(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 November 2015 (19.11.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/175673 A1

(51) International Patent Classification:
A61B 5/00 (2006.01)

(21) International Application Number:
PCT/US2015/030589

(22) International Filing Date:
13 May 2015 (13.05.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/992,430 13 May 2014 (13.05.2014) US

(71) Applicant: **UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC.** [US/US]; 223 Grinter Hall, Gainesville, FL 32611 (US).

(72) Inventors: **PITTS, Teresa Elizabeth**; c/o University Of Florida Research Foundation, Inc, 223 Grinter Hall, Gainesville, FL 32611 (US). **BOLSER, Donald Clementz**; c/o University Of Florida Research Foundation, Inc, 223 Grinter Hall, Gainesville, FL 32611 (US). **DIXON, Warren E.**; c/o University Of Florida Research Foundation, Inc, 223 Grinter Hall, Gainesville, FL 32611 (US).

(74) Agent: **BIANCO, Paul, D.**; Fleit Gibbons Gutman Bongini & Bianco, 21355 East Dixie Highway, Suite 115, Miami, FL 33180 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: REDUCING APNEA OR SNORING USING AFFERENT STIMULATION

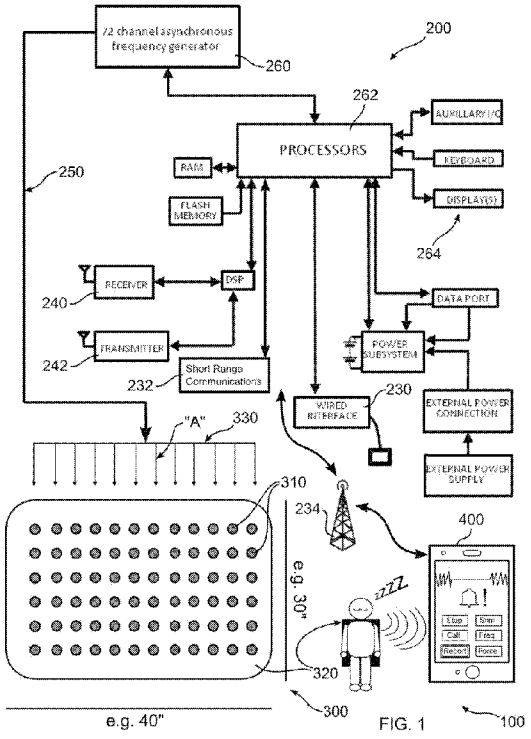

FIG. 1

(57) Abstract: A system and method for reducing apnea or snoring in a patient. The system includes: a sensor for electronically sensing patient data corresponding to a current sleep or snoring state of the patient; a transmitter to transmit the sensed data, using at least one of wired or wireless communication, to one or more electronic data processors; software, stored on non-transitory media, executable upon the one or more electronic processors to determine if the patient data indicates a current state of sleep; a signal generator, controllable by the one or more processors, configured to generate a wave signal; and a plurality of vibratory actuators positionable in contact with the patient's body. The actuators are configured to receive a signal from the signal generator, when the one or more processors determines the current sleep state to be a state of apnea or snoring, and to transmit vibration to the patient to change a sleep state of the patient to no longer be a state of apnea or snoring.

WO 2015/175673 A1

Published:

— *with international search report (Art. 21(3))*

REDUCING APNEA OR SNORING USING AFFERENT STIMULATION

FIELD OF THE INVENTION

The invention relates to a system and method for reducing sleep apnea or snoring, and in particular, by stimulating the body to resume normal breathing.

BACKGROUND OF THE INVENTION

Sleep disordered breathing, also known as sleep apnea, is a serious and prevalent health care problem in the United States. Most commonly, sleep apnea is recognized as obstructive in nature, consisting of periodic occlusions of the pharyngeal airway during sleep. These occlusions result in profoundly low blood oxygen levels, hypertension, and heart complications during the night. Sleep apnea can also include slowing or temporary cessation of breathing due to issues in the central nervous system.

The prevalence of this disorder in the U.S. is high. At least 9% of women and 24% of men have mild or worse sleep apnea. Of these, severe sleep apnea occurs in 4% of women and 9% of men. Furthermore, there is a strong bias against diagnosis of women for sleep apnea, such that this medical problem is likely to go undiagnosed for longer periods of time in women than in men.

Patients with sleep apnea have a 2.9 fold increased incidence of hypertension compared to those without this disorder. Stroke and depression are also strongly associated with sleep apnea. Taken together, mortality over an 18 year period is 3 fold higher for patients with sleep apnea than those without this disorder.

Treatment of this disorder has evolved over time. Historically, pharyngeal surgery intended to enlarge the airway (uvuloplasty) was a frequently employed. However, this intervention was associated with significant acute and subacute morbidity and was only effective in about 50% of patients. Weight loss has been encouraged by physicians but not all patients with sleep apnea suffer from obesity and this method is not always effective.

CPAP (continuous positive airway pressure) has been used in the last 25 years. CPAP consists of a positive airflow applied to the nose via a mask fitted to the nose of the subject that is connected to an air pump with plastic hoses. The positive pressure applied through the nose by the pump minimized collapse of the pharyngeal airway during sleep. Although this treatment proven to be effective in relieving the symptoms of sleep apnea, CPAP requires subjects to wear a facemask attached to tubes when retiring to bed. This apparatus is

cumbersome and is associated with dry mouth, claustrophobia, significant nasal symptoms such as sinusitis and nosebleeds, and swallowing air. These issues have led to a refusal rate of 40% (2, 3) by patients when offered this treatment method and of those that begin CPAP therapy, as many as 50% (4-7) are uncompliant.

As many as 50% of men over 60 suffer from habitual snoring (8). Loud and bothersome snoring is strongly associated with sleep apnea and is often reported by spouses, leading patients to seek treatment. However, not all snorers suffer from sleep apnea (8). Many snorers suffer from an intermediate syndrome in which obstructive sleep apnea is not manifest but the patient exhibits excessive daytime sleepiness (8). As in sleep apnea, the upper airway relaxes during deep sleep and vibrates during breathing creating the distinctive snoring sounds. Snoring is typically considered a significant annoyance to spouses, however, it can be associated with health risks even if the patient does not have a clinical diagnosis of sleep apnea. Patients that snore but do not have sleep disordered breathing can have an increased risk of hypertension (9, 10). Treatment for scoring can include uvulopharyngoplasty, which is an invasive surgical procedure involving removal of pharyngeal tissue (8). This treatment induces significant morbidity and there is a high rate of recurrence of snoring (8).

SUMMARY OF THE INVENTION

A system for reducing apnea or snoring in a patient comprises: a sensor for electronically sensing patient data corresponding to a current sleep or snoring state of the patient; a transmitter to transmit the sensed data, using at least one of wired or wireless communication, to one or more electronic data processors; software, stored on non-transitory media, executable upon the one or more electronic processors to determine if the patient data indicates a current state of sleep; a signal generator, controllable by the one or more processors, configured to generate a wave signal; and a plurality of vibratory actuators positionable in contact with the patient's body. The actuators are configured to receive a signal from the signal generator, when the one or more processors determines the current sleep state to be a state of apnea or snoring, and to transmit vibration to the patient to change a sleep state of the patient to no longer be a state of apnea or snoring.

A method of reducing snoring or apnea in a patient, comprises: electronically sensing data corresponding to a current sleep state of the patient; communicating the sensed data to one or more electronic data processors; executing software, stored on non-transitory media, upon the one or more electronic processors to determine if the patient data indicates a current state of sleep; using the one or more processors, when the one or more processors determines

the current sleep state to be a state of apnea or snoring, to cause a signal to be transmitted to a plurality of vibratory actuators positioned in contact with the patient's body. The actuators are configured to transmit vibration to the patient to change a sleep state of the patient to no longer be a state of apnea or snoring.

The plurality of vibratory actuators can be assembled into a mat positionable in contact with the patient. In an embodiment, the plurality of vibratory actuators includes electric motors. The transmitter can include a cell phone to communicate the patient data to the one or more electronic data processors. In some embodiments, the cycle-by-cycle varied frequencies generated by the signal generator are between 0.1 and 500 Hz.

The sensor can include at least one of pulse oximeter, pulse rate monitor, microphone, and video camera. In any embodiment, the signal generator is configured to vary the signal transmitted to the plurality of vibratory actuators over time to reduce adaptation by the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 depicts a system of the disclosure including a vibratory mat positionable in contact with a patient, and a processing subsystem responsive to a signal indicative of a sleep state or duration/amplitude of snoring and/or a snoring sound of a patient, to cause vibration within the mat responsive to the signal;

FIG. 2 depicts the system of FIG. 2, wherein separate sensors are connectable to the processing subsystem;

FIG. 3 is an exemplary computer system useable as part of a system of the disclosure; and

FIG. 4 is an exemplary mobile transmitting computer system useable as part of a system of the disclosure.

DETAILED DESCRIPTION OF THE INVENTION

As required, detailed embodiments are disclosed herein; however, it is to be understood that the disclosed embodiments are merely examples and that the systems and methods described below can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis

for the claims and as a representative basis for teaching one skilled in the art to variously employ the present subject matter in virtually any appropriately detailed structure and function. Further, the terms and phrases used herein are not intended to be limiting, but rather, to provide an understandable description of the concepts.

The terms "a" or "an", as used herein, are defined as one or more than one. The term plurality, as used herein, is defined as two or more than two. The term another, as used herein, is defined as at least a second or more. The terms "including" and "having," as used herein, are defined as comprising (i.e., open language). The term "coupled," as used herein, is defined as "connected," although not necessarily directly, and not necessarily mechanically.

In accordance with the disclosure, and with reference to the figures, a system 100 is used to reduce or eliminate the symptoms of sleep apnea. System 100 includes a processor subsystem 200 configured to detect symptoms indicating apnea or snoring by measuring parameters of a patient before, during, and after the patient experiences apnea or other sleep disordered breathing (referred collectively herein, for convenience, as apnea). Subsystem 200 causes patient stimulator 300 to mechanically stimulate a patient during symptoms of apnea, for example by introducing a vibratory energy to the skin of the patient. The inventors have found that such mechanical stimulation provokes a physiological change in the patient experiencing apnea or snoring, to cause the patient to resume normal breathing. Subsystem 200 includes one or more processors 262 and associated components, as described elsewhere herein.

Patient stimulator 300 can cause mechanical stimulation by one or more transducers or actuators 310, of the type including mechanical, electromechanical, hydraulic, piezoelectric, acoustic, or any other known or hereinafter developed actuator type. In FIG. 1, actuators 310 are indicated by circles arranged upon a mat 320. In one embodiment, actuators 310 are individual vibration causing motors. One example of such a motor is found in cell phones, which include a motor, a motor output shaft, and an imbalanced weight attached to the shaft (not shown). In an embodiment, the frequency of the vibration can be adjusted using subsystem 200, or the frequency can be predetermined. Other actuator 310 types may similarly output vibration at a desired or predetermined frequency, for example an instantaneous random frequency. Frequencies can be as low as a single pulse or movement (< 1 Hz), to between 1 and 100 Hz, or substantially more than 100 Hz, for example 5000 Hz. In one embodiment, the inventors have found a vibration at 10 Hz to be effective. Frequencies can fluctuate within a band in a manner which is varied from cycle to cycle within this range. Additionally, very low frequencies do not produce sound detectable by the patient, and which

might otherwise excessively arouse the patient during sleep. In other embodiments, it can be advantageous for actuators 310 to produce sound.

Actuator 310 is attached or formed upon mat 320 to transmit vibratory energy into 320, or to transmit vibratory energy directly to the patient, who is positioned upon mat 320. In an embodiment, mat 320 is sized and dimensioned to cover a substantial portion of a large skin area of the patient, for example the front or back of the torso. For adults, the inventors have found a mat of 30 inches by 40 inches to be effective. However, as humans vary widely in size, mat 320 can likewise be sized and shaped to correspond to a size of the patient. Thus, mat 320 can be much smaller, for example as small as several inches or less on a side for an infant, or much larger, for example 60 by 80 inches or larger, for a large adult. In the embodiment shown, mat 320 is substantially rectangular in shape, to correspond to a human torso. However, mat 320 can be shaped to correspond to, and be used in contact with, any other portion of the human body. This can include one or more, or combinations of, the foot, calf, thigh, hip, buttocks, spine, head, abdomen, chest, shoulder, upper arm, lower arm, and/or hand.

As may further be seen in FIG. 1, an electrical or electronic contactor array 330 transmits a signal and power from a signal and power cable 250 connected to processor subsystem 200, to actuators 310. An illustrative number of arrows "A" within contactor array 330 are shown; there may be more or less arrows each representing a contact with an individual actuator 310, or set of actuators 310. In an embodiment, processor subsystem 200 can activate individual actuators 310, or can activate actuators 310 in groups or all together. A frequency generator 260 can be provided with a number of channels corresponding to the number of actuators 310 (in the example shown, 72), or sets of actuators 310, that it is desired to independently control. In an embodiment, the signal to cause actuation can be transmitted from subsystem 200 to actuators 310 using a wireless signal, in which a receiver, power supply, and signal generator (if needed), can be associated with actuators 310.

In accordance with the disclosure, relatively highly sensitive skin areas have been found to be advantageously subjected to mechanical stimulation to reduce apnea or snoring. Such areas include the bottom of the feet, chest wall, back, or neck. In certain embodiments, particularly where mat 320 must conform to certain areas of the body, mat 320 can be shaped to fit, and can be provided with fasteners to secure mat 320 in place.

In one embodiment, when apnea or snoring is detected, or is expected to occur, mechanical stimulation using actuators 310 can be initiated. Processor subsystem 200 can be configured, for example using software or other timing device, to produce an output at a

range of frequencies which can be varied on a cycle-by-cycle bases for a predetermined time period. The range of frequencies which can be varied on a cycle by cycle bases and time period can, in one embodiment, be adjusted by the patient or a medical practitioner. In another embodiment, the frequency and/or time period is varied, in order to counteract any physiological adaptation by the patient. This variation can be varied, predetermined, or calculated based upon observed or measured patient parameters. Variation can include variable frequencies, a pattern of changing frequency, for example a frequency sweep, length of on-time when the actuator 310 is active, and intervals between on-time.

Cycle-by-cycle bases herein includes a vibration corresponding to a continuous series of wave output, for example pulses or square waves. Each wave in the series is a cycle. In this context, the duration of a single wave in this series in milliseconds divided into 1 yields the instantaneous frequency. The very next wave can have a different duration and thus instantaneous frequency and so on over the entire series. The durations of individual cycles are bound by the upper and lower limits of the frequencies detailed herein, including 1-5000 Hz, or individual cycle durations of 0.2 ms to 1 second. In an embodiment, the range is 1-100 Hz or 10 ms to 1 second for individual wave cycle durations.

Sensed, evaluated, or measured patient parameters can include patient movement, breathing rate, blood oxygen saturation, or acoustic output (e.g. snoring). In one embodiment, patient parameters are used to determine the frequency and timing of mechanical feedback, or the frequency and timing of patterns of mechanical feedback. The parameters are evaluated by subsystem 200 in accordance with best current knowledge of indicators of apnea. Currently, intermittent or extended periods between breath, a stillness of the patient, and a drop in blood oxygen, are all possible indicators of apnea.

In an embodiment, the voltage or power level of actuators 310 can be varied, to change an intensity of mechanical stimulation. This intensity can be varied on a cycle-by-cycle basis or fit to a predetermined custom pattern, as with frequency and timing. Variation of any combination of frequency, timing, and intensity can be correlated with feedback from sensors 340 (FIG. 2) associated with the patient and providing input to processor subsystem 200. In FIG. 2, sensors 340 illustrated include an oxygen saturation sensor 342, heartbeat rate 344, audio 346 including any or all of breathing, stirring/moving, coughing/gasping, heartbeat, for example, motion sensor 350, and video 348, which can be analyzed by subsystem 200 for patient movement, eye movement, or rise and fall of the patient's chest, for example. Sensors other than the examples provided in FIG. 2, which collect data regarding patient parameters,

can be used, including for example sensors for skin conductivity, or subcutaneous or ingested sensors.

In an embodiment, audio data captured by audio sensor 346 which can be a microphone, is analyzed by processor subsystem 200 to count breaths of the patient over one or more time intervals. An accelerometer motion sensor 350 can be used to measure the patient's sleep state, wherein movement of the patient can be measured by the accelerometer, and the data analyzed by processor subsystem 200 in comparison to sleep states associated with apnea or snoring. In the embodiment of FIG. 2, accelerometer 350 is connected to mat 320, whereby any movement of the mat is recorded. Alternatively, accelerometer 350 can be attached to the patient. Similarly, any sensor herein can be attached to mat 320 or the patient or both, as desired, for the best therapeutic result for the patient. A pulse oximeter type oxygen sensor 342 can be used to determine the number and duration of oxygen desaturation events associated with apnea or snoring. Any or all sensory inputs to subsystem 200 can be analyzed to determine if the patient is adapting to mechanical stimulus provided by actuators 310, and can vary the pattern as needed to counteract such adaptation.

In one embodiment, actuators 310 include between about 20 and about 72 asynchronous vibratory motors which are embedded within mat 320. The magnitude of the vibratory motion can be 1 mm or less, although this is an exemplary value and substantially smaller (e.g. as low as 0.1) or larger (e.g. as high as 20 mm) magnitudes can be effective. In an embodiment, the extent of force or magnitude, and any other actuator parameters discussed herein, is adjustable or tunable by the patient or a medical practitioner for optimal amelioration of apnea or snoring. In another embodiment, the extent of force of magnitude is varied on a cycle-by-cycle basis from 0.1 mm to 20 mm. Mat 320 can be placed under a sheet over which the patient lies while sleeping. Embodiments with sufficiently high magnitude can be placed under additional bedding material. In an embodiment, processor subsystem 200 activates actuators 310 to the greatest extent during the REM portion of the patient's sleep cycle, which typically corresponds to a higher incidence of apnea and snoring. Alternatively, periods of activity can be tuned for individual patients based upon human or sensor observance of patterns of apnea or snoring for an individual patient. Tuning can be carried out by software executing within subsystem 200, or by entering operational values into subsystem 200.

As can be seen in FIGS. 1 and 2, processor subsystem 200 can include any one or more of a wired output 230, short range wireless output 232, or long range wireless output 234. Examples of such single or bidirectional communication protocols include wired protocols

which can include serial, parallel, FIREWIRE, USB, or ETHERNET; short range wireless protocols which can include BLUETOOTH, WIFI, or cellular network; and long range protocols which can include TCP/IP, the Internet, and the various cellular networks, such as the 4G network. Other protocols are known, and may be hereinafter developed, which can be used within a system 100 of the disclosure. While various components may be illustrated on only FIG. 1 or FIG. 2, it should be understood that these components can be included in either embodiment of system 100, as described herein, and as benefits the patient.

Using either short or long range communication methods, a medical practitioner can remotely monitor a patient's sleep state and symptoms of apnea, and can take action if needed to ameliorate a problem condition. For example, a medical practitioner can use software executing upon a web browser or a smartphone application to increase a magnitude or other intensity of mechanical stimulation, or could otherwise contact the patient or a caregiver if further action is needed. In a further embodiment, subsystem 200 can use the various communication protocols without human intervention based upon patient parameters, to initiate reporting or corrective action.

One or more Additional receivers 240 and transmitters 242 can be provided as part of subsystem 200. While these components can also be used for communicating outside system 100, in an embodiment they are provided for communicating with sensors 340, 350, and with actuators 310. Receiver 240 and transmitter 242 can provide wired or wireless communication or both, as needed to communicate with the various sensors 340, 350, and actuators 310.

Processor subsystem 200 can be contained within a controller box, including controls which may be manipulated by hand, for controlling the various parameters described herein. Additionally or alternatively, a display screen and human interface components 264 can be included for programming and using system 100. Various signal and power leads can be provided for connecting sensors and actuators to the patient and to subsystem 200.

In accordance with the disclosure, and with reference to FIG. 1, a cell phone 400 can be used to monitor a patient for symptoms of apnea. Audio and/or video inputs to the cell phone can be used to observe the patient as described herein. An application executing within the cell phone can transmit a signal when conditions of apnea are observed. The signal can be transmitted locally, for example using BLUETOOTH, or using the cell network, for example 4G, to communicate with a receiver associated with subsystem 200. Upon receipt of the signal, subsystem 200 can cause actuators 310 to activate in order to cause the patient to change their sleep status and resume normal breathing. A current breathing state of the

patient can then, once again, be monitored using the cell phone as described. It should be understood, in this embodiment, that some functions of subsystem 200 can be processed by the processor within cell phone 400. In FIG. 2, it may be seen that sensors form part of system 100, and a separate sensing device, such as cell phone 400, is not a requirement, but could still be employed for additional or alternative input.

An embodiment of the disclosure including system 100 can be used each night or other sleeping period by a patient to reduce apnea. In an embodiment, a single system 100 can be used to monitor and stimulate more than one patient, for example patients in a clinic, or spouses who each exhibit symptoms of apnea or snoring. In this manner, cumbersome or uncomfortable alternatives, such as C-PAP, can be avoided, and patient compliance and health can be improved.

Exemplary Computing Components

FIG. 3 illustrates an exemplary system architecture for a computer system 1000, such as a process controller, or other processor on which or with which the disclosure may be implemented. Some or all of these components can be included within subsystem 200, or within sensor or actuator subassemblies. Additionally, some or all of these components can be used within computers in communication with system 100. The exemplary computer system and components of FIG. 3 are for descriptive purposes only. Although the description may refer to terms commonly used in describing particular computer systems, the description and concepts equally apply to other systems, including systems having architectures dissimilar to FIG. 10. Computer system 1000 can control temperatures, motors, pumps, flow rates, power supplies, ultrasonic energy power generators, and valves, using actuators and transducers. One or more sensors, not shown, provide input to computer system 1000, which executes software stored on non-volatile memory, the software configured to receive inputs from sensors or from human interface devices, in calculations for controlling system 200.

Computer system 1000 includes at least one central processing unit (CPU) 1105/262, or server, which may be implemented with a conventional microprocessor, a random access memory (RAM) 1110 for temporary storage of information, and a read only memory (ROM) 1115 for permanent storage of information. A memory controller 1120 is provided for controlling RAM 1110.

A bus 1130 interconnects the components of computer system 1000. A bus controller 1125 is provided for controlling bus 1130. An interrupt controller 1135 is used for receiving and processing various interrupt signals from the system components.

Mass storage may be provided by DVD ROM 1147, or flash or rotating hard disk drive 1152, for example. Data and software, including software 400 of the disclosure, may be exchanged with computer system 1000 via removable media such as diskette, CD ROM, DVD, Blu Ray, or other optical media 1147 connectable to an Optical Media Drive 1146 and Controller 1145. Alternatively, other media, including for example a media stick, for example a solid state USB drive, may be connected to an External Device Interface 1141, and Controller 1140. Additionally, a device 100 in accordance with the disclosure may be connected to computer system 1000 through External Device Interface 1141, for example by a USB connector, BLUETOOTH connector, Infrared, or WiFi connector, although other modes of connection are known or may be hereinafter developed. A hard disk 1152 is part of a fixed disk drive 1151 which is connected to bus 1130 by controller 1150. It should be understood that other storage, peripheral, and computer processing means may be developed in the future, which may advantageously be used with the disclosure.

User input to computer system 1000 may be provided by a number of devices. For example, a keyboard 1156 and mouse 1157 are connected to bus 1130 by controller 1155. An audio transducer 1196, which may act as both a microphone and a speaker, is connected to bus 1130 by audio controller 1197, as illustrated. It will be obvious to those reasonably skilled in the art that other input devices, such as a pen and/or tablet, Personal Digital Assistant (PDA), mobile/cellular phone and other devices, may be connected to bus 1130 and an appropriate controller and software, as required. DMA controller 1160 is provided for performing direct memory access to RAM 1110. A visual display is generated by video controller 1165 which controls video display 1170. Computer system 1000 also includes a communications adapter 1190 which allows the system to be interconnected to a local area network (LAN) or a wide area network (WAN), schematically illustrated by bus 1191 and network 1195.

Operation of computer system 1000 is generally controlled and coordinated by operating system software, such as a Windows system, commercially available from Microsoft Corp., Redmond, WA. The operating system controls allocation of system resources and performs tasks such as processing scheduling, memory management, networking, and I/O services, among other things. In particular, an operating system resident in system memory and running on CPU 1105 coordinates the operation of the other elements of computer system 1000. The present disclosure may be implemented with any number of commercially available operating systems.

One or more applications, such as an HTML page server, or a commercially available communication application, may execute under the control of the operating system, operable to convey information to a user.

Exemplary Mobile Computing Components

FIG. 4, is a block diagram of an electronic device and associated components 800, which can be used in carrying out the disclosure. Some or all of these components can be included within subsystem 200, or within sensor or actuator subassemblies. Additionally, some or all of these components can be used within computers in communication with system 100. In this example, an electronic device 852 is a wireless two-way communication device with voice and data communication capabilities. Such electronic devices communicate with a wireless voice or data network 850 using a suitable wireless communications protocol. Wireless voice communications are performed using either an analog or digital wireless communication channel. Data communications allow the electronic device 852 to communicate with other computer systems via the Internet. Examples of electronic devices that are able to incorporate the above described systems and methods include, for example, a data messaging device, a two-way pager, a cellular telephone with data messaging capabilities, a wireless Internet appliance or a data communication device that may or may not include telephony capabilities.

The illustrated electronic device 852 is an example electronic device that includes two-way wireless communications functions. Such electronic devices incorporate communication subsystem elements such as a wireless transmitter 810, a wireless receiver 812, and associated components such as one or more antenna elements 814 and 816. A digital signal processor (DSP) 808 performs processing to extract data from received wireless signals and to generate signals to be transmitted. The particular design of the communication subsystem is dependent upon the communication network and associated wireless communications protocols with which the device is intended to operate.

The electronic device 852 includes a microprocessor 802 that controls the overall operation of the electronic device 852. The microprocessor 802/262 interacts with the above described communications subsystem elements and also interacts with other device subsystems such as flash memory 806, random access memory (RAM) 804, auxiliary input/output (I/O) device 838, data port 828, display 834, keyboard 836, speaker 832, microphone 830, a short-range communications subsystem 820, a power subsystem 822, and any other device subsystems.

A battery 824 is connected to a power subsystem 822 to provide power to the circuits of the electronic device 852. The power subsystem 822 includes power distribution circuitry for providing power to the electronic device 852 and also contains battery charging circuitry to manage recharging the battery 824. The power subsystem 822 includes a battery monitoring circuit that is operable to provide a status of one or more battery status indicators, such as remaining capacity, temperature, voltage, electrical current consumption, and the like, to various components of the electronic device 852.

The data port 828 of one example is a receptacle connector 104 or a connector that to which an electrical and optical data communications circuit connector 800 engages and mates, as described above. The data port 828 is able to support data communications between the electronic device 852 and other devices through various modes of data communications, such as high speed data transfers over an optical communications circuits or over electrical data communications circuits such as a USB connection incorporated into the data port 828 of some examples. Data port 828 is able to support communications with, for example, an external computer or other device.

Data communication through data port 828 enables a user to set preferences through the external device or through a software application and extends the capabilities of the device by enabling information or software exchange through direct connections between the electronic device 852 and external data sources rather than via a wireless data communication network. In addition to data communication, the data port 828 provides power to the power subsystem 822 to charge the battery 824 or to supply power to the electronic circuits, such as microprocessor 802, of the electronic device 852.

Operating system software used by the microprocessor 802 is stored in flash memory 806. Further examples are able to use a battery backed-up RAM or other non-volatile storage data elements to store operating systems, other executable programs, or both. The operating system software, device application software, or parts thereof, are able to be temporarily loaded into volatile data storage such as RAM 804. Data received via wireless communication signals or through wired communications are also able to be stored to RAM 804.

The microprocessor 802, in addition to its operating system functions, is able to execute software applications on the electronic device 852. A predetermined set of applications that control basic device operations, including at least data and voice communication applications, is able to be installed on the electronic device 852 during manufacture. Examples of applications that are able to be loaded onto the device may be a personal information

manager (PIM) application having the ability to organize and manage data items relating to the device user, such as, but not limited to, e-mail, calendar events, voice mails, appointments, and task items.

Further applications may also be loaded onto the electronic device 852 through, for example, the wireless network 850, an auxiliary I/O device 838, Data port 828, short-range communications subsystem 820, or any combination of these interfaces. Such applications are then able to be installed by a user in the RAM 804 or a non-volatile store for execution by the microprocessor 802.

In a data communication mode, a received signal such as a text message or web page download is processed by the communication subsystem, including wireless receiver 812 and wireless transmitter 810, and communicated data is provided the microprocessor 802, which is able to further process the received data for output to the display 834, or alternatively, to an auxiliary I/O device 838 or the Data port 828. A user of the electronic device 852 may also compose data items, such as e-mail messages, using the keyboard 836, which is able to include a complete alphanumeric keyboard or a telephone-type keypad, in conjunction with the display 834 and possibly an auxiliary I/O device 838. Such composed items are then able to be transmitted over a communication network through the communication subsystem.

For voice communications, overall operation of the electronic device 852 is substantially similar, except that received signals are generally provided to a speaker 832 and signals for transmission are generally produced by a microphone 830. Alternative voice or audio I/O subsystems, such as a voice message recording subsystem, may also be implemented on the electronic device 852. Although voice or audio signal output is generally accomplished primarily through the speaker 832, the display 834 may also be used to provide an indication of the identity of a calling party, the duration of a voice call, or other voice call related information, for example.

Depending on conditions or statuses of the electronic device 852, one or more particular functions associated with a subsystem circuit may be disabled, or an entire subsystem circuit may be disabled. For example, if the battery temperature is low, then voice functions may be disabled, but data communications, such as e-mail, may still be enabled over the communication subsystem.

A short-range communications subsystem 820 provides for data communication between the electronic device 852 and different systems or devices, which need not necessarily be similar devices. For example, the short-range communications subsystem 820 includes an infrared device and associated circuits and components or a Radio Frequency

based communication module such as one supporting Bluetooth® communications, to provide for communication with similarly-enabled systems and devices, including the data file transfer communications described above.

A media reader 860 is able to be connected to an auxiliary I/O device 838 to allow, for example, loading computer readable program code of a computer program product into the electronic device 852 for storage into flash memory 806. One example of a media reader 860 is an optical drive such as a CD/DVD drive, which may be used to store data to and read data from a computer readable medium or storage product such as computer readable storage media 862. Examples of suitable computer readable storage media include optical storage media such as a CD or DVD, magnetic media, or any other suitable data storage device. Media reader 860 is alternatively able to be connected to the electronic device through the Data port 828 or computer readable program code is alternatively able to be provided to the electronic device 852 through the wireless network 850.

All references cited herein are expressly incorporated by reference in their entirety. It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. There are many different features to the present invention and it is contemplated that these features may be used together or separately. Thus, the invention should not be limited to any particular combination of features or to a particular application of the invention. Further, it should be understood that variations and modifications within the spirit and scope of the invention might occur to those skilled in the art to which the invention pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention.

References:

1. Young T, Palta M, Dempsey J, Peppard PE, Nieto FJ, Hla KM. Burden of sleep apnea: Rationale, design, and major findings of the wisconsin sleep cohort study. WMJ : official publication of the State Medical Society of Wisconsin 2009;108:246-249.

2. McArdle N, Devereux G, Heidarnejad H, Engleman HM, Mackay TW, Douglas NJ. Long-term use of cpap therapy for sleep apnea/hypopnea syndrome. American journal of respiratory and critical care medicine 1999;159:1108-1114.

3. Engleman HM, Martin SE, Douglas NJ. Compliance with cpap therapy in patients with the sleep apnoea/hypopnoea syndrome. Thorax 1994;49:263-266.

4. Popescu G, Latham M, Allgar V, Elliott MW. Continuous positive airway pressure for sleep apnoea/hypopnoea syndrome: Usefulness of a 2 week trial to identify factors associated with long term use. Thorax 2001;56:727-733.

5. Hui DS, Choy DK, Li TS, Ko FW, Wong KK, Chan JK, Lai CK. Determinants of continuous positive airway pressure compliance in a group of chinese patients with obstructive sleep apnea. Chest 2001;120:170-176.

6. Hoffstein V, Viner S, Mateika S, Conway J. Treatment of obstructive sleep apnea with nasal continuous positive airway pressure. Patient compliance, perception of benefits, and side effects. The American review of respiratory disease 1992;145:841-845.

7. Rolfe I, Olson LG, Saunders NA. Long-term acceptance of continuous positive airway pressure in obstructive sleep apnea. The American review of respiratory disease 1991;144:1130-1133.

8. Trotter MI, D'Souza AR, Morgan DW. Simple snoring: Current practice. The Journal of laryngology and otology 2003;117:164-168.

9. Nieto FJ, Young TB, Lind BK, Shahar E, Samet JM, Redline S, D'Agostino RB, Newman AB, Lebowitz MD, Pickering TG. Association of sleep-disordered breathing, sleep apnea, and hypertension in a large community-based study. Sleep heart health study. JAMA : the journal of the American Medical Association 2000;283:1829-1836.

10. Morgan BJ, Dempsey JA, Pegelow DF, Jacques A, Finn L, Palta M, Skatrud JB, Young TB. Blood pressure perturbations caused by subclinical sleep-disordered breathing. Sleep 1998;21:737-746.

THE CLAIMS

What is claimed is:

1. A system for reducing apnea or snoring in a patient, comprising:

a sensor for electronically sensing patient data corresponding to a current sleep or snoring state of the patient;

a transmitter to transmit the sensed data, using at least one of wired or wireless communication, to one or more electronic data processors;

software, stored on non-transitory media, executable upon the one or more electronic processors to determine if the patient data indicates a current state of sleep;

a signal generator, controllable by the one or more processors, configured to generate a wave signal;

a plurality of vibratory actuators positionable in contact with the patient's body, the actuators configured to receive a signal from the signal generator, when the one or more processors determines the current sleep state to be a state of apnea or snoring, and to transmit vibration to the patient to change a sleep state of the patient to no longer be a state of apnea or snoring.

2. The system of claim 1, wherein the plurality of vibratory actuators are assembled into a mat positionable in contact with the patient.

3. The system of claim 1, wherein the transmitter includes a cell phone to communicate the patient data to the one or more electronic data processors.

4. The system of claim 1, wherein cycle-by-cycle varied frequencies generated by the signal generator are between 0.1 and 500 Hz.

5. The system of claim 1, wherein the plurality of vibratory actuators includes electric motors.

6. The system of claim 1, wherein the sensor includes a microphone.

7. The system of claim 1, wherein the sensor includes at least one of pulse oximeter, pulse rate monitor, microphone, and video camera.

8. The system of claim 1, wherein the signal generator is configured to vary the signal transmitted to the plurality of vibratory actuators over time to reduce adaptation by the patient.

9. A method of reducing snoring or apnea in a patient, comprising:

electronically sensing data corresponding to a current sleep state of the patient;

communicating the sensed data to one or more electronic data processors;

executing software, stored on non-transitory media, upon the one or more electronic processors to determine if the patient data indicates a current state of sleep;

using the one or more processors, when the one or more processors determines the current sleep state to be a state of apnea or snoring, to cause a signal to be transmitted to a plurality of vibratory actuators positioned in contact with the patient's body, the actuators configured to transmit vibration to the patient to change a sleep state of the patient to no longer be a state of apnea or snoring.

10. The method of claim 9, wherein a cell phone is used to communicate the patient data to the one or more processors.

11. The method of claim 9, further including using a signal generator to drive the plurality of actuators.

12. The method of claim 11, wherein cycle-by-cycle varied frequencies generated by the signal generator are between 0.1 and 500 Hz.

13. The method of claim 9, wherein the plurality of vibratory actuators include electric motors.

14. The method of claim 9, further including instructing the patient to place a mat in contact with the patient's body during sleep, the mat containing the plurality of vibratory actuators.

15. The method of claim 9, further including gathering patient data using sensors.

16. The method of claim 15, wherein the sensors include a microphone.

17. The method of claim 15, wherein the sensors include at least one of pulse oximeter, pulse rate monitor, microphone, and video camera.

5

18. The method of claim 9, wherein the signal the signal transmitted to the plurality of vibratory actuators is varied over time to reduce adaptation by the patient.

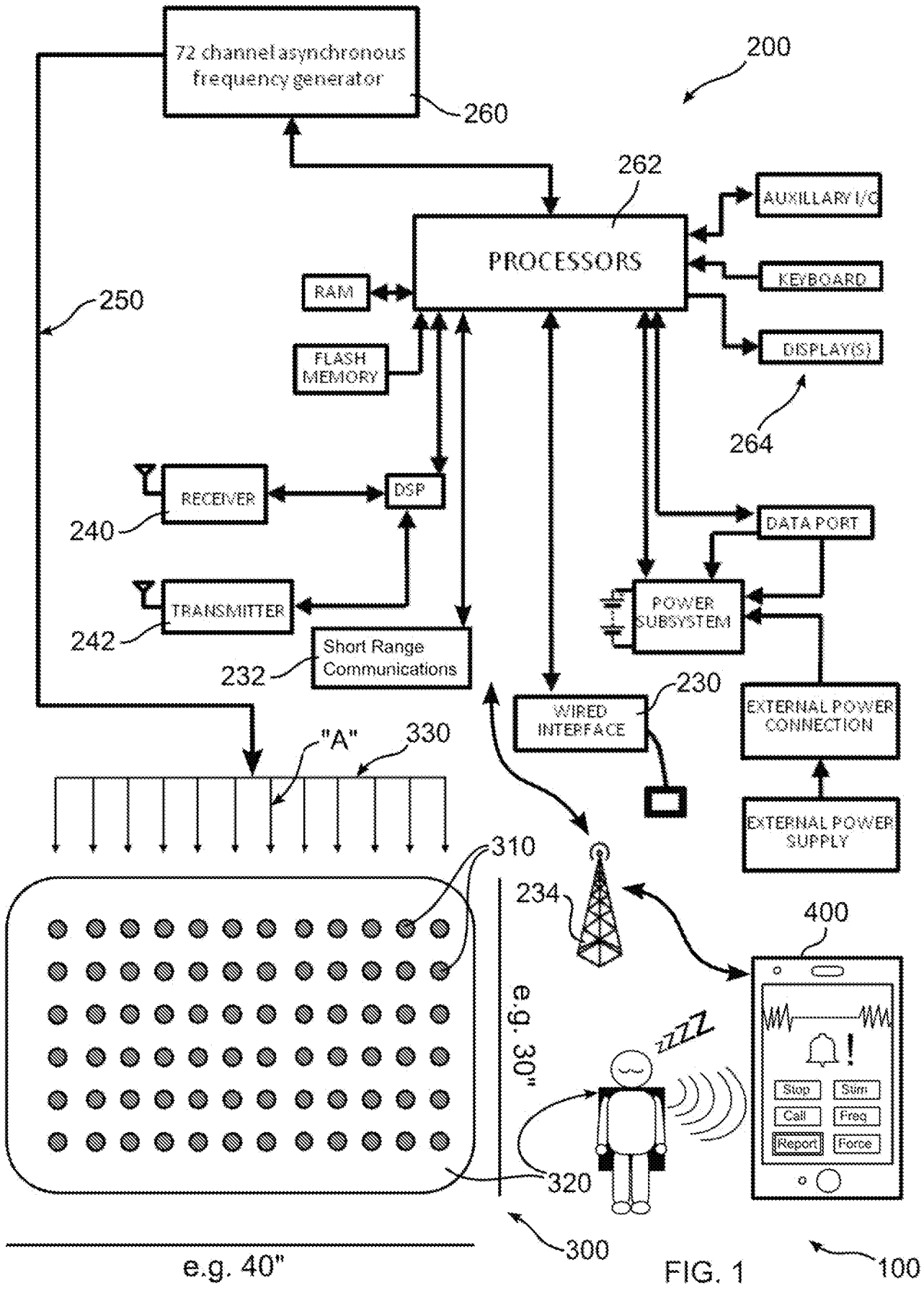
72 channel asynchronous frequency generator
260
200
262
AUXILLARY I/O
PROCESSORS
KEYBOARD
RAM
250
FLASH MEMORY
DISPLAY(S)
264
RECEIVER
DSP
240
DATA PORT
TRANSMITTER
242
POWER SUBSYSTEM
Short Range Communications
232
WIRED INTERFACE
230
EXTERNAL POWER CONNECTION
"A"
330
EXTERNAL POWER SUPPLY
310
234
400
e.g. 30"
ZZZZ
Stop
Stim
Call
Freq
Report
Force
320
300
e.g. 40"
100

FIG. 1

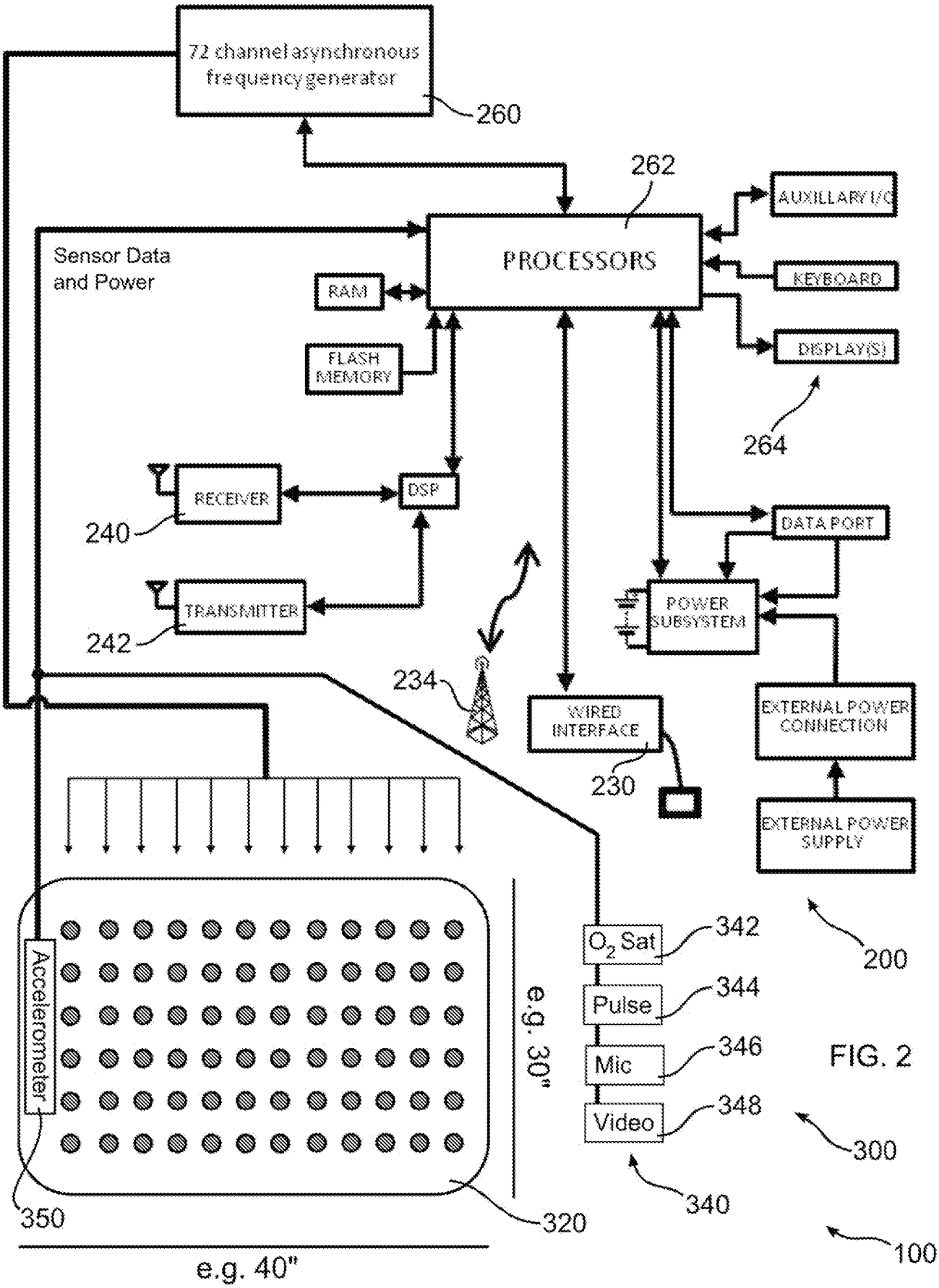
72 channel asynchronous frequency generator
260
262
PROCESSORS
AUXILLARY I/O
KEYBOARD
DISPLAY(S)
264
Sensor Data and Power
RAM
FLASH MEMORY
RECEIVER
240
DSP
TRANSMITTER
242
DATA PORT
POWER SUBSYSTEM
234
WIRED INTERFACE
230
EXTERNAL POWER CONNECTION
EXTERNAL POWER SUPPLY
200
O_2 Sat
342
Pulse
344
Mic
346
Video
348
300
340
Accelerometer
350
320
e.g. 30"
e.g. 40"
100

FIG. 2

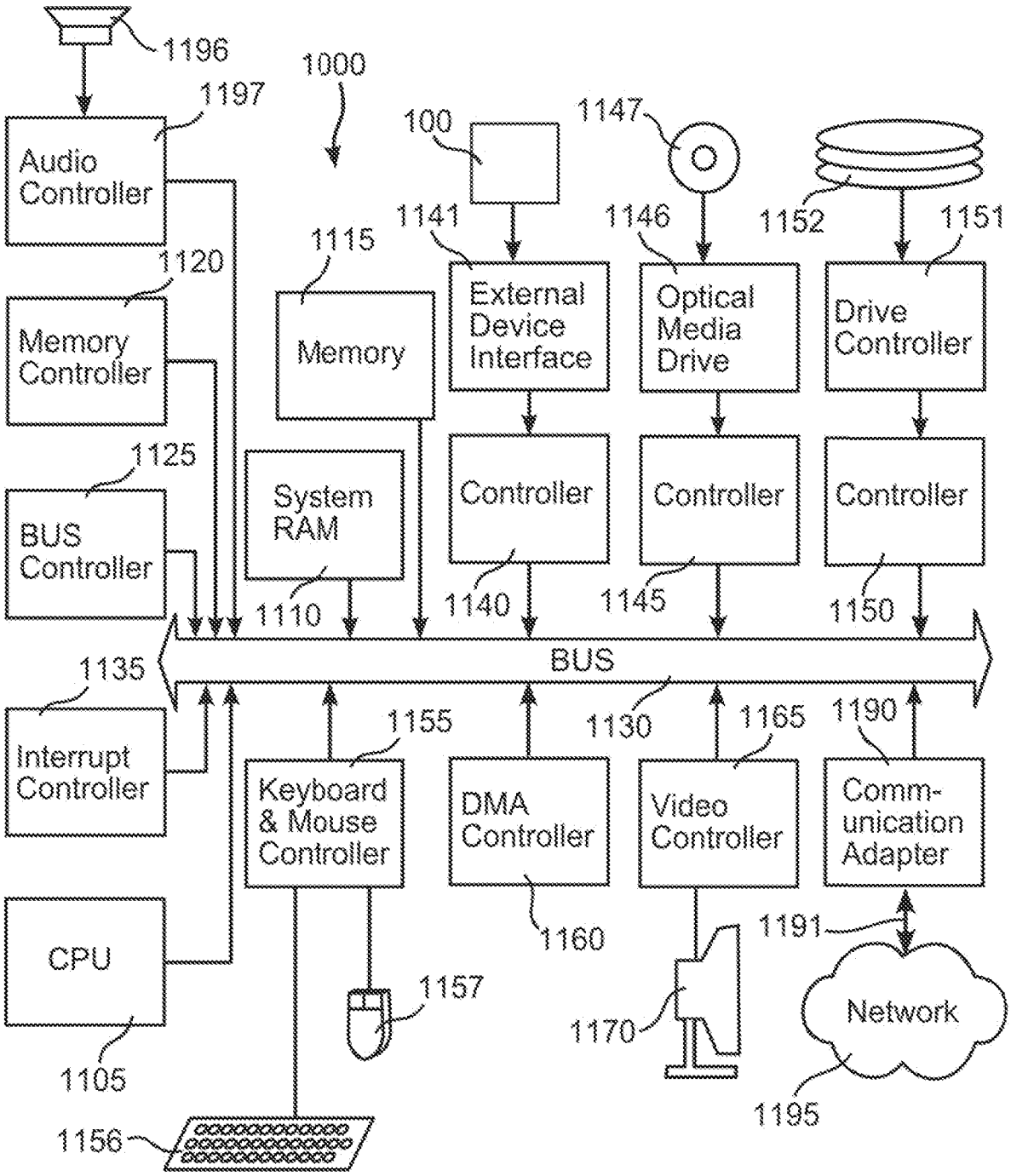
1196
1000
1197
100
1147
Audio Controller
1141
1146
1152
1151
1115
1120
External Device Interface
Optical Media Drive
Drive Controller
Memory Controller
Memory
1125
System RAM
Controller
Controller
Controller
BUS Controller
1110
1140
1145
1150
BUS
1135
1155
1130
1165
1190
Interrupt Controller
Keyboard & Mouse Controller
DMA Controller
Video Controller
Comm-unication Adapter
CPU
1160
1191
1157
1170
Network
1105
1195
1156

FIG. 3

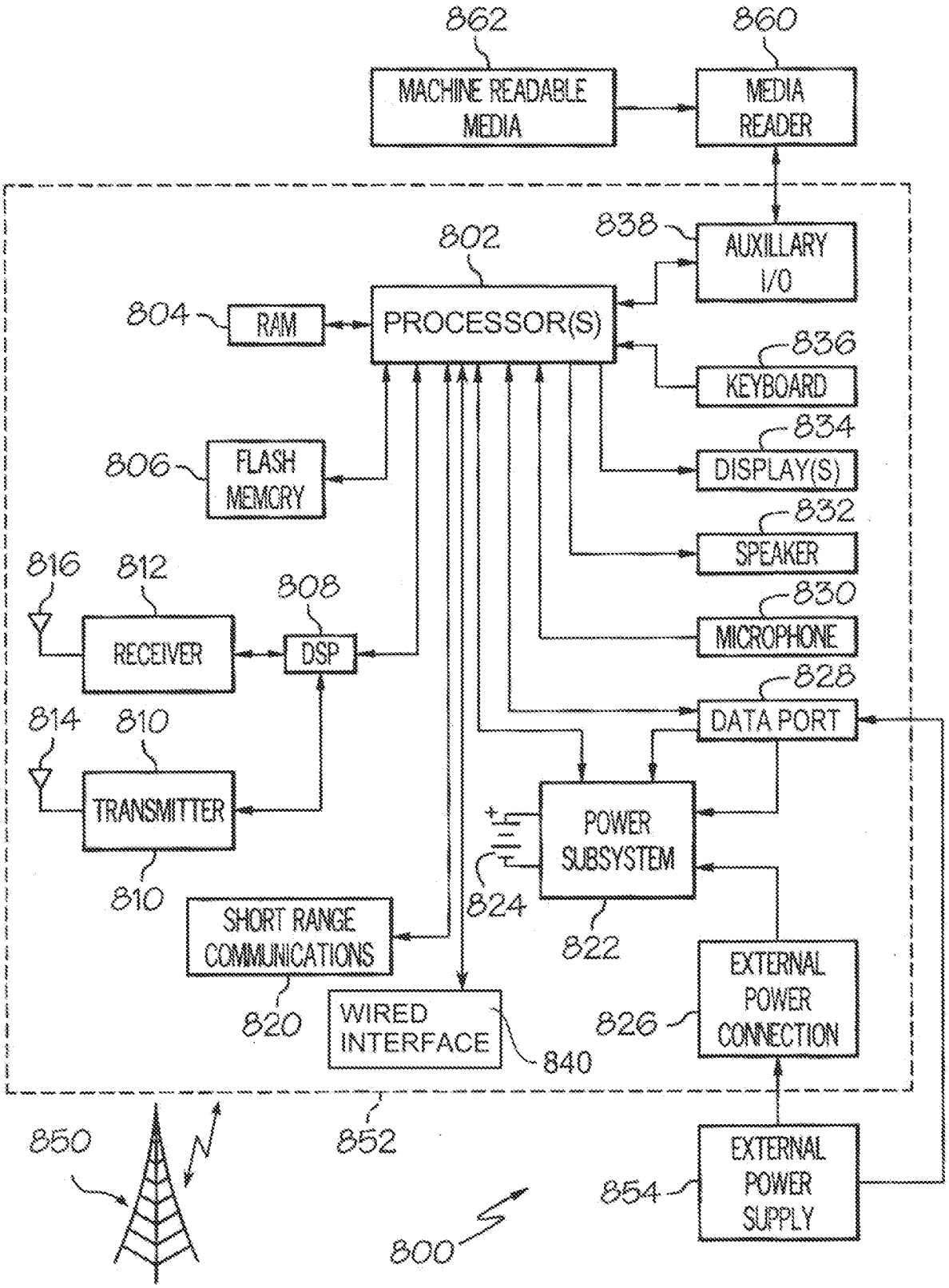
862
MACHINE READABLE MEDIA
860
MEDIA READER
838
AUXILLARY I/O
802
PROCESSOR(S)
804
RAM
836
KEYBOARD
834
DISPLAY(S)
806
FLASH MEMORY
832
SPEAKER
816
812
808
830
MICROPHONE
RECEIVER
DSP
828
DATA PORT
814
810
TRANSMITTER
POWER SUBSYSTEM
824
810
822
SHORT RANGE COMMUNICATIONS
EXTERNAL POWER CONNECTION
820
WIRED INTERFACE
826
840
850
852
EXTERNAL POWER SUPPLY
854
800

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/030589

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/00 (2015.01)
CPC - A61B 5/00 (2015.07)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00, 5/04, 5/05, 5/053, 5/08, 5/11, 5/103 (2015.01)
CPC - A61B 5/00, 5/04, 5/05, 5/053, 5/08, 5/11, 5/103 (2015.07) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/300, 301, 409, 534, 536, 595

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar
Search terms used: apnea, sensor, vibration, processor, mat

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/0295083 A1 (DOELLING et al) 01 December 2011 (01.12.2011) entire document	1-18
A	US 2010/0152553 A1 (UJHAZY et al) 17 June 2010 (17.06.2010) entire document	1-18
A	US 2005/0197588 A1 (FREEBERG) 08 September 2005 (08.09.2005) entire document	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2015	14 AUG 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)