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Garcia Molina et al.

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(54) **SYSTEM AND METHOD FOR ADJUSTING THE INTENSITY OF SENSORY STIMULATION DURING SLEEP BASED ON SLEEP SPINDLES**

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A61B 5/00 (2006.01)
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(52) **U.S. Cl.**
CPC ***A61B 5/04845*** (2013.01); ***A61B 5/048*** (2013.01); ***A61B 5/4812*** (2013.01); ***A61B 5/6803*** (2013.01); *A61B 5/6831* (2013.01)

(58) **Field of Classification Search**
None
See application file for complete search history.

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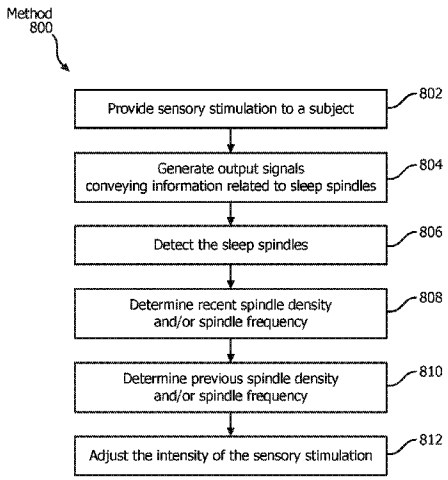
Primary Examiner — Etsub D Berhanu

(57) **ABSTRACT**

The present disclosure pertains to a system configured to adjust an intensity of sensory stimulation delivered to a subject during a sleep session based on sleep spindles in the subject during the sleep session. The system is configured to adjust the intensity of the stimulation based on a sleep spindle frequency and/or a sleep spindle density. The system is configured to determine a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on detected sleep spindles, and to determine a previous spindle density and/or a previous
(Continued)



spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles. The system controls the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency.

14 Claims, 8 Drawing Sheets

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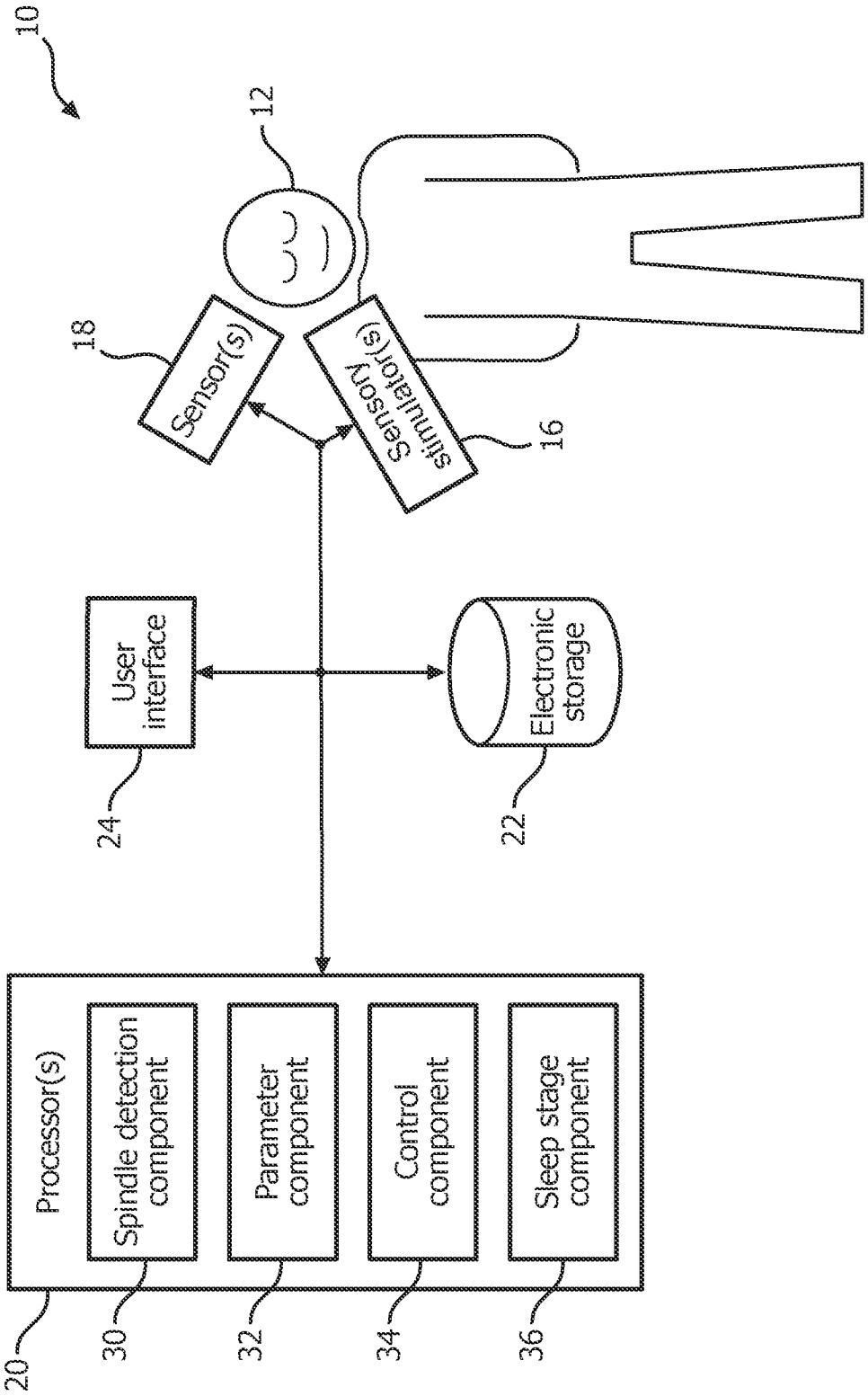
10
12
18
Sensor(s)
Sensory stimulator(s)
16
User interface
24
Electronic storage
22
Processor(s)
20
Spindle detection component
30
Parameter component
32
Control component
34
Sleep stage component
36

FIG. 1

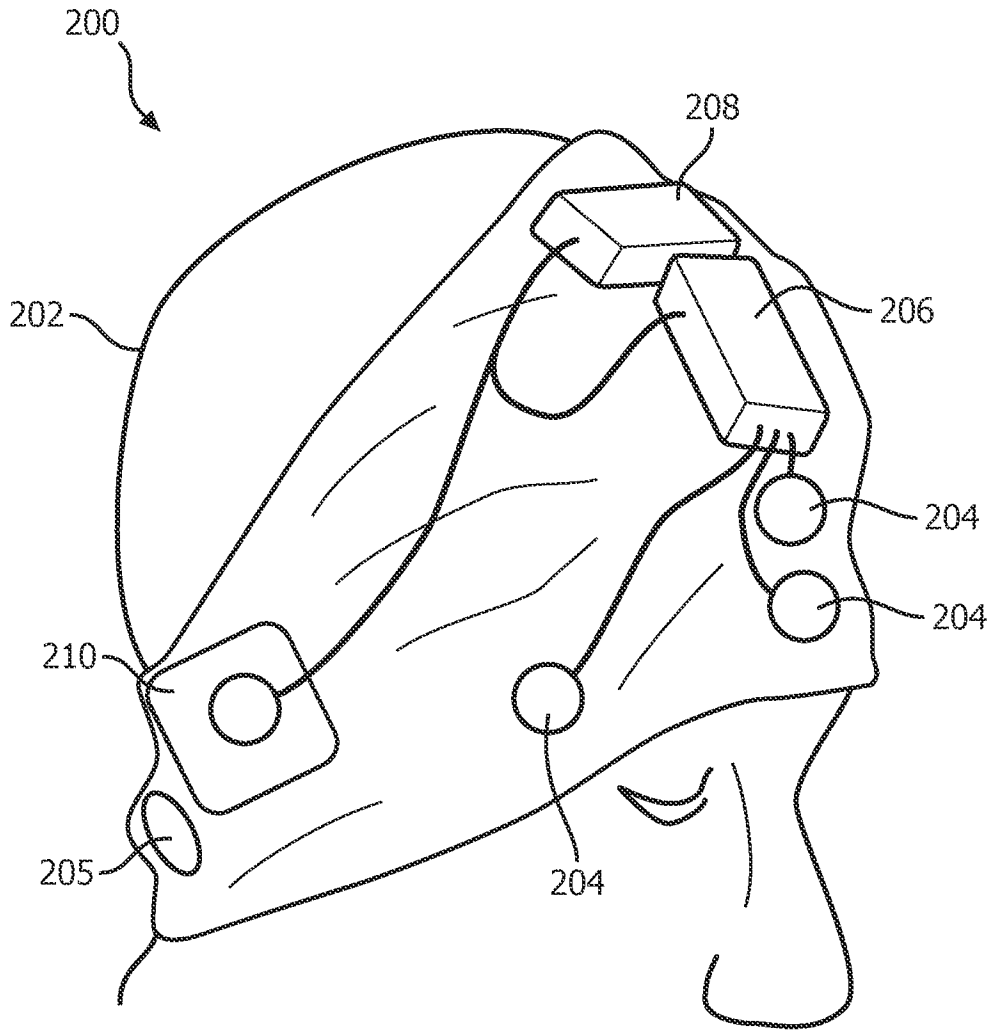

FIG. 2

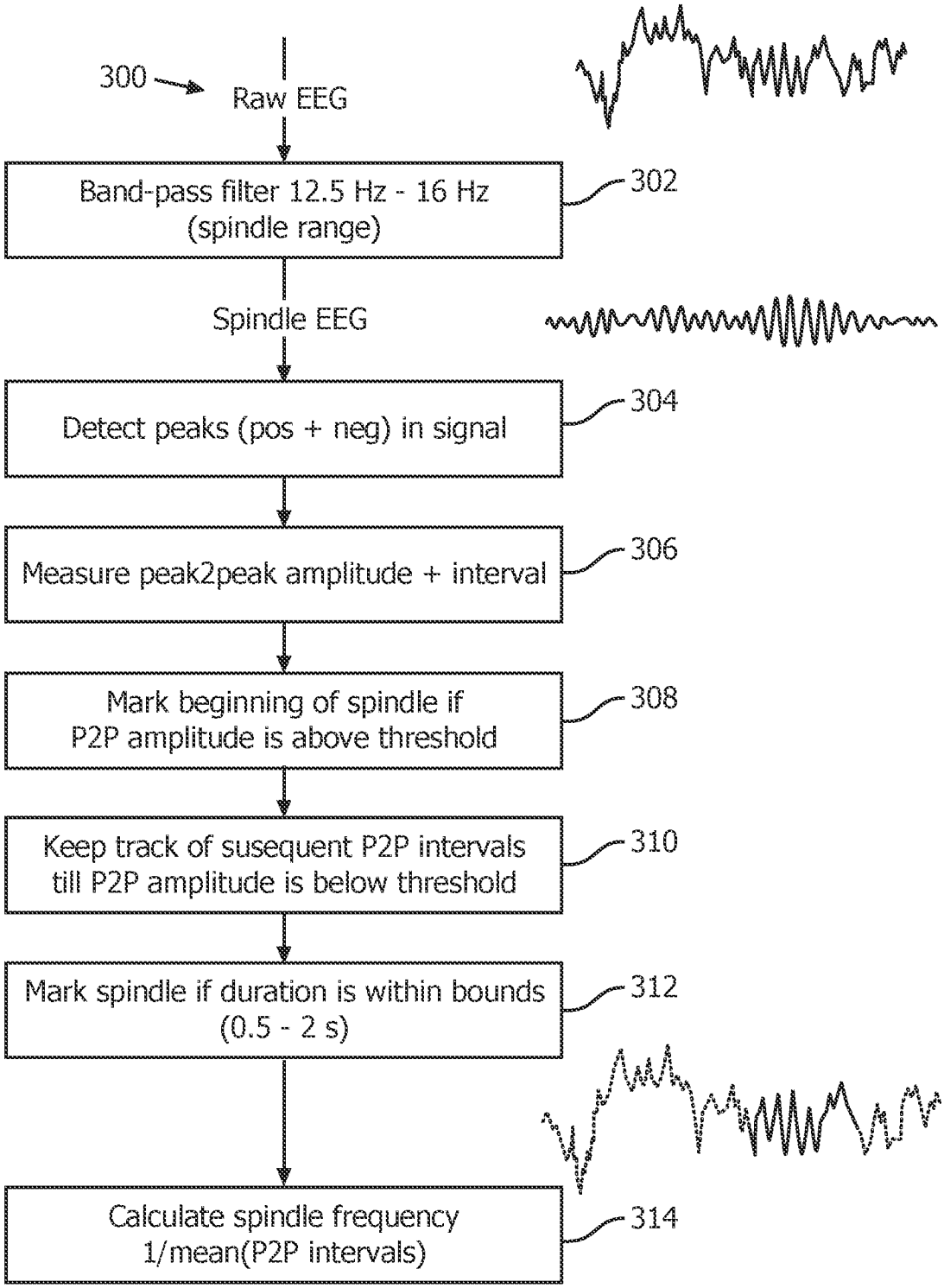
300
Raw EEG
Band-pass filter 12.5 Hz - 16 Hz
(spindle range)
302
Spindle EEG
Detect peaks (pos + neg) in signal
304
Measure peak2peak amplitude + interval
306
Mark beginning of spindle if
P2P amplitude is above threshold
308
Keep track of susequent P2P intervals
till P2P amplitude is below threshold
310
Mark spindle if duration is within bounds
(0.5 - 2 s)
312
Calculate spindle frequency
1/mean(P2P intervals)
314

FIG. 3

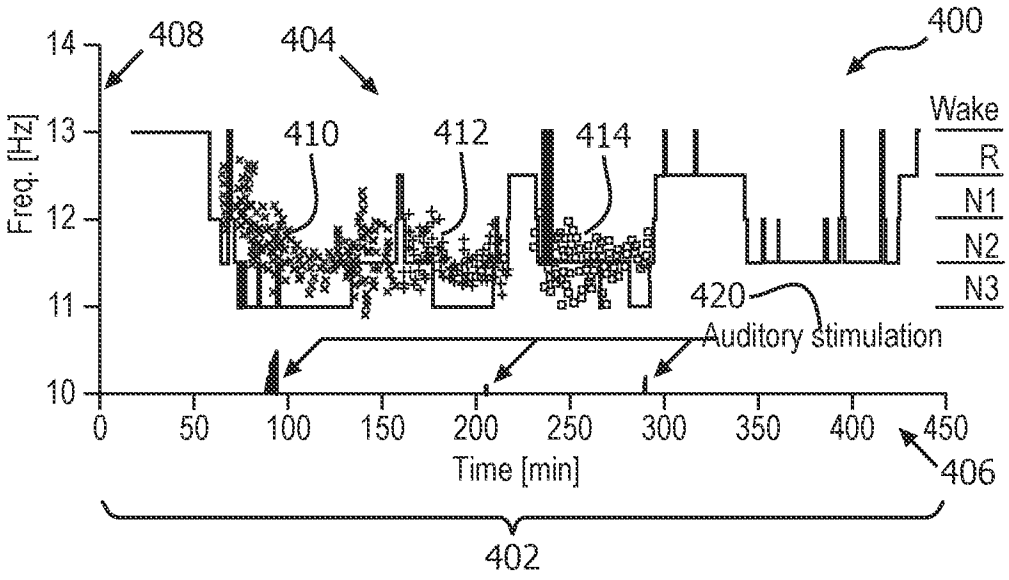

FIG. 4a

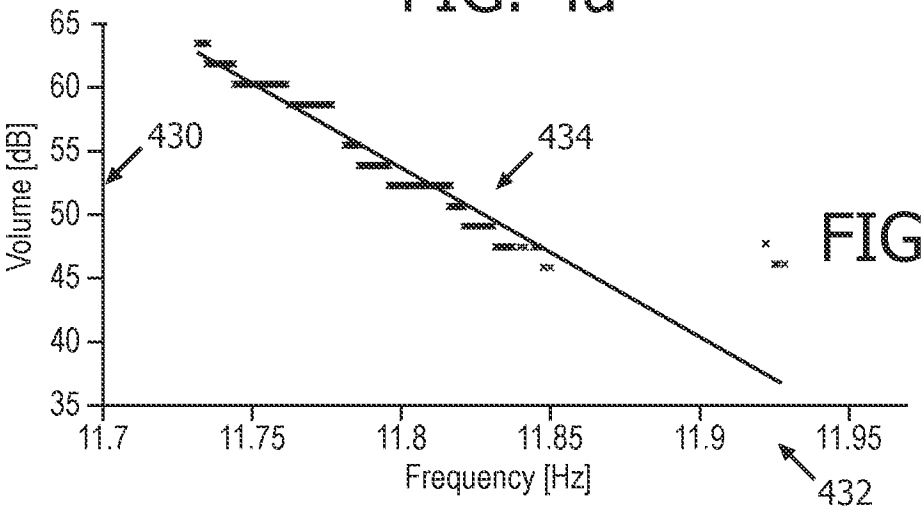

FIG. 4b

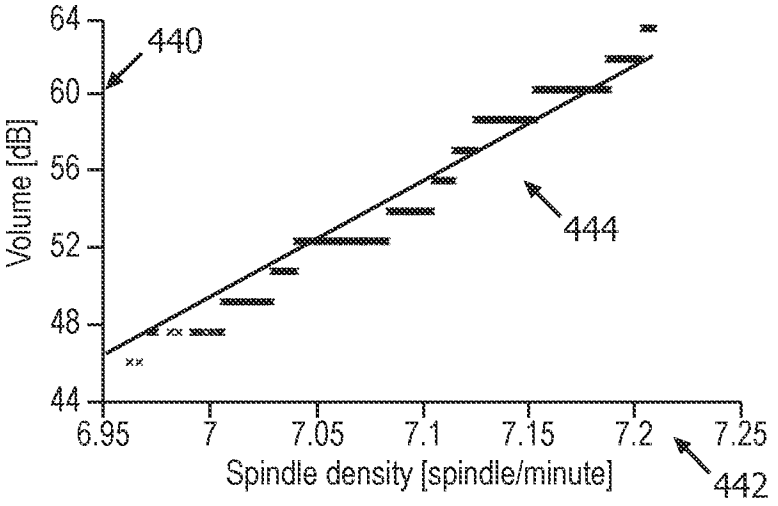

FIG. 4c

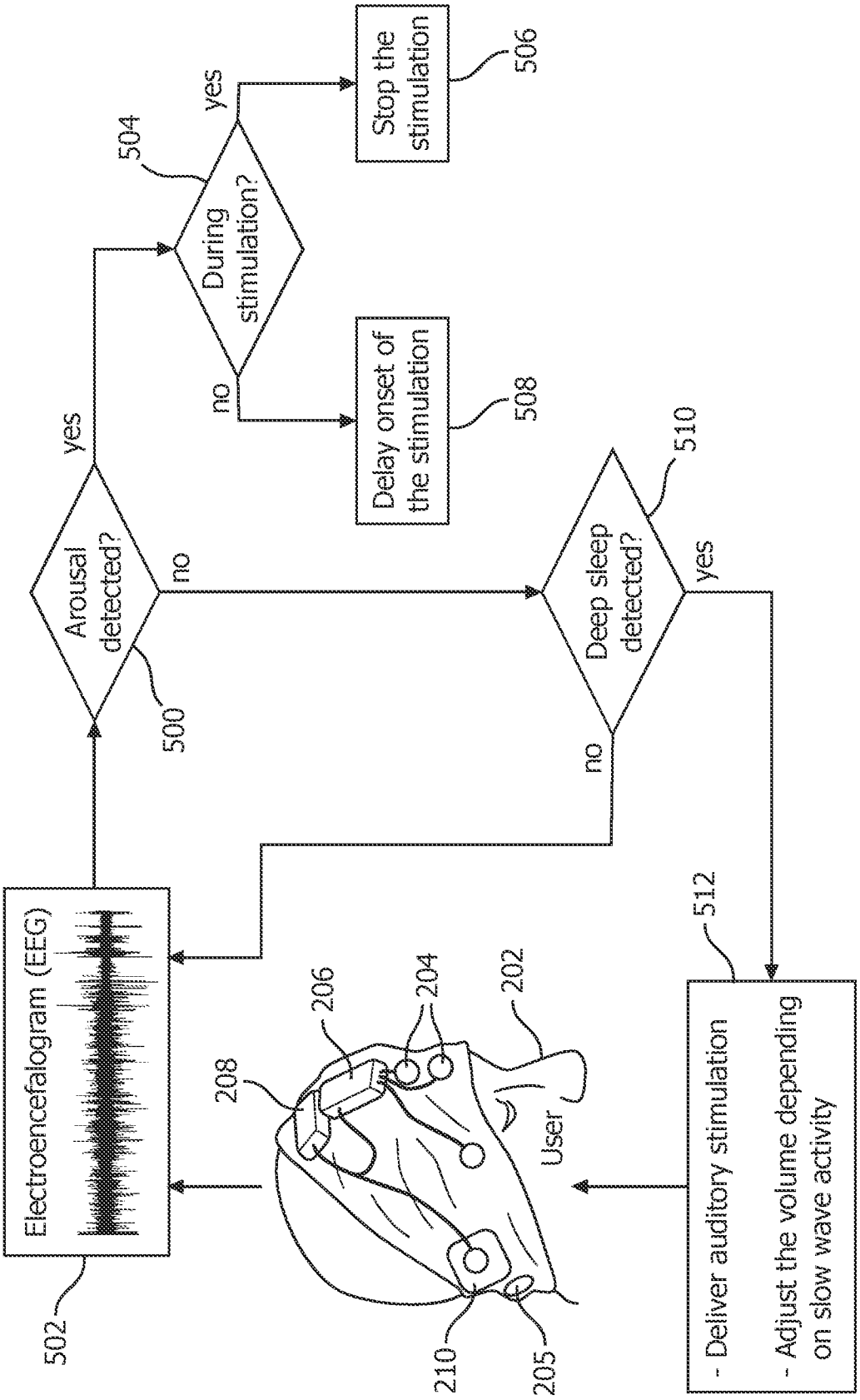
Arousal detected?
500
yes
no
During stimulation?
504
yes
no
Stop the stimulation
506
Delay onset of the stimulation
508
Deep sleep detected?
510
yes
no
Electroencefalogram (EEG)
502
- Deliver auditory stimulation
- Adjust the volume depending on slow wave activity
512
User
202
204
206
208
210
205

FIG. 5

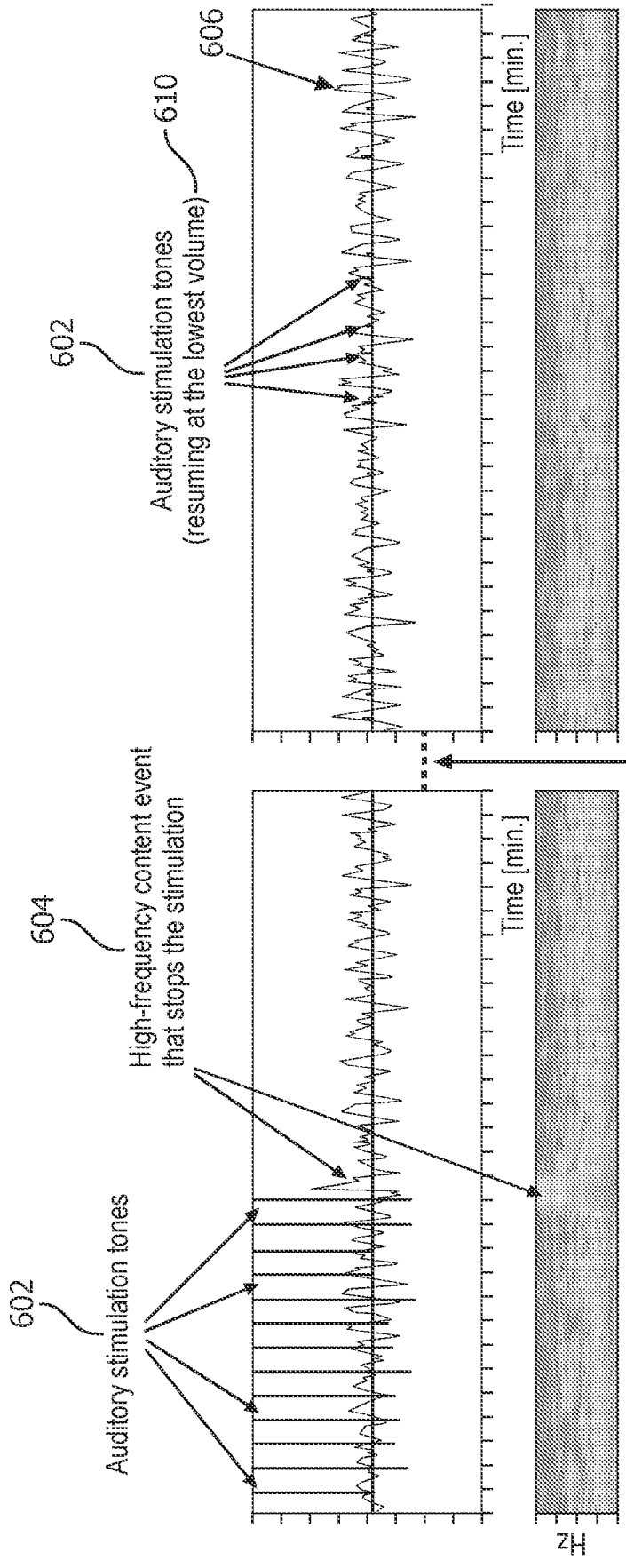
602
Auditory stimulation tones
604
High-frequency content event that stops the stimulation
Time [min.]
Hz
1.5 minutes
608
602
Auditory stimulation tones (resuming at the lowest volume)
610
606
Time [min.]
600

FIG. 6

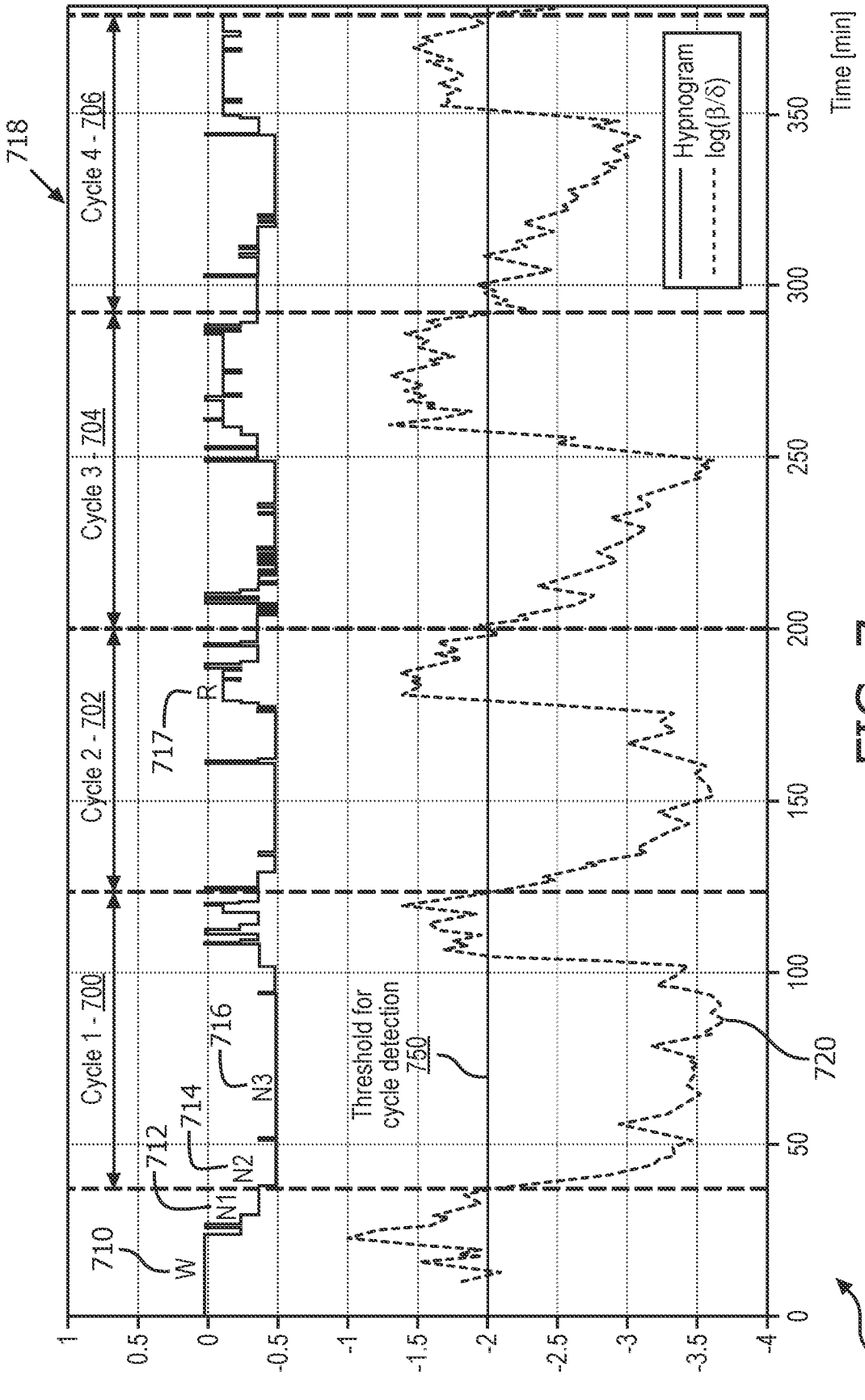
718
Cycle 1 - 700
Cycle 2 - 702
Cycle 3 - 704
Cycle 4 - 706
710
W
712
N1
714
N2
716
N3
717
R
Threshold for cycle detection 750
720
708
Hypnogram
log(β/δ)
Time [min]
1
0.5
0
-0.5
-1
-1.5
-2
-2.5
-3
-3.5
-4
0
50
100
150
200
250
300
350

FIG. 7

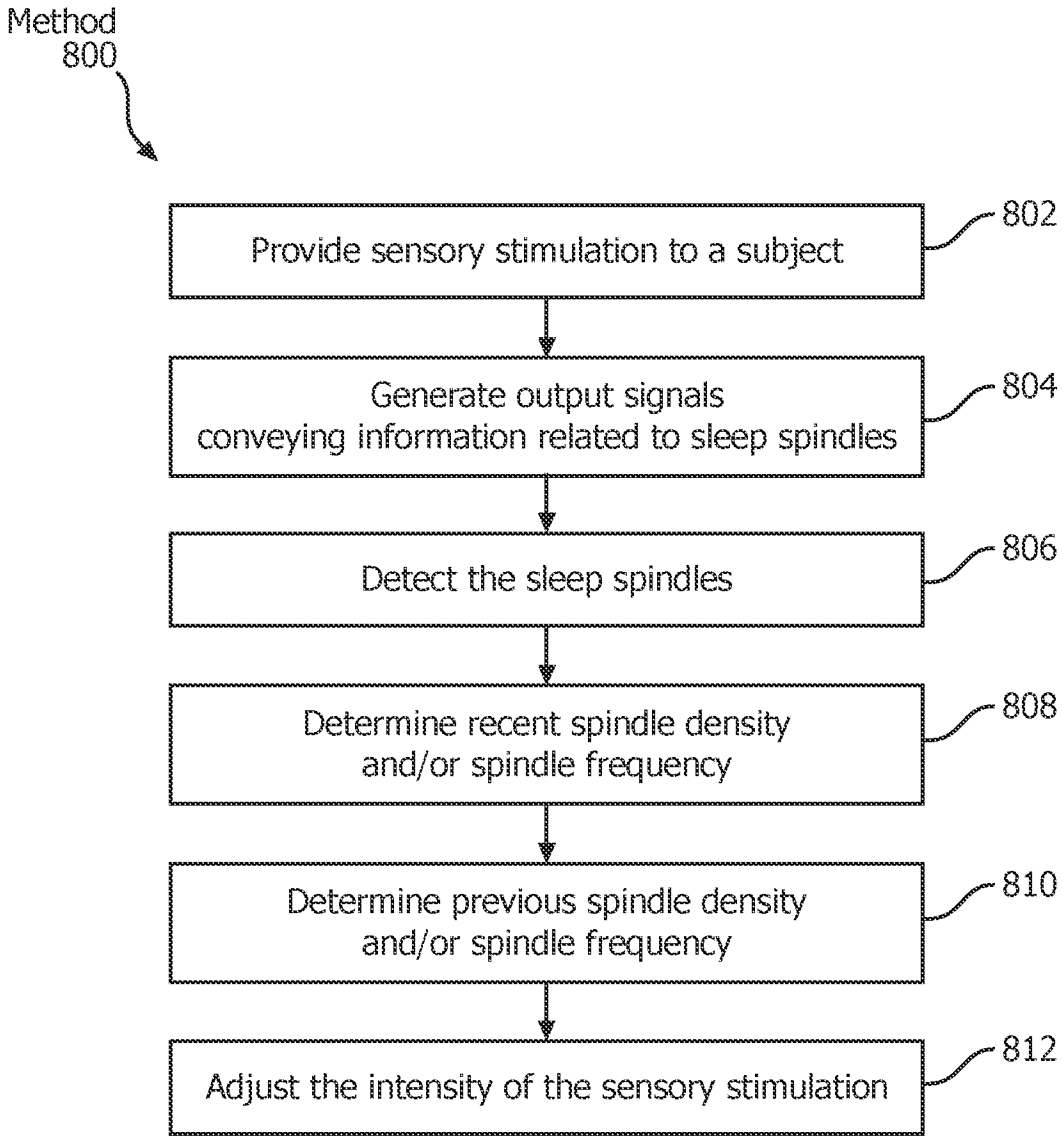
Method
800
Provide sensory stimulation to a subject
802
Generate output signals
conveying information related to sleep spindles
804
Detect the sleep spindles
806
Determine recent spindle density
and/or spindle frequency
808
Determine previous spindle density
and/or spindle frequency
810
Adjust the intensity of the sensory stimulation
812

FIG. 8

SYSTEM AND METHOD FOR ADJUSTING THE INTENSITY OF SENSORY STIMULATION DURING SLEEP BASED ON SLEEP SPINDLES

CROSS-REFERENCE TO PRIOR APPLICATIONS

This application is the U.S. National Phase application under 35 U.S.C. § 371 of International Application Serial No. PCT/IB2015/055074, filed on Jul. 6, 2015, which claims the benefit of U.S. Application Ser. No. 62/021,333, filed on Jul. 7, 2014. These applications are hereby incorporated by reference herein.

BACKGROUND

1. Field

The present disclosure pertains to a system configured to adjust an intensity of sensory stimulation delivered to a subject during a sleep session based on sleep spindles in the subject during the sleep session.

2. Description of the Related Art

Systems for monitoring sleep are known. Sensory stimulation during sleep is known. Sensory stimulation during sleep is often applied continuously and/or at intervals and intensities that do not correspond to sleeping patterns of a subject. The present disclosure overcomes deficiencies in prior art systems.

SUMMARY

Accordingly, one or more aspects of the present disclosure relate to a system configured to adjust an intensity of sensory stimulation delivered to a subject during a sleep session. The system comprises one or more sensory stimulators, one or more sensors, one or more physical computer processors, and/or other components. The one or more sensory stimulators are configured to provide sensory stimulation to the subject. The one or more sensors are configured to generate output signals conveying information related to sleep spindles in the subject during the sleep session. The one or more physical computer processors are configured, by computer readable instructions, to: detect the sleep spindles in the subject based on the output signals; determine a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on the detected sleep spindles; determine a previous spindle density and/or a previous spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles, wherein a beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session; and control the one or more sensory stimulators to adjust the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency.

Yet another aspect of the present disclosure relates to a method for adjusting an intensity of sensory stimulation delivered to a subject during a sleep session with an adjustment system. The adjustment system comprises one or more sensory stimulators, one or more sensors, one or more physical computer processors, and/or other components. The method comprises providing sensory stimulation to the subject with the one or more sensory stimulators; generating, with the one or more sensors, output signals conveying information related to sleep spindles in the subject during the sleep session; detecting, with the one or more physical computer processors, the sleep spindles in the subject based on the output signals; determining, with the one or more physical computer processors, a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on the detected sleep spindles; determining, with the one or more physical computer processors, a previous spindle density and/or a previous spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles, wherein a beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session; and controlling, with the one or more physical computer processors, the one or more sensory stimulators to adjust the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency.

Still another aspect of present disclosure relates to a system configured to adjust an intensity of sensory stimulation delivered to a subject during a sleep session. The system comprises means for providing sensory stimulation to the subject; means for generating output signals conveying information related to sleep spindles in the subject during the sleep session; means for detecting the sleep spindles in the subject based on the output signals; means for determining a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on the detected sleep spindles; means for determining a previous spindle density and/or a previous spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles, wherein a beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session; and means for controlling the means for providing sensory stimulation to adjust the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency.

These and other objects, features, and characteristics of the present disclosure, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a system configured to adjust an intensity of sensory stimulation delivered to a subject during a sleep session based on sleep spindles in the subject during the sleep session.

FIG. **2** illustrates a headband worn by a subject.

FIG. **3** illustrates sleep spindle detection.

FIG. **4** illustrates a hypnogram for a given subject who received auditory stimulation during a sleep session and sleep spindles that were detected during the sleep session.

FIG. **5** illustrates delaying and/or stopping sensory stimulation responsive to detecting a possible arousal event.

FIG. **6** illustrates a sleep session where the provided stimulation is interrupted due to the detection of a possible event with high-frequency content which is determined by the system to be an arousal.

FIG. **7** illustrates four sleep cycles within a sleep session.

FIG. **8** illustrates a method for adjusting an intensity of sensory stimulation delivered to a subject during a sleep session with an adjustment system.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

As used herein, the singular form of "a", "an", and "the" include plural references unless the context clearly dictates otherwise. As used herein, the statement that two or more parts or components are "coupled" shall mean that the parts are joined or operate together either directly or indirectly, i.e., through one or more intermediate parts or components, so long as a link occurs. As used herein, "directly coupled" means that two elements are directly in contact with each other. As used herein, "fixedly coupled" or "fixed" means that two components are coupled so as to move as one while maintaining a constant orientation relative to each other.

As used herein, the word "unitary" means a component is created as a single piece or unit. That is, a component that includes pieces that are created separately and then coupled together as a unit is not a "unitary" component or body. As employed herein, the statement that two or more parts or components "engage" one another shall mean that the parts exert a force against one another either directly or through one or more intermediate parts or components. As employed herein, the term "number" shall mean one or an integer greater than one (i.e., a plurality).

Directional phrases used herein, such as, for example and without limitation, top, bottom, left, right, upper, lower, front, back, and derivatives thereof, relate to the orientation of the elements shown in the drawings and are not limiting upon the claims unless expressly recited therein.

FIG. **1** is a schematic illustration of a system **10** configured to adjust an intensity of sensory stimulation delivered to a subject **12** during a sleep session based on sleep spindles in the subject during the sleep session. The restorative value of sleep may be increased by enhancing sleep slow waves using sensory (e.g., auditory) stimulation during deep sleep. Sleep slow waves are associated with slow wave activity (SWA) in subject **12** during the sleep session. SWA corresponds to the power of an electroencephalogram (EEG) signal in the 0.5-4.5 Hz band. In some embodiments, this band is set to 0.5-4 Hz. SWA has a typical behavior throughout cyclic variations of a given sleep session. SWA increases during non-rapid eye movement sleep (NREM), declines before the onset of rapid-eye-movement (REM) sleep, and remains low during REM. SWA in successive NREM episodes progressively decreases from one episode to the next. SWA may be estimated from an EEG for subject **12** during a given sleep session.

System **10** is configured to adjust, in real-time or near real-time, the intensity (e.g., volume) of sensory stimulation to enhance the slow waves without provoking arousals in subject **12**. System **10** is configured to adjust the intensity of the stimulation based on sleep spindles detected in subject **12** during the sleep session. Sleep spindles reflect the activity of the thalamo-cortical network during sleep and are prevalent during deep sleep. A spindle may be characterized as a group of rhythmic waves (e.g., visible via the EEG) with a progressively increasing then gradually decreasing amplitude. Sleep spindles may comprise an electroencephalographic (EEG) hall-mark of non-rapid eye movement (NREM) sleep. Spindles may be classically described as waxing-and-waning 10-16 Hz oscillations lasting about 0.5-2 s. The amplitude of spindles depends on the EEG recording site. Spindles are typically more prominent in central locations (e.g., EEG location Cz). Spindle density is a good indicator of sleep stability (e.g., resistance to sleep disruption). Frequency of spindles decreases as sleep deepens and increases as sleep lightens. System **10** is configured to adjust the intensity (e.g., volume) of the stimulation based on a sleep spindle frequency, a sleep spindle density, and/or other information to enhance SWA without arousing subject **12**. For example, if the spindle density increases, a volume, for example, of the stimulation may be increased. If the frequency of spindles decreases, the volume, for example, of the stimulation may be increased.

The sensory stimuli may include different types of sensory stimuli. The different types may include odors, sounds, visual stimulation (e.g., lights flashed on open and/or closed eyes), touches, tastes, and/or other types of sensory stimuli. By way of a non-limiting example, system **10** may be configured to deliver acoustic tones to subject **12**. In some embodiments, system **10** may comprise one or more of a sensory stimulator **16**, a sensor **18**, a processor **20**, electronic storage **22**, a user interface **24**, and/or other components.

In FIG. **1**, sensory stimulator **16**, sensor **18**, processor **20**, electronic storage **22**, and user interface **24** are shown as separate entities. This is not intended to be limiting. Some and/or all of the components of system **10** and/or other components may be grouped into one or more singular devices.

For example, FIG. **2** illustrates a headband **200** worn by a subject **202**. Headband **200** includes sensing electrodes **204**, a reference electrode **205**, one or more devices associated with an EEG **206**, a wireless audio device **208**, and one or more audio speakers **210**. Audio speakers **210** may be located in and/or near the ears of subject **202**. The reference electrode **205** may be located behind the ear of subject **202**. In the example shown in FIG. **2**, sensing electrodes **204** may be configured to generate output signals conveying information related to the frontal EEG of subject **202**, left/right ocular information for subject **202**, and/or other information. The output signals may be transmitted to a computing device (e.g., a bedside laptop) wirelessly and/or via wires. Acoustic stimulation may be delivered to subject **202** via wireless audio device **208** and/or speakers **210**. An audio signal including information related to auditory stimulation may be generated by the computing device and received by wireless audio device **208**. Sensing electrodes **204**, reference electrode **205**, and devices **206** may be represented, for example, by sensor **18** in FIG. **1**. Wireless audio device **208** and speakers **210** may be represented, for example, by sensory stimulator **16** shown in FIG. **1**.

Returning to FIG. **1**, sensory stimulator **16** is configured to provide sensory stimuli to subject **12**. Sensory stimulator **16** is configured to provide sensory stimulation to subject **12** prior to a sleep session, during a sleep session, after a sleep session, and/or at other times. Sensory stimulator **16** is configured to provide sensory stimulation to subject **12** without causing arousals during sleep. For example, sensory stimulator **16** may be configured to provide sensory stimuli to subject **12** during slow wave sleep in a sleep session. Sensory stimulator **16** may be configured to provide sensory stimulation to subject **12** to induce and/or adjust SWA in subject **12**. In some embodiments, sensory stimulator **16**

may be configured such that inducing and/or adjusting SWA includes inducing, increasing, and/or enhancing sleep slow waves in subject **12**.

In some embodiments, sensory stimulator **16** may be configured to induce, increase, and/or enhance sleep slow waves through non-invasive brain stimulation and/or other methods. Sensory stimulator **16** may be configured to induce, increase, and/or enhance sleep slow waves through non-invasive brain stimulation using sensory stimuli. As described above, the sensory stimuli may include odors, sounds, visual stimulation, touches, tastes, and/or other stimuli. For example, acoustic tones may be provided to subject **12** to induce, increase, and/or enhance sleep slow waves. Examples of sensory stimulator **16** may include one or more of a music player, a tone generator, a collection of electrodes on the scalp of subject **12**, a unit to deliver vibratory stimulation (also known as somato-sensory stimulation), a coil generating a magnetic field to directly stimulate the brain's cortex, light generators, a fragrance dispenser, and/or other devices.

Sensor **18** is configured to generate output signals conveying information related to sleep spindles in subject **12** during the sleep session, a current sleep stage of subject **12**, and/or other information. The current sleep stage of subject **12** may correspond to one or more of non-rapid eye movement (NREM) stage N1, stage N2, or stage N3 sleep, rapid eye movement (REM) sleep, and/or other sleep stages. In some embodiments, NREM stage 3 or stage 2 sleep may be slow wave sleep. Sensor **18** may comprise one or more sensors that measure such parameters directly. For example, sensor **18** may include electrodes configured to detect electrical activity along the scalp of subject **12** resulting from current flows within the brain of subject **12**. Sensor **18** may comprise one or more sensors that generate output signals conveying information related to such parameters indirectly. For example, one or more sensors **18** may generate an output based on a heart rate of subject **12** (e.g., sensor **18** may be a heart rate sensor located on the chest of subject **12**, and/or be configured as a bracelet on a wrist of subject **12**, and/or be located on another limb of subject **12**), movement of subject **12** (e.g., sensor **18** may include a bracelet around the wrist and/or ankle of subject **12** with an accelerometer such that sleep may be analyzed using actigraphy signals), respiration of subject **12**, and/or other characteristics of subject **12**. Although sensor **18** is illustrated at a single location near subject **12**, this is not intended to be limiting. Sensor **18** may include sensors disposed in a plurality of locations, such as for example, within (or in communication with) sensory stimulator **16**, coupled (in a removable manner) with clothing of subject **12**, worn by subject **12** (e.g., as a headband, wristband, etc.), positioned to point at subject **12** while subject **12** sleeps (e.g., a camera that conveys output signals related to movement of subject **12**), and/or in other locations.

Processor **20** is configured to provide information processing capabilities in system **10**. As such, processor **20** may comprise one or more of a digital processor, an analog processor, a digital circuit designed to process information, an analog circuit designed to process information, a state machine, and/or other mechanisms for electronically processing information. Although processor **20** is shown in FIG. **1** as a single entity, this is for illustrative purposes only. In some embodiments, processor **20** may comprise a plurality of processing units. These processing units may be physically located within the same device (e.g., sensory stimulator **16**), or processor **20** may represent processing functionality of a plurality of devices operating in coordination.

As shown in FIG. **1**, processor **20** is configured to execute one or more computer program components. The one or more computer program components may comprise one or more of a spindle detection component **30**, a parameter component **32**, a control component **34**, a sleep stage component **36**, and/or other components. Processor **20** may be configured to execute components **30**, **32**, **34**, and/or **36** by software; hardware; firmware; some combination of software, hardware, and/or firmware; and/or other mechanisms for configuring processing capabilities on processor **20**.

It should be appreciated that although components **30**, **32**, **34**, and **36** are illustrated in FIG. **1** as being co-located within a single processing unit, in embodiments in which processor **20** comprises multiple processing units, one or more of components **30**, **32**, **34**, and/or **36** may be located remotely from the other components. The description of the functionality provided by the different components **30**, **32**, **34**, and/or **36** described below is for illustrative purposes, and is not intended to be limiting, as any of components **30**, **32**, **34**, and/or **36** may provide more or less functionality than is described. For example, one or more of components **30**, **32**, **34**, and/or **36** may be eliminated, and some or all of its functionality may be provided by other components **30**, **32**, **34**, and/or **36**. As another example, processor **20** may be configured to execute one or more additional components that may perform some or all of the functionality attributed below to one of components **30**, **32**, **34**, and/or **36**.

Spindle detection component **30** is configured to detect sleep spindles in subject **12**. Spindle detection component **30** is configured to detect the sleep spindles based on the output signals from sensor **18** and/or other information. FIG. **3** illustrates sleep spindle detection. An EEG signal (e.g., output signals from sensor **18**) **300** is band-pass filtered in a spindle frequency band (e.g., a range from about 12.5 Hz to about 16 Hz) **302**. Positive and negative peaks are detected **304**, and the peak-to-peak (peak2peak or P2P) amplitudes and the peak-to-peak-interval durations are determined **306**. In some embodiments, typical peak-to-peak amplitudes may be about 10 to about 30 microvolts, for example. In some embodiments, the duration of the spindle event may be about 500 to about 2000 milliseconds, for example. In some embodiments, if a determined amplitude is above a preset threshold (τ) such as about 17 microvolts, for example, the previous positive peak is marked as the beginning of a "candidate-spindle" **308**. Subsequent peak-to-peak intervals are stored in a buffer (e.g., electronic storage **22**) until the peak-to-peak amplitude decreases to a level that is back below the threshold τ **310**. If the duration of the candidate-spindle falls within a typical spindle-duration range (e.g., about 500 to about 2000 milliseconds), then the candidate-spindle is tagged as a "detected spindle" **312**. The average spindle frequency is then determined **314** based on the inverse of the average peak-to-peak-interval duration (see the description of the parameter component below).

Returning to FIG. **1**, parameter component **32** is configured to determine one or more parameters related to sleep spindles in subject **12**, one or more parameters related to a current sleep stage of subject **12**, parameters related to the sensory stimulation provided to subject **12**, and/or other parameters. Parameter component **32** is configured to determine parameters based on the output signals from sensor **18**, the spindles detected by spindle detection component **30**, and/or other information. The parameters may include a quantity of spindles, a spindle density, a spindle frequency, a sleep stage, a sensory stimulation intensity level, a sensory stimulation timing, a number of microarousal events (e.g., a

microarousal is a high frequency event occurring in the EEG which has comparatively high amplitudes such as about 50-100 microvolts) during a recent period of time (e.g., the last minute), and/or other parameters.

Parameter component **32** is configured determine a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on the detected sleep spindles and/or other information. For example, parameter component **32** may determine a spindle density and/or a spindle frequency for the most recent minute of the sleep session. In some embodiments, the recent spindle density and/or frequency may be an average density and/or frequency determined based on multiple density and/or frequency determinations during the most recent minute. In some embodiments, the recent spindle density and/or frequency may indicate a relative change in spindle density and/or frequency from the start of the most recent minute to the end of the most recent minute. In some embodiments, the recent spindle density and/or frequency may be and/or be based on a single density and/or frequency determination.

Parameter component **32** is configured to determine a previous spindle density and/or a previous spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles and/or other information. For example, parameter component **32** may determine a spindle density and/or a spindle frequency for the five minutes of the sleep session leading up to the most recent minute. In some embodiments, the previous spindle density and/or frequency may be an average density and/or frequency determined based on multiple density and/or frequency determinations during the previous period of time. In some embodiments, the previous spindle density and/or frequency may indicate a relative change in spindle density and/or frequency from the start of the previous period of time (e.g., the beginning of the five minute period) to the end of the previous period of time (e.g., the end of the five minute period). In some embodiments, the previous spindle density and/or frequency may be and/or be based on a single density and/or frequency determination.

The spatial arrangement and the periods of time (the durations) for the recent period of time (e.g., one minute) and the previous period of time (e.g., five minutes) described above is not intended to be limiting. The recent period of time and/or the previous period of time may have any length that allows system **10** to function as described herein. In some embodiments, a beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session. In some embodiments, the previous period of time ends before the recent period of time begins. In some embodiments, the previous period of time ends substantially when the recent period of time begins. In some embodiments, the previous period of time ends after the recent period of time begins (e.g., the previous period of time and the recent period of time overlap). In some embodiments, the spindle densities and/or frequencies determined by parameter component **32** are stored in electronic storage **22**.

Control component **34** is configured to control sensory stimulator **16** to adjust the intensity of sensory stimulation provided to subject **12** based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency. In some embodiments, control component **34** is configured to cause sensory stimulator **16** to increase the intensity of sensory stimulation responsive to an increase in the recent spindle density relative to the previous spindle density and/or a decrease in the recent spindle frequency relative to the previous spindle frequency. For example, control component **34** is configured to cause sensory stimulator **16** to increase a volume of audible tones responsive to an increase in the recent spindle density relative to the previous spindle density and/or a decrease in the recent spindle frequency relative to the previous spindle frequency. In some embodiments, control component **34** is configured to cause sensory stimulator **16** to decrease the intensity of sensory stimulation responsive to a decrease in the recent spindle density relative to the previous spindle density and/or an increase in the recent spindle frequency relative to the previous spindle frequency. For example, control component **34** is configured to cause sensory stimulator **16** to decrease a volume of the audible tones responsive to a decrease in the recent spindle density relative to the previous spindle density and/or an increase in the recent spindle frequency relative to the previous spindle frequency.

By way of a non-limiting example, if control component **34** detects a change of about +0.1 spindles-per-minute in the recent spindle density with respect to the previous spindle density (e.g., the average of the density values stored in electronic storage for the previous five minutes), control component **34** may control sensory stimulator **16** such that the volume (e.g., for auditory stimulation) of the stimulation is increased by about 6 dBs. If a change of about −0.1 spindles-per-minute is detected, then the volume of the stimulation may be increased by about 6 dBs. If a change of about +0.05 Hz is detected in the recent spindle frequency with respect to the previous spindle frequency, then the volume of the stimulation may be decreased by about 6 dBs. If a change of about −0.05 Hz is detected, then the volume of the stimulation may be increased by about 6 dBs. These examples are not intended to be limiting. The changes of 0.1 in spindle density and/or 0.05 Hz in spindle frequency may be customized for an individual user using based on information from previous sleep sessions of the individual user and/or other information.

FIG. **4** illustrates a hypnogram **400** for a given subject who received auditory stimulation **420** during a sleep session **402** and sleep spindles **404** that were detected during sleep session **402**. In FIG. **4**A, the detected spindles **404** and the hypnogram **400** are shown for a representative night of sleep by the subject. The horizontal axis **406** indicates the time in minutes from the beginning of the sleep session and the vertical axis **408** indicates the frequency of the detected spindles in Hz. Spindles **410** occur during a first sleep cycle, spindles **412** occur during a second sleep cycle, and spindles **414** occur during a third sleep cycle. A sleep cycle corresponds to an orderly progression through successive sleep stages (described below), from light sleep to deep sleep and then followed by rapid eye movement (REM) sleep. Sleep cycles are detected in real-time based on an EEG, and/or by other methods. Timing and intensity of auditory stimulation **420** delivered to the subject is roughly indicated by the vertical lines rising from horizontal axis **406** (a longer line represents a louder tone). The frequency of the spindles follows a "u-shape" trend within a sleep cycle. A slight trend towards decreasing spindle frequencies is observed across sleep cycles. Within a cycle it is possible to establish a polynomial regression to demonstrate a relationship between the spindle frequency and the time. For the particular example in FIG. **4**A, a second-order polynomial provided an appropriate fit-accuracy while preventing overfitting.

In FIG. **4**B, the volume of the tones in decibels (dB) **430** is plotted versus the extrapolated (using the polynomial regression) spindle frequency **432** at the time of the tone. A

linear trend **434** indicates that when the volume of the stimulation is higher, the spindle frequency is lower. For this particular example the volume (in decibels) negatively correlates with the frequency through the regression equation: $V \approx 1595.3 - 130.7 \times f$. Thus, a decrease in the spindle frequency of about 0.05 Hz, for example, translates in an increase of the stimulation volume of about 6.5 decibels. In FIG. **4**C, the volume of the tones in decibels (dB) **440** is plotted versus the extrapolated (using a second order polynomial regression) spindle density (in spindles per minute) **442** at the time of the tone. A linear trend **444** indicates that when the volume of the stimulation was higher, the spindle density was higher. For this particular example, the volume (in decibels) positively correlates with the spindle density (δ) through the regression equation: $V \approx -372.7 + 60.3 \times \delta$. Thus, an increase in the spindle density of about 0.1 spindles/minute, for example, translates to an increase of the stimulation volume of about 6 decibels.

Returning to FIG. **1**, in some embodiments, control component **34** is configured such that the intensity (e.g., volume) of the stimulation is not always adjusted responsive to spindle density and/or spindle frequency changes. In some embodiments, (e.g., where the stimulation is already at a predetermined maximum intensity in deep sleep and the spindle density decreases), system **10** may be configured such that a decrease in spindle density does not affect the intensity of the stimulation.

In some embodiments, control component **34** is configured to control sensory stimulator **16** to provide the sensory stimulation during the sleep session such that the sensory stimulation does not unintentionally wake subject **12**. Controlling sensory stimulator **16** to provide sensory stimulation so subject **12** is not unintentionally aroused from sleep may be accomplished by controlling the timing, frequency, intensity, and/or other parameters of the stimulation. For example, control component **34** may cause sensory stimulator **16** to deliver acoustic stimulation to subject **12** to increase sleep slow waves just after subject **12** has fallen asleep, and not while subject **12** is falling asleep.

In some embodiments, control component **34** is configured to detect a possible arousal event in subject **12** based on the output signals. In some embodiments, control component **34** is configured to detect possible arousal events, and/or the likelihood of producing arousals based on the instantaneous EEG power in the beta band (described below), and/or by other methods. An arousal event may include waking from sleep and/or other arousal events associated with wakefulness of subject **12**. Responsive to detecting the possible arousal event, control component **34** may cause sensory stimulator **16** to cease providing sensory stimulation and then determine whether the possible arousal event was a false arousal event. Responsive to determining that the possible arousal event was a false arousal event, control component **34** may cause sensory stimulator **16** to resume providing sensory stimulation with an intensity determined based on the recent spindle density relative to the previous spindle density and/or the recent spindle frequency relative to the previous spindle frequency.

For example, FIG. **5** illustrates delaying and/or stopping sensory stimulation responsive to detecting a possible arousal event. Control component **34** (FIG. **1**) is configured to control sensory stimulator **210** such that a volume of auditory stimulation (for example) is first provided at a level that is approximately equal to a hearing threshold (e.g., subjectively determined via a calibration during wakefulness) of a subject and then progressively adjusted (e.g., increased) as described above (based on the detected sleep spindles). (In some embodiments, an upper limit for the intensity of the sensory stimulation (e.g., volume) may also be subjectively determined during a previous calibration.) Possible arousal events **500** are detected based on EEG signals **502** (e.g., output signals from sensor **18**). If a possible arousal is detected by system **10** during stimulation **504**, control component **34** (FIG. **1**) controls a sensory stimulator **210** such that the stimulation stops **506**. If an arousal is detected outside the stimulation period, the onset of the stimulation is delayed **508**. If no arousal is detected, then the system attempts to detect deep sleep **510**. If deep sleep is detected, the auditory stimulation is delivered **512**. As described above, responsive to determining that the possible arousal event was a false arousal event, control component **34** may cause sensory stimulator **210** to resume providing sensory stimulation with an intensity determined based on the recent spindle density relative to the previous spindle density and/or the recent spindle frequency relative to the previous spindle frequency. System **10** does not automatically revert back to the lowest intensity level in such situations.

In contrast, responsive to detecting a possible arousal event (whether false or actual), prior art systems automatically revert back to their lowest sensory stimulation intensity level when restarting delivery of sensory stimulation to a subject. For example, FIG. **6** illustrates a sleep session where the stimulation **602** provided by a prior art system is interrupted due to the detection of a possible event **604** with high-frequency content which is determined by the system to be an arousal. Even if slow-wave sleep continues and large slow-waves are visible in the EEG **606**, the stimulation **602** resumes only after more than 1.5 minutes **608** have passed. In addition, the stimulation starts at the lowest volume **610** which constitutes a loss of opportunity to stimulate. System **10** overcomes this inefficiency by resuming the provision of sensory stimulation with an intensity determined based on the recent spindle density relative to the previous spindle density and/or the recent spindle frequency relative to the previous spindle frequency. System **10** does not automatically revert back to a lowest intensity level to restart sensory stimulation. System **10** is configured such that the intensity of the acoustic stimulation is adjusted according to the level of thalamo-cortical polarization (e.g., as indicated by detected sleep spindles) in order to avoid undesired arousals and sleep fragmentation.

Returning to FIG. **1**, sleep stage component **36** is configured to determine the sleep stage of subject **12** one or more times during the sleep session. Sleep stage component **36** is configured to determine the sleep stage based on the output signals, the detected spindles, an EEG, and/or other information. Sleep stages of subject **12** may include one or more of NREM stage N1, stage N2, or stage N3 sleep, REM sleep, and/or other sleep stages. In some embodiments, N1 and/or N2 corresponds to a light sleep state and N3 corresponds to a deep sleep state. In some embodiments, NREM stage N3 or stage N2 sleep may be slow wave (e.g., deep) sleep. In some embodiments, slow waves may not be present throughout the whole N3 period, for example, but it may be significantly more likely that such slow waves are present during N3. Slow waves may also be present (although to a lesser extent) during N2, for example. In some embodiments, sleep stage component **36** determines sleep stages based amounts of power in one or more bands of the EEG (e.g., beta, spindle, alpha, theta, delta), and/or related to other characteristics of the brain activity of subject **12**. Typical band-limit values are about 8-12 Hz (alpha), about 15-30 Hz (beta), about 11-16 Hz (sigma/spindle), about

30-60 Hz (gamma), about 0.5-4 Hz (delta), and/or about 4-8 Hz (theta). In some embodiments, sleep stage component **36** determines deep sleep based on a logarithm of the ratio between the beta and delta power (log(beta/delta)). For example, if this ratio is less than −3, then subject **12** is sleeping deeply.

In some embodiments, control component **34** is configured to control sensory stimulator **16** to adjust the intensity of the stimulation based on the sleep stage determinations by sleep stage component **36**. For example, the volume of auditory stimulation may be increased when log(beta/delta) has a decreasing trend over time. Control component **34** may be configured to control sensory stimulator **16** to adjust the intensity of the stimulation based on the sleep stage determinations in addition to and/or instead of controlling sensory stimulator **16** based on the changes in spindle density, the changes in spindle frequency, and/or other information.

For example, FIG. **7** illustrates four sleep cycles **700**, **702**, **704**, **706** within a sleep session **708**. As described above, a sleep cycle corresponds to an orderly progression through successive sleep stages, from light sleep to deep sleep and then followed by rapid eye movement (REM) sleep. The orderly progression through successive sleep stages **710** (wakefulness), **712** (N1), **714** (N2), **716** (N3), **717** (REM) is illustrated in hypnogram **718**. The logarithm of the ratio between the beta and delta power **720** indicates sleep depth. If this ratio breaches a threshold of −2, for example, a sleep cycle may be starting and/or ending **750**. If this ratio is lower than −3, for example, then the sleep is at its deepest. In some embodiments, the volume of the stimulation is increased when log(beta/delta) has a decreasing trend (e.g., which can be estimated using a 30-second long window).

Returning to FIG. **1**, electronic storage **22** comprises electronic storage media that electronically stores information. The electronic storage media of electronic storage **22** may comprise one or both of system storage that is provided integrally (i.e., substantially non-removable) with system **10** and/or removable storage that is removably connectable to system **10** via, for example, a port (e.g., a USB port, a firewire port, etc.) or a drive (e.g., a disk drive, etc.). Electronic storage **22** may comprise one or more of optically readable storage media (e.g., optical disks, etc.), magnetically readable storage media (e.g., magnetic tape, magnetic hard drive, floppy drive, etc.), electrical charge-based storage media (e.g., EPROM, RAM, etc.), solid-state storage media (e.g., flash drive, etc.), and/or other electronically readable storage media. Electronic storage **22** may store software algorithms, information determined by processor **20**, information received from subject **12**, and/or other information that enables system **10** to function properly. Electronic storage **22** may be (in whole or in part) a separate component within system **10**, or electronic storage **22** may be provided (in whole or in part) integrally with one or more other components of system **10** (e.g., processor **20**).

User interface **24** is configured to provide an interface between system **10** and subject **12**, and/or other users through which subject **12** and/or other users may provide information to and receive information from system **10**. This enables data, cues, results, and/or instructions and any other communicable items, collectively referred to as "information," to be communicated between a user (e.g., subject **12**) and one or more of sensory stimulator **16**, sensor **18**, processor **20**, and/or other components of system **10**. For example, an EEG may be displayed to a caregiver via user interface **24**. Examples of interface devices suitable for inclusion in user interface **24** comprise a keypad, buttons, switches, a keyboard, knobs, levers, a display screen, a touch screen, speakers, a microphone, an indicator light, an audible alarm, a printer, a tactile feedback device, and/or other interface devices. In some embodiments, user interface **24** comprises a plurality of separate interfaces. In some embodiments, user interface **24** comprises at least one interface that is provided integrally with sensory stimulator **16** and/or other components of system **10**.

It is to be understood that other communication techniques, either hard-wired or wireless, are also contemplated by the present disclosure as user interface **24**. For example, the present disclosure contemplates that user interface **24** may be integrated with a removable storage interface provided by electronic storage **22**. In this example, information may be loaded into system **10** from removable storage (e.g., a smart card, a flash drive, a removable disk, etc.) that enables the user(s) to customize the implementation of system **10**. Other exemplary input devices and techniques adapted for use with system **10** as user interface **24** comprise, but are not limited to, an RS-232 port, RF link, an IR link, modem (telephone, cable or other). In short, any technique for communicating information with system **10** is contemplated by the present disclosure as user interface **24**.

FIG. **8** illustrates a method **800** for adjusting an intensity of sensory stimulation delivered to a subject during a sleep session with an adjustment system. The system comprises one or more sensory stimulators, one or more sensors, one or more processors, and/or other components. The operations of method **800** presented below are intended to be illustrative. In some embodiments, method **800** may be accomplished with one or more additional operations not described, and/or without one or more of the operations discussed. Additionally, the order in which the operations of method **800** are illustrated in FIG. **8** and described below is not intended to be limiting.

In some embodiments, method **800** may be implemented in one or more processing devices (e.g., a digital processor, an analog processor, a digital circuit designed to process information, an analog circuit designed to process information, a state machine, and/or other mechanisms for electronically processing information). The one or more processing devices may include one or more devices executing some or all of the operations of method **800** in response to instructions stored electronically on an electronic storage medium. The one or more processing devices may include one or more devices configured through hardware, firmware, and/or software to be specifically designed for execution of one or more of the operations of method **800**.

At an operation **802**, sensory stimulation is provided to a subject. In some embodiments, the sensory stimulation is and/or includes audible tones. The sensory stimulation may be provided prior to a sleep session, during a sleep session, after a sleep session, and/or at other times. The sensory stimulation may be provided without causing arousals during sleep. For example, sensory stimuli may be provided to subject during slow wave sleep in a sleep session. In some embodiments, operation **802** is performed by one or more sensory stimulators the same as or similar to sensory stimulator **16** (shown in FIG. **1** and described herein).

At an operation **804**, output signals conveying information related to sleep spindles in the subject during a sleep session, information related to a recent sleep stage of the subject, and/or other information are generated. In some embodiments, operation **804** is performed by one or more sensors the same as or similar to sensors **18** (shown in FIG. **1** and described herein).

At an operation **806**, sleep spindles in the subject are detected. Sleep spindles are detected based on the output

signals. In some embodiments, operation **806** is performed by a physical computer processor the same as or similar to processor **20** (shown in FIG. **1** and described herein).

At an operation **808**, a recent spindle density and/or spindle frequency is determined. The recent spindle density and/or spindle frequency is determined for a recent period of time during the sleep session based on the detected sleep spindles. In some embodiments, operation **808** is performed by a physical computer processor the same as or similar to processor **20** (shown in FIG. **1** and described herein).

At an operation **810**, a previous spindle density and/or spindle frequency is determined. The previous spindle density and/or spindle frequency is determined for a previous period of time during the sleep session based on the detected sleep spindles. A beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session. In some embodiments, operation **810** is performed by a physical computer processor the same as or similar to processor **20** (shown in FIG. **1** and described herein).

At an operation **812**, an intensity of the sensory stimulation provided to the subject is adjusted. The one or more sensory stimulators are controlled to adjust the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency. In some embodiments, an intensity of the sensory stimulation (e.g., a volume of audible tones) is increased responsive to an increase in the recent spindle density relative to the previous spindle density or a decrease in the recent spindle frequency relative to the previous spindle frequency. In some embodiments, an intensity of the sensory stimulation (e.g., a volume of audible tones) is decreased responsive to a decrease in the recent spindle density relative to the previous spindle density or an increase in the recent spindle frequency relative to the previous spindle frequency. In some embodiments, operation **812** is performed by a physical computer processor the same as or similar to processor **20** (shown in FIG. **1** and described herein).

In some embodiments, operation **812** includes determining a sleep stage of the subject based on the output signals and adjusting the intensity of sensory stimulation based on the determined sleep stage. In some embodiments, operation **812** includes detecting a possible arousal event based on the output signals; responsive to detecting the possible arousal event, causing the one or more sensory stimulators to cease providing sensory stimulation; determining whether the possible arousal event was a false arousal event; and responsive to determining that the possible arousal event was a false arousal event, causing the one or more sensory stimulators to resume providing sensory stimulation with an intensity determined based on the recent spindle density relative to the previous spindle density and/or the recent spindle frequency relative to the previous spindle frequency.

Although the description provided above provides detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the disclosure is not limited to the expressly disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present disclosure contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

What is claimed is:

1. A system configured to adjust an intensity of sensory stimulation delivered to a subject during a sleep session, the system comprising:

one or more sensory stimulators configured to provide sensory stimulation to the subject;

one or more sensors configured to generate output signals conveying information related to sleep spindles in the subject during the sleep session; and

one or more physical computer processors configured by computer readable instructions to:

detect the sleep spindles in the subject based on the output signals;

determine a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on the detected sleep spindles;

determine a previous spindle density and/or a previous spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles, wherein a beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session;

control the one or more sensory stimulators to adjust the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency, wherein controlling the one or more sensory stimulators includes, responsive to the recent spindle density and the previous spindle density being determined, increasing the intensity of the sensory stimulation responsive to an increase in the recent spindle density relative to the previous spindle density;

detect a possible arousal event based on the output signals;

responsive to detecting the possible arousal event, cause the one or more sensory stimulators to cease providing sensory stimulation;

determine whether the possible arousal event was a false arousal event; and

responsive to determining that the possible arousal event was a false arousal event, cause the one or more sensory stimulators to resume providing sensory stimulation with an intensity determined based on the recent spindle density relative to the previous spindle density and/or the recent spindle frequency relative to the previous spindle frequency.

2. The system of claim **1**, wherein the one or more sensory stimulators are configured such that the sensory stimulation comprises audible tones, and wherein the one or more physical computer processors are configured to cause the one or more sensory stimulators to increase a volume of the audible tones responsive to the increase in the recent spindle density relative to the previous spindle density or, responsive to the recent spindle frequency and the previous spindle frequency being determined, a decrease in the recent spindle frequency relative to the previous spindle frequency.

3. The system of claim **1**, wherein the one or more sensory stimulators are configured such that the sensory stimulation comprises audible tones, and wherein the one or more physical computer processors are configured to cause the one or more sensory stimulators to decrease a volume of the audible tones responsive to a decrease in the recent spindle density relative to the previous spindle density or, responsive to the recent spindle frequency and the previous spindle

frequency being determined, an increase in the recent spindle frequency relative to the previous spindle frequency.

4. The system of claim **1**, wherein the previous period of time ends at the same time as, or immediately before, the recent period of time begins during the sleep session.

5. The system of claim **1**, wherein the previous period of time ends after the recent period of time begins such that the previous period of time and the recent period of time overlap during the sleep session.

6. The system of claim **1**, wherein the one or more sensors are configured such that the output signals convey information related to a sleep stage of the subject during the sleep session; and

wherein the one or more physical computer processors are further configured to determine the sleep stage of the subject based on the output signals and control the one or more sensory stimulators to adjust the intensity of the stimulation based on the determined sleep stage.

7. A method for adjusting an intensity of sensory stimulation delivered to a subject during a sleep session with an adjustment system, the adjustment system comprising one or more sensory stimulators, one or more sensors, and one or more physical computer processors, the method comprising:

providing sensory stimulation to the subject with the one or more sensory stimulators;

generating, with the one or more sensors, output signals conveying information related to sleep spindles in the subject during the sleep session;

detecting, with the one or more physical computer processors, the sleep spindles in the subject based on the output signals;

determining, with the one or more physical computer processors, a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on the detected sleep spindles;

determining, with the one or more physical computer processors, a previous spindle density and/or a previous spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles, wherein a beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session; and

controlling, with the one or more physical computer processors, the one or more sensory stimulators to adjust the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency, wherein controlling the one or more sensory stimulators includes, responsive to the recent spindle density and the previous spindle density being determined, increasing the intensity of the sensory stimulation responsive to an increase in the recent spindle density relative to the previous spindle density;

detecting a possible arousal event based on the output signals;

responsive to detecting the possible arousal event, causing the one or more sensory stimulators to cease providing sensory stimulation;

determining whether the possible arousal event was a false arousal event; and

responsive to determining that the possible arousal event was a false arousal event, causing the one or more sensory stimulators to resume providing sensory stimulation with an intensity determined based on the recent spindle density relative to the previous spindle density and/or the recent spindle frequency relative to the previous spindle frequency.

8. The method of claim **7**, wherein the sensory stimulation comprises audible tones, and wherein a volume of the audible tones is increased responsive to the increase in the recent spindle density relative to the previous spindle density or, responsive to the recent spindle frequency and the previous spindle frequency being determined, a decrease in the recent spindle frequency relative to the previous spindle frequency.

9. The method of claim **7**, wherein the sensory stimulation comprises audible tones, and wherein a volume of the audible tones is decreased responsive to a decrease in the recent spindle density relative to the previous spindle density or, responsive to the recent spindle frequency and the previous spindle frequency being determined, an increase in the recent spindle frequency relative to the previous spindle frequency.

10. The method of claim **7**, wherein the one or more sensors are configured such that the output signals convey information related to a sleep stage of the subject during the sleep session, the method further comprising;

determining the sleep stage of the subject based on the output signals; and

controlling the one or more sensory stimulators to adjust the intensity of the stimulation based on the determined sleep stage.

11. A system configured to adjust an intensity of sensory stimulation delivered to a subject during a sleep session, the system comprising:

means for providing sensory stimulation to the subject;

means for generating output signals conveying information related to sleep spindles in the subject during the sleep session;

means for detecting the sleep spindles in the subject based on the output signals;

means for determining a recent spindle density and/or a recent spindle frequency for a recent period of time during the sleep session based on the detected sleep spindles;

means for determining a previous spindle density and/or a previous spindle frequency for a previous period of time during the sleep session based on the detected sleep spindles, wherein a beginning of the previous period of time occurs before a beginning of the recent period of time during the sleep session;

means for controlling the means for providing sensory stimulation to adjust the intensity of sensory stimulation provided to the subject based on a comparison of the previous spindle density to the recent spindle density and/or the previous spindle frequency to the recent spindle frequency, wherein controlling the means for providing sensory stimulation includes, responsive to the recent spindle density and the previous spindle density being determined, increasing the intensity of the sensory stimulation responsive to an increase in the recent spindle density relative to the previous spindle density;

means for detecting a possible arousal event based on the output signals;

means for, responsive to detecting the possible arousal event, causing the means for providing sensory stimulation to cease providing sensory stimulation;

means for determining whether the possible arousal event was a false arousal event; and

means for, responsive to determining that the possible arousal event was a false arousal event, causing the

means for providing sensory stimulation to resume providing sensory stimulation with an intensity determined based on the recent spindle density relative to the previous spindle density and/or the recent spindle frequency relative to the previous spindle frequency.

12. The system of claim **11**, wherein the means for providing sensory stimulation are configured such that the sensory stimulation comprises audible tones, and wherein the means for controlling the means for providing sensory stimulation are configured to cause the means for providing sensory stimulation to increase a volume of the audible tones responsive to the increase in the recent spindle density relative to the previous spindle density or, responsive to the recent spindle frequency and the previous spindle frequency being determined, a decrease in the recent spindle frequency relative to the previous spindle frequency.

13. The system of claim **11**, wherein the means for providing sensory stimulation are configured such that the sensory stimulation comprises audible tones, and wherein the means for controlling the means for providing sensory stimulation are configured to cause the means for providing sensory stimulation to decrease a volume of the audible tones responsive to a decrease in the recent spindle density relative to the previous spindle density or, responsive to the recent spindle frequency and the previous spindle frequency being determined, an increase in the recent spindle frequency relative to the previous spindle frequency.

14. The system of claim **11**, wherein the means for generating output signals are configured such that the output signals convey information related to a sleep stage of the subject during the sleep session; and

wherein the system further comprises means for determining the sleep stage of the subject based on the output signals and controlling the means for providing sensory stimulation to adjust the intensity of the stimulation based on the determined sleep stage.

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