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(72) Inventor; and
(71) Applicant : **PRINSELL, Jeffrey** [US/US]; Suite B300, 1950 Spectrum Circle SE, Marietta, GA 30067 (US).

(74) Agents: **CARLIN, Gregory, J.** et al.; McKeon, Meunier, Carlin & Curfman, LLC, Suite 500, 817 W. Peachtree Street NW, Atlanta, GA 30308 (US).

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(54) **Title**: SLEEP ONSET DETECTION SYSTEM AND METHOD

(57) **Abstract**: A sleep onset detection and alarm system that, for example, may be reusable and portable and may include an adap-ted-fit headband that houses a unilateral awake/sleep computer monitor, bilateral auditory/vibratory alarms, and a plurality of EEG and EOG and an optional EMG electrode sensors that awaken the user at unintentional sleep onset. The selection and placement of particular EEG, EOG, and optional EMG electrodes, data acquisition, and sleep stage determination is based on current established sleep medicine science and technology and follows standardized guidelines outlined the AASM Manual. The system for applying the guidelines, however, enables its use in practical (nonlaboratory) applications and/or for detection of sleep onset and prevention of unintentional sleep such as in the workplace or while driving instead of merely study of sleep.

# SLEEP ONSET DETECTION SYSTEM AND METHOD

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 61/495,151, filed on June 9, 2011, which is incorporated by reference herein in its entirety.

## BACKGROUND

The present invention relates to sleep detection systems and more particularly to systems for detecting the onset of sleep.

It is sometimes important to awaken someone who unintentionally falls asleep during normal awake times or situations due to excessive daytime sleepiness (EDS). EDS is very common in the general population and adversely affects cognitive performance. Falling asleep or "dozing off" at inappropriate times can be deadly when driving a car or bus, piloting an airplane or boat, engineering a train, operating dangerous machinery, taking care of hospitalized patients, monitoring aircraft traffic, and during other tasks that involve the safety of others.

## SUMMARY

A sleep onset detection and alarm system is disclosed that, for example, may be reusable and portable and may include an adapted-fit headband that houses a unilateral awake/sleep computer monitor, bilateral auditory/vibratory alarms, and a plurality of EEG and EOG and EMG electrode sensors that awaken the user at unintentional sleep onset. The selection and placement of particular EEG, EOG, and optional EMG electrodes, data acquisition, and sleep stage determination is based on current established sleep medicine science and technology and follows standardized guidelines outlined in the *AASM Manual for the Scoring of Sleep Events: Rules, Terminology, and Technical Specifications* published by the American Academy of Sleep Medicine in 2007 ("AASM Manual"). The system for applying the guidelines, however, enables its use in practical (non-laboratory) applications and/or for detection of sleep onset and prevention of unintentional sleep such as in the workplace or while driving instead of merely the study of sleep.

A system for detecting sleep onset in a wearer includes at least one EEG sensor and at least one EOG sensor. A head cover system of the system is configured to position and hold at least one of the sensors against a scalp of the wearer. An alarm system is configured to process

signals from the EEG and EOG sensors, detect onset of sleep and generate an alarm to facilitate wakefulness in the wearer.

The head cover system, for example, may include a plurality of bands, wherein one of the bands encircles a head of the wearer. At least one cross band extends from a first end attached to the encircling band and over the head to attach at a second end to the encircling band.

The encircling band may support at least one reading EEG sensor and at least one reference EEG sensor and the cross band supports at least one reading EEG sensor.

The cross bands may be two cross bands, wherein one of the cross bands extends over a frontal region of the head and the other one of the cross bands extends over a central region of the head.

Six reading EEG sensors may be employed wherein two of the reading EEG sensors are configured to be supported by the frontal region cross band. Two of the reading EEG sensors are configured to be supported by the central region cross band. Also, two of the reading EEG sensors are configured to be supported at an occipital region location of the head by a posterior portion of the encircling band.

In another aspect, the system includes a pair of outer canthi sensors for the EOG sensors.

The encircling band may include laterally spaced mastoid portions configured to support mastoid reference EEG sensors and/or alarms.

The cross bands may be configured to allow separation and attachment of two sub-portions, such as by use of fasteners supported at their midpoints. In this configuration, the fasteners are located generally along a medial line of the head.

The cross bands may include thin, inelastic strips of material. Also included may be a chin strap that attaches to the encircling band.

The bands may be configured for progressive securing starting at the front of the head and working toward the back. And, the band may be configured to support wires connected to the electrodes.

A monitor supported by the head cover system just above and behind the ear of the wearer may be included in the alarm system. The monitor is configured to receive signals from the EEG and EOG sensors. The monitor may be configured to determine sleep onset with the EEG and EOG signals and includes an alarm configured to trigger in response to detection of sleep onset.

The alarm may be a sound or vibration alarm. To facilitate the alarm function, the alarm may be configured for postauricular positioning. For example, the alarm may have a concave anterioinferior border configured to rest against a convex structure of the ear. The alarm may also be configured to direct sound toward an external acoustic meatus of the wearer. Also, the alarm may be configured to communicate via bone conduction.

The alarm may also be worn on an ear, such as in the pinna of the ear.

The head cover system may house the monitor and include a mastoid extension supported by the encircling band to detachably support the alarm.

EMG sensors may also be employed in the present system. For example, an EMG (or two) sensor(s) may be positioned below the chin and the alarm system is further configured to use EMG signals from the EMG sensors to detect onset of sleep. A third EMG sensor may also be employed.

Also disclosed is a method of assembling a sleep onset detection system. The method includes positioning at least one EEG sensor against the scalp and at least one EOG sensor against a skin surface by progressively assembling a plurality of bands from a front to back of a head. And, a monitor device is secured to the plurality of bands. The monitor device is configured to detect sleep onset with signals from the sensors and also includes an alarm configured to trigger at sleep onset.

Also, the method may include parting hair of the head to ensure a secure fit of the scalp sensors. The bands are assembled using fasteners, first at the back of an encircling band and then at a top of the head for the remaining ones of the bands. For example, a frontal cross band may be assembled next and then a central region cross band. Each of the bands include or support an EEG, EOG and an optional EMG sensor or sensors.

The method may further include custom fitting the bands to the head of the wearer.

During assembly, the monitoring device may be positioned to place the alarm in a postauricular position. For example, the alarm may include a concave anteriorinferior border that's positioned against a convex structure of the outer ear. The alarm may be secured to direct sound toward an external acoustic meatus. Or, the monitor device may be positioned to place the alarm in a pinna of the ear.

A chin strap may be positioned under the chin of the wearer to further secure the bands and the sleep onset detection system.

## BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Figure 1 is a front elevation of a sleep onset detection and alarm system on a head of a wearer;

Figure 2 is a side elevation view of the system of Figure 1;

Figure 3 is a plan view of the system of Figure 1;

Figure 4 is a bottom view of the system of Figure 1;

Figure 5 is a rear elevation view of the system of Figure 1;

Figures 6a and 6b are close up perspective views of ear anatomy;

Figures 7a and 7b are close up perspective views of a monitor and alarm of the system of Figure 1;

Figures 8a and 8b are perspective views of the monitor of Figures 7a and 7b, including the alarm attached to the monitor.

Figures 9a and 9b are perspective views of the monitor of Figures 8a and 8b, but with the alarm detached; and

Figure 10 is a schematic of a computer system for carrying out functions of a sleep onset detection and alarm system.

DETAILED DESCRIPTION

Disclosed is a sleep onset detection and alarm system 5 that, for example, may be reusable and portable and may include an adapted-fit headband 10 that houses a unilateral awake/sleep computer monitor 12, bilateral auditory/vibratory alarms 14, and a plurality of EEG and EOG and possibly EMG sensor electrodes that awaken the user at unintentional sleep onset. The selection and placement of particular EEG, EOG, and optional EMG electrodes, data acquisition, and sleep stage determination is based on current established sleep medicine science and technology and follows standardized guidelines outlined the AASM Manual. The system 5 for applying the guidelines, however, enables its use in practical (non-laboratory) applications and/or for detection of sleep onset and prevention of unintentional sleep such as in the workplace or while driving instead of merely study of sleep.

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

The corresponding structures, materials, acts, and equivalents of all means or step plus function elements in the claims below are intended to include any structure, material, or act for performing the function in combination with other claimed elements as specifically claimed. The description of the present invention has been presented for purposes of illustration and description, but is not intended to be exhaustive or limited to the invention in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art without departing from the scope and spirit of the invention. The embodiment was chosen and described in order to best explain the principles of the invention and the practical application, and to enable others of ordinary skill in the art to understand the invention for various embodiments with various modifications as are suited to the particular use contemplated.

Any combination of one or more computer readable medium(s) may be utilized. The computer readable medium may be a computer readable signal medium or a computer readable storage medium. A computer readable storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples (a non-exhaustive list) of the computer readable storage medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

A computer readable signal medium may include a propagated data signal with computer readable program code embodied therein, for example, in baseband or as part of a carrier wave. Such a propagated signal may take any of a variety of forms, including, but not limited to, electro-magnetic, optical, or any suitable combination thereof. A computer readable signal medium may be any computer readable medium that is not a computer readable storage medium and that can communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device.

Program code embodied on a computer readable medium may be transmitted using any appropriate medium, including but not limited to wireless, wireline, optical fiber cable, RF, etc., or any suitable combination of the foregoing.

Computer program code for carrying out operations for aspects of the present invention may be written in any combination of one or more programming languages, including an object oriented programming language such as Java, Smalltalk, C++ or the like and conventional procedural programming languages, such as the "C" programming language or similar programming languages. The program code may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

Aspects of the present invention are described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to embodiments of the invention. It will be understood that each block of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

These computer program instructions may also be stored in a computer readable medium that can direct a computer, other programmable data processing apparatus, or other devices to function in a particular manner, such that the instructions stored in the computer readable medium produce an article of manufacture including instructions which implement the function/act specified in the flowchart and/or block diagram block or blocks.

The computer program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other devices to cause a series of operational steps to be performed on the computer, other programmable apparatus or other devices to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

According to current established sleep medicine science and technology (*Principles and Practice of Sleep Medicine*. 5th edition, Elsevier, 2011), the most reliable physiologic measures of sleep onset are EEG and EOG. EMG is also usually employed with EEG and EOG for the scoring of sleep stages in conventional diagnostic sleep studies. Sleep onset in normal adults most commonly occurs from the awake state (W) to non-rapid eye movement (NREM) stage I sleep (N1).

However, other sleep stages occasionally occur at sleep onset, particularly as a result of sleep deprivation, which is not uncommon in adults with EDS. For example, REM sleep (R) - onset can occur in persons deprived of normal amounts of R sleep (and in narcolepsy). Like R, NREM stage (N2) and stage 3+4 (N3) can occasionally occur at sleep onset as compensatory rebound in sleep deprivation or as intrusion as a result of pathology or psychotropic substances. Hence, it is necessary to be able to detect all sleep stages because all (even though N1 is the most common) might occur at sleep onset.

Current established sleep medicine science and technology described in the AASM Manual provides standardized guidelines for the placement of EEG, EOG, and EMG electrodes, data acquisition, and sleep stage determination. The EEG electrodes, whose placement abide by the "International 10/20 System" (*EEG Clin. Neurophysiol.* 1958:10; pp. 371-375), necessary for sleep staging include: occipital leads to detect alpha waves, which are the hallmark brain waves of W and whose attenuation defines the onset of N1 from W; central leads to detect vertex sharp waves of N1, sleep spindles of N2, and sawtooth waves of R; and frontal electrodes to detect K complexes in N2 and slow (delta) waves in N3. Bilateral EOG electrodes (outside the lateral canthi) detect: eye blinks, reading eye movements and rapid eye movements (REM) of W; rolling slow eye movements that can occur before EEG alpha attenuation in N1; and REM in R. Bilateral submentalis EMG activity is generally higher in W, lower in N1-3, and very low with transient bursts in R, but are relatively nonspecific (in comparison with EEG and EOG) for sleep onset. Hence, according to the current AASM manual standards, together in combination all of the frontal, central, and occipital EEG and bilateral EOG leads can detect all stages of sleep that might occur at sleep onset. The AASM manual standards, notably, may change or evolve over time and adaptation to such changes are envisioned as part of the present invention.

As shown in FIGS. 1-5, the system for detection of sleep onset 5 includes an electrode arrangement, such as the electrodes recommended by the AASM Manual guidelines for the detection of sleep stages. The EEG electrodes, placed according to the International 10/20 System, for example include: occipital leads to detect alpha waves, which are the hallmark brain waves of W and whose attenuation defines the onset of N1 from W; central leads to detect vertex sharp waves of N1, sleep spindles of N2, and sawtooth waves of R; and frontal electrodes to detect K complexes in N2 and slow (delta) waves in N3.

Bilateral EOG electrodes (outside the lateral canthi) are used to detect: eye blinks, reading eye movements, and rapid eye movements (REM) of W; rolling slow eye movements that can occur before EEG alpha attenuation in N1; and REM in R. Bilateral submentalis EMG activity is generally higher in W, lower in N1-3, and very low with transient bursts in R, but are relatively nonspecific (in comparison with EEG and EOG) for sleep onset.

Also, the system 5 may use unilateral EEG frontal (F3 or F4), central (C3 or C4), and occipital (O1 or O2) with reference mastoid (M1 or M2); bilateral EOG (E1 and E2) with reference Fpz; and optional unilateral submentalis EMG (EMG1 or EMG2) with a midline chin reference (EMG-R), electrodes are utilized to detect sleep stages. The derivations for EEG are F4-M1, C4-M1, and O2-M1 (back-up F3-M2, C3-M2, and O1-M2 are ready in case the scalp-borne F4, C3, and O2 electrodes dislodge or malfunction); EOG are E1-Fpz and E2-Fpz; and EMG are either EMG1-EMG2 (the other serving as a backup in case of dislodgement or malfunction) with the mid-chin reference (EMG-R).

The exemplary system 5 can detect the onset of the following sleep stages. Stage W (awake) is detected primarily by EEG alpha rhythm with eye closure (versus low amplitude beta and alpha frequencies without the rhythmicity of alpha when the eyes are open) and, secondarily (in the occasional absence of discernable alpha waves), EOG eye blinks, reading eye movements, and rapid eye movements (REM) with normal or high EMG chin muscle activity.

Stage N1 (the most common first stage of sleep from the awake state in normal adults) is detected primarily by EEG low amplitude mixed frequency activity following alpha attenuation and, secondarily (in persons who do not generate discernable alpha rhythm), vertex sharp waves, and EOG rolling slow eye movements that sometimes commence before alpha attenuation.

Stage N2 is detected by EEG K complexes, and sleep spindles. Stage N3 is detected by EEG slow wave activity. Stage R is detected by EEG baseline low amplitude mixed frequency activity and sawtooth waves that usually precede EOG bursts of REM, and very low EMG tone with transient bursts of activity.

Those of ordinary skill in the art understand that the AASM Manual also defines arousals, major body movements and sleep staging in children. Thus, embodiments of the present invention may incorporate those standards.

The EMG is optional in this invention for several reasons. First, though helpful (but somewhat less important than EEG and EOG) for the scoring of sleep stages in diagnostic sleep studies, submentalis EMG is nonspecific for the onset of sleep. EMG activity is generally higher in W, lower in N1-3, and very low with transient bursts (that typically correspond to EOG REM and EEG sawtooth activity) in R.

Second, the additional three chin electrodes and connecting wires might be a deterrent for use of this device (see, e.g., FIGS. 1, 2 and 4). Hence, the user should consider the relatively limited benefit for precise sleep onset determination versus the cumbersome inconvenience of wearing additional facial electrodes, when deciding whether to use the optional EMG component. Accordingly, standard (EEG and EOG input) and optional (to also included EMG input) computer software options are available in the monitor, and the chin transmission wires can be attached or removed from or tucked onto the back of the headband 10.

The system 5 may also include a single, small, lightweight, flat, rectangular monitor 12, powered by rechargeable lithium batteries 16. The monitor 12 is secured to the outside of the headband 10 and located just above and behind a single ear (FIG. 7) and receives the EEG and EOG and optional EMG waves via transmission wires from the electrodes. These physiologic waves are amplified, filtered, and converted from analog to digital signals for digital resolution, analysis, and interpretation. The monitor's processor computes these physiologic parameters in an awake/sleep algorithm. When sleep rhythms are identified (and distinguished from the baseline W), the monitor activates, via a transmitter 18, the wireless alarms 14, as shown in FIGS. 8 and 9.

The postauricular alarm 14 components are configured to emit auditory noise and vibratory buzz at the detection of sleep onset. The alarm 14 component also informs the user if electrode leads are ill-fitting or loose and when the batteries are low. The user can turn on and off either option, with a menu selection of ring tones and an adjustable volume, with a control panel 20 located on the alarm components.

For example, the user might prefer only the vibratory option while in the presence of others, versus both components on the loudest settings when alone, particularly when concerned with safety such as while driving a car. The alarm 14 components are strategically located behind both ears, and below the unilateral monitor, so as to be hidden from frontal view and to be anatomically close for acoustic reception. Specifically, the postauricular alarm earpiece has a raised concave anteroinferior border that rests against the convex curvature of the outer concha to direct sound towards the external acoustic meatus (see, e.g., FIG 6 for normal ear anatomy), while seated on the mastoid to also transmit via bone conduction (i.e., like a vibrating tuning fork). Alternatively, the wireless alarm component can be worn on the ear, inside the pinna.

The postauricular alarm components can be detached 24 from the superior ledge of the mastoid extension 26 of the headband 10 (see FIG 9) and moved to other sites to conceal from view (e.g., in social settings) such as in a pocket, beneath clothing, on the wrist or arm, or even placed offsite (e.g., on the dashboard of a car). Additional backup alarms can be connected via the transmitter 18 in the monitor 12 and amplified for remote telemetry surveillance of job performance and to awake or replace somnolent workers, particularly those in responsibility for the safety of others. Alternative alarm designs can be utilized. Commercial (e.g., like an earphone) or custom-fabricated (e.g., like a hearing aid) alarm pieces can be worn inside the ear pinna for enhanced hearing acuity.

The unique portable headband 10 (FIG 1-5), which houses the components including for example, but not limited to, the monitor-alarm system and electrodes, has multiple desirable features. It is made of a soft, elastic, plastic-like, water-repellant material that is light-weight, thin, flexible, comfortable, durable for reuse, and easily cleansable. It comes in several sizes that are determined by head circumference for standardized EEG electrode placement as per the International 10/20 System listed in sleep medicine textbooks and the AASM Manual.

Once custom-fitted, calibrated, tested, and instructed on self-use, it is worn from that time forward without additional assistance of a trained technician. No tedious repeat measurements, fittings, or adjustments for proper electrode placement are necessary since it is worn only by the same adult user, whose head circumference does not change.

The headband-borne device is seated on the head by the user from front to back and secured snugly with overlapping or loop-and-hook Velcro straps: first in the back, and secondly on the top. This headband seating sequence method facilitates secure attachment of each EEG electrode from front to back and then on top of the head (see, e.g., FIGS. 2, 3 and 5). That is, placed electrodes are not loosened or dislodged during placement of remaining electrodes. EOG and optional EMG electrodes are placed after the headband is seated (see, e.g., FIGS. 1, 2 and 4).

The thin straps of the headband 10 minimize (see, e.g., FIGS. 1, 2, 3 and 5) heat accumulation and sweating or discomfort that might otherwise occur with full head coverage. The thin head straps also allow hair to be easily parted to expose the scalp for necessary secure EEG electrode placement. This snug custom-fit headband 10 maintains inward pressure on the placed electrodes against the scalp to minimize impedance and thereby enhance brainwave signal conduction, as well as to minimize potential loosening or dislodgement of the EEG electrodes, which might otherwise cause loss or distortion of brainwave signals and artifact or “noise” interference, particularly when the user is moving his/her head in an ambulatory work environment. An optional removable (e.g., via hook-and-loop tape) elastic chinstrap is available to ensure a snug fit, particularly in adults with long or oily head hair.

The headband 10 design houses all the standard EEG, EOG, and EMG electrodes (listed in the AASM Manual) for accurate and reliable sleep onset detection. EEG frontal, central, occipital, mastoid electrode receptacles are located on the inner side of the headband and connect to the monitor by thin insulated transmitting wires that are embedded within the headband. Even when the postauricular alarms 14 are detached, the mastoid reference electrodes remain intact on the underside of the mastoid extensions 26 of the headband 10 (see, e.g., FIG 9).

As shown in FIGS. 9a and 9b, the bilateral alarm components 12 may be detachable from the bilateral mastoid extensions 26 from the encircling band 10, e.g., as an alternative to attaching to the monitor 12 or in instances where there is no monitor 12. The alarms snap into alarm attachments 24 of the bilateral mastoid extensions of the encircling band. As a result, they need not snap into the monitor, rather, they visually abut the inferior edge of the monitor.

Additionally, the mastoid extension 26 may house the mastoid reference electrodes on its underside (secured against the postauricular skin). Also, it may support the alarms structurally and functionally to direct sound against the concha towards the external auditory meatus as well as allowing for bone conduction.

This headband feature of electrode and connecting wire immobilization and insulation minimizes potential brainwave signal distortion, artifact, or noise interference that might otherwise adversely affect the accurate and reliable detection of sleep onset. Thin insulated transmitting wires from the bilateral EOG and optional EMG electrodes connect to the headband above the ears and behind one ear that houses the monitor, respectively.

Disposable, inexpensive, generic, small, round electrode pads are snapped onto the electrode receptacles, and the paper covering is removed to expose the adhesive collar and conduction paste and collodium-like adhesive gel in the central portions of the pads (e.g., like activating a BANDAID dressing) before seating the headband. The headband can also employ active dry electrodes, which might be more user-friendly than wet electrodes.

Several design features enhance tolerance and, hence, compliance with intended use. The headband 10 is lined with soft, foam-like material for custom-fitting comfort, and the outer smooth surface can have stylish colors and designs or can be covered with hair (e.g., bangs in the front and long hair on the sides and back) versus a cap, hat, or wig. The small, flat, light-weight, single monitor 12 and bilateral alarms 14 are hidden behind the ears so as to not be as noticeable from the frontal view and not interfere with wearing eyeglasses, headphones, caps, or hats.

Wireless alarms worn on the ear, inside the pinna, are also socially-acceptable. All EEG electrodes are concealed from view, on the inner side of the headband. Skin-colored EOG electrodes, symmetrically placed 1 cm below and lateral to the outer canthi, do not interfere with vision and can be partially obscured by eyeglasses. Two of the 3 skin-colored EMG electrodes are below the chin and, hence, are not readily visible with normal head posture. The facial EOG and optional EMG transmission wires are also skin-colored and follow the path of eyeglasses' arms and lower jaw line, respectively, so as to not be too noticeable (see, e.g., FIGS 1, 2 and 4).

This headband-borne monitor and alarm device system can accommodate and incorporate scientific and technologic advances in sleep medicine such as refinements in the definition and detection of sleep onset. The processor's awake/sleep algorithm in the monitor 12 can be customized to learn sleep onset patterns of the particular user, and can be periodically updated with innovations in EEG, EOG, EMG, and other input parameters such as memory, behavior, sensory (e.g., auditory, visual, olfactory, and pain) stimuli, motor reflexes, respiration, cardiac, autonomic (sympathetic and parasympathetic) activity, and other integrative functions that might be affected significantly at sleep onset.

The headband 10 can accept additional electrodes (e.g., for additional EEG measurements) via additional straps and can serve as a receiving base for connecting wires from other body sites for additional input (e.g., masseter for EMG, chest for electrocardiography, and earlobe for pulse oximetry and temperature, wrist for actigraphy and peripheral arterial tonometry) that might be defined as useful (but only if tolerable to wear in ambulatory settings such as in the workplace), perhaps in combination, to aid in the detection of sleep onset.

Wireless technology might reduce or replace electrodes and the detection of sleep onset may be automated.

Referring now to Fig. 10, a schematic diagram of a central server 500, or similar network entity, configured to implement a sleep onset detection and alarm system is provided. As used herein, the designation "central" merely serves to describe the common functionality the server provides for multiple clients or other computing devices and does not require or infer any centralized positioning of the server relative to other computing devices.

As may be understood from Fig. 10, in this embodiment, the central server 500 may include a processor 510 that communicates with other elements within the central server 500 via a system interface or bus 545. Also included in the central server 500 may be a display device/input device 520 for receiving and displaying data. This display device/input device 520 may be, for example, a keyboard or pointing device that is used in combination with a monitor. The central server 500 may further include memory 505, which may include both read only memory (ROM) 535 and random access memory (RAM) 530. The server's ROM 535 may be used to store a basic input/output system 540 (BIOS), containing the basic routines that help to transfer information across the one or more networks.

In addition, the central server 500 may include at least one storage device 515, such as a hard disk drive, a floppy disk drive, a CD Rom drive, or optical disk drive, for storing information on various computer-readable media, such as a hard disk, a removable magnetic disk, or a CD-ROM disk. As will be appreciated by one of ordinary skill in the art, each of these storage devices 515 may be connected to the system bus 545 by an appropriate interface. The storage devices 515 and their associated computer-readable media may provide nonvolatile storage for a central server. It is important to note that the computer-readable media described above could be replaced by any other type of computer-readable media known in the art. Such media include, for example, magnetic cassettes, flash memory cards and digital video disks.

A number of program modules may be stored by the various storage devices and within RAM 530. Such program modules may include an operating system 550 and a plurality of one or more (N, wherein N in the context of Fig. 10 refers to integers 1, 2, 3. . . etc.) modules 560. The modules 560 may control certain aspects of the operation of the central server 500, with the assistance of the processor 510 and the operating system 550. For example, the modules may perform the functions described above and illustrated by the figures and other materials disclosed herein. Exemplary modules include a sleep onset detection module 565 that uses EOG and EEG and optional EMG sensor inputs to detect sleep onset and an alarm module 570 that is configured to trigger a sound or movement alarm in response to sleep onset detection.

The flowchart and block diagrams in the figures illustrate the architecture, functionality, and operation of possible implementations of systems, methods and computer program products according to various embodiments of the present invention. In this regard, each block in the flowchart or block diagrams may represent a module, segment, or portion of code, which comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that, in some alternative implementations, the functions noted in the block may occur out of the order noted in the figures. For example, two blocks shown in succession may, in fact, be executed substantially concurrently, or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved. It will also be noted that each block of the block diagrams and/or flowchart illustration, and combinations of blocks in the block diagrams and/or flowchart illustration, can be implemented by special purpose hardware-based systems that perform the specified functions or acts, or combinations of special purpose hardware and computer instructions.

Advantageously, embodiments of the present invention address the shortcomings of the prior art. Measures of alertness and many physiologic parameters exhibit false positives (sensitivity but not specificity) for the detection of sleep onset. Prior art devices worn while driving a car that detect and respond to eyelid closure, head nodding, a relaxed grip on a steering wheel, and impaired concentration detected by concurrent performance tests or vigilance games (that can detract from driving) are flawed in that these actions can also occur in the absence of sleep. Actigraphy, which detects changes in body movement, can misinterpret motionless as sleep. Peripheral arterial tonometry such as peripheral vasoconstriction induced by sympathoadrenergic alpha receptor activity and oxyhemoglobin desaturations measured by pulse oximetry during obstructive sleep apnea events, changes in heart rate, temperature, sweating, altered breathing, and other physiologic parameters are not specific for the moment of sleep onset.

These alarm systems might be activated by drowsiness or decreased mental alertness, which are not necessarily sleep onset. These false positives (for sleep onset) might actually be a source of irritation and frustration of being continually stimulated to “wake up” even though they are not asleep, which often creates intolerance and non-compliance with their intended use.

Polysomnography (PSG), the gold standard for evaluating sleep, is more accurate for detecting sleep onset than the above-described prior art devices. However, it employs numerous electrodes and connecting wires (for many physiologic parameters in addition to the EEG, EOG, and EMG used for sleep staging) that must be placed and calibrated by a technician and, thus, are cumbersome and impractical for an ambulatory person to wear during typical ambulatory work environments. PSG and portable ambulatory monitors, which utilize less physiologic parameters, are used for sleep staging and to diagnose neurologic disorders such as epilepsy or sleep disorders such as obstructive sleep apnea. Both store information that must be downloaded for computer software analysis that is performed later at separate site.

However, neither conventional PSG nor portable monitors have sleep onset detection alarm components designed to awaken the user from unintentional falling asleep during inappropriate times such as on the job or driving. Although both utilize established sleep medicine science and technology (to determine sleep onset and sleep stages with EEG, EOG, and EMG), a fundamental difference is that PSG and portable monitors strive to diagnose and correct or improve sleep from a medical perspective,

In contrast, embodiments of the present invention strive to awaken from sleep onset in a commercial setting. Use in such practical environments for sleep onset detection and avoidance of unintentional sleep such as in the workplace or while driving – as opposed to sleep study in a laboratory or clinical setting – is enabled by use of a reusable ambulatory custom-fit headband-borne computer monitor component that analyzes sleep onset variables in real-time.

Reference Numbers/Letters

10 Headband

12 Awake/sleep computer monitor

14 Postauricular auditory/vibratory Alarms

16 Power source with Lithium batteries

18 Transmitter to the alarms

20 Alarm control panel

22 Alarm speakers

24 Alarm attachment

26 Mastoid extension of the headband

| | |
|---|---|
| $F_3$, $F_4$, $F_{pz}$ | Left and right Frontal EEG electrodes and mid-frontal reference |
| $C_3$ and $C_4$ | Left and right Central EEG electrodes |
| $O_1$ and $O_2$ | Left and right Occipital EEG electrodes |
| $M_1$ and $M_2$ | Left and right Mastoid reference electrodes |
| $E_1$ and $E_2$ | Left and right EOG electrodes |
| $EMG_1$, | Left submentalis EMG electrode |
| $EMG_2$, | Right submentalis EMG electrode |

$EMG_1$ Mid-chin reference EMG electrode

V Velcro straps

The corresponding structures, materials, acts, and equivalents of all means or step plus function elements in the claims below are intended to include any structure, material, or act for performing the function in combination with other claimed elements as specifically claimed. The description of the present invention has been presented for purposes of illustration and description, but is not intended to be exhaustive or limited to the invention in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art without departing from the scope and spirit of the invention. The embodiment was chosen and described in order to best explain the principles of the invention and the practical application, and to enable others of ordinary skill in the art to understand the invention for various embodiments with various modifications as are suited to the particular use contemplated.

CLAIMS

1. A system for detecting sleep onset in a wearer, the system comprising:

at least one EEG sensor and at least one EOG sensor;

a head cover system configured to position and hold at least one of the sensors adjacent a scalp of the wearer; and

an alarm system configured to process signals from the EEG and EOG sensors, detect onset of sleep and generate an alarm to prevent unintentional sleep in the wearer.

2. A system of Claim 1, wherein the head cover system includes a plurality of bands, wherein one of the bands encircles a head of the wearer and at least one cross band extends from a first end attached to the encircling band and over the head to attach at a second end to the encircling band.

3. A system of Claim 2, wherein the encircling band supports at least one reading EEG sensor and at least one reference EEG sensor and wherein the cross band supports at least one reading EEG sensor.

4. A system of Claim 3, wherein the at least one cross band includes two cross bands, one of the cross bands extending over a frontal region of the head and the other one of the cross bands extending over a central region of the head.

5. A system of Claim 4, further comprising six reading EEG sensors, wherein two of the reading EEG sensors are configured to be supported by the frontal cross band, two of the reading EEG sensors are configured to be supported by the central region cross band and two of the reading EEG sensors are configured to be supported at an occipital location on the head by a posterior portion of the encircling band.

6. A system of Claim 5, wherein the at least one EOG sensor includes a pair of outer canthi sensors.

7. A system of Claim 6, wherein the encircling band includes laterally spaced mastoid portions configured to support mastoid reference EEG sensors.

8. A system of Claim 4, wherein the cross bands include fasteners configured to allow separation and attachment of two sub-portions of each of the cross bands.

9. A system of Claim 8, wherein the fasteners are configured for positioning generally along a medial line of the head.

10. A system of Claim 4, wherein the bands include thin strips of material.

11. A system of Claim 10, wherein the thin strips are inelastic.

12. A system of Claim 11, wherein each of the bands includes at least one fastener configured to allow progressive securing of the bands from front to back.

13. A system of Claim 12, further comprising a chin strap configured to attach to at least one of the bands.

14. A system of Claim 12, wherein the encircling and cross bands are configured to support wires connected to the sensors.

15. A system of Claim 1, wherein the alarm system includes a monitor supported by the head cover system just above and behind an ear of the wearer.

16. A system of Claim 15, wherein the monitor is configured to receive signals from the EEG and EOG sensors.

17. A system of Claim 16, wherein the monitor is configured to determine sleep onset with the EEG and EOG signals and includes an alarm configured to trigger in response thereto.

18. A system of Claim 17, wherein the alarm is at least one of a sound or vibration alarm.

19. A system of Claim 17, wherein the alarm is configured for postauricular positioning.

20. A system of Claim 19, wherein the alarm has a concave anterioinferior border configured to rest against a convex structure of the outer ear.

21. A system of Claim 20, wherein the alarm is configured to direct sound toward an external acoustic meatus of the wearer.

22. A system of Claim 21, wherein the alarm is also configured to communicate via bone conduction.

23. A system of Claim 17, wherein the alarm is configured for wearing on an ear of the wearer and inside a pinna of the ear.

24. A system of Claim 17, wherein the head cover system includes at least one encircling band and further includes a mastoid extension configured to detachably support the alarm.

25. A system of Claim 1, further comprising at least one EMG sensor positioned below the chin and wherein the alarm system is further configured to use EMG signals from the EMG sensors to detect onset of sleep.

26. A system of Claim 25, wherein the at least one EMG sensor includes three EMG sensors.

27. A system of Claim 26, wherein two of the EMG sensors are positioned below a chin of the wearer and on reference EMG sensor on a mid-chin of the wearer.

28. A method of assembling a sleep onset detection system, the method comprising:

positioning at least one EEG sensor against a scalp and at least one EOG sensor against the skin by progressively assembling a plurality of bands from front to back of a head; and

securing a monitor device, the monitor device configured to detect sleep onset with signals from the sensors and having an alarm configured to trigger at sleep onset, to the plurality of bands.

29. A method of Claim 28, wherein assembling includes securing fasteners of the bands first at a back of an encircling band and then at a top of the head of remaining ones of the bands.

30. A method of Claim 29, further comprising assembling a frontal cross band and a central region cross band in order, after assembling the encircling band.

31. A method of Claim 30, wherein each of the encircling and cross bands includes one or more of the EEG sensors.

32. A method of Claim 31, further comprising fitting the encircling and cross bands to the head.

33. A method of Claim 28, further comprising positioning the alarm in a postauricular position.

34. A method of Claim 33, wherein securing the alarm includes positioning a concave anterioinferior border of the alarm against a convex structure of the outer ear.

35. A method of Claim 34, further comprising securing the alarm to direct sound toward an external acoustic meatus.

36. A method of Claim 32, wherein securing the monitor device includes positioning the alarm in a pinna of the ear.

37. A method of Claim 28, further comprising attaching a chin strap by connected the chin strap to the encircling band and extending the chin strap under a chin.

38. A method of Claim 31, further comprising receiving a wire of the EOG sensor into the encircling band.

39. A method of Claim 38, further comprising receiving a wire of an EMG sensor into the encircling band.

40. A system of Claim 3, wherein the encircling band further supports a frontal reference EOG sensor.

# Headband-borne Sleep Onset Monitor-Alarm Device

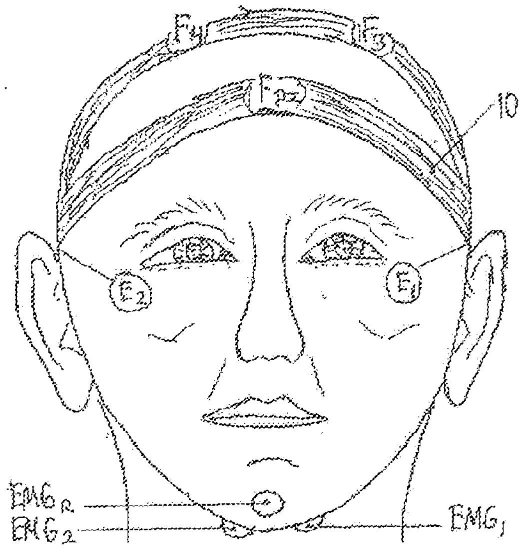


Fig 1. Front of head

10 Headband components:

12 Awake/Sleep computer Monitor (unilateral, shown on Left side)

14 Auditory/Vibratory Alarms (bilateral)

$M_{1,2}$ Mastoid } references

$F_{pz}$ Forehead

$F_{3,4}$ Frontal EEG

$C_{3,4}$ Central EEG

$O_{1,2}$ Occipital EEG

} Electrodes on inner side of headband with thin insulated connecting wires to Monitor embedded inside headband

$E_{1,2}$ EOG electrodes on Outer Canthi (below & outside both eyes)

$EMG_{1,2,R}$ EMG electrodes on Submentalis (reference on mid-chin)

} skin-colored wires follow eyeglass arms & jaw line to headband

V Velcro straps (back & top of headband)

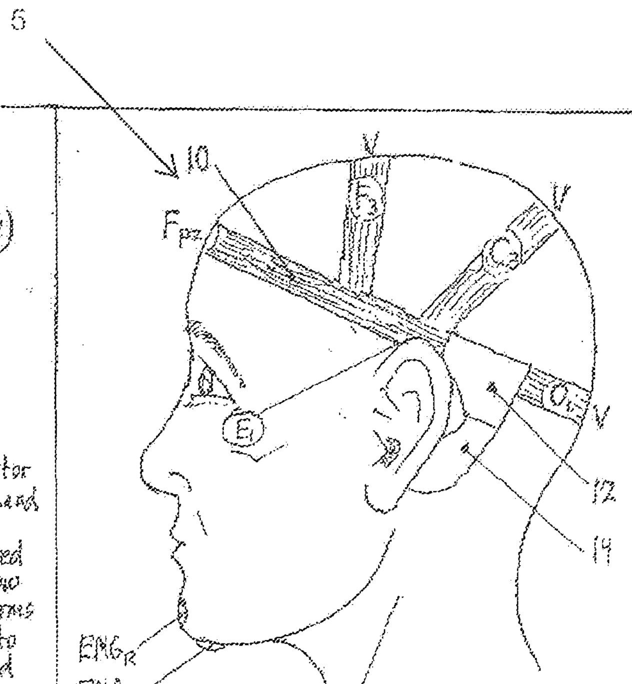


Fig 2. Side of head

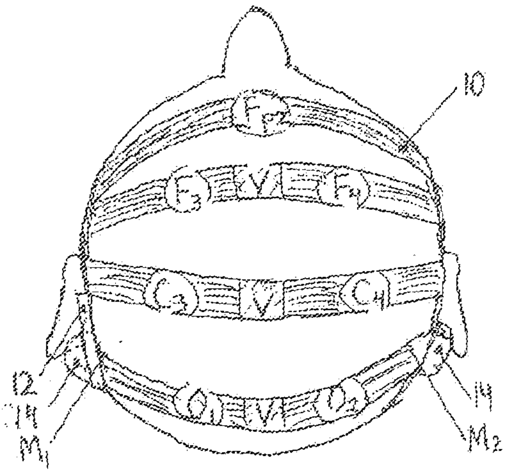


Fig 3. Top of head

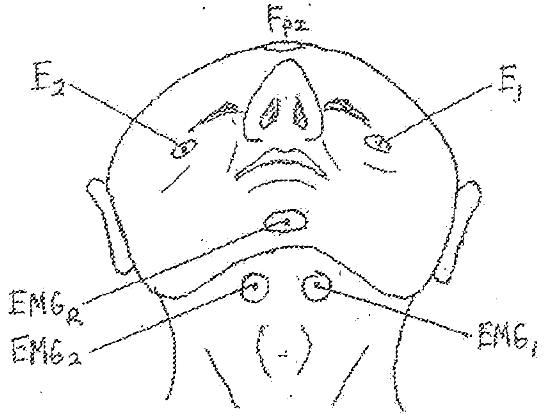


Fig 4. Front view of head tilted backwards

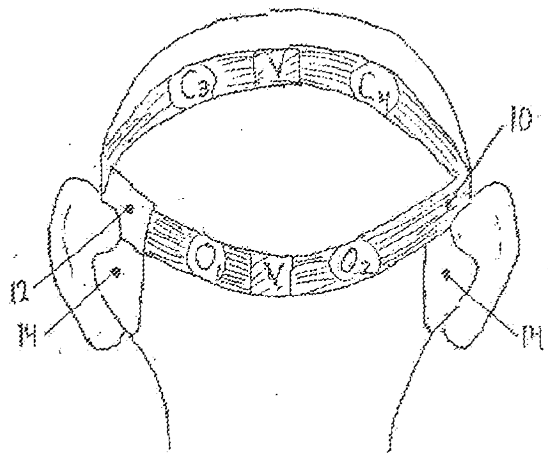


Fig 5. Back of head

Headband-borne Sleep Onset Monitor-Alarm Device (Right side same except no Monitor)

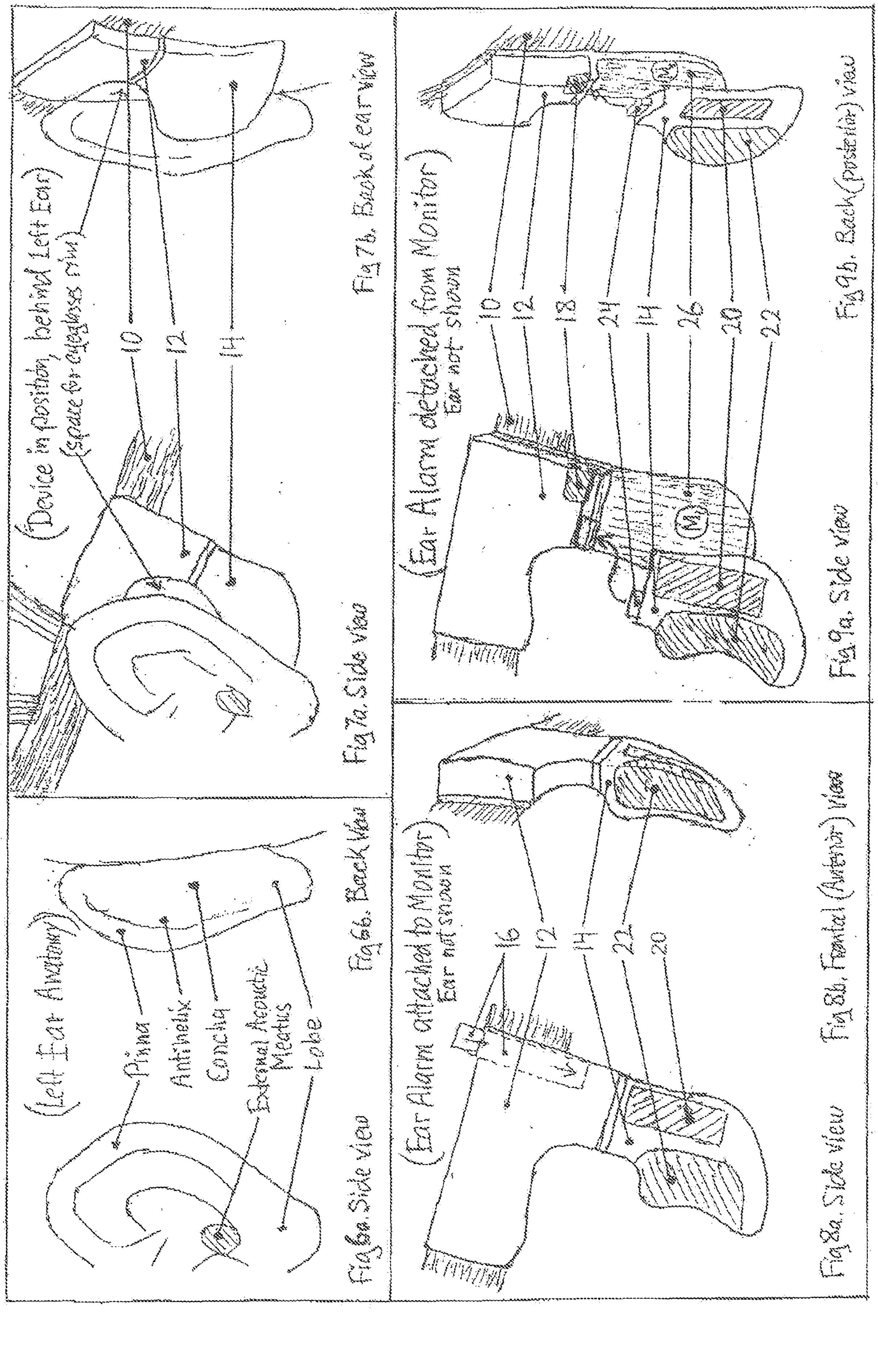



Fig 6a. Side view

Fig 6b. Back View

Fig 7a. Side view

Fig 7b. Back of ear view

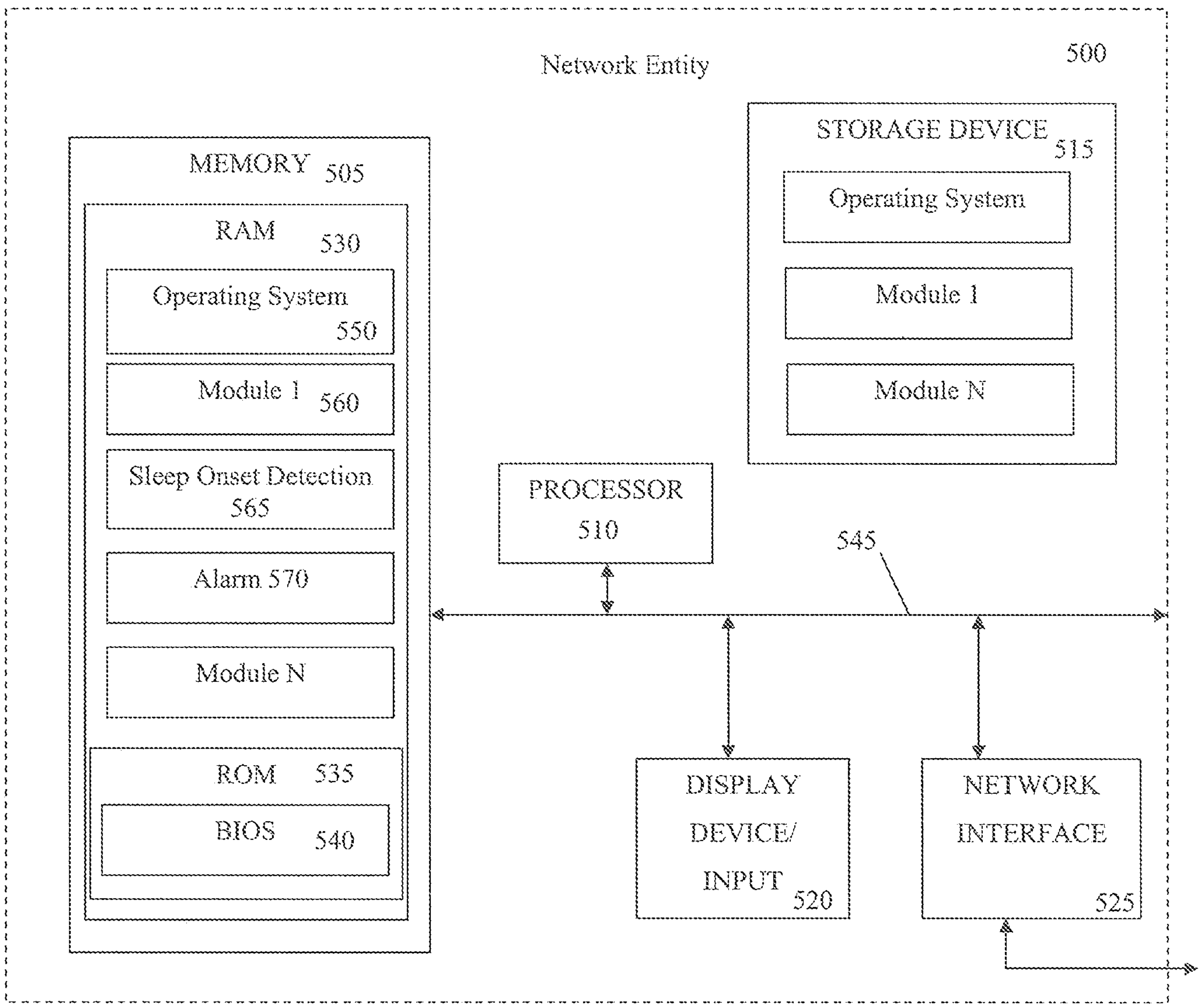
Fig 8a. Side view

Fig 8b. Frontal (Anterior) view

Fig 9a. Side view

Fig 9b. Back (posterior) view

Fig. 10


Network Entity
500
MEMORY 505
RAM 530
Operating System 550
Module 1 560
Sleep Onset Detection 565
Alarm 570
Module N
ROM 535
BIOS 540
STORAGE DEVICE 515
Operating System
Module 1
Module N
PROCESSOR 510
545
DISPLAY DEVICE/ INPUT 520
NETWORK INTERFACE 525