous positive airway pressure, and that of Cooper and Geva being from the fields of biomedical monitoring. Examiner respectfully points out that as per MPEP section 2141.03, if the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983).

In Item IV. E. 1, in the eight page, Appellant points out that in order to establish a case of obviousness, Examiner must provide motivation to combine the references from the perspective of one

of ordinary skill in the art. Examiner acknowledges however respectfully points out that motivation as required is detailed by the Examiner in items 21 and 24 of the Action of 04/12/2021, particularly by way of the motivation to allow data to be suitably displayed for review on a mobile device screen and to save the patient from excess travel and quickly provide a clinician with patient data.

In Item IV. E. 2, in the eight page, Appellant raises the issue with regard to claim 35 that the prior art does not teach or disclose a method of treating a sleep-related breathing disorder comprising steps of providing a therapy during a first time period to a subject while sleeping with a PAP or CPAP device while data is being collected from a flow or pressure sensor during a time period, the flow or pressure sensor which is integrated into the PAP or CPAP device; transmitting the data or information based on the data from the flow or pressure sensor to a cellular phone via a radio frequency wireless link; outputting apnea events determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to see an efficacy of the therapy; and retransmitting the data or information based on the data as well as transmitting or retransmitting the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician as claimed. Examiner respectfully points out first that Appellant's Remarks refer to the proposed amended version of claim 35 of 07/12/2021, which as per the Advisory Action of 09/23/2021 has not been entered, thus are not commensurate with the scope of the claims as addressed in the outstanding Action of 04/12/2021.

In Item IV. E. 2, in the ninth page of the Appeal Brief Appellant raises the issue that Rappaport does not teach or disclose determining apnea events rather the PAP in in Rappaport indicates whether apnea(s) are alleviated at various pressures. As detailed above Examiner respectfully points out that Appellants remarks refer to a proposed amended claim which has not been entered thus to limitations not required by the claims as presented on 11/17/2020. Further Examiner respectfully disagrees on the

basis that in Column 11, lines 38-46 of Rapoport apnea events are expressly recited to be detected during PAP thus are determined by said detection.

In Item IV. E. 2, in the tenth page, first paragraph of the Appeal Brief Appellant raises the issue that Cooper does not monitor flow or pressure on a therapy device such as PAP or any therapy device for that matter. Examiner respectfully contends that Cooper is not relied upon for monitoring of flow or pressure in a therapy device but merely for transmission of data. Examiner respectfully maintains that the application of wireless transmission of clinical data as taught by Cooper to the flow and pressure of Rapoport would reasonably result in transmitting data as claimed.

In Item IV. E. 2, in the tenth page, second and third paragraphs of the Appeal Brief Appellant raises the issue that Geva teaches an electrode system whereby electrode data is uploaded with Appellant's invention collects pressure and flow data from a PAP device. Examiner respectfully contends that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In Item IV. E. 2, in the eleventh page, second and third paragraphs of the Appeal Brief Appellant raises the issue that nowhere in any of the references do they teach or disclose using flow or pressure sensors on a patient's PAP device for tracking the efficacy of the therapy and sharing that information with the patient on their cellular phone while at the same time sharing that information with the patient's clinician so the therapy can be adjusted if necessary, and doing so wirelessly, in real- time, through the Internet and/or cellular systems. Examiner respectfully contends that that the features upon which Appellant relies (i.e., steps of tracking and sharing) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In Item IV. E. 2, in the eleventh page, fourth paragraph of the Appeal Brief, regarding claim 37 Appellant raises the issue that the art of record does not teach or disclose wherein the therapy can be modified based in part on the wirelessly retransmitted data or information as claimed in that one skilled in the art would understand that Rapoport does not teach modifying therapy based on wirelessly transmitted information as set forth in claim 35. Examiner respectfully disagrees on the basis that in Column 16, lines 47-56, as detailed in the outstanding Action, Rapoport discloses modification based on transmitted data while wireless transmission would have been obvious in view of Coper as detailed regarding claim 35. Examiner respectfully points out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In Item IV. E. 2, in the twelfth page, first paragraph of the Appeal Brief, Appellant raises the issue that there is no rational basis for the Examiner's position that it would have been obvious to one of ordinary skill in the art to modify Rapoport to include transmitting data or information to a cellular phone as taught by Cooper in that Cooper does not output the calculated data on a cellular phone available to the patient. Examiner respectfully disagrees on the basis that Examiner points out that output to a cellular phone available to a patient is not required by the claims, nor is the rationale of displaying to a patient relied upon in the proposed combination but rather supplying data for display thus providing better understanding towards efficacy.

In Item IV. E. 2, in the twelfth page, first paragraph of the Appeal Brief, Appellant raises the issue that there is no rational basis for the Examiner's position that it would have been obvious to one of ordinary skill in that this is hindsight analysis by the Examiner. Examiner respectfully disagrees on the

basis that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, Examiner respectfully maintains that the proposed modification would have been obvious without impermissible hindsight in that the motivation to allow display of data for better understanding towards efficacy was known in the art such as by way of Paragraph 171 of Cooper reciting calculation to draw distinction between physiological effects.

In Item IV. E. 2, in the thirteenth page, second paragraph of the Appeal Brief, Appellant raises the issue that the Examiner fails to determine the level of ordinary skill in the art. Examiner respectfully disagrees on the basis that Examiner points out that the prior art itself reflects an appropriate level of ordinary skill in the art, the art of Rapoport being from the field of continuous positive airway pressure, and that of Cooper and Geva being from the fields of biomedical monitoring. Examiner respectfully points out that as per MPEP section 2141.03, if the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. Chore-Time Equipment, Inc. v. Cumberland Corp., 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983).

In Item IV. E. 3, in the fourteenth page, first and second paragraphs of the Appeal Brief, Appellant raises the issue Brand does not teach a wireless connection in real time as claimed, and Brand does not teach the communication of the type of data and its transmission as with the present invention. Examiner respectfully contends that the feature of real-time communication is present in the teaching of Cooper in Paragraph 21, as applied with regard to claim 35. Further Examiner respectfully

points out that Brand is relied upon merely for the particular protocol, Bluetooth, as required by claim 36 thus is not relied upon for the cli Brand does not teach a wireless connection in real time as claimed, and Brand does not teach the communication of the type of data and its transmission as with the present invention her med type of data. Examiner respectfully points out that the claimed data type is disclosed by Rapoport in Column 13, lines 19-24 thereof.

In Item IV. E. 3, in the fourteenth page, fourth paragraph and raises the issue that the Examiner fails to determine the level of ordinary skill in the art. Examiner respectfully disagrees on the basis that Examiner points out that the prior art itself reflects an appropriate level of ordinary skill in the art, the art of Rapoport being from the field of continuous positive airway pressure, and that of Cooper and Geva and Brand being from the fields of biomedical monitoring. Examiner respectfully points out that as per MPEP section 2141.03, if the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. Chore-Time Equipment, Inc. v. Cumberland Corp., 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983).

In Item IV. E. 3, in the twelfth page, first paragraph of the Appeal Brief, Appellant raises the issue that the Examiner has not given valid teaching, suggestion or motivation to have modified Rapoport to include the teachings of Cooper, Geva and Brand. Examiner respectfully disagrees on the basis that Examiner points out that motivation as required is detailed by the Examiner in items 21 and 24 of the Action of 04/12/2021, particularly by way of the motivation to allow data to be suitably displayed for review on a mobile device screen and to save the patient from excess travel and quickly provide a clinician with patient data, and in item 30 of the Action of 04/12/2021 particularly the motivation to achieve wireless RF communication by means of a phone known in the art of medical devices.

In Item IV. E. 5 Appellant raises the issue that Burton, does not teach or disclose the method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the

remote location by the technician, clinician or physician as claimed, or wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician as claimed. Appellant raises the issue that Burton teaches of reprogramming the PAP by a number of means but particularly the "ramp times", and "ramp delay times" and alleges that these are comfort settings that allow the therapy not to be as intrusive and can allow the therapy to start after the patient falls asleep, not the therapy itself. Examiner respectfully disagrees on the basis that Examiner maintains that the settings adjusted in Burton pertain directly to timing and pressure of therapeutic gas delivery (as per Column 7, lines 15-28 of Burton) thus are therapeutic settings thus that Burton teaches adjustment of CPAP as required by the claim. Further Examiner respectfully points out first that Appellant's Remarks refer to the proposed amended version of claim 35 of 07/12/2021, which as per the Advisory Action of 09/23/2021 has not been entered, thus are not commensurate with the scope of the claims.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/NED T HEFFNER/
Examiner, Art Unit 3785

Conferees:
/SAMCHUAN C YAO/
Supervisory Patent Examiner, Art Unit 3785

/VICTORIA MURPHY/
Primary Examiner, Art Unit 3785

Requirement to pay appeal forwarding fee. In order to avoid dismissal of the instant appeal in any application or ex parte reexamination proceeding, 37 CFR 41.45 requires payment of an appeal

forwarding fee within the time permitted by 37 CFR 41.45(a), unless appellant had timely paid the fee for filing a brief required by 37 CFR 41.20(b) in effect on March 18, 2013.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/641,715	Filing Date 07/05/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	08/19/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 20	= 9		x $50 =	450
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	450

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/DAWN BREWER/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	15641715	Filing Date	2017-07-05	Docket Number (if applicable)	CMD-101	Art Unit	3785
First Named Inventor	Hani Kayyali			Examiner Name	Ned Heffner		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 502704

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

X Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Brian Kolkowski/	Date (YYYY-MM-DD)	2022-08-19
Name	Brian Kolkowski	Registration Number	36847

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	15641715
Filing Date:	05-Jul-2017
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	680	680
		Total in USD ($)		**680**

Electronic Acknowledgement Receipt

EFS ID:	46448248
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	19-AUG-2022
Filing Date:	05-JUL-2017
Time Stamp:	14:19:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$680
RAM confirmation Number	E20228IE21083898
Deposit Account	502704
Authorized User	Mark Pennington

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CMD-101_19Aug2022_Amendment.pdf	323289 5e2cd708b52047a939509cba40d3f3d8c20f5997	yes	25
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Argument after Notice of Appeal		1	1	
	Claims		2	9	
	Applicant Arguments/Remarks Made in an Amendment		10	25	
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	CMD-101_19Aug2022_IDS.pdf	1265401 ae8b782d8960e9c25b9c97b86f0047b65dae66b9	no	10
Warnings:					
Information:					
3	Request for Continued Examination (RCE)	CMD-101_19Aug2022_RCE-form.pdf	1667130 fd4c8e59ca103f6af61b5d3f05c4ce225b8858d7	no	3
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	38006 ab6733e3f184e5265f7d81d80c247ebd14212ed0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3293826		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	15/641,715	Art Unit:	3735
Filed:	July 5, 2017	Docket No.:	CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method		
Examiner:	Ned Heffner		

August 19, 2022

AMENDMENT AND REQUEST FOR CONTINUED EXAMINATION

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This amendment is being filed in the above captioned application in response to a Reply Brief filed in an appeal to the USPTO Trial and Appeal Board dated June 21, 2022. The Applicants believe that no extension of time is necessary, however, if one is due the Applicants herein petition for the extension of time and authorize any fees to be deducted from their deposit account. The Applicants use their credit card to pay for Request for Continued Examination fees that are due. The Applicants believe that no additional fees are due in conjunction herewith, but if any fees are found to be owed, the Applicants authorize the Director to withdraw the funds from their deposit account: 502704. The following amendments are respectfully submitted.

IN THE CLAIMS:

Please amend claims 32, 35, 36, 37, 38 and 40 as follows, and add new claims 41-49:

1. (cancelled)
2. (cancelled)
3. (cancelled)
4. (cancelled)
5. (cancelled)
6. (cancelled)
7. (cancelled)
8. (cancelled)
9. (cancelled)
10. (cancelled)
11. (cancelled)
12. (cancelled)
13. (cancelled)
14. (cancelled)
15. (cancelled)
16. (cancelled)
17. (cancelled)
18. (cancelled)
19. (cancelled)
20. (cancelled)

21. (previously presented) A method of treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject; and

adjusting or titrating the therapy to the subject using at least part of the data from both the first and second sensor signals to improve therapy to the subject during a second time period after the first time period when data is no longer collected.

22. (previously presented) The method of claim 21, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and the data from the second integrated sensor is transmitted wirelessly directly from the PAP or CPAP device to the data acquisition box in real time.

23. (previously presented) The method of claim 21, with the further step wherein the data from the first and second sensors is at least in part transmitted from the data acquisition system by cellular service to a remote data storage station for review remotely by medical personnel, and the medical personnel provides a command signal transmitted by cellular service for titrating or adjusting the PAP or CPAP device automatically if

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necessary to adjust the flow or by communicating with an individual near the subject or with the subject to adjust the PAP or CPAP device.

24. (previously presented) The method of claim 21, wherein the steps of the method can be used to adjust or titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas during the second time period when data is no longer collected from the first sensor.

25. (previously presented) The method of claim 21, wherein the data acquisition system comprises the first and an additional third sensors having signals, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

26. (previously presented) The method of claim 21, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals that are specific to the subject being treated for improved treatment during the second time period when data is no longer collected from the first sensor.

27. (previously presented) A method of determining the effectiveness of the therapy used in treating a sleep-related breathing disorder comprising steps of:

attaching a first sensor for collecting data to a subject sleeping at home or at a facility remote from a sleep analysis lab and receiving positive airway pressure (PAP) or continuous positive airway pressure (CPAP) therapy;

concurrently providing therapy during a first time period to the subject with a PAP or CPAP device while data is being collected from the first sensor;

ResMed Corp. - Ex. 1002
Page 294

connecting, before or after attaching the first sensor to the subject, the first sensor to a data acquisition system, the data acquisition system comprising a data acquisition box, which is separate from the PAP or CPAP device and adapted for receiving a first electrical signal from the first sensor;

collecting data from the first sensor attached to the subject during the first time period while the subject attempts to sleep;

collecting data from a second sensor during the first time period, the second sensor which is integrated into the separate PAP or CPAP device from the PAP or CPAP device and transmitting the data from the second sensor to the data acquisition system, the separate PAP or CPAP device adapted for delivering a flow of pressurized gas to the subject;

determining an effectiveness of the therapy delivered by the separate PAP or CPAP device using at least part of the data from both the first and second sensor signals.

28. (previously presented) The method of claim 27, wherein the data acquisition box and the PAP or CPAP device each have a wireless RF connection and can communicate directly with each other through the wireless connection in real-time.

29. (previously presented) The method of claim 27, wherein the data from the first and second sensors is in part transmitted from both devices in real-time.

30. (previously presented) The method of claim 27, wherein the steps of the method can be used to adjust and titrate the PAP or CPAP device to better identify and distinguish between obstructive, central and complex sleep apneas after the time period when data is no longer collected from the first sensor.

31. (previously presented) The method of claim 27, wherein the separate PAP or CPAP device is automatically titrated or adjusted based on physiological signals from the data acquisition system that are specific to the subject being treated for improved

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treatment during the second time period when data is no longer collected from the first sensor.

32. (currently amended) The method of claim ~~33~~27, wherein the PAP or CPAP device is adjusted or titrated by utilizing more robust data collection by relating the data from the first sensor to the second sensor for improved treatment during the second time period when data is no longer collected from the first sensor.

33. (previously presented) The method of claim 27, wherein the data acquisition system comprises an additional third sensor having a signal, the sensors including a respiratory effort belt sensor, and a pulse oximetry sensor; and the second integrated sensor of the PAP or CPAP device is a flow or pressure sensor wherein the PAP or CPAP device is adjusted or titrated using in part data from all three sensors to improve therapy to the subject utilizing the PAP or CPAP after the time period when data is no longer collected from the first and third sensors.

34. (previously presented) The method of claim 33, wherein the data acquisition system comprises an additional fourth sensor for determining body position of the subject.

35. (currently amended) A method of treating a subject's sleep~~-related breathing disorder~~ apnea comprising steps of:

providing a therapy to a subject ~~while sleeping with~~using a PAP or CPAP device while sleeping, the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device;

collecting data with the PAP or CPAP device ~~while data is being collected~~ from the ~~a first~~ flow or pressure sensor during a time period of the therapy ~~the flow or pressure sensor which is integrated into the PAP or CPAP device~~;

analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;

transmitting, in either order, both 1) the collected data, and/or ~~information based on~~ the quantified level of severity data ~~from the flow or pressure sensor~~ to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone to a remote station via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and

~~outputting apnea events calculated~~further determining the therapy efficacy data with either the processor of the PAP or CPAP device, the second processor or server configured with a second software at the remote station, or the cellular phone using the first software further provided ~~for the cellular phone based on the data from the flow or pressure sensor on a~~to receive and display ~~of the cellular phone for the subject to better understand~~see the quantified level of severity data and/or therapy efficacy data to the subject or a care provider~~of the therapy; and~~

~~retransmitting the data or information based on thelevel of severity data as well as the apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or an Internet for review by a clinician, technician or physician~~.

36. (currently amended) The method of claim 35, wherein the cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time.

37. (currently amended) The method of claim 35, wherein the therapy can be modified based in part on the wirelessly ~~re~~transmitted data or information.

38. (currently amended) The method of claim 35, wherein the steps of the method can be used to train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during ~~the~~a second time period ~~when data is no longer collected~~with data from the first sensor.

39. (previously presented) The method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician.

40. (currently amended) The method of claim ~~35~~49, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician from a remote location.

41. (new) The method of claim 35, including the step of storing the collected data, the quantified level of severity data from either the PAP or CPAP device transmitted to the remote station, and/or data based on the transferred data on a database with similar data from treatments of many other subjects.

42. (new) The method of claim 41, wherein the database is stored on a central server or on a group of servers remote to the test location, the central servers or the group of servers upon which the second software is stored on a computer readable medium and executed by the central server or the group of servers.

43. (new) The method of claim 42, including the step of analyzing the data on the database with a relationship algorithm or a neural network to determine an optimal treatment for the subject.

44. (new) The method of claim 42, wherein the PAP or CPAP device, the software on the cellular phone or the remote station determine a total sleep time.

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45. (new) The method of claim 42, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using one or more of a Short-Time Fourier Transform, a Discrete Fourier Transform, a Fast Fourier Transform, a recursively identified system model, a standard deviation technique, a time-frequency signal analysis and/or a Wavelet signal analysis to determine the quantified level of severity data.

46. (new) The method of claim 42, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using a time-frequency signal analysis to determine the quantified level of severity data.

47. (new) The method of claim 37, where a rich data set is used to determine treatment from the collected data from multiple nights of treatment.

48. (new) The method of claim 35, wherein the PAP or CPAP further comprises a firmware and/or a third software which along with the first software can be updated from the remote station or a different remote server.

49. (new) The method of claim 35, further comprising the step of alerting the subject's technician, clinician or physician of issues related to the therapy efficacy.

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REMARKS

In this case claims 21-47 are now pending (including new claims 41-49), and 35-40 are rejected. Claims 21-34 have been allowed. Claims 32, 35, 36, 37, 38 and 40have been amended. The Applicants respectfully traverse the rejections below.

The Applicants are filing an Amendment and Request for Continued Examination. With all due respect, this should not have been necessary as the Applicants amendments made in their July 12, 2021 amendment did not change the scope of the claims and were in response to the Examiner's claim objections and section 112 rejections and further comported with the Examiner's suggested modifications to the claims in his objection and rejection. The Examiner, however, has based much of his appeal reply brief not arguing the substantive rejections but rather in his mind that the Applicants appeals brief is arguing claim amendments he suggested but were then not admitted and thus deemed moot. Unfortunately the reason for the Applicants arguing these amendments in their response is because the Examiner never issued an Advisory Action Before the Filing of an Appeal Brief until September 23, 2021 – eleven days after the Applicants Appeal Brief was due and fourteen days after it was filed.

This being said – the Applicants will further attempt to narrow this case to make it even more clear that any of the disclosures of the art of record do not teach the presently claimed invention. Along with the filing of this new amendment the Applicants believe this now more clearly limits the present invention, the Applicants also are filing under MPEP 609.02 an information disclosure statement listing the references cited in continuing cases based on the parent case so the information can be printed with this patent should it issue based on the continuing applications.

By filing this Request for Continued Examination, the Applicants in effect, according to the rules, have withdrawn their appeal.

Claim Objections – Not Entered

Claim 32 was objected to for depending on Claim 33. The Applicants corrected this mistake and Claim 32 now depends on Claim 27.

Claim 35 was objected to for the term "an Internet". The Applicants have now amended the claim to read "the Internet".

This objection is now moot and the Applicants ask the Examiner to withdraw this rejection.

Claim Rejections – 35 U.S.C. § 112 – Not Entered

Claim 35 was rejected under 35 USC 112(a) or 35 USC 112(pre-AIA), first paragraph, as failing to comply with the written description requirement.

Due to the amendments to claim 35 this rejection is now moot, and asks the Examiner to withdraw this rejection.

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

The Examiner objects to the use of the term "retransmitting the data or information based on the data as well as the determined apnea events from either the PAP or CPAP device, or the cellular phone to a remote station via a cellular system or the Internet for review by a clinician, technician or physician."

The Applicants submit that this language is clear, but have suggested an amendment that might make this language clearer.

The Examiner further objects to the limitation "outputting apnea events determined by either the PAP or CPAP device, or the cellular phone using software provided for the cellular phone based on the data from the flow or pressure sensor on a display of the cellular phone for the subject to better understand the efficacy of the therapy". The Examiner object's to the term "better understand" as to the metes and bounds. The Applicants have changed the term to "see". The Applicants believe one skilled in the art would understand that by outputting the number of apnea events while undergoing therapy mean to eliminate such events to a subject's phone after therapy would alert the subject and better help them understand the efficacy of their last night's therapy.

The Examiner objects to the use of the term Bluetooth as it is a trademark in Claim 36. The Applicants would point out that Bluetooth is also understood to be a standard and have amended the claim to make this clear.

The Examiner objects to the antecedent basis for the term "the second time period" in Claim 38. This has been amended to read "a second time period".

The Applicants submit that their clarifying amendments overcome the 112 rejections, and request for withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 103

To provide legal context as well as an analytical framework for the remarks that follow, the Applicant wishes at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an assertion of *prima facie* obviousness the examiner must perform the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that "secondary considerations" such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, "the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis." MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the examiner errs in performing any of the *Graham* factual inquiries, the examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the examiner committing error in performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

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With specific regard to the examiner's obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Applicant would direct particular attention to the requirement that "[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill." *See* MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the examiner's burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an "indication of the level of ordinary skill," *MPEP 2141(II)(C)*, the examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the examiner in such a way as to render the claimed invention obvious. *See In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and examiner for failing to provide "any evidentiary support or reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant" and further noting that *KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* "did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references").

Thus, in order for the examiner to properly establish a *prima facie* case of obviousness the examiner must first make the factual inquiries required by *Graham* and, if relying on a combination of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the examiner falls short in meeting any of these requirements then the examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. *See In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) ("If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent"). As stated in

the United States Patent and Trademark Office's own rules, "[a] prima facie case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard..." *See* 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination "it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor" (emphasis added).

In all of the above, the Applicants wish to emphasize the high bar to which the examiner is held during the examination process and hereby respectfully request that in the ongoing prosecution of the present application that the examiner provide explicit and detailed analysis of any grounds of rejection relied upon. *See, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)* ("[an obviousness] analysis should be made explicit," citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

Claims 35 and 37 were previously rejected under pre-AIA 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rappaport et al ("Rappaport") in view of U.S. Pat. Pub. No. 2005/0222502 to Cooper ("Cooper"), and further in view of U.S. Pat. Pub. No. 2004/0073098 to Geva ("Geva") . The Applicants traverse and submit the claims as now amended overcome this rejection.

More specifically, with respect to Claim 35, Rappaport, Cooper or Geva alone or together do not teach nor disclose a method of treating a subject's sleep apnea comprising steps of providing a therapy to a subject using a PAP or CPAP device while sleeping, the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device; collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy; analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy; transmitting, in either order, both 1) the collected data, and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular

system, or b) the cellular phone via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and further determining the therapy efficacy data with either the processor of the PAP or CPAP device, the second processor or server configured with a second software at the remote station, or the cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider as claimed.

The self-adjusting or auto-titrating device in Rappaport, an example is shown in FIG. 18 and an example of the algorithm used by the device in FIG. 17, is then used to collect data as to determine how to alleviate apneas. The PAP device 86 has a flow sensor 72 and a pressure sensor 90. The data collected with these sensors is run through various electronics 76, 78, 80 on the PAP device and through an algorithm as shown in FIG. 17 through which the patient is tested at various flow pressures to determine whether the patients apnea(s) are alleviated. This data is then stored in memory 81. FIG. 22 shows the patient then returns the auto-PAP with the stored data 164. The stored data is then analyzed 166 to determine the proper set pressure for the patient 168. In Rappaport "[the] patient sleeps at home with the therapy device for the required number of nights…[and] returns the therapy device or its storage module for analysis of the stored data." This data (and this data alone) from the self-adjusting device is then used to adjust the PAP or CPAP device. The data from Rappaport is not shared with the patient let alone sent to the patients cellular phone or through a cellular system directly to a remote station as is the present invention.

Rappaport does not teach or disclose determining a quantified level of severity data based on the subject's sleep apnea symptoms rather the PAP in Rappaport indicates whether apnea(s) are alleviated at various pressures. Rappaport collects flow and pressure data 162 at these various pressures. Further, the apparatus in Rappaport needs to be returned by the patient to the remote location for the data to be downloaded and analyzed 164, rather than directly from the PAP or CPAP device through a cellular system or the first software provided for a cellular phone through the cellular system or the Internet. The data in Rappaport is then analyzed at the remote location to determine

the amount of flow limiting and apnea present 166. The present invention instead analyzes and provides a quantified level of severity of the subject's sleep apnea during treatment the PAP or CPAP device and from this the subject's therapy efficacy is determined. This data is then forwarded to the remote location either by the cellular phone or the PAP, and this quantified level of severity and/or the subject's therapy efficacy is displayed for the subject to better understand the efficacy of their treatment.

The Examiner refers to FIG. 17 and Col. 11, lines 38-47 as showing that Rappaport identifies apneas, however what Rapport says is this

> In addition, the detection of apneas is used to initiate the decision to raise the controlled positive pressure. If two apneas of a duration of ten seconds or longer occur within one minute, then the controlled positive pressure is raised. If one long apnea having a duration of twenty seconds or longer occurs, then the controlled positive pressure is raised. If an apparent apnea is associated with a very high leak flow implying a condition of mask disconnect, then the controlled positive pressure is returned to a predetermined or preset pressure.

Clearly Rappaport's teaching and disclosure relates to an automatic titration software or firmware on the PAP or CPAP device auto titration system. There is no evidence in Rappaport that these steps are reported to a remote station let alone on software used on a cellular phone, and furthermore the apnea identification in Rappaport is used to adjust the pressure of the PAP or CPAP device and not to report quantified level of severity data of the sleep disorder symptoms of a patient undergoing a set therapy and transmitting that data wirelessly through a cellular phone using a cellular system or from the PAP or CPAP itself to a remote station.

Cooper monitors various respiratory events by deriving these events from the signal on a pulse oximeter – not a pressure or flow sensor within a therapy device. In fact Cooper does not monitor flow or pressure on a therapy device such as a PAP or any therapy device for that matter. The apparatus in Cooper uses the cellular phone for data collection for diagnostics not to display information about efficacy of therapy to the patient carrying the cellular phone. Any apnea events in Cooper are derived from the pulse oximeter signal not from a flow or pressure sensor. The specific embodiment of the apparatus in Cooper for patient monitoring that the Examiner refers to is where the sensor is a photodiode, likely a pulse oximeter, where data is collected and "blood flow cycling

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with hypopnea and voltage transition characteristic of arousal peaks in the blood volume signal" are Examiner. This calculation can be performed either remotely or via a mobile phone processor. Clearly these calculations are not based on flow or pressure data. Also further, even if level of severity of the subject's symptoms were being calculated in Cooper – this is not being calculated while the subject is receiving therapy and even if it were the level of severity symptoms in the present invention are being determined by a processor on the therapy device whereas in Cooper it is being processed by at best by the cellular phone, which is its function in Cooper. Additional the Applicants point out again that the respiratory parameters are not used in Cooper for the patient to better understand the efficacy of a PAP or CPAP treatment. The respiratory events in Cooper are calculated and displayed after the data is transferred to a remote system for analysis so whomever is monitoring the system in Cooper can review it on a built in LCD screen or so an alarm is set off to warn those monitoring the patient. Clearly the respiratory events are not displayed on the cellular phone as alleged by the Examiner. The data in Cooper is further transferred to the remote system either wirelessly or by the removal and physical transfer of memory. There is no indication this is inherently accomplished via the Internet or a cellular system.

Geva, FIG. 30, on which para. 0294 (referenced by the Examiner) is based teaches an electrode system whereby the electrode (EKG) data is uploaded to a first cellular phone where the data may be pre-processed by software on the cellular phone, the data is then transferred to a remote server where it is fully processed and then afterwards send to a physicians cellular phone for review by a physician.

The present invention on the other hand collects pressure or flow data from a PAP device which is used to determine a quantified level of severity of the subject's symptoms and from that a measure of the efficacy of the therapy by looking, in part, quantified level of severity data that occur in the presence of the therapy. The quantified level of severity data of the subject's symptoms is determined by the processor of the PAP or the CPAP device, and that along with other data from the therapy are then sent on to a remote station for review by a clinician, technician or physician. The method of the present invention allows the data and quantified level of severity data to be passed directly to the remote station or through the cellular phone and the cellular phone is further used to

provide information to the subject or their care provider. This information is displayed for the subject to see the efficacy of their therapy. The present invention allows not only the patient but their clinicians to be aware of the efficacy of the patient's therapy as presently configured, and to adjust or titrate the therapy efficiently, quickly and remotely. The determination or calculation of these apnea events are performed on either the PAP device or the patient's cellular phone.

Nowhere in any of the references do they teach or disclose using flow or pressure sensors on a patient's PAP device for tracking the efficacy of the therapy and sharing that information with the patient on their cellular phone while at the same time sharing that information with the patient's clinician so the therapy can be adjusted if necessary, and doing so wirelessly, in real-time, through the Internet and/or cellular systems.

This Application was initially filed in 2005, and a CIP was filed in 2007. There was nothing like this using cellular phones, PAP therapy, cellular systems and the Internet at that time so it is clear the Examiner is using a hindsight approach with the Applicants claims as a roadmap and is not viewing the claims as a whole.

With respect to the method of claim 37, Rappaport, Cooper nor Geva teach or disclose wherein the therapy can be modified based in part on the wirelessly transmitted data or information as claimed. The Examiner relies on Rappaport for this teaching. The Examiner cites to the teaching on Col. 16, lines 47-56 of Rappaport which indicates that if the analysis determines that there are still a significant number of sleep-disordered breathing episodes during the night and the therapy devices does not restore normal breathing, then the patient is referred to a sleep lab for a more comprehensive study, step 160. One skilled in the art would understand this does not teach modifying therapy based on wirelessly transmitted information as set forth in claim 35.

In an attempt to explain the purported combination of these references, the Examiner merely makes a unsupported conclusory observations. The Applicants, however, remind the Examiner that these observations must be supported.

The Examiner states "Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the method of Rappaport to include "transmitting the data or information based on the data from the first sensor to

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a cellular phone; outputting the apnea events calculated using data from the first sensor on a display of the cellular phone as taught by Cooper." There is no rational basis for this argument. First and foremost since Cooper does not output the calculated data on a cellular phone available to the patient. Second, because obviously this is a hindsight analysis by the Examiner. The Examiner then states it would be obvious to combine Geva with Rappaport "to include the method step of retransmitting the data and transmitting the calculated apnea events wirelessly via a cellular system as taught by Geva in order to save the patient from excess travel and to quickly provide the physician with the patient's data." There is no rational basis for this argument as well. First, Geva does not retransmit the calculated apnea events from either the patient's cell phone or their therapy device as the present invention does. Instead Geva does the complete analysis of the subject's electrode data (diagnostic) at the remote station. Again this is clearly hindsight analysis where the Examiner is using the Applicants claims as a roadmap for his rejection. Clearly, the present invention displays the apnea events so the subject can understand the efficacy of their therapy and either forwards the data or transmits it from the PAP to a remote location so the subject's therapy provide can review the data and provide for therapy adjustment if necessary. Furthermore with the present invention this can all be done remotely without the need for the patient to return the PAP device for the data analysis and calculation.

Further, the Examiner has so far failed to explicitly define or establish the level of ordinary skill in the art, and none of the references adequately provides the level implicitly. As before, numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Rappaport, Geva and Cooper references? What are the similarities between the claimed invention and Rappaport, Geva and Cooper? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relies upon a conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to

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support his analysis of the Graham factors, but has failed to do so. The Applicants therefore respectfully request the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary skill in the art or to the Examiner's conclusions. The Applicants further suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and request that the Examiner therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which the rejection is based. *See* 37 C.F.R. § 1.104(d) (2).

The Applicants further respectfully submit that the Examiner has not given any valid teaching, suggestion, or motivation in or external to the references, or from the references cited as a whole, for the person of ordinary skill to have modified the reference of Rapoport to include the teachings of Cooper and Geva. The Applicants respectfully request that the Examiner either support the conclusions of motivation with references or, if such allegation is based on personal knowledge, provide an affidavit as to such including the factual underpinning for such conclusions. *See* 37 C.F.R. § 2144.03. In *re Eynde* states that "[t]he facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." *In re Eynde*, 480 F.2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973). Similarly, *KSR Int'l Co. v. Teleflex, Inc.* requires that "[obviousness] analysis should be made explicit." *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007). *KSR* goes on to explain that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning." It is often "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15.

Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Claim 36 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,299,581 to Rappaport et al ("Rappaport") in view of U.S. Pat. Pub. No. 2005/0222502 to Cooper ("Cooper"), and further in view of U.S. Pat. Pub. No.

2004/0073098 to Geva ("Geva"), as applied to claim 35 , in further view of U.S. Pat. Pub. 2003/0183226 to Brand ("Brand"). The Applicants traverse and submit the claim overcomes this rejection

The Applicants incorporate their above remards with respect to Rappaport, Cooper, and Geva.

With respect to Claim 36, Rappaport, Cooper, Geva nor Brand teach or disclose the method wherein the cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time as claimed. The Examiner cites to Brand for this teaching. However para. 0079 of Brand does not teach a wireless connection in real time as claimed, and Brand does not teach the communication of the type of data and its transmission as with the present invention. In Brand the data that is being transmitted is whether an respiratory inhaler is being used and what types and amounts of dosing is being provided to the patient. In the present invention the volume of data is significantly larger making it unlikely the communications system of Brand could be used for data transmission in the present invention.

In an attempt to explain the purported combination of these references, the Examiner merely makes a unsupported conclusory observations. The Applicants, however, remind the Examiner that these observations must be supported.

The Examiner states "Brand teaches Bluetooth standard is a known RF frequency communication means of a phone known to be used in conjunction with medical devices." There is no rational basis for this argument. The question is not whether Bluetooth can be shown to transfer data between medical devices and a cellular phone in real time, but rather whether Bluetooth standard can be used to transfer fairly large volumes of data between a PAP and a cellular phone in real time. If this was an invention for digitizing radiological images, which require very large volumes of data would Brand support this teaching for Bluetooth standard in real time. No. Similarly it does not support this combination of references being used to attack the present invention. Clearly this is a hindsight analysis by the Examiner where the Examiner is using the Applicants claims as a roadmap for his rejection.

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Further, the Examiner has so far failed to explicitly define or establish the level of ordinary skill in the art, and none of the references adequately provides the level implicitly. As before, numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Rappaport, Cooper, Geva and Brand references? What are the similarities between the claimed invention and Rappaport, Cooper, Geva and Brand? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relies upon a conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to support his analysis of the Graham factors, but has failed to do so. The Applicants therefore respectfully request the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary skill in the art or to the Examiner's conclusions. The Applicants further suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and request that the Examiner therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which the rejection is based. *See* 37 C.F.R. § 1.104(d) (2).

The Applicants further respectfully submit that the Examiner has not given any valid teaching, suggestion, or motivation in or external to the references, or from the references cited as a whole, for the person of ordinary skill to have modified the reference of Rapoport to include the teachings of Cooper, Geva and Brand. The Applicants respectfully request that the Examiner either support the conclusions of motivation with references or, if such allegation is based on personal knowledge, provide an affidavit as to such including the factual underpinning for such conclusions. *See* 37 C.F.R. § 2144.03. In *re Eynde* states that "[t]he facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." *In re Eynde*, 480 F.2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973). Similarly, *KSR Int'l Co. v. Teleflex, Inc.*

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requires that "[obviousness] analysis should be made explicit." *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007). *KSR* goes on to explain that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning." It is often "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15.

Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Claim 38 was rejected under pre-AIA 35 USC 103(a) as being unpatentable over Rappaport in view of Cooper, and Geva, as applied to claim 35, in view of U.S. Pat. No. 5,953713 to Behbehani ("Behbehani"). The Applicants traverse and submit the claim overcomes this rejection.

The Applicants incorporate their above remarks with respect to Rappaport, Cooper and Geva. Given the above comments, the Applicants request that the Examiner withdraw this rejection.

Claims 39 and 40 were rejected under pre-AIA 35 USC 103(a) as being unpatentable over Rappaport in view of Cooper, and Geva, as applied to claim 35, in view of U.S. Pat. No. 6,349,724 to Burton ("Burton"). The Applicants traverse and submit the claim overcomes this rejection.

The Applicants incorporate their above remarks with respect to Rappaport, Cooper and Geva. The Examiner relies on Burton for the teachings of the limitations of Claims 39 and 40. Burton, however, does not teach or disclose the method of claim 35, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician as claimed, or wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician as claimed.

Burton uses various sensors for diagnosis or long term studies, or for alerting a health care worker about the patient's condition requiring immediate action. That,

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however, is not the same as real-time adjustment of a PAP by the technician, clinician or physician in real-time who are viewing the data at a remote location or station.

The Examiner points to a number of teachings in Burton for titrating a patient through a wireless connection. In Col. 2, lines 13-15 of Burton it teaches that data may be sent to a remote site by "telemetry, telephony or by mailing the data card." The Examiner further points to Col. 7, lines 18-28 of Burton which states "[t]he ramp times, ramp delay times and other parameters can be programmed into the controller/microprocessor 82 by means of information stored on a data card 210 inserted into a data card port 115. Alternatively the microprocessor may be programmed by a computer 200…the computer may be remotely located at a hospital or sleep clinic and connected through the internet by wire or wireless phone systems or positioned adjacent the dual pressure gas delivery device."

This however is not the same wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician. Burton teaches of reprogramming the PAP by a number of means but particularly the "ramp times", and "ramp delay times". These are comfort settings that allow the therapy not to be as intrusive and can allow the therapy to start after the patient falls asleep – not the therapy itself. This is not adjusting or titrating the therapy. This further is being done by a computer and not by a "clinician, technician or physician at a remote location".

Given the above comments, the Applicants request that the Examiner withdraw this rejection.

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Page 314

Conclusion

Given the reasons set forth above, the Applicants request the Examiner withdraw the above rejections. For all the above reasons the Applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

August 19, 2022
Dated

/Brian M. Kolkowski/

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PTO/SB/08a (01-22)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15641715
Filing Date	2017-07-05
First Named Inventor	Hani Kayyali
Art Unit	3785
Examiner Name	Ned Heffner
Attorney Docket Number	CMD-101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5353788		1994-10-11	Laughton Miles	
	2	5704345		1998-01-06	Michael Berthon-Jones	
	3	6475153	B1	2002-11-05	Khair et al.	
	4	6533729	B1	2003-03-18	Khair et al.	
	5	7942824	B1	2011-05-17	Kayyali et al.	
	6	8069852	B2	2011-12-06	Burton et al.	
	7	8308641	B2	2012-11-13	Moroney, III et al.	
	8	8356594	B2	2013-01-22	Ujhazy et al.	

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	First Named Inventor	Hani Kayyali
	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	9	8365730	B2	2013-02-05	Baker, Jr. et al.	
	10	8545416	B1	2013-10-01	Kayyali et al.	
	11	5237990		1993-08-24	Psaros et al.	
	12	7757690	B2	2010-07-20	Stahmann et al.	
	13	5645043		1997-07-08	Long et al.	
	14	5961447		1999-10-05	Raviv et al.	
	15	6029664		2000-02-29	Zdrojkowski et al.	
	16	6138675		2000-10-31	Michael Berthon-Jones	
	17	6229581	B1	2001-05-08	Yamamoto et al.	
	18	6431171	B1	2002-08-13	Burton et al.	
	19	6551252	B2	2003-04-22	Sackner et al.	

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	First Named Inventor	Hani Kayyali
	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	20	6832609	B2	2004-12-21	Wright et al.	
	21	6889691	B2	2005-05-10	Eklund et al.	
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	23	7190995	B2	2007-03-13	Chervin et al.	
	24	7195013	B2	2007-03-27	Keith G. Lurie	
	25	7204250	B1	2007-04-17	David Burton	
	26	7225809	B1	2007-06-05	Bowen et al.	
	27	7309314	B2	2007-12-18	Grant et al.	
	28	7575005	B2	2009-08-18	Mumford et al.	
	29	7662101	B2	2010-02-16	Lee et al.	
	30	7668579	B2	2010-02-23	Lawrence A. Lynn	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	31	7670295	B2	2010-03-02	Sackner et al.	
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	33	8172766	B1	2012-05-08	Kayyali et al.	
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	37	6532959	B1	2003-03-18	Michael Berthon-Jones	
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	39	6336454	B1	2002-01-08	Farrell et al.	
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	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020032386	A1	2002-03-14	Sackner et al.	
	2	20030135127	A1	2003-07-17	Sackner et al.	
	3	20040116784	A1	2004-06-17	Benjamin Gavish	
	4	20040200474	A1	2004-10-14	Keith G. Lurie	
	5	20060042627	A1	2006-03-02	MacMillan et al.	
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	Attorney Docket Number	CMD-101

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	15	20100043795	A1	2010-02-25	Ujhazy et al.	
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	19	20040138576	A1	2004-07-15	Wright et al.	
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	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	21	20040254493	A1	2004-12-16	Chervin et al.	
	22	20050081847	A1	2005-04-21	Lee et al.	
	23	20050085738	A1	2005-04-21	Stahmann et al.	
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	25	20050165323	A1	2005-07-28	Montgomery et al.	
	26	20050188991	A1	2005-09-01	Sun et al.	
	27	20050217674	A1	2005-10-06	Burton et al.	
	28	20050268916	A1	2005-12-08	Mumford et al.	
	29	20060084877	A1	2006-04-20	Ujhazy et al.	
	30	20060247546	A1	2006-11-02	Kazuo Imose	
	31	20040210153	A1	2004-12-21	Tsukashima et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15641715
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First Named Inventor	Hani Kayyali
Art Unit	3785
Examiner Name	Ned Heffner
Attorney Docket Number	CMD-101

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Brian Kolkowski/	Date (YYYY-MM-DD)	2022-08-19
Name/Print	Brian Kolkowski	Registration Number	36847

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I20228MC52532800	2202	CLAIMS IN EXCESS OF 20	$450.00	Deposit Account

Electronic Patent Application Fee Transmittal

Application Number:	15641715
Filing Date:	05-Jul-2017
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	2202	9	50	450
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**450**

Electronic Acknowledgement Receipt

EFS ID:	46466223
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	23-AUG-2022
Filing Date:	05-JUL-2017
Time Stamp:	13:19:28
Application Type:	Utility under 35 USC 111(a)

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

CPC								
Symbol							**Type**	**Version**
A61B	/	5	/	4818			F	2013-01-01
A61M	/	16	/	00			I	2013-01-01
A61M	/	16	/	0003			I	2014-02-04
A61B	/	5	/	4836			I	2013-01-01
A61B	/	5	/	08			I	2013-01-01
A61B	/	5	/	02			A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	09 March 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	5	/	02	
A61B	/	5	/	08	

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	09 March 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

U.S. Patent and Trademark Office

Part of Paper No.: 20230313

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	21	10	30	19	39	28	48								
2	22	11	31	20	40	29	49								
3	23	12	32	21	41										
4	24	13	33	22	42										
5	25	14	34	23	43										
6	26	15	35	24	44										
7	27	16	36	25	45										
8	28	17	37	26	46										
9	29	18	38	27	47										

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791 (Primary Examiner)	09 March 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 8

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61M 16/00; 16/0003	08/14/2020	Charles Vivian
A61B 5/4818; 5/4836	08/14/2020	Charles Vivian
A61M 16/00; 16/0003	03/24/2021	MS
A61B 5/4818; 5/4836	03/24/2021	MS
A61B5/4818 or A61B5/08 or A61B5/4836 or A61M16/00 or A61M16/0003 or A61B5/02	03/03/2023	/NN/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
128	204.23	08/14/2020	Charles Vivian
600	529-543	03/03/2023	/NN/

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

/MATTHEW STANDARD/ Examiner, Art Unit 3785	/N.N/ Primary Examiner, Art Unit 3791

ResMed Corp. - Ex. 1002
Page 334

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3791

Search Notes		
Search Notes	**Date**	**Examiner**
Inventor Name Search	08/14/2020	Charles Vivian
Keyword search terms: cell, cellular, mobile, phone, telephone, smartphone	08/14/2020	Charles Vivian
Updated Inventor and Applicant search	03/17/2021	MS
See EAST search history	03/24/2021	MS
SEARCH (attached): US-PGPUB, USPAT, USOCR, FIT, FPRS, EPO , JPO, Derwent, IBM_TDB, Keyword, Inventor, Applicant, IDS, Forward/Backward Citation, USPC, CPC, Interference searches	03/03/2023	/NN/

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	A61B5/4818 or A61B5/08 or A61B5/4836 or A61M16/00 or A61M16/0003 or A61B5/02	03/09/2023	/NN/

/MATTHEW STANDARD/ Examiner, Art Unit 3785	/N.N/ Primary Examiner, Art Unit 3791

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Page 335

Bibliographic Data

Application No: 15/641,715

Foreign Priority claimed: ○ Yes ◉ No

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

Verified and Acknowledged: /NAVIN NATNITHITHADHA/ Examiner's Signature | /NN/ Initials

Title: Integrated Sleep Diagnostic and Therapeutic System and Method

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/05/2017	128	3791	CMD-101
RULE			

APPLICANTS

INVENTORS

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Dan Bishop, Tallmadge, OH, UNITED STATES

Brian M. Kolkowski, Leroy, OH, UNITED STATES

CONTINUING DATA

This application is a CON of 13074901 03/29/2011 PAT 9730632

13074901 is a CON of 11879934 07/19/2007 PAT 7942824

11879934 is a CIP of 11266899 11/04/2005 PAT 8172766

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

07/13/2017

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

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Cleveland Medical Devices Inc.

4415 Euclid Ave. Ste. 500

Cleveland, OH 44103

UNITED STATES

FILING FEE RECEIVED

$730

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L324	55	((("KAYYALI") near3 ("Hani")) OR (("BISHOP") near3 ("Dan")) OR (("KOLKOWSKI") near3 ("Brian"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:33 AM
L325	122205	(A61B5/4818 OR A61B5/08 OR A61B5/4836 OR A61M16/00 OR A61M16/0003 OR A61B5/02).cpc. OR (600/528-543).CCLS.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:33 AM
L326	5	("20050217674"|"5645043"|"6029664"|"6138675"|"6229581").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L327	20	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		5645043-$ or US-6431171-$ or US-7204250-$).did.					
L328	0	(quantitative$3) AND (realtime OR (real ADJ2 time)) AND L14	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L329	7	(realtime OR (real ADJ2 time)) AND L14	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L330	4	(quantitative$3) AND L14	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L331	5	("20050217674"|"5645043"|"6029664"|"6138675"|"6229581").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L332	20	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L333	15	L19 NOT L18	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L334	107	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) SAME (adjust$4 OR control$4 OR regulat$4 OR chang$3)) AND ((respir$6 OR breath$3 OR thorac$3 OR chest OR lung OR breast OR torso OR abdom$5) WITH (belt OR strap OR vest OR garment OR cloth$3)) AND ((pulse OR oximet$4 OR oxymet$4) WITH (sensor$3 OR sensing OR measur$6 OR detect$5 OR monitor$3	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		OR transducer OR probe)) AND (sleep$3 WITH (disorder OR condition OR disease OR illness OR apne$3 OR symptom)) AND ((600/529-543,484) OR ("128"/$)).ccls.					
L335	107	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) SAME (adjust$4 OR control$4 OR regulat$4 OR chang$3)) AND ((pulse OR oximet$4 OR oxymet$4) WITH (sensor$3 OR sensing OR measur$6 OR detect$5 OR monitor$3 OR transducer OR probe)) AND L21	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L336	109	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH (adjust$4 OR control$4 OR regulat$4 OR chang$3)) AND ((respir$6 OR breath$3 OR thorac$3 OR chest OR lung OR breast OR torso OR abdom$5) SAME (belt OR strap OR vest OR garment OR cloth$3)) AND ((pulse OR oximet$4 OR oxymet$4 OR saturation) WITH (sensor$3 OR sensing OR measur$6 OR detect$5 OR monitor$3 OR transducer OR probe)) AND (sleep$3 WITH (disorder OR condition OR disease OR illness OR apne$3 OR symptom)) AND ((600/529-543,484) OR ("128"/$)).ccls.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L337	109	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		(adjust$4 OR control$4 OR regulat$4 OR chang$3)) AND ((pulse OR oximet$4 OR oxymet$4 OR saturation) WITH (sensor$3 OR sensing OR measur$6 OR detect$5 OR monitor$3 OR transducer OR probe)) AND (sleep$3 WITH (disorder OR condition OR disease OR illness OR apne$3 OR symptom)) AND L26					
L338	1	(US-20050115561-$).did.	(US-PGPUB)	OR	ON	ON	2023/03/09 08:34 AM
L339	1	L28 AND ((respir$6 OR breath$3 OR thorac$3 OR chest OR lung OR breast OR torso OR abdom$5) SAME (belt OR strap OR vest OR garment OR cloth$3))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L340	1	L28 AND ((respir$6 OR breath$3 OR thorac$3 OR chest OR lung OR breast OR torso OR abdom$5) WITH (sensor$3 OR sensing OR detector OR probe OR monitor OR transducer))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L341	1	(US-20050115561-$).did.	(US-PGPUB)	OR	ON	ON	2023/03/09 08:34 AM
L342	1	L31 AND ((pulse OR oximet$4 OR oxymet$4 OR saturation) WITH (sensor$3 OR sensing OR measur$6 OR detect$5 OR monitor$3 OR transducer OR probe))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L343	1	L31 AND (realtime OR (real ADJ2 time))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L344	1	L31 AND (wireless$3 OR transmi$6 OR transceiver OR communicat$5)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L345	1	L31 AND (wireless$3)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L346	1	L31 AND ("EEG" OR electroenceph$ OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		brain OR brainwave$5)					
L347	1	L31 AND ("ECG" OR "EKG" OR electrocardiograph$)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L348	5	("20050217674"|"5645043"|"6029664"|"6138675"|"6229581").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L349	35	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$ or US-20020032386-$ or US-20030135127-$ or US-20050197588-$ or US-20060042627-$ or US-20060070624-$ or US-20070209662-$ or US-20040200474-$ or US-20050115561-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$ or US-6551252-$ or US-7225809-$ or US-7670295-$ or US-5961447-$ or US-7195013-$ or US-7309314-$ or US-7668579-$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L350	18	("20030000528"|"20040163648"|"20040254493"|"20050081847"|"20050165323"|"20050217674"|"20050268916"|"20050188991"|"20060247546"|"5645043"|"6029664"|"6138675"|"6229581"|"6431171"|"6889691"|"7190995"|"7204250"|"7575005").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L351	18	L39 NOT L40	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM

L352	27	("20030000528"|"20040163648"|"20040254493"|"20050081847"|"20050085738"|"20050115561"|"20050165323"|"20050217674"|"20050268916"|"20050188991"|"20060247546"|"5645043"|"5961447"|"6029664"|"6138675"|"6229581"|"6431171"|"6551252"|"6889691"|"7190995"|"7195013"|"7204250"|"7225809"|"7309314"|"7575005"|"7668579"|"7670295").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L353	35	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$ or US-20020032386-$ or US-20030135127-$ or US-20050197588-$ or US-20060042627-$ or US-20060070624-$ or US-20070209662-$ or US-20040200474-$ or US-20050115561-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$ or US-6551252-$ or US-7225809-$ or US-7670295-$ or US-5961447-$ or US-7195013-$ or US-7309314-$ or US-7668579-$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L354	36	L42 OR L43	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L355	27	("20030000528"|"20040163648"|"20040254493"|"20050081847"|"20050085738"|"2005011556	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM

		1"|"20050165323"|"20050217674"|"20050268916"|"20050188991"|"20060247546"|"5645043"|"5961447"|"6029664"|"6138675"|"6229581"|"6431171"|"6551252"|"6889691"|"7190995"|"7195013"|"7204250"|"7225809"|"7309314"|"7575005"|"7668579"|"7670295").PN.					
L356	35	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$ or US-20020032386-$ or US-20030135127-$ or US-20050197588-$ or US-20060042627-$ or US-20060070624-$ or US-20070209662-$ or US-20040200474-$ or US-20050115561-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$ or US-6551252-$ or US-7225809-$ or US-7670295-$ or US-5961447-$ or US-7195013-$ or US-7309314-$ or US-7668579-$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L357	36	L45 OR L46	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L358	30	L47 AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND ("CPAP" OR "PAP" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		(positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND (pulse OR pulsewave$5 OR oximet$4 OR oxymet$4) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6) WITH (belt OR strap OR piezoelect$5 OR sensor$3 OR sensing OR transducer OR electrode OR detect$4 OR biosensor$3 OR biosensing OR biotransducer OR bioelectrode OR biodetect$4))					
L359	30	L48 AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6) WITH (belt OR strap OR piezoelect$5 OR sensor$3 OR sensing OR transducer OR electrode OR detect$4 OR biosensor$3 OR biosensing OR biotransducer OR bioelectrode OR biodetect$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L360	0	(("600"/$) OR ("128"/$)).ccls. AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND (pulse OR pulsewave$5 OR oximet$4 OR oxymet$4) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6) SAME (belt OR strap OR piezoelect$5))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L361	0	(("600"/$) OR ("128"/$)).ccls. AND (sleep$4 WITH	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		(disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6) SAME (belt OR strap OR piezoelect$5))					
L362	0	(("600"/$) OR ("128"/$)).ccls. AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand$3 OR compress$4) SAME (belt OR strap OR piezoelect$5))					
L363	0	L52 AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand$3 OR compress$4) SAME (belt OR strap OR piezoelect$5))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L364	0	(("600"/$) OR ("128"/$)).ccls. AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		oxymet$4) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand$3 OR compress$4) SAME (belt OR strap OR piezoelect$5))					
L365	0	L54 AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand$3 OR compress$4) SAME (belt OR strap OR piezoelect$5))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

L366	0	(("600"/$) OR ("128"/$)).ccls. AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND ((("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) SAME (pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) SAME (respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand$3 OR compress$4) SAME (belt OR strap OR piezoelect$5))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L367	0	L56 AND ((("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) SAME (pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) SAME (respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (movement OR moving OR motion OR expansion OR expand$3 OR compress$4) SAME (belt OR strap OR piezoelect$5))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

L368	13	L47 AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L369	0	(("600"/$) OR ("128"/$)).ccls. AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5 OR vest OR band))					
L370	0	L59 AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5 OR vest OR band))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L371	45	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$ or US-20020032386-$ or US-20030135127-$ or US-20050197588-$ or US-20060042627-$ or US-20060070624-$ or US-20070209662-$ or	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		US-20040200474-$ or US-20050115561-$ or US-20080269583-$ or US-20080066753-$ or US-20070161913-$ or US-20070135724-$ or US-20060135878-$ or US-20060084877-$ or US-20040138576-$).did. or (US-20020185130-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$ or US-6551252-$ or US-7225809-$ or US-7670295-$ or US-5961447-$ or US-7195013-$ or US-7309314-$ or US-7668579-$ or US-7018341-$ or US-6832609-$).did.					
L372	26	((diagnosis OR diagnose OR diagnosing OR sever$6 OR evaluat$5 OR output$5) WITH sleep$4 WITH (disorder OR symptoms OR abnormal$5 OR illness OR apnea OR apneic OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND L61	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L373	37	(transmi$6 OR transceiv$5 OR wireless$3 OR radio OR radiofrequenc$3 OR antenna OR telemet$4) AND L61	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L374	18	((transmi$6 OR transceiv$5 OR wireless$3 OR radio OR radiofrequenc$3 OR antenna OR telemet$4) SAME ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		ventilation OR ventilator OR respirator)) AND L61					
L375	0	(("600"/$) OR ("128"/$)).ccls. AND ((transmi$6 OR transceiv$5 OR wireless$3 OR radio OR radiofrequenc$3 OR antenna OR telemet$4) SAME ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND (adjust$6 OR regulat$5 OR control$5 OR set$5)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L376	0	(("600"/$) OR ("128"/$)).ccls. AND ((transmi$6 OR transceiv$5 OR wireless$3 OR radio OR radiofrequenc$3 OR antenna OR telemet$4) SAME ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND (adjust$6 OR regulat$5 OR control$5 OR set$5)AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5 OR vest OR band))					
L377	0	(("600"/$) OR ("128"/$)).ccls. AND ((transmi$6 OR transceiv$5 OR wireless$3 OR radio OR radiofrequenc$3 OR antenna OR telemet$4) SAME ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND (sleep$4 WITH (disorder OR abnormal$5 OR apne$4 OR hypoapne$5 OR hyperapne$5 OR illness OR disease OR condition$3)) AND (adjust$6 OR regulat$5 OR control$5 OR set$5) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5 OR vest OR band))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L378	0	L67 AND ((transmi$6	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09

		OR transceiv$5 OR wireless$3 OR radio OR radiofrequenc$3 OR antenna OR telemet$4) SAME ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5 OR vest OR band))					08:34 AM
L379	0	L67 AND ((transmi$6 OR transceiv$5 OR wireless$3 OR radio OR radiofrequenc$3 OR antenna OR telemet$4) SAME ("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L380	0	(("600"/$) OR ("128"/$)).ccls. AND (("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		(belt OR strap OR piezoelect$5))					
L381	0	(("600"/$) OR ("128"/$)).ccls. AND ((("CPAP" OR "PAP" OR (positiv$4 ADJ2 airway ADJ2 pressure) OR ventilation OR ventilator OR respirator) WITH (adjust$6 OR regulat$5 OR control$5 OR set$5)) AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5 OR vest OR band))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L382	0	L71 AND ((pulse OR pulsewave$5 OR oximet$4 OR oxymet$4 OR saturation) WITH (detect$5 OR sensor$3 OR sensing OR transducer OR meter$3 OR probe OR monitor$3 OR biodetect$5 OR biosensor$3 OR biosensing OR biotransducer OR biometer$3)) AND ((respir$6 OR breath$3 OR exhal$6 OR expir$6 OR pulmonar$3 OR lung OR chest OR torso OR abdomen) SAME (belt OR strap OR piezoelect$5 OR vest OR band))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L383	1	("20020185130").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

L384	27	("20030000528"|"20040163648"|"20040254493"|"20050081847"|"20050085738"|"20050115561"|"20050165323"|"20050217674"|"20050268916"|"20050188991"|"20060247546"|"5645043"|"5961447"|"6029664"|"6138675"|"6229581"|"6431171"|"6551252"|"6889691"|"7190995"|"7195013"|"7204250"|"7225809"|"7309314"|"7575005"|"7668579"|"7670295").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L385	15	((jonathan NEAR2 wright) OR (anthony NEAR2 ujhazy)).inv. AND CPAP AND pulse AND (respiratory ADJ2 movement)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L386	15	L75 AND (sleep$3 WITH (disorder OR symptom OR condition OR illness))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L387	0	L75 AND (realtime OR (real ADJ2 time))	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L388	15	L75 AND (nebuliz$3 OR medication OR medicine OR drug OR agent)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L389	50	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$ or US-20020032386-$ or US-20030135127-$ or US-20050197588-$ or US-20060042627-$ or US-20060070624-$ or US-20070209662-$ or US-20040200474-$ or US-20050115561-$ or US-20080269583-$ or US-20080066753-$ or US-20070161913-$ or US-20070135724-$ or US-20060135878-$ or	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		US-20060084877-$ or US-20040138576-$).did. or (US-20020185130-$ or US-20040116784-$ or US-20100043795-$ or US-20100258126-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$ or US-6551252-$ or US-7225809-$ or US-7670295-$ or US-5961447-$ or US-7195013-$ or US-7309314-$ or US-7668579-$ or US-7018341-$ or US-6832609-$ or US-7662101-$ or US-7878198-$).did.					
L390	24	L79 NOT L74	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L391	50	(US-20080276939-$ or US-20080257349-$ or US-20060247546-$ or US-20050268916-$ or US-20050165323-$ or US-20040254493-$ or US-20040163648-$ or US-20050217674-$ or US-20030000528-$ or US-20050081847-$ or US-20050085738-$ or US-20020032386-$ or US-20030135127-$ or US-20050197588-$ or US-20060042627-$ or US-20060070624-$ or US-20070209662-$ or US-20040200474-$ or US-20050115561-$ or US-20080269583-$ or US-20080066753-$ or US-20070161913-$ or US-20070135724-$ or US-20060135878-$ or US-20060084877-$ or US-20040138576-$).did. or (US-20020185130-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		20040116784-$ or US-20100043795-$ or US-20100258126-$).did. or (US-7575005-$ or US-7190995-$ or US-6889691-$ or US-6229581-$ or US-6138675-$ or US-6029664-$ or US-5645043-$ or US-6431171-$ or US-7204250-$ or US-6551252-$ or US-7225809-$ or US-7670295-$ or US-5961447-$ or US-7195013-$ or US-7309314-$ or US-7668579-$ or US-7018341-$ or US-6832609-$ or US-7662101-$ or US-7878198-$).did.					
L392	34	("20020185130"|"20030000528"|"20040138576"|"20040163648"|"20040254493"|"20050081847"|"20050085738"|"20050115561"|"20050165323"|"20050217674"|"20050268916"|"20050188991"|"20060084877"|"20060247546"|"5645043"|"5961447"|"6029664"|"6138675"|"6229581"|"6431171"|"6551252"|"6832609"|"6889691"|"7018341"|"7190995"|"7195013"|"7204250"|"7225809"|"7309314"|"7575005"|"7662101"|"7668579"|"7670295"|"7878198"). PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L393	51	L81 OR L82	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/03/09 08:34 AM
L394	32	((severit$4 OR level OR depth OR stag$3) WITH (apne$4 OR hypopne$5 OR hypoapne$5 OR hyperapne$5)) AND L83	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L395	31	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		(adjust$4 OR control$4 OR regulat$4 OR chang$3)) SAME (signal$3 OR data OR sens$5 OR information OR parameter)) AND (apne$4 OR hypopne$5 OR hypoapne$5 OR hyperapne$5) AND L83					
L396	31	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH (adjust$4 OR control$4 OR regulat$4 OR chang$3)) SAME (signal$3 OR data OR sens$5 OR information OR parameter)) AND L85	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L397	10	((("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) WITH (adjust$4 OR control$4 OR regulat$4 OR chang$3)) SAME (signal$3 OR data OR sens$5 OR information OR parameter)) AND ((apne$4 OR hypopne$5 OR hypoapne$5 OR hyperapne$5) WITH (index OR indices)) AND L83	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L398	6	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) SAME ((radio OR radiofrequenc$3 OR "RF" OR wireless$3) WITH (transmi$6 OR transceiv$3 OR telemet$5 OR communicat$5 OR receiv$3 OR antenna))) AND L83	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L399	0	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		respirator) SAME ((radio OR radiofrequenc$3 OR "RF" OR wireless$3) WITH (transmi$6 OR transceiv$3 OR telemet$5 OR communicat$5 OR receiv$3 OR antenna)) SAME acquistion) AND (600/484,529-543).ccls.					
L400	181	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) SAME ((radio OR radiofrequenc$3 OR "RF" OR wireless$3) WITH (transmi$6 OR transceiv$3 OR telemet$5 OR communicat$5 OR receiv$3 OR antenna))) AND (apne$4 OR hypopne$5 OR hypoapne$5 OR hyperapne$5) AND ((600/484,529-543) OR (128/204.21-204.26)).ccls.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L401	181	(("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) SAME ((radio OR radiofrequenc$3 OR "RF" OR wireless$3) WITH (transmi$6 OR transceiv$3 OR telemet$5 OR communicat$5 OR receiv$3 OR antenna))) AND L90	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L402	46	("10076269"|"10543328"|"20020185130"|"20040138576"|"20040163648"|"20040210153"|"20040254493"|"20050085738"|"20050115561"|"20050217674"|"20050268916"|"20060042627"|"20060084877"|"20060135878"|"20070135724"|"20070161913"|"20070209662"|"20080066753"|	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

		"20080257349"|"20080276939"|"20100043795"|"20100258126"|"5353788"|"5704345"|"5803078"|"6138675"|"6152129"|"6336454"|"6431171"|"6532957"|"6532959"|"6832609"|"7018341"|"7190995"|"7204250"|"7225809"|"7575005"|"7662101"|"7757690"|"7878198"|"7942824"|"8069852"|"8172766"|"8356594"|"8545416"|"9533114").PN.					
L403	165115	(A61B5/085 or A61B5/4815 or A61B5/02055 or A61M16/0051 or A61M16/0069 or A61M2016/0027 or A61M2016/0039 or A61M2202/0208 or A61M2205/3553 or A61M2205/3561 or A61M2205/3584 or A61M2205/3592 or A61M2230/04 or A61M2230/10 or A61M2230/14 or A61M2230/202 or A61M2230/205 or A61M2230/60).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L404	7	"20070161913"	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L405	1	("20070161913").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L406	0	L182 AND (phone OR cellular OR (base adj2 station) OR "PDA" OR telephone)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L407	1	L182 AND (software OR program$5 OR algorithm$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM

L408	1	("20080257349").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L409	0	((cell OR cellular OR phone OR telephon$5) SAME (chip OR card)) AND L185	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L410	0	((cell OR cellular OR phone OR telephon$5)) AND L185	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L411	0	((cell OR cellular OR phone OR telephon$5 OR SIM) NEAR5 card) AND L70	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L412	7212	((KAYYALI NEAR2 HANI) OR (SCHMIDT NEAR2 ROBERT) OR ((("MODARRES-ZADEH") OR (MODARRES ADJ2 ZADEH)) NEAR2 MOHAMMAD) OR (KOLKOWSKI NEAR2 BRIAN)).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT)	OR	OFF	OFF	2023/03/09 08:34 AM
L413	20	L189 AND (cellular NEAR5 card)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L414	132	L180 AND (cellular NEAR5 card)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM

L415	39	("CPAP" OR "PAP" OR (positive ADJ2 airway ADJ2 pressure) OR ventilat$4 OR respirator) AND (((sleep$3 NEAR8 (disorder OR illness OR condition OR obstructi$4)) OR apne$3 OR hypoapne$3 OR hyperapne$3 OR hypopne$3) SAME (treat$5 OR therap$6)) AND ((cell OR cellular) NEAR5 card)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L416	39	L192 AND ((cell OR cellular) NEAR5 card)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L417	2	("8172766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L418	0	L194 AND ((cell OR cellular) NEAR5 card)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L419	3	("8545416").pn.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L420	1	("8545416").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L421	1	((US-20070155208-	(US-PGPUB)	OR	ON	ON	2023/03/09

		A1).did. AND PGPB.dbnm.)					08:34 AM
L422	1	L198 AND ((cell OR cellular OR SIM) NEAR5 card)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L423	53	((US-20070135724-A1 OR US-20060042627-A1 OR US-20060070624-A1 OR US-20070209662-A1 OR US-20040200474-A1 OR US-20050115561-A1 OR US-20080269583-A1 OR US-20080066753-A1 OR US-20070161913-A1 OR US-20080257349-A1 OR US-20060135878-A1 OR US-20060084877-A1 OR US-20040138576-A1 OR US-20020185130-A1 OR US-20040116784-A1 OR US-20100043795-A1 OR US-20100258126-A1 OR US-20030135127-A1 OR US-20080276939-A1 OR US-20060247546-A1 OR US-20050268916-A1 OR US-20050165323-A1 OR US-20040254493-A1 OR US-20040163648-A1 OR US-20050217674-A1 OR US-20030000528-A1 OR US-20050081847-A1 OR US-20050085738-A1 OR US-20020032386-A1 OR US-20050197588-A1 OR US-20070155208-A1).did. AND PGPB.dbnm.) OR ((US-5961447-A OR US-7195013-B2 OR US-7309314-B2 OR US-7668579-B2 OR US-7018341-B2 OR US-6832609-B2 OR US-7662101-B2 OR US-7878198-B2 OR US-7575005-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM

		7190995-B2 OR US-6889691-B2 OR US-6229581-B1 OR US-6138675-A OR US-6029664-A OR US-5645043-A OR US-6431171-B1 OR US-7204250-B1 OR US-6551252-B2 OR US-7225809-B1 OR US-7670295-B2 OR US-8172766-B1).did. AND USPT.dbnm.) OR ((US-8172766-B1).did. AND DWPI.dbnm.)					
L424	7	"20070161913"	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/09 08:34 AM
L425	7	L201 AND (program OR software OR algorithm)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L426	7	L201 AND (display)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L427	3	L201 AND (cellphone OR phone OR telehpone)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2023/03/09 08:34 AM

			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L428	1	((US-20070155208-A1).did. AND PGPB.dbnm.)	(US-PGPUB)	OR	ON	ON	2023/03/09 08:34 AM
L429	1	L205 AND ((cellphone OR phone) SAME (display))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L430	1	L205 AND ((cellphone OR phone) AND (display))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/09 08:34 AM
L431	536	(((severity NEAR5 symptom) OR ((efficacy OR affective$4) NEAR5 (therap$6 OR treatment OR treat$3))) WITH (display$3 OR screen OR output$4)) AND (L403 OR L325)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK,	OR	ON	ON	2023/03/09 10:36 AM

			TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L432	282	(((severity NEAR5 symptom) OR ((efficacy OR affective$4) NEAR5 (therap$6 OR treatment OR treat$3))) WITH (display$3 OR screen OR output$4)) AND (L403 OR L325)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/03/09 10:36 AM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

PTO/SB/08a (01-22)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15641715
Filing Date	2017-07-05
First Named Inventor	Hani Kayyali
Art Unit	3785
Examiner Name	Ned Heffner
Attorney Docket Number	CMD-101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5353788		1994-10-11	Laughton Miles	
	2	5704345		1998-01-06	Michael Berthon-Jones	
	3	6475153	B1	2002-11-05	Khair et al.	
	4	6533729	B1	2003-03-18	Khair et al.	
	5	7942824	B1	2011-05-17	Kayyali et al.	
	6	8069852	B2	2011-12-06	Burton et al.	
	7	8308641	B2	2012-11-13	Moroney, III et al.	
	8	8356594	B2	2013-01-22	Ujhazy et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Hani Kayyali
	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	9	8365730	B2	2013-02-05	Baker, Jr. et al.	
	10	8545416	B1	2013-10-01	Kayyali et al.	
	11	5237990		1993-08-24	Psaros et al.	
	12	7757690	B2	2010-07-20	Stahmann et al.	
	13	5645043		1997-07-08	Long et al.	
	14	5961447		1999-10-05	Raviv et al.	
	15	6029664		2000-02-29	Zdrojkowski et al.	
	16	6138675		2000-10-31	Michael Berthon-Jones	
	17	6229581	B1	2001-05-08	Yamamoto et al.	
	18	6431171	B1	2002-08-13	Burton et al.	
	19	6551252	B2	2003-04-22	Sackner et al.	

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	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	20	6832609	B2	2004-12-21	Wright et al.	
	21	6889691	B2	2005-05-10	Eklund et al.	
	22	7018341	B2	2006-03-28	Wright et al.	
	23	7190995	B2	2007-03-13	Chervin et al.	
	24	7195013	B2	2007-03-27	Keith G. Lurie	
	25	7204250	B1	2007-04-17	David Burton	
	26	7225809	B1	2007-06-05	Bowen et al.	
	27	7309314	B2	2007-12-18	Grant et al.	
	28	7575005	B2	2009-08-18	Mumford et al.	
	29	7662101	B2	2010-02-16	Lee et al.	
	30	7668579	B2	2010-02-23	Lawrence A. Lynn	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	31	7670295	B2	2010-03-02	Sackner et al.	
	32	7878198	B2	2011-02-01	Farrell et al.	
	33	8172766	B1	2012-05-08	Kayyali et al.	
	34	10543328	B1	2020-01-28	Kayyali et al.	
	35	10076269	B1	2018-09-18	Kayyali et al.	
	36	9533114	B1	2017-01-03	Kayyali et al.	
	37	6532959	B1	2003-03-18	Michael Berthon-Jones	
	38	6532957	B2	2003-03-18	Michael Berthon-Jones	
	39	6336454	B1	2002-01-08	Farrell et al.	
	40	6152129		2000-11-28	Michael Berthon-Jones	
	41	5803078		1998-09-08	Mark E. Brauner	

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	1	20020032386	A1	2002-03-14	Sackner et al.	
	2	20030135127	A1	2003-07-17	Sackner et al.	
	3	20040116784	A1	2004-06-17	Benjamin Gavish	
	4	20040200474	A1	2004-10-14	Keith G. Lurie	
	5	20060042627	A1	2006-03-02	MacMillan et al.	
	6	20060070624	A1	2006-04-06	Kane et al.	
	7	20060135878	A1	2006-06-22	Wright et al.	
	8	20070135724	A1	2007-06-14	Ujhazy et al.	
	9	20070161913	A1	2007-07-12	Farrell et al.	

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	First Named Inventor	Hani Kayyali
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	10	20070209662	A1	2007-09-13	Bowen et al.	
	11	20080066753	A1	2008-03-20	Martin et al.	
	12	20080257349	A1	2008-10-23	Hedner et al.	
	13	20080269583	A1	2008-10-30	Daniel Reisfeld	
	14	20080276939	A1	2008-11-13	Mikael Tiedje	
	15	20100043795	A1	2010-02-25	Ujhazy et al.	
	16	20100258126	A1	2010-10-14	Ujhazy et al.	
	17	20020185130	A1	2002-12-12	Wright et al.	
	18	20030000528	A1	2003-01-02	Eklund et al.	
	19	20040138576	A1	2004-07-15	Wright et al.	
	20	20040163648	A1	2004-08-26	David Burton	

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	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

	21	20040254493	A1	2004-12-16	Chervin et al.	
	22	20050081847	A1	2005-04-21	Lee et al.	
	23	20050085738	A1	2005-04-21	Stahmann et al.	
	24	20050115561	A1	2005-06-02	Stahmann et al.	
	25	20050165323	A1	2005-07-28	Montgomery et al.	
	26	20050188991	A1	2005-09-01	Sun et al.	
	27	20050217674	A1	2005-10-06	Burton et al.	
	28	20050268916	A1	2005-12-08	Mumford et al.	
	29	20060084877	A1	2006-04-20	Ujhazy et al.	
	30	20060247546	A1	2006-11-02	Kazuo Imose	
	31	20040210153	A1	2004-12-21	Tsukashima et al.	

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Art Unit	3785
Examiner Name	Ned Heffner
Attorney Docket Number	CMD-101

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EXAMINER SIGNATURE

Examiner Signature	/NAVIN NATNITHITHADHA/	Date Considered	02/22/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3785
	Examiner Name	Ned Heffner
	Attorney Docket Number	CMD-101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Brian Kolkowski/	Date (YYYY-MM-DD)	2022-08-19
Name/Print	Brian Kolkowski	Registration Number	36847

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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81177 7590 03/15/2023

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

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 03/15/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

TITLE OF INVENTION: Integrated Sleep Diagnostic and Therapeutic System and Method

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	06/15/2023

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PTOL-85 (Rev. 02/11)

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

81177 7590 03/15/2023
Cleveland Medical Devices Inc.
4415 Euclid Ave. Ste. 500
Cleveland, OH 44103

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

TITLE OF INVENTION: Integrated Sleep Diagnostic and Therapeutic System and Method

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	06/15/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
NATNITHITHADHA, NAVIN	3791	128-204230

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

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

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

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

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

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

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

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

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

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

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

ResMed Corp. - Ex. 1002
Page 379

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 03/15/2023

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

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 03/15/2023

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

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

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

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

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 15/641,715	Applicant(s) Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791	AIA (FITF) Status No

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

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

1. ☑ This communication is responsive to See Continuation Sheet.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 21-49 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

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

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791

Continuation of 1. This communication is responsive to: the Request for Continued Examination, Amendment, Remarks, and Information Disclosure Statement, filed 19 August 2022

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Patent Trial and Appeal Board, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 19 August 2022 has been entered.

Response to Amendment

3. According to the Amendment, filed 19 August 2022, the status of the claims is as follows:

Claims 35-38 and 40 are currently amended;

Claims 21-34 and 39 are previously presented;

Claims 41-49 are new; and

Claims 1-20 are cancelled.

4. The objections of claims 32 and 35 are withdrawn in view of the Amendment, filed 19 August 2022.

5. The rejection of claims 35 under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement, is withdrawn in view of the Amendment, filed 19 August 2022.

6. The rejection of 35-40 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention, is withdrawn in view of the Amendment, filed 19 August 2022.

Response to Arguments

7. Applicant's arguments, see Remarks, pp. 14-20, filed 19 August 2022, with respect to the rejection of claims 35 and 37 under 35 U.S.C. 103(a) as being unpatentable over Rapoport et al, U.S. Patent No. 6,299,581 B2 ("Rapoport"), in view of Cooper et al, U.S. Patent Application Publication No. 2005/022502 A1 ("Cooper"), and further in view of Geva, U.S. Patent Application Publication No. 2004/0073098 A1 ("Geva"), have been fully considered, and are persuasive. The rejection of claims 35 and 37 has been withdrawn.

8. Applicant's arguments, see Remarks, pp. 21-23, filed 19 August 2022, with respect to the rejection of claim 36 under 35 U.S.C. 103(a) as being unpatentable over Rapoport in view of Cooper, and further in view of Geva, as applied to claim 35, and further in view of Brand et al, U.S. Patent Application Publication No. 2003/0183226 A1 ("Brand"), have been fully considered, and are persuasive. The rejection of claim 36 has been withdrawn.

9. Applicant's arguments, see Remarks, p. 23, filed 19 August 2022, with respect to the rejection of claim 38 under 35 U.S.C. 103(a) as being unpatentable over Rapoport in view of Cooper, and further in view of Geva, as applied to claim 35, and further in view of Behbehani et al, U.S. Patent No. 5,953,713 A ("Behbehani"), have been fully considered, and are persuasive. The rejection of claim 38 has been withdrawn.

10. Applicant's arguments, see Remarks, pp. 23-24, filed 19 August 2022, with respect to the rejection of claims 39 and 40 under 35 U.S.C. 103(a) as being unpatentable over Rapoport in view of Cooper, and further in view of Geva, as applied to claim 35, and further in view of Burton et al, U.S. Patent No. 6,349,724 B1 ("Burton"), have been fully considered, and are persuasive. The rejection of claims 39 and 40 has been withdrawn.

Reasons for Allowance

11. Claims 21-49 are allowed.

12. The following is an examiner's statement of reasons for allowance:

As to Claims 35-49, neither Rapoport, Cooper, Geva, Brand, Behbehani, Burton nor the prior art of record teaches the method of treating a subject's sleep apnea of base claim 35, including the following, in combination with all other limitations of the base claim:

> analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;
>
> transmitting, in either order, both 1) the collected data, and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone via the cellular system or the Internet for further analysis with a second processor or a server at the

remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and

further determining the therapy efficacy data with either the process or of the PAP or CPAP device, the second processor or server configured with a second software at the remote station, or the cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider.

.

13. The statement of reasons for allowance of claims 21-34 is provided in the prior Office Action, mailed 17 August 2020.

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

Conclusion

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

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

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

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

/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791
03/09/2023

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15641715
Filing Date	2017-07-05
First Named Inventor	Hani Kayyali
Art Unit	3791
Examiner Name	Navin Natnithithadha
Attorney Docket Number	CMD-101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6167258		2000-12-26	Schmidt et al.	
	2	8069852	B2	2011-12-06	Burton et al.	
	3	5704345		1998-01-06	Michael Berthon-Jones	
	4	6287264	B1	2001-09-11	Andrew Hoffman	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050211249	A1	2005-09-29	Wagner et al.	
	2	20020022973	A1	2002-02-21	Sun et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

	3	20020165462	A1	2002-11-07	Westbrook et al.	
	4	20050239838	A1	2005-10-27	Edgar et al.	
	5	20010018557	A1	2001-08-30	Lynn et al.	
	6	20030236450	A1	2003-12-25	Richard J. Kocinski	
	7	20030213489	A1	2003-11-20	Mechlenberg et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2005096737	WO	A2	2005-10-20	Farrell et al.		
	2	2002078775	WO	A2	2002-10-10	Genger et al.		
	3	2005028029	WO	A2	2005-03-31	Stahmann et al.		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Jasemian et al., Evaluation of realtime, remote monitoring telemedicine system using the Bluetooth protocol and a mobile phone network, Journal of Telemedicine and Telecare 2005, Vol. 11, Issue 5, at 256	
	2	Woodward et al., Wireless Telemedicine: The Next Step, 4th Int'l IEEE EMBS Special Topic Conference on Information Technology Applications in Biomedicine, 2003, at 43	
	3	Rasid et al., Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks," IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005, at 35	
	4	Mohd Fadlee A Rasid, Multi-Channel GPRS-Based Mobile Telemedicine System With Bluetooth and J2ME Interfaces, Doctoral Thesis, Department of Electronic and Electrical Engineering, Loughborough University (October 2005)	
	5	D. Alan Lankford, Wireless CPAP Patient Monitoring: Accuracy Study, Telemedicine Journal and e-Health, Vol. 10, No. 2, 2004, at 162	
	6	R. Paradiso, et al., Wearable Health Care System for Vital Signs Monitoring, 4thAnnual IEEE Conf. on Information Technology Applications in Biomedicine, 2003, at 283	
	7	M. J. Moron, E. Casilari, R. Luque and J. A. Gazquez, A wireless monitoring system for pulse-oximetry sensors, 2005 Systems Communications (ICW'05, ICHSN'05, ICMCS'05, SENET'05), 2005, at 79-84	
	8	Guilleminault C, van den Hoed J, and Mitler MM, Clinical overview of the sleep apnea syndromes. In: C Guilleminault and WC Dement (Eds), SLEEP APNEA SYNDROMES, Alan R Liss, New York, 1978, pp. 1-12	
	9	Christian Guilleminault and Vivien C. Abad, Obstructive sleep apnea syndromes, Med. Clin. N. Am. 88, 2004, pp. 611-630	
	10	Francoise J. Roux and Janet Hilbert, Continuous positive airway pressure: new generations, Clin. Chest Med. 24, 2003, at 315-342	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

	11	The AASM Manual for the Scoring of Sleep and Associated Events, 2007	
	12	Kirianaki, et al., DATA ACQUISITION AND SIGNAL PROCESSING FOR SMART SENSORS, 2002, John Wiley & Sons Ltd	
	13	Elena, et al., Design of a Mobile Telecardiology System Using GPRS/GSM Technology, Engineering in Medicine and Biology, 2002, Departamento Ingeniería Electrónica, Escuela Superior Ingenieros	
	14	ResMed AutoSet T Service Manual	
	15	ResMed AutoSet Spirit Service Manual 1	
	16	ResMed AutoSet Spirit Service Manual 2	
	17	ResMed AutoSet Spirit Service Manual 3	
	18	ResMed AutoSet Spirit, AutoSet Respond, S7 Elite Service Manual	
	19	Resmed S7 Elite Clinician's Manual	
	20	ResMed AutoSet Spirit, AutoSet Respond, AutoSet S7 Elite Service Manual	
	21	ResMed AutoSet Spirit, AutoSet Respond, AutoSet S7 Elite Service Manual 2	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

	22	ResMed S8 AutoSet Vantage System Clinician's Manual	
	23	ResMed S8 Elite/AutoSet Service Manual	
	24	ResMed ResLink Service Manual	
	25	ResMed ResTraxx Quick Reference Guide	
	26	ResMed AutoSet Respond Clinician's Manual	
	27	ResMed ResTraxx Wireless Patient Monitoring Flyer	
	28	ResMed ResTraxx Wireless Patient Monitoring Atlas	
	29	ResMed FDA 510(k) application letter	
	30	ResMed FDA 510(k) application summary	
	31	ResMed VPAP III & VPAP II Series Data Management Guide	
	32	ResMed VPAP II Clinician's Guide	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
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	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

If you wish to add additional non-patent literature document citation information please click the Add button Add

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Brian Kolkowski/	Date (YYYY-MM-DD)	2023-04-05
Name/Print	Brian Kolkowski	Registration Number	36847

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Electronic Patent Application Fee Transmittal

Application Number:	15641715
Filing Date:	05-Jul-2017
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	104	104
		Total in USD ($)		**104**

Electronic Acknowledgement Receipt

EFS ID:	47793765
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	05-APR-2023
Filing Date:	05-JUL-2017
Time Stamp:	09:55:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$104
RAM confirmation Number	E202345058246561
Deposit Account	502704
Authorized User	Mark Pennington

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	CMD-101_5Apr2023_IDS-letter.pdf	137675 6abeedf81f659a543d245fbe739752627a37d537	no	2
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Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	CMD-101_5Apr2023_IDS.pdf	1265699 f752c3bf8d07a97d1717e828cf6709d263686656	no	8
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Information:					
3	Non Patent Literature	NPL01-Jasemian-TelemedicinewithBluetoothandmobilephonenetwork.pdf	2803439 369cf14b685bcde8a9bf2a2a3fa1b41bf8c1d85f	no	5
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Information:					
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5	Non Patent Literature	NPL03-Rasid-BluetoothTelemedicineProcessor.pdf	3409437 f02d0e2c2ece23c028c3fecc1e9322a3480d9c02	no	9
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Information:					

7	Non Patent Literature	NPL06-Paradiso-WearableHealthCareSystems.pdf	385659 e4d226140dfd49524d22b7bb4508d61df0a9d03a	no	4
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Information:					
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Information:					
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Information:					
19	Non Patent Literature	NPL18-AutoSetSpirit-Respond-S7Elite-servicemanual-r.pdf	4007252 7a75267ca20d6f1a64be55c2a609d355b6d547d1	no	66
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20	Non Patent Literature	NPL04-Rasid-MultiChannelGPRSMobileTelemedicineSystem-r.pdf	5807303 ba37e09c055339d8ee5cdf1f7cfd7a3899230d40	no	235
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22	Non Patent Literature	NPL20-AutoSetSpirit-Respond-S7Elite-servicemanual-r.pdf	4022336 9f1f5621051a678d085ccd176261636be183866d	no	66
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34	Non Patent Literature	NPL32-VPAPII-cliniciansmanual.pdf	5817139 22d7d2e650e81b6b601a00fe6e6a96af12c1e756	no	62
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Information:					

35	Fee Worksheet (SB06)	fee-info.pdf	37982 408c13fedd3cae8b82a8236a6190061a6210139e	no	2

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Kayyali et al.		
Serial No.:	15/641,715	Art Unit:	3791
Filed:	July 5, 2017	Docket No.:	CMD-101
For:	Integrated sleep diagnostic and therapeutic system and method		
Examiner:	Navin Natnithithadha		

April 5, 2023

INFORMATION DISCLOSURE STATEMENT FOLLOWING NOTICE OF ALLOWANCE AND CERTIFICATION STATEMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This Information Disclosure Statement (IDS) is submitted in the above-captioned application after the mailing of a Notice of Allowance, which was mailed on March 15, 2023. Applicant apologizes for the submission at this stage of prosecution, but note that the references were brought to Applicant's attention through their attorneys for a related legal matter when the references were asserted during discovery. Further, an *Inter Partes Review* was filed on March 22, 2023 in that related legal matter, IPR# 2023-00565. Applicant has not evaluated the references for relevance to the claims of the present application, but the references were alleged to be relevant to related patents by a third party, and the Applicant believes it is within the duty of good faith and candor (37 C.F.R. § 1.56) to present the references to the Office so that such relevance may be evaluated. Some of the references cited in the IPR belong to the Applicant, but were not included in the present case or its parent cases because they were not believed to be material to the patentability of any such applications.

Applicant further certifies that, other than those references and items of information belonging to the Applicant but not previously submitted for lack of materiality, no item of information contained in the information disclosure statement was cited in a

communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

Applicant maintains small entity status, herewith submits the $104 small entity fee for submission of an IDS pursuant to 37 C.F.R. § 1.17(p). If any additional fees are required, Applicant hereby authorizes the Director to withdraw such funds from their deposit account: 502704.

The Applicant respectfully submits the accompanying IDS and references for proper review.

Respectfully submitted,

April 5, 2023
Dated

/Brian Kolkowski/
Brian M. Kolkowski
Reg. No.: 36.847
Attorney for the Applicant
Cleveland Medical Devices Inc.
4415 Euclid Ave., Suite 400
Cleveland, OH 44103
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(216) 649-0397 FAX
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FEE ADDRESS INDICATION FORM

Application Number	15641715	Art Unit	3791
Filing Date	05-Jul-2017	Examiner Name	NAVIN NATNITHITHADHA
First Name Inventor	Hani Kayyali	Attorney Doc. Number	CMD-101

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

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

Customer Number:	81177 Cleveland Medical Devices Inc. 4415 Euclid Ave. Ste. 500 Cleveland OH 44103 UNITED STATES 216-649-0376 bkolkowski@clevemed.com

Signature :

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

Signature	/Brian Kolkowski/	**Date**	04-13-2023
Name	Brian M. Kolkowski	**Registration Number**	36847

Electronic Patent Application Fee Transmittal

Application Number:	15641715
Filing Date:	05-Jul-2017
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Filer:	Brian M. Kolkowski/Mark Pennington
Attorney Docket Number:	CMD-101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPL ISSUE FEE	2501	1	480	480
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

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

Electronic Acknowledgement Receipt

EFS ID:	47835756
Application Number:	15641715
International Application Number:	
Confirmation Number:	5750
Title of Invention:	Integrated Sleep Diagnostic and Therapeutic System and Method
First Named Inventor/Applicant Name:	Hani Kayyali
Customer Number:	81177
Filer:	Brian M. Kolkowski/Mark Pennington
Filer Authorized By:	Brian M. Kolkowski
Attorney Docket Number:	CMD-101
Receipt Date:	13-APR-2023
Filing Date:	05-JUL-2017
Time Stamp:	10:22:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$480
RAM confirmation Number	E20234CA22278422
Deposit Account	502704
Authorized User	Mark Pennington
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.20 (Post Issuance fees) 37 CFR 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	60549 51e5768651a9370177fe4d143a2d6b4a89943ad4	no	2
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Information:					
2	Maintenance Fee Address Change	web85feeaddress.pdf	42443 6669ecdff23efadd49979d84af9b8a2c1af14202	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	40438 64034e08dd47bb200de78459ce9a18a0a3314329	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	143430		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
15641715	05-Jul-2017	Hani Kayyali	CMD-101	5750

TITLE OF INVENTION :

Integrated Sleep Diagnostic and Therapeutic System and Method

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Small	Utility under 35 USC 111(a)	3791	204230	NAVIN NATNITHITHADHA

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
$480	$0	$480	15-Jun-2023	$0

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

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

2.Entity Status

Change in Entity Status

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

◉ Applicant asserting small entity status. See 37 CFR 1.27.
Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

○ Applicant changing to regular undiscounted fee status.
Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

Doc Code: IFEE PTOL/85B-EFS

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

3.The Following Fee(s) Are Submitted:

☒ Issue Fee

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

☐ Publication Fee

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

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

4.Firm and/or Attorney Names To Be Printed

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

1. BRIAN KOLKOWSKI
2.
3.

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

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

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

6.Signature

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

Signature	/Brian Kolkowski/	**Date**	04-13-2023
Name	Brian M. Kolkowski	**Registration Number**	36847

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61M 16/00; 16/0003	08/14/2020	Charles Vivian
A61B 5/4818; 5/4836	08/14/2020	Charles Vivian
A61M 16/00; 16/0003	03/24/2021	MS
A61B 5/4818; 5/4836	03/24/2021	MS
A61B5/4818 or A61B5/08 or A61B5/4836 or A61M16/00 or A61M16/0003 or A61B5/02	03/03/2023	/NN/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
128	204.23	08/14/2020	Charles Vivian
600	529-543	03/03/2023	/NN/

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

/MATTHEW STANDARD/ Examiner, Art Unit 3785	/N.N/ Primary Examiner, Art Unit 3791

ResMed Corp. - Ex. 1002
Page 415

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	Art Unit
	NAVIN NATNITHITHADHA	3791

Search Notes		
Search Notes	**Date**	**Examiner**
Inventor Name Search	08/14/2020	Charles Vivian
Keyword search terms: cell, cellular, mobile, phone, telephone, smartphone	08/14/2020	Charles Vivian
Updated Inventor and Applicant search	03/17/2021	MS
See EAST search history	03/24/2021	MS
SEARCH (attached): US-PGPUB, USPAT, USOCR, FIT, FPRS, EPO , JPO, Derwent, IBM_TDB, Keyword, Inventor, Applicant, IDS, Forward/Backward Citation, USPC, CPC, Interference searches	03/03/2023	/NN/

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	A61B5/4818 or A61B5/08 or A61B5/4836 or A61M16/00 or A61M16/0003 or A61B5/02	03/09/2023	/NN/

/MATTHEW STANDARD/ Examiner, Art Unit 3785	/N.N/ Primary Examiner, Art Unit 3791

ResMed Corp. - Ex. 1002
Page 416

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

CPC						
Symbol					**Type**	**Version**
A61B	/	5	/	4818	F	2013-01-01
A61M	/	16	/	00	I	2013-01-01
A61M	/	16	/	0003	I	2014-02-04
A61B	/	5	/	4836	I	2013-01-01
A61B	/	5	/	08	I	2013-01-01
A61B	/	5	/	02	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	15 June 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

U.S. Patent and Trademark Office

Part of Paper No.: 20230620

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	5	/	02	
A61B	/	5	/	08	

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	15 June 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

U.S. Patent and Trademark Office — Part of Paper No.: 20230620

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	21	10	30	19	39	28	48								
2	22	11	31	20	40	29	49								
3	23	12	32	21	41										
4	24	13	33	22	42										
5	25	14	34	23	43										
6	26	15	35	24	44										
7	27	16	36	25	45										
8	28	17	37	26	46										
9	29	18	38	27	47										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	15 June 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

U.S. Patent and Trademark Office

Part of Paper No.: 20230620

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15641715
Filing Date	2017-07-05
First Named Inventor	Hani Kayyali
Art Unit	3791
Examiner Name	Navin Natnithithadha
Attorney Docket Number	CMD-101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6167258		2000-12-26	Schmidt et al.	
	2	8069852	B2	2011-12-06	Burton et al.	
	3	5704345		1998-01-06	Michael Berthon-Jones	
	4	6287264	B1	2001-09-11	Andrew Hoffman	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050211249	A1	2005-09-29	Wagner et al.	
	2	20020022973	A1	2002-02-21	Sun et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

	3	20020165462	A1	2002-11-07	Westbrook et al.		
	4	20050239838	A1	2005-10-27	Edgar et al.		
	5	20010018557	A1	2001-08-30	Lynn et al.		
	6	20030236450	A1	2003-12-25	Richard J. Kocinski		
	7	20030213489	A1	2003-11-20	Mechlenberg et al.		

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2005096737	WO	A2	2005-10-20	Farrell et al.		
	2	2002078775	WO	A2	2002-10-10	Genger et al.		
	3	2005028029	WO	A2	2005-03-31	Stahmann et al.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	Jasemian et al., Evaluation of realtime, remote monitoring telemedicine system using the Bluetooth protocol and a mobile phone network, Journal of Telemedicine and Telecare 2005, Vol. 11, Issue 5, at 256	
	2	Woodward et al., Wireless Telemedicine: The Next Step, 4th Int'l IEEE EMBS Special Topic Conference on Information Technology Applications in Biomedicine, 2003, at 43	
	3	Rasid et al., Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks," IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005, at 35	
	4	Mohd Fadlee A Rasid, Multi-Channel GPRS-Based Mobile Telemedicine System With Bluetooth and J2ME Interfaces, Doctoral Thesis, Department of Electronic and Electrical Engineering, Loughborough University (October 2005)	
	5	D. Alan Lankford, Wireless CPAP Patient Monitoring: Accuracy Study, Telemedicine Journal and e-Health, Vol. 10, No. 2, 2004, at 162	
	6	R. Paradiso, et al., Wearable Health Care System for Vital Signs Monitoring, 4thAnnual IEEE Conf. on Information Technology Applications in Biomedicine, 2003, at 283	
	7	M. J. Moron, E. Casilari, R. Luque and J. A. Gazquez, A wireless monitoring system for pulse-oximetry sensors, 2005 Systems Communications (ICW'05, ICHSN'05, ICMCS'05, SENET'05), 2005, at 79-84	
	8	Guilleminault C, van den Hoed J, and Mitler MM, Clinical overview of the sleep apnea syndromes. In: C Guilleminault and WC Dement (Eds), SLEEP APNEA SYNDROMES, Alan R Liss, New York, 1978, pp. 1-12	
	9	Christian Guilleminault and Vivien C. Abad, Obstructive sleep apnea syndromes, Med. Clin. N. Am. 88, 2004, pp. 611-630	
	10	Francoise J. Roux and Janet Hilbert, Continuous positive airway pressure: new generations, Clin. Chest Med. 24, 2003, at 315-342	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

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	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

	11	The AASM Manual for the Scoring of Sleep and Associated Events, 2007	
	12	Kirianaki, et al., DATA ACQUISITION AND SIGNAL PROCESSING FOR SMART SENSORS, 2002, John Wiley & Sons Ltd	
	13	Elena, et al., Design of a Mobile Telecardiology System Using GPRS/GSM Technology, Engineering in Medicine and Biology, 2002, Departamento Ingeniería Electrónica, Escuela Superior Ingenieros	
	14	ResMed AutoSet T Service Manual	
	15	ResMed AutoSet Spirit Service Manual 1	
	16	ResMed AutoSet Spirit Service Manual 2	
	17	ResMed AutoSet Spirit Service Manual 3	
	18	ResMed AutoSet Spirit, AutoSet Respond, S7 Elite Service Manual	
	19	Resmed S7 Elite Clinician's Manual	
	20	ResMed AutoSet Spirit, AutoSet Respond, AutoSet S7 Elite Service Manual	
	21	ResMed AutoSet Spirit, AutoSet Respond, AutoSet S7 Elite Service Manual 2	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

	22	ResMed S8 AutoSet Vantage System Clinician's Manual	
	23	ResMed S8 Elite/AutoSet Service Manual	
	24	ResMed ResLink Service Manual	
	25	ResMed ResTraxx Quick Reference Guide	
	26	ResMed AutoSet Respond Clinician's Manual	
	27	ResMed ResTraxx Wireless Patient Monitoring Flyer	
	28	ResMed ResTraxx Wireless Patient Monitoring Atlas	
	29	ResMed FDA 510(k) application letter	
	30	ResMed FDA 510(k) application summary	
	31	ResMed VPAP III & VPAP II Series Data Management Guide	
	32	ResMed VPAP II Clinician's Guide	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/NAVIN NATNITHITHADHA/	Date Considered	06/15/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15641715
	Filing Date	2017-07-05
	First Named Inventor	Hani Kayyali
	Art Unit	3791
	Examiner Name	Navin Natnithithadha
	Attorney Docket Number	CMD-101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Brian Kolkowski/	Date (YYYY-MM-DD)	2023-04-05
Name/Print	Brian Kolkowski	Registration Number	36847

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.N/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 06/15/2023

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

EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3791	

MAIL DATE	DELIVERY MODE
06/15/2023	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.

Corrected ***Notice of Allowability***	**Application No.** 15/641,715	**Applicant(s)** Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA	**Art Unit** 3791	**AIA (FITF) Status** No

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

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

1. ☑ This communication is responsive to See Continuation Sheet.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 21-49 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

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

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791

Continuation of 1. This communication is responsive to: the Information Disclosure Statement, filed 05 April 2023

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05 April 2023 was filed after the mailing date of the Notice of Allowance on 15 March 2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Reasons for Allowance

3. Claims 21-49 are allowed.

4. The following is an examiner's statement of reasons for allowance:

As to Claims 35-49, neither Rapoport, Cooper, Geva, Brand, Behbehani, Burton nor the prior art of record teaches the method of treating a subject's sleep apnea of base claim 35, including the following, in combination with all other limitations of the base claim:

> analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;
>
> transmitting, in either order, both 1) the collected data, and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and
>
> further determining the therapy efficacy data with either the process or of the PAP or CPAP device, the second processor or server configured with a second software at the remote station, or the cellular phone using

the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider.

5. The statement of reasons for allowance of claims 21-34 is provided in the prior Office Action, mailed 17 August 2020.

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

Conclusion

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

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

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

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center,

visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791
06/15/2023

Examiner-Initiated Interview Summary	Application No. 15/641,715	Applicant(s) Kayyali et al.		
	Examiner NAVIN NATNITHITHADHA	Art Unit 3791	AIA (First Inventor to File) Status No	Page 1 of 1

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

Date of Interview: 15 September 2023

Issues Discussed:

Proposed Amendment(s)

Examiner proposed, by Examiner's Amendment, to amend claim 40 to be dependent on claim 39 instead of claim 49. Claim 40's dependency to claim 49 appears to be a typographical error because the claim refers to subject matter in claim 39 and not claim 49.
Attorney agreed to the Examiner's Amendment.

/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	

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

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

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

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

CPC							
Symbol						**Type**	**Version**
A61B	/	5	/	4818		F	2013-01-01
A61M	/	16	/	00		I	2013-01-01
A61M	/	16	/	0003		I	2014-02-04
A61B	/	5	/	4836		I	2013-01-01
A61B	/	5	/	08		I	2013-01-01
A61B	/	5	/	02		A	2013-01-01

CPC Combination Sets								
Symbol						**Type**	**Set**	**Ranking**	**Version**
	/		/						

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	15 September 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

U.S. Patent and Trademark Office — Part of Paper No.: 20230921

ResMed Corp. - Ex. 1002
Page 435

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	5	/	02	
A61B	/	5	/	08	

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	15 September 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

U.S. Patent and Trademark Office — Part of Paper No.: 20230921

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/641,715	Kayyali et al.
	Examiner	**Art Unit**
	NAVIN NATNITHITHADHA	3791

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	21	10	30	20	39	28	48								
2	22	11	31	21	40	29	49								
3	23	12	32	22	41										
4	24	13	33	23	42										
5	25	14	34	24	43										
6	26	15	35	25	44										
7	27	16	36	26	45										
8	28	17	37	27	46										
9	29	19	38	18	47										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	29	
/NAVIN NATNITHITHADHA/ Primary Examiner, Art Unit 3791	15 September 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

U.S. Patent and Trademark Office Part of Paper No.: 20230921

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Page 437

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 09/18/2023

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

EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3791	

MAIL DATE	DELIVERY MODE
09/18/2023	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.

Corrected ***Notice of Allowability***	**Application No.** 15/641,715	**Applicant(s)** Kayyali et al.	
	Examiner NAVIN NATNITHITHADHA	**Art Unit** 3791	**AIA (FITF) Status** No

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

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

1. ☐ This communication is responsive to _____.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 21-49 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

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

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian M. Kolkowski on 15 September 2023.

The application has been amended as follows:

- -

40. (currently amended) The method of claim 39 ~~49~~, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician from a remote location.

- -

Reasons for Allowance

3. Claims 21-49 are allowed.

4. The following is an examiner's statement of reasons for allowance:

As to Claims 35-49, neither Rapoport, Cooper, Geva, Brand, Behbehani, Burton nor the prior art of record teaches the method of treating a subject's sleep apnea of

base claim 35, including the following, in combination with all other limitations of the base claim:

> analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;
>
> transmitting, in either order, both 1) the collected data, and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and
>
> further determining the therapy efficacy data with either the process or of the PAP or CPAP device, the second processor or server configured with a second software at the remote station, or the cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider.

5. The statement of reasons for allowance of claims 21-34 is provided in the prior Office Action, mailed 17 August 2020.

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

Conclusion

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

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

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

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

/NAVIN NATNITHITHADHA/
Primary Examiner, Art Unit 3791
09/15/2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	01/02/2024	11857333	CMD-101	5750

81177 7590 12/13/2023

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

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

The Patent Term Adjustment is 1801 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

Applicant will be able to obtain more detailed information by accessing the Patent Center (https://patentcenter.uspto.gov).

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

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Hani Kayyali, Shaker Heights, OH;
Dan Bishop, Tallmadge, OH;
Brian M. Kolkowski, Leroy, OH;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/641,715	07/05/2017	Hani Kayyali	CMD-101	5750

81177 7590 01/04/2024

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

EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3791	

MAIL DATE	DELIVERY MODE
01/04/2024	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.

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.
15/641,715	02-Jan-2024	11857333

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

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants